Modular updates Selection and Oversight Panel (MSOP) – summary of the shortlisting and prioritisation meetings

18 December 2024 and 24 February 2025

Following the approval by the NICE board of the new framework for making modular updates to NICE’s manuals in May 2024, NICE set up MSOP, a standing committee responsible for overseeing modular updates, prioritising candidates for modular updates from those identified from stakeholders, and routing prioritised updates to the appropriate work programmes. This document summarises the key decisions in MSOP’s meetings on 18 December 2024 and 24 February 2025.

# Stakeholder suggested modular updates

The online form for stakeholders to submit candidates for modular updates was open from 8 October 2024 to 30 November 2024. Selected stakeholders were contacted about the form on 29 October 2024 via the [Modular updates progress and look ahead report 2024](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.nice.org.uk%2FMedia%2FDefault%2FAbout%2Fwhat-we-do%2Four-programmes%2Fnice-guidance%2Fmodular-updates-progress-and-look-ahead-report.docx&wdOrigin=BROWSELINK) and sent a reminder on 21 November 2024. The form was also promoted via social media posts, the NICE health and social care newsletter and internal NICE newsletters.

In total 42 submissions were received from a range of stakeholders, as summarised in Table 1. Candidates relating to the same topic were combined, leaving a total of 17 unique candidate modular updates on the longlist.

Table 1 Overview of stakeholder suggested modular updates 2024/25

|  |  |
| --- | --- |
|  | **Number** |
| Valid submissions received | 41\* |
| Unique candidate modular updates following removal of duplicates | 17 |
| Submitted by | - |
| Manufacturer | 28/41 |
| Evidence Assessment Groups | 1/41 |
| Group representing patients or carers | 2/41 |
| NICE | 5/41 |
| Industry trade association | 5/41 |

\*One update was removed as insufficient information was provided by the stakeholder

The candidate modular updates were shortlisted by MSOP at the 18 December 2024 meeting. A total of 6 candidate modular updates were shortlisted for further consideration by MSOP.

1. Surrogate endpoints
2. Publishing review protocols – guidelines
3. EQ-5D-5L value set
4. Carer quality of life
5. Critical appraisal and external validity of trial evidence
6. Structural uncertainty

MSOP selected 2 modular updates from the shortlist of 6 candidates at the 24 February 2025 meeting. The selected modular updates are:

1. EQ-5D-5L value set
2. Surrogate endpoints

Both of the selected modular updates were routed to NICE’s Science Policy and Research team, who will be responsible for evidence development and managing the consultation and sign-off processes. While work on these modular updates will begin in 2025/26, the EQ-5D-5L value set update in particular is anticipated to take longer than a year to complete.

MSOP decisions for each candidate modular update are summarised in Table 2.

