

1 **Developing NICE guidelines: the manual**

3 **Glossary**

4 **Abstract**

5 Summary of a study, which may be published alone or as an introduction to a full
6 scientific paper.

7 **AGREE (Appraisal of Guidelines for Research and Evaluation)**

8 An international collaboration of researchers and policy makers whose aim is to
9 improve the quality and effectiveness of practice guidelines. The [AGREE II](#)
10 [instrument](#), developed by the group, is designed to assess the quality of guidelines.

11 **Allocation**

12 The process by which study participants are allocated to a treatment group.

13 **Applicability**

14 How well an observation or the results of a study or review are likely to hold true in a
15 particular setting.

16 **Association**

17 Statistical relationship between 2 or more events, characteristics or other variables.
18 The relationship may or may not be causal.

19 **Audit trail**

20 Clear record of actions so that the reasons for the actions are apparent to a third
21 party. For example, the reasons for changes to a draft guideline should be clearly
22 recorded.

23 **Baseline**

24 A set of measurements before any intervention starts (after any initial 'run-in' period
25 with no intervention), with which subsequent results are compared.

1 **Bias**

2 Systematic (as opposed to random) deviation of the results of a study from the 'true'
3 results, caused by the way the study is designed or conducted.

4 **Case-control study**

5 An observational study to find out the possible cause(s) of a disease or condition. This is
6 done by comparing a group of patients who have the disease or condition (cases) with a
7 group of people who do not have it (controls) but who are otherwise as similar as
8 possible (in characteristics thought to be unrelated to the causes of the disease or
9 condition). This means the researcher can look for aspects of their lives that differ to see
10 if they may have caused the condition.

11 For example, a group of people with lung cancer might be compared with a group of
12 people the same age who do not have lung cancer. The researcher could compare how
13 long both groups had been exposed to tobacco smoke. Such studies are retrospective
14 because they look back in time from the outcome to the possible causes of a disease or
15 condition.

16 **Citation searching**

17 Citation searching (also known as 'snowballing') can help to identify additional
18 research. It has 2 dimensions:

19 • Backward citation searching is reviewing references cited in studies identified for
20 inclusion in the review.

21 • Forward citation searching involves searching for additional studies that cite
22 articles known to be relevant (such as those identified for inclusion in the review).

23 **Cohort study**

24 An observational study with 2 or more groups (cohorts) of people with similar
25 characteristics. One group has a treatment, is exposed to a risk factor or has a particular
26 symptom and the other group does not. The study follows their progress over time and
27 records what happens.

1 **Committee**

2 The advisory group that considers the evidence and develops the recommendations,
3 taking into account the views of stakeholders. NICE has [standing committees](#) (which
4 work on multiple guidelines) and [topic-specific committees](#) (which are put together
5 for a single guideline topic). Members include [practitioners](#) and professionals (both
6 specialists and generalists, and/or academics), care providers and commissioners,
7 people using health and care services and/or their family members or carers, or
8 people from communities affected by the guideline.

9 **Committee chair**

10 A member of the committee who leads committee meetings, and ensures that the
11 committee keeps to the scope of the guideline, works collaboratively and adheres to
12 NICE's [equality policy](#) and principles on social value judgements (see the entry on
13 social value judgements in our website [glossary](#)). The chair completes the equality
14 impact assessment with the developer at scoping and final guideline stages,
15 approves the draft guideline for consultation, and advises the developer on
16 responses to comments from registered stakeholders.

17 **Comparator**

18 The standard (for example, another intervention or usual care) against which an
19 intervention is compared in a study. The comparator can be no intervention (for
20 example, best supportive care).

21 **Conceptual framework**

22 A theoretical structure of assumptions, principles and rules, which holds together the
23 ideas comprising a broad concept. A conceptual model has been defined as the
24 abstraction and representation of complex phenomena of interest in some readily
25 expressible form, such that the individual stakeholders' understanding of the parts of
26 the system, and/or the mathematical representation of that system, can be shared,
27 questioned, tested and ultimately agreed.

28 **Confidence interval (CI)**

29 The confidence interval is a way of expressing how certain we are about the findings
30 from a study, using statistics. It gives a range of results that is likely to include the
31 'true' value for the population. A wide confidence interval indicates a lack of certainty

1 about the true effect of the test or treatment – often because a small group of
2 patients has been studied. A narrow confidence interval indicates a more precise
3 estimate (for example, if a large number of patients have been studied).

