NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health and Social Care Directorate

Quality standards

Process guide

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About this guide

This guide describes the process used in the development of NICE quality standards. It will be updated as described in section 8.

This guide replaces ‘Developing NICE quality standards: interim process guide’ (published July 2009). It was first published in October 2012 and revised in 2013 and 2014 to take into account minor changes to the quality standards development process.

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Introduction

The National Institute for Health and Care Excellence (NICE) is a Non Departmental Public Body responsible for providing national guidance, setting quality standards and managing a national database to improve health and social care.

Further details about NICE and its work programmes are available.

The NICE Quality Standards Programme was established in 2009 to manage the development of quality standards. NICE quality standards, as developed by the Health and Social Care Directorate, are central to supporting the Government’s vision for an NHS and Social Care system focused on delivering the best possible outcomes for people who use services, as detailed in the Health and Social Care Act (2012).

This guide details the process that NICE uses to develop quality standards. Figure 1 sets out an overview of this process.

Figure 1 Overview of the NICE quality standard development process

Quality standards developed by NICE are published on the NICE website and are also available from other supporting organisations, such as professional and patient or service user organisations.
Please note that throughout this guide the term ‘quality standards’ refers to all quality standards produced by NICE. The principles of developing NICE quality standards for healthcare, social care and public health, or combinations of these, are the same, although in some circumstances the development process may differ. Where this is the case, the differences are clearly explained.

NICE is very grateful to everyone who contributed to the development of this guide (see appendix A ‘Acknowledgements’).

**Selecting and sequencing topics for quality standards**

**Topics for quality standards**
The Health and Social Care Act 2012 states that:

‘The relevant commissioner may direct NICE to prepare statements of standards in relation to the provision of:

- NHS services,
- public health services, or
- social care in England.’

The Department of Health and other key partners worked with NICE to develop a core list of topics for quality standard development in health-related topics which was referred to NICE in March 2012. Future topics will be referred to NICE by NHS England for health-related areas, and by the Department of Health and Department for Education for areas such as social care.

**Sequencing of topics**
NICE will work with NHS England and other partners to prioritise topics for development on an annual basis. Further details relating to the process for sequencing of topics, and the timetable for delivery, can be found on the [NICE website](https://www.nice.org.uk).
1 The NICE Quality Standards Programme

1.1 What is a NICE quality standard?

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a set of specific, concise statements and related measures that are:

- derived from evidence-based guidance, such as NICE guidance or NICE-accredited guidance
- produced collaboratively with the NHS, social care or public health organisations, along with their partner organisations, patients, carers and service users.

Evidence from the underpinning guidance relating to effectiveness and cost effectiveness, people’s experience of care or services, safety issues, equality and resource impact is considered during the development process.

NICE quality standards do not provide a comprehensive service specification. They define priority areas for quality improvement based on consideration of the topic area.

The policy remit for quality standards applies to England only. It will be for the UK devolved administrations to decide on local policy. Where appropriate, service level agreements will be put in place.

1.2 Components of a quality standard

There are 2 main components to a quality standard: the quality statement and the quality measure. Each quality standard contains 6–8 quality statements (with a maximum of 15 in exceptional circumstances) with related measures.

The quality statements (enhanced or developmental) are clear, measurable and concise. Generally, quality statements are enhanced statements that describe high-priority areas for quality improvement and are aspirational (they describe high-quality care or service provision) but achievable. However some
quality statements are considered to be developmental in nature as they set out emergent areas of practice that have the potential to lead to wide-spread benefits in improving outcomes over time, but which require specific and significant changes to be put in place. Each statement specifies 1 concept or requirement for high-quality care or service provision (for example, a single intervention, action or event). In exceptional circumstances a statement may contain 2 concepts or requirements if they are closely linked (for example, treatment or service options that depend on the results of an assessment).

**Quality measures** accompany each quality statement, and can be used to assess the quality of care or service provision specified in the statement

In addition, each statement is accompanied by a description of its implications for different audiences (service providers, health, public health and social care practitioners, commissioners, patients, service users and carers), the guidance used, the sources of data for measurement, definitions of the terms used and, where relevant, equality and diversity considerations.

### 1.3 How quality standards are used

NICE quality standards provide clear descriptions of high-priority areas for quality improvement. They help organisations improve quality by supporting comparison of current performance, using measures of best practice to identify priorities for improvement, and can provide information for commissioners and providers on how best practice can be used to support high-quality care or services.

They may also demonstrate practice that has the potential to have widespread benefits in improving outcomes over time, but may require specific changes to be put in place, therefore helping organisations to improve quality in the longer term.

