Board meeting

20 March 2024

NICE methods agenda

Purpose of paper

For approval.

Board action required

The Board is asked to note and approve the methods priorities for business year 2024/25 and beyond.

Brief summary

At the December 2023 Board meeting, a paper was presented and approved detailing progress on a rolling programme of methods work to underpin NICE’s transformation. Since then, progress has been made on the forward methods agenda, including through 2024/25 business planning. The Executive Team has also agreed measures to improve the organisation and coordination of methods work across NICE, clarifying responsibilities and accountabilities.

This paper sets out the proposed methods priorities for next year and beyond.

Board sponsors

* Nick Crabb, Interim Director of Science, Evidence and Analytics
* Jonathan Benger, CBE, Chief Medical Officer and Interim Director, Centre for Guidelines
* Mark Chapman, Interim Director of Medical Technology Evaluation
* Helen Knight, Director of Medicines Evaluation

NICE methods agenda

**Organisation of methods work**

1. It has been agreed that leadership and coordination of NICE’s methods work should be through the Science, Evidence and Analytics (SEA) Directorate. The guidance producing directorates, as well as SEA, require colleagues engaged in new methods development and implementation so delivery of new methods is through a NICE-wide methods community under SEA leadership. A Methods Leadership Group, comprising senior colleagues across NICE, has been established to support this delivery model.

**Priorities for 2024/25**

**The inclusion of technology appraisals in guidelines**

1. This is a major area of transformation, to improve the usability of our guidance. To provide a better experience for our end users, help increase the adoption of NICE guidance, and provide better outcomes for patients and better use of NHS resources, we have developed approaches to the incorporation and integration of technology appraisals in guidelines such that all relevant information on a topic, can be conveniently accessed through the guideline. The inclusion of technology appraisals in guidelines will be the initial focus and in time, we will extend to our guidance on HealthTech.
2. An interim methods and process statement for incorporating and integrating NICE technology appraisals into guideline topic areas was approved by the Board in December 2023 and is currently the subject of a public consultation. We plan to address consultation comments and pilot the approaches in 3-4 topic areas using a published interim process and methods manual. This will allow us to further consider operational matters and to understand if further detail on methods and processes is warranted in the final documentation. We plan to adapt the methods and process details as appropriate in response to learnings either within the pilots or from stakeholder responses to consultation.
3. The inclusion of technology appraisals in guidelines and extension to guidance on HealthTech will be a multi-year programme involving multiple NICE Directorates. In 2024/25, methods work will focus on the iterative development and testing of methods leading to demonstrably robust methods that can be applied effectively both prospectively and to the backlog of existing recommendations.

**Modular updates and methods research on health inequalities**

1. This is a key priority to improve the relevance of NICE guidance, by ensuring appropriate and consistent consideration of health inequalities. Considerable methods work on health inequalities has been undertaken to date, and we need to be clear on NICE’s approach within our manuals. Given the range and complexity of potential options for taking account of health inequalities in guidance production, we consider that on-going research will be required in addition to setting out our current approach and methods in our manuals.
2. In 2024/25, through modular updates to NICE’s manuals, we will deliver clarity on NICE’s approach to considering health inequalities in guidance production allowing consistent application by NICE teams and committees and consistent advice to life sciences companies developing submissions. We will also agree a programme of research to ensure that NICE methods evolve to reflect best practice in accounting for health inequalities. Research is likely to include collaborations with academic partners as well as inhouse “test and learn” approaches, such as trialling distributional cost effectiveness analyses.

**Review of the severity modifier in medicines evaluation**

1. This is a key priority to improve the relevance and fairness of NICE guidance by ensuring appropriate and consistent use of the severity modifier. The methods paper presented to the Board in December 2023 showed lower than expected use of the severity modifier and proposals for a review in 2024/25. The reasons for lower than expected use are not yet clear.
2. In 2024/25, we will conduct a review, with support as appropriate from the NICE Decision Support Unit (DSU), leading to a full understanding of the reasons for the lower than expected use of the severity modifier and the identification of any necessary remedial actions. Remedial actions if needed, will also be implemented within the 2024/25 business year. If, for example, methods are found to be appropriate but not fully understood by companies, and application of the severity modifier is not consistently requested, we may need to issue clarification and ensure that the NICE Advice service can provide support in this area to companies. If methods changes are needed, these would be delivered via a modular update to the CHTE manual.

