NICE integrated topic prioritisation and strategic principles

1. Background – NICE's transformation

NICE's purpose is to help practitioners and commissioners get the best care to people fast, while ensuring value for the taxpayer. We've achieved this for 25 years, 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, we are introducing a new overarching approach to prioritisation and topic selection. This will be overseen by a single prioritisation board that will guide the selection and coordination of our guidance development.

This document provides an overview of how we propose to approach this and includes the following:

- NICE's integrated topic prioritisation manual. The manual provides an overview of the process through which NICE will identify new topics and updates for prioritisation, and the decision-making framework that will be used by the NICE prioritisation board. This will replace NICE health technology evaluation topic selection: the manual. Central to the approach are key criteria to inform consideration of the priority of topics. These have been developed from existing approaches to guidance topic selection at NICE, a 'NICE Listens' deliberative public engagement and the strategic vision for the organisation.
- NICE's strategic principles for public health, social care and rare diseases. These strategic principles will guide the prioritisation of topics related to public health,

social care and rare diseases, and are the outcome of engagement with key stakeholders. They are designed to complement NICE's existing core principles, for use alongside the new integrated prioritisation process outlined above, to ensure that these topics are not overlooked.

2. NICE integrated topic prioritisation manual

This manual sets out the process for how new guidance topics and updates to existing NICE guidance are identified, prioritised and routed at NICE. '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 NICE's health technology evaluations: the manual, NICE's interventional procedures programme manual and Developing NICE guidelines: the manual.

The types of NICE guidance that will be considered by this integrated topic prioritisation manual include:

2.1 Guidelines or guideline topic areas

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

2.2 Health technologies guidance

Health technologies guidance includes guidance on diagnostics, devices, digital health technologies and interventional procedures. Examples of diagnostics and 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). Examples of interventional procedures include new or significantly modified procedures that involve making an incision, a puncture or entry into a body cavity, or use ionising, electromagnetic or acoustic energy. This also includes established procedures where safety, efficacy or costs need to be reviewed.

2.3 Medicines

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

2.4 Combination or integrated topics

These are combinations of more than 1 type of intervention (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, using a medical device with an app or software to deliver a medicine, virtual wards integrated topic advice that include a clinical guideline and health technology guidance.

2.5 Other topics that have patient benefits

Other topics are eligible to be considered if they are regulated (or seeking regulation) as a medicine or medical device or have patient benefits with assurance for safety and performance. Examples include human tissue products (for example, donor organs), interventions delivered by healthcare professionals (for example, laboratory testing or techniques, or rehabilitation programmes) and vitamins that are regulated as a medicine because they are used to prevent or treat a specific condition.

3. Summary of the integrated topic prioritisation process

The integrated topic prioritisation process is designed to ensure that NICE guidance reflects national priorities for health and care, in line with NICE's principles.

If a new topic or update of an existing guidance addresses a national priority (see section 4) and meets the pre-stage 1 eligibility criteria (see section 6), a topic briefing is prepared, and the topic is assessed using a prioritisation framework (see section 7). 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 (see section 6.1.1).

The NICE strategic principles for public health, social care and rare diseases (section 12) will also be considered throughout the whole process of integrated topic prioritisation, from pre-stage 1 to stage 2.

For the integrated topic prioritisation processes, see appendix 1: supporting document: process diagrams.

The 2024 Department of Health and Social Care voluntary scheme for branded medicines, pricing, access and growth states that NICE will evaluate new active substances and significant licence extensions for existing medicines except where there is a clear rationale not to do so. These new medicines do not need to go through the NICE integrated topic prioritisation process; however, in exceptional circumstances, medicines not falling into these categories, for example established medicines, may be considered by the NICE prioritisation board.

The prioritisation board will also make highly specialised technologies routing decisions (appendix 3).

4. Identifying priorities for the health and care system

For new topics or updates, 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.

5. Identifying new topics and updates of existing guidance

5.1 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 NHS England 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 to NICE's topic intelligence and monitoring team.

5.2 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.