NICE quality standards are not mandatory but they can be used for a wide range of purposes both locally and nationally. For example:

- Patients, service users, carers and the public can use the quality standards as information about what high-quality care or services should include.
• Health, public health and social care practitioners can use audit and governance reports to demonstrate the quality of care as described in a quality standard, or in professional development and validation.

• Provider organisations and practitioners can use the quality standards to monitor service improvements; to show that high-quality care or services are being provided and highlight areas for improvement; and to show evidence of the quality of care or services as described in a quality standard through national audit or inspection.

• Commissioners can use the quality standards to ensure that high-quality care or services are being commissioned through the contracting process or to incentivise provider performance.

Although the standards are not targets, providers and commissioners should have due regard to them when planning and delivering services, as part of a general duty to secure continuous improvement in quality.

The development of NICE quality standards includes a consideration of outcomes, as presented in relevant frameworks such as the NHS Outcomes Framework and Social Care Outcomes Framework.

The Care Quality Commission may use data from quality standard measures in its risk estimations. It may also align any special reviews and studies it undertakes with the relevant quality standards.

1.4 Key principles and activities of the NICE Quality Standards Programme

NICE operates the Quality Standards Programme according to its core principles. These include:

• a comprehensive evidence base as described in NICE or NICE-accredited guidance

• independent advisory committees

• input from experts, patients, service users and carers

• transparent process and decision-making

• genuine consultation
- effective dissemination and implementation
- regular review.

The key activities of the Quality Standards Programme 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 resource impact of quality standards
- consider the equality impact of quality standards
- regularly review and update quality standards
- seek alignment with other national quality initiatives.
2 Who is involved in developing quality standards?

2.1 Quality Standards Advisory Committees (QSACs)

Each QSAC assesses information on current practice, prioritises quality improvement areas for statement development and advises on the content of the quality standards.

Each QSAC is made up of

- 21 standing members, including the committee chair
- up to 5 specialist committee members from the key source guidance development groups.

Standing and specialist committee members usually meet twice for each quality standard to:

- apply their professional, expert or lay perspectives to prioritise areas for quality statement and measure development using information from a range of sources collated by NICE
- debate the invited expert testimony, summary report and briefing papers
- consider the resource impact of the standard
- consider the equality impact of the standard
- consider feedback from stakeholders
- refine draft quality statements
- contribute to the development of supporting products to accompany the quality standard, such as 'NICE support for commissioners and others using the quality standard'
- contribute to the development of indicators for national programmes, such as the Quality and Outcomes Framework for primary care and the ClinicalCommissioning Group Outcomes Indicator Set (CCG OIS).

If the QSAC needs further information on a specific issue, additional topic expert advisers can be invited to present expert testimony. They will take a
limited part in the general debate on the quality standard and will not be involved in drafting or revising the quality statements and measures.

After stakeholder consultation and internal validation the QSAC submits the quality standard to the NICE Guidance Executive, which acts under delegated powers of the NICE Board to approve the quality standard for publication. See section 3.7 for more information.

2.1.1 **How QSAC members are appointed**

Standing members of QSACs include commissioners, GPs and other primary care professionals, experts in quality measurement, social care experts, local authority representatives, lay members¹, secondary care providers and public health practitioners. They are recruited in line with NICE policies on committee recruitment.

Specialist committee members are selected from the membership of relevant guidance development groups, and usually include the chair and a lay member. The appointment of specialist committee members for each topic will be agreed by the NICE quality standards team in conjunction with the QSAC chair. They are appointed for the duration of the quality standard development, and during this period they are full members of the QSAC with the same decision-making responsibilities.

2.1.2 **How invited topic expert advisers are identified**

Topic expert advisers may be invited to attend QSAC meetings to discuss publications detailing variation of quality in practice in the topic area. Invited topic expert advisers may include national clinical leads, national policy leads and experts from national audit developers or national regulators (for example the Healthcare Quality Improvement Partnership and the Care Quality Commission), professional specialist societies, royal colleges, patient/lay/service user organisations and commercial organisations.

¹ The term ‘lay member’ is used to cover all lay people involved in developing NICE quality standards, including organisations representing patients, carers and service users.
Invited topic expert advisers may be identified by the QSAC specialist committee members and agreed with the QSAC chair and NICE project team. They will have experience of the topic area and up-to-date knowledge on issues related to the development of the quality standard, such as current practice or patient or service user experience.

