NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE
SELECTION OF TOPICS

A consultation paper

Department of Health
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NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE: SELECTION OF TOPICS

This consultation paper seeks views on some proposed changes to the way in which the Department of Health (DH) selects topics for referral to the National Institute for Health and Clinical Excellence (NICE).

The main purpose of the changes is to

- ensure that NICE's stakeholders – patients, healthcare professionals public health partners, the wider NHS and manufacturers of healthcare products – have clear opportunities to make an input into the selection of topics;
- help us ensure that NICE's work programme addresses topics of importance to patients and professionals and makes the best use of NHS resources;
- integrate the selection of public health topics into the selection process; and
- improve the timescale for referral of topics to NICE.

1. OVERVIEW

1.1 NICE is a special health authority. It was set up in April 1999 to give advice to the NHS on the clinical and cost effectiveness of drugs and treatments. From 1 April 2005 it took over the public health functions of the former Health Development Agency.

1.2 NICE develops three forms of clinical guidance:

- clinical guidelines (management of particular clinical conditions),
- technology appraisal guidance (guidance on specific health interventions, pharmaceuticals, devices and treatments), and
- guidance on the safety and efficacy of interventional procedures.

1.3 NICE also develops two types of guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector:

- Public health programme guidance (- on programmes that will help to prevent disease or improve health and so reduce health inequalities).

- Public health intervention guidance (- on the effectiveness and the cost effectiveness of particular interventions).

1.4 Clinical guidelines, technology appraisals and public health guidance are referred to NICE by the Secretary of State. Selection of these topics is covered here.

2. SELECTION OF TOPICS

2.1 It is not intended that NICE looks at every new drug, intervention, behaviour or technology. Rather the intention is that NICE focuses its efforts on those new products, interventions or programmes that meet certain criteria – e.g. where the evidence is unclear, where there is a significant impact on the NHS or where there is evidence of significant variation in practice. The selection of topics for NICE's work programme therefore is a task of considerable importance. It involves balancing two strands:

- the need to give early priority to guidance relating to the best use of existing interventions, focussing on those areas where improving clinical and public health practice or access to care would have the greatest benefit for patients and make the best use of NHS resources;

- responding in a positive way to the opportunities created by clinical innovation.

2.2 The arrangements for selecting topics therefore need to be informed by the best possible analysis and advice, including advice from NICE itself, and to be fully responsive to the needs of the NHS and its patients. To achieve these aims, DH wishes to ensure that the selection arrangements are clear and open in relation to the process and to its final outcomes, and in particular that all stakeholders – including patients, their representatives, healthcare professions, the wider NHS, the healthcare industries and individual manufacturers – have clear opportunities to propose topics and to comment on proposals.

2.3 The current arrangements already allow for a considerable amount of input from NICE and from all stakeholders, although this is not always widely appreciated.

2.4 Topics are referred to NICE in "waves" and there are generally two referrals each year. It is our intention to maintain this batching of referrals, but the frequency may change. While we understand that this does bring with it an element of delay it does allow for planning by DH, NICE and more importantly the NHS.

2.5 The following section on pages 4-7 describe the current arrangements, while section 4 on pages 8-13 sets out our proposals for how they can be strengthened. Methods for responding to the consultation are set out in section 5.

3. CURRENT ARRANGEMENTS

3.1 The existing arrangements only cover the selection of clinical topics not public health topics.

3.2 Under the existing topic selection system, possible topics for referral to NICE emerge from a variety of sources:

- horizon scanning of new pharmaceutical products by the National Horizon Scanning Centre at Birmingham University;
- through the Health Technology Assessment programme website managed by the National Co-ordinating Centre for Health Technology Assessment at Southampton University ;
- suggestions made through the NICE website from the NHS, professional groups and the public; and
- suggestions from National Clinical Directors and DH policy leads which underpin and support Department objectives.

