NICE National Institute for Health and Care Excellence

The social care guidance manual

Process and methods

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www.nice.org.uk/process/pmg10

Contents

1 Introduction

This is not the current manual. From January 2015, guidelines were developed using Developing NICE guidelines: the manual.

The National Institute for Health and Care Excellence (NICE) is the independent organisation responsible for providing national guidance and advice on promoting good health and preventing and treating ill health.

From 2013, NICE has an expanded remit to produce guidance and set quality standards for social care.

Further details about NICE and its work programmes are available from What we do.

1.1 NICE guidance

NICE develops guidance across several areas and on a range of topics. NICE social care guidance:

- sets out the care and services that are suitable for most people with a specific condition or need in England
- sets out the care and services suitable for particular groups or people in particular circumstances (for example, when being discharged from hospital)
- aims to improve the quality of care and services
- assesses the effectiveness and cost effectiveness of care and services to address the needs of service users
- is developed using a process that takes account of the views of people who might be affected by the guidance[1]
- is based on the best available evidence and expert consensus when necessary
- is developed using recognised methods that are robust and transparent
- is used to help develop NICE quality standards.

All types of NICE guidance are developed using the best available evidence and by involving stakeholders in a transparent and collaborative manner. Stakeholders include:

- organisations that represent the interests of service users and carers
- social care and health practitioner organisations
- providers and commissioners of social care services (including service users that purchase their own care)
- organisations that fund or carry out research in social care
- voluntary organisations (including both those that provide services and those that represent the interests of specific populations)
- companies that have an interest in the guidance being developed.

More information for registered stakeholders can be seen on the NICE website.

NICE operates the Social Care Guidance Programme according to its core principles. These include:

- input from experts, service users and carers
- transparent process and decision-making
- consultation
- effective dissemination and implementation
- regular review.

1.2 Equality and social value judgements

NICE is committed to promoting equality, eliminating unlawful discrimination and actively considering the implications of its guidance for human rights. It aims to comply fully with all legal obligations to:

- promote race and disability equality and good relations, and equality of opportunity between men and women **and**

- eliminate unlawful discrimination on the grounds of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, family origin, religion or belief, gender, sex or sexual orientation in the way it carries out its functions and in its employment policies and practices.

NICE's equality scheme sets out how it is meeting its obligations on equality and discrimination. Currently, NICE's work in this area extends beyond the legal requirements: socio-economic status and specific disadvantaged or vulnerable groups are listed in recommendations, where appropriate. (For example, this could include looked-after children, asylum seekers and people who are homeless.)

All NICE guidance, and the procedures NICE uses to develop its guidance, follow the principles set out in Social value judgements: principles for the development of NICE guidance (second edition, 2008). (This publication is currently being updated to incorporate NICE's new remit for social care.)

1.3 Who this manual is for

This guidance manual explains how NICE develops and updates social care guidance. It provides advice on the technical aspects of guidance development and the methods used. It is aimed primarily at staff at the NICE Collaborating Centre for Social Care (NCCSC) and at members of the Guidance Development Groups (GDGs) that develop the individual guidance (see section 1.8.1). It is also likely to be useful and of interest to a broader audience, including developers of other guidance, such as NICE clinical guidelines or NICE public health guidance.

The advice in this manual draws on international guideline development methodology, and the experience and expertise of the teams in the Centre for Public Health Excellence and the Centre for Clinical Practice at NICE, and the National Collaborating Centres that work with NICE. It is based on internationally acceptable criteria of quality, as detailed in the appraisal of guidelines research and evaluation II (AGREE II) instrument, and adapted for use in social care guidance development. It is designed to fulfil the requirements of the NICE accreditation scheme.

The structure of this manual follows the development of NICE social care guidance from inception through to publication. The guidance development process is summarised in section 1.8.2. There is also information in section 13 on the support NICE and the NCCSC provide to help organisations use the guidance.

1.4 NICE social care guidance

There is no agreed definition of social care. However, it generally refers to all forms of personal care and other practical assistance for children, young people and adults who need extra support. This includes:

- vulnerable children and young people (those who are at risk of, or who are already experiencing social and emotional problems)
- children, young people and adults with learning or physical disabilities or mental health problems
- people who misuse drugs or alcohol
- older people.

NICE social care guidance provides a set of action-oriented recommendations, based on the best available evidence, for social care or social care services. The recommendations are relevant to service users, their families and carers, and communities. They are also relevant to social care providers, social care managers and commissioners.

Effective social care guidance will improve outcomes for service users and carers, change the process of social care provision and planning, improve social care practice and ensure efficient use of public resources. Specifically, it can be used to:

- let service users and carers know what they should be able to expect from social care services
- ensure that care commissioned and provided has been shown to work and be cost effective
- increase the national consistency of social care provision
- support the development of inter-agency and inter-professional working
- support professional decision-making and continued professional development
- develop standards for assessing the practice of social care practitioners and providers
- educate and train people working in the social care sector to help service users and their carers make informed decisions

- improve communication between service users, social care practitioners and providers.

1.4.1 Service guidance

Sometimes, social care guidance may need to focus on or include specific recommendations on, service provision. Service guidance is developed primarily for service providers and commissioners, rather than social care practitioners. It focuses on the broad configuration and provision of social care services. Generally, service guidance recommendations will fall into the following categories:

- effectiveness of particular service models
- timing of an intervention and referral
- access to the service
- competencies needed to achieve safe, effective and person-centred interventions.

1.4.2 Quality standards

Topics for new social care guidance are likely to inform the development of subsequent quality standards.

NICE quality standards are a concise set of statements designed to drive and measure priority quality improvements within a particular area of care. NICE quality standards are derived from the best available evidence, such as NICE guidance and other evidence sources accredited by NICE. They are developed independently by NICE, in collaboration with NHS and social care professionals, their partners and service users. Effectiveness, cost effectiveness, people's experience of using services, safety issues, equality and cost impact are considered during the development process.

1.5 Types of knowledge and evidence

NICE social care guidance draws on evidence and knowledge from across a spectrum of sources that use different methods and approaches. Sources include:

- organisations

- practitioners
- policy makers and the wider policy context
- research, gathered systematically with a planned design
- service users and carers.

NICE social care guidance needs to be based on a wide variety of evidence and other forms of information (Lomas et al. 2005) (see section 4). This includes knowledge gathered using explicit, systematic and replicable research and social research methods. It also includes models, theories, expert testimony, mapping, practice reviews, consultation and practice.

NICE social care guidance is developed using methods and processes that can incorporate these different types of knowledge and evidence at various stages.

1.5.1 Best available evidence

Evidence is drawn from a range of disciplines and research models. Evidence is selected and appraised according to well-defined criteria. It is summarised according to general principles developed by NICE and using methods that are appropriate for a range of research evidence types.

The core issues are:

- What is the most appropriate type of evidence to answer the question (see below and section 4 for further information)?
- How can the most relevant evidence (published and unpublished) be identified (see sections 5.2-5.3)?
- How can the quality of evidence be assessed (see section 6.2)?
- How can evidence from different kinds of research be combined, in particular, quantitative and qualitative data (see section 6.3)?

A randomised controlled trial is normally the most appropriate study design for judging the efficacy or effectiveness of interventions. However, such studies may not always be available when evaluating the effectiveness of approaches and aspects of service delivery, and may not always report all important outcomes. In addition, because of the complexity

of social care provision and the context of its delivery, the findings often have to be supplemented by data from other study designs.

To assess factors that affect effectiveness, such as acceptability to service users, it may also be necessary to consider other types of evidence, such as qualitative studies of user or practitioner views and experience.

Other evidence, including clinical and epidemiological evidence, can be used to examine outcomes, context, process and adoption (implementation), as well as barriers to and facilitators of interventions. There is little academic consensus about how best to synthesise information from different study designs or research models or about how to use the evidence synthesis to develop guidance.

It may therefore be important to consider:

- evidence as an adjunct to studies of service effectiveness, to explore issues such as acceptability
- evidence about the impact of context and process on effectiveness
- underlying theories and models that may provide insight into variation in effectiveness.

For each of these, different methods of appraisal and synthesis will be appropriate.

1.6 Stakeholders

Stakeholders are central to the development of NICE social care guidance. Guidance is subject to scrutiny and validation by stakeholders throughout development to ensure the recommendations are realistic and appropriate (see sections 2.5, 2.6 and 11.1).

1.7 Quality assurance principles

In addition to the broader values outlined above, NICE social care guidance is produced in accordance with NICE's quality assurance principles, which are designed to ensure that guidance is credible, robust and relevant:

- Guidance development processes are governed by clear, published statements of methods and process, including a standard timeline. These processes are updated at regular, predetermined intervals.
- Guidance publications are authorised for publication by the Guidance Executive, on behalf of the NICE Board.

1.8 The development process for social care guidance

The development time for NICE social care guidance is usually around 18–24 months (from the start of scoping to publication) for standard guidance. However, there will be flexibility, depending on the size and scope of the topic.

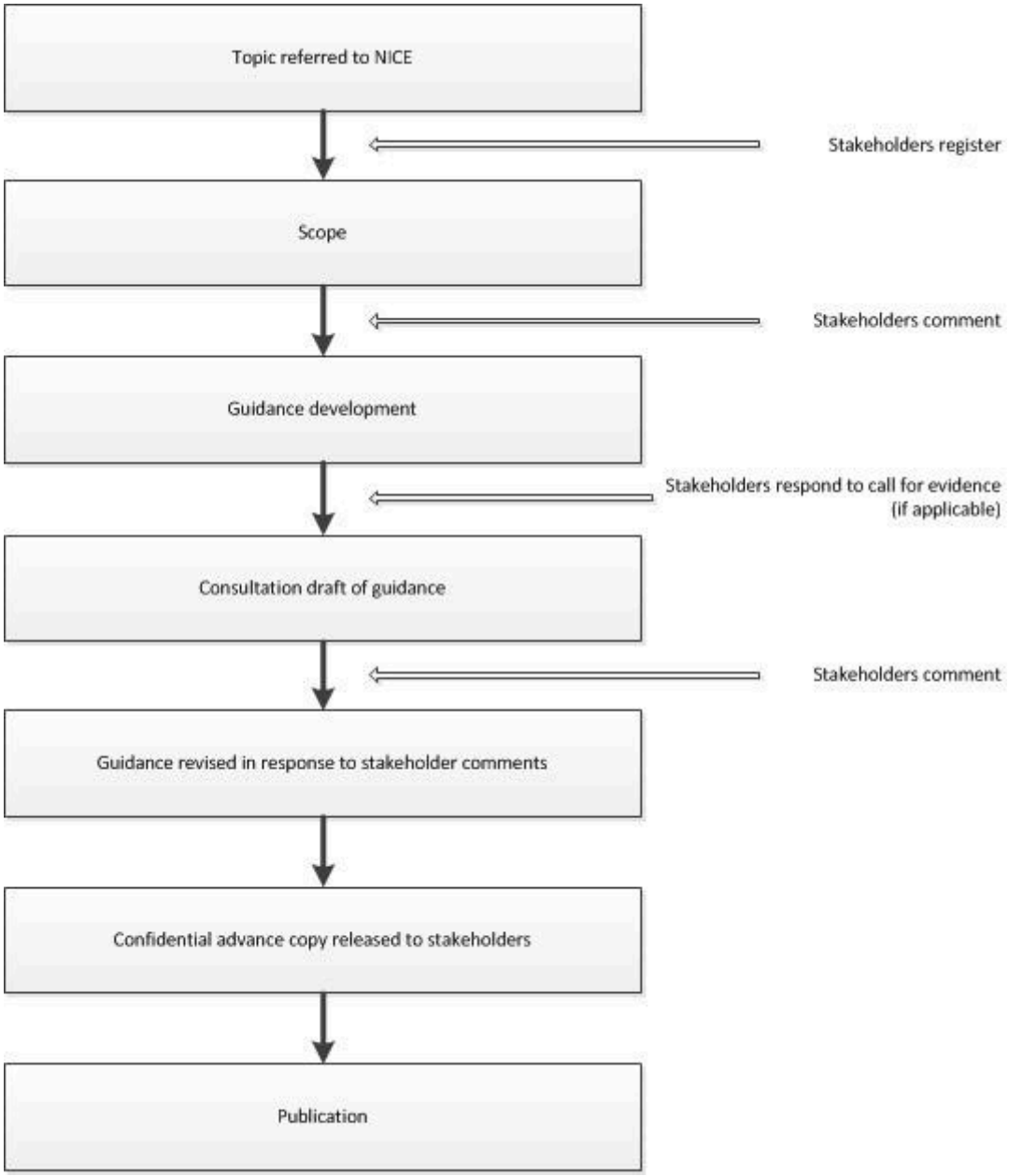
1.8.1 Who is involved?

