

Public Involvement Programme

Hints and tips when preparing to be a Patient Expert for a Single Technology Appraisal (STA)

Dear Patient Expert,

Thank you for agreeing to take part in a National Institute for Health and Care Excellence (NICE) Technology Appraisal. We look forward to welcoming you at NICE.

Who is this for?

This is aimed at people who are attending the Technology Appraisal Committee meeting as a Patient/Carer Expert. In this document, we will refer to you as 'you' and sometimes as 'Patient Expert'.

It contains general information on what to expect as a Patient Expert, how you can prepare for the meeting, what you might expect in the meeting and what will happen afterwards.

Before the meeting, the project manager for the Committee will send you additional information, specifically about the appraisal in which you are to take part.

If you have any questions or concerns or need help including practicalities, such as needing to be accompanied by your carer, please contact either of the Public Involvement Advisers for Technology Appraisals, Heidi Livingstone at heidi.livingstone@nice.org.uk (020 7045 2183) or Laura Norburn at laura.norburn@nice.org.uk (0161 870 3023).

Please note: there are 2 processes for technology appraisals at NICE:

- Multiple Technology Appraisal (MTA)
- Single Technology Appraisal (STA).

This document is for the **STA process**. Please contact Heidi (see above) if you need the MTA version or if you would like to check which version you should use.

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1 Before the Meeting

1a Short personal statement

Before the Committee meeting, all experts are asked to submit a personal statement to the Technology Appraisal Committee. This is done to give the Committee information about the Patient Expert's experience of the condition and therapy under appraisal. The statement helps Committee members understand the views and experience of each Patient Expert, and enables them to focus their questions.

The personal statement will also help the 'lay lead' pull together key patient issues to present in the meeting. The 'lay lead' is 1 of the 3 Committee lay members who has special responsibility for highlighting patient issues. The earlier you can send us your personal statement, the better, as it helps the 'lay lead' incorporate the main patient issues into the slides.

Personal statements are produced using a template which will be sent to you as part of your invitation to act as Patient Expert. Personal statements are circulated to the Committee in advance of the meeting and are published on the [NICE website](#), alongside all other relevant documentation seen by the Committee for that topic, after the meeting.

You may produce your own personal statement or, if your nominating organisation has already made a statement, you can state that you wish to agree with that, by indicating so on the appropriate form (which is provided as part of your invitation).

1b Preparation

In preparation for the meeting, you should consider whether you would like to request a closed session so that any personal or sensitive information that you do not wish to disclose in public may be considered in private (see section 2b). If so, it will be necessary to discuss this with the Chair before the meeting. Please contact Heidi or Laura, in the Public Involvement Programme (details on page 1), who will put you in contact with the Chair.

You can also prepare for the meeting by:

(i) Thinking about the condition and/or therapy:

- What is your background and experience of the condition and therapy under appraisal?
 - When did you first come into contact with the condition and/or therapy?
 - What impact have the condition and therapy had on your life?
 - If you are a patient or carer yourself, think about significant events, such as when treatment started and completed, onset of adverse or beneficial effects, and changes in quality of life. In the meeting, you should be factual and precise – for example, if you experienced pain, think about how severe it was and how long it lasted.
- In your view, what are the benefits and downsides of the therapy under appraisal?
- How does the therapy compare with other therapies?
- What difference (if any) has the therapy under appraisal made to you?
- What would be the implication if the therapy was not available?
- What is the impact on your home life, social life and your ability to work?
- What is the impact on your family and friends?

(ii) Familiarising yourself with the appraisals process. The [NICE website](#) contains useful information. The Public Involvement Programme has also prepared information sheets on other stages of the appraisal process. You need to have a basic understanding of:

- why technologies are appraised
- how decisions are made
- the implication of NICE guidance for the NHS

It is sometimes useful to be familiar with the previous input into the appraisal from patient and carer organisations and other consultees (stakeholders who can submit statements and lodge appeals), but as a Patient Expert your role is solely to represent your own views and experience.

You will receive a lot of information from NICE before the meeting, but are not expected to read through all of it in detail. The 'premeeting briefing' (written by the NICE Lead Technology Analyst and sent out with the Committee papers) summarises the main findings from the written evidence base, including submissions received. Some Patient Experts prefer to read only the premeeting briefing, while others find it a useful introduction to the rest of the papers.

