NICE National Institute for Health and Care Excellence

Process and methods guides

Developing NICE guidelines: the manual appendices A to I

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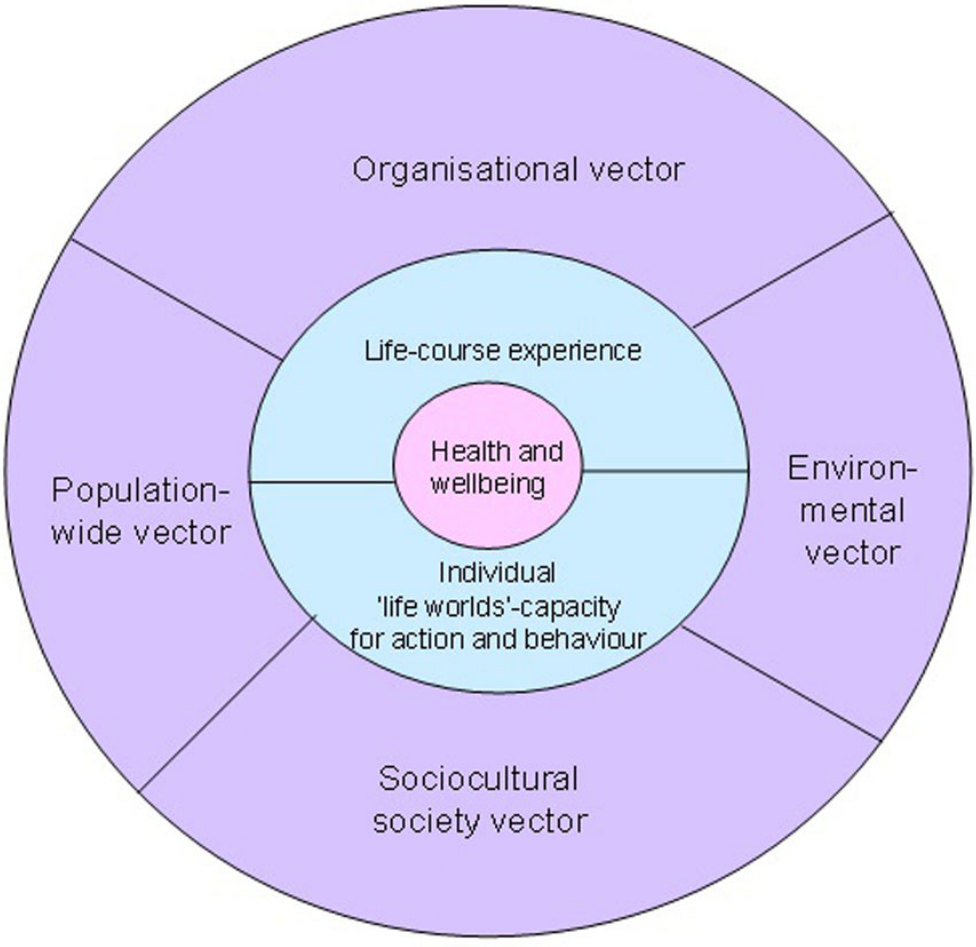
Contents

Appendix A: Conceptual frameworks and logic models – examples

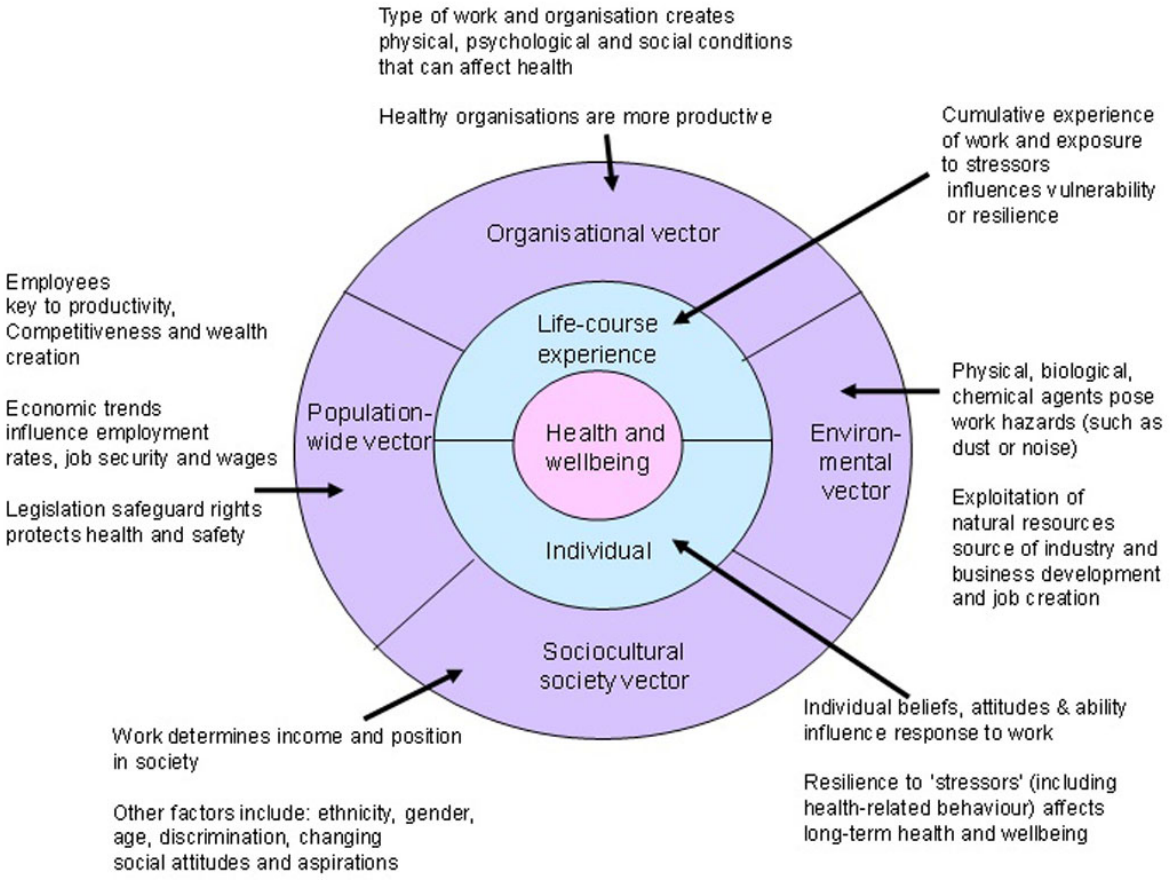
Conceptual frameworks will differ depending on the guideline topic and the issues being considered. Examples from the public health perspective are provided below, but other frameworks may be more appropriate depending on the topic and focus of the guideline.