6. Prioritisation framework: eligibility criteria

6.1 New topics eligible to be considered at pre-stage 1

New topics identified may be suitable for individual NICE guidance, or multiple pieces of NICE guidance (combined or integrated topics). Eligibility criteria outlined in section 6.3 will be applied to facilitate the prioritisation process and routing decisions.

6.1.1 Types of NICE guidance for review using the pre-stage 1 eligibility criteria

- Guidelines or guideline topic areas (see section 2.1)
- Health technologies guidance (see section 2.2)
- Medicines (see section 2.3)
- Combination or integrated topics (see section 2.4)

- Other topics that have patient benefits (see section 2.5)

6.2 New topics not routinely eligible for consideration

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 are not eligible for consideration.

Established interventional procedures

These are procedures in standard clinical practice with a well-known efficacy and safety profile. This is unless there is new information on safety, efficacy or cost that needs to be reviewed, or the procedure has changed, which might affect its safety, efficacy or cost.

Health technologies that will not receive regulatory approval in the UK within 12 months

The appropriate regulatory approval is usually a UK Conformity Assessed (UKCA) or CE mark, but other regulatory processes or quality procedures can apply instead of, or in addition to, these. For example, the Human Tissue Authority regulates human tissue transplants, the United Kingdom Accreditation Service regulates in-house diagnostic tests, and the Care Quality Commission (CQC) regulates services. In some cases, it can be unclear if the technology is a device, medicine or other product such as a cosmetic. These are considered 'borderline products' (Medicines and Healthcare products Regulatory Agency [MHRA] guidance explains the borderlines between medical devices and medicines or other products). Devices, diagnostics, digital technologies and other topics without regulatory approval for use in the UK are not eligible to be considered for topic selection if approval is more than 12 months away. These topics are eligible to be considered if they are expected to secure regulatory approval within 12 months.

New topics that involve use of an unlicensed technology

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

New topics that involve use of an off-label medicine or technology

Off-label technologies have UK regulatory approval but are being used differently to how the manufacturer has instructed. Off-label technologies will not be considered unless new regulatory approval has been sought. Off-label medicine topics may be addressed within an existing relevant guideline.

Digital health technologies 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 eligible to be considered. Examples include communication platforms or productivity tools that optimise patient flow through clinics or help assign staff rotas.

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

Generic or biosimilar medicines are not eligible to be considered if the branded version is recommended in a NICE technology appraisal or highly specialised technologies guidance (see the European Medicines Agency definitions of generic medicine and biosimilar medicine). This is because recommendations in a technology appraisal or highly specialised technologies guidance usually apply to the generic or biosimilar medicine. Occasionally, when a branded medicine is recommended in a technology appraisal or highly specialised technologies guidance, a recommendation for a biosimilar medicine may be incorporated into guideline recommendations if there is a significant cost impact. If the branded version is not recommended in NICE guidance or in a guideline, or has not yet been considered for NICE guidance, the new generic or biosimilar can be considered for NICE technology appraisal or highly specialised technologies guidance by request to NICE

or contacting the National Institute for Health Research (NIHR) Innovation Observatory.

Antimicrobials (antibiotics, antiparasitics, antifungals)

NICE is developing innovative models with NHS England (NHSE) for the evaluation and purchase of antimicrobials to inform future policy.

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 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 clinician to diagnose cancer in people presenting with symptoms).

Prophylactic vaccinations

These are considered by the Joint Committee on Vaccination and Immunisation.

Other topics

Substances such as food, drinks, nutritional supplements, cosmetics, toiletries and personal protective equipment are not eligible to be considered. 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).

Topics with special circumstances

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 or sustainability issue.

6.3 Pre-stage 1 eligibility criteria for new topics

New topics are assessed against the pre-stage 1 eligibility criteria outlined in sections 6.3.1 to 6.3.4. New topics that meet the pre-stage 1 eligibility criteria will

progress to stage 1 of the prioritisation process. In some circumstances, new topics may be routed directly to guidance production without being assessed by the integrated topic prioritisation process. These are highlighted below in sections 6.3.2 to 6.3.4. The amount and quality of information available on an identified new topic can vary. Companies or other relevant 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 pre-stage 1 eligibility criteria, it is not progressed further. The new topic can be reconsidered when NICE is alerted that further information is available.

