NICE National Institute for Health and Care Excellence

NICE-wide topic prioritisation: the manual

NICE process and methods
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1 Our transformation

NICE's purpose is to help practitioners and commissioners get the best care to people fast, while ensuring value for the taxpayer. We have achieved this since 1999, delivering a huge body of guidance, grounded in the principles of independence, transparency and rigour. These are principles that are globally respected and will never be compromised.

However, the health and care system has changed rapidly since our inception, so we too must evolve. Our principles and fundamental priorities remain the same. But we are evolving to meet the changing needs of our users, increasing our focus on the relevance, timeliness, usability, affordability, and demonstrable impact of our products.

As part of this transformation and to support NICE's strategic objective to focus on what matters most, we are implementing an organisation-wide approach to topic prioritisation. This is overseen by a single prioritisation board that guides the selection and coordination of our guidance development.

This manual sets out the process for how new guidance topics and updates to existing NICE guidance are identified, prioritised and routed at NICE, and the decision-making framework used by the NICE prioritisation board. It replaces the manual on NICE health technology evaluation topic selection, and section 1.4 of the manual on developing NICE guidelines.

To complement and assist the prioritisation of topics related to public health, social care and rare diseases, the NICE prioritisation board also uses NICE's strategic principles for the prioritisation of public health, social care and rare diseases. These principles guide the application of the prioritisation framework in these areas.

2 Types of topics the manual covers

This section covers the types of topics considered by NICE. Section 3 lists topics that we do not usually consider for guidance development.

'Topic prioritisation' covers prioritisation of new topics and updates to existing NICE guidance.

For the methods and processes used to develop specific types of guidance, see the manuals on:

- NICE's health technology evaluations
- NICE's interventional procedures programme
- developing NICE guidelines.

2.1 Topics for guidelines or guideline recommendations

A guideline usually includes recommendations on topic areas in clinical care (primary, secondary and community care), social care and public health.

2.2 Topics that involve use of health technologies

Health technologies cover diagnostics, medical devices, digital technologies and interventional procedures.

Examples of diagnostics and medical devices include technologies, techniques, strategies and pathways that help diagnose, prognose, predict or symptomatically screen for health conditions, and 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).

Interventional procedures topics cover new or significantly modified procedures that involve making an incision, a puncture or entry into a body cavity, or using ionising,

electromagnetic or acoustic energy. They sometimes cover established procedures where safety, efficacy or costs need to be reviewed.

2.3 Topics that involve use of medicines

These cover new active substances in their first indication or that have extensions to their marketing authorisation to add a significant new therapeutic indication (see the Department of Health and Social Care's 2024 voluntary scheme for branded medicines, pricing, access and growth).

2.4 Combination topics

These are combinations of more than 1 type of medicine and/or health 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.

2.5 Other topics that have direct patient benefits

Other topics are eligible to be considered for guidance if they are regulated (or seeking regulation) (also see section 3) as a medicine or medical device or have direct patient benefits with assurance for safety and performance. Examples include human tissue products (for example, donor organs), interventions delivered by healthcare professionals (for example, self-care technology) and vitamins that are regulated as a medicine because they are used to prevent or treat a specific condition.

3 Topics that are not usually considered by NICE

3.1 Medicines that will not receive regulatory approval for use in the UK within 24 months

The appropriate regulatory approval for medicines is usually a marketing authorisation. Medicines outside a 24-month timeframe for regulatory approval in the UK are not considered by NICE.

3.2 Established interventional procedures

Interventional procedures that are standard clinical practice and have a well-known efficacy and safety profile (including robotic delivery of an established interventional procedure) are not considered by NICE unless:

- there is new information that requires the safety, efficacy or cost of the procedure to be reviewed, or
- the procedure has changed, which might affect its safety, efficacy or cost.

3.3 Medical devices, diagnostics and digital technologies that will not receive regulatory approval in the UK within 12 months

Medical devices, diagnostics and digital technologies without appropriate regulatory approval for use in the UK are not considered by NICE if approval is more than 12 months away. These topics are considered if they are expected to secure regulatory approval within 12 months. 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.

3.4 Digital technologies listed in tier A or B of NICE's evidence standards framework

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 considered by NICE. Examples include productivity tools that target appointment communications or help assign staff rotas.

3.5 New topics that involve use of an unlicensed medicine

These are unlicensed medicines that require regulatory approval for their use outside of research in the UK, but approval is not expected within the next 24 months.

