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REVIEW ARTICLE

Are Health Technology Assessments Keeping Pace with Health Equity Priorities: A Review of Existing Approaches and Discussion of Emerging Practices

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ABSTRACT

Health technology assessments are evaluation tools used by decision makers and governing bodies to evaluate the relative effectiveness, safety, and cost of new health technologies. Despite the significant access and reimbursement implications of the decisions informed by health technology assessments, health equity is not consistently included in these assessments. This review explores current health technology assessment approaches using global examples, examines how health technology assessments include health equity considerations, reviews how health equity is not optimally included in health technology assessments using a case study example, and discusses emerging practices to include more health equity related metrics using examples from sponsors and health technology assessment agencies. Results show that health technology assessments do not have a consistent, clearly defined measures of health equity impact or methods to include health equity-oriented measures in assessments. Additionally, most do not provide differentiated value assessments for health equity-oriented data or impact. However, innovators and health technology assessment organizations are presenting new approaches to evaluation. Some outside groups are advocating for change and investing in developing health equity checklists and frameworks for incorporation in health technology assessments. Moving forward, more research is needed to understand how to best incorporate heath equity-oriented measures into health technology assessments and how innovators can get more involved to inform both product development and evaluation efforts. If done well, health technology assessments can be developed to reward technologies and research programs that have a significant and measurable impact on delivering more equitable health outcomes.

Introduction

Health equity is an aspirational goal "achieved when everyone can attain their full potential for health and well-being," as defined by the World Health Organization.[1] Rooted in the historical underpinnings of structural inequities and social determinants of health, health disparities continue to persist today across race, ethnicity, gender, socioeconomic status, and more. Advancing health equity necessitates collective action at every level across and beyond the health ecosystem. In recent years, health equity has become a core focal point for health organizations due to a combination of greater awareness of health disparities and mounting pressure from regulatory bodies. In the United States, the Centers for Medicare and Medicaid Services, Federal Drug Administration, and the National Committee for Quality Assurance released a range of new requirements affecting payer, provider, and pharma organizations. These mandates and guidelines are aimed toward changing how health equity is incorporated into strategy, addressed in clinical trials, measured and monitored in data analytics, and driven through the workforce.[2,3] These changes highlight how health equity is emerging as an increasingly important health system goal beginning to be addressed in policy and practice.

Health technology assessments (HTAs) evaluate the relative effectiveness, safety, and cost of new health technologies like drugs and medical devices. The findings from HTAs are frequently a key input for commercial and governmental payers to make access and reimbursement decisions and for health policymakers to determine budget spending. This in turn impacts how manufacturers determine research priorities and invest in evidence development to support market access and product launch. These assessments serve as gatekeepers as well as arbiters of value for new healthcare products. Their methods offer a window into health system or assessment organization values, by weighing the relative merits of different clinical and economic outcomes to reflect their health system priorities. For example, a cancer drug that extends progression-free survival by 6 months, but not overall survival, may be highly valued by one HTA assessment if quality of life is an important metric. If that same product costs twice as much as the standard of care, it might be rejected by another group prioritizing cost and longer-term outcomes. Similarly, a diabetes drug that shows greater tolerability among indigenous people or higher adherence rates among low socio-economic-strata patients might never get positive marks for those attributes if the HTA doesn't consider sub-group analyses in their methodology. Because the result of HTAs frequently determine population access to a product, it becomes necessary to understand how and if HTA organizations are evaluating clinical, quality and access impact to those who need the new product most or who are most likely to fail on existing therapies – not based on biology but based on social determinants of health.

While HTAs commonly evaluate data related to safety, clinical efficacy, and cost, they largely do not consider the technology's impact on equitable health outcomes.[4] Exploring if and how health equity is examined by HTAs can shed light on where investments in health equity by innovators are valued, and to what degree they are overlooked within the HTA process. As noted, recent policy changes in the United States are beginning to require more diverse participation in clinical trials, though how the availability of the associated population-specific data will be leveraged by HTA organizations is unclear.[5] For example, there is no clear incentive for a company who invests in oversampling high-risk, multi-morbid patients in a clinical development program, assesses and presents their data by sub-population, or explores the relative value of different delivery modalities to high-risk patients. Evaluation of health technologies through a health equity lens has the potential to expand access to high-quality healthcare for marginalized communities, increase investment in data that demonstrates impact in hard-to-reach populations, highlight affordability gaps, and encourage prioritization of health equity considerations from the start of innovation. This study reviews the current state of health equity considerations within HTAs, emerging practices, and preliminary deliberations for how health equity could be incorporated moving forward.

