

Health Disparities in US-Based Value Assessment Frameworks

Background and objectives

The United States (US) has finally reached a point where there is broad agreement and urgency to address health disparities and healthcare inequality. Some estimates suggest that disparities or inequities in health and healthcare have led to approximately \$93 billion in excess medical care costs, \$42 billion in lost productivity every year in the US,¹ and the incalculable societal costs.

Health and healthcare disparities exist across many disease states and are driven by social and economic inequities.

01 "Health disparities" primarily refers to subpopulations that experience a higher burden of illness, injury, disability, or mortality relative to the broader population.¹

02 "Healthcare disparities" include differences in insurance coverage, access to care, use of care, and quality of care, which are not justified by underlying health status or treatment preferences.^{1,2}

03 "Health inequities" stem from systematic differences in ethnicity, age, gender, and socioeconomic status, which have significant costs to both individuals and society.³

As the US looks to incorporate broader elements of value in healthcare coverage decisions, a logical starting point is examining health disparities in value assessment frameworks (VAFs). In particular, the Institute for Clinical and Economic Review (ICER) has been gaining traction among US payers, who are increasingly using ICER's recommendations in their formulary decision making.⁴ However, there is a limited understanding of how VAFs incorporate or address health disparities. To better understand how health and healthcare disparities are being considered in US-based VAF processes and outputs, we reviewed select ICER reports and other US-based VAFs across a sample of therapeutic areas (TAs).



In this issue brief, we describe the findings from this research and include recommendations for how healthcare stakeholders can more meaningfully incorporate health and healthcare disparities and population heterogeneity as part of their research and decision making.

ICER's approach to health disparities

While ICER's approach to value assessment and its mission reflect an awareness of the importance of addressing health and healthcare disparities, we found there was a general lack of incorporation of health and healthcare disparities after reviewing ICER reports across 6 key TAs (see Table 1).

Table 1. ICER's overall approach to health disparities



ICER's mission is to provide high-value care to all patients at a fair price⁵



Prioritizes selection of topics that "involve vulnerable populations with the potential to reduce disparities"⁶



Includes a voting question on an intervention's ability to reduce important health disparities to capture the presence of disparities for policymakers as a potential other benefit/disadvantage⁷



Explores scenario analysis methods to capture impacts on disparities in life expectancy across different subpopulations when feasible⁷



Described the importance of new leadership members' previous experience with closing health disparity gaps in a recent press release⁸



Included assessing digital apps to reduce health disparities for people with disabilities as one of its non-drug topics in 2020⁹

