American Cancer Society
Cancer Action Network
555 11th Street, NW
Suite 300
Washington, DC 20004
202.661.5700
www.acscan.org

August 21, 2015

Lowell Schnipper, MD
Chair, Value of Cancer Care Task Force
American Society of Clinical Oncology
2318 Mill Road, Suite 800
Alexandria VA, 22314

Re: ASCO Value Framework Comments

Dear Dr. Schnipper:

The American Cancer Society Cancer Action Network (ACS CAN) is pleased to offer comments on ASCO's *Conceptual Framework to Assess the Value of Cancer Treatment Options* (Framework). ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

We believe that it is imperative that patients be at the center of decision making about their treatment. In order to accomplish this, patients must be equipped with clear, accurate and up-to-date information about their disease and all of their treatment options. When faced with a cancer diagnosis, individuals often find themselves thrust into an unfamiliar environment where they are expected to make decisions that will ultimately shape their quality of life and the course of their treatment. Thus, the availability of consumer-friendly information is imperative to help patients determine the treatment options that best meet their needs. Unfortunately in today's environment much of the treatment information a patient receives is written in medical jargon, might not encompass the most current treatments available, and does not aid in informed decision-making.

ASCO has attempted to address the need for comparative information through the creation of the Framework and is to be commended for its efforts. We also appreciate ASCO initially consulting with stakeholder groups during the creation of the Framework. We believe that there is a strong need for tools that can empower patients to make informed choices about their care; however, we do have some concerns — in particular that the tool as designed does not provide patients with the information they need to make informed treatment decisions — and suggestions related to specific aspects of the Framework as it is now designed.

The Framework's Dual Intent

The Framework is intended to be a multi-use tool that drives public policy discussions about drug pricing while simultaneously helping with shared decision-making between patients and their oncologists. To accomplish this the Framework extracts outcomes data from published head-to-head clinical trials of therapeutic options and then converts those outcomes into numerical "Net Health Benefit" (NHB) scores that nominally represent a drug's benefit relative to a comparator drug. The NHB is calculated from a drug's toxicity profile combined with a drug's clinical benefit, which is derived from overall survival, progression-free survival, or response rate data. The Framework has two variants, one for curable disease, and one for advanced disease, with differing maximum scores for each variant. Then the Framework seeks to provide patients with an associated cost for each drug choice. This cost would be given both in terms of the overall acquisition cost and the portion of the cost for which the patient is responsible.

We believe that the Framework's multiple objectives are fundamentally different and cannot be accomplished utilizing the same tool. A tool optimized for one purpose does not optimally serve the other purpose. We therefore recommend that ASCO consider splitting the functions of the Framework into two separate tools so that the shared decision-making aspect can be optimized without introducing into the doctor-patient interaction considerations of public policy issues such as the macro issue of overall prescription drug costs over which the patient has no control. Our comments below focus primarily on suggestions to optimize the Framework for use as a shared decision-making tool.

Focus on Prescription Drug Costs

By focusing solely on the issue of prescription drugs, the tool fails to provide a complete picture of an individual patient's treatment options and may skew the patient toward prescription drug therapy when another therapy or a combination of therapies may be in the individual's best interest. The Framework does not include additional details about the options that patients would find important to inform their treatment decisions, such as whether and how often a patient might have to travel to a facility for the given treatment choices (e.g., is the treatment administered orally or intravenously daily) or whether other non-drug options like surgery, radiation, or watchful waiting exist for their condition.

Appropriate Level of Information Processing

The American Cancer Society serves cancer patients through the National Cancer Information Center, available 24/7 and 365 days of the year so that patients, caregivers and survivors-can receive information, referrals and resources related to a cancer diagnosis. From these calls we know that many individuals who are newly diagnosed report feeling overwhelmed and are often unaware of information and resources to help them understand their cancer diagnosis and treatment options.

A typical cancer patient lacks the appropriate training and time to review and synthesize all of the scientific literature tied to their disease and/or treatment options, which means that there is great value in a consumer-friendly summarization of the current state of evidence around disease and treatment choices. That is why the American Cancer Society makes available on its website consumer-friendly information regarding various treatment options.

Tabulating key statistics like overall survival, progression-free survival, response rates, and rates of adverse events from the literature is a relatively objective form of data simplification. The Framework uses these statistics as the input to a mathematical algorithm that reduces these multiple inputs into a single NHB score.

While extracting key statistics from literature does not objectively change those statistics, once the statistics are mathematically combined into one NHB score, subjective notions of value are introduced by virtue of how the statistics are combined. Clinical outcomes amount to 80 percent of the total basic NHB score and toxicities account for 20 percent of the score. This assumes that patients place four times more emphasis on the clinical outcomes than toxicity. We believe that a tool intended to empower patients should allow them to express their individual preferences related to their own treatment choices. While ASCO has indicated that some future version may allow patients to assign variable weights to the major inputs, there are other individual nuances that are not captured. A given patient may, for instance, have a different willingness to experience neuropathy versus nausea. As currently drafted, the Framework assumes that certain patient preferences can be universally attributed to all patients. In fact, this is not the case. A mathematical formula shared by all patients is not conducive to individualization.