You should receive all the documents for the Committee meeting up to 2 weeks in advance of the meeting. To ensure that you receive the documentation as early as possible, it is important that you complete and return your confidentiality form. If this form has not been completed and returned, you will not be able to receive any confidential documentation.

Experts attending the Committee meeting are not asked to make a presentation, but are offered the opportunity to introduce themselves, respond to specific questions from Committee members and make a closing comment if they find there is anything of relevance to the Committee's discussion that they have not yet contributed.

1c Identifying key points

What are the main issues for this technology from the patient's or carer's perspective? You may find it helpful to identify 3 or 4 key points that you think are most important when considering the patient or carer view of the therapy being appraised. These are the points you need to try to include in the Committee discussion or in your closing statement.

1d Questions you may be asked

Although it is not possible to know exactly what you will be asked in advance of the meeting, questions will typically be about your personal experience of the condition and therapy. Occasionally, there may be very few questions for you if the evidence and submissions are so clear that no extra clarification is needed. It is not possible to know how many or few questions there might be in advance.

2 At the meeting

2a Venue

Technology Appraisal Committee meetings are held at NICE offices in either Central London or Central Manchester. The Committee itself is quite large and, as meetings are also attended by people other than Committee members, there can be more than 50 people present (on average there are approximately 35 people taking part in the meeting plus observers in the public gallery). Despite the number of people in the room, the Chair tries to make everybody feel as comfortable as possible (see also section 2c below). To help everyone in the room hear, the Committee members, experts and manufacturers all have desk microphones to use in the meeting.

2b Attendance

Technology Appraisals Advisory Committees are now open to the public as part of NICE's commitment to openness and transparency. There is potential for up to 20 people to observe the meeting. We anticipate that many of these places will be taken by interested members of the public and may also include members of the press and people from stakeholder organisations including drugs manufacturers (see section 6). It will be useful for you to consider this factor in preparation for the meeting.

The meeting will be held in 2 parts – with the first part open to the public and the second part closed to everyone except the Committee members and NICE team, to protect confidential data and to enable patient submissions to be considered privately. If you are asked about personal or sensitive matters in the meeting which you do not wish to discuss in public, you may ask the Chair for discussion to take place in private.

Non-Committee members attending the meeting might include:

- NICE staff
- Members of the Evidence Review Group (academic researchers who write a report on the evidence for the appraisal)
- Clinical Experts and other Patient Experts
- Sponsors or manufacturers of the technology being discussed
- Observers (usually members of NICE staff attending as part of a training programme, or people researching NICE or the appraisal process)
- Members of the public (observing – see section 6)

You will have the opportunity to meet with a member of the Public Involvement Programme and the other experts before the meeting. Sometimes it will also be possible to introduce you to the Committee Chair, the NICE Project Manager and Lay Members of the Committee. We hope this will help experts feel comfortable and welcome at the meeting, and make participating in the meeting easier. Please feel free to ask these people any outstanding questions you may have before the meeting starts.

2c Meeting style

Committee meetings follow a relatively formal process. This is necessary because of the large number of people involved in the meeting; it also helps the process to be consistent across all appraisals. For most appraisals, the members of the Committee will usually be on first name terms and the tone of the meeting will be friendly. Committee meetings may have more than 1 technology appraisal on the agenda; therefore, Committee members may have already been involved in several hours of discussion before you are invited to join the meeting.

Even if you are a Patient Expert for the first technology of the day, you may be asked to 'sit out' for the first 10–15 minutes of the meeting. This is to give the Committee time to discuss 'any

other business' relating to previous Committee meetings for other technology appraisals that may be confidential.

2d *Introductions*

All experts, including the Patient Experts, are expected to introduce themselves briefly to the Committee. Because of time constraints, the Committee will not introduce themselves, but all attendees will have a name plate in front of them.

Introduce yourself as a Patient Expert, and briefly, in no more than a minute or so, outline your experience of the condition and therapies being appraised. If you are representing other patients, this is a good time to say who these patients are and how you are representing their views. If you do not represent others than yourself, please say so.

