

Consideration for Health Disparities in Value Assessment Frameworks

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Background: Cost-effectiveness analysis (CEA) compares interventions based on relative value and is an integral part of value assessment. Despite recommendations for economists to consider disparities in CEAs that impact health-care resource allocation decisions, the perception held by stakeholders is that value assessment frameworks are inconsistent in practice.

Methods: We reviewed value assessment reports produced by a United States (US)-based value assessment organization to identify how patients and caregiver input may contribute to how the organization considers health disparities. We purposefully extracted and categorized information relevant to health disparities from report sections on Patient and Caregiver Perspectives and Contextual Considerations and Other Potential Benefits to represent the data acknowledged by the organization's patient engagement efforts. We conducted a thematic analysis of the text in these sections and mapped to a health disparities framework endorsed by the National Institute on Minority Health and Health Disparities (NIMHD).

Results: Nineteen evidence reports were included in our analysis. We identified 30 equity-related themes from external stakeholder perspectives or acknowledged in the report and 17 equity-related themes that reflect the actions taken by the economic model developers to address health disparities as a formal part of the CEA. We found examples of the value assessment organization explicitly considering health disparities in cost-effectiveness estimates. However, explicit considerations were not consistent across reports and were not necessarily aligned with patient and caregiver input during model development or consistent with the organization's own contextual considerations.

Conclusion: Our findings highlight the need for a systematic approach for the consideration of health disparities within a value assessment framework and more transparency around how final cost-effectiveness approaches are determined.

Plain Language Summary: Value/health technology assessment (V/HTA) organizations help review and evaluate the cost-effectiveness of new treatments compared to current therapies for different diseases. The methods used are sometimes informed by patient and caregiver input, but not always. In this study, we review reports developed by a US-based V/HTA and map the information the organization collected from patients and caregivers to a commonly used health disparities framework. We found that while many reports address common areas of health disparities, there was not a systematic and transparent approach of collecting or implementing this information.

Keywords: patient-centered outcomes research, health disparities, cost-effectiveness, patient engagement

Introduction

A health disparity refers to a health difference, based on one or more health outcomes, adversely impacting a defined disadvantaged population.¹ These health outcomes may include a higher incidence or prevalence of disease, earlier or more aggressive progression, excessive morbidity or mortality from specific conditions, a greater burden of disease measured by population health metrics, poorer health behaviors, or worse outcomes on validated self-reported measures.¹ Health outcomes are motivated by more factors than direction interaction and access to health care. For instance,

outcomes can also be driven by genetics, social, or economic factors, which combine to propel individual health behaviors.²

The cost-effectiveness analysis (CEA) compares health interventions based on the relative value provided between two or more interventions.³ The CEA has been recognized as a key component of value assessment and health technology assessment frameworks developed by governments and private organizations. These assessments are intended to guide decision-makers in selecting interventions that maximize the benefits to a country or health system in the face of economic scarcity, gain value, and may also include consideration of other factors such as health benefits, affordability, societal impact, the burden of disease, innovation, ethics, equity, and unmet needs.^{4,5} There has been a push to adapt CEAs to explicitly address health equity concerns. Specifically to provide more information on which populations benefit or are disadvantaged by introducing a new health technology or program.⁶ Novel CEA methods have emerged to address these concerns, including equity impact analysis, equity trade-off analysis, and distributional cost-effectiveness analysis.⁶ In addition to these advancements, health economists have repeatedly recommended that CEA's explicitly consider disparities when the analysis has the potential to impact health-care resource allocation decisions.^{7,8} Despite these efforts, a recently published review of 55 value assessment frameworks found only 27 (49%) incorporated equity as a quantifiable value attribute.⁴

