National Institute for Health and Care Excellence (NICE)

Centre for Health Technology Evaluation

Topic selection processes – Proposals for change

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Introduction

1. The NICE Centre for Health Technology Evaluation (CHTE) is responsible for developing the following guidance outputs:

* Diagnostics guidance (DG)
* Highly specialised technologies guidance (HST)
* Interventional procedures guidance (IPG)
* Medical technologies guidance (MTG)
* Technology appraisals guidance (TA)

1. Topic selection plays an important role in the development of NICE guidance, recognised in the recently published [NICE principles](https://www.nice.org.uk/about/who-we-are/our-principles) (principle 1). Across NICE a variety of bespoke processes are used to identify, select and route topics to the various guidance producing programmes.
2. Topic selection is the process for deciding which topics NICE will produce guidance on and has been designed to support the guidance development process so that topics chosen will protect patient safety and support healthcare professionals and others to provide care of the best possible quality.
3. The update of these processes gives us the opportunity to ensure appropriate governance and oversight of this important function at NICE. Topic selection for the various NICE guidance types operates in a system governed and affected by a wide and complex range of factors, including Ministerial referral and company notifications; and has a major impact on expenditure in the NHS. The governance of our topic selection system must therefore be fit for purpose.

Background

Existing processes

1. Within the Centre for Health Technology Evaluation, 3 distinct processes are used, more or less aligned with the type of technology or procedure of interest:

* Device and diagnostic topics are managed by the Medical Technologies Evaluation Programme. Information about the processes used is published in the Medical technologies evaluation programme process guide [(https://www.nice.org.uk/process/pmg34/chapter/identifying-selecting-and-routing-technologies-for-evaluation)](file:///\\nice.nhs.uk\Data\CHTE\CHTE%202020\4.%20Workstreams\2.%20Single%20topic%20selection%20process\5.%20Project%20team%20&%20SG%20papers\(https:\www.nice.org.uk\process\pmg34\chapter\identifying-selecting-and-routing-technologies-for-evaluation))
* Medicine topics are managed under a standalone Topic Selection process for Technology Appraisals and Highly Specialised Technologies. Information about the processes used is published on the NICE website [(https://www.nice.org.uk/about/what-we-do/our-programmes/topic-selection#ta-selection)](file:///\\nice.nhs.uk\Data\CHTE\CHTE%202020\4.%20Workstreams\2.%20Single%20topic%20selection%20process\5.%20Project%20team%20&%20SG%20papers\(https:\www.nice.org.uk\about\what-we-do\our-programmes\topic-selection%23ta-selection))
* Procedure topics are managed by the Interventional Procedures team. Information about the processes used is published in the Interventional Procedures programme manual [(https://www.nice.org.uk/process/pmg28/chapter/introduction)](file:///\\nice.nhs.uk\Data\CHTE\CHTE%202020\4.%20Workstreams\2.%20Single%20topic%20selection%20process\5.%20Project%20team%20&%20SG%20papers\(https:\www.nice.org.uk\process\pmg28\chapter\introduction))

Status of NICE guidance

Technology Appraisal guidance:

* There is a legal requirement for relevant health bodies to comply with the published recommendations as per [Section 7 (6) of the NICE (Constitution and Functions) and the HSCIC (Functions) Regulations 2013.](http://www.legislation.gov.uk/uksi/2013/259/regulation/7/made)
* NICE must recover the cost of developing Technology appraisal guidance from the company that expects to market the technology in England, in accordance with [UK Statutory Instrument 2018 No.1322](http://www.legislation.gov.uk/id/uksi/2018/1322)

Highly specialised technologies guidance:

* There is a legal requirement for relevant health bodies to comply with the published recommendations as per [Section 8 (6) of the NICE (Constitution and Functions) and the HSCIC (Functions) Regulations 2013.](http://www.legislation.gov.uk/uksi/2013/259/regulation/8/made)
* NICE must recover the cost of developing Highly specialised technology guidance from the company that expects to market the technology in England, in accordance with [UK Statutory Instrument 2018 No.1322](http://www.legislation.gov.uk/id/uksi/2018/1322)

Medical technologies guidance:

* The legal requirement, Section 7 (6) of the NICE (Constitution and Functions) and the HSCIC (Functions) Regulations 2013, for relevant health bodies to comply with the published recommendations does not apply
* Criteria are being developed for recommended and cost saving technologies to receive a MedTech funding mandate as per 3.118 of the [NHS Long Term Plan](https://www.longtermplan.nhs.uk/)
* NICE do not recover the cost of the developing Medical technologies guidance from the company