3.6 New topics that involve use of an off-label medicine

Off-label medicines have UK regulatory approval but are being used differently to how the manufacturer has instructed. Off-label medicines will not be considered by NICE unless new regulatory approval has been sought for significant indications as stated in the 2024 voluntary scheme for branded medicines pricing, access and growth. Off-label medicines may be addressed within an existing relevant guideline.

3.7 New generic or biosimilar medicines if the branded version is recommended in NICE guidance

Generic or biosimilar medicines are not considered by NICE 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 by the NICE prioritisation board for a rapid update of NICE technology appraisal or highly

specialised technologies guidance by request to NICE or contacting the National Institute for Health Research (NIHR) Innovation Observatory.

3.8 Antimicrobials (antibiotics, antiparasitics, antifungals)

NICE and NHS England (NHSE) have developed an innovative model for the evaluation and purchase of antimicrobials.

3.9 Topics intended for use in national, proactive population-based screening

These are considered by the UK National Screening Committee. Some technologies have more than 1 intended use. For example, a test used to screen for cancer is not considered by NICE 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 clinician to diagnose cancer in people presenting with symptoms).

3.10 Prophylactic vaccinations

These are considered by the Joint Committee on Vaccination and Immunisation (JCVI). However, therapeutic vaccinations (for example, for cancer or another condition) are considered by NICE.

3.11 Other topics

Substances such as food, drinks, nutritional supplements, cosmetics, toiletries and personal protective equipment are not considered by NICE. This includes topics that are not regulated (or seeking regulation) as medical devices or medicines, consumer apps that are not regulated by Software as a Medical Device (SaMD) or those that do not have direct patient benefits (such as scheduling tools).

3.12 Topics with special circumstances

In some exceptional circumstances, topics that are not usually within NICE's remit may be

considered. This might be done to support policy or another organisation's decision making, or to address an equality or sustainability issue.

4 Summary of the NICE-wide topic prioritisation process

The NICE-wide topic prioritisation process is designed to ensure that NICE guidance reflects national priorities for health and care, in line with NICE's principles. The process involves the following:

- national priorities for the health and care system are identified (see section 5)
- if a new topic or update of an existing guidance addresses a national priority (see section 6) and meets the eligibility criteria (see section 7), a topic briefing is prepared for the NICE prioritisation board (see section 9.1)
- the new topic or update is assessed using the prioritisation framework (see sections 9.2 and 9.3), alongside the NICE strategic principles for public health, social care and rare diseases where appropriate.
- the NICE prioritisation board decides whether new NICE guidance or an update to existing guidance should be prioritised for further development, and what type(s) of guidance the topic is likely to be best addressed by.
- the decision and brief rationales from the NICE prioritisation board are published on the NICE website.

The 2024 voluntary scheme for branded medicines, pricing, access and growth states that NICE will continue to evaluate all new active substances and significant indications, except where there is a clear rationale not to do so. These new active substances and significant indications will not go through the NICE-wide topic prioritisation process and will be routed to technology appraisal guidance, except when there is a clear rationale not to do so (see section 7.1.3).

The NICE prioritisation board will make highly specialised technologies (HST) routing decisions using the HST criteria (see appendix 1 for the vision for the HST programme and the routing criteria to HST guidance).

5 Identifying priorities for the health and care system

NICE identifies the priorities of the health and care system by engaging with national policy teams, clinical leaders, patient groups, system partners, national innovation awards and commissioners, to gather information on potential topics. Feedback and intelligence will also be sought from NICE Impact and Partnerships Directorate and NICE Science, Evidence and Analytics Directorate.

6 Identifying new topics and updates of existing guidance

6.1 New topics

New topics that meet the priorities of the health and care system are identified from a range of sources, including:

- National Government or NHSE policy
- the National Institute for Health Research (NIHR) Innovation Observatory
- information from companies on UK PharmaScan and the NHS Innovation Service for health technologies
- notifications to NICE on interventional procedures, from health and care staff and companies, among others
- input from NICE system intelligence working in partnership with Integrated Care Systems (ICSs)
- suggestions from other organisations or stakeholders, such as the royal colleges, specialist societies, NHS Innovation Service, Health Innovation Networks
- suggestions from health and care staff and the public (excluding companies) that are made via the topic suggestion proforma or topics@nice.org.uk.

