



Turning The Tide AGAINST CANCER

Through Sustained Medical Innovation

Oncology Clinical Pathway Best Practices: Understanding the Current State of Pathway Development, Implementation and Evaluation

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A Note from the Turning the Tide Against Cancer Co-Conveners

Since its inception in 2012, the mission of the Turning the Tide Against Cancer Through Sustained Medical Innovation (T3)* initiative has been to identify policy solutions that sustain oncology innovation while addressing the issue of rising healthcare costs. Over the last few years, the co-conveners of the T3 initiative have regularly offered concrete and practical recommendations for enabling efficient and effective cancer care while ensuring continued innovation, including recommendations aimed to:

- Strengthen the evidence base for better patient value;
- Develop and apply new tools for high-value decision making in healthcare;
- Expand patient-centered, value-based payment models;
- Modernize regulatory pathways to keep pace with science and research;
- Adapt to continual scientific advances and modern oncology practices; and
- Ensure transparency in design of tools and models.

In 2015, the T3 co-conveners hosted a roundtable on alternative payment models, from which emerged the articulated need for clinical pathways to be transparent, representative of patient priorities, evidence-based, and regularly updated to reflect current scientific evidence and clinical advances.[†]

In the summer of 2016, the T3 co-conveners brought together a multidisciplinary group of experts[‡] from the oncology community to leverage their different perspectives and to develop consensus around the critical elements that pathways must have to deliver high-quality and high-value oncology care. The initiative then commissioned Discern Health to facilitate an assessment of how current pathway programs align against the consensus best practices. This report details those best practices and Discern's findings.

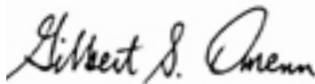
We have reached a point where the cost of cancer care has become an acute concern for many patients, and the oncology community is working to find strategies that balance personalized care and patient access. Ultimately, though, we need to be sure that any strategy implemented supports patients obtaining the care that is the right care, and best care, for them.

Sincerely,



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*The Turning the Tide Against Cancer (T3) co-conveners are the American Association for Cancer Research, the Personalized Medicine Coalition, and Feinstein Kean Healthcare.

[†]Miller AM, Omenn GS, Kean MA. The Impact of Alternative Payment Models on Oncology Innovation and Patient Care. Clin Cancer Res. 2016 May 15;22(10):2335-41.

[‡]See Appendix A for expert working group participants.

Executive Summary

Clinical practice guidelines, standard of care, and clinical pathways are tools used to guide treatment decisions in oncology care, but the distinction between them is not always clear. As defined by the Institute of Medicine, guidelines include *“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.”* Clinical guidelines typically incorporate standard of care, which the National Cancer Institute defines as, *“treatment that is accepted by medical experts as proper treatment for a certain type of disease and that is widely used by healthcare professionals.”*⁹ Pathways, however, are considered to be evidence-based decision-support tools that can be used to direct treatment options, but ultimately there is no clear differentiator between a guideline and a pathway. When used appropriately, pathways can help clinicians make sense of quickly evolving science, ensure patients receive the right care at the appropriate time, help standardize care and limit unnecessary variation. When used in combination with other tools and solutions, clinical pathways can support the goals of a patient-centered, value-based healthcare delivery system. However, if not designed or implemented appropriately, pathways can create barriers to patient choice, impede access to innovative oncology care, and limit physician autonomy.

Expert Working Group Identifies Best Practices for Pathways

To understand how oncology pathways can meet their potential of supporting patient access to optimal care, the Turning the Tide Against Cancer Through Sustained Medical Innovation (T3) initiative convened a multidisciplinary expert working group to understand how pathways can sustain innovation while enabling high-quality, patient-focused care. During the summer of 2016, the working group engaged in a two-phase project designed to

- Come to consensus around a set of best practices for oncology clinical pathways that balances innovation with patient access, and
- Conduct an assessment of select pathways and pathway programs to determine how closely they align with the identified best practices.

Analysis Finds Pathways Lack Transparency and Patient Engagement while Increasing Provider Burden

For the purposes of this expert working group exercise and this report, 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. The pathway best practices created by the expert working group stress a need for transparency, patient involvement and evidence-based decision making. After completing an assessment of seven pathway programs against the consensus best practices, our analysis found the following:

- There is little transparency in how pathways are developed and modified, how regimens are chosen, and whether cost-effectiveness plays a role in which pathways are considered on-pathway versus off-pathway.
- Pathway developers do not frequently engage stakeholders, specifically patients, in pathway development and instead see patient engagement as the role of providers.
- Pathways can increase provider burden for two reasons – healthcare teams may face redundant workflows due to lack of interoperability and integration between the pathway and electronic medical record, and providers must track how their use of specific pathways meets variable goals across multiple payers (e.g., decision support, prior authorization, etc.).
- No one stakeholder group is accountable across the pathway process from development through evaluation, which can lead to gaps in oversight.

⁹ National Academy of Sciences Institute of Medicine. Clinical Practice Guidelines We Can Trust. March, 2011. Available at: <https://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Report-Brief.aspx>. Accessed July 18, 2016.

**National Cancer Institute. Standard of Care. In NCI Dictionary of Cancer Terms. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=346525>. Accessed February 2, 2017.

Oversight Is Needed for Oncology Clinical Pathways

The lack of accountability across the lifecycle of a pathway, while problematic, can be rectified. Several independent bodies within the U.S. healthcare system provide oversight and support accreditation, including URAC and the National Committee for Quality Assurance (NCQA). Some groups focused specifically on oncology, such as the American Society of Clinical Oncology (ASCO), the American College of Surgeon's Commission on Cancer, or the National Comprehensive Cancer Network (NCCN), have worked to support accreditation processes, as well. As part of the stakeholder community, these organizations work with other stakeholders to develop quality measures and standards, with the goal of supporting high-quality, value-driven, patient-centered care. Such oversight is currently missing when it comes to oncology clinical pathways.

