



*National Institute for
Clinical Excellence*

Guidance for

Patient/Carer

Groups

Guidance for

Patient/Carer

Groups

This document can be made available in large print, braille or audio format on application.

Guidance for Patient/Carer Groups

Issue date: June 2001

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. 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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Acknowledgements

The Institute is very grateful to the members of the Advisory Group, whose names are listed in Appendix A, for their time and expertise and to those who responded to the consultation exercise for their valuable contributions.

Guidance for Patient/Carer Groups

The National Institute for Clinical Excellence (the Institute) is a part of the NHS. Following an appraisal¹ the Institute produces guidance for both the NHS and patients/carers on technologies such as:

- pharmaceuticals (*e.g. medicines*)
- medical devices (*e.g. artificial hip joints*)
- diagnostic techniques (*e.g. tests to confirm illness*)
- surgical procedures (*e.g. key-hole surgery for colorectal cancer*)
- health promotion (*e.g. the role of diet vs. medicines in disease management*)
- other therapeutic interventions (*e.g. cognitive therapy*).

As part of this appraisal the Institute invites contributions (submissions) from:

- manufacturers
- organisations that represent health professionals
- organisations that represent patients/carers.

The Institute is committed to involving patients/carers in its decision-making. As a national body the Institute does this through the groups that represent patients/carers at a national level in England and Wales. From the patient/carer organisations we seek an understanding of the patient perspective. This document is designed to help those organisations in the preparation of their submission.

This document is provided to patient/carer organisations with the letter that is sent to them inviting them to contribute to the Institute's appraisal of a specific technology. This document also aims to explain what else could be required from a patient/carer organisation when it contributes to an appraisal.

Please note this document is not intended to provide full details of all aspects of the Institute's work and does not relate to the Guidelines and Audit work programme².

This document should be read, where relevant, in conjunction with the related documents '*Guide to the Technology Appraisal Process*'¹ and '*Guidance for Appellants*'¹.

1. What is this document and why have we produced it?

¹ Further information on the appraisal process can be found on the nice web site (www.nice.org.uk) and in the Institute's publications '*Guide to the Technology Appraisal Process*' and '*Guidance for Appellants*'

² www.nice.org.uk

There are many users of the NHS. Different groups use different terms to identify their interaction with the NHS, for instance service user, customer, and carer. In this document we have used the phrase patient/carer to represent those who use or might use the NHS.

In preparing this document the Institute worked with an advisory group and consulted with groups that represent patients and carers. Details of the development process and membership of the advisory group plus those who responded to the consultation can be found in appendix A.

Appendix B provides summary details on the Institute and its work.

2. What is the process of technology appraisals?

The Institute will undertake appraisals of new and established technologies³, as formally requested by the Department of Health (DH) and the National Assembly for Wales (NAW). Figure 1, provides an overview of the appraisal process.

Full details of the appraisal process and membership of the Appraisals Committee are available on the Institute's web site (www.nice.org.uk), together with the publications '*Guide to the Technology Appraisal Process*' and '*Guidance for Appellants*'.¹

The make-up of the Appraisals Committee represents the Institute's stakeholders and includes lay representation. In addition patient/carer representatives may attend the committee meeting as experts as a part of the process.