2.2 **NICE teams**

2.2.1 **Quality standards team**

The quality standards team at NICE leads the development of quality standards and is responsible for:

- preparing briefing papers and drafts for consideration by the QSACs during development and validation of the quality standard
- managing the consultation process, preparing a summary report of consultation comments and suggestions for consideration by the QSAC and ensuring QSAC decisions are fed back into the quality standards development process
- acting as the main contact at NICE for QSAC members and liaising with other NICE teams as needed
- offering support and advice to the QSACs as needed
- preparing quality statements and measures for publication
- ensuring NICE’s processes and methods for development of quality standards are followed in line with agreed timelines
- providing internal validation and consistency checking.

The quality standards team is committed to improving practice and methods for developing quality standards. The processes and methods used are constantly being evaluated to improve them for future topics.

2.2.2 **Accreditation team**

The NICE [accreditation scheme](#) awards an accreditation mark to guidance producers whose guidance complies with a set of accreditation criteria. The accreditation team works closely with the quality standards team to identify accredited guidance for use in quality standards.
2.2.3 Public Involvement Programme (PIP) team

The PIP team supports the recruitment of QSAC lay members, who bring patient, service user or carer perspectives to the QSAC’s work. PIP offers support and advice to the lay members during the quality standard development process. It also encourages organisations representing patient, service user, carer and community interests to register as stakeholders and comment during the topic overview engagement exercise and consultation stage of quality standard development.

2.2.4 Information services team

The information services team conducts literature searches on the topics referred for quality standard development as required. These are searches of relevant guidance, policy, audits and national reports that may help in the development of the quality standard.

2.2.5 Costing and commissioning team

The costing and commissioning team considers the cost of implementing the changes needed to achieve the quality standard at a local level. The team identifies potential cost savings and highlights the areas of care or service provision in the quality standard that have potential implications for commissioners. The team also directs commissioners and service providers to a package of support tools that can assist with the implementation of NICE guidance and service redesign. This information is set out in ‘NICE support for commissioners and others using the quality standard’, which is published with the quality standard on the NICE website.

2.2.6 Implementation team

The implementation team provides support to key audiences and organisations to maximise the uptake of guidance and quality standards. This is achieved by assessing the aids and barriers to implementation, and providing practical support tools for commissioning, service improvement and education and learning. The team also produces reports on the uptake of guidance that are used to inform the development of the quality standard. Engagement by the implementation team with national bodies and local
organisations, including through its field team of local implementation consultants, supports the use of quality standards and facilitates shared learning.

2.2.7 Health Technologies Adoption Programme

The Health Technologies Adoption Programme (HTAP) facilitates the adoption of selected medical and diagnostic technologies across the NHS. The Programme supports the development of bespoke adoption support and where possible clinical audit resources for developmental quality statements.

2.2.8 Publishing team

The publishing team is responsible for ensuring that all quality standards publications are accurate, clear and consistent. The publishing team’s editors review the draft and final versions of the quality standards. The editors also draft a lay version for patients and carers or service users, and work with the costing and commissioning team to make sure the tools that help providers and commissioners use the quality standards are clear and understandable.

2.2.9 External communications team

The external communications team is responsible for communicating and disseminating quality standards.

2.3 Health and Social Care Information Centre

The Health and Social Care Information Centre is the national source of comparative data on health and social care for secondary uses.

Its representatives provide technical advice on developing quality measures, and may attend QSAC meetings in an advisory capacity.
3 Process for developing quality standards

Quality standard topic scheduled for development

Quality standards team develops topic overview and publishes it on the NICE website

Registered stakeholders are invited to identify key areas for quality improvement, including emergent areas of practice. Stakeholders have 2 weeks to respond.

QSAC prioritises areas of care or service provision for which quality statements and measures should be developed

Quality standards team drafts the quality standard. The draft standard is published on the NICE website for consultation with stakeholders

Stakeholders have 4 weeks to comment on the draft quality standard

QSAC meets to consider stakeholders’ comments and the quality standard is revised, quality assured by NICE and approved for publication by NICE’s Guidance Executive

The quality standard is published on the NICE website

Times are from the start of the development process and are indicative only
### 3.1 Developing a topic overview

The NICE quality standards team develops a topic overview for each quality standard, based on the referral. The overview describes core elements of the 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 statements. Key source guidance is typically NICE guidance. If other guidance is used it should meet NICE’s accreditation criteria. If there are some gaps in the areas of care that could potentially be covered within a quality standard, this is highlighted in the overview.

The overview also includes national or routine indicators and performance measures that are relevant to the standard, and lists any related quality standards.

