NICE consultation on the first modular update of the Guide to Health Technology Evaluation (PMG36)

The NICE technology appraisals programme recently consulted publicly on integrating the interim methods and process guide for the proportionate approach to technology appraisals into the Guide to Health Technology Evaluation.

This report presents the comments received, our response and changes made.

NICE, October 2023

Executive summary

1. The consultation received a generally supportive response to the manual updates, with widespread requests for monitoring and consistency of the new approaches and clarity on timings.
2. We propose to make changes to the proposals for length of time for clarification during a cost comparison appraisal and we are providing new process diagrams and clear timelines to support stakeholders in understanding the new approaches.
3. Many respondents were concerned regarding the possibility of inappropriate routing to a cost comparison and the need to reroute to a single technology appraisal (STA) causing delays. NICE is confident this risk is low and managed appropriately and the new approach to cost comparison topics is being monitored internally to ensure early identification of any issues and actions required.

Background

Taking a proportionate approach to Technology Appraisals

1. NICE’s proportionate approach to technology appraisals project aimed to increase the capacity for publishing appraisals by 20% from 2023–24 onwards. We developed new approaches using test-and-learn principles, exploring ideas and developing them through direct experience in active health technology evaluations. NICE engaged with stakeholders throughout the project and incorporated real-time input and feedback throughout.
2. The interim methods and process guide for the proportionate approach to technology appraisals was published in April 2023. This interim process and methods applied to all topics which started their evaluation from this date.

The consultation

1. In June 2023, NICE consulted on integrating the interim methods and process guide for the proportionate approach to technology appraisals into the formal Guide to health technology evaluation.
2. The methods and processes described within the interim guide covered:
   * Cost comparison process
   * Streamlined decision-making, and
   * Operating efficiently, which included:
     1. An Opt-in approach to technical engagement,
     2. Aligning topics in the same disease indication
     3. Handling confidential information
3. Comments were invited on the updated sections of the manual only. Table 1 lists the new and updated sections of the manual:

Table 1

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| --- | --- | --- |
| Manual section number | New, updated or replaced content | Details |
| Section 1.3.25, 2.6, 5.5.9-10, 5.6.4 | Updated and new content | Cost comparison – Expert input, identifying, submitting, timings and evidence assessment |
| Section 5.2.4-5 | New content | Aligning processes for topics following similar timelines |
| Section 5.4.1-21 | New and Updated | Information handling – confidential information |
| Section 5.7.1-6 | New content | Topic progression |
| Section 5.7.7 | Updated | Technical engagement |
| Section 5.7.37-41 | Updated | Committee decisions outside of formal meetings |

1. The consultation closed on 25 July 2023 and received 338 individual comments within 29 stakeholder responses. Figure 1 shows the number of comments across each updated section of the manual.

Figure 1

**General Points**

1. Most responses to the consultation came from industry, with a small number of responses from patient organisations.
2. Respondents were largely supportive of the changes and NICE welcomed this feedback and were especially grateful for suggested amendments to improve the clarity of the information within the manual, the majority of which have been implemented. Respondents particularly noted that they appreciated the simplified approach to marking confidential information, the revised approach to topic scheduling and the introduction of the progression decision step.
3. Respondents have requested clarification on process steps and timings throughout responses, particularly calling for the reintroduction of process diagrams and clear timelines. NICE recognises the importance of clear process and timelines to enable stakeholders to plan and these will be introduced as separate documents held, and clearly identified, on the NICE website.
4. The highest number of responses requesting action or change from NICE focussed on stakeholder involvement in progression decisions (including technical engagement), ensuring consistency across progression decisions, the importance of making the correct decision on routing to cost comparison appraisal, clarification timings during a cost comparison appraisal and the sharing of unredacted documents with experts selected for involvement in NICE evaluations.

**Cost Comparison**

Includes identification, timings, evidence submission, expert input and evidence review for the cost comparison process

**Summary of comments received**

1. A significant number of comments were received on cost comparison appraisals. NICE noted that respondents were particularly concerned about the importance of reaching the right decision on routing a topic to a cost comparison process and the impact that incorrect decision making and subsequent re-routing to the single technology appraisal process could have with regards to delaying patient access.
2. Industry respondents were keen that companies had control over the decision to make a cost comparison submission or submit for a single technology appraisal.
3. Respondents were generally happy with the approach to managing low risk topics in a proportionate way using the cost comparison approach but noted that this should extend to the work done by the external assessment group. Stakeholders reflected that that further work on proportionality and pragmatism is required in the external assessment reports.
4. Almost all industry respondents requested to change the timing to respond to the clarification request; increasing it from 5 working days to 10 working days. They expressed the view that with the current average number of clarification questions received, this timeline was unachievable. They also noted inconsistency between the use of working and calendar days throughout the manual.
5. Stakeholders were concerned about the input of the expert voice into cost comparison appraisals and requested clarification and reassurance on their use within this approach.
6. Respondents requested more information on the experience and input of the NICE medicine’s optimisation team into the cost comparison identification process. They also requested clarification on the type of evidence the company needed to provide for cost comparison topics and when it should be provided.