Sifting Process

3.3 Both NCCHTA and NHSC perform an initial sift of the topic proposals against published selection criteria - see paragraph 3.5. An initial sift against the selection criteria is important in ensuring only those topics that are likely to be a priority for the NHS go forward to the Advisory Committee for Topic Selection (ACTS). Topics are sifted out at this stage for a variety of reasons which include:

- proposals that do not have a clear licensing position;
- where there is not enough of an evidence base to support a detailed analysis of the proposal; or
- which are too limited in their scope

3.4 Once the sift is completed, the NCCHTA and NHSC prepare briefing notes on the topics to be considered by ACTS. Before the briefing notes are sent to ACTS, the comments of experts on the proposed topics are sought. The expert comments provide a valuable view from those working in healthcare, especially those in specialist fields, as to whether the topic proposals deal with relevant healthcare issues and if NICE guidance would helpful to the NHS.

The selection criteria

3.5 It has never been the intention that all new technologies would be appraised by NICE. Therefore selecting the technologies which should be appraised is a fundamental aspect of the process. The selection criteria need to be widely understood and supported as well as applied rigorously. These are attached at annex A.

3.6 The selection criteria seek to apply two complementary tests to the selection of topics for NICE:

i are there reasons for thinking that clinical practice in the relevant area could be improved, with benefits for patients either directly (through wider use of more clinically and cost effective interventions) or indirectly (through discouraging use of less clinically and cost effective interventions and freeing up resources for use elsewhere in patient care)? and

ii would guidance from NICE add value? This has two aspects – whether there is likely to be any significant controversy in the absence of guidance, and whether the evidence base is adequate for NICE to develop useful guidance.

3.7 The existing selection criteria were developed with NICE's clinical work programme (appraisals and clinical guidelines) in mind and the criteria do not have a public health focus to them.

Advisory Committee for Topic Selection (ACTS)

3.8 ACTS meets quarterly and is made up of representatives of professional and patient groups, the NHS and industry and is chaired by a senior official of the DH. The role of ACTS is to decide whether topic proposals provided by the NCCHTA and NHSC are suitable for NICE to produce guidance on. ACTS selects topics against the published selection criteria. The topics selected by ACTS form the basis of a proposed work programme (a "wave") to be referred to NICE. In addition ACTS agree the proposed remit for all the topics in the "wave."

3.9 At this stage the clinical guidelines and technology appraisals comprising the wave undergo two separate stages of further work.

Clinical Guideline Pre-Referral Meetings

3.10 Clinical guidelines which are deemed suitable for referral to NICE by ACTS are subject to further discussion at a pre-referral meeting. These meetings are attended by DH, NICE and selected healthcare professionals.

3.11 The purpose of the meeting is for these parties to have a preliminary discussion about the remit of the guideline (the clinical question the guideline will address). The meeting also serves to identify some of the main issues that are likely to arise in the guideline development process, if the guideline is referred to NICE.

Technology Appraisal Scope Development

3.12 The technology appraisals which ACTS has deemed suitable for inclusion in a proposed "wave" undergo further work at NICE, where the scope of the appraisal is developed. The scope builds on the

appraisal remit proposed by ACTS and forms the basis on which NICE will develop its guidance.

Joint Planning Group

3.13 Once the scope development and pre-referral meetings are complete, the "wave" proposed by ACTS is then shared with the Joint Planning Group (JPG). This is a group of senior officials from DH, NICE and the NHS. JPG examines ACTS proposals and provides advice to Ministers on:

- the suitability of proposed topics for the single or multiple appraisal process;
- the strategic and policy significance of topics;
- the potential resource and implementation consequences of NICE guidance;
- the priority to be given to each topic; and
- NICE's capacity to handle the proposed topics.

