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JNCCN

Journal of the National Comprehensive Cancer Network

SUPPLEMENT

NCCN White Paper Equity in Cancer Care: Pathways, Protocols, and Guidelines

Jessica K. DeMartino, PhD, and Jonathan K. Larsen, MPP

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JNCCN is dedicated to improving the quality of cancer care locally, nationally, and internationally while enhancing the collaboration between academic medicine and the community physician. JNCCN is further committed to disseminating information across the cancer care continuum by publishing clinical practice guidelines and reporting rigorous outcomes data collected and analyzed by experts from the world's leading care centers. JNCCN also provides a forum for original research and review papers focusing on clinical and translational research and applications of the NCCN Guidelines in everyday practice, as well as correspondence and commentary.

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275 Commerce Drive
Suite 300
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Equity in Cancer Care: Pathways, Protocols, and Guidelines

Jessica K. DeMartino, PhD, and Jonathan K. Larsen, MPP

Abstract

The quality of patient care varies based on numerous factors, such as health care setting, geographic location, access to medications, insurance coverage, and treatment protocols. Recently, the issue of whether use of clinical pathways can reduce costs and inappropriate variability in care has been the subject of much debate. As clinical treatment guidelines and pathways are increasingly deployed in oncology practice, they have a growing impact on the quality of treatment and how it is delivered. To fulfill the current need to discuss the use of pathways and clinical treatment guidelines in oncology and to address how patient care is impacted by their use, the National Comprehensive Cancer Network convened the NCCN Oncology Policy Summit: Equity in Cancer Care—Pathways, Protocols, and Guidelines. The summit was a forum to discuss the use and implementation of pathways, including how much flexibility pathways should allow in care, pathways' impact on public and private health insurance benefit design, what data is used to select pathway regimens and protocols, and ultimately what impact pathways may have on variation in care. The use and implementation of clinical treatment guidelines in practice was also explored from a variety of perspectives. (*JNCCN* 2012;10[Suppl 1]:S1–S9)

Executive Summary

The quality of patient care often varies based on numerous factors, such as health care setting, geographic location, access to medications, insurance coverage, and treatment protocols. Variations in health care are well established, often leading to different services being pro-

vided with varied outcomes, depending on location.^{1–3} Recently, whether the use of clinical pathways (referred to throughout as *pathways*), which are evidence-based treatment protocols designed to manage patient care, can reduce costs without reducing the quality of care has been the subject of much debate. The ability of pathways to reduce inappropriate variability in care is also in question. Increasingly, payors are considering pathways in oncology when contracting with providers as a mechanism to improve quality, reduce variability, and decrease costs. This raises questions regarding what data are being used to determine treatment options included in a pathway, the consistency with which they are monitored, how they affect reimbursement and insurance, and ultimately how they are affecting patient outcomes. In addition, debate exists over what impact clinical practice guidelines and pathways have on parity in care. As clinical treatment guidelines and pathways are increasingly deployed in oncology practice, they have a growing impact on the quality of treatment and how it is delivered.

To fulfill the current need to discuss the use of pathways and clinical treatment guidelines (referred to throughout as *guidelines*) in oncology and address how patient care is impacted by their use, NCCN convened the NCCN Oncology Policy Summit: Equity in Cancer Care—Pathways, Protocols, and Guidelines in Washington, DC, on Friday, May 11, 2012. The summit featured 2 expert roundtable discussions addressing the clinical, administrative, patient, payor, and pathway-developer perspectives regarding the use and implementation of both guidelines and pathways; a question and answer session addressing the development of pathways; and several overview presentations regarding the use of pathways and clinical practice guidelines. Attendees included patient

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Correspondence: Jessica K. DeMartino, PhD, National Comprehensive Cancer Network, 275 Commerce Drive, Suite 300, Fort Washington, PA 19034. E-mail: demartino@nccn.org

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advocacy groups, providers, policy-makers, industry, payors, pathway company representatives, and other relevant stakeholders. The summit was a forum to discuss the use and implementation of pathways, including how much flexibility pathways should allow in care, pathways' impact on public and private health insurance benefit design, what data are used to select pathway regimens and protocols, and ultimately what impact pathways may have on variation in care. The use and implementation of clinical treatment guidelines in practice was also explored from a variety of perspectives. Identifying the benefits and limitations of guidelines and pathways to improve care for all patients was a major focus of the summit.

