

Quality standards: process guide

NICE process and methods

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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 was first published in October 2012 and revised in August 2013, April 2014, May 2016, November 2020 and July 2021 to take into account minor changes to the quality standards development process.

Introduction

The National Institute for Health and Care Excellence (NICE) is a non-departmental public body responsible for providing national guidance and advice to improve health and social care.

For more information about NICE and its work programmes, see [about NICE on the NICE website](#).

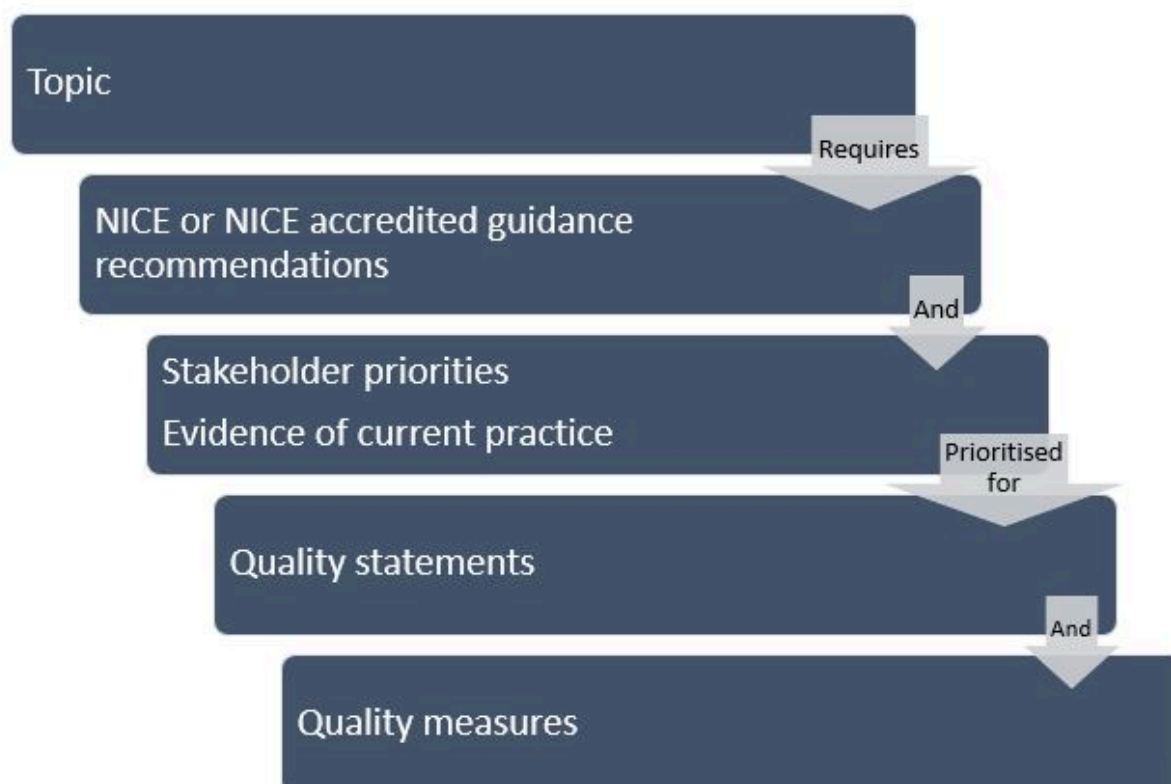
In this process guide, the term stakeholders is used to include both stakeholders and respondents unless otherwise stated (see [section 4.1](#)).

NICE quality standards

The NICE Quality Standards Programme was established in 2009 to manage the development of quality standards, and sits within NICE's Health and Social Care Directorate. NICE quality standards 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 (see [published quality standards](#)) 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 quality standards apply in England and Wales (see the [UK government website](#) and [Welsh government website](#)). Decisions on how they may apply in Scotland and Northern Ireland are made by the Scottish government and Northern Ireland Executive.

NICE is very grateful to everyone who contributed to the development of this guide.

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 Social Care and other key stakeholder organisations 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 and Improvement for health-related areas, and by the Department of Health and Social Care and Department for Education for areas such as social care, public health and education.

Sequencing of topics

NICE will work with NHS England and Improvement 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 at [selecting and prioritising guideline and quality standard topics on the NICE website](#).

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, people using services and carers.

Evidence from the underpinning guidance relating to 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.

1.2 Components of a quality standard

There are 2 main components to a quality standard: the quality statements and the quality measures. Each quality standard typically contains 5 quality statements with related measures.

