York Health Economics Consortium

NO HALF MEASURES: HEALTH INEQUALITIES IN TECHNOLOGY APPRAISAL

Final Report

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Foreword

"*Black women in the UK are four times more likely to die in pregnancy or childbirth, the healthy life expectancy gap between the most and least deprived communities is 19.6 years and people with learning disability have a life expectancy gap of 15 years compared to the average population. Facts like these led to an NHS commitment to review funding allocations based on health inequalities and unmet need*" [1].

- Dr Bola Owolabi: Director, Health Inequalities at NHS England

The COVID-19 pandemic highlighted how certain disadvantaged communities are disproportionately affected by healthcare issues [2, 3]. Following shortcomings in care for people with sickle cell disease, including the tragic avoidable death of Evan Nathan Smith in 2019, the All-Party Parliamentary Group on Sickle Cell and Thalassaemia published the 'No one's Listening' report in 2021 [4]. This highlighted the extent of inequalities in funding and prioritisation for sickle cell compared with other conditions. Similarly, the NHS Race and Health Observatory released a rapid evidence review in 2022 which examined inequalities experienced by black, Asian and minority ethnic people within the health system [5]. This suggested that racial stereotyping, discrimination and differential care is still commonplace.

The National Institute for Health and Care Excellence (NICE) provides guidance and recommendations for new healthcare technologies in England and Wales. NICE uses a deliberative process to consider the technology, which often focusses on the clinical benefit as well as the value for money it represents. Whilst the committee discussions also cover other aspects of value (e.g. impacts on health inequalities or disease severity) the process does not always provide a transparent conclusion about how health inequalities impacted the final recommendation.

There has been significant effort to raise awareness of health inequalities in the NHS, as well as work by NICE to ensure that its work and guidelines consider health inequalities. Work conducted by NICE includes societal engagement on health inequalities, review of existing NICE guidelines and trialling new methods to evaluate health inequality impacts [6-9]. This work has not been formally extended to, or applied in, the technology appraisal process. Hence, there is an opportunity to expand and improve the work already done on health inequalities by NICE. Through engagement with stakeholders from a range of organisations and a review of the literature, this report makes a series of recommendations to improve how health inequalities are captured during the health technology appraisal process in the UK.

Executive Summary

1. BACKGROUND

Health inequalities in the UK are often described as unfair and avoidable differences in health between different groups within society [10-13]. Health inequalities exist because of a range of factors including access to good quality housing, access to education, crime, labour markets and income, protected characteristics and vulnerability. These are referred to as the wider determinants of health, or social determinants [14]. Health inequalities in the UK have been widely reported since the 1980s [15-18] and the gap between the most and least deprived in society has generally continued to increase over time [4, 19]. COVID-19 has highlighted how disadvantaged communities continue to be disproportionately affected by healthcare issues. Multiple reports have also been released which indicate the continued issues of discrimination, racism and differential care in the context of health inequalities [4, 5].

The impact of new health technologies on health inequalities is one of multiple aspects of value that should be considered during the health technology assessment (HTA) process. HTA bodies, such as the National Institute for Health and Care Excellence (NICE), are taking steps to address the impact on health inequalities in relation to the decisions that they make [6]. As of 2022, NICE has launched inequality briefings and communication campaigns, reviewed its current guidelines, and identified current evidence gaps on inequality [20]. However, during the technology appraisal process, it is not clearly defined exactly how health inequalities should be valued or how much weight it should be given in the decision-making process. In some cases, it is not clear if health inequalities have impacted the final decision in any way. There is no current guidance from NICE for presenting any quantitative or qualitative evidence on the impact of a new health technology on health inequalities, although NICE does make modifications for some aspects it considers to be of value.

This report aims to:

- Identify some existing methods of how health inequalities are captured by HTA bodies around the world.
- Describe and evaluate potential methods to capture impacts of health inequalities that could be used in HTAs in the UK.
- Summarise a range of stakeholder views on health inequalities in HTA.
- Discuss the potential wider consequences of using the various methods to account for health inequalities as part of HTA in the UK.
- Make recommendations for current and future policy or research objectives relating to health inequalities in HTAs in the UK.

2. METHODS

The approach to addressing the aims of this report can be broken down into three parts:

- **Part One:** We conducted a pragmatic literature search to gain an understanding of the various approaches to considering health inequalities, including from HTA bodies outside the UK.
- **Part Two:** In the second pragmatic search we focussed on the available methods that can be used to incorporate health inequalities into health economic evaluations. Benefits and limitations of the methods were also collected.
- **Part Three:** We conducted stakeholder interviews and a stakeholder workshop. Stakeholders were recruited from various organisations related to health care systems or decision making. The aim of this part was to:
    - Discuss any gaps in the literature.
    - Determine whether the wider literature reflected the stakeholders' views.
    - Understand the key factors and perspectives in decision making from multiple contexts.
    - Explore potential methods to more fully capture health inequalities in HTA methodology

3. RESULTS

For the most common technology appraisal process, HTA bodies state they weight an additional quality-adjusted life year (QALY) the same regardless of the characteristics of the individual receiving the QALY. There are examples of HTA bodies accounting for disease severity or rare diseases, which can be either through QALY modifiers, or alternative appraisal pathways with a higher willingness to pay (cost-effectiveness thresholds). However, HTA bodies generally do not explicitly quantify health inequalities in the technology appraisal process.

Some HTA bodies take an alternative approach to pharmaceutical reimbursement, such as Pharmac in New Zealand. The Pharmac approach is to use an 'options for investment' list based on consideration of a predetermined set of 16 value factors. Pharmac then uses a prioritisation process to rank all of the potential pharmaceutical funding options. Pharmac operates with a fixed budget and works its way down the prioritisation list.

A number of methods were identified in the pragmatic literature review, each having various strengths and limitations:

- **Equity-based weighting** (EBW) offers an analytically and conceptually simple method for decision makers. There are questions regarding the quality of the evidence used to determine the equity weights.
- **Distributional cost-effectiveness analysis** (DCEA) has numerous benefits, such as its generalisability to different disease areas. DCEA can also measure changes or differences

in health inequality. However, the requirement for additional data for specific patient populations may raise concerns in some technology appraisals but may work well for others.

- Qualitative aspects of **multi-criteria decision analysis** (MCDA) could be used to provide structure to the deliberative process. The quantitative approach to MCDA has limitations around how robust preferences are elicited for decision weights.

- **Extended cost-effectiveness analysis** (ECEA) and **mathematical programming** (MP) are less useful for UK HTA. This is due to ECEA mainly being focused on financial risk protection (ability to pay insurance) and MP's use of defined constraints, making it less useful for incremental analysis.

All stakeholders agreed there has been a shift in focus to reduce health inequalities in recent years. The suggestion among stakeholders was that this shift was for the better, due to the economic and social cost health inequalities create both for the individual and wider society. The importance of reflecting societal preferences in decision making was also noted. Many stakeholders held positive opinions regarding NICE's overall work with health inequalities, yet some queries were still evident regarding the way NICE's committees make decisions. This includes a lack of understanding of health inequalities on some committees and power dynamics that occur within committees.

All stakeholders agreed that a deliberative process should remain fundamental to any decision-making process and that any quantitative method to capture health inequalities should be used to guide this deliberative approach. Stakeholders believed that the generalisability or comparability of a quantitative method is one of the most important factors to consider with any method. They also noted the ability to measure the direction and size of the impact on health inequalities as being important. Some stakeholders emphasised that the burden on NICE committees needs to be accounted for if more complex tools and processes are implemented into decision making. However, continual improvement should still be sought for the understanding of health economic methods and inequalities. Training courses would be an important opportunity to facilitate how inequalities are measured and considered in technology appraisal.

The use of the index of multiple deprivation (IMD) within England was highly praised and seen as the best quantitative measure for deprivation, despite its limitations. Stakeholders raised the possibility of introducing new measures to capture deprivation alongside IMD. These measures could be more specific to different types of health inequalities, such as ethnicity-based deprivation measures.

Investigating the impact of a new technology on health inequalities is likely to be a costly and resource intensive activity. In addition, multiple stakeholders highlighted that health inequalities do not always get fair attention in committee deliberations. As such, unless companies have a clear incentive to provide additional evidence on health inequalities, this aspect will continue to be overlooked. Therefore, it is important for NICE to be clearer on the impact health inequalities should have on decision making and ensure it is properly discussed during committee deliberations. This additional clarity should act as an incentive for companies to then provide the additional evidence or analysis, which should in theory lead to a more informed decision-making process.

In summary, companies can, and should, provide additional analysis on health inequalities to NICE's committees. This should in turn afford the opportunity for greater flexibility and lead to a more informed decision-making process. It is also important to understand the extent that society values health gain in disadvantaged groups. Such insights can inform any method for evaluating health inequalities, such as equity-based weighting.

4. RECOMMENDATIONS

Key recommendations for companies:

- Contextualise the disease landscape with respect to health inequalities through more quantitative analysis. This could include descriptive statistics around disease burden or access to care for the relevant population.
- Companies should undertake internal or external training on the concepts of health inequalities, including how and why they exist.
- Aggregate DCEA may be useful for indications that have accessible and accurate data.

Key recommendations for NICE:

- Training should be offered to decision makers around understanding deeper aspects of health inequality, such as access to care and health education.
- NICE should be involved in research on societal preferences for health gain in disadvantaged populations. This should then inform an equity-based weighting for QALYs or aggregate DCEA, if NICE was to consider these methods.
- NICE should engage with Clinical Practice Research Datalink (CPRD) to support wider use of real-world datasets to support the inclusion of DCEA, given the cost concerns for companies to access to the government owned public health data set.
- NICE should operationalise some aspects of MCDA to better guide and structure the deliberative process, so that health inequalities are appropriately captured in any deliberations. This will require an independent review of how deliberations currently take place and adjusting the structure of the decision-making process. These changes should hopefully improve the transparency and consistency when making decisions.
- NICE should engage with companies on the feasibility of conducting DCEA as part of the submission and offer the DCEA prototype tool developed by NICE to respective companies.
- The NICE technology appraisal template should be updated to indicate to companies which type of analysis would be useful to provide in the context of health inequalities.
- NICE should make clear how health inequalities are valued in decision making, the level of autonomy that committee members have and document this with any other updates in their methods guide.
- NICE should be consistent in their approach to using EBW within healthcare decision making, including for health inequalities and all other potential uses.

