

Consultation themed responses: Including NICE technology appraisal guidance in guidelines

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Overview

From February to April 2024, NICE carried out a public consultation on proposed interim methods and processes for including NICE technology appraisals in NICE guidelines.

The comments we received in the consultation were extensive and wide ranging, with different stakeholder groups sharing often-polarised views on key aspects of our proposals.

We set out a way forward which will see NICE proceeding with incorporation of technology appraisals in guidelines - in line with NICE's commitment under the [2024 voluntary scheme for branded medicines pricing, access and growth](#) – a proposal that was generally well received by all stakeholder groups and which stands to improve user experience and increase adoption of our guidance, leading to better patient outcomes. But we will not progress the approach we proposed for integration at this stage. Instead, we will continue to review and update our approach to incorporation as required focusing initially on areas where incorporation is not likely to meet user needs.

The approach set out has been developed to support NICE's strategic ambition to produce high quality guidance that is relevant, timely, useable and impactful, and to provide clarity on the interim methods and processes that can be used to bring NICE technology appraisal guidance into NICE guidelines.

Introduction

NICE's core purpose is to help practitioners and commissioners get the best care to people fast, while ensuring value for the taxpayer. To support the changing needs and objectives of all parts of the health and care system, NICE is transforming to ensure its guidance remains relevant, timely, useable and has a demonstrable impact on health and care.

Currently, NICE's guidance is published according to the programme that developed it. NICE wants to bring together and make it easier for users to find all its guidance about a condition and support the delivery of NICE's strategic objective to provide guidance that is useful and useable. The aim is to provide a better experience for users and help increase the adoption of NICE guidance, leading to better outcomes for patients and better use of NHS resources.

To support this strategic objective, we developed interim methods and processes for including NICE technology appraisal recommendations in guideline topic areas. These interim methods and processes set out our proposed approach to including technology appraisal recommendations in guidelines by incorporation or integration, which were planned to be piloted on selected guideline updates.

This paper provides an overview of the public consultation on the interim methods and processes statement for including NICE technology appraisal recommendations in guideline topic areas. It summarises, by theme, the comments received during the consultation, along with the planned response to those comments, including changes to the proposed interim methods and processes statement. The themes and responses contained in this paper will be published on the NICE website alongside an updated version of the interim methods and process statement and Equalities and Health Inequalities Assessment (EHIA).

1 Engagement and consultation

- 1.1 A 9-week public consultation on the interim methods and processes for including NICE technology appraisals in NICE Guidelines was held between 5 February and 5 April 2024.
- 1.2 Engagement events were held ahead of the consultation, to inform stakeholders of the proposed approach and the consultation document. A [webinar](#) was held for external stakeholders: attendees included representatives from the voluntary and community sector; professional and industry membership organisations; topic-specific advisory groups, boards and forums; local, regional and national government bodies; public health, health and social care partners; academia and other arms-length bodies.
- 1.3 The consultation comprised of 2 documents:
- NICE's interim methods and processes for including NICE technology appraisal recommendations in guidelines, and
 - Equalities and Health Inequality assessment (EHIA) for methods and process changes.
- 1.4 Respondents were given the opportunity to provide detailed comments on all sections of the consultation document and the supporting EHIA. 117 respondents provided comments, 105 of which were provided on behalf of an organisation ([see table 1](#)). There was a total of 856 comments.

Table 1 Consultation responses by organisation type

Respondent	Percentage of organisations / individuals
Industry	38
Consultancy	3
Voluntary and community sector organisations	24
NHSE & DHSE	1

Respondent	Percentage of organisations / individuals
Royal colleges, academic & professional societies	9
Individuals (external to NICE)	2
Arms-length bodies, NHS trusts, ICB/ICS & NHS Wales	5
Other	8

- 1.5 There was cross-sector support for straightforward incorporation of NICE technology appraisal guidance into NICE guidelines, where relevant technology appraisal recommendations are presented, unchanged, within the guidelines. However, stakeholder feedback on the more complex proposed integration of technology appraisal guidance into NICE guidelines was mixed.

2 Key themes identified for incorporation and integration

2.1 The key themes that were identified from the consultation relating to incorporation of technology appraisals were:

- Support for incorporation of NICE technology appraisal guidance into NICE guidelines.

2.2 The rest of the themes identified from stakeholder comments on the consultation related to integration of NICE technology appraisals, and were:

- consideration of the broader policy and healthcare context
- impact on patient access to medicines
- timing of integration
- methodology
- mandatory vs advisory recommendations
- commercial considerations.