Table 2 Summary of MSOP decisions for stakeholder suggested modular updates

| **Title** | **Brief description** | **Decisions** | **Rationale** | **Action and routing** |
| --- | --- | --- | --- | --- |
| EQ-5D-5L value set | To enable the adoption of the value set from the new UK valuation study for the EQ-5D-5L into NICE’s reference case. | Selected | High priority, feasible. The modular update will aim to incorporate the EQ-5D-5L value set into manuals. It is not expected to be completed in 2025/26 because some activities cannot commence until the publication of the value set, timings for which are uncertain. | NICE Science Policy and Research team to start work in 2025/26. |
| Surrogate endpoints | To provide updated guidance on how surrogate endpoints can be used in cost-effectiveness modelling. | Selected | High priority, feasible. The modular update will draw on and refer to a [white paper](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.nice.org.uk%2FMedia%2FDefault%2FAbout%2Fwhat-we-do%2FResearch-and-development%2Fsurrogate-endpoints-report.docx&wdOrigin=BROWSELINK) which resulted from a NICE-led international collaboration with other health technology assessment (HTA) bodies. | NICE Science Policy and Research team to start work in 2025/26. |
| Critical appraisal and external validity of trial evidence | To clarify guidance on suitable tools (such as the Cochrane risk of bias tool to assess RCTs) to assess the internal and external validity of trial evidence. | Shortlisted but not selected | High priority, but not feasible due to limited resources. MSOP considered that a small change could be made to NICE health technology evaluations: the manual [PMG36] to clarify guidance, by referring to appendix H of Developing NICE guidelines: the manual [PMG20], without the need for a full modular update. | Medicines Evaluatinos and HealthTech Evaluation teams to review appendix H to assess suitability of referring to it in the technology evaluations manual.  Candidate will be reconsidered in next round of modular updates process. |
| Structural uncertainty | To update the manuals on structural uncertainty to facilitate committees to make more robust decisions and requests for structural scenarios, without halting the process through the judgement that a model is ‘not fit for purpose’. | Shortlisted but not selected | High priority but not feasible due to limited resources. MSOP considered that ongoing internal work would help to partially resolve this issue and commissioning of external work could be considered in this area. | Candidate will be reconsidered in next round of modular updates process. |
| Carer quality of life | To provide updated guidance on when and how carer quality of life should be incorporated into economic analyses. | Shortlisted but not selected | High priority but not feasible due to the large scope of the update and limited resources. MSOP recommended that NICE commission external work in this area, which could inform a future update. | NICE Science Policy and Research team to explore commissioning of external work by NICE Decision Support Unit.  Candidate will be reconsidered in next round of modular updates process. |
| Publishing review protocols – guidelines | To review the current process for how and where NICE publishes review protocols. | Shortlisted but not selected | Low priority, feasibility not assessed. MSOP considered that a clarification on publishing review protocols (if appropriate) could be provided without requiring a full modular update. |  |
| Discount rate | To update NICE’s discount rate from 3.5% to 1.5%. | Not shortlisted | MSOP felt that changing the discount rate would be a policy decision (not merely a methods update) that would have an impact on NICE’s cost-effectiveness thresholds. These are fixed until the end of 2028 through the [voluntary scheme for branded medicines pricing, access and growth](https://www.gov.uk/government/publications/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth). |  |
| Updating the threshold | To adjust NICE’s threshold upwards to reflect increases in taxation, healthcare budgets and the increase, in line with inflation, of NICE fees for appraisals. | Not shortlisted | NICE’s thresholds are fixed until the end of 2028 through the [voluntary scheme for branded medicines pricing, access and growth](https://www.gov.uk/government/publications/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth). |  |
| Applying the threshold | To provide more openness and transparency regarding the criteria NICE uses to assess uncertainty and how this affects their application of the threshold. | Not shortlisted | Internal work is ongoing in this area. MSOP discussed whether the work needs to be considered as a modular update and felt it would be better suited to wider discussions on consistency of the use of the threshold across all NICE programmes and committees. | This topic is to be added to the next Methods Leadership Group (internal NICE group) agenda for discussion. |
| Rare disease in HTA | To review issues related to the assessment of treatments for rare diseases, including a rarity modifier, definition of rare disease, improving transparency and flexibility of routing decisions and appeals, and incorporating carer quality of life. | Not shortlisted | The available evidence does not justify creating a rarity modifier. NICE has recently updated the [highly specialised technologies routing criteria](https://www.nice.org.uk/process/pmg46/resources/highly-specialised-technologies-nice-prioritisation-board-routing-criteria-15301445581/chapter/hst-routing-criteria), which relate to the definition and characteristics of ultra-rare diseases.rare diseases.  MSOP also felt that the introduction of a rarity modifier would be a policy decision (not merely a methods update) that would have an impact on NICE’s cost-effectiveness thresholds. These are fixed until the end of 2028 through the [voluntary scheme for branded medicines pricing, access and growth](https://www.gov.uk/government/publications/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth). |  |
| Severity modifier | To remove the opportunity cost neutrality requirement for the severity modifier and basing the modifier on societal preferences. | Not shortlisted | Opportunity cost neutrality is a key principle that NICE works under. Any change to NICE methods that were cost inflationary would have to be approved by the Department of Health and Social Care.  Recent work has been undertaken at NICE on the [severity modifier](https://indepth.nice.org.uk/what-is-nices-severity-modifier/index.html#:~:text=The%20severity%20modifier%20is%20an,treatments%20are%20valued%20more%20highly) and further research on societal preferences is in progress.  Currently this area of work is not ready for a modular update. |  |
| Re-evaluation of reference biologics | To create a process for re-reviewing technology appraisals of reference biologic treatments upon the entry of biosimilars to the market. | Not shortlisted | Internal work is ongoing in this area, but it is too early to form the basis of a modular update. See the [NICE position statement on biosimilar technologies.](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/technology-appraisal-guidance/biosimilar-technologies-nice-position-statement-information-for-the-public#:~:text=Biosimilar%20medicines%20%E2%80%93%20NICE's%20approach&text=The%20first%20biological%20medicine%20to,the%20reference%20(first)%20medicine.) |  |
| The use of registry data to inform guidance | To provide updated guidance on the use of registry data for clinical and cost-effectiveness estimates. | Not shortlisted | [The real-world evidence framework](https://www.nice.org.uk/corporate/ecd9/chapter/overview) provides guidance in this area. |  |
| Disruptive innovative therapies | To develop a new HTA approach for disruptive technologies, such as radioligand therapies, including an innovative approach to include high infrastructure costs. | Not shortlisted | More work needs to be done in this area before it could be considered for a modular update. It may be better suited as a NICE [HTA Lab](https://www.nice.org.uk/about/what-we-do/our-research-work/hta-lab) project. | This candidate will be routed to the HTA Lab for consideration as a candidate topic. |
| Impact on productivity included in HTA | To explore the inclusion of productivity costs either within the base case or as a specific non-reference case flexibility. | Not shortlisted | NICE’s 2022 [options appraisal for adopting a wider perspective](https://www.nice.org.uk/Media/Default/Get-involved/Meetings-In-Public/Public-board-meetings/december-22-pbm-options-appraisal-for-adopting-a-wider-perspective-in-NICE-assessments.docx) did not result in support for the inclusion of productivity effects.  Work is being carried out at NICE to look at how we can reduce health related economic inactivity across the system, but it is currently too early to translate this work into a modular update.  Ongoing work within NICE is announced here: HM Treasury policy paper: [New approach to ensure regulators and regulation support growth (HTML) - GOV.UK](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fa-new-approach-to-ensure-regulators-and-regulation-support-growth%2Fnew-approach-to-ensure-regulators-and-regulation-support-growth-html&data=05%7C02%7CSophieL.Hughes%40nice.org.uk%7Cc19a8fe0c5de44e2cd2808dd739c52a4%7C6030f479b342472da5dd740ff7538de9%7C0%7C0%7C638793837409825440%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMiIsIkFOIjoiTWFpbCIsIldUIjoyfQ%3D%3D%7C0%7C%7C%7C&sdata=KJdm81Q3r1krh0og%2FC%2B%2F7neKkCjYRE0oNdK7stFue8Y%3D&reserved=0) |  |
| Wider societal impacts of healthcare | To consider evolving NICE’s methods to allow full inclusion of wider societal impact to allow more patients to benefit from innovative medicines. | Not shortlisted | NICE’s 2022 [options appraisal for adopting a wider perspective](https://www.nice.org.uk/Media/Default/Get-involved/Meetings-In-Public/Public-board-meetings/december-22-pbm-options-appraisal-for-adopting-a-wider-perspective-in-NICE-assessments.docx) did not result in support for further exploration of formally adopting a societal perspective.  NICE’s guidance producing programmes already have flexibilities to include wider costs and benefits when especially relevant, but these are seen very rarely. |  |
| Preventative health modifier | To incorporate a preventive health modifier into NICE’s HTA framework. | Not shortlisted | MSOP felt that defining and developing a preventative health modifier would be methodologically difficult. It was proposed that societal preferences regarding prevention should be explored as part of the upcoming [NICE Listens](https://www.nice.org.uk/about/what-we-do/our-research-work/nice-listens) public dialogue on severity weighting. | NICE Listens team will explore options for incorporating views on prevention into the upcoming dialogue on severity weighting. |

