



*National Institute for
Health and Clinical Excellence*

**The National Institute for Health
and Clinical Excellence**

and

The Department of Health

**Topic selection process
for technology appraisals**

A consultation document

*Working in partnership with
the Department of Health*



March 2009

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1. Objectives

- 1.1 This consultation document seeks views on some proposed changes to the way in which technology appraisal topics are selected for referral to the National Institute for Health and Clinical Excellence (NICE).
- 1.2 The reasons for the changes to the topic selection process for technology appraisals are as follows:
- To improve the timeliness with which technology appraisal topics are referred to NICE, in order to facilitate timely NICE guidance on new drugs and therefore minimise the period of uncertainty between the introduction of new drugs into the NHS and final NICE guidance being issued.
 - To remove at least 3 months from the processing time for non-cancer technology appraisal topics, bringing the timescales into line with those for cancer topics.
 - To increase the transparency of the selection process through the introduction of more explicit selection criteria.
 - To ensure that NICE's stakeholders – patients, carers, the public, healthcare professionals, the wider NHS, and manufacturers of health technologies – continue to have appropriate opportunities to make an input into the selection of technology appraisal topics.
 - To help ensure that NICE's work programme addresses topics of importance to patients and professionals and makes the best use of NHS and NICE resources.

2. Overview

The National Institute for Health and Clinical Excellence

- 2.1 NICE is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
- 2.2 NICE develops four forms of guidance:
- Technology appraisal guidance (on the use of specific health interventions, pharmaceuticals, devices and treatments within the NHS).
 - Clinical guidelines (on the appropriate treatment and care of people with specific diseases and conditions within the NHS).
 - Guidance on the safety and efficacy of interventional procedures.
 - Public health guidance to improve health, prevent disease and reduce health inequalities.
- 2.3 Topics for technology appraisals, clinical guidelines and public health guidance are referred to NICE by the Secretary of State for Health. Topics for the interventional procedures programme are sent directly to NICE, usually by clinicians. They are not selected through the topic selection process.

This consultation

- 2.4 'High Quality Care For All', the final report of the Next Stage Review, published in June 2008, set out a commitment to look at ways of further improving the timeliness of NICE technology appraisal guidance.
- 2.5 This consultation is about the process for selecting technology appraisal topics for referral to NICE. Topics include new pharmaceuticals, biopharmaceuticals, devices and diagnostics that may be suitable for the NICE technology appraisals programme. The future development of arrangements for the selection of clinical guideline and public health guidance topics will be considered separately in the context of other developments, including the establishment of the National Quality Board (NQB).

Topic selection

- 2.6 The aim of the topic selection process is to ensure that appropriate topics are selected for the NICE work programmes so that NICE guidance is relevant, timely and addresses priority issues that will help improve the health of the population.
- 2.7 Not all new health technologies need be appraised by NICE. Some process of selection has, therefore, always been necessary. The existing selection criteria, which were the subject of consultation in 2006, are set out in appendix A.
- 2.8 Topics are referred to NICE in groups, called 'work programmes'. There are generally three work programme referrals each year.
- 2.9 NICE and the Department of Health introduced the Single Technology Appraisal (STA) process in 2005. The STA process appraises a single technology for a single indication against its current standard comparator and seeks to make NICE guidance available on treatments within 6 months of their launch in the UK market. For this to happen, topics should ideally be referred to NICE at least 15 months in advance of the anticipated date of marketing authorisation being granted.
- 2.10 This consultation document describes streamlined arrangements for identifying and referring topics to NICE for appraisal, building on changes already made for the selection of cancer topics following the Cancer Reform Strategy in December 2007¹. The proposed process will apply to all topics considered for referral to NICE's technology appraisal programme and will bring the elapsed time for considering non-cancer

¹ The Cancer Reform Strategy, published in December 2007, set out a 'default position' that all new cancer drugs and significant new marketing authorisation indications would be referred to NICE, providing that NICE agrees that: 1) there is a sufficient patient population and evidence base on which to carry out an appraisal, and 2) there is not a more appropriate alternative mechanism for appraisal. It also set out a commitment for DH and NICE to work together to ensure that gaps between licensing and publication of guidance are minimised so that, where possible, appraisal will be carried out in parallel with licensing.