2.3 It should be noted that there were concurrent NICE consultations during the period of this consultation, the outcomes of which (where relevant) will be considered in the final approach to bringing together NICE guidance. The other consultations were:

- [Process and methods for NICE-wide topic prioritisation](#)
- [Interim methods and processes for Late Stage Assessment \(LSA\) in HealthTech, and](#)
- [Working alongside people and communities at NICE: a strategy](#)

3 Findings from the consultation: implications for proposals and next steps

Summary of comments for key themes identified

Support for incorporation of NICE technology appraisal guidance into NICE guidelines

Summary of comments received

3.1 There was support for incorporation across the different stakeholder groups. There were some minor queries from stakeholders on operationalisation of the process and points of clarification, including:

- How incorporated technology appraisals will be presented within the guideline.
- Whether all technology appraisals will be incorporated, and whether this will give prominence to older, less effective treatments.
- How terminated technology appraisals, those with negative recommendations and highly specialised technologies would be covered.
- Whether the process described in consultation is materially different from the process that NICE currently has.

Comments on integration of NICE technology appraisal guidance into NICE guidelines

Broader policy and context

Summary of comments received

3.2 The focus of responses was different across stakeholders from different sectors.

- 3.3 Stakeholders from NHS and ICB organisations commented that integration could lead to increased patient access to clinically and cost-effective treatments. This group of respondents also stated that there was a need to review the funding requirement, and that technology appraisals with significant changes in their clinical effectiveness and/ or their costs should be prioritised. They also noted that there was a need to include consideration of biosimilars and generics. This group of stakeholders also said we should include other types of NICE guidance in the project.
- 3.4 Professional, clinical and academic groups commented that there is a need to withdraw guidance on technologies if they are no longer cost-effective. They commented that continuing to recommend the use of technologies that are no longer cost-effective leads to inefficient use of NHS resources that reduces the net population health.
- 3.5 Comments from patient groups and charities noted that integration of technology appraisals into guidelines has the potential to reduce the appeal of the UK as a launch market for new medicines, which could reduce access to medicines for patients. Some stakeholders in this group commented that integration offered the potential for increased implementation, reduced costs and improved care; noting that there would be clear pathways of care based on clinical and cost-effectiveness.
- 3.6 Responses from industry were strongly opposed to integration, stating that the proposal undermines the VPAG agreement and that there was no need for additional cost control given the appraisal process that all technologies have been through. Respondents also commented that the proposals reduce the appeal of the UK as a launch market and destabilise the life sciences sector.

Illustrative quotes received from respondents



The proposals will allow NICE to develop guidance throughout a product's lifecycle reflecting the evolving treatment options, evidence base and pricing for products.



A respondent from an academic organisation



We believe that NICE's technology appraisal recommendations should be integrated by doing a comparative analysis of the costs and benefits of all appropriate treatments.



A respondent from a voluntary and community sector organisation



Consequences for system-wide investment, [reduces] incentives for manufacturers to launch in the UK given high upfront cost of engaging with NICE TA



Life sciences industry respondent

Patient access to medicines

Summary of comments received

- 3.7 All stakeholders commented on access to medicines. Some stakeholders approved of using cost-effectiveness to ensure efficient allocation of resources, whereas others were concerned about risk of restricted choice of medicines and the potential impact of this on patient outcomes.
- 3.8 NHS and ICB respondents commented that integration would allow for the efficient allocation of NHS resources, and again there was mention of the need to include biosimilars and generics in integration, in this theme of responses. This group also noted the need for consideration of sequencing and hierarchies of treatments. This group of stakeholders also commented on the need for opportunities for price negotiations to maintain access to medicines.
- 3.9 Professional, clinical and academic groups shared similar comments to the NHS and ICB respondents. In addition, they also noted that the displaced health impacts of integration decisions need to be considered.

- 3.10 Patient groups and charities commented that integration of technology appraisals creates uncertainty of continued access to a range of treatments and could reduce choice of medicines for patients; they commented that this in turn could lead to worse patient outcomes and could also deepen health inequalities.
- 3.11 Industry respondents commented that the proposals could lead to less individualised treatment and worse patient outcomes if options were removed based on cost-effectiveness. It was also noted in responses that integration could undermine local commissioning decisions, that the proposal prioritises cost-effectiveness over clinical efficacy and that it could widen inequalities across devolved nations.

