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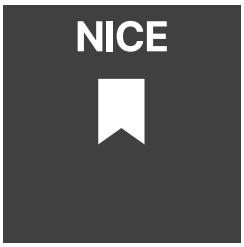

Developing NICE guidelines: the manual – appendices A to P

Audit and service improvement
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Contents

Appendix A: Service delivery – developing review questions, evidence reviews and synthesis

The scope should identify key areas that the guidance will cover. There are various types of review question that may be considered for service guidance; for example, these may cover:

- the content, configuration or integration of services, including the allocation of:
  - medical equipment or tools
  - staff, such as:
    - skills, mix and experience of staff
    - training requirements of staff
    - staffing levels (numbers and staff mix)
- access to services for patients, including:
  - the availability of services
  - the uptake of services
- timing and delivery of services, including:
  - diagnosis
  - treatment
  - transfer and referral
  - waiting times
- location of services, in terms of:
  - setting for delivery
  - economies of scales

    - geographic variation
- feasibility, with regard to:
    - resource constraints (including capacity, queues and waiting lists)
    - policy constraints.

The questions will compare possible service configurations, which may be existing variations to current services (national and international variations) or a proposed service configuration, with a current service configuration with respect to effectiveness and cost effectiveness.

Key outcomes of service delivery questions are likely to include measures of:

- service effectiveness:
    - health outcomes, including health-related quality of life
    - process outcomes (both directly and indirectly linked to outcomes)
    - compliance rates of staff
    - system failures
- service experience:
    - patient experience
    - family or carer experience
    - staff experience
- service resource use:
    - staff
    - equipment
    - time
    - costs
- service efficiency/optimisation:

  - cost effectiveness (cost–utility analysis)
  - cost consequence
  - cost saving
  - cost minimisations
- service equity (including health and geographical inequalities).

A key difference for service guidance compared with other guidelines is that, to adequately address the question, it is necessary to explore the underlying health and/or service concern first, and then assess the effectiveness of the various health service interventions in addressing this underlying issue. This requires an iterative approach to developing the review questions. The first step is to develop questions to explore the underlying problem, followed by developing questions around potential solutions and service models.

These types of review questions will often require the consideration of supplementary methodological approaches for identifying, assessing, synthesising and interpreting the evidence.

Evidence reviews will be iterative, with new searches and/or analysis being planned depending on the outcome of the initial reviews. For example, a search for studies exploring the effectiveness of a particular intervention may not produce any results. The next step would be to consider whether to search for evidence for a similar condition or another healthcare system. Alternatively, primary data may need to be identified or requested to inform recommendations. The guideline committee and NICE staff with responsibility for quality assurance should be consulted on the suitability of different types of evidence for developing recommendations.

Estimates of the relative effectiveness of service delivery interventions

It is helpful to distinguish between two general types of service delivery questions. One type concerns different pathways of care, different service configurations, interventions to be managed by different types of staff, whether a 'care team' approach is needed, and so on. These are questions for which trial evidence could in principle be found. For these kinds of questions, standard approaches to evidence identification and synthesis (for

example, those described in this guideline manual and on the NICE Decision Support Unit website) could, in principle, be used. However, for service guidance it is unlikely that one type of study or piece of evidence will be sufficient to inform recommendations. Therefore non-standard approaches to evidence synthesis will also need to be considered to enable the guideline committee to develop recommendations. Two specific problems that will often need to be addressed are:

- uncertainty about the quality and relevance of existing evidence on outcomes
- the need to consider evidence on process, intermediate or surrogate outcomes, such as uptake of services or compliance, rather than (or in addition to) evidence on outcomes.

A second type of service delivery issue relates to questions about the feasibility of providing access to services and procedures, or making them available within a certain time frame, rather than whether the services or procedures are effective. In these questions, estimates of the effect of providing the service, compared with not providing it, are needed for decision-making, whether based on cost-effectiveness analysis or on other criteria.

It should be emphasised that some service delivery guidance may present a combination of both access and availability issues as well as standard effectiveness issues.

Guidance on how to approach both kinds of problem, as well as on using consensus techniques when estimates based on published data cannot be obtained, is given in the following sections.

Finding studies that provide unbiased estimates of the effectiveness of service interventions is often difficult, for the following reasons:

- Service delivery interventions are inherently 'variable'. Even with a standard protocol, the precise way in which they are implemented at different sites or by different people is necessarily situation- and/or individual-dependent. This could be manifested by centre effects in multicentre trials.
- The relative benefit of a new intervention over 'standard' or pre-existing care is likely to depend on the 'intensity' of the current care. For example, the beneficial effect of a new patient reminder system on the uptake of screening for breast cancer depends on what the current arrangements are, and on current uptake. For example, the effect of

introducing a reminder system in the USA, where there is no systematic screening programme, will be quite different from the effect of adding the reminder system to existing infrastructure in the UK. In other words, results from studies carried out within other healthcare systems might not be easily generalised to the UK.

In these circumstances a standard systematic review is likely to identify a range of studies on interventions that are similar to the interventions being considered, but not necessarily the same, or which are described variably with respect to their components. In this case, the guideline committee will need to consider carefully fidelity and applicability issues, and ensure these are accounted for in the 'committee discussion' section of the guidance.

In most cases, the expert opinion of the guideline committee will be used to explore and estimate any impacts on the confidence in the results of such evidence, but quantitative methods for elicitation can be used. If quantitative methods for eliciting are to be used, the NICE Guidelines Technical Support Unit (TSU) should be contacted for advice on methods and on which types of evidence could be searched for.

Evidence on uptake and compliance outcomes

In some service delivery evaluations, measures of service uptake, patient satisfaction or compliance of health service staff are recorded, rather than data on clinical outcomes for patients. This is typically the case, for example, when the intervention is directed at changing staff behaviour or patient referral routes.

Such evidence can be used when analysing the effectiveness or cost effectiveness of a service delivery intervention, but only if there is also an estimate available – from whatever source – of the underlying effect of the procedure or treatment. It is then possible to combine estimates of the efficacy or effectiveness of the intervention with estimates of the effectiveness of the service delivery intervention in ensuring that the intervention is implemented. It is possible to combine evidence from trials reporting process outcomes alone, trials reporting outcomes alone, and trials reporting both.

The NICE TSU can be consulted for advice on how the two kinds of evidence can be combined within a single modelling framework.

Estimates of relative effectiveness for questions about access and availability

For questions about access and availability, there is a particular difficulty in deriving an estimate of relative effectiveness, over and above those described in the previous section. This would be the case, for example, where a procedure such as endoscopy for upper gastrointestinal bleeding is indicated. The question is not about whether endoscopy should be done, but whether or not the procedure can be safely delayed (for example, at night or at weekends) in patients whose symptoms suggest they are at lower risk.

Studies based on individual patient 'audit' data that relate outcomes to treatment parameters while controlling for patient characteristics are difficult to interpret. This is because patients in whom the treatment was withheld or delayed are always likely to be those who were considered to be at lower risk.

It is likely that better estimates of the effectiveness of such interventions can be derived from nationally collected data in which between-unit variation in outcomes, or variation between different time periods, can be related to the local policies and practices (for example, staffing levels) in operation at the time. For example, mortality rates within 1 or 2 days of hospital admission could be compared between weekends and weekdays, and hospitals where weekend cover was the same as weekday cover could also be compared with those where it is not. There are a number of examples where comparisons of this type have been published, for example by Dr Foster. Although these surveys avoid the problems of individual audit data, they are still observational and the use of aggregated data introduces further potential biases. The design of the data collection, and the analysis and interpretation of the data obtained, requires major input from clinical epidemiologists, expert clinicians, methodologists, operational research experts and people with relevant operational experience in the NHS.

A service delivery issue that is quite often examined in this way is the relationship between performance indicators and 'volume' (that is, number of cases seen per year). Such data are also used to establish 'institutional rankings'. Data of this type tend to show considerable overdispersion: in other words, there is far more variation between units than would be expected by chance. To determine whether individual units are performing at a level that requires some intervention, control charts can be used. There are also methods and processes for interpreting the relationships between performance and volume and the need to take into account general between-unit variation when trying to infer causal effects.

Appendix B: Approaches to additional consultation and commissioned primary research

This appendix outlines the processes and minimum reporting standards for additional consultation and commissioned primary research.

Additional consultation

An additional consultation to the routine stakeholder consultation only happens on an exceptional basis.

Additional consultation is a targeted engagement exercise to get feedback, independent from that provided by the committee. It may involve health and social care professionals, people using services and their family or carers, or both. It can be conducted either by NICE or by an externally commissioned organisation.

Deciding if additional consultation is needed

Reasons for additional consultation will vary depending on the topic and may become apparent at different stages of guideline development. Reasons include:

- concerns over draft recommendations, including the impact on health inequalities and equalities more broadly
- draft recommendations based on committee consensus and where there is committee uncertainty
- certain population groups not being represented on the guideline committee and routine consultation being unlikely to get a response from these population groups.

The aim of additional consultation may be to obtain feedback on:

- the relevance and acceptability of the draft recommendations from people affected by the guideline

- the feasibility of implementing the draft recommendations
- whether the draft recommendations reflect current practice, or the way services are currently organised.

Examples of using additional consultation

Examples of when additional consultation has been used include:

- NICE's guideline on jaundice in babies under 28 days: Healthcare professionals working in neonatology and midwives were consulted on the consensus bilirubin thresholds for managing hyperbilirubinaemia in babies of 38 weeks or more gestational age. The additional consultation was conducted before routine stakeholder consultation. The aim was to get topic expert views on the consensus bilirubin thresholds before wider public consultation. For more information see appendix P of the addendum to the full guideline on the NICE website.
- NICE's guideline on social, emotional and mental wellbeing in primary and secondary education: A series of online focus groups were run with children and young people aged 6 to 17 years from a range of diverse backgrounds across England. This aimed to gain insight into their perceptions of social, emotional, and mental wellbeing provision and processes in primary and secondary education. For more information see the focus group report on the NICE website.

The process

The process is:

- decide whether additional consultation is needed
- establish the aim and objectives
- follow the recruitment process for consultees
- establish the consultation method and process
- agree a proposal and timeframe
- report findings.

It is like the process for routine stakeholder consultation. Additional consultation usually

happens before or alongside the routine consultation.

The developer should contact the quality assurance team for an initial discussion as soon as the need for additional consultation is identified. If the work is likely to involve people using services or their family or carers, the developer should discuss their plans with the public involvement lead. If the aim is to test the feasibility of implementing guideline recommendations, it may be useful to involve a member of the field team for advice and support.

Details of the additional consultation must be clearly stated in a proposal document and in the methods document. The proposal needs to be signed off by the quality assurance team.

The information received from the additional consultation and responses to consultees should be published alongside the final guideline. The committee discussion section in the relevant evidence review and the rationale section in the guideline should say how the information affected the recommendations.

The proposal

The proposal should cover:

- the aim and objectives of the additional consultation
- characteristics and number of additional consultees needed
- recruitment methods for consultees, the approach to declaration of interests, and obtaining consent
- ethical considerations, including whether formal ethical approval is needed
- consultation methods
- data analysis or synthesis methods
- confidentiality (if additional consultation happens before the routine stakeholder consultation)
- the timeframe for additional consultation
- how feedback will be used to inform the recommendations

- how to respond to those who provide feedback.

Commissioned primary research

Commissioned primary research usually uses focus groups, interviews or online surveys, and involves health and care professionals, people using services and their family or carers, or both. It may include quantitative analysis of real-world data sources such as audit datasets.

Deciding if commissioned primary research is needed

Reasons for commissioned primary research will vary depending on the topic and may become apparent at different stages of pre-consultation guideline development. Reasons include:

- a lack of evidence to answer specific review questions
- a call for evidence or expert witnesses is not appropriate or is not expected to produce the evidence needed (see the appendix on call for evidence and expert witnesses)
- the committee's consensus is not sufficient for making recommendations

There may be a lack of evidence on:

- a specific topic (or that which is applicable to the UK)
- the views and experiences of people affected by the guideline
- specific populations listed in the guideline scope (for example, children and young people under 18).

The aim could be:

- to fill gaps in the evidence, which may include obtaining data (including real-world data) on:
  - specific interventions
  - specific populations (there is a lack of research on children and young people in

general)

- to obtain the views and experiences of people delivering or using services.

Examples of using commissioned primary research

Examples of how guidelines have used commissioned primary research:

- NICE's guideline on looked-after children and young people: Primary focus group research was commissioned to explore the views and experiences of looked-after children for a set of review questions covering:
  - care and placement stability
  - relationships and contact
  - health and wellbeing
  - learning
  - moving back to birth families or special guardianship
  - preparing care leavers for independent living.
- NICE's guideline on myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome (ME/CFS): Primary focus group research was commissioned to explore the views and experiences of children and young people with ME/CFS for a set of review questions covering:
  - identification and assessment before diagnosis
  - diagnosis of ME/CFS
  - management of ME/CFS
  - monitoring and review
  - information, education, and support for people with suspected or diagnosed ME/CFS and their families and carers.

The process

The process is:

- decide whether commissioned primary research is needed
- establish the aim and objectives
- follow the commissioning and recruitment processes
- establish the research methods and process
- consider whether ethical approval is needed
- agree a proposal and timeframe (including key milestones that align with guideline development timeframes; see box 1 for an example of key milestones)
- report findings.

The research should happen before routine stakeholder consultation and the committee should use the findings as part of the evidence base for developing recommendations.

The developer should contact the quality assurance team for initial discussion as soon as the need for commissioned primary research is identified. If the work is likely to involve people using services or their family or carers, the developer should discuss their plans with the public involvement lead.

Once the aim of the primary research is agreed, the developer should discuss the commissioning process with the quality assurance team.

Details of the commissioned primary research must be clearly stated in a proposal document as well as in the guideline methods document. The proposal should be discussed with the quality assurance team and approved by the centre director.

All outputs (including the final report) should be made available during routine stakeholder consultation. The committee discussion section in the relevant evidence review and the rationale section in the guideline should say how the information affected the recommendations.