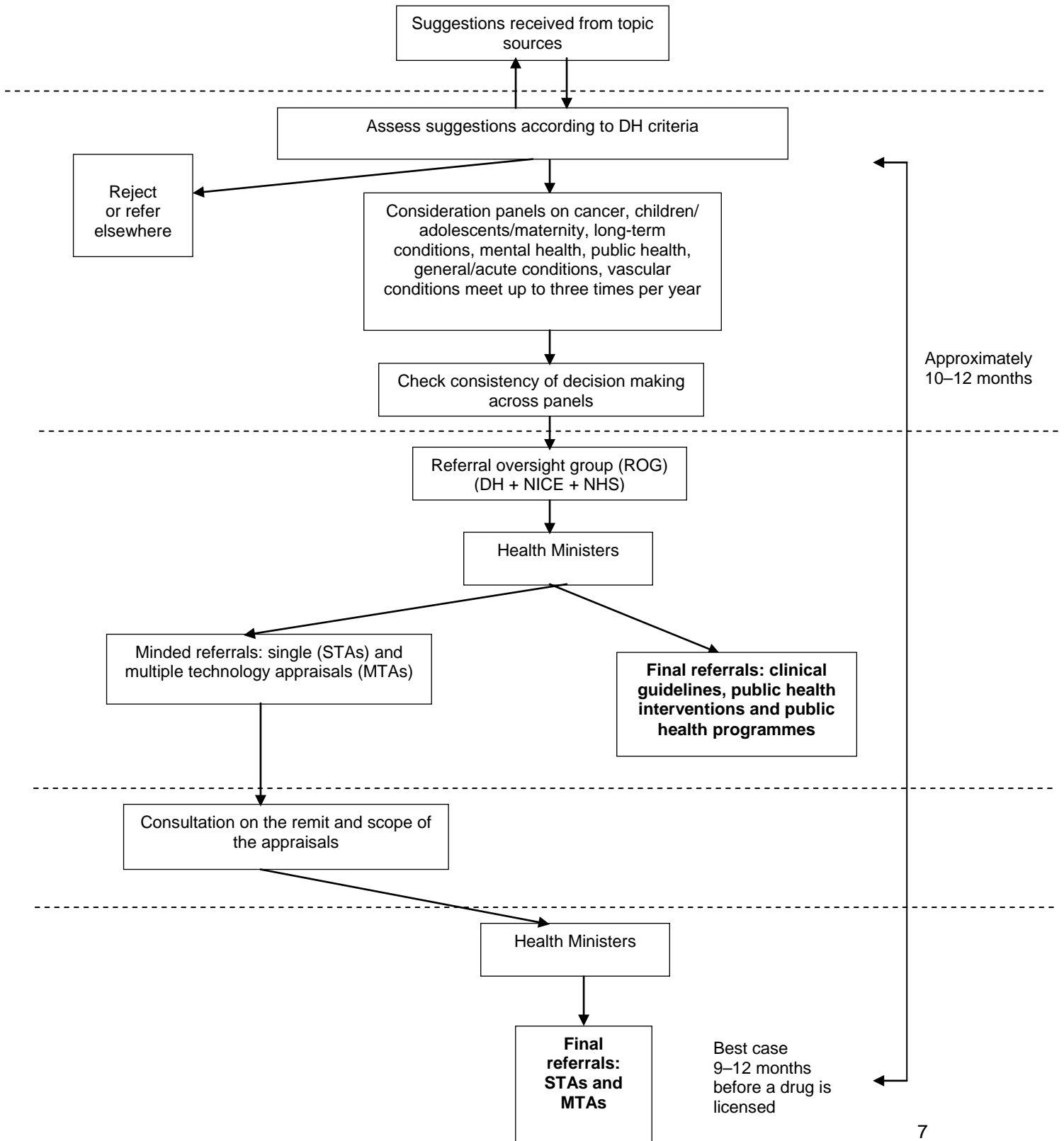
topics in line with the more rapid timescale that now applies to cancer topics.

- 2.11 This consultation paper also seeks views on the introduction of more explicit selection criteria for technology appraisals, improving the clarity and transparency of decision-making in the topic selection process.
- 2.12 Section 3 describes the current arrangements and section 4 sets out the proposals for how they can be streamlined. Section 5 describes the key changes to the proposed topic selection criteria. Section 6 outlines the questions for consultation and section 7 sets out arrangements for responding to the consultation.

3. Current arrangements

3.1 This section describes the current process for selecting topics for referral to NICE (see figure 1).

Figure 1 The current topic selection process



Summary of the existing topic selection process

Topic identification

3.2 The early stages of the topic selection process are administered by NICE. Possible topics for referral emerge from a variety of sources including:

- horizon scanning of new pharmaceutical and biopharmaceutical products by the National Horizon Scanning Centre at The University of Birmingham
- suggestions made through the NICE website
- topics identified by NICE
- suggestions from National Clinical Directors and DH policy leads, which underpin and support DH objectives.