2e *Conflict of interest*

The next stage of the meeting involves all the people taking part in the discussion making a 'declaration of interest'. This is a process where everyone is asked to say whether they have any personal or professional involvement with a company or product that might affect their objectivity (for example, if their position or department is funded by a pharmaceutical company). Sometimes, the Patient and Clinical Experts are asked to make the declarations as part of their introduction or when the Committee members are asked for theirs. Unless you have received payments from, or own shares in, the company whose products are being appraised, or a company whose products are being used as a comparison, you can simply answer 'none' when it is your turn to declare your interests.

2f *The Presentation*

After the introductions and 'declarations of interests', 2 or 3 members of the Committee (the 'lead team'), will give a presentation in 2 parts. The first part of the presentation outlines the clinical issues relating to the condition and the technology. This part also includes patients' issues prepared by the lead Lay Member of the Committee for this topic (see section 1a). If information provided by the Patient Expert is received early enough, it is often incorporated in the slides prepared by the 'lay lead' and presented to the Committee. The second part addresses issues of cost effectiveness. The presentations are essentially a summary of the evidence submitted to the Committee and aim to raise the key issues for discussion at the meeting.

While listening to the part of the presentation dealing with clinical issues, it is helpful for you to consider the following questions:

- Has the condition been defined correctly?
- Has the condition been fully represented?
- Have the 'problems' (if any) of the technology been fully represented?
- Have the 'benefits' (if any) of the technology been fully represented?
- Is the summary at the end of the presentation accurate?
- Do the key issues identified at the end of the presentation include key issues for patients?

The part of the presentation dealing with issues of cost effectiveness is more technical than the first because it deals with 'health-economic modelling'. Although it may be difficult for you to input into this part of the presentation, it is relevant to consider the following points:

- Have the clinical trials presented in the written documentation used a 'quality-of-life measure'?
- If so, has this measurement taken into account the quality-of-life issues that are important to patients?

2g Committee discussion

At the end of the presentation, there will be a summary of the main issues for discussion. The Chair and Committee members will seek clarification of the issues from the experts (Patient and Clinical Experts). Many questions will be directed at the expert panel rather than at the Patient Experts alone, although it is likely that at least some of the questions will be put specifically to the Patient Experts. The experts are asked a number of questions but are also encouraged to raise issues themselves and to participate fully in the Committee's discussion. You are not expected to comment in detail on the health-economic issues but are welcome to do so if you wish.

As noted earlier, the second part of the meeting will be put aside for dealing with issues of a more confidential nature without members of the public in attendance. You are entitled to request that the Chair holds a private session; however, this request must be made before the meeting (see section 1b above – 'Preparation').

The Committee is primarily made up of clinicians and other experts including health economists from the NHS and universities. It can sometimes be difficult for Patient Experts to answer questions that are put to the expert panel (Clinical and Patient Experts) as a whole. It is important, however, that you are proactive in answering questions and in raising issues that you think are important. The Patient Expert role is taken seriously by the Committee and the Chair will ensure that you get an opportunity to speak if you would like to make a comment. The following points may be helpful:

- *Don't wait to be asked a question* – if you have a comment to make about the presentation or want to ask questions to the Committee or the other experts, make it clear to the Chair that you have something to say.
- *If you want to make a point* – keep your arm raised until you are sure that the Chair has seen you. The Chair will keep a list of people who have indicated that they have something to say and he or she will take each comment in turn.
- *When you are speaking* – switch your desk microphone on as it will help everybody hear what you are saying.
- *The primary role of a Patient Expert* – is to ensure that the patient's experience is taken into account.
- *Give a balanced view* – evidence from patients is most effective if you address both positive and negative aspects on the use of a given technology.

2h Equalities

At NICE, we are committed to promoting equality and eliminating unlawful discrimination in our activities and guidance we produce.

The Committee has to bear in mind that a person's treatment should not be determined by their race, sex, disability, age, religion or belief, sexual orientation, gender reassignment or the fact that they are pregnant or have recently given birth. Equality issues can extend beyond these factors to any group of people that can be identified collectively as sharing a common characteristic and could need protection from discrimination.

Please bring to the Committee's attention if you think that this appraisal could:

- exclude any patients for which this treatment is licensed but who are protected by the equality legislation
- lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population
- lead to recommendations that have any adverse impact on people with a particular disability or disabilities.