6.3.1 Pre-stage 1 eligibility criteria for new guidelines or guideline topics

A new guideline or guideline topic may be selected for pre-stage 1 prioritisation 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.

6.3.2 Pre-stage 1 eligibility criteria for new interventional procedure topics

An interventional procedure may be selected 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.

Selected interventional procedures are directly routed to interventional procedures guidance for an assessment of the safety and efficacy evidence. The prioritisation board will be notified of these topics.

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 the prioritisation framework stage 1 and stage 2 (see section 7).

6.3.3 Eligibility criteria for new medicine topics

Medicines that meet the eligibility criteria (as stated in the 2024 Department of Health and Social Care voluntary scheme for branded medicines, pricing, access and growth) will be selected, except when there is a clear reason not to. For example:

- where there are changes to the dose, formulation or administration that will not significantly affect the clinical and cost effectiveness of the medicine **or**
- when 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 receive the technology for NICE guidance to be developed).

The NICE (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 (including health or medical technology) appraisal or highly specialised technology recommendation on a topic.

Selected medicines are directly routed to technology appraisals guidance.

In some circumstances when new medicines meet the criteria for routing to highly specialised technologies guidance, or require further ratification by the NICE prioritisation board (see appendix 3), a topic briefing will be developed for the NICE prioritisation board and will go straight to prioritisation framework stage 2 (see section 7.2.2).

6.3.4 Eligibility criteria for all other new health technology topics

A device, diagnostic, digital, or any other topic with direct patient benefits, may be selected 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 the selection thresholds may be considered, for example, special referrals by the Secretary of State to assess health technologies using NICE technology appraisal methodology.

For selected topics, a topic briefing will be developed to proceed through stage 1 and stage 2 (see section 7) of the prioritisation framework. 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 health technology topic may bypass the prioritisation process, for example, special referral by the Secretary of State.

All other health technology topics may be routed to the following NICE guidance outputs by the prioritisation board, which may include:

Guideline recommendations within an existing guideline pathway

A health technology topic may also be addressed as a topic area within an existing guideline where the technology is well placed in a guideline 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 technology that meets all the highly specialised technologies criteria (see appendix 3).

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).

6.4 Pre-stage 1 eligibility criteria for updates

This manual covers updates to all NICE guidance outlined in section 6.1.1.

Proposed updates to NICE guidance will be assessed using the following pre-stage 1 eligibility criteria. Updates that meet these criteria will not be assessed by the 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).
- The update is 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 an incorporated technology appraisal).
- The update is innovative and does not need guidance development team resources (for example, incorporation of NICE guidance into guideline recommendations, consolidation of the portfolio [see section 5 of appendix M in Developing NICE guidelines: the manual]).

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

7. Prioritisation framework stage 1 and stage 2

7.1 Developing topic briefings for prioritisation

If a new topic or an update is eligible for prioritisation at pre-stage 1, a topic briefing is developed to support decision making. NICE will keep its sponsor teams at the Department of Health and Social Care (DHSC) and NHS England (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 stage 2 criteria are met or not met. The topic briefing summarises:

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

The topic briefing will provide information on how the new topic or update meets prioritisation framework stage 1 and stage 2 criteria. Where appropriate, input will be sought from a relevant regulator, committee, or other organisations (such as NHSE, NHSE Transformation Directorate, Department of Health and Social Care, 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.

7.2 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.

7.2.1 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 avoidable illness, harm or care burden, significant morbidity, premature mortality and reduced 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? The availability of evidence should be in the context of the relevant topic area; for example, rare conditions will frequently have less evidence than more common conditions.

