NICE National Institute for Health and Care Excellence

NICE health technology evaluation topic selection: the manual

NICE process and methods

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Contents

About this guide

This is not the current manual. From 29 May 2024, health technologies are selected using the new NICE-wide topic prioritisation process.

This manual sets out the process for deciding how topics are identified, selected and routed for NICE guidance developed by the Centre for Health Technology Evaluation (CHTE). This includes diagnostics, highly specialised technologies, interventional procedures, medical technologies and technology appraisal guidance.

See NICE health technology evaluations: the manual and the interventional procedures programme manual for information about the methods and processes used to develop these types of guidance.

It is beyond the scope of this manual to consider how topics are identified and selected for NICE guidelines or evidence summaries because separate topic selection processes apply for these.

1 Summary of the topic selection process

1.1 This topic selection process is designed to ensure that NICE guidance is developed on topics that reflect national priorities for health and care, in line with NICE's principles.

1.2 If a topic addresses a national priority (see section 2) and meets the eligibility criteria (see section 4), a topic briefing is prepared (see section 5) to support decision making against the selection and routing considerations (see section 6). The topic selection oversight panel decides whether NICE guidance is needed and what type (see section 8).

1.3 It takes between 4 and 12 weeks for a topic to go through the process (see section 11). How long the process takes depends on how early the topic was identified and the availability of information relevant to the selection process.

2 Identifying priorities for the health and care system

2.1 National policies inform the priorities for medicine topics. The 2019 Department of Health and Social Care voluntary scheme for branded medicines pricing and access requires NICE to issue technology appraisal or highly specialised technologies guidance on all medicines that are new to the UK market or have a significant new therapeutic indication.

2.2 For other topics, NICE identifies the priorities of the health and care system and gathers information on potential topics by proactively engaging with national policy teams, clinical leaders, patient groups, system partners, national innovation competitions and commissioner groups.

3 Identifying topics

3.1 Topics that meet the priorities of the health and care system are identified from a range of sources including:

- the National Institute for Health Research (NIHR) Innovation Observatory
- information from companies on UK PharmaScan and NHS Innovation Service
- notifications made to NICE on new or significantly modified interventional procedures (by health and care staff and companies)
- suggestions emailed to NICE's topic selection team (topic.selection@nice.org.uk) from anyone including health and care staff and members of the public
- information given to NICE's topic selection team from other organisations such as NHS England and NHS Improvement and Academic Health Science Networks.

4 Eligibility criteria

4.1 Topics that are eligible to be considered

Devices

4.1.1 These are technologies that treat or prevent a health condition (including digital health technologies listed in tier C of NICE's evidence standards framework for digital health technologies). This includes those using artificial intelligence with fixed or adaptive algorithms. Examples include types of radiotherapy, implanted neuromodulators, and apps or software used to deliver cognitive behaviour therapy through a smartphone. Devices which are expected to get appropriate regulatory approval within 12 months are eligible.

Diagnostics

4.1.2 These are technologies, techniques, strategies and pathways used for an investigative medical purpose. This includes those to help detect, diagnose, monitor, prognose, predict or screen for health conditions (including digital health technologies listed in tier C of the evidence standards framework for digital health technologies). The term 'diagnostic' is used throughout this manual to indicate all such technologies. This includes in-house and companion diagnostics, and those using artificial intelligence with fixed or adaptive algorithms. For example, pathology tests, imaging technologies and software (such as CT scanners or dermatoscopes), measuring technologies (such as ECG (electrocardiogram) and bioimpedance devices), and apps or software for remote monitoring of a condition. Diagnostics which are expected to get appropriate regulatory approval within 12 months are eligible.

Interventional procedures

4.1.3 These are new or significantly modified procedures that use ionising,

electromagnetic or acoustic energy, or involve making an incision, a puncture or entry into a body cavity. These also include established procedures where safety, efficacy or costs need to be reviewed. Examples include inserting a tube into a blood vessel, doing treatment inside the body with an instrument inserted through the mouth and using a laser to treat eye problems.

Medicines

4.1.4 These are new active substances in their first indication or that have extensions to their marketing authorisation to add a significant new therapeutic indication (see the 2019 Department of Health and Social Care voluntary scheme for branded medicines pricing and access). Medicines which are expected to get appropriate regulatory approval within 24 months are eligible.