Diagnostics guidance:

* The legal requirement, Section 7 (6) of the NICE (Constitution and Functions) and the HSCIC (Functions) Regulations 2013, for relevant health bodies to comply with the published recommendations does not apply
* Criteria are being developed for recommended and cost saving technologies to receive a MedTech funding mandate as per 3.118 of the [NHS Long Term Plan](https://www.longtermplan.nhs.uk/)
* NICE do not recover the cost of the developing Diagnostics guidance from the company

Interventional procedures guidance:

* Interventional procedures guidance assesses the procedure’s safety and efficacy evidence only.
* The legal requirement, Section 7 (6) of the NICE (Constitution and Functions) and the HSCIC (Functions) Regulations 2013, for relevant health bodies to comply with the published recommendations does not apply
* NICE do not recover the cost of the developing Interventional procedures guidance

Existing Topic Selection processes

1. There are 3 major stages of Topic Selection

* Stage 1 – Topic identification
* Stage 2 – Topic Selection
* Stage 3 – Topic Routing

1. Potential topics can be identified using robust and effective horizon scanning systems. The NIHR Innovation Observatory is used to formally identify and filter medicine topics through to the standalone topic selection process for the Technology Appraisals and Highly Specialised Technologies programmes. The NIHR Innovation Observatory also utilise information provided directly by companies within UK PharmaScan (a secure online system hosted by NICE) to aid their horizon scanning techniques. HealthTechConnect (a secure online system also hosted by NICE) was launched in 2019 and is used to identify device, diagnostics and digital topics for the medical technologies evaluation progamme topic selection process. The NIHR Innovation Observatory do not identify or filter topics into this process.
2. In addition to the 3 major horizon scanning systems clinicians, patients and the public, and other organisations such as NHS England and Improvement can also identify potential topics for consideration in the Centre for Health Technology Evaluation programmes. This route is used more often for identifying topics for Interventional Procedures, Medical Technologies and Diagnostics guidance rather than for Technology Appraisals and Highly Specialised Technologies guidance.
3. All of the Centre for Health Technology Evaluation topic selection processes have gone through significant change over the years, from using external topic selection panels and committees, to decision making groups involving predominantly health system partners and NICE staff. Rather than continue to update the various approaches used for topic selection, there is now the opportunity to consolidate and provide information about them in a single topic selection manual to make information simpler and easier to find and understand.
4. A consolidation exercise will identify ways in which to make topic selection processes more agile, efficient and responsive and allow for confirmation of the governance arrangements for topic selection across the Centre for Health Technology Evaluation. Decisions to select a topic for either the Technology appraisals or the Highly specialised technologies programmes require a formal ministerial referral (under the 2013 Regulations), but the referral does not define the type of guidance that will be developed. This routing decision is considered a specific responsibility of NICE. Selection of topics for Medical technologies guidance, Diagnostics guidance and Interventional Procedures guidance does not fall under ministerial responsibility.

The link with NICE Connect and other policy initiatives

1. The NICE Connect programme will consider options for topic selection across NICE. All guidance producing programmes use some form of topic selection. However, in order to facilitate delivery of the commitments and requirements within the 2019 [Voluntary scheme for Branded Medicines Pricing and Access](https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access) the Centre for Health Technology Evaluation needs to run ahead of NICE connect and implement changes to its own topic selection processes in 2020. The changes proposed within this document are not considered to conflict with the wider ambition of NICE Connect for alignment and consolidation.
2. New responsibilities have recently been added to NICEs work. For example, the [Accelerated Access Review](https://www.gov.uk/government/publications/accelerated-access-review-final-report), the [government’s response](https://www.gov.uk/government/publications/accelerated-access-review-response) to it, the [Life Sciences Sector Deal 2](https://www.gov.uk/government/publications/life-sciences-sector-deal/life-sciences-sector-deal-2-2018), the 2019 [Voluntary Scheme for Branded Medicines Pricing and Access](https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access), and the [NHS Long Term Plan](https://www.longtermplan.nhs.uk/). All these policy initiatives place greater demands on NICE to issue guidance and advice on more topics, more quickly and with a greater degree of implementation support. New technologies have also emerged that are not explicitly included in existing processes, such as integrated technologies which could include a combination of digital, diagnostic or treatment components, and we need to consider where these topics should be routed.
3. A key component of the Accelerated Access Collaborative (AAC) and the NHS Long Term plan is to develop existing horizon scanning tools and techniques in order to improve forecasting and demand signalling for those products that require accelerated access and increased implementation support. The NIHR Innovation Observatory has been commissioned by the AAC to extend their current contractual arrangements to act as a key supplier of this information, utilising and analysing its digital capabilities and rich dataset. This will build upon the function that the Innovation Observatory already provides for identifying and filtering medicine topics and expand it to include devices, diagnostics and digital technologies. This may have the consequence of increased activity and requirements for topic selection.