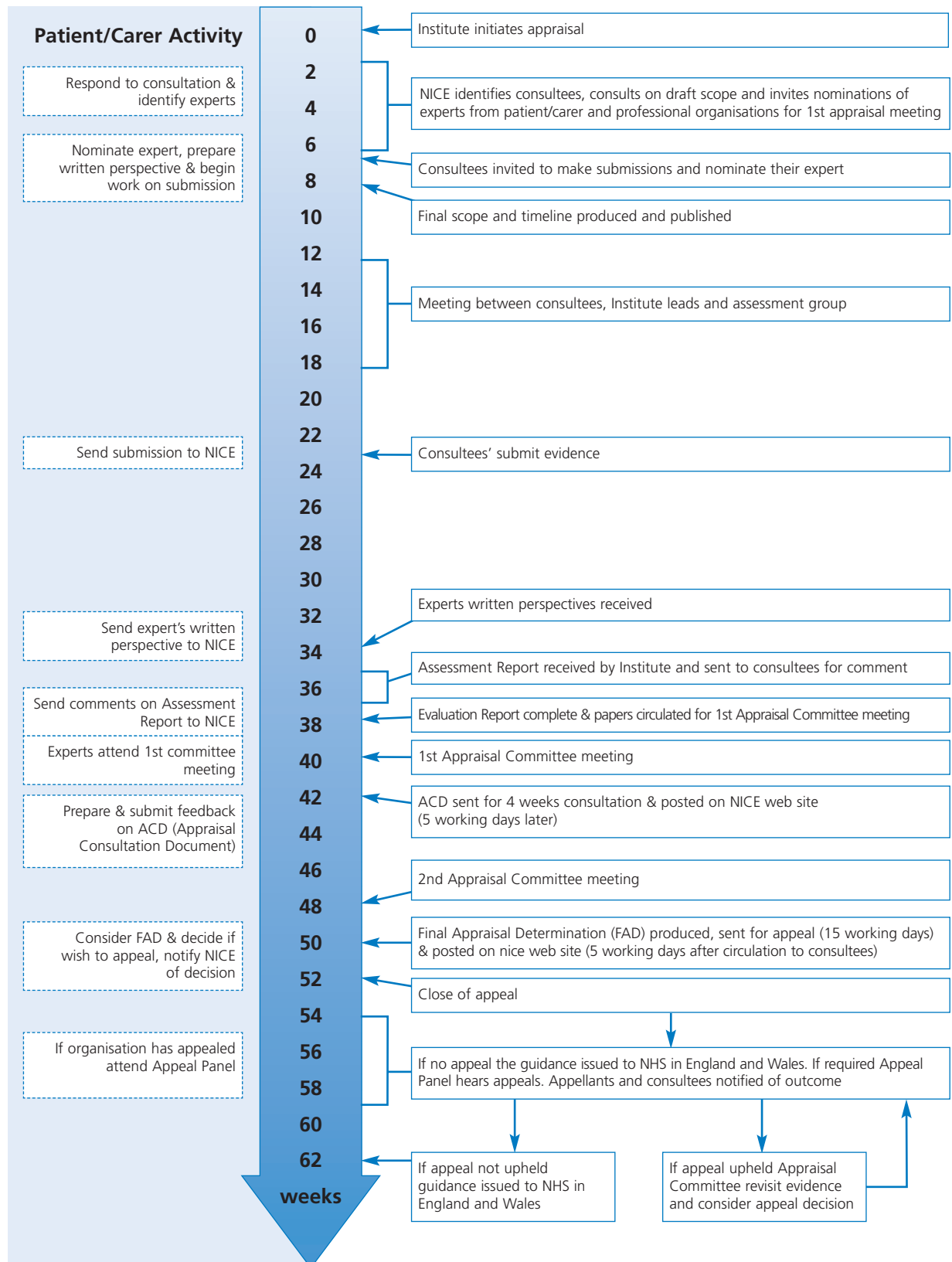
It is not possible to set fixed timescales for the process as the length of time needed for each stage may vary with the nature of the particular appraisal and the position of particular consultees.

The figures in this document are estimates of the number of weeks that will elapse in an average appraisal between the start of the process (Institute initiates appraisal) and that particular step. However certain time limits and consultation periods are referred to in the tables as "fixed", indicating that they will not be adjusted and will be the same in every appraisal, save in exceptional circumstances.

³ Technologies, in this context, refer to any intervention used to promote or improve health.

Figure 1: Overview of the technology appraisal process

(Timings are approximate)



3. How can patient/carer organisations contribute to the technology appraisal process?

Patient/carer organisations can contribute to the process by:

- recommending topics to be considered for the Institute’s work programme by the Department of Health and the National Assembly for Wales
- commenting on the scope⁴ and list of consultees to be involved in the appraisal
- preparing and submitting information that represents their unique perspective of the technology and its use. (Section 4 of this document provides guidance on preparing a submission)
- providing feedback during the consultation period
- appealing if they feel it is appropriate
- working with the Institute on the distribution of its guidance to patient/carers.

Section 5 of this document provides more detail on this topic.

4. Submissions from patient/carer organisations

4.1 What does the Institute need from patient/carer organisations?

From the patient/carer organisation the Institute is looking to gain an understanding of what its like to live with the disease or condition, in some instances what its like to use the technology and the difference the technology makes, if any.

The following provide examples of the sorts of views and information you might wish to include in your submission:

- The aim of the patient/carer organisation & who it represents (membership details etc)
- Living with the condition
- How the condition is currently managed
- Where the technology fits into the way the condition is currently managed
- The benefits/potential benefits of the technology
- The disadvantages/potential disadvantages of the technology (e.g. side effects, risks demanding treatment regimens etc)
- Meaningful outcomes for patients/carers
- The cost of the technology in relation to benefits
- The difference the technology makes/could make to:
 - Physical well being (e.g. symptoms such as pain)
 - Quality of life and well-being for patient and/or carer
 - Psychological health (e.g. mood or anxiety)

⁴ The scope is used to set the parameters for the appraisal. It will focus and steer the process.

-
- Length of life
 - Ability to work/carry out daily tasks
 - Facilitating independence
 - Physical functioning (e.g. preventing or improving mobility and other physical disability)
 - In the short vs. the long term (the following are examples of what is meant by this:
 - are there short term benefits with no long term impact on the condition?
 - are there no short-term benefits but there are benefits over a longer period?
 - Short term could refer to control of symptoms.
 - Long term difference might be increased survival rates)
 - Comments on whether the views submitted are common amongst the patient/carer group. (They may not be common but may still be important)
 - The source of the views/key issues raised should be provided, i.e. the submission should include information on how and where views submitted were gathered
 - It is helpful to include the names of any advisors the group used to support the preparation of their submission
 - Any other information your organisation feels is relevant
 - Declaration of interests. It would be appropriate for you to explain if you receive financial support, formal advice or collaborate in other ways with companies or commercial interests associated with the technology being appraised. The Institute understands that organisations often work with third parties, for example, commercial companies in the area. Declaring these interests does not invalidate your submission.