The topic overview is published on the [NICE website](https://www.nice.org.uk) along with advance notice of the topic development schedule and consultation phases.

At publication of the topic overview, NICE requests written submissions from QSAC specialist committee members and registered stakeholders (see section 4) asking them to:

- identify key areas for quality improvement, including emergent areas of practice that may be considered to be developmental
- highlight any national or routine indicators and performance measures not listed in the overview
- provide examples of published information on current practice (such as, reports of variation in care or service provision, evaluations of compliance with source guidance, or patient, carer or service user experience) to support the identified areas for quality improvement
- express interest in being a supporting organisation.

Submissions should be made on the proforma provided and received by NICE within 2 weeks of the request.

The NICE quality standards team then drafts a summary report of stakeholder comments and prepares briefing papers on proposed areas for quality improvement.
improvement. The briefing papers describe relevant guidance, policy context and current practice relating to each area for quality improvement, and include standards and indicators currently in use (for example, in national audits), related quality standards where applicable, and relevant safety issues.

3.2 Prioritising areas for quality improvement

At the first QSAC meeting for each topic, the topic overview, the summary report of stakeholder comments and the briefing papers are presented to the QSAC. The relevant national clinical or policy lead is also invited to give an overview, which is considered expert testimony by the QSAC members. Additional topic expert advisers may also be invited to present testimony relating to any published current practice submissions.

The QSAC then agrees prioritised areas of care or service provision for which quality statements and measures should be developed. If there is no source guidance available for a particular prioritised area of care or service provision, the QSAC may use a placeholder statement to indicate the need for evidence-based guidance to be developed.

Areas prioritised for enhanced quality statement development should:

- be areas of care where there is evidence or consensus that there is variation in the delivery of care to patients or service users (in particular aspects of care or services that are not widely provided and/or not considered to be standard practice, but that are feasible to provide)
- focus on key requirements for high-quality care or service provision that are expected to contribute to improving the effectiveness, safety and experience of care or services
- be measurable and therefore suitable for development as quality measures.

In addition, the following aspects should be considered:

- effectiveness, including cost effectiveness
- patient or service user experience
- patient or service user safety
- equality
- resource impact.

Particular attention should be given to any areas where there is potential to significantly improve quality and productivity. Quality improvement areas prioritised by the QSAC are validated as meeting the criteria above by the NICE quality standards team.

In addition, the QSAC may prioritise areas that are considered to be developmental. Like all quality statements, developmental quality statements will be underpinned by NICE or NICE-accredited guidance. A developmental quality statement should also:

- represent an emergent area of practice that is only currently being carried out by a minority of providers
- need specific, significant changes to be put in place, such as reconfiguration of services or new equipment
- have the potential to be widely adopted and therefore drive improvement in outcomes.

After the first QSAC meeting, the NICE quality standards team produces a concise set of quality statements (usually 6–8 statements, up to a maximum of 15 statements in exceptional circumstances) and measures for the agreed areas, with advice from the QSAC specialist committee members. The QSAC chair approves the quality statements and measures before they are approved by NICE for consultation.

### 3.3 Developing statements and measures

A fundamental principle of quality standard development is that the statements should be based on NICE guidance or NICE-accredited guidance. In many instances NICE guidance is the basis for the quality statements and measures.

Recommendations from NICE or NICE-accredited guidance are considered to be statements of ‘best practice’ care or service provision. They address aspects of care or services that are:
• considered essential by regulatory bodies or
• established practice for which there is evidence that the majority of practitioners have implemented the recommendation or
• good or effective practice for which there is evidence that the majority of practitioners have not implemented the recommendation.

Quality statements are derived from guidance recommendations where there is evidence that there are gaps in the implementation of the recommendation, where there is inappropriate variation in the implementation of the recommendation or where the recommendation represents an emergent area of practice. The statements therefore cover areas where quality can be improved, and where quality statements and measures could be used to support quality improvement initiatives.

3.4 Drafting the quality standard

A quality standard is made up of quality statements and associated quality measures.

A set of quality statements is drafted based on the agreed prioritised areas for quality improvement and derived from the source guidance.

Wording the quality statements

Enhanced quality statements describe specific, measurable aspects of care or service provision that people should expect to receive in a high-quality service. Developmental quality statements describe practice that may only be occurring in a minority of providers at present but has the potential to have wide-spread benefits to the quality of care over time. They both place the person at the centre of the care or service requirement, for example ‘People with [a requirement for social care] are offered…’ or ‘People with [condition] are offered…’. The statements should promote choice and involvement in decision-making.