Proposals for change

Summary of changes

1. This paper outlines proposals to:

* Consolidate existing eligibility, selection, and routing criteria to improve clarity
* Align decision making and stakeholder engagement processes to improve efficiency and better describe governance arrangements to improve accountability
* Better describe the topic selection processes and decisions to improve transparency

Consolidated identification, selection and routing criteria

Topic identification criteria

1. In response to the 2019 Voluntary Scheme for Branded Medicines Pricing and Access, identification criteria in use across the 3 existing processes will be updated to reflect the new responsibilities that NICE has for issuing guidance on topics that were previously considered to be out of remit, such as technologies for treating haemophilia and HIV.
2. The consolidated identification criteria (table 1) will increase the number and type of topics considered for NICE guidance, and this is being met by an expansion of NICEs capacity to develop Technology Appraisals guidance, Medical technologies guidance and Diagnostics guidance.
3. There is insufficient information available to estimate whether the expansions will balance with the increase in topics that are identified for potential guidance production, or whether there will be more topics than NICE can develop guidance on. Close monitoring and regular review will be part of the implementation plans.

Table 1 – Identification Criteria

| Identification of suitable technologies | Identification of un-suitable technologies |
| --- | --- |
| * **Devices**: including medical devices, other non-diagnostic health technologies, and digital health technologies in tier 3b of the [evidence standards framework](https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies) (including those using artificial intelligence incorporating fixed or adaptive algorithms) that treat or prevent a health condition, or inform clinical management decisions about treatment including those using artificial intelligence incorporating fixed or adaptive algorithms   **Diagnostics**: Technologies, techniques and strategies (including digital health technologies in tier 3b of the [evidence standards framework](https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies)) that diagnose, prognose, predict, or screen health conditions, including in-house diagnostics, companion diagnostics, and those using artificial intelligence incorporating fixed or adaptive algorithms   * **Medicines:** active substances that are new to the UK market or have a significant therapeutic licence extension (including therapeutic vaccines and advanced therapy medicinal products such as gene therapies and stem cells). * **Procedures**: new or significantly modified procedures that use ionising, electromagnetic or acoustic energy, or that involve an incision, a puncture, or entry into a body cavity. * Combinations of 1 or more of the above | Technologies that:   * are not going to be available in the UK within 24 months * involve use that will not have regulatory approval when it is used outside of research (unlicensed technologies) * have regulatory approval but will not be used in line with their approval (off-label technologies) * have been used widely by the target population in the UK and have a well-known safety, efficacy and cost profile, unless: * there is new information that brings their safety, efficacy, or cost into question or * there is a new variation that might have a different safety, efficacy, or cost profile to the established topic. * are population screening technologies in the remit of the UK National Screening Committee * are prophylactic vaccinations in the remit of the Joint Committee on Vaccination and Immunisation * digital health technologies in tiers 1, 2, or 3a of the Evidence Standards Framework * do not involve a technology or interventional procedure that are best considered by NICE guidelines. For example, exercise on prescription, rehabilitation programmes, care pathways. |

Selection Criteria

1. In order to consolidate, simplify, improve clarity and further build upon the requirements for NICE guidance from the different policy initiatives described above, new selection criteria will replace the existing selection of published selection criteria. Availability of evidence is not used as a criterion in the new selection criteria; this is because in a small number of cases, NICE guidance may be needed in the absence of evidence (for example to stop an ineffective activity from happening, to address a particular issue of safety or to stimulate appropriate research).
2. The proposed selection criteria below will replace over 15 different criteria used by Centre for Health Technology Evaluation teams to identify if a topic requires NICE to assess the cost and effectiveness evidence. However, decisions about how guidance will be developed (for example single or multiple technology assessments, or variations on traditional NICE guidance) will be made during guidance development, according to relevant processes and methods that may become available in future (as part of other NICE transformation work).
3. A device or diagnostic is likely to be selected if:

* it has benefits that are likely to be highly disruptive or lead to a stepwise change to an established care pathway in the UK; and
* a systematic assessment of the cost and system impacts is needed. For example, because there is uncertainty about the likely cost or system impact, or because the costs and impacts are expected to be significantly cost incurring or cost saving; and
* the benefits are supported by:
  + evidence of effectiveness (such as RCT, before/after studies, cohort studies, diagnostic test accuracy studies) that compares the technology to current practice in the UK health and care system or to an appropriate reference standard and
  + information about the expected resource impact of adopting the technology that is directly applicable to the UK health and care system such as reports or studies describing the cost and system impact of implementing the technology, or an economic model and
  + advice from experts (such as patients, carers, clinicians and commissioners) that confirms the benefits are desirable and are likely to be realised when adopted in the UK health and care system.

1. All new active substances and significant license extensions to add a new therapeutic indication will be selected, except where there is a clear rationale not to do so. For example, if the topic is a duplicate or has a significant overlap with an existing topic.
2. All new or significantly modified interventional procedures will be selected, if they are available to the NHS or independent sector, or about to be used outside of formal research.
3. Topics that do not meet the criteria are not progressed further. The topic may be passed on to other organisations that may have an interest in the topic, such as NHS England and Improvement. NICE will not set a review date for re-consideration of this decision (unless the decision is formally challenged).
4. If it is not possible to make a definitive 'yes' or 'no' decision against the criteria , the selection decision is deferred until additional information becomes available.

Routing criteria

1. More clarity needs to be provided to indicate how NICE determines which type of guidance producing programme a particular topic should be routed to. Options for routing are based on the type of technology and its value proposition. The selection and routing criteria are described in table 2 below.

Table 2 - Selection and routing criteria

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Topic type** | **Devices**  Technologies (including digital health technologies in tier 3b of the evidence standards framework) that treat or prevent a health condition, or inform clinical management decisions about treatment including those using artificial intelligence incorporating fixed or adaptive algorithms | **Diagnostics**  Technologies, techniques and strategies (including digital health technologies in tier 3b of the evidence standards framework) that diagnose, prognose, predict, or screen health conditions, including in-house diagnostics, companion diagnostics, and those using artificial intelligence incorporating fixed or adaptive algorithms | **Medicines**  active substances that are new to the UK market or have significant licence extensions | **Interventional procedures**  new or significantly modified procedures that use ionising, electromagnetic or acoustic energy, or that involve an incision, a puncture, or entry into a body cavity |
| **Examples** | * wound dressings, * catheters, * neuromodulators * apps/software used to deliver cognitive behaviour therapy via a smartphone. | * blood/urine/swab/tissue tests * imaging technologies (such as CT scanners, dermatoscopes) * measuring technologies (such as ECG, bioimpedance) * apps/software to enable remote diagnosis of a condition | * medicines * therapeutic vaccines * advanced therapy medicinal products (such as gene therapies, stem cells) | * inserting a tube into a blood vessel. * carrying out treatment inside the body using an instrument inserted via the mouth. * using a laser to treat eye problems. |
| **Selection criteria** | A device or diagnostic is likely to be selected if:   * it has benefits that are likely to be highly disruptive or lead to a stepwise change to an established care pathway in the UK; **and** * a systematic assessment of the cost and system impacts is needed. For example, because there is uncertainty about the likely cost or system impact, or because the costs and impacts are expected to be significantly cost incurring or cost saving; **and** * the benefits are supported by: * evidence of effectiveness (such as RCT, before/after studies, cohort studies, diagnostic test accuracy studies) that compares the technology to current practice in the UK health and care system or to an appropriate reference standard **and**   + information about the expected resource impact of adopting the technology that is directly applicable to the UK health and care system such as reports or studies describing the cost and system impact of implementing the technology, or an economic model **and**   + advice from experts (such as patients, carers, clinicians and commissioners) that confirms the benefits are desirable and are likely to be realised when adopted in the UK health and care system. | | All new active substances and significant license extensions will be selected, except where there is a clear rationale not to do so. For example, if the topic is a duplicate or has a significant overlap with an existing topic. | All new or significantly modified interventional procedures will be selected, if they are available to the NHS or independent sector, or about to be used outside of formal research.. |
| **Type of guidance (routing)** | **Medical technologies Guidance** (for cost consequence health economic analysis)  **Technology Appraisals Guidance** (for cost utility health economic analysis) | **Diagnostics guidance** (for cost utility health economic analysis, or for consequence health economic analysis) | **Technology Appraisals guidance** (for cost utility health economic analysis, or for cost comparison health economic analysis)  **Highly Specialised Technologies guidance** (for those meeting all of the HST criteria) | **Interventional procedures guidance** (for assessment of safety and efficacy. No health economic analysis is undertaken) |