The T3 Initiative Recommends that an Independent Body Serve in an Accreditation Capacity

Given this gap, and when taking into consideration the findings outlined in this report, the T3 initiative recommends identifying an independent third party that could serve in an accreditation or oversight capacity, and could be tasked with developing standards and measures for each part of the pathway phase, from development to monitoring and evaluation, including:

- Outlining standards for how treatment regimens are assessed and selected for on-pathway inclusion;
- Requiring stakeholder involvement, specifically patient involvement, in the development, monitoring and evaluation of pathways;
- Developing point-of-care tools or advocating for interoperability among electronic systems to ease the administrative burden for providers;
- Guiding the frequency of pathway updates that result from not just new scientific data, but also real-world evidence obtained during pathway monitoring and evaluation; and
- Establishing a disclosure system whereby patients are informed when a pathway is used to direct part of their treatment decision making.

High-Quality Oncology Care Depends on Getting Personalized Treatments to the Right Patients

The national discussion around value, and the need to balance cost with patient access to innovative care, has become critical to making sure patients obtain optimal benefit and are treated as individuals and not in a one-size-fits-all manner. When used correctly, pathways can have an important role in directing the right treatment to the right patient at the right time; however, we must ensure that these tools are appropriately constructed, implemented and monitored, to provide patients with the highest quality cancer care possible.

Table 1. Best Practices for Oncology Clinical Pathways

Development

- a. The pathway developer has a clearly defined governance process that:
 - i. Is supported by codified bylaws and procedures and outlines roles and responsibilities; and
 - ii. Includes multi-stakeholder input from at least:
 - 1. Patients;
 - 2. Actively practicing oncologists;
 - 3. Pharmacists; and
 - 4. Oncology social workers.
- b. The pathway developer ensures that the pathways are supported by high-quality clinical evidence.
 - i. Each clinical recommendation (or decision point) in the pathway cites current, high-quality clinical evidence and a level of evidence score.
 - ii. If high-quality clinical evidence is not available to support a specific decision point in a pathway, that decision point is supported by expert opinion, and is noted as such.
 - iii. Both the methodology used for classifying evidence as well as the level of evidence for specific decision points should be indicated.
- c. The pathway development and maintenance process is transparent to all stakeholders, including:
 - i. The names of the stakeholders involved in pathway development and maintenance;
 - ii. Any conflicts of interest for the stakeholders involved in development;
 - iii. The frequency of revisions;
 - iv. The criteria used to determine the inclusion of various treatment regimens; and
 - v. An opportunity for external stakeholders not involved in the pathway's development and maintenance to provide input to pathway development and maintenance.
- d. The pathway provides a mechanism for physicians to deviate from the pathway with documentation in response to a patient request, or when it is medically necessary based on the patient's entire clinical record.
- e. Pathway developers incorporate individual patient preferences in pathway criteria.
- f. Pathway developers should ensure the pathway works in combination with a practice's electronic medical record system.
- g. The pathway developer tests the pathway system for daily workflow operational usability before full implementation.
- h. The pathway designates the frequency of review and maintenance to ensure ongoing alignment with clinical evidence and best practices. At a minimum, the pathway should be reviewed when:
 - i. Relevant supporting clinical evidence is updated or practice-changing data are published;
 - ii. A new U.S. Food and Drug Administration (FDA) approval or additional indication is available for a treatment regimen.

Implementation

- a. Patients are informed when a pathway is being used to guide their care plan. At a minimum, the information should include:
 - i. The purpose and expected benefits of using pathways as an approach;
 - ii. Why a pathway is relevant to the patient and his/her treatment;
 - i. Whether participation in a pathway may limit a patient's treatment options or whether there may be alternative pathways to consider;
 - ii. The organization that developed the pathway and what its role is in the oncology community;
 - iii. Whether the patient's healthcare provider may receive financial incentives for adherence to the pathway at a patient level; and
 - iv. Contact information to access additional details about the pathway.
- b. Pathway details are available for clinicians and patients, including whether physicians can deviate from the pathway without penalty when it is appropriate for the patient.
- c. Staff is given adequate training for implementing the pathways, including:
 - i. Use of health information technology (HIT) systems to support pathway implementation; and
 - ii. Appropriately assessing whether patients meet inclusion/exclusion criteria.
- d. Physicians can deviate from the pathway without penalty when they believe it is medically appropriate for the patient.
- e. Patients enrolled in a clinical trial are considered on-pathway for purposes of calculating a pathway adherence rate.
- f. The pathway has a mechanism to follow excluded patients who fall outside the pathway protocol, in order to more completely capture patient specific data, and to ensure that the pathway is not too restrictive.

Monitoring and Evaluation*

- a. Monitoring
 - i. Payers and providers collaborate to monitor the use of the pathway to ensure accuracy, quality and appropriateness of care.
 - ii. There is a feedback monitoring mechanism that monitors adherence rates (and shares them with the payers and providers).
- b. Evaluation
 - i. Pathway developers should design their products to facilitate the measurement of relevant performance metrics focused on patients and their disease (including the appropriate time horizon for the various types of measures).
 - ii. The measure set should include:
 1. Patient-focused measures, such as quality of life, satisfaction, experience of care, ability to work, symptom and side effect management, and patient-defined outcomes;
 2. Clinical measures, such as patient outcomes (including mortality), complications and adverse events;
 3. Clinician-focused measures, such as satisfaction, clinical autonomy and compliance with pathways; and
 4. Resource use measures, such as length of stay, costs (both episodic and overall) and readmission rates.
 - iii. The pathway includes a protocol to collect and measure the necessary data to improve quality of care and optimize patient outcomes.
 - iv. Results are reported back to the implementing health system (to inform ongoing quality improvement efforts) and to the pathway developer (to inform pathway maintenance).

*Note: For the purposes of this document, "monitoring" is defined as a real-time, individual-level assessment, while "evaluation" is defined as a population-level assessment to determine a pathway's overall effectiveness.