Encapsulating these nuanced differences associated with treatment options into a single score actually obscures important differences rather than illuminating them. When thinking of analogous comparisons in the consumer world, cars are typically ranked on multiple different features – for example, gas mileage, safety, capacity, comfort, speed, and cost. A *Consumer Reports* review of cars would list a given car's score for each individual category, rather than combined into a single score, allowing consumers to independently evaluate the multiple dimensions on which each car was evaluated.

While the single score may have value in a public policy tool, that level of subjective simplification is not appropriate for helping patients make informed decisions based on their own unique values. We suggest performing only objective simplification akin to the tabulations of data found in the Framework Appendix.

Beta Testing, Health Literacy and Numeracy

Any tool developed from the Framework should be subject to extensive consumer testing by actual patients in order to gather information about the tool's usefulness and utility. Additional testing also should be conducted to determine the extent to which an oncologist is able to use this tool appropriately with patients. It is imperative that both the written form and the oncologist-patient discussion be consumer tested.

While it may not represent the final form of the intended clinical tool, the current NHB worksheet is not consumer-friendly, either in its appearance or its content. The appearance of the document is reminiscent of a tax form and fails to meet appropriate health literacy standards. Research has demonstrated that an individual's health literacy has a direct impact on his/her care.[1]

Areas within the Framework where there may be confusion include the choice of vocabulary and the interpretation of numerical scores. For example, under common use of a 100-point scale, a score under 50 would be viewed negatively, or as "failing," yet under the Framework any positive score would indicate an improvement over a previous therapy, a nuance that may not be intuitive. For the Framework to be successful, it must be intuitive to a first-time user with minimal explanation of the methodology.

In addition, individuals process information differently. According to some research, 71 percent of adults over aged 60 have difficulty using print materials; 80 percent have a difficulty using documents or charts; and, 68 percent have difficulty in interpreting numbers and performing calculations.[2] Given the fact that the risk of developing cancer increases with age, it is important that any product used with older patients takes into account how they use and process information. The National Institutes for Aging has developed specific guidelines for communicating information in print form to older Americans[3] and we strongly urge ASCO to include these standards in any consumer-facing materials. We understand that ASCO plans to develop a phone and computer application for the Framework. We strongly urge you to test this application with consumers.

---

[1] Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Viera A, Crotty K, Holland A, Brasure M, Lohr KN, Harden E, Tant E, Wallace I, Viswanathan M. Health Literacy Interventions and Outcomes: An Updated Systematic Review. Evidence Report/Technology Assessment No. 199. (Prepared by RTI International–University of North Carolina Evidence-based Practice Center under contract No. 290-2007-10056-I.) AHRQ Publication Number 11-E006. Rockville, MD. Agency for Healthcare Research and Quality. March 2011.

[2] Kutner, M., Greenberg, E., Jin, Y., and Paulsen, C. (2006). The Health Literacy of America's Adults: Results From the 2003 National Assessment of Adult Literacy (NCES 2006–483). U.S. Department of Education. Washington, DC: National Center for Education Statistics.

[3] National Institute on Aging, Making Your Printed Health Materials Senior Friendly, last updated Jan. 22, 2015, available at https://www.nia.nih.gov/health/publication/making-your-printed-health-materials-senior-friendly.

Finally, it is unclear how the Framework will be used with different subpopulations. Pediatric cancer patients have different needs and challenges than older cancer patients may have. It is unclear the extent to which this tool will be redesigned to assist patients with literacy challenges and/or individuals for whom English is not their primary language; the Framework is silent on the extent to which any written materials will be made available in different languages. We note that there has been much work developed by stakeholders to address this issue and we strongly encourage ASCO to include this work in their further Framework development.

Global versus Relative Comparisons

One aspect of the Framework that will both limit its application and could make its interpretation less intuitive is in the relative nature of the proposed NHB scores. Any drug's score is relative only to one other treatment. So, in cases where there are more than two options, the scores of the multiple drug options may not be comparable to each other if they were not all compared against the same standard of care. Consumers increasingly have become more familiar with the use of "star" ratings on websites; those ratings are global in nature and can be compared across different products. This is not the case with the current draft of the Framework and is likely to cause confusion.

In addition, the drug's maximum NHB scores are dependent upon the choice of measured outcomes reported in a clinical trial (e.g., overall survival, progression-free survival, or response rates). Testing the same two drugs against each other in two trials with different measured outcomes (response rate vs progression-free survival) would result in different scores. The intent of the lowered scores for trials based on response rate compared to overall survival is to convey confidence in the difference in outcomes between two drugs. However, there may be value in numerically expressing the confidence as a separate number in addition to the NHB score rather than lowering the NHB score itself.