Illustrative quotes received from respondents



This could allow for increased patient access to clinically- and cost-effective treatments where previous recommendations were optimised and help to ensure that TAs are updated to be reflective of the current pathway



A respondent from NHS/ ICB organisation



The proposal to pilot both integration and incorporation will create uncertainty and discrepancies in relation to patients' ability to access previously assessed treatments.



Voluntary and Community Sector group respondent

Timing

Summary of comments received

- 3.12 All stakeholders requested clarity and justification for the 3-year time-period between publication of a technology appraisal guidance and publication of the guideline into which it would be integrated.
- 3.13 NHS and ICB respondents commented that it was unclear what the rationale was for the 3-year time period, with some commenting that there should not be any time-limit for integration of technology appraisals. Some respondents noted that more rapid integration is needed when prices change and cheaper comparators become available. There was a high volume of comments that integration proposals would lead to an increased workload for local ICBs.
- 3.14 Similar to comments from NHS and ICB respondents, professional, clinical and academic groups also commented that more rapid integration is needed when prices change and cheaper comparators become available.
- 3.15 Patient group respondents had no specific concerns regarding the methodology, but concerns were expressed around the potential change in access to medicines.
- 3.16 Comments from industry stated that the proposals for integration were anti-innovation and were not supportive of the life sciences industry. They also commented that the proposed process was resource intensive and duplicated the work completed for the original technology appraisal. Further comments suggested that medicines which have been found to be clinically and cost-effective for the technology appraisal should not be reassessed, and that this process undermines the decisions made by the appraisals committee.

Illustrative quotes received from respondents



We believe that reassessment of TA recommendations in response to significant clinical and cost developments should take priority



NHS/ ICB organisations respondent



3 years [is] not long enough. Proposal significantly limits the opportunity

to realise investment.



Life sciences industry respondent

Methodology

Summary of comments received

- 3.17 The responses from stakeholders on this theme were polarised, with opposing views from industry compared with NHS bodies and academia.
- 3.18 NHS and ICB respondents noted the need for comparative analysis of all treatment options in a decision space, and put forward the view that assessment of cost-effectiveness is key to efficient use of NHS resources. They also commented on the need for treatments to be sequenced or put into a hierarchy as part of integration. The role of the budget impact test, with respect to effect on NHS and personal social services resources and any likely resource constraints, was also noted here.
- 3.19 Patient groups and VCS organisations raised concerns about the potential removal of severity modifiers and the impact of the proposals on rare diseases. They also noted that integration methods would need to ensure that outcomes for patients were improved.
- 3.20 Industry respondents commented that the proposals for integration reduced the robustness, rigour and transparency of NICE's methods. Respondents also commented that there was a lack of consistency in decision-making processes between technology appraisal committees and guideline committees and that these proposals devalued the technology appraisal process. Concerns were also raised about sequencing of treatments.

Illustrative quotes received from respondents



This could allow for increased patient access to clinically and cost-effective treatments where previous recommendations were optimised and help to ensure that TAs are updated to be reflective of the current

pathway.

”

NHS/ ICB organisation respondent

“

We are concerned about the removal / retro-active application of modifiers at the point of integration where there are differences in approach between TAs and guidelines, as this would have a huge impact on the evaluation of cancer treatments

”

Voluntary and Community Sector group respondent

“

Re-qualification or re-interpretation of NICE guidance in 'integration' would not be able to match the rigour and robustness of a NICE TA.

”

Life sciences industry respondent

Mandatory (appraisal) vs Advisory (guideline) recommendations

Summary of comments received

- 3.21 Concerns were raised by all respondents around the status of technology appraisal recommendations if they are integrated into guidelines. There were clearly differing views between industry and professional, clinical and academic groups.
- 3.22 NHS bodies and ICBs commented that there were implications for how mandatory funding applies if the populations were to be narrowed or widened as part of integration. This group of respondents also raised concerns about having multiple pieces of conflicting NICE guidance if mandatory funding was narrowed or widened.

- 3.23 Professional, clinical and academic groups raised concerns over technology appraisals having a funding requirement with no end-date; they noted that NICE should recommend options that it is confident represents value for money in the present-day environment.
- 3.24 Patient groups and VCS respondents commented that it is important that the legal status of a technology appraisal remains.
- 3.25 Respondents from industry commented that the funding requirement must remain in place and be unchanged. They also raised concerns that the proposals for integration would make guidelines mandatory (rather than their current advisory status). Respondents noted that the scope for the proposed integration methods and processes was wider than that of a technology appraisal; given the inclusion of sequences and extended populations. Lastly, they commented that there is already a multiple technology assessment (MTA) process and technology appraisal review process in place, and therefore these mechanisms should be used rather than creating a new process.