Availability and access

Will the 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 [Medicines and Healthcare products Regulatory Agency], CE or UKCA [UK Conformity Assessed] mark, DTAC [Digital Technology Assessment Criteria]) for the relevant pharmaceuticals or health technologies
- current health and care structure or configurations can adopt or adapt and deliver the interventions or services.

7.2.2 Omitting stage 1

Stage 1 is omitted for:

- new topics formally notified directly from NHSE and DHSC
- updated topics of all guidance
- routing decision on technology appraisal or highly specialised technologies (guidance on all medicines that are new to the UK market or have a significant new therapeutic indication, as per the 2024 Department of Health and Social Care voluntary scheme for branded medicines, pricing, access and growth).

These topics will go directly to stage 2.

7.3 Prioritisation framework stage 2 criteria

If a new topic is deemed suitable at stage 1, or an update requires further ratification, 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.

7.3.1 Stage 2 criteria

Budget impact

The likely impact on health and care system budgets of implementing the potential topic guidance. This may be a disinvestment opportunity, be cost saving or cost neutral, or more expensive or cost incurring to the system.

System impact

The potential impact of the 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 size of the relevant target population, and the anticipated potential of guidance to improve patient or service user outcomes by addressing gaps or variations in current practice.

Evidence quality

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

Health inequalities

The potential for the guidance or update to introduce, increase or reduce health inequalities, or have no health inequalities impact.

Environmental sustainability

The potential for the guidance or update to reduce the use of healthcare services through prevention of ill health, support disinvestment and reinvestment plans (for example, medicines or products prioritised for substitution or disinvestment in Delivering a net zero NHS report, Environmental principles policy statement or other subsequent statutory NHSE guidance related to the environmental duties in the Health and Care Act 2022).

7.4 Assessment

Each stage 2 criterion will be assessed as having a:

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

The NICE prioritisation board will discuss the topic in detail and vote to agree an overall final decision on the relative priority for NICE to develop guidance in that topic area.

For positive final decisions, the NICE prioritisation board will further discuss routing considerations, based on all the information available from pre-stage 1 to stage 2. The final routing decision could include developing single guidance or multiple and integrated guidance products (see section 6.1.1).

The NICE (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 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 3. For all other guidance, NICE develops this in accordance with the relevant legislation.

7.5 Possible outcomes for a topic that has not been prioritised

For a topic that has not been prioritised, 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 the National Institute for Health and Care Research (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).

8. 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
- maintains a 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 will share all topic briefs with the Department of Health and Social Care (DHSC) and NHS England (NHSE) before each prioritisation board meeting. Feedback from DHSC and NHSE, if any, will be considered by the prioritisation board as part of their decision making, but the 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 horizon scanning and system intelligence functions will feed into the prioritisation board and produce regular reports to support prioritisation and the development of the annual forward view.

See appendix 2 for the membership and terms of reference of the NICE prioritisation board.

9. Communicating prioritisation and routing decisions

All prioritisation decisions are shared with the Department of Health and Social Care (DHSC) and NHS England (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)
- 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 including technologies 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. Technologies that already have UK regulatory approval and have been launched in the UK are scheduled for development as soon as is practical. Scheduling for development considers the existing NICE guidance development schedule and external factors such as ongoing studies to generate relevant evidence.

9.1 Integrated 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. The request for clarification will not usually offer an opportunity to revisit or overturn the prioritisation board's decision, which is based on careful consideration of the evidence and relevance for future guidance development, unless 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 send questions for clarification by email to the NICE clinical directorate within 10 working days of publication of the prioritisation board's decision. The questions submitted will be reviewed by the topic prioritisation team in the clinical directorate 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 escalated and considered at the next available NICE guidance executive meeting. The guidance executive will direct a final response within 10 working days after the guidance executive meeting.

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

10. How long does the integrated topic prioritisation process take?

The length of time taken for a new topic or update to complete the integrated 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 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 integrated topic prioritisation process.

11. Opportunities for engagement and support before and during the integrated 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.

11.1 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's topic intelligence and monitoring team (for any other topic).
- 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.

