ONCOLOGY TIMES

Independent News on
HEMATOLOGY / ONCOLOGY

October 10, 2015 • Volume 37, Number 19 • oncology-times.com

Where ASCO's New Cancer Care Value Plan Falls Short

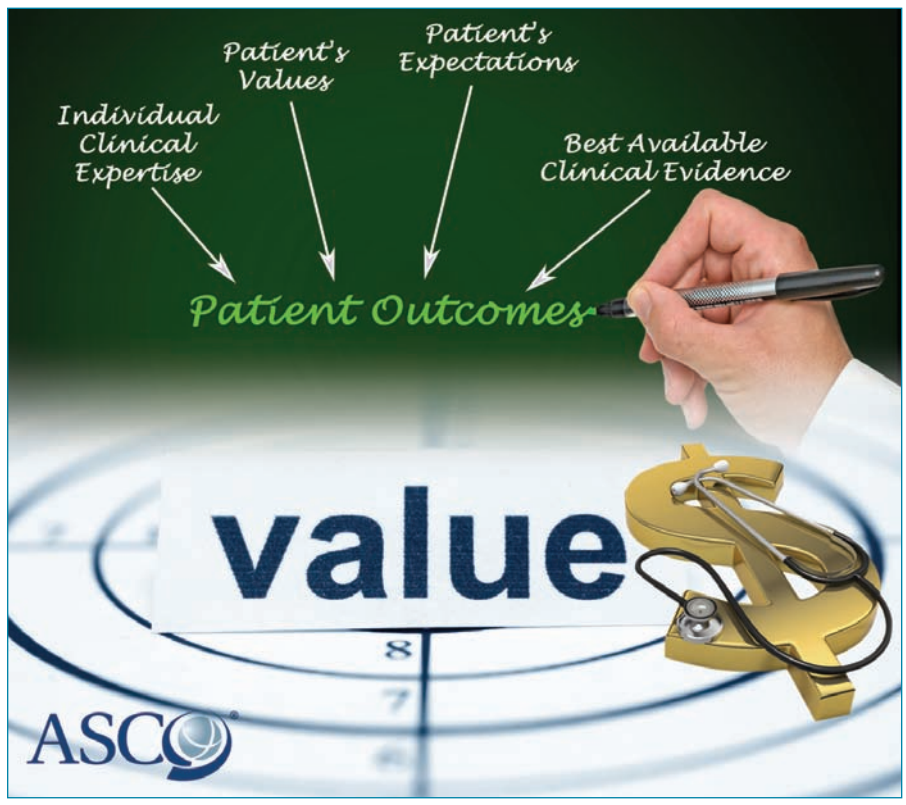
BY LOLA BUTCHER

The proposal for a "value framework" that could be used to evaluate cancer treatment options is a great idea, but putting a framework down on paper shows just how difficult it is to consider value in oncology.

That's the consensus of observers who shared their perspectives on the framework proposal put forth by the American Society of Clinical Oncology (*JCO 2015;33:2563-2577*).

"There's no question that every specialty should be looking at value—and oncology, in particular," said Thomas Feeley, MD, Head of the Institute for Cancer Care Innovation at the University of Texas MD Anderson Cancer Center. "This is very timely, and I think they have a tremendous approach to looking at value for medical oncology."

Continued on page 10



Conference Sounds Alarm about the Dangers of Overdiagnosis

BY PEGGY EASTMAN

BETHESDA, MD—Some 350 participants from throughout the world and from a broad range of professional backgrounds gathered here on the grounds of the National Institutes of Health for a conference focused on preventing overdiagnosis and overtreatment in medicine, exploring the concept that more isn't always better when it comes to high-quality care.

This third annual meeting, which had the theme "Winding Back the Harms of Too Much Medicine," was co-sponsored by the National Cancer Institute's Division of Cancer Prevention and the University of Oxford's Centre for Evidence-Based Medicine. Conference partners included the Dartmouth Institute; Bond University's Centre for Research in Evidence-Based Practice; *BMJ;* and *Consumer Reports*.

The conference was designed to examine the factors driving overtreatment for nonprogressive disease—overtreatment that could cause harm, said Barry Kramer, MD, MPH, Director of NCI's Division of Cancer Prevention.