Combination or integrated technologies

4.1.5 These are combinations of more than 1 type of technology (either sequentially or simultaneously) to achieve or enhance the intended effect. Examples include using several medicines with distinct mechanisms of action to form a combination regimen and using a medical device that integrates a monitor, an algorithm and a medicine to deliver treatment.

Other technologies that have direct patient benefits

4.1.6 Other technologies are eligible to be considered if they are regulated (or seeking regulation) as a medicine or medical device, or have direct patient benefits. Examples include human tissue products (for example donor organs), interventions delivered by healthcare professionals (for example a self-care technology) and vitamins that are regulated as a medicine because they are used to prevent or treat a specific condition.

4.1.7 In some exceptional circumstances, topics that are not usually eligible may be considered. This might be done to support policy or another organisation's decision making, or to address an equality issue.

4.2 Topics that are not usually eligible to be considered

Devices, diagnostics, digital technologies

Technologies that will not get appropriate regulatory approval in the UK within 12 months

4.2.1 Devices, diagnostics and digital technologies without appropriate regulatory approval for use in the UK are not eligible to be considered for topic selection if approval is more than 12 months away.

4.2.2 The appropriate regulatory approval is usually a UK Conformity Assessed (UKCA) or CE mark (as a medical device), but the Medicines and Healthcare products Regulatory Agency (MHRA) may apply different regulation procedures to certain products, such as in-house tests.

Technologies listed in tier A or B of the evidence standards framework

4.2.3 NICE's evidence standards framework for digital health technologies classifies digital health technologies by function and places them into evidence tiers. Digital health technologies listed in tier A or B are not normally eligible to be considered. Examples include productivity tools that target appointment communications or help assign staff rotas.

Established interventional procedures

4.2.4 These are procedures that are standard clinical practice and have a well-known efficacy and safety profile (including robotic delivery of an established interventional procedure). This is unless:

- there is new information and safety, efficacy or cost needs to be reviewed, or
- the procedure has changed, which might affect the safety, efficacy or cost

profile of the established procedure.

Medicines

Medicines that will not get appropriate regulatory approval in the UK within 24 months

4.2.5 The appropriate regulatory approval for medicines is usually a marketing authorisation. Medicines without regulatory approval for use in the UK are not eligible to be considered for topic selection if approval is more than 24 months away.

Unlicensed medicines

4.2.6 These are unlicensed technologies that require regulatory approval for their use outside of research in the UK but are not expecting to get approval within 24 months.

Off-label medicines

4.2.7 These have UK regulatory approval but are being used differently to how the company has instructed.

New generic or biosimilar medicines

4.2.8 Generic or biosimilar medicines are not eligible to be considered if the branded version is recommended in NICE technology appraisal or highly specialised technologies guidance (see the European Medicines Agency's definitions of generic medicines and biosimilar medicine). This is because the recommendation usually applies to the generic or biosimilar medicine. If the branded version is not recommended, does not have NICE guidance or is not recommended in a NICE guideline, the new generic or biosimilar can be considered for a rapid update of

NICE technology appraisal or highly specialised technologies guidance by request, emailing topic.selection@nice.org.uk or contacting the NIHR Innovation Observatory.

Other topics and technologies

4.2.9 Items like foods, drinks, nutritional supplements, cosmetics, toiletries, personal protective equipment and general equipment are not eligible to be considered.

Antimicrobials

4.2.10 NICE is developing innovative models for the evaluation and purchase of antimicrobials to inform future policy. New antimicrobials will be included in NICE evidence summaries until the project is completed.

Technologies that are intended to be used for national, proactive population-based screening

4.2.11 These are considered by the UK National Screening Committee. Some technologies have more than one intended use. For example, a test used to screen for cancer is not eligible to be considered for its use in a proactive national cancer screening programme, but the same test can be considered for its use outside of screening programmes (for example, when used by a GP to screen for cancer in people presenting with symptoms).

Prophylactic vaccinations

4.2.12 Prophylactic vaccinations are not eligible for consideration because this is the role of the Joint Committee on Vaccination and Immunisation. However, therapeutic vaccinations (for example for cancer or another condition) are eligible for consideration.