6.2 Updates

Updates that meet the priorities of the health and care system are identified by NICE monitoring mechanisms. This includes horizon scanning, evidence monitoring, and suggestions from internal and external sources, for example, notifications from committee members, topic experts, health and care staff and the public through NICE enquiries and suggestions via the topic suggestion proforma or topics@nice.org.uk

7 Eligibility criteria for using the prioritisation framework and direct routing to guidance development

7.1 Eligibility criteria for new topics

New topics are assessed against the eligibility criteria outlined in sections 7.1.1 to 7.1.4.

The amount and quality of information available on an identified new topic can vary. Companies or other relevant organisations or people may be contacted to provide more information. Any commercial in confidence information will be handled according to NICE internal commercial in confidence policies.

When there is not enough information to assess a new topic against the eligibility criteria, it is not progressed further. The new topic can be reconsidered when NICE is alerted that further information is available.

7.1.1 New guidelines or guideline topics

A new guideline or guideline topic may be selected for assessment using the prioritisation framework if:

- it is within NICE's remit to address, not the remit of, for example, the Joint Committee on Vaccination and Immunisation (JCVI), National Screening Committee (NSC), UK Health Security Agency (UKHSA), Care Quality Commission (CQC) **and**
- there is a gap in the existing NICE guidance portfolio **or**
- there is significant and unwarranted variation in practice.

7.1.2 Topics that involve use of new interventional procedures

An interventional procedure may be selected for assessment by the interventional procedures programme if it is:

- new or significantly modified and available to the NHS or independent sector **or**
- about to be used outside of formal research **or**
- an existing procedure that warrants review in relation to safety, efficacy or cost.

All selected interventional procedures are directly routed to interventional procedures guidance for an assessment of the safety, efficacy evidence or cost. All these topics will be shared with the NICE prioritisation board so it will have the oversight of the whole NICE guidance portfolio.

In some circumstances, where there is uncertainty on a new topic that needs ratification or further routing decision from the NICE prioritisation board, a topic briefing will be developed for use with the prioritisation framework (see section 9).

7.1.3 Topics that involve use of new medicines

New medicines that meet the criteria stated in the 2024 voluntary scheme for branded medicines, pricing, access and growth will be selected for assessment by the technology appraisal programme, except when there is a clear rationale not to do so. For example, when:

- changes to the dose, formulation or administration that 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 NHSE'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).

All medicines that meet the criteria in the 2024 voluntary scheme for branded medicines, pricing, access and growth are directly routed to technology appraisal guidance without using the NICE-wide topic prioritisation process. These topics will be shared with the NICE prioritisation board so it will have the oversight of the whole NICE guidance portfolio.

Where the criteria in the 2024 voluntary scheme for branded medicines, pricing, access and growth are not met, that is, when there is a clear rationale not to select a topic for

technology appraisal guidance, NICE will directly seek support for a non-selection decision from NHSE. All selection and non-selection decisions will be reported to the NICE prioritisation board.

When new medicines meet the criteria for routing to highly specialised technologies guidance (see appendix 1 for the vision for the HST programme and the routing criteria to HST guidance), a separate topic overview will be developed for the NICE prioritisation board for routing decision using the HST criteria.

The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 require a direction from the Secretary of State before NICE is able to make a technology appraisal or highly specialised technology recommendation on a topic (medicines and health technologies).

7.1.4 Topics that involve use of new health technologies

A medical device, diagnostic, digital, or other health technology with direct patient benefits, may be selected for assessment using the prioritisation framework if:

- a systematic assessment of the cost and effects on the system is needed (for example, because there is uncertainty or because the topic is expected to be significantly cost incurring or cost saving)
- 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, before and after 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
  - information about the expected resource impact of adopting the technology that is directly applicable to the UK health and care system
  - advice from experts (such as patients, carers, clinicians and commissioners) that confirms that benefits are meaningful and likely to be realised when adopted in the UK health and care system.

In exceptional circumstances, topics that do not fulfil these criteria may be considered by

NICE, for example, special referrals by the Secretary of State to assess health technologies using NICE technology appraisal methodology.

For topics that meet the criteria in this section of the manual, a topic briefing will be developed for use with the prioritisation framework (see section 9). Stage 1 will usually be omitted where the topic is a direct formal notification from NHSE or the Department of Health and Social Care (DHSC).

