A preliminary assessment of ICER's new HTA methods that support health equity

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Background

- The Institute for Clinical and Economic Review (ICER) publishes approximately 8 to 10 evidence reports per year that evaluate the cost-effectiveness and comparative clinical value of new drugs. Their value assessment framework (VAF) allows for standardized analysis of the comparative cost and clinical value of these therapies.[1-3]
- In March 2023, ICER released their white paper "Advancing Health Technology Assessment Methods that Support Health Equity," to give recommendations for health technology assessment (HTA) bodies to help societies improve health equity for racial, ethnic, and socially disadvantaged groups.[4]
- In September 2023, ICER finalized their VAF with specific modifications to their methodology and procedures that address health equity concerns, most of which were adapted from their health equity white paper released in March 2023.[4]
- Understanding how ICER continues to incorporate health equity into their new framework is important for both biopharma companies and healthcare decision-makers, as considerations of health equity are increasingly becoming an integral part of healthcare decision-making.

Objective

- To examine ICER's integration of health equity factors within their VAF through a review of their Final Evidence Reports since the release of their white paper on health equity.

Methods

- All of ICER's publicly available Draft Evidence Reports (N=3) and Final Evidence Reports (N=3) published between March 2023 and October 2023 were reviewed.
- We identified 7 parameters ICER outlined in their white paper to consider health equity within their Final Evidence Reports (**Figure 1**), which were further divided into 8 measurable equity factors.
- Health equity factors were extracted and compared between the Final Evidence Reports and their respective Draft Evidence Report to determine the final implementation of health quality measures.
  - A quantitative comparison of the 8 measurable health equity-related factors was performed by 2 independent reviewers.
  - Two independent reviewers conducted a qualitative assessment of the final policy recommendations to summarize the responsibilities and actions required from various stakeholders to improve health equity.

Figure 1. Health equity parameters and measurable equity factors in ICER's white paper

1	**Selecting healthcare interventions for assessment**	Discussion of disparities in report background
2	**Engaging patients and patient groups in the HTA process**	Evidence of engagement with the diverse patient populations in report background
3	**Evaluating diversity of participants in clinical trials**	Participant-to-disease prevalence ratio (PDPR) score, ICER Sample Diversity Rating Tool score
4	**Analyzing results by subpopulations**	Subpopulation analysis
5	**Measuring the opportunity to reduce health disparities**	Health Improvement Distribution Index (HIDI) Score, distributional cost-effectiveness analysis (DCEA)
6	**Promoting health equity through quantitative methods of cost analysis**	DCEA, multiple criteria decision analysis (MCDA)
7	**Promoting health equity through deliberative methods of appraisal**	California Technology Assessment Forum (CTAF) voting on the impact on health equity

Key: CTAF – California Technology Assessment Forum; DCEA – distributional cost-effectiveness analysis; HIDI – Health Improvement Distributional Index; HTA – health technology assessment; ICER – Institute for Clinical and Economic Review; MCDA – multiple disease criteria decision analysis; PDPR – participant-to-disease-prevalence ratio.

Methods (cont.)

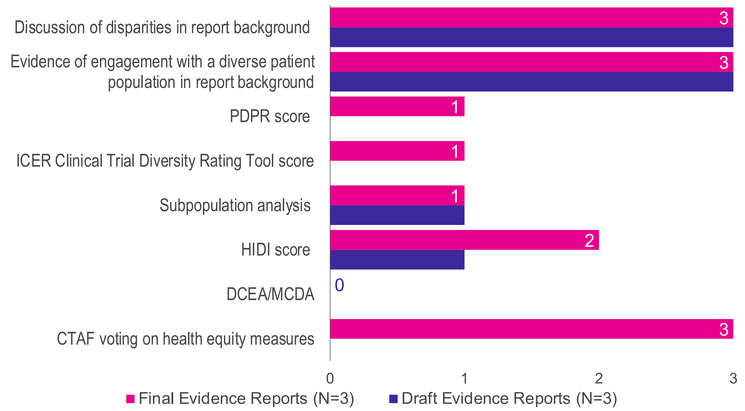
- The ICER Clinical Trial Diversity Rating Tool is a framework developed by ICER to consistently and objectively evaluate clinical trial diversity. An overall diversity rating is provided for the following demographic characteristics: race/ethnicity, sex, and age.[4]
- The participant-to-disease prevalence ratio (PDPR) score is an ICER-developed metric that assigns a score between 0 and 3 to each demographic category based on the estimated PDPRs. Using the cumulative score and pre-defined cut points, a rating of "good," "fair," or "poor" is used to communicate the overall level of racial and ethnic diversity in a clinical trial.[4]

Results

Analysis of reports

- Overall, the application of the 8 health equity factors was not consistent between the Draft and Final Evidence Reports (**Figure 2**).