4.2 What *doesn't* the Institute need to receive from patient/carer organisations?

The Institute will conduct a review of the published research on the technology. It will also review the technical specifications and the formal clinical and cost effectiveness data from manufacturers. The Institute does not expect to receive this data from patient/carer organisations. However if you wish these data can, of course, form part of your submission.

You may wish to provide the Institute with your views on the nature of the existing scientific evidence, for instance, the outcome measures used and how they relate to patients or carers.

4.3 What could my submission look like?

a) Length/design

This is up to your organisation. NICE does not expect all submissions to be the same. Some submissions have been less than one side of A4 whilst others have been significantly longer. The appraisals team have suggested that there is no minimum length for a submission but that a maximum of 20 pages is appropriate. If a submission is longer than 10 pages it should contain an executive summary of no more than 3 sides of A4.

b) How should you submit?

The Institute would like to receive submissions electronically (e-mail or disc) if possible, and uses Microsoft software packages and Rich Text Format (rtf) documents. The Institute also accepts submissions in a paper format.

c) Other patient organisations/joint submissions

At the start of the appraisal process the Institute will write to patient/carer organisations requesting their comments on the scope. In the same letter the Institute will list the other organisations it has contacted. If you feel that an organisation has been included inappropriately or that an organisation is missing from the list please let the Institute know as soon as possible.

The Institute really wants patient/carer organisations to contribute. If you want to work with another patient/carer organisation that has been approached by NICE and prepare a joint submission then you should do so.

d) Examples of material that may help you to develop your submission

Existing material

- Relevant documents/materials produced by your organisation
- Submissions from your organisation to the Department of Health and National Assembly for Wales or other relevant bodies/organisations
- The organisation's internal policy documents
- The organisation's own patient information leaflets/briefing material on the technology
- Previously collected members' views and anecdotes on the topic
- Copies of relevant correspondence between the organisation and others
- Material produced by others.

New material

Some organisations may want to develop new material for their submission to the Institute. Please note this is **NOT** a requirement of the Institute's process but you are welcome to collect it if you wish to do so. Examples of some work that groups have undertaken is:

- Commissioned research e.g. focus groups with members
- Membership surveys/questionnaires
- Workshops and subsequent reports
- Newsletter articles/and responses to them
- Analysis of patient/carer views with the organisation (e.g. calls to a help-line)
- Other methods of consultation with members.

This section provides further detail about where patient/carer organisations can contribute to the appraisal process and has been converted into a short check-list (appendix C).

5.1 Scoping

Institute activity

The Institute will 'scope' the appraisal and identify the proposed consultees for each technology appraisal. They will send you a letter inviting you to comment on the scope and the list of consultees.

In addition, they will ask you to nominate either yourself and/or members of your organisation as possible expert attendees at the first meeting of the Appraisal Committee meeting. If they are asked to attend the meeting they will be representing the patient/ carer group and will be asked to summarise the patient/carer views and respond to questions.

Please note it may be that not all of the nominees are invited to attend.

Patient/carer contribution/activity

- Decide if your organisation wants to contribute to the appraisal.
 - If you **don't want** to contribute please let the Institute know in writing.
 - If you **want** to contribute send the Institute your comments on the scope and the names and details of your expert nominees.
- Check the list of consultees who have been approached and if there is a group you feel is inappropriately included or is missing from the list let the Institute know.
- Read the *Guidance for Patient/Carer Groups* (this document).
- Read the Institute's document entitled '*Guide to the Technology Appraisal Process*'.

5. How can patient/carer organisations contribute at each stage of the technology appraisal process?

5.2 Invitation to submit and nominate experts

Institute activity

The Institute formally asks interested parties to prepare their submissions of evidence and at the same time commissions its evaluation of the technology. The Institute will send you a letter, at least 16 weeks before the submission date, inviting you to prepare a submission.

The letter will also include a confidentiality agreement, and a document explaining confidentiality and the process of technology appraisals.

Institute activity

The Institute will write to the patient/carer experts who are invited to attend the 1st Appraisal Committee meeting.

They will be asked to submit a written perspective and sign a confidentiality agreement. Full details of the meeting date and submission date for the perspective will be included.

Patient/carer contribution/activity

- If you haven't already done so decide if your organisation wants to contribute to the Appraisal.
 - If you **don't want** to contribute please let the Institute know in writing. (e-mail or fax preferably)
 - If you **do want** to contribute send the following to the Institute:
 - receipt of invitation to prepare a submission
 - signed confidentiality agreement
- Check the list of consultees who have been agreed and if there is a group you feel is inappropriately included or is missing from the list let the Institute know.
- Read the *Guidance for Patient/Carer Groups* (this document).
- Read the *Guide to the Technology Appraisals Process* document.
- Start work on preparing your contribution (submission). Cross refer to section 4 of this document.

Patient/carer contribution/activity

- Ensure that your expert signs and returns their confidentiality agreement to the Institute if required to do so.
- Note the due date for sending the written perspective to the Institute.
- Ensure that the expert(s) begin work on preparing their perspective.