Quality statements are clear, measurable and concise. Most quality statements describe 'enhanced practice', which is both aspirational and achievable. A minority of quality statements describe 'developmental practice', which indicates outstanding performance. Developmental statements focus on cutting-edge service delivery or technology requiring specific and significant changes over time to lead to wide-spread benefits.

Each quality 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, people using services 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 Using quality standards

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 wide-spread benefits in improving outcomes over time, but may require specific changes to be put in place, thereby 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:

- People using services, carers and the public can use the quality standards to identify components of a high quality service.
- Health, public health and social care practitioners can include information in audits and other quality improvement programmes 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. Organisations from the independent sector may also consider using the quality standards to ensure that the services they provide are of high quality.

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

NHS England and Improvement has also committed to making NICE quality standards an integral part of its plans to improve quality over the next 5 years ([NHS Five year forward view](#)). NICE works closely with the Care Quality Commission (CQC) to ensure consistency between their inspections and the NICE quality standards. NICE quality statements describing enhanced practice can be used to demonstrate good services during a CQC inspection. Statements describing developmental practice can indicate an outstanding service. Further information on how quality standards are used by the CQC is available on the NICE website.

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
- advisory committees made up of professionals and lay members independent of NICE (see [section 2.1 Quality Standards Advisory Committees](#))
- input from experts, people using services and carers
- transparent processes and decision-making
- consultation

- effective dissemination and use
- 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 people using services 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 such as national audits and the Commissioning for quality and innovation (CQUIN) framework.

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. They also advise on the update of published quality standards.

Each QSAC is made up of

- 21 standing members, including the committee chair
- approximately 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 expert professional or lay perspectives to prioritise areas for quality statement and measure development using information from a range of sources collated by NICE
- debate 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.

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. They do not have voting rights and do not count towards the quorum.

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](#).

More details on [how the QSACs work can be found in the terms of reference and standing orders on the NICE website](#).

2.1.1 How QSAC members are appointed

Standing members of QSACs include commissioners, primary care professionals, experts in quality measurement, social care experts, local authority representatives, [lay members](#), secondary care providers and public health practitioners. They are recruited in line with [NICE policies and procedures for recruitment and selection to advisory bodies](#). Positions are advertised on the NICE website and other appropriate places (for example, NICE Twitter, social media and websites of stakeholders, the medical royal colleges and professional organisations), and relevant stakeholders are notified. Candidates are required to submit a declaration of interests, a CV and covering letter, or an application form in the case of lay members.

Specialist committee members are selected from the membership of relevant guidance development groups, and always include a lay member. The appointment of specialist committee members for each topic will be agreed by the NICE quality standards team in liaison with the guidance producing centre and QSAC chair if necessary. 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. If it is not possible to appoint all roles from the relevant guidance development groups, additional open recruitment will take place via the NICE website.

2.1.2 Declarations of interest

Members, both standing and specialist, and chairs of the QSACs are required to act according to [NICE's policy on declaring and managing interests](#).

2.1.3 How invited topic expert advisers are identified

Topic expert advisers may be invited to attend QSAC meetings to provide expert testimony on 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, the medical royal colleges, organisations representing people using services and carers, and commercial organisations.

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 experience of using services.

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
- managing the review and update of published quality standards.

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

NICE-accredited guidance can be used to support the development of quality standards. The team manages a programme to renew the accreditation status of accredited guidance and developers.

2.2.3 Public Involvement Programme

The Public Involvement Programme supports the recruitment of QSAC lay members, who bring the perspectives of people using services and carers to the QSAC's work. The Public Involvement Programme offers support and advice to the lay members during the quality standard development process. It also encourages organisations representing people using services, carer and community interests to register as stakeholders and comment during the topic 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, review and update of quality standards. Searches include a mix of websites and other sources. The selection of sources will vary according to the quality standard topic in development.

2.2.5 Resource impact assessment team

The resource impact assessment 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.

2.2.6 System support for implementation team

The implementation support 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. Engagement with national bodies and local organisations supports the use and review of quality standards and facilitates shared learning.

2.2.7 Adoption and impact team

The adoption and impact team facilitates the adoption of selected medical and diagnostic technologies across the NHS. The team supports the development of bespoke adoption support and where possible clinical audit resources for developmental quality statements. They also produce reports on the uptake of guidance and quality standards.