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Abbreviations

AOTMiT	Polish Agency for Health Technology Assessment
CADTH	Canadian Agency for Drugs and Technologies in Health
CEA	Cost-effectiveness analysis
CPAG	Clinical Priorities Advisory Group
CPRD	Clinical Practice Research Database
DCEA	Distributional cost-effectiveness analysis
EAG	Evidence Assessment Group
EBW	Equity based weighting
ECEA	Extended cost-effectiveness analysis
FRP	Financial risk protection
HAS	French Authority for Health
HIQA	Health Information and Quality Authority
HTA	Health technology assessment
ICD	International Classification of Diseases
ICER	Incremental cost-effectiveness ratio
ICER-US	Institution for Clinical and Economic Review
ICS	Integrated care system
IMD	Index of multiple deprivation
INFARMED	National Authority of Medicines and Health Products
KCE	Belgian Health Care Knowledge Centre
MCDA	Multi-criteria decision analysis
MP	Mathematical programming
NHS	National Health Service
NICE	National Institute for Health and Social Care Excellence
PHARMAC	Pharmaceutical Management Agency
QALE	Quality-adjusted life expectancy
QALY	Quality-adjusted life year
SBU	Swedish Agency for Health Technology Assessment and Assessment of Social Services
SMC	Scottish Medicines Consortium
SWF	Social welfare function
UK	United Kingdom
WHO	World Health Organisation
WTP	Willingness to pay

1 Introduction

1.1 Background

Health inequalities in the UK are often described as unfair and avoidable differences in health between different groups within society [10-13]. Health inequalities exist because of a range of factors including access to good quality housing, access to education, crime, labour markets and income, vulnerability and protected characteristics. These are often referred to as the wider determinants of health, or social determinants [5]. The number of people with poor health is not distributed equally across the population. Differences in health may also occur due to various characteristics, such as age or gender, which are not necessarily direct causes of health inequalities. On average, those with poor health are more concentrated among people with limited access to the resources that enable an economically secure and prosperous life [21]. For example, life expectancy is more than 18 years lower in the most deprived population quintile compared with the least deprived population quintile in the UK [22]. The impact of health inequalities has been made more evident in the recent Covid-19 pandemic. Death rates from Covid-19 in England are more than double in the most deprived areas compared with the least deprived areas [23]. The year prior to Covid-19 (2019), it was estimated that health inequalities caused an additional cost to the NHS of £4.8billion [24].

Recently, the Government has made progress in improving key determinants of health, such as reducing rates of smoking and introducing measures to reduce obesity. For example, However, the benefits have not been spread equally across the population. NHS England has developed its Core20PLUS5 approach to reducing health inequalities [25]. This approach targets the most deprived 20% of the national population as identified by the national index of multiple deprivation (IMD). It also targets specific populations that may experience health inequalities, such as ethnic minority communities and people with a learning disability. Five clinical areas are given focus including maternity, severe mental illness, chronic respiratory disease, early cancer diagnosis, and hypertension case-finding. In 2022, NHS England confirmed it would maintain its focus on tackling health inequalities in the 2022-23 priorities and operational planning guidance [26]. In addition, integrated care systems (ICS) are expected to take a lead role in tackling inequalities, building on the Core20PLUS5 approach at both national and system level.

Despite government announcements and new policies to tackle inequalities, there is concern that the Governments' current talk of inequality is more of a 'buzz word', with little action or progress actually being made [27]. A report by the Sickle Cell Society found that there were frequent reports of negative attitudes towards sickle cell patients [4, 28]. This included evidence that suggested that such attitudes are often underpinned by racism, while there had been no real improvement in these respective inequalities over the past decade. An NHS Race Observatory report highlighted how people from Asian groups, in particular, experienced a much larger fall in planned hospital care during the pandemic than people from White, Black or Mixed ethnic groups [29]. Another report by the NHS Race Observatory highlighted that there remain clear barriers to seeking help for mental health problems for some ethnic minority groups, rooted in a distrust of both primary care and mental health care providers. This also includes a fear of being discriminated against in healthcare [5]. Therefore, it is important to turn the discussions on inequalities into clear actions.

Impact on health inequalities is one consideration of multiple aspects of value when assessing the merit of new health technologies. Health technology assessment (HTA) bodies, such as the National Institute for Health and Care Excellence (NICE), consider multiple aspects of value when assessing new technologies, and are keen to consider the impact on health inequalities in relation to the decisions that they make [6]. As of 2022, NICE has made steps towards addressing health inequalities through a review of its current guidelines, inequality briefings, communication campaigns and identifying current evidence gaps [20]. However, during the technology appraisal process, it is not clear exactly how health inequalities should be valued or how much weight the topic should be given in the decision-making process. In some cases, it is not clear if health inequalities have impacted the final decision in any way. There is no current guidance from NICE for presenting any quantitative or qualitative evidence on the impact of an intervention on health inequalities, although NICE does modify its HTA processes and thresholds for aspects it considers to be of value. For example, in the new 2022 methods guide [30], NICE provides additional weight to health benefits for more severe conditions. This decision has been made to allow for more equitable access to treatments for severe conditions. NICE has also conducted a programme of public engagement, which includes aspects on health inequalities to develop a better understanding of public opinion on moral, ethical and social value issues [31]. Nonetheless, NICE has yet to work out how to do this for a range of different aspects in an accurate and consistent manner, such as health inequalities.

NICE is currently trialling a prototype tool for evaluating inequalities as part of its guidelines, which is a distinct process from the technology appraisals programme [32]. The tool allows for the results of a cost-effectiveness analysis (CEA) to be used as inputs alongside other factors (such as population measures and IMD distribution) to generate inequality outputs that can be used in committee discussions. This tool is being trialled on weight management guidelines and metastatic spinal cord compression guidelines [20].

An example of NICE incorporating inequalities into its HTA decision-making can be found in the appraisal for crizanlizumab for preventing sickle cell crises in sickle cell disease [33]. Due to the treatment's ability to reduce health inequalities, the committee was willing to accept an incremental cost-effectiveness ratio (ICER) above the threshold. The threshold used in HTA represents the amount a decision-maker is willing to pay for a unit of health outcome.

Although the appraisal of crizanilzumab represents an important step to addressing inequalities within NICE decision-making, it is not clear how future submissions may deal with this issue. A recent appraisal for another intervention in sickle cell disease, voxeletor, was not approved for use in the UK NHS. Both the crizanilzumab and voxeletor appraisals featured base case cost-effectiveness over the threshold, with uncertain evidence. Nonetheless, crizanilzumab was approved with respect to health inequalities, yet voxeletor was not. If NICE wishes to make decisions which consider health inequalities, consistency and transparency will be key for future appraisals. Combined with the work NICE is already doing, there is a need to improve transparency in the technology appraisal process.

1.2 Aims

The aims for this report are to:

- Identify existing methods of how health inequalities are captured by HTA bodies around the world.

- Describe and evaluate potential methods to capture impacts of health inequalities that could be used in HTAs in the UK.
- Summarise a range of stakeholder views on health inequalities in HTA.
- Discuss the potential wider consequences of using the various methods to account for health inequalities as part of HTA in the UK.
- Make recommendations for current and future policy or research objectives relating to health inequalities in HTAs in the UK.

2 Methods

2.1 Part One: Targeted Review of Current Approaches to Health Inequalities in HTA

We conducted a pragmatic literature review to understand how health inequalities are addressed within HTA across the world. We conducted the search during the week of 21st November 2022. This was done using the relevant HTA body websites, as well as the ISPOR pharmacotherapy guidelines summaries [34]. The search was designed to identify documents likely to contain summaries of the expected evidence required for technology appraisal, and if any mentioned considerations for inequalities or equity. These were either the reference case, guidelines, or manuals for technology appraisal.

We limited our inclusion criteria to English language documents. From these documents, we created summaries based on the information provided surrounding equity or inequality in the decision-making process.

2.2 Part Two: Targeted Review of Approaches to Capture Health Inequalities in Economic Evaluation

Building on the work associated with part one, we conducted an additional pragmatic literature search. This was conducted to identify recent papers to understand the different approaches to capturing health inequalities in economic evaluation, as well as benefits and drawbacks for introducing the methods into HTA. We did not limit the search to the UK, meaning we looked at methods applied across the world to assess the impact of interventions on health inequalities.

We conducted the search using PubMed and Google Scholar, using the terms: inequality; equity, health technology assessment; economic evaluation; cost-effectiveness in multiple combinations. We did not limit the search to traditional publishing methods, and conducted searches to identify relevant grey literature as well. In both cases, the searches were restricted to the years 2010-2022. The focus of the searches was to identify previous systematic reviews around health inequalities and equity in economic evaluation which could then be used to identify further relevant papers. Overall, many relevant studies were identified, including two systematic reviews.

2.3 Part Three: Stakeholder Interviews and Workshop

As part of the scoping for this review, one of the key identified ‘gaps’ in the evidence base was the lack of stakeholder involvement in determining feasible methods. This was important for three reasons; to understand how any approach may work in practice within HTA, reflections on the current process and what need to be improved. Therefore, five interviews were set up with stakeholders across different organisations related to healthcare systems or decision-making. These included NICE, Office for Health Improvement & Disparities, NHS England, and charities within the UK, as well as the Pharmaceutical Management Agency (Pharmac) from New Zealand to get an alternative perspective.

The first objective of the stakeholder interviews was to identify how different perspectives shape decision making. The second objective was to discuss any potential evidence gaps identified from the literature search, or to confirm that the literature reflected the stakeholder opinion well. Questions were designed prior to the interview and were tailored to the individual stakeholder based on their expertise. Interviews were conducted in a flexible format, so that the participant could lead the conversation to the topics they perceived to be most important. The base set of questions which were used as preparation for the interviews is presented in Appendix A.

Following the individual stakeholder interviews and pragmatic literature review, an interactive workshop was convened, with a panel of HTA stakeholders and academics. The aims of this workshop were to discuss gaps identified in the literature review and address any potential contrasting opinions raised in the individual interviews

3 Current Approaches to Inequalities in HTA

3.1 Summary of Currently Used Approaches to Health Inequalities

Each HTA body holds slightly different perspectives when it comes to addressing inequalities. Overall, the approach to technology appraisal in most countries is that an additional quality-adjusted life year (QALY) should be weighted equally regardless of the characteristics of the individual receiving it. Some HTA bodies have alternative appraisal routes, such as routes for interventions in rare diseases, which have different decision criteria to standard technology appraisal routes. Considerations of equity or inequality tend to vary in technology appraisals. For example, NICE considers whether the technology could address the inequality in the distribution of health among society [30]. Similarly, the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) considers whether the clinician's views may influence the technology's usage, which leads into aspects of health inequalities [35]. Further detail is provided in Table 3.1.