Section 1: Introduction and Background

Introduction

Clinical practice guidelines, standard of care, and clinical pathways are ubiquitous in cancer care, but the distinction between them is not always well understood. As defined by the Institute of Medicine, clinical practice guidelines are “*statements that include 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.*”¹ Clinical guidelines also typically incorporate standard of care, which is understood as “treatment that is accepted by medical experts as proper treatment for a certain type of disease and that is widely used by healthcare professionals.”² In contrast, clinical pathways are considered to be practical decision-support tools, still evidence based, but distilled to support directed treatment decisions for specific types of patients. Ultimately, there is no bright line differentiating pathways and guidelines for oncology.

Broadly speaking, when designed appropriately, pathways can help clinicians stay informed of and make sense of quickly evolving science, ensure that patients receive the optimal care at the appropriate time, help to standardize care and limit unnecessary variation.³ When used in combination with other tools and solutions, clinical pathways can support the goals of a patient-centered, value-based healthcare delivery system. However, if not designed or implemented appropriately, pathways can create barriers to patient choice and access to innovative oncology care, and also limit physician autonomy.⁴ Stakeholders both within and outside of the oncology community have begun working together to assess how pathways are developed, understand their inherent benefits and limitations, and lay out recommendations for their development and implementation.^{5,6,7,8,9}

To understand how oncology pathways can meet their potential of supporting patient access to optimal care, the Turning the Tide Against Cancer Through Sustained Medical Innovation (T3) initiative convened a multidisciplinary expert working group (see Appendix A) to understand how pathways can sustain innovation while enabling high-quality, patient-focused care. During the summer of 2016, the working group engaged in a two-phase project designed to:

- Come to consensus around a set of best practices for oncology clinical pathways that balances innovation with patient access, and
- Sample selected pathways and pathway programs to assess how closely they are aligned with the identified best practices.

This report details the ‘Best Practices for Oncology Clinical Pathways’ (Table 1) developed by the expert working group, presents the findings of the pathways assessment, and describes the complex interrelationships among pathway developers, physicians, insurance organizations and an array of intermediaries. For the purposes of this expert working group exercise and this report, oncology clinical pathways can be 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.*

Background

Treatment protocols, including guidelines and pathways, have been an integral component of cancer care from the earliest days of systematic research. In fact, the concept of testing specific treatment regimens systematically and documenting the results was pioneered by early cancer researchers.¹⁰ There is broad consensus within the medical community that evidence-based treatment – offering patients regimens proven effective through rigorous science – is the foundation of treatment. However, as the oncology treatment paradigm evolves more rapidly than ever before, tension now exists between those who advocate proceeding on the basis of incontrovertible existing evidence, versus those who are willing to pursue the promise of longer life, better quality of life, or the chance of a cure on the basis of emerging evidence.

A Proliferation of Pathways

The emergence of new medical technology, including novel classes of therapeutic drugs and innovative surgical procedures, has dramatically increased the cost of oncology care in the past decade.¹¹ In order to balance concurrent demands for evidence-based treatment, cost management and continued innovation, the cancer community is working to assess and implement a variety of novel healthcare delivery strategies. Patient preferences, quality management and financial implications for physicians and patients have all become important factors in treatment decision making.

In addition, payers are grappling with the high cost of oncology treatment and the demand by employers and patients to moderate the cost of healthcare, particularly as patients face higher co-payments, deductibles and premiums. Historically, health insurers and physicians have tried multiple strategies to mitigate cost and quality concerns, including alternative payment models,^{12,13} prior authorization systems, programs to increase use of evidence-based treatment protocols,^{14,15,16} and most recently, the 'oncology medical home.'¹⁷ In 2015, the Centers for Medicare and Medicaid Services (CMS), one of the most influential payers in oncology care, announced it will begin shifting its reimbursement models to reward high-value oncology care, not high-volume care.¹⁸ In July 2016, practices began participating in the CMS Oncology Care Model (OCM),¹⁹ a voluntary program under which CMS will pay enhanced reimbursement to oncology practices that provide care coordination and patient navigation services, while also utilizing national treatment guidelines.²⁰

As the desire to adhere to evidence-based medicine while incentivizing value becomes more widespread, many payers are increasingly turning to clinical pathways as tools to facilitate this process. The overarching goal is to incentivize the use of a more cost-effective treatment regimen when comparable clinically effective treatment options are available at significantly different price points. Unfortunately, initiatives to improve evidence-based practice and efficiency in oncology care have not been coordinated.

The field of oncology care is now facing a proliferation of pathways and authorization programs implemented by payers, payer intermediaries and provider groups, each slightly different and very few of which are interoperable. As provider groups consolidate and respond to payer initiatives, many oncology groups have adopted pathways and administrative management tools to improve care, increase the availability of data, maximize reimbursement, and add leverage to contract negotiations with payers. Thus, physicians contracted to multiple insurers, as most are, are subject to a wide variety of both internal and external administrative requirements for demonstrating medical necessity and the evidence base of their proposed treatments.

Methodology

Representatives from the following stakeholder groups were invited to participate in the expert working group: patient advocates, oncology care providers, the biopharmaceutical industry, health information technology experts and payers. The working group was asked to fulfill the following objectives:

- Come to consensus around a list of 'Best Practices for Oncology Clinical Pathways' (Table 1) that balances innovation with high-value oncology care (Phase I); and
- Assess how closely currently utilized pathway programs align with this list of best practices (Phase II).

For Phase I of the project, the working group was presented with, and asked to respond to, an initial draft of best practices, which was developed based on a literature review of key quality issues and recommendations related to clinical pathways. That literature review identified four key domains of pathway quality (i.e., development, implementation, monitoring, and evaluation), as well as expert opinion on best practices within each domain. The results of the literature review emphasized the importance of clinical leadership, reliance on current evidence, and multi-stakeholder participation in pathways. The initial draft best practices for oncology pathways was based on those principles. After the initial draft best practices was developed, the T3 co-conveners conducted an online survey of its expert working group members to gauge the relative importance of various components included in the draft. The draft best practices were then revised using the survey results, and subsequently refined through a series of expert working group conference calls.