1. Historically, diagnostics that offered a value proposition that requires an assessment using cost consequences analysis were typically routed to the Medical Technologies Evaluation Programme. Diagnostics that required a cost utility health economic analysis were routed to the Diagnostics Assessment programme. It is proposed that all diagnostic, irrespective of the value proposition will now be routed to the Diagnostics Assessment programme.
2. Generally, devices that offered a value proposition that required an assessment using cost effectiveness analysis were evaluated by the technology appraisal programme using the established Technology Appraisal committees. It is proposed that devices requiring a cost-effective analysis will continue to be appraised within the technology appraisal programme but the Medical Technologies Advisory Committee will be utilised as the independent decision maker. This will enable NICE to maximise opportunity to use the specialism and experience of each independent committee, via technology type.
3. At the routing stage, consideration will also be given as to whether a NICE guideline would be a more appropriate product in which to consider the topic. In this consideration the following question will be asked:

* Is the medicine, device, diagnostic or procedure:
* in the scope of a new or existing NICE guideline that is in development or being updated? Or
* considered to be part of standard care in the UK, but is not included in an existing NICE guideline?

1. For topics that answer 'Yes' to the questions above the Centre for Health Technology Evaluation team will liaise with the NICE Centre for Guidelines for consideration for inclusion in a NICE guideline. In some exceptional cases, a topic may still be selected for Technology Appraisals, Highly Specialised Technologies, Medical Technologies Guidance or Diagnostics Guidance even if the topic is suitable for inclusion in a guideline if there is an urgent need to assess the topic before a new guideline is published or an existing guideline updated.

Multiple routing decisions

1. Some topics will require assessment in more than 1 type of NICE guidance and this may be inevitable in specific circumstances. For example, a topic many require both interventional procedures guidance to assess safety and efficacy of a procedure and other guidance (such as medical technologies or technology appraisals) to assess the clinical effectiveness and costs/resource use of the procedure or a technology used within the procedure. The guidance could be developed simultaneously or sequentially. NICE will aim to minimise these scenarios and progressively seek to find alternative methods and processes of assessment to reduce duplication across our individual programmes of work.

Topic Prioritisation

1. Once there is experience of using the identification, selection and routing criteria, information will be available to determine whether further work is needed to prioritise topics selected for guidance development if it is found that there are more topics than there is capacity to develop guidance. Topic prioritisation will mostly be needed for topics routed to Medical Technologies or Diagnostics guidance, because there are so many technologies that could be considered and both programmes have a capacity limit. Should the volume of medicines that require appraisal increase, the charging regime for Technology Appraisals and Highly Specialised Technologies allows for these programmes to expand capacity accordingly.

Aligning processes

1. The 3 existing Centre for Health Technology Evaluation topic selection processes vary in terms of steps and time taken and resources used. There is potential to align topic selection process steps where unnecessary variation exists, and also take steps to increase consistency, transparency and inclusivity within the topic selection process wherever possible. This is an area that NICE has previously received negative feedback on.
2. A diagram of the topic selection process (including the proposed criteria) is outlined in appendix 1.

Scoping

1. Non-cancer topics being considered for Technology Appraisal and Highly Specialised Technologies guidance currently go through a scoping process in order to inform selection and routing decisions, whereas the scoping process is completed after selection and during the guidance development process for cancer medicine topics being considered for Technology Appraisal and Highly Specialised Technologies and other types of NICE guidance.
2. The requirement for a scope to be developed and consulted upon before a topic is selected for Technology Appraisal or Highly Specialised Technologies will be removed. Instead, scope development and consultation will occur closer to the guidance development stage with the purpose of confirmation of a routing decision into either Technology Appraisal or Highly Specialised Technologies programmes. This will create consistency with other NICE guidance and guideline development processes.

