



ICER Reviews and the Aging Population

A Review of Recent ICER Reports and Recommendations to Advance Aging Equity in Value Assessment



Background

The Institute for Clinical and Economic Review (ICER) is a non-governmental organization that conducts value assessments of emerging care interventions. ICER considers whether a medicine is “affordable,” which includes consideration of spending money and resources on the intervention rather than for other potential uses in the healthcare system.¹ ICER’s cost-effectiveness analyses (CEA) operate from the “whole system” perspective and review patient populations in aggregate to determine which drugs merit coverage based on their price and estimated total impact for the average patient with a given disease.² According to ICER, the outputs from these analyses are intended to “align [US] spending to ... get the most health we can out of the dollars available.”³

While it is sensible to consider the amount of benefit for money spent in a cost constrained health system, ICER’s framework estimates the value for an average patient and does not consider the health needs of individual patients or patient groups that are not represented by that average. Any individual patient’s treatment goals and response to a medication will not inherently and

implicitly agree with the conclusions of the ICER aggregate assessment.

ICER’s methodology tends to under- or devalue the impact of diseases on older adults or patients with disabilities.⁴ This is in large part, but not exclusively, due to ICER’s reliance of the Quality Adjusted Life Year (QALY) to aid payers in making coverage decisions. The QALY calculates a given treatment’s impact on extension and quality of life, with more QALYs indicating higher total health. Because older adults have fewer overall years of life ahead of them to extend, medications used by older adults will have a lower QALY score. By definition, spending money to preserve or improve the health of an older or sicker person is less cost effective than spending money to improve the health of a person with fewer health challenges.⁵ Therefore, using QALYs to calculate the value of treatment for an older population reinforces the broader societal problem of undervaluing the lives of older adults. Similarly, the QALY framework provides lower value for symptomatic treatments which may improve an individual’s lived experience with a disease but not increase life expectancy. Because of this, concerns persist around whether outcomes important to patients with a

¹ Pearson, Steve. “The ICER Value Framework: Integrating Cost Effectiveness and Affordability in the Assessment of Health Care Value.” *Value in Health*, 21:3. Mar 2018.

<https://www.sciencedirect.com/science/article/pii/S1098301518300214>

² Institute for Clinical and Economic Review. “Cost-Effectiveness, the QALY, and the evLYG.”

<https://icer.org/our-approach/methods-process/cost-effectiveness-the-qaly-and-the-evlyg/>

³ Institute for Clinical and Economic Review. “ICER’s Impact.” <https://icer.org/who-we-are/history-impact/>

⁴ National Council on Disability. “Quality-Adjusted Life Years and the Devaluation of the Life with Disability.” Nov 6 2019.

https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

⁵ For example, an equitable extension of life for two years for a sicker person, in comparison to a healthier person, would be assessed as of lower value under use of the QALY.

given condition are prioritized—such as the ability to work, use the bathroom on one’s own, or care for a loved one.

These impacts are not limited to the aging population, but to all beneficiary groups that may be outside of an “average person.” The beauty of the U.S. is its diversity, and there is no average U.S. patient. However, there are many patients who receive less than average outcomes due to historic and current discrimination present in our health system. Patients that are impacted by ICER’s average value measure reflect the diversity of the US population, with radical differences in race, gender, ethnicity, age, disability, and underlying conditions.

The diversity of these populations – and the outcomes that are valued most highly within subgroup communities – as well as the countless other factors that impact an individual’s response to a course of treatment, make it paramount that value assessment methods are flexible and able to incorporate inputs from sources that reflect the value of outcomes that are most important to patients.