Once the working group members came to consensus around the best practices, they identified pathway programs of interest for Phase II of the project, the pathways assessment, based on their knowledge of the current field of oncology practice. For each of the identified organizations, the T3 initiative worked with Discern Health, an outside research firm, to conduct a thorough review of each organization's website. Several organizations initially identified for review were eliminated due to corporate acquisitions, mergers or change in business model. In addition, National Comprehensive Cancer Network (NCCN) guidelines were added to the review list as a benchmark since they were frequently referenced as the source guidelines for clinical pathways.

Staff then worked with Discern to contact each of the developing organizations to request an interview with an individual involved in the development and implementation of the pathway and request samples of the pathways if the pathways were not publicly available. Only NCCN guidelines and Anthem-AIM pathways are available to the public. Pathways in eviti's Advisor are available to physicians with registration. Via Oncology made pathways available to the T3 initiative after a Non-Disclosure Agreement was signed.

Following website review and, when possible, an interview, a profile of each organization was constructed providing general information about the organization's approach, and specific information regarding compliance with its pathway. Profiles were sent back to each organization with a request that the organization complete missing information and make corrections as

Table 2: Companies Reviewed for this Report

Developer Name	Payer (Y/N)	Pathway Licensed and Used in Multiple Products (Y/N)	Website Review Conducted (Y/N)	Interview Conducted (Y/N)	Type of Pathway Program
Alabama Blue Cross Blue Shield (BCBS)	Y	N	Y	N	Alabama BCBS is a payer incentive program, with pathways administered by AIM.
Anthem-AIM (includes Empire Blue Cross)	Y	N	Y	Y	Anthem-AIM is a payer incentive program, with pathways administered by AIM.
Cardinal Specialty Health Solutions (P4 and PathWare)	N	N	Y	Y	PathWare is a pathways management software. Cardinal tools will show any pathways selected by the user. Cardinal does not develop or license any pathways directly.
eviti Advisor	N	Y	Y	Y	eviti Advisor is an evidence library for decision support (eviti Connect is a separate tool used for authorization).
McKesson Clear Value Plus	N	N	Y	N	McKesson Clear Value Plus is a pathway management software program that includes some pathways based on guidelines and licensed from NCCN and modified for 'value.' It offers options to create preferences and integrates with some EMRs.
National Comprehensive Cancer Network (NCCN)	N	Y	Y	N	NCCN is a guideline developer whose guidelines frequently serve as the source of pathways, which are modified by others.
New Century Health (NCH)	N	N	Y	Y	NCH is a medical management firm that conducts prior authorization for multiple payers. It licenses NCCN guidelines and modifies some pathways for 'value.' NCH may administer incentive programs for payers, as well.
Via Oncology	N	N	Y	Y	Via Oncology is a provider-developed pathway.

needed. Note that following the web review and an interview, Cardinal Health was excluded from the study. The organization has a software tool that displays pathways along with outcomes and cost information, but does not develop or modify pathways.

Information on the companies and the data collection process is summarized in Table 2. The organizations varied significantly in their business models. They also varied in the amount of information and the level of detail publicly available. Because the actual pathways and policies were not available for review, we could not directly verify some of the information (for example, whether each item in a pathway included a citation). In these instances, we accepted information provided to us verbally by the developer. Where we were able to find general descriptive information but not details, we rated the organization as being in 'partial' compliance. Table 3 provides web links to pathway practices or the provision of information that we found unusual or exemplary.

The findings presented in the following sections correspond to the Best Practice Recommendations presented in Table 1. Because of the diversity of organizations represented in the sample, and the small size, we report the findings qualitatively.

Table 3: Best Practice Examples	
Transparency of Pathways	
National Comprehensive Cancer Network (NCCN) Guidelines Anthem-AIM Pathways and work sheets	
Disclosure of Conflict of Interest and Participants	
NCCN Guidelines McKesson Clear Value Plus Pathways	
Patient Information	
NCCN Information for Patients	
Reporting and Metrics	
Via Oncology's reporting portal	

Section 2: Findings

Current Environment

Key Takeaway: Oncology pathways are complex tools used by multiple interconnected stakeholders (for definitions, see Appendix B: Clinical Pathway Stakeholder Groups).

- Most organizations involved in pathway development and implementation have intersecting businesses or elements of businesses. For example, NCCN guidelines are incorporated in eviti Advisor's library tool, which is used in AIM pathways, which are embedded in Anthem's Oncology Quality Care program. Other pathway developers also start with NCCN guidelines and make modifications or add 'preferences.'
- Software companies have emerged to help providers manage the complexity of pathways. They allow users to display the pathway, criteria for use and expected revenue to the provider. They also allow practitioners to sort by payer to determine the payer-preferred pathway. These software programs do not interface yet with prior authorization functionality.
- A number of the organizations identified for assessment have been acquired or merged. For example, P4 pathways were purchased by Cardinal Health and essentially retired. The Blue Cross Blue Shield of Michigan collaboration with the Michigan Oncology Clinical Treatment Pathways Program has also been recently retired.

Key Takeaway: Pathways can be constructed to meet different goals, depending on payers' needs.

