Cost, Coverage, and Comparative Effectiveness Research: The Critical Issues for Oncology

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ABSTRACT

A new national initiative in comparative effectiveness research (CER) is part of a broad and long-term evolution toward greater reliance on scientific evidence in clinical practice and medical policy. But CER has been controversial because of its high profile in the health care reform effort, its instantiation in a prominent new national research institute, and lingering concerns that the ultimate goal of CER is to empower the government and private insurers to reduce health care costs by restricting access to expensive new medical tests and treatments. This article presents an analysis of the policy development behind CER and focuses on its potential impact on insurance coverage and payment for oncology services. By itself, CER will not solve the tension that exists between the goal of innovative, personalized care and the eroding affordability of cancer treatment in the United States. But CER does offer an important opportunity for progress. Oncologists have taken important first steps in acknowledging their responsibility for addressing cost issues; as a professional society, they should now move forward to assume leadership in the effort to integrate clinical evidence with considerations of cost effectiveness to guide clinical practice and insurer policies.

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INTRODUCTION

Comparative effectiveness research (CER) is not a new idea, but it has become a powerful brand over the past few years. Much like its even more recent congener, patient-centered outcomes research, the term CER represents an ideal form of research with several distinguishing characteristics: it addresses problems of real significance to patients and clinicians; it compares health care services or programs in a head-to-head manner; it focuses on results obtained in the real world of typical patients and clinicians; it achieves this generalizability while remaining sensitive to individual patient characteristics and values; and, ultimately, it produces better evidence to guide health care decisions.^{1,2} Of course, if this were all there was to CER, it would be hard to imagine the level of controversy that has surrounded it. But in neither the policy community nor the public arena has the issue of CER been seen as exclusively about research topics, study design, or how patients and clinicians can use evidence more effectively. Deeper concerns about CER have been raised and have always been, at their root, about how the evidence produced from CER may be applied in efforts to control health care costs.

There is no doubt that the policy questions posed by CER have been magnified because of its

association with health care reform. During the run-up to the formal legislative process, the idea of CER became a popular fixture among the mechanisms touted by administration figures to reduce health care costs.³ That express purpose gave rise to a corollary concern among many stakeholders: that the results of CER would be used by government and private payers to clamp down on access to costly treatments. Unfortunately, any chance for a reasonable public discussion of the possible uses and misuses of CER was drowned out by the endemic vitriol of the political environment surrounding the Affordable Care Act.

So where do we stand today, as the embers of concern about CER still smolder, the new national CER institute gains its footing, and the CER agenda moves forward with growing momentum? One thing seems certain: no matter the outcome of legal challenges to the broader framework of health care reform, the drive for greater use of evidence as a means to improve quality and lower costs in health care is here to stay. This will come as little surprise to oncologists. In oncology, clinicians and researchers have long been acutely aware of the need for better evidence on the comparative effectiveness of different tests and treatments. Oncologists are also well acquainted with the ethical and policy questions raised when conducting this kind of research among patients with cancer; they are equally familiar with

the dilemmas that often arise in applying the results of CER to patient care in a context of limits—limits in the ability of evidence to guide individual care, limits in the length of every human life, and limits in the financial resources that individual patients, and even a society as wealthy as ours, can dedicate to health care.^{4,5}

But the future promises only greater dilemmas over access to new oncology treatments in an environment of continued financial stress.⁶ What role will CER play in this evolving policy landscape? And what should oncologists do to meet the challenge? After first framing the discussion by reviewing the history of the controversies over CER during the health care reform process, the major goal of this article will be to analyze the critical issues that the field of oncology will face moving forward as it continues to serve as a prominent battleground in controversies over evidence, the cost of health care, and the struggle for decision-making power within the US health care system.

