American Society of Clinical Oncology Policy Statement on Clinical Pathways in Oncology

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Abstract

The use of clinical pathways in oncology care is increasingly important to patients and oncology providers as a tool for enhancing both quality and value. However, with increasing adoption of pathways into oncology practice, concerns have been raised by ASCO members and other stakeholders. These include the process being used for pathway development, the administrative burdens on oncology practices of reporting on pathway adherence, and understanding the true impact of pathway use on patient health outcomes. To address these concerns, ASCO's Board of Directors established a Task Force on Clinical Pathways, charged with articulating a set of recommendations to improve the development of oncology pathways and processes, allowing the demonstration of pathway concordance in a manner that promotes evidence-based, high-value care respecting input from patients, payers, and providers. These recommendations have been approved and adopted by ASCO's Board of Directors on August 12, 2015, and are presented herein.

INTRODUCTION

As the leading medical professional oncology society committed to conquering cancer through research, education, prevention, and the delivery of high-quality patient care, ASCO has spent more than two decades actively promoting quality improvement programs to ensure that patients continue to receive high-quality care. As the demand to curb health care costs and provide more transparency related to clinical outcomes has grown along with the complexity of precision medicine, ASCO has focused its attention on strategies that promote both high-quality and high-value cancer care. One strategy that is playing an increasing role in promoting quality and value is the use of oncology pathways in clinical practice.

When appropriately designed and implemented, oncology pathways are detailed, evidence-based treatment protocols for delivering quality cancer care for specific patient presentations, including the type and stage of disease. Oncology pathways balance the considerations of clinical efficacy, safety, toxicities, cost, and scientific advances, including the growing personalization of therapy based on molecular diagnostics.[1,2]

A number of challenges have arisen throughout the United States with the growing use of oncology pathways in the day-to-day practice of cancer care. In October 2014, ASCO's State Affiliate Council, representing 47 members of state and regional affiliate programs, voiced concerns regarding oncology clinical pathways as currently deployed. Among the identified concerns were variability and frequent inadequacies related to quality,

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criteria, transparency, conflicts of interest, and input from providers, as well as the unsustainable administrative burdens related to the multitude of oncology pathways that must be tracked and managed by an individual oncology practice. The concerns of the Council, along with the concerns of ASCO's Clinical Practice Committee, were presented to the ASCO President and Board of Directors in November 2014, leading to the approval of a new task force to address these many concerns.

In January 2015, ASCO established the Task Force on Clinical Pathways to review the current landscape of oncology pathway use and recommend a set of principles for the development and use of clinical pathways in cancer care. The Task Force gathered and reviewed extensive information regarding the rapidly evolving environment of oncology pathways in the United States. The deliberations of the Task Force have been reviewed and were approved by ASCO's Board of Directors on August 12, 2015, as recommendations by ASCO for the development and use of clinical pathways in oncology.

CLINICAL PATHWAYS IN ONCOLOGY

Oncology pathways increasingly are being used by institutions, clinicians, commercial organizations, payers, and other health systems as a way to improve patient care by limiting undesirable variability and reducing cost while providing for the optimal course of care for a patient's specific diagnosis. Many large payers are partnering with oncology providers and pathway companies to implement oncology pathways as a means of reducing variation and controlling costs.

Some payers are providing incentives to providers to use oncology pathways, offering increased reimbursement and case management fees for oncology pathway adherence, as well as shared savings, preapproved coverage, and risk sharing. Information from providers, payers, and pathway companies suggests that the number of oncology pathway users is growing, particularly in the treatment of breast, lung, and colorectal cancers. Currently, at least six oncology pathway companies in the United States are actively marketing their services to insurers. Each of the identified vendor organizations offer oncology pathways for major cancer types, whereas only two offer pathways for rare cancers, such as glioblastoma multiforme.

Specialty benefits management organizations represent another intermediary between payers and providers to manage the oncology benefit. Specialty benefits management organizations may contract with payers, providers, or both. A significant focus may be placed on utilization of oncology drugs. At least one active specialty benefits management organization serves as the administrator of the oncology pathway programs for insurers, focusing on utilization and compliance issues under oncology pathways.