More information about equalities at NICE is available in [NICE's equality scheme](#).

2i ***Closing Comment***

When the Chair is satisfied that the experts have been asked all the relevant questions, the experts are invited to make a closing comment. Although you are by no means obliged to make a closing comment, this is an opportunity to emphasise any important points and to add any information that you may feel has been overlooked. Even though you are about to leave the meeting, the decision on the technology has not yet been made and what you say here can still have an impact.

3 After you leave the meeting

3a The Committee's decision

Part 2 of the meeting continues after the experts, manufacturers and members of the public leave the meeting. The Committee has to consider the impact of their decision on all patients and the NHS as a whole.

Often, a new therapy may be better but more expensive than a previous treatment. Every time NICE recommends the use of such a technology (drug or medical device) to the NHS, savings from existing budgets have to be made to pay for the new treatment. In practice, this often means that something else can no longer be paid for. The Committee need to be as certain as possible that the effectiveness and benefits of the new therapy would outweigh the potential cut of a service or treatment for patients with the same or other conditions. You may hear the Committee refer to this as 'opportunity costs'.

The Committee discussion is based around all the evidence, which includes:

- Manufacturer(s) evidence submission(s)
- Evidence Review Group (ERG) report
- Patient and carer organisation's written submissions of evidence
- Professional organisation's written statements of evidence
- The Evidence Review Group's responses to the Committee's
- Responses given by experts to the Committee's questions

Based on all the evidence, the Committee considers 2 main things:

- i) *Clinical effectiveness* – how well the treatment or therapy works, compared with current treatment in the NHS?
- ii) *Cost effectiveness* – is the new treatment or therapy good value for public money, compared with current treatment in the NHS?

To do this, NICE uses a measure known as QALYs (quality-adjusted life years). You will hear this discussed in the part of the meeting that you attend. QALYs consider quality of life, as well as length of life. They are a standard measure allowing evidence to be presented in a standard way so that the Committee can make decisions about treatments for completely different conditions in the same way.

Example of how a QALY is calculated

Patient X has a serious, life-threatening condition.

- If he continues receiving standard treatment, he will live for 1 year, with a quality of life of 0.4 (0 or below = worst possible health, 1 = best possible health)
- If he receives the new drug, he will live for 1 year 3 months (1.25 years), with a quality of life of 0.6.

The new treatment is compared with standard care in terms of the QALYs gained:

- Standard treatment: 1 (year's extra life) \times 0.4 = 0.4 QALY
- New treatment: 1.25 (1 year, 3 months extra life) \times 0.6 = 0.75 QALY

The new treatment leads to 0.35 additional QALYs (that is: $0.75 - 0.4$ QALY = 0.35 QALYs).

When we calculate how much it costs (including drug price, but also hospital costs, tests and check-ups) per QALY of benefit, the answer that we get is an ICER (Incremental Cost Effectiveness Ratio).

Example of how an ICER is calculated

If the cost of the new drug is assumed to be £10,000 and standard treatment costs £3000, then the difference in treatment costs is £7000.

The difference in treatment costs is then divided by the difference in QALYs to calculate the cost per QALY gained.

The ICER is $7000 \div 0.35 = £20,000$ per QALY gained.

If the ICER calculation shows the new treatment or therapy is 'good value for money', the treatment will normally be approved (the Committee will use the term 'cost effective'). If the benefits of the treatment are outweighed by the costs, the ICER is likely to be high, and then the treatment is not considered to be 'good value' for public money (not 'cost effective'), and will normally not be approved.

NICE currently considers treatments or therapies that have an ICER:

- under £20,000, to be cost effective
- between £20,000 and £30,000, to sometimes be cost effective depending on the strength of the evidence
- over £30,000, to be rarely cost effective unless there are very special circumstances.

The data that are used in the calculations are sometimes not clear, and so the Committee would need help understanding the information. The Committee asks the experts questions in the first part of the meeting and gets the views of stakeholders from written submissions.

There are other things that the Committee thinks about, not just the ICERs. These include patient preferences, reliability and clarity of the data, whether the new treatment or therapy is innovative, whether the new treatment is life-extending for patients at the end of their life, and

whether there are special 'equalities' issues (the need to consider the effect of the decision on protected groups, such as disabled people – see section 2h above).