The key groups and individuals involved in developing social care guidance are the NCCSC, the GDG for the topic, NICE and registered stakeholders. The GDG will include social care practitioners, other professionals, service users and/or carers. The various groups are involved at different points in the process and have different responsibilities. These are described in this manual.

1.8.2 Summary of the social care guidance development process

Social care guidance topics are referred from the Department of Health, and the Department for Education for topics related to children or young people. The key stages in the development of NICE social care guidance are summarised in figure 1.

Figure 1 Key stages in the development of NICE social care guidance



1.8.3 Publication and adoption of social care guidance

Social care guidance is published in a range of digital formats, including the web format and NICE Pathways.

The web format contains links to the background and evidence for the guidance.

Social care guidance will also appear in many NICE Pathways. This practical online

resource brings together all relevant NICE guidance on a given topic, with links to adoption tools and to related NICE guidance and other pathways.

The tools produced by NICE and the NCCSC are intended to help people put the guidance into practice. This may include communities, service users and their families and carers, as well as social care providers, social care managers and commissioners. (See section 13 for information about the support available to help adopt the recommendations.)

All versions of social care guidance, and the associated adoption tools, are published on the NICE website.

1.8.4 Practical information

As it becomes available, the following information about each piece of social care guidance is published on the NICE website:

- a list of registered stakeholders
- contact details of the NCCSC
- details of the NICE project team
- members of the GDG
- a schedule for development of the guidance
- the consultation draft of the scope
- the final scope
- the Equality Impact Assessment forms for the guidance (completed at the scoping stage and before the guidance is signed off by NICE)
- a table of stakeholder comments on the consultation draft of the scope and responses
- project history and information on progress of the guidance
- economics plan, review protocols and search strategies
- the consultation draft of the guidance

- a table of stakeholder comments on the consultation draft of the guidance and responses
- the published guidance and pathway
- details of related NICE guidance
- tools to support adoption of the guidance.

1.9 Updating the social care guidance manual

The social care guidance manual will be reviewed by NICE in accordance with internal processes and timescales. This includes the planned development of an integrated manual for all guidance development across NICE (scheduled for late 2013/14). The processes for social care guidance will need to be updated in line with any changes to the interim manual or the future integrated manual.

We welcome comments on the content of this manual and suggested subjects for inclusion. These should be addressed to: socialcaremanual@nice.org.uk.

1.9.1 Interim updates

In some situations, it may be necessary to make small changes to the social care guidance development process before a formal update is due. These may be either minor insubstantial changes ('bug fixes') or more significant changes for which formal consultation with stakeholders is necessary. For small changes to be put in place without stakeholder consultation, they must fulfil all of the following criteria:

- no fundamental stage in the process is added or removed
- no fundamental method, technique or step is either added or removed
- no stakeholders will obviously be disadvantaged
- the efficiency, clarity or fairness of the process or methodology will be improved.

Changes that meet all of these criteria will be published on the NICE website. The manual will be updated, and changes from the previous version of the manual will be listed. Stakeholders in social care guidance under development at the time of the change will be notified if they are affected by the change. Stakeholders in newly commissioned guidance

will be advised to consult the website at the start of the project to familiarise themselves with the updated development process.

1.10 References and further reading

Lomas J, Culyer T, McCutcheon C et al. (2005) Conceptualizing and combining evidence for health system guidance: final report. Ottawa: Canadian Health Services Research Foundation

Pawson R (2006) Evidence based policy: a realist perspective. London: Sage

[1] People who might be affected by the guidance include social care practitioners and providers, healthcare and other professionals, service users and their carers and families, social care service managers, local authorities, the public, government bodies and suppliers of social care services, including voluntary and commercial organisations.

2 The scope

Preparing the scope is the first step in developing social care guidance. It determines the details of the review work (see section 6). The scope is conducted in 4 stages:

- stage 1: selecting key issues and drafting the scope (section 2.3)
- stage 2: checking the selected key issues with stakeholders (section 2.4)
- stage 3: consulting on the draft scope (section 2.5)
- stage 4: finalising the scope after consultation (section 2.6).

This section describes what the scope is, the role of the scoping group and the process used at each stage to develop the scope.

2.1 Purpose of the scope

The purpose of the scope is to:

- provide a brief overview of the policy and practice context in which the guidance will be developed
- provide an overview of what the social care guidance will include and what will not be covered
- identify the key issues that need to be included
- set the boundaries of the development work so that it informs the quality standard
- ensure equality issues are identified and considered
- set parameters for the development of detailed review questions (see section 4.2) and the search strategy (see section 5) from the key issues
- provide information to the social care sector, stakeholders and the public about the expected content of the guidance
- ensure the guidance can be developed within the specified time period and within the available resources.

The scope provides a framework within which to conduct the guidance development work. The title of the guidance (as given in the scope) needs to be considered very carefully so that it adequately reflects the content of the scope.

The scope briefly describes the topic, current services, level of need and aspects of care or service provision that the guidance will cover in terms of the following:

- Populations to be included or excluded. For example, different age groups or people with certain types of condition or specific needs or at specific stages of care. Or groups that may merit specific consideration (for example, people from particular ethnic groups or with learning disabilities).
- Service setting – for example, care homes.
- Types of approaches and aspects of service delivery. For example, assessment processes, support services, rehabilitation, re-ablement, information and support. It is important that the scope is as specific as possible about the activities that the guidance aims to cover.
- Topic-specific information and support for service users and carers.
- The main outcomes that will be considered.
- Links with other NICE guidance, including guidance to be updated or incorporated within the new guidance.
- Links to other related guidance, such as statutory guidance (see section 8).
- NICE pathways that relate to the guidance topic.
- Links with relevant quality standards.

2.2 The scoping group

The scope is prepared by a scoping group. The composition of this group will depend on the guidance topic, but should include NICE Collaborating Centre for Social Care (NCCSC) representatives, the Guidance Development Group (GDG) chair (once appointed), the GDG social care topic adviser (if there is one) and NICE representatives.

NCCSC representatives should include a director or senior member of staff (chair of

scoping group), a project manager, an information specialist, a systematic reviewer and an economist. NICE representatives should include a technical lead, a programme lead, a Public Involvement Programme lead for the guidance and the Quality Programme lead for social care (or equivalent).

The role of the scoping group is to:

- identify key issues and draft the scope, based on information from any pre-scoping work
- revise the draft scope after the stakeholder scoping workshop (see section 2.4.1)
- prepare the draft scope for consultation
- respond to stakeholder comments
- finalise the scope after consultation.

2.3 Stage 1: identifying key issues and drafting the scope

Stage 1 includes considering the key issues for inclusion in the scope, which may have emerged in a pre-scoping meeting, searching the literature, considering any equalities issues and consulting experts.

2.3.1 Identifying the key issues

Identifying the most important aspects of care or service provision that the guidance will cover is a critical part of the process because it determines the breadth and depth of the work. It ensures the guidance focuses on areas where providers and commissioners of social care most need advice.

This process should ensure that a range of care or services for the topic is considered for inclusion in the scope and could be used in the subsequent NICE quality standard.

Review questions may be included in the scope; these specify in more detail the particular approaches and aspects of service delivery to be compared and the outcomes of interest (see section 4). Key issues should be as specific as possible, indicating the relevant

population and the alternative strategies that are being considered. Examples of key issues are shown in box 2.

Box 2 Examples of key issues that could be included in draft scopes for consultation

Issues relating to services

- Training to assist foster carers in managing difficult behaviour
- Rehabilitation programmes to support people back to work

Issue relating to assessment

- Assessment methods to establish home support needs for people living with dementia

Several criteria should be considered when identifying the key issues (see box 3).

Identifying related NICE guidance (either published or in development) is a key element of scoping. This will help to see where and how the recommendations will fit into NICE pathways. It will also help identify any instances where the guidance may update, or overlap with, recommendations made in other NICE guidance.

The scoping group should ensure that it has considered equality issues when identifying the key issues and drafting the scope (see section 2.3.3). The NCCSC (in discussion with the scoping group) should also consider the composition of the GDG at this stage (see section 3.1.1).

Box 3 Factors to consider when identifying key issues and drafting the scope

Uncertainty or disagreement on best practice

Is there:

- variation in current care provision?
- evidence suggesting that common practice may not be best practice?
- debate in the literature?

Potential to improve outcomes or make better use of resources

- How many people are affected?
- What is the potential for improved outcomes at acceptable cost?
- What is the potential for reducing ineffective care?
- What is the potential for achieving cost savings with no, or limited, adverse effect on outcomes?

Potential for avoiding unlawful discrimination and reducing inequalities

- Consider possible inequalities (see section 1.2).
- Are exclusions listed in the scope (for example, populations, interventions or settings) justified?
- Will inequalities in prevalence, access, outcomes or quality of care for any groups (including those with protected characteristics) be addressed in the scope?

Likelihood that the guidance could contribute to change

- Is a new review of the evidence or an economic evaluation likely to reduce existing uncertainties?
- How does the guidance fit with existing legal frameworks, statutory and professional guidance or government policies, and what is its anticipated impact?
- What is the potential for achieving consensus within the GDG and in the wider stakeholder community?

Other important factors

- Need to update other NICE guidance.
- How the topic relates to NICE pathways.

Main outcomes

The scope includes a section listing the main outcomes of interest. This need not be an exhaustive list, but is likely to include: quality of life, capability, functioning, effectiveness, cost effectiveness, resource use and safety. It should also include some important condition- or service-specific outcomes. Quality of life is a critical outcome and should always be included in the list. It is also desirable to specify any adverse effects of different approaches and aspects of service delivery considered in the guidance.

2.3.2 The scoping search

A scoping search of the literature is important to identify previous guidance, key systematic reviews and economic evaluations relevant to the guidance topic. This search should not aim to be exhaustive.

A scoping search should include a brief search of key sources, for example, government department, charity, and other community and voluntary sector websites to identify relevant policies and documents. A broad search of the published literature should also be undertaken using a key database, for example NHS Evidence or Social Care Online.

More information on literature searching is given in sections 5.2 and 5.3.

Further searches to identify systematic reviews and economic evaluations will be necessary once the review questions have been determined (see sections 4 and 5).

In addition to the results of the scoping search, the scoping group should consult the background documentation, if applicable. This may include briefing papers and documentation related to decisions about reviewing NICE social care guidance (see section 14).

2.3.3 Equality issues at the scoping stage

During development of the scope, it is important to consider and assess any equality

issues to establish:

- whether, and to what extent, the guidance is likely to be relevant to the promotion of equality and the elimination of unlawful discrimination
- whether, and to what extent, it would be proportionate to include particular equality issues in the scope.

Considerations will be reflected in the equality impact assessment (see section 2.6.2).

2.4 Stage 2: checking selected key issues with stakeholders

It is essential to seek the views of experts in the field and stakeholders to confirm that the key issues identified by the scoping group are relevant and appropriate. This includes user-led organisations, and organisations that represent the interests of people with the condition or who use the services and their carers.

2.4.1 The stakeholder scoping workshop

Before the consultation on the draft scope, registered stakeholders (see section 2.5.1) are invited to a scoping workshop to talk about the key issues identified by the scoping group. One person from each registered stakeholder organisation may attend.

Organisations are permitted to nominate more than one representative in some circumstances (for example, if an organisation represents the views of both practitioners and service user groups) if space permits and with the agreement of NICE. The aim of the workshop is to have representatives from various stakeholders who can represent as wide a range of views as possible.

People attend the workshop from their own perspective and do not represent the views of their stakeholder organisation, but should bring as wide a perspective of views as possible. Attendees, including representatives of relevant service user and carer organisations, should have specific knowledge of, or experience in, the topic area.

The stakeholder scoping workshop is in addition to the formal consultation on the scope. Stakeholder organisations may also wish to submit comments in writing during consultation, as described in section 2.5. Depending on the needs of stakeholder groups,

virtual methods, such as webinars, may be used in place of face-to-face workshops.

The objectives of the scoping workshop are to:

- obtain feedback on the selected key issues, including highlighting any important adoption considerations
- identify which service user or population subgroups should be specified (if any)
- consider existing NICE Pathways and how the planned guidance topic relates to them
- seek views on the composition of the GDG (see section 3.1.1)
- encourage applications for GDG membership.

At the workshop, the scoping group provides details about:

- the scope
- the guidance development process
- the nature of stakeholder input into the guidance (including the involvement of service users and carers)
- the processes for recruitment to the GDG.