5.3 Preparing and submitting your initial contributions

Institute activity

Institute invites consultees to a group meeting with the Institute's Executive and Technical leads and representatives from the assessment group. The meeting is to explain the appraisal process and explore technical aspects of the appraisal.

Patient/carer contribution/activity

- Ensure that you know the date of the meeting.
- Identify issues your organisation wishes to raise prior to the meeting.
- Attend the meeting.
- Following the meeting consultees may contact the assessment group to make and respond to technical queries.
- Make sure that key dates are in your diary (dates for all submissions and dates for consultations) – if you wish to check them do so at this meeting.

Institute activity

The Institute receives submissions from stakeholders.

Patient/carer contribution/activity

- Send your contribution (submission) to the Institute by the due date.
- Remember the Institute prefers electronic communication if possible.

Institute activity

The Institute receives written perspectives from experts

Patient/carer contribution/activity

- Ensure that your experts have submitted their perspectives by the due date.
- Remember the Institute prefers electronic communication if possible.

Institute activity

The Assessment report (output from the independent review) is received by the Institute and circulated to stakeholders who have two weeks to provide their comments.

Patient/carer contribution/activity

- Send your comments to the Institute by the due date.
- Remember the Institute prefers electronic communication if possible.

Institute activity

The Institute combines the Assessment Report, the feedback from the consultation, the submissions and personal perspectives from the professional and patient/carer groups, and the executive summaries of the manufacturers /sponsors submissions to form the evaluation report.

Patient/carer contribution/activity

- Please note submissions from patient/carer organisations are inserted verbatim into the Evaluation Report. They are not edited, nor is any text removed.
- This report is circulated with any other papers to all of those attending the Appraisal Committee meeting and as a part of the later consultation.

5.4 The appraisal and consultation

Institute activity

1st Appraisal Committee meeting and consideration of the evidence.

Institute activity

Institute's Appraisal Committee prepares appraisal consultation document (ACD) and circulates it to stakeholders for a 4 week period of consultation. 5 days after sending to the consultees the Institute publishes the ACD on its website.

The evaluation report will accompany the ACD.

These are usually circulated within seven days of the 1st committee meeting.

Institute activity

2nd Appraisal Committee meeting to consider the original evidence and the ACD in light of the feedback received.

The committee prepares a final appraisal determination (FAD) and submits it to the Institute, usually within 7 days of the meeting.

Patient/carer contribution/activity

- Nominated patient/carer experts attend meeting if requested by the Appraisal Committee.
- This will mean attending a meeting, usually in London.
- They will be asked to summarise the patient/carer view on the technology and the wider implications for the NHS and patients/carers; and respond to questions from the committee.
- The Institute will meet expenses.

Patient/carer contribution/activity

- Acknowledge receipt of ACD and evaluation report using form enclosed with letter (fax or post).
- Forward evaluation report and ACD to your experts if you want their views.
- Other than the ACD and the FAD, documents and information are considered confidential and should not be passed to third parties. Cross refer to the confidentiality agreement you have signed, section 6 of this document and the *Guide to the Technology Appraisal Process* document.
- Prepare your response to the ACD, this should not contain new evidence.
- Send your comments to the Institute by the closing date. The date will be clearly indicated in the covering letter.

Patient/carer contribution/activity

No action required.

Institute activity

The Institute circulates the FAD to consultees who have 15 days to decide if they wish to lodge an appeal.

Five days after sending the FAD to the consultees the Institute publishes it on its website.

During this period the Institute will correct factual errors brought to its attention.

It is not possible to appeal against the FAD simply because the appellant does not agree with it. The Appeal Panel will not consider appeals unless the grounds for appeal are clearly identified and fall within one or more of the following grounds:

- *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.*

Institute activity

If there is no appeal the guidance will be issued to the NHS and the public.

Patient/carer contribution/activity

- Acknowledge receipt of FAD to Institute using reply form enclosed.
- Other than the ACD and the FAD, documents and information are considered confidential and should not be passed to third parties. Cross refer to the confidentiality agreement you have signed, section 6 of this document and the *Guide to the Technology Appraisal Process* document.

- Decide if the organisation wants to appeal. You will have 15 working days to do so. The closing date for submitting an appeal and information about appeals will be provided in the covering letter from the Institute that accompanies the FAD/guidance.

- If you decide to appeal do so in writing following the instructions you were provided with in the letter that was sent with the FAD, this will explain the reasons for an appeal, who to appeal to, and the deadline for receipt of your letter.

- At this time the Institute may send you a patient/carer text that explains the proposed guidance and ask you for your comments, should you have any.

This is not an opportunity to comment on the material nature of the guidance but is an opportunity to advise the Institute if the language and terminology is inappropriate for the patients/carers you represent.

If you have any comments send them to the Communications Director following the instructions that will be provided.

The Institute values the comments it receives to help it communicate effectively with patient/carers.

Patient/carer contribution/activity

- Liaise with the Institute regarding launch dates and any additional copies of the patient leaflet or guidance for your members.
- You will receive a copy of the final printed guidance from the Institute at the same time that it is issued to the NHS.