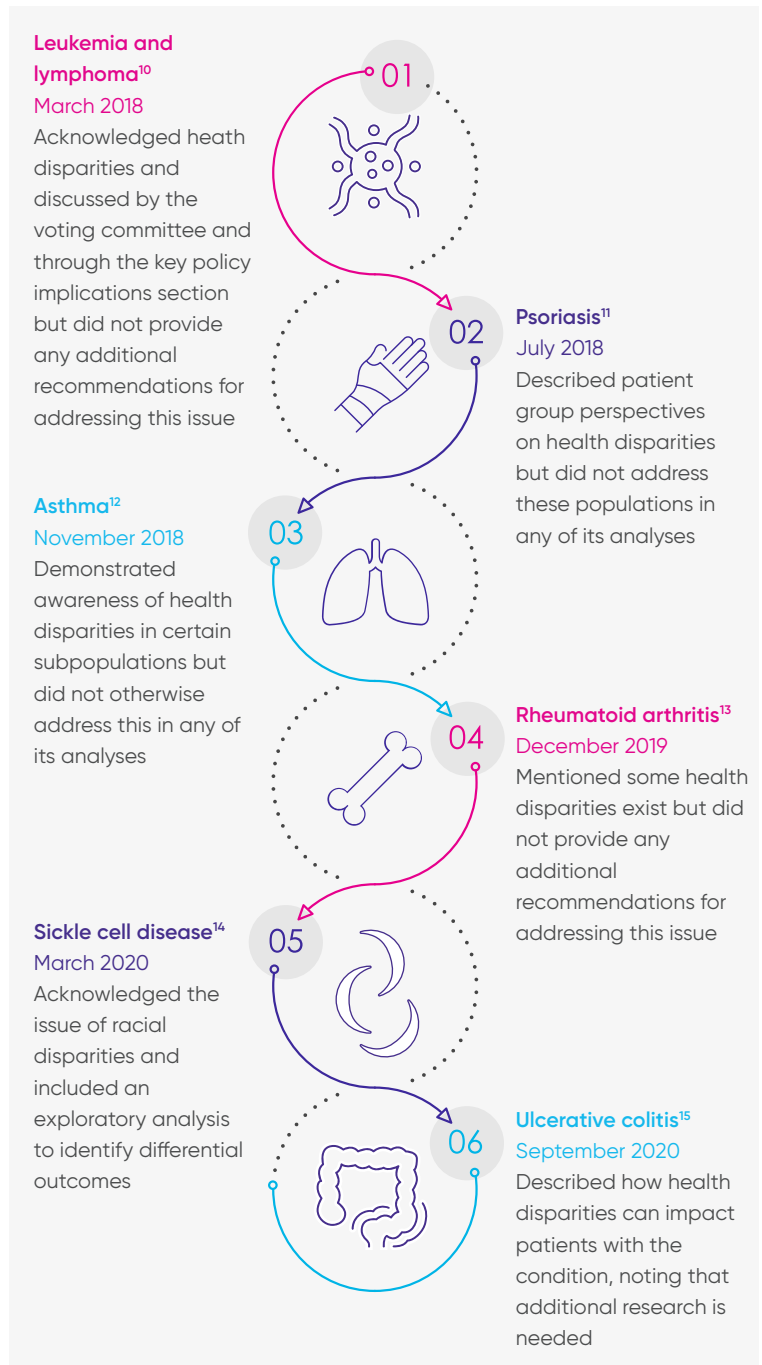


In 4 of the 6 ICER reports reviewed, ICER broadly acknowledged that health or healthcare disparities within the TA exist, but these were not discussed in detail or analyzed in any way (see Figure 1). The remaining ICER reports for ulcerative colitis (UC) and sickle cell disease (SCD) went into detail about issues related to health disparities.

In the UC report, ICER described how health disparities can impact patients with the disease. As part of the report section on UC's impact on patients, ICER highlighted efforts being made by the Crohn's and Colitis Foundation in collaboration with the US Centers for Disease Control and Prevention to study minority populations, as well as how the presence of more severe disease among racial and ethnic minorities can exacerbate issues surrounding access to treatment. Furthermore, ICER noted that there are poorly understood differences in how racial and ethnic minorities experience UC and data are lacking to better understand the impact of these disparities on individuals with UC. However, health disparities were not otherwise discussed in the report and were not formally considered in any of the analyses, including ICER's assessment of cost-effectiveness.

Throughout the SCD report, ICER emphasized the need to address racial health disparities to improve access to effective treatments. The report includes a section titled, "Insights Gained from Discussions with Patients and Patient Groups," with a subsection for racial bias that describes how racial disparities are particularly problematic in SCD. Racial disparities were also directly incorporated in ICER's economic model via multiple exploratory analyses in the context of decreased life expectancy and the potential gains from improved access to therapy. Specifically, the model included an analysis with a SCD population matched to a control population to assess the impact on life expectancy if all individuals with SCD were able to access treatment. The analysis demonstrated a 1% decrease in life expectancy that was specifically related to racial disparities. There were some noted limitations of the analysis, including that it did not capture the full psychosocial impact of racism, which primarily affects underserved populations. Nevertheless, the SCD report was the only ICER evaluation where health disparities were included in the form of a quantitative assessment, which emphasized the importance of addressing racial disparities to reduce barriers to treatment.

Figure 1. Summary of references to health disparities in ICER reports for select therapeutic areas








Key: ICER – Institute for Clinical and Economic Review.

Other US-based VAF approaches to health disparities

Other US-based VAFs assessed included the Memorial Sloan Kettering Cancer Center (MSKCC) Drug Abacus, American Society of Clinical Oncology (ASCO) Value Framework, National Comprehensive Cancer Network (NCCN) Evidence Blocks, Innovation and Value Initiative (IVI) Value Model, and Patient-Centered Outcomes Research Institute (PCORI). Although all US-based VAFs include addressing health disparities as part of their organizational priorities, most do not explicitly consider health and healthcare disparities and population heterogeneity as part of their frameworks (see Table 2).