Pharmac in New Zealand takes a different approach to many other HTA bodies. In deciding which medicines should be subsidised, Pharmac utilises a framework of 16 factors for consideration within the domains of: need, health benefit, costs and savings, and suitability. However, Pharmac must make its funding decisions within a capped budget, so legally it must manage the price and volumes of medicine when making these decisions [36]. This process is similar to that adopted by the Clinical Priorities Advisory Group (CPAG) within the NHS, which adopts the wider NHS England prioritisation process.

Some HTA bodies are yet to provide details regarding their approach to inequalities in their guidelines (e.g., French National Authority for Health (HAS)). A summary of approaches to health inequalities from 12 HTA bodies are presented in Table 3.1. These 12 are summarised to show a range of approaches from across the world.

Table 3.1: Summary of implementation of inequalities in HTA bodies

Country	HTA agency/body	Health inequality considerations	Current approach
England and Wales	National Institute for Health and Care Excellence (NICE) [30]	An additional QALY has the same weight regardless of the characteristics of the individuals receiving the health benefit, except in specific circumstances (e.g., severity weighting). Other issues likely to affect the evaluation include: ▪ Issues relating to advancing equality of opportunity, eliminating unlawful discrimination, and fostering good relations between people with protected characteristics and society as a whole. ▪ Potential issues relating to health inequalities, including whether the technology could address inequality or unfairness in the distribution of health across society.	Deliberative process only
Scotland	Scottish Medicines Consortium (SMC) [37]	A QALY has equal weighting regardless of the associated characteristics of the individual receiving it. SMC accepts discussion of equity considerations with submissions.	Deliberative process only
Ireland	Health Information and Quality Authority (HIQA) [38]	Additional QALYs gained should be assumed to be of equal value, regardless of any considerations for specific characteristics of the population. However, an attempt should be made to meet the needs of decision-makers by highlighting potential equity considerations in the report. Incorporating equity weights into QALY calculations is proposed so that societal concerns regarding severity of health and the ability to realise benefits in health are considered. However, there are significant methodological issues concerning the derivation of equity weights and the circumstances and mechanisms by which these would apply to QALY calculations.	Deliberative process only
Canada	Canada's Drug and Health Technology Agency (CADTH) [39]	All outcomes should be weighted equally regardless of the characteristics of people receiving, or affected by, the technology. Concerns relating to the unfair distribution of health outcomes can, in theory, be addressed by using differential weighting of outcomes, with health gains for the disadvantaged being given a higher value. If costs and outcomes differ among subgroups defined in terms of equity-related characteristics, this should be reported, allowing decision-makers to assess the distributional impacts of the investment in question. Although the reference case analysis should weight all outcomes equally (regardless of the characteristics of people receiving the health benefit), analyses should be presented in a disaggregated manner, with full descriptions of the relevant patient populations, to allow for consideration of any subsequent distributional and equity-related policy concerns.	Could incorporate multiple methods, including distributional cost effectiveness analysis as additional scenarios. Generally just a deliberative process though.

Country	HTA agency/body	Health inequality considerations	Current approach
US	Institution for Clinical and Economic Review (ICER-US) [40]	Utilises scenario analysis techniques to investigate how new technologies may affect differences in life expectancy among various subpopulations. A five-point voting system is used to assess an intervention's capacity to fairly target disadvantaged groups.	Deliberative process, but with some supplementary quantitative analysis available
Poland	Agency for Health Technology Assessment (AOTMiT) [41]	Considers the following issues: ▪ Whether groups of patients will be favoured or discriminated. ▪ If there will be equal access to the new technology. ▪ If the technologies benefits are equally spread across the population. ▪ If the technology alleviates any unmet significant health need.	Deliberative process only
Sweden	Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) [35]	Considers the following issues: ▪ If there are resource or organisational barriers that will restrict access for certain populations. ▪ If clinician's views may influence the technologies usage. ▪ If certain interests will lead to unequal access to patients.	Deliberative process only
New Zealand	Pharmaceutical Management Agency (Pharmac) [42]	Considers the impact of a decision of those that are facing health disparities because of underlying disadvantage, separately from the illness itself, such as ethnicity, culture, location, or socioeconomic status. Committed to improving health outcomes of Māori and being a great Te Tiriti/The Treaty partner. Committee discusses their view on the weighting of each factor and conclude the ranking of importance using an options for investment list. There is no cost-effectiveness threshold.	Deliberative process only
Belgium	Belgian Health Care Knowledge Centre (KCE) [43]	As no weights that represent distributional preferences of the general public according to the populations affected are available, QALYs should not be weighted. Therefore, a QALY is a QALY no matter who receives it.	Deliberative process only
France	French National Authority for Health (HAS) [44]	Equity issues not stated.	No clear approach to equity
Portugal	National Authority of Medicines and Health Products (INFARMED) [45]	Equity issues not stated.	No clear approach to equity
Japan	CORE2 Health [46]	Equity issues not stated.	No clear approach to equity

QALY – Quality-adjusted life year

3.2 Current Reviews of Approach to Inequalities in HTA

Some HTA bodies are trying to adopt new approaches to consider inequality in their HTA processes. After receiving funding from The Commonwealth Fund, ICER-US has launched an initiative to evaluate and advance HTA methods that support health equity [47]. The findings from this will be used to guide ICER-US' update to its value assessment framework, as well as informing the work of other national HTA groups. As part of this initiative, ICER-US will arrange a senior advisory group, that consists of HTA and policy experts, patient advocates, and payers that will provide guidance and feedback throughout the process.

NICE is currently trialling a prototype tool to develop inequality outputs that can be used to inform committee discussions. The aim of the tool is to guide systematic, transparent, and robust considerations of health inequalities within the guidelines development process [7]. As the tool is still in its early stages of development, NICE will continue to trial and monitor the impact of the tool to ensure it is having the desired impact and usefulness to inform the guidelines it is being used on [7].

HIQA has recently launched a revised Catalogue of National Health and Social Care Data Collections in Ireland [48]. This presents an overview of the data currently being gathered by national health and social care data collections in Ireland in one accessible location. It is hoped that the catalogue will be used by a range of stakeholders, including researchers, policy makers, and healthcare professionals. The health data being collected have the potential to highlight impacts on health inequalities, which could be used in the HTA process.

4 Overview of Potential Methods for Capturing Inequalities

The pragmatic literature review identified multiple systematic reviews, as well as various summary articles of different methods associated with capturing health inequalities [49-53] . A summary of the identified methods that could be used in HTA is presented in Table 4.1.

Table 4.1: HTA methods summary

Method	Description
Deliberative process	Deliberative process involves the discussion of inequality issues at committee meetings, which leads to value judgements being made in discussion, although this can be contextualised with some quantitative analysis [54].
EBW	EBW involves the use of weights to give higher priority to certain individuals and groups with impaired health [55].
ECEA	ECEA represents an extension to standard CEA by incorporating additional non-health benefits, mainly using financial risk protection (the ability to pay for healthcare) [56].
DCEA	DCEA focuses on the distribution of health effects and pays careful attention to the distribution of health opportunity costs from displaced expenditure within a fixed health care budget [51]. A full DCEA models the cumulative inequality impact of an intervention across the course of disease and treatment, including differences in effectiveness. An aggregate DCEA focuses on inequalities generated by differences in healthcare need (i.e., disease prevalence or incidence) and utilisation only and does not involve decision model adaptation [51].
MP	MP uses mathematical optimisation techniques with the goal of maximising health gains subject to specific constraints on the analysis [53].
MCDA	MCDA uses a set of approaches to aid decision-making, where decisions are based on more than one criterion, which makes explicit the impact on the decision of all the criteria applied and the relative importance attached to them [57].

EBW – Equity-based weighting; ECEA – Extended cost-effectiveness analysis; DCEA – Distributional cost-effectiveness analysis; MP – Mathematical programming; MCDA – Multi-criteria decision analysis; CEA – Cost-effectiveness analysis

A summary of the key aspects and methods for each of the equity evaluation methods is presented in Table 4.2. This highlights the differences in the reported outcomes between each of the methods, while Sections 4.1 to 0 discuss each method in more detail. It is important to note that multiple methods could be used at once to analyse and understand impacts on health inequalities. For example, even if a quantitative method is implemented, a deliberative process would likely still be useful for decision making.

Table 4.2: Summary of key aspects of potential methods to analyse health inequalities in HTA from the literature

Aspect	Deliberative process only	EBW	ECEA	DCEA (aggregate)	DCEA (conventional)	MCDA	MP
Approach to inequality fully incorporated into CEA?	No- incorporates through discussion process.	Yes- Incorporates weights straight into CEA.	No- Measures changes in outcome inequality distribution.	No- method reports changes in inequality distribution.		No- inequality is its own score and weighting compared to CEA outcomes.	Yes- incorporates defined constraint into the CEA.
Can explicitly measure extent to which healthcare outcomes distributed across groups?	No	No	Yes	Yes		Yes – if included as MCDA criteria.	No
Method for incorporating inequality	Discussion creates value judgement of inequality importance.	Weights outcomes by derived factor.	Derives distributional financial risk protection outcomes (could be applied to other outcomes, such as education).	Derives distributional cost-effectiveness and inequality impact.		Weightings assigned to every decision aspect, with each given a score to rank multiple strategies. Can also be done more qualitatively.	Constraints included as part of the optimisation analysis.
Need to modify CEA?	No	Small modifications- to account for weighting.	Yes	Yes	No	No	Yes
Impact on CEA outcomes?	Unchanged	Re-weighted for adjustment factor.	Distribution of cost assessed across subgroups.	Distribution of costs, QALY and QALE assessed across relevant subgroups.		Unchanged	Change dependent on constraint included.
Use aggregate CEA outcomes only?	Yes	Yes	No	No	Yes	Yes	No
Inequality adjusted evaluation outcome?	ICER (in context of wider discussion).	ICER	ICER & extended criteria outcomes, usually financial risk protection.	ICER, inequality measure and/or SWF.		Score or rank overall and for each criteria.	ICER or specific optimisation objective.
Criteria for decision making	Can be with or without WTP threshold.	WTP threshold	WTP threshold	WTP threshold given inequality aversion parameter.		Highest rank or score out of available interventions.	WTP threshold or optimisation objective.

CEA – Cost effectiveness analysis, EBW – Equity based weighting, ECEA – Extended cost effectiveness analysis, DCEA – Distributional cost effectiveness analysis, MCDA – Multi-criteria decision analysis, MP – Mathematical programming, ICER – Incremental cost effectiveness ratio, WTP – Willingness to pay, QALE – Quality adjusted life expectancy, QALY – Quality adjusted life year, SWF – Social welfare function

4.1 Deliberative Process Only

Deliberative process only involves the considered, specific and deliberate discussion of the advantages and disadvantages of a decision problem, based on set decision-making criteria [58]. When conducted properly, the process should aim to comprehensively cover the relevant issues in a consistent way. The process should also engage those who are affected by the outcome of the decision. The process leads to healthcare resource allocation decisions that incorporate wider dimensions of value considered important to the decision-maker. This could be social values, such as non-health benefits, equity and fairness, or practical issues with implementing the technology [59]. This is the overarching approach adopted by many HTA bodies, including NICE, as outlined in Section 3.