- Although most entities use the same source information, they modify or display the evidence or pathways to direct providers to different preferences. Payers may require providers to access the pathway information in a unique web-based portal or non-interoperable software program as part of prior authorization for payment. Thus, there is a high administrative burden associated with accessing and managing similar, but not identical, pathways from multiple sources.
- The same pathway may be used in different ways by different customers. Development of a pathway and the linkage with financial incentives are often distinct processes. For example, eviti Advisor hosts a library of all evidence-based, recognized treatment pathways. The pathways can be accessed by providers at no charge for decision support. The library is also licensed to other users such as payers or medical groups. Users set preferences, 'flag' certain pathways as a preferred pathway or modify them. Adherence to a preferred pathway is measured and/or incentivized by the user – a payer or medical group – not the pathway developer.
- Clinical pathways identified for this project are more limited in scope than initially anticipated. All of the pathways and guidelines assessed, except those of Via Oncology and NCCN, were specific to medical oncology drugs, and to physicians. Their scope did not include other oncology therapies (radiotherapy and surgery), or other types of practitioners.

Alignment with Expert Working Group Best Practices

Key Takeaway: There is an important lack of transparency in how pathways are developed.

- Pathways are treated as proprietary and are not available for public review, which makes it difficult to understand how pathways are developed or how pathways issued by different organizations differ from each other.
- There is no information to show how evidence is weighed in determining which treatments are on-pathway versus not, how payer preferences are weighted, or how disagreements are resolved. Developers state that pathway preferences are generally determined first by treatment efficacy, then by treatment toxicity and strength of evidence, then by cost, but no further detail is usually given. All pathway-related organizations included in this assessment did state they rely on evidence-based information and most provided descriptive information about their processes. They also engaged practicing oncologists to review and develop pathways in various ways.

Key Takeaway: Clinical pathways add to the administrative burden for the oncology care team.

- A plethora of organizations develop or use pathways in a confusing array of products and programs, including decision-support tools, practice management tools, prior authorization programs, and incentive programs, which means the oncology care team cannot assume all pathways accomplish a singular goal.

- Incentive programs also vary from payer to payer, adding another layer of burden. Payers use different rules to implement variable incentive payment programs, the goal of which is to direct practitioners to more cost-effective treatment regimens when treatments that are deemed to be equally effective are available.
- In addition to using pathways to accomplish different goals, every payer has a separate pathway IT infrastructure for their pathway, as well, which means providers have to access multiple tools at the point of care.

Key Takeaway: There are limited efforts to engage with patients about pathways or inform them when pathways are being used to manage available treatment.

- No evidence was found that patients are involved in the development or implementation of pathways. Additionally, there is also a lack of patient input into many of the NCCN guidelines, which serve as the source for many commercial pathway programs.
- A few of the pathway organizations reviewed provide patient information or descriptive information about the need for evidence-based treatment. They do not provide information on the risks and benefits of using specific pathways.
- Payers expect that practitioners discuss treatment preferences, cost and effectiveness with patients prior to seeking authorization for a particular pathway. They provide no guidance to practitioners about informing or disclosing the use of pathways to patients.

Key Takeaway: There are no universal best practices covering the frequency of pathway updates or the integration of real-world data into pathway revisions.

- Pathway developers do monitor and update pathways to ensure that pathways reflect the latest evidence, but prior authorization and incentive programs may experience a lag time.
- No payer pathway integrates with provider EMRs. As a result, no patient specific data are available for treatment evaluation or quality management purposes. EMRs contribute to this problem by each having a unique data architecture.

Detailed Findings

Pathway Development

Key Takeaway: Almost all pathways have a formal development and governance process, but the details regarding updates, stakeholder engagement, and submission of feedback vary.

- Many of the organizations reviewed for this report are accredited by an external organization, including URAC and the National Committee for Quality Assurance (NCQA), both independent, non-profit entities aimed at pursuing high-quality healthcare. As such, they are required to have organizational policies and procedures in place for governance, as well as policies for grievances, appeals, and quality assurance. Accreditation applies to these broader organizational processes, not necessarily to the pathway product.
- Most pathways reviewed reported that their pathway development process usually starts by reviewing a recognized guideline, such as NCCN guidelines, and from there the developer or payer will consider other evidence (strength of evidence, new data, cost) in an effort to refine it.
- All of the developers have a formal process of updating the pathways at least quarterly, and also in response to changes to a source guideline (i.e., NCCN guidelines), a new U.S. Food and Drug Administration (FDA) approval, or new evidence.
- Developers appeared to consider oncology pathways to be physician-oriented, rather than multidisciplinary tools. Some indicated that pharmacists may be involved in development if needed, but none included patients, nurses or social workers. A few included or intended to add some recommendations for ancillary service providers.
- All organizations involve practicing oncologists in pathway review and development, some as staff and some on advisory committees. There was highly variable information available as to the composition and role of advisory committees, as well as conflict of interest disclosures relating to participants.
- All of the organizations have some process for providing input on the pathways, but often instructions on how to provide comments were very difficult to find. Only a few – NCCN guidelines and McKesson pathways – clearly indicate how to submit comments and how the information will be reviewed.

Key Takeaway: All of the pathways assessed are stated to be based on high-quality evidence, though few developers make it clear how they weight or prioritize evidence when updating their pathway.

- All of the pathways were stated to be based on high-quality evidence, and most pathway developers referenced the same source guidelines, such as NCCN.
- While every organization modifies their pathways in response to changes in source guidelines (usually efficacy, toxicity, cost), none of them provided information on weighting or prioritizing the evidence used to make changes.

Key Takeaway: Pathway developers vary significantly in how transparent they are with information concerning the development of their pathway.

- Some pathway organizations list all of the pathway development advisors with their affiliations, and also make the pathways themselves available. Others provide only general descriptive information about the type of people involved and the pathway itself.
- Many pathways are considered proprietary and as such are not available for review by non-license holders. Only the provider-developed source guidelines (NCCN, ASCO, or American Society of Hematology) were directly accessible, as were the pathways used by Anthem-AIM. Via Oncology provided access to the pathways after completion of the data collection phase.

Key Takeaway: Many developers include a process by which patients can receive treatment off-pathway for medically necessary reasons; they do not usually develop an option for taking a patient off-pathway due to patient preference.