4 **Consultation table**

5 A table of all the comments received by NICE during consultation on a scope or draft
6 guideline. The committee considers the comments received, and the developer then
7 responds to the comments in the table.

8 **Contractors**

9 Organisations contracted to do some aspects of guideline development for NICE.
10 This might include doing evidence reviews or [fieldwork](#), or the developer role.

11 **Co-opted members**

12 An expert invited to 1 or more meetings to contribute to formulating
13 recommendations in a specific part of the guideline. They take part fully in
14 discussions, but do not have voting rights or count towards quorum. Co-opted
15 members can include people with expertise in user, carer or community experience
16 and views, as well as those with professional or practitioner expertise.

17 **Core members (standing committee)**

18 The core members of a [standing committee](#) include at least 1 practitioner and 1 lay
19 member, and may include an economist. A standing committee usually has between
20 6 and 12 core members. They serve for an initial period of up to 3 years and work on
21 all guidelines developed by the committee during that period.

22 **Correlates review**

23 Correlates reviews describe relationships between epidemiological factors and
24 outcomes.

25 **Cost–benefit analysis**

26 This is a type of economic evaluation in which the costs and benefits are measured
27 using the same monetary units (for example, pounds sterling) to see whether the
28 benefits exceed the costs.

1 **Cost-consequences analysis**

2 This is a type of economic evaluation in which the costs (such as treatment and
3 hospital care) and the consequences (such as health outcomes) of a test or
4 treatment are compared with those for a suitable alternative. Unlike cost-benefit
5 analysis or cost-effectiveness analysis, it does not attempt to summarise outcomes
6 in a single measure (such as the quality-adjusted life year) or in financial terms.
7 Instead, outcomes are shown in their natural units (some of which may be monetary)
8 and it is left to decision-makers to determine whether, overall, the treatment is worth
9 carrying out.

10 **Cost-effectiveness analysis**

11 This is a type of economic evaluation in which the benefits are expressed in
12 non-monetary terms related to health, such as symptom-free days, heart attacks
13 avoided, deaths avoided or life years gained (that is, the number of years by which
14 the intervention extends life). Cost-effectiveness analysis assesses the cost of
15 achieving the same benefit by different means. Cost-effectiveness analysis is also
16 used as an umbrella term to cover all types of economic evaluation.

17 **Cost-minimisation analysis**

18 In a cost-minimisation analysis, the costs of different interventions that provide the
19 same benefits are compared. If they are equally effective, only the costs are
20 compared because the cheapest intervention will provide the best value for money.
21 In practice, there are relatively few cost-minimisation analyses because it is rare for
22 2 healthcare interventions to provide exactly the same benefits.

23 **Cost-utility analysis**

24 This is a type of economic evaluation in which the benefits are assessed in terms of
25 both quality and duration of life, and expressed as quality-adjusted life years
26 (QALYs).

27 **Cross-sectional survey**

28 An observational study in which a population is examined to see what proportion has
29 a particular outcome or has been exposed to a specific risk factor, or both.
30 Cross-sectional surveys are usually used to determine the prevalence of outcomes
31 or exposures to risk factors in populations. This type of survey may also be called a

1 cross-sectional study or a prevalence study. Although cross-sectional surveys often
2 provide useful estimates of disease burden for a particular population, they are less
3 reliable for determining the prevalence of very rare conditions or conditions of short
4 duration. Because cross-sectional surveys are descriptive rather than analytical, they
5 cannot be used to estimate the relationship between cause and effect.

6 **Decision-analytic model (and/or technique)**

7 A model of how decisions are or should be made. This could be one of several
8 models or techniques used to help people to make better decisions (for example,
9 when considering the trade-off between costs, benefits and harms of diagnostic tests
10 or interventions). See also [Markov modelling](#).

11 **Delphi technique**

12 A technique used for reaching agreement on a particular issue, without the
13 participants meeting or interacting directly. It involves sending participants a series of
14 questionnaires asking their views. After completing each questionnaire, participants
15 are asked to give further views in the light of the group feedback until the group
16 reaches a predetermined level of agreement. The judgements of the participants
17 may be analysed statistically.