Institute activity

If you have decided to appeal.

In the event of an appeal, the Institute will not release the names of the appellant(s), except to other appellants, until the decision of the appeal has been published.

If the appeal is not upheld then the guidance is issued to the NHS in England and Wales.

If the appeal is upheld then the FAD is returned to the Appraisal Committee who consider it and the original evidence in light of the appeal panel's comments.

Patient/carer contribution/activity

- The chair of the Appeal Panel will consider if your views constitute an appeal. If they do not, the chair will write to inform you.
- If they do constitute an appeal, then the Institute will contact you regarding the appeal and provide you with details of the appeal date and guidance on what is expected.
- The guidance for appellants is in a separate document.⁵
- Documentation and details of appellants are considered confidential and information should not be passed to third parties. Cross-refer to the confidentiality agreement you have signed, section 6 of this document and the *Guide to the Technology Appraisal Process* document.

6. Confidentiality in the appraisal process

The following documents will be released to consultees during the appraisal process:

- Appraisal scope
- Assessment protocol
- Assessment report (material provided as 'commercial in confidence' having been removed)
- Evaluation report and any supplement(s) to it ('commercial in confidence' data having been removed)
- Appraisal Consultation Document (ACD)
- Final Appraisal Determination (FAD).

The ACDs and FADs are not regarded as confidential documents. They will be posted on the Institute's website 5 working days after they have been sent to consultees.

Other than the ACDs and the FAD, information and documents submitted to or generated by the Institute in the course of its appraisal process are subject to the following policy on confidentiality:

⁵ NICE publication, *Guidance for Appellants*

-
- a) The Institute will not comment on the content of an appraisal until the process has been completed and its guidance has been produced, other than in the circumstances set out in paragraph (b) below.
- b) The Institute reserves the right to comment on an appraisal before the appraisal process has been completed in the event that confidential appraisal documentation is released without the Institute's permission. The decision to make such a comment will be taken by the chairman or vice-chairman of the Institute on the recommendation of two executive directors. Consultees will be informed of this decision as soon as practicably possible.
- c) Organisations invited to make submissions to an appraisal ('consultees', see further below) will be required to sign a confidentiality agreement before they will be recognised as consultees and appraisal documentation released to them.
- d) Appraisal documents released to consultees by the Institute must be kept securely at all times. The Institute considers that those within the consultees' organisation who see appraisal documentation are bound by the terms of the confidentiality agreement signed by the consultee organisation.
- e) Consultees may release the appraisal documentation to third parties where:
- this is clearly necessary to enable the consultee to formulate its contribution to the appraisal; and
 - the third party has seen and agreed to be bound by the terms of the confidentiality agreement.
- Any organisation or individual not in the direct employment of the consultee organisation is a third party.
- f) Consultees may discuss confidential appraisal documentation with other consultees, but before doing so each consultee must satisfy itself that the other has signed and returned their confidentiality agreement to the Institute.
- g) Where information submitted to the Institute is designated by a consultee as being 'commercial in confidence', the Institute undertakes not to release this information to a third party. However, the Institute may ask the consultee to forego such restrictions on release where either:
- there appears to be no obvious commercial reason for the restrictions; or
 - such restrictions would make it difficult or impossible for the Institute to show the evidential basis for its guidance.
- h) The Institute reserves the right to use in its evaluation report, appraisal documents and appraisal determinations any material which is submitted to it during the course of an appraisal which is not designated by the consultee as being "commercial in confidence" or which ceases to be so designated under paragraph (g) above. However the Institute will not release to a third party any documents received by it from consultees, including submissions,

correspondence, responses to formal consultation and statements of appeal against the FAD, unless the originator of the documents consents to the release.

- i) In the event of an appeal, the Institute will not release the names of the appellant(s), except to other appellants, until the decision of the appeal has been published.

Glossary

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| Appeal | <p>The Appeal is an integral part of the appraisal process. The FAD (final appraisal determination) and its associated guidance document are circulated to stakeholders who have 15 working days to appeal. The Institute will hear an appeal based on one or more of the following grounds:</p> <ul style="list-style-type: none">i) The Institute has failed to act fairly and in accordance with the appraisal procedure;ii) The Institute has prepared guidance which is perverse in the light of the evidence submitted;iii) The Institute has exceeded its powers. |
| Appeal panel | <p>Appeals are heard by a panel independent of the appraisal process. The panel will comprise of 5 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.</p> |
| Appraisal | <p>Appraisal is the process of determining the clinical and cost effectiveness of a technology.</p> |
| Appraisal Committee | <p>The Appraisal Committee is a unique body. It combines patient advocates, NHS clinicians and managers, academic experts and industry representatives. The members are appointed for three years. Full details of committee members are available on the Institute's website. For each appraisal the committee declare any interests and therefore some members may be excluded from taking part. The standing committee will be supplemented by technology-specific experts brought in for the day – they will bring invaluable first hand knowledge to the committee's work. To date they have included professionals and patient/carer representatives.</p> |

**Appraisal
Consultation
Document
(ACD)**

This is the document prepared by the Appraisal Committee after their first consideration of the evidence. It reflects their initial thoughts based on the data contained in the evaluation report and the representations of the health professionals and patient/carer organisations that attended their meeting. It is circulated to consultees for 4 weeks consultation and posted on the Institute’s website 5 days after it has been sent to consultees.

