NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Modular update to NICE manuals

Health inequalities

Task and finish group report

January 2025

Contents

Executive summary

1. Reducing health inequalities is one of NICE's core principles and a renewed commitment to tackle health inequalities is in our 2021-2026 strategy.

2. Within NICE health technology evaluations, decisions made by committees take account of health inequalities as laid out in NICE's health technology evaluations manual, NICE's statutory duties and NICE's principles. While committees have to date received qualitative information on health inequalities for some topics, the growth of quantitative techniques means that more guidance is needed on how to conduct, present and consider evidence on health inequalities in company submissions.

3. NICE has released a position statement to provide clarity to companies on how to present quantitative evidence on health inequalities in technology appraisal and highly specialised technologies programmes (NICE, 2024).

4. The purpose of this modular update is to build on the content of the position statement and update the manual for health technology evaluations. This will provide coherent guidance to committees, technical teams and stakeholders on how health inequalities should be considered.

5. The modular update seeks to provide clarity on what health inequalities evidence is relevant for technology evaluations and how this will be considered by committees. The conditions for judging when a health inequality impact is substantial and should influence a recommendation is not affected by the update. The consideration of health inequality impacts within a technology evaluation will continue to be in exceptional circumstances only, such as in the appraisal of

exagamglogene autotemcel for treating transfusion-dependent beta-thalassaemia in people 12 years and over (TA1003).

6. The proposed modular update on health inequalities will update the health technology evaluation manual to include the explicit acknowledgement of quantitative health inequality analysis outlined in the position statement. This includes the following changes:

    - That companies or stakeholders can submit evidence to justify the inclusion of health inequality analysis as part of an evaluation.
    - Specifying the methods that can be used to conduct health inequality analysis within economic evaluations, termed distributional cost-effectiveness analysis (DCEA). We note that these would be supplementary analyses only.
    - How committees should incorporate health inequality evidence into their deliberations. It states that committees determine the relevance of health inequality impacts, will not make optimised recommendations for subgroups defined by social characteristics and can apply flexibility to the cost-effectiveness threshold if the inequality reductions are considered substantial.

7. In addition, we will also provide a technology evaluations methods support document that stipulates a set of recommendations for conducting DCEAs. This is a new type of document that we propose for supporting non-reference case analyses. The content of this document will be subject to consultation, and will cover quality assurance of the evidence underpinning the analyses, providing advice relating to key input parameters and the presentation of results.

8. Within NICE guidelines, health inequalities are taken into account systematically during the development process and via quantitative analysis when data allows. This was the focus of a major update to the manual for developing NICE guidelines in January 2024. For this

reason, the manual for developing NICE guidelines is considered up-to-date and the current modular update on health inequalities does not apply.

Background

9. NICE is committed to promoting equality, tackling discrimination, and reducing health inequalities as part of our role in delivering evidence-based guidance to improve population health and make access to health and care services more equitable. Reducing health inequalities is one of NICE's core principles and a renewed commitment to tackle health inequalities is in our 2021-2026 strategy.

10. In 2020, a task and finish group considered the potential adoption of a health inequalities modifier as part of the health technology evaluations process, methods and topic selection review. It concluded that while there may be a moral case for valuing technologies that reduce inequalities more highly, further work would be required to address the complexities of designing and implementing such a health inequalities modifier.

11. These complexities were spotlighted in 2023, when a company submitted a distributional cost-effectiveness analysis (DCEA) as the base case in their evidence submission in a technology appraisal (TA). DCEAs expand on the typical economic evaluation approaches used in NICE assessments by producing evidence on how population health changes are expected to be distributed between social groups. NICE has released a position statement to provide clarity to companies on how to present quantitative evidence on health inequalities in TA and highly specialised technologies (HST) submissions (NICE, 2024). The aim of the position statement is to:

    - encourage the submission and use of quantitative assessments of health inequalities

- support committees to consider the results of DCEA in accordance with the remit of the programme
- exclude any consideration of a quantitative modifier using quality-adjusted life year (QALY) weights or health inequality impact that use an inequality aversion parameter.