Older Adults and ICER’s Health Equity Framework

ICER has written extensively about the use of health equity in their reports; however, their assessments do not routinely incorporate or assign value to factors related to age. For the purposes of

this paper, health equity will be defined as the Robert Wood Johnson Foundation defines it – “Health equity means that everyone has a fair and just opportunity to be as healthy as possible.”⁶ However, ICER’s current efforts to evaluate how their assessments handle health equity only explicitly mention individuals from communities of color, without reference to persons with a disability or older adults.⁷

ICER has historically considered health equity to be a “contextual consideration” in their work, meaning that it is not an easily defined or useable metric within their methodology. ICER acknowledges this in their latest Value Assessment Framework (VAF), stating,

ICER has explored options for measuring the degree to which treatments may result in greater or lesser inequality across racial or socio-economic groups in the US. Data to support application of available methods are lacking in the US, and none of these methods have been adopted as standards within other Health Technology Assessment (HTA) agencies. Nonetheless, where judged feasible, ICER may explore through scenario analyses methods to capture the impact of new technologies on disparities in life expectancy

⁶ Robert Wood Johnson Foundation. “What is Health Equity?” May 1 2017.

<https://www.rwjf.org/en/library/research/2017/05/what-is-health-equity-.html>

⁷ Institute for Clinical and Economic Review. “ICER Launches Initiative to Evaluate and Advance Health Technology Assessment Methods that Support Health Equity.” Jul 11 2022. <https://icer.org/news-insights/press-releases/hta-methods-health-equity-paper-2023/>

*across different subpopulations in the US health care system.*⁸

The theme that there is not enough available data to support robust evaluation has been repeated in nearly every external communication ICER has released on their use of health equity. In the same VAF document, ICER notes that where possible, the patient populations included in their evaluation are the ones for which a treatment is indicated. Further, they note that subgroup analysis can only be done on a medication “data permitting.”⁹ Subgroup analysis is done when a group has variation in baseline risk that might lead to a change in an intervention’s level of efficacy or impact for that group, often the exact populations for whom additional analysis of equity is the most important.

However, clinical trials typically include exclusion criteria that disqualify individuals from participating in a trial based on comorbidities, age, and other factors. The goal of exclusion criteria is to help isolate and ensure results are reflective of the impact of the intervention, rather than other factors. As a result, clinical trial data often reflects a population that differs significantly from real-world users. Also, long-standing issues with lack of representation of communities of color in

clinical trials results mean that differential impacts may not always be evident in clinical trial data.¹⁰

The data ICER uses comes from published or publicly available sources, including peer-reviewed journals, supplementary appendices, briefing documents used by regulatory authorities, and conference proceedings. While ICER states that they prefer to use data from randomized controlled trials (RCTs), when such data are not available comparative clinical effectiveness analysis may require “indirect comparisons through formal network meta-analysis.” ICER notes that types of real-world evidence (RWE)¹¹ may help complement other types of evidence, and that they have “consistently sought to incorporate analysis of RWE into [their] reports whenever it can provide additional perspective.” ICER often releases their analysis prior to an FDA approval and product launch in order to inform price negotiations. However, this often prevents incorporation of late-stage trial and real-world data into their quantitative analyses.

In July of this year, ICER received a grant from The Commonwealth Fund to “evaluate procedural changes that could further support health equity goals in health technology assessment.” The

⁸ Institute for Clinical and Economic Review. “2020-2023 Value Assessment Framework.” Jan 31 2020. https://icer.org/wp-content/uploads/2020/10/ICER_2020_2023_VAF_102220.pdf

⁹ Ibid.

¹⁰ National Minority Quality Forum. “Traditional Value Assessment Methods Fail Communities of Color and Exacerbate Health Inequities White Paper.” <https://www.nmqf.org/nmqf-media/traditional-value-assessment-methods>

¹¹ Real-world evidence consists of the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real-world data from sources such as data registries, electronic health records, claims data, and patient-generated data.

intent of this effort is highly relevant, as it is imperative to understand the extent to which equity factors have been meaningfully incorporated in recent ICER reports to provide accurate insights into the systemic impact of ICER's analyses/recommendations and support meaningful change. However, paying ICER to critique their own methodology may present an inherent conflict of interest, and such self-assessment is unlikely to address long-standing concerns around equity put forth by the National Council on Disability¹² and others around the foundational discriminatory impact of several of ICER's preferred methodologies such as the quality-adjusted life year (QALY) and estimated value of life-years gained (evLYG).¹³

