Board meeting

16 December 2022

Options appraisal for adopting a wider perspective in NICE assessments

Purpose of paper

For review and approval

Board action required

This report describes and appraises policy options regarding the perspective of economic analyses conducted by NICE, which dictate what types of cost and benefit are accounted for.

The Board is asked to support the recommendation made in the report that NICE should retain its current approach to perspective and update its processes to ensure consistent application of its current flexibilities so that assessments include wider costs and effects when relevant.

Brief summary

NICE uses a health sector perspective in its reference case for health economic assessments that routinely weighs direct health benefits against health sector and personal social services costs. NICE's guidance-producing programmes also include flexibilities in their approach to consider non-health benefits and other public sector costs when relevant.

Including economic productivity effects in assessments is ethically problematic because it entails valuing interventions differently based on the working status of the recipient population. Children, long-term sick and unemployed people and retired people are systematically disadvantaged when these effects are counted.

Formally broadening the perspective of NICE assessments would require substantial further research being undertaken - notably on valuing non-health benefits and opportunity costs and determining the relative value of health and non-health effects in decision-making. It would also require co-ordination with other public sectors to align methods and maximise outcomes across public expenditure. These activities would entail a multi-year programme of work and require significant NICE resources. The volume of this work would be disproportionate to any expected benefits to the quality of NICE decisions given the existing flexibilities to include relevant wider effects.

We therefore recommend that NICE does not change its reference case perspective for economic analysis. Instead, we recommend updates to internal processes to ensure consistent application of its current flexibilities and reduce the risk of relevant non-health outcomes and non-health sector costs not being included in the scope of an assessment and considered by committees.

Board sponsor

Felix Greaves, Director, Science, Evidence and Analytics

Introduction

Economic evaluations conducted as part of NICE assessments play a crucial role in determining the recommendations on what interventions and programmes represent good value for money for the NHS and other social and public health services in England. A central component of these analyses is the 'perspective' taken on what categories of cost and outcomes should be counted within the evaluation.

The decision on which perspective should be taken is a complicated issue that involves arguments about how to value health-related interventions and programmes and how the objectives of the health sector should be balanced against other public sector expenditure.

The choice of perspective is outlined by the 'reference case' specified in each of the NICE programmes' methods guidance (NICE, 2022, 2014a). The perspective currently recommended is commonly referred to as the 'health sector' perspective and requires economic evaluations to estimate the following effects:

* for outcomes, direct health benefits for patients and, when relevant, for other people (mainly carers)
* for costs, those borne by the NHS or personal social services.

The rationale for a health sector perspective is that it focuses NICE assessments on securing the best possible health outcomes from NHS resources (Greaves and Boysen, 2021).

The appropriate choice of perspective in economic evaluations is an area of active debate. Critics of the health sector perspective argue that it misses relevant aspects of treatment value (Jönsson, 2009) and that a 'societal' perspective should be adopted that includes a broader range of costs and outcomes, such as improved economic productivity or educational performance.

The COVID-19 pandemic has highlighted how wider societal outcomes can be important for evaluating the value of health interventions, where vaccines and other treatments were seen as a means of preventing lockdowns and school closures in addition to the direct health benefits (Appleby, 2020).

However, broadening the perspective of economic evaluations would also require NICE to reconsider aspects of its methods and processes in order to ensure the consistency and transparency of its assessments. Incorporating wider effects raises issues relating to availability of additional effectiveness evidence, the need for co-ordination with other public sector decision-makers and the identification of social values that influence how the different categories of effects are weighted and combined.

These reflections motivated the NICE Board to commission this options appraisal paper as part of the 2021/2022 business plan. The objective is to identify the perspective options available to NICE alongside their respective policy implications.

Our approach comprised three parts:

* a targeted literature review of published research and NICE documentation
* a series of internal engagement meetings with over 20 members of senior NICE staff with expertise in evaluation methods
* discussions with external organisations, including selected European health technology assessment (HTA) agencies with experience in adopting a wider perspective, and the Department of Health and Social Care (DHSC).