A conceptual framework for public health interventions

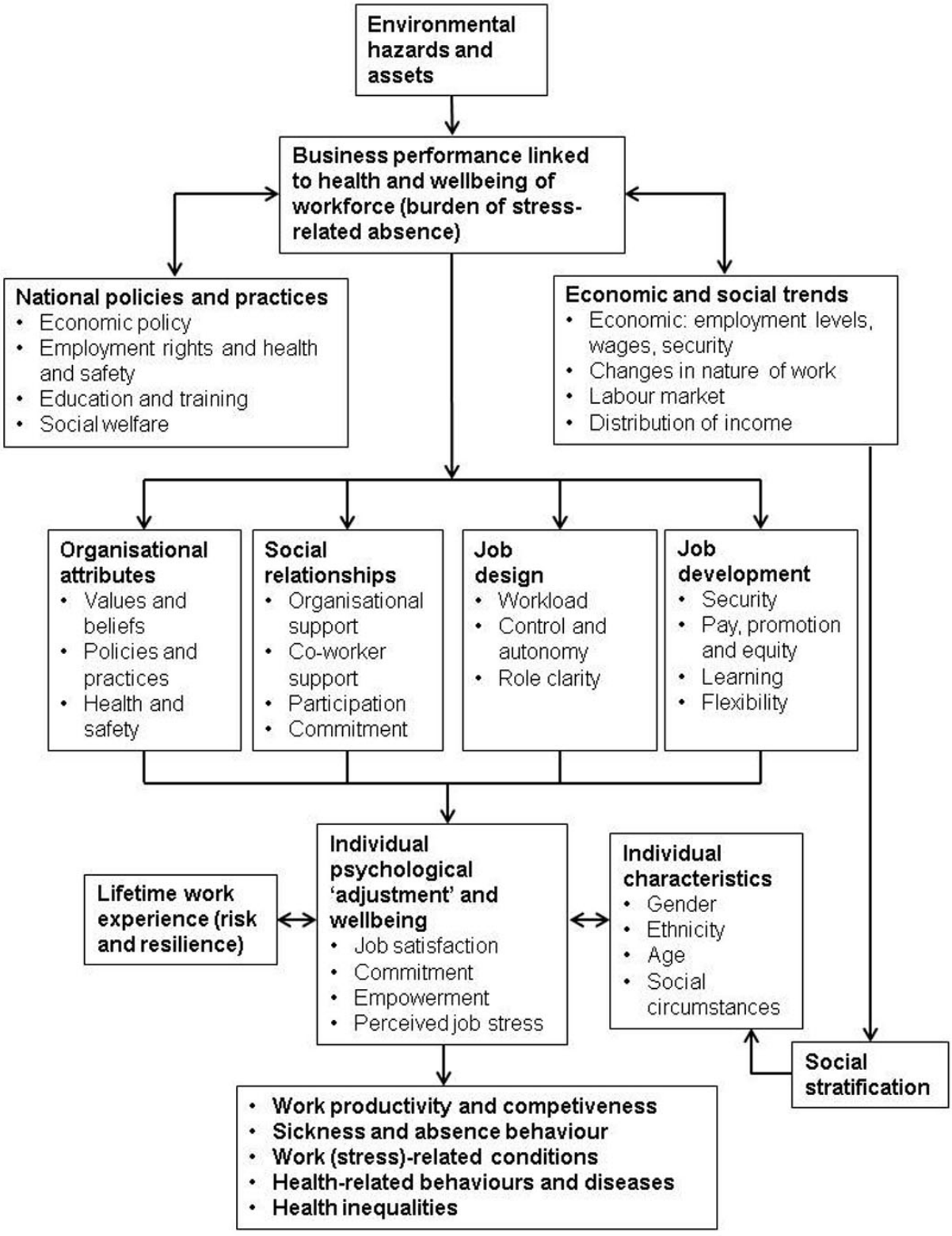
Kelly MP, Stewart E, Morgan A et al. (2009) A conceptual framework for public health: NICE's emerging approach. Public Health 123: e14–20



A conceptual framework for promoting wellbeing at work



A logic model for promoting wellbeing at work



Appendix B: Involving people affected by the guideline: children, young people and adults

This appendix sets out advice and points to consider when there is a lack of evidence on the views and experiences of people affected by the guideline, or when NICE's standard processes require adaptation or supplementation to incorporate user perspectives. This could be, for example, in topics covering children and young people, or people with a learning disability or cognitive impairment. It looks at additional work that may be required at 1 or more stages of guideline development.

For topics covering children and young people, NICE's patient and public involvement policy includes a set of principles for involving them and an appendix about safeguarding.

Planning

When starting the development of a new guideline which includes a population group unable to directly participate in the normal development processes[1], the Developer should consider the options for ensuring that these people's perspectives inform the guideline. This also applies to other population groups where the nature of the topic or the lack of evidence indicates that additional work may be required. This should be reflected in planning, including identifying resources for any additional work that may be needed. The perspectives of parents and carers are important but should not be regarded as a proxy for the experiences and views of people using services.

When the Developer engages with people affected by the guideline, they should ensure that participants receive feedback on their contribution or the findings of the consultation and how this information has been used. For commissioned work, the contractor should agree with the Developer an appropriate process for giving feedback to participants. The provision of feedback to participants should be specified in contracts.

Committee membership

The Developer, NICE's Public Involvement Programme (PIP) lead, and other contributors to the scope need to consider the ability and age range of the population covered by the topic and their implications for recruitment to the Committee. For some topics, it may be possible to recruit

young people aged over 16 or people with a cognitive impairment as members of the Committee, or as co-opted members or topic experts. The PIP lead can target adverts to specific groups, such as young people aged 16–25, and will work with the Developer on tailored support where this is needed.

Reference group of people using services (Committee 'subgroup')

When Committee membership is not possible, one option for the Developer to consider is the use of an additional reference group to help the Committee identify users' perspectives and priorities at key stages of guideline development. This could involve commissioning a stakeholder organisation or other agency with expertise in working with people affected by the guideline to set up and run the group. Properly supported, a reference group has the potential to provide insight about user perspectives on specific questions or issues identified by both the Committee and people using services themselves, at different stages of the process.