Ministerial role

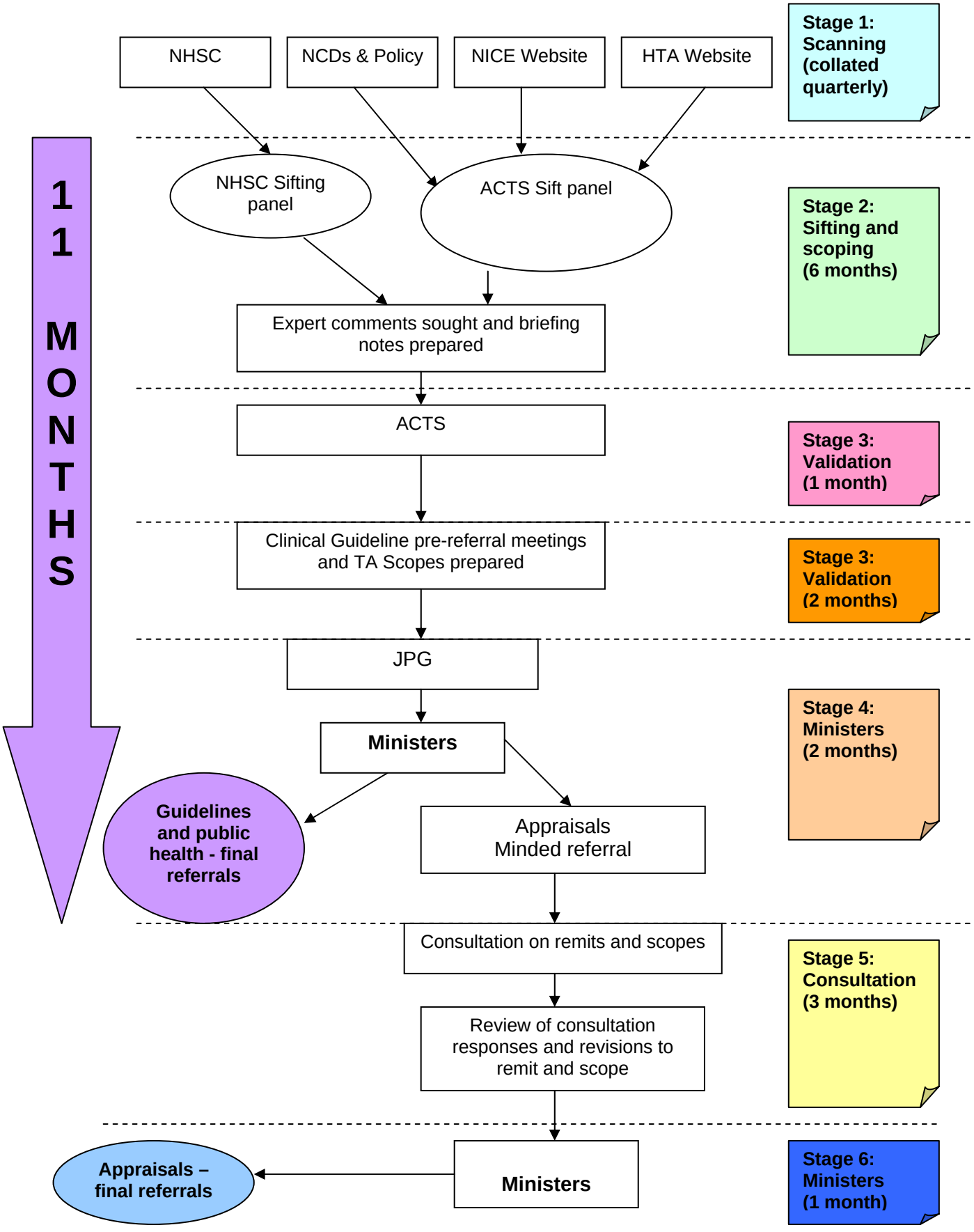
3.14 Advice is given to Ministers (on the basis of comments provided by both ACTS and JPG) on possible topics. This advice includes the impact for both finance and manpower on the NHS and NICE's capacity to deal with the work programme.

Consultation

3.15 Once Ministers have formed a view the clinical guidelines and public health topics are referred to NICE. For technology appraisals Ministers will form a preliminary view on the topics they are minded to refer, interested parties are then consulted by NICE on the draft remit and the draft scope of the proposed appraisal.

3.16 Comments on the draft remit are then considered by Ministers who make the final decision on whether to refer the topic and the remit NICE will be asked to appraise.