12. NICE strategic principles: a complementary approach to public health, social care and rare disease topics

NICE brings a set of unique strengths to the areas of public health, social care and rare diseases. However, guidance on these topics may draw on a wider evidence base, and population benefits and value for money of interventions in these areas is often harder to articulate. Therefore, we are introducing a set of complementary strategic principles to guide prioritisation in these areas and ensure they are not disadvantaged by the new unified prioritisation process.

The strategic principles outlined below are designed to be used alongside NICE's prioritisation criteria and will help to ensure we deliver against NICE's core purpose and objectives. They sit alongside, but do not replace, the core principles that underpin all NICE guidance and standards. It is intended that they will be applied to

all relevant areas of work at NICE and support the prioritisation board's decision making in these areas.

12.1 Oversight and engagement

This work was guided by a Strategic Principles Working Group, with oversight from the NICE clinical directorate. In 2023, the Working Group met with key internal representatives for each area before holding a series of internal and external engagement events with relevant stakeholders. The external stakeholders engaged included representatives from the voluntary and community sector; patient advocacy groups; professional membership organisations; topic-specific advisory groups, boards and forums; local government; public health, health and social care partners; academia; other arms-length bodies.

12.2 Strategic principles for public health

12.2.1 Definition

NICE believes that public health is about helping people to stay healthy and avoid getting ill; this includes work on a whole range of areas such as tobacco and alcohol, drugs recovery, sexual health, pregnancy and children's health.

12.2.2 Background

The regulations arising from the Health and Social Care Act 2012 provide NICE with a function of giving advice or guidance, providing information and making recommendations about any matter concerning or connected with the provision of public health services in England. The legislation also provides that the function is only exercisable on the direction of Secretaries of State.

The public health landscape has changed greatly in recent years with the creation and dissolution of some central organisations, and the establishment of Integrated Care Systems in England. Public health and prevention are increasingly important in a landscape of limited resources and increasing demand for health and care services. In light of this shifting landscape and NICE's new centralised prioritisation approach, it is timely for us to work with partners to clearly define our role and set out where we can add most value to the system.

12.2.3 Principles

The following principles will be used to guide our approach to the prioritisation and development of public health guidance:

1) We will prioritise developing and updating public health guidance only where there is new evidence, an opportunity for system support and health gain, and a clear route to effective implementation.

2) We will recognise the importance of prevention as well as treatment when scoping guidance across the NICE portfolio.

3) We will focus our selection of public health guidance to support implementation in practice. This will mean being explicit, where the evidence shows we can be, about our intended audience, thinking beyond implementation in traditional health settings.

4) Where there is appropriate evidence, we will consider the impact of the wider determinants of health (such as social, economic and environmental factors) on health outcomes during the prioritisation of new and updated guidance across NICE.

5) We will ensure alignment with other relevant organisations within the health and care system, such as NHS England, UK Health Security Agency and the Office for Health Improvement and Disparities. We will collaborate on areas of joint interest and avoid duplication of effort by focusing on the areas where we can add the greatest value.

6) We will work closely with research partners to highlight where research gaps limit evidence-based recommendations.

12.3 Strategic principles for social care

12.3.1 Definition

NICE recognises that social care comprises a wide range of activities delivered by a complex system of organisations and professionals. This includes areas such as social work, residential, domiciliary and rehabilitation services, safeguarding,

community and family support alongside many other services. Predominantly led by local authorities, the underpinning values of social care are centred around supporting the independence, choice and autonomy of individuals, safeguarding vulnerable people from harm and developing communities that are inclusive, accessible and respect diversity. Unlike healthcare, social care is not always free at the point of access and many aspects of social care are charged for or self-funded by individuals and families.

12.3.2 Background

The regulations arising from the Health and Social Care Act 2012 provide NICE with a function of giving advice or guidance, providing information and making recommendations about any matter concerning or connected with the provision of social care in England. The legislation also provides that the function is only exercisable on the direction of Secretaries of State.

