June 30, 2023

Submitted electronically to publiccomments@icer.org.

Steven D. Pearson, MD, MSc
President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Re: Methods Update: Value Assessment Framework

Dear Dr. Pearson:

The Society for Women’s Health Research (SWHR) appreciates the opportunity to provide input to the Institute for Clinical and Economic Review (ICER) on its Methods Update: Value Assessment Framework.

SWHR, a more than 30-year-old national nonprofit organization based in Washington, D.C., is widely recognized as a thought leader in promoting research on biological sex differences in disease and eliminating imbalances in care for women through our science, policy, and education work.

As an organization whose focus centers on raising awareness of the unique needs of women and closing knowledge and health care gaps, SWHR is committed to ensuring that health care value assessments account for women and their diverse needs as patients, caregivers, and often as the chief health decision maker of the family. We therefore submit the following comments for ICER’s consideration as it works to finalize its 2024 Health Care Value Assessment Framework.

Recognizing the Uniqueness of Each Patient

Within the document of proposed changes, ICER states that to inform medical policies, it “takes a ‘population’ level perspective as opposed to trying to serve as a shared decision-making tool to be used by individual patients and their clinicians.”

While SWHR acknowledges that ICER is attempting to “support deliberation on medical policies,” ICER’s reports are being utilized by payers and other stakeholders in order to make formulary decisions.1 As a result, this population-level, one-size-fits-most approach oversimplifies the value of new drugs by ascribing certain characteristics to patients regardless of individual circumstances. As SWHR notes in its Policy Principles: Health Care Value Assessment, “Patient subpopulations can differ in their response to a given therapy (i.e.,

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heterogeneity of treatment effect). Therefore, value assessments for new therapies should take into consideration factors, such as patients who cannot tolerate currently available therapies, are contraindicated for these therapies, have heterogeneous responses to these therapies, or for whom these therapies are ineffective or whose conditions have progressed.” Further, values are dynamic and change over time as patients’ individual circumstances and experience of treatment and illness evolve throughout the course of disease. Making decisions based on an “average” patient, especially when it can affect coverage decisions that could have implications for care, could do a major disservice to those who are relying on a given treatment.

SWHR appreciates ICER’s acknowledgement that within value assessment frameworks there is an “inherent tension between average findings in clinical studies and the uniqueness of every patient” and that there is “diversity in the way that patients view the balance of risks and benefits of different treatment options.” SWHR also appreciates that ICER will continue to include a “Heterogeneity in Subgroups” to review subgroup effects of a given treatment. However, SWHR is concerned that a “population-level” focus could have negative unintended consequences when it comes to not only a physician’s ability to prescribe a certain medication to a patient, but also to a patient’s ability to access the said medication due to cost.

Ensuring Clinical Trial Diversity

ICER states that it will provide an overall diversity rating for the demographic characteristics of “race/ethnicity, sex, and age, specifically among adults 65 and older.”

SWHR supports policies and practices that ensure trial participation reflects the overarching patient/treatment population as well as policies that allow data to be disaggregated by key demographic information. SWHR strongly encourages ICER to separate race and ethnicity. As noted in a 2021 JAMA editorial, race and ethnicity “have important, albeit contested, social meanings. Neglecting to report race and ethnicity in health and medical research disregards the reality of social stratification, injustices, and inequities and implications for population health, and removing race and ethnicity from research may conceal health disparities.”

Additionally, SWHR would urge ICER to consider both sex and gender as part of its demographic consideration. Incorporating both sex and gender data analysis will allow for better data analysis, which could in turn, lead to improved health outcomes.

Weighing Use of Certain Metrics

SWHR echoes the concerns of the Partnership to Improve Patient Care (PIPC) regarding ICER’s reliance on Quality-Adjusted Life Years (QALY) as a measure of disease burden. This subjective measure may overlook certain health equity considerations and may limit the health benefits that can be captured. As noted in the 2019 National Council on Disability’s (NCD) report on

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QALYs, the NCD found “sufficient evidence of the discriminatory effects of QALYs to warrant concern, including concerns raised by bioethicists, patient rights groups, and disability rights advocates about the limited access to lifesaving medications for chronic illnesses in countries where QALYs are frequently used.”

While SWHR acknowledges ICER’s comment that it will emphasize that “policymakers who prefer or who may be mandated to consider only measures of health gain other than QALYs find results at every threshold based solely on the equal value of life-years gained (evLYG),” the Society remains concerned about the continued presence of QALYs within the Framework and recognizes that groups, such as PIPC, believe that the evLYG measure “has many of the same underlying shortcomings of the QALY.”

SWHR encourages that ICER continue to explore measures that will better represent the unique needs and preferences of patients and people with disabilities.

Thank you for the opportunity to provide comment on ICER’s Methods Update: Health Care Value Assessment Framework. If you have questions about the information included above, please do not hesitate to contact me at kathryn@swhr.org.

Sincerely,

Kathryn G. Schubert
President and Chief Executive Officer
Society for Women’s Health Research

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