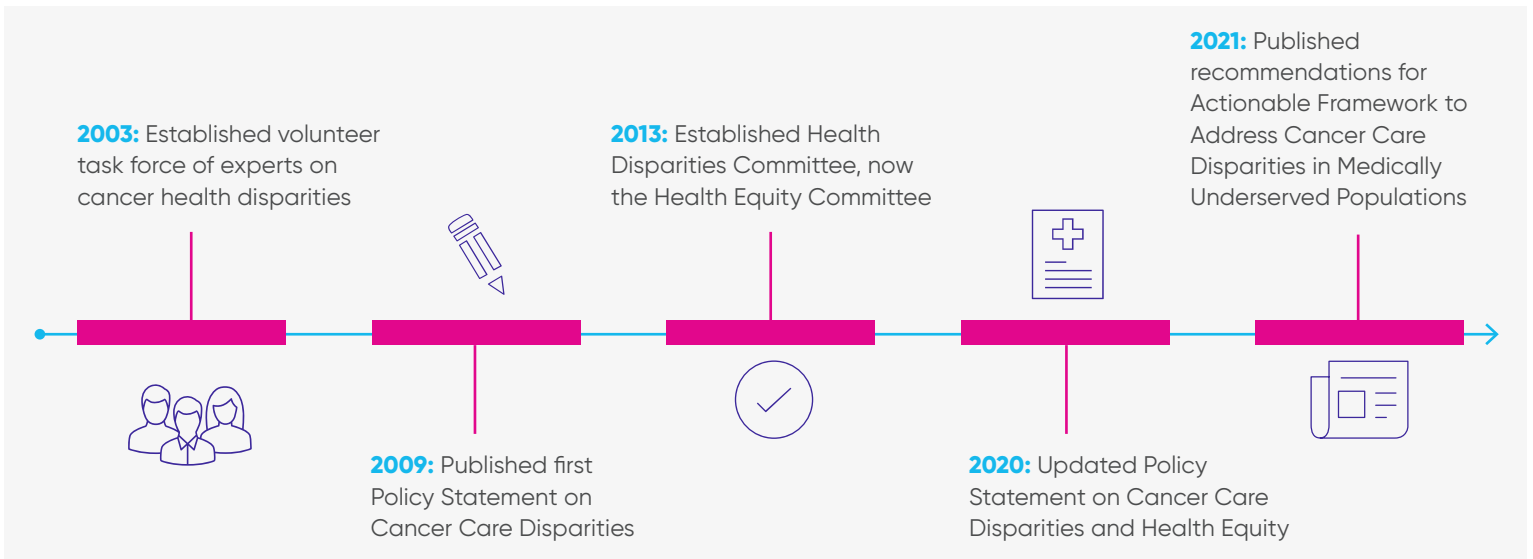
Table 2. Summary of other US-based value frameworks

Organization/VAF	Year introduced	Framework characteristics addressing health disparities	Other priorities in addressing health disparities
	2010 (created through the Affordable Care Act)	Provides funding for research projects across many therapeutic areas, including projects addressing health disparities	As of March 2021, funded 105 research studies to help patients at risk for health disparities
 Memorial Sloan Kettering Cancer Center	2015	Addresses humanistic burden (burden of disease and unmet need), but factors associated with health or healthcare disparities are not specifically incorporated as a modifiable input	No initiatives identified
 National Comprehensive Cancer Network	2015	Available across many drugs for oncology indications, but does not address health disparities specifically	<ul style="list-style-type: none"> Established an Elevating Cancer Equity Working Group Published Equity Report Card (2021) and developed policy recommendations to address disparities
 American Society of Clinical Oncology	2016	Includes out-of-pocket costs and quality of life, but does not address health disparities specifically	<ul style="list-style-type: none"> Established a Health Equity Committee in 2020 Published "Policy Statement on Cancer Care Disparities and Health Equity" (2009; 2020) Published "Recommendations for Actionable Framework to Address Cancer Care Disparities in Medically Underserved Populations in US" (2021)
 INNOVATION AND VALUE INITIATIVE	2016	<ul style="list-style-type: none"> Open-source model for select indications Framework addresses impact of morbidity on quality of life and key patient characteristics (eg, sex, age, disease activity, and functional status at baseline), but race/ethnicity and other factors related to health disparities are not incorporated 	<ul style="list-style-type: none"> Published "Principles for Value Assessment" (2021), which supports reducing health disparities and improving health equity Hosted a 3-part webinar series on advancing equity in value assessment, including a section on "Methods in Value Assessment that Support Equity" in June 2021