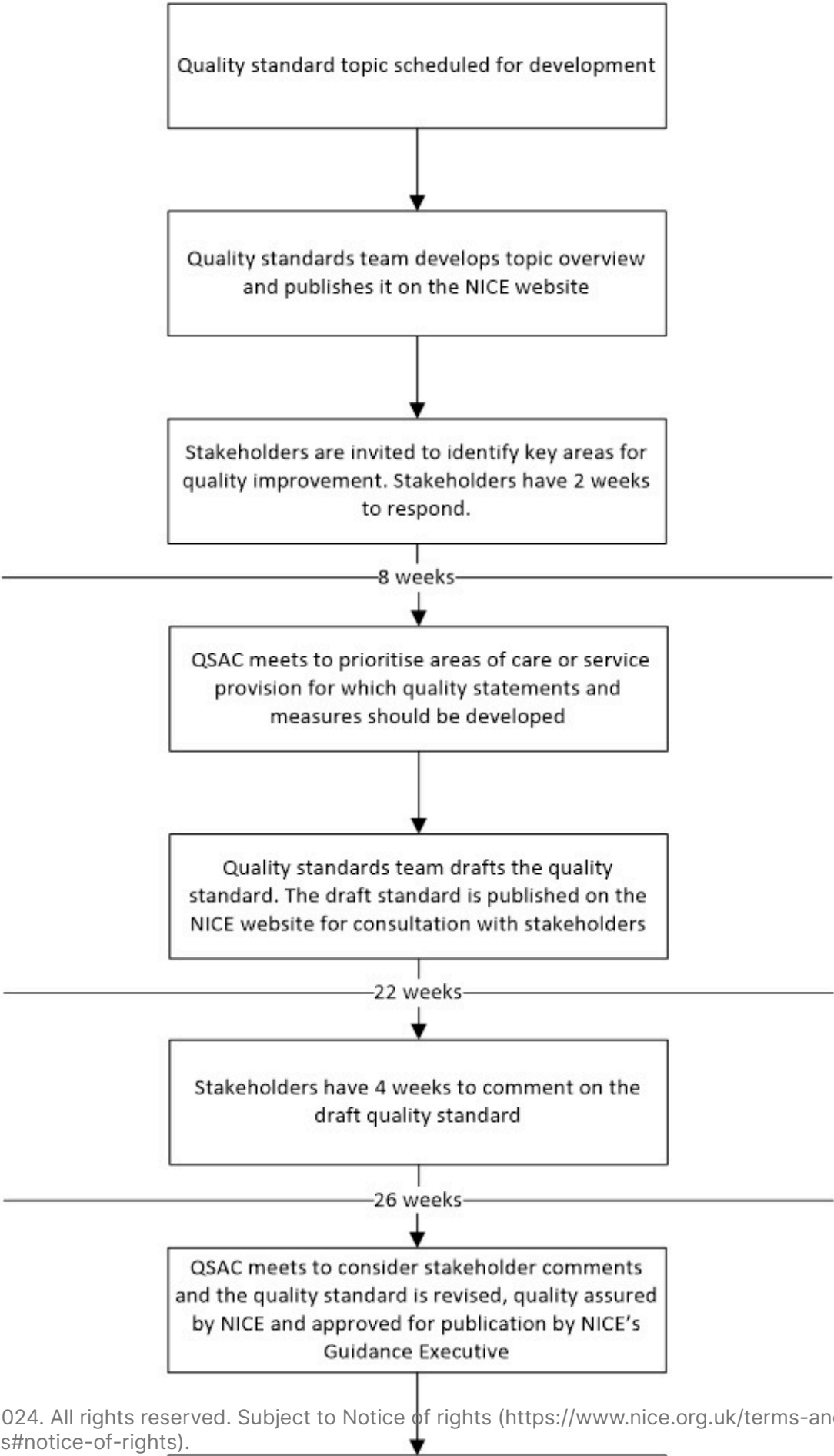
2.2.8 Publishing team

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.

2.2.9 External communications team

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

3 Process for developing quality standards



3.1 Developing a topic overview

The NICE quality standards team develops a topic overview for each quality standard, based on the referred topic. 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 topic overview is published on the NICE website 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 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
- provide examples of published information on current practice (such as, reports of variation in care or service provision, safety concerns, evaluations of compliance with source guidance, or experiences of people using services) to support the identified areas for quality improvement
- express interest in being a supporting organisation.

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

Where relevant, the NHS England and Improvement Patient Safety Team submits information on safety issues within a particular topic. This feedback is submitted either in a form or full patient safety report.

The NICE quality standards team then drafts a summary report of stakeholder comments and prepares a briefing paper on proposed areas for quality improvement. The briefing paper describes relevant guidance, policy context and current practice relating to each area for quality improvement, and includes relevant safety issues, standards and indicators

currently in use (for example, in national audits) and related quality standards where applicable.