Continued on page 30

Myeloma Exome Analysis Uncovers Clinical Insights

BY KURT SAMSON

A study using whole exome sequencing in approximately 500 myeloma patients has revealed a range of different mutation types in genes and molecular pathways—some negative and some neutral—that appear to influence patient survival (***Blood, doi.org/10.1182/blood-2015-05-644039***).

Using the findings, the researchers also used the data to develop a staging system to better identify patients at higher risk of relapse and premature death. The study was funded by the United Kingdom's Institute of Cancer Research at Royal Marsden Hospital's Division of Molecular Pathology, as well as the Fondation Française pour la Recherche contre le Myélome et les Gammapathies, in Paris.

Believed to be the first whole exome analysis exclusively among myeloma patients, the results are published online ahead of print in the *Journal of Clinical Oncology* (***doi: 10.1200/JCO.2014.59.1503***). The team also used the data to develop a staging system to better identify patients at higher risk of relapse and premature death.

Continued on page 18

FDA Actions

Pages 19 and 29

CRITIQUING ASCO'S CANCER CARE VALUE PLAN

Continued from page 1

That said, Feeley and others interviewed for this article all see challenges in measuring elements of value in cancer care to allow for a meaningful comparison of therapies for individual patients who must consider their own medical, personal, and financial situations.

The lead author of the ASCO Statement, Lowell Schnipper, MD, Chair of the Society's Value in Cancer Care Task Force and the Theodore W. and Evelyn G. Berenson Professor of Medicine at Harvard Medical School, Chief of Hematology/Oncology at Beth Israel Deaconess Medical Center, and Clinical Director of the Beth Israel Deaconess Cancer Center, called the document a first draft that will be revised to reflect feedback from members of the oncology care community.

"This is something that will clearly need to evolve," agreed Al Benson III, MD, Associate Director for Clinical Investigations at Robert H. Lurie Comprehensive Cancer Center at Northwestern University—who was not involved in drafting the ASCO statement—was also asked for his perspective. "But [the statement's] publication is further forcing the discussion as to how we deal with value for our patients."

Focus about to Get Sharper

Patients, payers, and health care providers have all become increasingly focused on the topic of value in recent years, but that focus is about to get sharper. The Centers for Medicare & Medicaid Services wants to have 50 percent of its payments coming through value-oriented payment models such as accountable care organizations and bundled payments by the end of 2018.

Cancer care is squarely in CMS's sights. In 2016, about 100 oncology practices are expected to contract with CMS to try the Oncology Care Model, a payment reform that the government thinks will improve the value of cancer care.

Many private payers are also experimenting with new ways to pay for cancer care. Like CMS, they want to pay for value, which means paying as little as possible for the best patient outcomes.

continued on page 12

Value Framework Primer

ASCO's proposal for a value framework to help oncologists and their patients compare the value of new cancer treatments with standard therapies is the most ambitious undertaking yet for the organization's Value in Cancer Task Force, noted ASCO President Julie Vose, MD, MBA, Chief of the Division of Hematology & Oncology at the University of Nebraska Medical Center.

"Value and cost are some of the biggest issues in health care today, and cancer care costs have been a particular focus of discussion and debate," she said at a presscast for reporters when the proposal was introduced. "There are very few tools, unfortunately, that doctors and patients can use to objectively assess the costs and benefits, and standardized information is really largely unavailable."

High Costs of Cancer Drugs

Cancer care costs are expected to increase from $125 billion in 2010 to $158 billion in 2020. ASCO's framework focuses exclusively on the costs of cancer drugs, the most rapidly growing component of those costs, said Richard L. Schilsky, MD, ASCO's Chief Medical Officer and member of the Task Force. New cancer drugs now cost on average about $10,000 a month, with some exceeding $30,000, he noted.

High costs are hurting patients financially—and hurting their care. For example, he noted, a study found that 20 percent of cancer patients took less medication than prescribed because they were concerned about costs (***Zafar et al: The Oncologist 2013;18:381-390***). And even though data show that a majority of patients would like to discuss costs with their oncologists (***Bullock et al: JOP 2012;8:e50-e58***), Schilsky said such conversations remain rare.

"The reality is that many patients don't get this information from their doctors, and many doctors don't have the information they need to talk with their patients about costs. The result is that many patients, even those with relatively good insurance coverage, are surprised by and unprepared for the high costs that they will bear out-of-pocket for some of these drugs."

