NICE National Institute for Health and Care Excellence

NICE quality standards: process guide

NICE process and methods
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Contents

1 Introduction

The National Institute for Health and Care Excellence (NICE) produces useful and usable guidance for the NHS and wider health and care system. We help practitioners and commissioners get the best care to patients, fast, while ensuring value for the taxpayer.

1.1 What is a NICE quality standard?

NICE quality standards set out priority areas for quality improvement in health, public health and social care. Each quality standard typically contains 5 quality statements with related measures.

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

NICE quality standards apply in England and Wales (see the UK Government website and the Welsh Government website). Decisions on how they may apply in Scotland and Northern Ireland are made by the Scottish government and Northern Ireland Executive.

New topics can be referred to NICE by NHS England (NHSE) or the Department of Health and Social Care (DHSC).

1.2 Quality statements

Quality statements are clear, measurable and concise.

Each quality statement should specify 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 that depends on the results of an assessment).

Each quality statement should also focus on the people using services and promote choice and involvement in decision-making. However, if the quality statement is addressing service delivery the responsible organisation may be the focus of the statement.

In addition, each statement is accompanied by:

- a description of its implications for different audiences
- reference to the underpinning evidence source
- sources of data for measurement
- definitions of the terms used
- relevant equality and diversity considerations.

1.3 Quality measures

Quality measures accompany each quality statement. They address care or service processes and, if appropriate, care or service structures or outcomes.

Most 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. If an outcome can be attributed to a single statement and used at a local level, it will be included as a quality measure.

Any timeframes for delivery of interventions or actions should be derived from the underpinning evidence source or expert advice received during development.

Related national quality 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.

1.4 Underpinning evidence sources

NICE quality standards are underpinned by NICE guidance or, if NICE guidance is not available, other high-quality evidence-based sources such as guidance from Royal Colleges, international guideline developers and reports from national inquiries.

The acceptability of using externally developed evidence sources to underpin a NICE

quality standard will be explored with stakeholders and is subject to approval by NICE's guidance executive.

The quality of guidance produced externally will be assessed using the AGREE II instrument. The quality of evidence sources not suitable for assessment using AGREE II will be assessed on a case-by-case basis.

2 Maintaining published NICE quality standards

2.1 Updating NICE quality standards

NICE maintains a library of published NICE quality standards and continually gathers intelligence to identify events that may trigger an update including changes in:

- underpinning evidence source
- priorities for quality improvement
- national data sources
- context such as national policy, legislation or infrastructure.

This list is not exhaustive, and individual events will be considered on a case-by-case basis.

Changes to published quality standards that do not alter the intent of statements may be made directly by NICE to ensure accuracy, correct errors and improve usability. To reduce the burden on stakeholders, these changes will not usually be subject to consultation.

2.2 Standing down NICE quality standards

A NICE quality standard may be suitable to be stood down and removed from the library if feedback from the health and care system indicates it is no longer relevant, for example if it has been superseded by statutory requirements.

The endorsing body (DHSC or NHSE) will be notified before the proposal is presented to NICE's guidance executive for approval. Supporting organisations will be notified and asked to remove cross-references from their websites. The NICE quality standard will be removed from the NICE website.

3 Approaches for new and updated NICE quality standards

Key stages in the development of new and updated NICE quality standards are:

- Topic engagement to receive stakeholder suggestions on key areas for quality improvement.
- Prioritising areas for quality improvement.
- Consultation with stakeholders.
- Reviewing consultation comments and agreeing any changes.
- Validation by NICE's guidance executive and referring organisation (NHSE or DHSC).

Development of new or updated NICE quality standards will use proportionate approaches that consider:

- The urgency of the health and care system need.
- Opportunities to limit duplication of effort in the health and care system.
- The extent of any required update.

Use of the different approaches for developing and updating quality standards will be monitored on an annual basis.

3.1 Quality standards advisory committee

New and updated NICE quality standards will usually be developed using the NICE quality standards advisory committee (QSAC). The committee includes professionals, practitioners and lay members and consists of:

- standing members (a core membership who work across topics)
- specialist members with experience specifically related to the NICE quality standard under discussion.

For more details, see the QSAC – terms of reference and standing orders.

3.2 NICE guideline committees

To support NICE's strategic vision of providing timely guidance and publishing new and updated quality standards at the same time as underpinning guidelines, a relevant NICE guideline committee with QSAC input may be used for development. The involvement of the QSAC input is intended to provide some balance and independence from the guideline committee.

This method for QS development may be used in situations where the standard QSAC approach as set out in paragraph 3.1 does not support timely publication.

Representation from the QSAC will be agreed as needed to develop the NICE quality standard; the number of QSAC representatives may vary in accordance with the needs of the topic.