Both the proposal and the final report of the additional consultation should be available as appendices on publication of the guideline.

The proposal

The proposal should cover:

- the aim and objectives of the commissioned primary research
- number and characteristics of participants to be recruited
- considerations of consent, confidentiality and data protection
- recruitment strategy
- ethics considerations, including whether formal ethical approval is needed
- sampling method
- data analysis methods
- feedback mechanism for participants
- reporting standards
- anticipated timeframe and costs
- milestones and expected outputs, for example, the final report may summarise themes from participants' views to inform or fine-tune the final recommendations.

The report

The report of the primary research should follow the same structure as the proposal. It should include sections on the aim and objectives, recruiting participants, methods used, analysis of data and all the findings from the primary research.

The developer should conduct a formal critical appraisal of the final report, using appropriate checklists from the appendix on appraisal checklists, evidence tables, GRADE and economic profiles. For example, the CASP checklist will be suitable for commissioned primary research using qualitative methods such as focus groups or 1-to-1 interviews.

Commissioning an external contractor

Primary research is conducted by an external contractor.

The contractor should:

- be an academic or research organisation, or an organisation that works with people affected by the guideline and has research expertise
- be separate from the developer and the committee, unless there are exceptional circumstances (for example, when specific expertise or access to specialist networks can only be provided via a committee member)
- have a good record of research in the proposed field (for example, qualitative or participatory research), and ideally experience in the topic area, as well as expertise in working with people affected by the guideline.

The developer may be asked to help the contractor, for example by generating a list of research participants.

If an external contractor is commissioned, the commissioning process should follow NICE's Standing Financial Instructions. This involves developing a project specification, issuing invitations to tender, and selecting a contractor based on clear and auditable criteria.

Recruiting participants

The recruitment strategy should take into account the aims and objectives of the commissioned primary research, the topic, the groups, the range of views needed, and other relevant issues.

When planning primary research with children and young people, school holidays and exam schedules should be considered.

Equality issues may require getting a representative spread of practitioners or people using services, but may also mean focusing on seldom-heard groups or people with recent experience of working with them.

Different sampling methods may be used to recruit participants. Sampling should be guided by the topic and will depend on the:

- health and care professional groups delivering the service
- make-up or case-mix of the population affected by the guideline (including factors

such as age groups, geographical issues, and access), to ensure appropriate representation of all people affected

- scope of the guideline
- review questions
- inclusion criteria for the research.

'Snowballing' (gathering participants via other participants or networks) and purposive or other non-random techniques may be used to ensure all relevant groups are represented.

Random sampling (randomly selecting participants from the relevant groups) or quota sampling (selecting a fixed number of participants, randomly or purposively from these groups) may be useful for large-scale surveys or if there are many potential participants but not enough of them in each relevant geographical area.

The proposal should explicitly state the groups of participants to be recruited, the recruitment strategy, including sampling method, the number of participants to be recruited, considerations of consent, confidentiality and data protection. The developer or external contractor should ensure the sampling frame and sample take account of equality issues.

Establishing methods and processes

The research method should take into account the topic, the groups involved and other issues.

The NICE real-world evidence framework provides advice on situations where primary quantitative analysis of real-world data may be appropriate and outlines best practices for identifying and assessing data sources and doing the analysis.

When involving people affected by the guideline, the methods and materials used should be tailored to the age, ability and culture of participants.

Commissioned primary research may use group-based methods, 1-to-1 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.

Group-based methods

Group-based methods include focus groups, participative workshops and 'virtual' (electronic) groups. These may be appropriate when:

- potential participants have clear 'professional identities' and the 'field' is well established
- it is possible to contact enough people in a geographical area to set up a focus group or workshop
- the issues discussed are unlikely to be confidential or sensitive and anonymity will not be necessary.

The following may be considered:

- More than 1 participative workshop or focus group or virtual meeting; these should take place in more than 1 geographical area and will normally be a half day but may take up to a day. If it is not feasible to organise this many workshops or groups, the decision on how many should be convened must be agreed with NICE.
- If it suits the needs of the project, separate participative workshop or focus group or virtual meetings can be arranged for different practitioner or user groups. This will depend on the number of participants and should be agreed with NICE.
- For some topic areas, academic researchers may be included in the commissioned primary research. In such cases, a separate meeting should be convened for them, using the same processes. This should be agreed with NICE.
- Topic guides, prompts or supporting materials must be developed in collaboration with the guideline committee, and agreed by NICE.

1-to-1 or paired in-depth interviews

Interviews may be carried out face-to-face, by telephone or online. They may be appropriate when:

- it is not possible to get groups together because the topic is a relatively new area, the number of possible participants is limited or there are geographical or time constraints
- participants may have mobility difficulties or be unable to travel

- the issues discussed are likely to be confidential or sensitive and anonymity may be needed
- in-depth responses are needed.

Interviews may be structured or semi-structured, depending on the topic and the groups involved. Semi-structured interviews allow complex or difficult issues to be explored and so are likely to be more useful than structured interviews. All interviews should focus on areas in which views and experiences are needed, or on draft recommendations.

Individual or paired interviews are usually more expensive to set up than group work, and the need for in-depth or individual contact should be weighed against the available resources at the planning stage.

Surveys

Group-based methods and interviews are the best way to find out opinions. But they may not be suitable in all circumstances, for example, because of the sensitivity of the topic, confidentiality issues, or difficulties in recruiting participants. In such cases, surveys that use semi-structured and open-ended questions could be more appropriate. Surveys may be carried out by telephone, online, on paper or by using vote casting or polling.

Surveys gather opinions in a quick and less obtrusive manner than group-based approaches and interviews. The responses can also be quantified. But surveys do not allow the same depth of exploration and, generally, should only be used if other methods are unsuitable. Formal consensus methods such as Delphi survey and RAND appropriateness could be modified for the survey if appropriate.

Analysis of data

There are different ways of analysing data from commissioned primary research, depending on the methods used for data collection and whether it is qualitative or quantitative. Some descriptive summary statistics should be provided, for example, characteristics of participants and attendance or response rates.

Quantitative analysis should include a clear statistical data analysis plan, including a priori plans for sub-group analysis or co-variate adjustments.

Group-based methods and interviews are likely to generate qualitative data. Analysis may

be performed using qualitative research software, or by hand, but the method should be fully reported in the proposal and the final report.

Qualitative data can be broken down into common and consistent themes for each of the questions asked, using, for example, a content analysis approach. Usually, 1 researcher should prepare an initial analysis, which should be verified by 'blind' coding and sorting of a sample of the transcript by a second researcher. For examples of this kind of analysis, see part 3 (chapters 7 to 13) of Silverman (2004) or Ritchie and Spencer (1993).

Once the analysis is complete, participants' quotes may be selected to illustrate each theme. These quotes should be coded to keep participants anonymous and to allow the quotes to be distinguished. When transcripts are processed, ensure confidentiality and data protection are fully considered. As with data from clinical trials, transcripts should be kept for at least 5 years (see the National Institute for Health and Care Research's clinical toolkit).

Surveys are likely to involve a mixture of quantitative and qualitative data. Quantitative data may be analysed and presented using summary statistics or may involve more advanced approaches such as regression analysis and multi-variable adjustments (which need agreeing a priori). When formal consensus methods such as Delphi survey and RAND appropriateness have been modified for the survey, specific analytical methods, for example, thresholds for agreement, should be stated in the proposal and the final report.

The developer or external contractor should ensure the methods for analysing the data and reporting standards are discussed and agreed with NICE.

Feedback mechanism

The developer or external contractor should agree with NICE a process for giving feedback to all participants. Providing feedback to participants should be specified in contracts. This should include an evaluation exercise, a follow-up session or sharing interim findings via email.

Agreeing the proposal

The proposal for the commissioned primary research should include information on the:

- aim and objectives

- recruiting participants
- methods used
- ethics considerations, including whether formal ethical approval is needed
- timeframe of the primary research
- data analysis
- feedback mechanism.

The proposal and the final report of the commissioned primary research should be included as part of the guideline or guideline appendices.

The developer and the external contractor should agree with NICE the approaches and methods to use, including a summary of the issues to be covered. Similarly, the methodology and any questions or support materials used must be developed and agreed with NICE. For example, NICE should:

- be briefed by the developer and external contractor in detail before work begins
- agree final documents (including the proposal) and comment on draft recruitment letters
- agree on topic areas and research questions
- agree sampling frames and samples, and other supporting materials
- agree approaches on how to get participants from key groups involved, including people who work with or are from seldom heard groups or those who share characteristics protected under equality legislation
- have access to transcripts of all data
- discuss and agree techniques for data analysis and themes for data presentation
- comment on the commissioned primary research report before the final draft is submitted.

Obtaining ethical approval

Most primary research commissioned for NICE guidelines falls under the category of 'service evaluation' and so is outside the remit of NHS research ethics committees. However, the quality assurance team, the developer and the external contractor should consider ethical issues each time commissioned primary research is planned, to ensure appropriate expertise, and that policies and procedures for the safety and welfare of participants are in place. If there is any doubt, the developer or external contractor should consult the national Research Ethics Service. The developer or external contractor is responsible for seeking ethical approval, if it is needed.

For topics covering children and young people, NICE's patient and public involvement policy includes a set of principles for involving them and has an appendix about safeguarding. The national Research Ethics Service should also be consulted for topics covering children and young people and other vulnerable groups such as adults with learning disabilities or frail older people.

Box 1: examples of key milestones

Milestones	Timeline/ Date
Start-up meeting with contractor Recruitment of research participants Data collection period Contractor submits draft report to developer, who shares with committee Developer and committee provide comments on draft report, including a formal quality assessment of report by developer. Contractor submits revised report to developer, who shares with committee Contractor submits slides for presentation to committee (if necessary), who shares with committee Presentation of report at committee meeting Contractor submits final report after committee meeting	

Appendix C: Key roles and responsibilities of committee members

The committee chair

The committee chair is required to attend a specific induction session (see the section of the manual on induction for committee members) ideally before guideline committee meeting number 1.

The chair needs an understanding of NICE's guideline development process, and may have some background knowledge about the guideline topic but should not have any direct interests (in accordance with the NICE declarations of interest policy) that relate to the areas within the scope of the guideline. The chair signs off the equality impact assessment at scoping and final guideline stages. The chair ensures that the committee takes full account of the evidence in developing recommendations and considers the analysis and interpretation of the evidence prepared by the developer. Shortlisting and interviews of committee members will be undertaken by the committee chair or vice-chair.

To facilitate the effective working of the committee, the chair:

- may be involved in developing the scope and setting boundaries for the work
- helps to plan the committee meetings
- runs the committee according to the principles set out in the Terms of Reference and Standing Orders
- establishes a climate of trust and mutual respect among members
- provides opportunities for all members, including members with additional needs, to contribute to the discussions and activities of the committee.

The chair also gives committee members if requested feedback and comment, on an annual basis, on their contribution for personal development. The chair is given feedback and comment on their own contribution on an annual basis from a senior member of NICE staff if requested. The developer may also provide feedback on an ongoing basis or as required.

All committee members

Committee members are expected to:

- Review and abide by the Terms of Reference and Standing Orders for guideline committees.
- Contribute constructively to meetings and have good communication and team-working skills; this should include a commitment to considering the needs of people using services, family members and carers.
- Use their background knowledge and experience of the guideline topic to advise the developer on carrying out systematic reviews and economic analyses.
- Read all relevant documentation and make constructive comments and proposals at (and between) committee meetings.
- Work with the developer and other members of the committee to develop, prepare and write the rationales for the recommendations.
- Work with the developer and other members of the committee to write up the committee's discussion of the evidence.
- Work with other members of the committee to develop recommendations based on the evidence or on consensus if evidence is poor or lacking.
- Help ensure that the guideline as a whole, and particularly the recommendations, is worded sensitively (for example, that people using services or population groups are treated as people, not as objects of assessments or interventions).
- Advise the developer on how to identify best practice in areas for which research evidence is absent, weak or equivocal.
- Consider, with other members of the committee, the feasibility of the recommendations and highlight any potential implementation issues to NICE. This may provide contextual information or inform resource impact assessment and potentially other implementation activity, including the identification of examples from practice or external support resources to assist people using the guideline (see the chapter of the manual on resources to support putting the guideline into practice).
- Agree, with other members of the committee, the minutes of committee meetings.

Committee members are not routinely expected to:

- carry out review of the evidence
- search the literature
- write up the evidence.

Additional roles for lay members of committees

Lay members of the committee have the same roles and responsibilities as other committee members, but they are also often able to offer specific expertise to:

- help ensure that review questions include issues that are important to people using services, their family members and carers, or the community affected by the guideline
- raise awareness of grey literature (for example, surveys of people using services) that highlights issues that may be relevant to the work of the committee
- indicate the extent to which published evidence has measured and taken into account outcomes that are considered important by people using services, their family members and carers, or the community affected by the guideline
- highlight areas where the guideline may need to acknowledge the choice and preferences of people using services, their family members and carers, or the community affected by the guideline
- help ensure that recommendations address issues and concerns of people using services, their family members and carers, and the public (where relevant)
- advise on the practicality of implementing the guideline (for example, medicines adherence)
- advise on the key messages contained in the information for the public section of the topic webpage.

Appendix D: Guideline committee Terms of Reference and Standing Orders

Terms of reference

General

1. The committee will operate as an advisory committee to NICE's Board.

2. The committee will advise NICE on:

- any development of review questions from key issues in the scope
- how to identify best practice in areas where research evidence is absent, weak or equivocal
- the effectiveness, and cost effectiveness of interventions, actions and measures to improve the health and social care of the public
- opportunities and challenges that may be faced in implementing the recommendations that might require additional resources or implementation efforts at a local level.

3. The committee will throughout guideline development:

- develop a guideline for the relevant audiences in accordance with the agreed process and methods manual
- submit its recommendations to NICE's guidance executive, which will have powers delegated by the Board to consider and approve the recommendations
- be accountable to the NICE director (or delegated senior member of the NICE team) responsible for the guideline
- be collectively responsible for its recommendations
- acknowledge that the intellectual property of content arising from the guideline development process belongs to NICE

- follow NICE's equality policy and take account of socioeconomic factors and their influence on health and ill health
- adhere to NICE's key principles that are universal to all guidance and standards.