Illustrative quotes received from respondents



If NICE is to discharge its duty to the NHS, positive TA guidance cannot be a golden ticket that guarantees market access in perpetuity. Rather, NICE should only continue to recommend options that it is confident represent an effective use of resources in the present-day environment to which its guidance applies.



Respondent from a clinical and academic sector



A key benefit of obtaining positive NICE guidance has been the permanent funding mandate. Real risk that the removal of funding,... will undermine company confidence in the value of securing a positive NICE recommendation



Life sciences industry respondent

Commercial considerations

Summary of comments received

- 3.26 In stakeholder comments there was an overall perception that commercial options would be highly complex to implement as part of integration.
- 3.27 NHS and ICB respondents commented that price changes of interventions should be a key trigger for integration of technology appraisal guidance into guidelines. Stakeholders from this group also noted that integration could be an opportunity to renegotiate simple Patient Access Schemes (PAS), and that commercial engagement should include ICBs and CMUs. Comments were also received saying that there is a need to reflect the pricing of procurement and commissioning arrangements.
- 3.28 Professional, clinical and academic groups also commented that price changes should be a key trigger for integration of technology appraisals into guidelines. They also noted the complexities of price negotiation when looking at multiple comparators.
- 3.29 Some patient groups and VCS organisations raised concerns around confidential pricing. Some respondents suggested that commercial pricing would be undermined by the proposals for the integration of technology appraisals into guidelines, and questioned how it may affect access to medicines.
- 3.30 Respondents from industry commented that spending is protected by VPAG., which sets a limit for NHS expenditure on branded medicines, beyond which pharmaceutical companies pay rebates back to the NHS. They also noted that commercial negotiations would be complex with multiple options available; operational concerns were raised in the event that multiple companies are involved, or if the treatment has more than 1 indication reliant on PAS discounts.

Illustrative quotes received from respondents



it is essential that guideline integration allows for the possibility of price

negotiation and where necessary withdrawal of guidance

”

A respondent from a clinical and academic organisation

“

We are concerned that confidential pricing could be undermined by this process. This element is highly respected by pharma partners and in turn allows the NHS to benefit from globally competitive pricing for many high cost treatments.

”

Voluntary and Community Sector group respondent)

“

The value of any drug is fixed by its lowest value indication... the NHS already captures value from multi-indication treatments in excess of the ICER thresholds

”

A life sciences industry respondent

Our response and any changes to proposals

- 3.31 Incorporation was generally well-supported by respondents from across the different sectors. We will therefore proceed with prospective and retrospective incorporation of technology appraisals as per the VPAG agreement and publish the interim methods and process statement for bringing together NICE guidance which outlines the details on this process.

- 3.32 Key principles for incorporation of technology appraisal recommendations that the updated interim methods and processes outlines are that:
- The technology appraisal will be presented in the guideline at the appropriate point in the care pathway,
 - No assessment will be done comparing the intervention with other treatment options,
 - The technology appraisal recommendation and funding requirement (when applied for positive recommendations) will remain in place, and
 - That there will no change to the meaning, intent or eligible population for which there is a funding requirement (when applied) in the recommendation(s).
- 3.33 NICE will regularly review our approach to incorporation, updating where required, to ensure our guidance continues to meet user needs.
- 3.34 In line with the [2024 voluntary scheme for branded medicines pricing, access and growth](#), NICE has committed to increasing its efforts for timely update of guidelines to incorporate technology appraisals into NICE guidelines.
- 3.35 The proposals for integration of technology appraisal guidance into guidelines were welcomed by some stakeholders (e.g. professional groups, commissioners, researchers) and strongly opposed by other groups (e.g. industry and some voluntary and community sector organisations). Taking into account feedback from all stakeholder groups during consultation, NICE has agreed to focus initially on incorporation rather than integration. Instead, as NICE works to deliver on its commitment to incorporate technology appraisals within guidelines, we will continue to review and update our approach as required focussing initially on areas where the incorporation of technology appraisals is not likely to meet user needs.

3.36 Examples of limitations of the incorporation process include situations where:

- New evidence is available which might support expanding the patient population in the existing technology appraisal recommendation to improve health outcomes
- NICE has identified a NICE technology appraisal recommendation is no longer aligned with current clinical practice
- It is difficult for users to navigate crowded decision points (for example, where there are both NICE technology appraisals and other types of NICE guidance)