NICE National Institute for
Health and Care Excellence

NICE

Developing NICE guidelines: the manual – appendices

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

An additional consultation for a guideline is considered only on an exceptional basis and is additional to the routine stakeholder consultations (see section 10.1 of the manual). Additional consultation is a targeted engagement exercise to obtain a range of views and experiences, independent from the committee, either to inform the evidence and draft recommendations, or to test the feasibility of implementing the draft recommendations or their relevance and acceptability to those affected by the guideline. This appendix outlines approaches that could be used when additional consultation is needed involving specific groups of professionals or people using services and carers. Additional consultation may be conducted during guideline development or at the same time as the public consultation on the draft guideline.

Points to consider include:

- deciding whether additional consultation is needed

- aim of additional consultation

- commissioning process

- obtaining ethical approval

- the proposal and time frame of the additional consultation

- reporting findings.

This appendix also describes how findings from an additional consultation are used to finalise the recommendations.

Deciding whether additional consultation is needed

Reasons for additional consultation will vary depending on the topic, and may become apparent at different stages of guideline development. They might include a new area for NICE guidelines during update, a lack of evidence on the views and experiences of people using services, or concerns raised by key stakeholders.

Sometimes health and social care inequalities or impacts on equality are a particular concern, for example, people affected by the guideline find it difficult to engage with health and social care

services.

Sometimes a particularly complex topic needs a whole system approach. Configuration of services may be central to the efficacy of a set of recommendations and input from a particular group of health and social care practitioners may be needed.

Occasionally a guideline includes an area of rapidly changing practice, with publication of evidence lagging behind change. It may be necessary to test the draft recommendations with frontline practitioners, or providers or commissioners of services.

In some exceptional cases, the developer may commission an additional consultation with people affected by the guideline to obtain:

- their views on specific aspects of the guideline, review questions or issues raised by the committee

- their views and experiences of relevant health and social care services.

The developer may also wish to commission an additional consultation with people affected by the guideline to test the relevance and acceptability of selected draft recommendations. This may be undertaken at the stakeholder consultation stage (see also section 10.1 of the manual), or earlier in the process to validate emerging draft recommendations.

Examples of how guidelines have used the methods described above include:

- Due to limited evidence and in the absence of representative views from the committee, young people with life-limiting and life-threatening conditions were asked for their views and opinions on selected review questions, including their preferences for place of care, information and communication provision, personalised care planning, and psychological care (Report, appendix L, NICE guideline on end of life care for infants, children and young people with life-limiting conditions).

- In the absence of evidence, the developer worked with Alder Hey Children's Hospital to survey children about their views and experiences of sedation for diagnostic and therapeutic procedures. Trust staff obtained real-time feedback via hand-held touch screen computers which young children can use (chapter 7, full guideline on sedation in children and young people).

- In the absence of representative user experiences, people in prison were consulted on their experiences of prison health services to help refine draft recommendations. The developer commissioned User Voice to conduct focus groups with a range of serving prisoners, including people with disabilities, women, older people, long- and short-term prisoners, and those with a history of substance misuse (appendix V, NICE guideline on physical health of people in prison).

- Children and young people on the autistic spectrum were consulted on emerging draft recommendations (developed from a qualitative literature review) for improving access to and experience of care. The purpose was to validate findings where appropriate and to allow feedback on areas in which the children and young people felt that the qualitative literature was either not representative of their views or that evidence was missing (chapter 4, section 5.2, full guideline on management of autism in children and young people).

- In the absence of conclusive evidence, healthcare professionals working in neonatology and midwives across the country were consulted on the consensus bilirubin thresholds for managing babies 38 weeks or more gestational age with hyperbilirubinaemia (addendum to NICE guideline on jaundice in newborn babies under 28 days). The additional consultation was conducted during the development of the guideline before public consultation. The aim of the additional consultation was to seek validation from healthcare professionals and midwives on the consensus bilirubin thresholds for managing babies 38 weeks or more gestational age with hyperbilirubinaemia before wider public consultation.

- Due to a lack of published evidence, additional consultation with adult and paediatric neurologists, general practitioners and other healthcare professionals was conducted during guideline development to run a 1-round modified Delphi to gain consensus on signs and symptoms associated with suspected neurological conditions presented in primary care (NGXX Suspected neurological conditions, publication date: to be confirmed).