3b After the Committee's decision

The Committee's discussions will agree on the contents of the guidance.

One of the following 2 processes will be followed:

- i) If the guidance is broadly in line with the licence for the therapy, there is no formal consultation. The Committee produce a Final Appraisal Determination document directly from this first meeting, and it contains the final recommendations made by the Committee to NICE.
- ii) If the guidance is restrictive however, the Committee produces an Appraisal Consultation Document (ACD). This is draft NICE guidance and is completed 3 weeks (15 working days) after the Committee meeting. It is sent out to all consultees, commentators and experts for comments, and is posted on the NICE website for open public consultation 1 week later.

Consultees, commentators and experts have 4 weeks (20 working days) to comment on the Appraisal Consultation Document. As comments can result in changes to the document, it is also a good idea for Patient Experts to submit their own formal written comments, individually or jointly with the nominating organisation. Please do not use the website to send your comments, as this is only for the general public.

After comments on the Appraisal Consultation Document have been collated, Committee members reconvene at a second meeting to review the document in light of the comments received. In this meeting, the Chair summarises the first meeting and takes the Committee through the comments that have been received. The amended Appraisal Consultation Document then goes on to form the Final Appraisal Determination (FAD) document and the contents of this final version are agreed at the second meeting.

Experts are only occasionally invited back to the second Committee meeting if the Chair feels that more clarification is needed. (If you wish to observe the second meeting, please see section 6.)

In both processes, if the patient organisations that have been involved in the appraisal are not happy with the proposed guidance, they have the option of appealing through the formal appeals process. Appeals against a Final Appraisal Determination can be lodged if:

1. NICE has failed to act fairly and in accordance with its published procedures.
2. The Final Appraisal Determination is perverse in light of the evidence submitted (that is, if another similar group of people would have been unlikely to make the same decision based on the evidence)
3. NICE has exceeded its powers.

The Public Involvement Programme staff at NICE are available to answer queries, but cannot assist organisations who are appealing against an appraisal decision with their appeal.

4 Expenses and honorarium

Patient Experts can claim a £75 fee (or honorarium) as well as travel and subsistence costs for attending a NICE Technology Appraisal Committee meeting. Please see our [policy](#) explaining your entitlement.

Key areas and reminders are highlighted below:

4a £75 fee (or honorarium)

You can claim £75 for attending the committee meeting. When you use the online expenses system (see 4e below) you choose the option on the left hand side called “Honorarium-Lay member” to claim.

4b Travel

If you arrange your own travel by public transport or taxi, it is important to keep any tickets or receipts relating to the journey, so that you can submit them with your claim. If you would like NICE to book your trains, please contact the Committee team. If you plan to travel by car, please note that there is standard allowance per mile set out in [policy](#).

4c Subsistence

If you attend the meeting for 5 hours or more including travel time from your home or office, then you are entitled to claim subsistence for food and drink. Rather than claiming back what you actually eat, we have set rates depending on how long you are away (from home or office). This means that you do not need to provide us with receipts for food and drink. The full information is set out in Appendix 2 of the [policy](#). Here is a quick summary:

Time away from home or office including travel time	Allowance
5 hours or more	£5
10 hours (arriving home or your usual place of work before 7 pm)	£10
10 hours (arriving home or your usual place of work after 7 pm)	£15
24 hours or more (unlikely)	£20

Occasionally, depending on the timing and length of a Committee meeting, Patient Experts are invited to join the Committee for lunch. In this case, you do not need to claim subsistence to cover lunch. Also, if you need to stay overnight in a hotel paid for by NICE and breakfast is included, then you cannot claim subsistence for breakfast. Please note that if you book your own hotel NICE has a cap on the amount that we can reimburse you.

4d Carer expenses

To help Patient Experts attend our Committee meetings, we provide expenses to pay for carers if you need them. This includes childcare and caring for an ill or disabled person.

Additionally, if you need a carer or personal assistant specifically to enable you to attend a meeting when you would otherwise be unable to do so, we will pay for their travel and subsistence expenses in line with the Patient Experts’. We will also reimburse the cost of hiring a carer (up to a maximum of £10 per hour or £60 per day). If you would like more information, please see the [policy](#) or let us know.

