Board meeting

15 May 2024

Development of a framework for a modular approach to updating NICE manuals

Purpose of paper

For review and approval.

Board action required

The Board is asked to approve the framework for making modular updates to NICE manuals.

Brief summary

A modular update is a review of methods and/or processes informing NICE’s guidance, limited to a specific subject area, that may result in an update to NICE’s manuals.

This paper presents a proposed modular updates framework which sets out how we will: identify and prioritise modular updates to the manuals, review the evidence and propose changes to the manuals, engage and consult with stakeholders, and implement the modular updates.

The paper has been developed and reviewed by a cross-NICE working group including representation from Science Policy and Research (SP&R), Centre for Health Technology Evaluation (CHTE) (Medicines and HealthTech) and Centre for Guidelines (CfG). The framework supports NICE’s efforts to harmonise methods and processes across different programmes and directorates. It applies to manuals across CHTE and CfG (PMG20, PMG28, PMG36 and PMG37).

Board sponsor

Nick Crabb, Interim Director of Science, Evidence and Analytics

Development of a framework for a modular approach to updating NICE manuals

What is the modular updates framework?

In January 2022, when the new combined methods and process manual for its health technology evaluation programmes (NICE health technology evaluations: the manual [PMG36]) was published, [NICE stated its commitment to adopting a more modular approach to updating its methods and processes](https://www.nice.org.uk/news/article/nice-publishes-new-combined-methods-and-processes-manual-and-topic-selection-manual-for-its-health-technology-evaluation-programmes).

A modular update is a review of methods and/or processes informing NICE’s guidance, limited to a specific subject area, that may result in an update to NICE’s manuals.

The modular updates framework will ensure that our methods and processes are flexible and responsive to changes in the health and care landscape. It will also promote consistency in how our manuals are updated and provide a mechanism for prioritising updates in areas that matter most. It will allow external stakeholders to contribute, including to the identification of candidates for modular updates and the content of updates, thus helping to ensure that the NICE manuals meet the needs of users.

The framework supports NICE’s efforts to harmonise methods and processes across different programmes and directorates and, eventually, to move towards a single guidance development manual. It applies to:

* [Developing NICE guidelines: the manual [PMG20]](https://www.nice.org.uk/process/pmg20/chapter/introduction)
* [Interventional procedures programme manual [PMG28]](https://www.nice.org.uk/process/pmg28/chapter/introduction)
* [NICE health technology evaluations: the manual [PMG36]](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation)
* [NICE health technology evaluation topic selection: the manual [PMG37]](https://www.nice.org.uk/process/pmg37/chapter/about-this-guide)

# Sources of modular updates

There are three main mechanisms for establishing the need for and prioritising modular updates:

* Updates needed to deliver business priorities
* Updates needed to reflect changes to how NICE operates

Updates selected from candidates suggested by internal and external stakeholders.

Updates needed to deliver business priorities will be referred by the NICE Executive Team (ET). For example, the NICE 2024/25 business plan includes an organisational aim to develop new methods for addressing health inequalities. The plan to achieve this aim includes a commitment to deliver manual updates to clarify NICE’s approach to considering health inequalities in guidance production.

Updates needed to reflect changes to how NICE operates will be initiated by the relevant directorates. For example, NICE is introducing an integrated topic prioritisation approach to help deliver our transformational objective to focus on what matters most. The new approach will make some sections of the current manuals out of date. Those sections will therefore need updating to reflect wider changes.

Modular updates falling under these two categories will proceed directly to the module routing step and will not be subject to the earlier steps in the framework. See 37 to 40 for details of how these updates will be overseen.

Details of the steps involved in identifying, shortlisting and prioritising candidates for modular updates suggested by stakeholders are described below (see 15 to 36).

Overarching process

Figure 1 outlines the main steps in the overall process. The scoping and the evidence development and stakeholder engagement steps may not be required for all updates, for example, updates needed to reflect changes to how NICE operates. The sponsor is responsible for deciding whether these steps are required.

All aspects of the process will be reviewed regularly and updated as required to ensure the framework is appropriate, proportionate and meets the needs of NICE and our stakeholders.

Figure 1: Modular updates process

Shortlisting and prioritisation

Routing

Scoping\*

Evidence development and stakeholder engagement

Draft recommendation

Consultation

Post-consultation updates

Sign-off

Identification of candidates of modular updates

Implementation

# Proposed timelines for modular updates

The first two steps of the modular updates process will normally take place annually, linked to the NICE business planning cycle. NICE will limit the number of modular updates it selects and actively works on each year.