Flowchart of Existing Topic Selection Process



4. PROPOSED NEW PROCESS

4.1 A fundamental change is proposed to the administration of the topic selection process. The early stages of the new process will be administered by NICE through a new topic selection team. NICE already has a significant role in selection of topics and building on the existence of the topic selection function of its website it is appropriate for NICE to manage the early information gathering and assessment stages of the topic selection process. However, the later decision making stages of the process will remain with the DH and Ministers.

4.2 Topics will continue to emerge from a variety of sources. Additionally NICE will identify or generate topics in key areas such as public health, devices, procedures and diagnostics. For example, the new National Reference Group for Health and Well-Being proposed in *Our health, our care, our say,* is expected to become an important source of ideas for new guidance topics to support the commissioning and delivery of effective community-based care.

Sifting Process / Initial Assessment

4.3 It is proposed that suggested topics would be collated quarterly by NICE and batched for referral to the most appropriate consideration panel(s) which will cover both clinical and public health issues – see paragraph 4.6.

4.4 An initial sift of the topics against the selection criteria would be made to eliminate:

- duplicate suggestions;
- topics already on the work programme;
- those covered within the scope of guidance being produced or already published; and
- those not appropriate for NICE to undertake.

This initial sift would be carried out by the topic selection team based at NICE.

4.5 Once the initial sift of topics is completed, a full list of the topics to be considered would be compiled by the topic selection team . The topic selection team would source the following information which would begin to build a topic profile which may include:

- details of the disease, behaviours or lifestyle;
- current treatments/practice, interventions or programmes;
- how any new technology will work;
- the size of the patient group likely to benefit or the group at risk;
- the anticipated financial cost or saving to the NHS of NICE's likely recommendations;
- the impact on the NHS and public health partners in other resource terms eg. HR;

- possible variations in practice if NICE guidance were not available; and
- total impact (financial & other) without NICE guidance being issued.

This information and the rationales for already eliminated topics would be submitted to the consideration panel for them to assess.

Selection Criteria

4.6 The existing selection criteria need to be expanded so that they are also applicable to the selection of public health topics. Our ideal is that there is one set of criteria but perhaps split into two subsections, a) clinical and b) public health. Details of these criteria are at annexes A and B.

4.7 Public Health topics do not have the same sort of evidence base or economic data as clinical topics and consequently present challenges when assessed against clinical criteria.

4.8 Due to the broad scope of public health topics and their ability to cut across both appraisal and clinical guideline guidance, it is important to have one process for the selection of all topics. This way, linkages between the different guidance work programmes can be made at an early stage to avoid duplication of effort and possible contradictory advice being provided to the NHS.

Q1. Do you agree that there should be one set of criteria for the selection of both clinical and public health topics or are separate criteria needed?

Q2. What changes to the criteria are required?

Q3. Will the proposed information base at section 4.5 provide enough information to determine whether a topic meets the selection criteria or not?

Consideration panels

4.9 To determine if a topic meets the selection criteria it is proposed that consideration panels should be established to cover both clinical and public health topics. The panels would assess against the selection criteria the potential topics identified by the sifting process for referral to NICE's clinical and public health work programmes.

4.10 Initially these panels are proposed to be in the following areas:
- Children;
- Older People;
- Cancer;

- Mental Health;
- Coronary Health - including vascular diseases;
- Women's health;
- Public health; Including for example; smoking, alcohol, obesity, sexual health and health inequalities
- Chronic conditions (eg; diabetes, asthma, RA, MS etc); and
- Others including acute issues (eg. surgery, trauma etc)

Over time it may be necessary to revisit the focus of the panels, removing or adding topic areas as NHS priorities shift. It would be for the topic selection team to ensure that proposals cutting across the consideration panels were considered appropriately.

Q4. Are there additional disease or public health areas(in terms of patient number, severity, morbidity) which would require their own panel?

Q5. Can any of these proposed panels be merged?

4.11 It is proposed that each panel would be headed by either a relevant National Clinical Director or a leading clinician in the field or a public health specialist. Membership of the panel may include:

- healthcare professionals
- public health partners (including those in local authorities and the independent sector)
- patient, carer and lay representatives;
- NHS management representatives;
- DH Policy leads;
- National Collaborating Centres;
- NHSC;
- NCCHTA; and
- Industry (both drugs & devices).