The main advantage of the deliberative process only approach is that theoretically, it should be transparent [60]. This is because the key outcomes of why the decision was reached should be detailed, and any trade-offs detailed, such as health inequalities versus the cost-effectiveness of a new health technology. Other key aspects to this type of process include allowing decision makers to better understand benefits and weaknesses for each health technology, by covering a set agenda of considerations. This also results in an easier process to identify evidence gaps and future research potential, as well as reducing selection bias at committee stage [58].

Nevertheless, there are some drawbacks to the deliberative process when used alone. When it comes to the committee stage, these conversations may be relatively informal and unstructured [50, 60, 61]. Without a formal guide to the decision-making process; key issues such as inequality may be overlooked, decisions may be reached in an incoherent way, or the biases of decision makers may not be challenged. Therefore, if the deliberative process is not implemented in a structured manner, it may lead to a lack of transparency. For instance, in the NICE methods guide, it is not clear to what extent the decision is influenced by the impact on health inequality [30].

It is also difficult to account for incremental differences in inequality impact within this framework i.e., all inequality improving interventions may be implicitly given a similar value in terms of health inequality impact [61]. Without any quantitative analysis to add context to the impact on inequalities, it is difficult to truly consider incremental differences in inequality in the decision-making process. Overall, using only a deliberative process may result in a lack of coherent decision making, where the impact of addressing health inequalities on the decision is unknown.

4.2 Equity-Based Weighting (EBW)

EBW involves the use of numerical weights, to give greater (or lesser) influences to specific groups of people [53]. In In CEA, this could involve weighting QALYs, costs or the cost-effectiveness threshold in relation to the decision problem, with most studies tending to re-weight QALYs [51, 55]. EBW aims to explicitly value the benefit of reduction in health inequalities, which can be used to guide the decision maker about how much this is valued within the decision problem [50].

Multiple systematic reviews have detailed over 15 studies where EBW has been conducted across multiple countries with different types of health technologies [52, 53]. The key data

requirement for this method is the ability to disaggregate the societal preference for augmenting the cost-effectiveness results by using a weighting function (e.g. QALYs, costs or the cost-threshold). The majority of these studies used elicitation-based preference methods to capture societal preferences. Since 2022, NICE has implemented a disease severity modifier, although this modifier is not based on societal preference. This is one example of a modifier which could be valued using elicitation-based preference methods. The disease modifier applies higher weights to the QALYs gained from introducing an intervention, meaning those additional QALYs are weighted either 1.2x higher, or 1.7x higher. The exact modifier is dependent on how severe the disease is (based on the capacity to benefit).

Social welfare functions (SWFs) are another method for eliciting societal preferences around inequality. A health-related SWF ranks all possible distributions of health variables (life-years, QALYs). A SWF can combine decrements for total health with an aversion to inequalities between social groups.

Elicited preferences are associated with limitations, which are noted within the literature. Questions around inequality or equity can be posed in an isolated manner, without properly tying inequality to other aspects of value, such as cost-effectiveness. This leads to the information collected gathering opinions of what is important rather than judgements on how important something is [62]. Furthermore, many types of bias exist in eliciting preferences. Some of these biases with cannot or are often not adequately controlled, such as availability bias or framing effects i.e. the suitability of how the question is posed.

SWFs draw from welfare economics and more sophisticated normative frameworks, but are developed at a very high general level of societal preferences, rather than specific to healthcare [63]. Therefore, there tends to be some empirical and theoretical issues, such as correlation of inputs used to estimate a SWF and the underlying impact this has on the results.

Although the EBW method offers an analytically and conceptually simple solution for decision makers, there are concerns over the comprehensiveness and quality of the evidence used to determine the equity weights. NICE has acknowledged the need for a study to capture societal preference for using modifiers in CEA, including for their disease severity modifier [64]. Extending the work NICE has already conducted on understanding societal preference is an opportunity to better understand and improve the practicality of using EBW.

4.3 Extended Cost-Effectiveness Analysis (ECEA)

ECEA incorporates the distribution of both health benefits and financial risk protection (FRP) benefits (prevention of illness-related impoverishment) per monetary expenditure on specific policies in a given country [51]. Inequality can then be captured through subgrouping of the population based on specific criteria (such as socioeconomic deprivation), with FRP outcomes subsequently compared across different groups [53]. Therefore, the purpose of the ECEA method is to explicitly quantify multiple consequences beyond just standard CEA per population subgroup (defined by a measure of inequality) for a given intervention [65]. These consequences are:

- The health benefits procured by the intervention
- The private expenditures and costs averted by the intervention,

- The FRP benefits provided by the intervention, and the total net costs of the intervention.

ECEA focusses on FRP outcomes, due to middle- and low-income countries having a major objective of universal medical coverage [51, 53, 56, 66, 67]. Although there have been other studies which have looked to branch out into other objectives, such as education; this type of extension is in its infancy [68]. Theoretically, ECEA could be conducted with agriculture of environmental benefits as well, or some other value factor. However, it may be difficult to link these other impacts to inequality outcomes.

The key benefit to ECEA is incorporating additional information on decision-making factors, which would otherwise not be included in standard CEA [51]. The fact that current research is almost solely focused on FRP means that the applicability to a system with universal healthcare free at the point of use is severely limited.

4.4 Distributional Cost-Effectiveness Analysis (DCEA)

DCEA focuses on the distribution of health effects and pays careful attention to the distribution of health opportunity costs from displaced expenditure within a fixed health care budget [51]. It also aggregates all costs and effects into the common metric of net health benefit as well as presenting findings in disaggregated form [53]. The DCEA framework has two main stages [49]:

1. Modelling social distributions of health associated with each intervention.
    - Estimating the baseline health distribution.
    - Modelling changes to this baseline distribution due to health interventions being compared, allowing for the distribution of opportunity costs from additional resource use.
    - Adjusting the resulting modelled health distributions for alternative social value judgements about fair and unfair sources of health variation.
2. Evaluating social distributions of health.
    - Using the estimated distributions to quantify the change in total population health and unfair health inequality due to each intervention.
    - Ranking the interventions based on dominance criteria.
    - Analysing any trade-offs between improving population health and reducing unfair health inequality, allowing for alternative specifications of the underlying social welfare function.

When conducting a DCEA, there are two types of methodology: a full DCEA or an aggregate DCEA. A full DCEA aims to model the cumulative inequality impact of an intervention across the course of disease and treatment, such as incidence, treatment uptake, adherence, and treatment effectiveness [49]. A full DCEA involves incorporating additional data on social variation in each of these areas, which are challenging to identify (if they exist at all) and adding complexity to the analysis. Aggregate DCEA focuses on inequalities generated by differences in healthcare need (i.e., disease prevalence or incidence) and utilisation only. Aggregate DCEA

does not involve decision model adaptation to capture differences in treatment effectiveness and prognosis [51, 53, 69, 70].

Providing that the underlying data exist, DCEA can be adapted to specific interventions or disease areas, and is, therefore, generalisable [49]. Although aggregate DCEA covers less detail compared with a full DCEA, less data is required, which makes aggregate DCEA more achievable [53].

Other key benefits that are highlighted in the wider literature when conducting DCEA include [51, 53, 69, 70]:

- The integrated approach with cost-effectiveness outcomes, which allows for easier consideration when making decisions.
- Data availability in the UK to stratify by social deprivation using IMD.
- The ability to measure changes or differences in inequality.
- Multiple tutorials on best practice approaches, which means that the method can be implemented widely among technical staff.

There are challenges associated with conducting DCEA. DCEA requires additional data beyond just the standard CEA so that benefits and opportunity costs can be scaled up from the average patient to a wider population [71]. These additional data requirements include an accurate estimate of IMD data for the exact population modelled in the CEA. In order to estimate the underlying prevalence of the disease by IMD, access to large patient level data sets such as the Clinical Practice Research Datalink (CPRD) is required, which can be costly to access. Depending on the type of disease being captured, the population may be very specific, meaning that broad assumptions may be required to match people in the dataset with the specific population.

DCEA is conducted using net health benefit which can only be estimated if a decision-making body (such as NICE) accepts the estimated rate of exchange, i.e., the opportunity cost of a QALY. This is valued at £20,000 to £30,000 per QALY by NICE [30]. However, if the threshold used is too high to represent the true opportunity cost, this would lead to inaccurate estimations of the incremental benefit by deprivation group, given health forgone by each IMD quintile would not be correct [53, 71]. This would be even more important if there was a social gradient in the opportunity cost value. The same DCEA could have different results depending on who conducts the analysis unless there is an agreed opportunity cost between decision makers, academics and industry. This also leads onto a wider economic argument surrounding the cost threshold, and if it should be based on the opportunity cost of health, or the willingness to pay for health [72].

Measuring social deprivation is done using IMD, which is a combined measure of the wider determinants of health. IMD does not incorporate more specific characteristics. such as ethnicity or gender. Similar to EBW, there is currently a lack of evidence and understanding for how societies value inequality [53]. More recent examples of DCEA generally uses Atkinsons index as a measurement metric, but this is not very specific to healthcare preferences. However, DCEA can present outcomes for a range of inequality aversion values i.e. our preference to reduce health inequalities or not widen health inequalities.

4.5 Mathematical Programming (MP)

MP approaches use mathematical optimisation techniques with the aim of maximising health gains (or an alternative healthcare metric) subject to specific equity constraints within the CEA [53]. This is conducted by using specific equity goals which are employed as constraints within the CEA framework, and then mathematical algorithms are used to optimise modifiable aspects (e.g., treatment choice) of the modelled healthcare system. By running MP analysis with and without the equity constraints, the difference in cost can be interpreted as the cost of equity [73]. In an equity-oriented example, such constraints could include ensuring a minimum level of service provision for disadvantaged patient groups and regions, or specifying a maximum level of resource use disparity between patient groups [52]. The choice of constraint and the ability of MP to optimise outcomes are dependent on the availability and analytical structure of modifiable parameters built into the modelling framework, as well as data available to populate these constraints [53].