18 **Design-oriented conceptual model**

19 This is an explicit simplification and abstraction of the problem-oriented conceptual
20 model, mediated by what is feasible and by the availability of evidence and data.

21 **Developer**

22 The team responsible for scoping the guideline, identifying and reviewing the
23 evidence, undertaking economic analyses, supporting the committee and writing the
24 guideline in light of the committee's discussions and decisions. The team includes
25 administrators, coordinators and [project managers](#) who provide administrative and
26 management support to the committee, plan and schedule the work, arrange
27 meetings, and liaise with stakeholders and all other people and organisations
28 contributing to guideline development.

1 **Discounting**

2 Costs and perhaps benefits incurred today have a higher value than costs and
3 benefits occurring in the future. Discounting health benefits reflects individual
4 preference for benefits to be experienced in the present rather than the future.
5 Discounting costs reflects individual preference for costs to be experienced in the
6 future rather than the present.

7 **Dosage**

8 The amount of a medicine to be taken, including the size and timing of the doses.

9 **Economic evaluation**

10 The comparative analysis of alternative courses of action in terms of both their costs
11 and consequences.

12 **Economist**

13 A person with skills in economic analysis whose role is to advise on economic
14 aspects of the key issues or questions, review economic literature, prioritise topics
15 for further analysis and carry out additional cost-effectiveness analyses.

16 **Effect (as in treatment effect, effect size)**

17 The observed association between interventions and outcomes, or a statistic to
18 summarise the strength of the observed association.

19 **Effectiveness**

20 The extent to which an intervention produces an overall benefit under usual or
21 everyday conditions. In this manual effectiveness includes cost effectiveness unless
22 otherwise indicated.

23 **Endorsement**

24 The NICE endorsement programme formally endorses resources produced by
25 external organisations that support the implementation of NICE guidance and the
26 use of quality standards in part or in full.

1 **Epidemiological review**

2 Epidemiological reviews describe a problem in terms of its causes, distribution,
3 control and prevention, and can be used to help focus the review questions. For
4 example, an epidemiological review of accidents would provide information on the
5 most common accidents, morbidity and mortality statistics, and data on inequalities
6 in the impact of accidents.

7 **Equity**

8 Fair distribution of resources or benefits.

9 **Evidence**

10 Information on which a decision or recommendation is based. Evidence can be
11 obtained from a wide range of sources, including randomised controlled trials,
12 observational studies and expert opinion (of practitioners, people using services,
13 family members and carers).

14 **Evidence profile**

15 A table summarising, for each important outcome, the quality of the evidence and the
16 outcome data (used as part of the GRADE approach to assessing the quality of the
17 evidence).

18 **Evidence review**

19 Identifying and reviewing the evidence, and undertaking economic analyses:

- 20 • The information specialist identifies relevant literature to answer the review
21 questions (see chapter 5), creates databases to manage the search results and
22 keeps a log of search results and strategies.
- 23 • The systematic reviewer critically appraises the evidence, distils it into tables and
24 writes brief summaries (including GRADE tables, GRADE-CERQual or evidence
25 statements, if used). The reviewer also summarises the main issues for the
26 committee and contributes to its discussions.
- 27 • The economist identifies potential economic issues to be considered in the
28 guideline and performs economic analyses.

1 **Exceptional update**

2 Update of a guideline carried out sooner than originally planned because new data
3 have become available.

4 **Exclusion criteria (literature review)**

5 Explicit criteria used to decide which studies should be excluded from consideration
6 as potential sources of evidence.

7 **Exclusion criteria (study participants)**

8 Criteria that define who is not eligible to participate in a study.

9 **Expert Advisers Panel**

10 The Expert Advisers Panel provides a single repository of experts and practitioners
11 (who have been through a robust recruitment process) for the NICE Centre for
12 Guidelines, and can be called upon to contribute to various guideline development
13 activities such surveillance reviews and guideline updates.

14 **Expert witness**

15 An expert invited to attend a committee meeting to provide evidence from their
16 experience and specific expertise. Expert witnesses answer questions from
17 committee members and may be invited to present evidence in the form of expert
18 testimony, which is published on the NICE website when the guideline is published.
19 Expert witnesses are not members of the committee. They have expert knowledge of
20 1 or more of the following areas: experience and views of practitioners; people using
21 services; carers or the community and voluntary sector; government and policy; or
22 research and practice.