Oncology pathways can also be used as a novel method of clinical integration between a variety of practices desiring affiliations or participation in accountable care organizations that do not share a common electronic health record. Oncology pathways may provide an important tool in the future for independent hospitals and oncology groups to collaborate within integrated systems, yet still maintain their autonomy and culture.

Studies are beginning to demonstrate that the use of pathways in oncology can reduce costs while maintaining or improving quality of care. For example, a study of patients with non–small-cell lung cancer showed that certain outpatient costs were 35% lower for those patients treated according to pathways while maintaining equivalent health outcomes.[3] In another study, the treatment of colon cancer on a pathway resulted in a savings of more than 30%.[4]

Despite these reported advantages, pathway programs are generating growing criticism from the provider and patient communities (unpublished data). Although the desired outcome of oncology pathways is to improve care for patients while promoting value, the manner in which pathways are currently being developed and used in oncology has raised significant concerns involving patient access, quality of care, and transparency in the weighing of information on clinical outcomes, toxicities, and costs in final pathway development.

The sheer number of pathways has created intense administrative burdens because oncology practices are forced to sift through the various requirements and preferences of the pathway program of each payer on a patient-by-patient basis. Although the penetration of oncology pathways differs throughout the United States, some oncology practices report the need to adhere to eight or more different pathways for the same type and stage of cancer because of the different requirements of the payers covering patients served by their practices. In addition, authorization processes are most often separate from the electronic medical record where clinicians document information and order therapies. Clinician burnout and impending workforce shortages are real challenges for members of ASCO, and the Task Force is significantly concerned that the proliferation of oncology pathways will exacerbate an already tenuous situation.[5,6]

The lack of transparency and consistency being applied to pathway design has caused alarm and created distrust within the oncology community. Oncologists have expressed concern that a significant number of oncology pathways lack adequate grounding in the clinical literature. Patient advocates have raised concerns regarding the lack of patient choice under some pathways and the lack of transparency regarding quality, toxicity, and cost considerations.[7] Many observers feel there has been a shift from caring for the patient to caring for the pathway, and there is a growing sentiment in the oncology community that this trend is eroding both the doctor-patient relationship and the overall quality of cancer care.

RECOMMENDATIONS

Clinical pathways in oncology have significant potential to improve the quality of patient care and to promote value. However, several challenges exist in the way oncology pathways are developed and implemented under current practices that must be addressed as rapidly as possible. To this end, ASCO has developed the following recommendations for clinical pathway development and implementation in the oncology setting.

Recommendation 1: A Collaborative, National Approach Is Necessary to Remove the Unsustainable Administrative Burdens Associated With the Unmanaged Proliferation of Oncology Pathways

A primary concern among oncology providers today is the significant administrative burden that is arising from the need to adhere to multiple oncology pathways when treating similar patients. The administrative burden of demonstrating pathway concordance, obtaining preauthorizations, and securing warranted variations placed on oncology providers is significant, and this burden is compounded by the proliferation of different oncology pathways. We urge payers to collaborate with the oncology community to adopt flexible policies enabling individual oncology practices to select a single pathway program for all of their patients meeting the same diagnostic criteria, regardless of health insurer. ASCO is prepared to play a supportive role to review, evaluate, or develop oncology pathway criteria and content to promote an efficient, consolidated approach to protecting the best interests of patients and meeting the needs of both providers and payers. We urge stakeholders to work together in a proactive, prompt manner to address this untenable situation and not wait for a solution to be imposed on the health care system.

Recommendation 2: Oncology Pathways Should Be Developed Through a Process That Is Consistent and Transparent to All Stakeholders

The oncology pathway development process today, in many cases, is not transparent to patients and providers, and it is not consistently applied across pathway companies and payer programs. ASCO recommends that the development of all oncology pathways satisfies a list of threshold criteria to help ensure the quality of oncology pathways. To this end, Table 1 depicts a set of guiding principles for the development of clinical pathways in oncology. Methodologies for oncology pathway development should be transparent to the public, and potential conflicts of interest by the companies and individuals involved in pathway development should be disclosed to the public.