In 2020, the Institute for Clinical and Economic Review (ICER), a non-profit value/health technology assessment (V/HTA) organization in the United States (US), updated its value assessment framework to improve incorporating the values and experiences of patients into assessments while simultaneously informing decisions aimed at "achieving sustainable access to high-value care".⁹ With no official US-based V/HTA agency, ICER plays an integral role in the US healthcare industry, serving as the nearest equivalent to a V/HTA body, guiding decision-making processes.^{10,11} Furthermore, given its influence, ICER evaluations often impact payer decision-making and may even impact political discussions. In July 2022, ICER announced, with support from The Commonwealth Fund, the launch of a new equity-focused initiative that would evaluate procedural and methodological changes that could support health equity goals in V/HTA.¹² Steven Pearson, ICER President at the time, explained the goal of this initiative was to "...identify best practices where possible to guide V/HTA in the US and create the conditions for accelerating the use of V/HTA to support society's goal of improving health equity".¹² By doing this, ICER aims to set a precedent for incorporating elements of health equity into value assessments.

One key component of the ICER announcement was that this initiative would also include a multi-stakeholder advisory group to ensure diverse perspectives guide the overall program.¹² Gerlach et al conducted a study of 7 ICER reports published between 2014 and 2016 to quantify the number, type, and sources of stakeholder engagement submitted to ICER draft reports and found that the most involved stakeholders were drug manufacturers (63%) and patient and patient advocacy groups (18%).¹³ ICER's efforts to engage patients and patient advocacy groups have evolved since its inception in 2006, with the introduction of public deliberations in 2010 and the launch of a new patient engagement program in 2020.¹⁴

The Second Panel on Cost-Effectiveness in Health and Medicine described two broad strategies for equity concerns in CEA: 1) integrating equity directly within CEA quantitatively by assigning specific weights within the analysis and 2) presenting equity concerns qualitatively alongside the CEA.¹⁵ The latter approach has been most frequently used in both CEA and value assessment research, which begs the question: What prevents health economists from explicitly highlighting the impacts of health disparities in current CEA studies to allow more focused consideration of health disparities or acknowledging the existing gaps? The challenges most frequently reported include the scarcity of evidence available, difficulty measuring impacts or assigning appropriate weighting, lack of patient and community engagement, and disagreement on implementation approach.^{4,8}

The importance of integrating considerations for health disparities and equity is further underscored by persistent disparities across various demographic groups. These disparities stem from a complex interplay of social, economic, and environmental factors disproportionately affecting marginalized communities. For instance, minority populations may experience increased rates of chronic disease or lower access to care.¹ Innovative methods have been developed to ensure cost-effectiveness analyses consider these disparities, but less than half of current frameworks explicitly include equity as a value attribute. The Institute for Clinical and Economic Review (ICER) has updated its framework to better reflect

patient values and launched initiatives to integrate health equity into value assessments. Including considerations for health disparities into value assessment frameworks enhances the transparency and accountability of decision-making processes.⁸

Since 2018, US-based payers have been surveyed by a clinical research organization to determine the role and reach of ICER evidence reports in payer decision-making.¹⁶ Following the 2020 ICER methodology changes, payer representatives felt the increased incorporation of real-world evidence and adding a section on heterogeneity and subgroups would be the most meaningful for payer decisions.¹⁶ Additionally, payers acknowledged that the findings from CEAs were often used when considering value-based pricing arrangements with manufacturers.¹⁶ Given the impact of CEA on US payer decision-making, the CEA methods used to formally consider it should align with best practices in health disparities research. Therefore, for this study, we have adapted an existing conceptual model of health disparities research to understand how considerations of health disparities are integrated into V/HTA economic models.