Aim of additional consultation

The aim of an additional consultation must be clearly stated in the proposal for NICE as well as in the guideline methods. The aim could include, for example:

- obtaining expert view or opinions, or testing the feasibility of recommendations with policy makers, commissioners, health and social care providers and practitioners

- identifying barriers and facilitators to implementing recommendations with policy makers, commissioners, health and social care providers and practitioners

- obtaining users' views and experience of health and social care services to fill evidence gaps

- obtaining users', and their families' or carers', experience and views to fine-tune the recommendations.

These are just a few examples. Developers should consult NICE staff with responsibility for quality assurance for initial discussion as soon as the need for additional consultation is identified. If the work is likely to involve people using services or their carers, the developer should also discuss their plans with NICE public involvement staff, who can advise on options and methods for involving people affected by the guideline, including targeted consultation to obtain their views. They can also signpost to external resources and sources of more specialist advice.

Agreeing who should be commissioned to do the work

Once the aim of additional consultation is agreed, the developer should then discuss the commissioning process with NICE staff with responsibility for quality assurance. Additional consultation may be conducted by the developer or by an external contractor.

When the decision is made to commission an external contractor, the developer and NICE should consider an academic or research organisation, or an organisation that works with people affected by the guideline and has research expertise. This organisation should be separate from the team involved in compiling evidence reviews for the guideline and the committee, unless there are exceptional circumstances. For example, specific expertise in the topic or access to specialist networks is needed. However, the team may be asked to help the contractor, for example, by generating a list of participants.

The contractor should have a good record of qualitative or participatory research and, ideally, should have experience in the topic area, as well as expertise in working with people affected by the guideline.

The developer should document the reasons for the additional consultation, with a proposal including the methods to be used, and the anticipated time and costs. The proposal should be discussed with members of NICE staff with a quality assurance role, and approved by the centre director. If the work is approved, the reasons and methods should be documented in the guideline.

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.

Obtaining ethical approval

In principle, additional consultation falls into the category of 'service evaluation' and so is outside the remit of NHS research ethics committees. However, NICE, the developer and external contractor (if commissioned) should consider the ethical issues each time an additional consultation is planned to ensure appropriate expertise, and that policies and procedures are in place for the safety and welfare of participants. If there is any doubt, the developer or external contractor should consult the national Research Ethics Service. The developer or external contractor (if commissioned) is responsible for seeking ethical approval, if required.

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.

The proposal

The proposal for the additional consultation should include information on the:

- aim and objectives

- recruiting participants

- methods used

- timeframe of the additional consultation

- analysis of data

- feedback mechanism.

The proposal and the final report of the additional consultation should be included as part of the guideline or guideline appendices.

The developer or the external contractor (if commissioned) 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 or external contractor (if commissioned) in detail before work begins

- agree final documents and comment on draft recruitment letters

- help develop topic guides (for example, summaries of the recommendations and key questions for discussion)

- agree sampling frames and samples, and other supporting materials

- discuss 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 additional consultation report before the final draft is submitted.

Aim and objectives

The aim of the additional consultation should be clearly stated in the proposal. The proposal should also state the expected outputs, for example, the final report may summarise themes from participants' views, which would be used to inform or fine-tune the final recommendations.

Recruiting participants

The developer and external contractor (if commissioned) should consider the recruitment strategy carefully, taking into account the purpose of the additional consultation, the topic, the groups, the range of views required, and other relevant issues.

If the purpose of the consultation is to test the feasibility of implementing recommendations, participants should be chosen to represent a broad range of stakeholder groups in the statutory, non-statutory and voluntary sectors, where applicable. This may include people who work with the target populations covered by the guideline and other users of the guideline, such as health and social care practitioners, commissioners, policy makers, people using services, and if appropriate their families or carers. Participants do not have to be from an organisation that is registered as a NICE stakeholder.

When planning an additional consultation with children and young people, school holidays and

exam schedules should be taken into account.