Recommendation 3: Oncology Pathways Should Address the Full Spectrum of Cancer Care, From Diagnostic Evaluation Through Medical, Surgical, and Radiation Treatments, and Include Imaging, Laboratory Testing, Survivorship, and End-of-Life Care

Oncology pathways should support the development of comprehensive cancer care plans by addressing the full spectrum of cancer care that will maximize opportunities for value-based medical outcomes. To the maximum extent possible, as supported by the existing evidence, oncology pathways should define aspects of oncology care beyond the selection of anticancer agents, including but not limited to the types of supportive care, palliative care, end-of-life care, laboratory tests, molecular diagnostic and pathology tests, imaging, surveillance, survivorship, and other services the patient should receive.

Recommendation 4: Oncology Pathways Should Promote the Best Possible Evidence-Based Care in a Manner That Is Updated Continuously to Reflect the Rapid Development of New Scientific Knowledge, As Well As Insights Gained From Clinical Experience and Patient Outcomes

The primary goal of oncology pathways should be to help ensure real-time deployment of scientific advances and care management that leads to high-quality care for individuals with cancer. As the volume of new scientific information

Table 1. Guiding Principles for the Development of Clinical Pathways in Oncology

Practicing oncologists should play a central role in developing and revising oncology pathways.
The quality of the evidence used in developing an oncology pathway, and the process for continuously updating and enhancing the recommendations in the oncology pathway, should be robust and transparent. This process should be set up in such a way as to ensure that oncology pathway updates are implemented as soon as practice-changing scientific information becomes available.
Full disclosure of methodologies, with associated conflicts of interest, should be provided for oncology pathways committee members, vendors, insurers, and any other individuals or entities that contribute to the development of pathway content.
Clinical pathway programs in oncology should identify the following key parameters: The proportion of patients the oncology pathway is intended to cover, within the type of cancer on which the oncology pathway focuses; The expected adherence rate and the actual adherence rate with the most recent version of the oncology pathway; The measured outcomes associated with adherence to the oncology pathway (in absolute terms and/or relative to other oncology pathways); and The costs of care associated with adherence to the oncology pathway (in absolute terms using the Medicare payment standards, including the normal 20% patient copay) relative to other oncology pathways.
The following mechanisms should be put into place to guide communication between the provider and payer when offpathway or on-pathway modification decisions are being considered. An appeal process and mechanism for arbitration should be in place for use when there are disagreements between the physician's desired care plan and the oncology pathway care plan. A treatment approval process should be in place to guide decision-making for uncommon cancers where they may be no guidelines in place. Mechanisms should be available to address dose modifications of regimens/agents while receiving therapy. Mechanisms should be in place to monitor and improve prior authorization processes.

continues to accelerate in the field of oncology, the need for continuous pathway updates is critical to ensure high-quality care. The emergence of rapid learning systems will further accentuate the need for both rapid pathway refinements and more granular pathways that address the distinct needs of different patient subpopulations. Pathway updates should be validated and implemented as practice-changing information becomes available. Rapid learning clinical decisions represent a challenge to the traditional algorithms for patient care and may support more tailoring of therapies for specific patients. As such, evidence-based rapid learning clinical decisions supported by expert opinion should be considered pathway adherent. These updates should not depend only on annual, semiannual, or quarterly time frames. Additional goals of oncology pathways should be to promote value, control costs, and minimize undesirable treatment variability.

Recommendation 5: Oncology Pathways Should Recognize Patient Variability and Autonomy, and Stakeholders Must Recognize That 100% Concordance With Oncology Pathways Is Unreasonable, Undesirable, and Potentially Unsafe

A well-designed pathway program should allow for a universally accepted rate of nonadherence to accommodate unique clinical circumstances that are best addressed off pathway. Rigid oncology pathway programs can impede patient care if the treatment options are too limited or not reflective of the full range of options that are considered the standard of care. Although pathways should be used to reduce inappropriate variation, appropriate variation that allows for a range of options for patients with varied comorbidities and therapeutic goals should be supported without significant administrative burdens. Payers should allow for a reasonable transitional period when an oncology practice is initially subject to oncology pathways, accounting for patients who have already initiated care and providing adequate time for oncology providers to implement the new protocols.