Goals

The goal of the value framework is to facilitate those conversations between physicians and patients. Task force Chairman Lowell Schnipper, MD, noted that the framework is not meant to be a ranking or a calculator for individual drugs: "It's a way to provide information in a standardized and objective way to both physicians and patients about the value of new treatment options that emerge from clinical trials comparing a standard of care to a new treatment option."

Future Refinements

He said ASCO intends to refine the framework in future iterations that reflect feedback from stakeholders. In the meantime, the organization will also be working on a software program that physicians could use to apply the value framework to new therapies as they emerge from clinical trials.

"We envision sometime in the future to have a software that is curated with many comparative trials, such that it would be very easy for a patient to see, for a given clinical indication, what the treatment options are," Schnipper said. "And then the patient might literally [use the software program to] adjust their preference as they discuss whether length of life is most important to them or absence of toxicity is more important."

"This is a tool, and is by no means a substitute for the physician's judgment, or for patient preference," Schnipper said. "So this framework is hoped to facilitate conversations in which the options for patients' preference with respect to different possible therapies are explained. Thus, it's not about limiting options, but in fact, it's about broadening them."

ADVANCED LUNG CANCER

Continued from page 9

non-abandonment, such as 'whatever action we do take and however that develops, we will continue to take good care of you; we will be with you all the way.'"

Such a statement helps to allay fear, anxiety, and depression in patients who may believe that their oncologist is giving up on them. The guideline also notes that there is a stigma associated with lung cancer because of its link to smoking, and this stigma can increase depression and decrease quality of life.

The document also notes that some patients may misunderstand their diagnosis and prognosis and think that their advanced NSCLC is curable. In one cited study, one-third of patients with advanced NSCLC reported that their cancer was curable at baseline, and a majority reported getting rid of all their cancer as a goal of treatment.

> "There are insufficient data to recommend routine third-line cytotoxic therapy."

Therefore, states the guideline, "A dedicated session with the patient and preferably a caregiver should take place immediately after diagnosis to honestly and completely discuss the diagnosis, treatment (benefits and risks), prognosis, and palliative care concurrent with any anticancer therapy. Physicians should 'talk with patients about palliative care and end-of-life preferences early on, not in the weeks before death.'"

Also recommended is that a similar discussion take place before each new therapy is considered, especially third-line and beyond treatment.

VALUE

Continued from page 11

> "The proposal is a great idea, but putting a framework down on paper shows just how difficult it is to consider value in oncology."

But even as the new payment systems are marching forward, those who know cancer care best point out this challenge: Exactly what constitutes value in cancer care has yet to be sorted out.

"The simplistic concept of 'we need to improve health care by improving our outcomes and controlling our costs' resonates with everyone, but when you get into the details, it gets a little bit murky," Feeley said.

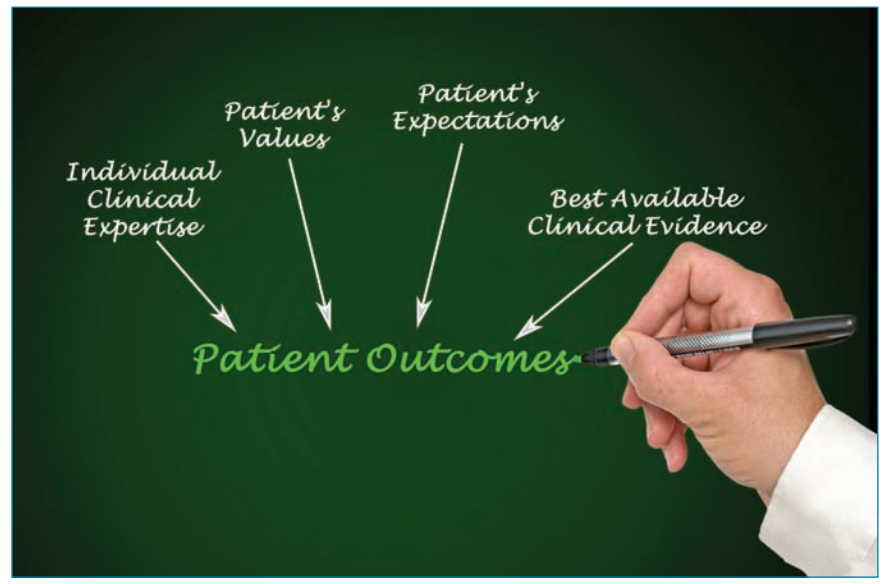
ASCO is one of several entities that is tackling the challenge. This fall, the National Comprehensive Cancer Network is expected to introduce a tool that will compare the value of therapy options. And earlier this year Memorial Sloan Kettering Cancer Center released the first iteration of DrugAbacus, an interactive tool that lets users compare the actual price of a cancer drug with its value.