Where changes are needed, the manuals will be updated periodically, for example once per year, with multiple modular updates made together if appropriate. This is to ensure the manuals evolve to reflect best practice and align with NICE’s strategic priorities while minimising instability for stakeholders and NICE staff, committees and faculties. Occasions may arise when updates need to be made urgently and there will be flexibility to update manuals more frequently if necessary.

Once a candidate modular update has been selected it will be routed to the appropriate NICE team for evidence development, consultation and sign-off. It is acknowledged that this may take longer than a year to complete and any recommended changes will be implemented in the next manual update.

# Identification of candidates for modular updates suggested by stakeholders

Figure 2 outlines in more detail the steps involved in identifying, shortlisting and prioritising candidates for modular updates suggested by stakeholders.

Figure 2: Identification, shortlisting and prioritising candidates for modular updates

Longlist of candidate modular updates

Initial prioritisation and feasibility information

First MSOP review

Final shortlist

Full prioritisation and feasibility information

Second MSOP review

Modules prioritised

**1. Identification**

**2. Shortlisting**

**3. Prioritisation**

NICE will be responsible for selecting methods and process areas which might be suitable for a modular update. We are committed to listening to our stakeholders and prioritising modular updates that will ensure that our manuals meet the needs of our users.

All candidates for modular updates suggested by stakeholders will be collated and similar candidates grouped together by the SP&R team to form a longlist. There will be three main streams whereby candidates can be identified for inclusion on the longlist:

1. **Feedback from stakeholder liaison**

NICE will proactively liaise with selected internal and external stakeholders about candidate modular updates. The SP&R team will prepare a report on the progress of modular updates selected in previous rounds, summarising where they are up to in the process and, for those completed, the impact they have had. This will also include a summary of candidates that were not selected as modular updates but alternative action was taken (see 31 and 35). The report will then look forward and outline initial candidates identified for consideration in the next round. Stakeholders will be given the opportunity to send feedback on the document and propose additional candidates via the web form.

1. **Web form**

Candidates for modular updates may be suggested by any stakeholder via a web form on the NICE website.

The form will be open for two months each year and will be promoted internally and externally.

1. **Candidates from previous modular update rounds**

Candidates from the previous modular update round that were deemed feasible and important but were not selected in that round may be included.

# Selection of modular updates from candidates suggested by stakeholders

Once a longlist has been developed, the SP&R team will collate a summary of key details on the candidates for modular updates. Candidates on closely related topics may be combined.

Any corrections or clarifications will be routed immediately to the appropriate manual lead for approval, without the need for review by a panel. Once identified and routed, corrections will follow the existing processes for making corrections to the manuals.

The longlist of candidate modular updates will be discussed by a dedicated panel (see 25) for shortlisting and prioritisation.

## Modular updates Selection and Oversight Panel (MSOP)

The Modular updates Selection and Oversight Panel (MSOP) will be a standing committee with cross-directorate representation. It will be responsible for prioritising candidates for modular updates from those identified from stakeholders, and routing prioritised updates to the appropriate work programme. MSOP will meet twice a year, first to decide on shortlisting and second to decide on prioritisation and routing.

In exceptional circumstances, an additional meeting may be convened if MSOP needs to make a decision about whether to prioritise work on a modular update and that decision cannot fit within the usual process and timetable.

Minutes of MSOP meetings will be published on the NICE website.

Membership

MSOP will have sufficient senior representatives to ensure that organisational priorities are communicated and reflected at both decision points. Technical and programme management staff from the SP&R team will provide support to the panel but will not be voting members. There are currently no plans to include external members on MSOP. Input will be sought from representatives from NHS England and the Department for Health and Social Care sponsor teams to inform the discussions. External stakeholders may be invited to discuss specific items on an ad hoc basis.

## First MSOP review – shortlisting of candidate updates

At the first meeting, MSOP will review the initial longlist of candidate updates collated during the module identification. The criteria for shortlisting will include:

* Whether the candidate update is within the scope of NICE’s remit and NICE’s manuals
* Whether it is feasible to deliver and implement the candidate update
* Whether the candidate update would promote alignment or create misalignment between the manuals
* Whether the candidate update aligns with NICE strategic priorities and key performance indicators.

As part of this process, MSOP will determine whether there is ongoing work that is directly or indirectly relevant to the candidate update such as NICE-led or externally-led research projects or HTA Lab projects. This is to avoid duplication of effort, and to consider if there is any existing learning that the suggested modular update can be built on.

Outcomes for candidate modular updates at this meeting include:

* Include in shortlist and progress to next stage
* Not feasible or appropriate to progress – consider further action if appropriate (e.g. position statement, include in longlist for next modular update round)
* Not a modular update – consider further action if appropriate (e.g. progress as a correction, referral to External Assessment Group management group to propose technical support document by Decision Support Unit, update supporting documents).