5 Topic briefings

5.1 Developing a briefing for topics that are eligible for selection

5.1.1 Once a topic has been determined as eligible for selection, a briefing is developed to support decision making. The briefing includes:

- a description of the technology
- intended use and position in the care pathway
- regulatory status
- relevant evidence
- input from the company or person who suggested the topic
- related NICE guidance and guidelines.

5.1.2 The briefing may also include the following information:

- input from the regulator
- input from the committee
- input from relevant organisations (such as NHS England and Improvement, NHSX, Academic Health Science Networks, Office for Life Sciences and NHS Supply Chain)
- input from relevant experts (such as patient, clinical and academic experts).

5.2 Devices, diagnostics and digital health technologies

5.2.1 NICE develops topic briefings on devices, diagnostics and digital health

technologies.

5.2.2 A subgroup of the topic selection oversight panel (see section 8) with specific expertise decides which topic briefings on devices, diagnostics and digital health technologies to publish as medtech innovation briefings (MIBs). These are developed following the MIBs process and methods statement.

5.2.3 The subgroup makes these decisions by considering:

- Is there need for information about the topic?
- Is there potential for useful clinical or system outcomes, quality of life, cost and resource impact?
- Is there publicly available evidence or information relevant to the technology that can be summarised and critically appraised?
- Is there NICE guidance or high quality, up-to-date reviews from a NICE-accredited source already available?

5.2.4 If the device, diagnostic and digital health technology topic is not selected for briefing development, the company or the person who suggested the topic to NICE is informed of:

- the decision
- the reasons why
- whether the topic can be reconsidered for a MIB or NICE guidance in future.

5.3 Interventional procedure topics

5.3.1 NICE develops a topic briefing on all interventional procedures. For some topics, development of the briefing may be postponed until relevant information is available (such as clinical opinions, regulatory information, or evidence). The topic is progressed as soon as NICE is made aware that the information is available.

5.4 Medicine topics

5.4.1 The National Institute for Health Research (NIHR) Innovation Observatory develops topic briefings on medicines.

6 Selection and routing considerations

Topics identified as eligible to be considered are assessed against the selection and routing considerations (see sections 6.1 to 6.3).

The amount and quality of information available on an identified topic can vary. Companies or other relevant organisations, or people, may be contacted to provide additional information.

When there is not enough information to assess a topic against the selection considerations, it is not progressed further. The topic can be reconsidered when NICE is made aware that further information is available.

Table 1 shows the technology types and the type of guidance that may be developed.

Table 1. Technology types and the type of guidance that may be developed

Technology types	Type of guidance developed
Diagnostics	Diagnostics
Devices (cost-saving and cost-neutral technologies)	Medical technologies
Devices (cost-incurring technologies) Medicines	Technology appraisal
Interventional procedures only	Interventional procedures
Medicines only	Highly specialised technologies

6.1 Selection and routing considerations for interventional procedure topics

6.1.1 An interventional procedure is likely to be selected if it is:

- a new or significantly modified interventional procedure that is available to the NHS or independent sector, or about to be used outside of formal research, or

- an existing interventional procedure that needs its safety, efficacy or costs reviewing.

Interventional procedures guidance

6.1.2 Selected interventional procedures are routed to interventional procedures guidance for an assessment of the safety and efficacy evidence. Topics are considered and selected as quickly as possible because guidance is important for protecting the safety of patients.

6.1.3 If a device, diagnostic, digital, combination or integrated technology, or any other technology with direct patient benefits is used within a new or significantly modified interventional procedure and an assessment of the procedure's safety and efficacy is needed, the procedure is routed to interventional procedures guidance. If the clinical and cost evidence also needs assessing, multiple routing decisions may apply (see section 8.5).

6.2 Selection and routing considerations for medicine topics

6.2.1 Medicines that meet the eligibility criteria will be selected, except when there is a clear rationale not to do so. For example, when:

- changes to the dose, formulation or administration will not significantly affect the clinical and cost effectiveness of the medicine, or
- appropriate access to the medicine is provided by an existing policy (such as NHS England's policy on commissioning medicines for children in specialised services) or when a new policy can be developed (for example, when not enough people are eligible to have the technology and NICE guidance would not provide value for the NHS)
- it is appropriate to assess the medicine within a NICE guideline (for example, a new medicine within an existing class).