Format of the referral

1. The wording of the formal ministerial referral (known as the 'remit') to the Technology Appraisals programme and the Highly Specialised Technologies programme are currently different in formats:

* Technology Appraisals: To appraise the clinical and cost effectiveness of [insert technology name] within its marketing authorisation for treating [insert indication]
* Highly Specialised Technologies: To evaluate the benefits and costs of [insert technology name] within its marketing authorisation for treating [insert indication] for national commissioning by NHS England

1. In order to implement the change described above, the wording of the remits require alignment. New wording is proposed below:

* To appraise the clinical and cost effectiveness of [insert technology name] within its marketing authorisation for treating [insert indication]

Formalising the opportunity for challenge

1. Over the past months, the NICE Senior Management Team has considered routing decisions coming from the Technology Appraisal and Highly Specialised Technologies decision-making panel where they have been challenged by stakeholders. A formal process for stakeholders to challenge topic selection routing decisions (including application of criteria) for all guidance development programmes will be introduced.

Topic selection panel

1. Currently 3 different topic selection decision making groups support the 3 different selection processes. The groups meet at different frequencies and there is some cross over in the membership / attendees at the meetings. There may be inefficiency in this approach because some technologies (particularly devices with a cost incurring value proposition) can be discussed by different groups leading to duplicative effort, loss of corporate knowledge and potential inconsistency in decision making.
2. In order to promote efficiency and consistency in the decision-making process, we proposed to consolidate the 3 existing topic selection panels into a single panel to oversee the application of the identification, selection and routing criteria. This panel will be called the Topic Selection Oversight Panel (TSOP).
3. The Topic Selection Oversight Panel membership will include senior NICE staff and will retain the capacity for external expertise to be provided from the Department of Health and Social Care and NHS England and Improvement. Membership will also be extended to include lay members. There will be a small core set of formal decision makers with a wider range of advisory members that would be invited to provide input relevant to technology type and value proposition.
4. The core membership of the Topic Selection Oversight Panel decision makers will be as outlined below:

* Director – Centre for Health Technology Evaluation, NICE
* Director – Centre for Clinical Guidelines, NICE
* Programme Director(s) – representative of the Centre for Health Technology Evaluation, NICE
* Committee Chair(s) – representative of various CHTE committees
* Lay member(s)
* Consultant Clinical Adviser(s)
* Department of Health and Social Care representative
* NHS England and Improvement representative

1. Further exploration of the benefits of the creation of the Topic Selection Oversight Panel will be conducted with formal Terms of Reference see appendix 2. The terms of reference describe the governance arrangements, and escalation process for routing decisions that are subject to challenge.
2. The Interventional Procedures programme will continue to hold a separate topic selection discussion (known as the Newly Notified Procedures meeting) in order to select procedures for guidance development. It is appropriate for this group to continue to meet regularly due to the importance of safety and the speed of decision making required. If this group takes a decision not to progress a procedure for guidance development or would like to transfer a topic to another guidance development programme, that decision will be ratified by the Topic Selection Oversight Panel. This provides an appropriate level of governance to this decision and a formal escalation process where the decision to not progress with guidance development is challenged.

**N.B – the principles of change listed in paragraphs 31 – 41 have been implemented as requested by the NICE Board in March 2020 (pre-consultation). NICE took the opportunity during the COVID-19 pandemic to implement the efficiency savings to allow topics that were paused during the pandemic to re-start their assessment quicker as NICE returned to business as usual from 1 June. We would still welcome your comments on the Topic Selection Oversight Panel (TSOP) and its membership as described in paragraphs 36 - 41.**

Single topic selection manual

1. A single topic selection manual will be developed and will replace multiple existing published topic selection processes. It aims to contextualise information, set out processes clearly and simply, and make it easier for those involved and interested in Centre for Health Technology Evaluation topic selection to find and understand with the ultimate aim of increasing transparency of NICE processes. It also supports the ambitions of NICE Connect to help stakeholders and the public access the information they need quickly and easily.

Updated and standardised documentation and terminology

1. Documentation used throughout the process will be standardised in so far as differences within technology type will allow.
2. Terminology will be consolidated and standard definitions of common terms will be provided (table 3).

