

August 21, 2015

Allen S. Lichter, MD, Chief Executive Officer
Richard Schilsky, MD, Chief Medical Officer
Lowell Schnipper, MD, Chair, Value in Cancer Care Task Force
American Society of Clinical Oncology
2318 Mill Road, Suite 800
Alexandria, VA 22314

Re: Draft ASCO Conceptual Framework to Assess the Value of Cancer Treatment Options

Dear Dr. Lichter, Dr. Schilsky, and Dr. Schnipper:

The undersigned organizations, which represent cancer survivors, appreciate the opportunity to comment on the conceptual framework to assess the value of cancer treatment options that was described in an American Society of Clinical Oncology Statement published online on June 22, 2015, in the *Journal of Clinical Oncology*. Some of the undersigned organizations saw a previous version of the value framework during brief meetings in August 2014 and provided input on the work at that time.

In recent years, our organizations have focused on the importance of a cancer treatment planning process for all newly diagnosed cancer patients. We believe that such a treatment planning process can foster shared decision-making and also can encourage the coordination of the multi-disciplinary elements of cancer care. As more cancer patients receive treatment that is targeted and as molecular diagnosis increasingly becomes part of the cancer care experience, the quality of the treatment planning process becomes even more important. We see treatment planning as a critical means of improving overall cancer care quality.

We have also seen the treatment planning process as a means for assisting patients in arriving at their own value proposition, because treatment planning will assist patients in assessing the benefits of treatment options in terms of survival advantage, the quality of life that patients will experience according to different treatment options, and the cost that patients will personally bear under different treatment scenarios. In addition, a meaningful treatment planning process asks a patient to consider the goals of treatment, an inquiry that can also be very helpful to patients and families as they confront not only initial treatment decisions but also end-of-life care issues. Some have also recommended that a patient's overall cost of care – including all elements of cancer treatment – be considered in the treatment planning process because it conveys the societal burden associated with treatment options, but there is healthy ongoing discussion about this final element of care planning.

In recent years, our organizations have pursued a number of different efforts aimed at encouraging treatment planning for all cancer patients. Our efforts have included: 1) participating in Institute of Medicine (IOM) meetings to define a comprehensive treatment planning process, 2) advancing payment

reforms that will ensure adequate reimbursement to oncologists for the time and expertise required to undertake treatment planning efforts for their patients; 3) encouraging quality measures that will assess oncologists' treatment planning efforts, and 4) fostering patient demand for treatment planning and preparation to participate in shared decision-making.

Our work has sought implementation of treatment planning consistent with the definition advanced by IOM. The following are the components that might be included in a patient-specific cancer care plan, according to the IOM:

- Patient information
- Diagnosis, including specific tissue information, relevant biomarkers, and stage
- Prognosis
- Treatment goals (curative, life-prolonging, symptom control, palliative care)
- Initial plan for treatment and proposed duration, including specific chemotherapy drug names, doses and schedule as well as surgery and radiation therapy (if applicable)
- Expected response to treatment
- Treatment benefits and harms, including common and rare toxicities and how to manage these toxicities, as well as short-term and late effects of treatment
- Information on quality of life and a patient's likely experience with treatment
- Who will take responsibility for specific aspects of a patient's care
- Advance care plans, including advance directives and other legal documents
- Estimated total and out-of-pocket costs of cancer treatment
- A plan for addressing a patient's psychosocial needs
- Survivorship plan, including a summary of treatment and recommendations for follow-up monitoring and care¹

We have evaluated the value framework in the context of treatment planning and how it might improve patient access to a treatment plan and a shared decision-making process. Our analysis has been undertaken in a manner consistent with the articulated aims of the framework. In describing the core principles that guided the work of the ASCO Value in Cancer Care Task Force, the authors stated, "The framework is designed to eventually assist in facilitating shared decision making with patients about clinical benefits and costs."

We have considered whether the value framework, as currently described, is useful to patients and their oncologists. We have a number of questions about the value framework and reservations about whether it will improve the shared decision-making and treatment planning process.