6.2.2 Selected medicines are routed to technology appraisal guidance unless they meet the criteria for routing to highly specialised technologies guidance (see section 7).

Highly specialised technologies guidance

6.2.3 This guidance is for any medicine that meets all the highly specialised technologies criteria (see section 7).

6.3 Selection and routing considerations for all other topics

6.3.1 A device, diagnostic, digital, combination or integrated topic is likely to be selected if the following apply:

- a systematic assessment of the cost and effects on the health system is needed
- there is an unmet clinical need or an unmet health system need
- it has benefits that are likely to be highly disruptive or lead to a stepwise change to a care pathway in the UK, and
- the benefits are supported by:
  - evidence (such as randomised controlled trials, pre- or post-marketing studies, cohort studies, diagnostic test accuracy studies or other study designs; this includes evidence generated outside the UK that can be generalised to UK practice) showing the technology's effectiveness compared with current practice in the UK health and care system or an appropriate reference standard, and
  - information about the expected resource impact of adopting the technology that is directly applicable to the UK health and care system, and

- advice from experts (such as patients, carers, clinicians and commissioners) that confirms the potential benefits are meaningful and likely to be realised when adopted in the UK health and care system.

Diagnostics guidance

6.3.2 This guidance is for all diagnostic topics.

Medical technologies guidance

6.3.3 This guidance is for therapeutic devices and procedures that need a cost-minimisation analysis.

Technology appraisal guidance

6.3.4 This guidance is for medicines, and any other technologies that need a multiple technology assessment or a cost-utility analysis.

6.3.5 In some exceptional circumstances, topics that do not fulfil the selection considerations may be considered. This might be done to stop an ineffective activity happening, to address a particular issue of safety, to stimulate appropriate research or when system support is required.

7 Highly specialised technologies

7.1 The Highly Specialised Technologies Programme

7.1.1 The Highly Specialised Technologies Programme evaluates technologies for very rare, and often very severe, diseases that need the specific considerations and flexibilities permitted by the programme. Specifically, it evaluates technologies that:

- meet the definition of a highly specialised technology, as described in legislation in Schedule 4 of the NHS Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012, or may potentially need nationally coordinated delivery approaches, and
- need consideration using the methods and processes of the Highly Specialised Technologies Programme, as identified through the highly specialised technologies routing criteria.

7.1.2 NICE's standard technology appraisals methods and processes are designed to be flexible and adaptable for all technologies and conditions. So, they are suitable for most technologies that treat rare conditions and small populations.

7.1.3 The Highly Specialised Technologies Programme is designed to be used in exceptional circumstances. Its purpose is to evaluate technologies for very rare diseases that have:

- small numbers of patients
- limited or no treatment options
- challenges for research and difficulties with collecting evidence, because of the uniqueness of the disease.

7.1.4 The Highly Specialised Technologies Programme aims to:

- encourage research on, and innovation for, very rare conditions when there

are challenges in generating an evidence base that is robust enough to bring the product to market

- secure fairer and more equitable treatment access for very small populations with very rare diseases
- recognise that an approach that maximises health gain for the NHS may not always be acceptable: it could deliver results that are not equitable.

7.1.5 The Highly Specialised Technologies Programme acknowledges that:

- It is important for NICE to apply appropriate limits on the very rare populations that can potentially be routed to the programme. This is because the Highly Specialised Technologies Programme is a deliberate departure from the standard technology appraisal process (valuing the benefits from these technologies more highly by having a much higher incremental cost-effectiveness ratio [ICER] threshold) for the reasons outlined above.
- Each time NICE routes a topic to the Highly Specialised Technologies Programme it is deciding that, if the technology is recommended, the NHS must commit to allocate resources that would have otherwise been used on activities that would be expected to generate greater health benefits.
- NICE has sought to strike a balance between the desirability of supporting access to treatments for very rare diseases against the inevitable reduction in overall health gain across the NHS that this will cause. Both considerations are valid and important, and neither can be given absolute priority over the other. Therefore, the Highly Specialised Technologies Programme criteria and their anticipated application intentionally do not seek to capture every case when there are challenges in generating an evidence base or when there is a small population with a rare disease.
- This approach ensures that technologies routed to the Highly Specialised Technologies Programme fulfil the vision of the programme and manages the displacement in the wider NHS.