4. Individual committee members will:

- declare all relevant interests, sign a declaration of interest form and inform NICE of any additions or changes to declared interests throughout the development process, in accordance with the declaration of interests policy for NICE advisory committees
- sign a confidentiality agreement with NICE relating to any information designated confidential by NICE, such as draft recommendations, committee discussions, academic or commercial-in-confidence material or sensitive personal data.

Membership

5. Committee members will be appointed by the developer, and committee membership will reflect both the spread of interests and expertise required for the business of the committee and NICE's values of equality and diversity.

6. The chair and members of the committee will be appointed in accordance with NICE's appointments to advisory bodies policy and procedure.

7. Committee members will be drawn from the NHS, local government, the academic community and other areas, as appropriate, as agreed by the developer and NICE staff with responsibility for guideline quality assurance. They will include practitioners, commissioners and providers, people using services, their family members and carers, and advocates.

8. The committee will have a minimum of 7 voting members with additional members agreed on a topic-by-topic basis according to need. Each committee will have a chair. Topic-specific committees may have a topic adviser, and will include professional and practitioner members, and at least 2 lay members. Standing committees will have core members and topic expert members. All committee members are selected for their expertise and not as representatives of their organisations.

9. Co-opted members may be included as additional members of a committee for 1 or more specific meetings. Co-opted members are part of the committee, join in discussion

and contribute to formulating the recommendations. However, they are not full members, do not have voting rights and do not count towards the quorum.

10. Expert witnesses may be invited to attend and advise the committee on specific topics and can be drawn from a wide range of areas as appropriate. They are invited to present evidence (either as appraisable data, or as expert testimony). For more information see the appendix on call for evidence and expert witnesses. They also help the committee to consider and interpret the evidence, but they are not members of the committee so they should not be involved in the final decisions or influence the wording of the recommendations. Expert witnesses have no voting rights and do not count towards the quorum.

Standing orders

General

11. These Standing Orders describe the procedural rules for managing the work of the committee as agreed by NICE. The committee will act as an advisory body to NICE. Nothing in these Standing Orders shall limit compliance with NICE's Standing Orders so far as they are applicable to these Bodies.

12. The appointment of advisory committees is at the discretion of the Board subject to any direction as may be given by the Secretary of State.

13. Members of the committee shall be bound by these Standing Orders and will be expected to abide by the 7 principles for the conduct of public life as recommended by the Nolan Committee, which are:

- selflessness
- integrity
- objectivity
- accountability
- openness
- honesty

- leadership.

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

15. Behaviour by committee members and attendees at committee meetings such as bullying, harassment and victimisation is unacceptable to NICE. NICE is committed to taking the necessary action to ensure that such behaviour does not occur, and to taking the appropriate action in the event that it does occur.

16. For **topic-specific committees**, the chair and members of the committee will either be appointed for the duration of the development of the guideline or for up to 3 years to work on multiple guidelines within a topic area. This may be extended by mutual agreement to a further term of up to 3 years and up to a maximum term of office of 10 years.

17. For **standing committees**, the chair and core members will be appointed for an initial period of up to 3 years. This may be extended by mutual agreement to a further term of up to 3 years and up to a maximum term of office of 10 years.

18. For standing committees, when a committee member is appointed chair of the committee of which they are a member, the new position will count against the 10-year total.

19. For standing committees, the topic expert members are usually recruited for a specific guideline, but may be appointed for up to 3 years so that they can work on subsequent guidelines. They are recruited in accordance with NICE's appointments to advisory bodies policy and procedure.

20. The removal or substitution of committee members and the general constitution of an advisory committee shall be at the discretion of NICE.

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

Interpretation

22. During the course of a committee meeting, the chair of the committee can suspend the meeting to seek advice from senior members of NICE with responsibility for guideline

quality assurance on the final interpretation of the Standing Orders.

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

Chairs and vice-chairs

24. Meetings will be conducted by the chair or in their absence, an officially appointed vice-chair or a nominated deputy.

25. The vice-chair will be appointed in accordance with NICE's appointments to advisory bodies policy and procedure.

26. The vice-chair's appointment will be for the duration of guideline development for topic-specific committees, or for a 3-year term for standing committees with an option to re-appoint.

27. In standing committees, if a committee member has been appointed to vice–chair from within the committee, the new term will count against the 10-year total. For example, if a member serves one 3-year term and is then appointed to vice-chair for another 3-year term, this will be regarded as having served 6 years as a member of the committee.

28. The chair, or the vice-chair or deputy nominated by the chair in the chair's absence, may take action on behalf of the committee outside of scheduled committee meetings when urgent decisions are required and it is impracticable to convene a special meeting of the committee.

29. In committee meetings, the chair:

- ensures that committee members declare any new conflicts of interest that have arisen since their last declaration and handles any conflicts as they arise, in line with the declaration of interests policy for NICE advisory committees
- steers the discussions according to the agenda
- keeps the group discussion unified and discourages disruption or dominance by any members

- encourages constructive debate, without forcing agreement
- prevents repetitive debate
- summarises the main points and key decisions from the debate
- signs off meeting minutes once approved by the committee.

30. The chair must ensure that NICE's equality policy and key principles that are universal to all guidance and standards are adhered to. The chair approves the equality impact assessment at scoping and final guideline stages.

31. The chair approves the draft guideline before sign-off by NICE, and advises the developer on responses to stakeholder comments as appropriate.

Voting

32. The decisions of the committee will normally be arrived at by a consensus of committee members present. Voting will only be used for decision-making in exceptional circumstances. Before a decision to move to a vote is made, the chair will, in all cases, consider whether continuing the discussion at a subsequent meeting is likely to lead to consensus.

33. Voting will be anonymous and decisions determined by a simple majority of non-conflicted committee members present at a quorate meeting.

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

35. Only committee members present at the meeting will be eligible to vote. There will be no proxy voting.

36. Co-opted members, expert witnesses, developer staff, NICE staff and observers will not be eligible to vote.

Quorum

37. The quorum is set at 50% of the full membership of the committee, in accordance with paragraph 3 in the membership section of these terms of reference, and includes both

core and topic expert members and the chair (but excludes co-opted members, expert witnesses, developer staff, NICE staff and observers). The quorum should be rounded up to the next whole number when there is an odd number of committee members.

38. No recommendations should be confirmed unless the meeting is quorate. This provision also applies if a member is excluded because of a conflict of interest and as a result membership falls below the quorum. At the discretion of the chair on advice from a senior member of NICE staff, a meeting may proceed if it is not quorate on the basis that any recommendations formulated or decisions made are considered draft and are shared with the full committee for comment and approval.

39. The balance of the committee are such that even if the meeting is quorate, an appropriate spread of members' interests should be represented at each meeting. It is also important that for standing committees the mix of core and topic expert members is appropriate, and topic expert members are not in a majority. If, in the view of the chair, the spread of interests is insufficient for the business under consideration, the meeting or part of the meeting may be suspended or adjourned until a later date.

Collective responsibility

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

41. Members of the committee are not permitted to submit comments as stakeholders during the consultation on the draft guideline (see the chapter on the validation process for draft guidelines, and dealing with stakeholder comments in the manual). If a committee member is involved with a registered stakeholder organisation, they should not submit comments during the consultation on behalf of that organisation – someone else in the organisation should draft and submit the comments.

Confidentiality

42. On appointment, committee members (including co-opted members) will be required to sign a confidentiality agreement with NICE relating to any information designated confidential by NICE such as draft recommendations, committee discussions, academic or commercial-in-confidence material or sensitive personal data.

43. Confidential papers and confidential information disclosed in committee deliberations

should not be discussed with colleagues who are not members of the committee, with other organisations, the media, or members of the committee who are excluded from discussions because of a conflict of interest.

44. If committee members are asked by external parties – including stakeholders or their professional organisation – to provide information about the work of the committee, they should discuss the request with the developer. They should also declare this at the next committee meeting. Any enquiries from the media should be directed immediately to NICE's enquiry handling team (nice@nice.org.uk) and the developer.

45. Co-opted members, expert witnesses and observers invited by the committee will sign a confidentiality form if confidential information is included in meeting papers, or if attending part of a meeting where confidential information is being discussed.

Arrangements for meetings

46. NICE will ensure that face-to-face committee meetings take place in venues that are accessible to, and have facilities for, disabled people.

47. Meetings of the Committee shall be held at such times and places as are deemed necessary to facilitate the conduct of its business.

48. Committee members may also be required to attend a working group that may be associated with the committee and will be expected to contribute to virtual discussions and occasional teleconferences as appropriate.

49. Developers shall determine which aspects shall appear on every agenda in advance of each meeting.

50. Any other business shall be discussed at the discretion of the chair.

51. Meetings will normally begin at 10:00 am and finish no later than 5:00 pm unless otherwise advised.

52. Committee members will be expected to attend for the full day unless agreed in advance with the chair or unless they have declared a conflict of interest to 1 or more discussions.

53. Laptops and other devices are to be used in a committee meeting by members solely to conduct the business of the meeting.

54. The developer will make all reasonable attempts to agree each meeting date well in advance and committee members are expected to keep proposed dates free until they are confirmed.

Access by members of the public

55. When committee meetings are open to the public, the following provisions will apply.

56. Public access will be enabled to meetings of standing committees; topic-specific committees will be held in private.

57. If considered necessary because of the confidential nature of the business to be transacted, the agenda for meetings held in public will be divided into 2 parts. Part 1 will be open to the public and part 2 will be closed to the public to enable the committee to discuss confidential information whereupon Standing Orders 61 and 65 will apply.

58. Only members of the committee and NICE staff, co-opted members, observers invited by NICE, and the developer will be present for part 2 of the meeting. However, at the discretion of the chair, experts such as practitioners, people using services, their family members or carers, and manufacturers may be invited to remain in order to discuss confidential or personal medical information that was not discussed in part 1. Once the information concerned has been discussed, the experts will leave the meeting and will take no further part in its deliberations.

59. Usually 20 working days before each committee meeting held in public, a public notice of the time and place of the meeting, along with the public part of the agenda, shall be displayed on NICE's website. The final agenda will be displayed on the NICE website usually 5 working days before the meeting.

60. The public and representatives of the press shall be allowed access to observe all formal meetings of the committee for part 1 of the agenda but shall not be entitled to ask questions or otherwise engage in the business of the committee.

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

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

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

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

Other observers

63. NICE staff and invited guests (for example, visiting academics) may attend committee meetings as observers, with the permission of the chair.

64. Observers do not need to register via NICE's website. Observers should not sit with members of the public and should not enter into committee discussions unless invited to do so by the chair.

65. Observers can attend part 2 of meetings held in public if the chair and centre director agree. Observers who are not NICE or developer staff or are not commissioned to provide a service to NICE should sign a confidentiality agreement if they wish to attend a topic-specific committee meeting or part 2 of a meeting held in public.

Minutes

66. The draft minutes of the committee meetings shall be drawn up and submitted to the next meeting for approval by the committee. The minutes of the final committee meeting will be circulated and approved by email.

67. The approved minutes will be published on NICE's website subject to the redaction of any confidential or otherwise exempt material within 20 working days of approval.

Declarations of interest

68. Anybody applying to be a member of a NICE advisory committee must declare any interests as part of the application process, in line with the declaration of interests policy for NICE advisory committees.

69. All standing committee members must make an annual declaration of interests in line with the declaration of interests policy for NICE advisory committees.

70. All committee members must declare in writing before – and orally at the start of – each committee meeting any interests that are relevant, or could be perceived to be relevant, to the work of the committee. Declarations of interest will be recorded in the minutes and published on the NICE website.

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

72. Experts invited to provide expert testimony, and co-opted members will make a declaration of interest before committee meetings and in accordance with declaration of interests policy for NICE advisory committees. This declaration will be reaffirmed again at the start of each meeting. These will be recorded in the minutes and published on the NICE website.

73. Co-opted members will not be able to take part in a meeting if they have a conflict of interests. Expert witnesses may still be asked to give their evidence if they have a conflict of interest, but this will be at the discretion of the developer and NICE staff with a responsibility for quality assurance.

Suspension of Standing Orders

74. Except where this would contravene any statutory provision, any 1 or more of the Standing Orders may be suspended at any meeting. This should be agreed with the developer and NICE staff with responsibility for quality assurance, and a simple majority of those present and eligible to participate should vote in favour of the suspension.

75. Any decision to suspend Standing Orders shall be recorded in the minutes of the meeting.

76. No formal business may be transacted while Standing Orders are suspended.

77. NICE's Audit Committee shall review all decisions to suspend Standing Orders.

Petitions

78. Petitions from the public will not be received directly by or responded to by the committee. Anyone wishing to present a petition will be directed to NICE staff with responsibility for guideline quality assurance.

Recording of meetings

79. The recording of proceedings or the taking of pictures at committee meetings by public attendees is not allowed.

80. The recording of meetings is permitted by the developer where agreed by the committee, and for the purposes of facilitating guideline development or promoting transparency. Recordings will be deleted on approval of the meeting minutes.

Record of attendance

81. A record will be kept of committee members' attendance at committee meetings via the minutes.

82. Members of standing committees are expected:

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

83. Members of topic-specific committees are expected:

- to attend all of their committee's meetings.

84. If committee members are unable to attend a committee meeting, deputies are not permitted.

85. Members who are unable to meet either of these expectations may be asked to stand down from the committee in accordance with Standing Order 20.

86. If a committee member is unable to fulfil their duties (for example, because of illness), another recruitment process may be considered to replace that person.

Terms of Reference

87. Committee members must comply with the Terms of Reference that set out the scope of the committee's work and its authority.

Review of Terms of Reference and Standing Orders

88. These Terms of Reference and Standing Orders will be reviewed every 3 years.

Appendix E: Code of conduct for committee members

This code sets out the responsibilities of NICE and the committee, and the principles of transparency and confidentiality. The following principles should be read alongside the Terms of Reference and Standing Orders.