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 paper is presented to the QSAC. The relevant national clinical or policy lead may also be 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. Quality statements will describe either enhanced or developmental practice.

Areas prioritised for quality statements describing enhanced practice should:

- be areas of care where there is evidence or committee consensus that there is variation in the delivery of care (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 experience of care or services as well as their safety and effectiveness
- be measurable and therefore suitable for development as quality measures.

Areas prioritised for quality statements describing developmental practice will, like all quality statements, be underpinned by NICE or NICE-accredited guidance. A developmental quality statement should also:

- represent an emergent area of cutting-edge service delivery or technology currently being carried out by a minority of providers and indicating outstanding performance
- need specific, significant changes to be put in place, such as redesign of services or new equipment
- have the potential to be widely adopted over time to drive improvement in outcomes.

In addition, for quality statements describing both enhanced and developmental practice the following aspects should be considered:

- experiences of people using services
- safety of people using services
- equality
- resource impact.

At the first QSAC meeting, the committee is provided with a summary of any resource implications identified in the guideline costing reports, including cost savings that have not been suggested by stakeholders. The committee is asked to ensure that, where possible, potential costs are balanced with potential cost savings. The Guideline Resource and Implementation Panel (GRIP) has been established to review estimates of resource impact and workforce implications of guidelines and consider the timing of resource impact by financial year. Where available, the QSAC will be provided with an implementation statement on affordability and workforce implications for the guidelines reviewed by the GRIP.

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.

If there is no source guidance available for a particular area of care or service provision, the QSAC may use a placeholder statement to indicate that the area was agreed to be a priority for quality improvement but could not be included as a quality statement because of a lack of underpinning guidance. A placeholder statement indicates the need for evidence-based guidance to be developed.

After the first QSAC meeting, the NICE quality standards team produces a concise set of quality statements 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.

The NICE or NICE-accredited guidance used to underpin quality standards can be topic-specific or concern treatment commonly used in the management of the topic under consideration (such as safety guidance).

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

Statements usually 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 for people using services. However, if the quality statement is addressing

service delivery the responsible organisation may be the focus of the statement, for example '[a particular service/organisation] provides...'.

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 people's experience of care or services as well as their safety and effectiveness, 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.

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 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 characteristics of people using services. 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, (such as national audits or other quality improvement projects) that could be used to measure the quality statement are also highlighted.

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, 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 non-registered stakeholders and individuals are reviewed by the committee but are not included in the summary prepared by the NICE quality standards team. These comments are not made available on the NICE website.

Comments received after the deadline for submission will not 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
- organisations representing the interests of people using services and 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 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.

Registered stakeholders are notified on the day of publication by an email containing a link to the quality standard.

3.9 Reviewing published quality standards

Quality standards are regularly reviewed. For each published quality standard an initial review decision is made by the Health and Social Care Directorate. There are 3 possible review decisions:

- Alignment of the quality standard to updated source guidance.
- Full update if more comprehensive amendments are required to reflect changes in the areas for quality improvement, new NICE or NICE-accredited guidance or new national priorities.
- No changes necessary.

A summary of the review (including initial review decisions) is presented to Guidance Executive for approval. This is then published on the NICE website and stakeholders are notified.

Where possible this review process will be timed to align with the process for agreeing the annual quality standards work programme with the bodies that commission the NICE quality standards, including NHS England and Improvement and the Department of Health and Social Care.

3.10 Aligning to new and updated guidance

New and updated NICE and NICE-accredited source guidance is monitored continually through the year to identify the need to align published quality standards.

The quality standards team liaises with the NICE guidance team or NICE-accredited organisation undertaking the source guidance update to stay up-to-date with progress

during development. During guidance consultation, the potential impact of the update on the quality standard is assessed by the quality standards technical team and any potential changes to the quality standard are noted. The findings of this assessment are shared with selected members of the guideline development group involved in updating the relevant guidance for validation and then the final decision on alignments is taken by Guidance Executive.

Wherever possible, alignments to quality standards will be published at the same time as the updated guidance. Other NICE teams are informed so any relevant support products are amended accordingly and republished at the same time.

If the assessment of the updated guidance finds that no changes are necessary, this decision is published on the quality standard web page within 2 weeks of Guidance Executive approval.

3.11 Full updates

The quality standards team carries out a regular review of all quality standards published to identify whether a full update is needed.

The review looks at the following areas to determine the impact on each quality standard:

- feedback on changes in the areas for quality improvement
- priority areas identified by NHS England and Improvement, Public Health England and the Department of Health and Social Care.