This White Paper explores the use of guidelines and pathways in oncology and incorporates the discussions and ideas that were raised at the NCCN Oncology Policy Summit.

Clinical Practice Guidelines

Clinical practice guidelines have been looked to as a way to assist health care providers in clinical decision-making and ultimately to improve high-quality care for all patients through decreasing inappropriate variation in care.⁴ Two types of evidence-based guidelines are available: those that address care over a continuum and those that are an exhaustive review of a specific clinical issue. The broader type of guidelines, such as the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines), are a process map of integrated interventions over time. The NCCN Guidelines address coordination of care across the continuum of care, including references as appropriate. Other guidelines, such as ASCO Clinical Practice Guidelines, are more focused, constituting a comprehensive review of a specific clinical issue, often with an extensive analysis of the available literature. Comprehensive guidelines are often built on high-level evidence where it exists, with gaps in the evidence supplemented with expert judgment and consensus to cover the continuum of care.

The NCCN Guidelines are a comprehensive, multidisciplinary set of clinical algorithms and supporting documents developed in collaboration with 21 major United States cancer centers, all NCCN Member Institutions. NCCN Guidelines, covering 97% of malignancies affecting individuals with cancer, contain thousands of decision points and

are updated continuously, with reviews occurring at least annually and more frequently if, for example, a new drug is approved by the FDA or a major finding is announced at a conference. A level of evidence and consensus is assigned to each recommendation based on the best evidence available at the time it is derived. The NCCN Guidelines are developed and updated by 47 individual panels, composed of more than 950 clinicians and oncology researchers from the 21 NCCN Member Institutions and their affiliates, who volunteer more than 18,000 hours per year to the mission. These panel members are multidisciplinary, disease-specific subspecialists who are both clinicians and researchers. In addition, each guideline undergoes annual institutional review wherein it is circulated for comment among the multidisciplinary faculty at each NCCN Member Institution.

The goal of the NCCN Guidelines is to help oncologists make the major clinical decisions encountered in managing patients through providing ready access to synthesized information. The NCCN Guidelines provide recommendations for appropriate care for most but not all patients; however, individual patient circumstances must be considered when applying these recommendations. Factors that may impact clinical recommendations include comorbidities, patient status, scheduling, route of treatment administration, and choice. Guidelines offer a range of appropriate treatments for specific situations that are addressed.

Clinical Pathways

Pathways are evidence-based treatment protocols that are used by payors and clinicians. They are often selections of the most cost-effective treatment options that have the greatest efficacy and minimize toxicities. Currently, the focus of pathway developers and users has been on the higher-incidence malignancies, such as breast, colon, prostate, and lung cancers, and certain types of blood cancers. Most pathways began by focusing on chemotherapy, but have started to broaden their focus to include more of the continuum of care, including end of life/palliative care, surveillance, imaging, and supportive care. The companies developing pathway programs include eviti, New Century Health, P4 Pathways, US Oncology, and Via Oncology. Although other companies may be developing pathways, this White Pa-

per focuses on these 5 companies only. The information on these companies provided in the following sections comes directly from their Web sites, comments made at the NCCN Oncology Policy Summit, or additional literature.