In some circumstances, a topic that involves use of a health technology may bypass the topic prioritisation process, for example, special referral by the Secretary of State.

Topics that involve use of health technologies may be routed to the following NICE guidance outputs by the prioritisation board:

Guideline recommendations within an existing care pathway

A topic that involves use of a health technology may be addressed as a topic area within an existing guideline where the technology is or can be part of an existing care pathway.

Health technologies guidance

This may include guidance on diagnostics, devices, digital technologies or interventional procedures.

Highly specialised technologies guidance

This guidance is for any health technology that meets all the highly specialised technologies criteria (see appendix 1 for the vision for the HST programme and the routing criteria to HST guidance).

Technology appraisal guidance

This guidance is for technologies, procedures and any other topic that requires a multiple technology assessment or a cost-utility health economic approach (diagnostic technologies are only considered in exceptional circumstances).

7.2 Eligibility criteria for updates of existing

guidance

This manual covers updates to all NICE guidance.

Proposed updates to NICE guidance will be assessed using the following eligibility criteria. Updates that meet the following criteria will not be assessed by the NICE prioritisation board. They will be allocated directly to guidance development teams for progression where the update is:

- related to a safety alert that NICE must respond to (for example, MHRA drug safety update, Health Services Safety Investigations Body report, coroner's Regulation 28 report or others).
- an alignment of guidance related to content that has already been approved by the prioritisation board (for example, the update of a quality standard related to updated guideline recommendations, or the update of guideline recommendations as a consequence of an update to incorporated technology appraisal recommendations)
- innovative (see appendix N of the manual on developing NICE guidelines) and does not need significant guidance development team resources (for example, incorporation of other NICE guidance into guideline recommendations, and consolidation of the guidelines portfolio (see section 5 of appendix M of the manual on developing NICE guidelines).

Only updates that need ratification or a routing decision will be considered by the prioritisation board. In these circumstances, a topic briefing will be developed for use with stage 2 of the prioritisation framework, omitting stage 1.

8 NICE prioritisation board oversight

All new topics or updates (as stated in sections 7.1.2 to 7.1.4 and 7.2) that bypass the NICE-wide prioritisation process, and any innovative pilot projects, such as the NICE Late Stage Assessment (LSA) in HealthTech and the DHSC Medical Technology Innovation Pathway, will be shared with the NICE prioritisation board so it will have an oversight of the whole NICE guidance portfolio.

9 Prioritisation framework stage 1 and stage 2

9.1 Developing topic briefings for prioritisation

If a new topic or an update is eligible for assessment using the prioritisation framework (see section 7), a topic briefing is developed to support decision making.

NICE will keep its sponsor teams at the DHSC and NHSE updated on all proposed new topics and updates that will be assessed by the prioritisation board.

The topic briefing will provide information on the new topic or update, and how the prioritisation framework stage 1 and/or stage 2 criteria are met or not met. The topic briefing summarises:

- title of the new topic or update
- context (including description of the health technology, if applicable)
- related NICE guidance
- potential impact on related NICE guidance.

Where appropriate, input will be sought from a relevant regulator, committee, or other organisations (such as NHSE, NHSE Transformation Directorate, Greener NHS, DHSC, Office for Health Improvement and Disparities, Health Innovation Networks, Office for Life Sciences and NHS Supply Chain), and relevant topic experts (such as patients, clinical and academic experts). The prioritisation framework uses a 2-stage approach for most new topics.

The NICE strategic principles to public health, social care and rare diseases will be applied alongside the prioritisation framework, where appropriate, particularly when considering health and care need, population impact, and health inequalities.

9.2 Prioritisation framework stage 1 criteria

The prioritisation framework stage 1 criteria are used to determine if a new topic is appropriate for NICE to address. Information in the topic briefing will be used to assess each criterion qualitatively with an initial judgement of a yes or no.

The NICE prioritisation board will conclude an overall final decision whether the new topic should proceed to stage 2 or not, with clear rationales on the trade-off among the 4 criteria specific to the topic of interest.

New topics that do not proceed to stage 2 may be revisited later if new information or intelligence become available.

9.2.1 Stage 1 criteria

NICE's role

What value will NICE add to the health and care system by producing guidance?

For example, can NICE produce guidance that is useful and useable to users through:

- evaluations of clinical and cost effectiveness
- decision making by independent, multidisciplinary committees
- robust methodology and processes
- objective review of evidence.