CER IN THE ERA OF HEALTH CARE REFORM

Before the storm clouds surrounding health care reform began to gather in 2008, the idea of CER had a low profile in the United States. Although not formally labeled CER, there had always been a steady stream of federally funded clinical research comparing the outcomes of different tests and treatments, and in the early 2000s, a Republican Congress had allotted the federal Agency for Healthcare Research and Quality a relatively small amount of money specifically to perform “comparative effectiveness reviews” of health services. All this was uncontroversial and little noticed by policy makers.⁷

But this halcyon period for CER began to fade as health care reform rose to the top of the political agenda and as cost control emerged as an increasingly visible challenge. It was at that point that CER began to be promoted by multiple groups and figures as an important mechanism for reducing unnecessary variation and overuse of medical treatments, leading to lower costs through the use of better evidence by patients, clinicians, and insurers.^{7,8}

At this juncture, policy and political considerations were strongly influenced by the example of existing programs of CER evidence review in other countries. These programs, such as the Pharmaceutical Benefits Advisory Committee in Australia and the National Institute for Health and Clinical Excellence in England, had for many years conducted reviews of the clinical effectiveness—and cost effectiveness—of new drugs and other health interventions and were integral parts of the coverage decision-making process within their respective national health systems.⁹ In a small minority of cases over the years, these agencies had denied coverage for licensed, effective medicines when the amount of clinical benefit in relation to the cost was viewed as providing insufficient value, given other priorities in the health care system. Prominent among these rejected medicines were new cancer drugs, including at one time or another some of the drugs introduced to treat early breast cancer, colorectal cancer, glioma, head and neck cancer, leukemia, mesothelioma, multiple myeloma, and lung cancer.¹⁰

Given these precedents, it was but a short conceptual leap for some in the United States to surmise an analogous role for the new federal CER program being promoted actively in health policy circles by health plans and Democrats in Washington. If this was the intended path, it looked to many that the outcome would be explicit governmental rationing of expensive treatments. In the midst of a rising

chorus of warnings about the dangers of expanded federal powers, it took just a dash of political alchemy to produce, in a field of many worthy competitors, the most deplorable epithet of the entire health care debate: the claim that a national CER institute would inevitably serve as a government “death panel.”¹¹

This was nonsense. For one thing, instead of judging existing evidence to make coverage and reimbursement decisions, as was the role of international agencies, all the early white papers, academic articles, draft legislation, and final language of the Accountable Care Act emphasized a different role for the new federal CER program in the United States: to commission new studies to generate better evidence for patients and clinicians. Efforts to synthesize existing evidence to help inform health care decisions were still included in the thinking about a new CER initiative, but the focus was clearly on sponsoring prospective clinical trials and registries, as well as conducting new analyses of patient outcomes from data in insurance claims systems, electronic medical records, and other databases.

Also at odds with the claims being made, the new national CER initiative to be created under health care reform was not even going to be a government panel at all. New funding for CER would be overseen by a new, independent nonprofit organization, the Patient-Centered Outcomes Research Institute (PCORI). Background information on PCORI is provided in Table 1. PCORI is governed by a multistakeholder board of 21 individuals that includes physician representatives alongside members drawn from life science companies, private health plans, hospitals, and patient advocacy organizations, with only two representatives from the federal government. The structure of the PCORI Board was intended to ensure that CER would not become overly influenced by the need of the government to control health care costs.

PCORI is thus outside government; its ability to even indirectly influence coverage and reimbursement decisions is also carefully circumscribed. The institute cannot make any kind of recommendations regarding insurance coverage or reimbursement (Table 2). The legislative language also prohibits Medicare from using the results of PCORI-funded research as the only basis for coverage decisions, allowing consideration of the evidence, but only as part of many inputs into decisions, and without any kind of direct on-off switch for coverage based on CER results.

