



*National Institute for
Clinical Excellence*

Guidance for

Healthcare

Professional

Groups



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Guidance for Healthcare Professional Groups

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About the technology appraisal series

This document is one of a set of five, which describe the process the Institute uses to undertake technology appraisals and provide guidance to the organisations invited to contribute to these appraisals.

When a submission to the Institute is being considered or prepared, the statement of process should be read in conjunction with the guidance documents referred to below. All five documents are available on the Institute's website: www.nice.org.uk

Note: Documents 1, 2 and 5 replace the Institute's publication entitled *Appraisal of New and Existing Technologies: Interim Guidance for Manufacturers And Sponsors December 1999*.

Ordering information

These publications can be ordered by telephoning the NHS Response Line on 0870 1555 455 and quoting the relevant reference number below. The price is £10.50 each with a 10% discount for orders between 5 and 50 copies. Discounts for orders over 50 by application to NICE. The five technology appraisal documents are:

Title	Ref. No.
1. Guide to the Technology Appraisal Process	N0010
2. Guidance for Appellants	N0011
3. Guidance for Patient/Carer Groups	N0012
4. Guidance for Healthcare Professional Groups	N0013
5. Guidance for Manufacturers and Sponsors	N0014

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Guidance for Healthcare Professional Groups

The National Institute for Clinical Excellence provides guidance to the National Health Service (NHS) on the use of selected new and established health technologies^{1,2}. The Institute's functions in this context are as set out in the Secretary of State's and the National Assembly for Wales' Directions³.

"to appraise the clinical benefits and the costs of those interventions notified by the Secretary of State and the National Assembly for Wales and to make recommendations".

The Institute assesses the evidence of all the clinical benefits of an intervention in the broadest sense. This will include the impact on the quality of life (e.g. relief of pain and disability) as well as likely effects on mortality, and estimates of the associated costs. In the light of the evidence the Institute reaches a judgment as to whether, on balance, the intervention can be recommended as a cost-effective use of NHS resources in general, or for specific indications, or for defined subgroups of patients. Where there is already an intervention for a condition the committee will estimate the net impact on both costs and benefits of the new intervention.

The Institute's appraisal process relies on information and input from a number of sources including professional organisations. This document provides guidance on the form and format of the submission by professional organisations.

The Institute undertakes appraisals of new and established technologies⁴, as formally requested by the Department of Health (DH) and the National Assembly for Wales (NAW). The types of technology referred will include the following:

- pharmaceuticals
- medical devices
- diagnostic techniques
- surgical procedures
- other therapeutic interventions
- health promotion

1. Background

2. The technology appraisal programme

1 Department of Health. A First Class Service: Quality in the new NHS. Leeds; 1998

2 Department of Health. Faster Access to Modern Treatment: How NICE Appraisal will Work. Leeds; 1999

3 National Institute for Clinical Excellence. Framework Document. London; 2000

4 Technologies, in this context, refer to any intervention used to promote or improve health.

2.1 Identification of products for appraisal

The DH and the NAW select technologies for appraisal based on one or more of 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 (e.g. 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 instance, 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?

For new technologies under development, the DH and the NAW would normally expect (when the process reaches maturity) to provide manufacturers or sponsors with advance warning that their technologies are likely to be the subject of referral to the Institute. The Institute will give manufacturers and sponsors a minimum of four months notice to prepare their submission to the appraisal.

2.2. The appraisal process

The appraisal by NICE of both new and existing technologies encompass:

- their clinical effectiveness;
- their cost effectiveness; and
- their wider NHS implications.

The first step in the scoping process is a search of the literature relating to the technology which will be undertaken by the Institute's information specialist. The scope of an appraisal will usually define a number of distinct elements including:

- the patient population involved and any relevant sub-groups;
- the interventions being examined;
- the comparisons being made with the referred technology;
- the relevant outcomes for determining the effectiveness of the technology.