Methods

Conceptual Framework

In 2017, the National Institute on Minority Health and Health Disparities (NIMHD) introduced a framework, building on Bronfenbrenner's ecological model to help assess minority health and disparities research and identify priorities for the future.¹⁷ The NIMHD framework creates a matrix with two axes depicting the relationship between domains of influence on health and levels of influence on health. The domains of influence include biological, behavioral, physical environment, sociocultural environment, and health-care system.¹⁷ The biological domain includes physiological indicators (eg, comorbidities, inflammation, and genetic variation) that may explain biological vulnerabilities. The behavioral domain includes actions and psychological processes that may impact health, such as attitudes, preferences, and coping mechanisms. The physical environment includes the influence of home, work, or community exposures (eg, residential and geographical).¹⁸ The sociocultural environment domain refers to group norms, beliefs, values, and responses of groups that impact health.¹⁸ Finally, the health-care system domain was added by the NIMHD to specify the sociocultural and physical environmental factors observed in care delivery.¹⁷

Bronfenbrenner argued that health and human development are influenced by factors at multiple levels, from the individual to the societal.¹⁹ The interpersonal level describes the dyadic influences frequently represented in patient-caregiver and patient-provider relationship models. The community level reflects the local community or neighborhood impacts. Finally, the societal level captures a more expansive community such as states, regions, nations, or the globe.¹⁷ As many economic evaluations include productivity outcomes that may impact employers, an employer level was added in the adaptation presented in this paper.

For the purposes of this ICER evidence report review, we first focus on sections that describe formal stakeholder feedback and contextual considerations included in the evidence report by ICER to identify themes relevant to the different domains and levels of influence clearly acknowledged as important for value assessment. Then we use the same approach to assess the quantitative methods ICER modelers use to identify themes relevant to the domains and levels of influence on health disparities to determine how ICER patient and stakeholder engagement methods were translated into the estimates for cost-effectiveness.

Overview and Sampling

We completed a review of final ICER evidence reports to assess the inclusion of health disparities in ICER value assessments conducted for pharmacological treatments in the US. Since ICER's last major update to their value assessment framework was in 2020, our focus was on all reports published after January 1, 2020.⁹ To increase comparability between studies for pharmacological treatments, we excluded special assessments, real-world evidence updates, non-pharmaceutical evaluations, and any reports that were incomplete at the time of this review. This study was exempt from institutional review as it did not involve human subjects.

Data Extraction

ICER evidence reports are organized by sections that include: 1) Background; 2) Patient and Caregiver Perspectives; 3) Comparative Clinical Effectiveness; 4) Long-term Cost Effectiveness; 5) Contextual Considerations and Other Potential Benefits; 6) Health Benefit Price Benchmarks; 7) Potential Budget Impact; and 8) Policy Recommendations. We purposefully extracted and categorized information relevant to health disparities from the sections on Patient and Caregiver Perspectives (Section 2) and Contextual Considerations and Other Potential Benefits (Section 5) to represent the data acknowledged by the ICER team and external stakeholders as important considerations for the value discussion. For these sections, we extracted the exact language used by the external stakeholders or the research team where special considerations may be necessary to account for potential health disparities. We also extracted additional information from the Long-term Cost Effectiveness sections to describe the methods used in each analysis including items such as study perspective, time horizon, cost-effectiveness determination, and subgroup analyses. Each evidence report was reviewed by two independent reviewers, and any discrepancies in data extraction were discussed until consensus was reached.

Data Analysis

We conducted a thematic analysis combining inductive and deductive approaches to assess information relevant to the consideration of health disparities.^{20,21} Themes were identified through an examination of patient, caregiver, and stakeholder perspectives presented in included evidence reports. Themes were then mapped to the NIMHD research framework. We describe each theme based on the level of influence (Individual, Interpersonal, Employer, Community, and Society) and the domain of influence (Biological, Behavioral, Physical Environment, Sociocultural Environment, and Health-Care System) to specifically map to the conceptual framework described above. We also summarize the modeling methods used in each report in terms of base case analysis perspective, time horizon, and any subgroups evaluated.