Evidence-based practice is becoming increasingly important within social care and, in an extremely challenged system, there is a moral imperative to use resources for maximum benefit. NICE can help to ensure social care is based on reliable evidence regarding what works. The move towards new and integrated ways of working, including the establishment of Integrated Care Systems in England, offers new opportunities. NICE is well placed to bridge the gap between health and social care and support best practice within integrated systems of care.

12.3.3 Principles

NICE recognises the significant interdependence between health and social care. We are committed to supporting an equal partnership that recognises the importance of both in addressing current challenges in the health and care system.

The following principles will be used to guide our approach to the prioritisation of social care guidance:

1) We will seek to integrate social care in all our guidance, where appropriate, embedding a social care lens across prioritisation and subsequent guidance development.

2) We will use the partnership working opportunities presented within Integrated Care Systems and other models of integration to inform our approach to prioritisation. Preference will be given to the interface between health and care provision, favouring integrated outputs over standalone guidance where this is feasible, useful and usable.

3) We will not prioritise standalone social care guidance unless there is a compelling reason to do so. For example, where there is significant new evidence emerging on a cross-system priority combined with a clear route to effective implementation.

4) We will focus on the questions that matter most to the sector and topic areas where sufficient evidence exists to support recommendations, and there are clear routes to implementation.

5) We will recognise that the nature of evidence within social care may be different to that available within clinical medicine.

6) We will focus our selection of social care guidance to support implementation in practice. This will mean being explicit, where the evidence shows we can be, about our intended audience, thinking beyond implementation in traditional health settings.

7) We will work closely with research partners to highlight where research gaps limit evidence-based recommendations.

12.4 Strategic principles for rare diseases

12.4.1 Definition

A rare disease, as defined by Orphanet, is a condition that affects less than 1 in 2,000 people. NICE considers diseases that affect less than 1 in 50,000 people to be ultra rare.

12.4.2 Background

Rare diseases are often severe, usually life limiting and often occur in the paediatric population where the impact of effective treatments on the individual and their family

are profound. The Department of Health and Social Care's Rare Disease Framework estimates that there are over 7,000 rare diseases, 80% of which have an identified genetic origin. One in 17 people in the UK are affected by a rare disease at some point in their lives, which amounts to over 3.5 million individuals. People with rare diseases can be at risk of becoming unsupported in the healthcare system. Populations are small and geographically dispersed, and so the impact of national work can be underestimated. This, coupled with the lack of evidence on disease course and effective treatments, means that guidance on rare diseases may be overlooked. It is therefore important to ensure that these patients are afforded an equitable focus. The highly specialised technologies programme (see appendix 3) provides guidance for ultra-rare diseases with the aim of encouraging research and development while securing fairer and more equitable access to treatment in this area of high unmet need.

12.4.3 Principles

1) The following strategic principles outline NICE's approach to developing guidance relating to rare diseases and will inform decision making by NICE's prioritisation board:

2) We aim to create an attractive environment that stimulates innovation for global researchers, developers and pharmaceutical companies to find and develop innovative and cost-effective treatments for severely life limiting or debilitating rare diseases with few or no treatment options currently available. We will do this by considering whether a condition significantly shortens life or severely impairs its quality, how rare it is and the availability of existing treatments before evaluating topics and new technologies for cost effectiveness.

3) With the exception of health technology evaluations, where NICE's responsibilities are clearly defined, we will not routinely produce guidelines that relate to single rare diseases. Instead, we will seek to identify commonalities between conditions that enable us to provide products that can be applied across multiple rare disease groups.

4) We will proactively collaborate with rare disease stakeholders, ensuring we communicate with patients and experts across multiple organisations to inform a shared understanding of NICE methods and processes in both clinical guidelines and technology appraisals. We will also ensure alignment with the UK Rare Diseases Framework and work with stakeholders to increase the evidence base relating to rare diseases.

Appendix 1: NICE integrated topic prioritisation process

See the separate supporting document, integrated topic prioritisation process diagram (pdf version).