4e How to make your claim

You need to make your expenses claim within 3 months of the date of the meeting. Please use the [online expenses system](#) with scanned copies of all required receipts attached.

If you do not have access to the online system or have difficulties when using it, please let us know so that you can use an alternative system. You will still need to give us your receipts.

Please note that your expenses will be paid into your bank account as we can no longer issue cheques.

5 What to do if you are contacted by the press

In the development of most NICE technology appraisals, press releases are often produced. These coincide with the publication of the Appraisal Consultation Document and Final Appraisal Determination. They may be produced by NICE, the manufacturer and sometimes registered patient and carer organisations. A press release may be issued under embargo the day before publication. It is possible you may be contacted by the media then or on the publication day itself.

As with all things related to the media, the interest in any particular appraisal will be dependent on what else is in the news on the day. If you are approached and are willing to take part in interviews you may do so, but please be mindful that the Appraisal Consultation Document and Final Appraisal Determination do not constitute final guidance to the NHS. If asked about your attendance at the Committee meeting, please do not quote any of the Committee members directly.

If a journalist asks about future dates or timescales or anything you are unsure of, please refer them to the press office at NICE (0845 003 7782) who can help them.

6 Observing committee meetings from the public gallery

Our Committee meetings are open to the public, including the general public, members of patient and carer organisations, the press and manufacturers (often drugs companies). We welcome observers from your nominating organisation, or if you have friends or family who would like to observe, then they are also welcome.

There is often a second Committee meeting 2 months after the meeting you attend. Patient and Clinical Experts are not often invited back to participate in the second meeting. This is because the evidence gathering and clarification stage finishes in the first meeting. In the second meeting, the Committee considers the comments received about the Appraisal Consultation Document. However, you, and members of your nominating organisation, are welcome to observe from the public gallery.

People in the public gallery can stay for the first part of the meeting – the part attended by the Patient and Clinical Experts and the manufacturers. Unlike Patient Experts, members of the public gallery are there to observe only and not take part. Members of the public are not allowed to record (either audio or video), take photographs or use laptops, but they can take handwritten notes. They cannot quote you or any of the Committee members directly.

To attend the public gallery, you need to register via our [website](#), 20 working days before the meeting. You will receive an email from the Committee team letting you know when registration is open, along with the registration link.

Please note that people in the public gallery are observers only and not participants, so we cannot provide expenses.

If you would like any more information about observing meetings from the public gallery, please let Heidi or Laura know.

Checklist

Before the meeting

- ✓ Have you sent in your short personal statement to NICE, or indicated you agree with your nominating organisation's statement?
- ✓ Have you returned your confidentiality agreement to NICE?
- ✓ Have you thought about any sensitive information that you would like the Committee to consider in a closed session, and contacted the Chair if appropriate?
- ✓ Have you read through the NICE and Public Involvement Programme documents explaining the appraisals process?
- ✓ Do you feel that you have a basic understanding of the appraisals process?
- ✓ Do you understand your role in the appraisals process?
- ✓ Are you familiar with the submission of evidence from your organisation?
- ✓ Have you read the 'premeeting briefing' sent out with all the papers for the Committee meeting?
- ✓ Have you followed up, in the main written evidence, any of the issues raised in the 'premeeting briefing' that are of interest to you?
- ✓ Have you spoken to the Public Involvement Programme project manager to ask any last-minute questions?

If you answered 'no' to any of these questions, please contact the Public Involvement Programme as soon as possible.

At the meeting

- ✓ Do you have a pen and paper as it will be helpful to make notes in the meeting?
- ✓ Are you familiar with the questions you need to think about when listening to the presentations?
- ✓ Are you aware that you can request, of the Chair, that any personal or sensitive information you would like to raise can be considered in private?
- ✓ Do you know how best to get yourself heard at the meeting?
- ✓ Remember to keep in mind the limitations of the NICE remit.

After the meeting

- ✓ If you want to, jot down a few notes to describe your experience as a Patient Expert.
- ✓ Remember to comment on the Appraisal Consultation Document (ACD) when it is distributed – this will usually be 3 weeks after the meeting. All consultees have 4 weeks to submit comments.

Contact details for the Public Involvement Programme

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