Also, at any time, interested persons or organisations can suggest a quality standard is updated by emailing qualitystandards@nice.org.uk. All comments will be considered as part of the review process.

Following the decision that a quality standard needs a full update, it will usually be considered as part of the process for agreeing the annual quality standards work programme with the bodies that commission the NICE quality standards, including NHS England and Improvement, the Department of Health and Social Care and Public Health England. A small number of full updates will be agreed as part of NICE's annual work programme with the relevant commissioners.

A full update of a quality standard follows the same process as the development of a new quality standard. The updated quality standard replaces the original quality standard.

Amendments in exceptional circumstances

Amendments to address exceptional circumstances (such as safety concerns, withdrawal of drugs or interventions and significant changes to legislation) are assessed separately on a case-by-case basis in line with NICE policy.

Correcting errors in published quality standards

Corrections or changes to a published quality standard will be made if an error:

- puts people using services at risk, or impacts on their care **or**
- damages NICE's reputation **or**
- significantly affects the meaning of the standard.

If it is necessary to correct an error in a published quality standard, we will follow NICE's internal policy for dealing with errors. The individual or organisation who reported the error will be contacted in writing, and we will explain our rationale for the decisions and actions taken.

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. Stakeholders may also include 'respondents' who are tobacco companies with an interest in a particular quality standard topic. They can register to comment on the topic engagement and the draft quality standard and their comments are made public with those of other registered stakeholders. The term 'respondent' acknowledges NICE's commitment to Article 5.3 of the World Health Organisation's Framework Convention on Tobacco Control. This sets out an obligation to protect the development of public health policy from any vested interests of the tobacco industry.

When registering and commenting on the topic overview and draft quality standard, stakeholders are asked to disclose whether their organisation has any direct or indirect links to, or receives or has ever received funding from, the tobacco industry. NICE will still carefully consider all consultation responses from the tobacco industry and from those with links to the industry. Disclosures will be included with the published consultation responses and within presentations to the committee.

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

- The organisations registered as stakeholders for the NICE guidance on which the quality standard is based are automatically registered as stakeholders for the quality standard.
- The list of organisations registered as stakeholders for the 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

members, with the support of other NICE teams such as the Public Involvement Programme and implementation teams.

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 (see [section 3.1](#) and [section 3.5](#)). The following table summarises stakeholder involvement at the different stages of development.

Development stage	Stakeholder involvement
Topic engagement	<p>2-week period during which stakeholders are invited to submit comments on key areas for quality improvement (see section 3.1).</p> <p>Stakeholders are invited to express interest in formally supporting the quality standard when the topic overview is published (see section 4.3).</p>
Consultation	<p>4-week period during which stakeholders are invited to submit general feedback and comments on individual quality statements. Stakeholders may also be invited to respond to specific questions about the quality standard (see section 3.5).</p> <p>Stakeholders are also invited to express interest in formally supporting the quality standard during consultation (see section 4.3).</p>

4.2 How NICE communicates with stakeholders

Stakeholders are provided with advance notice of the topic development schedule, including the dates of the topic 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 form 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 Formal support of quality standards

When the topic overview is published and again during the draft quality standard consultation phase, eligible stakeholders and respondents are invited to express interest in formally supporting the quality standard. The eligibility criteria are listed on the NICE website. 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. This may include activities such as:

- producing print or online articles for the organisation's website or newsletter
- using the organisation's social media channels to promote the quality standard
- using conferences and other speaking opportunities to present information on the quality standard
- running workshops to help other organisations understand how using the quality standard can add value.

All supporting organisations are listed on the web page for the relevant quality standard along with a link to their website.

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. During the development of each quality standard, consideration is given to whether and to what extent the standard is likely to be relevant to eliminating unlawful discrimination, advancing equality of opportunity and fostering good relations for people with the protected characteristics detailed in the Equality Act 2010. Conclusions from this analysis are 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)

QSAC meetings are open to members of the public and press. This supports NICE's commitment to openness and transparency and enables stakeholders and the public to better understand how quality standards are developed and consultation comments taken into account. Anyone who wishes to attend can register via the [meetings in public page on the NICE website](#).

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
- equality analyses
- 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.

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 works with all NICE guidance development programmes, including internal and external guidance developers, to ensure that guidance recommendations can be used to form the basis of quality statements by being clear, specific, sufficiently detailed and measurable.

7.2 NICE indicator programme

NICE is responsible for a programme of work to develop quality indicators for the Quality and Outcomes Framework (QOF) for primary care and the Clinical Commissioning Group Outcomes Indicator Set (CCG OIS) from NICE guidelines and quality standards and NICE-accredited guidance.