- All pathway developers acknowledge the need for off-pathway practice. They distinguish ‘off-pathway and evidence-based’ from ‘off-pathway and not evidence-based.’ Use of pathways is connected both to payer prior authorization programs and incentive programs (see Example), with payers designating pathways that align with their specific value criteria as being high-value pathways. Depending on the type of entity administering the pathway, the consequences for going off-pathway vary. For example:
 - *Off-pathway but evidence-based:* This might occur if a provider selects a pathway that is consistent with NCCN guidelines but is not identified as a payer-designated high-value pathway. These treatment requests are typically approved in prior authorization but are not eligible for incentives.
 - *Off-pathway and not evidence-based:* A treatment course not consistent with NCCN guidelines would fall out of automated approval and be subject to medical review by the payer’s medical management process. This treatment would also not be eligible for incentive.
 - *Off-pathway due to clinical trial:* Payers and medical groups vary as to whether participation in clinical trials is considered on-pathway for incentive purposes. A proposed treatment in a clinical trial may be subject to medical review to determine which aspects of the treatment will be covered under the patient’s benefit plan.
- Patients going off-pathway due to patient preference is not addressed by any of the organizations in this sample. Interview respondents indicated that physicians discuss preferences with the patients and that the preferences should be reflected in the pathway authorization requests submitted to the payer or prior authorization form. Some respondents noted that decision-support tools show all evidence-based options, including payer-designated high-value pathways, and that providers use these tools to inform patients and determine preferences.

Example: Pathway Deviations:

New Century Health (NCH) provides prior authorization of oncology treatment plans for payers and helps to administer incentive programs. Any proposed treatment regimen consistent with an appropriate NCCN guideline is authorized for payment. Those not on an pathway consistent with NCCN guidelines are reviewed for approval or denial. A subset of modified NCCN treatment guidelines are identified through NCH as equally effective and more cost effective. If individual providers select these for 80% of patients covered for the payer, the provider is eligible for the payer’s incentives. NCH recently changed its policy and now considers clinical trial participation to be on-pathway, as well.

Key Takeaway: The lack of interoperability and integration between pathway and EMR IT infrastructures is problematic, resulting in increased administrative burden for the oncology care team.

- There is a widespread lack of interoperability among pathways, EMRs, and payer portals. Pathways used or developed by payers are not integrated with practice EMRs. Various respondents indicated that interoperability is the 'holy grail,' but noted technical challenges add to the administrative burden of the care team, such as downloading separate order sets and benefit plans and managing multiple payer requirements.
- Payer pathways typically require that providers fill out a patient worksheet and then have the data entered onto the payer's prior authorization web portal by an administrative staff person. This process entails duplicate entry of patient information (both in the EMR and the payer portal).
- Provider-developed pathways, specifically Via Oncology, link to the provider/practice management system and offer real-time decision support and have some interoperability with certain brands of EMRs. Via Oncology recommends that oncology groups using the pathways for decision support and quality improvement negotiate with payers to allow the Via Oncology pathways to be used in place of the payer-supplied pathways.

Pathway Implementation

Key Takeaway: Pathway developers do not see communication with the patient around the role and use of pathways in oncology treatment as their responsibility.

- No developer or payer provided guidance on how their pathways should be communicated to patients being treated on a pathway. Several – notably the NCCN guidelines and Via Oncology pathways – had supplemental information or guidelines available to patients that explained the value of evidence-based medicine, offered educational information, and suggested that patients use the information for a discussion of treatment options with their provider.
- During one-on-one interviews, developers were puzzled about the need to disclose to patients that they were being treated on-pathway. They commented that oncology treatment has always been protocol-driven, and that it is the oncologist's responsibility to discuss treatment options with the patient. Several developers also noted that there are many conflicting incentives in oncology practice, not all of which are payer-driven.
- Patients who actively seek information around the role and use of pathways, particularly the pathways used to guide a patient's specific treatment, may have difficulty finding it. While Anthem-AIM, eviti Advisor and NCCN make their pathways and/or guidelines available at no charge to patients and practitioners, other developers and payers do not make the pathways available to non-customers.
- Developers did not provide readily available contact information for patients to obtain more information.

Key Takeaway: While developers have created training tools to help oncology care teams handle activities such as prior authorization, tools geared toward integrating pathways into provider workflows have not yet been created.

- The development of oncology pathways and software tools aimed at integrating pathways into provider workflow, appear to be separate areas of capability. There are many brands of EMRs and many prior authorization web portals. To ensure universal interoperability, either EMR developers and pathway software developers would all have to use the same data transmission protocols, or the pathway developer would have to create interoperable versions for each brand of EMR. This integration has not occurred. McKesson states they have integrated pathways with several brands of EMR and display pathways according to payer preferences, but we were not able to view this functionality.
- Pathway tool and software training is available for discrete purposes. Payers using pathways for prior authorization, or as part of an incentive program, offer training on how to use the web portal to transact the activity. Payers and pathway developers do not provide providers with training on how to interact with patients about the use of pathways or on how to use pathways to support shared decision-making with patients.

Key Takeaway: Pathways can be used as tools to both facilitate authorization of oncology treatment (prior authorization) and track pathway adherence for incentive programs.

- Many payer organizations link pathway adherence to a simplified approval process during prior authorization. As noted earlier, when a pathway is being used for prior authorization purposes, on-pathway treatments are approved more efficiently than off-pathway treatments. Additionally, some pathways may be indicated by payers as 'preferred' pathways. Providers who treat according to the 'preferred' pathways may receive more prompt payer approval for treatment and also become eligible for incentive payments. The complexity of the case could play a role in speed of review, as well; off-pathway treatment review can be fast-tracked for complex medical issues.
- All pathways included in this review were accompanied by clear information that off-pathway treatments are expected for some patients, and that the provider should make this determination. Prior authorization for off-pathway treatment is conducted on a case-by-case basis.
- There are different implications of going off-pathway depending on whether financial incentives are associated with pathway adherence. No 'penalties' were identified for not treating a patient on-pathway, but the provider may lose eligibility for an incentive payment. A lack of incentive may be viewed by many as a penalty.