Health and care need

Will the guidance address health and care need by reducing:

- avoidable illness
- harm or care burden
- significant morbidity
- premature mortality

- low quality of life?

Are there related national policies or targets that indicate that the topic is of national importance (for example, the Major Conditions Strategy, NHS Long Term Plan or annual NHS priority areas)?

Evidence availability

Is evidence available or expected to support further exploration of guidance products?

Is there:

- sufficient volume of evidence
- limited evidence
- lack of, or no, evidence?

The assessment of the availability of evidence should be proportionate within the context of the relevant topic area, for example, there will often be less or limited evidence for rare diseases, compared with more common conditions. The assessment should be contextual with an equitable focus in relation to the topic area.

Availability and access

Will the health technologies, interventions or services under consideration be available for implementation in the health and care system?

For example:

- there is appropriate marketing authorisation or regulatory classification (for example, MHRA, CE or UKCA mark, or digital technology assessment criteria (DTAC) for the relevant medicines or health technologies
- the current health and care structure or configurations can adopt or adapt and deliver the interventions or services.

9.2.2 Omitting stage 1

Stage 1 is omitted for:

- new topics formally notified directly from NHSE and DHSC
- updated topics that need to go through the topic prioritisation process.
- routing decisions for medicines to technology appraisal or highly specialised technologies using the HST criteria (new active substances and significant indications as stated in the 2024 voluntary scheme for branded medicines, pricing, access and growth).

These topics will go directly to stage 2. For routing decisions on technology appraisals or highly specialised technologies, the HST criteria (see appendix 1 for the routing criteria to HST guidance) will be used by the NICE prioritisation board instead of the prioritisation framework stage 2 criteria.

9.3 Prioritisation framework stage 2 criteria

If a new topic is deemed suitable at stage 1, or an update requires further ratification or a routing decision, a more detailed set of criteria is used to support decision making at stage 2. This will examine whether a topic or an update should be prioritised by NICE.

9.3.1 Stage 2 criteria

Budget impact

The likely impact on health and care system budgets of implementing the new or updated guidance. This may be:

- a disinvestment opportunity
- cost saving or cost neutral
- more expensive or cost incurring to the system.

A topic area that is more expensive or cost incurring to the system does not necessarily mean it will be disadvantaged during consideration. The decision from the NICE prioritisation board is based on a deliberation of the trade-offs across all criteria.

System impact

The potential impact of the new or updated guidance on health and care infrastructure, and capacity and capability for implementation. For example, the guidance may:

- address current system infrastructure or workforce capacity constraints or burden
- have no or negligible impact on current system infrastructure or workforce capacity (for example, it could be incorporated into the existing care pathway)
- be challenging to achieve because of infrastructure or workforce capacity constraints in the relevant public funded services.

Population impact

The potential impact of the new or updated guidance on the target population, for example:

- the size of the target population
- the anticipated potential of guidance to improve patient or service user outcomes by addressing gaps or variations in current practice.

Consideration of population impact will not merely focus on the prevalence of the condition, but will also consider whether the target population is experiencing severely life-limiting or debilitating diseases (for example, rare diseases) with a lack of, or no, treatment options.

Evidence quality and system intelligence

Availability of:

- evidence that meets NICE's quality requirements and addresses relevant clinical and service outcomes
- accurate system intelligence that indicates gaps or variations in current practice, or where there is a need for NICE to inform best practice.

The assessment of the quality of available evidence will be contextual to the topic area, acknowledging that some topic areas are not suitable or ethical to be addressed by

randomised controlled trials, for example, topic areas in rare diseases, children and young people, and the effectiveness of invasive surgical procedures.

Health inequalities

The potential for the new or updated guidance to:

- introduce, increase or reduce health inequalities
- have no health inequalities impact
- address one of the Core20Plus5 priority areas.

As different health inequalities may be simultaneously impacted to different degrees and in opposing ways in different sub-populations, a breakdown of the criterion to sub-criteria to indicate opposing impact may be appropriate during the assessment.

Where there is appropriate evidence or intelligence, the impact of the wider determinants of health (such as social, economic and environmental factors) on health outcomes will also be considered during the deliberations of the NICE prioritisation board.

Environmental sustainability

The potential for the new or updated guidance to reduce avoidable production and consumption of healthcare through:

- the prevention of ill health and the future need for services
- appropriate disinvestment and/or
- the existence of a link between the guidance and a medicine or product prioritised for substitution/disinvestment in the Delivering a Net Zero NHS report or subsequent statutory NHSE guidance related to environmental duties in the Health and Care Act 2022.