This is followed by a structured discussion of the key issues.

People attending the scoping workshop are sent an initial draft of the scope. This outlines the background to the guidance, groups, services and settings that will be covered, those that will not be covered and the key issues selected. This initial draft is intended as a starting point for discussion. This document is posted on the NICE website during consultation on the scope.

For some topics, additional meetings or specific discussions with key stakeholders may be needed. However, this will be exceptional and documented in the full guidance.

2.5 Stage 3: consulting on the draft scope

The scoping group considers the issues raised at the scoping workshop and refines the draft scope for consultation. The draft scope may be modified by NICE after discussion

with the scoping group. It is then posted on the NICE website for a 4-week period of public consultation. Comments are invited from registered stakeholder organisations.

2.5.1 Stakeholder organisations

Organisations representing social care practitioners and other professionals, local authorities, the NHS and service users and carers, as well as private and independent sector organisations, or voluntary and community organisations with an interest in a particular topic, can register as stakeholders if they meet the criteria on the NICE website. For example, organisations may include those with an interest in housing, education, welfare benefits or advocacy.

Registered stakeholder organisations comment on the draft scope (and later on the draft guidance; see section 11). The NICE website contains details about how to register as a stakeholder and how to contribute to the guidance development process.

Members of the scoping group and the NCCSC's adoption support lead for the guidance (see section 13) routinely review the list of registered stakeholders to check whether any key organisations are missing. Stakeholders attending the scoping workshop are also encouraged to identify potential stakeholders who are not registered.

2.6 Stage 4: finalising the scope after consultation

2.6.1 Dealing with stakeholder comments

The scoping group finalises the scope in light of comments received.

Stakeholders may ask for additional aspects of care to be included in the guidance, but this could make the development of the guidance unmanageable within the time permitted. Therefore, the effect on overall workload needs to be considered before the scope is expanded in response to stakeholder comments. However, suggestions that might make the guidance more useful, and so improve care or services, should not be ignored. This may entail removing other 'lower-priority' areas if they do not affect the related quality standard.

Suggestions clearly outside the original remit should not be included. If the scoping group considers that a request to expand the scope would mean the guidance could not be

completed on schedule, this should be discussed with NICE.

All stakeholder comments, and the actions taken by the scoping group and NICE in response to each comment, are clearly documented in a 'scope consultation table'. This is published on the NICE website with the final scope. The process for responding to stakeholder comments should follow the principles described in section 11.2.

2.6.2 Equality impact assessment

Before the scope is signed off, an equality impact assessment form is completed to show what equality issues have been identified and considered during scoping. This is published on the NICE website.

2.6.3 Signing off the final scope

The final scope is signed off by NICE. Once the scope has been signed off, the GDG should not make changes without consulting NICE (see section 2.7).

The final scope, stakeholder comments and responses to stakeholder comments are posted on the NICE website.

2.7 Amending the final scope after publication on the NICE website

In exceptional circumstances, the final scope that has been signed off and posted on the NICE website may need amending. For example, if a scope does not cover an important area of care. The decision on whether to amend the scope is made by NICE, based on advice from the NCCSC.

3 The Guidance Development Group

Convening an effective Guidance Development Group (GDG) is one of the most important stages in producing NICE social care guidance. The GDG agrees the questions to be addressed by the evidence reviews, considers the evidence, develops the recommendations and advises on adoption support. Membership of the GDG therefore needs to be multidisciplinary and comprise:

- social care practitioners and other professionals (both specialists in the topic and generalists)
- social care providers or commissioners
- service users or carers.

The exact composition of the GDG should be tailored to the topic covered by the social care guidance. It should reflect the range of stakeholders and groups whose activities, services or care will be covered by the guidance, and should include at least 2 members who have experience or knowledge of service users and carer issues.

During guidance development, people who are not members of the GDG but who have relevant expertise may be asked to attend meetings to take part in specific discussions (see section 3.1.7).

Members of the GDG are not permitted to submit comments as stakeholders during the consultation on the draft guidance (see section 11). If a GDG 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.

This section describes the core elements of forming and running a GDG, including the appointment and role of the chair and members.

3.1 Forming the Guidance Development Group

The chair and members of the GDG are appointed for the duration of the development of a particular piece of guidance. The chair is appointed before the guidance scoping stage

and is a member of the scoping group. If appropriate, a social care topic adviser for the guidance is also appointed before scoping (see section 3.1.3). Other GDG members are appointed after discussion about GDG membership at the stakeholder scoping workshop (see section 2.4.1).

The chair and GDG members are recruited and appointed in accordance with NICE's policy on Appointments to guidance producing bodies advisory to NICE (November 2006).

3.1.1 The composition of the Guidance Development Group

The composition of each GDG is agreed between the NICE Collaborating Centre for Social Care (NCCSC) and NICE during the scoping phase. A workable size for a GDG is between 13 and 15 people. This balances the opportunity for people to contribute effectively with the need for a broad range of experience and knowledge. Members of the GDG should have sufficient credibility to command the respect of people within their field. The GDG has 3 key constituents:

- the chair
- the social care topic adviser
- members from the social care professions, providers and commissioners, and from other professions if relevant
- service user and carer members.

The GDG will be supported by technical and project management staff from the NCCSC.

For some guidance topics, it may be important for the GDG to include an epidemiologist with knowledge of the subject. The GDG may also be supported by expert witnesses who are invited for specific areas only (see section 3.1.7).

As far as possible, the GDG will have an appropriate balance with regard to the principles of NICE's equality scheme.

Ideally, GDG members should represent a geographical spread across England, but this will be influenced by the expertise available.

All GDG members should be committed to developing the social care guidance according

to the processes set out in this manual, and to working within NICE's equality scheme (see section 3.2.3). They are expected to attend all GDG meetings (usually between 7 and 12).

New members should not usually be added to the GDG after the first GDG meeting has taken place, because this may disturb the group dynamic. If a GDG member is unable to fulfil their duties (for example, because of illness), another recruitment process may be considered to replace that person. If GDG members are unable to attend a GDG meeting, deputies are not permitted.

People are GDG members in their own right and do not represent any particular organisation or group.

If service guidance is being developed (see section 1.4.1), or if the social care guidance contains a service guidance component, additional members should be appointed to the GDG to reflect this. This might include input from:

- commissioning bodies in England
- relevant practitioner networks
- a chief executive or local authority representative, such as a director of adult social services, with an interest in the topic.

Additional GDG members recruited for service guidance are subject to the same recruitment process as other GDG members (see below).

At any time, the GDG can invite expert witnesses to meetings, particularly where specific expertise is needed on an important issue related to the guidance.

The following sections outline the roles of GDG members and describe how the members should be appointed.

Vacancies for GDG positions are posted on the NICE website. Other means are also used to alert people to GDG vacancies. These include circulating the information to all registered stakeholder organisations, liaising with any relevant professional, practitioner, community or voluntary organisation or group, and using local networks.

3.1.2 The Guidance Development Group chair

To work well, a GDG needs an effective chair. The GDG chair is a member of the scoping group (see section 2.2) and should therefore be recruited before work starts on the scope.

The chair guides the GDG in terms of task (developing the guidance) and process (how the group works). The chair also helps the GDG to work collaboratively, ensuring a balanced contribution from all members (see box 4).

The chair need not be an expert in the guidance topic because specialist knowledge is provided by other GDG members. The chair is appointed for their expertise and skill in chairing small groups, and although they may have some knowledge of the topic, this is not their primary role in the group.

Box 4 Key roles and functions of the GDG chair

The chair attends an induction session (see section 3.3.1).

The chair needs a detailed understanding of NICE's social care guidance development process, and may have some background or basic understanding of the guidance topic.

The chair should also have a good overall understanding of social care and the context in which the guidance will apply.

To help the working of the group, the chair:

- gets involved in the scoping group to help determine the scope and boundaries for the work
- sets up the rules for how the GDG operates, based on the principles set out in sections 3.4.2–3.4.3
- assists with the planning of the GDG meetings
- establishes a climate of trust and mutual respect among members
- provides opportunities for all members to contribute to the discussions and activities of the group
- may meet individual GDG members outside GDG meetings.

In GDG meetings, the chair:

- ensures that GDG 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 policy
- 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 GDG.

The chair must ensure that NICE's equality scheme and social value judgements

document are adhered to (see sections 1.2 and 3.2.3).

The chair approves the draft guidance, before sign-off by NICE, and advises the NCCSC on responses to stakeholder comments.

Appointing the chair

In accordance with NICE's policy on Appointments to guidance producing bodies advisory to NICE (November 2006), the position of GDG chair is advertised on the NICE website. It may also be advertised on the NCCSC web pages of the organisation that hosts the NCCSC, and in other appropriate places identified by the NCCSC. The NCCSC tells the stakeholder organisations about the advertisement.

3.1.3 The social care topic adviser

If appropriate, a social care topic adviser with specialist topic knowledge may be appointed. The social care topic adviser is a member of the GDG, but also works closely with the NCCSC team to provide topic-specific support.

The social care topic adviser is a member of the scoping group (see section 2.2) and is therefore appointed before work starts on the scope.

The social care topic adviser's exact responsibilities will differ depending on the guidance and the expert input needed. It may include, for example, working with the systematic reviewer on the evidence reviews (if expert topic-specific knowledge is needed), or checking the guidance to ensure the terminology and language is correct.

Appointing the social care topic adviser

If a social care topic adviser is to be appointed, the position is advertised on the NICE website. It may also be advertised on the NCCSC web pages of the organisation that hosts the NCCSC, and in other appropriate places identified by the NCCSC. NICE tells the stakeholder organisations about the advertisement.

3.1.4 Social care practitioner members

Social care practitioner members of the GDG should be recruited shortly after the stakeholder scoping workshop (see section 2.4.1). They should represent the perspectives

of the social care practitioners (and other professionals if relevant), providers and commissioners involved in the care or services covered by the guidance topic.

Social care practitioner members are on the GDG as members with appropriate knowledge and skills; detailed research expertise is not necessary, although an understanding of evidence-based practice is essential. They are not expected to represent the views of their professional organisations.

A GDG has, on average, between 6 and 8 practitioner members; the list of professions represented is agreed between the NCCSC and NICE as part of the work plan.

The roles and responsibilities of the practitioner members of the GDG are shown in box 5.

Box 5 Key roles of practitioner members of the GDG

GDG practitioner members are expected to:

- agree the review questions, based on the key issues in the scope
- contribute constructively to meetings and have good communication and team-working skills; this should include a commitment to the needs of service users and carers
- use their background knowledge and experience of the guidance topic to provide guidance to the NCCSC technical team about carrying out systematic reviews and economic analyses
- read all relevant documentation and make constructive comments and proposals at (and between) GDG meetings
- with other members of the GDG, develop recommendations based on the evidence reviews, or on consensus if evidence is poor or lacking
- advise on how to identify best practice in areas for which research evidence is absent, weak or equivocal
- with other members of the GDG, consider adoption issues arising from recommendations; this information will inform the needs assessment process carried out by the NCCSC and help NICE develop tools to assist people using the guidance (see section 13)
- with other members of the GDG, approve the review protocols (see section 4.4)
- with other members of the GDG, agree the minutes of GDG meetings.

They are not routinely expected to:

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

Appointing practitioner members

Vacancies for practitioner members of the GDG are advertised on the NICE website. They may also appear on the website of the NCCSC or the professional body that hosts the NCCSC, and in other appropriate places identified by the NCCSC. NICE tells registered stakeholder organisations about the advertisement.

3.1.5 Service user and carer members

At least 2 members of each GDG should have experience or knowledge of issues that are important to service users and carers (the 'service user' and 'carer members'). This is to ensure their views, as well as the views of practitioners, are taken into account in the guidance development process.

In general, service user and carer members will have direct experience of the condition or services being covered – as a service user, carer or family member, or as an officer or member of a service user or carer organisation or support group. They should be willing to reflect the experiences of a wide network of service users, rather than basing their views only on their own experience. However, they do not represent the views of any particular organisation.

Professional and practitioner groups are well represented on GDGs, so service users and carer members do not usually have a social care practitioner background.

Service user and carer members have equal status with other members of the GDG. Their specific roles are shown in box 6.

Box 6 Key roles of service user and carer members of the GDG

Service user and carer members carry out the same functions as other GDG members (see box 5), but they are often able to offer specific expertise in:

- ensuring that review questions embrace service user as well as professional and practitioner issues
- raising awareness of grey literature[a] known to them (for example, service user surveys) that highlights service user issues that may be relevant to the work of the GDG
- considering the extent to which published evidence has measured and taken into account outcome measures that service users consider important
- highlighting areas where service user and carer preferences and choice may need to be acknowledged in the guidance
- ensuring that recommendations address service users' issues and concerns and those of their families and carers (where relevant)
- ensuring that the guidance as a whole, and particularly the recommendations, is worded sensitively (for example, treating service users as people, not as objects of assessments or interventions).

