

Guide to the Technology Appraisal Process

April 2004

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About this document

This document is one of a set that describes the process and methods that NICE uses to undertake technology appraisals and provide guidance for the organisations invited to contribute to these appraisals.

The documents in the set, which will be published during 2004, are:

- *Guide to the Technology Appraisal Process* (reference N0514)
- *Guide to the Methods of Technology Appraisal* (reference N0515)
- *Contributing to a Technology Appraisal: A Guide for Patient/Carer Groups* (reference N0516)
- *Contributing to a Technology Appraisal: A Guide for Healthcare Professional Groups* (reference N0517)
- *Contributing to a Technology Appraisal: A Guide for Manufacturers and Sponsors* (reference N0518)
- *Contributing to a Technology Appraisal: A Guide for NHS Organisations* (reference N0519)
- *Technology Appraisal Process: Guidance for Appellants* (reference N0520)

These documents are available from the NICE website (www.nice.org.uk) or can be ordered from the NHS Response Line (telephone 0870 1555 455 and quote the appropriate reference number).

Note: this set of documents replaces the Technology Appraisals Process Series published in June 2001.

Nothing in this document shall restrict any disclosure of information by the Institute that is required by law (including in particular but without limitation the Freedom of Information Act 2000).

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Foreword

This document is one of a set that describes the process and methods that the Institute uses to undertake technology appraisals and provide guidance for the organisations invited to contribute to these appraisals.

The documents are:

1. *Guide to the Technology Appraisal Process*
2. *Guide to the Methods of Technology Appraisal*
3. *Contributing to a Technology Appraisal: A Guide for Patient/Carer Groups*
4. *Contributing to a Technology Appraisal: A Guide for Healthcare Professional Groups*
5. *Contributing to a Technology Appraisal: A Guide for Manufacturers and Sponsors*
6. *Contributing to a Technology Appraisal: A Guide for NHS Organisations*
7. *Appraisal Process: Guidance for Appellants*

Consultees to the Institute's technology appraisal programme should read this guide in conjunction with the documents listed above. All documents will be published during 2004 and will be available from the Institute's website (www.nice.org.uk) and from the NHS Response Line (see the inside front cover for details). The technology appraisal process is also summarised in *A Guide to NICE*, which is available from the Institute's website and the NHS Response Line (reference number N0521).

Documents 3–6 are designed to provide detailed notes for each of the consultee communities on how to contribute effectively to the technology appraisals process.

Acknowledgements

The Institute is very grateful to the members of the Process Working Party (see Appendix A) for their contribution to the production of this document.

1 Introduction

1.1 The purpose of this document

- 1.1.1 This document sets out the process, including timescales, that the National Institute for Clinical Excellence (NICE or the Institute) follows in undertaking technology appraisals. The purpose of this document is to describe a uniform, open and transparent process by which all technology appraisals are conducted. The process is designed to achieve robust guidance for the NHS, developed in an open and transparent way that allows maximum understanding and input from consultees and stakeholders.
- 1.1.2 This document should be read in conjunction with the Institute's *Guide to the Methods of Technology Appraisal*.
- 1.1.3 The document should also be read, where relevant, in conjunction with the related documents on contributing to an individual appraisal that have been prepared for patients and carers, manufacturers and sponsors, professional groups and NHS organisations. These documents will be published during 2004 and will be available on the Institute's website (www.nice.org.uk) and from the NHS Response Line (see the inside front cover for details).
- 1.1.4 See page 28 for a glossary of terms used in this document.

1.2 General description of the appraisal process

- 1.2.1 The National Institute for Clinical Excellence (NICE or the Institute) is part of the NHS. It is the independent organisation responsible for providing national guidance on treatments and care of people using the NHS in England and Wales. Further details about the Institute and its work programmes are available in *A Guide to NICE*, which is available on the Institute's website or from the NHS Response Line (telephone 0870 1555 455 and quote reference N0521).
- 1.2.2 One of the Institute's responsibilities is to provide guidance to the NHS on the use of selected new and established health technologies. The guidance issued about the use of a health technology is based on an appraisal of that technology.
- 1.2.3 It is the Secretary of State for Health and the Welsh Assembly Government that formally refer technologies to the Institute for appraisal. The types of technology referred include:
 - ▶ pharmaceuticals
 - ▶ medical devices
 - ▶ diagnostic techniques
 - ▶ surgical procedures
 - ▶ other therapeutic technologies
 - ▶ health promotion activities.
- 1.2.4 The purpose of the appraisal carried out by the Institute is as described in the directions of the Secretary of State for Health and the Welsh Assembly Government – that is, to appraise the health benefits and the costs of those technologies notified by the Secretary of State for Health and the Welsh Assembly Government and to make recommendations to the NHS in England and Wales.
- 1.2.5 An appraisal considers the evidence of the health benefits and costs of a health technology or technologies. This includes the impact on quality of life (for example, relief of pain and disability), and the probable effects on mortality. It also considers estimates of the associated costs, concentrating particularly on costs to the NHS and Personal Social Services.
- 1.2.6 Evidence for a technology appraisal is derived from a number of sources, including a technology assessment (see section 4.4.1) carried out by an independent academic group (the 'Assessment Group'), information ('evidence') provided by the consultees to the appraisal process (see

Box 4.1, page 11), and the participation of selected clinical specialists and patient experts (see section 4.4.3).

- 1.2.7 The evidence is considered by the Institute's Appraisal Committee (see Box 4.1, page 11), which reaches a judgement as to whether, on balance, the technology can be recommended as a cost-effective use of NHS resources in general, or whether it can be recommended for specific indications or subgroups of patients, if this is more appropriate. The Appraisal Committee evaluates the impact on both costs and benefits of any technology under consideration. This judgement is referred to as the appraisal determination, and once the appraisal process is complete, the determination is submitted to the Institute. The Appraisal Committee's determination is the basis of the guidance that the Institute issues to the NHS in England and Wales. See the Institute's *Guide to the Methods of Technology Appraisal* for further information on the methods used for technology appraisal.
- 1.2.8 In reaching the decision, the Institute and the Appraisal Committee take into account the factors listed in the directions of the Secretary of State for Health and the Welsh Assembly Government, namely:
 - ▶ the broad clinical priorities of the Secretary of State for Health and the Welsh Assembly Government (for example, as set out in *National Priorities and Planning Framework 2003–2006* and in National Service Frameworks, or any specific guidance on individual referrals)
 - ▶ the degree of clinical need of the patients with the condition under consideration
 - ▶ the broad balance of benefits and costs
 - ▶ any guidance from the Secretary of State for Health and the Welsh Assembly Government on the resources likely to be available and on such other matters as they think fit
 - ▶ the effective use of available resources.
- 1.2.9 The Institute also takes into account the longer-term interests of the NHS in encouraging innovation in technologies that will benefit patients.

2 Selection of technologies

- 2.1 The Institute cannot begin the appraisal of specific technologies until they are formally referred to it by the Secretary of State for Health and the Welsh Assembly Government.¹
- 2.2 A potential list of topics for individual appraisals is produced by the Advisory Committee on Topic Selection (ACTS). This Committee recommends technologies for appraisal, based on the following criteria.
- ▶ Is the technology likely to result in a significant health benefit, taken across the NHS as a whole, if given to all patients for whom it is indicated?
 - ▶ Is the technology likely to result in a significant impact on other health-related Government policies (for example, reduction in health inequalities)?
 - ▶ Is the technology likely to have a significant impact on NHS resources (financial or other) if given to all patients for whom it is indicated?
 - ▶ Is the Institute likely to be able to add value by issuing national guidance? For example, in the absence of such guidance, is there likely to be significant controversy over the interpretation or significance of the available evidence on clinical and cost effectiveness?
- 2.3 The technologies proposed by the ACTS are reviewed by Ministers for Health who decide which technologies should be selected for further consultation on whether they should be referred to the Institute.

¹ Further information about the process for selecting technologies for referral to the Institute can be obtained in England from the NICE Liaison Unit, Department of Health, Quarry House, Quarry Hill, Leeds, LS2 7UE (www.doh.gov.uk/nice/index.htm) and in Wales from the Performance, Quality and Regulation Division 2, NHS Quality Division, Welsh Assembly Government, Cathays Park, Cardiff, CF1 3NQ.

3 Developing the scope for the technology appraisal

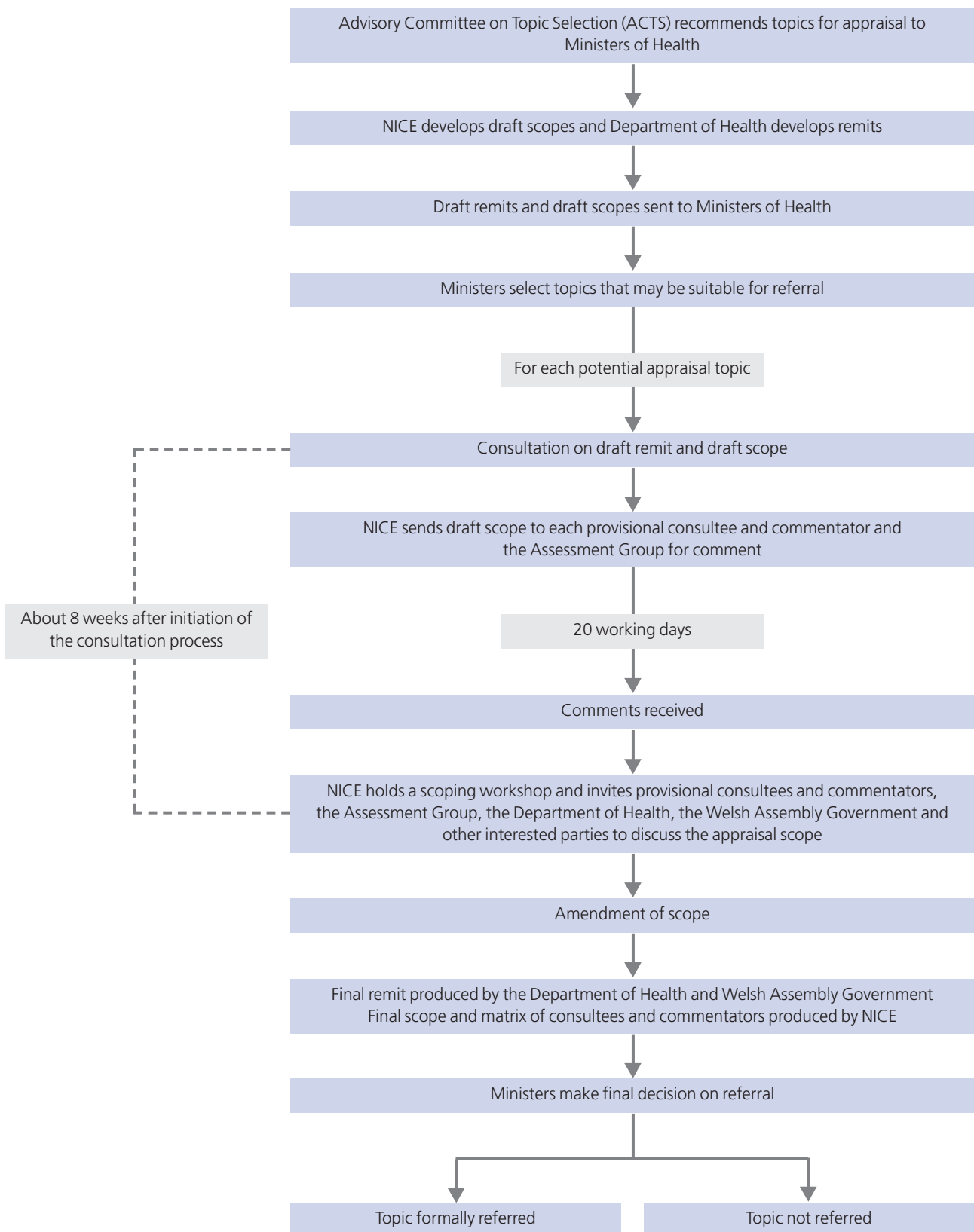
3.1 Provisional list of technologies for referral

- 3.1.1 Once a provisional list of appraisals selected for further consultation is decided by Ministers, and before a formal referral, the Institute works with the Department of Health and the Welsh Assembly Government to develop a scope for the appraisal. The steps involved in developing the scope begin before the technology is formally referred to NICE for appraisal. At this stage, there is no guarantee that the technology will be referred.
- 3.1.2 When Ministers have provisionally decided on the list of technologies for appraisal (known as a 'wave') that may make up the referral to NICE, the Institute undertakes the following tasks:
- ▶ develops a draft scope
 - ▶ identifies organisations that may wish to participate in the appraisal
 - ▶ consults (in conjunction with the Department of Health and Welsh Assembly Government) on the draft scope for the appraisal
 - ▶ holds a scoping workshop.
- 3.1.3 The steps involved in developing scope are shown in Figure 1 (page 5).

3.2 Developing the draft scope

- 3.2.1 During topic selection, the Department of Health and the Welsh Assembly Government provide the Institute with a draft remit for the appraisal. The Institute then undertakes a draft scoping process, which sets the provisional parameters of the appraisal and identifies the potential questions that would need to be asked about each technology. The scope will steer and focus the appraisal if the technology is formally referred to the Institute.
- 3.2.2 The first step in the scoping process is identification of information relating to the technology and preparation of a draft scope. The Institute's information specialists, working with the Institute's Technical Leads, undertake this task, which includes conducting a literature search, speaking with clinical specialists and contacting the manufacturer or sponsor of the technology.
- 3.2.3 The draft scope of an appraisal aims to define a number of elements, including:
- ▶ the clinical problem and the population(s) and any relevant subgroups for whom treatment with or use of the technology is being appraised
 - ▶ the technology and the setting for its use
 - ▶ the relevant comparator technologies (and their treatment settings) – usually, the relevant comparators are the treatment(s) used in current clinical practice in the NHS to manage the disease/condition, which may include no treatment (for further details, see the *Guide to the Methods of Technology Appraisal*)
 - ▶ the principal health outcome measures appropriate for analysis
 - ▶ the measures of costs to be assessed
 - ▶ the time horizon over which the benefits and costs will be considered
 - ▶ special considerations and issues that are likely to affect the appraisal.
- 3.2.4 For further information on scoping the appraisal, refer to the *Guide to the Methods of Technology Appraisal*.
- 3.2.5 Unless the Department of Health or the Welsh Assembly Government indicates otherwise, appraisals do not normally include consideration of the use of a technology for indications for which regulatory approval has not been granted in the UK.

Figure 1 Steps in developing the scope.



- 3.2.6 Further refinement of the draft scope may be undertaken at the request of Ministers.
- 3.2.7 Ministers review the proposals of the ACTS together with the corresponding draft remits and scopes and decide on the technologies that they are minded to refer to the Institute for appraisal.

3.3 Consultation

- 3.3.1 The next step is a consultation stage on the scope. This process is initiated once Ministers are minded to refer a 'wave' of topics to the Institute. The Institute then identifies the organisations that might be interested in the appraisal. These fall into two groups: consultees and commentators (see Box 4.1, page 11). The Institute sends the draft remit and draft scope to provisional consultees and commentators, and to the Assessment Group, together with the list of provisional consultees and commentators, for comment. Comments should be submitted to the Institute within 20 working days. The draft scope is also posted on the Institute's website for information.
- 3.3.2 Manufacturers and sponsors are asked to include in their comments on the draft scope any information regarding pending licence applications for their technologies. This must include the timeframe within which regulatory approval is anticipated.

3.4 The scoping workshop

- 3.4.1 After provisional consultees and commentators have submitted their comments on the draft remit and draft scope, a meeting is held to which the Assessment Group, all provisional consultees and commentators, the Department of Health, the Welsh Assembly Government, and other interested parties are invited. A senior member of the appraisals team or one of the Institute's Executive Directors chairs the scoping workshop.
- 3.4.2 The scoping workshop is held approximately 8 weeks after the initiation of the consultation period. The aims of the meeting are to:
 - ▶ ensure that the scope is appropriately defined
 - ▶ discuss the issues raised by consultees and commentators during consultation on the draft scope
 - ▶ identify important data pertinent to the appraisal
 - ▶ ensure that relevant issues are highlighted to the Assessment Group to inform the development of their protocol.
- 3.4.3 It is important that sufficient clinical expertise is fed into the development of the scope.
- 3.4.4 Manufacturers are encouraged to provide preliminary details of the evidence that they would submit to an appraisal.

3.5 Final scope

- 3.5.1 Taking into account comments received on the draft scope and the discussions at the scoping workshop, the Department of Health and the Welsh Assembly Government prepare a final remit and the Institute produces a final scope and a final matrix of consultees and commentators for the appraisal, in anticipation of receiving a formal referral from the Secretary of State for Health and the Welsh Assembly Government.
- 3.5.2 Discussions at the scoping workshop also assist the Assessment Group in developing its protocol for the technology assessment. For further information, see the Institute's *Guide to the Methods of Technology Appraisal*.
- 3.5.3 The final scope is submitted to Ministers for a decision on whether the technology appraisal is suitable for formal referral to the Institute. Occasionally, as a result of the information gathered during scoping, the Department of Health and the Welsh Assembly Government may decide not to refer a technology or group of technologies for which a draft remit and scope have been developed and consulted upon.
- 3.5.4 If Ministers decide that the technology is suitable for referral, the technology is formally referred to the Institute and, at this point, the Institute begins the appraisal process.

4 The appraisal process

Section 4 sets out the appraisal process carried out by the Institute, under the following headings:

- ▶ Starting the appraisal
- ▶ Disclosure of information
- ▶ Process timelines
- ▶ Evidence and assessment
- ▶ Appraisal
- ▶ Appeal
- ▶ Publication.

These sections describe the steps taken at each stage in the appraisal process. Each section contains a table summarising the steps in that stage and the approximate timing of the steps. Figures 2 and 3 (pages 8–10) summarise the appraisal process from its start to the publication of guidance.

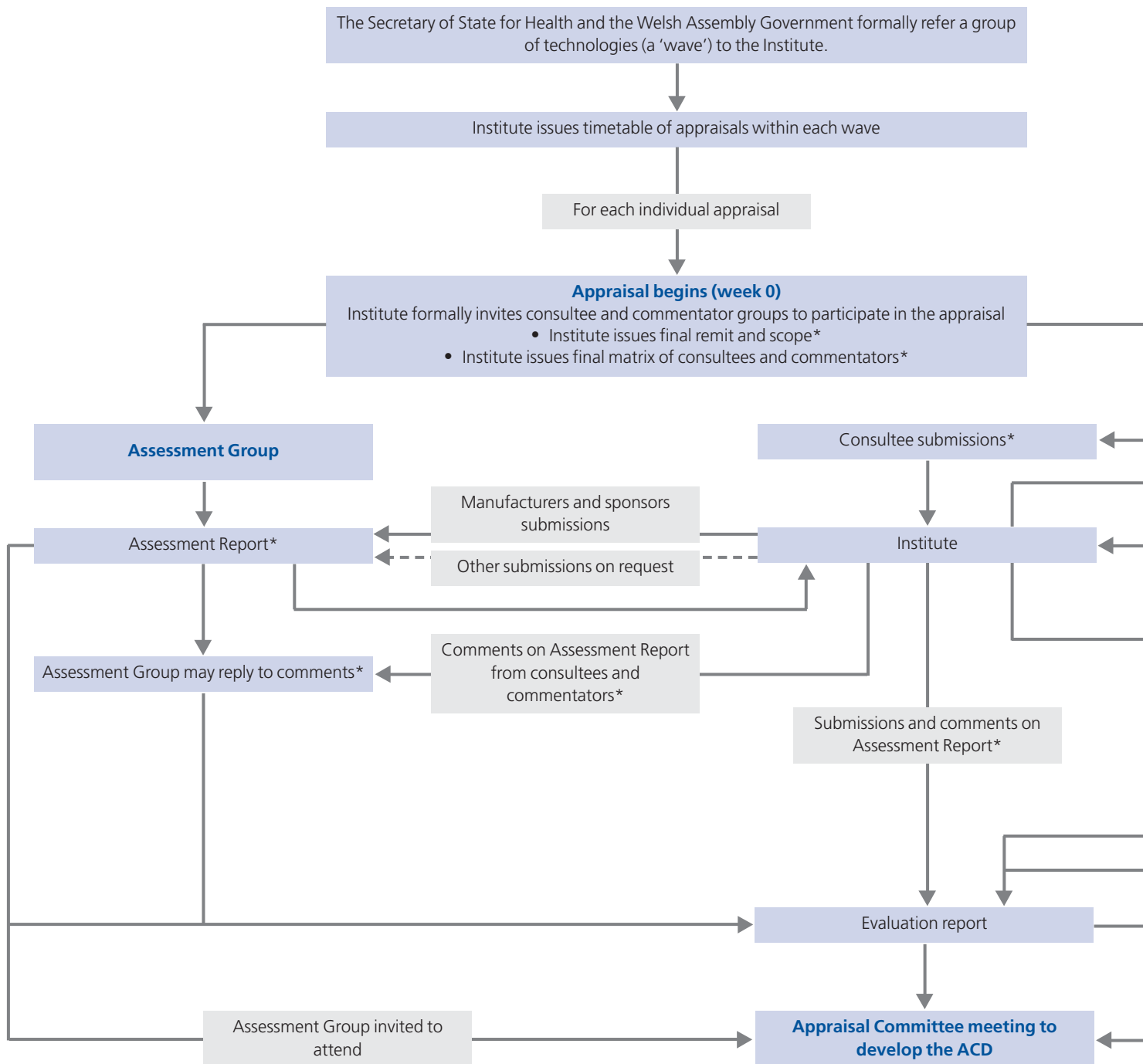
4.1 Starting the appraisal

- 4.1.1 The timeline for an individual appraisal starts (week 0) when the Institute invites consultees and commentators to participate in the appraisal.
- 4.1.2 Topics for appraisal are referred to the Institute in groups, known as ‘waves’. After a wave of topics has been referred, the Institute finalises the list of consultees and commentators who will participate in each appraisal. In order to map appraisals onto the schedule of Appraisal Committee meetings, individual appraisals within each ‘wave’ start at different times. The Institute will normally publish the timetable for all appraisals in each ‘wave’ within 6 weeks of referral.
- 4.1.3 At the start of an individual appraisal, the final remit and final scope (see section 3.5), the name of the Assessment Group and the final matrix of consultees/commentators for the appraisal are posted on the Institute’s website. Each appraisal of a technology is assigned to a project team at the Institute, the members of which are listed on the website. The roles of key members of the project team are summarised in Box 4.1 (page 11).
- 4.1.4 The Assessment Group is formally commissioned to prepare the Assessment Report at the point at which the final scope and matrix are issued. The final scope and final matrix of consultees and commentators are issued to all invited groups with the formal invitation to participate in the appraisal.

4.2 Disclosure of information

- 4.2.1 The Institute will not put into the public domain, nor circulate among consultees, any documents for consultation before the technology concerned has received regulatory approval.
- 4.2.2 The Institute requires manufacturers and sponsors of technologies under appraisal to sign a statement declaring that all relevant material pertinent to the appraisal has been disclosed to the Institute.
- 4.2.3 To ensure that the appraisal process is as transparent as possible, the Institute considers it highly desirable that evidence pivotal to the Committee’s decisions should be publicly available. Ideally, all the evidence seen by the Appraisal Committee should be available to all consultees and commentators. Under exceptional circumstances, unpublished evidence is accepted under agreement of confidentiality. Such evidence includes ‘commercial in confidence’ information and data that are awaiting publication (‘academic in confidence’).

Figure 2 Summary of the appraisal process to development of the Appraisal Consultation Document (ACD).



*Component of the Evaluation Report

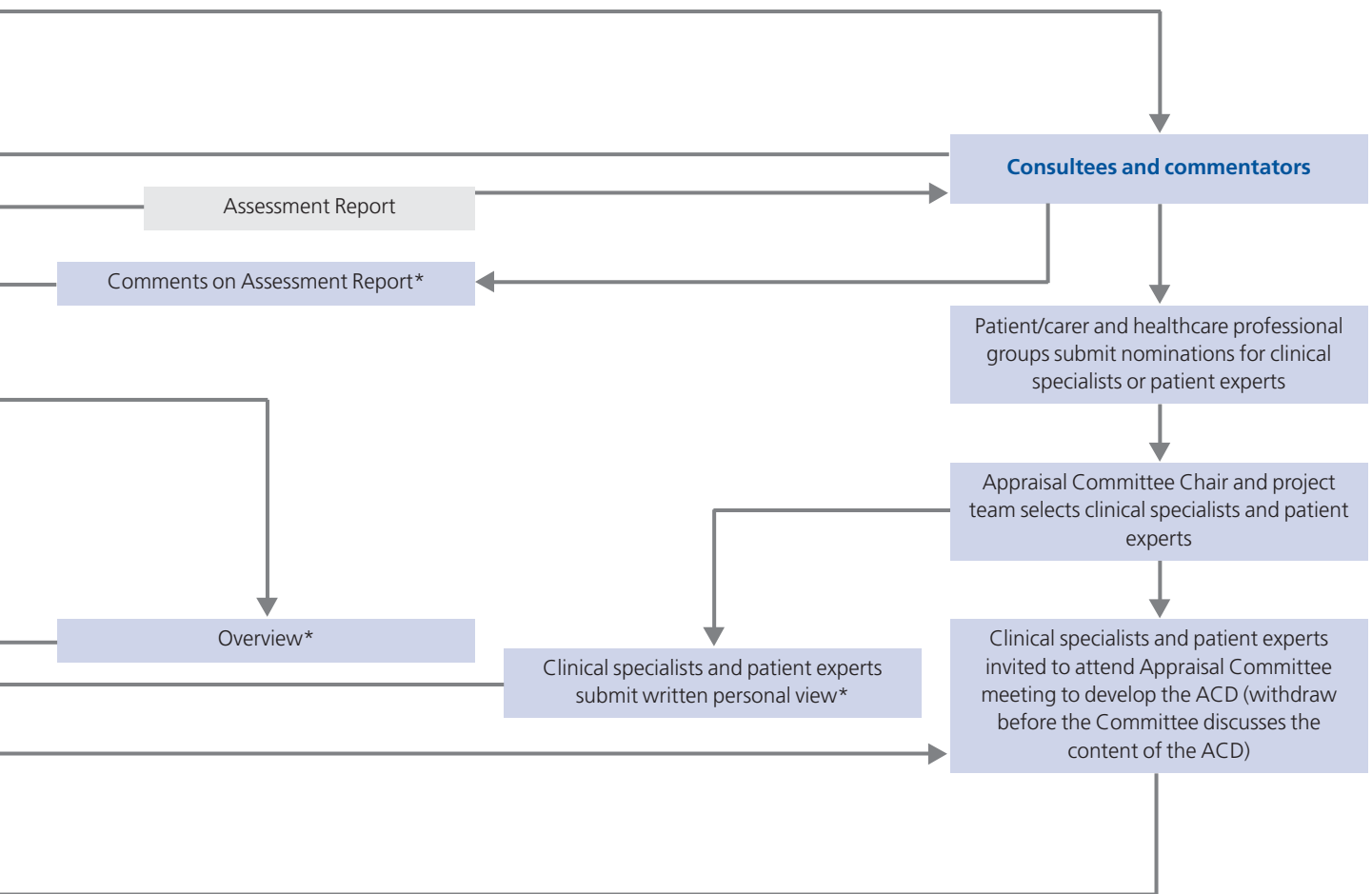
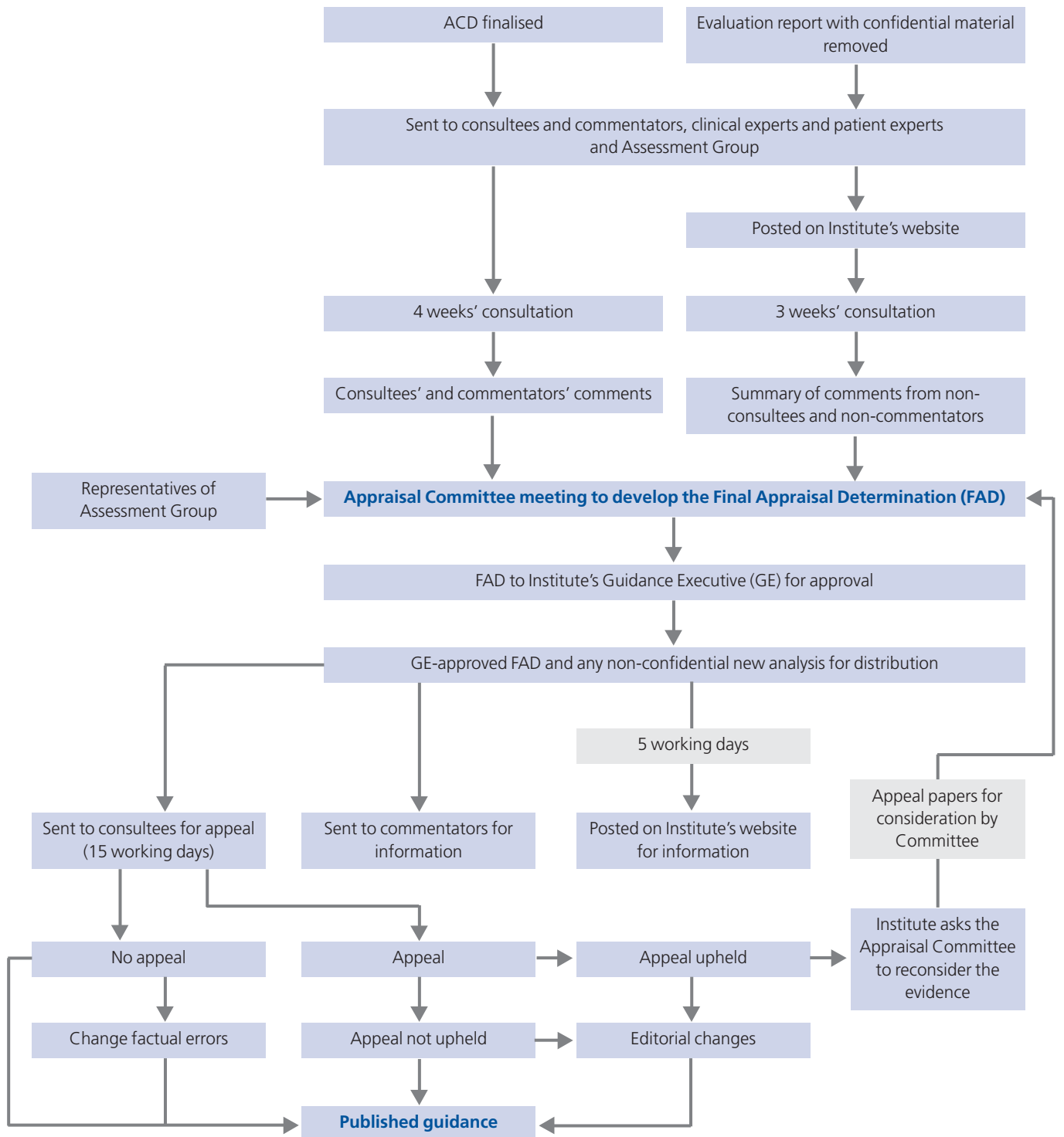


Figure 3 Summary of the appraisal process from consultation on the appraisal consultation document to publication of guidance.



Box 4.1 Key participants in the appraisal process.

Appraisal Committees	Standing advisory committees of the Institute. Members are appointed for a 3-year term and are drawn from the NHS, patient/carer organisations, relevant academic disciplines and the pharmaceutical and medical devices industries. Names of Appraisal Committee members are posted on the Institute's website.
Consultees	Organisations that accept an invitation to participate in the appraisal: the manufacturer(s) or sponsor(s) of the technology; national professional organisations; national patient organisations; the Department of Health and the Welsh Assembly Government; relevant NHS organisations in England and local health boards in Wales. Consultees can participate in the consultation on the draft scope, the Assessment Report and the Appraisal Consultation Document and consultee organisations representing patient/carers and professionals can nominate clinical specialists and patient experts to present their personal views to the Appraisal Committee. All consultees are given the opportunity to appeal against the Final Appraisal Determination (FAD).
Commentators	Organisations that engage in the appraisal process but that are not asked to prepare a submission dossier, and that receive the FAD for information only, without right of appeal. These organisations are: manufacturers of comparator technologies; NHS Quality Improvement Scotland; the relevant National Collaborating Centre (a group commissioned by the Institute to develop clinical guidelines); other related research groups where appropriate (for example, the Medical Research Council [MRC], National Cancer Research Institute); other groups (for example, the NHS Confederation, NHS Information Authority and NHS Purchasing & Supplies Agency, the <i>British National Formulary</i> , and the British Medical Association).
Assessment Group	An independent academic group (commissioned by the NHS Research and Development Health Technology Assessment Programme [HTA Programme] to assist in the appraisal) prepares an Assessment Report on the health technology (a review of the clinical and cost effectiveness of the technology(ies) based on a systematic review of the literature and a review of manufacturer and sponsor submissions to the Institute) – see section 4.4.1.
Institute staff	
Appraisal Programme Director	The Appraisal Programme Director (APD) is responsible for the delivery of the appraisal programme. In addition to, and in conjunction with, the Executive Lead, the APD is responsible for signing off consultation documents at various stages of an individual appraisal. The APD is also responsible for ensuring that appraisals are conducted in accordance with the published appraisal process and methodology.
Technology Appraisals Project Manager	The Project Manager is responsible for planning individual appraisal timelines, ensuring the timeline and process are followed, and liaising with consultees, commentators and other individuals and organisations contributing to the appraisal.
Technical Lead	The Technical Lead is responsible for the technical aspects of the appraisal, including liaising with the Assessment Group, scoping the appraisal, preparing drafts of consultation documents and advising the Appraisal Committee on technical aspects of the appraisal. There may be more than one Technical Lead for an appraisal.
Executive Lead	The Executive Lead is responsible for steering the appraisal through the stages of the process, resolving policy issues and for signing off documents for consultation.
Communications Lead	The Communications Lead is responsible for disseminating and communicating the technology appraisal guidance to the appropriate groups within the NHS in England and Wales, and to patients and the public, and for ensuring that the guidance is available on the NICE website when it is released.

- 4.2.4 The Institute expects consultees to keep confidential material within a submission to an absolute minimum. When a consultee believes that part of a submission needs to be treated as confidential, the rationale for doing so should be clearly stated and should be consistent with the principles set out below.
- ▶ Information that has been put into the public domain, anywhere in the world, may not be marked as confidential.
 - ▶ The results of clinical trials submitted for appraisal that relate to products that have received regulatory approval should be available for scrutiny. When it has been decided that release of trial results will occur through a journal publication, at a date later than the first release by the Institute of documentation quoting data from the trial, as a minimum, a structured abstract should be made available for public disclosure. The content of the structured abstract should be a synopsis derived from a recognised format for a full trial report such as that provided by the CONSORT statement (www.consort-statement.org).
 - ▶ The same principles apply to the release of information submitted in the form of economic models. The full economic model, in electronic format, should be available for scrutiny by the Institute and the Assessment Group. A structured abstract of economic models submitted by consultees should, as a minimum, be made available for public disclosure.
- 4.2.5 The Institute asks consultees to reconsider restrictions on release of data when either there appears to be no obvious reason for the restrictions, or such restrictions would make it difficult or impossible for the Institute to show the evidential basis for its guidance.
- 4.2.6 Confidential information submitted by consultees is made available for review by the Assessment Group and the Appraisal Committee and the clinical specialists and patient experts invited to attend the Appraisal Committee meeting. Confidential information may be distributed to consultees with permission from the data owners.
- 4.2.7 The documents that are released to consultees and commentators during the appraisal process are shown in Box 4.2. The Institute posts these documents on its website at least 5 working days after they have been sent to consultees and commentators. These documents are not considered confidential when they are posted on the website.

Box 4.2 Documents made available by the Institute during the appraisal.

Document	For further information see section:
Appraisal remit and scope	3
Matrix of consultees and commentators	4.1
Assessment protocol	4.4.1
*Evaluation Report	4.5.1
*Appraisal Consultation Document (ACD)	4.5.2
*Comments from consultees and commentators on the ACD	4.5.3
*Summary of comments received via the web on the ACD	4.5.3
*Table prepared by the Technical Lead, showing the Institute's responses to comments received on the ACD	4.5.4
*Final Appraisal Determination (FAD)	4.5.4
*Documents are released to consultees and commentators who have signed a confidentiality agreement before they are published on the website.	

- 4.2.8 The Institute hopes that consultees will take steps to ensure that their individual submissions are made available – for example, by placing the submission on the consultee’s own website.
- 4.2.9 The Institute will not comment on the content of an appraisal until the process has been completed and its guidance has been produced, other than in the circumstances set out below.
- ▶ If there has been an unauthorised disclosure from a confidential document, the Institute reserves the right to make public comment. The decision to do so will be taken by the Chair or Vice Chair of the Institute on the recommendation of two Executive Directors. Consultees and commentators will be informed of this decision as soon as possible after it has been taken.
 - ▶ If a public comment on the Appraisal Consultation Document (ACD) or Final Appraisal Determination (FAD) is made that misleads or misinforms other consultees or the public, the Institute reserves the right to issue a correction.
- 4.2.10 Organisations participating in an appraisal are required to sign a confidentiality agreement before they are recognised as formal consultees and commentators and appraisal documentation is released to them.
- 4.2.11 It is the responsibility of the consultees and commentators, and any other party that has signed a confidentiality agreement for the appraisal, to keep documents not otherwise in the public domain confidential and secure at all times. The Institute considers individuals within a consultee or commentator organisation who see appraisal documentation to be bound by the terms of the confidentiality agreement signed by the consultee or commentator organisation.
- 4.2.12 Consultees and commentators must not disclose confidential appraisal documents until the time that the Institute makes documents public.
- 4.2.13 Any organisation or individual not in the direct employment of the consultee or commentator organisation is a third party. Consultees and commentators may release the appraisal documentation to third parties when:
- ▶ this is clearly necessary to enable the consultee or commentator to formulate its contribution to the appraisal, and
 - ▶ the third party has seen and agreed to be bound by the terms of the confidentiality agreement.
- 4.2.14 Consultees and commentators may discuss confidential appraisal documentation with other consultees and commentators but, before doing so, each consultee or commentator must be satisfied that the others have signed and returned their confidentiality agreements to the Institute.
- 4.2.15 The Institute reserves the right to use in its Evaluation Report, ACDs and FADs any material that is submitted to it during the course of an appraisal that is not designated by the consultee as being ‘confidential’, or which ceases to be so under 4.2.5 and 4.2.6. Reference will be made in the Evaluation Report to the existence of documents that have been designated as confidential by the originator.

4.3 Process timelines

- 4.3.1 It is not possible to set absolute timescales for all stages of the process. The length of time needed for each stage of the appraisal can vary depending on the nature of the particular appraisal. The timings set out in Boxes 4.3, 4.4 and 4.5 are indicative of the minimum number of weeks that elapse for each part of an appraisal as it goes through the process.
- 4.3.2 Certain time limits and consultation periods are normally fixed. Consultees and commentators are provided with key dates for each appraisal with their invitation to participate.
- 4.3.3 Throughout an appraisal, up-to-date information about timing and progress is available on the Institute’s website, and further information and clarification are available from the Project Manager.
- 4.3.4 The Institute will advise consultees and commentators at the earliest opportunity of any extension to the timelines for an appraisal and the reason(s) for that extension.

4.4 Evidence and assessment

4.4.1 Assessment Report

- 4.4.1.1 Once the draft scope of the appraisal has been defined, the Institute asks the NHS Research and Development Health Technology Assessment Programme (HTA Programme) to commission an Assessment Report. The HTA Programme commissions the Assessment Report from one of a number of academic centres. Occasionally, the Assessment Report may be commissioned from another source.
- 4.4.1.2 The Assessment Group begins its task by developing a protocol. The protocol is derived from the scope of the appraisal, which is informed by the comments from organisations invited to attend the scoping workshop.
- 4.4.1.3 The HTA Programme and the Institute sign off the final assessment protocol after the technology has been referred to the Institute. The assessment protocol is available within 3 weeks of the start of an individual appraisal.
- 4.4.1.4 The Assessment Group prepares an Assessment Report – a review of the clinical and cost effectiveness of the technology or technologies based on a systematic review of the literature and a review of manufacturer and sponsor submissions to the Institute. The Assessment Report may include a de novo assessment of cost effectiveness. Further details can be found in the Institute's *Guide to the Methods of Technology Appraisal*.
- 4.4.1.5 The Assessment Report is prepared in accordance with the quality criteria of the HTA Programme (www.hta.nhsweb.nhs.uk) and a defined template. The content and quality of the Assessment Report are the responsibility of its authors. The Assessment Group does not propose recommendations on the use of the technology for the NHS – the Institute is responsible for developing the recommendations that form the guidance on the use of the technology that is issued to the NHS in England and Wales. The recommendations are informed by the Assessment Report and other evidence submitted and comments made by consultees and commentators.
- 4.4.1.6 The Assessment Report is submitted to NICE and is used as the basis of the appraisal. The Assessment Group may further develop the report for subsequent publication as a topic within the monograph series *Health Technology Assessment* (www.soton.ac.uk/~hta).
- 4.4.1.7 Once the Institute has received the Assessment Report, it contacts consultees and commentators by email to let them know when they can expect to receive their copy of the report.
- 4.4.1.8 The Institute sends the Assessment Report, with any confidential material removed, to consultees and commentators for their comments. Consultees and commentators have 20 working days to submit their comments on the Report to the Institute. These comments are presented to both the Assessment Group and the Appraisal Committee and later published as part of the Evaluation Report.
- 4.4.1.9 The Assessment Group may produce an economic model in support of the Assessment Report. If the model does not contain information that was designated as confidential in the submission, the Institute offers consultees and commentators the opportunity to receive by email a read-only version of the model, for information only. Requests for the model must be made in writing, and it is supplied on the basis that the consultee or commentator agrees, in writing, to the following conditions for its use.
- The economic model and its contents are confidential and are protected by intellectual property rights, which are owned by the relevant Assessment Group. It cannot be used for any purpose other than to inform the recipient's understanding of the Assessment Report.
 - The model must not be re-run with alternative assumptions or inputs.
 - The consultees or commentators will not publish the model wholly or in part, or use it to inform the development of other economic models.
- 4.4.1.10 The Institute sends the Assessment Report to consultees and commentators again after the Appraisal Committee meeting as part of the Evaluation Report supporting the Appraisal Consultation Document (ACD) (see section 4.5.2). Consultees and commentators may include any

further comments on the Report with their comments on the ACD under a separate heading. These comments are also presented in full to both the Assessment Group and the Appraisal Committee.

- 4.4.1.11 The Assessment Report, together with consultee and commentator responses on the report, is posted on the Institute's website at the same time as the ACD (see section 4.5.2).

4.4.2 Consultee submissions

- 4.4.2.1 When the appraisal begins, all consultees are invited to make submissions to the Institute. The Institute does not accept unsolicited submissions (that is, from parties other than consultees).
- 4.4.2.2 The Institute does not issue guidance on a technology before it receives UK regulatory approval. The Institute will not issue documents for consultation (including Assessment Reports) until regulatory approval has been granted. Some appraisals begin before UK regulatory approval for one or more of the products involved has been granted. In such cases, the appraisal of the product or products concerned will only proceed past the point that the Assessment Report is released to consultees, once regulatory approval in the UK has been granted. The appraisal of products that do have regulatory approval will continue. The manufacturer(s)/sponsor(s) of technology(ies) for which the appraisal has been suspended will be invited to become commentators.
- 4.4.2.3 Consultees have at least 14 weeks to prepare their submissions.
- 4.4.2.4 Consultee groups representing patient/carer organisations and patient experts are offered support from the Patient Involvement Unit throughout the assessment and appraisal phases (that is, up to the point of issue of the FAD).
- 4.4.2.5 The Institute offers consultee groups representing patients/carers and healthcare professionals a financial contribution towards the cost of participating in the appraisal. Payments will normally be made only into a corporate bank account of the consultee organisation. Exceptionally, a payment may be made into a personal bank account but only after written authorisation to do so has been received from the consultee organisation.
- 4.4.2.6 Submissions from manufacturers and sponsors are forwarded to the Assessment Group to inform the preparation of the Assessment Report. Submissions from other consultees are also made available to the Assessment Group on request.
- 4.4.2.7 Further advice about the general structure and content of submissions is available in the specific guides for groups participating in an appraisal (see Foreword, page ii).
- 4.4.2.8 Consultees preparing submissions may contact the Assessment Group and vice versa, in order to make and respond to technical enquiries. The Institute prefers communications between consultees and the Assessment Group to be by email. The Institute's Technical Lead and Project Manager must be copied into all communications between the consultees and the Assessment Group. Under exceptional circumstances, the Institute will organise a face-to-face meeting between two parties to discuss technical issues. Such meetings will only be arranged when issues involved cannot be resolved by other means.
- 4.4.2.9 The Institute does not review or approve submissions during their preparation.

4.4.3 Participation of clinical specialists and patient experts

- 4.4.3.1 While the Assessment Report is being commissioned and prepared, and consultees are preparing their submissions, the Institute begins to organise the next stage of the process – the meetings of the Appraisal Committee. All healthcare professional groups and patient/carer groups that are consultees or commentators for the appraisal are invited to nominate clinical specialists or patient experts to take part in the first Appraisal Committee meeting.
- 4.4.3.2 Clinical specialists and patient experts are chosen from the nominations by the Chair of the Appraisal Committee in discussion with the Institute's project team on the basis of the extent and nature of their experience of the technology, the disease and the services provided by the NHS to patients with the condition(s) that the technology is designed to treat. Clinical specialists and

patient experts are invited to attend meetings of the Appraisal Committee on the following conditions.

- ▶ They agree to be bound by the terms and conditions of the Institute's Confidentiality Acknowledgement and Undertaking.
 - ▶ They agree to their name and affiliation appearing on the ACD and the final guidance.
 - ▶ They are prepared to declare, at the Appraisal Committee's meeting, any interests they have in the technology under appraisal.
 - ▶ They have no other conflict of interest that might preclude their involvement with the appraisal.
- 4.4.3.3 Additionally, the following criteria are used to inform the selection of clinical specialists.
- ▶ They are in active clinical practice and have specialist expertise in the particular area of the appraisal.
 - ▶ Their principal place of work is within the NHS.
 - ▶ They hold no official office (that is, no paid employment, unpaid directorship or membership of a standing advisory committee) with any of the manufacturers of the technology or any manufacturer of a directly competing technology.
- 4.4.3.4 Usually, two clinical specialists and two patient experts are selected. They are asked to submit a short (maximum of four pages), written personal view on the technology and the way it should be used in the NHS in England and Wales. The written personal views are put before the Appraisal Committee and made available during the period of consultation on the ACD as part of the Evaluation Report. Further advice about the contribution of clinical specialists and patient experts is available in the specific guides for groups participating in an appraisal.
- 4.4.3.5 The Institute informs consultees and commentators of the names and affiliations of the selected clinical specialists and patient experts invited to take part in the Appraisal Committee meeting. This information is also posted on the NICE website.

Box 4.3 Timeline for the appraisal process: starting the process and preparing the Assessment Report*.

		Weeks (approx.) since process began
Step 1	Organisations invited to participate in the appraisal as consultees or commentators	0
Step 2	Submissions from consultees received	14
Step 3	Submissions from manufacturers and sponsors sent to the Assessment Group	15
Step 4	Selected clinical specialists and patient experts invited to attend Appraisal Committee meeting and asked to submit a written personal perspective	16
Step 5	Assessment Report received by Institute	28
Step 6	Assessment Report sent to consultees and commentators for comment	30
Step 7	Selected clinical specialists and patient experts submit written personal perspectives	32
Step 8	Comments on Assessment Report from consultees and commentators received by Institute	34
Step 9	Evaluation Report compiled and sent to Appraisal Committee	36
*Timelines may change in response to individual appraisal requirements.		

4.5 Appraisal

The Appraisal Committees are standing advisory committees of the Institute constituted to encompass the full range of perspectives on the use of a technology in the NHS. Members of the Appraisal Committees are appointed for a 3-year term and are drawn from the NHS, patient/carer organisations, relevant academic disciplines and the pharmaceutical and medical devices industries. Each Committee considers its own list of technologies – ongoing topics are not moved between the Committees. Further information about the current composition and membership of the Institute’s Appraisal Committees is available on the Institute’s website.

The appraisal stage of the process consists of four elements:

- consideration of the evidence at an Appraisal Committee meeting to develop an ACD
- preparation of and consultation on the ACD
- review of the ACD in the light of comments from consultation at a second Appraisal Committee meeting
- preparation of the FAD.

4.5.1 Appraisal Committee meeting to develop the ACD

- 4.5.1.1 At the meeting to develop the ACD, the Appraisal Committee undertakes its initial consideration and discussion about the evidence on a technology. More information about how the Appraisal Committee considers the evidence and makes its decision is available in the *Guide to the Methods of Technology Appraisal*. The written evidence is provided in the form of the Evaluation Report and the oral evidence is drawn from discussions with invited clinical specialists and patient experts and the Assessment Group representatives. The consideration of the evidence leads to the development of the ACD, which sets out the provisional views of the Appraisal Committee.
- 4.5.1.2 Comments from consultees on the Assessment Report may lead to a decision to undertake additional analysis before the Committee meeting to develop the ACD. The additional analysis is incorporated into the Evaluation Report for distribution with the ACD (see section 4.5.2).
- 4.5.1.3 Usually, additional analysis will be completed in time for the scheduled Committee meeting, but when this cannot be achieved, the Institute may extend the timelines for the appraisal. The Institute will advise consultees and commentators at the earliest opportunity of any extension to the timelines for an appraisal and the reason(s) for that extension.
- 4.5.1.4 In preparation for the meeting, an Evaluation Report (the Committee papers) is circulated to the Appraisal Committee and the clinical specialists and patient experts invited to attend the meeting. The Evaluation Report comprises:
- the final scope of the appraisal and the final list of consultees and commentators
 - the full Assessment Report, containing confidential material, and any supplements to it
 - comments from consultees and commentators on the Assessment Report
 - an overview written by the Institute’s Technical Lead for the appraisal
 - the full submissions from the professional, patient/carer and NHS organisation consultees
 - the executive summaries of the manufacturer or sponsor submissions (the full manufacturer submissions are available to the Committee)
 - the written perspectives of the patient experts and clinical specialists attending the Appraisal Committee meeting
 - the Assessment Group’s written response, if any, to the comments on the Assessment Report
 - supplementary analysis, if any, undertaken on behalf of the Institute.
- 4.5.1.5 The agenda for the meeting is normally published on the Institute’s website 5 working days before the meeting takes place.
- 4.5.1.6 The Appraisal Committee invites selected clinical specialists and patient experts to inform their consideration of the technology (see section 4.4.3).
- 4.5.1.7 Patient experts and clinical specialists are asked to submit, before the meeting, a written personal view of the role of the technology, particularly providing insights not available in the published

literature. Further details on these submissions can be found in the Institute's *Guide to the Methods of Technology Appraisal*.

- 4.5.1.8 At the Appraisal Committee meeting, two members of the Appraisal Committee (the 'Lead Team') make a brief presentation to the other members to introduce the topic of the appraisal. The presentation usually has the following format:
- ▶ overview of the condition for which the technology is indicated, including the epidemiology and pathophysiology relevant to the Appraisal Committee's considerations
 - ▶ overview of the technology and its place in the pathway of care for the condition and relevant alternative treatments/comparators
 - ▶ overview of the evidence on clinical effectiveness
 - ▶ overview of the evidence on cost effectiveness and, where appropriate, clarification and critique of the economic models received
 - ▶ identification of issues of importance for consideration by the Appraisal Committee to facilitate the discussion.
- 4.5.1.9 The presentation does not pre-empt the Committee's debate or the formulation of the guidance.
- 4.5.1.10 The clinical specialists and patient experts then have the opportunity to comment on the technology and its use in the NHS. Clinical specialists and patient experts are encouraged to interact fully in the debate with the Committee, including both responding to and posing questions. The clinical specialists and patient experts are asked to withdraw from the meeting before the Committee discusses the content of the ACD.
- 4.5.1.11 Representatives of the Assessment Group also attend the meeting and may bring with them a written response to issues on the Assessment Report raised in the comments from the consultees and commentators. The Appraisal Committee may seek further clarification from the Assessment Group representatives on the Assessment Report and discuss relevant issues raised through the consultation on the Assessment Report. Assessment Group representatives are encouraged to interact fully in the debate with the Committee. Assessment Group representatives may remain present during Committee discussions in order to answer any further questions the Committee may have; however, they play no part in decision-making. The Committee may decide that additional analysis of the evidence is needed.
- 4.5.1.12 Representatives from the National Collaborating Centre that is responsible for developing the Institute's clinical guidelines in areas related to the topic under appraisal are also invited to attend the meeting to observe and to contribute as advisors to the Committee.
- 4.5.1.13 The Appraisal Committee concludes the discussions of the technology and agrees the content of the ACD that sets out its provisional recommendations. The NICE project team drafts the ACD according to the instructions of the Appraisal Committee.
- 4.5.1.14 The minutes of an Appraisal Committee meeting provide the Committee with an accurate record of its proceedings and discussions and also inform the public of the matters discussed at the meeting. The minutes include a list of attendees.
- 4.5.1.15 Unconfirmed minutes of the Appraisal Committee meeting are posted on the Institute's website within 15 working days of the meeting. Confirmed minutes are posted on the website when they have been approved by the Committee (normally within 8 weeks of the meeting).

4.5.2 Consultation on the ACD

- 4.5.2.1 The ACD summarises the evidence and views that have been considered by the Appraisal Committee and sets out preliminary recommendations.
- 4.5.2.2 The ACD does not constitute the Institute's final guidance for a technology. The recommendations made are provisional and may change in response to consultation.
- 4.5.2.3 The Institute contacts consultees and commentators by email after the Appraisal Committee meeting to let them know when they can expect to receive their copy of the ACD.
- 4.5.2.4 The Institute usually circulates the ACD to consultees and commentators 15 working days after

the Appraisal Committee meeting. In exceptional circumstances, this may take longer. If the Institute expects a delay, consultees and commentators will be informed as soon as possible.

- 4.5.2.5 The ACD usually contains the following elements:
- ▶ the Appraisal Committee's preliminary views and provisional recommendations for guidance to the NHS on the technology and how it should be used
 - ▶ a description of clinical need and practice in the relevant disease area
 - ▶ a description of the technology, including its principal characteristics, licensed indication and dosage, mode of action, and cost per item or cost per course of treatment
 - ▶ a summary of the evidence available to the Appraisal Committee
 - ▶ a summary of how the Appraisal Committee has interpreted the evidence
 - ▶ a preliminary assessment of the impact on NHS resources if the provisional recommendations were to be implemented
 - ▶ proposed recommendations for further research
 - ▶ proposals for implementation and audit based on the recommendations
 - ▶ related NICE publications existing or in development
 - ▶ proposed date for review of guidance.
- 4.5.2.6 The ACD, together with the Evaluation Report (with confidential material removed), is sent to consultees and commentators and the clinical specialists and patient experts for consultation, and to the Assessment Group.
- 4.5.2.7 Consultees and commentators have 4 weeks in which to submit comments on the ACD. The purpose of the consultation is to gather comments on the Appraisal Committee's provisional views and to determine whether the recommendations within the ACD are an appropriate interpretation of the evidence considered. Consultees and commentators are invited to comment on:
- ▶ whether all the evidence available to the Committee has been appropriately taken into account
 - ▶ whether the summaries of clinical effectiveness and cost effectiveness are reasonable interpretations of the evidence
 - ▶ whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS
 - ▶ whether the preliminary views on the impact on resources and implications for the NHS are appropriate.
- 4.5.2.8 Comments from consultees and commentators must be submitted to the Institute in writing, preferably by email. The Institute reserves the right not to consider comments received after the close of consultation.
- 4.5.2.9 The ACD, with an electronic comment facility, and the Evaluation Report, with confidential material removed, are posted on the Institute's website 5 working days after they have been circulated to consultees and commentators. A summary of comments received through the website consultation is submitted to the Appraisal Committee for consideration. (Note that the website comment facility must not be used by consultees and commentators to submit their comments on the ACD.)
- 4.5.2.10 At the ACD stage, new data will be accepted only if they are likely to materially affect the provisional recommendations in the ACD, and only by prior agreement with the Appraisal Programme Director. The new data must be presented in an appendix to the comments on the ACD. If new data are submitted, the timeline before the next Appraisal Committee meeting may need to be extended to allow for further assessment.
- 4.5.2.11 When new data submitted by consultees and commentators lead to a substantial revision of the ACD, the Appraisal Programme Director, the Chair of the Appraisal Committee and the Executive Lead will decide whether it is necessary to prepare another ACD. If so, the consultation process will be repeated. The decision to produce another ACD will extend the timeline for the appraisal. The additional evidence will be circulated with the new ACD.

4.5.3 Appraisal Committee meeting to develop the FAD

- 4.5.3.1 The Appraisal Committee meets again to consider the ACD in the light of the comments received. Before the meeting, the Committee members receive the full text of the comments from the consultees and commentators and a summary of comments received through the website consultation. Representatives of the Assessment Group and the relevant National Collaborating Centre are invited to attend the meeting. If clarification of issues raised during the consultation period is required, the Chair of the Appraisal Committee can, at his or her discretion, invite one or more of the experts, consultee or commentator organisations to attend part of the meeting.
- 4.5.3.2 The Appraisal Committee completes its discussion of the technology and agrees the content of the FAD that sets out its final recommendations. The NICE project team drafts the FAD according to the instructions of the Appraisal Committee.
- 4.5.3.3 The agenda for the meeting is normally published on the Institute's website 5 working days before the meeting takes place.
- 4.5.3.4 A list of attendees is made available to the public in the minutes of the meeting.
- 4.5.3.5 Unconfirmed minutes of the meeting are posted on the Institute's website within 15 working days of the meeting and confirmed minutes are posted on the website when they have been confirmed by the Appraisal Committee, normally within 8 weeks of the meeting date.

4.5.4 Distribution of the FAD

- 4.5.4.1 After the Appraisal Committee meeting, the Institute contacts consultees and commentators by email to let them know when they can expect to receive their copy of the FAD.
- 4.5.4.2 The Institute usually circulates the FAD within 30 working days after the Appraisal Committee meeting. The Institute will notify consultees and commentators if it expects a delay in the circulation of the FAD.
- 4.5.4.3 The comments on the ACD received from consultees and commentators and a summary of the comments received through the website consultation, together with a summary table of these comments and the action taken in response to them, is supplied with the FAD when it is sent to consultees and commentators. This information will also be posted on the Institute's website at the same time as the FAD.
- 4.5.4.4 In exceptional circumstances – for example, if a relevant report is published while the FAD is being developed or as a consequence of comments from consultees or commentators – the Institute or the Assessment Group may undertake further analysis before the circulation of the FAD. Any such analysis will be distributed to consultees and commentators and posted on the Institute's website at the same time as the FAD.
- 4.5.4.5 When the FAD is posted on the website, the Institute also posts the summary table of comments on the ACD with the Institute's responses.

4.5.5 Guidance Executive

- 4.5.5.1 The Appraisal Programme Director and the Executive Lead undertake a final review, sign off the FAD and submit a report to the Institute's Guidance Executive. The Guidance Executive, which comprises the Institute's Executive Directors and the Institute's Programme Directors, approve the FAD for publication on behalf of the Board.

4.5.6 Publication of the FAD

- 4.5.6.1 Following approval by the Guidance Executive, the FAD is issued to consultees so that they can consider whether to appeal. Commentators are sent the FAD for information only. The FAD will be posted on the Institute's website for information 5 working days later. New, non-confidential data submitted by consultees and commentators or further analysis undertaken by the Institute or the Assessment Group during development of the FAD will be distributed to consultees and commentators and will be posted on the Institute's website with the FAD. Subject to any appeal by consultees, the FAD will form the Institute's guidance on the use of the appraised technology.

- 4.5.6.2 The Guidance Executive will correct any factual errors in the FAD before it is published as guidance.

Box 4.4 Timeline for the appraisal process: appraisal*.

		Weeks (approx.) since process began
Step 10	Appraisal Committee meeting to develop an ACD, attended by patient experts and clinical specialists	37
Step 11	ACD produced and distributed. ACD posted on Institute's website 5 working days later	40
Step 12	Fixed 4-week consultation period on ACD	40–43
Step 13	Appraisal Committee meeting to consider comments on ACD from consultees and commentators and comments received through the consultation on the Institute's website. Appraisal Committee agrees the content of the FAD	45
Step 14	FAD produced and distributed. FAD posted on Institute's website 5 working days later	51
*Timelines may change in response to individual appraisal requirements.		

4.6 Appeal

- 4.6.1 Consultees are given 15 working days from receipt of the FAD in which to lodge an appeal. The details of the Institute's appeal process are set out in a separate document (*Technology Appraisal Process: Guidance for Appellants*) and the following is only a brief summary of the process. Any appeal must be in writing and must be lodged with the Institute by the deadline and in the manner indicated in the guidance for appellants. Appeals are heard by the Institute's Appeal Panel.
- 4.6.2 It is not possible to appeal against the FAD simply because the appellant does not agree with it. An appeal is not an opportunity to reopen arguments and issues upon which the Appraisal Committee has reached a determination. The Appeal Panel will not substitute its own judgement for that of the Appraisal Committee or look afresh at the evidence submitted to the Appraisal Committee, and will almost certainly not accept new evidence.
- 4.6.3 The Appeal Panel will not consider appeals unless the grounds for appeal are appropriate and fall within one or more of the following categories.
- ▶ The Institute has failed to act fairly and in accordance with its published procedures.
 - ▶ The FAD is perverse in the light of the evidence submitted.
 - ▶ The Institute has exceeded its powers.
- 4.6.4 The Board of the Institute will appoint the members of the Appeal Panel. The Panel will comprise five members drawn from the Institute's Appeals Committee. This Committee, which will be chaired by the Vice Chair of the Institute, will consist of all those who may be asked by the Institute to sit on its appeal panels. Members of the Panel will have had no previous involvement in the appraisal in question. The Panel will consist of one Non-Executive Director of the Institute who will chair the appeal, two further Non-Executive Directors of the Institute or one further Non-Executive Director of the Institute and one member from within the NHS, one member with experience of the relevant industry or clinical field and one member with experience of patient or carer organisations.
- 4.6.5 The Institute will inform the appellant(s) of the membership of the Appeal Panel as soon as possible after an appeal has been lodged and will endeavour to hear an appeal within 10 weeks of the appeal being lodged.

- 4.6.6 The Appeal Panel will consider the appellant’s representations in public. Submissions by appellants will be made in the presence of the other appellants, the public and the press unless there are issues of confidentiality. For further information about appeal procedures for submissions that contain confidential information, see *Technology Appraisal Process: Guidance for Appellants*.
- 4.6.7 The Appeal Panel will endeavour to send its decision to the Institute within 21 days of the hearing, but there may be circumstances in which a longer interval is necessary. The Institute’s Guidance Executive will then consider the Appeal Panel’s decision.
- 4.6.8 If the appeal is upheld and it is necessary for the FAD to be returned to the Appraisal Committee, the Institute will inform consultees, including the appellants, of the arrangements for doing so. In most cases the appraisal process will resume at Step 13 (see Box 4.4, page 21), as described in section 4.5.3.
- 4.6.9 If the appeal is dismissed, or if it is upheld but it is not necessary to refer the FAD back to the Appraisal Committee, the Guidance Executive will consider any editorial changes to be made in response to the decision before issuing its guidance to the NHS. Arrangements will then be made to publish the decision of the Appeal Panel together with the guidance to the NHS in accordance with the Institute’s monthly publication schedule (see section 4.7). Consultants, including appellants will be informed of the date of publication and will receive the decision of the Appeal Panel 2 working days in advance of its publication.

Box 4.5 Stages in the appeals process*.

Step 15	Any appeals lodged (fixed 15 working day period).
Step 16	If necessary, Appeal Panel convened by the Institute.
Step 17	If necessary, Appeal Panel hearing.
Step 18	Appeal Panel decision received by the Institute.
Step 19	Appeal Panel’s decision considered by the Guidance Executive.
Step 20	FAD referred back to the Appraisal Committee (usually to Step 13) or arrangements made for publication of the guidance to the NHS (with or without editorial changes) together with the Appeal Panel decision.
Step 21	Consultees, including appellants, are informed of the guidance publication date and receive the decision of the Appeal Panel 2 working days in advance of its publication.
*Timelines for the appeals stage vary and are set at the time appeals are lodged.	

4.7 Publication

- 4.7.1 If there is no appeal, an appeal is dismissed, or an appeal is upheld but the FAD does not need to be referred back to the Appraisal Committee, the Institute makes arrangements for the guidance to be published. Publication takes place on the fourth Wednesday of each month. The elapsed time between the appeal decision and the FAD being cleared through the Guidance Executive and publication of the guidance is a function of the time needed to prepare documents for publication and will vary.
- 4.7.2 Where it is necessary, following an appeal, for the FAD to be returned to the Appraisal Committee, the appeal decision will be published within 3 weeks of its consideration by the Guidance Executive, along with the arrangements for consideration by the Committee. In these circumstances consultees, including appellants, will be informed of the appeal decision and arrangements for further consideration at least 2 working days in advance of its publication.
- 4.7.3 The Institute’s technology appraisal guidance, including a lay version, is available on the Institute’s website.

5 Updating technology appraisal guidance (reviews)

- 5.1 When the Institute publishes its guidance, it will indicate the date on which the guidance will be considered for review. This date is referred to as the 'review date'. The date refers to the month and year in which the Institute will consult with relevant organisations on proposals for reviewing the guidance.
- 5.2 The length of time between the issue of the guidance and the review date will vary depending on the anticipated rate of development in the evidence for the technology, and on prior knowledge of when pivotal ongoing research is to be reported. Experience to date shows that this period varies from 1 to 5 years. The Institute has standardised its arrangements for determining appropriate review dates (see Box 5.1).

Box 5.1 Criteria for the assignment of a technology appraisal review date.

Evidence base	Review date
Rapid change anticipated	1 year
Change anticipated	3 years
Known pivotal research ongoing	Will vary according to the expected reporting dates of the studies
Slow change anticipated	5 years
No change anticipated	None

- 5.3 It is possible that evidence that may make a substantial impact on the current guidance will become available in advance of the official review date for the guidance. The Institute, or consultees or commentators to the original appraisal, can identify such evidence. The Institute's Guidance Executive considers the likely impact of the new evidence on the validity of the guidance. If the Guidance Executive considers that the emerging evidence is of particular significance, then the review date for the guidance may be brought forward. The Institute will not review any guidance earlier than 1 year after its publication.
- 5.4 Planning the most appropriate timing for reviewing technology appraisal guidance is a complex process. Furthermore, the expanding work of the Institute presents the opportunity for increased integration between work programmes. Before a review is planned into the work programme, the Institute gathers information and conducts a literature search to inform its proposal on the best approach to updating the guidance. The aim of collecting this information is to identify new indications for the appraised technology(ies), new related technologies, the progress of ongoing trials referred to in the existing guidance or Assessment Reports, information that would satisfy the recommendations for further research in the existing guidance, and new evidence published since the searches undertaken for the Assessment Report were run. The Institute may at this point seek information from consultees involved in the original appraisal.
- 5.5 In the light of this information, the Institute's Guidance Executive will decide on one of the following options for reviewing the guidance.
- The guidance should be planned into the appraisal work programme.
 - The decision to review the guidance should be deferred.
 - The guidance should be combined with a review of a related technology and conducted at the scheduled time for the review of the related technology.
 - The guidance should be combined with a new appraisal that has recently been referred to the Institute.

- The guidance review should be incorporated into an ongoing clinical guideline.
 - The guidance review should be referred to ACTS because it would best serve the NHS by being developed as a clinical guideline.
 - The guidance should be referred to ACTS because the scope of the review has changed substantially.
 - The guidance should be transferred to the 'static guidance list' (that is, guidance that remains valid but does not require a scheduled review, see section 5.8).
 - The guidance should not be reviewed but be withdrawn (that is, the guidance no longer applies).
- 5.6 The option agreed by the Guidance Executive for reviewing the guidance will be sent to the consultees, commentators and Assessment Group involved in the original appraisal. They will be given 20 working days to submit comments on the proposed option. The proposals will be posted on the Institute's website 5 working days after the consultees, commentators and the Assessment Group have been notified.
- 5.7 Comments received will be discussed at a second meeting of the Guidance Executive, which will review the proposal in the light of comments received. A final decision on the most appropriate option for updating the guidance will then be made and consultees will be informed in writing of the final decision of the Guidance Executive. The final decision will also be posted on the Institute's website.
- 5.8 It is anticipated that, eventually, the evidence base for a technology and its diffusion into the NHS will stabilise at a point at which no further update to guidance on its use is required. In this circumstance, the guidance will be transferred to a 'static list' and no further update of guidance will be planned. Topics on the static list may be transferred back to the active list for further appraisal if new evidence becomes available that is likely to have a material effect on the last guidance issued.
- 5.9 If a piece of guidance needs updating within the appraisal programme, the review will be timetabled and will follow the standard appraisal timelines and appraisal process.
- 5.10 Typically, an Assessment Group commissioned by the HTA Programme will prepare an updated Assessment Report for the review. If the scope of the original appraisal has not been altered, the Assessment Group will use the original search strategy to find studies on the clinical and cost effectiveness of the technology. However, for most reviews, it is likely that the scope will need to be modified, and therefore new search strategies will be developed, additional evidence will be reviewed and an updated economic evaluation undertaken.
- 5.11 Consultees will not be required to submit a full dossier as for the original appraisal, but will be asked to indicate what new evidence they consider should be taken into account and provide any new data they have that is not in the public domain. Further guidance is available in the relevant guides for contributing to a technology appraisal.
- 5.12 In all cases in which reviews take place, the Assessment Group preparing the update will assess new information from manufacturers/sponsors. If it is decided that a piece of guidance does not need a standard update, but instead falls under one of the other categories mentioned above, consultees and commentators will be advised accordingly. If appropriate, the associated new timelines and/or scopes and other relevant details will be distributed to consultees and commentators.

APPENDIX A Steering Group and Working Party

This document has been developed by a steering group and working party, as set out below.

Steering Group

Andrew Dillon (Chair)
Chief Executive, NICE

David Barnett (Chair, Methodology Working Party)
Chair, Appraisals Committee

Carole Longson (Chair, Process Working Party)
Appraisal Programme Director, NICE

Process Working Party

Carole Longson (Chair)
Appraisal Programme Director, NICE

Melanie Corris
Deputy Programme Manager, National Coordinating Centre for Health Technology Assessment

Kathleen Dalby
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Andrea Sutcliffe
Planning and Resources Director, NICE

Ruth Frankish
Senior Information Specialist, NICE

Marian Hodges
Senior Editorial Manager, NICE

Lynn Kerridge
Acting Executive Director, National Coordinating Centre for Health Technology Assessment

George Levy
Chief Executive, Motor Neurone Disease Association

Nina Pinwill
Technology Appraisal Project Manager, NICE

Mark Salmon
Business Manager, NICE

Rod Taylor
Senior Lecturer, Department of Public Health and Epidemiology, University of Birmingham

APPENDIX B Appraisal process: diagrammatic timeline





APPENDIX C Glossary

Abstract

Summary of a study, which may be published alone or as an introduction to a full scientific paper.

Appraisal Committee

A standing advisory committee of the Institute. Its members are drawn from the NHS, patient/carer organisations, relevant academic disciplines and the pharmaceutical and medical devices industries.

Appraisal Programme Director

The Appraisal Programme Director (APD) is responsible for the delivery of the appraisal programme. In addition to, and in conjunction with, the Executive Lead the APD is responsible for signing off consultation documents at various stages of an individual appraisal. The APD is also responsible for ensuring that appraisals are conducted in accordance with the published appraisal process and methodology.

Assessment Group

An independent academic group commissioned by the NHS Research and Development Health Technology Assessment Programme (HTA Programme) to assist the Appraisal Committee.

Assessment protocol

Written instructions for the conduct and analysis of the assessment of a technology.

Assessment Report

In technology appraisals, a critical review of the clinical and cost effectiveness of a health technology/technologies. It is prepared by the Assessment Group. To prepare the report, the Assessment Group carries out a review of the published literature and the submissions from manufacturers and sponsors.

Audit

See 'Clinical audit'.

Carer (caregiver)

Someone other than a health professional who is involved in caring for a person with a medical condition.

Clinical audit

A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.

Clinical effectiveness

The extent to which an intervention produces an overall health benefit in routine clinical practice.

Clinical specialist

In technology appraisals, clinical specialists act as expert witnesses to the Appraisal Committee. They are selected on the basis of specialist expertise and personal knowledge of the use of the technology and other treatments for the condition. They provide a view of the technology under current clinical practice, with insights not typically available in the published literature.

Commentator

Organisations that engage in the appraisal process but that are not asked to prepare a submission dossier, and that receive the Final Appraisal Determination (FAD) for information only, without right of appeal. These organisations are manufacturers of comparator technologies, NHS Quality Improvement Scotland; the relevant National Collaborating Centre; other related research groups and other groups where appropriate.

Commercial in confidence

See 'In confidence material'.

Comparator

The standard intervention against which the intervention under appraisal is compared. The comparator can be no intervention, for example, best supportive care.

CONSORT statement (Consolidated reporting of clinical trials)

Recommendations for improving the reporting of randomised controlled trials in journals. A flow diagram and checklist allow readers to understand the conduct of the study and assess the validity of the results.

Consultation

The process that allows stakeholders and individuals to comment on initial versions of NICE guidance and other documents so their views can be taken into account when the final version is being produced.

Consultee

Organisations that accept an invitation to participate in the appraisal. Consultees can participate in the consultation on the draft scope, the Assessment Report and the Appraisal Consultation Document. Consultee organisations representing patient/carers and healthcare professionals can nominate clinical specialists and patient experts to present their personal views to the Appraisal Committee. All consultees are given the opportunity to appeal against the Final Appraisal Determination (FAD).

Cost-effectiveness analysis

An economic study design in which consequences of different interventions are measured using a single outcome, usually in 'natural' units (for example, life-years gained, deaths avoided, heart attacks avoided, cases detected). Alternative interventions are then compared in terms of cost per unit of effectiveness.

Cost-effectiveness model

An explicit mathematical framework, which is used to represent clinical decision problems and incorporate evidence from a variety of sources so that the costs and health outcomes can be estimated.

Dosage

The prescribed amount of a drug to be taken, including the size and timing of the doses.

Effectiveness

See 'Clinical effectiveness'.

Epidemiological study

The study of a disease within a population, defining its incidence and prevalence and examining the roles of external influences (for example, infection, diet) and interventions.

Evaluation Report

In technology appraisals, the written evidence considered by the Appraisal Committee.

Evidence

Information on which a decision or guidance is based. Evidence is obtained from a range of sources including randomised controlled trials, observational studies and expert opinion (of clinical professionals and/or patients).

Health-related quality of life (HRQL)

A combination of an individual's physical, mental and social well-being; not merely the absence of disease.

Health technology

Any method used by those working in health services to promote health, prevent and treat disease and improve rehabilitation and long-term care. Technologies in this context are not confined to new drugs or pieces of sophisticated equipment.

In confidence material

Information (for example, the findings of a research project) defined as 'confidential' as its public disclosure could have an impact on the commercial interests of a particular company or the academic interests of a research or professional organisation.

Indication (specific)

The defined use of a technology as licensed by the Medicines and Healthcare products Regulatory Agency (MHRA).

Licence

See Product licence.

Medicines and Healthcare products Regulatory Agency (MHRA)

The Executive Agency of the Department of Health protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.

National Coordinating Centre for Health Technology Assessment (NCCHTA)

Part of the Wessex Institute for Health Research and Development at the University of Southampton. The NCCHTA coordinates the Health Technology Assessment (HTA) programme on behalf of the NHS Research and Development programme. The aim of the HTA programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who make policy for, use, manage and work in the NHS.

Outcome

Measure of the possible results that may stem from exposure to a preventive or therapeutic intervention. Outcome measures may be intermediate endpoints or they can be final endpoints.

Patient expert

Act as expert witnesses to the Appraisal Committee. They have experience of the use of the technology either personally or as part of a representative group. They provide an individual view on the risks and benefits of the technology from personal experience as a patient or carer, and an understanding of the wider range of patient/carer views.

Patient Involvement Unit

The Patient Involvement Unit is funded by NICE. It works with the Institute to develop and support opportunities for patient and carer involvement in the development of the Institute's guidance.

Product licence

An authorisation from the MHRA to market a medicinal product.

Quality of life

See 'Health-related quality of life'.

Remit

The brief given to the Institute by the Department of Health and Welsh Assembly Government when a technology is referred to NICE for appraisal.

Systematic review

Research that summarises the evidence on a clearly formulated question according to a pre-defined protocol using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, collate and report their findings. It may or may not use statistical meta-analysis.

Technical Lead

An appraisals team member who has responsibility for the technical aspects of the appraisal, including liaising with the Assessment Group, scoping the appraisal, preparing drafts of consultation documents and advising the Appraisal Committee on technical aspects of the appraisal. There may be more than one Technical Lead for an appraisal.

Technology

See 'Health technology'.

Technology assessment

The process of evaluating the clinical, economic and other evidence relating to the use of a technology so that guidance on its most efficient use can be formulated.

Time horizon

The time span used in the NICE appraisal which reflects the period over which the main differences between interventions in health effects and use of healthcare resources are expected to be experienced, and taking into account the limitations of supportive evidence.



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