And what about the ability of PCORI to fund research looking at costs or value? The question of whether cost, cost effectiveness, or some other measure of value was to be part of the agenda of a federal CER initiative continued to be hotly debated throughout the years leading up to the passage of the Accountable Care Act.¹² Some commentators, policy makers, and physician groups, including the American College of Physicians, argued that evidence on cost and cost effectiveness should be integral components of CER.^{13,14} They believed that it was disingenuous to pretend that cost was not an important consideration, and that added rigor and transparency could be brought to discussions of cost—in the context of evidence on clinical effectiveness—if evidence on effectiveness and cost were included jointly as part of CER research and reviews. It was also argued that it would be particularly useful to include cost-effectiveness analyses as part of CER, because only through the lens of cost effectiveness could long-range clinical benefits and utilization be estimated and compared across different treatment approaches. Without cost effectiveness, there was no way for the true value of higher-priced new tests and treatments to be fully appreciated, penalizing expensive but ultimately

Table 1. Information on PCORI

Feature	Information
Location	Washington, DC
Mission statement	PCORI helps people make informed health care decisions—and improves health care delivery and outcomes—by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader health care community
Organizational structure	Independent, nonprofit institute
Governance	21-member governing board, which includes individuals representing patients and health care consumers; clinicians; private payers; manufacturers and developers of drugs, devices, and diagnostics; independent health service researchers; and leaders in federal and state health programs and agencies; the initial executive director is family physician and health services researcher Joseph Selby, MD
Methodology committee	17-member methodology committee works to develop and advance the science and methodologies of CER; members are experts in fields including health services research, clinical research, CER, biostatistics, genomics, and research methodologies
Funding levels	\$160 million in 2012, rising to > \$500 million per year by 2014; funding sources include annual transfers from the Medicare Trust Fund and a per-capita fee assessed from private health insurers
Grantmaking	PCORI will fund a mix of grants and contracts; a small number of pilot project grants on priority setting, patient engagement, and other process issues have been awarded to date; to guide future grantmaking, a draft of national research priorities has been posted for public comment Current priorities are: <ul style="list-style-type: none"> • Assessment of options for prevention, diagnosis, and treatment • Improving health care systems • Communication and dissemination research • Addressing disparities • Accelerating patient-centered outcomes research and methodologic research

Abbreviations: CER, comparative effectiveness research; PCORI, Patient-Centered Outcomes Research Institute.

cost-effective services by leaving upfront cost as the dominant consideration in medical policy decisions.

Other commentators, policy makers, and physician groups argued the reverse: that there were important reasons why cost considerations of any kind should be formally excluded from the scope of work of a new federal CER initiative.¹⁵ Some emphasized that without a single-payer system, the wide variation in prices and costs across health systems in the United States made a centralized attempt to evaluate cost or cost effectiveness unhelpful and potentially misleading. Others were worried that introducing cost considerations in any format would stifle innovation and prove a slippery slope toward denial of coverage for expensive interventions.¹⁶ And there were some strong supporters of CER who were against including cost, because they perceived that in the existing political climate, anything less than total exclusion of cost considerations would make CER a favored target of Republican lawmakers, weakening the chances of CER being retained as part of the final health care reform package.

Table 2. Limitations on Uses of CER in the Patient Protection and Affordable Care Act

Type of Limitation	Specific Limitation Wording
Cannot include mandates for coverage or payment	
Section 6301(d)(8)(A)(iv)	The Institute shall ensure that the research findings do not include practice guidelines, coverage recommendations, payment, or policy recommendations
Section 6301(j)(1)(A)	Nothing in this section shall be construed to permit the Institute to mandate coverage, reimbursement, or other policies for any public or private payer
Section 1182(a)	Materials, forums, and media used to disseminate the findings, informational tools, and resource databases shall not be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment
Can only use evidence if part of larger process	
Section 1182(a)	The Secretary may only use evidence and findings from research . . . to make a determination regarding coverage . . . if such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations
Section 1182(b)(2)	Nothing in section 1181 shall be construed as authorizing the Secretary to deny coverage of items or services . . . solely on the basis of comparative clinical effectiveness research
Cannot use evidence in a manner that assigns a lower value to life with disability	
Sections 1182(c)(1) and 1182(d)(1)	The Secretary shall not use evidence or findings from comparative clinical effectiveness research . . . in determining coverage, reimbursement, or incentive programs . . . in a manner that: <ol style="list-style-type: none"> 1) Treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill 2) Precludes, or with the intent to discourage, an individual from choosing a health care treatment based on how the individual values the tradeoff between extending the length of their life and the risk of disability
Cannot develop or use a dollars-per-QALY or similar cost-effectiveness threshold as part of recommendations or to determine coverage or payment	
Section 1182(e)	The PCORI . . . shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs . . .

Abbreviations: CER, comparative effectiveness research; PCORI, Patient-Centered Outcomes Research Institute; QALY, quality-adjusted life-year.

Ultimately, the concerns about cost held sway. The final legislative language for PCORI labeled its formal task as “clinical comparative effectiveness research.” Funding was prohibited for cost-effectiveness analyses that would compare services using the traditional metric of cost per additional quality-adjusted life year (QALY) gained. There was, however, no blanket exclusion of cost or value measures, and when the first draft definition of patient-centered outcomes research was released by PCORI in 2011, it did include a goal of assessing health care value. The institute received nearly 600 comments on this early working definition, with drug companies and providers raising strong concerns that use of the word value might signal that cost analyses would be part of future PCORI studies.¹⁷ In response, PCORI Executive Director Joe Selby made a point of saying in public, “You can take it to the bank that PCORI will never do a cost-effectiveness analysis.”^{18(p1)} But Selby continued on in the same interview to say that in the future, the institute would “listen to what patients want researched, including the possibility of, for instance, whether cost sharing affects adherence to medication regimens, which in turn affects the health of patients.”^{18(p1)} Therefore, although the classic cost-effectiveness analysis has been firmly excluded from the range of activities at PCORI, cost in some form, albeit not provider or insurer costs, may still be considered at some point in the future as a relevant part of CER.

COVERAGE OF AND PAYMENT FOR ONCOLOGY DRUGS

From this history, it is clear that PCORI was designed in a way to minimize the potential impact of CER on insurance coverage and reimbursement. All the elements were aligned: an independent, nongovernmental structure and governance, explicit prohibition on making recommendations regarding coverage, exclusion of cost and cost-effectiveness considerations, and even the new label and unmistakable emphasis on patient centeredness as the driving maxim of the research. All these features reinforce one another in ways that inhibit the use of CER in coverage and reimbursement.¹⁹ Looking at this overall picture, one overseas observer deemed the new CER initiative in the United States to be “teethless.”^{20(p432)}

But in some ways, insurance systems in the United States, both public and private, have always faced significant constraints using CER data, or more often the lack of it, as the basis of coverage policies that limit access to new services. Nowhere is this truer than for oncology drugs. The lack of good comparative effectiveness evidence for oncology drugs, particularly for off-label uses, has been well described and sorely lamented.^{21,22} But a complex legislative and regulatory framework shields cancer drugs from potential strategies that would apply a standard of evidence based on comparative effectiveness, as opposed to efficacy versus placebo, as a mechanism to restrict coverage.²³ For Medicare Part B injectable drugs, federal law requires Medicare to cover any drug used in an “anticancer chemotherapeutic regimen,” as long as the use is “for a medically accepted indication.”^{23(p629)} These indications are defined broadly as any use approved by the US Food and Drug Administration, which rarely requires comparative effectiveness information for licensing, as well as the uses listed in one of several drug compendia. The lack of systematic and comprehensive evidence review among drug compendia is well documented; what is equally clear is that they have never required high-quality evidence from head-to-head trials or even from rigorous

indirect comparisons as a standard to judge whether to list an off-label indication for a cancer drug.^{21,24} The case is similar for oral drugs provided through Medicare Part D by contracting private plans. All drugs in certain categories in which the treated condition is major or life-threatening must be included on these formularies, no matter whether there is evidence of comparative effectiveness or not. The prototypical example given of this kind of drug are those used in the treatment of cancer.²⁵ There is therefore a strong legal and regulatory bulwark against potential efforts to use comparative effectiveness as the standard for coverage decisions for oncology drugs, and this is unlikely to change in the foreseeable future.