MP has generally not been applied in healthcare, meaning its practical application in HTA is not well reported [52, 53]. One key issue is that the application of MP is constrained to measurable constraints, so cannot really explore value judgements [52]. For example, using a constraint that the cost-effective option cannot be inequality reducing, could lead to extreme results. In this case, the optimised result could be a health technology that is extremely cost-ineffective, but marginally improves health inequalities. Hence, the use of MP does not allow for any measurement of inequality impacts, so must be estimated using another method alongside MP. Although practically feasible, in a world where there are trade-offs to decision making, this type of analysis inherently becomes less useful [51].

4.6 Multi-Criteria Decision Analysis (MCDA)

The premise of MCDA is to evaluate the impact of multiple heterogenous parameters (“criteria”) on treatment outcomes in order to make more informed decisions. Certain criteria may be given greater weight than others, dependent on the overall objectives of the analysis; for example, equity criteria may be given greater weight than those of efficiency [53]. There are different types of MCDA, but any MCDA involves at least three steps: defining the decision problem, selecting the criteria that reflect relevant values of society, and constructing a performance matrix to assign weights to specific criteria [74]. MCDA is generally implemented by establishing preferences between options (e.g., health care technologies) by reference to an explicit set of criteria. These are set by decision-makers and are required to be measurable and relevant to society. These criteria can be used to assess the extent to which implementing a healthcare technology is favourable or not [57]. The performance of each health technology (either interventions or comparators) in every criteria is then evaluated, resulting in either a qualitative ranking of the health technologies by decision makers or a quantitative scoring. This can then be used to identify the most suitable technology based on this ranking or scoring system.

The key benefit of a qualitative MCDA is that it adds transparency and structure to the deliberative process, fostering in-depth consideration of the decision criteria, which can also then improve the consistency of decision making [59]. However, there are concerns raised over the decision makers ability to apply different criteria without underlying biases, while previous evidence has suggested unbalanced power dynamics in the deliberation process of qualitative

MCDA [53, 57, 74]. Literature has already highlighted how HTA bodies like NICE use aspects of MCDA in their deliberation, although there is some critique that this could be incorporated more, adding further structure to the way committees deliberate on a decision [59, 61, 74].

The key benefit to quantitative MCDA, where weights and scores are applied to all decision criteria, is that the decision-making is transparent. [57]. By using this approach, underlying biases should be limited compared to a wider deliberative process, and this should lead to an improved consistency in the decisions being made [74]. There are limitations to the quantitative approach which include [53, 74]:

- This type of process may not lead to a deliberative process to discuss more uncertain or important aspects, which would still be extremely important for making any decision. This is because the weights are assigned quantitatively to the criteria, however, this does not account for uncertainty or value judgements which impact decision making.
- The process for understanding the weights and scores to be used in decision making is often made among a small sample of people, with no consensus on the most robust way to elicit preferences.

Multiple studies have highlighted the issues around preference elicitation, such as stated preference not reflecting true preferences in real life [74, 75]. Furthermore, it is important to have societal preferences underpin any weights used on the criteria to make the decision.

5 Stakeholder Feedback

Engagement with HTA stakeholders from key organisations was noted as a limitation of previously published work. Stakeholder engagement is important to understand the practicalities of implementing any changes in the HTA pathway [52, 53]. This section is split into themes which summarise the feedback that was received from academics and public decision-making bodies.

5.1 Importance of Health Inequalities

All stakeholders consulted believed that over recent years, they had witnessed an increase in focus on health inequalities in public decision making. Most stakeholders expected this to be a permanent fixture in light of the new processes being developed to incorporate health inequalities into decision making. The increased attention towards inequalities can be linked back to NHS England's Core20PLUS5 initiative, which was mentioned in many stakeholder interviews as well as the workshop [25].

Multiple stakeholders noted that changes to HTA processes may not be implemented as quickly as desired. Stakeholders at NICE believed changing processes on health inequalities was important to the long-term goals of NICE and they hoped new methods could be rolled out quickly. It was highlighted in one stakeholder interview that even though health inequalities have become more prominent in the decision-making process, the focus on health inequalities may not be permanent in some decision-making perspectives within wider government. This opinion was in contrast with the majority of stakeholders. The point highlighted by this stakeholder was that aspects of decision-making are subjective, change over time, and are difficult to disentangle from politics, which often has a rapidly moving landscape. This same stakeholder also raised the increasing importance of budget constraints for decision making, and that by approving less cost-effective interventions with the aim of reducing inequalities, this may put public finances at greater risk.

The majority of stakeholders highlighted that decision makers do not always fully understand the impact or causes of health inequalities, and the wider economic impact this has on society. This means health inequalities are not always adequately represented in decision making. Even though more research is being undertaken, stakeholders reiterated how further training on the importance and causes of inequalities is still required. Stakeholder training is seen as one of the key drivers to better incorporate health inequalities into technology appraisals.

5.2 Decision Making Perspectives

5.2.1 Preferences for decision making

All stakeholders highlighted the importance of reflecting societal preferences as closely as possible within the decision-making process. However, more research is needed to fully understand societal preferences, and what is of value to people when making decisions. NICE has already begun engaging in this research and is looking to expand what is currently being done. In 2022, NICE published its 'NICE Listens' project which is a new public engagement programme aimed at understanding societal preferences [31]. Current topics that are being explored include health inequalities and environmental sustainability. Similarly, a stakeholder

from Pharmac highlighted how one of their research priorities is to better understand societal preferences in New Zealand. A request has been sent out for research into inequality preferences, with a view to incorporating this research into their current HTA process.

Multiple stakeholders commented on the limitations of preference elicitation. This is because preferences change over time, while most methods for capturing preferences use stated preferences, which incur underlying biases. The most important bias mentioned was that stated preferences do not tend to match revealed preferences, i.e., the way people make choices in stated elicitation methods do not match what they would do in real life. The other point raised was that when confronted with multiple aspects important to decision-making, participants often weight all aspects as important, meaning trade-offs can be difficult to elicit. Although these limitations were mentioned, stakeholders still believed this research was worthwhile, and an important opportunity to better address health inequalities.

5.2.2 Clinical priorities advisory group (CPAG)

One stakeholder from NHS England highlighted the CPAG [76], which provides recommendations to NHS England regarding its approach to commissioning services, treatments, and technologies. CPAG adopts a similar process to that used by Pharmac, in which technologies are ranked based on various factors and then funded based on these priorities until the budget is exhausted. The ‘options for investment list’ implemented by this ranking allows for treatments and technologies that are not necessarily as cost effective but have other desirable impacts, to still be recommended for implementation. This ranking method can also fund treatments that may be particularly inequality reducing, depending on the decisions made by the committee. The stakeholder from NHS England believed that it would be interesting to see if this method would work in an institution larger than CPAG, such as NICE, although was generally in approval of the NICE process. This stakeholder did not cover any transparency issues associated with different types of deliberative processes. These potential issues are discussed in Section 6.2.

5.3 NICE Decision Making

5.3.1 NICE process

All stakeholders commented that, in terms of facilitating the discussion of evidence, the NICE process covers a lot of components well. Multiple stakeholders highlighted that even though there may be some flaws, the general process has been improving over time. [77]. However, some stakeholders also commented on the lack of structure occurring sometimes during NICE processes, which may indicate the framework is not being applied correctly, or a review of the framework may be required. This finding suggests that there is an opportunity to improve the deliberative process, with more transparency and structure around the decision-making process.

Health inequalities are apparently at the forefront of NICE’s thinking during the decision-making process. NICE wants to investigate how equality legislation, as well as varying costs and outcomes between population groups, are incorporated into current NICE processes. Stakeholders raised multiple examples where inequality arguments have been applied strongly when considering the population demographics being evaluated, the size of the population of

interest, and burden of illnesses. Previous examples referenced include health technologies for Hepatitis C.

5.3.2 NICE prototype tool

So far, the DCEA tool NICE is trialling [32] has only been used in guidelines (such as smoking cessation and weight management) and not in technology appraisals. The tool has mostly received positive feedback, but some committee members believe that it has generated multiple queries. Some of this concern is related to the uncertainty regarding the data used in the tool, as well as the limited evidence base around health inequalities other than IMD scores. The tool is slowly being incorporated into committees for NICE guidelines, yet there is still more training required for the committee members to fully understand and incorporate the tool into their decision making. For committee members, this is mainly for the interpretation of the results from DCEA. The training of new methods and analysis should be a continued goal by NICE, with stakeholders welcoming further training on these topics. There are plans to expand the tool across NICE and develop the initial prototype to make it more useful for activities conducted by NICE.

5.4 Methodological Approaches

5.4.1 Components of methodological approaches

As part of the stakeholder engagement, components of any methodological approach or tool to guide discussions around inequalities were captured to gain some indication of what is most important or least important when using a particular method. All stakeholders highly valued the generalisability or comparability of any method, so that it could be used in different disease areas or different health technologies. The rationale for this was that generalisability creates consistency across the healthcare system when making decisions. Stakeholders also valued the ability to measure the direction and the size of the impact on inequalities from any intervention, with this being particularly important for any discussion at the committee stage.

Integration with cost-effectiveness outcomes for any analysis on inequalities was generally found to be less important, with some mixed comments on this topic across stakeholders. Those who were more heavily involved in NICE processes for decision making stated how the integration with cost-effectiveness outcomes tends to make it easier for committees to interpret the evidence in their discussion, rather than having it as another outcome in the analysis. Other stakeholders pointed out that given the process should be deliberative, it does not matter if there is not one central quantitative result (such as cost-effectiveness) to guide the deliberation. For instance, it should in theory be fine if the quantitative analysis for health inequalities is separate, as long as it is useful and interpretable evidence. Stakeholders generally found the conceptual complexity and ease of interpretability important for any quantitative analysis on inequalities, but were quite accepting that committee training should help with this for any new methods. One stakeholder explained that simplified methods may be more useful to remove some of the decision-making burden from committees.

5.4.2 Deliberative process

All stakeholders discussed the value of the deliberative process, highlighting how decisions cannot be made solely on specific thresholds, given the many nuances behind decision making. However, it was raised on multiple occasions that more quantitative work could be done to underpin the deliberative process, giving a wider context to any discussion on inequalities. The feedback from stakeholders was that this does not necessarily mean implementing a particular method already stated in Section 4, but could just include some descriptive statistics around disease burden or access to care. This could help shape any conversation relating to inequalities. Stakeholders from NICE explained that they are continually reviewing the committee process. Although detail was not given on how they would address a compelling case for health inequalities if a technology was less cost-effective.

The importance of a deliberative process was not debated by stakeholders, but some stakeholders raised the fact that sometimes committee deliberations can appear to be less structured. The structure of the deliberation was stated to be highly dependent on the chair or topic in question. The importance of maintaining structure and purpose in deliberations was highlighted, with one stakeholder discussing how the qualitative process or general underlying principles of MCDA can be further incorporated into the way NICE makes decisions. It was noted that MCDA would take some time to operationalise but would support improvements to the decision-making process. The benefit of a more structured deliberation should lead to greater consistency, transparency and understanding of the trade-offs in the decision-making process.