**Assessment
Report**

The assessment report is commissioned by the Institute. It is prepared following the independent review of the published literature and the manufacturers’ submissions.

**Confidentiality
agreement**

The confidentiality agreement is circulated to all parties as part of the appraisal process. Cross refer to section 6 of this document.

Consultees

As part of this appraisal the Institute invites contributions from: manufacturer(s)/sponsor(s), patient/carer and professional groups, the Health Technology Board for Scotland and two health authorities. These organisations are known as stakeholders or consultees.

**Disease
management**

This refers to the steps taken in the management of a disease and its progression.

**Evaluation
Report**

The evaluation report is prepared by combining the assessment report and the full submissions from patient/carer organisations, the executive summaries of the manufacturers/sponsors submissions (note these are inserted verbatim into the evaluation report) and any other information provided to the committee, for example the experts’ written perspectives.

| | |
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| Experts | As a part of the process the Institute asks the patient/carer organisations and professional bodies to nominate individuals to attend and inform the 1st Appraisal Committee meeting. Those that attend the meeting are referred to as experts. |
| Final Appraisal Determination (FAD) | This is the document produced by the Appraisal Committee following their second consideration of the technology, in light of the feedback received following consultation on the ACD. It is sent to consultees who have 15 working days to decide if they wish to appeal. Five days after it has been sent to consultees, it is published on the Institute's website. |
| Guidance | When the Institute publishes the results of its technology appraisal to the NHS in England and Wales the document is called guidance. |
| Guidelines | There is a second strand to the Institute's work, the production of clinical guidelines. The production of guidelines follows a separate process and is not covered by this or the other documents in this series. |
| Patient/carer | There are many users of the NHS. Different groups use different terms to identify their interaction with the NHS; for instance service user, customer, and carer. In this document we have used the phrase patient/carer to represent those who use or might use the NHS. |
| Scope | The scope sets the parameters of its appraisal and identifies the questions that need to be asked about each technology. The scope is prepared after consultation with stakeholders. |
| Stakeholders | As part of this appraisal the Institute invites contributions from: manufacturer(s)/sponsor(s), patient/carer and professional groups, the Health Technology Board for Scotland and two health authorities. These organisations are known as stakeholders or consultees |

Submission

This is the term used for the document that stakeholders send to the Institute to inform the appraisal. If a submission is longer than 10 pages it should contain an executive summary of no more than 3 sides of A4. See section 4 of this document.

Technologies

Technologies refers to:

- pharmaceuticals (*e.g. medicines*)
- medical devices (*e.g. artificial hip joints*)
- diagnostic techniques (*e.g. tests to confirm illness*)
- surgical procedures (*e.g. Key-hole surgery for colorectal cancer*)
- health promotion (*e.g. the role of diet vs. medicines in disease management*)
- other therapeutic interventions (*e.g. cognitive therapy*).

Appendix A

Development of this document

The National Institute for Clinical Excellence really wants to receive the patient/carer contribution. Patient organisations working with the Institute suggested that organisations such as their own might find it helpful to receive advice on preparing a submission for a NICE technology appraisal.

The Institute worked with the following advisory group to develop a draft document for consultation. Advisory group members were selected because of their experience of the technology appraisal process, their understanding of the Institute's work and to provide a range of patient/carer views from the small organisation to the large.

| | |
|--------------------------|--|
| Frederick George | Non Executive Director NICE and a Baptist Minister |
| Marcia Kelson | Senior Research Fellow, College of Health |
| George Levvy | Chief Executive, Motor Neurone Disease Association, & Chair, Patients Involved with NICE (PIN) |
| Barbara Meredith | Policy & Communications Officer Age Concern London |
| Jean Mossman | Chief Executive CancerBACUP |
| Karin Pappenheim | Chief Executive, The Haemophilia Society |
| Anne-Toni Rodgers | Communications Director – NICE |
| Nicola Russell | Policy Officer, MS Research Trust |

The draft document was circulated to over 200 patient/carer organisations groups and posted on the Institute's website in order that the Institute and the advisory group could receive views and feedback. They were particularly keen to receive views with regard to the following points:

1. Would this document be of use? (If not, why not?)
2. Were there any questions that were not covered by the document?
3. Was there any information that would be helpful that was not contained in the document?
4. Was the language/style of the document acceptable?
5. Were the diagrams clear and helpful – if not how could they be improved?
6. Any other comments/feedback.