Key principles of guideline development

NICE's guideline development process:

- uses the best available evidence and robust and transparent methods to develop recommendations that are clearly written
- involves people affected by the guideline (including stakeholder organisations that represent the interests of people using services, their family members and carers, and the community, bodies that represent professionals and practitioners working in health and social care, local authorities, providers and commissioners of care and services, commercial industries and research bodies)
- advances equality based on NICE's key principles that are universal to all guidance and standards
- considers the feasibility of implementing the recommendations.

Each committee should ensure that its guideline is developed in line with these requirements. It should also ensure that the guideline cross-refers to or incorporates any relevant recommendations from NICE's other guidance programmes (for example, technology appraisal or interventional procedure guidance) as set out in the guideline scope (see the chapter of the manual on linking to other guidance). It should also consider recommendations from relevant national policy. The committee should also follow NICE's key principles that are universal to all guidance and standards and adhere to NICE's equality policy.

Status of committee members

Committee members are appointed to a committee by virtue of their relevant experience or because they have specific technical skills or knowledge. If members are from stakeholder organisations, NICE and the committee assume that these members bring this perspective to the group, but are not representing their organisations. For topic-specific committees, chairs and members are appointed for the period of development of a guideline or for up to 3 years to work on multiple guidelines within a topic area, with membership subject to renewal for a maximum total period of up to 10 years. Standing committee chairs and core members are appointed for a 3-year period, with membership subject to renewal for a period of up to 10 years. Topic expert members of standing committees are appointed for the period of development of a guideline.

Committee members are co-authors of the guideline although the intellectual property of content arising from the guideline development process belongs to NICE. As such, they should respect the rights of NICE both to publish the final guideline and associated products (for example, products to support implementation) and they should notify NICE of any proposed publications related to their work on the guideline.

Responsibilities of NICE and committee members

NICE undertakes to ensure that:

- the committee is properly resourced to produce the guideline
- all members of the committee are provided with appropriate access to available resources
- the support needs of all members of the committee are met to enable them to contribute fully to the work of the committee
- appropriate training is offered to committee members to enable them to play a full part in the development of the guideline
- committee members are provided with annual feedback and comment on their contribution when requested for revalidation or personal development
- technical support is provided during the development of the guideline.

Committee members undertake to:

- set aside enough time to attend committee meetings and properly inform the development of the guideline through their personal and professional knowledge
- raise any concerns about process or details in the draft guideline with the committee, and try to resolve these issues within the committee, with support from the developer
- contribute positively to the work of the committee and the development of the guideline
- take full account of the evidence in developing recommendations
- consider the analysis and interpretation of evidence prepared by the evidence review team
- act in a professional manner, show good manners and be courteous to colleagues and staff at all times (committee members should behave in a polite, efficient and respectful manner and without bias or favour, using the highest standards of conduct expected in public life and service while on NICE duty)
- be impartial and honest in the conduct of their official business, use public funds entrusted to them to the best advantage of NICE and do nothing that is deliberately intended to damage the confidence of the public or stakeholders in NICE
- ensure that there is rigorous adherence to NICE's key principles that are universal to all guidance and standards and the NICE equality policy
- read and adhere to NICE's policies on hospitality, declarations of interest and travel and subsistence.

Transparency

NICE believes that its guidelines will be more meaningful if those who are intended to benefit from them and those who have the responsibility for implementing them have had the opportunity to be involved in their development.

The guideline development process is designed to be transparent. However, information and discussions may be restricted when material has been provided under agreement of commercial or academic confidentiality. There is therefore a need for arrangements that protect the confidentiality of documents and discussions. In order to protect confidentiality, NICE expects committee members:

- to regard the discussions held in any closed committee sessions as confidential
- not to discuss confidential papers and confidential information disclosed in committee discussions with colleagues who are not members of the committee, colleagues within their own organisation, other organisations, the media, or members of the committee who are excluded from discussions because of a conflict of interest
- to respect the confidentiality of documents supporting published or in development NICE guidance, including guidance from other NICE programmes, if such documents are received by the committee.

Bullying, harassment and victimisation are unacceptable. NICE is committed to taking the necessary action to ensure that they do not occur, or if they do occur that they are dealt with appropriately.

Appendix F: Suggested sources for scoping

Suggested sources for scoping

Type of information	Source
NICE guidance and products	• NICE website – published and in development
Other guidance and standards	• Evidence search (NICE Evidence Services) • Trip database — Clinical knowledge summaries • Websites of national organisations, including devolved nations (for example, NHS England, Public Health England, Social Care Institute for Excellence [SCIE], Public Health Wales, NHS Scotland, Public Health Agency -NI) • Royal college/professional body websites • Charity, and other community and voluntary sector websites (including equality organisations, for example, Race Equality Foundation's Better Health briefings) • Patient and service user organisation websites (NICE's Public Involvement Programme [PIP] can advise further)

Type of information	Source
Guidelines, reviews and economic evaluations	• Cochrane Database of Systematic Reviews (CDSR) • Epistemonikos • Scottish Intercollegiate Guideline Network (SIGN) • The Campbell Collaboration • Health Technology Assessment (HTA) database – last updated October 2016 • Health Technology Wales • International HTA Database • Guidelines International Network • Health Evidence • National Institute for Health Research's Health Technology Assessment Programme • Prospero • Database of promoting health effectiveness reviews (DoPHER) • ECRI Guidelines Trust • NHS Economic Evaluation Database (NHS EED) – last updated Dec 2014 • Bibliographic databases (where required)

Type of information	Source
Policy and legislation	• Government and other policy websites, including devolved nations (for example, legislation.gov.uk, Department of Health, Scottish Government, Welsh Government) • Regulatory authority websites (for example, General Dental Council, General Medical Council)

Type of information	Source
Datasets, audits, surveys, registries	• Adult Social Care Survey • Adult Inpatient Survey • Care Quality Commission • Clinical Practice Research Datalink (CPRD) • Community mental health survey • Data.gov • English Longitudinal Study of Ageing (ELSA) • GP Patient Survey • Health Data Research UK (HDRUK) Gateway • Healthcare Quality Improvement Partnership (HQIP) directory • Health Survey for England • Hospital Episode Statistics (HES) • Medicines and Healthcare products Regulatory Agency (MHRA) • National Audit Office • National Cancer Data Repository (NCDR) • National Cancer Patient Experience Survey • Adult Social Care Workforce Data Set (ASC-WDS) • NHS Digital Data Collections • NHS Improvement • Nuffield Trust

Type of information	Source
	• PHE Public Health Profiles • Prescribing Observatory for Mental Health (POMH) • Primary Care Mortality Database • QResearch • Regulation and Quality Improvement Authority • The Health Improvement Network (THIN) database • Bibliographic databases (where required)
Information on the experiences of patients, service users and carers, or the target population	• Websites/databases of people's experiences of health and social care (for example, Healthtalk.org, Youthhealthtalk.org, Patient Voices Healthwatch, The Patient Experience Library, National Voices) • Patient and service user organisation websites (NICE's PIP can advise further) • Bibliographic databases (where required)

Statistics	• Faculty of Public Health
	• NHS Digital
	  – A–Z NHS Digital Official and National Statistics Publications
	• UK Data Service
	• Office for National Statistics
	  – Disease-specific statistics, for example, CancerStats

Appendix G: Sources for evidence reviews

The selection of sources to search for evidence reviews should be determined by the subject of the review question and the type of evidence sought (see the chapter of the manual on identifying the evidence: literature searching and evidence submission).

The following list is not exhaustive and other sources may be appropriate. To aid the selection of sources, the databases have been listed according to the primary focus of the subject coverage, but note many databases cover more than one subject.

Evidence reviews primarily make use of published studies and reports, but there may be occasions when sources of data at the individual patient level may be of benefit (for example, to verify the typical characteristics of a population of patients in England). Some tools for identifying sources of individual patient data are also listed.

The sources listed in the appendix on sources for scoping should also be considered for evidence review searches.

Databases

Biomedical

- British Nursing Index (BNI)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- Cochrane Database of Systematic Reviews (CDSR)
- Cumulated Index to Nursing and Allied Health Literature (CINAHL)
- Embase
- EMCare
- Epistemonikos
- Health Technology Assessment (HTA) – last updated October 2016

- International HTA Database
- MEDLINE/MEDLINE in Process

Economics

- EconLit
- NHS Economic Evaluation Database (NHS EED) – last updated December 2014
- Paediatric Economic Database Evaluation (PEDE)
- Health Technology Assessment (HTA) database
- ScHARR Health Utilities Database (HUD)
- Websites of HTA agencies
- RePEc (Research Papers in Economics)

Education

- British Education Index (BEI)
- Educational Resources Information Center (ERIC)

Management

- Health Business Elite
- Health Management Information Consortium (HMIC)

Psychology

- PsycINFO

Sociology and social care

- Applied Social Science Index and Abstracts (ASSIA)

- CareKnowledge
- Social Care Online
- Social Policy and Practice
- Social Science Citation Index
- Social Services Abstracts
- Social Welfare Portal (British Library)
- Sociological Abstracts

Other

- Allied and Complementary Medicine (AMED)
- Campbell Collaboration
- Database of Promoting Health Effectiveness Reviews (DoPHER)
- Physiotherapy Evidence Database (PEDro)
- SportDiscus
- Transport
- Trials Register of Promoting Health Interventions (TRoPHI)
- Greenfile

Websites

- Websites of national organisations, for example, Care Quality Commission, Department of Health, NHS England, Public Health England, MHRA
- Websites of professional bodies and other organisations relevant to the topic
- Websites of research institutes and consultancies relevant to the topic
- NICE Evidence search

- Trip
- Kings Fund
- Grey Matters (CADTH)
- European Medicines Agency
- US Food & Drug Administration
- Healthtalk.org
- Youthhealthtalk.org
- The Patient Experience Library
- National Voices
- Ipsos MORI
- Joseph Rowntree Foundation
- School for Social Care Research
- Traverse (previously known as OPM)
- Personal Social Services Research Unit (PSSRU)
- Picker Institute
- Social Policy Research Institute
- Websites of other organisations for people using services, including the target population, family members and carers

Conference abstracts

- Embase
- British Library Inside Conferences (BLIC)
- Google Scholar
- Conference websites relevant to the topic

Ongoing trials

- ClinicalTrials.gov
- EudraCT
- ISRCTN Registry
- WHO ICTRP

Institutional and thesis repositories

- CORE
- OpenDOAR (The Directory of Open Access Repositories)
- EThOS (British Library)
- Open Access Theses and Dissertations (OATD)

Patient-level data sources

- Health Data Research UK (HDRUK) Gateway
- Health Quality Improvement Partnership (HQIP) directory
- NHS Digital Data Collections
- Data.gov
- Office for National Statistics (ONS)
- PHE Public Health Profiles
- UK Data Service

Appendix H: Appraisal checklists, evidence tables, GRADE and economic profiles

Appendix H is contained in a separate PDF.

Appendix I: Review protocol for [add key area, for example, unplanned hospital admission / Flu vaccination]

Appendix I is contained in a separate PDF.

Appendix J: Call for evidence and expert witnesses

There are 2 approaches to seek evidence from stakeholders:

- A call for evidence: the developer asks registered stakeholders (and other organisations or individuals as needed) to submit evidence in response to a specific question. This can be useful when there may be relevant evidence that was not identified by the searches (see the section on examples of relevant evidence not routinely identified by searches).
- Expert witnesses: the developer asks experts to provide evidence based on their experience and specific expertise, or to help the committee interpret the evidence. They may attend committee meetings to provide their testimony and answer questions from committee members.

Both approaches are designed to provide committees with additional relevant information for decision making. These approaches may be appropriate when:

- there is ongoing research because a condition, intervention or service is relatively new
- studies have been published only as abstracts
- there are unpublished data on the off-label use of medicines or on harms
- there are unpublished economic models
- there are unpublished records (at a national or local level) of the experiences of people using services, their family members or carers, or practitioners working in services.

This appendix only covers approaches that provide additional evidence or expertise. See the chapter on decision-making committees for information on how we ensure that committees have the knowledge and experience to interpret the evidence (for example, by inviting co-opted members to the committee).

Documenting the chosen approach

Evidence can be sought to address a review question, or to support guideline

development without directly addressing a review question.

The following criteria should be met and documented before deciding whether to use a call for evidence or expert witnesses:

- The results of all relevant formal searches for evidence should have been assessed and a gap in the evidence identified (unless it has been agreed upfront that formal searches are unlikely to find evidence and therefore have not been conducted).
- If additional evidence will be sought to address a review question, the committee should consider whether there is enough evidence to make recommendations, and agree that the following are not appropriate options:
  - making recommendations based on either informal or formal consensus
  - only making recommendations for research
  - making no recommendations.
- The committee has a reasonable expectation that they will be able to make recommendations based on evidence from stakeholders or experts.
- Seeking evidence from stakeholders or experts will be an efficient use of the developer's time and will add value to the guideline (as agreed with the quality assurance team). In particular, the developer should be confident that seeking evidence from stakeholders or experts is a better way of getting more evidence than modifying the review protocol to broaden the searches (for example, by including a wider range of study designs or including evidence from indirect populations).

Deciding whether to use a call for evidence or expert witnesses

Once a decision has been made to request evidence, a call for evidence should usually be the first approach. If expert witnesses are used instead of, or as well as, a call for evidence, this decision should be documented (specifically, why a call for evidence was not considered appropriate or sufficient).

Call for evidence

A call for evidence can be made at any point during guideline development, but ideally it should happen early on. The amount of time given to respondents to submit evidence

depends on the type of evidence and level of detail needed. It is typically 2 to 4 weeks but can be longer.

A call for evidence needs a protocol that specifies the inclusion and exclusion criteria for the types of evidence that will be considered. If the question used for the call for evidence is identical to an existing review question for the guideline, the call for evidence can use the same protocol. If the call for evidence question used does not match a review question, a new protocol should be developed.