We provide a summary of the health sector perspective and the societal perspective in the next section. We then examine the range of ethical, practical and methodological issues that NICE would need to address if a wider societal perspective were to be adopted. We conclude by outlining and evaluating the perspective options available to NICE.

An overview of health sector and societal perspectives

Health sector perspective

A health sector perspective has been recommended in most NICE programmes since its formation. This means economic evaluations conducted as part of NICE assessments weigh the survival and quality of life benefits of health-related interventions, services and programmes against the cost impacts on the NHS and personal social services.

The justification for the health sector perspective is strongest where the resource allocation decisions relate to a publicly funded healthcare system with a given budget set by central government, as is the case with the NHS.

Societal perspective

Why consider a societal perspective?

While interventions treating other types of health conditions and diseases do not have the same far-reaching societal effects as COVID-19, many will create benefits outside of their health impacts. These are not accounted for when adopting a health sector perspective. This means that when adopting a health sector perspective, NICE may be rejecting treatments that would otherwise be recommended had the wider societal benefits been included.

The likelihood of these societal effects potentially influencing a recommendation decision will depend on the intervention type. Treatments for childhood diseases, for instance, will invariably affect educational outcomes and interventions that improve outcomes in serious mental disorders will likely generate benefits for the criminal justice sector.

An influential report from the Second Panel on Cost-Effectiveness in Health and Medicine recommended that a societal perspective be presented alongside a health sector one to "ensure that all consequences… are considered regularly and comprehensively" (Sanders et al., 2016, p. 1096).

Health inequality impacts and future healthcare costs that are unrelated to the intervention or disease area under evaluation are two categories of effect that are often raised in discussions on widening the evaluation perspective. Both arguably fall within the health sector perspective as they relate to healthcare costs and health outcomes. Therefore, neither is considered under the societal perspective in this paper.

We also consider environmental sustainability as a separate concern from the types of wider outcomes and costs discussed in this paper. This is because the key reasons for considering the environmental impacts of healthcare are to protect human health and to offset future healthcare resource use, both of which are inextricably linked to planetary health (The Lancet Public Health, 2022). NICE has a separate programme of work in progress to establish an overall strategy for supporting the environmental sustainability of the health and care system.

'Full' societal perspective

A full societal perspective is the widest possible perspective that can be adopted in an economic evaluation, in which all relevant societal costs and outcomes are accounted for. By having full information on societal effects, decision-makers would be theoretically able to make societally optimal decisions about expenditures across health and other public sectors.

The range of wider effects that would need to be incorporated under a full societal perspective is large. As we explore in the following section, there are many challenges associated with widening the perspective to include just a single additional societal effect. Table 1 illustrates the potential array of wider societal effects identified by the Second Panel on Cost-Effectiveness in Health and Medicine (Sanders et al., 2016). Uniformly adopting this type of societal perspective has been recognised as practically infeasible (Culyer, 2021).

Table 1. A full societal perspective covers a wide array of outcomes and costs (adapted from Sanders et al. (2016))

|  |  |  |
| --- | --- | --- |
| Healthcare sector | Informal healthcare sector | Non-healthcare sectors |
| Health outcomes* Survival
* Quality of life

Medical costs* Healthcare payer
* Out of pocket
 | Patient time costUnpaid caregiver-time costsTransportation costs | ProductivityConsumptionSocial servicesLegal / Criminal justiceEducationHousing |

'Partial' societal perspective

A 'partial' societal perspective, which incorporates only a subset of wider societal effects, is a pragmatic alternative that tries to account for additional aspects of value without imposing excessive technical and methodological complexity. This approach has been adopted in a select few countries that do not use a health sector perspective (Claxton et al., 2010), and can be implemented in one of two ways:

* flexibly, where the subset of wider societal effects varies on a case-by-case basis
* consistently, where the subset is fixed across assessments.

A flexible approach allows the most relevant wider effects to be considered in each assessment but means that many interventions are not then evaluated using the same criteria.

A consistent approach requires a process of selecting the subset of wider societal effects to be included in every assessment. For example, selection could be based on which effects are most commonly deemed relevant, tend to have the largest effect size or have the highest social value.