[a] Grey literature is defined as reports that are not formally published or have limited distribution, such as institutional reports, and that may not be identified through the common bibliographic retrieval systems

Appointing service users and carer members

Service users, carers and other members of the public can apply to become GDG members by responding to advertisements posted on the NICE website. NICE's Public Involvement Programme and the NCCSC contacts registered service user and carer stakeholder organisations to alert them to these advertisements. However, a person does not need to be a member of a registered stakeholder organisation to apply. For further details, see information on service user and public involvement.

3.1.6 NICE Collaborating Centre for Social Care team

A core team from the NCCSC supports the GDG. This team usually includes the NCCSC director, an information specialist, a lead systematic reviewer, an economist and a project manager (the lead systematic reviewer may also act as project manager).

NCCSC staff who act as members of a GDG are voting members. However, to ensure that the NCCSC does not have too much influence in a vote, no more than 3 NCCSC members are allowed to vote on any one issue. For each vote, the NCCSC should decide which of its staff are the most appropriate to vote; these would normally be staff with particular knowledge of the issue.

Information specialist

The information specialist identifies relevant literature to answer the review questions developed by the GDG and the NCCSC team (see sections 4, 5 and 6). The role of the information specialist involves:

- contributing to the setting of review questions and review protocols
- designing and testing search strategies (see section 5.2.2)
- contributing to discussions among the NCCSC team and in GDG meetings as needed, including deciding whether a search is needed and gathering key terms and synonyms
- identifying which databases should be searched
- drafting, refining and executing search strategies
- creating databases of the search results using reference management software (including removing duplicates), in preparation for sifting by a systematic reviewer (see section 6.1)
- maintaining audit trails, including keeping a log of search results, rationales and strategies
- keeping track of which papers are ordered for which review question in the document delivery process.

In addition, the information specialist advises on issues such as copyright and licences, metadata, archiving and record management.

Systematic reviewer

The role of the systematic reviewer is to provide summarised tables of the evidence for other GDG members. The role involves:

- contributing to the setting of review questions and review protocols
- assessing and selecting published abstracts
- critical and quality appraisal of evidence using a validated system
- distilling evidence into tables
- synthesising evidence into statements
- maintaining comprehensive audit trails.

The systematic reviewer attends the GDG and is crucial to the dissemination, presentation and debate of the evidence within the GDG.

Economist

The role of the economist is to identify potential economic issues for consideration within the guidance and to perform economic analyses. The economist is a core member of the GDG, and their role is described in more detail in section 7.1.

Project manager

The project manager plays a crucial role in overseeing and facilitating the guidance development process.

3.1.7 Non-Guidance Development Group members attending Guidance Development Group meetings

People who are not members of the GDG may also attend GDG meetings as either expert witnesses or observers. They may be social care practitioners or other professionals, service users or carers, other experts, or NICE or NCCSC staff. They are expected to follow the code of conduct of the GDG and to sign the confidentiality agreement form (see section 3.2.2).

Expert witnesses

If the GDG does not have sufficient knowledge or expertise to make recommendations in a particular area, it may call on expert witnesses – external experts who can provide additional evidence from their experience and specific expertise – to help the GDG make decisions. These can include people with a service user and carer perspective.

Expert witnesses attend a GDG meeting because of their knowledge in a particular area. However, they are not full members of the GDG; they do not have voting rights, and they should not be involved in the final decisions or influence the wording of recommendations. They should submit a declaration of interests form before attending the GDG meeting.

Observers

An observer at a GDG meeting may be asked to sit apart from the group, and should enter into discussions only if invited to do so by the GDG chair.

Observers at GDG meetings may include members of NICE staff (for example, social care fellows, the programme manager, the technical adviser, the NICE public involvement lead, the lead editor and members of NICE's implementation team). They may also include members of the NCCSC (for example, members of other guidance project teams). Observers who are not members of NICE staff or members of the NCCSC are required to sign a declaration of interests form, and need the permission of the group to attend.

3.1.8 Public access to social care guidance development meetings

From April 2014, NICE social care guidance meetings will be open to members of the public and press. This supports NICE's commitment to openness and transparency and will enable stakeholders and the public to understand how social care guidance is developed and consultation comments taken into account.

To promote public attendance at social care guidance meetings, NICE will publish a notice with a draft agenda alongside a registration form on its website at least 20 working days before the meeting. Members of the public who wish to attend the meeting should return the completed registration form 10 working days before the meeting. Up to 20 places are available, depending on the size of the venue. To allow wide public access, NICE reserves the right to limit attendees to 1 representative per organisation. The final meeting agenda will be published on the website 5 working days before the meeting. For further details,

see information for people attending a NICE committee meeting.

If an item on the agenda includes commercial- or academic-in-confidence information, it is discussed at a separate session of the meeting, from which the public is excluded. The decision to hold a separate session is made by the GDG chair and the responsible NICE director.

3.2 Code of conduct and declarations of interests

3.2.1 Declaring interests

All GDG members and anyone who has direct input into the guidance (including NCCSC and NICE staff, expert witnesses and expert peer reviewers) must complete declaration of interests forms at various points in guidance development, including at the application stage for GDG membership. Declarations of interests are published in the final guidance.

3.2.2 Code of conduct and confidentiality

NICE has developed a code of conduct (see appendix A) for GDG members and other people who attend GDG meetings.

This code sets out the responsibilities of NICE and the GDG, and the principles of transparency and confidentiality.

All people who see documents or who are party to discussions relating to guidance before public consultation are required to sign the confidentiality agreement form before becoming involved.

3.2.3 Social value judgements and equality scheme

All GDG members should be provided with a copy of NICE's most recent report on social value judgements: Social value judgements: principles for the development of NICE guidance (second edition, 2008) and be made aware of NICE's equality scheme and action plan. (The social value judgements document is currently being updated to incorporate NICE's new remit for social care.)

3.2.4 Dealing with enquiries on Guidance Development Group work

If GDG members are asked by external parties – including stakeholders, their professional organisation or the media – to provide information about the work of the GDG, they should contact the NCCSC or NICE for advice.

3.3 Identifying and meeting training needs

3.3.1 Chair

The person selected to perform the crucial role of GDG chair may need support and training so that they can carry out their role effectively. The chair needs in-depth knowledge of the NICE social care guidance development process and an understanding of group processes. Anyone appointed as a GDG chair is required to attend an induction session (see box 7), which covers the key tasks that the chair is expected to perform.

Box 7 Content of the GDG chair induction session

- Key principles for developing NICE social care guidance
- Formulating review questions
- Reviewing evidence
- Introduction to economics in NICE social care guidance
- Developing and wording recommendations
- Introduction to implementation science
- Principles of facilitation
- NICE's equality scheme
- Declaring interests and dealing with conflicts of interest
- How the work of the GDG is planned and organised

3.3.2 Training for all Guidance Development Group members

To work effectively, GDG social care practitioners, professional members and service user and carer members may need training and support in some technical areas of guidance development, such as systematic reviewing and economics. Training should be provided for all GDG members and include components similar to those outlined in box 7.

3.3.3 Training for service user and carer members

All service user and carer members of the GDG are offered training by the Public Involvement Programme at NICE. This is over and above any training they may receive alongside other members of the GDG and covers topics such as:

- an introduction to economics in guidance
- critical appraisal
- developing recommendations from evidence.

In addition, the training gives service user and carer members support to participate and the opportunity to learn from people who have been on previous GDGs.

3.4 Guidance Development Group meetings

3.4.1 Minuting the Guidance Development Group meetings

A summary of the minutes of each GDG meeting is made available on the NICE website; this includes:

- where the meeting took place
- who attended
- apologies for absence
- declarations of interests of those in attendance, including actions and decisions made about any conflict of interest
- a list of the subjects discussed

- date, time and venue of next meeting.

Minutes of GDG meetings are posted on the NICE website during guidance development, before guidance is published.

3.4.2 General principles

The GDG is multidisciplinary and its members bring with them different beliefs, values and experience. All these perspectives should be valued and considered. Each member should have an equal opportunity to contribute to the guidance development process.

It is important to check that the terminology GDG members use is understood by all and clarified if needed. The chair should ensure there is sufficient discussion to allow a range of possible approaches to be considered, while keeping the group focused on the guidance scope and the timescale of the project.

3.4.3 Quorum

The quorum of the GDG is 50% of appointed members. No business relating to the formulation of guidance recommendations may be conducted unless the meeting is quorate. If a member is excluded because of a conflict of interest and this causes membership to fall below the quorum, no business may be transacted.

Expert witnesses (see section 3.1.7) are not appointed members of the GDG and do not count towards the quorum.

3.4.4 Meeting schedule

There are likely to be 12–13 GDG meetings for most guidance topics, but this will depend on the size and scope of the topic. Most are 1-day meetings, but some may take place over 2 days.

3.4.5 The first 2 Guidance Development Group meetings

Specific aspects of the social care guidance development process are covered in the first and second GDG meetings.

The first meeting

The first meeting should focus on providing information for GDG members on the following subjects:

- process of social care guidance development
- how systematic reviews are performed
- role of economics in decision-making
- how service user and carer members contribute
- role of the GDG
- role of individual members of the NCCSC team.

GDG members should also be made aware of, and operate within, the principles contained in Social value judgements: principles for the development of NICE guidance (second edition, 2008) and NICE's equality scheme (see section 3.2.3). (The social value judgements document is currently being updated to incorporate NICE's new remit for social care.)

Staff from NICE will give presentations to explain how the elements of the social care guidance development process fit together, and the relationship to quality standards.

Mapping the service user's 'journey'

At this first meeting, the GDG should consider the 'pathway' or service user 'journey' and draft a flowchart of this process. This should include any areas of care or services that are integrated (or overlap) with healthcare provision or services.

The flowchart should be revised and updated throughout guidance development and may form the basis for any associated NICE pathway.

The second meeting

The second meeting should focus on agreeing the review questions, based on the scope. It may be helpful to establish an explicit framework that clarifies the objectives of the work, the specific tasks that need to be carried out and the timetable. This enables the group to focus and to develop a structured and well-defined working relationship.

Section 4 describes the process of developing review questions.

3.4.6 Working with NICE staff

At subsequent GDG meetings, the NICE lead editor for the guidance and leads from the NICE implementation team may give presentations or provide information to explain their roles. The NICE leads will also ask for nominations for GDG members to work with them on the following aspects:

- the NICE pathway – the GDG editorial nominees (see section 10.4)
- any adoption support tools – the GDG adoption support nominees and costing nominees (see section 13)
- promoting the guidance (see section 12.2).

The roles of the various GDG nominees are described in more detail in the sections of this manual indicated above.

3.5 Making group decisions and reaching consensus

3.5.1 Reaching agreement

GDG members need to make collective decisions throughout the development of social care guidance. For example, they need to agree review questions (section 4), interpret the evidence to answer these questions (section 6) and develop recommendations (section 9).

The role of the chair is to ensure:

- everyone on the GDG is able to present their views
- assumptions can be debated
- discussions are open and constructive.

The GDG chair needs to allow sufficient time for all members to express their views without feeling intimidated or threatened, and should check that all of them agree to endorse any recommendations. If the group cannot come to consensus in a particular

area, this should be reflected in the wording of the recommendation.

There are many different approaches to making group decisions and there is no blueprint about which approach should be used in which circumstances. Because GDGs function in different ways to reflect their individual members, it is difficult to be prescriptive about the approach. In the vast majority of cases, the GDG reaches decisions through a process of informal consensus. Some GDGs may choose to use more formal voting procedures for certain decisions, but it is beyond the scope of this manual to offer guidance on when these should be used, or which of the many variants might be used.

3.5.2 Using formal consensus methods outside the Guidance Development Group

Exceptionally, if the literature search has found no evidence that addresses the review question, the GDG may identify best practice by using formal consensus methods (for example, the Delphi technique or the nominal-group technique). If these techniques are used, the methods should be described in the guidance. **The use of these methods should be discussed on a case-by-case basis with NICE. The final decision on whether these methods are warranted will be made by NICE. If it is decided that such methods may be used, the planning and methods will be clearly documented and the methods described.**

3.6 References and further reading

Elwyn G, Greenhalgh T, Macfarlane F (2001) Groups: a guide to small groups. In: Healthcare, Management, Education and Research. Abingdon: Radcliffe Medical Press

National Institute for Health and Clinical Excellence (2006) Appointments to guidance producing bodies advisory to NICE. London: National Institute for Health and Clinical Excellence.