The developer should make it clear to stakeholders that NICE will not consider the following material as part of a call for evidence:

- promotional material
- unsubstantiated or non-evidence-based assertions of effectiveness
- opinion pieces or editorial reviews
- potentially unlawful or other inappropriate information.

Occasionally, relevant data are held by regulatory authorities. If this is the case, the regulatory authority may be asked to release the data as part of the call for evidence.

Normally, only references or links should be submitted, or details of contacts for unpublished research. The developer will then obtain full copies of all relevant papers or reports, paying a copyright fee if necessary. If the data sources are open access or the copyright holder has given permission, copies of full papers (in electronic or hard copy form) can be submitted.

Confidential information

Information or data that may be considered confidential can include data that may influence share price values ('commercial in confidence') and data that are deemed intellectual property ('academic in confidence', that is, awaiting publication).

Confidential information should be kept to an absolute minimum. For example, information submitted should be limited to the relevant part of a sentence, a particular result from a table or a section of code. NICE does not allow a whole study to be designated confidential. As a minimum, a structured abstract of the study or economic model must be

made available for public disclosure during consultation on the guideline. Results derived from calculations using confidential data are not considered confidential unless back-calculation to the original confidential data is possible.

When the developer sends out a call for evidence, respondents are asked to complete a checklist that identifies the location of all confidential information contained in their submission, and for how long the information is likely to remain confidential. In addition to completing the checklist, respondents should indicate the part of their submission that contains the confidential information. All confidential information should be underlined. Information that is submitted under 'commercial in confidence' should also be highlighted in turquoise; information submitted under 'academic in confidence' should be highlighted in yellow. The underlining and highlighting should be maintained so that the committee knows which parts are confidential.

When documents are prepared for consultation and publication, NICE works with the data owners to agree a compromise between confidentiality and transparency, and strive to release as much information as possible. Any confidential information is removed, and a note added to explain what has been done.

Submitting evidence

Respondents should submit published and unpublished data using a submission form for a call for evidence. They should also complete a:

- checklist for confidential information
- disclosure form for links with the tobacco industry
- declaration.

Information is available to help respondents identify confidential information and fill out the checklist.

Documenting evidence received in response to a call for evidence

Information received in response to a call for evidence should be recorded systematically and checked against evidence identified from other searching (for example, literature searches), to make sure it has not already been assessed.

All evidence provided should be screened against the protocol. If any evidence is excluded, the reasons for this should be explained. The reasons for exclusion should be as detailed as the reasons given when a study identified from literature searching is excluded at full-text level.

All evidence should be analysed and reported in the same way as information found from searches. See the section in the manual on reviewing the evidence. For example:

- If evidence directly addresses a review question, it should be quality assessed, analysed and reported in the same way as evidence from searches.
  - This includes presenting the evidence in evidence tables, quality assessment of the individual studies (see the appendix on appraisal checklists, evidence tables, GRADE and economic profiles), and analysis and full GRADE or CERQual profiles (if relevant).
  - The call for evidence should be reported in an appendix to the evidence review. The results of the call for evidence should be discussed in the discussion of the evidence review, alongside the discussion of the evidence from the searches.
  - When an evidence review contains evidence from both searches and a call for evidence, it should be clear which recommendations are based on which sources of evidence or combinations of evidence types.
- If the evidence is used to set parameters for a health economic model, the limitations and uncertainties in the evidence should be considered and discussed in the same way as for parameters from other sources.

Disclosing links with the tobacco industry

When submitting evidence in response to a call for evidence, 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. Disclosures will be included with the evidence presented to the committee.

Expert witnesses

There are 2 ways to use expert witnesses in guideline development:

- Expert evidence: getting analysable data in the same way as a call for evidence, but from selected experts rather than all stakeholders.
- Expert testimony: providing information to the committee that cannot be formally analysed or quality assessed.

Expert witnesses can come from a variety of backgrounds, and include both professionals and lay people. The same processes and reporting standards should be used for all expert witnesses. Additional support and adjustments should be provided if needed for a witness to take part.

Expert evidence

Expert witnesses may be invited to provide expert evidence (appraisable data) to the committee after a call for evidence, or without holding a call for evidence:

- After a call for evidence: respondents who have provided evidence as part of this process may be invited to provide additional evidence as expert witnesses. There should be a clear explanation of what additional evidence is needed, beyond what was supplied through the call for evidence. There should also be a clear justification for why it is appropriate to invite a particular respondent and not others.
- No call for evidence: sometimes it is clear that a wider call for evidence would not be helpful and only a limited number of people should be invited to submit evidence. For example, the data needed might be held by 1 organisation (such as a national registry). There should be a specific justification for why a call for evidence was not considered appropriate, and for the choice of experts invited to provide evidence.

As with a call for evidence, the evidence from an expert witness should be analysed and reported in the same way as evidence from searches.

Expert testimony

When seeking expert testimony, there should be a specific justification for why a call for evidence was not considered appropriate or sufficient, and for the choice of experts invited to give testimony.

The expert should be given specific topics and questions to answer at the committee meeting. They should not just be invited to give their views on a broad topic.

The expert should complete a structured form (with support from the developer, if needed) summarising their testimony. The form should contain all the relevant information shared with the committee. If this form was completed before the meeting, it should be updated after the meeting with any additional information not previously included. See the form for expert testimony.

Expert testimony provides data that cannot be reported in the same way as data from searches or calls for evidence. Because of this, an alternative approach to reporting is needed. As a minimum:

- The forms summarising the expert testimony should be reproduced and summarised in the evidence review document.
- The committee discussion section should give the committee's views on the validity and applicability of the expert testimony. If more than 1 person gave expert testimony on the same topic, the level of consistency between the testimonies should be discussed, along with the committee's views on possible reasons for any inconsistencies.
- The committee discussion section in the evidence review and rationale section in the guideline should make it clear when recommendations are wholly or partly based on expert testimony. This explanation should indicate which parts of the testimony link to specific recommendations, and summarise the committee's discussion of how confident they were that the testimony supported the recommendations. The explanation should cover all the standard elements for a discussion section: effectiveness, cost effectiveness, implementation issues, and ethical considerations.

Examples of evidence not routinely identified by searches

- Ongoing research when an intervention or service is relatively new
- Interim study results (not yet published) for longer-term studies
- Studies that have been published only as abstracts
- Health needs assessments
- Protocols

- Local pilot studies
- Data on health inequalities
- Business cases
- Financial reports
- Analyses of primary data
- Data from patient registries and healthcare databases
- Unpublished studies of the experiences of people using services, their family members or carers, or practitioners
- Unpublished data about the off-label use of medicines
- Unpublished data on harms
- Audit data
- Implementation case studies
- Unpublished economic models

Example webpage for a call for evidence

Call for evidence – end of life care for adults: service delivery

What we need

We need the following information for the guideline we are developing on end of life care for adults:

Service delivery models to:

- identify people who may be entering the last year of their life
- support people to stay in their preferred place of care (for example, out of hours services)

- facilitate smooth transitions between care settings (for example, discharge planning teams)
- facilitate continuity and coordination of care (for example, multidisciplinary team working)
- reduce inappropriate and avoidable hospital admissions (for example, community health services and telehealth)
- facilitate discharge back to the community from other settings (for example, rapid discharge pathways).

We are particularly interested in information promoting equality of opportunity relating to age, disability, sex, gender identity, ethnicity, religion and belief, sexual orientation or socio-economic status.

We would like information on:

- service delivery models that report measurable outcomes, for example:
  - the number of people who die in their preferred place of death
  - quality of life
  - use of hospital and community services (including staff time or any other information on resource use)
  - costs associated with providing or implementing the service delivery model.

We cannot accept promotional material, non-evidence-based assertions of effectiveness or opinion pieces.

Sending information

For published information, send reference details only (authors, title, date, journal or publication details [including volume and issue number, and page numbers]). Do not send a PDF or Word document, or a paper copy.

For unpublished information, send:

- a link to any relevant trials registered with the Cochrane Central Register of Controlled

Trials, or with the US National Institutes of Health trials registry

- paper or electronic copies of other relevant unpublished information.

Highlight any confidential sections (unpublished research or commercially sensitive information) in unpublished information. For more details about this, see the section on commenting on the draft guideline in the chapter on the validation process for draft guidelines and dealing with stakeholder comments.

Complete the call for evidence form [insert link] and the checklist for confidential information form [insert link], including the declaration of any links with, or funding from, the tobacco industry. Please email these forms with any relevant information by [insert deadline] to: INSERT EMAIL ADDRESS HERE

Alternatively, please send hard copies to:

INSERT POSTAL ADDRESS HERE

We look forward to receiving this information and thank you in advance for your help.

Submission form for a call for evidence

Call for evidence – [insert guideline title]

Please send the information before XX/XX/XXXX

- When submitting evidence that is published, please send reference details only (authors, title, date, journal or publication details [including volume, issue and page numbers]).
- We are unable to accept electronic or hard copy of published material unless data sources are open access, or the copyright holder has given permission.
- We can accept unpublished reports, and local reports and documents.

Respondent organisation or individual	Evidence submission (Details of evidence that relates to the questions. Please specify which question you are referring to)	Published or unpublished material	How the evidence can be obtained (For published material, please include full reference details: author, date of publication, full title of paper or report and where a copy can be obtained) [For unpublished material, please send details of contacts]
-	-	-	-

Information for respondents on a call for evidence

Section 1 – How to identify confidential information

To ensure that the guideline development process is as transparent as possible, NICE considers that evidence the committee has used to make its decisions should be publicly available. Ideally, all the evidence seen by the committee should be available to all stakeholders. Under exceptional circumstances, unpublished evidence can be accepted under agreement of confidentiality. However, NICE expects stakeholders to keep confidential material within a submission to an absolute minimum. Confidential data includes:

- commercial in confidence data, which may influence share prices
- academic in confidence data, which are awaiting publication and deemed to be intellectual property.

Such data should be consistent with the following principles:

- Information in the public domain, anywhere in the world, may not be marked as confidential.
- Results of trials relating to products that have received regulatory approval should be available for scrutiny.

- When trial results are due to be published in a journal after they would be released by NICE, as a minimum a structured abstract should be made available for public disclosure during consultation on the guideline. The structured abstract should follow a recognised format for a full trial report, such as that provided by the CONSORT statement.
- The same principles apply to the release of information in the form of an economic model. The full economic model, in electronic format, should be available for scrutiny by the developer. As a minimum, a structured abstract of the economic model should be submitted for public disclosure during consultation on the guideline.

Confidential information will be reviewed by the developer and the committee and – when necessary – any external experts (expert witnesses) will be invited to attend committee meetings.

- If information is confidential, then any specific mention of that information will be removed or 'blanked out' from the draft guideline for consultation and the final guideline published on the NICE website. The confidential information will not appear in the final guideline, unless the confidential status is removed before publication.
- NICE asks respondents to reconsider any restrictions on the release of data if there appears to be no obvious reason for them, or such restrictions would make it difficult or impossible for NICE to show the evidence for its recommendations.

Section 2 – Important notes to consider before completing the checklist for confidential information

- Marking a whole submission confidential is not acceptable.
- For each submission, respondents should complete the checklist below.
- In addition to the checklist, all confidential information should be underlined. Commercial in confidence information should also be highlighted in turquoise and academic in confidence information should be highlighted in yellow. Please make sure that the checklist is completed accurately and corresponds to the highlighted and/or underlined text in your submission.
- Results derived from calculations incorporating confidential data will not be considered confidential unless releasing those results would enable back-calculation to the original confidential data.

- If the status of information changes during guideline development, a new checklist for confidential information must be completed as soon as possible.
- If the confidential status of information is expected to change during guideline development, exact embargo dates (for example, after a conference presentation) or approximate dates (for example, after an article has been accepted for publication) should be given.
- If no checklist for confidential information is received with a submission, all information in that submission and any accompanying appendices or attachments will automatically be considered not to be confidential.

Section 3 – Checklist for confidential information

To be completed in full and returned to [insert name], [insert role] (preferably electronically), as a separate file to your evidence submission, by the submission deadline.

If the developer does not receive a completed checklist, then all information contained in your submission will be considered as not confidential.

Respondent:

Guideline title:

Summary of the evidence submitted:

Does your submission contain any confidential information (see previous for more information)? Please check appropriate box

No

If no, please proceed to section 4 – Disclosure

Yes

If yes, please complete the following table in full (insert or delete rows as necessary).

All confidential information should be underlined. Information that is submitted under 'commercial in confidence' should also be highlighted in turquoise; information submitted under 'academic in confidence' should be highlighted in yellow. The underlining and highlighting should be maintained so that the committee knows which parts are confidential.

Checklist for confidential information

Page where confidential information appears	Nature of confidential information (commercial in confidence or academic in confidence)	Rationale for confidential status	Timeframe of confidentiality restrictions
-	-	-	-
-	-	-	-
-	-	-	-

Please state whether the timeframe given is exact or approximate. For academic in confidence material, please state either the date and title of the conference at which the information will be made public, or the date of submission and title of the journal to which the relevant paper has been submitted, together with the journal's stated turnaround time.

Section 4 – Disclosure form for links with the tobacco industry

Disclosure form

Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.

Section 5 – Declaration

I confirm that all relevant material pertinent to the call for evidence has been disclosed to the developer.

I confirm that any confidential sections of the submission have been underlined, any commercial in confidence sections have been highlighted in turquoise and any academic in confidence have been highlighted in yellow, and that if any change occurs to the above information, a new checklist will be submitted.

Name of person completing checklist:

Contact details (telephone/email):

Date:

Form for expert testimony

Expert testimony to inform NICE guideline development

Section A: Developer to complete

Name:	
Role: **[for example, lay / practitioner / academic]**	
Institution/Organisation (where applicable): **Contact information:**	
Guideline title:	
Guideline Committee:	
Subject of expert testimony: **[for example, tuberculosis service delivery]**	
Evidence gaps or uncertainties:	[Research questions or evidence uncertainties that the testimony should address are summarised below] .