What approach does NICE currently take on perspective

NICE methods guidance states the default perspective for economic evaluations should be that of the health sector but that wider societal effects can be included in exceptional circumstances when they are deemed especially relevant. This can be agreed during the scoping phase of the assessment in consultation with stakeholders and, for technology appraisals, must be explicitly agreed with the DHSC.

Wider outcomes and costs are typically included when a considerable proportion of the intervention cost or cost impact is incurred outside of the health sector. This occurs most regularly when evaluating public health and social care programmes, where service costs are primarily borne by local authorities. They were also included in the technology evaluation of nalmafene for reducing alcohol dependency (NICE, 2014b). Cost savings in the criminal justice sector were modelled as a scenario in this appraisal but did not affect the committee's recommendations as the drug was already cost-effective in the base case scenario. Similarly, non-health benefits can be included independently if they are deemed substantial enough. Examples of assessments where these wider outcomes were included are anti-bullying interventions (NICE, 2009) and cochlear implants for children (NICE, 2019), where educational outcomes were considered. Wider outcomes have historically been considered on a more regular basis within the Highly Specialised Technologies (HST) programme.

Effects on economic productivity, which occur by reducing absenteeism and presenteeism in the workplace, can only be included for guidelines and only in exceptional circumstances, such as when evaluating workplace health interventions funded by employers. Productivity effects are prohibited in technology appraisals.

Committees also have input into how and when wider effects are considered within an assessment. Guideline committees collaborate with the NICE technical team and other stakeholders when developing the assessment scope, economic plan and evidence review. Technology evaluation committees can deliberate on non-health factors during the structured decision-making process even when they have not been included in the scope.

NICE's current approach to perspective can therefore be loosely defined as a health sector perspective but with capacity to flexibly implement a partial societal perspective in exceptional cases.

NICE had previously explored incorporating wider societal benefits into its assessment process as part of the 'value-based assessment' proposals that were considered in 2014. However, we did not identify anything in the public domain that outlined NICE's rationale against widening its perspective from this period. We note that it would be useful, following the consideration of this paper by the Board, to formally outline NICE's position via an article in an academic journal or other means.

Considerations when adopting societal perspective

In this section we explore the range of ethical, practical and methodological challenges that NICE would face if it were to routinely adopt a wider societal perspective. Some may be applicable to all of the societal perspective approaches described in the previous section, whilst others may be applicable to a specific approach only.

Ethical implications of including productivity effects

The most common form of wider societal effect that HTA agencies include in their assessments is economic productivity. This represents the value of allowing economically productive individuals to return to work and reduce absenteeism and presenteeism from illness.

Benefits to health and economic productivity are highly correlated. Health interventions that improve health outcomes will also usually improve economic productivity. Consequently, formally including productivity effects would be expected to systematically enhance the value of more effective interventions affecting young or working age populations.

An implication of this is that older and non-working populations will be disadvantaged because no productivity benefits will be associated the interventions affecting them. Over time, NHS (and other public) resources may shift towards interventions that affect young or working age populations for whom this extra value is added and a positive recommendation decision is more likely.

This could come into conflict with NHS principles of equality of access to healthcare based on need. It could also be interpreted as age discrimination, which is a protected characteristic under the Equality Act 2010. These concerns motivated Swedish HTA agency TLV to switch from a partial societal perspective that included productivity costs to a health sector perspective in in 2015 (TLV, 2021).

Incorporating wider societal effects risks higher prices for health technologies

As with productivity effects, many other wider societal benefits would also be expected to be positively correlated with health benefit. For example, interventions improving child health would be expected to improve educational attainment and treatment for drug misuse to reduce criminal activity.

The inclusion of these benefits under a wider societal perspective would be expected to only add value to interventions that are already more effective. This in turn could motivate manufacturers of health technologies to increase what they consider to be the economically justifiable price for the NHS. Under a health sector perspective these wider benefits accrue to society incidentally.

Reducing their relatively high pharmaceutical expenditure (amongst OECD countries) was the motivation for Portuguese HTA agency INFARMED to switch to a health sector perspective in 2019 (Perelman et al., 2019), having previously included productivity costs under a wider societal perspective. The inclusion of productivity savings from more effective treatments resulted in lower incremental cost-effectiveness ratios, which were then used by manufacturers to justify higher prices during negotiations.

