Health inequalities modular update consultation: Responses to themes

May 2025

In April 2024, NICE initiated a modular update to its <u>health technology evaluations</u> <u>manual</u> on the topic of health inequalities. NICE produced the proposed content of the modular update in January 2025. In accordance with NICE's principles of reviewing our process and methods and offering people the opportunity to comment on our recommendations, we then consulted with stakeholders on the proposed modular update content.

This document provides a themed response to the consultation which informed the changes to the health inequalities modular update.

Engagement and consultation overview

- A public consultation on health inequalities modular update was held between 6 January and 31 January 2025. Stakeholders were given the opportunity to provide detailed comments and responses on all sections of the consultation document and the supporting documentation.
- We received 135 comments within responses from 26 individuals and organisations, including trade bodies representing the views of their members. More details are provided in table 1.
- 3. Some respondents provided numerous comments (on multiple sections and themes) within one individually submitted comment, therefore the number of distinct comments was substantially larger than the figure quoted above.

Table 1 Consultation responses	by respondent type
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Respondent type	Number of organisations (or individuals)	Percentage (of 135 comments)
Industry	8	30%
Trade bodies/associations	3	14%
University/academic	5	19%

Respondent type	Number of organisations (or individuals)	Percentage (of 135 comments)
Consultancy	2	10%
Voluntary and community sector organisations	5	17%
NHS England & Department of Health and Social Care	3	10%

- 4. Key themes and questions that emerged from the consultation were:
 - When health inequalities impacts should be considered by NICE committees
 - The decision to not apply explicit weights to quality-adjusted life years based on social characteristics
 - How technologies that increase health inequalities should be considered by NICE
 - How qualitative evidence on health inequalities will factor into recommendations
 - The resources required to conduct distributional cost-effectiveness analyses (DCEAs)
 - Guidance given to committees regarding the implementation of the modular update.
- 5. This document summarises the comments we received on the consultation, our responses and, where applicable, any subsequent changes that will be made to the modular update. These are organised into 3 sections, relating to evidence on health inequalities, committee consideration of health inequalities and methods guidance on distributional cost-effectiveness analyses. Responses to the comments within each section are organised into the broader themes covered by the consultation comments.

Section 1: Evidence on health inequality impacts

Summary of comments received for section 1

- 6. Respondents were supportive of NICE providing extra guidance on how health inequality impacts are considered by NICE committees and what the evidence should look like. There was broad acknowledgement that reducing health inequalities is a valuable social objective that can be supported by NICE evaluations and recommendations.
- 7. There was agreement amongst respondents that this was a potentially complex area of analysis to integrate into NICE processes and methods. The proposals should be pragmatic and proportionate given the resource burden that producing and critiquing this evidence places on NICE and its stakeholders.
- 8. Respondents consistently emphasised the importance of qualitative evidence on health inequalities. This type of evidence can provide valuable information on the experience of people from disadvantaged or underserved social groups. Respondents noted that the value of qualitative evidence can be even greater in the context of health inequalities because the measurement of social characteristics in quantitative evidence is often inconsistent and incomplete, resulting in large data gaps. There was concern that this could result in differential access to new treatments for some social groups that are not frequently included in research data.
- 9. Some respondents felt that NICE's current approach to health inequalities, which has primarily used qualitative evidence and does not provide guidance on quantitative evidence, was appropriate. One noted that the modular update proposals did not include a rationale for change.
- 10. A common concern raised by respondents was that the inclusion of health inequalities evidence in company evidence submissions for technology evaluations should not be mandatory. Respondents noted that the costs to companies of producing this evidence routinely would be substantial.
- 11. Other respondents felt that the modular update could potentially discourage company evidence submissions that did not include health inequality analysis,

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which could have adverse consequences for patient access to health technology. One respondent suggested that some basic descriptive information on differences in disease prevalence by social group could be provided routinely, which would enable consistent consideration of health inequalities across evaluations without the need for extensive analysis.