Scope of the Project

The Alliance for Aging Research has previously raised concerns about the impact of ICER's use of averaging metrics, including but not limited to the QALY and evLYG. However, the goal of this paper is to accurately reflect the ways in which older adults have been incorporated into ICER's recent CEA efforts. In total, between 2020 and October of 2022, ICER has released or partially released 29 final reports. This paper seeks to discuss how older adults are treated in those reports. Additionally, this analysis considers the intersectional identities that go hand in hand with

aging, including racial and ethnic groups, gender, sexual orientation, and disability where they are applicable.

Discussion

As the term "contextual consideration" might indicate, ICER does not have a standardized methodology of incorporating societal impact into their CEA, even if that data was always readily available. While ICER does have tools that are explicitly meant to account for health equity in the kind of quantitative analysis they prioritize, those analyses are not used consistently or often in ICER's guidance to policymakers, manufacturers, or payers, nor do they positively or negatively impact ICER's price recommendations. As a result, these value assessments undervalue the people in the U.S. health system with the highest needs: older adults, individuals with a disability, and medically marginalized communities.

One major theme that emerged in this meta-analysis is ICER's assertion that clinical trials do not supply enough data on older adults and other underserved populations to allow them to accurately extrapolate what the impacts on those subgroups might be. While this claim is backed by data and a general scientific consensus that there is not enough diversity of enrollment in clinical trials in the U.S., it also does nothing to mitigate the potential severity of ICER's reports on patient access in those groups. Lack of

¹² National Council on Disability. "Quality-Adjusted Life Years and the Devaluation of the Life with Disability." Nov 6 2019.

https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

¹³ The evLYG assesses life-years gained but omits health state preferences. However, these assessments do not provide weight to symptomatic (i.e. non-life-extending) improvements.

data cannot be an excuse. We cannot ignore these populations. Rather, it is important to consider ways to adjust the methodology or gather population-specific data to assess value more accurately.

Further, there are disease states where it may not be possible to have sufficient clinical trial data on relevant subgroups, especially for any number of rare diseases that by definition have small patient populations. Without active efforts to address the impacts of averaging metrics on populations that are not “average” due to ethnicity, age, or disability, ICER’s recommendations actively perpetuate the disparities that already plague underserved populations.

This is a major concern. ICER’s recommendations are increasingly being used across the medical space, and therefore the act of shifting the responsibility for this kind of analysis entirely to other stakeholders reflects a lack of self-awareness on the part of ICER of their role in medical coverage decisions. If ICER wants to ensure that health equity is consistently incorporated into their analyses, the organization has a responsibility to collect the data necessary to do so or find other ways to address this issue.

As mentioned above, ICER’s methodologies have been criticized for their tendency to be discriminatory against patient populations because they

undervalue the lives of older adults and people with disabilities as they do not meet ICER’s implicit definition of a “quality” life. For example, a 70-year old individual that has no comorbidities can not be considered to be in “perfect health” according to QALY-based analyses that ICER utilizes.¹⁴ Similarly, therapeutic interventions that disproportionately impact older adults and other groups assessed as having a limited lifespan are evaluated as having less value because these populations have, on average, fewer “life years” to be gained. In the reports that were reviewed in the development of this paper, there was no mention of this concern or any steps to mitigate those effects. In fact, ICER has implicitly stated that they devalue the lives of the older population. In their previous review of Alzheimer’s Disease (AD), they categorized AD as a moderately impactful illness because it does not manifest across the entire lifespan, despite AD’s tendency to change nearly every aspect of the lives of both the individual living with the disease and their families and caregivers.¹⁵

ICER does attempt to reference the health disparities associated with the conditions covered in their reports, and the sources that ICER consults for their discussions on those topics are often include patient advocacy groups, community health professionals, and medical practitioners. We commend ICER’s public comment period and sincere efforts to listen to the concerns of