Methodology

A review of HTA methodologies and their approaches to including health equity considerations was conducted. To understand the current level of consistency and inclusion of health equity, we reviewed methods within and across HTAs from Australia, Canada, Germany, the United Kingdom, and the United States. Given that cardiovascular diseases are the leading cause of death globally and have significant health

disparities in terms of who is impacted and who has access to care, we conducted an evaluation of published HTAs for empagliflozin (brand name Jardiance), a drug with a recent indication for chronic heart failure[6]. This formed the basis for case study evaluation of how health equity measures or considerations showed up in published HTAs of a novel drug used to treat a disease with high disparities as a real-world application of assessment principles.

The current global HTA landscape, HTA methodologies, and case studies were then categorized by their included review criteria and assessed for health equity-oriented measures and metrics. Examples of HTA oriented measures and metrics identified and measured include the ability to conduct subgroup analysis on high-risk or high need populations and outcomes measures reflecting social determinant of health impacted measures. In parallel, a review of HTA improvement efforts related to health equity was conducted and used as a foundation for considering recommended next steps in conjunction with assessment findings.

Global Health Technology Assessment Landscape

In 2020-2021, the World Health Organization Secretariat conducted a survey across 127 countries to track the progress and development of country processes for HTAs. Most respondents (82%) said they have a systematic, formal health decision-making process at the national level, sub-national level, or both. Of the countries that have a systematic, formal health decision-making process, 62% refers to their process as HTA.[7] Health technology assessments are most advanced in industrialized countries, but there is an increasing number of middle-income countries using HTAs.[8] Current evaluation methodologies focus on the safety, clinical effectiveness, cost-effectiveness, and impact on patient quality of life of new products drawn from Phase 1-3 clinical data that describe the comparative impact of a novel product in a controlled setting to either placebo or a standard of care (see Table 1). Many also include a budget impact, cost-impact, or cost-effectiveness analysis drawn primarily from direct medical costs, or phase 4 real world evidence in their assessment.

Table 1: Guidelines for conducting an HTA as defined by the respective organization

Country	HTA Organization	Safety	Clinical Effectiveness	Cost Effectiveness (i.e., Health Economics)	Patient Quality of Life	Equity	Near Market Comparator	Health System Readiness (i.e., Organization Considerations)	Ethical and Social Concerns
Australia	Pharmaceutical Benefits Advisory Committee (PBAC)[9]	✓	✓	✓	✓		✓	✓	
Canada	Canadian Agency for Drugs and Technologies in Health (CADTH)[10]	✓	✓	✓	✓			✓	✓
Germany	The Federal Joint Committee (G-BA)[11]		✓	✓			✓		
United States	Agency for Healthcare Research and Quality (AHRQ)[12]	✓	✓		✓		✓		
United Kingdom	National Institute for Health and Care Excellence (NICE)[13]		✓	✓			✓		✓

Initially, HTAs were primarily used to support decisions to list or de-list pharmaceuticals and devices.[14] Today, HTAs can also inform a more robust health decision-making process, a more varied access landscape, and may include new methods of assessment. Countries with HTA organizations have differing attitudes towards the use of HTAs. Some countries use HTA extensively, while others use them less frequently or intermittently.[8] Stakeholders largely agree that there can't be a "one-size-fits-all" approach to HTAs for countries around the world, given differences in local healthcare priorities, cultural contexts, healthcare delivery infrastructure variance, and affordability differences.

How Health Equity Is Included in Health Technology Assessments

While most HTAs have well-established metrics for measuring the cost-effectiveness of new technologies in comparison to existing technologies, they do not include metrics to assess health equity impact.[15] Moreover, a standardized framework for assessing health equity impact does not currently exist.[16] While some analyze near-market comparators or alternative treatments, health system and organizational readiness, and ethical and social concerns, none of the HTAs directly evaluate equity in their key considerations for new drugs or medical technologies.

Similarly, health equity challenges appear significantly different in each market. In the United States, racial, ethnic, and socioeconomic disparities are prevalent. In other markets with more homogeneous racial/ethnic population mixes, disparities might relate more to urban/rural divides or be based on economic status. In China, for instance, research from the National Institutes of Health has shown a substantial gap in health equity between urban and rural populations, leading to rural populations lacking equitable healthcare access and receiving less reimbursement for treatments.[17] Japan, on the other hand, experiences health equity disparities along economic lines, with lower socioeconomic status individuals facing higher mortality rates than their high socioeconomic status counterparts.[18] These basic differences across markets make creating a single health equity lens and impact evaluation framework difficult.