The statements are not a verbatim re-statement of the relevant guidance recommendations. A statement may be related to the recommendations in the following ways.
• A single statement is developed from a single recommendation.
• A single statement is developed from a small number of closely related recommendations.
• A single statement is developed from a larger number of recommendations. Such a statement may include the words ‘in accordance with [NICE or NICE-accredited] guidance’.

Each quality statement should specify 1 concept or requirement for high-quality care or service provision (for example, a single intervention, action or event). Where appropriate, in exceptional circumstances, 2 concepts or requirements for high-quality care or service provision may be allowed when they are closely linked (for example, if treatment or service options are dependent on the results of prior assessment) and individual statements describing these would lack clarity. Quality statements should not contain 2 or more unlinked or loosely linked concepts.

Although each quality standard describes markers of high-quality, cost-effective care or service provision that, when delivered collectively, should contribute to improving the effectiveness, safety and experience of care or services, there may be individual outcomes that can be attributed to specific statements. These individual outcomes are specified in the quality standard.

Most quality statements consist of 1 sentence, although there may be instances where 2 sentences are used to describe related requirements for high-quality care or service provision.

**Developing the quality measures**

Quality measures are drafted after the wording of the quality statements has been agreed. They address the structure of care or services, process of care or service provision and, if appropriate, outcome of care or service provision.

The majority of measures are likely to be process measures because few outcome measures can be attributed to a single quality statement or used at local level to reliably assess the quality of care or service provision and allow comparisons between providers. Where an outcome can be attributed to a
single statement and can be used at a local level, it will be included as a quality measure.

All quality measures related to processes are expressed as a numerator and a denominator that define a proportion (numerator/denominator). The numerator is a subset of the denominator population. For example, if the quality measure is

‘the proportion of people identified as approaching the end of life who receive information on social, practical and emotional support available’

the numerator and denominator are:

- numerator – the number of people in the denominator receiving information on social, practical and emotional support available
- denominator – the number of people identified as approaching the end of life.

The numerator does not include people receiving information on social, practical and emotional support available who are not identified as approaching the end of life.

Any timeframes specified in the measure are also specified in the statement. The exception to this is when timeframes vary according to different circumstances or patient or service user characteristics. In such cases, descriptions such as ‘timely’ may be used in the quality statement, with specific timeframes being outlined in the measure and/or supporting definitions. For example, methods and follow-up schedules for surveillance after colorectal cancer vary. The quality statement is:

‘People free from disease after treatment for colorectal cancer are offered regular surveillance.’

The surveillance methods and follow-up intervals in the NICE guidance are specified in the measures.
The timeframes are taken directly from underpinning NICE or NICE-accredited guidance, or based on the expert advice and opinion of the QSAC.

**Other sections related to each quality statement**

The quality standard also includes information for different audiences about what the high-quality care described in each statement is, the guidance used, the sources of data for measurement, definitions of the terms used, and if appropriate, equality and diversity considerations. These sections are developed by the quality standards team in conjunction with the QSAC.

Any related national quality assured indicators or sources of routinely collected data that could be used to measure the quality statement are also highlighted. National indicators include those developed by the Health and Social Care Information Centre through its indicators for quality improvement programme.

For statements where national quality indicators do not exist, the quality measures should form the basis for audit criteria developed by providers and commissioners for local use in assessing and improving the quality of care.

**3.5 Consultation**

After the QSAC chair, on behalf of the QSAC and NICE, has agreed the draft quality standard, registered stakeholders are invited to comment on it through a formal consultation via the NICE website. The consultation period is 4 weeks. General feedback and comments on individual quality statements are accepted. Stakeholders may also be invited to respond to specific questions such as which quality statements are most important and why, whether there are important areas of care or service provision that are not included and if the proposed measures are appropriate. See section 4 for more information on stakeholder involvement.

Comments received from anyone who is not registered as a stakeholder or those received after the deadline for submission cannot be considered formally.
Field testing

For some quality standards, the QSAC may request that field testing is commissioned, for example, in settings or services where quality standards are new. Any request for field testing will be considered and approved, as appropriate, by the NICE quality standards team.

The aim of field testing is to examine the relevance, utility, acceptability, clarity and potential impact of the draft quality standards with:

- providers, professionals, commissioners and managers
- patients, service users or carers
- organisations representing the interests of patients, service users or carers.

Field testing is primarily a qualitative exercise; a range of views are needed and it can involve a number of methods. The NICE quality standards team considers the choice of methods carefully, taking into account the topic, the groups involved and other relevant issues. Methods may include the use of groups, one-to-one or paired in-depth interviews or surveys. In some cases – for example, if a range of groups are involved – a combination of approaches may be used. Field testing takes place during the consultation stage.