Section B: Expert to complete

Summary testimony: **[Please use the space below to summarise your testimony in 250 to 1,000 words. Continue over page if necessary.]**	
References to other work or publications to support your testimony' (if applicable):	
Disclosure: **Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.**	

Declaration of interests: **Please complete NICE's declaration of interests (DOI) form and return it with this form.**	**Note: If giving expert testimony on behalf of an organisation**, please ensure you use the DOI form to declare your own interests and also those of the organisation – this includes any financial interest the organisation has in the technology or comparator product; funding received from the manufacturer of the technology or comparator product; or any published position on the matter under review. The declaration should cover the preceding 12 months and will be available to the advisory committee. For further details, see the NICE policy on declaring and managing interests for advisory committees and supporting FAQs.

Expert testimony papers are posted on the NICE website with other sources of evidence during consultation and when the guideline is published. Any content that is academic in confidence should be highlighted and will be removed before consultation and publication if the status remains at this point in time.

Appendix K: Network meta-analysis reporting standards

Reporting results of network meta-analysis (NMA) should meet the criteria in the modified version of the PRISMA-NMA checklist specified below. The modified version of the checklist includes only a subset of items in the full checklist that are specifically applicable to reporting the results of network meta-analysis.

The full PRISMA-NMA statement with elaborations on each item is reported here: Hutton B, Salanti G, Caldwell DM et al. (2015) The PRISMA Extension Statement for Reporting of Systematic Reviews Incorporating Network Meta-analyses of Health Care Interventions: Checklist and Explanations. Annals of Internal Medicine 162: 777–84.

Modified PRISMA-NMA checklist (reproduced and modified with permission)

1. Describe the reasons for the evidence review in the context of what is already known, including why an NMA has been conducted.

2. Specify the study characteristics (for example, PICOs, length of follow-up) and report characteristics (for example, years considered, language, publication status) used to decide the eligibility of studies, giving the reasons for the characteristics used. Clearly describe eligible treatments included in the treatment network and note whether any have been clustered or merged into the same node (with justification).

3. Describe methods used to explore the geometry of the treatment network and potential biases related to it (for example, if there are important links in the network where the studies are at high-risk of bias). This should include how the evidence base has been graphically summarised for presentation, and what characteristics were compiled and used to describe the evidence base to readers.

4. State the principal summary measures (for example, risk ratio, difference in means). Also describe the use of additional summary measures assessed, such as treatment rankings and surface under the cumulative ranking curve (SUCRA) values, as well as modified approaches used to present summary findings from meta-analyses.

5. Describe the methods of handling data and combining results of studies for each NMA. This should include, but not be limited to:

a) handling of multi-arm trials

b) selection of variance structure

c) selection of prior distributions in Bayesian analyses

d) assessment of model fit.

6. Describe the statistical methods used to evaluate the agreement of direct and indirect evidence in the treatment network(s) studied. Describe efforts taken to address inconsistency when found.

7. Describe methods of additional analyses if done, indicating which were pre-specified. This may include, but not be limited to, the following:

a) sensitivity or subgroup analyses

b) meta-regression analyses

c) alternative formulations of the treatment network

d) use of alternative prior distributions for Bayesian analyses (if applicable).

8. Provide a network graph of the included studies to enable visualisation of the geometry of the treatment network.

9. Provide a brief overview of characteristics of the treatment network. This may include commentary on the abundance of trials and randomised patients for the different interventions and pairwise comparisons in the network, gaps of evidence in the treatment network, and potential biases reflected by the network structure (for example, publication bias).

10. Present results of each meta-analysis done, including confidence/credible intervals. In larger networks, authors may focus on comparisons versus a particular comparator (for example, placebo or standard care). League tables and forest plots may be considered to

summarise pairwise comparisons. If additional summary measures were explored (such as treatment rankings), these should also be presented.

11. Describe results from investigations of inconsistency. This may include such information as measures of model fit to compare consistency and inconsistency models, P values from statistical tests, or summary of inconsistency estimates from different parts of the treatment network.

12. Give results of additional analyses, if done (for example, sensitivity or subgroup analyses, meta-regression analyses, alternative network geometries studied, alternative choice of prior distributions for Bayesian analyses).

13. Discuss limitations at study and outcome level (for example, risk of bias), and at review level (for example, incomplete retrieval of identified research, reporting bias). Comment on the validity of the assumptions, such as transitivity and consistency. Comment on any concerns regarding network geometry (for example, avoidance of certain comparisons).

Appendix L: Process and methods for guidelines developed in response to health and social care emergencies

Introduction and overview

These process and methods are for the development, surveillance, updating and withdrawal of guideline recommendations developed in response to national health and social care emergencies.

The Civil Contingencies Act 2004 defines national health and social care emergencies. We will consider developing emergency guidelines in these situations if immediate action is needed on a national level to preserve or protect the ability of the health and social care sector to respond appropriately (for example the COVID-19 pandemic).

During health and social care emergencies, urgent guidelines are needed within a few days to a few weeks. The development time depends on the urgency of the referral, the complexity of the topic, the number of questions to be addressed, and the likely volume of evidence.

Depending on the nature of the health and social care emergency and how urgently the system needs advice, it may be the case that guidelines are developed first and recommendations on medicines are then superseded by NICE technology appraisal guidance. In this scenario, the relevant teams will discuss the most appropriate approach for including the NICE technology appraisal guidance into the guideline and when this should happen.

The recommendations developed to support the system during the emergency are subject to a living approach consisting of a frequent review of the evidence and regular updating as needed.

The short development time imposes trade-offs around shortening, omitting or accelerating the processes and methods used for developing standard NICE guidelines. However, transparency of decision making and reporting is one of our core principles,

underpinning the development of all NICE guidance. Transparency ensures that users can make judgements on the credibility and applicability of the guideline recommendations.

The short development time also means it is not possible to recruit a full independent advisory committee, as we do for standard guidelines. However, emergency guidelines still have an independent panel of experts to provide advice (see the section on independent advisory expert panel for more information).

Topic selection

The topics to cover and how quickly emergency guidelines are needed is agreed with the relevant commissioning body (for example, NHS England, the UK Health Security Agency (UKHSA) or the Department of Health and Social Care).

Who is involved

The guideline is developed by a development team (see the section on the health and social care emergency guideline development team), working with an independent advisory expert panel (see the section on the independent advisory expert panel).

During guideline development, we engage with stakeholders on the draft guideline. The length of time for this engagement depends on the urgency of the referral, the complexity of the topic, the number of questions to be addressed, and the likely volume of evidence (see the section on consultation).

Staff with responsibility for guideline surveillance undertake a pragmatic targeted approach to surveillance for emergency guidelines (see the section on surveillance and updating process).

Updating emergency guidelines is undertaken by staff with responsibility for guideline development. Targeted stakeholders are consulted on the draft update before publication. The length of time for this consultation depends on the urgency of the update (see the section on rapid evidence-based updates to recommendations).

All emergency guidelines and evidence-based updates are signed off by NICE's guidance executive.

Independent advisory expert panel

Because of the short development time for emergency guidelines, open recruitment of a topic-specific guideline committee is not feasible or practical. An independent advisory expert panel consisting of topic experts is used instead. The number of topic experts in the independent advisory expert panel depends on the urgency of the referral, the complexity of the topic, the number of questions to be addressed and the likely volume of evidence.

When possible, the same independent advisory expert panel that developed the original recommendations should be used when updating an emergency guideline.

Selecting professional experts

Selection of professional experts is based on the expertise needed to develop recommendations in the areas defined by the guideline scope. When selecting professional experts, decisions are underpinned by the seven principles of public life from the Committee on Standards in Public Life. To allow for rapid appointment, professional experts may be:

- identified by recommendations from national professional organisations, such as the Royal Colleges
- chosen from NICE's Centre for Guidelines' expert panel database (see below)
- existing or previous committee professional experts for other NICE guidance.

NICE's Centre for Guidelines' expert panel database

A database of clinicians and practitioners from a variety of specialties. The database is designed to give better access to expert advice when developing and updating NICE guidance.

Experts are selected for their knowledge and experience, and do not represent their organisations.

When recruiting from the database, we may invite specific experts or may ask for expressions of interest from all experts in a particular specialist area.

Experts may be invited to:

- give advice – for example, to advise on the impact of new evidence on existing guidance or to advise on current practice
- participate in committees or independent advisory expert panels as topic specialist members
- perform peer reviews – for example, reviewing part of the guideline, such as an evidence review.

Selecting lay members

The independent advisory expert panels should include lay members. This helps to ensure that the recommendations are relevant to people affected by them and acknowledges general or specific preferences and choice. When updating guideline recommendations, the development team should review the composition of the independent advisory expert panel and recruit additional lay members if needed. To allow for rapid appointment, lay members are selected by expressions of interest from:

- the Public Involvement Programme expert panel or
- existing or previous committee lay members for other relevant NICE guidance.

National voluntary and community stakeholder organisations may also be contacted to establish if they can nominate someone with the relevant experience.

What the panel does

See the guideline manual chapter on decision-making committees for information on what the panel does. In addition to information outlined in this section, members of the independent advisory expert panel also contribute to decisions to update recommendations.

Health and social care emergency guideline development team

See the guideline manual section on who is involved for information on who develops guideline recommendations.

Main stages of emergency guideline development

The development time for an emergency guideline is usually a few weeks (from receiving the referral to publication), depending on the urgency of the referral, complexity of the topic, number of questions to be addressed, and the amount of evidence.

The stages of development for an emergency guideline are the same as the main stages of development outlined in the guideline manual. However, because of the short development time, some of these stages may be done iteratively or in parallel. When the guideline is needed urgently, publication of recommendations will be prioritised, and publication of accompanying evidence reviews and supporting documents may be delayed.

Scoping

The scope is drafted by staff with responsibility for guideline development, working with the independent advisory expert panel.

The scope covers the issues set out in the topic referral from the referring body, and should include:

- questions for addressing the issues
- information on PICOs
- areas not covered by the guideline
- the target audience.

Staff with responsibility for guideline development identify any existing NICE recommendations covering the same areas as the new guideline.

The scope is signed off by a senior member of staff with responsibility for quality assurance and published on the NICE website.

Identifying the evidence

Targeted literature searches are conducted to identify published and preprint guidance and evidence relevant to the questions in the scope. Exhaustive literature searches (see the guideline manual chapter on identifying the evidence: literature searching and

evidence submission) are only done if guideline development time allows, and if published evidence is expected to address specific review questions.

If there is likely to be a shortage of published and preprint guidance and evidence, indirect evidence on other related or similar situations could also be searched for (for example, information on severe acute respiratory syndrome [SARS] and middle east respiratory syndrome [MERS] was used to inform early guidance in the COVID-19 pandemic). In this situation, advice is sought from the independent advisory expert panel. The rationale for any indirect evidence searches will be made clear in the review protocol.

If evidence is not expected to be available and indirect evidence is not suitable for developing recommendations, the independent advisory expert panel may develop recommendations through a process of informal consensus, informed by their expert knowledge and experience. If appropriate, they may also consider a call for unpublished evidence or draw on expert witnesses (see the appendix on call for evidence and expert witnesses).

The sources for targeted searches of relevant guidance could include:

- WHO databases
- UKHSA guidance and advice
- NICE guidance
- NICE-accredited or endorsed guidance or assessed as credible by the Emergency Care Research Institute (ECRI)
- Medicines & Healthcare products Regulatory Agency (MHRA), NHS England or National Patient Safety Alerts, or other official advice (for example, on infection control and prevention)
- guidance from professional organisations, with guidance from organisations in the UK prioritised over organisations in other countries
- other sources of guidance, as appropriate (for example, BMJ Best Practice, ECRI Guidelines Trust)
- national or international initiatives or networks established in response to a specific health and social care emergency (for example, COVID-END and ECC-19 for the COVID-19 pandemic).

The sources for targeted searches of published literature and preprints should include:

- WHO databases of global research
- Medline, Embase, the Cochrane Database of Systematic Reviews and the Cochrane Central Register of Controlled Trials
- trials registries, for example, ClinicalTrials.gov
- preprints from Europe PMC
- other literature collections as appropriate to the topic, such as the Centre for Evidence-based Medicine.

All search strategies are quality assured by a second information specialist and made available when the guideline is published.

Selecting the evidence

For information about literature searching and evidence submission, see the guideline manual section on identifying the evidence: literature searching and evidence submission.

Because these guidelines are urgent, a search for health economic evidence is not routinely conducted. A search can be done if evidence is known to be available or if there is uncertainty around the cost effectiveness of treatments or interventions included in the evidence review.

For the types of question and most appropriate study designs, see the guideline manual chapter on developing review questions and planning the evidence review.

References for all included guidance, published studies and preprints will be published.

Reviewing the evidence

For all included published studies and preprints, population characteristics and key findings are summarised.

See the guideline manual chapter on reviewing evidence for information about assessing risk of bias. The overall quality of the study is stated in the evidence review document.

Formal statistical analyses (for example meta-analysis) are not routinely conducted unless they are likely to add value to the decision-making process. For example, these analyses could be useful if there is a large amount of data for a specific treatment or intervention, with competing benefits and harms. If meta-analysis is done, and time permits, consider assessing the confidence in the findings by outcome using GRADE. See the guideline manual chapter on reviewing evidence for information about applying GRADE.

Health economic evaluation (literature review or new health economic analysis) is not routinely conducted unless it is likely to add value to the decision-making process.

If relevant, recommendations from other guidance (related NICE guidance and guidance developed by other organisations) can be used. For guidance sources that have not been NICE accredited, or assessed as credible by independent sources (such as ECRI), the AGREE II instrument (or a subset of the domains used in AGREE II) is used to assess quality if feasible.

When using recommendations from other guidance, the following information is documented:

- title of the guidance
- year of publication
- the authors and their declarations of interests (if available)
- whether the recommendations are based on evidence or opinion (or if it is unclear what they are based on).

All supporting documents will be made available on the NICE website (see the section on reporting information).

Writing the health and social care emergency guideline

A high-level summary of the evidence should be included, and it should be clear what evidence or expert opinion each recommendation is based on.

