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Closing the gap: do we need a framework for embedding equity in health technology assessment?

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Perspective

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Abstract

Objectives: Reducing health inequalities and improving health equity have become pressing priorities for health technology assessment (HTA) bodies and healthcare payers globally, particularly in light of the COVID-19 pandemic and its disproportionate impact on disadvantaged groups. Equity considerations are now being embedded across strategic frameworks and HTA processes in countries such as the UK, Canada, and Australia. Examples include NICE's Core20PLUS5 initiative and PBAC's policy shift allowing broader prescribing access to address care disparities. However, systematically incorporating quantitative equity measures into HTA presents significant challenges, given the diversity of equity subgroups and varying national contexts.

Methods: At the 2024 CDA-AMC Symposium, we convened stakeholders to discuss the challenges and opportunities for integrating equity into HTA.

Results: Key insights included ICER's framework for embedding equity across the HTA lifecycle and NICE's evolving application of Distributional Cost-Effectiveness Analysis (DCEA), as demonstrated in the appraisal of exagamglogene autotemcel for beta-thalassemia. DCEA, while increasingly recognized, requires robust real-world data and clearer guidance on trade-offs between equity and efficiency. Manufacturers are aligning equity goals with ESG priorities but seek greater clarity from HTA bodies on how equity evidence influences decision-making. NICE and ICER emphasize the need for deliberative processes to capture equity dimensions not reflected in traditional cost-effectiveness analysis.

Conclusion: Advancing health equity in HTA will require cross-sector collaboration to develop guidance, improve data infrastructure, and standardize methodologies. Equity-focused evidence generation across the "staircase of inequality" – from need to access and outcomes – can support more inclusive HTA and reimbursement decisions, ultimately fostering a fairer and more effective healthcare system.

Reducing health inequalities and improving health equity is a stated priority of health technology assessment (HTA) bodies and payers globally and highlighted as a goal of Universal Health Coverage endorsed by the UN General Assembly. Health equity is defined by the World Health Organization (WHO) as the absence of unfair and avoidable or remediable differences in health among population groups defined socially, economically, demographically, or geographically. Addressing inequality is becoming more urgent due to several factors, including the roles of inequalities in societal issues such as rising healthcare demand, the introduction of high-cost health technologies, budget restrictions, and competing priorities. The COVID-19 pandemic also highlighted the harsh implications of inequalities on health and related outcomes (1).

Healthcare providers and policymakers are increasingly incorporating equity considerations into their strategic frameworks to apply them both in the assessment of medicines and technologies as well as in the provision of healthcare services. For instance, equity considerations are integrated into strategic documents like the Canada's Drug Agency – L'Agence des médicaments du Canada (CDA-AMC) 2022–2025 Strategic Plan (2) in Canada and the Institute for Clinical Economic Review (ICER) White Paper 2023 (3). In practice, healthcare providers in the United Kingdom and Australia have already implemented equity-focused initiatives. Examples include National Health Service (NHS) England's Core20PLUS5 initiative for adults (4), children, and young people (5), the adaptation of National Institute for Health and Care Excellence (NICE) guidelines to equity considerations, and the expansion of the Australian prescribing competency framework.

The incorporation of equity considerations into HTA may tangibly influence recommendations and healthcare access. In July 2022, for example, Australia's Pharmaceutical Benefits

