



Consultation process for providing pathology input into NICE publications

Introduction

This document has been produced by the College with the purpose of assisting our pathologists in understanding our role as a stakeholder when contributing to the development of National Institute for Health and Care Excellence (NICE) guidance related to pathology.

As a stakeholder, the College has a direct relationship and/or involvement in NICE's objectives and work programme. The College represents the professional interests of our members by contributing with expert advice to the work of the Institute.

We require advice and contributions from the Specialty Advisory Committees (SACs) into this process as NICE relies on information and input from stakeholders in order to provide clinical guidelines containing recommendations for patient care and appraise the clinical benefits and costs of technologies.

If you are asked to review any documentation from NICE where you feel that pathology input should be sought in areas outside your field of experience or specialty, then please notify the Consultations and Engagement Officer (consultations@rcpath.org) immediately who will be able to ensure appropriate advice has been or will be sought.

The College acknowledges the contribution, support, help, advice and commitment of all its advisors.



The College is actively involved in the development processes of a range of NICE documents.

1. Guidelines

- clinical guidelines
- public health guidelines

2. Technology appraisal guidance

- single technology appraisal (STA)
- multiple technology appraisal (MTA)
- fast track appraisal (FTA)

3. Quality standards

4. Medical technologies evaluation programme (MTEP)

- diagnostics assessment programme (DAP)

5. Highly specialised technology appraisals

The process for each type is described in this document.

1 Guidelines

NICE guidelines provide evidence-based recommendations on a wide range of topics, from preventing and managing specific conditions, improving health and managing medicines in different settings, to providing social care and support to adults and children, safe staffing, and planning broader services and interventions to improve the health of communities.

NICE clinical guidelines provide recommendations on how healthcare professionals should care for people with specific diseases or conditions in the NHS in England and Wales. The recommendations are based on the best practice evidence available.

There are 6 stages to this process.



1.1 Stakeholders register interest

The College registers an interest in a particular clinical guideline by completing the online stakeholder registration form. The College then receives regular information by email about the proposed guideline.

1.2 Scope workshop

The College is invited to send 1 person to the scoping workshop (if held).

The purpose of this is to:

- provide an overview of the NICE clinical guideline development process
- describe how stakeholders can contribute to the guideline by:
 - commenting during the consultations on the draft scope and draft guideline
 - informing their members and associates about guideline development group (GDG) vacancies
- discuss the first draft of the scope and hear stakeholders' views on the key clinical issues that the guideline will cover.

In order to attend, the representative must complete the workshop attendance form and return it to the Consultations and Engagement Officer (consultations@rcpath.org).

1.3 Draft scope consultation

The draft scope is published on the NICE website and stakeholders are invited to submit comments within a 4-week consultation period. Representatives must complete the comments form and return it to the Consultations and Engagement Officer (consultations@rcpath.org) who coordinates the College's response to NICE.

After consultation, the developer finalises the scope in line with the comments received. The final scope is then posted on the NICE website, along with the scope consultation table, which contains the responses to stakeholder comments.



1.4 Consultation on the draft guideline

The draft guideline is developed based on relevant evidence. The evidence is considered by a committee made up of practitioners, professionals, care providers, commissioners, those who use services and family members or carers. The draft guideline is then published for consultation along with a set of particular questions for stakeholders to guide their comments. The College is invited to comment. The consultation period lasts for 6 weeks for standard guidelines and 4 weeks for short guidelines. Comments should be submitted using the comments form that is provided and returned to the Consultations and Engagement Officer (consultations@rcpath.org).

When commenting on the guideline, stakeholders should consult the scope (on the NICE website) to check what the guideline does and does not cover. Stakeholders can comment on the full guideline (which includes the draft recommendations as well as explanations of how the committee has interpreted the evidence to make the recommendations) and/or the 'NICE guideline' (which contains just the draft recommendations and only brief supporting information). The stakeholder feedback is considered by the committee and the guideline is revised.

1.5 Signing off the guidance

After agreed changes have been made to the guideline in response to consultation comments from registered stakeholders, the guideline is reviewed by NICE to ensure the correct quality assurance processes have been followed.

Once finalised an advance copy of the final guidance will be sent to registered stakeholders that have agreed to conditions of confidentiality 2 weeks prior to publication. This gives stakeholders a chance to highlight any substantive errors to NICE and prepare for implementation.

1.6 Publication

NICE formally approves the final guideline and publishes its guidance on their website.