If a candidate update is deemed not feasible or appropriate to progress but important for NICE to make a statement on, further action outside of the modular updates framework will be agreed and directed to the appropriate team.

If a candidate update is proposed again after previously being deemed not feasible or appropriate, this will be highlighted to MSOP who will decide whether there has been any change since the previous decision. If not, the candidate update will not be shortlisted.

## Second MSOP review – prioritisation of candidate updates

MSOP will review all shortlisted modular updates, decide which should be prioritised, and route prioritised updates into the appropriate work programme(s). In addition to the criteria from the first MSOP review, the criteria at this stage include:

* Whether the update would be consistent or inconsistent with the NICE principles
* The resources required by NICE and other stakeholders to implement the update
* The anticipated scale of the impact of the update on guidelines and evaluations
* The impact of the update on any protected characteristics or health inequalities
* Available evidence and any ongoing work in this area
* Whether the update is needed to reflect current practice

Taking these prioritisation criteria into account, outcomes for candidate modular updates at this meeting include:

* Feasible and a priority – progress to next stage
* Feasible but not a priority – consider further action if appropriate (e.g. position statement, include in longlist for next modular update round)
* Not feasible – consider further action if appropriate (e.g. position statement, referral to External Assessment Group management group to propose technical support document by Decision Support Unit, referral to NIHR's Policy Research Unit in Economic Methods of Evaluation of Health and Care Interventions (EEPRU)).

When the panel is first set up, the members will establish a ranking process for the scenario where there are multiple candidates identified as a priority and feasible. This will balance the resource demands of each selected update and their urgency. Any updates that are not possible to allocate to a team during the current round of modular updates will be added to the longlist for the next round.

## MSOP oversight of modular updates prioritised via other mechanisms

MSOP will not be responsible for prioritising modular updates needed to deliver business priorities or to reflect changes to how NICE operates (see 6 to 8).

For these categories of modular update, the project sponsor (who will also be a member of MSOP) is responsible for providing MSOP with an overview of the required update and demonstration that the standard prioritisation criteria have been adequately considered. This will be circulated to MSOP via email.

At the start of each MSOP meeting, any modular updates that were prioritised via other mechanisms will be noted, discussed if necessary, and minuted for transparency.

MSOP will be expected to consider all modular updates currently in progress, regardless of how they were prioritised, when making decisions about shortlisting, prioritising and routing candidates for modular updates from stakeholders.

# Module routing

During the second MSOP review there will be discussion of the resources required and available to action the modular update. This will include which manuals will be updated and which NICE team(s) the module will be routed to. Projects will be assigned a sponsor who will have oversight of the project.

The sponsor will set up a working group for each modular update (known as the Task and Finish (T&F) group). The T&F group will be an internal (NICE-led) group made up of members of the relevant teams across CHTE, CfG, Science, Evidence and Analytics (SEA) and the Clinical Directorate.

# Scoping

A scope will be developed for selected modular updates using a scoping template, if appropriate. A scope may not be required for all modular updates, for example, for updates needed to reflect changes to how NICE operates (see 7). The sponsor is responsible for deciding whether or not a scope is required.

The scope will:

* Summarise the modular update
* List the areas that will be updated, including specific questions that need addressing
* List any related areas that will not be covered by this modular update and justification if required.

The draft scope will be signed off by the sponsor. There will be no consultation at the scoping stage but the T&F group may engage with internal and external stakeholders, as required.

The scope will be published on the NICE website and shared with key internal contacts via the sponsor.

# Evidence development and draft recommendation

Evidence development is a review of the evidence relating to the modular update. This may be informed by primary research. The exact nature of the review of evidence will be dependent on the specific modular update, and whether the update relates to methods or process. An evidence development step may not be required for all modular updates, for example, for updates needed to reflect changes to how NICE operates (see 7). The sponsor is responsible for deciding whether or not an evidence development step is required.

The T&F group will liaise with external stakeholders who may be able to provide support or conduct work associated with the update. The nature of the stakeholder engagement will depend on the scope of the modular update.

During the evidence development stage, the sponsor should liaise with the Chairman, Chief Executive and Board Secretary (Associate Director, Corporate Office) to provide an overview of the modular update and agree whether Board sign-off is required or whether Guidance Executive (GE) approval is sufficient. This decision will take account of:

* The scope of the proposed modular update
* Whether the Board has discussed work related to the modular update previously.