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Advisory Committee (PBAC) broadened access to evolocumab by allowing prescriptions from general practitioners rather than restricting them to specialists, acknowledging the inequalities in access if restricted to specialist routes (6). The UK's NICE adapted obesity-related guidelines to consider higher health risks among some ethnic minorities at lower body mass index (BMI) thresholds (7). Similarly, NICE recently considered a distributional cost-effectiveness analysis for exagamglogene autotemcel (exa-cel, Casgevy), a treatment for sickle cell disease (SCD) and transfusion-dependent thalassemia, which disproportionately affect Black African and Caribbean populations (sickle cell disease) and Mediterranean, South Asian, Southeast Asian and Middle Eastern populations (thalassemia). This resulted in a willingness to accept greater uncertainty in clinical effectiveness data and to adjust the acceptable incremental cost-effectiveness ratio while being mindful of associated opportunity costs (8). These examples reflect a growing recognition of how inequities intersect with healthcare needs and outcomes and the evolving landscape where HTA can play a more substantive role in improving health equity. Both instances highlight direct, targeted interventions for specific issues, rather than attempts to incorporate quantitative (in)equity measures into existing appraisal frameworks. Incorporating equity considerations into HTA quantitatively, however, presents a range of challenges; not least is the availability of equity-relevant data; for example, quality-adjusted life expectancy (QALE) data, required to conduct a DCEA, is not available by ethnicity. Equity considerations are diverse and differ widely based on disease area, specific populations or equity subgroups, and national contexts.

The CDA-AMC 2024 Symposium featured a multidisciplinary panel to discuss the challenges and opportunities to systematically and comprehensively include equity considerations in HTA; in this commentary we provide a synthesis of the discussion that addressed the question of how health equity is considered in HTA. Jonny Pearson-Stuttard, Lane Clark & Peacock LLP, and the Royal Society for Public Health set the scene as to why health equity is of increasing importance to payers globally while highlighting that "one size does not fit all" to include equity considerations. Marina Richardson, ICER, shared learnings from ICER's 2023 white paper on inequalities, including the thought and considerations underpinning their recommendations. Susan Griffin, University of York, provided an overview of the technical considerations and opportunities for quantitative inclusion of health equity within economic evaluation. Christopher Lübker, Novo Nordisk and University of York, gave a perspective from medicine manufacturers as to why health equity is high on their agenda along with barriers to overcome for further investment in equity evidence generation. Finally, Stephen Duffield, NICE shared how considerations around addressing health equity are woven throughout NICE's work, including recent examples where quantitative equity considerations were captured in the HTA.

ICER highlighted these issues in its 2023 white paper, which presented a set of recommendations for HTA to advance conversations on improving health equity for disadvantaged and underserved groups, focusing on equity-related race, ethnicity, and socioeconomic status. ICER's recommendations advocate for integrating health equity throughout the HTA process – in topic selection, engaging patients and caregivers throughout the review process, evaluating the diversity of participants in clinical trials, and measuring the opportunity to reduce health disparities based on the disease prevalence in the subpopulation of interest compared to the prevalence in the overall population (9). ICER recognized the value of analyzing clinical evidence by subpopulations but suggested that cost-effectiveness estimates for subgroups based solely on race, ethnicity, or socioeconomic status not be conducted. This recommendation was primarily driven by the potential unintended consequences of conducting such analysis. It is possible that differential access to care, healthy food, or social supports impact health outcomes for certain populations that could then be inadvertently linked to outcomes from treatment. Additionally, when the cost-effectiveness analysis is used to support pricing and reimbursement, an analysis by subpopulation that is suggestive of a treatment being more cost-effective for one subgroup could then imply that it is less cost-effective for individuals who are not part of that subgroup (9). The white paper also emphasized the importance of the appraisal committee deliberation to consider aspects of health equity that may not have been fully captured in the clinical and economic synthesis of evidence – for example, having the committee vote on if the condition is of substantial relevance for people from a racial or ethnic group that have not been equitably served by, or have been excluded from, the health system, and if the treatment offers an opportunity to improve access to an effective treatment. Several emerging methods for equity-informed economic evaluations were highlighted, including for example, equity-based weighting, extended cost-effectiveness analysis, and distributional cost-effectiveness analysis (DCEA), however, ICER concluded that addressing data needs and appropriate interpretation and use in decision-making is needed before considered for routine use.