Results

We identified 25 evidence reports published after January 1, 2020. After initial screening, six reports were excluded because they were special assessments outside of the standard ICER framework or were evaluating non-pharmacologic interventions (Full summary of included reports in [Supplement 1](#)). A total of 19 ICER evidence reports were included for data extraction and qualitative synthesis using our health disparities framework. Of the 19 reports, 15 (79%) reported a health sector perspective for base case cost-effectiveness results, and 16 (84%) focused on a lifetime time horizon ([Table 1](#)).^{22–40}

Patient and Caregiver Perspectives or Contextual Consideration Themes

We identified 30 different themes in our sample that reflect external stakeholder perspectives and the ICER team's own assessment of areas where health disparities should be considered or taken into context when determining the value of a treatment. These themes were mapped to the adapted conceptual framework based on the distinct levels and domains of influence for health disparities research ([Table 2](#)).

Individual Level

At the individual level, each domain of influence is represented. For the biological domain, themes include problems with treatment, including unmet needs, heterogeneity of effects, and treatment side effects. Additional considerations include varying experiences over the life course of disease and the perception of need. For the behavioral domain, themes include the impacts of treatment on daily tasks and isolation from family and friends. Additional concerns include the complexity of treatment and its impact on adherence to treatment. For the physical environment domain, there is a theme of a lack of evaluation of home safety. For the sociocultural environment domain, the consistent theme is an excess burden on marginalized groups. Lastly, for the health-care system domain, there are concerns about health literacy impacts, costs as a barrier to access, and limited resources to support navigation of the health-care system.

Table 1 Description of Included Value Assessments Published by the Institute for Clinical and Economic Review (ICER) from 2020–2022

Assessment (Year)	Base Case Perspective	Time Horizon	Subgroup Analyses
Asthma (2021)	Health Care Sector	Lifetime	<ul style="list-style-type: none"> Allergic asthma Eosinophilic asthma
Alzheimer's Disease (2021)	Health Care Sector and Modified Societal Perspective	Lifetime	<ul style="list-style-type: none"> APOE ϵ4 carrier status Race
Anemia in Chronic Kidney Disease (2021)	Health Care Sector	Lifetime	<ul style="list-style-type: none"> Iron and Inflammation States Stages of CKD Incident DD-CKD
Atopic Dermatitis (2021)	Health Care Sector	5 years	<ul style="list-style-type: none"> Patient Age Disease severity Race
Beta Thalassemia (2022)	Health Care Sector and Modified Societal Perspective	Lifetime	<ul style="list-style-type: none"> Genotype Age
Bladder Cancer (2021)	Health Care Sector	Lifetime	<ul style="list-style-type: none"> Stratification by CIS \pm HG Ta/T1 and HG Ta/T1 alone
Chemotherapy-Induced Neutropenia (2022)	Health Care Sector and Modified Societal Perspective	Lifetime	<ul style="list-style-type: none"> NA
Cystic Fibrosis (2020)	Health Care Sector	Lifetime	<ul style="list-style-type: none"> Age Sex Lung function
Diabetes Type 2 (2022)	Health Care Sector	Lifetime	<ul style="list-style-type: none"> Established moderate to severe renal impairment Obesity Race and ethnicity/SES
Hemophilia A (2020)	Health Care Sector	Lifetime	<ul style="list-style-type: none"> NA
High Cholesterol (2021)	Health Care Sector	Lifetime	<ul style="list-style-type: none"> Patients with Heterozygous familial hypercholesterolemia Patients with Statin Intolerance Patients who have had an acute coronary syndrome in the past year
Hypertrophic Cardiomyopathy (2021)	Health Care Sector	Lifetime	<ul style="list-style-type: none"> Symptomatic non-obstructive HCM Symptomatic obstructive HCM
Lupus Nephritis (2021)	Health Care Sector	Lifetime	<ul style="list-style-type: none"> Race/Ethnicity
Migraine: Acute Therapies (2020)	Health Care Sector	2 years	<ul style="list-style-type: none"> Prior use of Triptans Patients receiving migraine preventative medications
Multiple Myeloma (2021)	Health Care Sector	Lifetime	<ul style="list-style-type: none"> NA
Myasthenia Gravis (2021)	Health Care Sector	2 years	<ul style="list-style-type: none"> NA
Non-Alcoholic Steatohepatitis (2020)	Health Care Sector	Lifetime	<ul style="list-style-type: none"> Diagnosis with Type 2 Diabetes
Sickle Cell Disease (2021)	Health Care Sector and Modified Societal Perspective	Lifetime	<ul style="list-style-type: none"> Population with higher pain crisis rate Younger cohort
Ulcerative Colitis (2020)	Health Care Sector	Lifetime	<ul style="list-style-type: none"> NA