12. The aim of this modular update is to build on and incorporate the guidance from the position statement into the NICE manual for health technology evaluations. This will provide coherent guidance to committees, companies, and technical teams on how health inequalities should be considered within health technology evaluations to encourage more consistent decision making.

Current approach in NICE manuals

13. Across NICE's guidance producing centres, our committees take health inequalities into account according to their respective manuals, NICE's statutory duties, and NICE's principles. Methods and processes to account for health inequalities vary between guidance programmes, often corresponding to the remit of the programme

14. When developing NICE guidelines, an equality and health inequalities assessment (EHIA) takes place at each stage in the process. For select topics, Health Inequalities Briefings (HIBs) are developed to provide staff and committees with evidence-based information on relevant health inequalities issues. HIBs include the formation of key questions and evidence-based recommendations to address health inequalities, and research recommendations to address gaps in the literature. The content of the HIBs is used to inform the EHIA and they are both published alongside the guideline.

15. When data allows, NICE guideline development teams may undertake a DCEA to understand how the health effects of an intervention are distributed across 5 socioeconomic groups in England based on the

neighbourhood index of multiple deprivation (IMD). This utilises a prototype tool (see more in previous and ongoing work by NICE).

16. The health technology evaluation manual states that details of any health inequalities issues should be included in the scope and guidance documents. Equality considerations are included at each stage of the process, from scoping and submission to external assessment and committee meetings. At consultation, stakeholders are invited to identify any equality issues that need special consideration. An Equality Impact Assessment (EIA) takes place at scoping and when the final guidance decision is reached. This is published alongside the final guidance.

17. The interventional procedures manual differs in how it specifies consideration of health inequalities. However, as this programme does not use economic modelling when producing guidance, health inequality analyses will not be relevant to this manual.

18. In practice, there are several important differences between the processes of guideline development and technology evaluation that explain the differences in approaches to health inequality considerations across NICE guidance programmes.

19. Notably, the remit of recommendations from TA and HST guidance does not extend to the implementation of the technologies in the NHS, which limits the extent for considering health inequalities by committees. HealthTech guidance has made recommendations around service delivery but this is uncommon.

20. The evidence reviews and economic modelling that underpin NICE guidelines are developed internally. Committees, stakeholders and NICE technical teams therefore have additional influences over the relevant evidence that support recommendations.

21. Technology evaluations in programmes that do not routinely require cost-effectiveness analysis (e.g. medical technologies) have potential for relevant health inequality impacts, particularly when a technology could improve access to care in underserved social groups.

22. Health inequalities are also a relevant factor during the selection of topics for NICE guidance programmes. The NICE-wide topic prioritisation manual states that the Prioritisation Board should consider how prospective topics could potentially introduce, increase or reduce health inequalities, and whether it addresses Core20Plus5 priority areas. Where evidence allows, deliberations will also consider the impact of the wider determinants of health (such as social, economic and environmental factors) on health outcomes.

Previous or ongoing work by NICE

23. In 2019, NICE established a dedicated workstream focussed on health inequalities that has led to methods and processes updates and strategic activities. Much of this work has taken place in the context of guideline development, which resulted in an update to the NICE guidelines manual in 2024. The EHIA tool has been developed to provide a structured framework for proactively identifying and reporting health inequalities at all stages of guideline development, replacing the equality impact assessment (EIA) tool in guidelines, quality standards and indicators. The HIBs continue to be piloted for select guideline topics.

24. NICE also commissioned a prototype tool for conducting DCEAs, noted above, which is being piloted in several NICE guidelines. Work is ongoing to update the tool and consider how it might be used more widely across guidance programmes.