P4 Pathways (A Cardinal Health Company)

According to the P4 Pathways Web site,

P4 Healthcare's Pathways Program partners with payers across the country to establish clinically proven, evidence-based oncology treatment protocols designed to promote the delivery of high quality, cost efficient patient care. These protocols seek optimal patient outcomes by ensuring selections of the most cost effective medications, minimizing side effects, reducing errors, and minimizing toxicities...Significant cost savings and enhanced care are realized by eliminating unnecessary medical costs, reducing hospitalization and selecting the most cost effective medications.⁵

P4 Pathways develops its pathways through collaboration with local oncology community leaders. This collaborative development is aimed at improving physician acceptance and compliance. Specifically, as described on the P4 Pathways Web site,

P4 Pathways manages the development of pathways by establishing a steering committee of locally based academic and community oncologists to ensure pathways reflect both rigorous evidence-based medicine and the clinical expertise in that region. The pathway development process often includes several meetings and appointed sub-committees to identify optimal pathways for specific tumor types. The Steering Committee meets quarterly or more frequently when warranted to approve updates, ensuring pathway protocols quickly incorporate any proven medical advancements. Pathways Programs are flexible to reflect the evolving standards of care in evidence-based medicine.⁵

As noted, P4 Pathways are currently organized on a regional basis, but in the future they may consider a centralized process for all users.

New Century Health

New Century Health is a specialty care management company that offers "... technology and clinical solutions that help to improve the quality of patient

care, reduce administrative work associated with the delivery of care, and lower therapeutic costs for payers and physicians."⁶

New Century Health works with Medicare, Medicaid, and private payors covering approximately 500,000 individuals, and suggests possible "...cost savings of up to 30%."⁶ New Century Health uses a national approach to developing pathways, and currently has pathways for 7 diagnoses and are in the process of developing 6 more. New Century Health recently started to have community physicians review the pathways monthly to look for changes that need to be made to reflect recent treatment changes and advances.

Via Oncology/D3 Oncology Solutions

Via Oncology describes their pathways as

...continually updated, physician-led, evidence-based algorithms for common oncology and malignant hematology patient presentations imbedded in a patient specific, point of care, decision support tool that allows cancer programs to ensure and demonstrate quality and efficiency for patients and other stakeholders.⁷

Although the pathway program initially focused on chemotherapy protocols for 3 or 4 diseases, these have expanded to cover 95% of cancer incidences and include decisions surrounding prognostic testing, imaging, radiation therapy, and supportive care.⁸

Further, Via Oncology's pathways

are developed by expert panels of disease-specific academic and community oncologists from around the country who meet quarterly to establish and update their consensus around a single-best treatment for each state and stage of disease based on a hierarchy of efficacy, toxicity, and cost...the committee examines if there are patient subpopulations for which that treatment is not appropriate (such as drug contraindications) and determines the best therapy that addresses that subpopulation, adding branches to the Pathways to ensure at least 80% coverage of possible presentations.⁷

For example, the lung cancer pathways include 18 main branches with an additional 41 suboptions branching off of those.⁸ Via Oncology also provides practices with the ability to easily customize the Via Oncology Pathways and Portal.

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eviti

According to their Web site, eviti is hoping to “transform the cancer treatment decision process with its innovative oncology platform called eviti Suite.” eviti Suite was, “...developed through a unique collaboration of leading oncologists, actuaries, insurance professionals and software engineers...” and hopes to empower “physicians with advanced oncology decision support and payors with real-time automated precertification, aligning quality care with the appropriate reimbursement.”⁹

Further, “eviti provides both software and clinical services and is backed by an extensive clinical library compiled and managed by expert oncologists.” eviti contains more than 1200 treatment regimens, addresses modalities for 120 cancer types, accounts for “outcomes, toxicities, costs, and efficacy” and assists with the reimbursement process. eviti claims to provide “a transformative decision-support solution to the cancer crisis by empowering physicians with advanced cancer strategies and oncology decision support – well beyond clinical pathways.”⁹

US Oncology

The Level I Pathways for US Oncology,

are evidence-based medicine guidelines that provide precise, clinically proven cancer-treatment regimens for the 14 most commonly diagnosed cancers....Level I Pathways are developed by a multi-disciplinary task force that is led by more than 1,000 practicing community oncologists in The US Oncology Network. Recommended pathways have been proven through high-quality research to have the best outcomes and the lowest toxicities for the majority of patients....Level I Pathways are reviewed quarterly and updated regularly as the science advances.¹⁰