Preliminary assessment of topic suggestions

3.3 Topic suggestions are all initially assessed by the topic selection team at NICE. The purpose is to:

- eliminate topics that do not meet NICE's remit or are otherwise inappropriate; and
- filter topics according to the DH selection criteria.

Filtering involves specialist clinical advisors as appropriate and progresses those topics that relate to significant health need, service impact and NICE's ability to add value. The key filtering considerations, each of which are scored 0–2, are:

- policy importance – topics that support a current government health policy priority are weighted more highly
- population affected – interventions used in larger populations are weighted more highly
- resource impact – topics that are expected to have a high or low resource impact are weighted more highly than resource-neutral topics
- variation in practice – topics that, in the absence of NICE guidance, are likely to result in significant variation in clinical practice are weighted more highly
- timeliness – topics that require assessment in order for NICE guidance to be issued as close as possible to the launch of the product in the UK are weighted more highly.

3.4 Scores for each topic are added to give a total, which acts as a guide in determining the priority of the topic. For those topics that achieve a high score during the filtering process, a detailed brief is prepared for the relevant expert topic selection consideration panel. Topics that do not achieve a high score are filtered out at this stage. These topics are also reviewed by the consideration panel, which will confirm the elimination and filtering decisions that have been made by the NICE team and may amend those decisions and identify topics for re-assessment.

Topic selection consideration panels

- 3.5 There are seven expert topic selection consideration panels that meet up to three times per year. These are:
- cancer
 - children, adolescents and maternity
 - vascular conditions (including renal conditions and diabetes)
 - long-term conditions
 - mental health
 - public health
 - general and acute conditions.
- 3.6 The panels are chaired by National Clinical Directors or other leading experts in the field and are made up of clinicians/public health specialists, generalists with a good understanding of the health service or public health, patient or carer representatives, representatives of the healthcare industries and representatives from the Healthcare Commission. DH policy leads attend as observers. Membership of the panels is published on the NICE website.
- 3.7 The panels follow standard procedures to:
- assess whether the preliminary assessment of topics was appropriate and the topics meet the published selection criteria (appendix A);
 - score topics by assigning a numerical score of between 0 and 5, with 5 signifying a topic that is considered a very high priority for referral and 1 for topics that are considered to be very low priority for referral;
 - recommend to the Referral Oversight Group (ROG) (see below) which topics should be referred; generally, a topic that scores 2.5 or less out of 5 will not be recommended for referral.

Consistency-checking group (CCG)

- 3.8 A meeting of a joint NICE/DH consistency-checking group (CCG) takes place shortly after each round of consideration panel meetings to check that decision making has been consistent across all seven panels.
- 3.9 Once these issues have been taken into account, the panels' recommendations are then forwarded to ROG.

Referral oversight group (ROG)

- 3.10 ROG is a DH-led group of senior representatives from the DH, NICE and the NHS. ROG meets three times a year following the CCG meetings.
- 3.11 ROG is chaired by the NHS Medical Director, Sir Bruce Keogh, and provides assurance to Ministers on the alignment of NICE's work programmes with overall health priorities. ROG also provides advice to Ministers on the final list of proposed topics for NICE's work programme, taking into account:

- the overall balance of NICE's work programme and the fit with national clinical and public health priorities;
- the potential implementation and resource consequences for the NHS and other services of the proposed work programme based on the extent and nature of the practice covered;
- the ability of NICE to deliver the work programme.

Ministerial role

3.12 Ministers make the final decision on which topics should be referred to NICE on the basis of the advice they receive from ROG and the consideration panels. Once Ministers have made a decision, the clinical guideline and public health topics are referred to NICE. For technology appraisals, Ministers make a 'minded referral'.

Minded referral and consultation

3.13 Ministers form a preliminary decision on the topics they are minded to refer to NICE. Interested parties are then invited by NICE to consult on the draft remit and the draft scope of the proposed appraisal.

Final referral

3.14 The results of the remit and scope consultation are submitted to DH. Ministers review the results of the consultation and make a final decision on whether to refer the topic to NICE and the remit for those topics that are to be referred.