Key Takeaway: Participation in clinical trials is treated inconsistently (e.g., off-pathway versus on-pathway) across pathway developers and payers; furthermore, there are no data collection protocols to follow outcomes for patients who go off-pathway.

- Eviti's Advisor tool proactively recommends clinical trials when the patient does not meet criteria for an evidence-based regimen and considers participation in these trials to be on-pathway. New Century Health (NCH), however, formerly did not count patients who participated in clinical trials as either on-pathway or off-pathway, which has implications in how a provider's pathways adherence percentage is calculated, and thus could affect whether a provider receives an incentive. NCH and Anthem-AIM recently announced they will now consider clinical trial participation to be on-pathway for the purpose of calculating adherence.
- None of the developers included in this assessment has a pathway-specific protocol for following patients being treated off-pathway, although many noted that the oncologist may continue to follow the patient. Since no pathways are integrated with EMRs, most respondents noted that they have no data with which to follow a patient after the prior authorization transaction or after a patient goes off-pathway.

Pathway Monitoring and Evaluation

Key Takeaway: No entity has access to all of the data desirable for monitoring of accuracy, quality and appropriateness of care.

- There was no evidence of universal monitoring or collaborative monitoring of pathway utilization. Most organizations have an advisory committee and collected the data that they were able to access.
- While prior authorization organizations, payers and provider groups track the rate of on-pathway versus off-pathway, no information was found regarding how that adherence data are provided to physicians.

Key Takeaway: Most pathways developers do not have access to all of the data necessary to fully evaluate the effectiveness or efficiency of their pathways.

- Pathway developers do not recommend specific quality, outcome or patient experience measure for evaluation of pathways. This may in part be attributable to a lack of access to and interoperability with EMR data. That said, pathway users – oncologists and oncology groups – may be using their own patient-level data to evaluate the care provided.
- Some companies offer the capability to benchmark performance of a specific user group to another group's performance. Anthem-AIM has engaged a data analytics firm, HealthCore, to evaluate aspects of its pathways program and has presented these data at an ASCO meeting.²¹
- Companies engaged in prior authorization can monitor off- and on-pathway rates. NCH commented that it monitors off-pathway rates, and will evaluate the pathway itself if the company detects an unusually high rate of change in off-pathway adherence. Significant changes could signify either that providers are ahead of updates to the pathway, or that providers do not understand protocols within the pathway.

Section 3: Discussion & Conclusion

Discussion

The findings of this expert working group report underscore the importance of evidence-based treatment protocols. While both guidelines and pathways can be viewed as treatment-guiding tools, the goals of these tools may differ. Payers, in particular, view pathways as a strategy to support the practice of evidence-based medicine, while addressing the urgent need to manage the costs of oncology care. As such, they are using pathways as a tool to direct physicians to effective treatment options, from both an economic and patient outcomes perspective.

However, the findings of our analysis also showed that while most pathways inherently have similar goals, their development, implementation, monitoring and evaluation can vary substantially. The analysis also found variability in pathway transparency. To be specific, it was neither clear how pathways were developed and modified, nor was it clear if pathways are chosen because of how cost effective they are.

One strategy to make pathways more transparent would be to include stakeholders, particularly patients or patient advocates, throughout the pathway process to review and provide feedback on preferences and other real-world considerations. Unfortunately, many pathway developers do not engage with stakeholders, and as such, they are developing tools that may limit treatment options, without talking to the primary party that is ultimately impacted – patients.

Part of the reason patient preference is not addressed may be due to the fact that the pathway developers assessed for this project suggested that patient engagement is the responsibility of the provider. While the working group agreed that providers do need to talk to patients about pathways, patient care preferences, and the full range of treatment options, they thought it was also crucial for developers to include patient feedback and develop pathways that are responsive to patient needs.

In addition, many of the pathway developers interviewed suggested that due to their inability to access the full range of patient data, developers cannot easily monitor and evaluate their pathways for effectiveness at the patient or population levels. This gap in oversight can have practical implications. If a pathway is not working for a particular patient population, developers may not know because they cannot access outcomes data; thus, the burden then falls to the providers and payers to alert the developer that their pathway should be updated, a process that could be inconsistently implemented.

The pathway developers that partook in this project did seem amenable to modifying or updating their pathways to suit payer and provider needs. In fact, depending on who licenses the pathway, pathways may serve multiple purposes in various settings – everything from decision support to prior authorization. They can also be customized to support different reporting preferences and even different incentive structures. Furthermore, multiple slightly altered pathways are currently in use for the same condition, each addressing a unique benefit design or promoting a payer's specific value criteria.

While customizable pathways work well for meeting the needs of various payers, they can cause administrative burden for providers, as they navigate diverse payer incentive structures and approval processes, which can be complex and highly specific to each payer. Adding to the administrative burden is the reality that most pathways have their own web portals that are required for approval, data submission, etc., as such, most pathways are not interoperable with EMRs. Healthcare teams may find themselves in situations where they have to access multiple electronic databases at the point of patient care, a situation that makes it difficult for the doctor to, in the exam room, focus solely on the needs of the patient and their family, potentially detracting from the doctor-patient relationship.

Conclusion

Stakeholders in the oncology community are increasingly searching for innovative tools to support value-based care. Clinical pathways have emerged as a strategy for payers seeking to implement market-driven, evidence-based means for containing costs. However, reservations about pathways remain. First, there are concerns that pathways can inappropriately limit patient access to necessary treatment or hamper physician autonomy in determining the best care plan for their patients. Additionally, because payer pathways are as unique and variable as the payers themselves, the administrative burden for their implementation falls to the healthcare team and can potentially distract from primacy of the patient-provider relationship.