The sponsor should also determine whether consultation is required for the proposed modular update. NICE will follow the constitution and functions regulations in determining whether consultation is necessary (see 59). Paragraphs 55 to 68 apply only to modular updates where consultation is conducted.

Once all appropriate evidence has been assessed, NICE will summarise the key findings in an evidence review document. This will include:

* Research undertaken, which may include:
  + Reviews of previous guidance documents where the update was, or could have been applicable (this could include all guidance documents or just focus on case studies)
  + Retrospectively piloting potential approaches. For example, applying the suggested modular update to already published technology appraisals, to consider what impact it would have had on cost effectiveness outcomes and existing published recommendations
  + ‘Test and learn’ approaches that have been conducted, if appropriate
  + Work undertaken by external groups, such as Decision Support Unit and Technical Support Unit
* Summary of stakeholder engagement / committee surveys, if conducted
* Summary of potential options for updates to the manual, and assessment of feasibility
  + This may include recommendations other than updating the manual, for example, development of a technical support document or a [NICE HTA Lab](https://www.nice.org.uk/about/what-we-do/our-research-work/hta-lab) project
* Equality considerations
* Conclusion and recommendations on update
* Summary of suggested updated wording for the manual
* Summary of which programmes across NICE will be affected by any changes.

The evidence review document above will include a recommended action as follows:

* Manual does **not** require updating – existing manual remains up to date and in line with current research
* Manual does **not** require updating at this time – further research is required
* Manual does require updating – a description of the updates required.

If the recommendation is that the manual does require updating, then the T&F group will develop an interim manual update document which includes the changes to be implemented in the manual. This interim manual update document will be included as an appendix to the evidence review document. For modular updates that do not require an evidence development step (see 47), an interim manual update document alone is required for consultation.

The final evidence review document will be published on NICE’s website and will remain available after the modular update has been completed. The interim manual update document will be available on the NICE website during the consultation period, after which it will be moved to NICE Archive.

# Pre-consultation technical sign-off

The sponsor is responsible for technical sign-off ahead of executive sign-off by the Guidance Executive (GE) and the Board (if required).

All suggested modular updates should be shared for information with all of the associate directors, programme directors and directors from CHTE, CfG, SEA and the Clinical Directorate before consultation.

# Pre-consultation executive sign-off

Modular updates will be signed off by GE and by Board (if required, see 49) before consultation. The sponsor is responsible for taking the modular update to GE and the Board.

The Board is asked to:

* approve the recommendation that a modular update is required or is not required
* approve the changes to the manual and any supporting documents for consultation
* approve the length of the consultation period
* indicate whether they are willing to delegate authority final sign-off to GE.

# Consultation

[The NICE constitution and functions regulations 2013](https://www.legislation.gov.uk/uksi/2013/259/made) states NICE must establish procedures for:

* the appraisal of health technologies and highly specialised health technologies
* the giving of advice or guidance, the provision of information or the making of recommendations
* and must consult such persons as it considers appropriate in establishing a procedure.

The length of the consultation period is flexible and will be agreed by GE at [pre-public consultation executive sign-off](#_Pre-consultation_executive_sign). Consultations are either 28 days (long) or 14 days (short). Please see Table 1 for distinctions between the consultation lengths.

Table 1: Consultation length for modular updates

|  |  |
| --- | --- |
| Length of time | When consultation length is issued |
| 14 calendar day consultation (short) | If there is a small degree of uncertainty in the evidence to support the change or if the subject area has previously been well defined in other related NICE outputs within the last 12 months. |
| 28 calendar day consultation (long) | If there is a reasonable degree of uncertainty about elements of the change, or whether the change should be implemented. |

The following documents will be shared for consultation:

* Evidence review document and recommendation (i.e. ‘Modular update required’ or ‘No modular update required’)
* Interim updated sections of the manual (if applicable) and any supporting documents
* Equalities and health inequalities impact assessment (EHIA).

NICE will publish the consultation documents and supporting documents on its website with an electronic comment facility.

At consultation, NICE invites comments on whether:

* all of the relevant evidence has been taken into account
* the interpretations of the evidence are reasonable
* the changes to be made to the manual are appropriate
* the proposed changes to the manual meet NICE’s aims of promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others,

At consultation, commenters will also be able to identify any factual inaccuracies and, if relevant, submit any additional evidence not originally reviewed as part of the evidence review. Any consultation comments received that are not relevant to the modular update will not be considered.

In some circumstances, a second consultation may be considered. For example, where significant additional evidence has been identified as part of the consultation which might fundamentally alter the findings of the original evidence review. NICE makes the final decision on whether a second consultation will be required.