**Response, including amendments to the proposals**

1. The cost comparison approach was developed to enable light-touch, faster evaluations for low-risk topics, where NICE and the committee already have a good understanding of the disease and the technologies, and the economic analysis can be based on cost comparison methods. The identification of a cost comparison topic is made with input from the company, patient groups, clinicians and NICE’s medicines optimisation team (MOT). This helps ensure early and robust selection of appropriate topics. During the committee decision making, input from additional committee members and experts is available if required, and an option to take the topic to a full committee meeting is also available. With the additional effort applied at the start of the process to identify, select and input into the routing decision, NICE is content that the risk of routing error will be low, although we acknowledge that it cannot be eliminated completely. NICE is monitoring this new approach to identification of topics for cost comparison and the use of the process overall and will identify and implement improvements. Input, engagement and feedback from our stakeholders is welcomed on any appraisal process.
2. To enable efficient management of the technology appraisal programme and manage resources proportionately, the final decision on routing to a cost comparison process must remain with NICE. However, NICE relies on company and stakeholder input to inform this decision and discussion on the routing to cost comparison is encouraged during the scoping consultation and at the decision-problem meeting before the appraisal begins. Decisions taken by NICE regarding routing and the assessment process used within the work programme are not subject to appeal.
3. NICE recognises the request for consistent proportionality across all aspects of the cost comparison approach, including the external assessment stage, and will look to address further requirements in this area.
4. NICE heard clearly that industry respondents were concerned about the clarification response timings for cost comparison appraisals. We accept that this will be challenging for the companies to achieve and have amended the process to allow for 14 calendar days (10 working days) as per the single technology appraisal process. We have also ensured consistency across the manual by only using calendar days to describe length of process stages and timelines.
5. NICE is committed to ensuring the input of experts into its recommendations. For cost comparison topics this input is managed proportionately, allowing for input from both clinical and patient experts but also managing these scarce resources in a way which is appropriate with regards to the low-risk nature of the topic and the experts availability. Our stakeholders have reported concerns with the multiple demands from NICE across guidance programmes and the difficulty in responding to all requests for input as the volume of our outputs increase. Key stakeholders are invited to input to scoping consultation. Clinical and patient experts are nominated, selected and asked to complete a formal statement for the cost comparison appraisal and these experts may be asked to answer questions from the committee if required.
6. The NICE medicines optimisation team (MOT) provides medicines expertise for NICE outputs through front-line clinical experience and supports a network of medicines and prescribing associates. The MOT engages with their associates to create a briefing report on the appropriateness of cost comparison. The MOT report is published alongside committee papers on the topic webpage and examples can be found on recently published topics using the cost comparison approach.
7. An update has been made to the manual to note that NICE welcomes early engagement from companies where they have identified that a cost comparison submission may be possible. This informal engagement with the appraisals team, especially during scheduling, is useful in the effective management of the appraisal programme and its capacity. The scoping consultation document states clearly the information requested from stakeholders to support cost comparison decisions and the submission template used during the cost comparison appraisal is available on the technology appraisal webpage on the NICE website.

**Aligning processes for topics following similar timelines**

**Summary of comments received**

1. Respondents recognised the efficiencies which would be achieved by aligning processes for topics following similar timelines but were concerned that any changes to timelines for one topic should never impact on another, and that only those following the same timings should be aligned. Respondents stated that managing confidentiality and being clear that these topics were considered separately was of great importance to them and that the committee meeting needed to be carefully managed.

**Response, including amendments to the proposals**

1. We have updated the manual to clarify that topics are considered independently, and that the alignment of processes would be cancelled should there be any delay to timings of one topic. NICE also agreed that this process would only apply to those running on the same timelines and have amended the manual to be clear that no topic would ever be delayed, or timelines shifted to allow alignment to take place.
2. Internal assessment and improvements to the running of committee, focussing on ensuring the management of committee time and allowing enough time for each topic on the agenda are continuously taking place within the technology appraisals programme. Attendees to NICE appraisal committee meetings should see the benefits of these internal improvements from the October 2023 committee meetings onwards.

**Information handling – updates to managing confidential information**

**Summary of comments received**

1. Overall stakeholders were happy with the simplification of the process and the redaction in the number of documents. They welcomed the flexibility of ICERs being reported in NICE documents as above or below a decision-making threshold (value). They were happy with the collaborative approach between NICE and the companies in the development of the methods and suggested continued monitoring of its implementation. There are comments on some of the confidentiality sections which were not within the scope of this update, including sharing of unredacted documents with patients and clinical experts and informing companies of ICERs when there are confidential discounts in place for comparator products. Additionally, this update to handling confidential information was targeted to technology appraisals (medicines). Categories of confidential information and methods for non-medicine technology evaluations is to be addressed in future modular updates.
2. Inconsistencies to the wording and the reference to academic in confidence information were highlighted, with consistency in approach requested.