Addressing gaps in evidence

Where there is a lack of published or publically available evidence on issues of importance to people affected by the guideline, the Developer should consider seeking information via a targeted call for evidence (see section 5.5 of the manual). They could also consider approaching key stakeholders who may have access to additional data sources such as surveys of people's views and experiences, who could present this as expert testimony (see section 3.5 of the manual).

For certain gaps in evidence, it may be appropriate to seek expert testimony from lay experts (in person, in writing or by video). Relevant stakeholder organisations may be able to support this type of input. The PIP lead can offer advice, and help in communications with stakeholders.

There is no minimum age for young people providing expert testimony. If a child or young person under 16 attends a Committee meeting, they must be accompanied by their parent, carer or other appropriate adult with responsibility for their welfare. For children contributing evidence to Committee meetings, special measures may be needed, such as giving testimony via video recording, or in private session. See the appendix on safeguarding in NICE's patient and public involvement policy.

Exceptionally, where the information gap cannot be addressed through existing mechanisms, the Developer may commission a consultation exercise with people affected by the guideline to obtain their views. For example, views may be sought on:

- specific aspects of the guideline, review questions or issues raised by the Committee that they would like more information on
- draft recommendations before or during stakeholder consultation.

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

- 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
- young patients were surveyed (in the absence of evidence) about their experiences of sedation for diagnostic and therapeutic procedures
- looked-after children and young people were consulted about their experiences of services as part of a practice survey and then later, the draft recommendations were tested with them.

(See Further information for more detail.)

Consultation on draft recommendations

The stakeholder consultation stage provides an opportunity for relevant organisations to include the views of people affected by the guideline in their responses to the draft guideline. NICE should encourage this in questions or points for stakeholders to consider as part of the consultation. However, for some topics this process may not be adequate.

In such exceptional cases, the Developer may commission a 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, as in the guideline on children and young people on the autistic spectrum (see 'Further information').

The main reasons for testing selected draft recommendations directly with people affected by the guideline are where:

- the topic covers novel or sensitive areas, or
- the evidence on the views of people using services is weak or lacking, or
- people using services have not participated in guideline development and they are unlikely to participate in stakeholder consultation on the draft guideline (for example, children).

Consultation methods and processes

Where a targeted consultation is required, the Developer should commission an agency with relevant expertise and a good track record in working with people affected by the guideline and using appropriate research techniques. The Developer should consider the recruitment strategy and choice of methods carefully, in line with the purpose of the consultation, taking into account the topic, the groups, the range of views required, and other relevant issues. It is important to engage seldom heard people in consultation processes, where relevant to the guideline. When planning a consultation with children and young people, school holidays and exam schedules need to be taken into account so as not to adversely affect timelines for the consultation and the feasibility of recruiting enough participants.

The consultation should be tailored to the age, ability and culture of participants, with materials and activities designed and adjusted to suit them. The contractor should agree the approaches to use with the Developer, including the process for giving feedback to participants on the findings and how they have been used. Similarly, the methodology, questions and support materials must be developed and agreed with the Developer.

The main types of methods that may be appropriate include:

- group-based methods such as focus groups, participative workshops and 'virtual' (electronic) groups
- 1-to-1 or paired in-depth interviews carried out face-to-face, by telephone or electronically
- surveys carried out by telephone, electronically, on paper or by using vote casting or polling.

Group-based methods and interviews are best for finding out how people feel and exploring topics in detail.

The most appropriate method should be determined by the Developer and contractor, taking into account the needs and preferences of the specific population involved in the consultation.

Techniques for eliciting people's views need to be tailored to suit the participants. For example, written methods will not work for people who cannot read or write well. When consulting young children, play based approaches are a good way of communicating with them. With older children and young people, games can work well, along with more conventional qualitative techniques. If questionnaires are used with young people, they should be kept short, taking no longer than 10 minutes to complete. Ideally, young people should be involved in designing both the content and style of the questionnaire (see Lightfoot and Sloper 2002).

The Developer should document the rationale for undertaking the targeted consultation, with a proposal including consideration of the methods to be used, and the anticipated 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 rationale and methods should be documented in the guideline.

Ethical issues

When commissioning work with people using services (and families and carers, where appropriate), Developers should satisfy themselves that the contractor has the appropriate expertise, policies and procedures for ensuring the safety and welfare of participants. The Developer and the contractor should consider the ethical issues and whether formal ethical approval is required. If there is any doubt, the contractor should consult the National Research Ethics Service. The contractor is responsible for seeking ethical approval, if required.

Further information

References and further reading

Lightfoot J, Sloper P (2002) Having a say in health: guidelines for involving young patients in health services development. University of York: Social Policy Research Unit

Shaw C, Brady L-M, Davey C (2011) Guidelines for research with children and young people. London: National Children's Bureau

See also references in appendix I.

Support from NICE's Public Involvement Programme

The Public Involvement Programme (PIP) offers advice and support to Developers and Committees on methods for involving people using health and social care services, carers and the public. We can:

- Advise on options and methods for involving people affected by the guideline, including consultation exercises to obtain their views. We can also signpost to external resources and sources of more specialist advice.
- Communicate with key stakeholders to encourage them to provide information on the views and experiences of people affected by the guideline.
- Target recruitment to attract applications for Committee membership from young people (16 years and over) and provide tailored support to those recruited.
- Comment on consultation proposals, protocols, consent forms, etc.

Examples of consultations commissioned by Developers

Management of autism in children and young people (2013) NICE guideline (CG170). The National Collaborating Centre for Mental Health commissioned the National Autistic Society (NAS) to consult people using services on emerging draft recommendations (developed on the basis of a qualitative literature review) for improving access to and experience of care. The NAS ran focus groups and conducted individual interviews with children and young people on the autistic spectrum. 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. See chapter 4 of the full guideline on the management and support of children and young people on the autism spectrum for further information.

Sedation in children and young people (2010) NICE guideline (CG112). In the absence of evidence on what it was like to be a child receiving sedation, the National Clinical Guidelines

Centre worked with Alder Hey Children's Hospital to survey children and young people 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. (The data collection system had been developed with input from children and young people.) See chapter 7 of the full guideline on sedation in children and young people for further information.