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Appendix 2: NICE prioritisation board terms of reference and membership

Terms of reference

The NICE prioritisation board:

- enables NICE to focus on what matters most
- sets the strategic direction that underpins consistent prioritisation decisions
- resolves strategic and directional challenges given divergent perspectives from across the organisation and among external stakeholders
- maintains alignment with related initiatives that inform prioritisation by being mindful of these, system need and demand
- provides an effective 'one organisation' approach to topic selection that ensures NICE outputs deliver coordinated, integrated outcomes
- ensures that resource implications and risks are identified and addressed
- fosters a transparent approach by publishing key information, decisions and outputs.

The NICE prioritisation board will approve both new work and updates of guidance topics. It will also stand down or retire topics when appropriate. There will be a mechanism to consult and inform key external stakeholders before and after the meetings as needed. This includes our sponsor teams.

Governance

- The Chief Medical Officer will chair the prioritisation board.
- The prioritisation board will meet every 4 weeks (this will be kept under review).
- Any urgent decisions needed between meetings will be taken by the chair and discussed with NICE's guidance executive.
- Other individuals not formally included as members may be invited to join specific meetings to provide subject matter expertise on specific topics.
- The quorum for the meeting will be 9 members in attendance, including at least 1 member from each of the 3 guidance producing centres (Centre for Guidelines, Medicines Evaluation and Medical Technology). If a member with specific

expertise (for example, expertise in sustainability and health inequalities) is unable to attend, they should nominate a deputy with delegated decision-making authority who will count towards the quorum.

- For decision making, two thirds of voting members will need to vote.
- The Chief Medical Officer is responsible for communication with guidance executive and the executive team. A summary of decisions from the prioritisation board will be agreed by guidance executive once a month. Once a quarter, a high-level report on priorities for guidance will be shared with the NICE board as part of the executive team update.
- A summary of decisions made by the prioritisation board will be communicated both internally and externally, and taken forward by the clinical directorate.
- The Chief Medical Officer will have a casting vote only to resolve a deadlock in decision making.
- The associate director of NICE Advice will be on the board in an advisory capacity and will not have voting rights.
- The prioritisation board terms of reference and membership will be reviewed every 6 months.
- Subgroups will have their own terms of reference.
- The Chief Medical Officer will escalate any issues or challenges to the guidance executive. If further escalation is needed, this will be to the executive team and finally to NICE's board.
- The decisions agreed at the prioritisation board meeting will be summarised in a monthly report. The frequency of this report may change depending on the schedule of the prioritisation board meetings. This report is for information only, and any issues for discussion by exception will be highlighted.
- An annual forward plan developed by the topic prioritisation team and approved by the prioritisation board will be shared with guidance executive for final sign-off before publication on the NICE website.

Membership

All members are asked to advise on suitability of topics for prioritisation and routing considerations.

Members

- Chief Medical Officer (chair)
- Clinical directorate: associate directors, topic intelligence and monitoring team (deputy chair)
- Clinical directorate: programme director (health inequalities)
- Clinical directorate: consultant clinical adviser
- Implementation and Partnerships: representative
- Science, Evidence and Analytics (evidence and sustainability): representative
- Centre for Guidelines (leadership): representative
- Centre for Guidelines (operational delivery): representative
- Centre for Health Technology Evaluation (CHTE) medicines (leadership team): representative
- CHTE medicines (operational delivery): representative
- CHTE health technology (leadership team): representative
- CHTE health technology (operational delivery): representative
- NICE Advice: associate director (in advisory capacity)
- Topic intelligence and office for digital health: associate director
- Publishing and Products: associate director
- Resource: associate director
- Strategy: associate director
- External communications: associate director
- 2 lay members

Support staff

- Clinical directorate: coordinator (secretariat)
- Clinical directorate: chief of staff

Observer

- Clinical fellow(s)

Duration of membership

Any member recruited solely for the purpose of participating in the board (such as lay members) will be subject to the NICE appointments to advisory bodies policy and procedure.

Other observers

NICE staff and NICE committee members may attend prioritisation board meetings as observers, with the agreement of the Chair.