5.4.3 Equity-based weighting (EBW)

All stakeholders were asked questions around EBW, given the recent recommendations by NICE not to include an explicit weighting for health inequalities [8, 30]. The response to the use of EBW for health inequalities were mixed. Some stakeholders generally supported the use of EBW, given its simplicity to implement as a useful scenario analysis. Yet, they believed that societal preferences could be sought to underpin what the weighting should be (with most discussing QALY weightings). If EBW for health inequalities were to be operationalised, eliciting societal preferences would be an important step in this process. Furthermore, it was raised that different tools for different aspects of decision-making leads to inconsistent decisions. For example, it is inconsistent to use EBW for disease severity, but not for health inequalities.

Some stakeholders raised limitations of using EBW, including:

- Lack of methods/criteria to determine if the weighting should be applied.
- Not being able to capture the size of the change in health inequalities in any useful detail.
- Not being able to account for the health opportunity costs of an intervention.

The health opportunity cost appeared to be the most important factor for academic stakeholders but was still raised by public body stakeholders such as NICE. If an intervention has its greatest impact in those who are most deprived, but it is not cost effective, it may displace other health gained in the most deprived areas. Ultimately this could increase health inequality. These nuances are hard to factor into the EBW approach. For these reasons, some

stakeholders were not supportive of adopting this method, with a preference for DCEA or additional descriptive statistics instead.

An alternative suggestion for EBW was rather than having a set weighting for health inequalities, a goal seeking analysis could be done as part of scenario analysis which indicates the QALY weighting required for the intervention to be cost effective. This can be applied for health technologies which have clear evidence that they would target and improve health inequalities. This scenario analysis could then be used to guide a deliberative process, since the goal seeking nature would give an indication of the trade-off required between health inequalities and cost-effectiveness to reach a threshold.

5.4.4 Distributional cost-effectiveness analysis (DCEA)

Most stakeholders believed that aggregate DCEA is probably the most useful tool for quantitatively capturing impacts on health inequalities. Multiple stakeholders highlighted the ability of DCEA to contextualise and steer committee discussions when there are trade-offs in the analysis. The tool also quantifies different levels of inequality aversion as part of scenario analysis.

Theoretically, DCEA can be used in most disease areas and is a very generalisable tool for capturing health inequalities. However, there were some practical issues raised which would need to be resolved before this method could be used for wider programmes at NICE. One example provided was that the tool uses ICD-3 codes to understand the disease population. These can be quite broad categories, so will not always align with population in technology appraisal. The IMD distribution of the broader category of disease may not match the subpopulation, so assumptions would have to be made about the burden of disease in many instances, meaning the tool provides less robust insights in this case. It was also noted that DCEA would be less useful for rare diseases which expect to go down the highly specialised technologies route, given the approach is more flexible here to cost-effectiveness.

5.5 Committees and Inequality

5.5.1 Burden on committees

Most stakeholders were keen to give the committees the best tools and evidence to make decisions, while balancing any excess burden of implementing lots of changes at once. Hence, there is a balance for future objectives to target the most effective ways to improve how health inequalities are addressed, while making sure these changes are manageable for committees. One stakeholder expressed how they believe that committees are very successful at delivering evaluations of new interventions already, meaning that simpler or more blunt tools and analysis may ease burden compared with more complex tools. Nevertheless, they did discuss how this was a trade-off, given that any introduction of a more granular method would likely capture the impact more accurately, so this should still be considered.

The majority of stakeholders highlighted that for any changes that are made, training the committees will be vital to make sure any changes are implemented with the highest quality standards. It was suggested that NICE regularly offers training to committees as part of their

technology appraisal preparation, so any updates around considering inequalities could be added to the current training.

5.5.2 Power imbalance

Two stakeholders believed that there tends to be a power imbalance within the committee when it come to the economic analysis. However, other stakeholders disagreed this was the case when this feedback was raised with them. The two who raised the power imbalance described how there may be only one or two health economists sitting on the committee, which means they provide a key component of committee decisions by aiding clinical experts to interpret the economic evidence. In these cases, bias or opinions of the health economists may sway or hold more power when discussing the evidence in the wider committee. Therefore, to ensure there is a balance of power between committee members, it is important that committee members receive adequate training so they can interpret economic analysis results. NICE is currently doing more work on making sure committees are adequately trained for the decision-making process, while some stakeholders did not see this as an issue for this very reason.

5.5.3 Understanding of Inequalities

Despite much work being done already to train and improve the understanding of health inequalities among committees, stakeholders provided some examples where committees do not fully understand or consider health inequalities. The most common example was that committees may state there are no concerns for inequalities, since the treatment will be offered to everyone regardless of sex, ethnicity, socioeconomic status, or other factors. Stakeholders stated how this does not take into consideration multiple factors associated with health inequalities including:

- Access to care among people with different backgrounds or characteristics.
- Health education, uptake of interventions and the willingness of different people to engage with management of their own health.
- Health opportunity costs associated with funding the intervention.

Multiple stakeholders therefore raised how more needs to be done to educate committees and understand some of the wider nuances associated with health inequalities.

5.6 Data Use and Availability

Most stakeholders discussed the use of IMD, and how this was a useful tool for capturing deprivation. The benefit of IMD is that it is reported quite widely in multiple datasets, which makes it particularly useful for quantitative analysis. Stakeholders generally perceived this as the best quantitative tool to capture differences in deprivation, since it captures location, crime rates and unemployment into a single score of deprivation. It was noted that IMD does still come with limitations. Since it is a single measure, it is not able to capture specific types of health inequalities, while certain nuances may be missed on a more granular level. For example, ethnicity is likely to factor into multiple components of IMD, so it is difficult to pinpoint exactly how ethnicity may impact deprivation using this relative measure. One stakeholder raised the fact that research has begun to look at an ethnicity related measure that captures

deprivation, although this is only at the early stages. Most stakeholders suggested that better data collection on health inequalities will be key to continuing improvements for addressing inequalities in technology appraisals.

Two stakeholders commented that data collection in trials is regularly conducted in a group that does not match the disease population. Examples included diseases which had a high prevalence of ethnic minority groups, yet trials would have very low representation of these groups. One stakeholders also noted that clinical trials can often cherry pick the healthiest group most likely to respond to treatment, while the true treated population may be sicker and less responsive. Therefore, it was suggested that NICE could be stricter around the population used in clinical trials for technology appraisals to improve representation of ethnic minority groups.

6 Discussion

There are now methods developed, as well as quantitative analysis, which can be used to facilitate and contextualise health inequalities within technology appraisal. Throughout the synthesis of the literature and discussion with stakeholders, an overarching theme was that more could be done to address health inequalities as part of HTA processes and that there are a variety of options to do this. If NICE were to adopt a particular approach, it is important to consider the following:

- The contrasting benefits of different approaches to inequalities.
- Whether multiple methods could be utilised.
- The potential policy implications associated with different approaches.

NICE has begun implementing multiple steps on health inequalities. Most of this has been focused on guideline development, with little change on the technology appraisal process. NICE has also launched the 'NICE Listens' engagement programme, to improve the understanding of public opinion and social values [9]. This research highlighted the following recommendations:

- Prioritisation of technologies that will have the greatest (positive) impact on quality life years for the greatest number of people (health optimisation). Participants believed that improving living conditions for most people would gradually improve them for all.
- Ensure that decisions on technology did not lead to loss of life years in more disadvantaged groups
- Prioritise guidance looking at preventative actions to improve health outcomes and tackle health inequalities.
- Health inequalities should be embedded into every NICE decision process.

This research did not aim to quantify any potential trade-off between health inequalities and other aspects of value, such as cost-effectiveness. The research did not conclude how health inequalities should be embedded into NICE's decision making, which is necessary for a transparent process. Similarly, the lack of clarity is also reflected in the NICE methods guide [30], which fails to include guidance on potential quantitative evidence for health inequalities, or how it will be valued during the appraisal. Therefore, there is an opportunity for NICE to expand this research and gain a better understanding how societal preferences can be accommodated practically into technology appraisal.

6.1 Traffic Light Assessment of Different Methods

Important components associated with the use of different methods to incorporate health inequalities in economic evaluation and HTA frameworks are described in Table 6.1. Alongside this is a traffic light assessment of each method, as well as a brief rationale for this rating. It is acknowledged that this ranking is entirely subjective, however, we feel that this is useful to contextualise some of the differences in benefits of adopting different methods. The traffic light

system implemented is based on York Health Economics Consortium's own value judgements on this topic from the analysis undertaken. Any judgements made are not necessarily a direct reflection of the literature or stakeholder opinions.

With regards to generalisability, DCEA provides the most flexible approach with clear application across disease areas and intervention type. This is shown through the explicit measurement of health inequalities in the outcome distribution, something that is relevant to all healthcare systems. In contrast, ECEA is often based on FRP, which is not particularly useful in a public-centred healthcare system which is free at the point of use. If other outcomes were selected, it is not clear how these would differ across disease area and how they would be incorporated into the decision-making process. There is an opportunity for further research in ECEA using alternative outcomes. However, alternative methods may still be more effective for capturing health inequalities in technology appraisal.

Some concerns we identified were the inability of deliberative process only, EBW and MP methods to explicitly measure changes in health inequality outcomes. Stakeholder feedback highlighted how this would be extremely important for implementing any changes to NICE processes. MCDA may also share this concern, but capturing any factor within this method would also include using another method to inform the MCDA. Deliberative process only is the current method adopted by NICE, where little is done to quantify inequalities as part of technology appraisals. Alternative methods such as DCEA and ECEA present an opportunity for NICE to explicitly measure these changes in health inequality outcomes.

Finally, with regards to analytical requirements around data availability and technical complexity, EBW and any type of quantitative MCDA would require the most data collection. EBW should be based on societal preferences, which would require detailed research into what weighting factor would represent societal values, and if this should differ by disease area or other characteristics. Similarly, quantitative MCDA would have to include preference weightings for all aspects of value, so would require more research than an EBW method. There is an argument that NICE should be prioritising this type of research anyway, but this should be made an even higher priority if either of these types of methods were to be adopted.

Although we have evaluated each method separately in the traffic light system, this is not to say that methods could not be used in conjunction with each other, to reduce the limitations of choosing only one method. This was a key point highlighted throughout stakeholder engagement, that while any method may be useful to inform health inequalities, deliberative process should still be at the heart of decision-making. It is important to note that despite some categories being assigned red, this does not necessarily mean this method should not be implemented. For example, a red score for 'How much change is required to the technology appraisal process at NICE?' is just indicative of how much resource may be required, rather than stating updates to methods should not occur. Even a major change to current NICE processes could represent a strong opportunity to improve evaluation in technology appraisal.