Self-harm (2004) NICE guideline (CG16). To inform the development of this guideline, Developers sought the views of adults who self-harmed on their experiences of services during the first 48 hours of care after an episode of self-harm. The findings from focus group discussions and an interview contributed to some of the guideline recommendations; for example, service users told researchers that they were not routinely offered anaesthesia or pain relief for sewing up wounds in the hospital emergency department. There was nothing in the published research to indicate this was an issue. The published guideline includes recommendations on adequate anaesthesia/analgesia and staff training to address this problem. See appendices 13–16 of the full guideline on self harm for further information.

Looked-after children and young people (2010) NICE guideline (PH28). For this joint NICE/Social Care Institute for Excellence (SCIE) guidance, looked-after children and young people were consulted during guidance development and again at the validation stage.

- SCIE commissioned Action for Children to conduct a 'practice survey' with children, young people and carers, as well as practitioners. This used SCIE's practice survey methodology to identify innovative and emerging practice in assessing, maintaining and improving the health and wellbeing of looked-after children and young people. The survey sought views about the acceptability, accessibility and effectiveness of targeted and specialist, as opposed to universal, interventions. See the practice survey main report (C3) for further information.
- Alongside fieldwork with practitioners, Action for Children was commissioned to gather the views of looked-after children and young people about the relevance, usefulness and acceptability of appropriate sections of the draft guidance. See the consultation on draft recommendations report (C4) for further information.

[1] These population groups could include children and young people, people with a learning disability or cognitive impairment, or people whose severity of illness prevents them, for example, becoming a Committee member.

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).

The Chair needs an understanding of NICE's guideline development process, and may have some background knowledge about the guideline topic. 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 evidence review team.

To facilitate the effective working of the Committee, the Chair:

- may be involved in the developing the scope and setting boundaries for the work
- runs the Committee according to the principles set out in the Terms of Reference and Standing Orders
- helps to plan the Committee meetings
- establishes a climate of trust and mutual respect among members
- provides opportunities for all members, particularly disabled people who are members, to contribute to the discussions and activities of the Committee.

The Chair also offers Committee members, on an annual basis, feedback and comment on their contribution for revalidation purposes or personal development. The Chair is offered feedback and comment on their own contribution on an annual basis from a senior member of NICE staff.

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 and evidence review team 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 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 and evidence review team 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 with NICE's implementation team. This will provide contextual information, inform the development of the information on implementation in the guideline and help NICE to signpost to or develop support products 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:

- review the evidence
- search the literature
- write the guideline.

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
- advise on the practicality of implementing the guideline (for example, medicines adherence)
- help ensure that recommendations address issues and concerns of people using services, their family members and carers, and the public (where relevant).

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 where requested, 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 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
    - follow NICE's equality policy and take account of socioeconomic factors and their influence on health and ill health
    - adhere to NICE's principles on social value judgements

- sign a declaration of interest form and inform NICE of any additions or changes to declared interests throughout the development process, in accordance with NICE's code of practice for declaring and dealing with conflicts of interest
- 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

1. 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.
2. Committee members will be drawn from the NHS, local government, the academic community and other areas, as appropriate, and as agreed by the Developer and the staff with responsibility for guideline quality assurance, and will include practitioners, commissioners and providers, people using services, their family members and carers, and advocates.
3. 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.
4. Co-opted members may be included as additional members of a standing 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.
5. 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. Expert witnesses have no voting rights and do not count towards the quorum.

Standing orders

General

1. 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.
2. 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.
3. 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.
4. 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.
5. The Chair and members of the Committee will be appointed in accordance with NICE's policy on Committee recruitment.
6. 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.

7. For **topic-specific Committees**, the Chair and members of the Committee will be appointed for the duration of the development of the guideline. Alternatively, a standing Chair will be appointed for an initial period of up to 3 years. This may be extended by mutual agreement to a further term of 3 years and up to a maximum term of office of 10 years.
8. 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 3 years and up to a maximum term of office of 10 years.
9. For standing Committees, when a Committee member is appointed Chair of the Committee of which they are a member, it will count as a new appointment.
10. 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.
11. The removal or substitution of Committee members and the general constitution of an advisory Committee shall be at the discretion of NICE
12. 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

1. 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.
2. 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

1. Meetings will be conducted by the Chair or in their absence, an officially appointed Vice-Chair or a nominated deputy.

2. The Vice-Chair will be appointed in accordance with NICE's policy on Committee recruitment.
3. The Vice-Chair's appointment will be for the duration of guideline development.
4. 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.
5. The Chair, or the Vice-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.
6. 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 NICE's code of practice for declaring and dealing with conflicts of interest
    - 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.
7. The Chair must ensure that NICE's equality policy and principles on social value judgements are adhered to. The Chair signs off the equality impact assessment at scoping and final guideline stages.
8. The Chair approves the draft guideline before sign-off by NICE, and advises the Developer on responses to stakeholder comments as appropriate.

Voting

1. 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.
2. Voting will be anonymous and decisions determined by a simple majority of Committee members present at a quorate meeting.
3. 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.
4. Only Committee members present at the meeting will be eligible to vote. There will be no proxy voting.
5. Expert witnesses, co-opted members and observers will not be eligible to vote.

Quorum

1. The quorum is set at 50% of Committee membership and includes both core and topic expert members and the Chair (but excludes co-opted members, expert witnesses and observers). Quorum should be based on the number of people in post, rather than the total potential membership. The quorum should be rounded up to the next whole number when there is an odd number of Committee members.
2. No business should be transacted unless the meeting is quorate. If a member is excluded because of a conflict of interest and membership falls below the quorum, no business may be transacted. There is no time limit for a quorum to be achieved but the start of the meeting or business transaction should be delayed if the meeting is not quorate.
3. The quorum must be achieved for the meeting to proceed. However, the needs of the Committee are such that even if the meeting is quorate, an appropriate spread of members' interests should be represented at each meeting. If, in the view of the Chair, the spread of interests is insufficient for the business under consideration, the meeting may be suspended or adjourned until a later date.

Collective responsibility

1. 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.
2. 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

1. On appointment, Committee 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.
2. 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.
3. 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.
4. Expert witnesses, co-opted members and observers invited by the Committee will sign a confidentiality form if confidential information is included in meeting papers, or if attending a part 2 discussion where meetings are held in public.

Arrangements for meetings

1. NICE will ensure that Committee meetings take place in venues that are accessible to, and have facilities for, disabled people.
2. Meetings of the Committee shall be held at such times and places as are deemed necessary to facilitate the conduct of its business.