Furthermore, patient engagement is not present at any stage of the pathway process, and many patients may not even be aware that their treatment options are being directed by a pathway. Finally, the siloed nature of the pathway stakeholders (payers, providers and developers) has led to a situation where there is no one party that oversees or is accountable for an individual pathway, from development through evaluation.

The lack of accountability across the lifecycle of a pathway, though problematic, can be rectified. In fact, there currently are independent bodies within the U.S. healthcare system that provide general oversight and help support accreditation, including the NCQA and URAC. Some groups focused specifically on oncology, such as the American Society of Clinical Oncology, the American College of Surgeon's Commission on Cancer, or the NCCN, have worked to support the accreditation process, as well. As key health stakeholder groups, these bodies create and endorse discrete quality measures, develop standards for health plans and providers, and support ongoing monitoring and evaluation of these measures and standards, all with the ultimate goal of improving patient outcomes. These organizations have experience working with small and large provider groups, payers, policymakers, the biopharmaceutical industry, and patients to build a system that prioritizes high-quality, value-driven, patient-centered care. This universal oversight is needed in the field of oncology clinical pathways.

Given this gap, and when taking into consideration the findings outlined in this report, the Turning the Tide Against Cancer initiative recommends identifying an independent third party that could serve in an accreditation or oversight capacity, from pathway development, to implementation, and to monitoring and evaluation. A future accrediting body could be tasked with developing standards and measures for each part of the pathway phase, including:

- Outlining standards for how treatment regimens are assessed and selected for on-pathway inclusion;
- Requiring stakeholder involvement, specifically patient involvement, in the development, monitoring and evaluation of pathways;
- Developing point-of-care tools or advocating for interoperability among electronic systems to ease the administrative burden for providers;
- Guiding the frequency of pathway updates that result from not just new scientific data, but also real-world evidence obtained during pathway monitoring and evaluation; and
- Establishing a disclosure system whereby patients are informed when a pathway is used to direct part of their treatment decision-making.

We have reached an inflection point in oncology care where there are real and acute concerns around how the cost of medicines impact patient access. Simultaneously, there is still a need to support innovation and patient-centered care. Determining innovative ways to deliver value-driven healthcare will be critical to making sure that patients benefit and are treated as individuals and not in a one-size-fits-all manner. When used correctly, pathways can have an important role in directing the right treatment to the right patient at the right time; however, we must ensure that these tools are appropriately constructed, implemented and monitored to provide patients with optimal cancer care.

APPENDIX A. Expert Working Group Participants

Participants from the T3 Clinical Pathways Expert Working Group are below. The views reflected in this paper are not necessarily the views of individual members of the expert working group or the organizations they represent.

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APPENDIX B. Clinical Pathway Stakeholder Groups

Medical management firms: These firms (i.e., AIM, New Century Health and eviti-Connect) perform ‘prior authorization’ services for provider groups, in which the company compares a proposed treatment regimen to a set of evidence-based guidelines. Commonly proposed treatments that meet the payer’s criteria are authorized automatically; a proposed treatment plan that does not follow a known course of treatment is deferred for a formal medical review. Medical management firms may flag a subset of ‘value’ pathways on behalf of payers; practices selecting these pathways are eligible for incentive payments.

Oncologists: Oncologists are the individual cancer care physicians who interface directly with patients to discuss various treatment options, determine which treatment protocol to use, oversee patient care and manage patient-specific information in a paper or electronic medical record (EMR).

Oncology group: The majority of oncologists practice in group settings. The group selects which EMR to adopt and negotiates agreements with various payers. Sometimes the group will elect to adopt preferred oncology treatment pathways, and may use this indicator of evidence-based practice to negotiate better reimbursement from payers. The group may create its own incentives or comparative reporting for participating providers, and may also negotiate agreements with payers in which the payer offers incentive payments relating to use of pathways. Oncologists and oncology groups serve patients insured through a wide variety of payers, and thus could be incentivized to follow various pathways for different payers and the oncology practice itself.

Pathway aggregators: A cadre of organizations (e.g., eviti Advisor, McKesson Clear Value Plus and Cardinal Health Specialty Solutions) license or use physician-developed pathways in other tools such as decision-support or analytic software. These aggregators may modify or sort pathways in different ways, and package them for customers including physicians, physician groups, or payers.

Pathway developers: There are numerous types of pathway developers. Physician-led societies may create the guidelines that underpin many of the pathways, or at a minimum may create the guidelines that underpin many of the pathways, including the National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO), and the American Society of Hematology (ASH). **Independent developers** (e.g., Via Oncology) develop proprietary pathways, and make the tools directly available to physicians, while also licensing their guidelines and pathways to decision-support and other vendors.

Medical management firms (e.g., New Century Health) may layer on an additional level of development to identify subsets of pathways that are both evidence-based and cost-effective.

Patients: Cancer patients are the individuals receiving oncology treatment and are the ultimate beneficiaries of oncology care. Their interaction with the healthcare system usually comes at the point of care with their healthcare provider or through verifying/securing coverage decisions with a payer. Direct interaction with pathway developers is limited.

Payers: Payers are third-party public or private health insurance providers. They usually license an oncology pathway tool from the developer for the purposes of decision support or prior authorization. Payers also may work with pathway developers to ensure the resulting pathway tool represents the payers’ specific value criteria.

Standard of care: Treatment that is accepted by the medical experts as proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy.²²



Frequently Used Acronyms

AACR – American Association for Cancer Research

ASCO – American Society of Clinical Oncology

ASH – American Society of Hematology

CMS – Centers for Medicare and Medicaid Services

EMR – Electronic medical record

FDA – U.S. Food and Drug Administration

FKH – Feinstein Kean Healthcare

NCCN – National Comprehensive Cancer Network

NCH – New Century Health

NCQA – National Committee for Quality Assurance

OCM – Oncology Care Model

PMC – Personalized Medicine Coalition

T3 – Turning the Tide Against Cancer Through Sustained Medical Innovation

URAC – URAC (formerly Utilization Review Accreditation Commission)

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