Table 6.1: Summary of methods or tools for evaluating inequalities in HTA at NICE

Method	Deliberative process only	EBW	ECEA	DCEA	MP	MCDA
Can the method measure the change and size of the impact on health inequalities?	Cannot consider change and size of impact on inequalities without any quantitative context.	Method cannot capture changes in inequalities, only applying modifiers to those interventions believed to address inequalities.	Can measure changes in the impact on the inequality outcome used if an appropriate extension can be used (in this case not FRP).	Can capture changes in inequality through the method, as well as changing preferences to inequality aversion.	Unable to capture any difference in the size of the impact. Can capture the direction though.	This would depend on the quantitative analysis to contextualise deliberation or provide a score.
Does the method require additional data compared to what is currently utilised?	No extra data required to deliberate on value. Although would benefit from some quantitative context.	Need to undertake large amount of research to elicit inequality preferences it include any modifier.	Depending on the outcome chosen in ECEA, data requirements could vary widely. FRP would not be suitable for the UK.	IMD is useful for the UK, but issues with accessing relevant data from CPRD to populate DCEA.	Little extra data may be required for some based on IMD. More specific indications may require more disease burden data in these subpopulations.	For non-quantitative MCDA, no extra data would be required, this would be more deciding how to structure deliberation. Quantitative MCDA would require significant data research into preferences for decision making.
How much change is required to the technology appraisal process at NICE?	Current system implemented, no real change.	Would require little change in the NICE process to implement.	Would require research into feasible outcomes to use beyond FRP. How this is weighted into the submission would also have to be researched.	Would require some change to advice including when and how this should be used within NICE processes.	Training probably required to technical staff for evaluation. Guidelines for constraints would need to be developed.	This would depend on the extent to the principles being implemented. Re-forming structure would require additional work, but a scoring system would be an overhaul to current methods by NICE.
How much additional training would be required at NICE?	Minimal training required, only to refine process.	Would require little training for committees to interpret the results.	Some training for committees to interpret the meaning of the extended results.	Training required for committees to interpret the evidence provided by DCEA.	Minimal training, as the interpretation should be similar to current system.	Out of all the methods, any changes to structure of way committees make decisions would require the most training. Any scoring system would take the most work.

Method	Deliberative process only	EBW	ECEA	DCEA	MP	MCDA
How generalisable is the method across disease areas? (e.g. chronic lifetime illness versus acute illness)	Can easily be applied to all types of disease areas or interventions.	Unclear if different disease areas should be given weighting based on societal preferences.	Some concern how this method would be applied to different disease areas. Outcome may differ depending on intervention.	Can be adapted for other disease areas, although this may be limited somewhat by data availability.	Unclear if constraints should differ between disease area or intervention.	If non-quantitative, structure of deliberation should apply across all disease areas. Quantitative method raises concern if different weights should be given to different disease areas.
Is the method transparent or easy to interpret?	Conceptually very intuitive, not particularly transparent over aspects of value.	Conceptually simple, the value of the weighting is transparent, even if how that was derived may not be.	Generally transparent and conceptually interpretable. Analysis not usually too complex.	Methodology is transparent, but the conceptual complexity to interpret the results is slightly more complex than other methods.	Method is transparent with clearly defined constraints, with outputs conceptually the same to standard cost-effectiveness results.	Clear structure allows for transparency of result. Conceptually makes sense as it is about structuring deliberations.
Does the method Integrate with cost-effectiveness outcomes?	Does not integrate inequalities with cost-effectiveness outcomes.	Directly included as an outcome from the cost-effectiveness results.	Integrates as an output of the CEA, but the output is a secondary result.	Needs fully incremental cost utility results and a measure of marginal opportunity cost. Is an extension of the CEA	Integrates directly with cost-effectiveness outcomes.	Cost-effectiveness analysis results incorporated into MCDA, rather than the other way around.
Is there additional technical requirements to implement the method?	No technical requirements to implement. Already conducted at NICE.	Very little technical requirements to implement the method.	Technically previous methods are well documented and not particularly onerous.	Particularly aggregate DCEA is now well documented, with tools developed to aid this analysis.	Method less well documented in healthcare and technically more sophisticated.	Either MCDA method would require some re-structuring and implementation.
Does the method offer a clear conclusion to the reimbursement decision?	This process does not offer a clear conclusion to the decision unless it is well reported and structured in deliberations.	Offers a clear conclusion through the cost-effectiveness results.	The results are included as part of the cost-effectiveness model but are not fully incorporated into the result.	Due to a lack of data on inequality aversion, a clear conclusion cannot be offered.	Offers a clear conclusion through the cost-effectiveness results that are optimised.	MCDA should be structured to offer a conclusion, although the underlying mechanism to reach it may not be clear.

CPRD- Clinical Practice Research Database, CEA- Cost-effectiveness analysis, EBW – Equity-based weighting, ECEA – Extended cost-effectiveness analysis, DCEA – Distributional cost-effectiveness analysis, MCDA – Multi-criteria decision analysis, MP – Mathematical programming, HTA – Health technology assessment, FRP – Financial risk protection.

6.2 Key Policy Considerations

From both the pragmatic literature review and the stakeholder engagement, six main methods were identified to potentially augment the current approach to health inequalities. Stakeholder engagement led to the idea that any tool or approach that is used should help guide and support the deliberative process. Hence, whatever is used to help inform impacts on health inequalities, deliberative process should still be at the centre of any decision-making approach. Quantitative analysis to add context and detail to a deliberative approach would generally be welcomed.

Deliberative processes must also deliver a transparent and clear approach to decision making. As highlighted in the literature, there are many reasons why theoretically this should be the case. Current structures of committees' centre around the discussion of the presented evidence generated through the appraisal, with value judgements made on the costs and benefits. In reality, there are practical barriers that can derail the ability to be transparent such as committee biases, lack of a coherent structure for deliberations, or the autonomy given to committees. Although discussions may consider multiple aspects of value, this deliberative process needs strict guidelines on how much flexibility committees have, in order to balance cost-effectiveness with needs or wants of society (such as health inequalities). Any future changes to the deliberative process must give greater clarity to how evidence on health inequalities is valued. If companies are going to produce greater evidence on health inequalities, there needs to be an incentive that this information will be accommodated by NICE.

When considering different tools or methods which could be used, all identified methods appear to have some limitations in their use. These limitations include generalisability issues, data issues, or difficulties in their interpretation. Due to ECEA's general application to low- and middle-income countries and financial risk, this method in its current form would not be applicable to NICE decision-making. Similarly, MP would also not be useful, given the decisions NICE makes form around incremental analysis, and any MP tool would likely not capture the nuances to really inform a deliberative process. MCDA methods which take a more quantitative scoring approach have significant data gaps for implementation in HTA at NICE. These data gaps are primarily eliciting all weightings for every different aspect of value which is important for decision making. This type of MCDA would likely require large changes in NICE processes, so this method is unlikely to be feasible, at least in the short- or medium-term. ECEA, MP and quantitative MCDA could be considered less useful than other potential methods already outlined in this report. YHEC would therefore recommend looking at alternative approaches.

NICE facilitates a structured deliberative process, however, this could further be enhanced by using parts of the MCDA framework. This would enable different aspects of value to be more fully considered. There are examples of some HTA bodies drawing more from an MCDA style approach to deliberation, such as Pharmac in New Zealand. The benefits of adding more structure to any deliberative process is not just to improve the consistency of the outcomes, but also to improve the transparency about which factors are considered by decision makers. For instance, there may be situations where NICE would be willing to approve health technologies which are above the cost threshold. This approval could be either related to health inequalities or another aspect of value. By implementing a more structured approach to committee

deliberations from qualitative parts of MCDA, a clearer rationale should be documented when decisions are made.

EBW was considered within the literature and with wider stakeholders to be a more simplistic tool for quantitatively capturing the impact of health inequalities. Some stakeholders saw the benefit of using this within technology appraisal, given this type of analysis would be an easier way to augment current NICE processes. However, three key issues were established. Firstly, EBW is unable to measure or capture the size of the impact the technology will have on health inequalities. EBW does not account for opportunity costs associated with implementing an intervention, which is key to understanding the impact on health inequalities. Without this type of analysis, it would be unclear when it would be suitable to apply a health inequality modifier. The second issue is the potential for double counting in the decision-making process. This is because the modifier may be used, but then health inequalities being discussed and implicitly weighted again as part of the deliberative process. Thirdly, there is a lack of genuine consultation to derive an equity weight to account for health inequalities. NICE has conducted research on societal preferences, but this only covers more qualitative aspects, rather than any quantification [31]. This does demonstrate NICE's willingness to engage in research to understand societal preferences, which could lead to a more quantitative research project.

As suggested by some stakeholders, EBW does offer an easy interpretable tool to consider health inequalities, which can be particularly transparent to incorporate into decision making. It is also important to note the inconsistency with using EBW for disease severity, but not health inequalities. Future research on societal preferences and how we quantify them should be prioritised, while understanding societies views on introducing a modifier should be sought. Other methods to capture health inequalities may still be more robust or preferable. This research gap presents NICE with an opportunity to better understand the feasibility of conducting EBW for health inequalities, while taking into account the strengths and limitations of the method.

The alternative suggestion of using EBW as threshold analysis may be useful to highlight how much QALYs would have to be weighted to reach a cost-effective outcome. The weighted results would be used for interventions which are expected to lead to changes in health inequalities. This would not use a specific threshold but would give the committees some context of discussing health inequalities in relation to cost-effectiveness. However, this type of analysis runs the risk of implicitly creating a severity weighting without eliciting societal preferences. This is because there may be a risk of committees implicitly assigning a value they would be willing to go up to. Rather than it be used as context in the deliberations, it may be used as an unofficial modifier threshold.

DCEA is a method which has been developed during the past decade [49, 51]. Given that NICE has developed a protype tool to use aggregate DCEA in some of their guidelines, this indicates that NICE prefers aggregate DCEA as a useful tool. This may be because DCEA:

- Captures the health opportunity cost of the intervention.
- Is presented alongside the cost-effectiveness results.
- Allows for measurement of the size of the impact on health inequalities.
- Is conceptually and technically feasible to implement.