Key: ASCO – American Society of Clinical Oncology; IVI – Innovation and Value Initiative; MSKCC – Memorial Sloan Kettering Cancer Center; NCCN – National Comprehensive Cancer Network; PCORI – Patient-Centered Outcomes Research Institute; US – United States; VAF – value assessment framework.

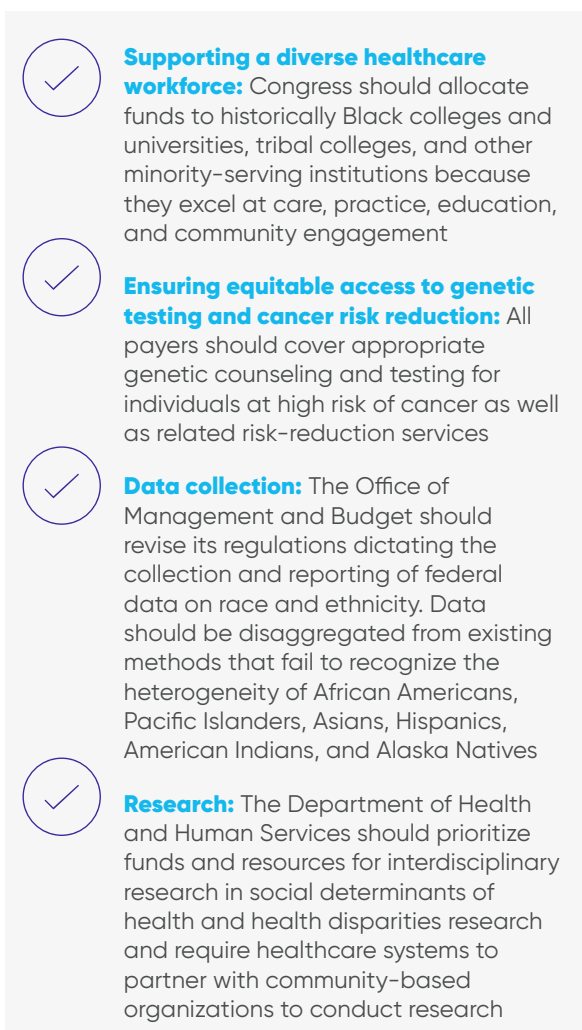
For example, although ASCO has implemented several initiatives to help address health disparities and inequities, including establishing a Health Equity Committee that has published several white papers on addressing disparities in cancer care, the ASCO Value Framework does not specifically incorporate health disparities within the value assessment process. **Figure 2** below demonstrates ASCO's history of implementing initiatives in health disparities. Similarly, while NCCN has established an Elevating Cancer Equity Working Group, which has developed policy recommendations for addressing health disparities in cancer care (see **Figure 3**), the NCCN Evidence Blocks do not specifically address disparities as part of the framework.

Figure 2. Timeline of ASCO initiatives in health disparities



Key: ASCO – American Society of Clinical Oncology.

