May 26, 2017

Lou Garrison, PhD & Peter J. Neumann, ScD
Co-Chairs
Initiative on US Value Assessment Frameworks Special Task Force
International Society for Pharmacoeconomics and Outcomes Research
505 Lawrence Square Blvd. South
Lawrenceville, NJ 08648

Dear Dr. Garrison and Dr. Neumann,

On behalf of the Cancer Support Community (CSC), we are pleased to submit the attached comments regarding the International Society for Pharmacoeconomics and Outcomes Research’s (ISPOR) Initiative on U.S. Value Assessment Frameworks. We recognize the need for this document and we appreciate the work that was done by the Special Task Force on this initiative as well as the opportunity to provide comments.

CSC is the largest professionally led nonprofit network of cancer support worldwide. We provide support, education, and hope to cancer patients, survivors, and their loved ones, and we touch more than one million people affected by cancer each year with social and emotional support, wellness and education programs, and awareness activities. Our mission is to ensure that all people impacted by cancer are empowered by knowledge, strengthened by action, and sustained by community.

Patient Input
It appears, from the list of Special Task Force participants, that there was not a patient advocate included on the panel to develop this document. Although many of the participants may in fact be patients, it can be assumed that they approached their role in this initiative from their professional standpoint. They also cannot represent the varied patient voices in the United States, particularly those that have historically been underserved. Although patient advocacy groups may have been involved in the process, this engagement needs to happen as early as possible before the document is largely drafted.

Despite this lack of proactive engagement, the initiative document refers to the “Value to the Patient” as evidenced in section 2.4. While we appreciate the following statement: “...a patient-centric approach means that the patient’s value considerations should serve as the essential starting point for shared decision-making level” we are also cognizant that input from the patient advocacy community was limited in drafting this document. That statement should also end at “starting point” as the patient’s value considerations should inform all value discussions and not simply within the shared decision making context. We ask that going forward
substantive input is provided from patients proactively versus through a reactive comment period.

The inclusion of patients in value assessments is supported by numerous entities including: 1) The National Health Council (2016) which highlights the domains of a “meaningful patient-centered value model” including patient partnership, transparency to patients, inclusiveness of patients, diversity of patients/populations, outcomes patients care about, and patient-centered data sources; 2) PhRMA which states that value assessment frameworks should ensure a strong role for physicians and patients who bring essential expertise and perspective and should play a central role; and 3) The National Pharmaceutical Council which states that interested stakeholders should be involved in the assessment process to represent all perspectives. In their Health Affairs article, DuBose and Westrich (2017) agree that as patients are the recipients of health care services, frameworks should incorporate components of value that are important to them. Not including that perspective can “lead to assessments that over- or under-estimate a therapy’s value” (DuBose and Westrich, 2017).

**Definition of Value**

While we recognize the mission of ISPOR as a health economics organization, it is critical to clearly delineate the differences between the concept of “value” as it pertains to medical treatments and devices, and assessment based primarily on the financial implications of those treatments and devices. Value cannot be divorced from the patient perspective and in fact, the patient perspective should be first and foremost in any value discussion. Any value framework cannot be a one-size-fits-all approach and the concept of value must be broader than budget impact and cost containment. Patients make different determinations regarding what they value most throughout their illness and service journeys. This is evident in incremental gains for patients who are coping with particularly deadly diseases.

In 2016, the National Health Council released the Patient-Centered Value Model Rubric and CSC was pleased to serve on the working group to develop that document. The National Health Council (2016) states that “value is individualized, disease-dependent and evolving”, and highlight the importance of “outcomes patients care about” which are those that patients have “identified as important and consistent with their goals, aspirations, and experiences.” The National Pharmaceutical Council (n.d.) states that the “measurement of value should include a broad array of benefits that are important to patients and society.” Further, we agree with the National Pharmaceutical Council (n.d.) which suggests that weights should be included in any value framework in order to accommodate varying user preferences. This methodology is also utilized in the DrugAbacus tool developed at Memorial Sloan Kettering. However, Neumann and Cohen (2017) state that even though there are value frameworks that are designed to incorporate user preferences, the final assessment may be inconsistent with those preferences. It is critical that user preferences are not only recorded and weighted, but also reflected in the final assessment.