# Modular updates in progress

Modular updates already in progress were noted by MSOP. These are summarised in Table 3.

Table 3 Modular updates in progress

|  |  |  |
| --- | --- | --- |
| ****Title**** | ****Description**** | ****Progress**** |
| Health inequalities | This methods update will provide guidance on how to incorporate health inequalities considerations in technology evaluations. It will focus on methods for measuring health inequalities, considering quantitative evidence of how health interventions affect these inequalities, and how best to use this evidence in decision-making. | Complete – updated health technology evaluations manual published in May 2025 |
| HealthTech programme process update 1 | This update will set out a unified process for NICE's HealthTech teams (formerly DAP, MTEP, IP) and clarify this for external stakeholders. This update will also provide updated methods guidance for Early Valuation Assessments (EVAs). | Post-consultation updates and sign-off. Consultation for this update is now closed and the wording for the update is being finalised. |
| HealthTech programme process update 2 | This update will provide further clarification and update to methods used for NICE HealthTech guidance. | Draft recommendation. Consultation for this update is currently estimated to take place in 2025. |
| EQ-5D-5L value set | This update will enable the adoption of the value set from the new UK valuation study for the EQ-5D-5L into NICE’s reference case. | Scoping. This update was prioritised in February 2025. |
| Surrogate endpoints | This update will provide updated guidance on how surrogate endpoints can be used in cost-effectiveness modelling. | Scoping. This update was prioritised in February 2025. |