US Oncology recognizes that “every patient is unique” and thus their “pathways are based on the 80/20 rule, which recommends therapies that work for the majority of patients” and

it is expected that 20% of patients will be treated off-pathway to accommodate the patient’s specific needs and clinical situation....All physicians in The US Oncology Network have access to Level I Pathways and the research that makes these pathways viable. Members can opt into methods to report on and track their adherence to pathways.¹⁰

Business Models

Pathway companies use 2 common business models. In the first model, a payor contracts with a pathway developer to develop pathways that are then marketed to the oncologists who are contracted with the payor. The payor provides incentives to the oncologists who use the pathways (the incentives offered by payors are discussed later). In the second model, oncologists work directly with pathway companies to develop pathways. The oncologists then work with their payors to develop incentives the payors will give to the oncologists for following the pathways.

Uptake of Pathways

The uptake of pathways by oncologists can be influenced by many factors, such as the size of a clinical practice. The practices least likely to participate are small and very large practices. Although gaining physician acceptance may be easy in a small practice, pathways may not generate enough cost savings to attract related incentive offers from contracted payors. In very large practices, getting buy-in from all physicians can be difficult, and these practices may not be interested in small financial gains that require major changes in the way care is delivered. Medium-sized practices may be most interested in using pathways and, because of the manageable number of physicians, practices this size may find it easier to adopt pathways.

Pathways that reflect the way physicians are already delivering care are more likely to be accepted. Pathway vendors can customize pathways to meet the needs of their physician clients. Many pathways provide enough flexibility to meet the needs of oncologists and patients, especially when the pathway recommendations are inappropriate based on the patient profile. Some pathways are updated regularly, but pathway companies must continue to refine their pathways and introduce more granularity to account for more specific patient scenarios, including stages/states of disease, specific biomarkers, toxicity issues, comorbidities, and patient choice. It is also important for pathways to incorporate new technologies, both diagnostic and interventional.

Pathway Restrictions

Although pathways may allow some clinical flexibility, pathway restrictions come in a variety of forms:

defined number of lines of therapy, limited number of treatment options within each line, limited use of an agent to a single line, and delayed inclusion of a product. These restrictions may impact the care patients receive. At the summit, all of the pathway companies reported that 10% to 20% of care is delivered off-pathway. Different methods of approving this off-pathway treatment were mentioned. In some cases, a physician may need to get approval from a group of consulting physicians to treat their patient in the desired off-pathway fashion.

Incentives to Use Pathways

Several options of incentives are offered for adherence to pathways. An adherence rate of 80% to 85% is usually required to receive the incentives. The most common incentives are a share of cost savings, an initiation fee, a higher reimbursement rate on drugs, and a lower risk of denied or delayed reimbursement. Tactics to drive oncologists' adherence may transition from financial incentives to variability in reimbursement dependent on treatment selection. In a recent collaboration between Blue Cross Blue Shield of Michigan (BCBSM) and Physician Resource Management (PRM) to use P4 Pathways, physicians were provided a \$5000 payment for the first year of the program to cover any extra costs and to provide a financial incentive to participate and meet approved compliance thresholds.¹¹ Additionally, reimbursement rates for several generic therapies associated with the implemented pathways were increased to remove perverse incentives. For those who met compliance requirements in year one, their evaluation and management codes would also be increased by 10%.

The number of participating oncologists and the restrictiveness of pathways are 2 variables that will affect future pathway growth. A level of restrictiveness may exist that physicians are unwilling to comply with and they in turn will not be willing to use pathways. Oncologists need clinical autonomy to make the correct decisions for their patients. Will pathways need to become increasingly more restrictive to keep delivering cost savings? Different incentive models will be needed to sustain the use of pathways. Additionally, as more companies develop pathways and more practices adopt them, the need to collect data to effectively evaluate their impact increases.

