

## **ICER's concern for patients: Where's the beef?**

By Patricia Goldsmith and Carole Florman

*Published by STAT on October 9, 2019*

The Institute for Clinical and Economic Review, commonly known as ICER, wants everyone to believe that it cares about patients and that its value assessments of new drugs and treatments are intended to help them.

How do we know that? It's become the organization's central talking point as it makes the rounds in advance of finalizing its revised Value Assessment Framework for 2020, which describes the methodology the organization will use in its assessments beginning next year.

We have represented CancerCare, an organization that provides free, professional support services to anyone affected by cancer, in a number of exchanges ICER has had with patient advocacy and support group. We have heard ICER leaders talk about how much they care about patients, how they want to find ways to better capture what value means to patients with a given condition, and how they are trying to make sure that treatments are priced fairly so they can be accessible to those who need them.

Well, golly, who could disagree with that?

There's just one problem: Despite the flurry of activity that feels like a politician's listening tour, and the practiced use of the phrases "patient-centered" and "patient values," there's very little "there" there. Or, as the memorable Clara Peller once asked, "Where's the beef?"

ICER is a private research organization that performs cost-effectiveness assessments of medicines and health care services. These assessments are used by health insurers and policy makers to determine whether to cover medicines and services. This work is controversial in part because ICER's calculations rely on the quality-adjusted life year (QALY), a measure that discriminates against older people and those with serious conditions.

ICER's proposed 2020 framework takes a few steps toward a more patient-centered approach to value assessment, such as committing to an increased use of real-world evidence in its reviews — with some significant caveats. But the organization has also doubled down on its use of the QALY; will continue to exclude disease-specific experts, patients, and caregivers from voting panels; and will maintain review schedules that signal a greater commitment to speed than accuracy and that can result in conclusions reached well before the full benefits — or shortfalls — of a particular drug or treatment are known.

Speaking at a recent National Health Council conference on value assessments, Julie Block, president and CEO of the National Eczema Association, joked that she had post-traumatic stress disorder from her experience providing input to ICER when it recently reviewed two new eczema drugs. According to Block, no one on the ICER team had any experience in dermatology and the eczema association was given very little time to comment on the draft findings. ICER told the association that patient stories could sway the voting panel, so Block and her small staff dropped everything to make sure that patients' voices were heard in

commenting cycles and during the single public meeting held during the review of the two drugs.

In the end, ICER voted that one of the drugs evaluated had “good value,” which means that people with eczema may have improved access to this new medication. When Block was asked how she’d decided whether the National Eczema Association would participate in the review, she said there was no choice as the stakes were simply too high to not participate.

Now imagine those stakes when it comes to a treatment for a rare and deadly cancer.

If ICER really wanted to consider patient experiences, why did it put the burden of quickly developing and presenting patient experience data squarely on the shoulders of patient advocacy groups? It said that ensuring complete data wasn’t its job. At the National Health Council’s conference on value assessment, ICER’s executive vice president and chief operating officer, Sarah Emond, said that patient groups can choose to provide input — on ICER’s schedule — or not. If they don’t, ICER will proceed with the information it has regardless of how complete it is.

That process doesn’t sound logical and patient-centered to us. If ICER wants to ensure its reviews are patient-centered and reflect the values and experiences of those who will be affected by its assessment of a particular treatment, here are six things it could do:

- Set review schedules cooperatively with patient advocacy groups so those groups have adequate time to plan and deliver the data that are so critical to a thorough value assessment.
- Gather and assess the impact of treatments on quality-of-life factors that patients with the disease think are most important. Real-world data and evidence provide a more comprehensive view of how a treatment affects their lives than the reported results of randomized controlled trials among a narrow population.
- Enlist experts in the target disease to be on voting panels, including clinicians, patients, and, when it comes to diseases affecting children, parents. ICER worries that specialists, patients, and parents will act with self interest which, in our experience, doesn’t include pushing for ineffective treatments or drugs.
- When considering treatments for rare diseases for which large-scale trials haven’t been conducted, wait until there is adequate real-world evidence from individuals who are using the treatment.
- Stop using the QALY as the metric for determining value. The QALY is an inherently discriminatory measure that discounts the value of a life year of older people and those with disabilities or serious illnesses and treats everyone as average.
- And stop pretending that the optional alternative to QALYs, the equal value of life years gained (evLGY), has fixed the QALY problem. While this new metric credits years of life extension without discounting for age, illness, or disability, it ignores a drug’s impact on symptoms. With the evLGY, a cancer drug that extends life by two years and dramatically improves a patient’s quality of life would be scored the same as a drug that extends life by two years but keeps her bedridden. We’re not economists, but that doesn’t make sense to us.

We all want to pay for value. No one — no patient, no caregiver, no clinician — wants to pay more for a treatment than the treatment is worth. The real questions are who is deciding

that worth and are they basing it on their own values or the values of those for whom the treatment is intended.

ICER describes itself as the “nation’s drug pricing watchdog.” But it seems to us that it is protecting the insurance companies that pay for treatments. If the organization truly wants to become the watchdog for the nation — which includes the people who use health care — it needs to research and quantify the value of treatments as they relate to the people who need them.

In other words, ICER needs to add real substance — the beef — to its disingenuous rhetoric.

*Patricia Goldsmith is the CEO of CancerCare, a national organization dedicated to providing free, professional support services to anyone affected by cancer. Carole Florman is CancerCare’s policy fellow. In 2018, CancerCare received financial support from more 750 individuals, organizations, and companies, including pharmaceutical companies, and collaborates with other cancer-related advocacy organizations. Its policy positions and advocacy efforts are determined independently.*