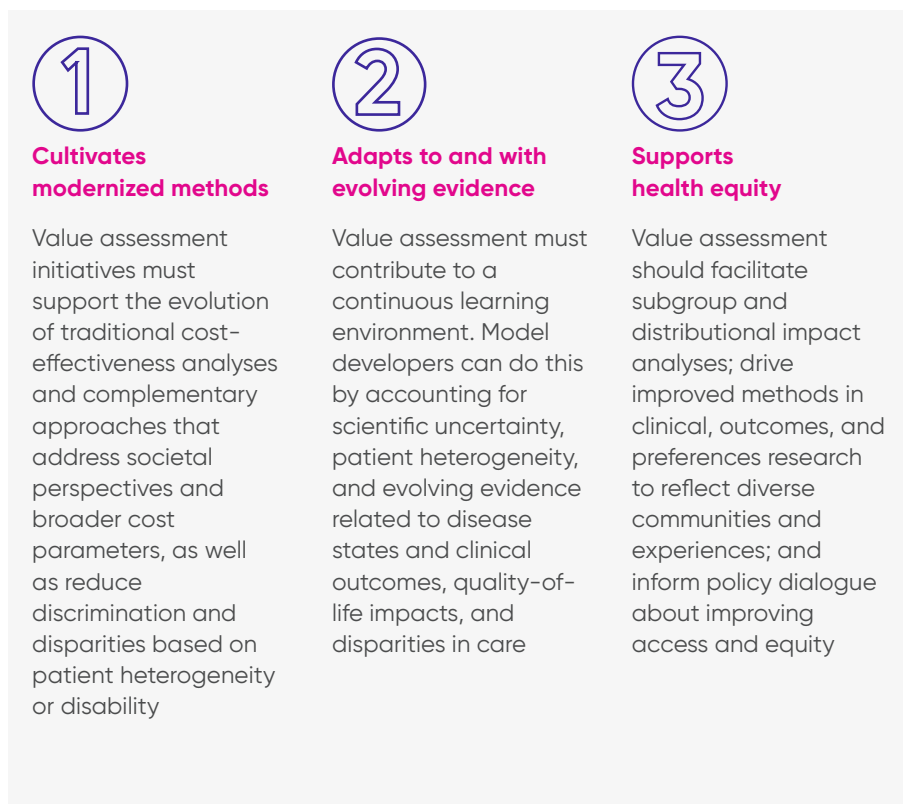
Figure 3. Policy change recommendations from NCCN’s Elevating Cancer Equity Working Group



Key: NCCN – National Comprehensive Cancer Network.

Similar to ICER, IVI’s mission and several core principles reflect a commitment to improving health disparities and health equity (see Figure 4).¹⁶ Additionally, IVI’s open-source models address the impact of morbidity on quality of life and key population characteristics such as sex, age, disease activity, and functional status at baseline; however, race/ethnicity and other factors related to health and healthcare disparities are not currently incorporated in the models.

Figure 4. IVI’s core principles



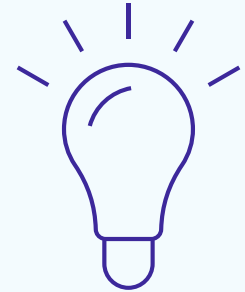
Key: IVI – Innovation and Value Initiative.



While PCORI does not have a value assessment model and is not formally considered a VAF, the organization informs healthcare decision making through its comparative clinical effectiveness research, horizon scanning, and evidence synthesis reports. Addressing health disparities is also 1 of PCORI’s 5 national priorities for research, and over 100 comparative clinical effectiveness research studies and related projects have been funded to help individuals at risk for health disparities.

Conclusions

Current VAFs in the US do not yet adequately incorporate health disparities in the value assessment process. Only 2 of the 6 ICER reports that were reviewed addressed health disparities in a meaningful way, and only 1 ICER report specifically included a quantitative analysis incorporating racial disparities. With the exception of IVI, other US-based VAFs also do not explicitly incorporate health or healthcare disparities in their respective frameworks, though 2 of these organizations have recently implemented other initiatives centered around addressing disparities in cancer care. A summary of the lessons learned and recommendations to improve value assessment in the US are listed below.



ICER rarely considers health disparities formally in its reports, noting a lack of published data in this space at the time of review; it is important to ensure these data are incorporated as inputs in its quantitative value assessments once available



ASCO recognizes that health disparities are important considerations for the health system and recommends conducting more research in this area to address barriers and promote equitable research participation



NCCN recommends requiring the FDA to consider trial diversity as part of the drug approval process to better address health disparities; it also suggests that implicit bias training will help address biases in care delivery



IVI incorporates some health disparities in its model framework; additional models should be developed to understand how this approach can lead to better outcomes across TAs with well-known disparities



PCORI plays an important role in funding health disparities research; data from these studies can be used to inform a future US value assessment strategy that better addresses inequities in healthcare

Key: ASCO – American Society of Clinical Oncology; FDA – Food and Drug Administration; ICER – Institute for Clinical and Economic Review; IVI – Innovation and Value Initiative; NCCN – National Comprehensive Cancer Network; PCORI – Patient-Centered Outcomes Research Institute; TA – therapeutic area; US – United States.

Key recommendations for stakeholders

Figure 5 below represents the key recommendations healthcare stakeholders should consider to better incorporate health and healthcare disparities in decision making. These stakeholders should work collaboratively to ensure that data on disparities are being generated and applied across the healthcare continuum.

Figure 5. Recommendations for key healthcare stakeholders

01 VAF organizations

- Make a concerted effort to quantitatively assess health and healthcare disparities and heterogeneity wherever possible, or, at minimum, include a call to action to conduct additional research where data gaps exist
 - It is also important for VAFs to consistently recognize where data are lacking and the resulting uncertainty created by these data gaps so healthcare decision makers can use caution when making conclusions that may disadvantage certain subpopulations as a result
 - Include research on health and healthcare disparities and heterogeneity that is multivariate (eg, understanding the combined impacts of socioeconomic status and race/ethnicity in a particular disease state, rather than just one of these factors)
- Ensure committees and panels that are charged with evaluating the evidence across different TAs are diverse and include proper representation of the populations being evaluated
 - Incorporate implicit bias training for all members
- Commit to adopting patient-centered value assessment methodologies in all assessments and solicit input from diverse patients, families, and caregivers, where possible
- Ensure that RWE is incorporated when the data become available
 - VAF organizations should be willing to accept and utilize RWE data to make quantitative assessments in the absence of, or to supplement, clinical trial data in specific populations
- Allow for open-source modeling with modifiable inputs for inclusion of data on populations with health and healthcare disparities

02 Manufacturers

- Commit to improving diversity among clinical investigators, educating minority and disenfranchised populations about the role of clinical trials, and improving community outreach so that research is more heterogeneous
- Plan studies, research, and development programs that promote inclusion of diverse populations and seek input from those communities throughout the process
- Conduct additional RWE studies looking at different subpopulations to examine health and healthcare disparities in access, quality of care, and outcomes

03 Payers and providers

- Use caution when using VAFs in healthcare decision making at a population level
 - Because VAFs rarely consider health disparities in assessments of value, it is important not to consider these recommendations in isolation when making formulary and medical policy decisions that impact access to treatment. This is particularly important for payers who serve vulnerable member populations (eg, Medicaid and Medicare) and providers who are working with patients of low socioeconomic status and/or are racial or culturally diverse
- Incorporate health equity and social determinants of health data elements in claims and EMR systems for all patients to provide a mechanism for managing health outcomes and cost of care that will improve healthcare decision making

Key: EMR – electronic medical record; RWE – real-world evidence; TA – therapeutic area; VAF – value assessment framework.

Methods

TAs that are commonly associated with health disparities and were evaluated by ICER within the last 3 years were selected. When choosing TAs, at least 1 oncology topic was targeted for inclusion as several US-based VAFs (ASCO, MSKCC, and NCCN) only evaluate oncology therapeutics. A framework was developed to weigh the different TAs in a health disparities context, and this framework was reviewed and confirmed by internal stakeholders to produce a final list of TAs that have the potential to impact value assessment. The final list of key TAs included asthma, psoriasis, rheumatoid arthritis, sickle cell disease, ulcerative colitis, and leukemia and lymphoma. ICER's methodology and reports on these 6 key TAs were reviewed, and references to health disparities were extracted and assessed. Other US-based VAFs were evaluated more broadly to determine if health disparities were being considered in their frameworks and output.

Research limitations

There are some limitations that should be considered when interpreting the findings of this research. First, only a sample of TAs with health and healthcare disparities were included and analyzed. Second, some VAFs do not have an updated methodology to include complex inputs such as health disparities. Finally, health and healthcare disparities are distinct but were evaluated at an aggregate level rather than addressing these concepts individually.

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