3.6 Reviewing consultation feedback

A summary of the consultation comments, prepared by the NICE quality standards team, and the full set of consultation comments are shared with the QSAC. The QSAC then meets to review the comments, and if undertaken the field testing report, and the quality standard is refined with input from the QSAC chair and members.

3.7 Validation and consistency checking

The revised quality standard then undergoes a process of internal quality assurance, consistency checking and approval by an associate director or a programme director in the NICE quality standards team who has not been directly involved in the development of the quality standard. This quality assurance considers both the process and content of the quality standard (including issues raised during the development of the quality standard).
Independent technical comments provided by a senior technical adviser at NICE are also considered. During this stage there is ongoing discussion with the QSAC chair, and QSAC members as appropriate, to agree changes to the quality standard. The quality standard is edited by the publishing team before being presented to the NICE Guidance Executive for final approval before publication.

**Guidance Executive**

When considering a quality standard for publication, the NICE Guidance Executive assesses whether it:

- addresses areas relevant to the topic overview
- follows the agreed process and methods
- is consistent with other related quality standards
- promotes equality and avoids unlawful discrimination
- is cogent and follows the agreed template.

If a major issue is identified by the NICE Guidance Executive, further work may be needed by the NICE quality standards team, the QSAC chair and the QSAC as appropriate. The NICE Guidance Executive does not comment at other stages during the development of a quality standard.

### 3.8 Publication

Once approved by the NICE Guidance Executive, the final quality standard is published on the [NICE website](https://www.nice.org.uk) and in the relevant [NICE pathways](https://www.nice.org.uk).

The following documents are published alongside the quality standard:

- a version of the quality standard written for patients or service users and carers
- bespoke adoption support to accompany any developmental quality statements.
- NICE support for commissioners and others using the quality standard
- alternative formats such as large-print versions of the documents, if appropriate.
Registered stakeholders are notified on the day of publication by an email containing a link to the quality standard.

### 3.9 Reviewing and updating

After the quality standard is published, the quality standards team collects and collates information from stakeholders and the QSAC that might affect any future updates. This includes any queries or comments received by NICE after publication, and additional information submitted by stakeholders.

If a correction is made or a standard is revised to reflect changes in the underpinning guidance before the review date, this is highlighted on the NICE website. All corrections and revisions are made after an internal review and approval by an associate director, programme director, or the NICE Guidance Executive, as appropriate.

Each published quality standard will be formally reviewed 5 years after publication. A 5-year period will allow services to respond to the quality improvement areas as described in the quality standard and embed any changes in usual practice.

The review will include consideration of updated and new guidance and evidence of ongoing or new areas for quality improvement, based on published information and stakeholder views. Where the evidence indicates that the priorities for quality improvement have changed, the quality standard will be updated.
4 Stakeholder involvement

4.1 How stakeholders are involved

NICE quality standards are developed involving stakeholders, who contribute through consultation. Stakeholders include national patient, service user and carer groups and voluntary organisations, healthcare professional and academic organisations, and commercial organisations.

The following methods are used to ensure the appropriate stakeholders are involved in the development of each quality standard:

- The list of organisations registered as stakeholders for the NICE or NICE accredited guidance on which the quality standard is based is used to identify potential stakeholders. The NICE quality standards team invites these organisations to register as stakeholders.
- The registered stakeholder list for each quality standard is reviewed and, if there are any omissions, relevant organisations are encouraged to register as stakeholders. This review is performed by the NICE quality standards team, the QSAC chair and QSAC specialist committee members, with the support of other NICE teams such as the PIP and implementation teams.

Registered stakeholders are invited to submit published current practice information based on the topic overview and consultation comments on the draft quality standard when these documents are published on the NICE website.

4.2 How NICE communicates with stakeholders

Stakeholders are provided with advance notice of the topic development schedule, including the dates of the topic overview engagement exercise and draft quality standard consultation phase. They are also kept updated throughout the quality standard development process and are notified by email and on the NICE website when a topic overview or a draft quality standard is available. Stakeholders are invited to submit comments on a proforma using a dedicated email address. The discussions regarding stakeholder comments and the associated decisions are summarised in the
QSAC meeting minutes and all stakeholders that submitted comments are sent a link to the minutes on the NICE website when the quality standard publishes.

Stakeholder consultation comments on the draft quality standard are also published on the NICE website.