7.1.6 However, it can be difficult to identify the exceptional circumstances when the highly specialised technologies methods and processes should be used because of the difficulty in getting the information needed. Proxy information is often

relied on and used to make subjective judgements. The routing criteria identify which technologies should be routed for highly specialised technologies guidance. These criteria help make subjective judgements as informed, justifiable, consistent and predictable as possible. NICE's capacity to develop highly specialised technologies guidance can react to need and there is no limit on the number of technologies that can be routed.

7.2 Highly specialised technologies routing criteria

7.2.1 Technologies will be considered eligible for routing to highly specialised technologies guidance if they fulfil the selection considerations, are selected (see section 6) and meet all 4 of the routing criteria.

Routing criteria 1: The disease is very rare

7.2.2 'Very rare' is defined as a disease that has a prevalence in England lower than 1 in 50,000 people, or about 1,100 people.

7.2.3 In exceptional circumstances, a technology may be routed to highly specialised technologies guidance even if the disease it treats has a prevalence above 1 in 50,000. This is a discretionary departure from normal policy, so it is not possible to fully define when this discretion may be used. A technology would need to clearly and strongly meet all the remaining routing criteria to possibly benefit. Even if all the criteria are met the decision to route a technology to the Highly Specialised Technologies Programme must still be judged to promote the purposes of that technology and align to the programme's vision.

Routing criteria 2: Normally, no more than 300 people in England are eligible for the technology in its licensed indication and no more than 500 across all its indications

7.2.4 The smaller the number of people eligible for the technology, the more likely this criterion will be met. A technology is unlikely to be considered suitable for the

Highly Specialised Technologies Programme if more than about 300 people are eligible for it.

7.2.5 If more than 300 people are eligible, the severity of the disease, unavailability of other effective treatments or a potential for significant benefits with the proposed technology are all considered. This is for the first indication under consideration for routing and it is capped at a maximum of 500 people for a technology with multiple indications. This includes all new active substances in their first indication and extensions to their marketing authorisation to add a significant new therapeutic indication, consistent with the definitions in the 2019 Department of Health and Social Care voluntary scheme for branded medicines pricing and access. NICE has the discretion to apply some flexibility in these cases based on information and evidence gathered by the scoping exercise.

Routing criteria 3: The very rare disease for which the technology is indicated significantly shortens life or severely impairs quality of life

7.2.6 The terms 'significantly' and 'severely' are not defined because they require judgement.

Routing criteria 4: There are no other satisfactory treatment options, or the technology is likely to offer significant additional benefit over existing treatment options

7.2.7 Satisfactory treatments may include authorised medicinal products, medical devices, or other methods of treatment used in England. The term 'significant' is not defined because it requires judgement.

8 The topic selection oversight panel

8.1 Responsibility of the panel

8.1.1 The topic selection oversight panel is mainly responsible for making the following decisions about topics that have been considered by the NICE team:

- selecting devices, diagnostics and digital health technologies for medtech innovation briefings (see section 5.2) and selecting and routing topics to any type of NICE guidance (see section 8.2)
- ratifying the NICE team's decision not to select a topic for interventional procedures guidance (see section 8.3)
- selecting and routing medicines to technology appraisal or highly specialised technologies guidance (see section 8.4).

8.2 Devices, diagnostics and digital health technologies

8.2.1 The topic selection oversight panel considers the briefing (if available, the medtech innovation briefing is used) and apply the selection and routing considerations to make their selection and routing decision (see section 6).

8.3 Interventional procedures

8.3.1 The topic selection oversight panel is informed about any topics that are not selected for interventional procedures guidance and is responsible for ratifying the NICE team's decision.

8.3.2 The topic selection oversight panel may be required to make a selection and routing decision on eligible interventional procedure topics if:

- the clinical and cost effectiveness of the interventional procedure also needs assessing, or
- another eligible topic is used within the procedure, such as a device, diagnostic or medicine.