¹⁴ Value Our Health. “What are you worth?” <https://valueourhealth.org/what-are-you-worth/>

¹⁵ Institute for Clinical and Economic Review. “Aducanumab for Alzheimer’s Disease: Effectiveness and Value Final Evidence Report and Meeting Summary.” Aug 5 2021. https://icer.org/wp-content/uploads/2020/10/ICER_ALZ_Final_Report_080521.pdf

those stakeholders that respond. However, without meaningful incorporation of this feedback into the CEA calculation itself, much of the functional impact of these factors on ICER's recommendations is lost. In reality, an average measure of value is never going to reflect diversity, so it is not only the methodology but also how these CEA are used to make decisions that need to be considered.

Additionally, ICER analyses often highlight the need for more research into disparities and where applicable, the need for policy shifts surrounding a disease condition among a minority group. ICER's advocacy to policymakers on the need for more diversity in clinical trials adds a reputable voice to that ongoing conversation.

Recommendations

ICER's current self-assessment process on how the organization incorporates health equity is an important opportunity to consider the adoption of reforms that can help address current concerns around the limited inclusion of aging-specific concerns. The Alliance encourages ICER to evaluate the following:

1. ICER should incorporate the experience of older adults and individuals with a disability in their consideration of health equity

Systemic discrimination against individuals of color is a vital and pressing issue in the U.S. healthcare system. Traditional value

assessments that represent an "average" or "typical" experience can marginalize the experience of minority populations and reinforce existing disparities in the healthcare system. However, ICER should also incorporate other groups that are marginalized and have historically experienced care access restrictions to ensure a holistic view of equity considerations.

2. ICER should regularly conduct follow-up analyses that incorporate real-world data, including on population subgroups of interest

Pre-market analyses provide limited opportunities to incorporate data on populations representative of ethnicity, age, disability, and severity of illness. A standardized timeframe to update initial assessments can provide ICER the opportunity to incorporate real-world data and information on adoption, utilization, and unmet need. ICER should consider publishing a range of estimated values based on differing patient profiles and considerations of value.

3. ICER should provide guidance on data quality standards needed for inclusion in assessments, and exercise flexibility when needed to incorporate equity considerations

Data registries, patient organization-driven data collection efforts, and

electronic health records provide opportunities for incorporation of post-market data on representative populations. However, clear guidance and standards are needed to ensure that data collection meets standards as collection tools are being developed to avoid risks of non-acceptance later. Further, ICER may consider additional flexibilities to allow for the incorporation of data sets that do not meet the rigorous – and expensive – standards of data collected during clinical trials.

4. ICER should re-evaluate their reliance on QALY and QALY-derivative analyses, and evaluate the adoption of value frameworks that permit differential valuations among patient subgroups

Independent government agencies, such as the National Council on Disability, patient advocacy organizations, and medical ethicists have raised concerns about discriminatory impacts resulting from the application of QALY-based analyses to coverage and pricing policies. ICER should consider investment and utilization of alternative methodologies that permit differential valuations, rather than reliance on averaging frameworks.

5. Consider the creation of an ombudsman to provide an ongoing feedback loop and recommendations to better

incorporate equity in assessments

Increasing list prices for drugs are driving growing interest in cost-effectiveness analysis. ICER serves as the leading source for CEA in the U.S. ICER's work is supported by private payers and some government payers, such as the Veterans Administration, who utilize the organization's assessments in price negotiations and in establishing formularies. However, this structure and overarching priority of managing healthcare expenses may lead to the exclusion of additional value considerations, including those related to equity due to concerns that such considerations may lead to higher valuations. Additionally, financial relationships could provide a barrier to ICER objectively evaluating the role of non-manufacturer U.S. healthcare stakeholders – including pharmacy benefit managers insurers, and providers – in rising list prices for pharmaceuticals.