# Post-consultation updates

The T&F group will review the consultation comments received, including any additional evidence, and, if appropriate, amend the proposed changes to manual. The evidence review document is modified to reflect any additional relevant evidence that has arisen from consultation.

The T&F group will develop a report summarising the consultation comments received, NICE’s response and any amendments made as a result of consultation. The consultation summary report is published on the NICE website at the implementation stage.

The sponsor is responsible for determining an appropriate timeframe in which any post-consultation updates should be completed.

# Post-consultation technical sign-off

The sponsor is responsible for technical sign-off ahead of executive sign-off by GE and the Board (if required).

All suggested modular updates should be shared for information with all the associate directors, programme directors and directors from CHTE, CfG and SP&R before final sign-off.

# Post-consultation executive sign-off

Final sign-off for all modular updates will be carried out by GE and the Board (if required). The sponsor is responsible for taking the modular update to GE and the Board.

GE is asked to approve the changes to the manual and any supporting documents for Board sign-off. Modular updates require sign-off by the Board after consultation, unless the Board has indicated previously that they are willing to delegate sign-off to GE.

# Implementation

Once a modular update has been signed off by the Board the manual will be updated on the NICE website. The manual ID (e.g. PMG36) will remain the same following a modular update.

Each manual has an ‘Update information’ section at the end of the manual. The ‘Update information’ section will be updated with:

* Date of manual update
* Brief summary of changes to manual.

Unless specified otherwise, the updated methods and processes will apply to all topics which start their evaluation after the date at which the updated manual is published. The updated methods and processes will be prospectively applied to guidance production.

For each modular update, the following documents will be published as supporting documents on the manual webpage:

* Evidence review document
* Consultation comments report
* Equalities and health inequalities impact assessment (EHIA) form
* Previous version of manual.

The previous version of the manual will remain available for reference whilst evaluations or guideline development is happening that follows the previous version of the manual. After this, the previous version of the manual will be moved to NICE Archive.

The T&F group should consider whether any updates are required to supporting documents.

The T&F group is responsible for arranging training on the modular update for all internal and external stakeholders.

The sponsor should monitor the implementation of modular updates, for example via databases (if established) or through regular catch-ups.

# Clarifications and corrections

In addition to modular updates, changes may need to be made to the manual due to corrections or clarifications:

* Corrections – can be immediately implemented without engagement. For example, making changes to the manual such as correcting typos, fixing hyperlinks, correcting ‘bugs’.
* Clarifications – needs some form of review and potentially targeted engagement before deciding whether a change to the manual is needed. A clarification to the manual should not involve a change to methods or processes.

Clarifications and corrections may be identified as part of the engagement for identification of candidates for modular updates. If so, these should be routed to the manual lead by the SP&R team.

In some cases there may be uncertainty regarding whether a clarification update would involve a change to methods or processes, particularly if there is inconsistency regarding how these methods or processes are currently applied. In cases of uncertainty, the manual owner should get sign-off by GE before changes to the manuals are implemented.

Clarification updates should be listed in the ‘update information’ section. Corrections do not need to be listed in the ‘update information’ section.

# Equalities and health inequalities impact assessment (EHIA)

NICE will review the recommendations for any impact on equalities and health inequalities. Health inequalities can be experienced by people grouped by a range of different factors including:

* protected characteristics groups as outlined in the Equality Act 2010
* socioeconomic status and deprivation
* belonging to vulnerable or excluded groups of society
* geographical area deprivation.

Impacts on equalities and health inequalities will be considered throughout the modular updates identification and implementation process. Health inequalities can be seen and measured through differences in: prevalence of conditions and mortality; behavioural risks to health, such as smoking; the wider determinants of health, such as housing and employment; access to care; the quality and experience of healthcare services.

At module routing, the EHIA form will be initiated and referred to throughout the development process.

Finance, HR, legal implications

No.

Cross organisational impact

The modular updates framework constitutes a change to how NICE manuals are updated, and applying it will lead to changes to the manuals. These changes will impact the work of NICE teams, particularly those in the guidance producing programmes. We have involved and engaged these teams in the development of the framework to ensure that it is appropriate and feasible.

The paper has been developed and reviewed by a cross-NICE working group including representation from Science Policy and Research (SP&R), Centre for Health Technology Evaluation (CHTE) (Medicines and HealthTech) and Centre for Guidelines (CfG). The framework supports NICE’s efforts to harmonise methods and processes across different programmes and directorates. It applies to manuals across CHTE and CfG (PMG20, PMG28, PMG36 and PMG37).

Board action required

The Board is asked to approve the framework for making modular updates to NICE manuals.

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