2 Technology appraisal guidance (STA, MTA and FTA)

Technology appraisal guidelines relate to the use of new and existing medicines, treatments and procedures in the NHS. The College must be invited to act as a stakeholder in the appraisal.

There are 8 stages of the NICE technology appraisal process.

2.1 Accepting invitation and commenting on the draft remit, scope and matrix

The College inform NICE whether or not they wish to be involved, and send comments to NICE on the draft remit, scope and matrix by the deadline. The comments form will be completed by the representative.

The College should also inform NICE if there are any stakeholders that should also be invited or removed from the matrix, or if there are any mistakes.

The College must provide NICE with the details of a named contact in our organisation who will coordinate the responses for this appraisal.

2.2 Attend the scoping workshop

The College is invited to send at least 1 representative to the scoping workshop (if held). At this workshop the proposed remit and scope of the appraisal will be finalised.

The College must provide the name of a representative who is willing to attend the workshop and share views and opinions regarding the proposed appraisal on behalf of the College.

At the scoping stage, a proposed topic may not be put forward for appraisal.

2.3 Appraisal

The College will receive an email to confirm that the appraisal is going ahead along with an invitation to register as a formal consultee/commentator in the appraisal process.



The College will:

- let NICE know if they wish to be involved
- make sure NICE have up-to-date contact details for those involved.

The representative will:

- sign the confidentiality agreement and return it to the Consultations and Engagement Officer (consultations@rcpath.org).

The College is invited to make a written submission. The submission, along with others received, will form part of the evaluation report and will be shared with everyone at the first Appraisal Committee meeting, as well as being posted on the NICE website.

The College comments will be written by the nominated specialist and sent to the Consultations and Engagement Officer (consultations@rcpath.org) for submission to NICE.

2.4 Invited to nominate clinical experts to join the Appraisal Committee

During the appraisal phase, the evidence is reviewed by the Appraisal Committee, which makes its recommendations to NICE. The Appraisal Committee meets at least twice and consists of:

- doctors
- nurses
- pharmacists
- NHS managers
- health economists
- statisticians
- lay representatives.



2.5 NICE may send the College a copy of the committee report for comment

For MTAs, an assessment group (AG) report is prepared. For STAs, an evidence review group (ERG) report is prepared.

The College will ask its advisor to make comments on the AG/ERG report by the deadline.

Any comments the College makes on this report will feed into the first Appraisal Committee meeting and form part of the evaluation report, which will be sent to consultees and posted on the NICE website.

2.6 Comment on the appraisal consultation document and evaluation report

Comments received on the appraisal consultation document (ACD) will be considered by the Appraisal Committee. After the meeting, the College will be sent a copy of the final appraisal determination (FAD).

2.7 Comment on the FAD

The advisor should provide comments to the College on the following:

- inform NICE whether the College agrees with the recommendations made in the FAD
- decide whether there are grounds to appeal; NICE must receive any appeal by the deadline.

2.8 Publication

NICE formally approves the final guideline and issues its guidance to the NHS in England and Wales.

The College has developed a process with the British Society for Haematology (BSH) to provide joint comments to NICE on haematology issues (see Appendix A).



3 Quality standards

NICE quality standards are a set of specific, concise statements that act as markers of high-quality, cost-effective patient care, covering the treatment and prevention of different diseases and conditions. Each quality standard contains 6–8 quality statements (with a maximum of 15 in exceptional circumstances). The policy remit for quality standards applies to England only and is not mandatory, however they can be used for a wide range of purposes both locally and nationally.

Quality standards are derived from the best available evidence; they are developed independently by NICE, in collaboration with the NHS and social care professionals, their partners and service users. The process of developing a quality standard is approximately 42 weeks.

The core principles of the Quality Standards Programme (QSP) are to:

- develop and publish quality standards that identify safe, effective and cost-effective care and services, based on NICE guidance or NICE-accredited guidance
- identify how quality standards can be used to improve outcomes, including quality of life and satisfaction with care for patients, service users and carers
- provide stakeholders with an opportunity to contribute through consultation processes that are inclusive, open and transparent
- consider the cost impact of quality standards
- consider the equality impact of quality standards
- regularly review and update quality standards
- seek alignment with other national quality initiatives.

There are 6 stages to this process.



3.1 Stakeholders' involvement

Stakeholders are identified from the list of organisation registered as stakeholders for the NICE or NICE-accredited guidelines.