- 12. Most industry stakeholders remarked on the costs of producing evidence on health inequalities in particular for generating all of the inputs of a DCEA, which could include estimating inequalities in disease prevalence, intervention uptake and treatment benefit. The costs of producing this evidence would be impractical for smaller companies. Other respondents felt that large hospital and primary care datasets could be routinely used to estimate some aspects of health inequality with less resource.
- 13. A number of respondents suggested that the relevance of health inequality considerations for a technology evaluation could be flagged at an early stage in the process. It was argued that this would help companies to generate and submit evidence on health inequalities where it was most relevant.
- 14. Respondents also highlighted the additional resource burden on other parts of the NICE process. Interpreting and critiquing complex health inequality analysis would have to be undertaken by NICE technical teams and external assessment groups (EAGs). Respondents suggested that NICE should ensure the relevant technical expertise is available for these tasks and that the timeliness of guidance could be affected, which could in turn affect patient access.

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The use of qualitative evidence on health inequalities

15. Qualitative evidence will continue to play an important role in the consideration of health inequalities in NICE evaluations. The modular update proposals focus on quantitative evidence on health inequalities because of the emergence of quantitative methods in economic evaluation that produce information on health inequalities. The rationale for undertaking this modular update is that NICE should provide additional guidance on this relatively new type of evidence.

- 16. However, quantitative analysis is unlikely to provide a complete picture of health inequality impacts, nor be produced in all relevant instances. This means that both qualitative and quantitative evidence on health inequalities can provide valuable insight within an evaluation.
- 17. We note that the proposed changes to the health technology evaluations manual include explicit recognition of qualitative health inequalities evidence in section 3.3.18. We have added clarification to the proposed new manual content on the relevance of qualitative evidence.

When evidence on health inequalities should be submitted

- 18. NICE confirms that the inclusion of evidence on health inequalities is optional for company submissions. As health inequality impacts will only be considered relevant by NICE committees in exceptional circumstances (see section 2), it would be an inefficient use of resources to generate, interpret and critique evidence on health inequalities across all technology evaluations. We have added detail to the proposed new manual content that clarifies that providing quantitative evidence on health inequalities is an optional supplementary analysis.
- 19. Companies will have the opportunity to discuss the potential inclusion of evidence on health inequalities during engagement with NICE technical teams, including during the development of the scope. However, it is important to note that deliberation on the relevance of the health inequality impacts, including any decision to apply flexibility to the NICE cost-effectiveness threshold, will be made by NICE committees at a later stage of the evaluation.
- 20. The potential for routine generation of descriptive statistics on health inequalities for a patient population is a potentially practical option for helping guide committee judgements on the relevance of health inequalities in an evaluation. This has been flagged as an area of important future research.

Quality assurance of evidence on health inequalities

21. Evidence on health inequalities included in company evidence submissions will reviewed by EAGs alongside the typical economic evaluation evidence.

Additional training and guidance will be provided to EAGs to ensure that reviews of evidence on health inequalities are consistent. Existing guidance principles for evidence, stated in section 3.2 of the health technology evaluations manual, will apply to evidence on health inequalities.

22. The modular update proposals should not affect the frequency that health inequality impacts are considered relevant to the value of technologies. As this will be in exceptional circumstances only, it is not anticipated that the update will affect timely production of NICE guidance or access to health technologies.

Section 2: Consideration of health inequalities evidence by NICE committees

Summary of comments received for section 2

- 23. Respondents felt that more detail could have been provided on when a committee would or would not consider a health inequality impact as relevant to the value of a technology. Several respondents sought a more precise definition of the term 'substantial impact' that committees will apply when making these judgements.
- 24. There were differing views on the value of evidence that can support judgements on whether the health inequality impact is substantial. Some respondents suggested data on inequalities in prevalence could be a useful source of information However, other respondents suggested that inequalities in prevalence would be common across disease areas.
- 25. Respondents were supportive of committees being able to consider how structural barriers can affect social groups accessing care and being included in research, which could reduce the availability or validity of evidence on health inequalities. Respondents sought more clarity on exactly how these considerations would factor into committee deliberations, alongside suggestions for how these concerns should be worded in the manual.
- 26. Many respondents would have liked more detail on how NICE committees will apply flexibility to the cost-effectiveness threshold when health inequality impacts were substantial. Several respondents asked whether these flexibilities allowed

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committees to apply thresholds within the NICE stated range of £20,000 to £30,000 per QALY gained or above the upper bound of £30,000 per QALY gained.