Recent Health Technology Assessment Examples Demonstrate How Health Equity is Not Optimally Considered

As the healthcare landscape evolves and new technologies and drugs are introduced, it is critical to ensure that these additions do not exacerbate existing health inequalities. Recent health technology assessments do not optimally incorporate health equity considerations in the evaluation process, especially surrounding diabetes, oncology, and chronic heart failure (CHF). To understand the relationship between HTAs and health equity considerations through a real-world example, recent HTAs for a pharmaceutical treatment for CHF were reviewed.

Chronic heart failure is a progressive condition in which the heart is unable to efficiently pump enough blood to meet the body's needs. Heart failure affects over 64 million people worldwide with an estimated cost of 9.9 million years of life lost to disability and $346 billion USD.[19] Like many disease areas, CHF is rife with disparities. Racial and ethnic minorities have the highest incidence, prevalence, hospitalization, and mortality rates for heart failure in the United States.[4] In Australia, the 12-month mortality rate for CHF was 1.9 times higher in Indigenous patients under 59 than non-Indigenous patients.[20] From 2000 to 2017, hospital admissions due to heart failure increased 34% more in East Germany than in West Germany, despite umbrella health system alignment upon reunification in 1990 with universal health coverage having also been mandated for all citizens and permanent residents in 2007.[21] Empagliflozin was introduced as an adjunct to standard-of-care therapy for the treatment of chronic heart failure and evaluated by multiple HTAs in 2021 and 2022 (see Table 2).

Across the identified HTAs, health disparities and health equity impacts were sparsely discussed. The Pharmaceutical Benefits Advisory Committee of Australia identified that the prevalence of heart failure is 1.7 times higher in Indigenous than non-Indigenous Australians and noted unequal sample sizes of race subgroups for clinical analysis, but no treatment interaction effects identified by race. The National Institute for Health and Care Excellence (NICE) in the UK identified differences between the clinical trial participant demographics and incidence demographics in the country on the basis of average age and gender imbalance. It also noted that SGLT2 inhibitors – the class of medications empagliflozin belongs to – have been found to be most effective in people with a Black or Asian family background.

Aside from these instances, the HTAs from either country do not otherwise directly address the role of health equity or its drivers. In the HTAs from Canada and Germany, no deliberation on health equity, health disparities, race, ethnicity, or other related subjects are mentioned.

Table 2: Implied Health Equity or Health Disparity Considerations in HTA Evaluations of Empagliflozin

Country	HTA Organization	Implied area of health equity or health disparity consideration						
		Disease Disparities	Clinical Trial Diversity	Equitable Clinical Efficacy	Implicit Bias	Implications For:		
						Equitable Access	Affordability	Equitable Care Quality
Australia	Pharmaceutical Benefits Advisory Committee (PBAC)[22]	✓ Disease prevalence disparity for Indigenous versus non-Indigenous Australians	--	✓ Discussion of treatment interaction effect by race	--	--	--	--
Canada	Canadian Agency for Drugs and Technologies in Health (CADTH)[23]	--	--	--	--	--	--	--
Germany	The Federal Joint Committee (G-BA)[24]	--	--	--	--	--	--	--
United Kingdom (UK)	National Institute for Health and Care Excellence[25]	--	✓ On the basis of age and gender	✓ Discussion of treatment interaction effect by race	--	--	--	--

Note: ICER has not yet published an evaluation on empagliflozin for this indication.

The Evolution of Health Technology Assessments Toward Supporting More Equitable Health

Organizations are beginning to prioritize the need to improve HTA methodologies and research how health equity should be systematically and comprehensively evaluated in HTAs. In 2021, the World Health Organization developed a comprehensive framework for HTA decision criteria, which includes assessment of safety, clinical effectiveness, economic considerations, budget impact analysis, organization impact, feasibility considerations, acceptability to health care providers, acceptability to patients and equity and ethical issues.[14] The broader assessment context was developed as a guide for implementing an HTA mechanism to inform the decision-making process, and equity issues were specifically identified as a dimension that HTAs should consider.