3.3 Development groups

A development group of individuals with appropriate expertise and experience may be convened to develop new and updated NICE quality standards.

Representation from the QSAC will be agreed as needed to develop the NICE quality standard; the number of QSAC representatives may vary in accordance with the needs of the topic.

This method for development may be used in situations where:

- there is an urgent health and care system need or
- the extent of an update is limited or
- use of the QSAC advisory committee as set out in paragraph 3.1 is not appropriate because publishing the details of individuals working on a quality standard might put a person at risk of harm.

3.4 Collaboration

To reduce duplication of effort in the health and care system, quality standards produced outside of NICE may be incorporated into, or cross-referred to from, the quality standard library. Generally, the QSAC will assess quality standards produced externally and ensure they:

- focus on high-priority areas for quality improvement
- are measurable
- are underpinned by high-quality evidence sources as outlined in section 1.4
- included lay members in development
- have been subject to stakeholder consultation.

Incorporation or cross-referral to externally produced quality standards is subject to validation by NICE's guidance executive and the commissioning body (DHSC or NHSE).

4 Prioritising areas for quality improvement

Areas prioritised for quality statements should:

- be areas of care with 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 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.

Resource impact and the potential to advance equality will also be considered.

Quality statements can be categorised as 'developmental' if they also:

- represent an emergent area of cutting-edge service delivery or technology currently being done 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.

The QSAC may use a 'placeholder' statement to indicate that an area was agreed to be a priority for quality improvement but could not be included as a quality statement because no evidence source was available. A placeholder statement indicates the need for an evidence source to be developed.

5 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 NICE quality standards. We encourage professional, patient, service user, carer, community and voluntary organisations, as well as organisations of groups protected by equality legislation, to register as stakeholders and get involved.

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 NICE guidance on which a quality standard is based are automatically registered as stakeholders for the NICE quality standard.
- Any organisations registered as stakeholders for evidence sources developed externally are invited by NICE to register as stakeholders.
- The registered stakeholder list for each NICE quality standard is reviewed and, if there are any omissions, relevant organisations are encouraged to register as stakeholders. This review is done by the NICE quality standards team with the support of other NICE teams such as the people and communities involvement and engagement team.

Registered stakeholders are given advance notice of the development schedule, including the dates of the topic engagement and consultation phase.

The NICE position statement on engagement with tobacco industry organisations sets out how NICE meets obligations under Article 5.3 of the WHO Framework Convention on Tobacco Control.

5.1 Topic engagement

In the early development stages of new and updated NICE quality standards, registered stakeholders are invited to submit suggestions for the key areas for quality improvement. This engagement period usually lasts for 2 weeks, however, it may be reduced but to no less than 5 working days if a more proportionate approach is appropriate to the circumstances.

Registered stakeholders are invited to:

- identify key areas for quality improvement, including emergent areas of practice that may be considered for developmental statements
- 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.

Comments received from unregistered stakeholders and individuals are reviewed by the committee but are not published on the NICE website.

5.2 Consultation

New and updated NICE quality standards will be subject to consultation with registered stakeholders. The consultation period usually lasts for 4 weeks, however, it may be reduced but to no less than 10 working days if a more proportionate approach is appropriate to the circumstances. Advance notice of a consultation will always be given.

Registered stakeholders are invited to comment on 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.

Comments submitted by registered stakeholders are included in summary reports and receive a written response at publication of the NICE quality standard. Registered stakeholders are notified by email when a new or updated NICE quality standard is published.

Comments received from unregistered stakeholders and individuals are reviewed by the committee but do not receive a written response and are not published on the NICE website.

5.3 Formal support of NICE quality standards

During both topic engagement and the consultation phase, eligible stakeholders and respondents are invited to express interest in formally supporting the NICE quality standard. The eligibility criteria are listed on the NICE website. Supporting organisations agree to undertake activities to increase awareness of the NICE 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
- using conferences and other speaking opportunities
- running workshops to help other organisations understand how using the NICE quality standard can add value.

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

6 Equality and diversity

We are committed to ensuring that our development process:

- fully meets duties under the Equality Act (2010) to have due regard to the need to eliminate discrimination, foster good relations and advance equality of opportunity in relation to people who share the protected characteristics of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation, including the public sector equality duty to tackle discrimination and provide equality of opportunity for all
- enables us to meet requirements under the Human Rights Act (1998)
- fully meets duties under the Health and Social Care Act 2012 to consider the degree of a person's need for health services or social care in England.