Table 2 Themes Related to Health Disparities from Patient Stakeholder and Contextual Consideration Sections

	Individual	Interpersonal	Employer	Community	Societal
Biological	Different experiences over life-course of disease Acuity of need Treatment side effects Unmet treatment needs Heterogeneity of treatment effects	Patient guilt influencing relationships Health impacts on caregiver Quality of life impacts on caregiver Impacts on ability to have children	None	None	None
Behavioral	Complexity of treatment regimen and impact on adherence Fatigue and brain fog impacting daily tasks Impact of isolation from friends and family	Caregiver behavior changes because of patient experiences Caregiver time spent supporting care Impact of isolation from patient	Missed work (absenteeism) Reduced productivity at work (presenteeism)	Impact on patient or caregiver time devoted to other activities that benefit local community	Impact on patient or caregiver time devoted to other activities that benefit society
Physical Environment	Lack of evaluation of home safety	None	None	None	None
Sociocultural Environment	Excess burdens on marginalized groups	None	None	Disproportionate access to providers for minorities	None
Health Care System	Health literacy impacts Limited resources to support system navigation Costs as a barrier to access	Underdiagnosis and misdiagnosis Other financial burdens for caregiver Limited resources for caregiver to support system navigation	Lack of support to help manage insurance benefits	Limited number of specialists or no available specialists	None

Interpersonal Level

At the interpersonal level, three domains of influence are represented. Each domain consistently includes themes related to relationships with caregivers. For the biological domain, themes include patient guilt influencing relationships, quality of life impacts on caregivers, health impacts on caregivers, and the inability to have children. For the behavioral domain, themes include changes in caregiver behaviors and time spent supporting care, as well as impacts of patient isolation. Lastly, for the health-care system domain, themes include the financial burden on caregivers, limited resources for caregivers to support system navigation, underdiagnosis, and misdiagnosis.

Employer Level

Two domains were represented at the employer level. In the behavioral domain, there is a concern for missed work (absenteeism) and reduced productivity at work (presenteeism), and in the healthcare system domain, there are consistent themes of a lack of support to manage insurance benefits.

Community Level

At the community level, the behavioral, sociocultural, and health-care system domains are represented. For the behavioral domain, the main theme is the impact of treatments on patients' or caregivers' time devoted to additional activities that benefit their local community. In the sociocultural domain, the main theme is disproportionate access to providers for minorities, and in the health-care system domain, the main theme is a limited number of specialists or no available specialists.

Societal Level

At the societal level, only the behavioral domain is represented. The main theme is the impact on patient or caregiver time able to be devoted to activities that benefit society.

Discussion

To our knowledge, this is the first analysis of reports generated by a US-based value assessment framework in the context of considering the influence of health disparities on value decisions. This analysis identified 30 themes across different domains of influence for health disparities, which were mapped to the NIMHD research framework. ICER evidence reports have been reviewed for many purposes, including assessing stakeholder engagement,^{13,41} evaluating ICER-estimated value-based price alignment with the net prices observed for pharmaceuticals,⁴² and assessing the impact of contextual considerations and other benefits on the final vote of ICER council members.⁴³ In our sample of ICER evidence reports published following their methods update in 2020, we found variability in considerations for health disparities. Considerations for health disparities were inconsistent across reports and were not necessarily aligned with patient/caregiver input published in ICER's contextual considerations.