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 from [standards and indicators on the NICE website](#).

Lists of committee members, minutes of meetings and consultation documents are published alongside [quality standards that are in development](#).

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: Committee terms of reference and standing orders

Terms of reference

1. Terms of reference

1.1 The Quality Standards Advisory Committees will operate as standing Advisory Committees of the Board of the Institute.

1.2 The Committees will assess information on current practice, prioritise quality improvement areas and develop quality standards for the NHS, social care and the wider public health community in accordance with the Institute's published quality standards methods and processes.

1.3 Quality standards will take into account any equalities issues relevant to the subject matter on a topic by topic basis.

1.4 The Committees will submit their quality standards to the Institute's Guidance Executive which will act under delegated powers of the Board in considering and approving the quality standard for publication.

2. Membership

2.1 Each Committee will normally have 21 standing members including the Chair. Approximately 5 specialist committee members will be invited to join the standing members for each quality standard topic. Membership may vary in accordance with the needs of the Committee. Standing and specialist committee members will have full voting rights and will count towards the quorum. See paragraph 1.2 for an outline of the role of the committees and their members.

2.2 Committee chairs and standing and specialist committee members are drawn from the NHS, public health and social care sectors, the voluntary sector and academia. They also include lay members.

2.3 The lay members will be drawn from the general population and will have direct experience of accessing health, public health and social care services. The lay members are expected to ensure that the Committee's recommendations embrace general public/specific population issues. They will help identify where public/specific population preferences and choice may need to be acknowledged in the quality standard.

2.4 Topic expert advisers may be invited to attend and address the Committees to provide expert testimony to assist in the development of the quality standard. They will not engage with formulating the quality statements and measures, will not have voting rights and will not count towards the quorum.

Date: July 2019

Review date: July 2022

Standing Orders

1. General

1.1 These standing orders ("the SOs") describe the procedural rules for managing the Committee's work as agreed by the Institute. Nothing of these standing orders shall limit compliance with the Institute's Standing Orders so far as they are applicable to this Committee.

1.2 The appointment of Advisory Committees is at the sole discretion of the Board subject to any direction as may be given by the Secretary of State.

1.3 Members of the Committee shall be bound by these SOs and will be expected to abide by the seven principles for the conduct of public life as recommended by the Nolan Committee which are:

- selflessness
- integrity
- objectivity
- accountability

- openness
- honesty
- leadership

1.4 Other members who may be co-opted from time to time at the discretion of the Committee shall be subject to the same principles.

1.5 The appointment, removal or substitution of members and the general constitution of the Committee shall be at the discretion of the Institute in accordance with its published procedures.

1.6 The chair and standing members of each Committee will be appointed for a period of 3 years. This may be extended by mutual agreement to a further 3 years and up to a maximum term of office of 10 years. The specialist component of each committee will be appointed for the duration of the development of each quality standard topic.

1.7 Observers who may wish to attend Committee meetings for educational or work related purposes must agree their attendance in writing in advance of the meeting in line with the Institute's arrangements for meetings in public.

1.8 All reasonable facilities shall be provided for members to ensure they have the opportunity to participate fully and equitably in the business of the Group.

2. Interpretation

2.1 During the course of the meeting, the Chair of the Committee shall be the final authority on the interpretation of SOs on which s/he may be advised by the Institute.

2.2 Statements of Committee members made at meetings shall be relevant to the matter under discussion at the time and the decision of the chair on questions of order, relevancy and interpretation (including conflicts of interest) shall be final.

3 Committee chair

3.1 Chairs of the Committee will be appointed by the Board and the meetings will be conducted by the chair or in his/her absence the Vice Chair.

3.2 The Vice Chair will be appointed by the Committee Chair. The Vice Chairs' appointment will be a period of 3 years in the first instance, renewable for a further period, of no more than 3 years, to a maximum of 10 years

3.3 The Chair, or the Vice Chair in the Chair's absence, may take action on behalf of the Committee outside of the scheduled Committee cycle when urgent decisions are required and it is impracticable to convene a special meeting of the Committee.

3.4 On the occasion(s) where the chair or vice chair are absent, another member of the committee can be used as proxy to fulfil the role.

4. Voting

4.1 The decisions of the Committee will normally be arrived at by a consensus of those members present. Before a decision to move to a vote is made, the Chair will, in all cases, consider whether continuing the discussion at a subsequent meeting is likely to lead to a consensus.

4.2 Voting will be anonymous and decisions determined by a simple majority of those members present at a quorate meeting.

