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Special Report

Clinical Cancer Research

Clinical Pathways: Recommendations for Putting Patients at the Center of Value-Based Care

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Abstract

Two major trends that have been affecting the provision of oncology care in the United States are a shift from volume-based to value-based care and a push toward patient-centered healthcare. However, these two trends are not always completely aligned with each other. Value-based payment models, including clinical pathways, are one strategy being implemented by oncology stakeholders to help encourage the uptake of value-based oncology care. If structured with the patient in mind, they can improve quality of care for patients with cancer, decrease inappropriate care while enabling appropriate personalization of care, and constrain rising prices by demanding a stronger link between cost and value. If not structured appropriately, they can limit patient choice, impede access to innovative treatments, and encourage one-size-fits-all oncology care. *Clin Cancer Res; 23(16); 1–5. ©2017 AACR.*

In the summer of 2016, the Turning the Tide Against Cancer initiative convened a working group comprised of a multidisciplinary group of stakeholders to come to consensus around a set of best practices for oncology clinical pathways that balance innovation with patient access. The project also included an assessment of select pathways and pathway programs to determine how closely they align with the identified best practices. This article focuses on the assessment and outlines four key findings about how pathways affect patient care:

1. There is little transparency to help patients understand how pathways are developed and modified, how payers and developers choose specific regimens for inclusion in their pathway, and whether and how payers and developers consider cost to designate on-pathway versus off-pathway treatments.
2. Pathway developers frequently do not engage patients in pathway development and maintenance and instead see patient engagement as an "after-the-fact" responsibility of providers.
3. Pathways can potentially interfere with the patient–provider decision-making process. Providers and health care teams may face redundant workflows due to managing multiple pathways. This is exacerbated by a lack of interoperability and integration between the pathway's IT infrastructure and the patient's electronic medical record (EMR), all of which add to provider burden at the point of care.
4. There remains a significant lack of accountability, particularly to patients, for the quality, effectiveness, and transparency of pathways.

Turning the Tide previously recommended that an independent third party or coalition of stakeholder groups should serve in an accreditation or oversight capacity for pathway tools. Now, the initiative also recommends that this body should partner with and actively engage the oncology patient community directly to not only encourage the development of patient-centered clinical pathways, but also encourage their adoption and use.

Introduction

Oncology care has been experiencing a shift from volume-based to value-based reimbursement over the past several years (1). As stakeholders, including payers, physicians, patients, and policymakers, seek solutions to improve care access and value, they have tested and adopted a wide range of alternative or "value-based" payment models. This focus on value has driven an increased interest in payment models, including clinical pathways, and other decision support as a means by which to maximize evidence-based care, while minimizing ineffective or costly treatments (2–6). In addition, as patients face increasing out-of-pocket costs after a cancer diagnosis, their concerns over the total cost of oncology care have become particularly acute (7–10). The popularity of clinical pathways has been growing; a 2012 McKinsey report estimated that by 2015, 25% of oncology lives will have been treated by clinical pathways (11). If structured well, these tools hold promise in supporting patient-centered care and improving care quality for patients with cancer. They also hold potential in reducing inappropriate and wasteful spending, and

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constraining rising prices by demanding a stronger link between treatment cost and value (12).

Concurrent with the shift from volume to value in oncology care has been a push toward patient-centered health care more broadly. For a health care infrastructure to be considered patient centered, it must prioritize patient needs and treatment goals, but many of the tools used to support treatment decision-making do not necessarily have the patients' needs as their primary focus and are not always sensitive to patient preference (9). In regards to clinical pathways specifically, a 2015 Cancer*Care* survey found that 82% of the 1,300 patients surveyed had not heard the term "clinical pathway" (13). When considering the Cancer*Care* survey findings in combination with the aforementioned McKinsey projection (11), it is possible that some of the patients included in the Cancer*Care* survey may have had their treatment determined by a pathway, a tool of which they may have no knowledge.

Given stakeholders' significant interest in clinical pathways as a tool to guide treatment decisions and drive value, as well as patients' interest in ensuring that pathways are of high quality and incorporate their needs and preferences, the Turning the Tide Against Cancer Through Sustained Medical Innovation (Turning the Tide) initiative decided to assess whether pathways were effectively facilitating patient access to high-quality and high-value oncology care. Our analysis suggested that a lack of accountability exists across the continuum of a pathway, which led to a recommendation that an independent third party serve in an accreditation or oversight capacity for these tools (14).