National Institute for Health and Clinical Excellence (2008) Social value judgements: principles for the development of NICE guidance, 2nd edition. London: National Institute for Health and Clinical Excellence.

4 Developing review questions and planning the systematic review

At the start of guidance development, the key issues listed in the scope need to be translated into review questions. In some instances, this may be done as part of the scoping process (see section 2). The review questions must be clear, focused and closely define the boundaries of the topic. They are important both as the starting point for the systematic literature review and as a guide for the development of recommendations by the Guidance Development Group (GDG). The development of the review questions should be completed soon after the GDG is convened.

This section describes, in principle, how review questions are developed, formulated and agreed. It describes the different types of review question that may be used, and provides examples. It also provides information on how to plan the systematic review.

4.1 Number of review questions

The number of review questions for each social care guidance topic depends on the topic and the breadth of the scope (see section 2). However, the number of review questions must be manageable for the GDG and the NICE Collaborating Centre for Social Care (NCCSC) within the agreed timescale. As a guide, 10–15 is a reasonable number of review questions for standard social care guidance.

This is based on the estimate that, on average, it is feasible to present a maximum of 2 systematic reviews at a GDG meeting. However, review questions vary considerably in terms of the number of studies included and the complexity of the question and analyses. For example, a review question might involve a complex comparison of several service models involving many individual studies. At the other extreme, a question might address the effects of a single, simple intervention and have few relevant studies.

4.2 Developing review questions from the scope

Review questions should address all areas covered in the scope, and should not introduce new aspects not specified in the scope. However, they contain more detail than the scope, and should be seen as building on the key issues in the scope.

Review questions are refined and agreed by all GDG members through discussions at GDG meetings. The different perspectives among GDG members help to ensure that the right review questions are identified, thus enabling the literature search to be planned efficiently. On occasion, the questions may need refining once the evidence has been searched.

Review questions are then used to develop protocols that detail how questions will be addressed.

4.2.1 Economic aspects

This section relates to the specification of questions for reviewing the effectiveness evidence.

Evidence about economic aspects of the key issues should also be sought from published economic evaluations and by conducting new modelling where appropriate. Methods for identifying and reviewing the economic literature are discussed in sections 5 and 6; economics modelling is discussed in section 7.

When developing review questions, it is important to consider what information is needed for any planned economic modelling. This might include, for example, information about quality of life, rates of adverse effects or use of social care services.

4.3 Formulating and structuring review questions

A good review question is clear and focused. It should relate to a specific service user problem or concern, because this helps to identify the relevant evidence.

Service user experience should be considered when developing all structured review questions. Review questions that focus on a specific element of service user (and, where appropriate, carer) experience may also merit consideration in their own right.

4.3.1 Types of evidence

Social care guidance recommendations are based on research and other types of evidence about what works generally, why it works and what might work (and how) in specific circumstances. Recommendations may also need to be based on evidence of

service user and carer experience of different types of intervention – and other issues related to context, ethics and theory (Tannahill 2008).

Recommendations will often therefore be based on evidence from multiple sources.

4.3.2 Types of review

Several high-quality reviews of the best available evidence are used to develop every piece of NICE social care guidance. These reviews explicitly address questions based on the scope. Rather than relying on the standard hierarchy of evidence, with randomised controlled trials (RCTs) at the top, a wide range of study designs and methodologies should be used to answer these questions (Petticrew and Roberts 2002). (See section 4.3.1.)

4.3.3 Types of review questions

The review questions are based on the key issues in the scope and the views of social care practitioners, decision makers and other stakeholders. However, the scope may include several other questions and potential considerations that reflect the nature of the specific issue being tackled and its context.

In addition to questions of effectiveness and cost effectiveness, there are often questions about the acceptability and accessibility of interventions, and service user or practitioner experiences.

The nature and type of questions determines the number and type of reviews and the type of evidence that is most suitable (for example, intervention studies and qualitative data).

Whatever method is used, the process for developing questions is the same.

Review questions should be clear and focused. The exact structure of each question depends on what is being asked, but it is likely to cover one of the following:

- extent and nature of the social care issue
- interventions that work in ideal circumstances and might work in specific circumstances or settings (the extent to which something works, how and why)
- a relevant programme theory or theory of change

- views and experiences of the target population (people who may be affected by the recommendation), including how acceptable and accessible they find the intervention
- practitioners' views, experiences and working methods (including any barriers to and factors supporting adoption of the intervention)
- cost effectiveness
- potential for an intervention to do harm.

At least 1 effectiveness review is developed for every piece of social care guidance. The decision on whether or not to use additional types of review depends on the topic area and the type, depth and breadth of relevant evidence available. Sometimes, a review may draw on a combination of different sources of evidence or types of data (for example, combining mapping information and qualitative data).

4.4 Planning the review

For each review, a review protocol that outlines the background, the objectives and the planned methods should be prepared.

4.4.1 Structure of the review protocol

The review protocol should include the components outlined in table 2.

Table 2 Components of the review protocol

Component	Description
Review question	Review questions as agreed by the GDG.
Objectives	Short description; for example 'To estimate the effectiveness and cost effectiveness of...' or 'To describe the views of...'.
Criteria for considering studies for the review	Detailed components of the review questions, for example the PICO (population, intervention, comparator and outcome) or SPICE (setting, perspective, intervention or phenomenon of interest, comparison, evaluation) framework or similar. Including the study designs selected.

How the information will be searched	Methods of searching (such as databases, hand searching, citation searches). Sources to be searched and any limits applied to the search strategies; for example, publication date, study design, language.
The review strategy	Methods to be used to review the evidence, outlining exceptions and subgroups. Whether meta-analysis will be used and, if so, how it will be conducted.

The review protocol is an important opportunity to look at issues relating to equalities that were identified in the scope, and to plan how these should be addressed. For example, if it is anticipated that the effects of an intervention might vary with service user age the review protocol should outline the plan for addressing this in the review strategy.

4.4.2 Process for developing the review protocol

All review protocols should be included in the draft of the guidance that is prepared for consultation. Any changes made to a protocol in the course of the work should be described. Review protocols are also published on the NICE website 5–7 weeks before consultation on the guidance starts.

4.5 Colloquial evidence

Most types of review focus on gathering and assessing research evidence. However, 'colloquial evidence' – about values, practice, judgement, operational considerations and interests – is also central to developing social care guidance. It can take the following forms.

4.5.1 Expert testimony

An expert witness may be invited to give expert testimony when:

- reviews have uncovered significant gaps in the evidence
- available evidence conflicts significantly
- the GDG wishes to seek the views and experiences of specific groups of practitioners or service users and carers.

Expert testimony can be used to provide a range of information about social care approaches and aspects of service delivery, including:

- context – for example, the policy or commissioning context
- effectiveness – for example, preliminary results from ongoing interventions or services
- service design and delivery – for example, detailed information on how a particular service is implemented with different groups of people
- experience – for example, views and experiences of groups of service users, carers or practitioners.

Experts may be identified via stakeholders, via GDG members, or in the course of carrying out the reviews (for example, key authors or researchers). The Public Involvement Programme will help to identify service user experts. Before the GDG meeting, the expert witness will be asked to prepare an expert testimony summary, including references to any relevant published work. This is treated as evidence and subject to consultation, along with any reviews.

Expert testimony takes the form of a short, focused presentation to the GDG, followed by discussion.

4.6 Equality and diversity

Specific issues in relation to groups identified in the Equality Act (or groups who are particularly disadvantaged in the topic under consideration) should be addressed. These issues should be identified during the topic selection and scope development. They should also be considered when developing the review questions.

4.7 References and further reading

Lomas J, Culyer T, McCutcheon C et al. (2005) Conceptualizing and combining evidence for health system guidance: final report. Ottawa: Canadian Health Services Research Foundation

Petticrew M, Roberts H (2002) Evidence, hierarchies, and typologies: horses for courses. Journal of Epidemiology and Community Health 57: 527–9

Tannahill A (2008) Beyond evidence – to ethics: a decision making framework for health promotion, public health and health improvement. Health Promotion International 23: 380–90

5 Identifying the evidence: literature searching and evidence submission

5.1 Introduction

The systematic identification of evidence is an essential step in developing social care guidance. Systematic literature searches should be thorough, transparent and reproducible. Searches should also minimise 'dissemination biases' (Song et al. 2000), such as publication bias and database bias, that may affect the results of reviews.

This section is aimed primarily at information specialists in the NICE Collaborating Centre for Social Care (NCCSC). It provides advice on the sources to search and on how to develop strategies for systematic literature searches to identify social care and economic evidence. It also provides advice on other areas of information management that form an important part of the social care guidance development process.

Calls for submissions of evidence from stakeholders and undertaking baseline assessments of service activity (for service guidance) are also covered.

The scoping search undertaken when drafting the scope of social care guidance is described in section 2.3.2.

5.2 Searching for evidence

NICE encourages the use of search methods that balance precision and sensitivity. The aim is to identify the best available evidence to address a particular question, without producing an unmanageable volume of results.

NICE supports innovative and flexible approaches to searching, because it is often not possible to know in advance where the best available evidence is likely to be located. The use of iterative searching (sometimes referred to as emergent searching) in which the evidence base is not pre-defined is welcomed, as is the use of grey literature sources, such as charity and government department websites.

The search for evidence involves:

- creating precise search questions and identifying the study types needed to answer those questions
- using an appropriate search approach – iterative or systematic
- matching key sources to the questions being asked (and not necessarily trawling all available sources just because they exist)
- adopting a pragmatic and flexible approach that allows a continual review of how best to find evidence and where
- having an understanding of the existing evidence base.

Identifying evidence for social care guidance involves searching a wide range of electronic resources. The list of information sources should be individually tailored for each review to ensure they are relevant to the guidance topic.

Searches should include a mix of core databases, subject-specific databases and other resources, depending on the subject of the research question and the level of evidence sought.

Database search strategies should be developed using an industry standard database (for example, Social Care Online) and translated into other sources. Database searches should be supplemented by alternative search approaches as appropriate to the topic, for example, hand searching, pearl growing and citation searching.

For innovative and alternative search methods (for example, iterative searching), a rationale for the approach and for subsequent search iterations should be included with any search strategies.

5.2.1 Databases and other sources to search

The databases and other sources that should be searched to identify evidence depend on the review question.

Core and subject-specific databases

The core databases listed in box 8 should be searched for most review questions, although this will be dependent on the specific question. Additional subject-specific databases and other resources may also need to be searched, depending on the subject

area of the review question and the type of evidence sought.

Box 8 Sources for the review question searches (listed in alphabetical order)

- Acompline
- AgeInfo
- ASSIA
- Association of Public Health Observatories (APHO)
- BOPCAS – British Official Publications current awareness service, provides bibliographic details of government publications with abstracts and some full text links
- British Education Index (BEI)
- Campbell Database of Systematic Reviews
- ChildData
- Cinahl
- Cochrane Database of Systematic Reviews – CDSR (Cochrane Reviews)[a]
- DUETS (UK Database of Uncertainties about the Effects of Treatments)
- Educational Information Resources Center (ERIC)
- EPPI-Centre list of systematic reviews
- Health Technology Assessment (HTA) Database (Technology Assessments)
- Joanna Briggs Institute Library of Systematic reviews
- MEDLINE/MEDLINE In-Process
- National Guideline Clearinghouse (USA)
- NHS Economic Evaluation Database (NHS EED) (Economic Evaluations)[b] and the Health Economic Evaluations Database (HEED), if subscribed to
- NHS Evidence
- Planex

- PsychInfo
- Relevant government departments
- Research and surveys on service user and carer experience, for example:
  - Adult Social Care User Survey
  - Personal Social Services Survey of Adult Carers
- Shaping Our Lives
- Social Care Online
- Social Services Abstracts
- Sociological Abstracts
- Turning Research into Practice (TRIP database)
- Web of Knowledge
- Websites of NICE and the National Institute for Health Research (NIHR) HTA Programme for guidance and HTAs in development
- Websites of relevant professional bodies and associations that may have produced guidelines guidance or reports (e.g. Dementia UK for issues related to living with dementia) and other organisations relevant to the topic (for example, Child Poverty Action Group).

Searches may also include a newspaper database (for example, Proquest Newspaper Library) depending on the topic.

For information about service user experience (including children and young people):

- Healthtalk Online
- Social Care Institute for Excellence
- YouthHealthTalk

Websites of relevant organisations that may report research on service users' views or experiences (NICE's Public Involvement Programme can advise further).