Manufacturers and sponsors are invited to submit data in relation to all of these issues. The details and timetable for the process are presented diagrammatically

in appendix A. In summary, the Institute commissions a systematic review of the literature to produce an assessment report. This is usually undertaken by a university-based department organised through the National Co-ordinating Centre for Health Technology Assessment. During this period all consultees [manufacturer(s)/sponsor(s), patient and professional groups, the Health Technology Board for Scotland and two health authorities] will also be invited as a group to a meeting with the Institute's executive and technical leads and representatives from the assessment group. The purpose of this meeting is to explain the appraisal process and to explore technical aspects of the appraisal. If manufacturer or sponsor consultees wish to discuss commercial in confidence matters at this meeting then the Institute will consider holding a separate meeting with that consultee for the purposes of that confidential discussion.

Submissions from patient and professional organisations, executive summaries of the manufacturer(s) or sponsor(s) submissions, the written perspectives of the experts invited to attend the meeting of the Appraisal Committee and the comments made by the consultees on the assessment report are added to the assessment report to form an Evaluation Report which is presented to the Institute's Appraisal Committee (see Appendix B). When the Committee meets, its members consider the report together with comments invited from clinical experts and patient advocates.

Their first deliberations result in an Appraisal Consultation Document (ACD) which goes out for consultation to all groups that submitted evidence for a four week period, during the final three weeks of which the ACD will be posted on the website. The committee, at its second meeting, revise the ACD in light of the comments and produce a Final Appraisal Determination (FAD). This is again released to the consultees and posted on the Institute's website five working days later. If this is acceptable then the FAD is presented to the Institute, which is then released as guidance to the NHS. If any of the consultees feel that there are grounds to appeal to the Institute over the contents of the FAD then they have 15 working days to lodge an appeal. There are only three grounds for appeal:

- 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.

Any appeal is heard by an Appeal Panel comprising of five members drawn from the Institute's Appeals Committee, all of whom will have had no prior involvement in 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 within the NHS, one member with experience of the relevant industry or clinical field and one member with experience of patient or carer organisations. If the appeal is upheld the Appraisal Committee will normally be asked to review the evidence.

The process of consultation and appeal are integral to the preparation of the Institutes guidance.

3. The role of professionals and their organisations

Professional organisations have a number of opportunities to input into the appraisal process. They can influence through:

- contributing to the process for selecting topics for the Institute's work programme;
- commenting on the scope and list of consultees;
- commenting on the assessment report;
- providing submissions;
- nominating experts to assist the appraisal committee in its interpretation of the evidence;
- appealing against the Final Appraisal Determination (FAD)

This section describes how professional organisations can best use their time to inform the Institute's guidance. Figure 1, provides an overview of the stages involved, relevant timescales and what can be expected. Please note that this is only a summary. A full statement of the process is set out in the *Guide to the Technology Appraisal Process*.

Figure 1: Response from professional organisations

Institute activity	Approximate timings	Professional response
The Institute asks interested parties to comment on the scope, to confirm their interest in contributing to the appraisal and to nominate clinical experts.	Four weeks after the Institute has initiated the appraisal	<ul style="list-style-type: none"> • Comment on the draft scope produced by the Institute. • Check consultees list and advise the Institute of any omissions. • Declare the organisation's interest in being involved as a consultee. • Nominate clinical experts. • Provide contact details.
Invites organisations to submit evidence, invites patient advocates and clinical experts to provide written perspectives and commissions the assessment report.	Normally at least four months before submission date (-4 months)	<ul style="list-style-type: none"> • Sign confidentiality agreement and confirm receipt of invitation to submit using form enclosed with letter. There will be a reply paid envelope for this purpose. • Read the <i>Guidance for Healthcare Professional Groups</i> and the <i>Guide to the Technology Appraisal Process</i>. • Allocate responsibilities within the organisation. • Organisations are welcome to prepare a joint submission with other professional groups. • During this period you will be contacted to nominate someone from your organisation to attend the first meeting of the Appraisal Committee, who may subsequently be asked to attend the first meeting of the committee.
Institute receives submissions.	0 months	<ul style="list-style-type: none"> • Send submission to the Institute.
Assessment report is received, reviewed by Institute and sent out for consultation.	+3.5 months	<ul style="list-style-type: none"> • Prepare comments on assessment report.
Institute produces evaluation report.	+3.75 months	
1st Appraisal Committee meeting/consideration.	+4.25 months	<ul style="list-style-type: none"> • Nominated professional to attend meeting if requested.