8.3.3 The topic selection oversight panel applies the selection and routing considerations (see section 6) to decide whether to select the interventional procedure or other eligible topic for NICE guidance. If the topic is selected, multiple routing decisions may apply (see section 8.5).

8.4 Medicines

8.4.1 The topic selection oversight panel is responsible for making selection and routing decisions on eligible medicine topics if:

- the medicine meets the highly specialised technologies routing criteria, or there are uncertainties about whether the criteria are met (see section 7.1)
- there are uncertainties about whether the medicine fulfils the medicines selection considerations
- the medicine fulfils the medicines selection considerations, but there is uncertainty about whether issuing technology appraisal guidance would add value (for example, because a new or existing policy allows people to have the medicine).

  All other topics that fulfil the medicines considerations are automatically selected and routed to technology appraisal guidance by the NICE team.

8.4.2 The topic selection oversight panel considers the topic briefing and applies the medicines and highly specialised technologies criteria to decide whether to route the medicine to technology appraisal or highly specialised technologies guidance, or to deselect the topic. Deselected topics may be referred to another organisation (such as NHS England and NHS Improvement) or considered for another output such as a NICE guideline, for which separate topic selection processes apply.

8.4.3 The NICE (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 require NICE to seek approval from the government before starting the development of technology appraisal or highly specialised technologies guidance. NICE does this by seeking a ministerial referral once a topic has been selected.

8.4.4 The ministerial referral does not specify whether to route the topic to technology appraisal or highly specialised technologies guidance because routing is NICE's responsibility.

8.5 Multiple routing decisions

8.5.1 Some topics may need more than 1 type of NICE guidance, for example interventional procedures that use a technology. NICE guidance may be needed to both assess the safety and efficacy of the procedure and the clinical and cost evidence of the technology used within the procedure.

8.5.2 The topic selection oversight panel considers topics that need more than 1 type of NICE guidance and whether they should be developed:

- in parallel, where NICE will publish 2 separate pieces of guidance on the topic at the same time
- in sequence, where NICE will publish 2 separate pieces of guidance at different times
- through a modified guidance development process where NICE will publish 1 piece of guidance that explicitly assesses the safety and efficacy of the procedure and the clinical and cost evidence of the technology.

9 Equalities and environmental sustainability

9.1 Equalities

9.1.1 The topic selection oversight panel considers whether there are any equality issues that need consideration, in line with NICE's equality scheme and the NICE strategy 2021 to 2026.

9.1.2 Any potential equality issues raised and considered for a topic are recorded in the topic selection decision that is published on the NICE website.

9.1.3 Topics selected for NICE guidance have any potential equality issues recorded in an equality impact assessment that is published with the scope and final guidance. Any relevant equality issues that relate directly to the guidance topic and recommendations are accounted for in the final guidance itself.

9.2 Environmental sustainability

9.2.1 The topic selection oversight panel considers whether there are any potential environmental sustainability issues that may need consideration, in line with NICE's commitment to sustainability.

10 Communicating selection and routing decisions

The company (or person who suggested the topic to NICE, if these people are different) are informed about the selection and routing decision.

Topic selection decisions are published on the NICE website with the:

- topic name and identification number
- indication it was considered for
- decision (if the topic was selected, confirmation of the routing, and any further information required)
- reason for the decision, including any information on equalities that contributed to the decision
- date of the decision.

Topics that are not selected can be reconsidered if the NICE team is made aware of new information that addresses the reasons for non-selection.

Once a topic has been selected, it is scheduled for NICE guidance development. Topics that do not have UK regulatory approval or that have not been launched in the UK are scheduled so that the guidance publishes alongside or as early as possible after approval and launch. Topics that already have UK regulatory approval and have been launched in the UK are scheduled for development as soon as possible. Scheduling for development considers the existing NICE guidance development schedule and external factors such as ongoing studies to generate relevant evidence.

10.1 Challenging a routing decision

10.1.1 In some exceptional cases, the company (or person who suggested the topic to NICE, if these people are different) may consider a routing decision made by the topic selection oversight panel to be inappropriate and may raise a formal

challenge to the decision.