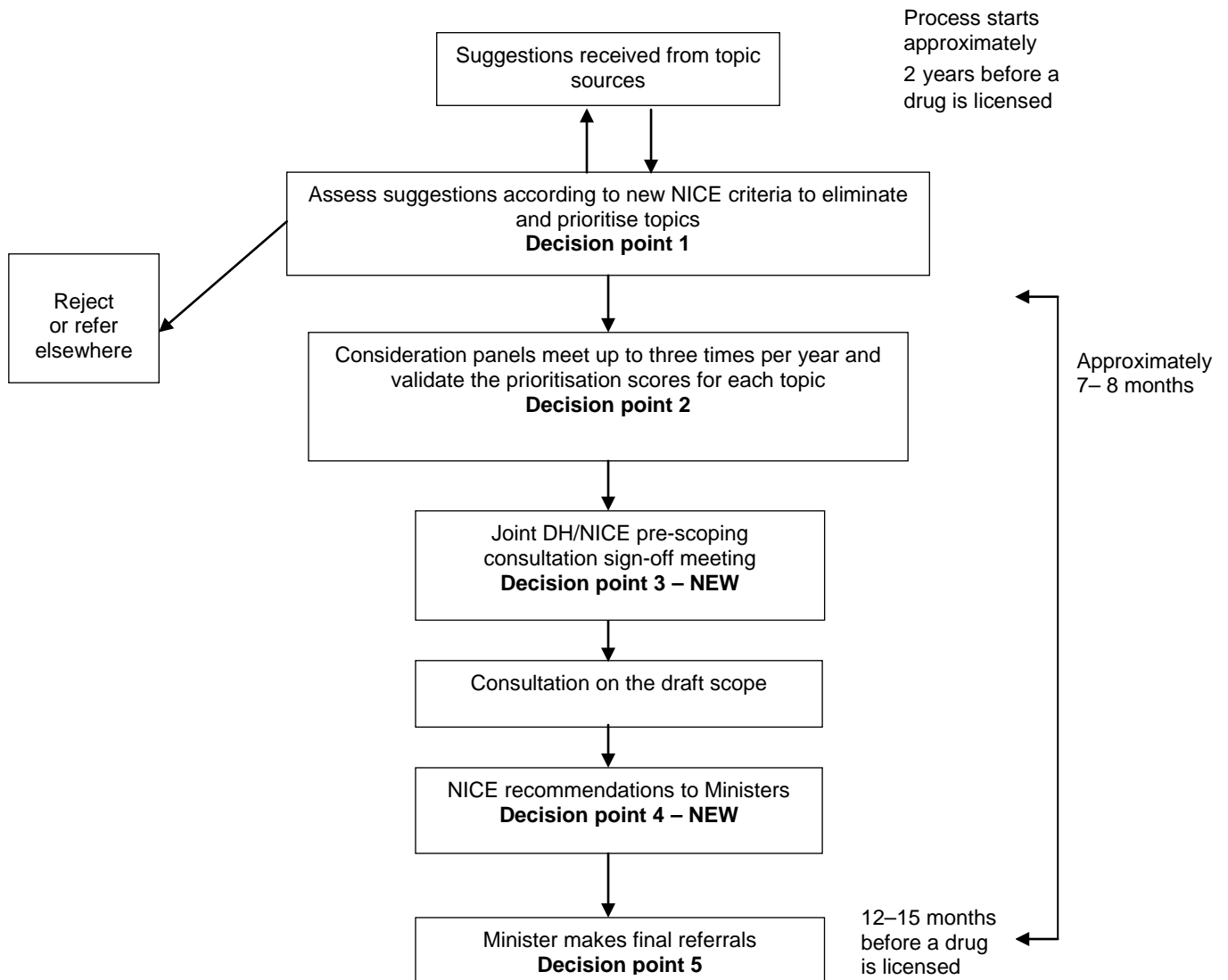
Cancer topics

3.15 In response to the Cancer Reform Strategy commitment, DH and NICE developed a separate, more rapid, topic selection process for the consideration of all significant new chemical entities for the treatment of cancer including all significant changes to licensed indications for existing cancer drugs. Under this process, suggestions agreed and prioritised by the cancer consideration panel proceed direct to consultation on the scope of the technology appraisal. There is therefore no role for ROG in the selection of cancer drug topics and no minded Ministerial referral stage. Ministers make a final decision on referral of the topic following the outcome of the scope consultation.

4. Proposed new process for technology appraisals

- 4.1 The proposed process outlined in figure 2 builds on the changes already made to the selection process for cancer topics.

Figure 2 Proposed topic selection process



Summary of key changes

Topic identification

- 4.2 No changes are proposed to this part of the process. The early stages of the topic selection process will continue to be administered by NICE with input on all significant new technologies from the National Horizon Scanning Centre.