Summary of available evidence

Methods for including equity considerations in cost-effectiveness analysis

25. DCEA describes the set of methods for producing evidence on health inequalities within an economic evaluation framework. Broadly defined, it produces estimates of incremental costs and outcomes of a technology over its comparator(s) by social subgroups, which are then scaled up to population level. DCEA explicitly accounts for opportunity cost of foregone outcomes that occurs when new technologies displace other health services. Results can be produced for health and non-health outcomes relevant to decision makers (Cookson et al., 2021). Applied DCEA case studies have typically evaluated changes to health inequalities in 2 ways:

    - Measures that describe the level of inequality reduction or increase, such as gaps, ratios and regression-based measures
    - Social welfare-based measures that weight health for each social group differently to produce an estimate of equity-weighted net health benefit. The weights are informed by studies of 'inequality-aversion' in the general public.

Public aversion to health inequalities

26. A systematic review on how averse the UK public are to inequalities in health outcomes across socioeconomic groups identified 15 studies, of which 7 estimated inequality aversion weights (McNamara et al., 2020). The review found that most studies (n=11) provide evidence in support of a more equal distribution of health benefits while 2 studies provided evidence in opposition. The evidence was inconclusive in 2 studies. Although general aversion to inequalities was reported, there were significant variation in the strength of this aversion and the methodologies used.

27. We identified 4 studies matching the search criteria of the original study. The findings were consistent with previous research, which show aversion to health inequalities in the general public (Asaria et al., 2023; Robson et al., 2024), which increased when the groups were labelled with social characteristics associated with health inequalities. The studies also found that reducing inequalities life-expectancy was more valuable than reducing those in pain or mobility (Arroyos-Calvera et al., 2023; McNamara et al., 2021).

28. In summary, the evidence suggests that the UK general population is willing to forego some improvement in population health to reduce health inequality. However, there is substantial uncertainty in the inequality aversion values elicited from the studies, which could arise from differences in study design, sample demographics or changes in social preferences over time.

Approaches taken by international HTA bodies

29. A recent review of HTA agency methods manuals (n=46) examined how different agencies approach equity (Saygın Avşar et al., 2024).

30. Currently, the only HTA agency to recommend the use of health inequality analyses in their methods manual is HTAIn in India. However, this does not include details on how this evidence should be produced, or how it should be considered alongside typical cost-effectiveness evidence by decision-makers.

Stakeholder engagement

31. To ensure the updated manual is useful and useable to NICE committees, we held a 3-hour online workshop to gather the views of 21 members (and former members) of TA, HST, HealthTech and guidelines committees. Participants were broadly supportive of NICE's proposals around evidence standards for health inequalities data and analyses, but raised several notable concerns:

- the additional uncertainty and complexity that quantitative evidence on health inequalities could add to the appraisal process
- the risk that companies “game” the system by submitting only evidence showing favourable outcomes
- whether the proposed changes would have a meaningful impact on the overall health inequality gap in England.

32. The feedback from the committee member workshop has directly informed the manual update by identifying the priority areas for providing clear guidance to companies on the types of methods and evidence NICE will accept when considering quantitative health inequality impacts.

33. It is not expected that individual pieces of NICE guidance would substantially impact on English population health inequalities, most of which are driven by factors other than healthcare. NICE’s decisions must be considered cumulatively and as part of wider system efforts and the national drive to reduce the health inequality gap. There may be some circumstances where a health technology could have important distributional impacts that are crucial for committees to consider in their decision making.

34. We sought the advice from the 5 following experts in the field of DCEA to inform a robust set of methods and evidence standards:

    - Professor Richard Cookson, University of York
    - Professor Susan Griffin, University of York
    - Dr Colin Angus, University of Sheffield
    - Dr Miqdad Asaria, London School of Economics
    - Dr Brendan Collins, University of Liverpool

35. Each expert provided written comments on specific technical questions via an online form and attended a 2-hour roundtable event where the

aim was to reach a consensus on topics, where possible. The broad topic areas covered in the roundtable event included: quality assurance of data and methods, uncertainty, health opportunity cost, and approaches to stratification. Broad consensus was reached on most topic areas, with the following exceptions:

- Whether to mandate probabilistic sensitivity analysis (PSA) as part of the DCEA submission. This is standard practice in cost-effectiveness analysis and effective quality assurance would identify inappropriate applications. The counterview was that a full PSA is not necessary and that deterministic sensitivity analysis would be sufficient to evidence the likelihood that a technology will impact health inequalities.
- What distribution of health opportunity cost should be used. The existing evidence addressing this question indicates that when NHS services are displaced by expenditure on new interventions, the forgone health benefits fall disproportionately on more deprived groups. However, some experts noted that this evidence has methodological limitations and that a flat health opportunity cost distribution would be the most appropriate base case assumption for DCEAs until further evidence became available to support an alternative assumption.

36. We held 2 pre-consultation webinars to share proposals of the modular update with industry stakeholders and voluntary and communities sector stakeholders, respectively. These were held to engage important stakeholders with the modular update process and familiarise them with the key aspects of the update. A total 94 people attended these sessions (38 for the industry webinar and 56 for the voluntary and communities webinar).

Inequality-increasing technologies

37. The burden of many health conditions falls disproportionately on socially disadvantaged groups. Data from the Office for National Statistics shows that age-standardised mortality rates are higher in more socially deprived groups for 31 out of 34 common physical health conditions. We identified little evidence on technologies that have the potential to increase health inequalities. However, there is potential for NICE to evaluate inequality-increasing technologies which will have relevance to NICE's methods. The most prominent instances of this relate digital health technologies and the risks of digitally excluding people in socioeconomically disadvantaged groups.

Proposed changes to the manual

38. The modular update on health inequalities seeks to provide clarity on what health inequalities evidence is relevant for technology evaluations and how this will be considered by committees. The conditions for judging when a health inequality impact is substantial and should influence a recommendation is not affected by the update. The consideration of health inequality impacts within a technology evaluation will continue to be in exceptional circumstances only, such as in the appraisal of exagamglogene autotemcel for treating transfusion-dependent beta-thalassaemia in people 12 years and over (TA1003).

39. The modular update on health inequalities will update the health technology evaluation manual to include the explicit acknowledgement of quantitative health inequality analysis outlined in the position statement. This includes the following changes:

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- How committees should incorporate health inequality evidence into their deliberations. It states that committees determine the relevance of health inequality impacts, will not make optimised recommendations for subgroups defined by social characteristics and can apply flexibility to the cost-effectiveness threshold if the inequality reductions are considered substantial.

40. In addition, we will also provide a technology evaluations methods support document (MSD) that stipulates a set of recommendations for conducting DCEAs. This is a new type of document that we propose for supporting non-reference case analyses. The content of this document will be subject to consultation, and will cover quality assurance of the evidence underpinning the analyses, providing advice relating to key input parameters and the presentation of results.

41. Within NICE guidelines, health inequalities are taken into account systematically during the development process and via quantitative analysis when data allows. This was the focus of a major update to the manual for developing NICE guidelines in January 2024. For this reason, the manual for developing NICE guidelines is considered up-to-date and the current modular update on health inequalities does not apply.

When health inequalities evidence should be considered

42. We recommend that quantitative evidence on health inequalities should only be considered by committees when the expected effects are proportionately meaningful.

43. The data requirements of DCEAs are substantially higher than those of typical economic evaluations considered by committees. This is because they require input parameters to be disaggregated by social characteristics, as well as requiring additional data on disease prevalence. This increases the likelihood of needing to make strong assumptions in DCEAs in the absence of evidence.

44. The MSD outlines key quality assurance questions relating to the data sources used in DCEAs and general advice on input parameter assumptions and sensitivity and scenario analyses.

Structured decision making: health inequalities

45. We recommend that the relevance of health inequality impacts to the value of the technology is decided by committees. This will be based on consideration of the size of health inequalities in the eligible patient population, the size of the estimated impact on health inequalities and the level of uncertainty in the health inequality analysis. This can include consideration of how structural or social barriers have limited the evidence base and generated additional uncertainty or bias.

46. Committees can account for the value of health inequality impacts in their recommendations by can applying flexibility to the cost-effectiveness threshold range. The degree of flexibility should be based on the judgement of the committee and not be prescribed by NICE. This is because the value of inequality impacts could depend on the complex interaction of multiple factors including the disease area, the social characteristics being considered, the social or health system determinants of the inequalities and the size of the impacts. However, we are explicit that recommendations cannot make optimised recommendations for subgroups based on social characteristics.

Proposed content for technology evaluations methods support document

47. The following points of guidance are provided to ensure greater consistency when considering quantitative health inequality evidence:

Stratification of social groups

48. We recommend that health inequality impacts are estimated using IMD to stratify social groups. The IMD is a measure of relative deprivation for small areas in the UK and correlates with other aspects of inequality, such as ethnicity, income, and education (ONS, 2020). Grouping the areas in quintiles provides a 5-level variable into which individuals can be placed based on their postcode. It is commonly used by the Office for National Statistics, the UK Health Security Agency and many other organisations in England to measure inequalities. As a result, considering inequalities by IMD will likely have the best data availability for estimating input parameters for DCEAs.

49. However, as it is a composite measure, IMD may underestimate inequalities if they are concentrated in specific aspects of deprivation. We have outlined examples where alternative or additional measures may be appropriate and specified what rationale is required in these circumstances.

Uncertainty

50. Given the limited availability of evidence on health inequalities, it is important to ensure the key uncertainties in a DCEA are explicitly acknowledged and explored where possible. Feedback from experts indicated that a full PSA may not be useful and that deterministic sensitivity analyses would be sufficient to inform committee deliberations. This aligns with feedback from committee members, who were concerned about the added complexity that DCEAs might bring to appraisals.

51. To ensure committees have a good understanding of the findings in the context of uncertainty, we have specified the need for companies to include a statement, with supporting evidence, on the likelihood that the technology under evaluation will increase or reduce the health inequality gap in the general population.

Uptake information

52. The NHS is legally obliged to fund medicines and treatments recommended in NICE's TA and HST guidance. This is reflected in the NHS Constitution for England, which states "you have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate". For this reason, we have advised that equal uptake should be assumed across all groups in the DCEA.

53. However, health inequalities may still occur because of differences in access to care or in health-seeking behaviour. Alternative scenarios may be presented when there is strong evidence to support this.

54. While TA and HST recommendations themselves cannot address implementation issues, information on uptake is required to provide a more complete picture of health inequality impacts and is useful in committee deliberations. It is also essential information for guideline committees to be aware of when TA and HST guidance is included in guidelines. We have provided guidance on the base case and scenario analyses related to uptake differences, and the evidence requirements around these.

Differential QALY weighting for social groups

55. DCEA can include a step in which differential weights are applied to the benefits and health opportunity costs by social group. These can take the form of either:

- direct equity weights that are derived for each group and applied to the net health benefit, or
- weights based on the level of inequality aversion present in society, that are derived from experimental and/or stated preference evidence and used to parameterise inequality and welfare indices such as the Atkinson index.

56. Weighting health benefits according to the social characteristics of the recipients is an important social value judgement that needs to be carefully validated. Published research studies eliciting social attitudes about health inequalities vary in their findings and are methodologically heterogeneous. The large range of inequality aversion estimates suggests substantial uncertainty in what is being captured by these stated preference studies. Furthermore, the conceptual basis for using them to support NICE recommendations has not been established.

57. For these reasons, we have specified that committees should not consider the application of QALY weights based on social group. Specifying differential weights for social groups would embed a set of social preferences into the health inequality analyses considered by NICE. These could potentially be challenging to alter in future were new conflicting evidence to emerge, which our review of the literature in this area indicates would be likely.

58. NICE will not commission further research into direct equity weights or societal inequality aversion parameters at this time. However, we will continue to monitor the evidence base and review this position if significant new evidence becomes available in the future.

59. We note that regardless of this uncertainty, the evidence suggests that the UK general population is willing to forego some improvement in population health to reduce health inequality, so we are satisfied that there is public support for our efforts to clarify and advance our methods for accounting for health inequalities.

Health opportunity cost

60. A key component of DCEA is to reflect the ‘net’ health inequality impact of a technology or intervention. This calculation requires an estimate of the ‘health opportunity cost distribution’. When technologies are cost increasing, this specifies how the forgone health benefits of displaced interventions are expected to be spread between social groups. When technologies are cost saving, it specifies how the health benefits of interventions that are funded using the freed-up resources are spread between social groups.

61. Estimating the health opportunity cost distribution is a complex task that involves analysing the relationship between healthcare expenditure and health outcomes at the general population level and stratifying the results by social group. There have been a limited number of studies that have addressed this issue, with each requiring strong assumptions to underpin the results. Notwithstanding these limitations, the studies have indicated the forgone health benefits will disproportionately affect those in the more deprived areas in England. This implies that new technologies that increase costs and affect IMD groups evenly would increase health inequalities because of the health opportunity cost gradient.

62. Due to the extensive methodological challenges involved with estimating the health opportunity cost distribution, this is expected to be a continued area of uncertainty in which NICE will closely monitor the evidence base. In the meantime, we advise using a flat health opportunity cost gradient while mandating scenario analyses with light and moderate gradients reflecting higher concentrations of health opportunity costs in more socially disadvantaged groups.

63. In the context of significant uncertainty, this cautious approach allows committees to consider how changing the assumption impacts the

results. We have identified this as a priority area on which we would we encourage and are keen to support research.

Outputs

64. Following feedback from experts, we have specified that total health benefit, health opportunity cost and net health benefit should be expressed in QALYs and presented for each IMD quintile. Presenting all 3 measures will allow committees to make deliberative judgements on the additional value of the estimated health inequality reduction.

65. A range of descriptive inequality metrics should also be calculated to assist the committee in interpreting the size of the health inequality impact. These can be simple gaps and ratios between the top and bottom of the distribution, or the results of simple regressions that can incorporate information on the net health benefits of groups in the middle of the distribution.

Equality considerations

Evidence on health inequalities

66. We considered how the structural and social barriers to participating in research could impact on availability of data to inform health inequality impacts. We have therefore noted that these potential sources of uncertainty and bias should be considered alongside the evidence and methods recommendations for conducting DCEAs. These concerns can be recognised by committees when making their recommendations. The manual updates state that can potentially tolerate higher levels of uncertainty in the evidence base when robust evidence of structural or social barriers is presented, which must be specific to the eligible population.

Health inequality impacts

67. Some methodological choices in the DCEA might lead to exacerbating health inequalities unintentionally. One such choice is about identification of the social groups to be included in the analysis. This update recommends the use of IMD which is a practical and widely used classification. However, it provides only a broad classification and more subtle inequalities among subgroups might be overlooked, such as certain ethnic minorities or people with specific disabilities.

68. To address this, committees could consider the use of different subgroups (other than those defined using IMD) where relevant, conditional upon companies presenting evidence to demonstrate why IMD is not suitable.

Structured decision making

69. A necessary step in conducting DCEAs is to calculate the net health benefits of a technology for subgroups defined by social characteristics. One potential way of using this information would be make optimised recommendations for these subgroups based on cost-effectiveness. This could potentially result in differential access to treatments between different social groups.

70. We therefore state that optimised recommendations cannot be made for groups defined by social characteristics. The selection of relevant subgroups within an evaluation should remain the same as it is currently, based on rationale that is clinically justifiable, methodologically robust, ethical, and lawful under equalities legislation.

71. We also note that the consideration of the health inequality impacts of technologies by committees is separate from NICE’s legal obligations on equality and human rights.

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