[a] Accessible via the Cochrane Library. Database name in parentheses is that used in the Cochrane Library.

[b] Accessible as part of the Cochrane Library and via the Centre for Reviews and Dissemination (CRD). The CRD website hosts the most up-to-date versions of the databases. Database names in parentheses are used in the Cochrane Library.

An awareness of the strengths and weaknesses of each database is important when undertaking a systematic literature search. The different databases index different journals, use different subject headings, cover different time periods and provide different amounts of bibliographic information. There will be overlap in the records retrieved from the different databases for a particular review question. Therefore cross-database searching, although time-consuming, is necessary to comprehensively identify evidence for social care guidance development.

Other sources of information

The sources listed in table 3 – which include databases and websites – can provide useful information about ongoing research, service user experience, practice audits and statistics to help guide Guidance Development Group (GDG) decision-making.

Table 3 Other sources of information

Source	Website
Care Quality Commission	www.cqc.org.uk
Conference Papers Index	www.csa.com/factsheets/cpi-set-c.php
Economic and Social Data Service	www.esds.ac.uk
Health and Social Care Information Centre	www.ic.nhs.ukw
Hospital Episode Statistics	www.hesonline.nhs.uk
Information about experiences	www.healthtalkonline.org www.youthhealthtalk.org

International Standard Randomised Controlled Trial Number Register	www.controlled-trials.com/isrctn
National or regional audits	Search by topic or geographical area for appropriate audit data
National or regional registers	Search to locate appropriate register
Office for National Statistics	www.ons.gov.uk/ons/index.htmlw
Personal Social Services Research Unit	www.pssru.ac.uk
Poverty site	www.poverty.org.uk
Surveys of user experiences	Search for relevant service user organisation websites; condition, service-specific or topic-specific as appropriate
The King's Fund	www.kingsfund.org.uk
UK National Statistics Publication Hub	www.statistics.gov.uk/hub/index.html
Web of Knowledge	http://wokinfo.com

5.2.2 How to search for social care evidence

Many of the principles listed in this section are also relevant to searching for economic evidence (see section 5.3).

Devising an overall search strategy

Review questions can be broken down into different parts, which can then be used to devise a search strategy. For example, using a structured approach such as the PICO (population, intervention, comparator and outcome) or the SPICE (setting, perspective, intervention or phenomenon of interest, comparison, evaluation) framework, a search strategy can be constructed for terms relating to the population; this can be combined with terms relating to the interventions and comparators (if there are any) to be evaluated.

It is important to remember that not all components of a review question will always be

mentioned in the abstracts or subject headings of database records – in particular, outcomes are often not mentioned. Therefore, it may not be advisable to include these components when developing a strategy. For guidance that is being updated, previous strategies can be used in search strategy design.

Additional searches

Because of the range of evidence needed for social care guidance, different approaches to searching are needed (such as snowball citation searching or hand searching). As with database searching, these should be considered at the outset and follow the same principles of transparency and documentation.

5.3 Searching for economic evidence

The approach to searching for economic evidence should be systematic, but targeted to identify studies that are most relevant to current social care practice in the UK and hence likely to be relevant for GDG decision-making.

Two types of search might be needed for economic evidence:

- A systematic search for economic evaluations relevant to the guidance and applicable to current social care practice in the UK should be performed. This should cover all review questions with potential cost or resource implications and should not be limited to the modelling priorities identified in the economic plan. This search should be conducted by the information specialist in consultation with the economist (see section 5.3).
- Additional searches may be necessary to identify other information needed for economic modelling. This may include information about prognosis, adverse effects, quality of life, resource use or costs, which is not always available from the searches conducted for the guidance. The information specialist and the economist should discuss the need for additional searches. See section 7.2.11 for more details about identifying model inputs, including searching for quality-of-life data.

Much of the advice in section 5.2.2 about how to search for social care evidence is also relevant to systematic searches for economic evaluations.

5.3.1 Initial search to identify economic evaluations

Most of the search for economic evaluations should be completed near the beginning of the guidance development process as an initial broad search. The first step is a search of a key economics database using the service user population terms, as for the initial topic background search. Other core databases should then be searched for the service user population terms with the addition of a published economics search filter.

A suggested strategy for searching for economic evaluations in the initial broad search is:

- NHS EED (NHS Economic Evaluation Database)[2], and HEED (Health Economic Evaluations Database) if subscribed to – all years.
- Econpapers.
- CEA Registry.
- HTA database – all years.

This initial broad search should be extended to identify recent papers that have not yet been referenced in the economics databases, by searching key subject-specific databases covering the most recent complete year.

Other subject-specific databases may be searched at this stage, at the discretion of the information specialist.

5.3.2 Further searches to identify economic evaluations

Further searches for economic evaluations may be needed for some review questions. The purpose of these searches is to try to ensure that all relevant economic evaluations are identified; some may not be retrieved by the initial search because of the inclusion criteria of the economics databases.

The need for additional searches and the criteria (such as date parameters) for them should be established by the economist in consultation with the information specialist. It may also be worthwhile to use a highly sensitive economics search filter.

The searches may be executed when needed or alongside other new searches, depending on the preference of the economist in consultation with the information specialist.

5.4 Publishing search strategies

Search strategies are published on the NICE website 5–7 weeks before consultation on the draft guidance starts, and are available to stakeholders during consultation. They should also be published at the same time as the final guidance.

5.5 Re-running searches

Searches undertaken to identify evidence for each review question may be re-run to identify any further evidence that has been published since the search was run initially. If this is done, it will be 6–8 weeks before the draft guidance is submitted to NICE.

5.6 Calls for evidence from stakeholders

For some questions, there may be good reason to believe that information exists that has not been found using standard searches. Examples include ongoing research in a field, if a service or intervention is relatively new, studies that have been published only as abstracts (see section 6.1.2), data on adverse effects, economic models and studies of the experiences of service users, carers or social care practitioners or other professionals.

In these situations, a call for evidence may be made to all registered stakeholders. This call should specify the question being addressed and details of the type of evidence being sought, for example the structured framework being used and study design for questions of effectiveness. A call for evidence may be made at any point during guidance development and stakeholders should usually be given 4 weeks to respond.

If it is likely that the regulatory authorities hold relevant data that have not been submitted in response to a call for evidence, the appropriate regulatory authority may be approached to release those data.

5.6.1 Confidential information

In addition to published studies, stakeholders may submit relevant unpublished data or studies in response to a call for evidence.

Box 9 summarises what may and may not be considered confidential by NICE.

Box 9 Information on what may and may not be considered confidential

Data that may be included as confidential include those that may influence share price values (commercial in confidence) or are intellectual property (academic in confidence; that is, awaiting publication).

Confidential information should be kept to an absolute minimum; for example, only 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 guidance.

Results derived from calculations using confidential data are not considered confidential unless releasing those results would enable back-calculation to the original confidential data.

Stakeholders should complete a checklist that lists and identifies the location of all confidential information contained in their submission. Stakeholders should also mark the part of their submission that contains the confidential information; for example, by using a highlighter pen on a hard copy, or the highlighter function in an electronic version. These markings should be maintained on those sections so that the GDG knows which parts are confidential.

Following the principles in box 9, the amount of confidential information should be kept to a minimum. As a minimum, a summary should be publicly available by the time of the consultation on the guidance. NICE needs to be able to justify the recommendations in social care guidance on the basis of the evidence considered by the GDG. NICE and the NCCSC will therefore work with the data owners to agree a balance between confidentiality and transparency.

5.6.2 Information not eligible for submission

Stakeholders are asked not to submit the types of evidence listed in box 10, because these will not be considered.

Box 10 Stakeholder material not eligible for consideration by the GDG

- Studies with weak designs if better designed studies are available.
- Promotional literature.
- Papers, commentaries and editorials that interpret the results of a published paper.
- Representations and experiences of individuals (unless assessed as part of a well-designed study or survey).

5.6.3 Contacting experts

Ongoing research may be needed to tell the GDG of important studies likely to be published or completed during the development – or soon after publication – of the social care guidance. Some types of research, notably intervention trials, are often documented in databases of ongoing research. However, these are not always up-to-date and it is advisable to ask experts in the area.

Experts can be identified and contacted via research networks, relevant journal abstracts via relevant reference lists, or GDG members.

5.7 Additional information for service guidance

In addition to evidence identified by routine literature searches, when developing service guidance (see section 1.4.1) the GDG needs information describing the current configuration of social care services, the level of activity and any significant regional variations. This helps the GDG to:

- identify the gaps between current social care practice, service provision and service user and carer experience, and what the GDG concludes should be in place
- shape the guidance and formulate recommendations that are likely to have the greatest effect on the service as well as on outcomes.

A detailed baseline assessment of service activity is needed, and should be conducted before the GDG starts work. This should be available for consideration early in the

guidance development process, and ideally early enough to be taken into account in the scope. The following data sources might be used in providing an overall picture of service configuration and activity:

- national or regional registers
- National Adult Social Care Intelligence Service reports, including social care activity, expenditure, workforce, user experience and joint strategic needs assessments
- Office of National Statistic reports
- local authority datasets
- national or regional practice audits
- surveys of service users' or carers' experiences.

Such information is also useful to the NICE costing and commissioning lead when developing the cost impact report and can be used in the needs assessment process undertaken by the NCCSC adoption support lead, as part of the adoption support development work.

Where a topic does include a substantive service guidance component, approaches as described in the NICE Interim methods guide for developing service guidance may be used. Such methods will be agreed with NICE from the outset and clearly documented in the final guidance.

5.8 Equality and diversity

All searches should be inclusive, capturing evidence related to all groups identified in the Equality Act (or to groups that are particularly disadvantaged with respect to the topic under consideration). Search strategies should be narrowed to specific groups only if these have been specified during the topic or scoping development phases.

5.9 References and further reading

Jenkins M (2004) Evaluation of methodological search filters – a review. Health Information and Libraries Journal 21: 148–63

Lefebvre C, Manheimer E, Glanville J (2011) Searching for studies. In: Higgins JPT, Green S, editors. Cochrane handbook for systematic reviews of interventions, version 5.1.0 (updated March 2011). The Cochrane Collaboration.

Song F, Eastwood AJ, Gilbody S et al. (2000) Publication and related biases. Health Technology Assessment 4: 1–115

[2] Accessible as part of the Cochrane Library and via the Centre for Reviews and Dissemination (CRD). The CRD website hosts the most up-to-date version of NHS EED.

6 Reviewing the evidence

Studies identified during literature searches (see section 5) need to be reviewed to identify the most appropriate data to help address the review questions, and to ensure the guidance recommendations are based on the best available evidence. The systematic review process used should be explicit and transparent. This involves 5 major steps:

- writing the review protocol (see section 4.4.1)
- selecting relevant studies
- assessing their quality
- synthesising the results
- interpreting the results.

The process of selecting relevant studies is common to all systematic reviews; the other steps are discussed below in relation to the major types of review questions. The same rigour should be applied to reviewing fully and partially published studies, as well as unpublished data supplied by stakeholders and expert testimony, if submitted.

Methods for developing clinical guidelines are relatively well established. However, this may not be the case for social care guidance. During development, it may become apparent that existing methods for considering evidence are not appropriate for social care topics. As part of the development process, the NCCSC should highlight to NICE any methodological development needs, and work with NICE to develop strategies to address them.

Detailed information on methods of reviewing and synthesising evidence can be found in the Cochrane Handbook.

6.1 Selecting relevant studies

The study selection process for social care studies and economic evaluations should be clearly documented, giving details of the inclusion and exclusion criteria that were applied.

6.1.1 Research studies

Before acquiring papers for assessment, the information specialist or systematic reviewer should sift the evidence identified in the search and discard irrelevant material. First, the titles of the retrieved citations should be scanned and those that fall outside the topic of the guidance should be excluded. A quick check of the abstracts of the remaining papers should identify those that are clearly not relevant to the review questions and can be excluded.

Next, the remaining abstracts should be scrutinised against the inclusion and exclusion criteria agreed by the Guidance Development Group (GDG). Abstracts that do not meet the inclusion criteria should be excluded. Any doubts about inclusion should be resolved by discussion with the GDG before the results of the study are considered. Once the sifting is complete, full versions of the selected studies can be acquired for assessment. Studies that fail to meet the inclusion criteria once the full version has been checked should be excluded; those that meet the criteria can be assessed. Because there is always a potential for error and bias in selecting the evidence, double sifting (that is, sifting by 2 people) of a random selection of abstracts should be performed periodically (Edwards et al. 2002).