3. 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.
4. Developers shall determine which aspects shall appear on every agenda in advance of each meeting.
5. Any other business shall be discussed at the discretion of the Chair.
6. Public access will be enabled to meetings of standing Committees; topic-specific Committees will be held in private.
7. 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 60 and 64 will apply.
8. Only members of the Committee and NICE staff, co-opted members, observers invited by NICE, the evidence review team and 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.
9. 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.
10. Meetings will normally begin at 10:00 am and finish no later than 5:00 pm unless otherwise advised.
11. 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.
12. Laptops and other devices are to be used in a Committee meeting by members solely to refer to the papers for the meeting.

13. The Developer will make all reasonable attempts to agree each meeting date in advance and Committee members are expected to keep these dates free until they are released.

Access by members of the public

1. When Committee meetings are open to the public, the following provisions will apply.
2. 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.
3. 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].
4. 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

1. NICE staff and invited guests (for example, visiting academics) may attend Committee meetings as observers, with the permission of the Chair.
2. 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.

3. Observers can attend part 2 of meetings held in public if the Chair and Centre Director agree. Observers who are not NICE staff or are not commissioned to provide a service to NICE should sign a confidentiality agreement if they wish to attend part 2 of the meeting.

Minutes

1. The draft minutes of the Committee meetings shall be drawn up and submitted to the next meeting for approval.
2. 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

1. All Committee members must make an annual declaration of interests in accordance with NICE's code of practice for declaring and dealing with conflicts of interest.
2. All members must make a declaration of any potential conflicts of interest that may require their withdrawal in advance of each meeting. This declaration will be reaffirmed again at the start of each meeting. Declarations of interest will be recorded in the minutes and published on the NICE website.
3. 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.
4. Experts invited to provide expert testimony, and co-opted members will make a declaration of interest before Committee meetings and in accordance with NICE's code of practice for declaring and dealing with conflicts of interest. 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.

Suspension of Standing Orders

1. Except where this would contravene any statutory provision, any 1 or more of the Standing Orders may be suspended at any meeting providing a simple majority of those present and eligible to participate, vote in favour of the suspension.

2. Any decision to suspend Standing Orders shall be recorded in the minutes of the meeting.
3. No formal business may be transacted while Standing Orders are suspended.
4. NICE's Audit Committee shall review all decisions to suspend Standing Orders.

Petitions

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

Recording of meetings

1. The recording of proceedings or the taking of pictures at Committee meetings by public attendees is not allowed.
2. 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.

Terms of Reference

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

Record of attendance

1. A record will be kept of Committee members' attendance at Committee meetings via the minutes.
2. 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.
3. Members of topic-specific Committees are expected:
    - to attend all of their Committee's meetings.

4. If Committee members are unable to attend a Committee meeting, deputies are not permitted.
5. Members who are unable to meet either of these expectations may be asked to stand down from the Committee in accordance with Standing Order 19.
6. 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.

Review of Terms of Reference and Standing Orders

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

Date: October 2014

Review date: October 2017

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 stakeholders 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 and makes social value judgements
- 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 the principles set out in NICE's principles on social value judgements 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. If members are from stakeholder organisations, NICE and the Committee assume that these members bring this perspective to the group, and are not representing their organisations. For topic-specific Committees, members are appointed for the

development of a guideline. Standing Chairs of topic-specific Committees and members of standing Committees are appointed for a 3-year period, with membership subject to renewal for a period of up to 10 years.

Committee members are co-authors of the guideline. They should respect the rights of NICE both to publish the final guideline and associated products (for example, products to support implementation) and to receive notification 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
- provide all members of the Committee with appropriate access to available resources and to the evidence used in the development of the guideline
- meet the support needs of disabled people who are Committee members
- offer appropriate training to Committee members to enable them to play a full part in the development of the guideline
- provide Committee members with feedback and comment on their contribution, when requested for revalidation or personal development
- provide technical support 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 social value judgements 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 and includes open debate in public. 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, 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: 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) • Websites of national organisations (e.g. 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 Better Health briefings) • Patient and service user organisation websites (NICE's Public Involvement Programme (PIP) can advise further)
Policy and legislation	• Government and other policy websites (for example, gov.uk) • Regulatory authority websites (for example, General Dental Council, General Medical Council)

Guidelines, reviews and economic evaluations	• Cochrane Database of Systematic Reviews (CDSR) • The Campbell Collaboration • Health Technology Assessment (HTA) database • International Guideline Library • National Institute for Health Research Health Technology Assessment Programme • NHS Economic Evaluation Database (NHS EED) • Health Economic Evaluations Database (HEED) • Bibliographic databases (where required)
Information on current practice	• Audit Commission • Care Quality Commission • Guidelines & Audit Implementation Network – GAIN Audits • Health and Social Care Information Centre • National Clinical Audit and Patient Outcomes Programme (NCAPOP) • National Audit Office • Bibliographic databases (where required)
Statistics	• Health and Social Care Information Centre • UK Data Service • UK National Statistics • Disease-specific statistics, for example, CancerStats

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, HealthTalkOnline, YouthHealthTalk, PatientVoices) • Patient and service user organisation websites (NICE's Public Involvement Programme (PIP) can advise further) • Bibliographic databases (where required)

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

- 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 Effectiveness (DARE)
- Embase
- MEDLINE/MEDLINE in Process

Economics

- EconLit
- NHS Economic Evaluation Database (NHS EED)
- Health Economic Evaluations Database (HEED)

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)
- Social Care Online
- Social Policy and Practice
- Social Science Citation Index
- Social Services Abstracts
- Sociological Abstracts

Other

- Allied and Complementary Medicine (AMED)
- OpenGrey
- Physiotherapy Evidence Database (PEDro)
- SportDiscus
- Transport
- UK Database of Uncertainties about the Effects of Treatments (DUETS)

Websites

- Websites of national organisations, e.g. Care Quality Commission, Department of Health, NHS England, Public Health England

- Websites of professional bodies and other organisations relevant to the topic
- HealthTalkOnline
- YouthHealthTalk
- 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

Ongoing trials

- ClinicalTrials.gov
- Current Controlled Trials
- United Kingdom Clinical Research Network's (UKCRN) Portfolio Database

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

Appendix H is contained in a separate PDF.

Appendix I: Fieldwork

Introduction

This appendix outlines points to consider when the decision has been made to conduct fieldwork for draft recommendations on a particular topic. Fieldwork is carried out only on an exceptional basis for guidelines in new or sensitive areas, and not as a matter of routine on all guidelines. Often, particularly for those topics where there are already related NICE guidelines, fieldwork findings add little to the insights generated by the consultation with stakeholders. Nevertheless, for areas in which NICE does not yet have good links with key practitioners and stakeholder groups it can be a valuable part of the guideline development process.