- 27. Respondents noted that the proposed content for section 6.2.36 to 6.2.39 of the health technology evaluations manual should be placed in section 6.3.8, as the latter relates to technologies where a threshold above £30,000 per QALY gained are discussed. Respondents were also interested in knowing exactly how much flexibility committees would be able to apply to the cost-effectiveness threshold, noting concern that there could be a lack of transparency around this aspect of committee deliberations.
- 28. There was significant feedback on how the modular update proposed to handle technologies that increase health inequalities. Respondents' views were mixed. Several noted that applying a lower threshold to health technologies that substantially increased health inequalities was essential to incorporate social concern for health inequalities in economic evaluations. Respondents noted that NICE's approach to considering health inequalities would be systematically biased if threshold flexibilities were only applied when there were health inequality reductions and not vice versa. It was also noted that using threshold flexibilities only for health inequality reductions risks increasing the cost impact of NICE recommendations on the health sector budget. A contrasting view was held by other respondents, who suggested that applying a lower threshold to technologies that increase health inequalities would act as a disincentive for pharmaceutical innovation and negatively impact patient access to medicines.
- 29. Respondents mentioned the importance of training NICE committees on the content of the modular update to ensure that they are able to appropriately interpret health inequality evidence and apply the threshold flexibilities relating to health inequality impacts. Respondents stressed that the implementation of the modular update content should be consistent across evaluations.
- 30. Respondents suggested that specialist committee members with expertise in health inequalities should be available for evaluations where evidence was

included in a company submission and would be deliberated on by the committee.

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Committee judgements on when health inequalities are relevant

- 31. Due to the complex nature of health inequalities, it is not practical to define a set of objective conditions for when health inequality impacts are substantial or not. There are many relevant aspects to health inequality, including inequalities in disease prevalence and uptake of and access to treatment. The causes of these inequalities can differ according to the disease area and the social characteristics associated with the inequalities. Committee judgements on the relevance of health inequality impacts can account for some or all of these factors, where they are applicable.
- 32. Judgements on whether the health inequality impacts of a technology are substantial should be made relative to what is offered by other health technologies and disease areas assessed by NICE. Inequalities in prevalence could provide a common yardstick to help support these judgements and identify the disease areas where there are the largest inequalities. This has been flagged as important area of future research to help with the implementation of the modular update.
- 33. Importantly, the modular update proposals do not affect the frequency that health inequalities should be considered relevant by NICE committees. Health inequality impacts currently fall under 'uncaptured benefits' in section 6.3.5 of the health technology evaluations manual. The modular update provides guidance on how these benefits can be captured in economic modelling, with committees having the same discretion as before to judge whether inequalities should factor into their recommendations.

Social or structural barriers to accessing care or participating in research

34. The availability and/or validity of evidence on health inequalities can be adversely affected by social or structural barriers to accessing care or being included in research faced by specific populations. This is explicitly acknowledged in the modular update proposals, which make allowances for these factors when committees consider the level of uncertainty in the evidence on health inequalities.

35. If and when the committee decides to apply flexibilities to the cost-effectiveness threshold to reflect the the value of health inequality impacts, the degree of flexibility will be dependent on the magnitude of the impact and the respective level of uncertainty. If the uncertainty can be attributed to social or structural barriers to accessing care or being included in research, committees will be able to apply a greater degree of flexibility to the cost-effectiveness threshold. This is contingent on robust evidence of social or structural barriers being presented to the committee.

Applying flexibilities to the cost-effectiveness threshold

- 36. The cost-effectiveness threshold is a benchmark incremental cost-effectiveness ratio (ICER) that committees use to make decisions about the acceptability of the technology as an effective use of NHS resources. The range varies depending upon a range of factors covered in section 6.3 of the health technology evaluations manual.
- 37. For technology appraisals, the committee's approach to recommending technologies with the following ICERs is articulated in the health technology evaluations manual, with benchmark values differing for other NICE guidance programmes:
 - Below £20,000 per QALY gained is usually considered an effective use of NHS resources
 - Between £20,000 and £30,000 per QALY gained the committee's decision will make explicit reference to the level of uncertainty and uncaptured benefits
 - Above £30,000 per QALY gained requires an increasingly stronger case for recommendation, considering the level of uncertainty and uncaptured benefits.