Table 3

| Issue | Current terms used | Proposed new term |
| --- | --- | --- |
| Inconsistency in how we refer to technologies that require Marketing Authorisations | Drug  Pharmaceutical  Medicine | Medicine (this will be defined as including other active substances) and is consistent with term used by the NICE medicines evidence summaries team |
| Inconsistency in how we refer to the entity that is responsible for the technology | Manufacturer  Company  Technology developer Sponsor  Marketing authorisation holder | Company |
| Inconsistency in how we refer to those providing input into topic selection | Expert  Specialist  Adviser  Witness | Expert |
| Lack of clarity about what ‘referral’ means and who can refer a topic to NICE | Referral  Notification  Request  Suggestion | A referral is the Ministerial instruction to proceed with either a Technology Appraisal or Highly Specialised Technology for a technology  All other means by which topics could be identified for the NICE work programmes are considered to be topic notifications. |
| Remit can be used to refer to the information provided to NICE by DHSC when a topic is referred, and to refer to the activities undertaken by NICE programmes | The remit provided by the DHSC to NICE | Remit should only be used to refer to the remit provided by Minister (via the Department of Health and Social Care) to NICE  A topic is ineligible for a NICE programme |
| Topic is out of remit for a NICE programme |
| Each programme has a different term for the document used to initiate consideration of a topic | Filtration form (medicines)  Newly notified procedure form (procedures)  Notification form/MIB topic selection form (devices and diagnostics) | Topic identification form |
| Each programme has a different term for the document used to make a selection decision | Briefing note (medicines)  Medtech innovation briefing (devices and diagnostics) | Briefing |
| Each programme has a different name for the group that makes the selection decision | Decision point meetings (medicines)  Newly notified procedures meetings (procedures)  Medical technologies topic oversight group (devices and diagnostics) | Topic Selection Oversight Panel |
| Stakeholders find multiple uses for the word ‘advice confusing’. This has been identified through NICEs reputational research and through feedback from PIP. | Advice to refer to published non-guidance outputs such as MIBs, evidence summaries, KTTs | NICE briefings |
| Advice provided to NICE by experts during the topic selection process | Expert input |
| Advice provided by the Scientific Advice team on a fee based service | Advice |

Transparency of topic selection decision making

1. Publication of topic selection decisions via the NICE website is variable across Centre for Health Technology Evaluation programmes:

* Medicine topics considered for Technology appraisal and Highly specialised technologies guidance have the selection decision published in a detailed Microsoft Excel spreadsheet (which includes those that have been selected)
* Procedure topics considered for Interventional Procedures guidance are listed in an interactive table that details why the topic has not been selected (selected topics are not included)
* Devices and diagnostics and digital technologies considered for any type of NICE guidance are listed in a Microsoft Word document. The document lists the topics that have been considered, but doesn’t state the selection decision

1. Having topic selection information published separately, and in different places makes it difficult for stakeholders and the public to find out information about the processes and subsequent decisions. It is recognised that we need to improve clarity and transparency for stakeholders on the reasons for selection and routing decisions.
2. Steps will be taken to standardise presentation of information and provide it more clearly on the NICE website. Standardised information to be provided will include:

* Topic Identification number
* Technology name
* Indication
* Type of Technology
* Decision
* Reason for the decision
* Date of the decision

1. Information received as part of the Topic Selection process that is regarded as commercial or academic in confidence (e.g. anticipated regulatory approval dates) will not be published.

Out of scope

1. NICE is also reviewing the criteria used to decide whether a new technology should be routed to Highly Specialised Technologies programme. The purpose of reviewing the criteria is to make them clearer and more specific, and the outcome easier to understand and more predictable for our stakeholders. This paper does not include proposals on the updated Highly Specialised Technologies criteria and therefore the criteria are not subject to consultation at this point. The Highly Specialised Technologies routing criteria are still under review and will be consulted upon in due course.
2. In the case of Technology Appraisals and Highly Specialised Technologies a formal Ministerial referral will still be required (as specified in The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013). The Ministerial referral does not define the type of guidance that will be developed.
3. The changes to topic selection for health technology evaluation will not impact on the overall process followed and time taken to develop and publish guidance on a topic.