6.1 Reducing health inequalities

Health inequalities arise because of the conditions in which we are born, grow, live, work and age. Health inequalities can be considered across 4 dimensions:

- socio-economic status and deprivation (for example, unemployment, poor housing, poor education, low income or people living in deprived areas)
- protected characteristics defined in the Equality Act 2010
- vulnerable groups of society, or 'inclusion health' groups (for example, vulnerable migrants, people who are homeless, sex workers, and Gypsy, Roma and Travellers)
- geography (for example, urban or rural areas, coastal areas).

Health inequalities can be measured through examining differences in 5 domains:

- health status (for example, life expectancy and prevalence of health conditions)
- behavioural risks to health (for example, smoking, diet and physical activity)
- wider determinants of health (for example, income, education and access to green spaces)

- access to care (for example, availability of treatments)
- quality and experience of care (for example, levels of patient satisfaction).

Having due consideration for groups that may be affected by equality and health inequalities issues is an aspect of our compliance with both general public law requirements to act fairly and reasonably, and human rights obligations. It is also aligned to duties placed on the integrated care systems as outlined in the Health and Care Act 2022. We also have a moral, leadership and strategic duty to address health inequalities given our reputational role in delivering robust, independent and trusted advice to the UK health and care system.

6.2 Approaches to reducing health inequalities

We use evidence-based approaches to help identify and address equality and health inequalities issues throughout the quality standard development process by:

- systematically identifying population groups that may experience health inequalities using an equality and health inequalities assessment form, which considers the 4 dimensions of health inequalities
- building on the key principles of co-design, co-production and community engagement to include diverse voices and perspectives that can help identify health inequalities and inform actions to reduce them
- proactively considering whether quality statements can advance equality and reduce health inequalities.

7 Validation

7.1 Guidance executive

When considering a new or updated NICE quality standard for consultation and final publication, NICE's 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 clear and follows the agreed template.

If a major issue is identified by NICE's guidance executive, further work may be needed by the NICE quality standards team as appropriate.

7.2 Endorsement (NHSE and DHSC)

Before publishing a NICE quality standard, endorsement from the referring organisation (NHSE or DHSC) is sought to ensure that NICE has:

- fulfilled the direction provided at the referral stage for the topic
- adhered to published processes
- engaged at all relevant points with all registered stakeholders.

8 Transparency

8.1 Attending meetings

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 NICE 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, or as yet unpublished NICE guidance 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 associate director.

If a guideline committee or development group is used, the public will usually be excluded.

8.2 Published papers

To ensure that the process is as transparent as possible, NICE considers it desirable that all information relevant to the development of NICE quality standards is publicly available. The following supporting documents are therefore published on the NICE website:

- briefing papers
- equality and health inequality impact analyses
- meeting minutes
- consultation summary reports including stakeholder consultation comments and NICE responses.

NICE quality standards are published on the NICE website (see published NICE quality standards) and are also available from other supporting organisations, such as professional and patient or service user organisations.

8.3 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).

9 Using NICE quality standards

NICE quality standards provide clear descriptions of high-priority areas for quality improvement and can:

- help organisations improve quality by supporting comparison of current performance using measures of best practice to identify priorities for improvement
- provide information for commissioners and providers on how best practice can be used to support high-quality care or services
- improve quality in the longer term by showing practice with the potential to improve outcomes over time, but that may need specific changes to be put in place first.

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 show 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 NICE quality 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 them to ensure that the services they provide are of high quality.

For more information, see how to use NICE quality standards on the NICE website.

10 Further information

The process guide will be updated every 3 years, or every 2 years in exceptional circumstances.

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 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 for NICE quality standards under development at the time of the change will be notified if they are affected by the change. Stakeholders for NICE 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 4 weeks.

Update information

December 2025: We updated the process guide to incorporate proportionate approaches to development introduced in July 2024 to enable flexibility and deliver useful and usable outputs:

- Using externally developed evidence sources to underpin NICE quality standards if NICE guidance is not available.
- Using guideline committees or development groups to develop NICE quality standards.
- Incorporating externally developed quality standards into the NICE quality standards library.
- We amended the required consultation length for updates to the NICE quality standards process guide to 4 weeks.

July 2024: We added an appendix on the interim process statement for a more proportionate approach to quality standard development, which describes the interim process changes that NICE will use to support proportionate approaches to the development and maintenance of NICE quality standards

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 updated throughout to align with:

- new NICE team structures
- removal of endorsing and supporting organisation logos from quality standard webpages
- 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 process guide throughout to reflect that:

- NICE's name changed to the 'National Institute for Health and Care Excellence'.
- NHS Commissioning Board is now NHS England.
- Commissioning Outcomes Framework (COF) is now the Clinical Commissioning Group Outcomes Indicator Set (CCG OIS).
- Stakeholder comments will not be formally considered if they are submitted by unregistered stakeholders or after the relevant deadline.

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