September 16, 2016

Steven D. Pearson, MD, MSc, FRCP
President, Institute for Clinical and Economic Review
One State Street, Suite 1050
Boston, MA 02109 USA


Dear Dr. Pearson,

On behalf of the Cancer Support Community, an international nonprofit organization that provides support, education and hope to over 1 million people affected by cancer each year, we appreciate the opportunity to respond to the request for comments regarding ICER’s non-small cell lung cancer report. Given the NSCLC report was developed under the current framework, CSC believes it to be flawed in a number of areas and that it should be re-worked to minimally meet the criteria outlined below. As appropriate, we will flag concerns which are heightened given the nature of the patient experience with lung cancer.

As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology professionals in the United States, CSC has a unique understanding of the cancer patient experience. Each year, CSC serves more than one million people affected by cancer through its network of 44 licensed affiliates - more than 120 satellite locations, and a vibrant online community - and delivers more than $40 million in free, personalized services each year.

Additionally, CSC is home to the Research and Training Institute - the only entity of its kind focused solely on the cancer patient experience. The Research and Training Institute has contributed to the evidence base regarding the cancer patient experience through its Cancer Experience Registry®, various publications and peer-reviewed studies on distress screening, and the psychosocial impact of cancer and cancer survivorship, to name a few. This combination of direct services and research uniquely positions CSC to provide organizations like ICER with feedback based on evidence as well as real world impact.

CSC acknowledges ICER’s intent to seek multi-stakeholder input as a part of the process involved in assessing the value and effectiveness of different oncology treatment regimes. Both the conversation on value and multi-stakeholder engagement is at the core of CSC’s work on access, and we are eager to work with you to move appropriate solutions forward.
CSC stands by our offer to create a panel of patients and caregivers living with NSCLC cancer to test the concepts and frameworks suggested by ICER.

Dr. Pearson, we remain concerned about several principles of the framework and your engagement requirements.

**Unrealistic formatting specifications and response time**

On a very basic level, the instructions you give for submitting feedback are limiting in both feedback opportunity and transparency. While encouraging public comment, you specifically limit the length of some submissions to 3 pages and require a font size of 12. Additionally, you require submission in a Word document and indicate that comments may be made public.

The two week public comment period does not allow adequate time to review ICER’s recommendations and solicit feedback from patients and experts. CSC thanks ICER for extending the time to respond to the NSCLC report and encourages ICER to consider review times that are even more generous in the future.

CSC encourages you to amend these practices to allow the respondent the time and space to provide full and complete feedback on your positions. Additionally, CSC believes you should allow submissions to be in pdf format and that you also make all comments publicly available throughout the entire development and review process.

**Inadequate patient representation**

CSC acknowledges the attempt to include patients on both the Governance Board and also the regional panels. CSC encourages ICER to consider the following:

1. There should be a sufficient number of patient representatives to allow an equal share of voice when votes are taken.
2. Patient representation on the Governance Board should include expertise and knowledge that represents the full spectrum of wellness, disease understanding and geography. This board should be expanded to include individuals who can represent or who have access to resources which would allow ICER to benefit from a more comprehensive level of information on the patient experience.
3. There should be patient representation as a part of the evidence report development. As an example, this lung cancer evidence report was developed and approved by a panel exclusive of patients. ICER does note that it received input/feedback from patient groups, including CSC, but it should be noted that CSC did not have access to any of the draft reports prior to or including this “final” draft report being made publicly available.

**Lack of clinical expertise**

In addition to ensuring patients on your panels have the appropriate level of expertise to fully understand complex clinical scenarios, CSC encourages ICER to require health care professionals serving on voting panels to have relevant and deep expertise in caring for patients with lung cancer. Specifically, CSC would like ICER to mandate that physicians serving on the voting panel for the lung cancer report have board certification in medical oncology and that they are actively treating patients with lung cancer.
Inconsistent methodology

CSC fully recognizes the importance of evidence in setting policy and when making decisions with patients. CSC encourages ICER to consider the following:

1. ICER must be transparent with all resources used in the development of evidence reports.
2. ICER must include a balance of data derived from controlled clinical trials (including observational trials) and real world evidence.
3. ICER must create principles to ensure that the use of data meets a high level of scientific credibility. For example, the use of cross-trial comparisons should be discouraged.
4. ICER must require peer-review by a panel of experts for all evidence reports.

Relevance and timeliness of recommendations

The plan for ICER to update recommendations as new data becomes available is unclear. For diseases with rapidly changing scientific discoveries, any organization making clinical recommendations must be nimble and responsive to the environment. CSC encourages ICER to implement the following:

1. A transparent timeline for review and update of previously published recommendations.
2. A deadline for decision that does not impact the ability of a patient to access a treatment option determined effective for a particular disease.
3. Expertise on the review and voting panel that mirrors the topic of scientific discovery.
4. Full transparency of the data used for decision making.

A quick search of clinicaltrials.gov reveals 699 studies listed for EGFR+ NSCLC and 71 studies listed for PD-1 and lung cancer. ICER should be prepared to address new information in rapid fashion as these trials mature.

Lack of consideration of the patient definition of value

CSC understands your use of quality-adjusted life year (QALY) as an endpoint but does not support this as an endpoint which is meaningful to patients. Multiple studies, including CSC’s Registry data, show that for patients with cancer and other long-term debilitating illness, there is a delicate balance between quality and quantity of life. In fact, some patients have reported a desire for a shorter overall survival in exchange for quality of life. The QALY framework assigns the exact same score to an individual who lives six months in perfect health and to an individual who lives a full year in a debilitated state. Patients would assign a very different level of value to each of these scenarios.