Exceptions where fieldwork would be carried out include occasions when NICE develops a guideline in a new or (scientifically or politically) controversial topic area. For an exception to be made, the case will need to be put to the NICE Centre Director for approval. During fieldwork, the draft recommendations are tested with policy makers, commissioners and practitioners to identify the barriers and facilitator to putting these into practice. Consultation with people affected by the guideline may be carried out at the same time as fieldwork with practitioners (see appendix B).

This appendix provides an overview of the fieldwork process including:

- points NICE considers when deciding to conduct fieldwork
- aim of fieldwork
- guiding principles of fieldwork
- commissioning process
- approaches used
- way ethical approval is achieved
- methods used
- analysis of data
- structure of the fieldwork report.

It concludes by describing how the fieldwork findings are used to finalise the recommendations and inform the implementation section of the guideline.

Points to consider when deciding to conduct fieldwork

A number of issues help NICE decide whether to conduct fieldwork in addition to the standard public consultation and evidence gathering processes. These issues can occur at different points during guideline development and will vary depending on the topic under consideration. Examples include considering whether NICE has developed any public health, clinical or social care guideline for a particular area, for example oral health, or taking into account any concerns raised by key stakeholders.

In other cases it may be that additional health and social care inequalities or impacts on equality are a concern, for example, a referral to develop guidelines for populations who find it difficult to engage with health and social care services.

In other circumstances it may be when a topic is particularly complex and requires a whole system approach. In this case the configuration of services may be a central component of the efficacy of a set of recommendations and input from a particular sub-set of health and social care practitioners may be required.

Other issues to consider will be whether the topic includes an area of rapidly changing practice. For example, advances in some areas of frontline practice can occur quickly on the ground and reports or publication of evidence lags behind. In this example it may be necessary to test the draft recommendations with frontline practitioners, or providers or commissioners of services.

These are just a few examples of the types of considerations NICE will take into account at particular points during guideline development when deciding whether to commission fieldwork. Some of these considerations also apply to decisions about testing draft recommendations with people affected by the guideline (see appendix B).

Aim of fieldwork

Fieldwork tests the feasibility of recommendations and identifies barriers and facilitators to their implementation with policy makers, commissioners, health and social care providers and practitioners. Practitioners may include people working in voluntary and community

organisations, as well as professionals such as GPs, nurses, social workers, nursing home managers and teachers.

People's experience and views are used to fine-tune the recommendations. The aim is to ensure they are understood and interpreted as the Committee intended, without the need for any additional information. This is important because many users read only the recommendations, and the NICE Pathway developed for the guideline contains the recommendations without the evidence or other information.

Guiding principles

Recommendations developed by the Committee are based largely on evidence presented in the reviews, particularly evidence about the effectiveness and cost effectiveness of interventions and programmes. This allows assessments to be made about the plausibility of an intervention or programme, under different circumstances and with different populations.

However, successful implementation depends on evidence-based recommendations being informed by practical experience. The context in which practitioners will be implementing the recommendations also needs to be considered, and practitioners are in the best position to advise on this. Such advice is generally provided by the Committee and through stakeholder involvement. As noted above, there are some situations where this advice is sought more widely. The aim of fieldwork is to determine:

- how feasible the recommendations are
- what barriers or challenges practitioners will face
- what facilitators, levers or opportunities exist to develop practice
- what support might be needed.

The following principles underpin fieldwork:

- High-quality fieldwork elicits practitioners' knowledge in a transparent, reliable and systematic way.
- Draft recommendations are presented as indicative only of what might work.

- Fieldwork allows participants' needs to be taken into account in the final recommendations.
- Fieldwork seeks to test the impact of draft recommendations on inequalities in health and social care, equity, and equality and diversity.

The exact questions participants are asked will vary from topic to topic, but **3 areas always need to be considered**:

- **Content of the recommendations** Are the recommendations relevant and appropriate for the groups responsible for delivering them? Are they clear and easy to understand for all these groups?
- **Practice** What is current practice in the area? How might these recommendations build on or change current practice or service provision? What are the implications of this? Should any other elements be covered in the recommendations?
- **Impact** What are the barriers to, and opportunities for, implementing the recommendations? What further resources, training or support might be needed? Are the recommendations relevant to other groups of practitioners? What is the best way to get information to the range of groups of practitioners involved? Are the recommendations sustainable? How would participants prioritise the draft recommendations?

The Developer should document the rationale for undertaking the fieldwork, with a proposal including consideration of the methods to be used, and the anticipated 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 rationale and methods should be documented in the guideline.

Fieldwork commissioning

NICE should commission an academic or research organisation to carry out the fieldwork. This organisation should be separate from the review team involved in compiling evidence reviews for the guideline, unless there are exceptional circumstances. (An exception might be made if, for example, specific expertise in the topic, or access to specialist networks, is needed). However, the review team may be asked to help the fieldwork contractor, for example, by generating a list of participants.

The fieldwork contractor should have a good track record in health- or social care-related qualitative or participatory research and, ideally, should have experience in the guideline topic area.

The commissioning process should adhere to 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.

Approaches to fieldwork

Fieldwork is a qualitative exercise; a range of views are required and it can involve a number of methods. NICE and the relevant Committee should consider the choice of methods carefully, taking into account the topic, the practitioner groups involved and other issues. It 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 practitioner groups are involved – a combination of approaches may be used.

The fieldwork contractor should agree the approaches to use with NICE. Similarly, the methodology and any questions or support materials used must be developed and agreed with NICE.

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
- NICE can contact enough practitioners in a geographical region to set up a focus group or workshop
- the issues discussed are unlikely to be confidential or professionally sensitive and anonymity will not be necessary.

1-to-1 or paired in-depth interviews

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

- it is not possible to get groups of practitioners together because it's a relatively new area, the number of possible participants is limited or there are geographic or time constraints
- the issues discussed are likely to be confidential or professionally sensitive and anonymity may be needed
- in-depth responses are needed.

Surveys

Group-based methods and 1-to1 or paired interviews (as outlined above) are the best way to find out participants' 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, electronically, on paper or by using vote casting or polling.

Surveys gather opinions in a quick, less obtrusive manner than group-based approaches and interviews. In addition, the responses can be quantified. But they do not allow the same depth of exploration and, generally, should only be used if other methods are unsuitable.