Incorporating benefits from other public sectors requires cross- sector co-ordination

Whereas the health sector perspective prescribes that NHS resources should be valued primarily in terms of their health impacts, a wider societal perspective expands the objectives to include those of other public sectors. Theoretically this should yield greater societal benefit across public sector decision-making.

The advantages of the wider societal perspective are contingent upon equivalent decision-making processes underpinning other public sector expenditure. For example, if benefits in educational attainment or cost savings in the education sector were decisive in determining a set of NICE recommendations, then there should also be routine economic evaluation of educational policies that include the estimation of health benefits and healthcare costs. Inconsistency across public sector decision-making could lead to underfunding in the healthcare (or other public) sector.

Achieving the promise of a wider societal perspective therefore requires consultation and co-ordination between public sectors over the way expenditure decisions are made.

In addition to needing a common evaluative approach, how to appropriately fund interventions that yield benefits across multiple sectors also needs to be co-ordinated. Options include new mechanisms for setting public sector budgets, joint funding of interventions between sectors based on the value of the respective benefits, or a system of budget transfers between sectors (Claxton et al., 2010).

Evidence quality on wider societal effects is generally weaker and will increase technical and resource burden on NICE

Robust evidence on the wider societal impacts of interventions and services assessed by NICE would be necessary if a societal perspective were to be adopted. Each wider societal outcome should be measured using a valid generic instrument (akin to the quality-adjusted life year for quantifying health benefits). Such instruments provide a common currency for evaluating treatments that ensures consistency and comparability across assessments. This represents another issue for operationalising a societal perspective that requires consultation and co-ordination between public sectors.

The effects of interventions and services on health outcomes and healthcare costs are regularly captured in randomised controlled trials, cohort studies and electronic health records. However, evidence generation for wider societal outcomes is not consistently carried out and, where wider outcomes and costs have been considered, analysts have often relied on weaker, more uncertain evidence. For example, the committees in a technology appraisal on cochlear impacts for children that accounted for educational benefits (NICE, 2019) and a guideline on hepatitis B and C testing that accounted for criminal justice benefits (NICE, 2013) both relied exclusively on expert testimony rather than quantitative evidence.

Additional resources will likely be required to generate, collect and appraise evidence on wider societal outcomes. Researchers and manufacturers designing and managing trials and studies could ideally extend their data collection and analysis plans at extra resource. However, the capacity to collect this information may be limited in smaller companies, such as medical device companies submitting to the Medical Technologies Evaluation Programme. This will directly influence the quality of evidence on wider societal effects that will feature in their submissions. This would pose new challenges for managing uncertainties in the evidence base underpinning NICE decisions, a commitment outlined in Pillar 1 of the NICE strategy 2021-26 (NICE, 2021a).

Within NICE, additional time and resource will likely be required to conduct evidence reviews on wider effects, incorporate them into economic models and appraise the validity of their use in manufacturer submissions. Careful consideration of these impacts should be made so that NICE's recent 5-year strategy pillar of rapid technology evaluation is not compromised.

Wider societal effects of displaced services should also be counted

When cost-increasing interventions are recommended by NICE, other NHS services are displaced in order to fund them. The health benefits from these displaced services are in part acknowledged by NICE's cost-effectiveness threshold, against which the cost-effectiveness of the new intervention is compared.

To ensure value for money for the NHS and beyond, adopting a wider societal perspective also means accounting for the wider benefits of any displaced services. If these displaced services were in the area of mental health, for example, then the NHS would potentially forgo a range of wider societal benefits in economic productivity and criminal justice (Hunter et al., 2021).

Quantifying the value of displaced services just in terms of health is a complex task (Edney et al., 2021) that has generated significant debate. How NICE accounts for the wider benefits of displaced services, such as changes to the cost-effectiveness threshold or the use of multiple thresholds that depend upon on the wider societal outcomes of interest, should be the subject of substantial further research and consultation with stakeholders.