Data from the Cancer Experience Registry continues to reveal the importance of quality of life as an important indicator of value to patients. This figure, taken from a recent analysis and presentation on patients in the Registry, indicates that quality of life may, in fact, be of greater importance to the majority of patients when making a treatment decision than length of life. Other value models (American Society of Clinical Oncology and the National Comprehensive Cancer Network) 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 patients assign to shorter, incremental gains.
Additionally, responses collected directly from cancer survivors in an open-ended question about how they define value in their cancer care show quality of life issues and attention to individual preferences and needs emerging as key factors. For example, one respondent wrote: “Value is most meaningful when it is applied to my individual life, and not to an algorithm or statistical fact.” Another notable trend is time with the health care team to fully understand all available options and the risk and benefit scenarios (including cost) associated with each. A respondent wrote: “A good team of doctors that works with you, not at you.”

Data from CSC’s Cancer Experience Registry, presented at the 2015 Association for Value-Based Cancer Care annual meeting demonstrates that in patients with metastatic breast cancer, only 5% of respondents conceived value as having any exchange-based meaning specific to health. As noted in the study, when defining value relative to health care, patients emphasized the importance of their relationship with Health Care Providers (HCPs) rather than the benefit of cost-effective treatment. Although quality, efficiency and cost transparency in value-based care are essential, patients may be more focused on quality care as it relates to the HCP–patient relationship than on value relative to efficiency/cost. While accounting for the clinical merits of a particular therapy is important, the current ICER model represents only a component of the overall care and may overshadow other dimensions of care that are also valuable to patients. CSC would like ICER to utilize a framework which more closely represents the endpoints that are meaningful to patients.

**Lack of consideration of low-grade chronic side effects**

ICER’s value framework does not include consideration of low-grade, chronic side effects. CSC acknowledges concerns regarding the lack of patient reported outcomes as a part of the formal data collection process and CSC sincerely looks forward to working with ICER on a plan to remedy future data collection requirements. The reality for patients is that long-term side effects are a significant part of their overall experience, ranging from quality of life, to financial considerations, to work and family challenges. As documented in the 2014 Index, Elevating the Patient Voice, the top concern people want more help managing is long-term side effects. Given the body of evidence currently available on long-term effects of the vast majority of the “prevailing standard of
Care”, CSC strongly encourages ICER to incorporate that information as an important component in the calculation of clinical-effectiveness.

**Focus on medications acquisition costs**

The impact on the individual in terms of personal health care spending is increasing and documented in the literature. Indeed, data from CSC’s Insight into Patient Access to Care in Cancer report demonstrates that patients are primarily concerned about costs related to insurance premiums, co-pays for services and co-pays for drugs.

We believe the focus solely on sales or acquisition costs to estimate treatment costs minimizes the reality and attention that should be placed on finding solutions that address the multitude of factors impacting elevated spending. Further, this narrow focus can significantly under-weight aspects of the delivery of care that contribute substantially to a patient’s calculation. Aligned with the patient voice, our broader community should focus its attention on creating a system that rewards the provision of comprehensive, quality care inclusive of transparency, shared decision-making and long-term risk/benefit disclosures.

**Lack of inclusion of financial toxicity**

The causes of financial toxicity in patients with cancer are becoming well recognized and the reality of the rising cost of health care is daunting and not sustainable. Patients report financial distress as more severe than other sources of distress associated with physical, social and emotional functioning (e.g., Delgado-Guay et al., 2015).

The current Value Assessment Framework does little to recognize the impact of the comprehensive nature of financial toxicity. In addition to patient cost sharing for medications and services, it is well documented that patients experience additional expenses related to their cancer treatment. Some expenses are more difficult to measure (parking, housing, etc.), but the framework could allow the capture of additional elements. In particular, ICER could apply some level of consideration to frequency of treatment as a part of the evaluation. Given the high cost of travel and time off work, a regimen that would be administered once per month may be less financially toxic to a patient than one administered every week, as one example. Additionally, this framework does not give consideration to the costs associated with interventions required as a comprehensive part of treatment. For example, supportive care agents needed to manage nausea, steroids required as a part of a treatment regimen, etc.

**Conclusion**

At the Cancer Support Community, we are acutely aware of the rising costs of treating cancer and support efforts that contain cost while ensuring the provision of truly comprehensive cancer care. We believe that patients who have knowledge and experience in the specific topic areas must be fully at the table in discussions about new cancer care models along with providers, payers and other stakeholders. All policy proposals should be evidence-based and promote a rich physician-patient dialogue and care planning that is customized for and with the individual cancer patient. We strongly believe that the process of developing new care models and payment structures and the implementation of those models in practice must be transparent. Patients have a right to know about their full suite of care choices, and the incentives that may influence their providers in terms of treatment recommendations.

In conclusion, CSC sincerely thanks you for the opportunity to comment on ICER’s draft evidence report on treatment options for advanced non-small cell lung cancer share the voices of patients living with cancer. We look forward to additional opportunities to contribute to ICER’s ongoing work.

CancerSupportCommunity.org Uniting The Wellness Community and Gilda's Club Worldwide
Please feel free to contact me at (202) 650-5382 or by email at linda@cancersupportcommunity.org if you have any questions or if we can be of further assistance.

Thank you again for your attention to this very important matter.

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References