**Quality Adjusted Life Year**

Throughout this document ISPOR makes it clear that although the quality adjusted life year (QALY) is not an ideal measure, nonetheless “it remains the method and metric of choice (Section 7, line 91).” It is unclear, short of a lack of viable alternatives, why the QALY continues to be the gold standard when the shortcomings of this measure, particularly from a patient
standpoint, are clear. It is encouraging that ISPOR incorporated concepts such as the “value of hope” (Section 2, line 319), “real option value” (Section 2, line 350), “equity” (Section 2, line 374), and “scientific spillovers” (Section 2, line 424). However, the QALY does not capture any of these metrics or others that represent the lived experiences of patients. ISPOR notes that “individuals vary in their preferences for health and other economic goods” and therefore “the value they place on different health care interventions will also vary.” We agree with this statement, but disagree that the QALY is a metric that is congruent with varying patient preferences.

Despite the evidence throughout ISPOR’s report that QALY is a flawed metric, “Recommendation 3.1: Apply conventional cost-effectiveness analysis in public and private coverage and reimbursement decision making” states that ISPOR “strongly endorses the use of cost-per-QALY metric to support health care decision making particularly in relation to the payer coverage and reimbursement decisions of both public and private insurers in the U.S.” Although Recommendation 3.2 suggests embracing future QALY refinements, it is challenging to understand how that can be congruent with the strong endorsement of the flawed metric.

Simply put, the QALY does not serve as an endpoint that is meaningful to patients. The QALY should not be used as a sole or primary measure of value. Multiple studies, including CSC’s Registry data, show that for patients with cancer and other chronic, debilitating illnesses, there is a delicate balance between quality and quantity of life. Patients have reported a desire for a shorter overall survival in exchange for higher quality of life. The QALY framework assigns the exact same score to an individual who lives six months in perfect health to an individual who lives a full year in a debilitated state. Patients may assign a very different level of value to each of these scenarios, which is why we support different weights applied to different outcomes and factors as noted above. Attention to individual preferences and needs is key. Other value models (American Society of Clinical Oncology, the National Comprehensive Cancer Network, and DrugAbacus) have taken similar approaches to assigning higher levels of value to endpoints such as overall survival without a full appreciation and representation to the value that patients assign to shorter, incremental gains. CSC encourages ISPOR to utilize a value assessment approach that more closely represents the endpoints that are meaningful to patients. CSC would be pleased to work with ISPOR to develop these endpoints.

**Individual vs. Population Perspectives**

In any discussion of value as it relates to healthcare products or services, it is critical for organizations to understand that although the intent may not be to create shared decision making tools to be used by individuals and their clinicians, this intention belies the real-world implications of value determinations. Our concern is that assessments from organizations will be used at all levels within the care system from the micro/individual to the macro/policy and payer levels. As DuBois and Westrich (2017) note, many of the value frameworks are operating “de facto, to influence health care decision making.” It is important for ISPOR to understand the
impacts of value assessments and carefully consider the repercussions, even if unintended, on
the lives of patients and their families in need of treatment and services. This is particularly
salient in an era of precision and patient-centered medicine. DuBois and Westrich (2017) also
state that “it is essential…that stakeholders also demand the necessary improvement to these
frameworks, and that their developers respond promptly and accordingly.”

In conclusion, we appreciate ISPOR’s attention to value initiatives and the opportunity to
submit these comments. This document serves as a methodological roadmap, and while it
should not guide policy decisions, it can be a starting point for important healthcare value
decisions. We are acutely aware of the rising costs of treating cancer and other diseases, and we
support efforts that contain costs while ensuring the provision of truly comprehensive care. As
such we reiterate our strong belief that patients and their loved ones should be at the center of
all value initiatives. We stand ready to suggest patient participants for any value assessments or
activities. We look forward to seeing the final version of this document and continuing to
collaborate with ISPOR in the future. If we can serve as a resource to your work, please do not
hesitate to contact me at efranklin@cancersupportcommunity.org or 202.650.3962.

Sincerely,

Elizabeth Franklin, LGSW, ACSW
Senior Director, Policy and Advocacy
Cancer Support Community Headquarters

References

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