10.1.2 A formal challenge can be made on the grounds that the routing criteria have not been appropriately applied during decision making. Challenges outlining the rationale for reconsideration must be submitted via email to topic.selection@nice.org.uk within 7 calendar days of notification of the panel's routing decision. If a challenge is submitted, this may impact or delay the final scheduling of the evaluation.

10.1.3 All challenges will be reviewed and if the challenge is accepted, the topic will be reconsidered by the topic selection oversight panel. If appropriate, the outcome of the reconsideration step will be ratified by a member of the NICE executive team.

10.2 Re-routing a topic

10.2.1 Sometimes the topic's routing decision may need to change because new information is identified during the scoping phase of guidance development, or a routing decision has been formally challenged. NICE reviews the topic with a rationale for the reconsideration, and if required, the topic selection oversight panel are asked to confirm.

10.2.2 The outcome of the reconsideration and the rationale are published on the topic page on the NICE website.

11 How long does the topic selection process take?

11.1 The length of time taken for a topic to complete the selection and routing process can vary, depending on the available information about the topic and how early NICE was alerted to the topic. For example, further enquiries may be needed to find out how widely it is used in the NHS or whether there is an evidence base to assess the topic with. It is not always possible to achieve the standard times for each stage.

11.2 It takes between 4 and 12 weeks to complete the topic selection process. Table 2 shows the timeline for topic selection.

Table 2. Timeline for topic selection

Week number	Topic selection activities
0	Technology identified.
1 to 4	Relevant eligibility criteria applied. • Technologies that are not eligible are not progressed further but can be reconsidered once the eligibility criteria are met.
4 to 12	Topic briefing developed for eligible technologies. • Companies, clinicians, patients, academics and regulators may be involved if relevant.

Week number	Topic selection activities
12 onwards	Selection decision and publication of the decision on the NICE website. Scoping and guidance development is scheduled. • Technologies already available to the UK are scheduled to begin the process as soon as possible. • Technologies that are not available in the UK are scheduled so that the guidance publishes alongside, or as early as possible after, UK availability. • The publication of available evidence may also be taken into consideration in scheduling.

12 Engagement and support

12.1 Opportunities before and during topic selection

12.1.1 NICE will routinely identify and contact relevant individuals and organisations at planned points in the topic selection process. This usually occurs at topic identification stage, topic briefing development, scoping and after topic selection oversight panel meetings.

12.1.2 There are also opportunities for companies and other interested individuals to talk to NICE (and other organisations when relevant) and seek support.

12.1.3 Information gathered during engagement and support may be shared (following the principles and requirements of data protection legislation outlined in NICE health technology evaluations: the manual) across the NICE teams on a need-to-know basis to support and enhance topic selection decision making. Information sharing is limited to:

- technology name
- indication
- regulatory information
- engagement information:
  - date of engagement
  - type of engagement or service used
  - information about the technology or its regulatory information, or both.

12.2 Tell NICE about a topic

12.2.1 Information about topics can be provided directly to:

- NICE's interventional procedures notification page (for interventional procedures)
- UK PharmaScan (for medicines)
- NHS Innovation Service (for devices, diagnostics and digital health technologies)
- NICE's topic selection team.

12.2.2 NICE's Office for Market Access can help inform market access strategies for all types of technology. They can provide help to understand the healthcare landscape, identify the most appropriate route to NHS access, and explore the value of the technology with system stakeholders.

12.2.3 NICE's scientific advice services can help companies develop evidence that demonstrates the clinical and cost effectiveness of all types of technology. They provide feedback on evidence generation plans, and help companies understand health technology assessment and the perspective of decision makers. They also provide a comprehensive peer review service for economic models that helps companies optimise the model's structure, computation, coding, usability and transparency.

12.2.4 For medicines that have been selected for NICE guidance, the NICE commercial and managed access teams can arrange discussions between NICE, NHS England and Improvement, and companies. This supports timely discussions to address issues of value, affordability and transactability, as appropriate, to give patients the fastest possible access to clinically and cost-effective treatments. Companies can email NICE's Commercial Liaison Team (which includes NICE's Patient Access Schemes Liaison Unit) at CLPT@nice.org.uk. The Commercial Liaison Team will then arrange discussions with the Managed Access Team at NICE or the NHS England and Improvement Commercial Medicines Directorate, or both, as necessary.

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