

Quality standards: process guide

NICE process and methods

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Introduction

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

The National Institute for Health and Care Excellence (NICE) is the independent body responsible for driving improvement and excellence in the health and social care system. We develop guidance, standards and information on high- quality health and social care. We also advise on ways to promote healthy living and prevent ill health.

Our aim is to help practitioners deliver the best possible care and give people the most effective treatments, which are based on the most up-to-date evidence and provide value for money, in order to reduce inequalities and variation.

Our products and resources are produced for the NHS, local authorities, care providers, charities, and anyone who has a responsibility for commissioning or providing healthcare, public health or social care services.

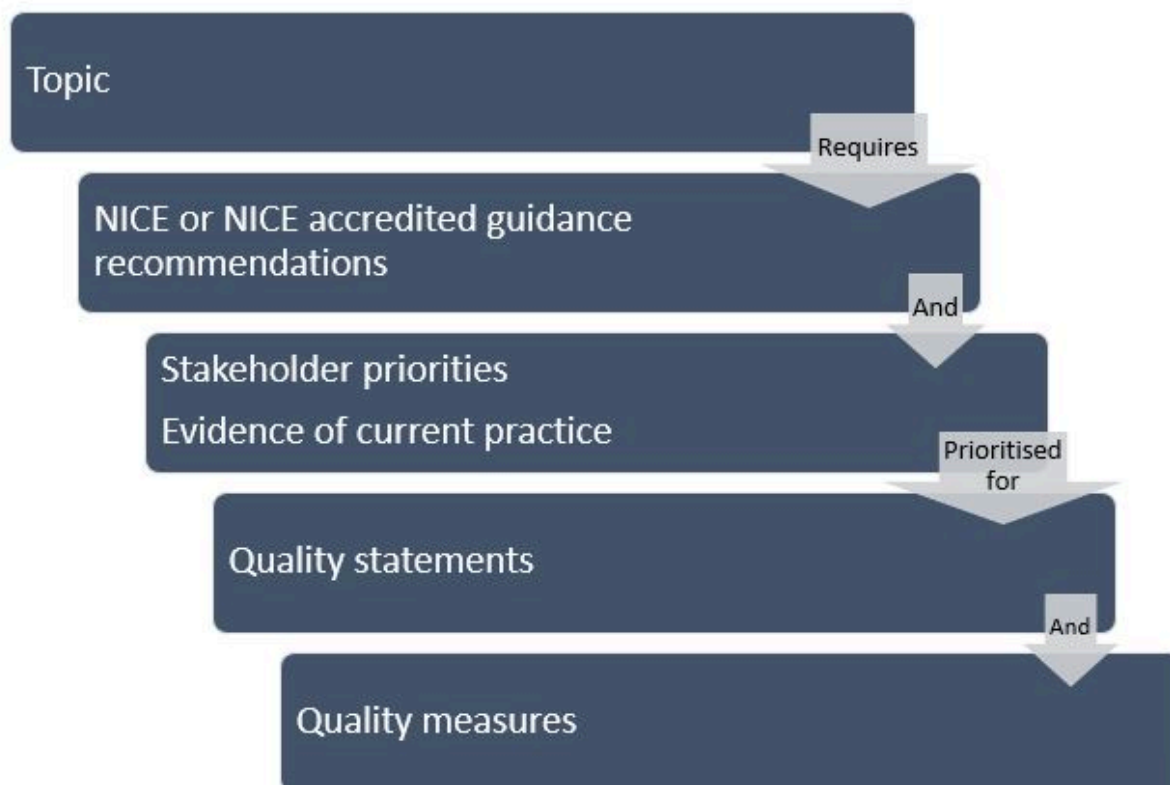
To find out more about what we do, visit [about NICE](#) on our website and follow us on Twitter: @NICEComms

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 on 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](#).

See the [Quality Standards Advisory Committees: terms of reference and standing orders](#) for more details on how the QSACs work.