9.3.2 Assessment, deliberation and decision making

Each stage 2 criterion will be assessed as having a:

- positive impact **or**

- negative impact **or**
- nil or neutral impact **or**
- unknown or unclear impact.

A fixed scoring and weighting approach will not be applied to the criteria because individual criterion will have different levels of impact based on the topic area of interest. For example, there should not be a fixed numerical score or weighting for population impact as a criterion when assessing the priority of high prevalence but self-limiting upper respiratory tract infections, in comparison to low prevalence but debilitating conditions such as motor neurone disease.

The decision-making approach is a combination of the framework and the NICE prioritisation board members' deliberations and discussions about the trade-offs between the different criteria specific to the topic area of interest.

After the deliberations, the NICE prioritisation board members will conduct a formal voting, each choosing one of the 4 ratings (-2 = very low priority, -1 = low priority, +1 = high priority, +2 = very high priority). An average positive score indicates an overall 'yes' decision on the relative priority for NICE to develop guidance in that topic area, while an average negative score indicates an overall 'no' decision. The rationales for the trade-offs and the deliberations by the NICE prioritisation board will be documented transparently and published on the NICE website.

For positive final decisions, the NICE prioritisation board will further discuss routing considerations, based on all the information available. The final routing decision could include developing single guidance or combination of guidance products.

The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 require a direction from the Secretary of State formally referring the topic before NICE is able to make a technology (for example, a medicine, health or medical technology) appraisal or highly specialised technologies recommendation on a technology.

NICE requests a Ministerial referral once a topic has been selected. The Ministerial referral does not specify whether the topic is routed to, for example, technology appraisal or highly specialised technologies guidance because routing is NICE's responsibility. For information on highly specialised technologies and the routing criteria, see appendix 1 for

the vision for the HST programme and the routing criteria to HST guidance. For all other guidance, NICE develops this in accordance with the relevant legislation.

9.3.3 Possible outcomes for a topic that has not been prioritised

For a topic that has not been prioritised at stage 2, the prioritisation board members will discuss possible outcomes that are more appropriate for addressing the topic or update. These may include:

- revisiting the topic or update later, for example, when more evidence or system intelligence becomes available
- producing an alternative NICE product such as a quality standard or clinical knowledge summary
- developing research recommendations with engagement from potential research funders, such as NIHR, UK Research and Innovation (UKRI), and the Association of Medical Research Charities (AMRC)
- cross-referencing to suitable guidance or guideline recommendations produced by other organisations
- engaging with external bodies to explore appropriate solutions (for example, the royal colleges, specialist societies, other arms-length bodies, or NHSE)
- no further action
- standing down content (for updates only).

10 NICE prioritisation board

The NICE prioritisation board has a decision-making role that drives forward NICE's strategic ambition to focus on what matters most and ensure that areas of greatest impact to the system are prioritised for guidance delivery.

The NICE prioritisation board:

- reviews and discusses topic briefs to decide which of these should be prioritised for guidance delivery, including routing of technology appraisal or highly specialised technology
- maintains an annual forward view of topics and a 'rolling plan' that it reviews and adjusts regularly, in response to changes in system need and demand
- shares its decisions with NICE's guidance executive and publishes these on the NICE website to ensure visibility and to enable effective sharing of information with our stakeholders.

We share all topic briefs with the DHSC and NHSE before each prioritisation board meeting. Feedback from DHSC and NHSE, if any, will be considered by the NICE prioritisation board as part of their decision making, but the NICE prioritisation board is independent of DHSC and NHSE, and these bodies are not represented on the board itself.

NICE prioritisation board members reflect a collective view of their teams and directorates, not their personal view. Outputs from the internal horizon scanning and system intelligence functions will feed into the NICE prioritisation board and produce regular reports to support prioritisation and the development of the annual forward view.

11 Communicating prioritisation and routing decisions

All prioritisation decisions are shared with DHSC and NHSE before publication on the NICE website.

NICE seeks a formal referral from DHSC or NHSE for new topics prioritised by the board.

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

NICE prioritisation board decisions are published on the NICE website with the:

- topic name and identification number
- decision (selected, further information needed, not selected with possible outcomes in section 9.3.3)
- brief rationale for the decision
- date of the decision.