Institute activity (continued)	Approximate timings	Professional response
Release of Institute Appraisal Consultation Document (ACD) for Consultation.	+ 5.5 months	<ul style="list-style-type: none"> • Acknowledge receipt of ACD using form enclosed (fax or post). • Prepare your response to the ACD. • Send your response to the Institute by the closing date. (The date will be clearly indicated)
2nd Appraisal Committee meeting/consideration and preparation of final appraisal determination (FAD).	+6.25 months	
The Institute releases the guidance document for appeal, and posts the FAD on the Institute's website.	+6.5 months	<ul style="list-style-type: none"> • Acknowledge receipt of guidance document to Institute using reply form enclosed. • Decide if the organisation wants to appeal. You have 15 working days to do so. The closing date and information about appeals will be in the covering letter from the Institute. • If you decide to appeal do so in writing following the instructions in the covering letter.
If there is no appeal the guidance will be issued to the NHS.	+7.75 months	<ul style="list-style-type: none"> • You will receive a copy of the final printed guidance from the Institute at the same time that it is issued to the NHS.
If you have decided to appeal.	+9.75 months	<ul style="list-style-type: none"> • The Institute will contact you regarding the appeal and provide you with guidance.

4. The professional organisation's submission

It is important to note that the Institute requests information from a number of sources for each appraisal. Academic institutions, the industry, patient groups, as well as professional organisations provide separate reports for the appraisal committee so each should concentrate on their unique perspective.

The assessment report is structured as:

- Background (epidemiological and health care issues)
- Clinical effectiveness
- Cost effectiveness
- The wider NHS implications

It may be useful for professional organisations to structure their submission in a similar way. However it is more important for professional groups to comment on issues that they think the Appraisal Committee should take into account within reviewing these sections rather than duplicate the assessment report.

4.1 Literature search

The assessment report commissioned from an academic unit concentrates on the published literature and undertakes further analysis as required e.g. modelling of cost effectiveness. A formal protocol is agreed between the Institute and the academic department which sets out in detail the questions that need to be responded to, and an appropriate search strategy is agreed. It is not therefore necessary for the professional organisation to undertake a detailed review of the literature. However what is useful is to comment on the quality of the literature that is likely to be available. It is particularly helpful for professional organisations to highlight specific issues of interpretation, e.g. the appropriateness of research based mainly on overseas studies when there is international variation in disease epidemiology and/or health care provision, or concerns over the quality of the literature in general or specific studies. Professional groups may be aware of current studies that are not yet complete, or their results not yet published. They may know of data sources that might not be incorporated into a formal systematic review yet yield useful information e.g. large clinical audit data sets, disease registers, etc.

4.2 Clinical effectiveness

Professional groups will be aware of discrepancies between outcome indicators used in research and those that are used by them and patients in routine daily practice. They should be able to comment on the validity of these indicators and indicate when caution should be used in their interpretation. They will be able to assess the relative role of the intervention compared to what is currently and likely to be available in the NHS and the importance that professionals place on the intervention. They should comment on the consensus or lack of it amongst the professional groups on the effectiveness, appropriateness and acceptability of the technology, identifying any major differences between professional groups e.g. general practitioners and consultants, specialists and generalists, doctors and nurses etc. They may be aware of the potential for side effects or adverse effects that may not be identified in a research setting.

4.3 Cost effectiveness

The technical aspects will be covered in the academic and industry submissions but again clinicians may wish to comment on relevant outcome indicators, and costs that should be included. Particularly useful are the likely opportunity costs (perhaps hidden) of implementing the technology in the NHS.