Recommendation 6: Oncology Pathways Should Be Implemented in Ways That Promote Administrative Efficiencies for Both Oncology Providers and Payers

Adherence to oncology pathways should trigger meaningful reductions in administrative requirements arising from payers. For example, prior authorization requirements should be removed automatically when oncology providers provide health services that are consistent with oncology pathways, including warranted variations. Payers should make concerted efforts to limit the administrative burdens placed on oncology providers to provide both on-pathway and off-pathway care to the minimum level necessary, avoiding

requirements for live conversations or redundant data entry beyond the information typically entered into electronic medical records. Payers should ensure timeliness in regimen approvals and updates to pathways as new information becomes available, and work to provide automated authorizations (through electronic medical records, whenever possible), including automated authorizations for warranted variations. Special consideration should be given to promoting efficiencies for oncology practices that do not have electronic monitoring systems, such as allowing oncology practices to attest to concordance with oncology pathways subject to audits by the payer. The additional costs of complying with payer requirements related to oncology pathway selection and adherence should be factored into payment for oncology services, because these costs are not typically included under the current payment levels assigned to the general codes for evaluation and management services or the codes for care management.

Recommendation 7: Oncology Pathways Should Promote Education, Research, and Access to Clinical Trials

Most insurers are required to cover the routine costs associated with clinical trials involving anticancer regimens under both federal and state requirements. This reflects the critically important role that clinical trials play in ensuring that individuals with cancer have access to the best and most appropriate clinical option for their disease. Oncology pathways should encourage participation in clinical trials meeting the terms of federal or state coverage requirements by considering them as on pathway. Pathways should also enhance patient screening and improve access to clinical trials. As pathway concordance, completion, and exceptions are tracked, this information should be incorporated into an aggregated learning system database (such as CancerLinQ) to allow analysis to promote the improvement of cancer treatment. This database should incorporate as many patient and treatment variables as practical to allow and foster discovery of important unanticipated knowledge. Performance information should be shared with the providers participating in a specific oncology pathway to allow for feedback on performance and quality. Robust oncology pathways can ultimately help with the collection of population data outside of small trials, which will advance understanding of the actual impact of therapies on toxicities, comorbidities, and survival. Such a system can add to the knowledge about the impact on small and diverse communities where there are limited trial data for outcomes and variations. Comparisons among pathways might increase the speed with which we are able to incorporate newly identified beneficial therapies, lessen delivery of futile care, and enhance better supportive and palliative care. Identification of variations in clinical and financial outcomes should be used to generate new hypotheses to further improve care outcomes.

Recommendation 8: Robust Criteria Must Be Developed to Support Certification of Oncology Pathway Programs. Pathway Programs Should Be Required to Qualify Based on These Criteria, and Payers Should Accept All Oncology Pathway Programs That Achieve Certification Through Such a Process

ASCO is committed to working with all stakeholders and is prepared to serve as an honest broker to ensure that oncology pathways used to guide clinical care for patients with cancer are of the highest quality and reflect the latest advances science has to offer. All stakeholders in the cancer community will benefit from the certification of comprehensive oncology pathway programs that promote the highest quality care delivered at a reasonable cost.

Recommendation 9: Pathway Developers, Users, and Private and Governmental Funding Agencies Should Support Research to Understand Pathway Impact on Care and Outcomes

Because pathway value, best design, use, implementation, and impact on patients and providers are not well understood, research should focus on pathway development, dissemination and implementation, cancer care delivery, patient experience, and impact on clinical outcomes and value.

CONCLUSION

When used appropriately, oncology pathways can be instrumental in managing value-based payment models being proposed and used going forward. However, oncology pathways must be developed and used appropriately and efficiently to guide care recommendations and coverage policies. In this statement, ASCO has proposed a series of recommendations to help ensure that clinical pathways are developed and implemented in ways that enhance—not diminish—patient care. ASCO acknowledges and promotes the vital

collaboration of all stakeholders to achieve the ultimate goal of evidence-based, high-value oncology pathways. JOP

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