Shared Decision-making vs. Payment Policy

In ASCO's position paper, Schnipper and his colleagues said the purpose of the value framework is to facilitate informed discussion about treatment options between patients and physicians. Some observers worry, however, that the framework will be used to call out some treatments for being "low value" when, in fact, they might be valuable for a specific patient.

"We feel there has been an overemphasis on cost, at the expense of understanding what the value of these new therapies can be to the individual patient who receives them," said Edward Abrahams, President of the Personalized Medicine Coalition. The coalition is an education and advocacy organization that has about 250 members—including pharmaceutical companies, payers, and hospitals—that focuses on regulations, reimbursement, and clinical adoption for personalized medicine.

Abrahams said he thinks the basic idea of a value framework is good, but he is concerned that it might be used to justify not prescribing or paying for



new high-cost treatments that have a low "net health benefit" in comparison with existing therapies: "Our concern is that it not lock us into a one-size-fits-all paradigm. It needs to build in enough flexibility so that it will not discourage treatments that work for particular patients, nor will it discourage investments in new approaches to treating cancer."

Specific Example

Marcus Neubauer, MD, Director of Oncology Services at McKesson Specialty Health, pointed to a specific example: To show how the value framework works, ASCO compared the value of pemetrexed plus cisplatin with the standard of care, which is cisplatin plus gemcitabine. The newer therapy is more expensive and scored zero net health benefit points because it did not add to overall survival.

"When you take all patients who were enrolled in that trial, there was no survival difference, but if you look at the patients with non-squamous cell lung cancer, there was a substantial benefit to the cisplatin-plus-pemetrexed group," Neubauer said. "I think many of us believe pemetrexed provides additional value when the treatment has been chosen appropriately based on histology."

Similarly, Benson, who serves on the editorial board of the Association for Value-Based Cancer Care, said he fears the framework may be used to set payment policy: "There is a concern that what is being designed to help the patient/clinician discussion will be used for purposes not intended."

The Task Force chose to use drug acquisition cost as the cost variable in the framework because that is the only information that is readily available and relatively uniform for all oncologists. The Statement notes that oncologists would need to research and present patient-specific out-of-pocket costs to have a meaningful discussion about the relative value of treatment options.

Benson said he believes that using the drug-acquisition cost may complicate physician/patient discussions because it highlights the societal cost of high drugs, rather than the actual cost for the patient at hand. The drug acquisition cost is meaningless to insured patients, while other factors—such as transportation to appointments, time away from work, and ability to enjoy life—that are not included in the framework are very important.

"When we're talking about a framework for individual patients, we need to focus on what is important for that

How the Framework Works

How does the framework compare treatments & therapies?

Three variables are evaluated: clinical benefit, toxicity, and cost. For a new drug, the framework determines a "net health benefit"—the summation of the clinical benefit and toxicity of the new treatment regimen as compared with the existing standard treatment. The clinical benefit of therapies for metastatic cancer is evaluated on overall survival, if that measure is available, or progression-free survival, if it is not.

How is 'net health benefit' calculated?

A point system is applied to score the individual elements of the net health benefit. Treatments for metastatic cancer are eligible for so-called bonus points if the regimen offers certain benefits, such as a treatment-free interval or palliation of symptoms. The maximum amount of points for a curative therapy is 100. The maximum for a treatment for advanced disease is 130, which includes 30 bonus points.

What data is used to score each variable?

Data comes from prospective randomized trials published in peer-reviewed journals.

What about information about cost?

Cost information is limited to the acquisition cost of the anti-cancer drug and the supportive care drugs needed to safely administer it. The oncology practice will be expected to research the patient's out-of-pocket responsibility and the oncologist will present that to the patient during the value discussion.

VALUE

Continued from page 12

individual patient," Benson said. "What is affordable for that patient based on their insurance plan? And then we must put that in context of the risk versus benefit of therapy, what the patient's overall life situation is, their prognosis, and all these critical factors to help inform the discussion, so the patient and their family can make the best decision possible."

Framework vs. Pathways

Approaching the topic from a different perspective, Neubauer said he thinks ASCO's value framework does not drive value as effectively as it could. Neubauer triggered the value movement in cancer care when he and colleagues at US Oncology published the first cost-effectiveness study of cancer care pathways (***OT 3/10/10 issue***).

Their finding—that use of a standard treatment pathway for patients with non-small-cell lung cancer can save money with no difference in survival—spawned the widespread deployment of standardized pathways.

Since then, McKesson, which purchased US Oncology, has continued to expand and refine the pathways program with the goal of advancing value-based care, Neubauer said. In his view, ASCO's value framework proposal appears to have "less of a commitment" to value than pathways. "If the cost is substantially more and the benefit is minimal or modest—compared with other treatment options—we would not even include a regimen on pathway because there is no additional value to the patient," he said.

So Many Unknowns

The value framework proposal highlights the lack of information available to make a thorough comparison between treatment options, Feeley says. For example, the task force lamented that it could not include patient-reported outcomes, timeliness of therapy, equity in access to cancer care, and patient-centeredness because that information is not captured in clinical trials.

To complicate matters further, the efficacy outcomes demonstrated in a clinical trial may not be on point for patients who are weighing their treatment options.

"We know a lot about oncology outcomes in clinical trials, but we don't know a lot about oncology outcomes when patients walk through the door with a given condition and a set of comorbidities," Feeley said.

Another unknown, for most oncologists, is a patient's out-of-pocket cost. The value framework does not include that information, which varies by patient, but oncologists are expected to research and present that information to patients as part of the decision-making discussion. "I emphasize that it's the doctor the patient wants to talk about cost with—preferentially compared with other members of the health care team," Schilsky said.

Insurance Information

Feeley noted that MD Anderson, like many health care organizations, has intentionally kept insurance information away from physicians. Rather, financial counselors discuss costs and payment with patients after treatment decisions have been made. "Our philosophy at MD Anderson has been that we don't want a patient's ability to pay to cloud people's judgment about what they think is best for an individual patient. So, we don't even have the ability in our medical record for a clinician to see what insurance the patient has, whether they have or do not have insurance, or what their out-of-pocket cost would be."

Benson said his reading of ASCO's proposal for a value framework underscores the need for new kinds of information, such as patient-reported outcomes, to be collected during clinical trials: "Those of us who design clinical trials—including the pharmaceutical industry—need to start thinking about this seriously," Benson said. "If we're really going to tackle value—what's important for an individual patient—there's much more information we have to provide to that individual."

Many private payers are also experimenting with new ways to pay for cancer care; like CMS, they want to pay as little as possible for the best patient outcomes.

ASCO's Value in Cancer Care Task Force

The 22-member Task Force included the following experts:

- Lowell Schnipper, MD, Chair, Beth Israel Deaconess Medical Center, Harvard Medical School;
- Joseph Bailes, MD, Texas Oncology, P.A.;
- Doug W. Blayney, MD, Stanford University Medical Center;
- Diane Blum, MSW;
- National Executive Service Corps, New York, NY;
- Nancy E. Davidson, MD, University of Pittsburgh Cancer Institute;
- Adam P. Dicker, MD, PhD, Sidney Kimmel Medical College, Jefferson Medical University;
- Patricia A. Ganz, MD, UCLA's Jonsson Comprehensive Cancer Center;
- J. Russell Hoverman, MD, PhD, Texas Oncology;
- Robert Langdon, MD, Nebraska Cancer Specialists;
- Allen Lichter, MD, ASCO CEO;
- Gary H. Lyman, MD, Fred Hutchinson Cancer Research Center;
- Neal J. Meropol, MD, University Hospitals Case Medical Center Seidman Cancer Center, Case Comprehensive Cancer Center;
- Therese Mulvey, MD, Southcoast Centers for Cancer Care, Fall River, Massachusetts;
- Lee Newcomer, MD, UnitedHealthcare;
- Jeffrey Peppercorn, MD, MPH, Massachusetts General Hospital;
- Blase Polite, MD, University of Chicago;
- Derek Raghavan, MD, PhD, Levine Cancer Institute, Charlotte, North Carolina;
- Gregory Rossi, PhD, AstraZeneca, Macclesfield, UK;
- Leonard Saltz, MD, Memorial Sloan Kettering Cancer Center;
- Deborah Schrag, MD, MPH, Dana-Farber Cancer Institute;
- Richard Schilsky, MD, ASCO Chief Medical Officer; and
- Thomas J. Smith, MD, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University.