Staff with responsibility for guideline development draft a summary (see the section on reporting information) giving brief explanations for each recommendation or group of recommendations. These include the independent advisory expert panel's discussions of:

- the overall quality of the evidence or confidence in the expert opinion
- the trade-off between benefits and harms
- the impact on equity, equality and health inequalities
- health economic evaluation (if conducted)
- the feasibility of implementation (for example resources, capacity, settings, and acceptability).

All emergency guidelines are labelled to indicate that they have been developed using a different approach to standard NICE guidelines.

Because these guidelines are urgent, the cost effectiveness and resource impact of recommendations is not routinely considered, unless it is likely to add value to the decision-making process. All recommendations made in these guidelines may impose an opportunity cost and resource impact on the health and social care system.

See the guideline manual section on formulating recommendations for research.

Consultation

The emergency guideline undergoes a targeted peer review. A range of stakeholders are invited to take part, including relevant national professional and patient or carer groups. The length of the consultation depends on the urgency and complexity of the guideline and may range from 1 day to 2 weeks.

Staff with responsibility for guideline development collate all comments from stakeholders, so the independent advisory expert panel can consider them. The panel then advises on changes to the guideline and responses to stakeholder comments. Comments from stakeholders are grouped in 'themes'. Thematic responses are provided to address these themes, instead of responding to individual comments.

All stakeholder comments and thematic responses are made available on the NICE website.

Declarations of interest

See the guideline manual section on code of conduct and declaration of interests.

Equalities and health inequalities considerations

See the guideline manual for how equalities and health inequalities are considered throughout development.

Guideline review and sign-off

Pragmatic checks and review are undertaken iteratively throughout guideline development by staff with responsibility for quality assurance.

NICE's guidance executive signs off the guideline before publication.

Surveillance and updating process

See the guideline manual chapter on ensuring that published guidelines are current and accurate for information about the surveillance process.

Identifying the evidence as part of a surveillance process

The approach to identifying evidence will depend on the context of the health and social care emergency. For example, in the early stages of the emergency, feedback from the health and social care system may be most relevant.

The information services team will conduct frequent update searches of literature and guidance. The frequency of searching will be reviewed over time, depending on the amount of new evidence being published.

Depending on the nature of the health and social care emergency, a surveillance repository of evidence may be set up. This will help with reuse of data in guideline updates (see the section on surveillance decisions and outcomes).

There will be ongoing screening of any new evidence that is identified. The frequency of screening will be reviewed over time, depending on the frequency and amount of new evidence identified by searches.

For primary studies, there will initially be no restrictions on study designs if only limited evidence is available. The inclusion criteria will be reviewed over time, depending on the amount and quality of the emerging evidence.

As additional review questions are prioritised and new recommendations developed, existing search methods for surveillance will be checked to make sure that they cover the PICOs of the new questions. We will update or expand the surveillance search as needed.

Because these guidelines are urgent, health economic evidence will not usually be considered as part of this surveillance process.

Identifying new and updated guidance from other organisations

At a minimum, surveillance searching of guidance from other organisations will include all sources listed in the section on identifying the evidence. When available, searches will be limited to sources judged as high quality or credible (for example, by ECRI assessments).

Intelligence gathering and event tracking

See the guideline manual section on surveillance assessment process for details.

Documenting surveillance reviews

A concise report will be written for each surveillance review, documenting the factors that were considered and presenting a rationale for updating (or not updating) the guideline.

Surveillance decisions and outcomes

Surveillance decisions and outcomes are based on continual assessment of the impact of all the new evidence and intelligence that has been identified. There are 4 possible surveillance outcomes:

- no update
- amend the recommendations
- rapid update of the recommendations
- withdraw the recommendations.

There will be no public consultation on surveillance decisions. Instead, professional experts (see the section on selecting professional experts) review the surveillance decision.

NICE's guidance executive will only be asked to approve surveillance decisions if the proposal is to withdraw the recommendations.

Types of surveillance decisions and outcomes

See the guideline manual section on surveillance assessment process.

Rapid evidence-based updates to recommendations

A pragmatic and flexible approach is used for updating guideline recommendations. This allows for rapid changes in response to emerging evidence. When possible, work conducted during surveillance will be reused (including evidence searches, data extraction and intelligence gathering).

Cost effectiveness and resource impact analyses are not routinely done during updates, unless it is likely to add value to the decision-making process.

Independent advisory expert panel for rapid updates

See the section on independent advisory expert panel for more information.

Literature searching

To speed up the development of new and updated recommendations for health and social care emergencies, the following approaches could be considered for identifying evidence:

- new update searches
- a search for relevant studies within the surveillance repository of evidence
- reusing data from a directly relevant, recently published systematic review (such as a Cochrane review)
- working with other organisations that are developing guidance in the same area, to share evidence identified through their processes.

New update searches

New update searches are recommended when there is likely to be evidence not identified by the surveillance searches, or if additional subject-specific resources are needed.

New update searches will be conducted using sources specified in the section on identifying the evidence.

Searching the surveillance repository

Searching the surveillance repository may be appropriate if the surveillance searches are likely to have identified all relevant evidence (for example, for simple updates of existing review questions in the guideline). A search of the surveillance repository can also be supplemented with a search of additional sources not covered by surveillance searches, or a call for evidence (see the appendix on call for evidence and expert witnesses), if necessary.

Use of a directly relevant systematic review

See the guideline manual chapter on reviewing evidence for details.

Identification of relevant data sources

The data and analytics team will be contacted with specific questions that cannot be answered using available evidence. These questions can then be matched to relevant data sources if available. Prioritisation for analysis, either internally or commissioned externally, will be considered.

Reviewing the evidence for rapid updates

See the section on reviewing the evidence.

Consultation on rapid updates

See the section on consultation for details.

Guideline quality assurance and sign-off for rapid updates

See the guideline manual sections on quality assurance and signing off the guideline recommendations.

Reporting information

The following information should be available on the NICE website to meet minimum reporting standards, although not all information may be available when the recommendations are published, depending upon the urgency of the guideline:

- the scope, including questions and review protocols (based on PICO) with inclusion and exclusion criteria
- all search strategies
- references of included guidance, published studies and preprints
- evidence tables with information on quality assessment (including health economic evidence tables if conducted)
- high-level summary table (linked to the evidence tables) that documents which identified evidence or expert opinion each recommendation is based on
- findings from analysis (for example forest plots) if meta-analysis is conducted
- GRADE profiles if GRADE is used
- health economic evaluation report if health economic evaluation is conducted
- evidence to decisions table, with brief rationales
- equality and health inequalities assessment form
- names of stakeholder organisations that are commenting on the guideline, stakeholder comments and thematic responses to stakeholder comments
- declaration of interests of the independent advisory expert panel.

Templates are available for the following:

- the scope

- high-level evidence summaries
- evidence to decision tables, with brief rationales.

Terms used

Surveillance repository

The surveillance repository is an EPPI-Reviewer review that includes all search results from when surveillance searches for a health and social care emergency begin, up to the current date. Studies are allocated to relevant codes in EPPI-Reviewer as part of screening, or excluded if not relevant to the guideline. The repository is designed so that studies can be identified and retrieved using the search and filter function in EPPI-Reviewer.

Appendix M: Interim principles for methods and processes for supporting digital living guideline recommendations

This statement sets out the interim principles for methods and processes that are used to develop NICE's digital living guideline recommendations. It is a living document that is reviewed on a quarterly basis.

To help meet NICE's strategic aims, the NICE guidelines programme is transforming to a more flexible and proportionate approach to allow us to focus on what matters most and to provide useful and useable advice. This flexible and proportionate approach will support the timely development or update of guideline recommendations, ensuring a sustainable living approach. We are testing this approach on selected topics within our guideline portfolio.

The key differences compared with the standard NICE guideline programme are:

- The update unit is changing from a guideline to a key priority area. To find out how we are prioritising our guideline portfolio, see the webpage on maintaining and updating our guideline portfolio.
- Engagement with stakeholders to find out what matters most to the health and care system.
- Moving to flexible approaches to surveillance that identify key changes in evidence and system feedback.
- Different approaches to how we update guideline recommendations in response to a change in evidence or health and care system priorities.

Proportionate, agile and responsive approaches

There are 6 key ways in which we are developing more proportionate, agile and responsive approaches to the development or updating of guideline recommendations. Decisions on updates are available on the NICE website.

1. Prioritisation of key priority areas

This includes categorising guidelines into topic suites, independent guidelines, and foundational guidelines. The NICE guideline portfolio is undergoing a prioritisation process to identify key priority areas where an update of recommendations is appropriate, initially in guideline suite content. This is an ongoing process that will include re-prioritisation to ensure that we focus on what matters most.

2. Multiple approaches to surveillance

Moving from fixed, planned surveillance to more responsive approaches enables timely updating of recommendations. This includes evidence monitoring alongside the consideration of current health and care system priorities and contextual feedback.

3. Use of the surveillance decision framework, followed by the multi-criteria decision framework, to assess if an update is needed, and the method and process to use

Following a signal from the evidence or the health and care system, a topic area for possible update is assessed using the surveillance decision framework. This enables a clear and systematic assessment of key domains to decide whether recommendations in this topic area should be updated.

If the decision is to update recommendations, there is a further assessment, using the multi-criteria decision framework, of the possible methods and processes for updating guideline recommendations.

For details of the areas assessed in this process, see the appendix on surveillance decision framework and multi-criteria decision framework for deciding whether to develop or update recommendations and the methods used for developing or updating.

4. Use of suite faculties to help us update or develop recommendations

Members of suite faculties are practitioners with experience in the topic covered by the suite. A suite faculty member could be involved in a range of activities relating to recommendation development and updating, including:

- supporting surveillance and monitoring activities
- validation of prioritisation of key priority areas within a suite
- assisting with content consolidation (see below)
- helping to agree committee constituencies for development work
- reviewing evidence and developing recommendations as part of a committee
- supporting dissemination of recommendations in the suite
- providing feedback on implementation
- providing informal advice and topic expertise as well as other activities involved in the guideline recommendation lifecycle.

Lay people are recruited to take part in these activities via the public involvement programme's expert panel.

5. Content consolidation

Our guideline portfolio currently contains over 20,000 recommendations. To achieve our strategic ambition of ensuring that we provide recommendations that are useful, useable, and focus on what matters most, we need to consolidate and streamline our content by:

- standing down recommendations that are not essential (as defined using the principles below), and
- amalgamating recommendations that overlap in content.

Consolidation of the extensive portfolio is an ongoing process. It may be done at any time, not necessarily when there is an update in progress.

Consolidated content will be published with a statement explaining what has been streamlined and that no changes to practice are intended.

Principles for consolidation

a. Stand down recommendations:

- that are covered in other NICE guidelines (agree a single source guideline for the recommendations and link from all other guidelines)
- that reflect good practice or general principles of care or that add contextual information not directly related to review questions or evidence (retain if there is evidence of poor practice or variation in practice)
- on prescribing information that is not already covered by the BNF, BNFc or SPC
- that repeat legislation or statutory guidance (retain if there is evidence that guidance is needed on how to follow the law or statutory guidance)
- on service delivery or service configuration that are not directly based on evidence, are no longer relevant to current health or care systems, or are not in line with national policy (retain if there is a strong rationale to keep them)
- on training or competency for health and care professionals or practitioners that are the responsibility of professional bodies
- on information provision and communication that are not based directly on evidence or that are already covered by other NICE products.

b. Amalgamate recommendations within a NICE guideline or topic suite that have similar, or overlapping content, unless there is a strong rationale for not doing so. The decision should be based on the most appropriate evidence or topic expertise that has underpinned the recommendations. Consider amalgamating recommendations that are taken from another NICE guideline and contextualised or adapted for the topic.

6. Options for validation

Validation of guideline recommendations and related outputs developed using the standard NICE guideline programme is by open stakeholder consultation. For digital living guideline recommendations, a proportionate approach to validation will be used. This will reflect the complexity of the update and a flexible range of approaches will be considered.

Review process

After review, these interim principles will be updated and, following the usual consultation process for manual updates, they will become part of the main methods and processes in developing NICE guidelines: the manual.

We welcome comments on the content of this statement. These should be addressed to GuidelinesManualUpdate@nice.org.uk.

Appendix N: Surveillance decision framework and multi-criteria decision framework for deciding whether to develop or update recommendations and which methods to use

The following frameworks can be used to decide whether to develop or update recommendations and which methods to use. They should be used in conjunction with the appendix on interim principles for methods and processes for supporting digital living guideline recommendations. This appendix is a living document that is reviewed on a regular basis.

Guideline details

Guideline number	For example, NGXXX
Topic area	-
Date signal from living monitoring received	Day Month Year
Currently recommended	Summary of recommendations in this area in the guideline or suite
Signals from monitoring	Brief summary of the signal sources, such as evidence and other intelligence

Surveillance decision framework

Strength, significance and volume of new evidence	Triggers from monitoring activity: significance of new evidence (including health economics evidence) or issues identified (such as bias and sample size). Are there ongoing trials or studies that we should wait for? Are they big impact trials? Are they likely to report within the next 6 months? Does the new evidence bridge a gap identified in the guideline (do they address the recommendations for research or an important new topic area)? Does the new evidence address previous lack of or limited evidence supporting existing recommendations?
Certainty of impact on existing recommendations	Original recommendations: was the area evidence-free or was there a high volume of evidence? Does the new evidence have information on important outcomes, such as patient outcomes? Does the new evidence apply to subgroups that were not addressed by current recommendations or where evidence was previously lacking? From system feedback: are there implementation challenges with the existing recommendations?
Safety issues	Does the new evidence suggest that a recommendation may be unsafe or harm patients?
Resource impact and health economics considerations	Is there a resource or health economics impact that may change the direction of recommendations? Is a health economics evaluation required? What was the evaluation for the current recommendations?
Health inequality issues	Are there health inequality issues that could be addressed by evidence review?