In 2022, the Partnership to Improve Patient Care, Global Liver Institute, National Minority Quality Forum, and the Preparedness & Treatment Equity Coalition published recommendations for organizations, health systems, payers, and policymakers on how to incorporate health equity into value assessments.[26] The report details the need to focus on addressing data gaps, improving methodologies contributing to health inequity, and increasing engagement, particularly among people excluded from the data.

Researchers at the University of Toronto have also developed a framework that can be used to develop a checklist of equity considerations that can be incorporated into HTAs alongside the usual efficiency metrics.**Error! Bookmark not defined.** The framework includes elements, such as embedded inequality, institutional bias, and implicit stereotyping. As a whole, the framework is meant to identify "red flags" in areas where decision-makers should further investigate matters of equity, and advisory bodies and decision-makers can use this framework to identify dimensions of health equity that should be considered in HTAs. Informed by this framework, other researchers have developed a health equity checklist that was piloted in a 2018 HTA.[27]

Recognizing the importance of health equity measures to comprehensive and effective HTAs, the Commonwealth Fund awarded the Institute for Clinical and Economic Review (ICER) with a grant to define methods to integrate health equity into HTAs with the ultimate goal of developing assessments that accurately and comprehensively measure the value of treatments to patients and society.[28] In its report, ICER shared key

recommendations for methods through which HTAs in the United States could improve health equity.[29] Consistent with previous research, ICER recommended that HTA bodies engage directly with diverse groups of patients to learn about their experiences and understand their perspectives of the potential health equity-related impacts of the intervention under review. Additionally, ICER recommends that governing bodies establish a minimum threshold for adequate representation of racial and ethnic populations in clinical trials and a sample diversity rating tool. The ICER report warns against analyzing and interpreting HTA results solely by race and ethnicity subpopulation and encourages careful consideration before investigation of differential subpopulation effects. Integration of social values and policy decisions is important to deliberative HTAs, and ICER recommends that governing bodies thoughtfully ingrate these considerations instead of using quantitative equity-informative economic evaluation only. Finally, ICER suggests that HTAs should accept the responsibility of providing information beyond just the technical analysis of the intervention under review, and HTAs should address potential policy interventions and highlight structural aspects of the health care system that should be changed to ensure that disparities are not exacerbated with the introduction of new interventions.

An example of this shift towards prioritizing health equity is the growing criticism of the quality-adjusted life year (QALY) methodology, which can be used to determine drug cost-effectiveness in terms of willingness to pay for each additional QALY gained from an intervention. To generate a QALY, quality of life is rated on a scale from 0 to 1, with 1 being "perfect health" and that value is multiplied by the years of life lived. Individuals with disabilities might be assigned a quality of life of 0.5, meaning they accrue fewer QALYs for each year of life lived versus perfectly healthy individual.[30] This can result in an intervention being labeled "not cost effective" and thus not eligible for reimbursement for this population. Because of these shortcomings, the use of QALY has been banned in determining cost-effectiveness in Medicare programs. Within the UK, QALY was so inhibiting to the pricing of cancer treatments that the NHS developed their own Cancer Drugs Fund to pay for cancer drugs despite poor QALY ratings.[31]

Although research into how health equity can be considered in HTAs is preliminary, a growing number of organizations are realizing the need to include health equity measures in HTAs.[32] Despite ongoing research into methods for including health equity in HTAs, a validated, standard health equity approach remains unimplemented. Additionally, the global application of health equity frameworks is undetermined.

Perspectives from the Manufacturers

The lack of consistent evaluation frameworks and clear guidance on the value that HTAs intend to place on health equity impact creates uncertainty for how innovators should invest in and prioritize measuring impact in this space. Despite variance in population health in specific markets, HTAs as they exist today have managed to develop a relatively consistent criteria and assessment approach. Since 2006, the European Union has been working diligently towards the incremental standardization of HTAs through the guidance of government bodies and transparency of the assessments.[33] As a multi-payer system, HTA bodies in the United States have more discrepancies as self-insured employers and private insurers contribute independent methodologies.[29] Over time, greater consistency in measures and approach has emerged generally but more work is needed. Efforts to develop aligned HTA methods and metrics overall lay the foundation for how to consider developing consistent parameters and metrics specific to health equity. If accomplished, this could accelerate how manufacturers invest in health equity-oriented products and data.