As we understand the Framework, a score based on a single number implies there is an optimal treatment with which the patient should proceed, even if the treatment does little to modify the overall trajectory of the disease. This reinforces our concern about communicating an NHB score rather than actual outcomes data, as creating the idea of a "winning" drug in a head-to-head comparison may interfere with important doctor-patient conversations about treatment goals and whether additional treatment is desired or likely to be effective in meeting that patient's goals.

Cost

The individual financial burden of cancer care can be significant. In fact, persons diagnosed with cancer are two and a half times more likely to suffer bankruptcy than individuals without cancer.[4]

The costs faced by cancer patients are not limited to coinsurance or copayments for chemotherapy drugs. There are costs for surgery, supportive treatments, primary care, provider consultations, housing for individuals who must travel long distances for treatment, transportation to and from treatments, child care, and missed work. To be truly useful, any patient decision aid should account for the full range of patient costs associated with a given treatment regimen and not just for one drug.

The proposed Framework contemplates providing the portion of a drug's cost for which the patient is responsible as well as the drug's acquisition cost. Clearly the patient's cost for a drug is important information to share with the patient, but unless a patient's financial obligation is determined as a portion of a drug's cost (coinsurance), the acquisition cost is extraneous information and should not be included as part of the Framework. The overall cost of a drug is only applicable when the Framework is applied as a public policy tool, but as noted above, we believe that the patient decision aid and the public policy functions of the proposed Framework should be split into separate tools.

It should also be noted that the importance of cost in making a treatment decision will vary greatly between patients. For some, cost will play no role in their decision, while for others cost differences between treatment choices may factor significantly into a treatment decision. Some patients may find the introduction of cost into a discussion about treatment options between a provider and a patient to be offensive and fear that the discussion of cost will unduly influence their recommended course of treatment. Other patients may appreciate the additional information. Given the spectrum of interest and sensitivities to issues of cost, careful consideration must be given to how and when the issue cost is introduced to a patient and who (nurse, oncologist, billing staff, etc.) is most appropriate to present issues of cost. We highly recommend ACSO conduct additional focus group testing to probe this issue.

Context and Usage of Framework

While the Framework purports only to be providing a tool to facilitate doctor-patient communications about the primary therapy choice, the usage of the tool is equally important. The intent of the Framework is to facilitate better conversations between oncologists and patients. Doctors or other support staff must be able and willing to take time to explain the meaning of all the options, and help determine a patient's goals for his treatment. Factors associated with scheduling, staffing, training and reimbursement will influence the success or

---

[4] Ramsey S, Blough D, Kirchhoff A, et al., Washington State Cancer Patients Found To Be At Greater Risk For Bankruptcy Than People Without A Cancer Diagnosis, Health Affairs, June 2013 vol. 32 no. 61, 143-1152.

failure of Framework, and should not be ignored. As discussed above, we urge ASCO to fully test the use of the Framework with oncologists – in order to ascertain how doctors are using the tool in their discussions with patients. This will enable ASCO to make refinements to the tool as needed.

To the extent the Framework provides a greater opportunity to have an open dialogue between a patient (and her family) and the oncologist, the Framework could be beneficial. However, we note that current Medicare and other reimbursement structures often fail to provide appropriate reimbursement to encourage the necessary open dialogue. Given this lack of reimbursement, we question the extent to which providers will engage lengthy dialogue necessary to allow patients the ability to truly understand all the ramifications of a given treatment.

The American Cancer Society supported the development of Oncotalk,[5] a tool designed to train physicians to better engage in shared-decision making with their patients regarding their treatment options. We encourage ASCO to incorporate the use of this tool as it develops and refines guidelines for oncologists' use of the Framework tool.

Further, ASCO has recognized the importance of early palliative care alongside treatment directed against a patient's cancer, so any new tool to help select treatment should acknowledge and promote the full range of treatments and services available to a patient diagnosed with cancer.

Conclusion

The goal of the Framework should be the creation of an intuitive, transparent, informative, and individualized decision aid for cancer patients. Attempting to use the Framework for both a decision aid and public policy tool results in a more complicated tool that interferes with the utility of the tool for patients and physicians. Further, the proposed Framework involves a process that invokes subjective data simplification that stands to make individual preferences more difficult for a patient to express. Creating single scores for individual drug options could actually obscure important information, and we encourage providing only objectively simplified information to patients. Further, the mathematical formula and overall construct is not intuitive. We agree with the need to provide patients with more information about their treatment choices, but believe that the proposed Framework focuses too narrowly on drug treatment choices and not the full spectrum of decisions (therapeutic and palliative) that a patient faces.

---

[5] More information on Oncotalk is available at http://depts.washington.edu/oncotalk/.

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the draft framework. We look forward to working with you as you further develop and improve this tool. If you have any questions, please feel free to contact me or have your staff contact Kirsten Sloan, Senior Director, Policy Analysis and Legislative Support, at Kirsten.Sloan@cancer.org or 202-585-3240.

Sincerely,

Christopher W. Hansen
President
American Cancer Society Cancer Action Network