However, the ICER assessment for Sickle Cell Disease (SCD) is a unique example where ICER presents detailed insights gained from discussions with patients and patient groups.²⁷ This assessment provides information on the totality of the condition and major concerns for patients and their families, such as stigma of disease, racial bias, and difficulty accessing providers. Considerations from these discussions can be seen in the co-base case models, which focus on changes in quality and length of life and include unique measures for patient quality of life and aims to capture impacts on patient's psychological well-being. ICER notes that economic models "cannot fully capture" the mental and emotional impact of structural discrimination, such as racism, that may greatly affect underserved populations, like those with SCD.²⁷ To illustrate this issue, the models include a comparison of the life expectancy of patients with SCD in their model to those in the US general population without SCD. And accounts for the fact that SCD treatments may reduce the disparity in life expectancy for treated patients by adding approximately 4 undiscounted life-years.²⁷ These additional benefits and contextual considerations help to illuminate the racial disparities in health care and the severe impact of SCD that can aid in future policy decisions. This assessment is distinct from others within this sample due to the level of detail and consideration in the base case. By highlighting broader societal impacts, this assessment underscores the need for comprehensive approaches for V/HTA to address health disparities and ultimately to improve outcomes for historically marginalized populations.

ICER assessments varied in including absenteeism and presenteeism costs. In the value assessment for belimumab and voclosporin for Lupus Nephritis, costs of absenteeism and data on patient unemployment were included along with "productivity loss associated with caregiving"²⁴ derived from a study of autosomal dominant polycystic kidney disease that assessed caregiver presenteeism.⁴⁴ The modified societal perspective for the assessment of targeted immune modulators for ulcerative colitis included both absenteeism and presenteeism costs derived from a US patient survey that used the Work Productivity and Activity Impairment (WPAI) questionnaire which has been widely used in other economic evaluations.³⁶ For the assessment of modulator treatments for cystic fibrosis, the economic analysis included an analysis of employment rates for cystic fibrosis patients treated with Kalydeco matched with untreated patients along with productivity losses due to acute pulmonary exacerbations.³² In the assessment of treatments for hemophilia A, the ICER report included "lost time from work for patients and caregivers"⁴⁰ from a prior study on the burden of hemophilia A in the US.⁴⁵ However, for the assessment related to bladder cancer, ICER cited a lack of evidence as a reason not to include productivity in the economic analysis despite multiple mentions of lost productivity impacts in other parts of the evidence report.³³ The variability in considering productivity costs emphasizes the importance of developing standardized methods to capture the full economic burden of disease ensuring comprehensive and equitable V/HTA across disease states, especially in the context of assessing potential health disparities.

Furthermore, while patients, caregivers, and patient advocacy groups have been systematically involved in the ICER value framework in more recent years, the implementation of these perspectives into the quantitative CEA methodology has been difficult. For example, during the ICER value assessment of Janus kinase inhibitors and

monoclonal antibodies for the treatment of atopic dermatitis, a joint letter was submitted in January 2021 from the patient groups serving as “Key Stakeholders” in ICER’s process specifically asked ICER to include 1) modifications to the economic model structure to account for subgroups, 2) considerations for patient heterogeneity with patients experiencing anxiety and depression and for patients experiencing higher out-of-pocket costs, 3) inclusion of caregiver impacts, 4) special consideration for the economically vulnerable, and 5) presenting a modified societal perspective as a co-base case.⁴⁶ Then in June 2021, these same advocacy groups responded to the open comment period with requests to account for depression/anxiety outcomes in the analysis, the explicit consideration of pediatric/adolescent scenario analyses and consideration of out-of-pocket costs.⁴⁷ In response, ICER stated that the data on depression and anxiety was “inadequate to extrapolate”, they were unable to perform economic analyses on adolescent and pediatric patients due to “insufficient evidence” for pediatrics in the therapies studied and that “estimating patient out of pocket costs is challenging given the variability in insurance designs in the US” prevented them from incorporating in their model.³⁰ The economic analysis section of the atopic dermatitis assessment further states the ICER model was validated by providing “preliminary model structure, methods and assumptions to manufacturers, patient groups, and clinical experts”⁴⁸ and based on the input received the model was adjusted, but makes no reference to the specific recommendations that were not incorporated into the model or why these recommendations were not considered. Patients, caregivers, and patient advocacy groups provided input on topics that could address health disparities throughout the ICER assessments included in this analysis, but it was not clear how this input was valued or systematically incorporated into the economic analysis. Moreover, for value assessment to be more widely accepted in the US, these determinations must be more transparent and additional guidance should be created for the consistent inclusion of topics to address health disparities.