6.1.2 Conference abstracts

Conference abstracts can be a good source of information in systematic reviews. For example, conference abstracts can be important in identifying published trials that may be missed and ongoing trials that are due to be published, or in estimating the amount of not-fully-published evidence (and so guiding calls for evidence and judgements about publication bias). However, the following should be considered when deciding whether to include conference abstracts as a source of evidence:

- Conference abstracts may not include sufficient information to allow confident judgements to be made about the quality and results of a study.
- It can be time-consuming to trace the original studies or additional data relating to the conference abstracts, and the information found may not always be useful.

Therefore:

- If sufficient evidence has been identified from full published studies, it may be reasonable not to trace the original studies or additional data related to conference abstracts.
- If there is a lack of or limited evidence identified from full published studies, the systematic reviewer may consider an additional process for tracing the original studies or additional data relating to the conference abstracts, to allow full critical appraisal and to make judgements on their inclusion in or exclusion from the systematic review.

6.1.3 Economic evaluations

The process for sifting and selecting economic evaluations for assessment is essentially the same as for social care studies. Consultation between the information specialist, the economist and the systematic reviewer is essential when deciding the inclusion criteria; these decisions should be discussed and agreed with the GDG. The review should be targeted to identify the papers that are most relevant to current practice and to GDG decision-making. The review should also usually focus on 'full' economic evaluations that compare both the costs and consequences of the alternative interventions and any services under consideration.

Inclusion criteria for filtering and selection of papers for review by the economist should specify relevant populations and interventions for the review question. They should also specify the following:

- An appropriate date range, as older studies may reflect outdated practices.
- The country or setting, because studies conducted in other social care systems might not be relevant to the UK. In some cases, it may be appropriate to limit consideration to UK-based or OECD (Organisation for Economic Cooperation and Development) studies.
- The type of economic evaluation. This may include cost–utility, cost–benefit, cost-effectiveness, cost-minimisation or cost–consequences analyses. Non-comparative costing studies, 'burden of disease' studies and 'cost of illness' studies should usually be excluded.

6.2 Assessing the quality of the evidence

6.2.1 Introduction

This section applies to the assessment of both qualitative and quantitative evidence.

The review team should assess the quality of evidence selected for inclusion in the review using the appropriate quality appraisal checklist (see section 6.2.2). This is a key stage in the guidance development process because the quality rating of studies will be reflected in the evidence statements (see section 6.4). These, in turn, are taken into account in the recommendations (along with other factors and considerations, see section 9.2).

Some of the more commonly used study types and their abbreviations are:

- quantitative studies: experimental
  - before-and-after study
  - non-randomised controlled trial (NRCT)
  - randomised controlled trial (RCT)
- quantitative studies: observational
  - before-and-after study
  - case–control study
  - cohort study
  - correlation study
  - cross-sectional study
  - interrupted time series (ITS)

- qualitative studies
  - document analysis
  - focus group
  - interview study
  - observation and participant observation
- economic studies
  - cost–benefit analysis
  - cost–consequences analysis
  - cost-effectiveness analysis
  - cost–utility analysis.

The quality of individual studies should be assessed using an appropriate quality appraisal checklist. This is to make a judgement about both the quality of execution of the study and its fitness-for-purpose in terms of answering the review question(s). Factors that influence judgements on the 'trustworthiness' of the study, such as its relevance to the review questions and how 'convincing' the results are, should be clearly described in the review.

Some studies, particularly those using mixed methods, may report quantitative, qualitative and economic outcomes. In such cases, each aspect of the study should be separately assessed using the appropriate checklist.

Similarly, a study may assess the effectiveness of an intervention using different outcome measures, some of which are more reliable than others (for example, self-reported levels of school attendance compared with a formal measure of attendance from the school). In such cases, the study might be rated differently for each outcome, depending on the reliability of the measures used. For further information on how to integrate evidence from qualitative and quantitative studies, see Dixon-Woods et al. (2004).

6.2.2 Quality assessment

Quality assessment is a critical stage of the evidence review process.

Internal validity

The systematic reviewer should use the relevant quality appraisal checklist to assess a study's internal validity: that is, to check whether potential sources of bias have been minimised and to determine whether its conclusions are open to any degree of doubt. The quality of each study should be rated as follows:

- ++ All or most of the checklist criteria have been fulfilled and where they have not been fulfilled, the conclusions are very unlikely to alter.
- + Some of the checklist criteria have been fulfilled and where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.
- – Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

If a study is not assigned a '++' quality rating, the review team should record the key reasons why this is the case in the quality appraisal checklist comments column, alongside the overall quality rating. They should also record these reasons in the evidence table and highlight them in the narrative summary.

External validity

The systematic reviewer should also use the quality appraisal checklist to assess the external validity of studies: the extent to which the findings for the study participants apply to the whole 'source population' (that is, the population they were chosen from).

This involves assessing the extent to which study participants are representative of the source population. It may also involve an assessment of the extent to which, if the study were replicated in a different setting but with similar population parameters, the results would have been the same or similar. If the study includes an 'intervention', then it should be assessed to see whether it would be feasible in settings other than that initially investigated.

Studies should be given a separate rating for external validity (++, + or –) prefixed with 'EV' (external validity).

Unpublished data and studies in progress

Reviewers are not expected to search unpublished data as a matter of routine. However, if time and resources allow, the systematic reviewer may obtain such papers, particularly from stakeholders and experts in the topic area (see section 5.6). Any unpublished data that the authors intend to publish as peer-reviewed literature should be quality-assessed in the same way as published studies. If additional information is needed to complete the quality appraisal checklist, the authors should be contacted if possible.

6.3 Extracting, synthesising and presenting the evidence

This section describes how to present data from quantitative and qualitative evidence and develop related evidence statements for both qualitative and quantitative evidence reviews.

Any expert or value judgements that have been made (including expert advice from third parties) should be reported in the review.

Both qualitative and quantitative evidence reviews should incorporate narrative summaries of, and evidence tables for, all studies. Concise detail should be given (where appropriate) on populations, interventions, settings, outcomes, measures and effects.

This includes identifying any similarities and differences between studies, for example, in terms of the study population, interventions and outcome measures.

6.3.1 Data extraction and evidence tables

The evidence tables can also be used as data extraction templates for included studies.

Evidence tables can help determine whether it is possible to calculate a summary estimate of effect, if applicable (see Conducting and presenting a meta-analysis in section 6.3.4).

Evidence tables for quantitative studies

Concise details (sometimes in bullet point or another list form) should be given on: bibliography (authors, date); study aim and type (for example, randomised controlled trial,

case–control); population (source, eligible and selected); intervention, if applicable (content, intervener, duration, and method, mode and timing of delivery); method of allocation to study group (if applicable); outcomes (primary and secondary, and whether measures were objective, subjective or otherwise validated); and key findings (including effect sizes, confidence intervals and their significance, for all relevant outcomes).

If given, exact p values (whether or not significant) and confidence intervals must be reported, as should the test from which they were obtained. If p values are not given, any descriptive statistics indicating the direction of the difference between intervention and comparator should be presented. If no further statistical information is available, then this should be clearly stated.

The quality ratings of the study's internal and external validity should also be given (see External validity in section 6.2.2). If study details are not reported (or not applicable), this should be clearly stated.

Evidence tables for qualitative studies

Concise details should be given on: bibliography (authors, date); location (for example, UK); funding details (if known); population or participants; study design; theoretical perspective; key aims, objectives and research questions; methods (including analytic and data collection technique); key themes or findings (including quotes from participants that illustrate these themes or findings, if appropriate); gaps and limitations; conclusions; and the study's quality rating.

6.3.2 Narrative summaries of quantitative or qualitative studies

The narrative summary provides an opportunity to place a study and its findings in context. It should highlight key factors influencing the results observed, and give an interpretation of the results and more on the detail presented in the evidence tables (see section 6.3.1).

The narrative summary should conclude with a short discussion, followed by 1 or more evidence statements. These should reflect the key findings, the quantity, quality and consistency of the evidence, and its applicability to the review question (including its applicability to the target population).

Narrative summaries of all studies and interventions should be incorporated in the main

findings of the evidence review. They should be organised by review question and could be divided into smaller subcategories, such as outcome measure, setting or subpopulation. The summary should be brief and, where possible, use tables or other methods to summarise and present key elements or features of the evidence.

6.3.3 Summary tables

If appropriate, short summary tables can be included with the main findings (usually preceding an evidence statement) or in the appendices. For example, these might:

- summarise the information gleaned for different review questions
- summarise the study types, populations, interventions, settings or outcomes for each study related to a particular research question
- organise and summarise studies related to different outcomes.

6.3.4 Other presentations of quantitative data

There are a range of ways to summarise and illustrate the strength and direction of quantitative evidence about the effectiveness of an intervention. Some of the most commonly used methods are described below, although this is not an exhaustive list.

Graphical presentation

Results from relevant studies (whether statistically significant or not) can be presented graphically.

Forest plots should be used to show effect estimates and confidence intervals for each study (when available, or when it is possible to calculate them). They could be used even when it is not appropriate to do a meta-analysis and present a pooled estimate (see Conducting and presenting a meta-analysis in section 6.3.4). However, the homogeneity of the outcomes and measures in the studies needs to be carefully considered: the forest plot needs data derived from the same (or justifiably similar) outcomes and measures.

If a forest plot is not appropriate, other graphical forms may be used (for example, a harvest plot [Ogilvie et al. 2008]).

When outcome measures vary between studies, it may be appropriate to present separate

summary graphs for each outcome. However, if outcomes can be transformed on to a common scale by making further assumptions, an integrated (graphical) summary would be helpful. In such cases, the basis (and assumptions) used should be clearly stated and the results obtained in this way should be clearly marked.

Conducting and presenting a meta-analysis

Meta-analysis data may be used to produce a graph if the data (usually from randomised controlled trials) are sufficiently homogenous and if there are enough relevant and valid data from comparable (or the same) outcome measures. If such data are not available, the synthesis may have to be restricted to a narrative overview of individual studies looking at the same question. In such cases, a forest plot (see Graphical presentation in section 6.3.4) is a useful way of illustrating the results.

A full description of data synthesis, including meta-analysis and extraction methods, is available in Undertaking systematic reviews of research on effectiveness (NHS Centre for Review and Dissemination 2001).

6.3.5 Other presentations of qualitative data based on analytic and structured techniques

The nature of qualitative evidence is such that it is unhelpful to set a prescriptive method for its synthesis and description. Qualitative evidence occurs in many forms and formats.

In some cases, the evidence may be synthesised and then summarised. In other cases, a narrative description may be adequate. The approach used depends on the volume and consistency of the evidence. If the qualitative literature is extensive, then a synthetic approach is preferable. If the evidence is more disparate and sparse, a descriptive approach may be more appropriate.

6.4 Deriving evidence statements

An evidence statement is a brief summary of 1 finding from a review of evidence that social care guidance is based on.

6.4.1 Introduction

This section applies to both qualitative and quantitative reviews. As described in section 6.3.2, each evidence review should include a narrative summary and should conclude with a short discussion and 1 or more supporting evidence statements.

The evidence statements should reflect the strength (quality, quantity and consistency) of the evidence and make a statement about its applicability. They may also highlight a lack of evidence. They should provide an aggregated summary of the evidence (from 1 or more studies) in relation to a key question or issue. In the case of intervention studies, they should also reflect what is plausible, given the evidence available about what has worked in similar circumstances.

Evidence statements are structured and written to help the GDG formulate and prioritise recommendations. They help it decide:

- whether or not there is sufficient evidence (in terms of strength and applicability) to form a judgement
- whether, on balance, the evidence shows that an intervention or programme can be effective or is inconclusive (where relevant)
- the typical size of effect (where relevant)
- whether the evidence is applicable to the target groups and contexts covered by the guidance.

Evidence statements that support the recommendations should be included in the final guidance document.

6.4.2 Structure and content of evidence statements

One or more evidence statements are prepared for each review question or its subsidiary questions. (Subsidiary questions may cover a type of intervention, specific population groups, a setting or an outcome.)

Once all the data have been collected, consideration should be given on how to group the evidence. For example, it could be grouped according to the similarity of the populations, interventions and outcomes covered in the studies.

However, the decision will be highly context-specific and will depend on the amount, breadth and depth of evidence. A separate evidence statement for each study should be avoided. Evidence statements based on so many studies that the statement becomes too generic and therefore meaningless are also to be avoided.

Short evidence statements should be presented, by outcome where possible, summarising the key features of the evidence on effectiveness (including harms as appropriate) and cost effectiveness.