Equality issues should be fully considered when choosing participants. This may mean getting a representative spread of practitioners or people using services, but it may also mean focusing on participants from seldom heard groups or people with recent experience of working with them. When testing the feasibility of implementing recommendations, the approach should be based on the content of the draft recommendations, whether or not they refer to the whole population or subgroups, and service delivery and policy issues.

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

- stakeholder groups identified as being responsible for taking action

- the make-up of the population affected by the guideline

- scope

- research questions

- inclusion criteria for the evidence reviews.

'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. Random and quota sampling may also be useful where there are a large number of potential participants, but there are 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 (if commissioned) should ensure the sampling frame and sample take account of equality issues. It should be agreed with NICE.

Methods used

Additional consultation is a targeted engagement exercise to obtain a range of views and

experiences either to inform the evidence and draft recommendations, or to test the feasibility of implementing the draft recommendations or their relevance and acceptability to those affected by the guideline. Additional consultation can involve a number of approaches and methods. NICE, the relevant committee and the developer or external contractor should consider the choice of methods carefully, taking into account the topic, the groups involved and other issues. When involving people affected by the guideline, the methods and materials used should be tailored to the age, ability and culture of participants. Additional consultation may include the use of groups, 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

- the developer (with support from NICE) can contact enough people in a geographical region 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 developer or external contractor (if commissioned) may also want to consider the following:

- more than 1 participative workshop or focus group or 'virtual' (electronic) group could be convened; these should take place in more than 1 geographical region 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' (electronic) group 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, researchers may be included in the additional consultation; 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 (such as the draft recommendations and the key areas of concern) must be developed in collaboration with, and agreed by, NICE

- if the purpose of the additional consultation is to test the feasibility of implementing guideline recommendations, a member of the NICE field team should attend at least 1 meeting.

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

- 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 a fixed-format interview. They should focus on, for example, areas in which views and experiences are needed, or the 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 1-to-1 or paired interviews are the best way to find out opinions. But they are not 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 additional consultation, depending on the methods

used for data collection. Some descriptive summary statistics should be provided, for example, characteristics of participants and attendance or response rates.

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. Where 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 www.ct-toolkit.ac.uk).

Surveys are likely to involve a mixture of quantitative and qualitative data. Quantitative data may be analysed and presented using summary statistics. These could be generated using various statistical software or calculators. Where informal 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 (if commissioned) should ensure the methods for analysing the data are discussed and agreed with NICE.

Feedback mechanism

The developer should ensure that all participants receive feedback on their contribution or the findings of the consultation and how this information has been used. For commissioned work, the external contractor should agree with the developer a process for giving feedback to all participants. Providing feedback to participants should be specified in contracts. This may include an evaluation exercise, a follow-up session or sharing interim findings via email.

Reporting and using the findings

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

These findings should be used to inform the guideline recommendations. The developer may present a summary of all the findings to the committee, and the committee should use this information to refine and prioritise the recommendations before or after the public consultation, depending on when the additional consultation is conducted. How the summary findings are used to inform committee's decision-making should be documented in the committee's discussion of the evidence.

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

Further information

References and further reading

Green J, Thorogood N (2004) Qualitative methods for health research: qualitative methods for health. London: Sage

Kelly MP, Chambers J, Huntley J et al. (2004) Method 1 for the production of effective action briefings and related materials. London: Health Development Agency

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Appendix C: Key roles and responsibilities of committee members

The committee chair

The committee chair is required to attend a specific induction session (see section 3.7 of the manual) 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 revalidation purposes or 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 chapter 12 of the manual).

- 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).

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 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 policy on recruitment and selection to advisory bodies.

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 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 their evidence in the form of expert testimony and are asked to provide a written paper, or to agree a summary of their evidence recorded by the developer. 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 policy on committee recruitment.

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 policy on committee recruitment.