23 **External validity**

24 The degree to which the results of a study hold true in non-study situations (for
25 example, in routine NHS practice). It may also be referred to as the [generalisability](#)
26 of study results to non-study populations. For example, the external validity of a
27 study that took place in Spain may be questioned if the results are applied to people
28 in Australia.

1 **Extrapolation**

2 In data analysis, predicting the value of a parameter outside the range of observed
3 values.

4 **Follow-up**

5 Observation over a period of time of a person, group or defined population to
6 observe changes in health status or health- and social care-related variables.

7 **Forest plot**

8 A type of graph used to display the results of a [meta-analysis](#).

9 **Formal consensus methods**

10 Formal consensus methods are techniques that can be used to enable a committee
11 to reach an agreement on a particular issue. Methods include [Delphi](#) and nominal
12 group techniques, and consensus development conferences. These methods may
13 be used during guideline development when there is a lack of strong research
14 evidence in a particular area.

15 **Free-text terms**

16 Terms used for searching that are not controlled vocabulary as used in the database
17 or information source, but standard terms used in natural language.

18 **Full update of a guideline**

19 When a guideline is identified for a full update, the existing guideline with its
20 recommendations, are stood down and a replacement guideline is developed with
21 new recommendations.

22 **Generalisability**

23 The extent to which the results of a study based on measurements in a particular
24 population or a specific context hold true for another population or in a different
25 context.

1 **GRADE (Grading of Recommendations Assessment, Development and**
2 **Evaluation)**
3 A systematic and explicit approach to grading the quality of evidence and the
4 strength of recommendations. GRADE is an evolving system and is continuously
5 being adapted and extended to cover different areas and types of evidence; for
6 example, CERQUAL for qualitative evidence and GRADE for diagnostic studies. See
7 the [GRADE Working Group](#) for the latest news and publications.

8 **Grey literature**

9 Literature that is not formally published or that has a limited distribution, such as
10 institutional reports. Grey literature may not be easily identified through standard
11 bibliographic retrieval systems.

12 **Health inequalities**

13 The gap in health status and in access to health services between different groups,
14 for example, those with different socioeconomic status or different ethnicity, or
15 populations in different geographical areas. More information on [health inequalities](#)
16 can be found on the [Department of Health and Social Care website](#).

17 **Health-related quality of life**

18 A combination of a person's overall physical, mental and social wellbeing; not merely
19 the absence of disease.

20 **Health Technology Assessment**

21 Independent research about the effectiveness, costs and broader impact of
22 healthcare (treatments and tests) for those who plan, provide or receive care in the
23 NHS. The Health Technology Assessment (HTA) programme is part of the National
24 Institute for Health Research (NIHR).

25 **Implementation**

26 The process of putting guideline recommendations into practice.

27 **In confidence material**

28 Information (for example, the findings of a research project) defined as 'confidential'
29 because its public disclosure could affect the commercial interests of a particular

1 company ('commercial in confidence') or the academic interests of a research or
2 professional organisation ('academic in confidence').

3 **Inclusion criteria (literature review)**

4 Explicit criteria used to decide which studies should be considered as potential
5 sources of evidence.

6 **Incremental cost-effectiveness ratio (ICER)**

7 The difference in the mean costs between 2 interventions, strategies or programmes
8 in the population of interest divided by the differences in the mean outcomes
9 between the 2 interventions, strategies or programmes in the population of interest.

10 **Index test**

11 The test in a study which is being compared with the best available test (the
12 reference standard).

13 **Indication (specific)**

14 The defined use of a medicine as licensed by the Medicines and Healthcare
15 products Regulatory Agency (MHRA).

16 **Indirect treatment comparison**

17 An analysis to compare interventions that have not been compared directly in a
18 head-to-head trial.

19 **Internal validity**

20 A measure of how well a research study has been designed and how well it avoids
21 bias. That is, the extent to which the cause-and-effect relationships in a study are
22 true for the people and conditions of the study.

23 **Key issues**

24 Key issues are included in the scope of a guideline and broadly define aspects of
25 care or service provision for which most advice is needed.

26 **Key questions**

27 Key questions are included in the scope of a guideline and are broad questions
28 related to the areas defined by the key issues. Key questions relate to the

1 effectiveness and cost effectiveness of interventions that are being considered for a
2 given population. Key questions are then used to develop more detailed review
3 questions.