Transparency

When comparing guidelines and pathways, one major distinction is in the transparency of what is included in each guideline or pathway. NCCN Guidelines are publicly available for all physicians, patients, payors, and manufacturers to use, review, and critique. Transparency was discussed with the pathway companies during the summit. In most if not all cases, the pathways, along with references, are available only to participating physicians. Currently, patients, nonparticipating physicians, pharmaceutical manufacturers, and the general public do not have access to view any pathways, although it is often noted that many pathways comprise a subset of NCCN Guidelines. US Oncology indicated they may be moving forward with allowing non-US Oncology physicians to access their pathways. The lack of transparency is in many ways a business issue. Millions of dollars are spent to develop pathways, and therefore pathway companies are often hesitant to share this information that they consider to be proprietary. Ultimately, it was predicted at the summit that everyone's pathways will end up being clinically similar and the execution of the pathways' associated software will be the factor that differentiates pathway products. It was also discussed that manufacturers are kept out of the discussion to limit influence on pathway developers. The NCCN Guidelines development process maintains transparency while countering undue influence from manufacturers through conflict of interest policies and firewalls. Although transparency can be seen as a business issue, patients and other interested groups are left in the dark regarding what constitutes a pathway and the criteria on which it is created.

Clinical Integration of Pathways

Oncology practices are faced with numerous pathways options, and choosing the appropriate system involves careful research and preparation. More research and related education is needed to help oncologists determine the impact of different pathways on practice. However, in some cases wherein certain payors may require the use of specific pathways, questions remain about how practices would adapt, considering they may be contracted with multiple insurance companies that could require an alternate pathway, or do not require pathways at all. This has the potential to complicate the administration and

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delivery of care, especially if practices must use different pathways and their corresponding software. It was suggested at the summit that physician-designed pathways would be preferable to those developed by health plans, because physician uptake and compliance would be higher if physicians are given an integral role in the development process.

Ability to effectively integrate pathways into existing practice is another challenge to broad implementation. From a practical perspective, the software associated with pathways must be compatible with existing electronic health records, when they exist, to ensure data are used efficiently, not duplicated, and useful to practices in reaching the intended goals of pathways, such as reduced variability in care and cost savings, with the ultimate goal of more consistent delivery of high-quality care. With increasing pressure on practices to stay financially viable, these goals are more important than ever. To make these systems effective, however, adequate staff resources and training are needed to ensure data are appropriately and accurately entered, which involves the investment of time and potential workflow reorganization.

Apart from the practical workflow aspects of implementation, some clinicians may be wary of pathways, because of the perception that they may limit reimbursable options for care and, in effect, reduce clinical choice in decision-making. Although pathways companies have emphasized flexibility in overall adherence to pathways, how care that deviates from the pathways will be addressed in cases involving reimbursement is not always clear. Despite these concerns, some state and regional oncology societies have begun to consider pathways more seriously as the cost of practicing continues to rise, with several starting to use pathways in practice.¹² Mariotto et al¹³ estimate that cancer costs between 2010 and 2020 will rise by 27% based on aging and population growth alone, and considerably more if the cost of cancer care itself continues to rise.

During the summit, it was suggested that pathways should be localized/regionalized due to cultural and price differences, because economics and practice patterns often differ at the local level. When designing their pathways, pathway companies must consider whether to cater them to local practice or offer a centralized pathway. For example, although P4 Healthcare has considered centralizing its path-

ways processes, it maintains local/regional processes because of this regional variation. If pathways are localized/regionalized, different care may be recommended based on location. It was also noted that, although pathways are typically consistent with NCCN Guidelines, they narrow the options described in the NCCN Guidelines and provide suggestions for when these options are appropriate.