Q6: Do you think that the membership of the panel provides the necessary expertise for a decision about the suitability of topics to be made?

4.12 Each panel will be required to assess potential topics against the selection criteria. The topic selection team will ensure that the panels apply the selection criteria consistently, through the production of a process manual and that topics are progressed expeditiously. Final recommendations of the panels will be vetted by a meeting of panel chairs and not by the topic selection team to ensure consistency of decision making.

Q7: Is a consistency of decision making by the panels necessary or desirable?

Q8: If so, do you think that other measures may be required to ensure consistency?

Q9: Do you agree that the chairs of the panels should take responsibility for vetting the suitability of proposed topics at a regular meeting as described at 4.12?

ACTS

4.13 In the current process the role of ACTS is to determine whether a potential topic meets the selection criteria for referral to NICE. In this new process the consideration panels will be providing this advice. These panels through their membership will engage with the wider NHS and specialist community to ensure that their assessment of a potential topic and the advice they provide is relevant and appropriate. Therefore the proposal is that ACTS is abolished.

Q10: Do you agree that ACTS should be abolished as the consideration panels will be carrying out its functions?

Technology Appraisal Scope Development

4.14 Each consideration panel will be asked to provide advice on the suitability of topics for referral to NICE. The panel will also make recommendations on the suitability of the topic for the single or the multiple appraisal process. It is recognised that the complexity of some single technologies will make them more suitable for the multiple process. The panel will need to also balance this against the guidance needs of the NHS eg sometimes it is better for the NHS to receive one piece of guidance covering 2/3 technologies for the same condition.

4.15 For multiple technology appraisals the panels will develop a draft scope which will help inform the decisions of the Joint Planning Group and Ministers.

Q11: Do you agree that it is appropriate for consideration panels to advise on the suitability of a topic for the single technology appraisal process?

Clinical Guideline Pre-Referral Discussions

4.16 The consideration panels would need to have a preliminary discussion about the remit of proposed clinical guidelines. The discussion would identify the main issues that are likely to arise in the guideline development process. The outcome of the discussion would inform the decisions of the Joint Planning Group and Ministers.

Public Health Guidance

4.17 The public health panel will identify whether their topics are intervention or programme guidance. It will also be necessary for the panel, through the DH policy lead, to engage in discussion with other Government Departments to secure their support for the referral of a proposed topic, which impacts upon their area of responsibility.

Referral of topics to JPG

4.18 Having determined the topics which meet the selection criteria for referral to NICE. The consideration panels will assess the relative priority of their topics and their decisions will be vetted at a meeting of all the panel Chairs. The topic selection team will then refer the proposed "wave" of clinical and public health topics to the DH for consideration by the Joint Planning Group (JPG).

Joint Planning Group

4.19 JPG will continue to make recommendations to Ministers. The membership of JPG will be revised to ensure that the needs of the NHS and the policy commitments (NSFs, White Papers etc) of DH are met. A major difference to the existing membership of JPG would be that the National Clinical Directors would not be included at this stage as their input would have been secured earlier in the process.

4.20 JPG will continue to advise Ministers on the

- suitability of proposed topics for the single or multiple technology appraisal process;
- strategic and policy significance of topics;
- potential resource and implementation consequences of NICE guidance; and
- priority to be given to each topic.