Pathways, Guidelines, and Standard of Care

Although these terms often are confused, clinical pathways are distinct from clinical guidelines or standard of care (SOC). The National Academy of Medicine (formerly the Institute of Medicine) defines guidelines as "recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" (15). Guidelines are typically based on, or incorporate the SOC, a term that the NCI (Rockville, MD) defines as "treatment that is accepted by medical experts as proper treatment for a certain disease and that is widely used by the healthcare profession" (16). Although clinical pathways are based on practice guidelines and SOC, pathways can be viewed more as practical and efficient decision support tools that distill guidelines and direct treatment decisions for specific populations of patients. In addition, pathways can be constructed to meet different goals, depending on the needs of the payer, that is, decision support, preauthorization, cost containment, etc., which means the benefits and drawback of specific pathways can also differ. In general, when designed appropriately, pathways can help patients access optimal care by keeping physicians informed of quickly evolving science, aiding evidence-based decision-making, and limiting unnecessary variation (17). However, pathways can also impede access to innovative oncology treatment, constrain provider autonomy, and, perhaps most importantly, may limit patient choice and preference.

Methodology

Throughout the summer of 2016, the Turning the Tide initiative convened a series of meetings with a multidisciplinary expert working group to understand how pathways can sustain innovation while enabling high-quality, patient-focused care. The working group, which included members from the patient advocacy, health care provider and researcher, biopharmaceutical, and health information technology stakeholder communities, were engaged in a two-phase project designed to:

- arrive at consensus around a set of best practices for oncology clinical pathways that balances patient access with quality and value in cancer care; and
- conduct an assessment of select pathways and pathway programs to determine how closely those programs align with the identified best practices.

The full list of consensus best practices and methodology behind their development is described elsewhere (14). In brief, the best practices were divided into three phases: development, implementation, and monitoring and evaluation. The best practices stressed the need for stakeholder engagement, transparency, and a focus on evidence-based shared decision-making. For the purposes of the expert working group exercise and this white paper, oncology clinical pathways were understood as "multidisciplinary care plans that translate evidence into specific guidance on the sequencing of care and the timeline of interventions for patients with specific diagnoses and characteristics."

After the consensus best practices were developed, the Turning the Tide initiative worked with Discern Health, a research firm, to conduct a review and informational interviews with representatives from seven pathway programs of interest (see Appendix A). The organizations included in this assessment reflected diverse approaches to pathway development, implementation, and utilization. Because of mergers and product changes, six organizations were included in the final assessment. Although not a pathways program, the National Comprehensive Cancer Network (NCCN) guidelines, which frequently serve as the foundational evidence source for many pathway developers, were also examined.

Discern Health created a profile for each pathway organization included in our assessment plus NCCN. These were sent to each organization with a request for review. Variable amounts of information were publicly accessible for these organizations. Some pieces of information, including governance documents and the pathways themselves, were rarely publicly available. Discern Health also accepted information that was provided verbally by the organization during direct interviews. Not all organizations responded to requests for interviews. The information presented here reflects company practice at the time of the research.

Findings

After completing an assessment of the pathway organizations against the consensus best practices, several overarching themes arose around how pathways can affect patient care. Our analysis identified the following key findings (summarized in Table 1):

Key finding 1: transparency

There is little transparency to help patients understand how pathways are developed and modified, how payers and developers choose specific regimens for inclusion in their pathway, and

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Table 1. Assessment key findings

1. There is little transparency to help patients understand how pathways are developed and modified, how payers and developers choose specific regimens for inclusion in their pathway, and whether and how payers and developers consider cost to designate on-pathway versus off-pathway treatments.
2. Pathway developers frequently do not engage patients in pathway development and maintenance, and instead see patient engagement as an "after-the-fact" responsibility of providers.
3. Pathways can potentially interfere with the patient–provider decision-making process. Providers and health care teams may face redundant workflows due to managing multiple pathways. This is exacerbated by a lack of interoperability and integration between the pathway's IT infrastructure and the patient's electronic medical record, all of which add to provider burden at the point of care.
4. There remains a significant lack of accountability for the quality, effectiveness, and transparency of pathways, particularly to patients.

whether and how payers and developer consider cost to designate on-pathway versus off-pathway treatments.

- None of the pathways included in this assessment had publicly available information pertaining to how developers or payers select which treatments are on-pathway versus not, how payer preferences are weighted, or how disagreements between payers, providers, pathways developers, etc., are resolved.
- All of the organizations included had general descriptive information about their pathway development processes publicly available. For example, pathway organizations generally identified the clinical guidelines they used as the source material and their hierarchy for making decisions, that is, on-pathway treatments are usually identified first by efficacy, then by treatment toxicity and strength of evidence, then by cost. However, only three organizations named the stakeholders involved in the pathway development process, only two provided details on the criteria used to include various treatments, and no organization provided details on how evidence, toxicity, and cost were weighted relative to each other. Two organizations made their pathways available at no charge to the public, and the guideline developer did the same with its pathway library. (Anthem-AIM and eviti Advisor make their pathways available at no charge to patients and practitioners; NCCN does the same with their guidelines).