A 2011 *Journal of Oncology Practice* article details a 2010 survey of oncology practices by Altos Solutions, an electronic medical record company. The survey attempted to identify the sources of pathways and the extent to which they are actively used in oncology practices. The company received 112 responses, and 80 practices reported that they use oncology pathways. The results of this survey showed that 37.5% and 7.5% of pathways were generated by practices and hospitals, respectively.¹⁴

Moffitt Cancer Center, an NCCN Member Institution, has taken this approach to pathway inclusion and developed its own pathways, which include efficacy, toxicity, and cost (average wholesale price) data. They are considering options for including the patient's copay with the pathway information for the future. This would increase the clinicians' ability to discuss cost with patients at the point of care, while also providing relevant efficacy and toxicity information to patients. The ideal of having pathways list the costs for 3 parties—patient, provider, and payor—was also suggested at the summit. Pathways will continue to be developed by both commercial parties, and practices and hospitals themselves.

Impact of Pathways on the Biopharmaceutical Industry

Along with the constantly evolving regulatory environment, biopharmaceutical companies are dealing with an ever-changing coverage and reimbursement environment. Implementation and use of pathways impacts the pharmaceutical industry in regard to the development and marketing of drugs and biologics. Industry needs their drugs placed on pathways to be used and reimbursed. However, pathway developers stressed that drugs will need to be innovative, be differentiated, or satisfy unmet needs to be included. For example, if a new drug has a specified molecular target and corresponding molecular test, it will have a much greater probability of being included in pathways. If a

“me too” drug is brought to the market, it will either need to have additional benefits and/or lowered toxicity, or be less expensive than current options. Inclusion of drugs on pathways will vary in speed from very quickly (< 30 days) for life-saving advances to much longer. The speed of inclusion can depend on the type and quality of supporting evidence. Companies should also consider the costs of associated services for new medications and interventions such as hospitalizations, emergency room visits, and supportive care. For many companies, having their drug placed on a pathway requires similar efforts as having their drug placed on formulary in the clinic.

Patients and Pathways

Patients are just beginning to understand the concept of personalized medicine, that each patient and each tumor is different, and that every drug works differently depending on the individual being treated. Physicians and patient advocacy groups must now begin to explain what it means to be treated on pathways, because many patients are unfamiliar with the concept. When explaining pathways to patients, care must be taken to explain that pathways are not contradictory to personalized medicine. Patients will need to understand that their physicians will have latitude to practice outside the pathways if needed. Furthermore, patients may need to see an entire pathway to understand that pathways can be stratified and patient characteristics are taken into consideration.

Patients must be made aware of the use of pathways and in turn must understand the following concepts to accept pathways:

- Pathways are developed by experts, and allow community oncologists to use the expertise of others to help treat their own patients.
- Pathways foster a multidisciplinary approach by incorporating the viewpoints of various types of physicians.
- Following pathways may improve outcomes. Patients will need to be told about relevant studies that support the use of pathways.
- Following pathways may save patients money. Patients will need to be shown possible cost savings.

Payors and Pathways

Many payors partner with providers and pathway companies to implement pathways. Use and monitoring of pathways can provide information on what payors are actually paying for. Claims data cannot provide the same level of granular information as data collected from pathways. Even with pathways, a need exists for more granular reporting to have all necessary data to measure outcomes. Payors are looking for compatible pathway systems that can be integrated with their existing systems. Payor–pathway developer collaborations provide an opportunity for both parties to benefit. At the summit, a major payor expressed that pathways fill the economic void that guidelines do not. Pathways are also viewed by payors as a way to deal with perverse financial incentives that currently exist, such as average sales price (ASP) plus 6%, and different payment incentives for intravenous and oral drugs or infusion and subcutaneous administrations. Payors highlighted some of the benefits of using pathways, such as simplifying workflows and removing precertification and prior authorization requirements. It was also warned that practices must be wary of contracts with payors that reward them simply based on cost savings, because that type of incentive model is not sustainable. This model is unsustainable because as the physicians practice closer to the “ideal,” no cost savings will be available to be shared.