Topics that are not prioritised can be reconsidered if the NICE team is made aware of new information that addresses the reasons for non-selection, and more than 6 months have elapsed since the original decision was published.

Once a topic has been selected, it is scheduled for NICE guidance development, subject to formal referral from DHSC or NHSE in accordance with Regulation 5 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.

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 is practical. Scheduling topics for development takes into account the existing guidance development schedule and external factors such as ongoing studies to generate relevant evidence.

12 NICE-wide topic prioritisation clarification process

The aim of the clarification process is to explain NICE's reason for its prioritisation decision(s) that are queried by stakeholders. Requests for clarification do not usually offer an opportunity to revisit or overturn the NICE prioritisation board's decision, which is based on careful consideration of the evidence and relevance for future guidance development. Exceptions would be if substantial new information or factual errors come to light, or in the case of very rare disease, there is evidence that the highly specialised technologies routing criteria have not been appropriately applied. In exceptional circumstances, NICE may change its decision on the routing of new topics or updates following input from stakeholders, and will specify the rationale for this change.

The clarification process will be published on the NICE website and will apply to all topics and routing decisions that the prioritisation board considers.

Stakeholders should complete the clarification proforma within 20 working days of publication of the prioritisation board's decision. The questions will be reviewed, and a response will be provided within 20 working days of the questions being received.

If a stakeholder returns with additional questions, these will be considered at the next available NICE guidance executive meeting. The guidance executive will produce a final response within 10 working days after the meeting.

Clarifications and any final response from the guidance executive will be sent directly to the stakeholder using a standard template and published on the NICE website.

13 How long does the NICE-wide topic prioritisation process take?

The length of time taken for a new topic or update to complete the NICE-wide topic prioritisation and routing process can vary. This depends on the information available on the new topic or update. For example, further enquiries may be needed to find out how widely a health technology is used in the NHS, or whether there is an evidence base on which to assess the new topic.

In general, it takes a minimum of 12 weeks to complete the NICE-wide topic prioritisation process.

14 Opportunities for engagement and support before and during the NICE-wide topic prioritisation

NICE will routinely identify and contact relevant individuals and organisations at planned points in the topic prioritisation process. This usually occurs at topic identification stage, topic briefing development and after NICE prioritisation board meetings.

Information gathered during engagement and support may be shared (in line with NICE confidentiality policy and agreements) across the NICE teams on a need-to-know basis to support and enhance topic prioritisation 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.

15 Tell NICE about a topic

There will be a common proforma for topic suggestions, with a single letterbox or email: topics@nice.org.uk.

Additionally, 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 Advice 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.
- NICE Advice can also 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. NICE Advice also provides a comprehensive peer review service for economic models that helps companies optimise the model's structure, computation, coding, usability and transparency.
- For medicines that have been selected for NICE guidance, the NICE commercial and managed access teams can arrange discussions between NICE, NHS England (NHSE) 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 [PASLU]). The Commercial Liaison Team will then arrange discussions with the Managed Access Team at NICE or the NHSE Commercial Medicines Directorate, or both, as necessary.

Terms used in this manual

Guidance

Evidence-based recommendations produced by NICE. There are 4 types of guidance:

- guidelines covering clinical topics, medicines practice, public health and social care
- health technologies guidance (this includes diagnostics guidance, medical technologies guidance and interventional procedures guidance)
- technology appraisal guidance
- highly specialised technologies guidance.

Routing

Decisions on what type of guidance NICE will produce.

Topic or topic area

Health and care issue or issues that require guidance on solutions. The solutions can be a medicine, a diagnostic, a medical technology, an interventional procedure, other interventions (for example, psychological therapy, rehabilitation therapy, exercise programme) or a combination of different interventions.

Appendix 1: highly specialised technologies

The vision

The Highly Specialised Technologies (HST) 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 HST Programme, as identified through the highly specialised technologies routing criteria.

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.

The HST 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.

The HST 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.

The HST 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 HST 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 HST 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 HST 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 HST Programme fulfil the vision of the programme and manages the displacement in the wider NHS.

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.

Routing criteria

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

Routing criteria 1: The disease is very rare

'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.

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 HST 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

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 HST Programme if more than about 300 people are eligible for it.

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 Department of Health and Social Care's 2024 voluntary scheme for branded medicines, pricing, access and growth. 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

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

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.

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