Decision point 1 – preliminary assessment of topics

- 4.3 As before, topic suggestions will be assessed by the topic selection team at NICE. The aim will be to:
- eliminate topics that do not meet NICE's remit or are otherwise inappropriate
 - filter topics according to the selection criteria, gathering specialist advisor input as necessary.
- 4.4 The key proposed change is that a new set of selection and prioritisation criteria is used at the filtering stage and at all subsequent decision point stages. The proposed new criteria are listed in appendix B and are discussed in more detail in section 5.

Decision point 2 – topic selection consideration panels

- 4.5 Consideration panel meetings will continue to be held three times per year. Where topics are urgent, briefings may be sent to a consideration panel by email for more rapid consideration.
- 4.6 The key proposed change is that the consideration panel will no longer allocate a score of 0–5 based on their judgement of the priority of that topic for guidance to be produced for the NHS. Instead, the panel will review and validate the allocated scores applied by the NICE topic selection team at the filtering stage against each new criterion, and will amend and adjust these as appropriate as part of the discussion of each topic, taking account of national policy priorities. This will improve the clarity and governance of the decision-making process. By the end of the meeting, the panel will have a ranked list of prioritised topics to be referred to the NICE work programme. This proposed change will ensure that a single set of criteria and a single scoring system is being used at all key decision points throughout the new process.

Decision point 3 – pre-scoping

- 4.7 Following the recommendations of the consideration panel, the NICE topic selection team will carry out an initial assessment of the topic and will produce a draft scope document. Because of the elapsed time and to take account of any additional information that may have been received following the consideration panel discussion, the NICE team will make a decision about whether the topic should proceed to the next stage – a consultation on the draft remit and scope of the technology appraisal. Decisions will be made using the proposed new criteria and by amending

the overall score against these to reflect the additional information received.

- 4.8 The CCG will cease to exist under the new arrangements and will be replaced by a pre-consultation “sign-off” meeting of senior NICE staff and DH officials.
- 4.9 Further key changes are that there will be no role in the selection of technology appraisal topics for the ROG, although topics will be presented for information and noting by this group, and there will be no Ministerial minded-referral stage for any technology appraisal topic. Technology appraisal topics will proceed straight to consultation on their draft remit and scope immediately following decision point 3.
- 4.10 Increasing the number of formal decision points is expected to deliver a more efficient process because resources are only being committed and applied to those topics that are regarded as true priorities. These topics will also be those that are progressing through the licensing process that will be occurring in parallel to this selection process.
- 4.11 The proposed removal of the CCG, the ROG and the Ministerial approval process for minded referrals is expected to save at least 3 months in processing time for each technology appraisal topic. This will increase the likelihood that NICE will issue guidance within 6 months of the launch of that intervention in the UK.

Decision point 4 – post consultation

- 4.12 After consultation on the draft scope and remit of the technology appraisal, a group of senior NICE staff and DH officials will meet again to consider the outcome of the consultation on the draft scope and remit. Because more information will be available on the topic at this later stage, the group will amend the scores against the proposed criteria to reflect the new information received. The group will then agree which topics should proceed to the next stage – recommending to Ministers which technology appraisals should be referred to the NICE work programme.

Decision point 5 – ministerial referral

- 4.13 Ministers will review the results of the consultation and the recommendations made. Ministers will take into account any relevant information, including DH priorities and government policy. They will then make the final decision on whether to refer the topic to NICE and, for those topics that are to be referred, the remit that NICE will be asked to appraise.

5. The proposed topic selection criteria

5.1 The existing topic selection prioritisation criteria can be found in appendix A and the proposed criteria in appendix B. The proposed criteria will be used to guide topic selection at each of the decision points in the new process. All decisions will be transparent and made available through the NICE website.

5.2 The existing criteria are currently used for the prioritisation of topics for all of NICE's work programmes including clinical guidelines and public health topics. The proposed criteria allow for a more relevant and focussed approach to the prioritisation of topics for the technology appraisals work programme only. The future development of arrangements for the selection of clinical guideline and public health guidance topics will be considered separately.

5.3 The default position on referral of new cancer drugs set out in the Cancer Reform Strategy (CRS), published in December 2007, remains in place. This set out a default position that all new cancer drugs and significant new marketing authorisation indications would be referred to NICE, providing that NICE agrees that:

- there is a sufficient patient population and evidence base on which to carry out an appraisal; and
- there is not a more appropriate alternative mechanism for appraisal (for example, the topic falls within the remit of the National Specialised Commissioning Group) .

The Cancer Consideration Panel will consider with NICE and DH how best to apply the new criteria in the context of the CRS commitment.