Figure 2. Equity-related factors across ICER Draft and Final Evidence Reports



Key: CTAF – California Technology Assessment Forum; DCEA – distributional cost-effectiveness analysis; HIDI – Health Improvement Distribution Index; ICER – Institute for Clinical and Economic Review; MCDA – multiple criteria decision analysis; PDPR – participant-to-disease prevalence ratio.

- For all Final Evidence Reports (N=3) released between March 2023 and October 2023, ICER most consistently incorporated the following health equity-related factors:
  - Discussion of disparities in the report background
  - Evidence of engagement with a diverse patient population in the report background
  - Inclusion of health equity considerations in criteria for California Technology Assessment Forum (CTAF) voting
- 2 of the 3 Final Evidence Reports did not include subpopulation analyses, PDPR scores, and ICER clinical trial diversity rating scores.[a]
- Quantitative methods for considering health equity (eg, DCEA, MCDA, or other equity-related cost-effectiveness analyses) were not used in any of the Final Evidence Reports.
- Overall, there were not many differences in the included health equity factors when Draft and Final Evidence Reports were compared. Health Improvement Distribution Index (HIDI) score, PDPR score, and ICER Clinical Trial Diversity Rating scores were infrequently included in Draft Evidence Reports but included in Final Evidence Reports. Due to ICER's evaluation process, CTAF voting was only included in Final Evidence Reports.[5]
- All Final Evidence Reports included voting on society's goal of reducing health inequities within CTAF votes. The most common equity-related factors referenced in CTAF votes were race/ethnicity, disease-related disparities, and socioeconomic factors (**Table 1**).

[a]ICER noted in the respective reports that the small sample size prevented the evaluation of the heterogeneity of treatment effect based on age, genotype, or other factors. Additionally, ICER noted an inability to calculate the HIDI in one evidence report due to uncertainties in the prevalence estimates for the disease state.

Results (cont.)

Table 1. Equity-related factors frequently identified in CTAF votes for "Potential Other Benefits or Disadvantages"

Equity factors	n (%)
Race/Ethnicity	3 (100%)
Socioeconomic	2 (66%)
Geographic	1 (33%)
Disease-related	3 (100%)
Gender	0

Key: CTAF – California Technology Assessment Forum.

- In all Final Evidence Reports (N=3) reviewed between March 2023 and October 2023, ICER most frequently provided recommendations for how different stakeholders might engage in opportunities to address health equity (**Table 2**).

Table 2. ICER key health equity policy recommendations per stakeholder

Stakeholders	ICER recommendations
All stakeholders	All stakeholders should take steps to facilitate access to potential cures in a way that does not exacerbate health inequities (eg, by race, geography, and health literacy) that characterize the US healthcare system
Manufacturers	Work with communities and patient groups to develop reliable methods for recruitment and retention of diverse populations
Payers	Consider wraparound programs that help address barriers to social determinants of health (eg, transportation, case management, benefit counseling)
Clinicians and clinical specialty societies	Develop programs to recruit and retain a diverse workforce
Patient organizations	• Develop programs to deliver culturally sensitive information • Collaborate with manufacturers and researchers to target the recruitment and retention of diverse populations for clinical trials

Key: ICER – Institute for Clinical and Economic Review.

Limitations

- This analysis only included health equity methods and factors highlighted within ICER's white paper and did not encompass all methods for considering health equity in value assessment.
- The results from this analysis are only preliminary, as only a small sample size of Final Evidence Reports was published during the analysis period.

Conclusions

- Although these results are limited in scope due to the small number of assessments published since the introduction of the new methodology, the findings suggest that ICER has made progress in incorporating their new HTA methods in their Final Evidence Reports.
- There remains an opportunity to more consistently incorporate both qualitative and quantitative measures of health equity in the consideration of product value.

References: 1. Penley B, et al. An assessment of the evolving methods and role of health equity factors in ICER's Final Evidence Reports. Poster presented at: ISPOR 2023; May 7-10, 2023; Boston, MA. **2.** Westrich K, Buelt L. The more things change, the more they stay the same? Reviewing ICER's revised value assessment framework. November 1, 2023. Accessed March 15, 2024. https://www.amerisourcebergen.com/insights **3.** Muir JM, et al. *Front Pharmacol*. 2023;14:1197259. **4.** Institute for Clinical and Economic Review. Advancing health technology assessment methods that support health equity. March 15, 2023. Accessed March 15, 2024. https://icer.org/wp-content/uploads/2022/07/ICER_Advancing-Health-Technology-Assessment-Methods-that-Support-Health-Equity_040523.pdf **5.** Institute for Clinical and Economic Review. ICER processes for conducting value assessments. September 25, 2023. Accessed March 15, 2024. https://icer.org/wp-content/uploads/2023/09

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