4 **Lay member**

5 A member of the committee who has personal experience of using health or care
6 services, or who is from a community affected by the guideline. A lay member can
7 also be someone with experience as a carer, an advocate, or a member or officer of
8 a voluntary or community organisation.

9 **Literature review**

10 A summary of the evidence from several studies, with conclusions about the
11 findings. It may or may not be systematically researched and developed.

12 **Logic model**

13 A model that incorporates the assumed relationships between action and outcomes
14 as described in the conceptual framework.

15 **Marketing authorisation**

16 This was previously known as a product licence. Marketing authorisation is granted
17 to medicines that meet the standards of safety, quality and efficacy set by a
18 medicines regulator (for example, the Medicines and Healthcare products Regulatory
19 Agency [MHRA] or the European Medicines Agency). It is normally necessary before
20 a medicine can be prescribed or sold.

21 **Markov modelling**

22 A decision-analytic technique that predicts future events occurring in a group over a
23 period of time by assigning group members to a fixed number of health states and
24 then modelling transitions among the health states.

25 **Medical devices**

26 All products, except medicines, used in healthcare for the diagnosis, prevention,
27 monitoring or treatment of illness or disability.

1 **Medicines and Healthcare products Regulatory Agency (MHRA)**
2 The Executive Agency of the Department of Health that is responsible for protecting
3 and promoting public health and patient safety by ensuring that medicines,
4 healthcare products and medical equipment meet appropriate standards of safety,
5 quality, performance and effectiveness, and are used safely.

6 **Meta-analysis**

7 A method often used in systematic reviews to combine results from several studies
8 of the same test, treatment or other intervention to estimate the overall effect of the
9 treatment.

10 **Meta-ethnography**

11 A process for sorting and combining the findings from qualitative studies.

12 **Model inputs**

13 Information needed for economic modelling. This may include information about
14 effectiveness, adverse events, diagnostic accuracy, prognosis, quality of life,
15 resource use and costs.

16 **Narrative summary**

17 Summary of findings presented as a written description rather than, for example, as
18 a graph or table.

19 **Net benefit estimates**

20 In cost-effectiveness and cost-utility analysis, the net benefit estimate can be
21 expressed in outcomes (for example, using quality-adjusted life years [QALYs]) or
22 monetary terms. The net health (or outcome) benefit is the difference between the
23 total expected QALYs (or outcome) and the health (or outcomes) expected to be
24 forgone elsewhere (the total expected costs divided by the maximum acceptable
25 incremental cost-effectiveness ratio [ICER] value). The net monetary benefit is the
26 difference between the monetary value of total expected QALYs (our outcome)
27 multiplied by the maximum acceptable ICER value [ICER] and total expected costs.

28 In cost-benefit analysis, the net benefit estimate is the estimate of the amount of
29 money remaining after all payments made are subtracted from all payments
30 received. This is used in the economic evidence profile for guidelines.

1 **Network meta-analysis**

2 An analysis that compares 3 or more interventions using a combination of direct
3 evidence (from studies that directly compare the interventions of interest) and
4 indirect evidence (from studies that do not compare the interventions of interest
5 directly).

6 **NICE guidance**

7 Recommendations produced by NICE. There are 5 types of guidance:

- 8 • guidelines covering clinical topics, medicines practice, public health and social
9 care
- 10 • interventional procedures guidance
- 11 • technology appraisals guidance
- 12 • medical technologies guidance
- 13 • diagnostics guidance.

14 All guidance is developed by independent committees and is consulted on.

15 **NICE guidelines**

16 Recommendations (and the evidence they are based on) on broad topics covering
17 health, public health and social care in England. NICE guidelines include clinical,
18 medicines practice, public health and social care guidelines.

19 **NICE Pathways**

20 NICE Pathways are a tool to help find NICE guidance quickly and easily – everything
21 NICE says on a topic in an interactive flowchart.

22 **Non-randomised controlled trial**

23 These are trials in which participants (or groups) are allocated to receive either the
24 intervention or a control (or comparison intervention) but the allocation is not
25 randomised. This type of study is often called a controlled before-and-after (CBA)
26 study.

1 **Observational study**

2 Retrospective or prospective study in which the investigator observes the natural
3 course of events with or without control groups (for example, cohort studies and
4 case-control studies).