- 38. Health inequality impacts have historically fallen under 'uncaptured benefits' in the descriptions above, but are now being considered separately under the modular update proposals. In practice, this means that the committee will deliberate around the appropriate benchmark ICER to judge the acceptability of the technology as an effective use of NHS resources, as before. If and when the committee decides to apply flexibilities to the cost-effectiveness threshold to reflect the value of health inequality impacts, then the appropriate benchmark ICER value can be increased for technologies that reduce health inequalities and reduced for technologies that increase health inequalities. We have added detail to the proposed new manual content that clarifies how flexibilities around the cost-effectiveness threshold will be applied.
- 39. The flexibility can therefore be applied to any technology where there is a substantial impact on health inequality, not only those with ICERs above £30,000 per QALY gained, and should not be placed in section 6.3.8 of the health technology evaluations manual.
- 40. The degree of flexibility available to committees will depend on a range of factors, including:
 - the magnitude of the health inequality impact
 - the uncertainty around the health inequality impact
 - the social characteristics associated with the inequality
 - the health system and wider social causes of the inequality.

Each of these aspects can vary and interact with each other in ways that affect how the committee might evaluate the health inequality impacts.

41. The uncertainty in the health inequality analysis will be considered separately from the uncertainty in the reference case analysis and will apply only to the threshold flexibility relating to health inequalities. A higher level of uncertainty around the health inequality impacts will reduce the degree of flexibility that committees should apply to the cost-effectiveness threshold. This can interact with the assessment of social or structural barriers to accessing care or being included in research mentioned above.

Technologies that increase health inequalities

- 42. In order to value health inequality impacts consistently, the modular update proposals acknowledge that if more value is attributed to technologies that reduce health inequalities, then technologies that increase health inequalities should be attributed less value, when holding all other factors constant. This is consistent with the existing approach to considering health inequalities as a potential uncaptured benefit in an evaluation. The broader social considerations relating to health inequalities are reflected in principle 9 of the <u>NICE principles</u>, which states that "If possible, our guidance aims to reduce and not increase identified health inequalities".
- 43. NICE is investigating how technologies that would substantially increase health inequalities can be identified and whether health inequality impacts can be estimated without imposing disproportionate resource demands on NICE and its stakeholders.
- 44. Health inequality impacts should only be considered relevant by committees for inequality increasing technologies in exceptional circumstances where the impacts are considered substantial and supported by robust evidence.

Implementation of the update and committee training

45. Training on health inequality analysis is being prepared for NICE committees, EAGs and technical teams. This is an essential component of successfully implementing the modular update and will be undertaken once it has been published. NICE will also monitor evaluations over time to ensure the consideration of health inequalities is undertaken accordingly.

Section 3: Distributional cost-effectiveness methods guidance

Summary of comments received for section 3

46. Respondents were supportive of DCEA being used to model health inequality impacts within NICE evaluations. There was broad agreement that DCEA represents the most validated quantitative methodology for analysing health inequalities and is an appropriate approach for NICE to recommend.

- 47. Several respondents noted that DCEAs can take several forms. An aggregate approach takes data on inequalities in prevalence and uptake of a technology and combines them with an average incremental cost and QALY output from an economic model. A full DCEA also looks at inequalities in incremental costs and QALYs by varying inputs in the economic model by subgroups defined by social characteristics. Respondents argued that these nuances were not reflected in the modular update proposals.
- 48. Respondents had differing views about the decision in the modular update proposals to not explicitly weight the health benefits of social groups differently. Several respondents supported this decision, noting that studies that elicit social preferences for deriving weights or an 'inequality aversion' parameter have produced a wide range of potential values. Others noted that explicit weighting is an overly prescriptive approach to considering health inequalities and adds an further layer of technical complexity for NICE and its stakeholders to handle within evaluations.
- 49. Some respondents were supportive of using an explicit set of weights to reflect concerns for inequalities. One respondent noted that the flexibilities that committees can apply to the cost-effectiveness threshold are a form of implicit weighting. Others argued that there is a strong conceptual basis for using mathematical functions like the Atkinson index to trade-off between population health and health inequality objectives, and that NICE could use a temporary set of weights while commissioning new research. This would be similar to the approach NICE has used for the EQ-5D-5L value set.
- 50. Respondents were interested in the rationale underpinning the recommendation to use a flat distribution of health opportunity costs as the starting assumption within a DCEA. This implies that when NHS services are displaced by expenditure on new health technologies, the forgone health benefits would on average be distributed equally between social groups. Respondents also suggested that it would be appropriate to provide more specific guidance on the appropriate scenario analysis that should be conducted around this highly uncertain input.

- 51. A related concern from respondents was about the cost-effectiveness threshold that should be used to calculate the health inequality impacts. It was noted that the value of the cost-effectiveness threshold is an input in DCEA that determines the magnitude of the health inequality impact.
- 52. Respondents were broadly supportive that health inequality analysis should assume that the uptake of technologies across social groups should be assumed equal unless robust evidence is provided to demonstrate otherwise. Some respondents expressed concern that this would disincentivise companies to investigate the potential benefits that technologies could provide to addressing inequalities in uptake. Others noted that the generation of evidence on inequalities in uptake would be challenging for companies. This has implications for robustly estimating health inequality impacts, as it is a common and influential driver of health inequalities.
- 53. There was substantial comment on the recommendation to use the Index of Multiple Deprivation (IMD) to stratify populations into relevant subgroups. Several respondents identified instances in which IMD, which combines information on 7 aspects of deprivation, would not be appropriate to analyse health inequalities. The most cited alternative stratification approach was by ethnicity. However, others felt that IMD had the strongest evidence base for estimating health inequality impacts and was the most practical choice for encouraging consistency across evaluations. Respondents also noted that the recommendation on IMD being used to create 5 subgroups was arbitrary, and that more granularity would be always be preferable to more accurately reflect inequalities.
- 54. Respondents suggested that further clarity around how the appropriate stratification for an evaluation should be agreed and conducted. Respondents advised that rather than assuming that IMD was the most appropriate approach to stratification, a rationale should instead be provided to demonstrate why IMD is appropriate for each instance it is used. Having an explicit rationale for a stratification approach in each instance would then provide a conceptual basis for using relevant data using the same stratification approach as part of the DCEA.

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- 55. Respondents discussed the possibility of stratifying populations by multiple social characteristics. One respondent requested that illustrative examples be provided on when this would be appropriate and what the analysis would look like.
- 56. Respondents offered differing opinions on the recommendation that probabilistic sensitivity analysis (PSA), an approach to analysing uncertainty that looks at the combined uncertainty from all input variables simultaneously, will not be required for DCEAs. Some respondents agreed that this would be a burdensome requirement for analysts to undertake. Others suggested that PSA is in the NICE reference case for economic evaluations and is the most robust method for analysing uncertainty.
- 57. Several respondents cautioned that the evidence base for rare diseases is typically smaller and that the resulting uncertainty should be taken into account by NICE in the context of health inequalities.
- 58. Respondents also queried the approach to deterministic sensitivity analysis outlined in the methods support document. Respondents queried whether the selection of input parameters would be made by the company, recommended by NICE and/or suggested by the EAG.

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Recommendations on aggregate and full DCEA

- 59. The principal differences between aggregate and full DCEA relate to the number of input parameters that vary by social characteristics. For aggregate DCEA this is typically prevalence and uptake only, whereas for full DCEA this could be a large range of parameters in an economic model, from treatment effectiveness to background mortality and health-related quality of life. The trade-offs between these two approaches have been well established, namely that using an aggregate approach is less resource intensive, while a full approach captures more potentially relevant aspects of inequality.
- 60. The recommendations on DCEA have not extended to what types of inequality should or should not be modelled, focusing instead on important assumptions

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and guidance on evidence standards. It is incumbent upon those undertaking the health inequality analysis to robustly demonstrate the magnitude of the health inequality impacts, which could be established through a full DCEA if there is strong evidence that incremental costs and QALYs vary according to the relevant social characteristics. We have added detail to the methods support document that clarifies that analysts conducting DCEAs have discretion over what aspects of inequality are accounted for in the analysis.

