

# Accelerating the Delivery of Patient-Centered, High-Quality Cancer Care

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## Abstract

Significant progress has been made in the past 50 years across the field of oncology, and, as a result, the number of cancer survivors in the United States is more than 14.5 million. In fact, the number of cancer survivors continues to grow on an annual basis, which is due in part to improved treatments that help people with cancer live longer, and improvements in early detection that allow doctors to find cancer earlier when the disease is easier to treat. However, in spite of this progress, innovation in cancer research and care is at risk as the rise in health care spending is leading to significant pressure to contain costs. As the oncology community seeks to ensure that innovation in cancer research and care continues, it is imperative that stakeholders focus their attention on the value that the research and care continuum provides. Over the past several years, the Turning the Tide Against Cancer initiative has worked with the cancer community to accelerate the delivery of patient-centered, high-quality cancer research and care, while addressing value and cost. This article highlights policy recommendations that resulted from the convening of an expert working group comprising leaders from across the oncology field. Of the recommendations, the co-conveners have identified several issue areas that merit particular focus in 2015:

- Support FDA's efforts to modernize its framework for bringing new medicines to patients, through facilitating and implementing innovative approaches to drug development and regulatory review.
- Ensure that cancer clinical pathways or similar decision-support tools are transparent; developed through a physician-driven process that includes patient input; and meet minimum standards for clinical appropriateness, timeliness, and patient centeredness.
- Support oncology decision-support tools that are timely, clinically appropriate, and patient centered.
- Build on existing efforts to convene a multistakeholder committee and develop a report on ways to define and measure value in oncology care, taking into account many of the complex dynamics associated with measuring value, including the interests and needs of patients, as well as the importance of committed and ongoing support for innovative research.

These policy options are intended to further the national dialogue and represent meaningful and actionable steps toward supporting cancer research and care that is innovative, efficient, and focused on the patient. *Clin Cancer Res*; 21(10); 2263–7. ©2015 AACR.

## Introduction

In the past 50 years, researchers and health care providers have made important strides in oncology research and care. As a result, the percentage of the U.S. population living with, through, or beyond cancer has more than tripled since the U.S. Congress passed the National Cancer Act of 1971 (1). Once an acute diagnosis, cancer has been transformed for many patients into a manageable, chronic condition. The scientific community's expanding knowledge of the human genome and the biology of cancer has supported the development of personalized therapies, targeting cancer at the molecular level and increasing the quality and average lifespan of the cancer patient population. Most importantly, many stakeholders are testing groundbreaking

approaches to treatment and care with a common goal in mind—patient-centered, high-quality medicine.

Yet, many cancer patients still face significant unmet needs. More than 1.6 million people in the United States will receive a cancer diagnosis in 2015, and more than 585,000 will lose their lives to the disease (2). As the Baby Boomer generation becomes Medicare eligible, the number of new cancer cases in the United States is expected to rise, reaching almost 2.4 million by 2035 (3). The growing population of cancer patients will place strains on preventative, screening, and treatment services, which may not be adequately paid for in a system that is increasingly pressured to lower costs.

Therefore, progress in oncology care and research is at a critical juncture. Although we are seeing increased demand for care and rapidly rising costs, the advances in the field of oncology continue to serve as the national model for ways to improve efficiency in the quality of the care that is provided, which ultimately has the potential to reduce cost within the health care system.

Scientific progress will continue to play a central role in meeting the challenge of rising cancer care costs as well as addressing patients' unmet needs. If society is to capitalize on research advancements and ensure that patients benefit from life-changing developments, policymakers need to incentivize the development of innovative interventions and safeguard the

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delivery of patient-centered, high-quality cancer care. The U.S. House of Representatives is currently working on the 21st Century Cures legislative initiative, which could have a significant impact on the development of innovative cancer treatments, including the use of existing therapies for new indications (4). The White House Precision Medicine Initiative (5), first announced at the President's State of the Union address, is also bringing renewed focus on the ways in which research and regulatory infrastructures are vital to advancing science toward personalized oncology.

The payment landscape is also shifting, with various value-driven payment models being developed and piloted with the goal of replacing fee-for-service and volume-driven payment. On January 26, 2015, in a historic announcement, the U.S. Department of Health and Human Services (HHS) set a clear timeline for moving Medicare beneficiaries from the traditional fee-for-service payment system to alternative payment models intended to improve clinical outcomes and make health care more efficient. Its goal is to link 30% of Medicare payments to alternative payment models that reward value over volume by 2016, increasing to 50% by the end of 2018 (6). The first alternative payment model announced by HHS after the introduction of this initiative was oncology focused (7).

While scientific advances are driving us toward personalized oncology care, it is critical that our regulatory and health care delivery systems are equipped to integrate patient centeredness and value into every day cancer research and care.

## The Turning the Tide Against Cancer Initiative

In 2011, the Personalized Medicine Coalition, the American Association for Cancer Research, and Feinstein Kean Health care launched the Turning the Tide Against Cancer initiative, a national effort aimed at identifying policies that will sustain medical innovation, while addressing the issue of rising health care costs. In 2014, the Turning the Tide Against Cancer initiative convened an expert working group to identify actionable policy options that will support the delivery of patient-centered, high-value oncology research and care and guide future Turning the Tide Against Cancer activities. The expert working group included participants from a range of disciplines, including physician scientists, practicing physicians, patient representatives, payers, pharmaceutical company officials, and health policy experts.

The expert working group focused on two key themes that have emerged from the initiative's work over the past 2 years and are directly relevant to the challenges of sustaining continued innovation to improve the outcomes that are important to patients while addressing the pressure associated with cost containment efforts: (i) how to foster a shift to patient centeredness in cancer research and care delivery and (ii) how to address cost and value in oncology in ways that align with patient centeredness and scientific progress. The expert working group developed policy options (listed at the end of this article) believed to represent meaningful and actionable steps toward supporting cancer research and care that is patient centered, innovative, and efficient. The policy options relate to a range of issues, including the FDA's efforts to advance personalized medicine, Medicare reimbursement policies, and payers' coverage for cancer care. The Turning the Tide Against Cancer initiative co-conveners released an issue brief based on the recommendations of the expert working group

during its second national conference held in October 2014 in Washington, DC.

## Areas of Focus for 2015

Given the active dialogue within the policy arena and the recent and ongoing developments affecting the cancer policy environment, we have an opportunity to make significant progress over the coming months. Several issue areas merit particular attention in order to address the challenges described above. These focus areas, which are included among the policy options, were chosen based on their timeliness and potential impact on cancer care and patient outcomes.

### FDA processes to advance personalized medicine

*Recommendation: FDA should promote the modernization of the framework for bringing new medicines to patients by facilitating and encouraging the use of innovative approaches to drug development and regulatory review, including the use of novel clinical trial designs, integration and consideration of patient perspective information in regulatory benefit–risk assessments, and use of observational research for pre- and post-market regulatory decision making.*

Many stakeholders agree that large, randomized clinical trial (RCT)-based drug development may not be the only appropriate model for 21st-century research, particularly for developing new medical products for serious or life-threatening diseases or unmet medical needs. Reforms to the research and regulatory infrastructure and process must encourage and facilitate the development of new therapies to keep pace with scientific progress. There are a number of opportunities to leverage existing advances—both in scientific knowledge and in research methodologies/trial designs—to encourage innovation. Numerous organizations are beginning to partner to capitalize on these advances and leverage shared knowledge, including Pfizer and 23andMe (8), Genentech and PatientsLikeMe (9), and Boehringer Ingelheim and the Duke Clinical Research Institute (10).

Larger and more diverse datasets are being generated through the real-world use of clinical and care delivery interventions and are subsequently being accessed to support health care decision making. The FDA's utilization of real-world electronic datasets in the full scope of its decision making, including applications for supplemental indications, revisions to drug labeling to reflect patient outcomes, definitions related to the nature of, or need for, Risk Evaluation and Mitigation Strategies (11), or fulfilling post-marketing commitments, has enormous potential to improve the quality of cancer care.