5 **Odds ratio (OR)**

6 An odds ratio compares the odds of something happening in one group with the
7 odds of it happening in another. An odds ratio of 1 shows that the odds of the event
8 happening (for example, a person developing a disease or a treatment working) is
9 the same for both groups. An odds ratio of greater than 1 means that the event is
10 more likely in the first group than the second. An odds ratio of less than 1 means that
11 the event is less likely in the first group than in the second group.

12 Sometimes probability can be compared across more than 2 groups – in this case,
13 one of the groups is chosen as the ‘reference category’, and the odds ratio is
14 calculated for each group compared with the reference category.

15 **P value**

16 The p value is a statistical measure that is used to indicate whether or not an effect
17 is statistically significant.

18 **People using services and the public**

19 Anyone who is using health or care services, or a member of the public affected by a
20 guideline.

21 **Personal social services**

22 Care services for vulnerable people, including those with special needs because of
23 old age or physical disability and children in need of care and protection. Examples
24 are residential care homes for older people, home help and home care services, and
25 social workers who provide help and support for a wide range of people (Department
26 of Health definition).

27 **PICO (population, intervention, comparison and outcome) framework**

28 A structured approach for developing review questions about interventions. The
29 PICO framework divides each question into 4 components: the population (the

1 population being studied), the interventions (what is being done), the comparators
2 (other main [treatment options](#)) and the outcomes (measures of how effective the
3 interventions are).

4 **Placeholder statements**

5 In NICE quality standards, placeholder statements are used for areas of care in need
6 of quality improvement but for which there is no evidence-based guidance available
7 to formulate quality statements or measures.

8 **Practitioner**

9 A healthcare, social care or public health worker.

10 **Pragmatic clinical trial**

11 A study comparing health interventions among a randomised, diverse population
12 representing clinical practice, and measuring a broad range of health outcomes. To
13 ensure generalisability, pragmatic trials should represent the intended patients to
14 whom the treatment will be applied as best as possible. (Definition from [GetReal](#)
15 [glossary](#)).

16 **Problem-oriented conceptual model**

17 This is a simplified, diagrammatic representation of the framework that describes the
18 resources, processes and interactions in the delivery of interventions.

19 **Prognosis**

20 A probable course or outcome of a disease. Prognostic factors are characteristics of
21 a patient or disease that influence the disease course. A good prognosis is
22 associated with a low rate of undesirable outcomes; a poor prognosis is associated
23 with a high rate of undesirable outcomes.

24 **Project manager**

25 The staff member who oversees and facilitates the guideline development process.

26 **Proprietary name**

27 The brand name a manufacturer gives to a medicine or device it produces.

1 **QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies-2)**

2 A tool for assessing the quality of studies of the accuracy of diagnostic tests.

3 **Qualitative research**

4 Qualitative research explores people's beliefs, experiences, attitudes, behaviour and
5 interactions. It asks questions about how and why, rather than how much. It
6 generates non-numerical data, such as a person's description of their pain rather
7 than a measure of pain. Qualitative research techniques include focus groups and
8 in-depth interviews.

9 **Quality-adjusted life years (QALY)**

10 A measure of the state of health of a person or group in which the benefits, in terms
11 of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year
12 of life in perfect health.

13 **Quality assurance**

14 NICE staff carry out quality assurance of the guideline, including reviews of the
15 evidence and any economic analysis, to ensure that it is up-to-date, credible, robust
16 and relevant. These staff may also be responsible for commissioning the developer.

- 17 • The centre director is responsible for ensuring that the guideline is produced in
18 accordance with this manual. The centre director is also responsible for appointing
19 the [committee chair](#) and committee members.
- 20 • The associate director is responsible for the development and quality assurance
21 of the guideline, and has delegated responsibility for approving the consultation
22 draft, the final guideline, and other documents, before final approval by NICE's
23 Guidance Executive. The associate director also advises the chair of the
24 committee and the developer on matters of method and process.
- 25 • The technical lead is responsible for the technical quality assurance of the
26 evidence reviews and other work undertaken by the developer. The technical lead
27 commissions, coordinates and quality assures any fieldwork.
- 28 • The economic lead is responsible for ensuring the technical quality of the
29 economic evidence and any economic analysis.