4.4 The implications of the technology for the NHS

This could include highlighting changes in work patterns that the adoption of the technology would require, and any reconfiguration of services. They should identify personnel, education and training issues that will need to be addressed. It would be useful to identify any clinical audit tools that would assist in monitoring the implementation of the guidance. Consideration should be given to the value of the technology as a stand-alone intervention or whether it should be linked to a clinical guideline.

5. Format of submission

This will depend on the type of organisation and how relevant the technology is to their main sphere of activity. Organisations vary considerably in their size, constituency, and resources available to them. It is quite legitimate for them to indicate to the Institute that they do not wish to submit and may identify other organisations. They may wish to draw the attention of the Institute to reports or clinical guidelines that are relevant to the appraisal. (All references in the submission should be provided on a separate A4 sheet at the end of the document).

The Institute is aware that it is making considerable demands on a number of organisations, not only in terms of the number of appraisals it consults on, but also the time constraints it imposes in order to adhere to its timetable. The Institute is particularly aware that its rapid timescales often do not fit in with the cycle of advisory committees of many institutions. Most organisations will have to delegate responsibility to individuals and the resulting submission may/may not have been endorsed at an organisational level. In each case the status of the submission should be stated. Any queries regarding the submission should be directed to the Institute at an early stage.

5.1 Length/design

If an organisation does wish to submit, then the document should not be longer than 20 pages. There is no minimum length.

5.2. Executive summaries

Executive summaries of no more than three sheets of A4 should be provided where submissions are longer than 10 pages.

5.3 Form

The Institute would like to receive submissions electronically and uses Microsoft Office software.

5.4 Other professional organisations/joint submissions

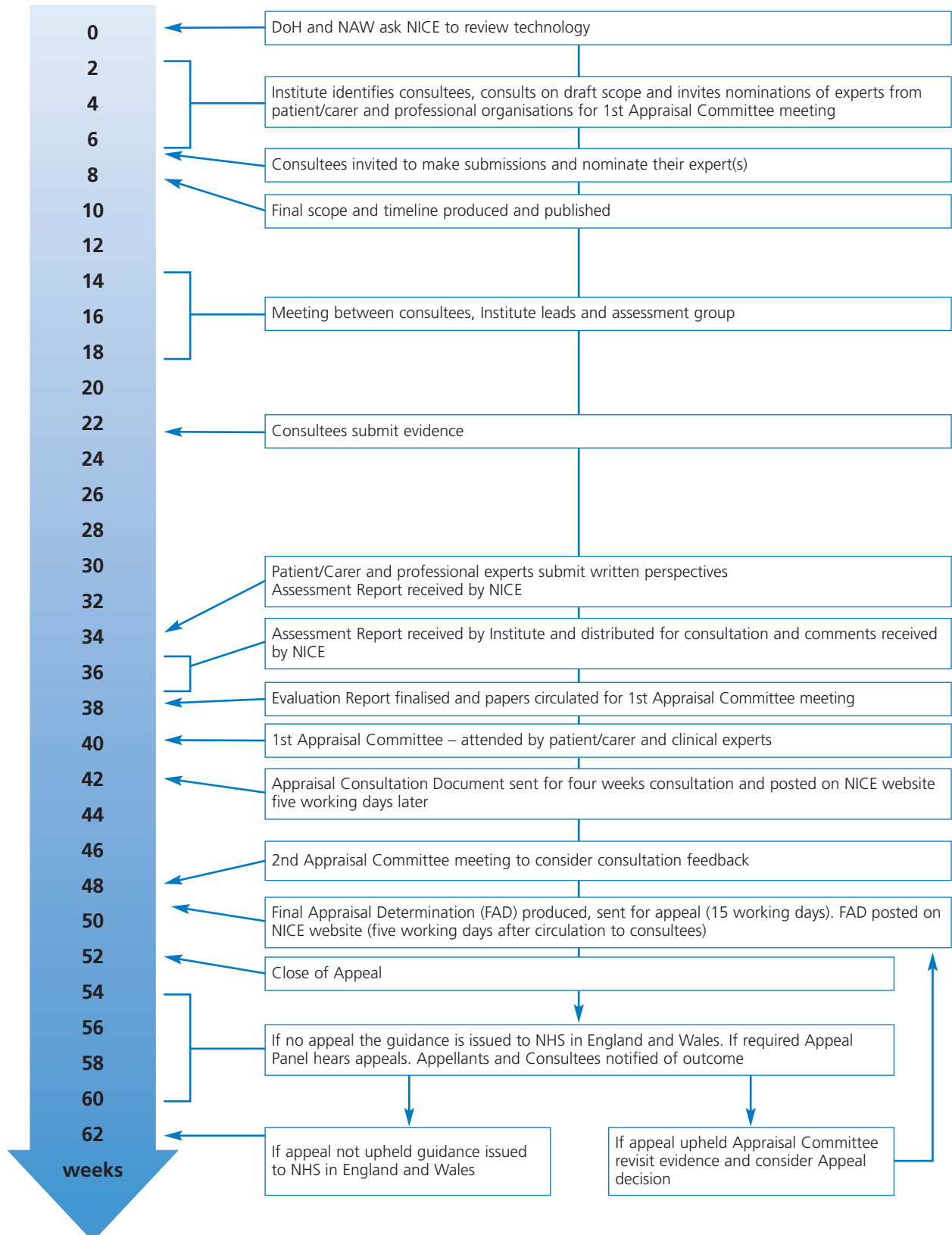
At the start of the appraisal process the Institute will write to professional organisations seeking comments on the draft scope. In the same letter the Institute will list the other organisations it has contacted. If you consider that a key professional group has been omitted please contact the Institute. In some circumstances a joint submission will be suitable e.g. college and specialist society.