Robust methodology for trading off between different societal effects is needed

If the information on wider societal impacts is to feed into NICE recommendation decisions, committees will need to factor a wide range of additional quantitative evidence into their deliberations. The different available approaches would each present new challenges for NICE to resolve.

The simplest method from a technical perspective is to provide committees with a table of results that separately details the range of societal costs and outcomes. NICE would therefore rely on their expert judgement and the deliberative process to weigh all the competing information appropriately. This would require additional guidance for committees on how much implicit weight should be given each societal effect so that decisions across different committees are made on a consistent basis.

Cost-benefit analysis is a form of economic evaluation that converts all outcomes to monetary units so that any set potential of effects can be aggregated into a cost-benefit ratio. While this is the approach advocated in HM Treasury's Green Book (HM Treasury, 2018), concerns around obtaining monetary valuations of health benefits have meant it has not been widely adopted in health economic evaluation (Brouwer et al., 2008). Other methods of explicitly weighting and combining all the societal effects, such as multi-criteria decision analysis, similarly pose significant challenges with their design and implementation (Baltussen et al., 2019). Both of these options would involve fundamental departures from NICE's current approach to economic evaluation.

The core issue common to all approaches for handling the trade-offs between societal effects is how to specify their relative social value. Extensive consultation with the general public and/or stakeholders would be required to justify what outcomes are prioritised in committee deliberations. If a formal analytical approach was to be pursued, work would need to be undertaken to establish whether a valid set of explicit quantitative weights could be estimated for combining all societal effects into a single value.

Flexibility versus consistency in the selection of wider societal effects

The partial societal perspective is the most feasible way of incorporating wider societal outcomes into NICE assessments. However, there are significant advantages and disadvantages associated with both the flexible (case-by-case wider effects) and consistent (fixed set of wider effects) approaches.

The advantage of a flexible approach is that assessments can be responsive to those wider societal effects most relevant to each intervention or programme under evaluation. When done routinely, this could create large variation in the sets of effects considered across assessments and would undermine the use of consistent cost-effectiveness thresholds that committees should apply when making recommendations. A consequent risk is that manufacturers could appeal decisions if particular societal effects were regularly included in other assessments but were not deemed relevant for their technology. This could also extend to previous historical NICE decisions where interventions were not recommended.

A consistent approach avoids this issue by evaluating interventions on the same criteria but may result in inefficient use of research and NICE resources where an intervention has minimal wider societal effects. In these instances, the information costs associated with the collection, identification and appraisal of evidence on wider societal effects will be high relative to their influence on committee deliberations and recommendations. NICE would need to efficiently triage interventions and technologies at the scoping phase of assessment to determine whether wider societal benefits were expected to be influential.

How wider societal effect evidence should be used in the NICE assessment process

The evidence generated on wider societal outcomes can potentially be incorporated into NICE processes in a variety of ways. These include being:

* combined with the health sector outcomes to form the 'base case' estimate of value for money presented to committees
* presented separately from health sector outcomes as part of a scenario analysis
* used as a modifier to provide committees with additional flexibility when assessing health sector outcomes
* used to determine other variables within the NICE assessment process (e.g. fast-track appraisal).

The first two of these alternatives would place the evidence on wider societal effects within the committee deliberations. NICE would need to provide additional guidance on how to weight wider societal outcomes against the health sector ones.

The latter two alternatives incorporate wider societal effects elsewhere in the NICE process and would require NICE to determine criteria under which a modifier or fast-track appraisal would be permitted. This could be an enormously complex process given the range of wider societal effects and the lack of consensus on how to value them using a common metric.

Three perspective options for NICE assessments

In this section we outline and evaluate the options available to NICE with respect to perspective. We do not propose an option to formally broaden the perspective of NICE assessments to incorporate wider societal effects into each of its assessments because of the ethical, practical and methodological challenges outlined above that would first need to be addressed. To even initiate the preliminary work of stakeholder engagement and identifying research needs would require significant resources over a multi-year period. These issues are discussed as part of Option 3.

Option 1: No change to current perspective or to process

The existing NICE approach to perspective to is to adopt a health sector perspective, but with flexibility to adopt a partial societal perspective in particular circumstances.