1 **Quality of life**

2 See [Health-related quality of life](#).

3 **Quality standards**

4 Quality standards set out the priority areas for quality improvement in health and
5 social care. They cover areas where there is variation in care. Each standard
6 includes a set of statements to help improve quality, and information on how to
7 measure progress.

8 **Quorum**

9 The smallest number of group members that must be present for a valid meeting.
10 The quorum of a committee is 50% of the total potential membership. No
11 recommendations should be confirmed unless the quorum is reached.

12 **Randomised controlled trial (RCT)**

13 Trials in which participants (or clusters) are randomly allocated to receive either
14 intervention or control. If well implemented, randomisation should ensure that
15 intervention and control groups differ only in their exposure to treatment.

16

17 **Real world data (RWD)**

18 An umbrella term for data regarding the effects of health interventions (for example,
19 safety, effectiveness, resource use) that are not collected in the context of highly
20 controlled RCTs. Instead, RWD can either be primary research data collected in a
21 manner which reflects how interventions would be used in routine practice or
22 secondary research data derived from routinely collected data. Data collected
23 include, but are not limited to, clinical and economic outcomes, patient-reported
24 outcomes (PRO) and health-related quality of life (HRQoL). RWD can be obtained
25 from many sources including patient registries and electronic medical records.
26 (Definition adapted from [GetReal glossary](#)).

27 **Real world evidence (RWE)**

1 Real world evidence (RWE) is the evidence derived from the analysis and/or
2 synthesis of real-world data (RWD). (Definition from [GetReal glossary](#)).

3 **Recommendations**

4 Specific advice in [NICE guidelines](#) on the care and services that are suitable for
5 most people with a specific condition or need, or for particular groups or people in
6 particular circumstances (for example, when being discharged from hospital).
7 Recommendations may also cover ways to promote good health or prevent ill health,
8 or how organisations and partnerships can improve the quality of care and services.

9 **Reference case**

10 The reference case specifies the methods considered by NICE to be the most
11 appropriate for estimating clinical and cost effectiveness when developing guidance.
12 These are also consistent with an NHS objective of maximising health gain from
13 limited resources.

14 **Reference standard (or gold standard)**

15 A method, procedure or measurement that is widely accepted as being the best
16 available to test for or treat a disease.

17 **Research recommendations**

18 Recommendations for future research that cover areas of uncertainty or gaps in the
19 evidence identified during guideline development.

20 **Respondent**

21 Tobacco companies with an interest in a particular guideline topic. They can register
22 to comment on the draft scope and the draft guideline and their comments are made
23 public with those of registered stakeholders. The term 'respondent' acknowledges
24 NICE's commitment to Article 5.3 of the WHO Framework Convention on Tobacco
25 Control. This sets out an obligation to protect the development of public health policy
26 from any vested interests of the tobacco industry.

27 **Review protocol**

28 A document that outlines the background, objectives and planned methods for an
29 evidence review.

1 **Review questions**

2 Review questions guide a [systematic review](#) of the literature. They address only the
3 [key issues](#) and questions covered in the scope of the guideline, and will usually be
4 structured with a framework (for example, using [PICO](#) or [SPICE](#)).

5 **Scoping search**

6 A search of key sources at the scoping stage to identify previous guidelines, [health](#)
7 [technology assessment](#) reports, key [systematic reviews](#), randomised controlled trials
8 and economic evaluations relevant to the guideline topic. The search also includes
9 the NICE website, government, charity, and other community and voluntary sector
10 websites to identify relevant policies and documents.

11 **Scoping workshop**

12 The scoping workshop is attended by registered stakeholders and is held when [key](#)
13 [issues](#) that need discussion have been identified by the developer. The workshop
14 may be held before during or after consultation.

15 **Search filter**

16 A collection of search terms designed to retrieve certain types of study (for example,
17 those using a specific study design or on a specific topic).

18 **Sensitivity (of a test)**

19 This refers to how well a test detects what it is testing for. It is the proportion of
20 people with the disease or condition that are correctly identified by the study test.

21 **Sensitivity analysis**

22 A means of exploring uncertainty in the results of economic evaluations. There may
23 be uncertainty because data are missing, estimates are imprecise or there is
24 controversy about methodology. Sensitivity analysis can also be used to see how
25 applicable results are to other settings. The analysis is repeated using different
26 assumptions to examine the effect of these assumptions on the results.