Ethical approval

In principle, fieldwork falls into the category of 'service evaluation' and so is outside the remit of NHS research ethics committees. However, NICE and the fieldwork contractor should consider the ethical issues each time fieldwork is planned. (If there is any doubt, the contractor should consult the National Research Ethics Service). The fieldwork contractor is responsible for seeking ethical approval, if required.

Fieldwork methods

The fieldwork contractor should agree any changes to the protocol for fieldwork with NICE before the fieldwork starts.

Fieldwork participants

Participants should be chosen to represent a broad range of stakeholder groups in the statutory, non-statutory and voluntary sectors. This may include people who work with the target populations covered by the guideline and other users of the guideline, such as service commissioners. It may also include practitioners working indirectly to promote the aspect of health or social care covered by the guideline. Please note, fieldwork participants do not have to be from an organisation that is registered as a NICE stakeholder.

Equality issues should be fully considered when choosing fieldwork participants. This may mean getting a representative spread of practitioners, but it may also mean focusing on participants with recent experience of working with disadvantaged groups. The approach should be based on the content of the recommendations, whether or not they refer to the whole population or subgroups of it and service delivery and policy issues.

Participants can include commissioners, policy officers, GPs, surgeons, health visitors, social workers, service managers and educational welfare officers.

Participants should also:

- have relevant experience and knowledge of the guideline topic
- operate mainly (but not exclusively) in a regional or local capacity.

Sampling

Sampling should be guided by the topic. It will depend on the:

- stakeholder groups identified as being responsible for taking action
- ultimate beneficiaries of 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 practitioner groups are represented.

Random sampling (randomly selecting participants from the relevant practitioner 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 practitioners, but there are not enough of them in each relevant geographical area.

The fieldwork report should explicitly state how participants were identified, sampled and recruited. The fieldwork contractor should ensure the final sampling frame and sample take account of the equity focus. It should be agreed with NICE.

Conducting the fieldwork

Once the method has been chosen (see the section on approaches to fieldwork), a summary of the issues to be covered should be developed. The summary should be based on the draft recommendations (and the related evidence statements and links from evidence to recommendations) and the 3 key areas of inquiry outlined in the section on guiding principles. The quality of the fieldwork approach (including sample and method[s] selected) should be quality assured by NICE. NICE should:

- brief the fieldwork contractor in detail before work begins
- agree final documents and comment on draft recruitment letters
- help develop topic guides (summaries of the recommendations and key questions for discussion)
- agree interview schedules or sampling frames and samples, and other supporting materials
- discuss how to get participants who work with key or vulnerable groups involved
- attend fieldwork groups and/or observe interviews (where possible)
- have access to transcripts of all data
- discuss and agree techniques for data analysis and themes for data presentation

- comment on the fieldwork report before the final draft is submitted.

Group-based approaches

The criteria for organising group-based fieldwork are outlined below. They can be adjusted to accommodate a particular fieldwork process, although the fieldwork contractor should agree any deviations from the set criteria with NICE. For further information about preliminary work in this area, see Kelly et al. (2004).

- The final sampling frame, recruitment and sample must be agreed with NICE and must take into account any planned comparisons between, for example, professions or geographical areas.
- Usually, between 4-6 fieldwork workshops or focus groups should be convened. These should take place in more than 1 geographical region and will normally be a half day but may be up to a day long. 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.
- Independent professional facilitators should be selected to lead each meeting. A background in the topic under consideration is not essential, but it is essential to have knowledge of the context and the methods used to translate research evidence into practice. Facilitators also need an understanding of the wider public sector (and other sectors, as appropriate, according to the range of practitioners attending the fieldwork sessions).
- The decision on how many to invite to each workshop or focus group should be discussed and agreed with NICE.
- If it suits the needs of the project, separate workshops or focus groups can be arranged for different practitioner groups. This will depend on the number of participants and should be agreed with NICE.
- For some topic areas, researchers need to be included in the fieldwork. 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, supporting evidence statements and the key areas of concern – see the section on guiding principles) must be developed in collaboration with, and agreed by, NICE.

- A member of the NICE implementation team should attend at least 1 fieldwork meeting.
- A member of the NICE team that commissioned the fieldwork may attend workshops or focus groups to answer any technical questions, but they should not be involved in the discussions.

1-to-1 or paired, in-depth interviews

The sampling for 1-to-1 or paired, in-depth interviews should follow the procedures outlined in the section on fieldwork methods. Specifically:

- Sampling frames, techniques and recruitment must be agreed with NICE.
- Samples and sample sizes must be agreed with NICE, taking into account any planned comparisons of practitioner groups that may be needed.
- Interview schedules must be developed in collaboration with, and agreed by, NICE.
- Any prompts or supporting materials (such as the draft recommendations, supporting evidence statements and the key areas of concern – see the section on guiding principles) should also be developed with, and agreed by, NICE.

Interviews may be structured or semi-structured, depending on the topic and the practitioner 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 the draft recommendations (and related evidence statements) and the 3 key areas of inquiry, as outlined in the section on guiding principles.

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.

Survey methods

If survey methods are used, sampling and recruitment should follow the principles outlined in the section on fieldwork methods. The fieldwork contractor should agree the approach, the sampling frame, final sample, how the survey will be done, and survey questions or the use of supporting materials with NICE.

Distribution and day-to-day management of any surveys used is the responsibility of the fieldwork contractor.

Recording groups and interviews

The way groups and interviews are recorded depends on the methods used. For example, software that automatically produces transcripts is available for online focus groups. This would differ from the way a 'traditional' face-to-face focus group would be recorded. The plenary discussions, group work and interviews should all be recorded (for example, on tape or digitally and then transcribed, or by using a scribe). Previous experience has shown that stenography is the best way for a scribe to record the points. All participants should consent in writing to the recording – and to its use in discussions and group work.

If a scribe is used, he or she should accurately record points raised against each question (mediating factors, barriers and solutions). They may also categorise each point according to whether it relates to strategy and policy development, commissioning, management or individual practice.

Structure of the fieldwork

The structure of fieldwork events depends on the methods adopted. Presentations may be used, for example, to give an overview of the recommendations (and if appropriate, the guideline document). In such cases, they should be kept succinct to make best use of time and strike the right balance between passive and active participation.

Topic guides, generated by the contractor (and approved by NICE), should be circulated to fieldwork participants before or at the beginning of sessions to facilitate discussions.