3.2 Development of quality standards

The quality standards team leads the development of quality standards. They develop a topic overview for each quality standard, such as the population and condition or services to be covered, and lists the key source guidance that will be used to underpin the quality statement.

3.3 Topic engagement (2 weeks)

The topic overview is published on the NICE website along with information of the consultation phases. NICE requests a written submission from the Quality Standard Advisory Committee (QSAC) members and stakeholders.

The College ask the QSAC to provide a relevant specialist advisor to provide advice and to provide written submission in the provided proforma within 2 weeks of the request. The QSAC reviews the submissions and prioritises areas to be covered by the quality standard. NICE then creates draft quality standards, which are approved by the QSAC chair.

At this stage the quality standards team will invite stakeholders to express an interest in formally supporting the quality standard when the topic overview is published.

3.4 Formal consultation (4 weeks)

After the QSAC chair, on behalf of QSAC and NICE, has agreed the short list of draft quality standards, registered stakeholders will be invited to submit comments on a proforma using a dedicated email address. College representatives should send their comments to the Consultations and Engagement Officer (consultations@rcpath.org) who will coordinate the College's response to NICE.

Stakeholders are again invited to express interest in formally supporting the quality standard.



3.5 Consultation feedback

The quality standard team collates the feedback from consultation and the results from field testing. They review this information and document their response to issues raised. The quality standard is refined with input from the QSAC.

3.6 Publication

Once a quality standard is approved by the NICE Guidance Executive, the final quality standards will be published on the NICE website. Each published quality standard will be formally reviewed 5 years after publication.

4 Medical technologies evaluation programme

The MTEP identifies medical technologies that have the potential to offer substantial benefit to patients and/or to the NHS and are likely to be adopted more consistently and more rapidly if NICE develops guidance on them.

4.1 Medical technologies evaluation programme

There are 7 stages to this process.

4.1.1 Invited to register an interest

The programme team will contact relevant professional and patient organisations informing them that an evaluation programme is being established for a specific topic and will invite these organisations to register an interest in being involved in the consultation process.

The SAC chair will be asked to identify whether or not this topic is of any interest to the College. If so, they will recommend an adviser to provide comments on the College's behalf.

4.1.2 Draft scope

The programme team will prepare a draft scope defining the most important questions about clinical and resource impacts. This document will be sent to registered organisations for consultation with any comments submitted within 5 working days. The assigned adviser will provide the College with any comments for submission to NICE.



4.1.3 Final scope

The final scope will be published on the NICE website 2 weeks after the consultation closes.

4.1.4 Draft recommendations

The Medical Technologies Advisory Committee (MTAC) will meet in public to develop the draft recommendations on this technology based on the sponsor's submission, the external assessment centre report, and contributions from expert advisers/patient and carer organisations.

4.1.5 Medical technology consultation document

NICE will issue a medical technology consultation document based on the MTAC's recommendations. Anyone is able to comment on this document, however notifications will be sent to relevant experts and organisations. The document will be published on the NICE website for 4 weeks. The advisor identified will be asked to undertake this on behalf of the College and send the comment to the College for submission.

4.1.6 Final guidance

The MTAC will collate the consultation responses and where necessary amend the draft recommendations. If the recommendations differ significantly, they will be sent out for a 2nd consultation. The MTAC's final recommendations will be submitted to the Guidance Executive for approval.

4.1.7 Publishing

Once the Guidance Executive approves the guidance it will go through a final resolution process to ensure NICE has followed the correct procedures. It will then be published on the NICE website and notifications of the publication date will be sent to registered organisations.

4.2 Diagnostics assessment programme

The DAP is a subset of the MTEP and was created to assess diagnostic technologies that have the potential to improve key clinical decisions, leading to improved treatment choice or improvements to quality of life. The programme also assesses diagnostics that can



improve the efficient use of NHS resources, including the potential to improve systems and processes for the delivery of health and social care. In practice, the programme concentrates on pathological tests, imaging, endoscopy and physiological measurement, since these represent most of the investigations performed on patients. Diagnostic technologies may be used for various purposes: diagnosis, clinical monitoring, screening, treatment triage, assessing stages of disease progression and risk stratification, etc.

There are 12 stages to the process.

4.2.1 Assessment topics choice

NICE's MTAC selects topics for assessment by the DAP.

4.2.2 Scope prepared

The scope defines the disease(s), the patients and the technology(ies) covered by the assessment and the questions it aims to answer. The DAP will develop this through a literature search along with contributions from manufacturers, expert advisers and the external assessment group (EAG).