**Process for modular updates**

1. The methods paper presented to the Board in December 2023 included an update on the process for modular updates. The Board will be asked to approve the final arrangements at the May meeting. The approach will then be rolled out leading to robust application to methods updates.

**Methods for HealthTech**

1. Consistency and standardisation of methods across NICE is an important principle, whilst also recognising that different product types and decision problems may sometimes need different methods. Some of the constraints through the NICE Regulations, for example, may not need to be applied to the evaluation of HealthTech and some system unmet needs that NICE guidance needs to address, may not fit well with approaches used for medicines. Similarly, decision problems in the new late stage evaluation work, intended to support procurement, may be sufficiently different to other decision problems at NICE, that different methods are justifiable. Early value assessment also requires decision-making under very high levels of uncertainty. A programme of methods work specifically focused on the needs of HealthTech will be undertaken by the Medical Technology Evaluation Directorate, with oversight from the SEA Directorate and Methods Leadership Group. Ensuring consistency with other methods and that only justifiable difference results, is an important focus. Key activities are outlined below. Here we describe the elements as discreet programmes in the HealthTech programme, however there will be inevitable overlap and this should be considered more a lifecycle approach.
2. We intend to develop an updated decision-making framework for committees to help (i) make decisions under high levels of uncertainty, and (ii) integrate impacts of technologies that the system considers important, but which aren’t well captured by currently used cost comparison and cost utility models (such as impact on capacity and user preferences).
3. Modelling needed for longer term health impact is likely to be a bottleneck for quicker assessments (such as early value assessments, or quicker full guidance). Work will build on a recent Decision Support Unit (DSU) paper to embed and put into practice suggested approaches for assessment groups. Further work will also look at the potential for greater consideration of system benefit (e.g. impacts on waiting lists) in cost effectiveness assessments.
4. We will also develop a framework or visual approaches to capture value propositions clearly and concisely. HealthTech often impart value in multiple ways, which need to be identified from an early stage of scoping to clarify important outcomes. The need for quicker assessments, and potentially earlier identification of key outcomes needed for evidence generation plans, requires a strong focus on understanding and presenting how stakeholders and companies envisage technologies imparting value.

**Strategic Methods Work**

1. In addition to delivering NICE’s immediate methods priorities through the activities above, it is important that NICE drives and influences best practice and maintains a leading international position in developing and applying fit-for-purpose methods that can adapt to product and policy innovation. Our main initiatives for this are outlined below.

**HTA Lab**

1. The HTA Innovation Laboratory (HTA Lab) has been established to develop creative solutions to complex problems in health technology assessment. It offers a ‘safe space’ for creating solutions in collaboration with system partners and stakeholders. It has successfully delivered impactful outputs in areas of strategic importance to NICE including virtual wards, disease modifying dementia treatments and multi-indication diagnostics. Funding to expand HTA Lab activities was agreed as part of the 2024 voluntary scheme for branded medicines pricing, access and growth (VPAG) investment programme.
2. In the short term, we will expand HTA Lab capacity, review governance arrangements taking account of the new VPAG funding and agree new topics, taking account of on-going and newly proposed topics.

**Portfolio of grant-funded research**

1. In 2023/2024, NICE has expanded its portfolio of grant-funded research projects with the addition of 7 new projects. These projects are funded by UKRI, through the government guarantee scheme for participation in HORIZON Europe, and Wellcome Trust. The projects align with NICE methods research priorities, covering topics of strategic importance to NICE including the use of real world data, artificial intelligence and precision medicine approaches, as well as HTA methods development. Through participation in these projects, NICE ensures its active involvement in shaping innovation and being an early adopter of new methods. In 2024/2025, we will continue to focus on partnering in projects that align with our methods research priorities and strategic objectives and ensure that outputs from these projects inform NICE methods development and modular updates.

**NICE Principles**

1. [The NICE Principles](https://www.nice.org.uk/about/who-we-are/our-principles) aim to help anyone interested in NICE better understand what we take into account when developing our guidance. We had previously indicated that it may be appropriate to update the NICE Principles to guide how NICE can align environmental sustainability to its core remit. We may do this as a targeted update or include as part of a broader review of the NICE Principles when we are further along NICE’s transformation journey. Timing has not yet been agreed for this work.

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