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 chapter 10 of 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 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 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 chapter 8 of the manual). 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 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 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

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

Guidelines, reviews and economic evaluations	- Cochrane Database of Systematic Reviews (CDSR) - Scottish Intercollegiate Guideline Network (SIGN) - The Campbell Collaboration - Database of Abstracts of Reviews of Effects (DARE) – last updated Dec 2014 - Health Technology Assessment (HTA) database – last updated October 2016 - International Guideline Library - Guidelines International Network - US National Guidelines Clearinghouse - Health Evidence - National Institute for Health Research's Health Technology Assessment Programme - Prospero - NHS Economic Evaluation Database (NHS EED) – last updated Dec 2014 - Bibliographic databases (where required)
Policy and legislation	- Government and other policy websites (for example, legislation.gov.uk) - Regulatory authority websites (for example, General Dental Council, General Medical Council)
Real world data	
Real world data (directory)	- RWE Navigator - Healthcare Quality Improvement Partnership (HQIP)

Datasets, audits, surveys, registries	- Adult Social Care Survey - Adult Inpatient Survey - Care Quality Commission - Clinical Practice Research Datalink (CPRD) - Community mental health survey - Cross-border Patient Registries Initiative (PARENT) - English Longitudinal Study of Ageing (ELSA) - GP Patient Survey - 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 - National Joint Registry - National Lung Cancer Audit - National minimum data set for social care (NMDS-SC) - NHS Digital - Clinical audits and registries - Data collections and data sets - NHS Improvement - Nuffield Trust

	- Prescribing Observatory for Mental Health (POMH) - Primary Care Mortality Database - QResearch - Regulation and Quality Improvement Authority - The Health Improvement Network (THIN) database - UK Cystic Fibrosis Registry - UK Renal Registry - 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 VoicesHealthwatch, 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 chapter 5 of the manual).

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.

The sources listed in appendix F 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)

- Database of Abstracts of Reviews of Effects (DARE) – last updated December 2014

- Embase

- Health Technology Assessment (HTA) – last updated October 2016

- MEDLINE/MEDLINE in Process

Economics

- EconLit

- NHS Economic Evaluation Database (NHS EED) – last updated December 2014

- CEA Registry

- 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 Information Resources 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, e.g. 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

- OpenGrey

- 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)

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

A call for evidence specifies the type of evidence being sought and, if appropriate, the review question being addressed. A call for evidence can be made at any point during the development of a guideline, but usually happens in the earlier stages. The time allocated for submission of evidence depends on the type of evidence and level of detail needed. A typical call lasts for 2 to 4 weeks, but it may be longer.

If it is likely that regulatory authorities hold relevant data, the appropriate regulatory authority may be approached to release those data as part of the call for evidence.

To simplify copyright considerations, 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. Copies of full papers, in electronic or hard copy form, should not be submitted in response to a call for evidence.

Submissions of evidence should contain sufficient detail of the methods used to conduct the study to enable NICE to conduct quality assessment.

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.

Registered stakeholders, relevant organisations or individuals approached are only able to submit evidence during a call for evidence, or during consultation on the draft guideline. Evidence submitted at other stages of guideline development is not considered, and the sender is informed.

Confidential information

Information or data that may be considered confidential 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 and the developer work with the data owners to agree a compromise between confidentiality and transparency, and strive to release as much information as possible. Any information that is still confidential is removed by the developer, and a note added to explain what has been done. NICE needs to be able to justify the recommendations in its guidelines on the basis of the evidence considered by the committee.

Documenting evidence received in response to a call for evidence

Information received from registered stakeholders, relevant organisations or individuals in response to a call for evidence should be recorded systematically and the details cross-checked against evidence identified through other searching (for example, to check if it has already been assessed). Information should be assessed in the same way as published studies identified through the searches (see chapter 6).

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.

Box 5.1 Examples of relevant 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

Business cases

Financial reports.

Analyses of primary data

Data from patient registries and healthcare databases

Studies of the experiences of people using services, their family members or carers, or practitioners

Data about the off-label use of medicines

Data on harms

Audit data

Implementation case studies

Economic models

Appendix K: Network meta-analysis reporting standards

Reporting of results of network meta-analysis 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 review in the context of what is already known, including mention of why a network meta-analysis has been conducted.

2. Specify study characteristics (for example, PICOS, length of follow-up) and report characteristics (for example, years considered, language, publication status) used as criteria for eligibility, giving rationale. 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. 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 network meta-analysis. 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:

e) Sensitivity or subgroup analyses.

f) Meta-regression analyses.

g) Alternative formulations of the treatment network.

h) 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, and so forth).

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).