4.2.3 Specialist committee members recruited

The Diagnostics Advisory Committee is an independent advisory committee. Specialist members with expert knowledge of the subject are recruited to the committee for the duration of the assessment.

The College may be invited to nominate a representative to the committee.

4.2.4 Scoping workshop

Once the draft scope has been developed, NICE will hold a scoping workshop. All registered stakeholders are invited to attend.

4.2.5 After the workshop

The DAP technical team revises the scope taking into account any comments made at the workshop. NICE will then agree the revised scope and send it along with the draft assessment protocol to the assessment subgroup. When the group approves the final scope it will be published on the NICE website.



4.2.6 Information provided by manufacturers

NICE invites manufacturer(s) of the technology being assessed to provide relevant published and unpublished information and data to the assessment.

4.2.7 Diagnostics assessment report prepared

The EAG develops an assessment protocol from the final scope, which NICE will sign off and publish on its website.

The EAG will then prepare the diagnostics assessment report (DAR) in line with the agreed criteria. The DAR, with confidential information removed, will then be sent to stakeholders for comment. Stakeholders have 10 working days to submit comments before they are passed to the committee for review.

Registered stakeholders are invited to comment on the report. The advisor identified will be asked to undertake this on behalf of the College and send comments to the College for submission.

4.2.8 Diagnostics advisory committee meeting

An independent advisory committee considers the assessment report and comments from stakeholders and the EAG's written response. The committee then formulates draft recommendations. The committee discussions are held in public.

4.2.9 Diagnostic consultation document produced

The advisory committee makes its provisional recommendations in the diagnostic consultation document (DCD).

Registered stakeholders have 4 weeks to comment on the DCD. The advisor will be asked to comment and send these to the College for submission.

The DCD is also made available on NICE website so that health professionals and members of the public can comment on it.



4.2.10 Final guidance produced

The committee considers the comments received on the DCD, then makes its final recommendations on how the technology should be used in the NHS in England and Wales.

4.2.11 Resolution

Once NICE formally approves the final guidance, individuals or organisations who commented on the draft guidance are notified. They can request corrections to the guidance due to breach of process or factual errors.

4.2.12 Guidance issued

If there are no resolution requests, NICE publishes the guidance on their website.

5 Highly specialised technology appraisals

Highly specialised technology (HST) evaluations are recommendations on the use of new and existing highly specialised medicines and treatments within the NHS in England. The highly specialised technologies programme only considers drugs for very rare conditions.

There are 7 stages to the process.

5.1 Stakeholders are identified

Consultee organisations will be identified specifically for each highly specialised technologies evaluation. The College will ask the SAC chair to nominate an adviser to provide comments on their behalf.

5.2 Preparation of the scope

NICE works with the Department of Health and Social Care (DHSC) to undertake a review of the manufacturer or sponsor submission and combines this with further evidence to develop a draft scope. The scope defines the disease, the patients and the technology covered by the evaluation and the questions it aims to answer. Consultees are requested to comment on the draft scope.



5.3 ERG report prepared

If the DHSC agrees to refer the HST to NICE for development, NICE will commission an independent ERG to technically review the evidence submission and prepare an ERG report.

This report includes all of the evidence that will be looked at by the Evaluation Committee:

- the ERG report and any comments received on it
- written submissions
- personal statements from patient experts and clinical specialists.

5.4 Evaluation committee

An independent advisory committee considers the evaluation report and hears evidence from nominated clinical experts, patients and carers. Evaluation Committee discussions are held in public.

5.5 Evaluation consultation document produced if needed

The Evaluation Committee prepares its recommendations in the form of an evaluation consultation document (ECD), but only if these recommendations are restrictive. (A restrictive recommendation will be one that is more limited than the instructions for use that accompany the technology.) The ECD is published on the NICE website and consultees are invited to comment within the 4 week consultation period.

5.6 Final evaluation determination produced

The Evaluation Committee considers the comments on the ECD if produced, then makes its final recommendations in the final evaluation determination (FED). The final recommendations are sent to the NICE project team for final review by the Guidance Executive.

Consultees will be sent an evaluation report at this stage comprising all the evidence seen by the appraisal committee. Consultees can also appeal against the final recommendations in the FED.



The assigned College adviser will be asked whether it is relevant to appeal and provide any comments to them for submission to NICE.

5.7 Guidance issued

If there are no appeals, or an appeal is not upheld, the final recommendations are published on the NICE website.