Confidentiality

Confidential information (such as academic or commercial-in-confidence material or sensitive personal data disclosed in panel discussions) will not be discussed with the media or members of the panel who are conflicted for the topic being discussed.

Declaring and managing interests

The NICE prioritisation board secretariat is responsible for ensuring that non-NICE members of the panel follow the NICE policy for declaring and managing interests for advisory committees.

Meetings and papers

- Meeting frequency will be planned to meet the operational needs of topic selection for timely guidance output.
- The clinical directorate will decide the agenda before each meeting.
- The secretariat will send the meeting papers to all attendees 1 week before the meeting.
- The minutes will record significant decisions and actions relating to the topics discussed.

Transparency

The NICE website will be updated with the prioritisation board's decision.

Accountability

The NICE prioritisation board has the authority to make final decisions about which topics are selected for guidance development and how that guidance is routed.

Review of terms of reference

The terms of reference will be reviewed annually.

Date: May 2024

Review date: May 2025

Appendix 3: Highly specialised technologies

NICE's highly specialised technologies programme identifies and evaluates technologies for very rare conditions that need the specific considerations and flexibilities permitted by this programme. Specifically, it evaluates technologies that:

- meet the definition for 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, and
- need consideration using the methods and processes of the highly specialised technologies 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 (including health or medical technologies) and conditions. So, they are suitable for almost all technologies that treat rare conditions and small populations. For more information about the methods and processes used for standard technology appraisals, see NICE's health technology evaluations: the manual. NICE's highly specialised technologies programme is a deliberate departure from this. It recognises the challenges of generating evidence in very small populations with severe, very rare conditions. It also acknowledges that an appropriate value framework is needed to evaluate technologies that meet the programme's criteria.

The programme has set criteria to identify technologies for very rare conditions for which there is substantial unmet need and people with those conditions would otherwise be disadvantaged. The highly specialised technologies methods and processes are only used in exceptional circumstances, that is, when all the following apply:

- There is a need to provide fair and equitable access to technologies for people with very rare and serious conditions that significantly shorten life or severely impair its quality.
- There are substantial challenges associated with the very rare condition, including difficulties in collecting enough good quality evidence.

- It is likely that the technology would not be recommended using standard methods and processes, even if provided with substantial discounts or other economic mechanisms.
- The developers are unable to recover the cost of bringing the technology to market under normal market conditions because of small patient numbers and other barriers to evidence generation, such as lack of natural history data for the condition.

However, it can be difficult to identify those exceptional circumstances when the highly specialised technologies methods and processes should be used because of the difficulties in obtaining the information needed. Proxy information is often relied on and used to make subjective judgements. Routing criteria have been developed to 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; there is no limit on the number of technologies that can be routed. Also, the routing criteria are not a tool to manage affordability or budget impact in the NHS. This is managed by other measures such as the budget impact test and commercial arrangements.

Highly specialised technologies routing criteria

Technologies will be considered eligible for routing to highly specialised technologies guidance if they fulfil eligibility criteria (see sections 6.3.3 and 6.3.4) for selection (see section 7) and meet all 4 of the highly specialised technologies routing criteria.

The condition is very rare

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

In exceptional circumstances, a technology may be routed to highly specialised technology guidance even if the condition 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 satisfy all of the remaining highly specialised technologies 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.

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 highly specialised technologies programme if more than about 300 people are eligible for it. If more than 300 people are eligible, the severity of the disease, and whether there is lack of other effective treatments or a potential for significant benefits with the proposed technology are all considered.

One-off treatments would normally be considered acceptable if they have an eligible prevalent population of up to about 50 people and an eligible incident population of no more than about 40 people a year. This is for the first indication under consideration for routing. This is capped at a maximum of 500 patients for a technology with multiple indications; this means 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 2024 Department of Health and Social Care 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.

The very rare condition 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.

There are no other satisfactory treatment options, or the technology is likely to be of significant additional benefit to 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.

ISBN: To be added.