Continuation of this approach would mean that wider aspects of value would be considered when interventions have a clear focus on non-health outcomes, or where a considerable proportion of the cost impact falls outside of the NHS. These provisions mean that NICE assessments will include wider effects when they are central to the value of an intervention.

These flexibilities are most often used in guideline development where wider effects are more common and influential. For example, the economic analysis conducted as part of a 2009 guideline on wellbeing in schools modelled the impacts of anti-bullying interventions on health, educational attainment and adult income (NICE, 2009). The flexibilities could also be used if NICE was to develop guidance on, for example, an intervention used in clinical settings where the primary objective is to reduce environmental impact rather than to improve patient health outcomes.

The current arrangements set a clear goal of maximising population health benefits for NICE to achieve when allocating NHS resources and contain flexibility to include different effects when dealing with non-NHS resources (e.g. local authorities).

The technical methods and processes underpinning cost-effectiveness analysis from a health sector perspective are now well established, having been regularly refined by NICE and its stakeholders over the last 25 years. This provides a strong foundation for NICE to achieve its strategic commitment to providing rapid and robust technology evaluation.

It is possible that under this approach, relevant aspects of treatment value (NICE, 2021b) may not be considered in economic evaluations of interventions where wider effects could be substantial and possibly influential in the recommendation decision. However, we engaged in an extensive consultation with colleagues across NICE guidance-producing programmes during the development of this paper and could not identify any assessments where it was felt that important wider effects were missed. However, a formal review would be required to establish this definitively.

Option 2: Retain existing approach to perspective and strengthen internal processes to ensure flexibilities are used consistently

This option considers ways in which internal processes can be updated so that there is routine consideration of whether existing flexibilities should be used for a given assessment. This would minimise the risk that wider outcomes and costs are not included in a scope when they are in fact relevant.

Within guideline development, flexibility on perspective is more regularly utilised. The Guidelines development manual specifies the conditions under which wider outcomes and costs should be included. It is also reflected within the scoping process and economic modelling phases, where prompts to consider relevant wider effects are already present on scoping templates. Non-health outcomes and costs can also be added at the request of the committee during the early phases of development. The forthcoming manual update presents a further opportunity to outline the circumstances under which technical teams should be applying a wider perspective.

For health technology evaluations, the risk of missing wider effects from an assessment scope is likely greater given that the CHTE process and methods manual does not specify conditions for when the DHSC should request their inclusion. We also note, however, that the likelihood of wider effects being relevant for products undergoing CHTE assessments is much smaller than interventions considered within guidelines as they are more clinically focused.

For consistency, CHTE could align the conditions for including wider effects to those in CfG:

* intervention funded from non-health public sector budget, or
* substantial non-health outcomes.

Minor amendments could also be made to existing processes during the topic selection and/or scoping phases of an assessment. This should include an additional checkpoint during the topic selection phase where the conditions for wider effects are applied to prospective interventions to flag instances where they could be included. Internal technical manuals can also be updated with guidance to analysts regarding how and when wider effects should be considered. Lastly, an update on the NICE policy on wider effects could be provided to committees so that any potential need for support on its implementation can be identified.

As technology evaluations are mostly of interventions delivered in a clinical setting with a focus on health improvement, we expect that use of these flexibilities will remain in exceptional cases only. We also note that these changes would not entail amendments to the recently updated health technology evaluations manual.

To develop a greater understanding of how committees incorporate wider effects into their recommendations, we also propose a future review of decisions undertaken by the HST programme, where wider effects are more commonly considered. This work will be undertaken by the Science Policy and Research Programme.

This option would not broaden the categories of wider effect permitted within NICE assessments. Productivity effects are currently excluded from NICE assessments, apart from when interventions are funded by employers. This position aligns with NICE commitments to principles of equality, given the ethical implications of favouring interventions affecting working age populations. We identified multiple European HTA agencies that have actively narrowed their perspective to exclude productivity effects for this reason. Consultation responses from industry and patient groups to the recent CHTE methods review also support NICE's current position.