5.4 The factors to be taken into account when considering each criterion have been described to allow for gaps in the information available about topics at the time they are being considered for selection. Key data may not be available on price, research outcomes or patient population. The challenge for the expert topic selection consideration panels is not only to consider and score topics based on the best information available at the time, but also to apply their professional judgement and experience when considering the relative importance of each topic, often in the absence of all the relevant information. However, it is necessary for the panels to consider topics at this early stage if NICE is to be able to produce its guidance close to the launch of that technology in the UK, which is when it is needed.

5.5 Published research and trial data on technologies that are at the topic selection stage will often be in progress or not available. This is why an assessment or an evaluation of the available research data does not feature as a key criterion in its own right. However, where research data are available, they will be presented to the consideration panels and will be taken into account in the discussion of the criterion 'potential for therapeutic benefit'.

5.6 The total number of points it is possible for each topic to score has been increased from the previous maximum of 5 to 20. Under the current system, many topics score equal points so the new scoring system should allow a greater ability for the system to separate competing topics.

5.7 Other key proposed changes are:

- **Resource impact** – this criterion will include consideration of the acquisition cost of the technology, together with the impact of implementing the guidance, for example on service, facilities, staff and training, rather than simply the acquisition cost of the technology. The scoring is structured such that topics that have the potential to deliver either significant cost savings or result in significant additional costs are scored highly.
- **Burden of disease** – this was previously looked at only in terms of patient numbers but this approach was unhelpful in taking into account both the population affected and the severity of the disease. These two key parameters of the disease burden will be separated out and scored separately.
- **Potential for therapeutic benefit** – this is a new criterion and will be applied to capture the extent to which a new technology is likely to claim measurable therapeutic benefit over currently available NHS treatments.
- **Patient population** – drugs for very small populations (that is, less than 1000 patients in the patient population defined in the marketing authorisation) will be given special consideration to determine whether an appraisal can add sufficient value and constitutes a good use of NICE resources. For example, if the price of the technology will result in an unacceptable incremental cost effectiveness ratio then the topic will not be progressed.

Small patient groups – A ‘cut off’ number of patients below which NICE will eliminate a topic from consideration is not being proposed. What is proposed is that NICE will give special consideration to drugs for very small populations on a case-by-case basis. For example, technologies affecting children, where disease populations are often small, will be given special consideration to ensure that they have an opportunity to benefit from NICE guidance.

The proposed new criteria will allow for a much fuller consideration of technologies for small populations because they also take into account the severity of the disease and the potential for therapeutic impact in a way that the previous criteria did not. The previous criteria arguably gave weighting to the size of the population alone. Under the proposed arrangements, technologies that do not score highly against the population criterion may still score highly overall if the technology is also

innovative, has a significant potential to deliver significant therapeutic benefit, and where the disease is severe and there are few alternative treatments available. This change will allow for a more equal consideration of technologies aimed at small populations.

The expected impact of these special considerations is that more technologies aimed at small populations will progress through topic selection and onto the NICE technology appraisal work programme.

- **Variation in practice** – this has been removed as a criterion for technology appraisals because it is difficult to assess and measure in advance of guidance being issued on a technology. This criterion is better suited to assessing the potential need for a clinical guideline or public health topic.
- **Timeliness and urgency** – this has also been removed as a criterion because the vast majority of appraisals considered at the topic selection stage are already planned up to 2 years in advance of their marketing authorisations so will all be timely in this context.
- **Policy importance** – the relevance of DH policy on topic prioritisation does not feature in the new criteria because it will be taken into account by the consideration panels, on advice from the National Clinical Directors and at decision points that involve DH and NICE.

6. Key questions for consultation

A) Changes to the topic selection process

The proposed process includes the following key changes when compared with the existing topic selection process outlined in section 2:

There will be no minded ministerial referral stage for any technology appraisal topics.

Q1. Do you agree the minded ministerial referral stage should be removed from the topic selection process for all technology appraisal topics?

There will be no role in the selection of technology appraisal topics for the Referral Oversight Group, although topics will be presented to this group for information.

Q2. Do you agree that ROG should no longer be a decision point in the topic selection process for technology appraisal topics?

There will be more formal decision points than under the previous process to help ensure that the process is efficient and that resources are only ever being applied to the most important topics that are progressing through the licensing system.

Q3. Do you have any comments or observations about the proposal to increase the number of formal decision points and the proposed process underpinning these?

B) Changes to the topic selection criteria

A number of changes have been made to the topic selection criteria to make them more relevant to the selection of topics for the technology appraisal work programme.

Q4. Do you agree that specific, separate criteria should be developed for the technology appraisal work programme?

The proposed criteria have evolved from a review of international published literature on prioritisation criteria and taken account of NICE's experience in this area.