Pathway Studies and Results

Limited studies are available to show clinical and financial outcomes of using pathways. A 2010 report by Neubauer et al¹⁵ showed measurable cost savings for patients with non–small cell lung cancer treated on a clinical pathway compared with those who received nonpathway treatment. Outpatient costs were 35% lower for patients on clinical pathways, with an average 12-month cost of \$18,042 for pathway versus \$27,737 for nonpathway treatment. A 2011 study by Hoverman et al¹⁶ used 2 databases to evaluate clinical outcomes and economic impact of adherence to Level I US Oncology Pathways in the treatment of colon cancer. Overall costs from the national claims database were lower for patients treated on-pathway, and use of pathways was associated with a shorter duration of therapy and lower rate of chemotherapy-related hospital admission. Survival for patients treated on-pathway was comparable to that reported in published literature.

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Recently Via Oncology partnered with Horizon Blue Cross Blue Shield of New Jersey to operate a pilot project that supports and evaluates Via Oncology Pathways in 2 oncology practices in New Jersey. Preliminary cost analyses indicate successful results in terms of lowering total cost of lung and breast cancer care for the pathway practices relative to nonpathway practices. Results from these studies are expected to be published by the end of 2012.⁸

A recent article in the *American Journal of Managed Care* highlighted and detailed the relationship among 3 organizations (BCBSM, PRM, and Cardinal Health Specialty Solutions [P4 Pathways]) that created a collaborative clinical pathway program.¹¹ To gauge the effectiveness of pathways, the authors chose to use physician compliance and behavioral changes as surrogate markers of cost savings, which can be difficult to show as a result of evolving patterns of care, new drug technologies, and data capture problems from revenue code and charge bundling for example. Baseline pathway compliance was high at 88% and increased to 95% in the first year of the program. Behavioral changes adopted by participants included converting from brand to generic regimens when equally effective and equitoxic; converting from more expensive to less expensive brand regimens under the same parameters; using molecular diagnostics to appropriately guide therapy; appropriate use of supportive care based on evidence; decreasing lines of therapy when evidence was lacking; and limiting late lines of therapy to single-agent cytotoxics. These changes all resulted in lower rates of emergency department and hospital use. Feinberg et al¹¹ believe that a sustainable reduction in variance inherently improves quality and lowers cost and can only be achieved through changes in physician behavior. It was also stated that it is virtually impossible to validate savings with the currently available data from payors and providers.

Although the results of these studies encourage the use of pathways, several considerations are appropriate when analyzing pathways studies. First, users of the data and results should be aware of the limitations of the data sources used. Electronic medical records and claims data are not research-quality data. Other potential issues to consider regarding data include lack of assurance over data abstraction, that ICD-9 codes may not be precise, and missing data fields. There may also be limitations in the methodology. Definitions

of what is considered on- and off-pathway should be clear and there should be assurance of comparable patient populations and clinical characteristics. Legitimate reasons for off-pathway treatment should be discussed and analyzed. The Feinberg study identifies several of these limitations and addresses the problem by using surrogate markers of physician compliance and behavioral changes instead of cost elements.¹¹ To fully gauge the effectiveness of pathways, more rigorous studies that measure meaningful clinical and financial outcomes are needed.

Conclusions

Variations in health care are well established and the cost of care continues to rise. As clinical treatment guidelines and pathways are increasingly deployed in oncology practice to control these variables, they will have a growing impact on how treatment is delivered and ultimately on health outcomes for patients. Stakeholder engagement and dialogue throughout the course of the summit validated the increasing role of guidelines and pathways in improving value and quality of care. Many variables can affect the uptake of pathways, including physician buy-in, financial incentives, ease of integration, and clinical value of the pathways. The limited studies on the use of pathways have reported modest results both financially and clinically, but care must be taken when evaluating these studies. It is important that the oncology community continues to work collaboratively to identify mechanisms for increasing the quality of care for people with cancer.

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