Greater clarity and consistency can help market access and health economics and outcomes research departments at BioPharma and device companies plan early in product lifecycles and allocate appropriate research budgets. Manufacturers need clear, time-bound metrics against which to design appropriate research programs to measure and then demonstrate the impact on health equity within and across HTAs. These measures will need to take health equity from a large, subjective concept into achievable, objective, and concrete goals towards which manufacturers can develop the evidence that HTA requires. Further, these goals need to be attainable in a reasonably short amount of time to support evidence generation. Improving health outcomes between the lowest risk/need and highest risk/need

deciles of the population may be a legitimate long-term goal for the health system, but this is not a practical endpoint for a clinical trial.

If health systems are serious about prioritizing health equity, they should consider both the carrot and the stick. Interventions that provide evidence of health equity improvement should gain some sort of advantage in the marketplace, and interventions that are likely to exacerbate health inequities should be discouraged. This will persuade manufacturers to consider the health equity implications of their pipelines and encourage investment in companies or assets with the potential to improve health equity in the population.

Incentives could be in the form of less restrictive access, or perhaps a higher price. For example, in incentivizing access for later-stage oncology treatments, NICE in the UK considers a higher cost per QALY threshold for treatments that meet these criteria. A similar increase in the acceptable cost per QALY, or the budget impact threshold, might be considered for interventions that have provided evidence of improvement in health equity. Disincentives might come in the form of reduced access or tougher price negotiations when an intervention is likely to exacerbate health inequity, especially in crowded therapeutic areas where there are many options.

Today, manufacturers who are focusing on bringing products to market that will disproportionately impact high risk/high-need populations are attempting to bring health equity into the conversation with HTA organizations and payers. They are discussing new types of data, the value of real-world evidence, and advanced modeling techniques that demonstrate potential differentiated impact on populations that healthcare innovation have historically underserved. Additionally, some are negotiating comparatively lower prices that lead to expanded and broad-based access. This type of innovation creates bi-directional accountability between the payers/HTAs and the companies bringing them new products to adapt approaches to development, pricing, access, and evaluation to fully change the health disparity curve.

Conclusions

Given the importance of HTAs in evaluating technologies and informing healthcare decision-making, there is an opportunity to develop HTA frameworks that more systematically consider health equity. Re-examining current evaluation methods with a health equity lens can help researchers identify ways to improve HTA methodology and address systematic exclusions and inequities that inform our decision-making. Additionally, incorporating health equity measures into HTA frameworks will incentivize companies to invest in areas that narrow outcomes and access gaps. Organizations that are responsible for developing health technology assessments can work to address health disparities and promote health equity by involving stakeholders from diverse backgrounds in the assessment process, consider the perspectives of disadvantaged populations, and use equity-focused criteria to evaluate technologies. By doing so, HTA organizations can help to enable greater accessibility and effectiveness for populations most in need, and recognize the impact of socioeconomic status, race, ethnicity, or other demographic factors to health outcomes in each setting.

As organizations consider additional ways to incorporate health equity into HTA processes, it will become increasingly possible to reward those companies investing in products that will be of benefit to therapeutic areas with high disparities or targeting high-risk patients specifically. It will also further incentivize pipelines that are assessed with a health-equity lens, thus driving investments towards products/programs with that focus. To do this, HTAs must develop, test, and deploy methodologies that prioritize equitable health outcomes versus general health outcomes.

More work is needed to develop specific metrics and methodologies, some of which is underway. These efforts should be conducted in cooperation not only with HTAs, companies, payers, and health economists but also with the communities of patients being served. Additionally, thinking through the broader context of care and the barriers patients face in optimizing outcomes can be a consideration in how health systems can achieve potential versus current state results. If using this lens, a collaborative and more comprehensive view of "what needs to be true for this new product to be successful in the real world, with high-risk patients" can be developed and worked towards. For example, people who live in rural communities may not be able to travel several hours to see the medical specialist to infuse an advanced therapy or assess progress. How companies and the healthcare systems they are interacting with overcome these

challenges can have a huge impact on delivering more equitable outcomes, and therefore should be included in how products are reviewed in HTAs. By focusing on health equity in HTAs, we can highlight the intersection of what manufacturers can achieve on their own to deliver impact and value to high-risk patients and where meaningful solutions needs to be developed and delivered collaboratively. More work is needed to research both optimal HTA approaches and how to deliver against value potential in the real world, across multiple care settings and target populations.

Conflicts of Interest Statement

The authors have no conflicts of interest to declare.

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