Q5. Do you agree that the proposed criteria will appropriately prioritise the selection of technology appraisal topics for NICE? Do you think there are any important omissions from the proposed criteria?

The proposed criteria treat very small patient populations in a particular way.

Q6. Do you agree that technologies designed for very small populations are the subject of appropriate selection criteria in section 5?

The proposed process incorporates a number of significant changes that have been drafted to increase the speed, governance, transparency and credibility of the NICE topic selection process.

Q7. Would you like to make any other additional comments about the proposals outlined in this consultation document?

7. Responding to the consultation

Consultation dates: 2nd March – 22nd May 2009

Consultation documents:

- Full document with proposed changes
- Comments proforma

Points to consider in the consultation:

- The seven specific questions posed in the document
- Points or areas that are not covered
- Potential inconsistencies
- The practical value of the proposed changes.

How to submit your comments:

Please use the comments proforma and return by email to:

topicselection2009@nice.org.uk

The Institute is unable to accept:

- More than one response per organisation or individual
- Comments received after the consultation deadline (5pm)
- Comments that are not on the correct proforma
- Confidential information or other material that you would not wish to be made public
- Personal medical information about yourself or another person from which your or the person's identity could be ascertained.

What will happen to your comments:

All comments (with the exception of personal and late comments) will be sent the topic selection team at NICE and the Department of Health for consideration.

A summary of the response to this consultation will be made available before or alongside any further action and will be placed on the NICE website. A link to the summary will be placed on the DH Consultations website.

Comments will be formally responded to and posted on the NICE website when the final process is published.

No action will be taken upon receipt of personal and late comments.

PLEASE NOTE: *the Institute reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of the Institute, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.*

Acknowledgement of comments:

You should receive an automated acknowledgement from the email box when you email your comments. If you do not receive this acknowledgement, please contact Rachel Hatton (Rachel.hatton@nice.org.uk) to ensure your comments have been safely received.

Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how processes are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Anticipated implementation date: July 2009

Further information:

http://www.nice.org.uk/getinvolved/suggestatopic/suggest_a_topic.jsp

In parallel with this consultation, DH and NICE are working together to shadow the proposed new arrangements in the form of a pilot so that the new process can start at the earliest opportunity. NICE will take this forward in the February and March round of topic selection consideration panels.

Changes proposed as a result of this consultation will be incorporated in the new process for topic selection.

Appendix A

Existing selection criteria for referral of topics to NICE

1. Is it appropriate for NICE to provide guidance on the topic? In particular:
 - a. Is the proposed topic within NICE's remit?
 - b. Has NICE already provided guidance or is NICE developing guidance on the proposed topic?
 - c. Is the proposed topic emerging as a future public health issue?
 - d. Is the proposed topic an ultra-orphan disease?
2. Would guidance promote the best possible improvement in public health and wellbeing or patient care, and the reduction of inequalities in health, given available resources? In particular, is one or more of the following satisfied?:
 - a. Does the proposed guidance relate to one of the public health or NHS clinical priority areas, or to other health-related government priorities?
 - b. Does the proposed guidance address an area of action where better evidence of cost effectiveness would be expected to lead to substantive cost-efficiencies in the delivery of quality programmes or interventions?
 - c. Does the proposed guidance relate to one or more interventions or practices that might impact significantly on NHS or other societal resources (financial and other)?
 - d. Does the proposed guidance relate to one or more interventions from which the NHS could disinvest without detriment to cost-effective patient care, thus freeing up resources for use elsewhere in the NHS?

And, for **public health topics**, one of the following:

- e. Does the proposed guidance relate to an area of public health action that has high policy priority in the DH or across government?
- f. Does the proposed guidance address an area of public health action that promotes population health or wellbeing, or relates to a significant burden of avoidable disease, disability, injury or early death in the population as a whole or in specific population subgroups?

And, for **clinical topics**, one of the following:

- g. Does the proposed guidance address a condition that is associated with significant morbidity or mortality in the population as a whole or in particular subgroups?

h. Does the proposed guidance relate to one or more interventions or practices that could:

- i. significantly improve patients' or carers' quality of life; and/or
- ii. reduce avoidable morbidity; and/or
- iii. reduce avoidable premature mortality; and/or
- iv. reduce inequalities in health;

relative to current standard practice if used more extensively or more appropriately?