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

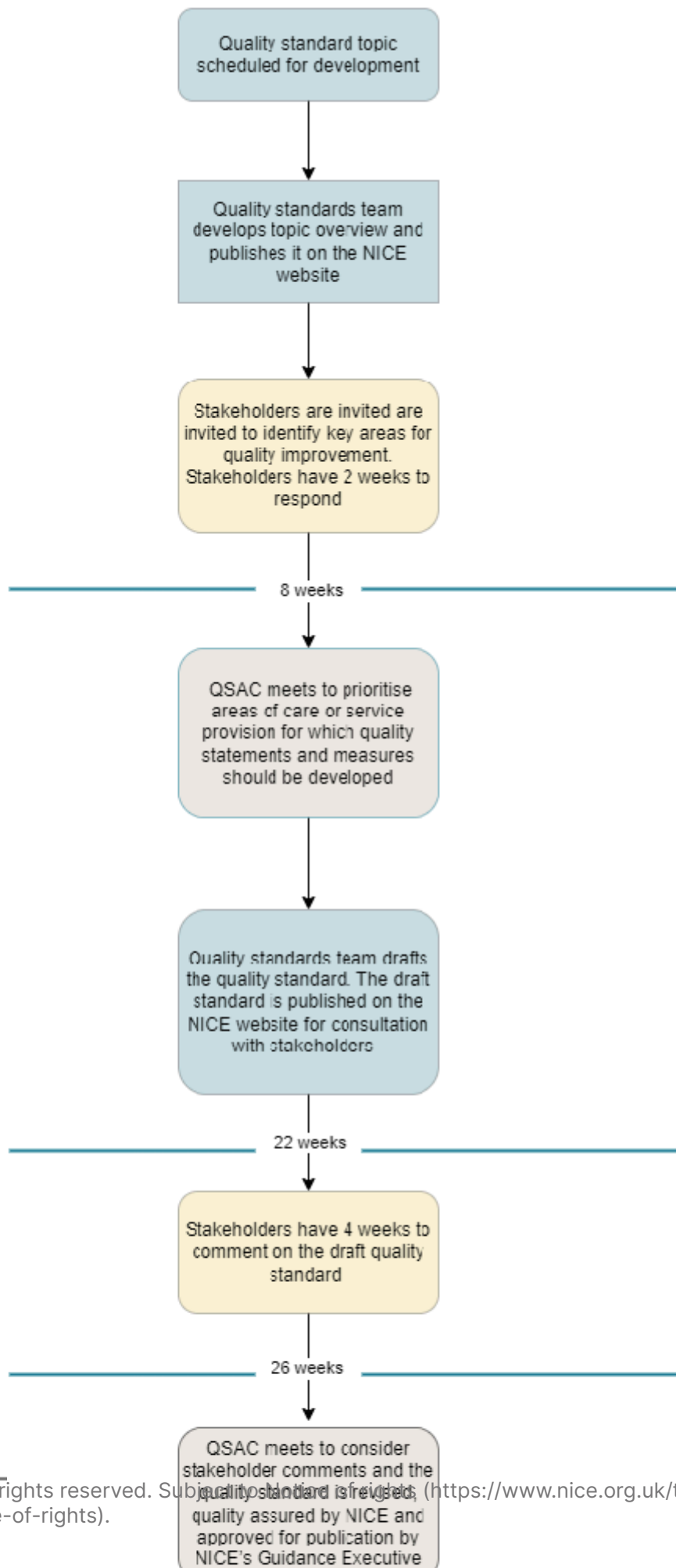
The publishing team is responsible for ensuring that all quality standards publications are accurate, clear and consistent. The publishing team's editors review the draft and final versions of the quality standards.

2.2.9 External communications team

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

3 Process for developing quality standards

Quality standard development process flowchart



3.1 Developing a topic overview

This section should be read in conjunction with the [interim process guide for a more proportionate approach to quality standard development](#)

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 on stakeholder involvement](#)) 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

This section should be read in conjunction with the [interim process guide for a more proportionate approach to quality standard development](#).