27 • Deterministic sensitivity analysis investigates how [bias](#) in selecting data sources
28 for key model parameters might affect the results.

1 • One-way sensitivity analysis (univariate analysis) varies each parameter
2 individually to investigate how this affects the results.

3 • Probabilistic sensitivity analysis assigns probability distributions to uncertain
4 parameters and incorporates these into models using decision-analytic techniques
5 (for example, Monte Carlo simulation).

6 **Shared learning examples**

7 These show how NICE guidance and standards have been put into practice by a
8 range of health, local government and social care organisations.

9 **Social care**

10 Social care generally refers to all forms of personal care and other practical
11 assistance for children, young people and adults who need extra support. This
12 includes:

13 • vulnerable children and young people (those who are at risk of, or who are already
14 experiencing social and emotional problems)

15 • children, young people and adults with learning or physical disabilities or mental
16 health problems

17 • people who misuse drugs or alcohol

18 • older people.

19 **Specificity (of a test)**

20 This refers to how well a test detects what it is testing for. The proportion of people
21 classified as negative by the [reference standard](#) who are correctly identified by the
22 study test.

23 **SPICE framework**

24 A structured approach for developing [review questions](#) that divides each question
25 into 5 components: setting, perspective, intervention, comparison and evaluation
26 (SPICE).

27 **Stakeholders**

28 Stakeholders are organisations with an interest in a particular guideline topic; they
29 may represent people whose practice or care is directly affected by the guideline.

1 They include: national organisations for people who use health and social care
2 services, their families and carers, and the public; local Healthwatch organisations;
3 national organisations that represent health and social care practitioners and other
4 people whose practice may be affected by the guideline, or who can influence
5 uptake of the guideline recommendations; public sector providers and
6 commissioners of care or services; private, voluntary sector and other independent
7 providers of care or services; companies that manufacture drugs, devices,
8 equipment or adaptations, and commercial industries relevant to public health;
9 organisations that fund or carry out research; government departments and national
10 statutory agencies.

11 As a party to the WHO Framework Convention on Tobacco Control, the United
12 Kingdom has an obligation to protect the development of public health policy from
13 the commercial and vested interests of the tobacco industry. When registering,
14 commenting on the draft scope and draft guideline, and submitting evidence in
15 response to a call for evidence, stakeholders are asked to disclose whether their
16 organisation has any direct or indirect links to, or receives or has ever received
17 funding from, the tobacco industry. We will still carefully consider all consultation
18 responses from the tobacco industry and from those with links to the industry.
19 Disclosures will be included with the published consultation responses and with
20 evidence presented to the committee.

21 Stakeholders are encouraged to get involved at all stages. Registered stakeholders
22 comment on the draft scope and draft guideline, may provide evidence, and support
23 implementation of the guideline.

24 **Standing committee**

25 A committee consisting of core members who work on multiple guidelines. Topic
26 expert members are brought in to work on specific guidelines.

27 **Survey**

28 See [cross-sectional study](#).

1 **Surveillance report**

2 A report that summarises the evidence and intelligence identified through the
3 surveillance process and explains the reasons for updating or not.

4 **Surveillance review**

5 The process of checking whether a guideline needs to be updated. This generally
6 includes consideration of new evidence and intelligence such as topic expert
7 feedback, changes to legislation or policy and information on implementation.

8 **Systematic review**

9 A review that summarises the evidence on a clearly formulated review question
10 according to a predefined protocol, using systematic and explicit methods to identify,
11 select and appraise relevant studies, and to extract, analyse, collate and report their
12 findings. It may or may not use statistical meta-analysis.

13 **Time horizon**

14 The time period over which the main differences between interventions in effects and
15 the use of resources in health and social care are expected to be experienced,
16 taking into account the limitations of the supporting evidence.

17 **Topic adviser (topic-specific committee)**

18 A member of the committee who also works closely with the developer to provide
19 topic-specific support.

20 **Topic expert members (of a standing committee)**

21 Experts on the topic of a guideline who join a standing committee to work on that
22 guideline. They may include [lay members](#), practitioners, providers and
23 commissioners.

24 **Topic-specific committee**

25 A committee consisting of members appointed for the development of a specific
26 guideline.

- 1 **Treatment options**
- 2 The choices of intervention available.