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Appendix 1

Appendix 2

**Topic Selection Oversight Panel Terms of Reference**

Remit of the panel

1. The Topic Selection Oversight Panel is responsible for selection of topics for guidance development in the Centre for Health Technology Evaluation (CHTE), including the routing to specific programmes of work.
2. Topics selected for the technology appraisal and highly specialized technologies programmes will be subject to further ministerial referral before inclusion in NICE’s work programme.
3. The Panel:
   1. Reviews topic briefings and decides whether to select topics for guidance development, and routes to the appropriate guidance producing programmes:
      1. Diagnostics Assessment Programme
      2. Highly Specialised Technologies Programme
      3. Medical Technologies Evaluation Programme
      4. Technology Appraisals Programme
   2. Reviews topic briefings and decides whether to select topics for development as a Medtech Innovation Briefings
   3. Ratifies non-selection decisions made by the Newly Notified Procedures group of the Interventional Procedures programme
   4. Escalate the stakeholder challenge to the NICE Senior Management Team which will act under delegated powers of the Board in ratifying the decision.

**Membership**

Decision-making members:

1. The following are designated as decision-making members

* Director of CHTE **(Chair)**
* Director of the Centre for Clinical Guidelines
* Programme director CHTE (x2)
* Chair of the relevant NICE advisory committee
* Consultant clinical adviser
* Associate director
* Lay Member (x2)
* Department of Health and Social Care representative
* NHS England and NHS Improvement representative

1. All members of the Topic Selection Oversight Panel are asked to advise on suitability of topics for selection for guidance producing programmes in CHTE, and where appropriate routing to specific programmes of work. Specific contributions expected from the members are listed here:

|  |  |
| --- | --- |
| **Participants** | **Specific roles and responsibility** |
| Director CHTE | Chair the meeting and sign-off panel decisions |
| Director, Centre for Guidelines | Advise on routing opportunities to guidance producing programmes outside of CHTE, including guidelines |
| Programme directors | Deputy chair of the meeting and sign-off panel decisions when chairing. |
| Committee chairs | Provide clinical insights, depending on the matter under discussion, and provide feedback from scoping activities |
| Consultant clinical advisers | Provide clinical insights and provide expertise in specific areas of work (medicines, medtech, interventional procedures) |
| Lay Member x 2 | Bring perspective of patients, people who use services, and carers to selection and routing of topics. |
| Department of Health and Social Care representative | Sponsor oversight of topic selection activity and support for ministerial referral process for relevant programmes |
| NHS England and NHS Improvement representative | Provide perspective on the impact of a topic selection decision on other NHS England related activities to support life science innovations |

1. Members will be asked to attend the meeting for the agenda item(s) relevant to the matters under discussion. The quorum will be 5 full members including the Centre Director (or someone with delegated authority to act on their behalf), 1 Committee chair, 1 associate director, 1 lay member, the Department of Health and Social Care representative (or someone with delegated authority to act on their behalf).

Advisory members:

* Technical Advisers (representing various guidance producing programmes)
* Senior Manager – Horizon scanning, topic selection and scoping
* Project Manager – Topic Selection
* Other Department of Health and Social Care representative(s)
* Other NHS England representative(s)

Secretariat

* Coordinator, Topic Selection
* Project Manager, Topic Selection

Other observers

1. NICE staff and invited guests (for example, NICE committee members) may attend Topic Selection Oversight Panel meetings as observers, with the permission of the Associate Director – Planning, Operations and Topic Selection.

Process for decision making

1. Decisions will be made based on consensus wherever possible. Only in exceptional circumstances, if consensus cannot be reached, will decision-making members of the panel be asked to vote.

**Confidentiality**

1. Confidential papers and confidential information such as academic or commercial-in-confidence material or sensitive personal data disclosed in panel deliberations should not be discussed with colleagues who are not members of the panel, the NICE Topic Selection team, other organisations, the media, or members of the panel who are conflicted for the topic.

**Meetings and papers**

1. Meeting frequency will be determined to best meet the operational needs of topic selection for timely guidance output.
2. The secretariat will send all attendees electronic versions of the topic information 1 week prior to the meeting.
3. NICE shall determine what matters shall appear on every agenda in advance of each meeting.
4. The minutes will record significant decisions and actions relating to the topics

**Transparency**

1. The NICE website will be updated with the panel’s decision**.**

**Accountability**

1. The Topic Selection Oversight Panel has the authority to make final decisions about which topics notified to the topic selection process are selected for guidance development and to which programme they are routed.
2. Where an external stakeholder challenges the decision that Topic Selection Oversight Panel have previously made, the panel will be asked to re-consider their position. The outcome of the re-consideration step will be ratified by the NICE Senior Management Team.

**Review of terms of reference**

1. These terms of reference and standing orders will be reviewed every 3 years.

Date: XX

Review date: XX