Given the growing importance of ICER and these potential conflicts of interest, the appointment of an ombudsman could provide an important independent voice. An ombudsmen would analyze commonly raised concerns, provide recommendations, and support accountability to ensure that initiatives to prioritize and value the promotion of health equity concerns are being pursued without undue deference to unrelated non-methodological considerations.

Conclusion

ICER's analyses often undercut the needs and desires of older populations and minimize the impact of disease burden on older adults. Their quantitative analysis devalues the impact of novel therapies when the therapies are focused on interventions that disproportionately serve populations over the age of 65. When impacts related to age are quantified, ICER's use of the QALY and evLYG results in assessments that provide a lower value to therapeutics that primarily treat older adults, relative to if similar treatment effects were applied to a younger population. As a result, ICER's analyses do not currently reflect the value of health equity in respect to the aging population.

ICER's health equity project will provide further insight into the changes that ICER will make to improve these problems in their reports. Findings from that project will be released in March of 2023. Anecdotally, stakeholders have noted that the report is expected to focus solely on the aspects of health equity pertaining to race and ethnicity. If that is the case, we hope that ICER will consider the aspects of ageism, ableism, and sexism in future reports.

This project will continue with a second White Paper following the release of ICER's report in 2023.

Appendix I: Definitions

Equal Value of Life Years Gained (evLYG):

A measure of any gains in length of life derived from a treatment, regardless of the treatment's ability to improve patients' quality of life. In other words, if a treatment adds a year of life to a vulnerable patient population – whether treating individuals with cancer, multiple sclerosis, diabetes, epilepsy, or a severe lifelong disability – that treatment will receive the same evLYG as a different treatment that adds a year of life for healthier members of the community.¹⁶

Randomized controlled trial (RCT):

A type of clinical trial where researchers randomly assign (by chance, like flipping a coin) the participants to different treatments and one of the treatments is considered a control treatment, such as placebo. This helps ensure the treatment groups are similar. It is designed to measure the effects of a treatment by fairly comparing a treatment to a control.¹⁷

Real-world data (RWD): Data about patient health and delivery of care, routinely collected as part of getting care or daily living. RWD can come from a variety of sources, such as electronic health records, health insurance claims and billing, mobile health apps, and

surveys. RWD are collected outside of a clinical trial.¹⁸

Real-world evidence (RWE): Clinical evidence from research studies that analyze real-world data (RWD)¹⁹

Quality Adjusted Life Year: The QALY aims to describe both the quality and quantity of life gained from use of a new medicine. QALY assessments assign a value to the patient group for which a treatment is intended. These assessments are based on the perceived value of living with a given condition in comparison to being in “perfect health.” The QALY is used as a common metric to enable comparisons across different diseases and innovations. The currency suggests that 1 QALY equates to one year in perfect health while 0 is death, so scores typically range from 0 to 1. There are cases where patients suggest their health state is worse than death (negative QALY) due to terminal disease or illness.²⁰

QALY Calculation: The QALY is calculated by multiplying the health state preference value by the time the patient is likely to spend in that state.

$$\text{QALY} = (\text{HRQoL or utility value associated with a given state of health}) \times (\text{time spent in health states})$$

¹⁶ Institute for Clinical and Economic Review. “Cost-Effectiveness, the QALY, and the evLYG.” <https://icer.org/our-approach/methods-process/cost-effectiveness-the-qaly-and-the-evlyg/>

¹⁷ National Health Council. “Real-World Evidence Glossary.”

<https://nationalhealthcouncil.org/additional-resources/real-world-evidence-glossary/>

¹⁸ Ibid.

¹⁹ Ibid.

²⁰ Axelson, Kirsten and Jayasuriya, Rajini. “Assessing the value of medicine for diverse patients: Implications of a QALY approach for health disparities.” Nov 11 2021. <https://media.crai.com/wp-content/uploads/2021/11/15184733/CRA-Implications-of-a-QALY-approach-for-health-disparities-1.pdf>