**Response, including amendments to the proposals**

1. NICE recognises the impact of the early engagement with industry stakeholders on changes to managing confidential information and links this to a largely positive response at consultation.
2. Updates to the manual have been made to remove the reference to academic in confidence information where it was no longer appropriate. The health technology evaluation manual covers multiple guidance programmes within the centre for health technology evaluation and notes that some reference to academic in confidence information is still warranted where it applies to other programmes.

**Topic Progression**

**Summary of comments received**

1. The introduction of the progression decision step was largely welcomed, with stakeholders appreciating the efficiencies which would be achieved for topics suitable for streamlining. Industry respondents called for company and expert input into the progression decisions along with clarity on the timing of publication, transparency on the rationale and the choice to appeal the decisions. There was also uncertainty on who is the final decision maker and requests to ensure consistency between them.
2. When considering the pausing of an appraisal, industry respondents requested this be first discussed with the company and the reasons for pausing should not be shared publicly on the NICE website as they are likely to be confidential. Some industry respondents also considered that pausing a topic may be inappropriate as the company have paid for a full appraisal.

**Response, including amendments to the proposals**

1. The introduction of the progression decision step is to allow NICE to identify the most appropriate next step for topics, achieving earlier access for patients where possible whilst also managing NICE and stakeholder resources in a proportionate way. To ensure the smooth running and effective management of resources within the appraisal programme, this decision must be taken by NICE, who will have access to and can assess the evidence submissions and external assessment report to inform next steps. The final decision is taken by the Associate Director responsible for the topic. Consistency is managed through internal programme oversight and management.
2. Any decision to pause a topic is taken after discussion with the company on how to progress the evaluation (section 5.4.31 of the manual). Stakeholders must be kept informed of progress with appraisals but NICE will not publish any information deemed to be confidential and will discuss the communications in advance with the company. NICE will continue to encourage companies to provide as much information as possible to ensure stakeholders are fully informed of the rationale for decisions made.
3. The Technology Appraisal programme is funded through a cost recovery model; recovering the cost of developing the guidance from the company that expects to market the technology in England. Paused topics are not expected to remain paused indefinitely. The progression of the appraisal (following the pause) will utilise NICE resources to determine the outcome of the appraisal.

**Technical Engagement**

**Summary of comments received**

1. Industry respondents requested company input and final decision on the use of the technical engagement stage. Respondents also called for detailed process diagrams and timelines to clearly show how topics progress both with and without technical engagement.
2. Industry respondents noted technical engagement is a step which allowed for the discussion of technical issues, submission of additional information, opportunity to adjust the pricing of the technology being considered and to respond to the evidence assessment report (EAR) and were concerned about the loss of these opportunities.

**Response, including amendments to the proposals**

1. As with the NICE response on the progression step, the final decision remains with NICE and the Associate Director to ensure proportionate and predictable management of the appraisals programme and its resources.
2. Process diagrams and timelines for topics with and without technical engagement have been developed and will be published on the NICE Technology Appraisal webpage.
3. For topics where outstanding issues and evidence gaps are identified and technical engagement will feasibly address these issues, the stage will allow for engagement, discussion and the submission of additional evidence where it is required. For topics which do not require technical engagement the NICE process allows for the discussion of technical issues and submission of additional evidence (if requested) at clarification. Opportunities for increasing simple PAS discounts or commercial discussions are covered in section 5.6.43 – 5.6.56 of the manual.

**Committee decisions outside of formal meetings**

**Summary of comments received**

1. Many respondents were unclear on the process for cost comparison appraisals if the sub-set of committee members could not reach a decision. Clarity was also requested on the involvement of stakeholders in committee decisions outside of a formal meeting, this included how experts are nominated and if they were invited to a meeting with the committee sub-set.

**Response, including amendments to the proposals**

1. The manual wording has been updated to be clear that no stakeholders are invited to attend a meeting for committee decisions outside of the formal appraisal committee meeting. The committee sub-set uses remote technology to consider evidence and come to a recommendation. References to the section of the manual covering the nomination of experts has also been included, to highlight that experts are nominated and selected for these topics in the same way as a standard appraisal. Where the manual states that experts are not normally invited to take part in the committee meeting discussion this refers to streamlined topics and does not change the approach for those going through the standard appraisal process.
2. NICE recognised the manual was unclear on the next steps for cost comparison topics should the committee sub-set be unable to make a decision and have added wording to note that the committee sub-set have the option of proceeding to a full committee meeting, consultation or re-routing the evaluation to follow the standard process.

Next steps

1. The latest version of the health technology evaluation manual, with amendments detailed in this response report, has been published on the NICE website. Changes made to the manual following consultation apply to topics starting from 01 November 2023.

National Institute for Health and Care Excellence

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