DCEA is one emerging method to incorporate equity more directly into HTA, through directly incorporating quantitative distributions of health needs and outcomes according to equity groups (10). DCEA requires comprehensive evidence across various stages coined the "staircase of inequality", quantifying the distribution across the equity subgroup: (i) who needs the intervention (e.g., prevalence and/or severity of disease); (ii) access and uptake of the intervention; (iii) efficacy (short and long term) and adherence; and (iv) opportunity costs. As real-world data (RWD) sources become more robust many of these stages are now being addressed empirically, but challenges remain. DCEAs are increasingly being published for both public health (11) and medical interventions (12) with increasing acceptance in the scientific community. However, for routine and systematic use, several challenges persist, including greater understanding of public preferences for the trade-off between overall population health and health equity. DCEA models the distribution of opportunity costs across equity subgroups and tradeoffs can often be visualized through equity-efficiency impact planes to demonstrate the relationship between population aggregate health and within-population inequalities.

Medicines manufacturers are also seeing reducing health inequalities as an increasing priority. Some have equity embedded in their core values through prioritizing patient access, while others see it as part of a broader focus on Environmental, Social, and Governance (ESG) principles (13). However, to encourage investment in additional evidence to demonstrate the impact of a medicine on inequalities, further guidance is sought from HTA bodies. Where possible, this would include coordinated guidance on which equity subgroups to prioritize for given conditions and how equity evidence would impact decision-making and, at best, providing incentives that align with payers' equity objectives. This would provide reassurance as to how equity-based evidence will be considered in HTA and reimbursement decisions, encourage its use, and embed it in long-term strategic objectives of manufacturers.

Tackling health inequalities is a key consideration for decision-making at many national HTA agencies. In England, for example, NICE have equity incorporated as a statutory duty, embedded within their guiding principles (14), their 5-year strategy (15),

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and methodological manuals. Meanwhile, many other activities indirectly address health equity; NICE's approach to rare diseases, for instance, allows for greater uncertainty in highly specialized technologies (HST) evaluations and the severity modifier (16) is, in some instances, used to improve outcomes for populations experiencing health disparities. NICE also leverage RWE to assess inclusivity within clinical trials and to help identify possible treatment effect variations.

Incorporating quantitative health equity considerations in HTA has been increasingly topical for NICE's committees. In early 2024, NICE appraised exagamglogene autotemcel for transfusion-dependent beta-thalassemia (8), utilizing a DCEA that stratified the population by income deprivation levels. Although the appraisal committee raised concerns about certain methods, such as the health inequality aversion parameter, the DCEA informed adjustments that led to the acceptance of a higher degree of uncertainty and an increased cost-effectiveness threshold, ultimately supporting the medicine's recommendation under a managed access scheme. NICE's evolving guidance on DCEAs reflects a shift toward acknowledging health inequalities where relevant, especially in cases with documented disparities in health outcomes across populations (17).

Despite increasing interest and discussion to systematically incorporate health equity in HTA, challenges to incorporating it in the most appropriate way, for a given context and medicine, persist. Clarity and consistency on the relevant equity concern is key while standardization of methods and more examples to understand how, where, and in what form, quantitative consideration of equity, such as DCEA, may be most appropriate. Data availability, the equity subgroup, condition, and markets of relevance are all key to improve awareness and acceptability of these methods. In the meantime, equity evidence must be developed for many steps in the staircase of inequality both for HTA submission but also for better articulation of the inequalities in unmet need to help form collaborations across the healthcare system to improve health equity – from representation in clinical trials through to accessing and uptake of novel medicines and the health, economic, and broader societal benefits that would bring.

Advancing health equity within economic evaluations of HTA will require collaborative efforts across HTA bodies, medicines manufacturers, academic institutions, data providers, healthcare providers, and the patient community. Cross-agency and geographical reviews to identify commonalities of consideration within HTA are required to enable the development of multi-payer relevant equity-related evidence by manufacturers. HTA agencies have a key role in developing and updating guidance to continue to advance health equity considerations within HTA processes; this should span the entirety of the process from prioritization of topics to knowledge mobilization. These efforts are critical for ensuring investment from all stakeholders, from medicine manufacturer to patient groups, in both pre- and post-launch equity-focused evidence.

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