3. Is NICE able to add value by issuing guidance? In particular, taking into account whether:

a. there is available in the topic area a substantive or developing body of research or related evidence, where plausible linkages between public health or clinical actions and outcomes can be demonstrated; and/or

b. there is emerging evidence of widespread variation in the efficacy of public health actions in the topic area, such that publication of formal guidance would make a significant difference to improving the effectiveness of public health programmes or interventions; and/or

c. there is evidence and/or reason to believe that, in the absence of guidance, there is or will be:

- i. inappropriate clinical practice; and/or
- ii. inappropriate variation in clinical practice; and/or
- iii. inappropriate variation in access to clinical interventions and/or treatment (between geographical areas or social groups).

4. Would it be timely for NICE to provide guidance on the proposed topic? In particular:

a. would the guidance still be relevant and timely at the expected date of publication; and/or

b. for new clinical interventions, does the balance of advantage for patient care lie with appraisal at time of launch or at some specified future date, taking account of:

- i. the possible impact on uptake or equity of access in the absence of guidance at time of launch
- ii. for surgical and related interventions, whether safety and efficacy have already been assessed (or will be assessed in the

near future) by the Interventional Procedures Advisory Committee; and/or

c. whether there is a degree of urgency for guidance caused by factors other than those listed above, for example is there significant public concern, is this a new disease, or is this emerging as an important new area for public health action?

Appendix B

Proposed new exclusion and selection criteria for technology appraisals.

Proposed exclusion criteria for technology appraisals (decision point 1)

1. **New formulations of an existing agent** – unless significant benefit to patients in terms of efficacy or fewer side effects can be demonstrated or unless the new formulation is at, or likely to be at, a significantly different price.
2. **Population screening** – issues better dealt with by National Screening Committee.
3. **Vaccination** – issues better dealt with by the Joint Committee on Vaccination and Immunisation (JCVI); although NICE are confirming with JCVI that they will consider therapeutic vaccines.
4. **HIV drug** – issues dealt with by the British HIV Association.
5. **Healthcare acquired infection** – topics that are within the remit of the Health Protection Agency Rapid Review Panels relating to *Clostridium difficile* and methicillin-resistant *Staphylococcus aureus* (MRSA)

Proposed new prioritisation criteria for technology appraisals (decision points 1–4)

1. Population (1–5)

The larger the population*, the more important a technology is for evaluation.

[0–1000 = 1**; 1001–10,000 = 2; 10,001–50,000 = 3; 50,001–500,000 = 4; >500,000 = 5]

*The population is the patient population defined in the marketing authorisation or otherwise indicated for the technology.

**Topics for patient communities of less than 1000 will be given special consideration.

2. Disease severity (1–5)

The greater the severity of the disease or condition, the more important evaluation becomes. This criterion should take into account: life expectancy; state of health prior to and after treatment; how far the individual is away from perfect health; and health states that incur social stigma.

Minor quality of life (QOL) impact, no disability = 1; definite QOL impact, but no significant mortality impact = 2; QOL impact, some disability or modestly increased mortality risk = 3; intermediate mortality impact or significant disability = 4; significant mortality risk = 5

3. Resource impact (1–5)

Consideration of the potential resource impact of guidance on the service, including consideration of the cost of implementing guidance and any additional service, facilities or staff requirements.

1–2 = The resource impact on the service will be negligible, that is, there will be little or no significant increase or decrease in the resources required to implement guidance on this topic.

3–4 = The resource impact on the service will be moderate e.g. requiring some changes to service and staffing arrangements.

5 = The resource impact on the service will be significant e.g. requiring major alterations to service configuration, facilities and/or infrastructure either at significant cost savings or at significant additional cost.

4. Therapeutic benefit (1–5)

Consideration of the extent to which a new technology claims measurable therapeutic benefit over currently available NHS treatments

1–2 = The technology will be of negligible potential additional therapeutic benefit.

3–4 = The technology will be of moderate potential additional therapeutic benefit.

5 = The technology will be of significant potential additional therapeutic benefit.

Appendix C

The Consultation Process

Criteria for consultation

This consultation follows the 'Government Code of Practice', in particular we aim to:

- formally consult at a stage where there is scope to influence the policy outcome;
- consult for at least 12 weeks with consideration given to longer timescales where feasible and sensible;
- be clear about the consultation process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees' 'buy-in' to the process;
- analyse responses carefully and give clear feedback to participants following the consultation;
- ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.

The full text of the code of practice is on the Better Regulation website at:

[Link to consultation Code of Practice](#)

Comments on the consultation process

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please

Contact: Rachel Hatton
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Please do not send consultation responses to this address.

Confidentiality of information

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the NICE.

NICE will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

Summary of the consultation

A summary of the response to this consultation will be made available before or alongside any further action and will be placed on the NICE website. A link to the summary will be placed on the DH Consultations website at:
<http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm>