



*National Institute for
Health and Clinical Excellence*

Issue date: September 2006

Guide to the single technology appraisal (STA) process

About this document

This document describes the processes used in the development of NICE single technology appraisals.

This document is available from the National Institute for Health and Clinical Excellence (NICE) website (www.nice.org.uk). Related documents about NICE's technology appraisals programme are also available from the website, including 'Guide to the technology appraisals process' and 'Guide to the methods of technology appraisal'.

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).

National Institute for Health and Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

Peter House
Oxford Street
Manchester
M1 5AN

www.nice.org.uk

N1117
ISBN: 1-84629-287-5
September 2006

© National Institute for Health and Clinical Excellence, September 2006. All rights reserved.

This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of the Institute.

Contents

Foreword.....	3
Acknowledgements.....	3
1 Introduction.....	4
2 Selection of technologies.....	7
3 The STA process.....	8
4 Evidence and assessment.....	19
5 Process timelines and publication of documents.....	22
6 Appeal process.....	25
7 Updating technology appraisal guidance (reviews).....	26
Appendices.....	30

Foreword

This document is part of a suite of publications about the technology appraisal programme of the National Institute for Health and Clinical Excellence (NICE). It should be read in conjunction with the Institute's 'Guide to the technology appraisals process' and 'Guide to the methods of technology appraisal' and, where relevant, with other related documents on contributing to an individual appraisal that have been prepared for patients and carers, manufacturers and sponsors, professional groups, and NHS organisations. When finalised, all these documents will be available on the Institute's website (www.nice.org.uk).

Acknowledgements

The Institute is very grateful to the members of the internal 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 Health and Clinical Excellence (NICE, or the Institute) follows when undertaking a single technology appraisal (STA). It describes a uniform, open and transparent process designed to achieve robust guidance for the NHS. It provides advice for organisations that are invited to contribute to an STA, and has been developed to improve general understanding of the process and to facilitate input from consultees and commentators.
- 1.1.2 The STA process is specifically designed for the appraisal of a single product, device or other technology, with a single indication, where most of the relevant evidence lies with one manufacturer or sponsor. (Typically, it is used for new pharmaceutical products close to launch.) The decision as to whether the appraisal of a technology is suitable for the STA process is made during topic selection. The STA process will normally be used to ensure that NICE is able to issue guidance to the NHS in England and Wales on new technologies soon after their introduction into the UK market. Once published, NICE technology appraisal guidance has the same status, regardless of whether it is the product of the multiple or the single technology appraisal process.
- 1.1.3 See appendix C for a glossary of terms used in this document.

1.2 *General description of NICE and the STA process*

- 1.2.1 NICE is part of the NHS. It is the independent organisation responsible for providing national guidance on the treatment and care of people using the NHS in England and Wales. Further details about the Institute and its work are available in 'A guide to NICE', which is available on its website (www.nice.org.uk) or from the NHS Response Line (telephone 0870 1555 455 and quote reference N0869).

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, based on an appraisal of those technologies.

1.2.3 The Secretary of State for Health formally refers technologies to the Institute for appraisal. These technologies include:

- pharmaceuticals
- medical devices
- diagnostic techniques
- surgical procedures
- other therapeutic technologies
- health promotion activities.

1.2.4 An STA considers evidence on the health effects, costs and cost effectiveness of a health technology in comparison with current standard treatment in the NHS in England and Wales. Health effects include both benefits and harms (side effects). This includes the impact on health-related quality of life (for example, relief of pain and disability), and the probable effects on mortality. It also considers estimates of any associated costs, concentrating particularly on costs to the NHS and Personal Social Services.

1.2.5 An STA typically compares the licensed use of a health technology with current standard treatment in the NHS in England and Wales. The Institute will develop a scope for the STA in consultation with consultees and commentators. The Institute's approach to scoping is outlined in 'Guide to the technology appraisal process' (section 3). Unless the Department of Health indicates otherwise, recommendations will not be made on unlicensed indications for the product being appraised.

1.2.6 There are several sources of evidence for an STA. The principal evidence is derived from a submission by the manufacturer/sponsor of

the technology. This evidence submission is based on a specification developed by NICE (see sections 3.1.1.2 and 4.1.1). A report reviewing the evidence submission is submitted by the evidence review group (ERG), an external organisation independent of the Institute. All STA consultees are invited to submit written statements to the Appraisal Committee on the technology, giving their views on whether or how it should be used in the NHS in England and Wales. All non-manufacturer/sponsor consultees and commentators are invited to nominate clinical specialists or patient experts to give oral evidence in the Appraisal Committee meeting.

- 1.2.7 The written and oral evidence is considered by the Institute's Appraisal Committee. The Committee decides whether the technology can be recommended as a clinically effective and cost effective use of NHS resources in general or, if more appropriate, whether it can be recommended for a specific subgroup of patients. The Appraisal Committee evaluates the impact on both costs/savings and benefits/harms of any technology under consideration.
- 1.2.8 The resulting decision is referred to as the 'final appraisal determination' and, once the process is complete, the determination is submitted to the Institute. This forms the basis of the Institute's guidance. For further information on the methods used, see 'Guide to the methods of technology appraisal'.
- 1.2.9 Normally, formal consultation takes place only if the Appraisal Committee's preliminary recommendations are substantially more restrictive than the terms of the licensed indication being appraised. Or, in the absence of a regulatory approval process (for example, for a device), if the recommendations are substantially more restrictive than the manufacturer/sponsor's claims for how the technology should be used.

1.2.10 In reaching the decision, the Institute and the Appraisal Committee take into account the following factors listed in the directions of the Secretary of State for Health:

- the broad balance of clinical benefits and costs
- the degree of clinical need of the patients with the disease or condition under consideration
- any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of the Institute by the Secretary of State and any guidance issued by the Secretary of State
- the potential for long-term benefits to the NHS of innovation.

2 Selection of technologies

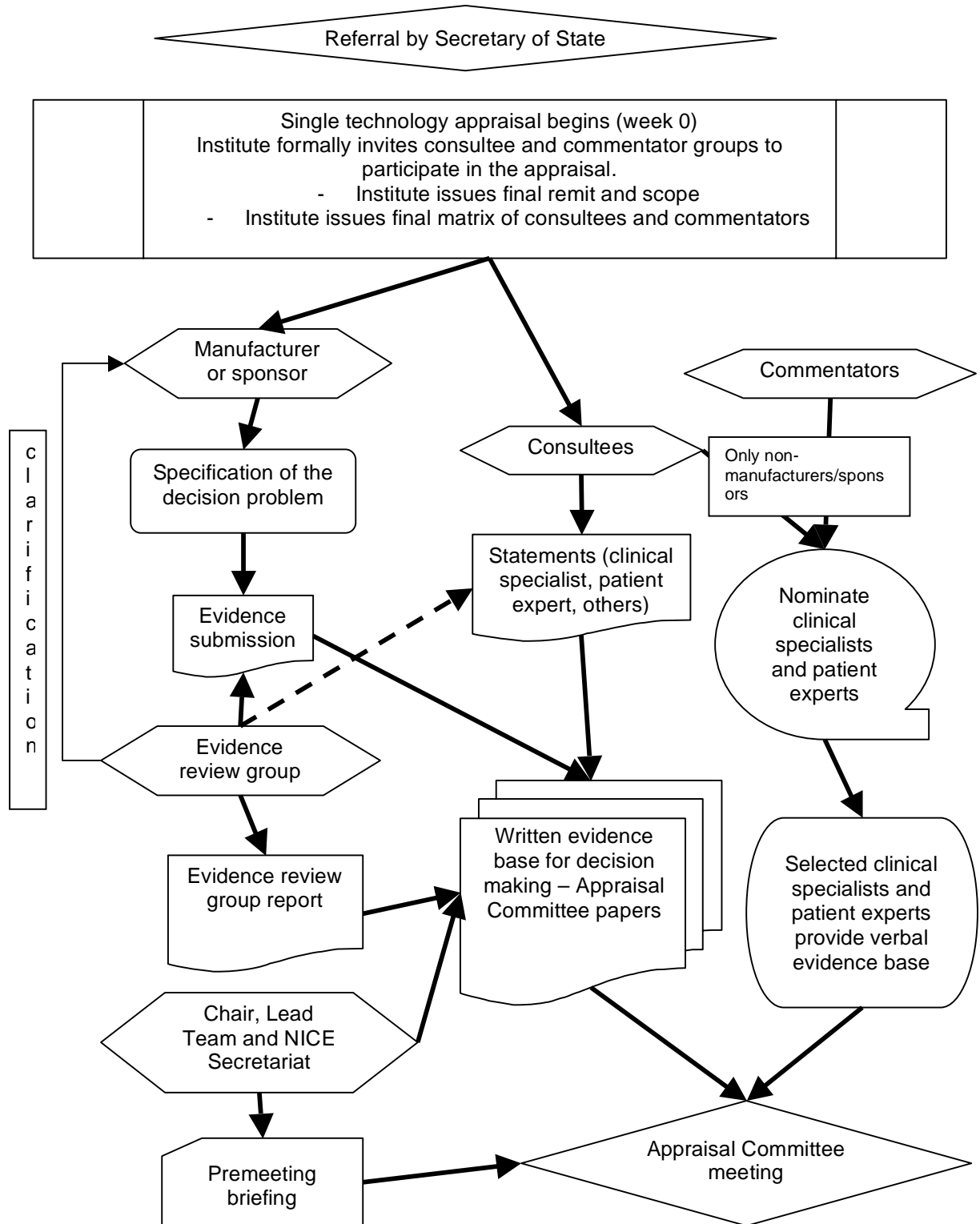
2.1 The Institute cannot begin the appraisal of a technology until it is formally referred to the Institute by Ministers.

2.2 Details of how technologies are selected for the STA programme can be found on the Institute's website (www.nice.org.uk). In addition, enquires in England can be made in writing to: NICE Liaison Unit, Department of Health, Quarry House, Quarry Hill, Leeds LS2 7UE. Enquires in Wales can be made in writing to: Performance, Quality and Regulation Division 2, NHS Quality Division, Welsh Assembly Government, Cathays Park, Cardiff CF1 3NQ.

2.3 In principle, any single technology for a single indication designated for referral by Ministers can be assigned to the STA programme for appraisal. Selection is based on a number of factors, such as the complexity of current standard treatments and the probability of the evidence base being held primarily by the manufacturer/sponsor.

3 The STA process

Figure 1 Summary of the STA process up to the first Appraisal Committee meeting



3.1 Overview

- 3.1.1 The STA process, from referral to the publication of guidance, consists of three distinct phases, preceded by an additional step, scoping, which is undertaken during topic selection. See appendix B for an overview of timelines pertinent to the STA process.
- 3.1.1.1 The draft scope for an STA is developed during the consultation on proposed topics for referral to the NICE technology appraisal programme. Manufacturers/sponsors and the wider consultee community are involved in the appraisal topic selection process. This ensures advance notice of a STA being planned (subject to referral). The final scope for the STA will be developed by the Institute on the basis of the remit issued by the Department of Health (see 'Guide to the technology appraisal process', section 3, 'Developing the scope for the technology appraisal') , and taking into account comments from consultees and commentators on the draft scope.
- 3.1.1.2 The STA process begins after the topic has been referred to the Institute by Ministers. The first phase (phase 1) is initiated either when NICE is notified that the manufacturer/sponsor of the selected product is applying to the regulatory authorities for a particular indication or, if the STA is not tracking a regulatory submission, at a point determined by NICE. NICE will then notify the manufacturer/sponsor of the STA and request an evidence submission. It will provide them with a detailed template for this submission. At the same time, all other consultees will be invited to complete statements relevant to the group they are representing. Manufacturers/sponsors and other consultees are given a minimum of 8 weeks to prepare the evidence submission and complete their statements, respectively. Depending on when a product is selected for an STA, and when regulatory approval (where relevant) is expected, they may be given longer.

- 3.1.1.3 Phase 2 begins when NICE receives the manufacturer/sponsor's evidence submission. It includes the ERG's independent review of the evidence submission (a minimum of 8 weeks), appraisal of the evidence and preparation of the recommendations. Only the evidence submission by the manufacturer/sponsor will be formally considered in the independent review. Other consultee statements are presented in full to the Appraisal Committee along with the evidence submission and review.
- 3.1.1.4 In the final phase (phase 3), a Final Appraisal Determination (FAD) document is issued containing the recommendations. If preliminary recommendations need to be consulted on first, an Appraisal Consultation Document (ACD) will be produced (see section 3.4.4.1). In such cases, the FAD is issued following consultation. This final phase will take between 7 and 15 weeks, depending on whether or not an ACD is issued. Following release of a FAD, consultees have 15 working days to lodge an appeal. The arrangements for making an appeal are set out in 'Technology Appraisals process – guidance for appellants' (see also section 6 of this process guide).
- 3.1.1.5 If no appeals are received, it will take between 32 weeks (where no ACD is issued) and 39 weeks (where an ACD is issued) to produce the guidance (from initiation of the appraisal to publication). The FAD will be put into the public domain at 27 weeks and 35 weeks, respectively.
- 3.1.1.6 Where the appraisal is tracking European regulatory approval, the first Appraisal Committee meeting will be organised at the earliest opportunity following publication of a positive opinion by the Committee for Human Medicinal Products (CHMP) of the European Medicines Evaluation Agency (EMA). The minimum elapsed time from regulatory approval to guidance publication will be between 6 weeks (no ACD issued) and 13 weeks (ACD issued).

3.2 Phase 1 – initiation of the STA and evidence submission

- 3.2.1 Topics for STAs are usually formally referred to the Institute in groups, known as ‘waves’. After a wave of STA topics has been referred, the Institute finalises the list of consultees and commentators who will participate in each STA. Under exceptional circumstances, the Department of Health may refer topics outside a ‘wave’, in which case the Institute may need to make special arrangements for the appraisal.
- 3.2.2 The final remit, the final scope, details of the ERG, and the final matrix of consultees and commentators will be posted on the Institute’s website at the earliest possible opportunity, and at least 8 weeks before the manufacturer/sponsor’s evidence submission deadline. Each STA is assigned to a project team at the Institute and the members will be listed on the NICE website. The roles of key members of the project team are summarised in appendix E.
- 3.2.3 The Institute will write to manufacturers/sponsors and consultees to inform them of key dates for the STA at the earliest possible opportunity, and at least 8 weeks before the manufacturer/sponsor’s evidence submission deadline.
- 3.2.4 If the STA is tracking a regulatory submission, the manufacturer/sponsor must notify the Institute when its dossier for the indication being appraised was submitted to the regulatory authorities. This notification should include the expected date of receipt of a positive opinion from CHMP (where appropriate) and the expected date of receiving marketing authorisation.
- 3.2.5 The timeline for an individual STA starts (week 0) when the Institute invites the manufacturer/sponsor of a technology to complete an evidence submission using a submission template.
- 3.2.6 The evidence review group (ERG) is formally commissioned to review the evidence submission received from the manufacturer/sponsor.

- 3.2.7 All consultees to the STA are invited to complete a statement on the effects (positive and negative) of the technology on the condition. These statements should be made using the appropriate templates available on the Institute's website (www.nice.org.uk). The templates explain the type and amount of information needed to complete them.
- 3.2.8 The manufacturer/sponsor is required to submit to the Institute a summary of their 'decision problem' for the evidence submission 2 weeks after being formally invited to provide an evidence submission for the STA. This summary should define the population, the intervention, the comparators and the outcomes relevant for the STA. It is part of the STA submission template (see section 4.1.1) and is used to ensure that the decision problem is specified appropriately in relation to the final scope issued by the Institute. On request, the Institute will provide help to ensure that the decision problem is specified appropriately.

3.3 Phase 2 – evidence review

- 3.3.1 On receipt of the manufacturer/sponsor's evidence submission, the Institute will assess whether the submission is complete and the decision problem is specified appropriately with reference to the final scope. If the submission is incomplete or the decision problem is not specified appropriately, the Institute will normally request clarification from the manufacturer/sponsor within 2 weeks of receiving the submission. If, following clarification, the Institute is not satisfied that the submission will constitute a suitable basis for the Appraisal Committee to make a decision, the manufacturer/sponsor may be asked to make a partial or full resubmission. Where such requests delay the published timeline, consultees and commentators will be told the reasons for the delay, and these will be posted on the Institute's website.
- 3.3.2 A technical review of the manufacturer/sponsor's evidence submission is undertaken by an external group, the ERG. Their remit is to critically

evaluate the submission and identify gaps in the evidence base that could lead the Institute to request further clarification from the manufacturer/sponsor (see section 4.2.2). Normally, the ERG is commissioned by the National Coordinating Centre for Health Technology Assessment (NCCHTA). However, the Institute may choose to use its Decision Support Unit (DSU) in individual cases.

3.3.3 The ERG prepares a report reviewing the evidence for the clinical effectiveness and cost effectiveness of the technology, based on a review of the manufacturer/sponsor's evidence submission. The report is prepared in accordance with the HTA Programme's quality criteria (www.hta.nhsweb.nhs.uk) and is consistent with the 'Guide to the methods of technology appraisal'. The content and quality of the report are the responsibility of its authors.

3.4 Phase 3 – appraisal

3.4.1 Overview

3.4.1.1 The appraisal stage of the STA process consists of a number of elements:

- consideration of the evidence at an Appraisal Committee meeting and discussion on the content of either a Final Appraisal Determination (FAD) or an Appraisal Consultation Document (ACD)
- preparation of and consultation on the ACD (if produced)
- review of the ACD (if produced) in light of comments from the consultation and discussion about the FAD's content at a second Appraisal Committee meeting
- preparation of the FAD, either at the end of the first meeting of the Appraisal Committee or, if an ACD has been produced, at the end of its second meeting.

3.4.2 Consideration by the Appraisal Committee

3.4.2.1 Appraisal Committees are standing advisory committees of the Institute constituted so that members 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. Further information about the current composition and membership of the Institute's Appraisal Committees is available on the Institute's website.

3.4.2.2 The Appraisal Committee considers the written and oral evidence on a single technology at its first meeting. The written evidence comprises the manufacturer/sponsor's evidence submission, statements by consultees to the STA, the ERG report and the NICE secretariat's premeeting briefing document (see 3.4.2.3). Oral evidence comes from discussions with invited clinical specialists, patient experts and ERG representatives. 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'.

3.4.2.3 A 'Lead Team' of two members of the Appraisal Committee is formed at the start of each STA process to help the NICE secretariat prepare a document known as the premeeting briefing. At the Appraisal Committee meeting, the Chair and the NICE Technical Lead make a brief presentation, based on the premeeting briefing, to introduce the STA topic. This presentation includes:

- an overview of the condition for which the technology is indicated, including the epidemiology and pathophysiology relevant to the Appraisal Committee's considerations

- an overview of the technology and its place in the pathway of care for the condition, and of relevant alternative treatments/comparators
- an overview of the evidence on clinical effectiveness
- an overview of the evidence on cost effectiveness, the manufacturer/sponsor's economic model and the ERG's critique of it
- key issues raised by consultees in their statements
- identification of important issues that the Appraisal Committee should consider.

3.4.2.4 Representatives of the ERG attend the meeting. The Appraisal Committee may ask these representatives for further clarification of the ERG report, and discuss relevant issues raised. ERG representatives may remain present during Committee discussions to answer any further questions the Committee may have.

3.4.2.5 Representatives from any of the National Collaborating Centres that are developing the Institute's clinical guidelines in related areas are also invited to observe and contribute as advisors to the Appraisal Committee meeting.

3.4.2.6 The invited clinical specialists and patient experts are encouraged to join in the debate with the Appraisal Committee and respond to questions it poses. They are asked to withdraw from the meeting before the Committee discusses the content of its recommendations. (For details of the selection procedure for the invited specialists and experts, see sections 4.3.3, 4.3.4 and 4.3.5.)

3.4.2.7 After careful consideration of the evidence, the Committee agrees the content of either a FAD (see section 3.4.3), which sets out its final recommendations, or an ACD (see section 3.4.4), which sets out preliminary recommendations for consultation.

- 3.4.2.8 Exceptionally, the Committee may ask the Institute to seek clarification from the manufacturer/sponsor, between the ACD and FAD meetings, of key evidence.
- 3.4.2.9 The Institute cannot issue a FAD or an ACD on a technology before that technology receives UK regulatory approval, where this is appropriate. Where an STA begins before UK regulatory approval has been granted, it will only proceed past the point when the ACD or FAD is released once UK regulatory approval has been granted, and once the technology's price and indication are known.

3.4.3 Preparation of the Final Appraisal Determination (FAD)

- 3.4.3.1 The NICE project team drafts the FAD according to the instructions of the Appraisal Committee.
- 3.4.3.2 The FAD contains the Committee's recommendations, a brief description of the technology, the main elements of the manufacturer/sponsor's evidence submission (plus clarification where appropriate), the key findings of the ERG, key issues raised by consultees to the STA, and the considerations taken into account by the Committee when interpreting the evidence.
- 3.4.3.3 The Institute's Guidance Executive¹ checks that the STA process has been properly followed and deals with any policy issues before the FAD is published as NICE guidance. Following approval by the Guidance Executive, the FAD is issued to consultees so that they can consider whether to appeal (see section 6). The FAD is also sent to commentators but for information only; they cannot lodge an appeal. If no ACD was produced as part of the STA, the Institute will send consultees and commentators the 'evaluation report' supporting the FAD after the Appraisal Committee meeting. This comprises the manufacturer/sponsor's evidence submission (minus

¹ The Guidance Executive, which comprises Executive Directors and Centre Directors of NICE, approves the FAD for publication on behalf of the Board.

any confidential information), statements by consultees, the ERG report and the NICE secretariat's premeeting briefing (minus any confidential information).

- 3.4.3.4 The FAD is posted on the Institute's website for information 5 working days after it has been released to consultees and commentators. The evaluation report will also be published on the website. If an ACD has been produced, a summary table of comments on the ACD (with the Institute's responses) will be posted on the website at the same time as the FAD. Any further evidence that resulted from a request for clarification by the Institute during an ACD consultation, and which has been considered by the Appraisal Committee, is distributed to consultees and commentators. It will also be posted on the website. Subject to any appeal by consultees, the FAD forms NICE guidance on the use of the appraised technology.
- 3.4.3.5 The grounds and arrangements for making an appeal (see section 6) are set out in 'Technology appraisals – guide for appellants'.

3.4.4 Consultation on an ACD

- 3.4.4.1 Normally, formal consultation (which involves producing an ACD) takes place only if the recommendations emerging from the Appraisal Committee are substantively restrictive. A substantively restrictive recommendation is likely to promote more limited use of the product than the terms of the licensed indication being appraised. This limitation will be judged significant for clinical practice in the reasonable opinion of the Committee. In the absence of a regulatory approval process (for example, for a device), a substantively restrictive recommendation will be one that is more limited than the manufacturer/sponsor's claims for how the technology should be used.

- 3.4.4.2 The ACD contains provisional recommendations, a brief description of the technology, the main elements of the manufacturer/sponsor's evidence submission (plus clarification when appropriate), the key findings of the ERG, key issues raised by consultees to the STA and the considerations taken into account by the Appraisal Committee in interpreting the evidence.
- 3.4.4.3 The Institute usually circulates the ACD for an STA to consultees and commentators 10 working days after the Appraisal Committee meeting. If the Institute expects a delay, consultees and commentators will be informed as soon as possible.
- 3.4.4.4 Consultees and commentators are invited to comment on whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for guidance to the NHS.
- 3.4.4.5 Comments from consultees and commentators must be submitted to the Institute in writing, preferably by email, by the specified deadline. The Institute reserves the right not to consider comments received after the close of consultation.
- 3.4.4.6 The Institute will send consultees and commentators the evaluation report, to support the ACD, after the Appraisal Committee meeting. This comprises the manufacturer/sponsor's evidence submission (plus clarification, where appropriate and with any confidential information removed), statements by consultees, the ERG report and the NICE secretariat's premeeting briefing (with any confidential information removed). All these documents (minus any confidential information) will be published on the Institute's website 5 working days after consultees and commentators have received them.
- 3.4.4.7 The period of consultation on the ACD can, in exceptional circumstances, be used for further clarification of key evidence with the manufacturer/sponsor.

4 Evidence and assessment

4.1 Evidence submission by the manufacturer/sponsor

- 4.1.1 The manufacturer/sponsor of a technology is requested to prepare an evidence submission to the Institute for an STA. This submission uses a specification that is based on the decision-analytical approach used by NICE to evaluate the clinical effectiveness and cost effectiveness of health technologies. This approach is outlined in 'Guide to the methods of technology appraisal'.
- 4.1.2 For model-based economic evaluations, a fully executable electronic copy of the model must be submitted. If the model is not constructed using either Excel or DATA software, the Institute should be informed in advance of submission. The ERG should have full access to the programming code. Care should be taken to ensure that the submitted versions of the model program and the content of the submission match.
- 4.1.3 If information in the manufacturer/sponsor's submission meets the criteria for it to be considered as 'commercial in confidence', or 'academic in confidence', then the relevant information must be highlighted and underlined. A checklist (provided by the Institute) of confidential information should be completed, giving the reasons for designating the information confidential and the time needed for the information embargo. If a checklist of confidential information is not completed then it will be assumed that there is no confidential information in the submission. The manufacturer/sponsor is asked to submit two versions of its submission: one with confidential information clearly marked and one with confidential information removed from the text.
- 4.1.4 The Institute needs to ensure that the best possible evidence submission is prepared for the Appraisal Committee. Although

Technical Leads cannot validate the submission, they will endeavour to help clarify substantive issues.

4.2 Evidence review group report

4.2.1 The ERG, via the Institute, may contact the manufacturer/sponsor during review of the evidence submission to clarify aspects of the submission. The Institute's Technical Lead and Project Manager will liaise between the manufacturer/sponsor and the ERG. Under exceptional circumstances, the Institute will organise a face-to-face meeting to discuss any issues that cannot be resolved by other means.

4.2.2 The ERG may suggest to the Institute that the manufacturer/sponsor should undertake additional analyses. These analyses will be included as addenda to the manufacturer/sponsor's submission. The ERG assesses the submission and writes a report which forms part of the Committee papers. The ERG report will later be released to consultees and commentators and put on the NICE website with either the ACD (if there is one) or the FAD.

4.2.3 The manufacturer/sponsor cannot submit additional data during the evidence review phase, unless this has been agreed before submission of the manufacturer/sponsor's evidence, or is requested by the Institute.

4.3 Participation of consultees, and clinical specialists and patient experts

4.3.1 All consultees on the matrix (see section 3.2.2) are asked to complete a statement on the technology, on the way in which it may or may not be used in the NHS in England and Wales, and on standard treatment for the disease or condition under consideration. Details about the structure, content and length of the statement are set out in the individual statement templates. The Institute does not accept

unsolicited submissions (that is, from parties other than the consultees).

- 4.3.2 These statements are sent to the ERG for information, given to the Appraisal Committee, made available during the ACD consultation (if an ACD is produced), and published on the Institute's website with the FAD as part of the evaluation report. Further advice about contributing to an STA will be available in the Institute's specific guides for groups participating in an STA.
- 4.3.3 All non-manufacturer/sponsor consultees and commentators are invited to nominate clinical specialists or patient experts to give oral evidence in the Appraisal Committee meeting. Clinical specialists and patient experts are chosen from these nominations by the Chair of the Appraisal Committee, in discussion with the Institute's project team. The decision is based on the extent and nature of their experience of the technology, the disease or condition that it is designed to treat, and the services currently provided by the NHS to treat patients with the condition(s). In addition, clinical specialists must:
- be active in clinical practice and have specialist expertise in the particular area of the appraisal
 - work principally within the NHS
 - hold no official office (that is, no paid employment, unpaid directorship or membership of a standing advisory committee) with the manufacturer/sponsor of the technology or any manufacturer/sponsor of a directly competing technology.
- 4.3.4 Clinical specialists and patient experts are invited to take part in meetings of the Appraisal Committee provided they meet a number of 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 (if there is one), the FAD and the final guidance.
- They are prepared to declare, at the Appraisal Committee meeting, any interests that they have in the technology under appraisal.
- They have no other conflict of interest that might preclude their involvement with the appraisal.

4.3.5 Usually, two clinical specialists and two patient experts are selected. They are not asked to submit a written personal view on the technology. Instead, they will be required to answer questions posed to them by the Appraisal Committee in the meeting. Further advice about the contribution of clinical specialists and patient experts will be available in the Institute's specific guides for groups participating in an STA.

4.3.6 The Institute will inform nominating consultees and commentators of the names and affiliations of the clinical specialists and patient experts invited to take part in the Appraisal Committee meeting. This information is also posted on the NICE website.

5 Process timelines and publication of documents (see appendix B for diagrammatic timeline)

- 5.1 The timeline and consultation periods are, other than in exceptional circumstances, fixed. Consultees and commentators are given key dates for each STA when they are invited to participate.
- 5.2 Throughout an STA, 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.
- 5.3 The Institute will inform consultees and commentators at the earliest opportunity of any extension to the timelines for an STA and the

reason(s) for that extension. This will occur only in exceptional circumstances.

- 5.4 After the submission invitation, the manufacturer/sponsor has a minimum of 8 weeks to prepare the evidence submission.
- 5.5 The manufacturer/sponsor must submit a final summary of the specification of the decision problem 2 weeks after formally being invited to submit to the STA.
- 5.6 After receipt of the manufacturer/sponsor's evidence submission, the ERG has a minimum of 8 weeks to review the submission and prepare its report.
- 5.7 Where necessary, the Institute will request further clarification from the manufacturer/sponsor of the information in their submission, normally within 2 weeks after having received it. The clarification may include a request for supplementary analysis.
- 5.8 The STA will be discussed by the Appraisal Committee at the earliest opportunity after the CHMP has published its positive opinion on the technology for the indication being appraised by the Institute.
- 5.9 The agenda for the Appraisal Committee meeting is normally published on the Institute's website 5 working days before the meeting takes place.
- 5.10 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 confirmed by the Appraisal Committee, normally within 8 weeks of the meeting.
- 5.11 Consultees and commentators have 4 weeks to submit comments on the ACD, where one is issued.

- 5.12 The Institute usually circulates the ACD (where one is issued) among consultees and commentators within 10 working days after the Appraisal Committee meeting. The ACD (with an electronic comment facility) and the committee papers (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 via 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.)
- 5.13 If an ACD is developed and consulted upon, the comments received from consultees, commentators and web responders on the ACD, together with a summary table of these comments and the action taken in response, will be sent with the FAD to consultees and commentators. This information will also be posted on the Institute's website at the same time as the FAD.
- 5.14 When consultation leads to a substantial revision of the ACD, the Centre Director and the Chair of the Appraisal Committee will decide whether it is necessary to issue another ACD. If so, the consultation process will be repeated and the timeline for the appraisal will be extended. Consultation responses, together with any additional evidence, will be circulated with the new ACD.
- 5.15 The Institute usually circulates the FAD within 5 weeks of the Appraisal Committee meeting. It will notify consultees and commentators if it expects a delay.
- 5.16 In exceptional circumstances, the Institute may request clarification or ask for further analysis before the FAD is circulated. This may occur, for example, if a relevant report is published while the FAD is being developed, or as a consequence of comments from consultees or commentators. Or the Appraisal Committee may make a specific request for clarification. Any such analysis will be distributed to

consultees and commentators and posted on the Institute's website at the same time as the FAD.

- 5.17 If there are no appeals, or an appeal lodged is dismissed with or without a hearing, the Institute will make arrangements for the FAD, as issued to consultees (subject to correction of any factual errors), to be published as guidance. The Institute will publish the guidance as part of its monthly schedule (on the last Wednesday of the month). The FAD, in its final form, will be put in the public domain for information through the Institute's website in advance of its formal publication as guidance.

6 Appeal process

- 6.1 Consultees are given 15 working days in which to lodge an appeal. Appeals must be made in writing and must be lodged with the Institute by the deadline and in the manner indicated. Appeals are heard by the Institute's Appeal Panel. 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.
- 6.2 Appellants cannot appeal against the FAD simply because they do not agree with it. The Appeal Panel will only consider appeals if the grounds 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.

The Institute's Board appoints members of the Appeal Panel. The Panel will comprise five members drawn from the Institute's Appeals Committee, all of whom will have had no prior involvement with the appraisal in question. The Panel will consist of at least one Non-Executive Director of the Institute (who will chair the appeal), at least one member from elsewhere within the NHS, one member with

experience of the relevant industry or clinical field, and one member with experience of patient/carer organisations.

- 6.3 An appeal received from an appellant will be acknowledged by the Institute. The Institute will also inform the appellant(s) of the membership of the Appeal Panel and the confirmed date of the appeal hearing as soon as possible after an appeal has been lodged.
- 6.4 The Appeal Panel will consider the appellant's representations in public. Its findings, along with the appellant's appeal documents, will be made public. The appellant's documentation and their identity will be made public on the morning of the appeal hearing.
- 6.5 The Institute will usually issue the outcome of an appeal within 28 days of the appeal hearing, but sometimes a longer interval may be necessary. The full text of the appeal decision will be made available to appellants 2 working days before it is made available to the other consultees and posted on the Institute's website.
- 6.6 If the appeal is upheld, the Institute will consider the appropriate course of action. The Institute's Guidance Executive may consider making editorial changes in response to the Appeal Panel's decision before issuing its guidance to the NHS. Or the Institute may ask the Appraisal Committee to reconsider the evidence, in which case the process will resume when the Appraisal Committee meets to prepare the FAD.

7 Updating technology appraisal guidance (reviews)

- 7.1 When the Institute publishes STA guidance, it will indicate the date when the guidance will be considered for review. This 'review date' is the month and year when the Institute will consult with relevant organisations on proposals for reviewing the guidance.
- 7.2 The length of time between publication of the guidance and the review date will vary. It depends on the anticipated rate of development of evidence for the technology, and on prior knowledge of when pivotal

ongoing research is to be reported. Experience shows that this period varies from 1 to 5 years. The Institute has standardised its arrangements for determining appropriate review dates (see Box A).

Box A	
Criteria for assigning a single 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

- 7.3 New evidence that could have a substantial impact on current guidance may become available before the official review date for that guidance. The Institute, or consultees or commentators involved in 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.
- 7.4 Many factors are involved in planning when single technology appraisal guidance should be reviewed. For example, the expanding work of the Institute presents the opportunity for increased integration between the various guidance programmes. Before a review is planned, the Institute gathers information and conducts a literature search to inform its proposal on the best approach to updating the guidance. The information gathered includes: new indications for the appraised technology(ies), new related technologies, the progress of ongoing trials referred to in the existing guidance, information that would satisfy the recommendations for further research in the existing guidance, and new evidence published since the searches undertaken for the original

evidence submission. The Institute may also seek information from consultees involved in the original appraisal.

7.5 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 review should be added into the appraisal work programme, and it will be decided whether the review will be an STA or a multiple technology appraisal (MTA).
- The decision whether to review the guidance should be deferred.
- The guidance review should be combined with the review of a related technology and conducted at the time scheduled for that review.
- The guidance review should be combined with a new technology 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 the topic selection process for consideration as a clinical guideline.
- The guidance review should be referred to the topic selection process because the scope of the review has changed substantially.
- The guidance should be transferred to the 'static list' (that is, guidance that remains valid but does not require a scheduled review; see section 7.11).
- The guidance should not be reviewed but withdrawn (that is, the guidance no longer applies).

7.6 The option agreed by the Guidance Executive for reviewing the guidance will be sent to the consultees, commentators and ERG involved in the original appraisal. These groups 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 ERG have been notified.

- 7.7 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. The final decision will also be posted on the Institute's website.
- 7.8 If a piece of guidance needs updating, the review will be timetabled and will follow the standard MTA or STA timelines and process.
- 7.9 Consultees will be asked to indicate what new evidence they consider should be taken into account and provide any new data they have that are not in the public domain.
- 7.10 In all review cases arrangements will be made to assess new information. If it is decided that a piece of guidance does not need a standard update, but instead falls into 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.
- 7.11 It is anticipated that, eventually, the evidence base for a technology and the diffusion of the technology into the NHS will stabilise. At this point no further updates will be required and the guidance will be transferred to a 'static list'. Topics on the static list may be transferred back to the active list for further appraisal if new evidence emerges that is likely to have a material effect on the most recent guidance issued.

Appendices

Appendix A Steering group and working party

Appendix B STA process timeline (diagram)

Appendix C Glossary

Appendix D Disclosure of information

Appendix E Key participants in the single technology appraisal process

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

Carole Longson
Centre Director, Centre for Health Technology Evaluation, NICE

David Barnett
Chair, Appraisals Committee

Andrew Stevens
Chair, Appraisals Committee

Nina Pinwill
Associate Director, Centre for Health Technology Evaluation, NICE (member until 1 March 2006)

Meindert Boysen
Associate Director STA, Centre for Health Technology Evaluation, NICE (member from 1 March 2006)

Working party

Nina Pinwill
Associate Director, Centre for Health Technology Evaluation, NICE (until 1 March 2006)

Meindert Boysen
Associate Director STA, Centre for Health Technology Evaluation, NICE (from 1 March 2006)

Catherine McEvoy
Senior Medical Editor, NICE

Cathryn Fuller
Technology Appraisals Project Manager, NICE

Sarah Garner
Technical Advisor, Centre for Health Technology Evaluation, NICE

Seren Phillips
Associate Director, Centre for Health Technology Evaluation, NICE

Marcia Kelson
Associate Director, Patient and Public Involvement Programme, NICE

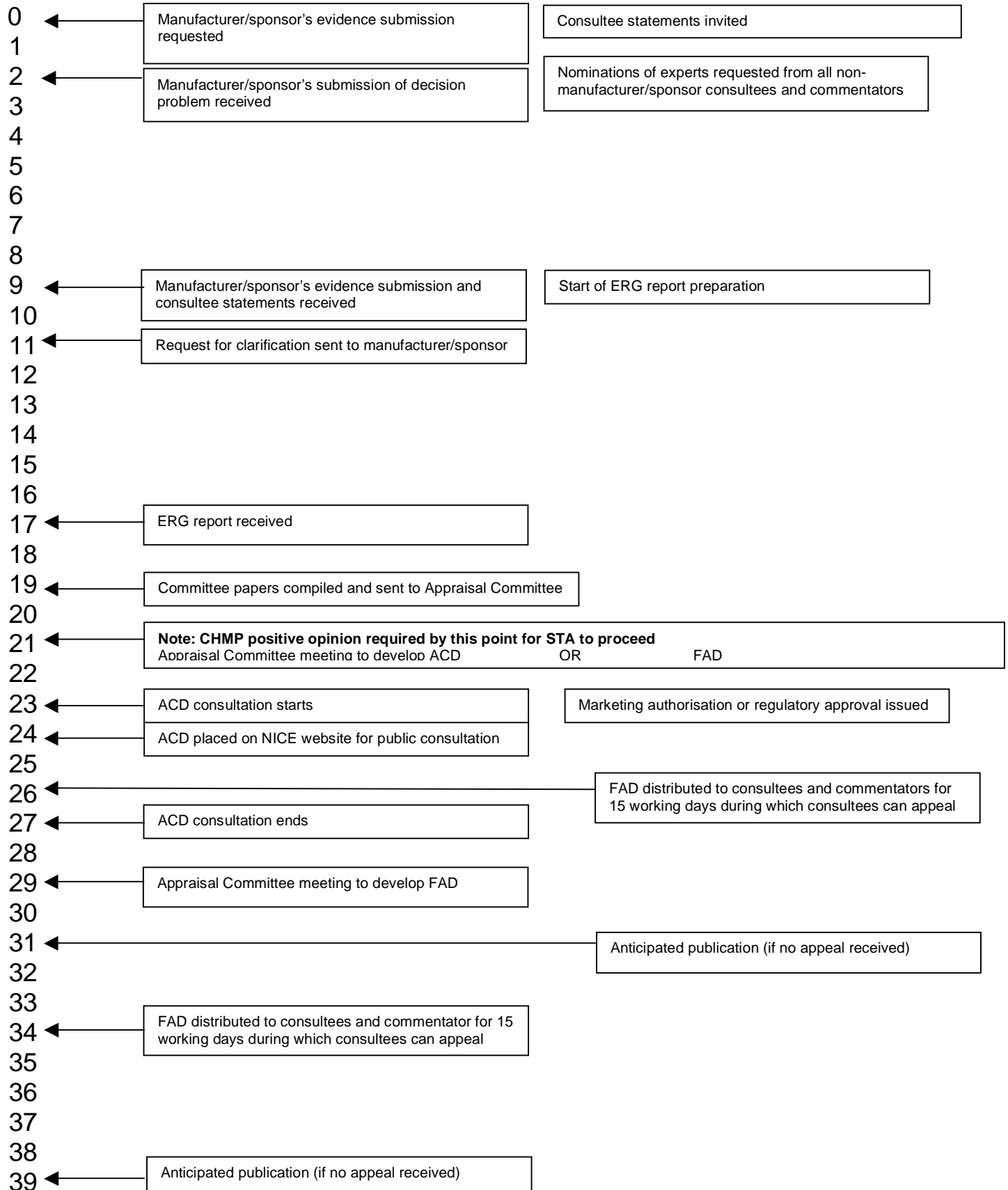
Ron Akehurst
Dean, School of Health and Related Research (SchARR), University of
Sheffield

Mark Sculpher
Professor of Health Economics, University of York
Member of Appraisal Committee, NICE

Ken Stein
Senior Clinical Lecturer in Public Health/Director, Peninsula Technology
Assessment Group (PenTAG), Peninsula Medical School, Universities of
Exeter & Plymouth
Member of Appraisal Committee, NICE

Appendix B STA process timeline

Weeks



Appendix C Glossary

Abstract

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

Academic in confidence

See 'In confidence material'

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.

Carer (caregiver)

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

CHMP opinion

In the area of medicinal products for human use, the European Commission is assisted by the Standing Committee on Medicinal Products for Human Use (CHMP). In the 'Community' or 'centralised' procedure of marketing procedures for medicines in the European Union, the CHMP is responsible for conducting the initial assessment of medicinal products for which a Community-wide marketing authorisation is sought.

Clinical effectiveness

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

Clinical specialist

In single 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 (future) use of the technology and other treatments for the condition. They are encouraged to interact fully in the debate with the Appraisal Committee and respond to questions posed by the Appraisal Committee.

Commentators

Organisations that engage in the appraisal process but are not asked to prepare a submission dossier. They 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. Commentator organisations representing non-manufacturers/sponsors can nominate clinical specialists and patient experts to orally present their personal views to the Appraisal Committee.

Commercial in confidence

See 'In confidence material'.

Comparators

All relevant technologies or interventions against which the intervention under appraisal is compared. Consideration is given to current practice and the natural history of the condition without suitable treatment. Although best alternative care is the essential comparator, treatments representing routine UK care are also important where they differ from best alternative care. Sometimes both technology and comparator form part of a treatment sequence. 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 consultees and commentators and individuals to comment on initial versions of NICE guidance and other documents so that their views can be taken into account when the final version is being produced.

Consultees

Organisations that accept an invitation to participate in the appraisal. Consultees can participate in the consultation, when applicable, on the Appraisal Consultation Document and the evidence considered in the single technology appraisal. Consultee organisations representing non-manufacturers/sponsors can nominate clinical specialists and patient experts to orally present their personal views to the Appraisal Committee. All consultees are given the opportunity to submit a written statement on their view or perspective on the technology and the way in which it may or may not be used in the NHS in England and Wales. All consultees are given the opportunity to appeal against the Final Appraisal Determination.

Decision problem

The decision problem describes the approach taken by manufacturer/sponsor in its evidence submission to answering the question as formulated in the final scope.

Economic evaluation / model

An economic study design which allows the consequences of different interventions to be measured against 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. An economic model is 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.

Effectiveness

See 'Clinical effectiveness'.

Epidemiology

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 specialists and/or patients).

Evidence review group (ERG)

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

Evidence review group report

In single technology appraisals, the evidence submission by the manufacturer/sponsor is technically reviewed by the evidence review group. The review is reported to the Institute as the evidence review group report.

Health-related quality of life

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 or 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 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) or the European Commission.

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)

The NCCHTA is part of the Wessex Institute for Health Research and Development at the University of Southampton. It 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 of exposure to a preventive or therapeutic intervention. Outcome measures may be intermediate or final end points.

Patient experts

Patient experts act as expert witnesses to the Appraisal Committee. They have experience of the medical condition for which the technology is (to be) used either personally or as part of a representative group. They are encouraged to interact fully in the debate with the Appraisal Committee and respond to its questions.

Patient and Public Involvement Programme

The Patient and Public Involvement Programme (PIIP) is part of NICE. It develops and supports opportunities for patient and carer involvement in the development of the Institute's guidance.

Product licence

An authorisation from the MHRA or the European Commission to market a medicinal product.

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.

Technology

See 'Health technology'

Appendix D Disclosure of information

- 1 The Institute adheres to the principles and requirements of the Data Protection Act and the Freedom of Information Act in dealing with information it receives during an appraisal.
- 2 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.
- 3 The Institute requires the manufacturer/sponsor of a technology undergoing an STA to sign a statement declaring that all relevant material pertinent to the STA has been disclosed to the Institute.
- 4 To ensure that the STA process is as transparent as possible, the Institute considers it highly desirable that evidence pivotal to the Appraisal 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').
- 5 The Institute expects consultees to keep confidential material within consultation responses to an absolute minimum. When a consultee believes that part of a response 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 as part of an appraisal of products that have received regulatory approval should be available for scrutiny. If trial results are due to be published in a journal after the Institute has released documentation quoting data from the trial, then, 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 ERG. A structured abstract of economic models submitted by manufacturers/sponsors should, as a minimum, be made available for public disclosure.
- 6 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.
 - 7 Confidential information submitted by consultees in responses can be made available for review by the ERG, the Appraisal Committee and the clinical specialists and patient experts. Confidential information may be distributed to consultees with permission from the data owners.
 - 8 The documents that are released to consultees and commentators during the appraisal process are shown in Box B. 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.
 - 9 The Institute hopes that consultees will take steps to ensure that their individual responses are made available – for example, by placing them on their own website.

Box B Documents made available by the Institute during the appraisal process.

Appraisal remit

Matrix of consultees and commentators

Final scope for the appraisal

Manufacturer/sponsor's evidence submission (confidential information removed)*

Clarification letters sent to the manufacturer/sponsor and the response to those*

Evidence review group report*

Statements by consultees*

Premeeting briefing note of the NICE secretariat*

Final Appraisal Determination (FAD)*

If produced, the Appraisal Consultation Document (ACD), and resulting comments from consultees and commentators on the ACD*

Summary of comments received via the web on the ACD (where produced)*

Table prepared by the Technical Lead, showing the Institute's responses to comments received on the ACD (where produced)*

* Documents marked with an asterisk are released to consultees and commentators who have signed a confidentiality agreement before publication on the website.

10 The Institute will not comment on the content of an STA 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 Board 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 comment is made publicly on an ACD or FAD that has the effect of misleading or misinforming other consultees or the public, the Institute reserves the right to issue a correction.
- 11 Organisations participating in an STA are required to sign a confidentiality agreement before they are recognised as formal consultees and commentators and before STA documentation is released to them.
 - 12 It is the responsibility of the consultees and commentators, and any other party that has signed a confidentiality agreement for the STA, 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 STA documentation to be bound by the terms of the confidentiality agreement signed by the consultee or commentator organisation.
 - 13 Consultees and commentators must not disclose confidential STA documents before the Institute makes documents public.
 - 14 Any organisation or individual not in the direct employment of a consultee or commentator organisation is a third party. Consultees and commentators may release the STA documentation to third parties when:
 - this is clearly necessary to enable the consultee or commentator to formulate its contribution to the STA, and
 - the third party has seen and agreed to be bound by the terms of the confidentiality agreement.
 - 15 Consultees and commentators may discuss confidential STA 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.
 - 16 The Institute reserves the right to use in its ACDs and FADs any material received during the course of an STA that is not designated by the consultee as being 'confidential', or which ceases to be so after the

specified embargo (see section 4.1.3). Reference will be made in the committee papers to the existence of documents that have been designated as confidential by the originator.

Appendix E Key participants in the single technology appraisal process

Appraisal Committee	A standing advisory committee of the Institute. Its 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.
Commentators	Organisations that engage in the appraisal process but are not asked to prepare a submission dossier. Commentators receive the FAD for information only, without right of appeal. They are not invited to submit a statement. Commentator organisations representing non-manufacturers/sponsors can nominate clinical specialists and patient experts to orally present their personal views to the Appraisal Committee. 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], the National Cancer Research Institute), and other groups (for example, the NHS Confederation, NHS Information Authority and NHS Purchasing & Supplies Agency, the British National Formulary, and the British Medical Association).
Consultees	Organisations that accept an invitation to participate in an appraisal: national professional organisations; national patient organisations; the Department of Health and the Welsh Assembly Government; relevant NHS organisations in England. Consultees can submit a statement and participate in the consultation on the Appraisal Consultation Document (ACD) (if produced). All consultees are given the opportunity to appeal against the Final Appraisal Determination (FAD). Consultee organisations representing non-manufacturers/sponsors are given the opportunity to nominate clinical specialists or patient experts to attend the Appraisal Committee meeting.
Evidence review group	An independent group that reviews the evidence in the manufacturer/sponsor's evidence submission, and may also prepare some additional analysis. This group is normally commissioned by the NHS Research and Development Health Technology Assessment Programme.
Selected clinical specialists and patient experts	These people are selected by the Chair of the Appraisal Committee from nominations by non-manufacturers/sponsor consultees and commentators. They are invited to attend the Appraisal Committee meeting to answer questions posed to them. They are not asked to submit a separate written statement.
Institute staff	
Director of Centre for Health Technology Evaluation (CHTE)	The Director is responsible for the delivery of the appraisal programme. In addition to, and in conjunction with, the Executive Lead, the Director is responsible for signing off documents at various stages of an individual appraisal. The Director is also responsible for ensuring that appraisals are conducted in accordance with the published appraisal process and methodology.
Associate Director – Single Technology Appraisals	The Associate Director is responsible for individual projects within the appraisal programme.

Technology Appraisals Project Manager	The Project Manager is responsible for planning individual appraisal timelines, ensuring that 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 assigned to each appraisal is responsible for the technical aspects of the STA. This includes liaising with the evidence review group and working with the Chair of the Appraisal Committee, to prepare the guidance document or drafts for the consultation document. It also includes advising the Appraisal Committee on technical aspects of the appraisal.
Executive Lead	The Executive Lead acts as the senior sponsor of an individual guidance topic on behalf of the Board of the Institute. The role is undertaken by the Institute's executive directors, to one of whom each guidance topic is allocated. Executive Leads provide the senior point of reference for the Centre Directors and their staff and help resolve policy questions which arise during guidance development. The Executive Lead works in partnership with the Centre Director, who has the primary responsibility for the guidance.
Communications Lead	The Communications Lead is responsible for disseminating the technology appraisal guidance to the appropriate groups within the NHS in England and Wales, and to patients and the public. They are also responsible for publicising the guidance and for ensuring it is available on the NICE website.
Editorial Lead	The Editorial Lead edits the ACD and FAD before they are published on the website. They prepare the quick reference guide and write the 'Understanding NICE guidance' version of the guidance. They are responsible for publication of all versions of the final guidance, both electronic and printed.

**National Institute for
Health and Clinical Excellence**

MidCity Place

71 High Holborn

London

WC1V 6NA

Peter House

Oxford Street

Manchester

M1 5AN

www.nice.org.uk

N1117

ISBN 1-84629-287-5

September 2006