Weighting QALYs by social characteristics

- 61. The flexibilities that committees can apply to the cost-effectiveness threshold when a technology has substantial impacts on health inequalities is not considered to be analogous to a fixed implicit inequality aversion parameter or QALY weighting being applied by committees in NICE evaluations. As noted above, the consideration of health inequality impacts involves a complex set of judgements relating to uncertainty, the social characteristics being considered and the social and health system causes of the inequality. These will vary substantially whenever health inequality impacts will be considered by committees.
- 62. This complexity and variability of health inequality considerations that could potentially arise across evaluations underpins the rationale for not recommending explicit QALY weighting approaches within DCEAs.
- 63. We also note some crucial differences between the use of temporary values for health-related quality of life and the potential use of a temporary set of QALY weights to reflect health inequality concerns. Health-related quality of life effects are a core component of the reference case analysis in NICE economic evaluations, making it necessary for a value set to be specified at any given time. Conversely, health inequality analyses are optional supplementary analyses that can be conducted without the use of explicit weighting.
- 64. Given the variability in studies that derive QALY weighting, there is also uncertainty that future research will arrive at a definitive set of weights that could be used to inform NICE recommendations. NICE therefore encourages research

on inequality aversion but has not committed to a programme of research that would yield a set of weights to use in health inequality analysis.

Distributions of health opportunity cost

- 65. Empirical research that seeks to estimate the distribution of forgone health benefits from new expenditure across social groups is highly complex, resulting in few studies that often require strong assumptions. Some studies have indicated that health opportunity costs could be more concentrated in more deprived groups, although it has also been argued that this gradient has been overestimated due to study limitations introducing bias. The uncertainty over the health opportunity cost distribution has informed NICE's position of recommending a flat gradient supported by scenario analysis. We have added detail to the evidence development document to clarify this rationale.
- 66. Specifying the health opportunity cost distributions to be used in scenario analysis would help to ensure consistency across assessments. We have added detail on recommended health opportunity cost scenarios to the methods support document.

Modelling inequalities in uptake

67. Differences in uptake across social groups can substantially influence the health inequality impact of recommending a new technology. Technologies that can improve the uptake of technologies in disadvantaged groups provide additional benefits in terms of health inequalities. The modular update encourages the generation of robust evidence relating to uptake, which can form a key part of a DCEA.

Stratification by IMD and other social characteristics

68. The modular update recommends the use of the IMD to stratify the population into social groups, as it has the largest evidence base, covers multiple aspects of disadvantage and can easily be calcuated from an individual's postcode. However, IMD has a number of limitations and will not be the most appropriate approach to stratification in all cases. We have added a recommendation in the methods support document for analysts to provide a rationale for the relevance

of IMD to the health inequalities associated with a disease area or health technology.

69. For a health inequality analysis to be consistent and coherent, evidence on health inequalities should have a consistent approach to stratification supported by an appropriate rationale. For example, it would not appropriate to provide a rationale for analysing health inequalities by ethnicity but use data by IMD in the DCEA. We have added a recommendation in the methods support document that outlines the stratification approach that is used in evidence on health inequalities should always be supported by a strong rationale.

Quantifying uncertainty in DCEAs

- 70. PSA is encouraged but not required for DCEAs as a means of quantifying uncertainty. It should be looked on favourably by committees considering health inequality impacts as providing a valid and robust measure of uncertainty. However, the key drivers of uncertainty in health inequality analysis can be appropriately explored in deterministic sensitivity analysis. We have added detail to the methods support document noting the benefits of including PSA in a health inequality analysis.
- 71. The choice of deterministic sensitivity analyses to be run within a DCEA is limited by the number of input parameters that are varied by social characteristics, but would likely include the disease prevalence rates, uptake of treatment and health opportunity cost distribution. Companies will have discretion over what sensitivity analyses to undertake and their submission will be reviewed by the EAG. We have added detail to the methods support document describing the approach that should be taken when undertaking deterministic sensitivity analysis in DCEAs.
- 72. Evidence generation is particularly difficult for certain technologies or populations, which would likely extend to evidence on health inequalities. When considering evidence on health inequalities, committees will apply the same principles as other types of evidence, outlined in section 6.2.34 of the health technology evaluations manual.