5.5. Possible headings and sections

In addition to the suggested sections presented in section 4 of this guidance it is useful to summarise the key issues that your professional organisation would like the Appraisal Committee to take particular notice of.

Appendix A

Diagrammatic timeline for the appraisal process



Appendix B

Composition of the Appraisal Committee

The Institute's Appraisal Committee comprises independent experts drawn from the health professions, patient-focused organisations, health economists, and NHS managers. Appointments are made by the Board of the Institute following consultation with the Secretary of State. Individuals take both a specific and a wider view of the evidence presented to them. None represent constituencies or organisations. The Appraisal Committee meets in private but the minutes are made public and placed on the Institute's website. Its procedures are regulated by standing orders, which are publicly available.

At each meeting, Appraisal Committee members declare any interests they may have and do not take part in appraisals where specific interests are declared. Professional and patient/carer experts, nominated by their referring organisation, attend the Appraisal Committee meeting.

Professor Ron Akehurst

Dean, School of Health & Related
Research
University of Sheffield

Dr Karl Claxton

Lecturer in Economics
University of York

Professor David Barnett (Chairman)

Professor of Clinical Pharmacology
University of Leicester

Professor Duncan Colin-Jones

Professor of Gastroenterology
University of Southampton

Professor Sir Colin Berry

Professor of Morbid Anatomy
St Bartholomew's and Royal London
School of Medicine

Professor Sarah Cowley

Professor of Community Practice
Development
Kings College, London

Dr Sheila Bird

MRC Biostatistics Unit,
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Dr Nicky Cullum

Reader in Health Studies
University of York

Professor Martin Buxton

Director of Health Economics
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Professor Terry Feest

Clinical Director & Consultant
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Mrs Sue Gallagher

Chief Executive
Merton, Sutton and Wandsworth
Health Authority

Dr Trevor Gibbs

International Medical Operations
Director
Glaxo-Wellcome R&D Ltd

Mr John Goulston

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The Royal Free Hampstead NHS Trust

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Chief Executive
Barnet & Chase Farm Hospitals NHS
Trust

Ruth Lesirge

Patient Representative
Director, Mental Health Foundation

Dr George Levvy

Patient Representative
Chief Executive, Motor Neurone
Disease Association

Dr Gill Morgan

Chief Executive
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Professor Miranda Mugford

Health Economist
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Siân Richards

General Manager
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Dr Rhiannon Rowsell

Pharmaceutical Physician
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