Feedback was received from the following:

- Afasic Organisation
- Aids Education & Research Trust, AVERT
- Alzheimer's Society
- Association for Glycogen Storage Disease UK, AGSD
- Association for Spina Bifida and Hydrocephalus, ASBAH
- Behcet's Syndrome Society
- British Brain & Spine Foundation
- British Dental Association
- British Dietetic Association
- British Epilepsy Association
- CancerBACUP
- Chronic Granulomatous Disorder
- Climb, The Research Trust for Metabolic Diseases in Children
- College of Occupational Therapists
- Coeliac Society Response
- Diabetes UK
- Ehlers-Danlos Support Group
- Fellowship of Depressives Anonymous
- Genetic Interest Group
- Headway National Head Injuries Association
- The Herpes Viruses Association, SPHERE
- Hospice SPC Council
- Laurence – Moon – Bardet – Biedl Society, LMBBS
- Lincolnshire Post-Polio Network (UK)
- Motor Neurone Disease Association
- Macmillan Cancer Relief
- Marie Curie Cancer Care
- Michael E Cadwallader
- The National Association for Colitis and Crohn's Disease
- The National Deaf Children's Society, NDCS
- National Schizophrenia Fellowship, NSF
- The Neurological Alliance
- Parkinson's Disease Society
- The Patients Association
- Plymouth Community Services
- The Psoriasis Association
- Restricted Growth Association, RGA
- Royal College of General Practitioners, RCGP
- Royal College of Obstetricians & Gynaecologists
- Royal College of Physicians
- Skin Care Campaign
- Steps National Office
- Tuberous Sclerosis Association
- United Kingdom Advocacy Network
- UK Carers Organisation
- Women's Health

This feedback was incorporated into a second draft that the advisory group reviewed and agreed amendments. The document was finalised following revisions to the appraisal process agreed at the February 2001 meeting of the Institute's board.

Appendix B

What is NICE and what does it do?

The National Institute for Clinical Excellence is a Special Health Authority for England and Wales. It is part of the National Health Service (NHS), and was set up on the 1st April 1999. Its role is to provide patients, health professionals and the public with authoritative, robust and reliable guidance on current 'best practice'.^{6,7}

The guidance is based on an appraisal of those technologies, including:

- pharmaceuticals (e.g. medicines)
- medical devices (e.g. artificial hip joints)
- diagnostic techniques (e.g. tests to confirm illness)
- surgical procedures (e.g. key-hole surgery for colorectal cancer)
- health promotion (e.g. the role of diet vs. medicines in disease management)
- other therapeutic interventions (e.g. cognitive therapy).

The nature of the appraisal carried out by the Institute is as described in the Secretary of State's and the National Assembly for Wales' Directions:⁸

"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".

This means that the Institute assesses the evidence of all the clinical benefits of an intervention (referred to in this document as a health technology) 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. Evidence is derived from a systematic review and from information provided by the consultees to the appraisal process.

In light of the evidence before it, the Institute's Appraisal Committee (a statutory committee, the membership of which is published on the Institute's website) will reach 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 Appraisal Committee will, as appropriate, estimate the net impact on both costs and benefits of any new intervention under consideration. This judgment is referred to as the appraisal determination,

6 Department of Health A First Class Service NHS Executive: Leeds 1998

7 Department of Health Faster Access to Modern Treatment: How NICE appraisal will Work. NHS Executive: Leeds 1999

8 Department of Health and National Assembly for Wales/National Institute for Clinical Excellence: Framework Document

and once the appraisal process is complete (including any appeal) the determination is submitted to the Institute. This determination is then used by the Institute as the basis of its guidance to the NHS in England and Wales.

In reaching its judgment the Institute will have regard to the factors listed in the Secretary of State and National Assembly for Wales' Directions, namely:

- the Secretary of State's and the National Assembly for Wales' broad clinical priorities (as set out for instance in National Priorities Guidance and in National Service Frameworks, or any specific guidance on individual referrals)
- the degree of clinical need of the patients with the condition under consideration
- the broad balance of benefits and costs
- any guidance from the Secretary of State and the National Assembly for Wales on the resources likely to be available and on such other matters as they may think fit
- the effective use of available resources.

A further factor, which the Institute will take into account in its appraisal, is the wish to be sympathetic to the longer-term interests of the NHS in encouraging innovation of good value to patients.

Selection of technologies for appraisal

The DH and the NAW will select technologies for appraisal based on the following criteria:

- Is the technology likely to result in a significant health benefit, taken across the NHS as a whole, if given to all patients for whom it is indicated?
- Is the technology likely to result in a significant impact on other health-related government policies (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?

Before deciding whether to refer a particular health technology to the Institute the DH and NAW consults with relevant patient bodies, professional bodies and manufacturers and sponsors of the technologies in question.

Until a technology, or set of technologies, is formally referred to the Institute by the DH or NAW, the Institute cannot commence the appraisal process described below. The Institute will not comment on speculation about possible referrals to NICE.

Further information about the process for selecting technologies for referral to the Institute can be obtained from *Dr Nick Clarke, MPI Division, Department of Health, Quarry House, Quarry Hill, Leeds, LS2 7UE*

Where can I find out more about the National Institute for Clinical Excellence?

Further information on the Institute is available from the NICE web site (www.nice.org.uk).