Ministerial Role

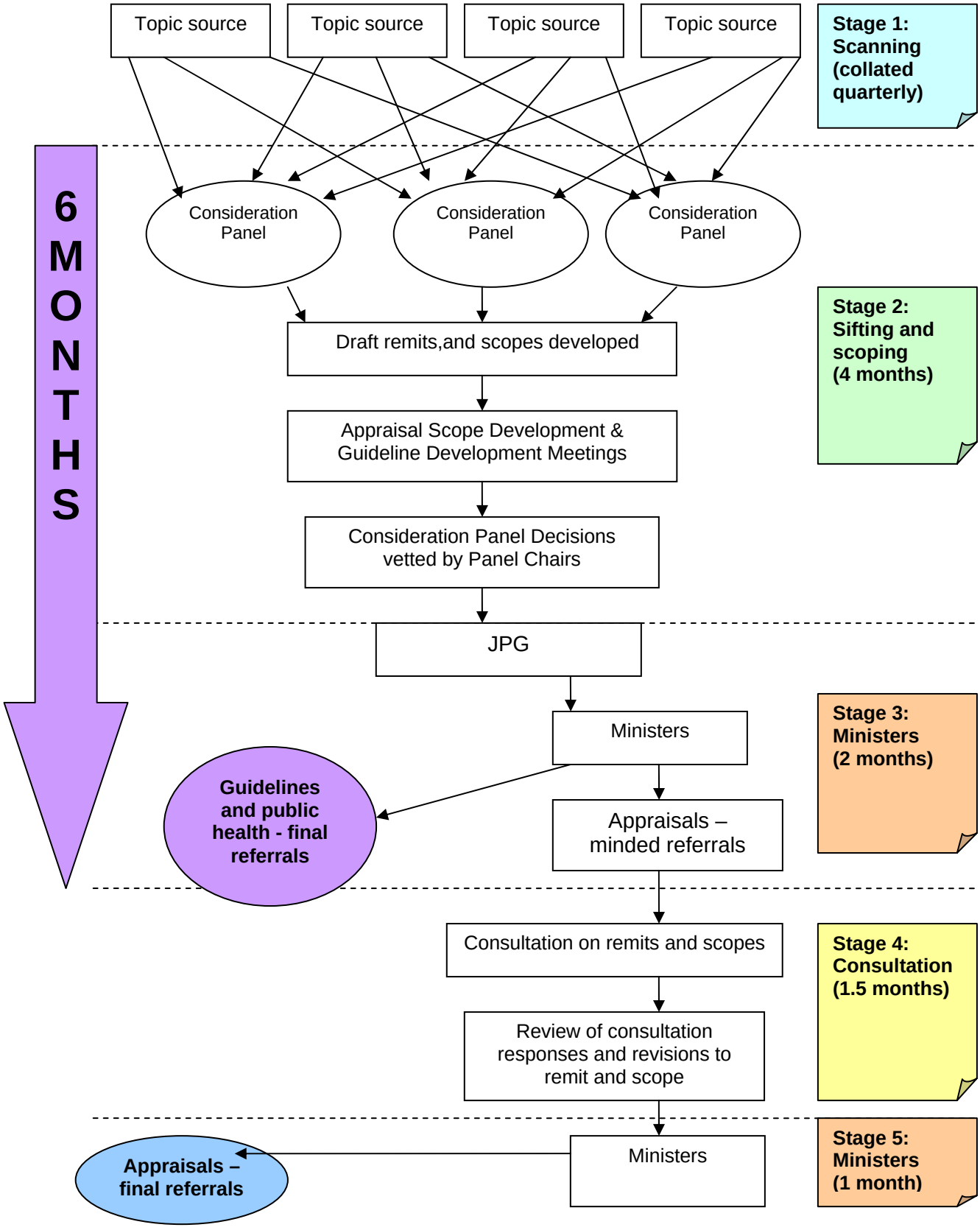
4.21 JPG's advice will be put forward to Ministers as in the existing process. Advice would still be given to Ministers (on the basis of comments provided by both the panel and JPG) on possible topics. Ministers will formally refer to NICE the clinical guidelines and public health topics.

Consultation.

4.22 As now for the clinical programme, Ministers will ask NICE to consult on the remit of all proposed technology appraisals. NICE will also consult on the scope of technology appraisals.

4.23 Comments on the draft remits and scopes will then be considered by Ministers who will make the final decision on whether to refer the topic and the remit NICE will be asked undertake.

Flowchart for the Proposed Topic Selection Process



5. Responding to the Consultation

5.1 Please send your responses to the consultation, either by e-mail or in writing to a dedicated mailbox at the Department of Health. The consultation will end on 9 June 2006.