In contrast, private insurers have shown increasing interest in using CER results—and costs—to create many new forms of financial incentives for patients, providers, and even manufacturers. For patients, this has taken the form of tiered benefit designs, in which higher tiers require higher out-of-pocket payments. Expensive oncology drugs are now usually placed in the highest tier, tier four, in which up to 20% to 33% of the overall cost must be borne by the patient. Unfortunately, many tier-four programs use cost alone as the factor in tier placement; comparative effectiveness is not taken into account. This is why bevacizumab for breast cancer, which has no effect on overall survival, and trastuzumab, which does, are often placed in the same tier.²⁵ Insofar as this kind of tiering of oncology drugs represents only the shifting of cost to sick patients, and fails to use evidence to support more cost-effective treatment options, it should be condemned as unethical and a threat to the basic idea of the social compact that underlies health insurance.

In using comparative effectiveness as a conceptual framework to help create new provider payment strategies, however, insurers have found better ways to integrate evidence and cost considerations. One key approach has been to provide incentives for physicians to choose less expensive chemotherapy options from among those considered equally effective for a particular condition. Insurers and intermediaries, such as pharmaceutical benefit managers (PBMs), can turn to independent evidence review and guideline organizations, such as the National Comprehensive Cancer Network (NCCN), to provide a menu of accepted drug regimens or other kinds of care pathways for a type of cancer. For example, NCCN guidelines for the treatment of recurrent and widespread non-small-cell lung cancer show multiple possible treatment regimens, some of which are much more expensive than others.²⁶ Insurers and PBMs are actively moving many provider contracts over to a model in which greater use of the less expensive regimens from within an accepted menu of options will produce savings that can be shared between the providers and insurers/PBMs.

Looking at this development, it is clear that it will be a key question for oncology to determine how CER will be used to define what are equal or comparable outcomes for different treatment plans. If there are minor differences in adverse effect rates, or even in efficacy rates, how will these be judged and ultimately weighed to decide if the overall outcomes should be considered equivalent? How will it be decided whether two treatment plans should be considered equivalent if there is no comparative evidence, or if there are some differences shown but only from poor-quality studies? Traditionally, these questions were largely answered by the individual oncologist considering the treatment options in light of the specific characteristics of an individual patient. But moving forward, with greater financial repercussions linked to these judgments, the pressure will rise on groups such as the NCCN to justify their rationale for judgments of what

constitutes a reasonable option. Oncology is likely to be in for protracted battles over how CER is used to judge what is equal enough to warrant strong preference for the less expensive options.

The future is also likely to see several other ways that CER will be linked to continued innovation in coverage and payment strategies for oncology drugs. When new drugs are approved by the US Food and Drug Administration and come into practice without studies of their comparative effectiveness against other active agents, it is likely that insurers will increase their use of coverage with evidence development (CED), in which coverage is made conditional on patient enrollment onto some kind of clinical trial or registry.^{26a} Although many questions about comparative clinical effectiveness can be best answered through randomized clinical trials, sample sizes for head-to-head active agent trials may prove too large to be feasible, and clinical registries will therefore prove an important option for gaining better evidence on longer-term benefits and adverse effects for many treatments.²⁷ As the national infrastructure for clinical registries receives greater funding through PCORI and other sources, the practical barriers to CED may be reduced, allowing insurers to use this mechanism more often. There has been concern that CED is coercive, but when there are important questions remaining about the comparative risks and benefits of new agents, it is not unreasonable to extend coverage with an expectation that additional evidence will be gathered.²⁸ Oncologists and their patients, however, should be active partners in discussion of when and how CED is implemented.

Another outcome to be anticipated is that CER will be used more often as a tool to set initial drug prices or as the basis of risk-sharing agreements with drug manufacturers. Many policy makers view coverage policy as too blunt an instrument to use as the primary mechanism to try to improve the cost effectiveness of clinical practice. So, instead of using coverage to say no to a drug because it cannot demonstrate comparative effectiveness commensurate with the high price being charged, insurers are becoming more interested in saying yes, but at a price or with some risk-sharing agreement commensurate with the status of comparative effectiveness evidence. Approaches of this kind include reference pricing, in which drugs of so-called equal effectiveness are reimbursed at the same (lower) price. More commonly used to price drugs in drug classes such as statins, this approach was recently used in Germany to price the new breast cancer drug eribulin, which was judged not to have demonstrable additional effectiveness over current treatment options.²⁹

In the United States, reference pricing of oncology drugs would face statutory and other barriers, but UnitedHealthcare has launched a program to reimburse the OncoType Dx genetic marker test for breast cancer under an agreement whereby if the number of women receiving chemotherapy when their test results suggest they do not need it exceeds an agreed on threshold, the insurer will negotiate a lower price.³⁰ Private insurers in the United States have also begun experimenting with risk-sharing agreements with drug manufacturers. In one prototypical model, an upfront price is agreed on for the drugs to treat an entire population, and the results of later evaluations of the comparative effectiveness of the drug are used to decide whether the drug performed as well as expected. If the drug turns out to be less effective than initially believed, the risk-sharing agreement would require the drug manufacturer to reimburse the insurer some of the initial payment.³⁰ One of the most notable agreements of this kind requires Johnson & Johnson to reimburse the British National Health

Service for the cost of bortezomib treatment for patients who do not respond after four cycles.^{31,32}

As important as these pricing schemes may be, however, over the next decade, the most important development in the application of CER to the way that oncology drugs are used in practice may involve insurers only indirectly. As Medicare and private insurers begin to accelerate the shift toward episode and global payment mechanisms, the financial risk for expensive oncology drugs will become largely a concern for providers themselves. Integrated provider groups, now often called accountable care organizations, will receive an increasing share of revenue from global payments, giving them different incentives when it comes to the selection of oncology treatments. Whereas insurers have been the traditional primary customer of CER for the purposes of using it to try to control cost, now it will be the provider groups with the incentive to convene the expert committees, create care pathways and algorithms, and decide what high-value and appropriate treatment selections are. None of this is will be new for larger provider groups, but global payments will focus their attention to an extent not seen before, and bring home the ownership of grappling with how best to apply CER results to provide high-quality, affordable oncologic care.

CER AND THE COST OF CANCER CARE

The history of the new CER initiative in the United States, along with the evolving ways that evidence of comparative effectiveness is being applied to the coverage, payment, and pricing for oncology drugs, forms a complex, mixed, and at times inconsistent picture that captures the unsettled dilemma of how to restrain the growth in the cost of health care without harming individual patients and without stifling clinical innovation. As described, there are well-established barriers to using CER more aggressively in coverage determinations, but there is more latitude, and thus more innovation, in the application of CER to payment and pricing. How insurers should use CER in designing medical policies is of immediate importance to clinicians and patients. Still, another question remains to be asked: what are the responsibilities of individual oncologists, and of the professional societies that represent oncologists, with regard to comparative effectiveness evidence and the cost of care?

The American Society of Clinical Oncology (ASCO) guidance statement on the cost of cancer care, published in 2009, makes a notable contribution to this discussion.³³ This statement argues that physicians have a societal responsibility to provide care that is evidence based to minimize waste. Importantly, it also notes that the individual oncologist must integrate cost implications for individual patients into treatment considerations. Clinicians are advised to communicate with their patients about their personal out-of-pocket expenses and work with them to factor in these costs in treatment decisions.