Option 3: Initiate further exploration of formally adopting wider societal perspective

Formally and routinely adopting a wider societal perspective would represent a significant departure from current NICE methods. Extensive further research both within NICE and in the wider academic community would be required to develop robust methods for identifying, measuring and valuing wider societal effects.

There are also significant evidence gaps on the wider societal benefits of currently provided services that were likely to be displaced by new interventions. Given that NICE formally acknowledges the health effects of displaced services when making its recommendations, the same approach should be taken were wider societal effects to be routinely included in its assessments. This would require NICE to investigate if and how its cost-effectiveness threshold should be changed.

Formally broadening the perspective of NICE assessments could risk creating conflicts with NICE's core principles. Firstly, the greater evidence requirements of a wider perspective could potentially compromise NICE's strategic commitment to provide rapid, robust and responsive technology assessment. More NICE resources would be required to identify and appraise additional evidence and to incorporate into economic modelling by either NICE staff or its external partners. Without additional resource, this would likely lengthen each assessment and reduce the overall number that NICE could conduct annually.

Pursuing this option would also commit a substantial proportion of the resources of the Science Policy and Research Programme over a multi-year period and subsequently require major methods revision across NICE. This activity would come at the expense of other critical transformation work.

Based on the current availability of evidence on wider effects, we would expect that broadening NICE's perspective would mean that NICE committees would have to base their decision-making on lower quality evidence. Combined with the current absence of accepted methods for quantifying wider societal effects, this could risk conflicting with NICE's commitments to methodological rigour in its assessments.

Accounting for costs and outcomes falling outside of the health sector would also alter the way in which NICE values NHS resources. Consultation and co-ordination should be undertaken with other public sector bodies on how public sector resource allocation decisions are made. This represents another branch of work that would require NICE resources over a multi-year period.

How to value health-related interventions and services fundamentally affects NICE's work but will be relevant to a wide array of stakeholders and public bodies. Were a broader societal perspective to be explored, NICE could be an appropriate forum in which to host this debate.

Decision-making bodies relevant to the health sector would include the Department of Health and Social Care, NHS England, HM Treasury, the UK Health Security Agency and the Department for Levelling Up, Housing and Communities. Departments responsible for other public sectors would ideally be consulted in the interests of co-ordinating cross-sector policy evaluation. Using previous NICE assessments as a guide, these would likely include the Department for Education and the Ministry of Justice.

Conclusion

This paper has outlined the options available to NICE on how it could include wider societal effects in its economic evaluations.

We recommend that the Board approve Option 2 and retain the existing approach to perspective while strengthening processes within NICE so that existing flexibilities are utilised optimally and consistently. The health sector perspective outlined in the reference case is appropriate for many interventions and technologies considered by NICE and sets a clear objective of securing the best possible health outcomes from NHS resources. We find that existing flexibilities to incorporate wider effects in NICE methods are appropriate. However, although we did not identify instances where the current arrangements did not allow for relevant wider effects to be considered in an assessment, the process improvements recommended in Option 2 will reduce the possibility that this could occur.

Despite legitimate theoretical arguments in favour of formally adopting a wider societal perspective, there are also substantial ethical, practical and methodological challenges that must be addressed for it to be implemented successfully and in line with NICE principles. Significant amounts of NICE resources over multiple years would be required to facilitate engagement with public institutions and other stakeholders and address the methods and evidence needs. We note that the commitment of these resources may not improve the quality of NICE recommendations and would likely limit NICE's ability to address other current priorities and strategic aims, and therefore do not recommend this option.

Board action required

The Board is asked to:

* Reflect on the existing flexibility in NICE methods guidance that allows wider societal outcomes to be incorporated into assessments and whether this is sufficient.
* Consider the ethical, practical and methodological challenges that need to be addressed for a formal change of perspective to be undertaken.
* Consider how the success of adopting a wider societal perspective is contingent upon extensive co-ordination across public sectors and would involve major resource implications for NICE over multiple years.
* Approve Option 2 to retain the current approach to perspective and strengthen NICE processes to ensure consistent application of its current flexibilities so that assessments include wider costs and effects when particularly relevant.

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December 2022