Key finding 2: patient engagement

Pathway developers frequently do not engage patients in pathway development and maintenance, and instead see patient engagement as an "after-the-fact" responsibility of providers.

- No organizations included in this assessment involved patients in the development, implementation, or monitoring and evaluation of their pathway tools, although the guideline developer did include some patients in their development process.
- Pathway developers viewed patient engagement, including communications, about the use of a pathways tool to guide treatment, and discussions about patient preferences on treatment goals, cost, effectiveness, side-effect burden, etc., as being the responsibility of the health care provider; as such, patient engagement did not occur until after a pathway tool was developed and implemented.
- None of the pathway developers provided patient-directed information or education around specific pathways (although some offered general cancer resources and treatment information). In addition, none of the pathway developers offered information to help providers disclose the use of pathways (or their related incentive programs) to patients (Via Oncology has developed informational materials for patients, including website content about the need for evidence-based treatment; NCCN has created a library of patient-focused treatment information to accompany their provider-focused guidelines).

Key finding 3: shared decision-making

Pathways can potentially interfere with the patient–provider decision-making process. Providers and health care teams may face redundant workflows due to managing multiple pathways. This is exacerbated by a lack of interoperability and integration between the pathway's IT infrastructure and the patient's EMR, all of which add to provider burden at the point of care.

- Pathways were used to meet a variety of different treatment and authorization goals and varied significantly depending on how they are implemented. This meant that health care providers and their teams could not assume all pathways were used to meet the same goals. As such, teams may need to track multiple similar, but not identical, pathway tools from multiple payer and developer sources.
- In addition, every payer had a unique web-based portal or IT infrastructure for their pathway that was usually noninteroperable with the providers' EMR system. This meant that providers may have to access and manage multiple tools at the point of care, which could interfere with patient–provider communication, hinder decision-making, and impair provider efficiency.
- Tools aimed at integrating pathways more broadly into providers' workflows at the point of care were, and still are, needed. These kinds of tools could help relieve some of the administrative burden and potentially facilitate a more informed and engaged patient/provider decision-making process (McKesson stated its pathways do integrate with several brands of EMRs and that the software can display pathway options according to payer preference. Via Oncology's product linked to a practice management system for real-time decision support capabilities but does not interface with payer portals or integrate with patient-specific EMRs).
- Patient participation in clinical trials was not treated consistently across pathways (e.g., off-pathway versus on-pathway). Under two pathways, providers' adherence metrics were negatively affected if they encouraged a patient to participate in a clinical trial, that is, recommended a clinical trial instead of the pathway. However, these pathway programs did indicate that not all patients were expected to be treated on pathway. That being said, more pathway programs did appear to be treating clinical trial participation as "on-pathway" for the purposes of provider adherence metrics.

Key finding 4: accountability

There remains a significant lack of accountability for the quality, effectiveness, and transparency of pathways, particularly to patients.

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- All pathway developers routinely monitored and updated their pathways to reflect updates in evidence. There were no standard practices for off-cycle pathway updates, or for the integration of real-world data into the pathways. Five pathway organizations used the NCCN guidelines as the foundational evidence source and updated their pathways in accordance with changes to the source guideline. Information on how the organizations weighted or assessed data outside of the guidelines, or guideline revisions, was not publicly available.
- Moreover, as these pathways did not integrate with a patient's EMR, patient-specific data were not available to pathway developers to monitor outcomes or evaluate the effectiveness, accuracy, quality, or appropriateness of the care provided. As such, none of the organizations included were conducting universal monitoring or collaborative monitoring of pathway-related outcomes at the time of this analysis (many pathway organizations included in our assessment stated that because patient outcome data resides in EMRs, pathway developers may not be able to access or assess these data).

Discussion

The findings of this assessment align with those of prior analyses of oncology clinical pathways. Specifically, our assessment confirms there is a lack of transparency in several aspects of how pathways are developed and implemented, in how a payer determines whether a treatment is on-pathway versus off-pathway, and whether the pathway integrates robust and relevant evidence (2–6). In addition, we found that pathways may not fully be meeting patient needs because patient feedback is not solicited in the development, implementation, or monitoring and evaluation processes, making it difficult to determine whether pathways are created with the end-user in mind, or are set up to support personalized and patient-centric medicine (2, 3, 6).