E-mail: responsesniceconsultation@dh.gsi.gov.uk

Responses to NICE Topic Selection Consultation
Department of Health
Room 5E46
Quarry House
Quarry Hill
Leeds
Yorkshire
LS2 7UE

ANNEX A

Selection Criteria for Clinical Topics

1. Would guidance promote the best possible improvement in patient care given available resources? In particular, are one or more of the following satisfied:

    a. does the proposed guidance relate to one of the NHS clinical priority areas, or to other government health-related priorities such as reducing health inequalities?

    b. does the proposed guidance address a condition which is associated with significant disability, morbidity or mortality in the population as a whole or in particular subgroups? and/or

    c. does the proposed guidance relate to one or more interventions which could significantly improve patients' or carers' quality of life and/or reduce avoidable morbidity or avoidable premature mortality, relative to current standard practice, or if used more extensively or more appropriately would do so?

    d. does the proposed guidance relate to one or more interventions which if more extensively used would impact significantly on NHS or other societal resources (financial and other)?

    e. does the proposed guidance relate to one or more interventions which could without detriment to patient care be used more selectively, thus freeing up resources for use elsewhere in the NHS?

2. Will NICE be able to add value by issuing guidance, taking into account the following factors:

    a. is the evidence base sufficient to develop robust guidance across most or all of the interventions to be covered by the proposed guidance?

    b. is there evidence and/or reason to believe that there is or will be inappropriate practice and/or significant variation in clinical practice and/or variation in access to treatment (between geographical areas or social groups) in the absence of guidance?

3. Would the most appropriate form of guidance consist of an appraisal, a clinical guideline, or a combination of the two, taking into account:

    a. the availability of an existing clinical guideline from NICE or from another authoritative source for the condition in question;

b. the degree of urgency for guidance on any specific intervention for the condition in question;

c. the possible complexity of the proposed guidance if formulated as an appraisal?

In general, the presumption is that guidance will take the form of a clinical guideline if no suitable guidance relating to the condition as a whole is available or in preparation. An appraisal should be considered if the perceived need relates to a particular intervention for a particular condition, and if either (a) there is an urgent need for guidance or (b) a clinical guideline for that condition is already available or in preparation.

4. For new 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 the following factors and the attached checklist:

a. the possible impact on uptake or equity of access in the absence of guidance at time of launch;

b. the likely robustness of the evidence base at time of launch;

c. the prospect of relevant additional data becoming available in the period immediately after launch;

d. 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?

ANNEX B

Suggested topic selection criteria for new guidance on public health programmes or interventions

i. The topic addresses an area of public health action that has high policy priority, in the Department of Health and/or across government, and that is expected to have a significant impact on population health improvement, disease prevention, and the reduction of health inequalities.

ii. The topic addresses a significant and/or complex area of public health action that is subject to uncertainty and/or controversy.

iii. The topic addresses an area of public health action where evidence of cost-effectiveness would be expected to lead to substantive cost-efficiencies in the delivery of programmes or interventions at local level.

iv. There is available in the topic area a substantive or developing body of research or related evidence concerning the effectiveness of public health programmes or interventions, that lends itself to evidence review and to which evidence review would add value.

v. The publication of formal guidance on implementation of public health programmes or interventions in the topic area would make a significant difference to improving the effectiveness of public health programmes or interventions.

vi. Publication of public health programme or interventions guidance on the topic in two to three years' time would still be relevant and timely.

Cabinet Office Code of Practice on Consultations

When seeking views on our proposals we follow the '*Cabinet Office Code of Practice on Consultation*'. In particular we aim to:

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
2. Be clear about what our proposals are, who may be affected, what questions are being asked and the timescale for responses
3. Ensure that our consultation is clear, concise and widely accessible
4. Give feedback regarding the responses received and how the consultation process influenced the policy
5. Monitor our department's effectiveness at consultation, including through the use of a designated consultation coordinator
6. Ensure our consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment, if appropriate

We welcome your comments on how well we have adhered to the criteria and suggestions for further improving the consultation process.

Please direct comments or complaints about the consultation process, but not your response to the consultation itself, to:

Steve Wells
Consultations Co-ordinator
Department of Health
Skipton House
80 London Road
London
SE1 6LH
E-mail: steve.wells@dh.gsi.gov.uk