- How can a calculation of net health benefit that assesses a new treatment regimen compared to the prevailing standard of care for a specific indication improve the communication between oncologists and their patients? We note that the net health benefit calculation will yield a score for a new treatment, compared to the current standard of care. Even if we accept the methodology for calculating net health benefit, the score would seem to support only a comparison of two treatments. A patient might be considering a wider range of treatment options than two options, and it is unclear how the net health benefit score for a single new

¹ Institute of Medicine, Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis, 201x.

treatment will be useful in treatment decision-making. It is also unclear how a number, attached to a single treatment option, will be used in doctor-patient communication. The comparison of two treatments to arrive at a net health benefit number falls short of a comparative clinical effectiveness analysis that might provide patients with valuable information about a range of treatment options.

- What assistance and training will ASCO provide oncologists to improve their communication of patient cost-sharing and overall cost of care? The IOM definition of cancer care planning includes communication of patient cost-sharing and overall cost of care as elements of a plan. We are aware that it is sometimes difficult for oncologists to calculate an individual's cost-sharing responsibilities, even if they dedicate staff to assist with this undertaking. We encourage ASCO to provide more assistance and guidance to oncologists about this communication effort so that every patient is assured accurate information about his or her cost-sharing responsibilities. We also note that ASCO recommends communication of drug acquisition cost to the patient. Drug acquisition cost may not be an accurate way of communicating overall cost of care to the patient, especially if the patient's care includes surgery, radiation therapy, and other elements beyond the drug in question. The communication of drug acquisition cost, if it is not put in the context of overall cost of care and also in the context of patient-cost sharing, will not assist patients in determining the value of their treatment options or aid in their treatment decision-making.
- How are oncologists to be trained to use the net health benefit score? ASCO makes clear that the value framework is not ready to be used in clinical practice. So that we might understand how the value framework may ultimately be used by oncologists and therefore might be of benefit to patients, we encourage greater explanation of how ASCO anticipates such use by oncologists. We are concerned that communication of a number that represents net health benefit will not improve doctor-patient communication and might in fact harm the treatment planning process.
- Does a toxicity calculation that considers only high-grade, acute toxicities provide patients the information they need about the impact of treatment on their quality of life? Patients are interested not only in acute toxicities but also chronic, low-grade toxicities and the potential late and long-term effects of treatment options. We note that the Task Force report suggests that future versions of the framework will incorporate information and a wider range of toxicities. We encourage a broader consideration of the side effects of treatments so that patients can more completely consider the impact of various therapies on their quality of life.

The article explains that the Value in Cancer Care Task Force has been renamed from its original name, the Task Force on the Cost of Cancer Care. The recommendations of the Task Force reflect a strong emphasis on cost of care, despite the change of name of the group. The task force members write that the physician has "a responsibility to be a good steward of health care resources." Moreover, the statement of the task force says that "It is the position of ASCO that oncologists should make informed decisions regarding the value of care, understanding both the most accurate and up-to-date information on the benefits and costs to patients and society."

The task force seems to assume that patients should also be good stewards of health care resources and that the communication of drug cost is part of the process of making cancer patients good stewards of health care resources. We believe this is a critical matter for discussion, and it is not a topic that we

have discussed in any meaningful way with ASCO. The responsibility of the patient to be a good steward of resources, the timing of this responsibility, and the importance of drug acquisition cost to triggering good stewardship are matters that we would like to discuss with ASCO and its task force members. Some of us are uncertain that a patient, at the time of treatment decision-making, is also prepared to act as a good steward of cancer care resources. But this is certainly a topic that we look forward to discussing.

We would also like to distinguish, now and for the purposes of additional deliberation with ASCO, the role of patients compared to the role of patient advocacy groups that represent survivors. We consider the stewardship of health care resources an important topic for consideration and potential action by our organizations, and we stand ready to engage with ASCO on that topic. When we engage in this public policy discussion, we request that the topics for consideration be expanded beyond a consideration of cancer drugs and their net health benefit scores and drug acquisition costs to a review of cancer care payment systems that may influence treatment choices and delivery of care, payment methodologies that may influence the site in which care is provided and the cost to the patient of such care, and other delivery and payment artifacts that work against patient-centered care.

We appreciate the hard work of the Value in Cancer Care Task Force and look forward to discussions with you in the future.

Sincerely,

CancerCare
Cancer Support Community
Kidney Cancer Association
Leukemia & Lymphoma Society
LIVESTRONG Foundation
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
Ovarian Cancer National Alliance
Sarcoma Foundation of America