Concerns around whether patient preferences or needs are being addressed by clinical pathways are compounded by two additional findings. One, our analysis again confirms others' findings that pathways can interfere with the patient–provider decision-making process by requiring redundant workflows, adding to the provider's administrative burden, hampering care flexibility, and potentially causing delays in patients receiving much-needed treatment (3, 5, 6). Two, our analysis adds to the concerns of others that there remains a lack of accountability around pathways, particularly when it comes to assessing quality metrics and incorporating patient outcomes, and ensuring that pathways are, in fact, supporting high-quality and appropriate care (2–6).

Recommendations

A 2016 Cancer*Care* survey of more than 3,000 adult cancer patients found that two thirds reported having enough information about the benefits and goals of their treatment plan, the possible side effects or symptoms of treatment, or why a specific regimen was being recommended (9). This is concerning when considering the findings of an earlier survey, which reported that the vast majority of patients thought it was important to understand more about the pathways that were guiding decision-making concerning their cancer treatment, including whether the scientific and medical evidence supports using a pathway (94%), whether a pathway would prevent the patient from receiving other treatments in the future (93%), whether other treatment options were available outside of the pathway (93%), and how effective the pathway was at treating other patients with the same disease (93%; ref. 13). Although clinical pathways have the potential to be a market-driven, evidence-based, and patient-centered approach to driving value in oncology care, the research conducted by Turning the Tide initiative and Discern Health found that there is no mechanism in place to hold those that develop and utilize pathways accountable for providing high-quality care and meeting the needs of patients.

Elsewhere, the Turning the Tide initiative has recommended that the gap in accountability could be overcome if an independent third party or coalition of stakeholder groups serves in an accreditation or oversight capacity for pathway tools, from pathway development through monitoring and evaluation (14). This group would be tasked with the development of standards for high-quality, patient-centered clinical pathways and applying those standards to both new and existing clinical pathways. There are already independent bodies, including the National Commission for Quality Assurance and URAC (formerly the Utilization Review Accreditation Commission) that provide general oversight and help support accreditation across the U.S. healthcare system, as well as oncology-specific bodies, such as NCCN, American Society of Clinical Oncology, and the American College of Surgeons' Commission on Cancer.

In addition, when considering the primary findings of the analysis conducted for this article, lack of transparent and patient-focused information, lack of patient engagement, potential interference with shared decision-making, and lack of accountability, the Turning the Tide initiative also recommends that an accrediting body or consortium should partner with and actively engage the oncology patient community directly in work that would not only encourage the development of patient-centered clinical pathways, but encourage their use and adoption, including:

- Developing, or requiring the development of, patient-facing materials that include information on the general purpose of pathway tools, as well as patient-focused information on why a specific pathway is recommended for a patient, and whether participation in a pathway will limit a patient's future treatment options; and
- Engaging patients in the development of any point-of-care tools to ensure that the tool supports and enhances, rather than detracts from or interferes with, the patient/provider decision-making process.

Clinical pathways play a significant and growing role in the future of health care delivery, as stakeholders seek to identify tools and information that will facilitate a shift toward a value-based system. When designed well and appropriately used, patient-centered clinical pathways can encourage individualized oncology treatment decision making, and steer patients and providers toward the right treatment, at the right time. If pathways are not evidence-based, transparent, or discourage the movement toward more personalized cancer care, they could limit patient access and choice, and thereby stifle the oncology community's ability to adequately address unmet medical need.

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The ever-increasing proliferation and utilization of clinical pathways makes it more important than ever that pathways take into account patient priorities, support informed and shared decision-making, and ultimately deliver high-quality care to the stakeholder who needs it most, the patient.

Appendix A. Companies Included in the Pathway Assessment

Pathway developers

Alabama Blue Cross Blue Shield (BCBS)
Anthem-AIM
Cardinal Specialty Health Solutions**
eviti Advisor
McKesson Clear Value Plus
New Century Health
Via Oncology

Guideline developer

NCCN (frequently serves as the source guidelines for pathway developers).

**Cardinal Health does not develop or modify pathways or license pathways directly, as such it was ultimately excluded from the assessment.

Disclosure of Potential Conflicts of Interest

G.S. Omenn has ownership interest (including patents) in Esanik Therapeutics, Etubics/NantCell, MedsynBio LLC, and Oncofusion Therapeutics. J. Sprandio is the medical director at Vantage Cancer Care Network and has ownership interest (including patents) in Oncology Management Services. No potential conflicts of interest were disclosed by the other authors.

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