The findings from this review indicate an inconsistency in the consideration of health disparities in ICER value assessments. Although ICER engages patients, caregivers, and advocacy groups, integrating these perspectives remains limited. These inconsistencies can perpetuate inequalities in healthcare decision-making, resulting in the continued marginalization of vulnerable populations and the risk that future policy decisions will not fully consider the experiences of all patients. To improve the accuracy and fairness of V/HTA assessments, it is important to develop clear and consistent methodologies that ensure the consistent inclusion of health disparity considerations, thereby promoting more equitable health-care policies. To start, health economists can map areas addressed in their V/HTA assessments to a health disparities framework, such as the NIMHD framework used in this paper. In this mapping process, there may be further evaluation in the depth of the analysis in each area to assess the quality of evidence available or identify potential gaps.

Limitations

This was the first time the NIMHD framework has been applied to CEA equity considerations. The framework may be limited in its validity for quantitatively assessing the presence or absence of a domain or level of influence in a value assessment report. Our qualitative data synthesis should be supported by future validation of a quantitative scoring process within each matrix box. This analysis focused on the output from one US-based value assessment organization, which could impact generalizability to other settings. We made this decision based on the volume and influence of ICER evidence reports on payer decisions in the US relative to other organizations with value assessment frameworks. We would encourage a similar review of other value assessment frameworks in the US and abroad. Finally, we relied on the information provided within published ICER evidence reports. We recognize that the ICER value assessment framework has evolved substantially over the past fifteen years, and an evidence report published previously may no longer reflect how ICER performs analyses.¹⁴ We minimized this limitation by focusing on reports released after 2020. Additionally, ICER reviews involve the work of different staff members, collaborations with multiple universities to develop the economic analysis, and multiple touchpoints with various stakeholders. To better understand contextual nuances that led to various methodological decisions, in-depth semi-structured interviews may be more appropriate to fully saturate all possible themes related to health disparities that were considered.

Recommendations

Future research should focus on validating the health disparities framework through quantitative scoring processes to complement the qualitative insights of this study. Expanding the analysis to include other value assessment frameworks both within and outside the US would provide a broader perspective on how health disparities are considered across different contexts. Incorporating diverse data sources, such as interviews and stakeholder feedback, could offer a more comprehensive view of health disparity considerations. Additionally, examining the historical evolution of the ICER framework and its impact on health disparities assessments could provide valuable insights. Lastly, employing in-depth semi-structured interviews or similar methods in future studies would help capture contextual nuances and fully explore all relevant themes related to health disparities. Additional work should also be done to organize patient experience data in a way that facilitates incorporation into economic models. All in all, future research should focus on integrating the identified themes into refined economic models to better capture health disparities. Additionally, developing standardized methodologies for consistently incorporating these themes into value assessments will promote more equitable and transparent evaluation processes.

Conclusions

After reviewing 19 ICER evidence reports for health disparities considerations, we found multiple examples where stakeholder input collected by ICER could inform economic modeling to account for potential disparities impacts. However, this was not consistent throughout the reports and methodological decisions whether to include a disparity-related factor into the final model were unclear. Our findings highlight the need for a systematic approach to considering health disparities within a value assessment framework and more transparency around how final cost-effectiveness approaches are determined.

Data Sharing Statement

All data generated or analyzed during this study are included in this published article (and its supplementary information files).

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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