4.3 Stakeholder support of quality standards

When the topic overview is published and again during the draft quality standard consultation phase, stakeholders are invited to express interest in formally supporting the quality standard. Organisations that agree to formally support the quality standard undertake activities to increase awareness of the quality standard and encourage those commissioning, providing and using services to use it. All supporting organisations are listed on the web page for the relevant quality standard.
5  Equality

NICE is committed to meeting its duties under the Equality Act 2010 on eliminating discrimination, harassment and victimisation; advancing equality of opportunity and fostering good relations; and complying with the Human Rights Act 1998. NICE’s equality scheme sets out how it is meeting its obligations on equality and discrimination and what it still needs to do.

Two aspects of NICE’s process for the development of quality standards that are of particular relevance to equality issues are stakeholder involvement and equality analysis. These are summarised below.

5.1  Stakeholder involvement

NICE aims to involve as wide a range of stakeholders as possible in its activities and applies this principle to the development of quality standards. We encourage professional, patient, service user, carer, community and voluntary organisations, as well as organisations of groups protected by the equality legislation, to register as stakeholders and get involved in consultations. See section 4 for more information about stakeholder involvement.

5.2  Equality analysis

NICE has adopted a systematic approach to equality analysis. Equality issues are considered and conclusions formally recorded at key stages of the quality standards development process, including development of the draft and final quality standards. This record is used to provide assurance to the NICE Guidance Executive and stakeholders that equality impact has been assessed.

Equality analyses are published when the draft standard is published for consultation and again when the final standard is published.
6 Transparency

NICE is committed to making the process of developing quality standards transparent to stakeholders and the public.

6.1 Public access to meetings of the Quality Standards Advisory Committees (QSACs) from April 2013

From April 2013, QSAC meetings will be open to members of the public and press. This supports NICE’s commitment to openness and transparency and will enable stakeholders and the public to understand how quality standards are developed and consultation comments taken into account.

To promote public attendance at QSAC meetings, NICE will publish a notice with a draft agenda alongside a registration form on its website at least 20 working days before the meeting. Members of the public who wish to attend the meeting should return the completed registration form 10 working days before the meeting. Most QSAC meetings are held at NICE’s office in Manchester, which is accessible to the public, including people with limited mobility. Up to 20 places are available, depending on the size of the venue. To allow wide public access, NICE reserves the right to limit attendees to 1 representative per organisation. The final meeting agenda will be published on the website 5 working days before the meeting. For further details see information for people attending a NICE committee meeting.

If an item on the agenda includes commercial- or academic-in-confidence information, it is discussed at a separate session of the meeting, from which the public is excluded. The decision to hold a separate session is made by the QSAC chair and the responsible NICE director.

6.2 Access to documents

To ensure that the process is as transparent as possible, NICE considers it desirable that all information relevant to the development of quality standards is publicly available. The following supporting documents are therefore published on the NICE website:
• topic overview
• briefing paper (at consultation stage)
• equality analysis
• draft quality standard consultation comments and summary report.

Links to the relevant policy context and key development guidance are also provided.

The minutes of the QSAC meetings are published on the NICE website after they have been ratified by the QSAC, and no later than 3 months after the meeting.

6.3  Freedom of Information Act 2000

Nothing in this document will restrict any disclosure of information by NICE that is required by law (including, in particular but without limitation, the Freedom of Information Act 2000).
7  Links with other NICE programmes

7.1  Guidance development programmes
The Quality Standards Programme has effective working relationships with all NICE guidance development programmes, including internal guidance developers and national collaborating centres, to ensure that recommendations in clinical guidelines, public health and social care guidance can be used to form the basis of quality statements by being clear, specific, sufficiently detailed and measurable.

7.2  Quality and Outcomes Framework Programme
NICE is responsible for a programme of work to develop quality indicators for the Quality and Outcomes Framework (QOF) for primary care. Using rigorous development methods, NICE will develop indicators from existing NICE quality statements and measures, where relevant, for potential inclusion within the QOF. The Health and Social Care Information Centre is closely involved in the development process for QOF indicators.

7.3  Clinical Commissioning Group Outcomes Indicator Set Programme
NICE is responsible for a programme of work to develop quality indicators for the Clinical Commissioning Group Outcomes Indicator Set (CCG OIS). Using rigorous development methods, NICE will develop indicators from existing NICE quality statements and measures, where relevant, for potential inclusion within the CCG OIS. The Health and Social Care Information Centre is closely involved in the development process for CCG OIS indicators.

7.4  NICE accreditation programme
The accreditation team confirms the accreditation status of the guidance used in the Quality Standards Programme.