Multi-criteria decision framework: proportionate approach to planning

Complexity and system priority	• Is this a complex topic area? • Is this a system priority? (For example, does it reduce waiting lists or current variation in practice?)
Methods of updating	• Is this topic area part of 'living' systematic review? Are there good quality external evidence reviews? (For example, Cochrane) • Does this need full systematic review and evidence synthesis? Does current evidence (old and new) give certainty? • Are there good-quality external guideline recommendations? Could we collaborate with an external organisation? • Update with or without full systematic review?
Committee input	• Do we need committee's input? • Committee's input: virtual or in-person meeting, email only or other efficient approach?
External validation	Full consultation or targeted engagement? Or no consultation? Give rationale.
Currency and overlap	• When was the topic area or review question being considered last reviewed or updated? • Does the topic area overlap with other suites, independent guidelines, or foundational guidelines? Or other NICE guidance?
Other contextual intelligence	• Should other factors or intelligence (not covered by the above) be considered? This could include ad hoc conversations with key people, or intelligence from enquiries, or field team or implementation feedback.

Final decision

Update with	• Full systematic review and evidence synthesis • No systematic review • External systematic review • Targeted review • Living systematic review • Collaboration with external developer • Curated content from external developer • Stand down recommendations with no further action Note: there could be combinations of the above
Health economic model	–
Committee or topic expert input	• Input through virtual or in-person meetings, or by email • No need for committee or topic expert input
Validation	• Public consultation • Targeted engagement • No consultation Note: a mix of validation options may be used, but will need to be justified in each case because this may be resource intensive

Appendix O: Surveillance – interim principles for monitoring approaches of guideline recommendations

Identification of key priority areas for monitoring

We have organised our guidelines portfolio into topic suites and within each suite key priority areas (KPAs) will be identified that consist of clusters of recommendations for active monitoring and associated updating. For details about topic suites and how we prioritise topics, see the webpage on maintaining and updating our guideline portfolio.

This appendix describes the interim principles for surveillance of KPAs using active evidence monitoring and active system monitoring.

We are in the process of defining KPAs and non-KPAs for topic suites. When KPA proposals for each topic suite have been validated, each KPA will be assessed to decide the most appropriate monitoring approaches at that time.

We will react to all intelligence received for other guidelines not in topic suites and will continue tracking ongoing studies in the surveillance internal system and central hub.

Monitoring approaches

There are 3 approaches for monitoring KPAs that will be used individually or in combination (including switching from 1 approach to another):

1. Active evidence monitoring of ongoing studies: systematically searching for ongoing studies that are assessed when results are published.

2. Active evidence monitoring of newly published studies: continuous searching of newly published evidence.

3. Active system monitoring: systematically collating and interpreting intelligence from various health and care system sources (for example safety alerts from the Medicines and

Healthcare products Regulatory Authority [MHRA], HSIB and others; other intelligence from faculties, enquiries from the public, and working with our system partners to identify areas of change).

For non-key priority areas (non-KPAs), intelligence and evidence submitted by stakeholders and the public will be recorded and used to establish a baseline for when to consider re-prioritisation of topics. It may also be valuable to reactively set up monitoring approaches when intelligence and evidence suggest a potential change or impact to current non-KPAs.

Choice of monitoring approaches

The choice of monitoring approaches includes an element of judgement. Decisions will be made by considering all the information collated through validation of the KPA, including:

- The number of updates a topic area has had, and the volume of evidence in each update.
- Uncertainty or gaps in the evidence during guideline recommendations development, including whether the guideline committee made recommendations for research for a topic area.
- Whether recommendations are based on fast-paced research evidence (with frequent new publications), or emerging evidence or driven by national policies.
- The number of studies and events we are already monitoring that are relevant to the KPA.
- Whether new evidence identified during surveillance activities support recommendations in a related KPA, or results in an update.

Review questions and search protocols for ongoing studies and published evidence

A review question for each KPA will be produced for both active monitoring of ongoing studies and for active monitoring of newly published evidence. Typically, the original guideline review question(s) underpinning recommendations in the KPA will be used. Where this is not possible, a review question will be adapted to cover the full KPA. This

may be necessary if new evidence is emerging in an area outside the scope of the original evidence review (for example, an identified gap in the topic area). Any adapted review questions will always include outcomes that were considered critical or important by the original guideline committee in the original review protocol.

Using the review question, a search protocol will be drafted using the PICO, or SPICE approach (the guideline manual has further information on developing review questions). This search protocol provides the basis for any systematic searching; detailing approaches, sources and limits (the guideline manual has further information about developing search protocols).

Active evidence monitoring: systematic searching for ongoing studies

If a KPA is suitable for systematic searching for ongoing studies, the information services team will carry out searches for ongoing studies using the key trials registries. These may include but not be limited to 1 or more of:

- The Cochrane Central Register of Controlled Trials (CENTRAL)
- ClinicalTrials.gov
- EudraCT
- ISRCTN Registry
- WHO ICTRP

A full list of sources of ongoing studies that could be used for monitoring can be found in the appendix on sources for evidence reviews.

Titles and details of the identified studies will be screened against the inclusion criteria defined in the KPA search protocol.

Studies meeting the inclusion criteria will be added to our internal system for monitoring ongoing studies and results will be assessed when the study publishes.

This search process will be repeated systematically to ensure that we identify all newly registered ongoing studies that are relevant to a KPA. The frequency of the search interval

will be decided for each KPA individually dependent on the volume of relevant results identified; a higher volume of relevant ongoing studies will result in more frequent searches. Before each search, the search protocol will be assessed to ensure it remains current. The need for searches to be continued will be informed by our re-prioritisation assessment for each KPA.

Active evidence monitoring: continuous searching of newly published evidence

If a KPA is suitable for continuous searching of newly published evidence, multiple bibliographic databases from those listed in the guideline manual section on sources will be searched. This will typically include Medline, Embase and the Cochrane Library.

A title and abstract sift will be carried out against the inclusion criteria defined in the KPA search protocol. The search process will be repeated systematically to ensure that we identify all newly published evidence relevant to a KPA.

The frequency of the search interval will be assessed and decided individually for each KPA. The volume of relevant studies, and the number of those impacting on recommendations will be used to decide on the interval between searches after the initial search. If a high number of relevant studies are identified, a fixed interval between searches from 1 to 3 months will be used. If the yield is low, a test-adjust-phase-out approach will be used resulting in the interval gradually increasing from 3 to 12 months. Decisions to change search frequency are also dependent on the impact of new evidence and other intelligence on recommendations in the KPA (see the section on active system monitoring below).

After 12 months of searches with a low yield of relevant and impacting studies, searching will be stopped. This decision will inform our re-prioritisation assessment.

Searching will also be stopped if an accumulation of studies is identified that has sufficient impact to trigger an update to 1 or more recommendations. This will be assessed alongside other intelligence identified through alternative monitoring methods (see the impact assessment section below).

Active system monitoring: systematically collating

intelligence from various sources

If a KPA is suitable for systematic collation of evidence from the health and care system, then all intelligence received or actively acquired about a related KPA will be logged in a central hub. This may include:

- information from other teams (such as intelligence from implementation, quality standards, technology appraisals and others)
- safety alerts (such as from MHRA, HSIB and others)
- relevant enquiries from the public
- intelligence provided by topic experts, guideline committees or faculties
- intelligence submitted by external stakeholders
- new national policies or legislations
- previous relevant public consultation comments
- intelligence from specific engagement activities with stakeholders.

We will consider these individual pieces of information in 2 ways, firstly when the information arrives it will be assessed to determine the impact on the related KPAs, and if any changes need to be made because of the new intelligence. Secondly, we will assess the cumulative body of intelligence (including evidence monitoring if the KPA has more than 1 monitoring approach), to see if the cumulative intelligence and evidence suggest a need to change recommendations relating to a KPA.

The need to continue active system monitoring will be assessed during re-prioritisation assessments for each KPA. Active system monitoring will also be stopped if an accumulation of intelligence and evidence is identified as sufficient to trigger an update to 1 or more recommendations. This will be assessed alongside other intelligence identified through alternative monitoring methods (see the impact assessment section below).

Impact assessment

The publication and accumulation of relevant ongoing studies, or the accumulation of relevant newly published evidence over time will be assessed for their impact on

recommendations in the KPA at each search timepoint, alongside other intelligence collated from active system monitoring. An impact may be shown if, for example, a large well conducted study is identified, or a significant volume of studies is identified consistently reporting superiority, ineffectiveness or harms for an intervention, or a change of significant national policy. Impact assessment is topic dependent and includes an element of judgement. See the appendix on surveillance decision framework and multi-criteria decision framework for deciding whether to develop or update recommendations and which methods to use.

Reactive monitoring of non-KPAs

For non-KPAs, we will conduct reactive monitoring of the intelligence and evidence and record in a central hub. This could include published studies, or information from any of the sources listed in the system monitoring section above. Information that is considered to be a safety issue related to a non-KPA will be assessed, and a decision will be made about the need to update the related recommendations. Information that is not considered to be a safety issue will be collated and assessed during the re-prioritisation of non-KPA.

Information on any changes to KPAs and non-KPAs during re-prioritisation will be available on the topic suite hub webpage.

Appendix P: Updating guideline recommendations

Types of update

NICE updates guideline recommendations in different ways depending on the specifics of the topic area, evidence base, and health and care system need. The drivers for and types of updates include:

- amending recommendation(s) based on new evidence, including health economic evidence
- amending recommendation(s) based on safety signals (for example, from the Medicines and Healthcare products Regulatory Agency or the Healthcare Safety Investigation Body
- amending or adding recommendation(s) for clarification
- aligning or amending recommendations across related topic areas to ensure consistency
- aligning, cross-referencing, incorporating or integrating recommendations across different NICE products
- amending existing cross-reference recommendation(s)
- adapting or cross-referencing to external guideline recommendation(s)
- amalgamating recommendations across related topic areas (consolidation work)
- standing down recommendation(s), including consolidation work
- correcting errors that are found after publication of the guideline.

Identification of topics for updating

NICE is prioritising the topics that are being actively monitored and updated. For further details on this process, see the appendix on interim principles for methods and processes

for supporting digital living guideline recommendations.

Updates of recommendations from topic areas

Updates of recommendations

NICE monitors existing recommendations as outlined in the chapter on ensuring that published guidelines are current and accurate and the appendix on surveillance – interim principles for monitoring approaches of guideline recommendations.

When recommendation(s) from a topic area have been identified for update, an assessment will be conducted to decide suitable methods and processes of update. This assessment is based on a multi-criteria decision framework (see the appendix on the surveillance decision framework and multi-criteria decision framework for deciding whether to develop or update recommendations and which methods to use) and aims to be proportionate and efficient.

Where suitable, updates of topic areas or recommendations will use the review questions and review protocols already defined by the existing guideline. These may be updated or adapted to reflect the change of evidence or practice identified through monitoring. Some topic areas for updates will need new review questions and new review protocols, for example to address gaps identified in the existing guidelines portfolio. Topic expertise will be sought during the development of the update. This expertise may come from a guideline committee, or through engagement with members of the faculties and Public Involvement Programme expert panel. For the roles of faculties and guideline committees, see the chapter on decision-making committees and the appendix on interim principles for methods and processes for supporting digital living guideline recommendations. For options on the types of topic expertise, see the multi-criteria decision framework (in the appendix on the surveillance decision framework and multi-criteria decision framework for deciding whether to develop or update recommendations and which methods to use).

Updates of all topic areas or recommendations are subject to the same principles of transparency of process and methodological rigour as new guidelines.

Proportionate external validation with stakeholder organisations will be sought for updates of recommendations. For further details on proportionate external validation, see the chapter on the validation process for draft guidelines, and dealing with stakeholder

comments, and the table on the multi-criteria decision framework in the appendix on surveillance decision framework and multi-criteria decision framework for deciding whether to develop or update recommendations and which methods to use. Information on updated recommendations will be available on the NICE website. This may include evidence reviews, rationale and impact sections, committee discussion sections, and other relevant documentation.

Full update of a guideline

With the strategic ambition to focus on topic areas that have the potential for the biggest impact on improving health and care outcomes, it is likely that there will be fewer full updates of guidelines than in the past.

If a full update of a guideline is needed:

- a new scope is prepared, following the process described in the chapter on the scope, **or**
- the scope of the published guideline is used and registered stakeholders are informed.

Recruitment of committee members follows the usual process. Where possible, the developer informs all members who were involved in the current published guideline that a new committee is being recruited. The composition of the committee should be tailored to new requirements if a new scope has been developed.

A guideline that has been fully updated replaces an existing guideline. The update has a new set of recommendations, a new set of rationale and impact sections, new evidence reviews and new sections detailing the committee's discussion of the evidence. When a full update is published, the old guideline is withdrawn.

Full guideline updates are always subject to public consultation. Stakeholder views are sought only on recommendations that have changed as a result of new or updated evidence reviews. Only comments in these areas will be responded to individually. Where there are multiple comments in the same sections of the guideline, theming of the comments for responses may be considered.

Routine editorial maintenance

Routine maintenance changes may also be made after publication or update of guideline recommendations. These include minor editorial amendments, such as updating or fixing broken links or changing standard texts in line with agreed template changes or NICE style.

Routine editorial maintenance of guideline recommendations allows us to improve the usability of recommendations without changing the intent, and therefore without the need for an evidence review or input from committee or topic experts.

Routine editorial maintenance can be conducted at any time, including during surveillance, or during the development of recommendations.

It can be undertaken alongside the consolidation of portfolio content. For further information on consolidation, see the appendix on interim principles for methods and processes for supporting digital living guideline recommendations.

Routine editorial maintenance might involve:

- adding or amending text to reflect changes to a medicine's marketing authorisation, to reflect changes in service configuration (for example, the setting up of integrated care systems) or a change to an organisation's name
- changes to reflect the latest government policy or statutes (for example, on alcohol consumption)
- amending recommendations to reflect the current practice context (for example, removing references to tools or resources that no longer exist)
- bringing recommendations in line with NICE's current policy on wording without changing the meaning of the recommendation.

As routine editorial maintenance does not change the meaning of the content of a recommendation, it does not require external validation.

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