4.3 The chair of the meeting will be included in the vote and in the event of there being an equality of votes the chair will have a second, casting vote.

4.4 Topic expert advisers invited to provide expert testimony and observers in attendance at the Committee will not have the right to vote. Any voting that occurs when either co-opted experts or observers have participated will be deemed as ineligible.

5. Quorum

5.1 The quorum is set at 50% of the full membership of the Committee, in accordance with ToR paragraph 2.1 for each Committee meeting (but excluding topic expert advisers). The quorum should be rounded up to the next whole number in the event of there being an odd number of Committee members.

5.2 No business relating to the development of quality standards should be transacted unless the meeting is quorate. If a member is excluded due to a conflict of interest and membership falls below the quorum, no business may be transacted. There is no time limit

for a quorum to be achieved but the start of the meeting should be delayed where the meeting is not quorate.

5.3 The quorum must be achieved for the meeting to proceed. However, the needs of the Committee are such that even if the meeting is quorate, an appropriate spread of members' interests should be represented at each meeting. It is also important that the mix of standing and specialist members is appropriate, and specialist members are not in a majority. If, in the view of the Chair the spread of interests, and balance of core and expert members is inappropriate for the business under consideration, the meeting may be suspended or adjourned until a later date.

5.4 Topic expert advisers and observers in attendance at Committee meetings will not count towards the quorum.

6. Collective responsibility

6.1 All members of the Committee shall abide by the principle of collective responsibility, stand by the recommendations of the Committee and not speak against them in public.

7. Confidentiality

7.1 Committee members will be required to sign a confidentiality agreement with the Institute relating to any information designated confidential by the Institute such as commercial in confidence material or sensitive personal data.

7.2 Confidential papers and other confidential information disclosed in Committee deliberations should not be discussed with colleagues who are not members of the Committee, other organisations or the media.

7.3 Topic expert advisers and observers in attendance at Committee meeting will sign a confidentiality agreement in advance and be subject to the same confidentiality regulations as Committee members.

8. Arrangements for meetings

8.1 The Institute will ensure that Committee meetings will take place in venues that are accessible to persons with disabilities.

8.2 It is planned for each Committee to meet seven times per year in Manchester, unless otherwise stated.

8.3 The Institute shall determine what matters shall appear on every agenda in advance of each Committee meeting.

8.4 No other business shall be discussed at the meeting save at the discretion of the chair.

8.5 Where considered necessary due to the confidential nature of the business to be transacted, the agenda item will be divided into two parts. Part 1 will be open to the public and part 2 will be closed to the public to enable the Committee to discuss confidential information whereupon SO 9.2 will apply

8.6 Only members of the Committee and Institute staff will be in present for part 2 of the meeting. However, at the discretion of the chair, expert advisers may be invited to remain in order to discuss confidential or personal information that was not discussed in part 1. Once the information concerned has been discussed, the expert advisers will leave the meeting and will take no further part in its deliberations.

8.7 Before each meeting of the Committee a public notice of the time and place of the meeting, and the public part of the agenda shall be displayed on the Institute's website at least five working days before the meeting.

8.8 Members will be expected to attend for the full day unless agreed in advance with the Chair.

8.9 The Committee secretariat will make all reasonable attempts to agree each meeting date in advance and Committee members are expected to keep these dates free until they are released.

9. Admission of members of the public

9.1 The public and representatives of the press shall be afforded facilities to observe all formal meetings of the Committee for part 1 of the agenda but shall not be entitled to ask questions or otherwise engage in the business of the Committee.

9.2 The public and representatives of the press shall be excluded from part 2 of the Committee meeting upon the chair moving the following motion:

That representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity in which would be prejudicial to the public interest" [section 1(2) Public Bodies (Admissions to Meetings) Act 1960].

9.3 Notwithstanding the above, the chair will have the discretion to adjourn the meeting at any time if the presence of the public is considered prejudicial to the effective conduct of the business of the meeting upon moving the following motion:

That in the interests of public order the meeting adjourn for (the period to be specified by the chair) to enable the Committee to complete business without the presence of the public" [section 1(8) Public Bodies (Admission to Meetings) Act 1960].

10. Minutes

10.1 The minutes of the Committee proceedings shall be drawn up and submitted to the next meeting for approval.

10.2 Draft minutes will be approved at the next meeting and published on the Institute's website subject to the redaction of any confidential or otherwise exempt material.

11. Declarations of Interest

11.1 All Committee members must make an annual declaration of interests in accordance with NICE's policy on declaring and managing interests for advisory committees. Generally these will be made at recruitment. The initial declaration covers the preceding 12 month period. Consideration should also be given to any new interests that are not currently held but will arise during involvement with the committee.