The challenges with using DCEA in technology appraisal are generally related to data availability. In the UK, data for a DCEA is likely to be captured using IMD from CPRD datasets. These datasets are costly to access; hence, the risk is that only those companies that have a technology which reduces inequalities will provide any analysis. This means that technologies that increase health inequalities will be considered as neutral, which inherently incorporates bias into the decision-making process. Companies may be unwilling to produce this analysis as well if the results of the DCEA are not truly incorporated into the deliberative decision-making process. Therefore, it is important that NICE continue to improve their deliberative process, so that all aspects of value are given fair reflection. Even if the data for a DCEA can be accessed by companies, the condition may be too specific in some cases to capture the population of interest.

Another challenge with DCEA is the requirement to estimate the true opportunity cost of health. If the cost-effectiveness threshold used is higher than the true opportunity cost, this would lead to inaccurate estimations of the incremental benefit by deprivation group, given health forgone by each IMD quintile would not be correct. If NICE was to implement DCEA in technology appraisal, they would have to understand and accept the consequences of getting the marginal opportunity cost wrong, given evidence this may be lower than the current NICE threshold [78]. This is not to say that the NICE threshold should necessarily equal the opportunity cost, as authors have argued this should be based on willingness to pay for health, but using the current cost-effectiveness threshold to represent opportunity cost may lead to incorrect evidence when using DCEA [72].

Implementing a clearer and more transparent methods guide and appraisal process creates an opportunity to better engage companies in health inequalities research. Despite some limitations with DCEA, these are limitations that can be overcome or controlled. DCEA presents an opportunity to more clearly account for health inequalities in technology appraisal.

As part of technology appraisals, it may be useful for NICE to advise companies if a DCEA would be suitable once the final scope and population is decided. This is because if the relevant population can be modelled, DCEA is likely the most appropriate tool to guide any committee deliberations on health inequalities. Also, given that NICE has developed a DCEA tool, this could potentially be used by companies or Evidence Assessment Groups (EAGs) to perform or update any DCEA, reducing the burden of analysis for those involved. By EAGs performing DCEA as well, this would prevent only focusing evaluation of health inequalities on those reducing them. EAGs could highlight technologies which would increase health inequalities, rather than assuming those who have not conducted a DCEA having a neutral impact on health inequalities. This is because if NICE consider technologies that reduce health inequalities as important, NICE must also consider the impact of technologies which widen health inequalities.

Overall, the view from the stakeholders was that quantitative evidence would be welcomed to support evidence in submissions on health inequalities. It was noted that even descriptive statistics around the burden of disease or access to care would be useful in any submissions. NICE stakeholders noted the health inequalities section of the company submission is often only populated with qualitative work, is not really populated at all, or more detail could be given. If a deliberative process at the committee stage of technology appraisal is using this information, descriptive statistics and any additional context would be worthwhile to better inform the discussions. The additional context on health inequalities is important because a true

deliberative discussion may be difficult if the context or size of the issue around health inequality is not detailed or understood. It is important to note that the current submission form lacks detail from NICE about what would be useful to be included on health inequalities [79]. Amending this with instructions or suggestions would be useful to encourage companies to submit this wider contextual evidence.

If companies are able to provide additional evidence on health inequalities, this may be costly or resource intensive for the company. Given different stakeholders have raised how health inequalities do not always get fair attention in committee deliberations, companies may have little incentive to spend significant resource to do this analysis (such as accessing CPRD datasets). It is important for NICE to be clearer on the impact health inequalities should have on decision making and making sure health inequalities is properly discussed during committee deliberations. This additional clarity for committee discussions should act as incentive for companies to then provide the additional evidence or analysis. The additional evidence generated should in theory lead to the opportunity for greater flexibility in decision making and a more informed decision-making process. Recommendations we have made in this report in Section 6.3 should help in supporting this decision-making process.

6.3 Recommendations for the NICE Technology Appraisal Process

6.3.1 Companies

As part of this report, we have provided the following recommendations:

Recommendation One:

Contextualise the disease landscape with respect to health inequalities through more quantitative analysis

At a minimum, it would be useful for companies to provide some quantitative context, in addition to any qualitative summaries. Descriptive statistics may include:

- Burden of disease for relevant population by IMD, or another measure of inequality.
- Access or uptake of care.

Recommendation Two:

Companies should undertake internal or external training on the concepts of health inequalities, including how and why they exist.

Recommendation Three:

Aggregate DCEA may be useful for indications that have accessible and accurate data

The company can discuss the feasibility with NICE advisors.

6.3.2 NICE

As part of this report, we have provided the following recommendations:

Recommendation One:

Training should be offered to decision makers around understanding health inequalities.

This would be to consider deeper aspects of inequality such as access to care and health education. This should include training for committees on the concept of opportunity cost, so there is a better understanding of the true impact to health of approving new treatments.

Recommendation Two:

NICE should be involved in research on societal preferences for health gain in disadvantaged populations. This should then inform an equity-based weighting for QALYs or aggregate DCEA, if NICE was to consider these methods.

- It is important to engage a range of local communities to better understand their views on health inequalities, as well as understand why they exist.
- Consult with society to see if they believe a modifier approach should be considered for decision making on health inequalities.
- This research should look to quantify aversion to health inequalities in the UK, which could be used in quantitative analysis, for either DCEA or EBW. The outcomes of public consultation should be used to inform how much weighting is applied to health inequalities in NICE decision making.

Recommendation Three:

NICE should engage with Clinical Practice Research Datalink (CPRD) to support wider use of real-world datasets to support the inclusion of DCEA, given the cost concerns for companies to access to the government owned public health data set.

- Current access to CPRD datasets is expensive and is likely to deter companies from engaging with this data.
- NICE could look to facilitate a deal which allows easier access to this data for prospective companies who are looking to submit to NICE. Data could then be used to inform the context of inequalities in the deliberation process.

Recommendation Four:

NICE should operationalise some aspects of MCDA to better guide and structure the deliberative process, so that health inequalities are appropriately captured in any deliberations.

This will require an independent review of how deliberations currently take place and adjusting the structure of the decision-making process. This should hopefully improve the transparency and consistency when making decisions.

Recommendation Five:

NICE should engage with companies on the feasibility of conducting DCEA as part of the submission, also offering the DCEA prototype tool developed by NICE to respective companies.

This would require technical advisors to recommend this, based on the feasibility to the specific technology appraisal. It is expected this would only be applied in a smaller subsection of technology appraisals. As part of this recommendation, it would also be useful to:

- Provide access to the NICE prototype tool for companies who plan to use DCEA as part of their submission.
- Provide training internally for NICE technical staff on DCEA and how to use the prototype tool going forward.

Encourage the external assessment centre to include a DCEA, even if the company chooses not to, but a DCEA would be feasible.

Recommendation Six:

The NICE technology appraisal template should be updated to indicate to companies which type of analysis would be useful to provide in the context of health inequalities.

Recommendation Seven:

NICE should make clear how health inequalities are valued in decision making, the level of autonomy that committee members have and document this with any other updates in their methods guide.

Recommendation Eight:

NICE should be consistent in its approach to using EBW within healthcare decision making, including for health inequalities and all other potential uses.

7 Conclusion

Health inequalities have an impact on deprived populations which leads them to act as an important consideration when assessing the value of new health technologies. This report has highlighted the importance of capturing health inequalities as part of the technology appraisal process. Multiple methods have been developed to capture impacts on health inequalities which could be incorporated into HTA. Furthermore, stakeholder views were aligned that there is a need to do more to evaluate the impact decisions have on health inequalities. NICE has begun actioning multiple steps on health inequalities, although this has currently led to little change on the technology appraisal process. Therefore, there is an opportunity for NICE to go one step further and provide a more transparent and clear process to accommodate health inequalities into technology appraisal.

By conducting this report, we have combined what is reported in the literature with key stakeholder views, to make important and feasible recommendations to consider for technology appraisal. These recommendations include further training both to companies and NICE, an increased effort from companies to provide greater analysis surrounding health inequalities within submissions, as well as steps NICE can take to facilitate this. The benefit of these recommendations is to facilitate a more transparent and consistent appraisal process, where health inequalities are adequately represented as part of deliberations. This would work towards NICE's own objectives to make a real impact in reducing health inequalities.

Although these recommendations focused more on what could be considered feasible in the short- or medium-term, it is important to note there are potential longer-term goals which could be useful for technology appraisal. These include greater coverage of IMD across relevant datasets, so more detail can be provided on deprivation, as well as the development of other measures which could be used. These could be specifically related to ethnicity or other factors which would be important to capture aspects of deprivation.

The recommendations we have made in this report should bring about greater transparency and consistency for decision making at NICE, to account for health inequalities. There are many reasons health inequalities should be considered valuable to decision making. Current processes do not always account for health inequalities adequately during technology appraisal, leading to an inaccurate reflection of the technology being appraised. We acknowledge the complexities of decision making for technology appraisal and the need to balance many different aspects of value, but there is space and opportunity to do more to account for health inequalities.

In summary, in the near future, companies can and should provide additional analysis on health inequalities to NICE's committees. This additional analysis should in turn lead to a more informed decision-making process. NICE should also provide guidance on the flexibility committees have to make decisions when there are trade-offs to different aspects of value. It is also important that work takes place to understand the extent that society values health gain in disadvantaged groups, to inform any method for evaluating health inequalities that may be considered by NICE, such as equity-based weighting.

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Appendix A

Core inequalities questions

Q: What do you think about decision makers current approach to inequalities? Is this changing or have you noticed increased attention on health inequalities?

Q: Is there a particular type of health inequality that is receiving more attention than others? E.g., socioeconomic deprivation, race, gender, geography.

Q: Can you envisage a scenario where it would be acceptable for there to be lower overall population health, as long as inequalities are improved?

Q: When we are considering aspects of decision making (clinical benefit, cost-effectiveness, inequalities etc.), who's preferences should determine this? The committee, other stakeholders or the general public?

Q: What do you think about the way NICE currently evaluates technologies in the HTA programme? Does it adequately incorporate aspects surrounding health inequalities?

Method specific questions

Q: If distributional cost effectiveness analysis was to be incorporated into HTA, how difficult would this be to implement? Would significant training be required for committee members?

Q: How important do you think generalisability to different disease areas or types of intervention is for evaluating the impact of health inequalities? Would it be plausible to assume a constant trade-off for inequality in decision making?

Q: Is incorporating inequality into the cost-effectiveness results important, or do you think these could be evaluated separately?

Q: For exploring any method for capturing health inequalities, there may be a trade-off between interpretability and transparency, and the complexity of the analysis. Is it more important for the method to be easily interpretable, or complex to capture more detail on inequalities?

Q: Do you think multi criteria decision analysis (MCDA) would be useful for evaluating health policy or interventions? How significant would this be to implement into healthcare decision making?

Q: Do you think introduction of a modifier (equity-based weighting) would be appropriate to account for health inequalities?