Appendix C

Suggested checklist

| Institute activity | Approx. timings | Patient/carer contribution | ✓ |
|---|---|--|---|
| NICE asks consultees to comment on the scope of appraisal, to provide feedback on proposed consultees & to nominate experts. | You will have a fixed two week period to provide your comments on the scope | Read the Guidance for Patient /Carer Groups (this document) and any documentation accompanying the letter | |
| | | Decide if organisation wants to contribute to the Appraisal | |
| | | If you don't want to contribute notify NICE know in writing | |
| | | If you do want to contribute send the Institute: | |
| | | <ul style="list-style-type: none"> your comments on the scope | |
| | | <ul style="list-style-type: none"> the names and details of your expert nominees Details of any consultees who you feel are inappropriately included or are missing from the list | |
| NICE formally asks consultees to prepare submissions of evidence and at the same time commissions its evaluation of the technology. | Seven weeks after the Institute initiates the appraisal | If you don't want to contribute notify NICE in writing. | |
| | | If you want to contribute return the following to NICE: | |
| | | <ul style="list-style-type: none"> Receipt of invitation to prepare a submission Signed confidentiality agreement | |
| | | Note key dates from the covering letter in your diary | |
| | | Start work on preparing your contribution (submission) Note submissions from patient/carer organisations are inserted verbatim into the Evaluation report. (Section 4 of the <i>Guidance for Patients/Carers</i> document) | |
| NICE asks selected experts to attend 1st Appraisal Committee meeting | Seven weeks after the start of appraisal | If nominee invited as an expert: | |
| | | <ul style="list-style-type: none"> Ensure your expert signs and returns their confidentiality agreement to the Institute if required to do so Note the date for sending their perspective to NICE Ensure that the expert(s) begin work on their perspective | |
| | | | |
| Meeting between consultees, Institute's lead staff & assessment group. | 13–18 weeks after the start of the appraisal | Ensure that you know the date of the meeting | |
| | | Identify issues your organisation wishes to raise prior to the meeting | |
| | | Ensure that key dates are in your diary – if you wish to check them do so at this meeting | |
| Institute receives submissions & expert perspectives | 23 & 34 weeks after the start of the appraisal | Send contribution (submission) to NICE by due date (23 – weeks after the start of the appraisal) | |
| | | Ensure experts have submitted their perspectives by due date (34 weeks after the start of the appraisal) | |
| Assessment report sent to consultees for comment | 35 to 37 weeks after the start of appraisal | Confirm receipt of document to NICE | |
| | | Read invitation letter & note instructions you will have 2 weeks to prepare your comments | |
| | | Submit your comments by the due date | |
| Papers for 1st Appraisal Committee meeting | 38 weeks after the start of the appraisal | Ensure that your experts are prepared for the meeting and have read the papers | |
| | | The meetings are usually in London. Has travel been organised? | |

| Institute activity | Approx. timings | Patient/carer contribution | ✓ |
|---|--|---|---|
| 1st Appraisal Committee meeting | 40 weeks after the start of the appraisal | Experts attend Appraisal Committee meeting if previously requested to do so | |
| | | Submit expense claims to Institute | |
| NICE consults on Appraisal Consultation Document (ACD) | 41-45 weeks after the start of the appraisal | Acknowledge receipt of ACD and Evaluation Report | |
| | | You will have four weeks to prepare & your comments. Note the submission date | |
| | | Review organisation's confidentiality arrangements the Evaluation report is a confidential document (Section 6 of the <i>Guidance for Patients/Carers</i> document) | |
| | | Forward ACD & Evaluation report to your experts if you want their views | |
| | | Prepare response to the ACD – this should not contain new evidence | |
| | | Send response to NICE by the closing date | |
| 2nd Appraisal Committee meeting | 48 weeks after the start of the appraisal | | |
| Institute circulates Final Appraisal Determination (FAD) for appeal | 49 weeks after the start of the appraisal | Acknowledge receipt of FAD to Institute | |
| | | You will have 15 working days to construct & submit any appeal. Note the closing date for responding re appeal | |
| | | Notify NICE of any factual inaccuracies in the FAD | |
| | | Be clear that you understand the grounds for appeal. Identify any grounds for appeal and decide if the organisation wants to appeal | |
| | | If you decide to appeal do so in writing following instructions provided with in the letter accompanying the FAD | |
| | | If you do not wish to appeal you do not need to notify the Institute, but it is helpful if you do so | |
| NICE will send you the patient/carer text for your comment | 49-50 weeks after the start of the appraisal | Decide if wish to review patient /carer text | |
| | | Check if any language or terminology is inappropriate for the group you represent | |
| | | Notify NICE of any proposed amendments by the due date | |
| If there are no appeals | 54-60 weeks after the start of the appraisal | Liaise with NICE re the launch date for the guidance. Note: the confidentiality agreement is still in place | |
| | | Order any additional copies of the patient leaflet for circulation to your members | |
| If you have decided to appeal | | NICE will contact you regarding the appeal and provide you with details of the appeal and guidance on what is expected. Details are provided in the Institute publication <i>Guidance for Appellants</i> (www.nice.org.uk) | |

The Technology Appraisals Process Series

1. Guide to the Technology Appraisal Process
2. Guidance for Appellants
3. **Guidance for Patient/Carer Groups**
4. Guidance for Healthcare Professional Groups
5. Guidance for Manufacturers and Sponsors



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