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

This section should be read in conjunction with the [interim process guide for a more proportionate approach to quality standard development](#)

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

This section should be read in conjunction with the [interim process guide for a more proportionate approach to quality standard development](#)

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 on developing a topic overview](#) and [section 3.5 on consultation](#)). 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: Interim process statement for a more proportionate approach to quality standard development

Introduction

To support the changing needs and objectives of all parts of the health and care system, [NICE is transforming](#) to ensure its guidance remains relevant, timely, useable and effective. To achieve these aims, the methods and processes that underpin NICE's guidance need to evolve.

This appendix describes the interim process changes that NICE will use over the next 24 months to support proportionate approaches to the development and maintenance of NICE quality standards. It should be read alongside the relevant sections of the [NICE quality standards process guide](#).

The interim process may be applied in the following situations:

- The health and care system needs a new or updated quality standard faster than the current process can deliver.
- The nature and extent of update needed to an existing quality standard does not justify the resource use associated with the full development process.
- To support the integration and/or incorporation of selected quality standards into NICE guidelines.

The changes outlined will be monitored and reviewed.

- NICE will use the interim process in selected quality standard topics over the next 24 months. This stage will inform a full update of the quality standard process guide.
- The updated quality standard process guide will be consulted on following the usual process for manual updates. This will then be finalised and published.

We welcome comments on the content of this statement. These should be addressed to

A proportional approach to how we develop and update existing quality standards

As well as utilising our existing processes for quality standard development, we are introducing more proportionate, agile and responsive approaches where appropriate as described in the introduction.

Key areas in the current process guide, where NICE may decide, to adopt a more proportionate approach are:

- Developing a topic overview (see [section 3.1](#))
- Changes to committee decision making outside of formal meetings, including:
 - Prioritising areas for quality improvement (see [section 3.2](#)),
 - Reviewing consultation feedback (see [section 3.6](#))
 - Utilisation of the guideline committee (see [sections 3.2](#) and [3.6](#))
- Consultation (see [section 3.5](#))
- Use of external guidance to support the development of quality standards.

Developing a topic overview

Where a proportional approach to topic engagement is applicable due to the narrower scope of a topic, the following options may be used:

- Reducing the topic engagement comment period to 5 working days
- Limiting topic engagement to topic specific professional and patient organisations and topic experts.
- Holding a workshop with topic specific professional and patient organisations and topic experts.

In such instances, minutes/a record of the workshop would be taken and published on the

NICE website.

Changes to committee decision making outside of formal meetings

Prioritising areas for quality improvement:

Where a proportionate approach is required to prioritise areas for quality improvement, a working group may be convened in place of a full quality standards advisory committee (QSAC) meeting. The working group will have the same remit as the full QSAC.

The working group will be chaired by an existing NICE committee chair. Membership of the working group will be drawn from:

- professional and lay representation from the QSAC committee; the number of QSAC representatives may vary in accordance with the needs of the topic.
- guideline committee professional and patient expert representatives.
- additional external professional and patient expertise will be invited where appropriate.

The needs of the working group are such that an appropriate spread of members' experience and expertise should be represented at each meeting. If, in the view of the chair, the spread of experience and expertise is inappropriate for the business under consideration, the meeting may be suspended or adjourned until a later date.

Decisions of the group will normally be arrived at by a consensus of those members present. If the working group concludes that it cannot make a decision on the quality standard content this will result in a full committee meeting.

Where a working group has been convened in place of a full committee meeting to agree prioritised areas of care, the same group will be convened to review the full set of consultation comments.

Reviewing consultation feedback

In some instances, such as where consultation comments demonstrate a high degree of

agreement with the draft quality standard, neither a full committee meeting, nor a working group will be convened to review the consultation comments. The committee will instead review the consultation comments and share any feedback with the NICE team and the chair via email.

If the committee chair concludes that further committee input is required to refine the quality standard based on the consultation comments, this will result in either a full committee meeting or a working group meeting with a subset of the committee.