11.2 All members will be prompted to update their declaration before each meeting (by email) and at the start of each meeting (orally). Any new interests declared at meetings will be recorded in the minutes, added to the Committee's interest register and published on the NICE website.

11.3 During the course of the meeting if a conflict of interest arises with matters under consideration the member concerned must withdraw from part of, or the entire meeting as appropriate.

11.4 Topic expert advisers invited to provide expert testimony will make a declaration of interest in advance of Committee meetings and in accordance with NICE's policy on declaring and managing interests for advisory committees. These will be recorded in the minutes and published on the NICE website.

12. Suspension of standing orders

12.1 Except where this would contravene any statutory provision, any one or more of the standing orders may be suspended at any meeting providing a simple majority of those present and eligible to participate vote in favour of the suspension.

12.2 Any decision to suspend standing orders shall be recorded in the minutes of the meeting.

12.3 No formal business may be transacted while standing orders are suspended.

12.4 The Institute's Audit Committee shall review all decisions to suspend standing orders.

13. Petitions

13.1 Petitions will not be received directly by the Committee and anyone wishing to present a petition will be directed to the Committee secretariat.

14. Recording of meetings

14.1 The recording of proceedings or the taking of pictures at Committee meetings is not allowed.

14.2 The chair of the Committee will have discretion to ask any member of the public gallery to leave if, in their opinion, they are acting in a manner prejudicial to the effective conduct of the meeting.

15. Terms of reference

15.1 Committee members must comply with the Committee's terms of reference which set out the scope of the Committee's work and its authority.

16. Record of attendance

16.1 A record will be kept of members' attendance at the Committee.

16.2 Members are expected:

- To attend at least 75% of their committee's meetings during a 12 month period
- Not to miss more than 2 consecutive committee meetings.

17. Review of standing orders

17.1 These standing orders will be reviewed every 3 years.

Date: July 2019

Review date: July 2022

Update information

Summary of changes to the process guide

Year	Chapter	Title	Revisions
2021	3.1	Developing a topic overview	This section has been updated to reflect changes to the topic overview and the sources used to develop it.
2021	3.9	Reviewing and updating	Amendments have been made to the process for reviewing quality standards.
2021	Appendix	Committee terms of reference and standing orders	Minor amendments to reflect a change in approach to working with topic expert advisers.
2020	General	NA	The process guide has been updated throughout to reflect that NHS England is now NHS England and Improvement.
2020	General	NA	The process guide has been updated throughout to reflect that the Department of Health is now the Department of Health and Social Care.
2020	General	NA	The process guide has been updated to include the scheduled update of the QSAC terms of reference and standing orders
2020	General	NA	The process guide has been updated to reflect changes to NICE internal teams
2018	3.2	Prioritising areas for quality improvement	Further detail was added regarding how the committees consider resource implications.
2017	3.9	Reviewing and updating	Amendments have been made to the process for aligning quality standards with updated NICE guidance.

Year	Chapter	Title	Revisions
2016	General	NA	<p>The process guide has been updated to align with:</p> <ul style="list-style-type: none"> • New NICE team structures • Removal of endorsing and supporting organisation logos from QS pages • Language change from 'revisions' to 'minor updates' • NICE's commitment to Article 5.3 of the WHO Framework Convention on Tobacco Control
2016	General	NA	Inclusion of the QSAC terms of reference.
2014	General	NA	Further information on the process for reviewing and updating published quality standards has been included.
2014	General	NA	The term 'endorsing organisations' has been changed to 'supporting organisations' throughout.
2014	General	NA	The process guide has been updated to include details of the process for producing developmental quality statements.
2013	General	NA	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'.
2013	General	NA	The process guide has been updated throughout to reflect that the Patient and Public Involvement Programme (PPIP) is now called the Public Involvement Programme.
2013	General	NA	The process guide has been updated throughout to reflect that the NHS Commissioning Board is now NHS England.

Year	Chapter	Title	Revisions
2013	General	NA	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)
2013	2.2.1	Quality standards team	The team will now be preparing a summary report of consultation comments and themed responses rather than responding to individual consultation comments and suggestions.
2013	3.5	Consultation	Stakeholder comments will not be formally considered if they are submitted by unregistered stakeholders or after the relevant deadline.
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 no longer be provided to stakeholder comments.
2013	4.2	How NICE communicates with stakeholders	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 at publication.
2013	6.2	Access to documents	Individual responses to stakeholder comments will no longer be produced.

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