Workshops, focus groups and interviews should be based on the structure outlined below. The structure will differ for surveys, but the elements outlined below should still be covered. If the fieldwork contractor wants to make any changes to the content and structure of sessions, it should agree them beforehand with NICE.

Session 1: purpose of the meeting

The lead facilitator explains the aims and objectives for the day and the values underpinning NICE's fieldwork process (see the sections on points to consider when deciding to conduct

fieldwork and aim of fieldwork). The facilitator describes the guideline development process, introduces the draft recommendations and describes how participants will help refine them. They should make explicit reference to health inequalities and impacts on equality – and so to the importance of judging the impact of interventions on different segments of the target population. The initial presentations may take around 20 minutes.

Session 2: participants' working environments

Participants consider the draft recommendations and comment on the context in which they operate. Social, political and economic factors relevant to participants' work – and the communities that they serve – may be raised here. This session may last for up to an hour.

Session 3: appraisal of draft recommendations and evidence statements

Group work can be run in different ways, depending on the project. For example, a large group convened on the same day can be subsequently divided into 4 or 5 multidisciplinary groups, each working with a facilitator. Alternatively, different sessions set up on different days can be arranged for each practitioner group – each with a facilitator.

If interviews (rather than groups) are being used, a series of 1-to-1 or paired sessions may also be set up.

Discussion focuses on the following question:

> 'Given that the evidence suggests that a particular kind of intervention/activity has worked in the following circumstances, and that this should form the basis of a recommendation, what would need to be done to make it work in your local situation?'

A follow-up prompt is:

> 'If this would not work, why not – and what would?'

Social and marketing research techniques can sometimes be useful (such as role play). It can also be useful to develop tools to help participants assess the feasibility and impact of each recommendation (for example, electronic key pads or q-sort techniques to help prioritise and sort sets of standard statements). Any techniques or tools used would need to be agreed with NICE.

Participants should also be asked to address the implications for health and social care inequalities and generally for their own practice or profession. To conclude, discussion could consider barriers to – and facilitators of – change, including potential local drivers for change.

Other issues that may be raised include:

- political drivers and imperatives for activity planning
- decision and influence
- partnerships
- budgets
- stakeholders
- consultation
- commissioning
- shared data and information services
- performance management
- prioritisation of recommendations
- examples of local good practice that may support the recommendations.

Session 4: feedback

At the end of group sessions, the facilitator may provide plenary feedback about the participants' view on implementation barriers, opportunities and solutions. Case study templates should be distributed for participants to note any points that have come up during the day or to submit case studies of local 'good practice'. These should be collected at the close of the session, or returned to the team by a specified date. Forms should be clearly marked with instructions for completion and return.

Evaluation and follow-up

At the end of each workshop, an evaluation of it may be completed by all participants. The facilitators should then liaise to share notes and transcripts. The fieldwork contractor should use

these as a basis for the fieldwork report. All original notes should be retained. Summary notes of each workshop or interview should be circulated to participants to check for accuracy.

Fieldwork analysis

Fieldwork analysis is dependent on the methods adopted but the following points are a guide. The fieldwork contractor should agree the way data are presented and analysed with NICE.

Data presentation

The fieldwork groups' discussions and/or interviews should be transcribed in full (electronically or by hand). If a survey approach has been used, responses should be collated, transcribed or recorded in full.

Analysis

The methods used for the fieldwork will affect how the analysis is done.

- For group-based fieldwork, data analysis should begin as soon as possible, and preferably in time to be included at the next fieldwork session. This approach may also be feasible if interviews and surveys are being used.
- For 1-to-1 interviews and surveys, analysis is usually carried out at the end of data collection.

Analysis may be performed using qualitative research software, or by hand, but the method should be fully reported in the fieldwork report.

The fieldwork data should be broken down into common and consistent themes, framed by the research questions, using a content analysis approach. Usually, 1 researcher should prepare an initial analysis. This 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 7–13) of Silverman (2004) or Ritchie and Spencer (1993).

Once the analysis is complete, participants' quotes should be selected to illustrate each theme. These quotes should be coded to keep participants anonymous and to allow the quotes to be distinguished (see the section on data presentation above).

Fieldwork report

The fieldwork report sent to the Committee is a summary of analysed fieldwork data and key points arising from it. An electronic copy of the final fieldwork report should also be sent to all participants by the fieldwork contractor.

Style and transcription notation

The fieldwork report should describe the aims of the fieldwork, the methodology used and the findings, drawing conclusions about how the guideline can be improved. The main section should cover the findings, summarising the emerging themes. It should be illustrated with verbatim quotes from participants as follows:

- Quotes should not be edited, other than to clarify where text is not clear. If an extra word is needed to make sense of a quote, it should be put in square brackets […] to indicate a word has been inserted.
- Short quotes should be inserted into the text and should be clearly marked with double quotation marks (" "). Longer quotes should be presented as inset paragraphs with double quotation marks.
- If words from the quote are omitted, they should be replaced by '(…)', but the omission must not alter the meaning of the original quotation.
- Quotes should be coded to keep the participant anonymous and allow for the distinction between different participants' comments.
- As with data from clinical trials, transcripts should be kept for at least 5 years (see www.ct-toolkit.ac.uk).

Using fieldwork findings to inform final recommendations

The fieldwork contractor should present a summary of the findings to the Committee. It should use this information to refine and prioritise the recommendations after the consultation. (This includes making them more specific for different groups of practitioners, where appropriate.)

For further details about developing and prioritising recommendations, see chapter 9 of the manual.

Equality and diversity

Equality and diversity issues should be considered at every stage of the fieldwork process – from commissioning the contractor to finalising the fieldwork report. For example, the fieldwork contractor should make every effort to ensure equality and diversity issues are considered when generating the fieldwork sample and the questions to be asked. These issues should also be considered when deciding on the approaches to use. In addition, fieldwork should specifically seek to determine:

- Does the guideline avoid unlawful discrimination?
- Are there ways in which the guideline could better promote equality and access to services?

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

Pope C, Ziebland S, Mays N (2000) Qualitative research in health care: analysing qualitative data. BMJ 320: 114–6

Ritchie J, Spencer L (1993) Qualitative data analysis for applied policy research. In: Bryman A, Burgess R, editors. Analysing qualitative data. London: Routledge pp 173–94

Silverman D, editor (2004) Doing qualitative research: a practical handbook. London: Sage

Tashakkori A, Teddlie C (2002) Handbook of mixed methods in social and behavioural research. London: Sage

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