The accreditation team also ensures the quality standards team is aware of any newly accredited and forthcoming guidance that may provide the basis for a quality standard.
8 Updating this process guide

The formal process for updating this process guide will begin 3 years after publication. In exceptional circumstances, and only if significant changes to the process of developing quality standards are anticipated, this interval will be reduced to 2 years.

We welcome comments on the content of this process guide and suggested subjects for inclusion. These should be addressed to: qualitystandards@nice.org.uk

Minor changes that may be made without further consultation are those that:

- do not add or remove a fundamental stage in the process
- do not add or remove a fundamental methods technique or step
- will not disadvantage any stakeholders
- will improve the efficiency, clarity or fairness of the process.

Changes that meet all of these criteria will be published on the NICE website. The process guide will be updated and changes from the previous version of the guide will be listed. Stakeholders in quality standards under development at the time of the change will be notified if they are affected by the change. Stakeholders in quality standards not yet under development will be advised to consult the website at the start of the project to familiarise themselves with the updated quality standards development process.

Any other changes will be made only after a public consultation that will normally last for 3 months.
9 Further information

Further information about the NICE Quality Standards Programme is available.

Published quality standards and quality standards in development include lists of committee members, minutes of meetings and consultation documents.

Topics for future quality standards that have been referred to NICE are listed in a library of quality standards.
10 Complaints

Formal complaints about the administration of the Quality Standards Programme should be made in accordance with NICE’s complaints policy and procedure.
Appendix A  Acknowledgements

The following teams within NICE have contributed to the preparation and development of this document.

- The Centre for Clinical Practice
- The Centre for Public Health Excellence
- The Centre for Health Technology Evaluation
- The Publishing team.
- Corporate office
- Health and Social Care Directorate
  - The Public Involvement Programme
  - The Implementation team
  - The Accreditation team.
  - The Health Technologies Adoption Programme
## Appendix B  Summary of changes to the process guide

<table>
<thead>
<tr>
<th>Year</th>
<th>Chapter</th>
<th>Title</th>
<th>Revisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>General</td>
<td>NA</td>
<td>The term ‘endorsing organisations’ has been changed to ‘supporting organisations’ throughout.</td>
</tr>
<tr>
<td>2014</td>
<td>General</td>
<td>NA</td>
<td>The process guide has been updated to include details of the process for producing developmental quality statements.</td>
</tr>
<tr>
<td>2013</td>
<td>General</td>
<td>NA</td>
<td>The process guide has been updated throughout to reflect the change of the Institute's name to the “National Institute for Health and Care Excellence”.</td>
</tr>
<tr>
<td>2013</td>
<td>General</td>
<td>NA</td>
<td>The process guide has been updated throughout to reflect that the Patient and Public Involvement Programme (PPIP) has is now called the Public Involvement Programme (PIP).</td>
</tr>
<tr>
<td>2013</td>
<td>General</td>
<td>NA</td>
<td>The process guide has been updated throughout to reflect that the NHS Commissioning Board is now NHS England.</td>
</tr>
<tr>
<td>2013</td>
<td>General</td>
<td>NA</td>
<td>The process guide has been updated to reflect that the Commissioning Outcomes Framework (COF) is now the Clinical Commissioning Group Outcomes Indicator Set (CCG OIS)</td>
</tr>
<tr>
<td>2013</td>
<td>2.2.1</td>
<td>Quality standards team</td>
<td>The team will now be preparing a summary report of consultation comments and themed responses rather than responding to individual consultation comments and suggestions.</td>
</tr>
<tr>
<td>2013</td>
<td>3.5</td>
<td>Consultation</td>
<td>Stakeholder comments will not be formally considered if they are submitted by unregistered stakeholders or after the relevant deadline.</td>
</tr>
</tbody>
</table>
| 2013 | 3.6     | Reviewing consultation feedback | A summary of consultation comments will be presented to the committee as currently happens and the quality standard will be
amended accordingly. Individual responses will however no longer be provided to stakeholder comments.

<table>
<thead>
<tr>
<th>Year</th>
<th>Section</th>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>4.2</td>
<td>How NICE communicates with stakeholders</td>
<td>The committee minutes will now summarise discussions and associated decisions regarding the stakeholder comments and stakeholders that submit comments will be sent a link to these minutes upon publication.</td>
</tr>
<tr>
<td>2013</td>
<td>6.2</td>
<td>Access to documents</td>
<td>Individual responses to stakeholder comments will no longer be produced.</td>
</tr>
</tbody>
</table>