In addition, patient-centered cancer care depends on understanding how patients are engaged in their own treatment decisions in order to identify areas of unmet need. It also relies on study designs that best capture the endpoints and outcomes that are meaningful to patients. Through its Patient-Focused Drug Development initiative (12), the FDA has embarked on an effort to develop a broad, systematic approach to gathering patients' perspectives on the severity of their diseases or unmet need. Although it is not yet clear how the agency will do so, the most recent reauthorization of the Prescription Drug User Fee Act (PDUFA V) commits the FDA to developing a proposal for how this information will inform the Agency's decision making (13). The FDA and other stakeholders should continue to actively consider the patient perspective and ways to improve the efficiency of the research and approval processes.

**Provider tools to drive and support oncology care**

*Recommendation: The Centers for Medicare and Medicaid Services (CMS) should ensure that cancer clinical pathways or similar decision-support tools used to guide clinical decision making are transparent to beneficiaries and the public; developed through a physician-driven process that includes patient input; and meet minimum standards for clinical appropriateness, timeliness, and patient centeredness. The Institute of Medicine (IOM) should consider convening a multistakeholder committee to make recommendations on standards for clinical pathways, including transparency, evidence quality, and incorporation of genetics tests and personalized medicine.*

*Recommendation: Federal health agencies, including HHS and the Office of the National Coordinator for Health Information Technology (ONC), should support oncology decision-support tools that are timely, clinically appropriate, and patient centered. In particular, ONC should propose certification standards for electronic health records (EHR) to improve the frequency of incorporating compendia updates and to ensure that clinical decision-support tools meet baseline standards for transparency, strength of evidence, and timeliness to ensure they reflect optimal cancer care, incorporate individualized patient preferences and needs, and keep pace with changes in research and treatment.*

Stakeholders are currently testing a range of new approaches to lowering the cost of providing care to cancer patients. For example, the Center for Medicare and Medicaid Innovation (CMMI) recently announced the Oncology Care Model, a demonstration program that seeks to incentivize more efficient oncology care through episode-based payments (14). Non-Medicare payers, such as UnitedHealthcare and Aetna, have piloted similarly driven programs (15, 16).

In order to achieve the benchmarks required of such alternative payment models, health care providers are increasingly relying on such tools as clinical treatment pathways, medical compendia, and health information technology (HIT) to provide information on current standards of care and guide medical decision making. These tools typically have the goals of reducing inappropriate variability in clinical practice and increasing efficiency (17).

When such tools are designed well and grounded in evidence-based medicine, they can facilitate use of the best available information to support high-quality, individualized care and support continuous learning in the health care system (18). However, without common standards for their development and little harmonization in care approaches across different pathways from different developers (19), tools such as clinical pathways often can cause confusion among physicians and reinforce variability in the quality of patient care.

Clinical pathways and decision-support tools can be quite sophisticated—based on the best available data and individual patient information—or standardized guides that can limit treatment options solely because of cost or based on a "typical" patient (20). The sophistication of decision-support tools often depends on the quality of data used as a basis for clinical recommendations. For example, HIT-enabled pathways or clinical decision-support tools may recommend a particular course of treatment for a patient based on clinical information published in drug compendia. However, there is currently no required timeline or process for EHR vendors to disseminate updates to drug compendia to their customers. As a result, information in EHRs can be out of date and prescribers may lack access to the latest product

information, including indications, necessary testing, allergies, interactions, and warnings.

Payers, including Medicare, should ensure that clinical pathways used in value-based payment programs, such as the Oncology Care Model, meet basic standards for transparency, evidence base, and clinical appropriateness and are updated regularly.

An evidence-based, consistent, and transparent (21) approach to developing decision-support tools is necessary, so that these tools leverage the best available evidence to promote high-quality care that is informed by patients' individual needs, preferences, and characteristics. This task could be undertaken by an entity such as the IOM, or by a voluntary collaboration among leading health plans, physician groups, and drug and medical device manufacturers. There may also be a role for ONC. ONC is responsible for the development of meaningful use criteria (22) and certification standards that support the usability, transparency, evidence strength, and timeliness of decision-support tools and any information housed within EHRs (i.e., compendia or pathways). ONC should also ensure that EHRs are designed to enable the collection of data that can be used to advance research and patient care (e.g., genomic information and patient-reported outcomes).

As public and private payers consider value-based payment models, particularly those that hold providers accountable for the cost of care, it will be important that any incentives seeking to drive care standardization (e.g., clinical pathway tools) remain clinically appropriate, rely on basic standards for medical evidence, and are developed through a transparent process to achieve the goal of patient-centered, high-quality care.

**Defining value in an era of cost containment**

*Recommendation: Building on existing efforts, the IOM should convene a multistakeholder committee and develop a report on how to define and measure value in oncology care that addresses dynamics previously identified by Turning the Tide Against Cancer leaders—variability in definitions of value within and among stakeholders and over time—so that methods for assessing value align with the needs of patients and continued scientific progress. The Patient-Centered Outcomes Research Institute (PCORI) should continue to support research to evaluate and identify innovative, effective methods for the use of decision-support tools to best communicate to patients and caregivers benefit, risk, and uncertainty in evidence. Research should include consideration of patient preference in treatment decision making.*

Even as the cost of cancer treatment comes under increased scrutiny, there is growing recognition of challenges in evaluating and communicating value in ways that are patient centered, in reflecting the various dimensions of quality, in accommodating the differences among and within stakeholder groups (e.g., patient subgroups) in how value is perceived, and in taking into account continual advances in research and clinical practice (23). Even within a narrow cost framework, a tradeoff exists between short-term costs, long-term costs, and costs that a patient experiences (e.g., cost sharing) versus those imposed on the health system. Patients are often willing to accept such tradeoffs (e.g., between incremental survival benefits and toxicity of a therapy), and this willingness may evolve throughout the course of treatment, particularly as patients experience changes in functional status and quality of life. Presently, there is no mechanism or model for understanding and determining (i) what these tradeoffs are, (ii) how they evolve, and (iii) how variances in patient preferences may affect interpretations of value at both the population and individual levels.

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With competing definitions and measurements of value that vary by stakeholder group, a common framework is needed for future discussions and decision making among payers, physicians, patients, and others involved in treatment decisions. This framework must accommodate patient preference, quality of life, and other critical factors weighed by patients in making value judgments. Our understanding of value evolves along with the research, science, and clinical practice related to it. Prior research has noted the extent to which existing evidence-based decision-support tools are challenged in keeping pace with the rapid rate of change in cancer care (24); as a result, these tools should be grounded in the latest clinical evidence—not just what is deemed the current standard of care. This approach will allow for more targeted treatments to be developed.

The IOM previously considered this important issue in its November 2009 workshop summary, "Assessing and Improving Value in Cancer Care" (25), which provides a starting point for renewed efforts in light of the significant and ongoing scientific advances that have occurred since then, as well as ongoing policy development. In addition, the American Society of Clinical Oncology's (ASCO) Value in Cancer Care initiative seeks to provide a framework for assessing value that accommodates differences in patient perspectives of value and reflects the value of oncology innovation, and also gives oncologists a tool for discussing value with their patients (26). Such a framework will need to define the different components that inform a more patient-centered notion of value—including survival, toxicity, harm, symptoms, palliation, convenience, functional status, and other relevant inputs—and weigh clinical value and cost in ways that reflect patient preferences, individual willingness to accept tradeoffs, and other needs more broadly.

### The way forward

We believe that there are a range of policy initiatives and activities that can be undertaken to foster and sustain innovation. This article is the result of clear interest from a diverse group of stakeholders in the research and clinical ecosystem who wish to advance these types of endeavors. Our objective is to maintain engagement with these stakeholders and to engage additional stakeholders in the hope that they will identify policies that will sustain progress against cancer by improving clinical outcomes that are important to patients in an era of cost containment. Such an undertaking will require significant dedication and robust dialogue, but most importantly, commitment to ensuring that the patient remains at the center of decision making.

## Turning the Tide Against Cancer Initiative Policy Options

The following are the policy options developed by the Turning the Tide Against Cancer expert working group (27).

*Private/public partnerships.* Congress should fund, and the NIH should implement, public/private partnerships to encourage the use and acceptance of innovative clinical trial designs that promote efficiency in drug development by, for example, enabling simultaneous study of multiple drug candidates.

*FDA framework modernization.* The FDA should continue to modernize its framework for bringing new medicines to patients by facilitating, and encouraging the use of, innovative approaches to drug development and regulatory review, including the use of

novel clinical trial designs, integration and consideration of patient perspective information in regulatory benefit–risk assessments, and use of observational research for pre- and post-market regulatory decision making.

*Clear and efficient FDA review process.* The FDA should continue making progress in defining and applying a clear, efficient, and coordinated review process for personalized medicine products.

*Data transparency.* HHS should establish a cross-department work group to identify opportunities to enhance data transparency and sharing in support of innovation in oncology, including sharing of data related to precompetitive collaborations, clinical trial data, and federal and state electronic datasets (e.g., Medicare claims data). Policies should maximize transparency and sharing of high-quality data, while supporting strong standards for protecting patient confidentiality and confidential commercial data.

*Quality and performance measures.* Congress should provide funding to support the development and updating of quality and performance measures for cancer care by private sector organizations (including oncology and related medical specialty societies and organizations with expertise in patient experience and patient-reported outcomes measures) through transparent procedures that include multistakeholder endorsement. CMMI should require use of robust, clinically driven, and endorsed clinical quality and patient-focused measures in alternative oncology payment models.

*Coverage for cancer care in health exchanges.* HHS and states should ensure patient access to quality and affordable care in federal and state health exchanges by requiring broader coverage of cancer services and drugs and assuring adequate networks of cancer providers.

*Oncology patient-centered medical homes.* CMMI should prioritize additional funding for Oncology Patient-Centered Medical Home (OPCMH) demonstrations, with a focus on supporting patient navigation, access to care providers and treatment options, and personalized, evidence-based treatment plans, using tools such as shared decision making. OPCMHs should incentivize adoption of advanced EHR and informatics and be evaluated against clear, patient-centered metrics, including measures of care quality and patient experience, and access to medically appropriate treatments and care providers.

*Medicare reimbursement policies.* Medicare reimbursement policies should support innovative practice models to improve patient access and support patient engagement. These policies may include payment for telemedicine, oncology nursing support, visiting consultants, e-mail, and use of mobile devices.

*Procedure codes for cancer tests and services.* CMS should adopt more specific codes (developed by the American Medical Association) to appropriately capture the complexity of cancer tests and services and ensure appropriate reimbursement, including reimbursement for molecular and personalized medicine testing as well as palliative care.

*Clinical pathways and decision-support tools.* CMS should ensure that cancer clinical pathways or similar decision-support tools used to guide clinical decision making are transparent to beneficiaries and the public; developed through a physician-driven process that includes patient input; and meet minimum standards for clinical appropriateness, timeliness, and patient centeredness. The IOM should consider convening a multistakeholder committee to make recommendations on standards for clinical pathways, including transparency, evidence quality, and incorporation of genetics tests and personalized medicine.

*Health information technology.* Federal health agencies, including HHS and ONC, should support oncology decision-support tools that are timely, clinically appropriate, and patient centered. In particular, ONC should propose certification standards for EHRs to improve the frequency of incorporating compendia updates and to ensure that clinical decision-support tools meet baseline standards for transparency, strength of evidence, and timeliness to ensure they reflect optimal cancer care, incorporate individualized patient preferences and needs, and keep pace with changes in research and treatment.

*Value definition.* Building on existing efforts, the IOM should convene a multistakeholder committee and develop a report on how to define and measure value in oncology care that addresses dynamics previously identified by Turning the Tide Against Can-

cer leaders—variability in definitions of value within and among stakeholders and over time—so that methods for assessing value align with the needs of patients and continued scientific progress. PCORI should continue to support research to evaluate and identify innovative, effective methods for the use of decision-support tools to best communicate to patients and caregivers benefit, risk, and uncertainty in evidence. Research should include consideration of patient preference in treatment decision making.

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