The ASCO statement thus talks about societal responsibilities to minimize waste, but the actions recommended focus largely on addressing the cost issues relevant only to the individual patient. This approach is consistent with many other professional society statements affirming that the role of the individual clinician at the bedside should be one of undivided commitment to providing the best possible care for the patient. It also follows a common path in identifying eradication of waste as the goal of evidence-based approaches. In bringing these issues to the fore, this is a laudable first

step. What might be the next step? I would join with others, including noted oncologists, who believe there remains a tremendous opportunity, in addition to a responsibility, for ASCO and other physician societies to push forward and increase their engagement on the issues of cost and CER.³⁴ To advance this discussion, I suggest the following three recommendations:

Oncologists should advocate for CER studies to capture use and cost information. The initial ASCO statement also called for the profession to promote the conduct and dissemination of cost-effectiveness research. This recommendation is worth repeating here, because the political pressures on PCORI to not fund this kind of research have been intense, and the voice of the physician community will be important in future deliberations regarding the scope of CER funded by PCORI, the National Institutes of Health, and other sources.

Oncologists should always select the less expensive option among available treatment choices if there is insufficient evidence to demonstrate that a more expensive approach provides enough clinical benefit to justify the cost. This recommendation drives to the heart of how individual oncologists can take actions that address not just patient out-of-pocket costs but societal costs as well. First, if there is insufficient evidence to demonstrate that more expensive treatment options are any better at all than other options, oncologists should select the less expensive option. That is the relatively easy part. Harder is when the more expensive option does offer a marginal clinical benefit, but it may be too inconsequential or uncertain to justify a much higher cost. Who is to decide what is a marginal clinical benefit, or what is too high a cost to pay for a small benefit? It should not be the individual oncologist sorting this out on his or her own. This is the uncalibrated form of bedside rationing that should remain off limits. Here, however, is the opportunity for professional societies, working in conjunction with patient groups and the broader community, to take the significant next step in supporting the long-term interests of their patients. ASCO should develop a plan for providing transparent judgments of what represents too small a marginal benefit to justify the expense. No single metric such as the cost per QALY is likely to suffice, but the cost per QALY and other measures should be considered as useful measures in a broader deliberation. ASCO and its community partners should work together to develop this process of deliberation, decide what components of evidence on benefit and cost should be considered, and produce guidance on what can be considered low-value oncology care options. Ultimately, this definition of value will have to define what the general threshold will be for the amount of money that is reasonable to spend for a certain magnitude of benefit. This will not be easy, but it represents the best way for oncology to take a leadership role in serving its patients' best interests.

Oncologists should formally integrate consideration of value into the development of clinical practice guidelines, quality measures, and standards for specialty licensure. Once a general approach to determining value has been developed, consideration of value should be integrated into all areas of education, practice, and policy. Clinical guidelines should have transparent indications of how value considerations are being analyzed and incorporated into the recommendations. Similarly, ASCO should seek to develop and support educational standards and quality measures that can evaluate whether individual oncologists and larger groups practice in an evidence-based, high-value manner.

These recommendations may be viewed as going too far, too fast. They may be viewed as completely misguided. But ultimately, the answers to the dilemmas about the high cost of cancer care can only be addressed if someone decides when a clinical benefit is significant enough to warrant a certain higher price, and when it is not. That decision will include consideration of the merits of comparative-effectiveness evidence and how it should be applied to guide individual care. It will also include considerations of how much cost sharing for individual patients is reasonable, and how coverage and pricing policies will affect future drug development and clinical innovation. No one believes there will be an easy answer to the balancing act among these considerations that will continue to be required in the future. But we are already at a point at which the ability of individuals and governments to afford cancer care is stretched to the breaking point. Dialogue between providers, patients, insurers, and manufacturers must address this challenge head on. The need for leadership in this dialogue from professional societies like ASCO is profound. So is the opportunity to serve the best interests of patients with cancer—those now, and those of the future.

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