Utilisation of the guideline committee (GC)

The guideline committee may be utilised to prioritise areas for quality improvement and review consultation feedback, in place of a full quality standards advisory committee (QSAC) meeting. In these instances, appropriate training will be provided to the professional and lay guideline committee members to ensure they are able to prioritise areas for quality improvement. Representation from the QSAC committee will be agreed as required for the development of the Quality Standard; the number of QSAC representatives may vary in accordance with the needs of the topic.

This approach may be undertaken as part of a testing and refining process to incorporate quality standard statements into NICE guidelines, and will support NICE's ambitions to integrate NICE guidance, making it easier for users to find all guidance about a condition.

Consultation: A flexible public consultation for registered stakeholders

Where a proportionate approach to consultation is required, NICE may reduce or extend the length of the consultation comment period depending on the extent of change to the existing content or the potential impact on the system. The minimum consultation period will be no less than 15 working days; advance notice of a consultation will always be given

Standing down of existing quality standards

If feedback from the health and care system indicates a quality standard is no longer adding value, such as when the quality standard has been superseded by statutory requirements, a quality standard may be suitable to be stood down and removed from the quality standards library. This could be applicable to quality standards which are

published, in development or awaiting development. Initial approval will be sought from an associate director in the Centre for Guidelines Directorate and the Centre for Guidelines Deputy Director before moving to a process of formal un-referral.

Formal un-referral will be sought following discussions with the endorsing body (Department of Health and Social Care or NHS England) before the quality standard is presented to the NICE Guidance Executive for final approval. Following agreement from the Guidance Executive, the quality standard will be stood down and removed from the NICE website.

Use of external guidance to support the development of quality standards

Quality standards are evidence-based and underpinned by NICE guidance or other sources of high-quality evidence.

With the approval of the Guidance Executive, high quality external guidance, such as guidance from royal colleges or international guideline developers, may be used to support the development of NICE quality standards.

Update information

July 2024

We published the [interim process statement for a more proportionate approach to quality standard development](#), which

describes the interim process changes that NICE will use over the next 24 months to support proportionate approaches to the development and maintenance of NICE quality standards

July 2021

We updated section 3.1 to reflect changes to the topic overview and the sources used to develop it. In section 3.9 we made changes to the process for reviewing quality standards.

We made minor changes to the appendix: Committee terms of reference and standing orders to reflect a change in approach to working with topic expert advisers.

November 2020

We updated the process guide throughout to reflect:

- NHS England is now NHS England and Improvement.
- Department of Health is now the Department of Health and Social Care.
- scheduled update of the QSAC terms of reference and standing orders
- changes to NICE internal teams

May 2016

We included the QSAC terms of reference in this guide and updated throughout to align with:

- 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

April 2014

We updated this guide to include further information on the process for reviewing and updating published quality standards. We changed the term 'endorsing organisations' to 'supporting organisations' throughout and included details of the process for producing developmental quality statements.

August 2013

We updated the following sections of the process guide to reflect changes to consultation comments:

- section 2.2.1 to reflect the quality standards team will now be preparing a summary report of consultation comments and themed responses rather than responding to individual consultation comments and suggestions.
- Section 3.5: Stakeholder comments will not be formally considered if they are submitted by unregistered stakeholders or after the relevant deadline.
- Section 3.6: 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.
- Section 4.2: 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.
- Section 6.2: Individual responses to stakeholder comments will no longer be produced.

We updated the process guide throughout to reflect that:

- NICE's name changed to the 'National Institute for Health and Care Excellence'.
- Patient and Public Involvement Programme (PPIP) is now called the Public Involvement

Programme.

- NHS Commissioning Board is now NHS England.
- Commissioning Outcomes Framework (COF) is now the Clinical Commissioning Group Outcomes Indicator Set (CCG OIS)
- The team will now be preparing a summary report of consultation comments and themed responses rather than responding to individual consultation comments and suggestions.

Stakeholder comments will not be formally considered if they are submitted by unregistered stakeholders or after the relevant deadline.

Minor changes since publication

2018

In section 3.2 on prioritising areas for quality improvement, we clarified how the committees consider resource implications.

2017

In section 3.9 on reviewing and updating quality standards, we have made minor changes to the process for aligning quality standards with updated NICE guidance.

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