The evidence statements should include the number of studies and participants, the quality of the evidence and the direction of estimate of the effect. An evidence statement may be needed even if no evidence is identified for an important outcome. Evidence statements may also note the presence of relevant ongoing research.

Examples of evidence statements

- There is moderate evidence of mixed quality from 4 retrospective US cohort studies (1 [++], 1 [+], 2 [–]) to suggest that looked-after children and young people who received transition support services (TSSs) were more likely to complete compulsory education with formal qualifications than those who had not received these TSSs; whereas 1 prospective US cohort study (+) reported a non-significant finding in favour of the comparison group.
- There is moderate evidence of a mixed effect with regard to the effect of TSSs on employment at case closing. Two US cohort studies, 1 prospective (+) and 1 retrospective (–) reported that those who had received TSSs were more likely to be employed at case closing than those who had not received TSSs, whereas 1 retrospective US cohort study (–) reported that those who had received TSSs were less likely to be employed at case closing than those who had not.

Both of the above examples are taken from Looked-after children and young people (NICE public health guidance 28).

6.5 Published guidance

Any relevant published guidance (from NICE and other agencies) should always be identified and considered, as well as relevant NICE guidance in development.

6.5.1 NICE guidance

Recommendations taken from published NICE guidance should be quoted verbatim. Published NICE guidance should be fully referenced and the evidence underpinning the recommendations left unchanged, provided it is not out of date.

6.5.2 Other published guidance

Relevant published guidance from other organisations may be identified in the search for evidence. If these are not from NICE accredited sources, they should be assessed for quality using the AGREE II (appraisal of guidelines research and evaluation II) instrument (Brouwers et al. 2010). The aim is to ensure they have sufficient documentation to be considered.

There is no cut-off point for accepting or rejecting a piece of guidance, and each GDG will need to set its own parameters. These should be documented in the methods section of the guidance, along with a summary of the assessment. The results should be presented as an appendix to the guidance.

Reviews of evidence from other guidance that cover questions formulated by the GDG may be considered as evidence if:

- they are assessed using the appropriate methodology checklist from this manual and are judged to be of high quality
- they are accompanied by an evidence statement and evidence tables
- the evidence is updated according to the process for exceptional updates of NICE social care guidance (see section 14.1.2).

The GDG should create its own evidence summaries or statements to include in the standard template. Evidence tables from other guidance should be referenced with a direct link to the source website or a full reference of the published document. The GDG should formulate its own recommendations, taking into consideration the whole body of evidence.

Recommendations from other guidance should not be quoted verbatim, except for recommendations from Department of Health or Department for Education social care policy or legislation.

6.6 Equality and diversity

In the discussion section of the evidence reviews, the following questions should be considered.

6.6.1 Are the evidence-review criteria inclusive?

All relevant inequalities data should be included in the reviews. At the data extraction stage, reviewers are prompted to refer to the PROGRESS-Plus criteria (age, sex, sexual orientation, disability, family origin, religion, place of residence, occupation, education, socioeconomic position and social capital; Oliver et al. 2008). Review inclusion and exclusion criteria should also take the relevant groups into account.

6.6.2 Have relevant data been appropriately extracted and presented in the evidence statements?

Equalities evidence should be considered during the drafting of reviews. It should be included in the data extraction process and should appear in the summary evidence statements.

6.6.3 What is the state of the evidence base?

This question aims to identify whether there are any gaps in the evidence in relation to inequalities. It also aims to identify whether the evidence has uncovered gaps in the scope of the guidance in relation to inequalities.

6.7 References and further reading

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7 Incorporating economic evaluation

7.1 The role of the economist in social care guidance development

7.1.1 The economic plan

The NICE Collaborating Centre for Social Care's (NCCSC's) economist works closely with the Guidance Development Groups (GDG) to ensure that economic evidence reviews are underpinned by the most plausible assumptions and review questions. Defining the priorities for economic evaluation should start during the scoping of social care guidance, and should proceed alongside development of the review questions.

The economic plan is a document that is prepared by the NCCSC's economist in consultation with the rest of the NCCSC, the GDG and NICE. It identifies initial priorities for further economic analysis and outlines proposed methods for addressing these questions (see sections 7.1.3 and 7.1.4). The economic plan is likely to be modified during guidance development; for example, as evidence is reviewed it may become apparent that further economic evaluation is not necessary for some aspects that were initially prioritised. The economic plan is published on the NICE website before the guidance goes out for consultation. The rationale for the final choice of priorities for economic analysis should be explained in the guidance.

7.1.2 Advising the Guidance Development Group on economic issues

The GDG should be encouraged to consider the economic consequences of the guidance recommendations as well as the implications for practice. A formal presentation outlining the basic principles of social care economics is given at the first GDG meeting. Further presentations may be useful later in the guidance development process.

It is particularly important for GDG members to understand that economic analysis is not about estimating the resource consequences of a guidance recommendation, but is concerned with the evaluation of both costs and benefits. GDG members must understand

that economic evaluation should compare the costs and consequences of alternative courses of action.

Within the context of the principles outlined in Social value judgements: principles for the development of NICE guidance (second edition, 2008) (note this is currently under review, see section 1.2), the GDG should be encouraged to consider recommendations that:

- are less effective than current practice, but free up resources that can be re-invested in public sector social care to increase the welfare of the population receiving social care, **or**
- increase effectiveness at an acceptable level of increased cost (see section 7.3).

GDG members may find it useful for the economist to outline economic concepts such as incremental analysis, the public sector perspective (including NHS and personal social services[3]), and measurement of social care-related outcome measures, including social care-related quality of life, capability and wellbeing.

7.1.3 Reviewing economic evaluations

Economic analysis should be underpinned by the best available evidence. The evidence should be based on, and be consistent with, that identified when defining the review questions. If expert opinion is used in the economic analysis, this should be clearly stated and justified in the guidance.

Identifying and examining published economic information that is relevant to the review questions is an important component of social care guidance development. Processes for searching, selecting, appraising and summarising economic evaluations are discussed in sections 5.3, 6.1.3, 6.3.3 and 6.3.5.

The general approach to reviewing economic evaluations should be systematic, focused and pragmatic. If a high-quality economic analysis that addresses a key social care issue and is relevant to current practice has already been published, then further modelling is probably not necessary.

Other published economic evaluations may not be relevant, for example, costs may differ from UK costs in non-UK studies. So time should not be spent critically appraising studies that are not likely to provide useful information for guidance decision-making. Search strategies and criteria for the inclusion and exclusion of economic evaluations should be

designed to filter out such studies (see section 5.3). The strategies and criteria used should be stated explicitly in the guidance and applied consistently.

7.1.4 Prioritising questions for further economic analysis

It is anticipated that the social care economic literature is unlikely to be so comprehensive and conclusive that no further analysis is necessary. Additional economic analyses are usually needed, and should be developed selectively, unless an existing analysis can easily be adapted to answer the question.

Close collaboration between the economist and the GDG is essential early in the guidance development process to ensure that:

- the most important questions are selected for economic analysis
- the methodological approach is appropriate
- all important effects and resource costs are included
- the evidence used is the best available and the assumptions are plausible
- results of economic analysis are interpreted appropriately, limitations are acknowledged and uncertainties are systematically addressed.

The number and complexity of new analyses depends on the priority areas and the information needed for robust decision-making.

Economic analysis is potentially useful for any question in which an intervention or service is compared with another. It may also be appropriate in comparing different combinations or sequences of interventions, as well as individual components of the social care service or intervention. However, the broad scope of much social care guidance means it may not be possible to conduct original analysis for every component.

Selecting questions for further economic analysis, including modelling, should be a joint decision between the economist, other GDG members and the NICE team. Selection should be based on systematic consideration of the potential value of economic analysis across all key social care issues.

An economic analysis will be more useful if it is likely to influence a guidance recommendation, and if the social care and financial consequences of the

recommendation are large. The decision about whether to carry out an economic analysis therefore depends on:

- the expected net benefit of the recommendation (the number of individuals affected and the potential impact on costs and social care outcomes per individual)
- the degree of uncertainty in the cost-effectiveness literature and the likelihood that economic analysis will clarify matters.

For a particular question, new economic analysis may not be warranted if the evidence is so uncertain that even providing a rough estimate of cost effectiveness is not possible. Alternatively, the published evidence on cost effectiveness may be so reliable that further economic analysis would be unnecessary. In addition, economic analysis may not be needed if it is obvious that the resource implications are modest in relation to the expected gains.

7.2 Economic reference case

Economic analysis should be undertaken in collaboration with the GDG, explicitly based on the guidance review questions, and should compare all relevant alternatives for specified groups of service users. Any differences between the review questions and the economic analysis should be clearly acknowledged, justified and explained, and be approved by the GDG.

A reference case for social care economic evaluation is outlined in table 4. Methods of social care economic evaluation are developing, and elements of the reference case reflect this; it may also be appropriate for the nature of economic evaluation to vary according to the type of social care being assessed or the quality of available evidence.

Table 4 Summary of the reference case

Element of assessment	Reference case	Section providing details
Defining the decision problem	The scope developed by NICE	7.2.1

Comparators	Interventions routinely delivered by the public and non-public social care sector	7.2.2
Perspective on costs	Public sector, including the NHS, personal social services and local authorities (and other public sector agencies as appropriate) Non-public sector funding, including family funding and the costs of unpaid care, if these contribute to outcomes	7.2.3
Perspective on outcomes	Effects on people for whom services are delivered (service users and/or carers)	7.2.4
Type of economic evaluation	Cost–utility analysis Cost-effectiveness analysis Cost–consequences analysis Cost–benefit analysis	7.2.5
Time horizon	To reflect all important differences in costs and outcomes	7.2.6
Synthesis of evidence on outcomes	Based on a systematic review	5.3
Measuring and valuing effects	Quality-adjusted life year (QALY) or 'social care QALY' with parallel evaluation based on capability measures where an intervention results in both capability and health or social care outcomes. ASCOT instruments may be used as measures of social care quality of life and ICECAP instruments may be used to measure capability	7.2.7
Source of data for measurement of effects	Reported directly by service users and/or carers	7.2.7

Source of preference data for valuation of changes in social care-related quality of life, capability, etc.	Representative sample of the UK public	7.2.7
Equity considerations	Equity considerations relevant to specific topics, and how these were addressed in economic evaluation, must be reported	7.2.8
Evidence on resource use and costs	Costs should relate to public sector (such as NHS, personal social services and local authority) resources and be valued using relevant prices; costs borne by service users and the value of unpaid care must also be included where they contribute to outcomes	7.2.9
Discounting	An annual rate of 3.5% on both costs and effects	7.2.10

7.2.1 Defining the decision problem

Economic evaluation should begin with a clear statement of the decision problem. This needs a definition and justification of the interventions or programmes being assessed and the relevant service users (including carers).

7.2.2 Comparators

The interventions or services included in the analysis should be described in sufficient detail to allow stakeholders to understand exactly what is being assessed. This is particularly important when assessing the cost effectiveness of services.

For social care guidance, comparators include interventions used or services delivered in the public and non-public sectors. The contribution of unpaid social care provided by families and carers may also be important. There should be agreement with the GDG on the most appropriate choice of comparator because of its important impact on the results of economic evaluation.

7.2.3 Perspective on costs

Social care-related outcomes are delivered by a range of providers, including various public sector agencies, commercial providers, the voluntary and community sector and unpaid (family) care. The costs are borne by various public sector agencies, service users and their families. The payer-provider matrix is complex and differs across the range of social care services and programmes; some social care is provided for carers, for example. Unlike healthcare, there is no universal model of who is liable to pay for social care services, and there may be local variation in eligibility criteria, including means testing.

There may be local variation in how decisions are made about which social care is provided, for example, in terms of the use of personal social care budgets. Social care economic evaluation must reflect this complex situation and so a multi-stakeholder perspective will be adopted, with exclusions justified.

A public sector perspective (including the NHS and personal social services, or local government) is used by NICE for public health economic analysis, if this is sufficient to capture all major costs and benefits. However, the perspective is flexible, and a societal perspective can be used where appropriate.

For social care, a flexible approach may be needed to take account of costs borne by the NHS, local authorities, education authorities, relevant publicly funded voluntary organisations or criminal justice services.

Scope for 'cost shifting' should be addressed in the economic evaluation, and the results of economic evaluation may need to be presented for different public sector agencies.

The cost of social care programmes and interventions may be borne by service users and their families, for example, when access to social care is means-tested. Some social care may also be provided on an unpaid basis, often by the carers of service users. There is the potential for costs to be shifted inappropriately from the public sector to families and unpaid carers.

NICE does not usually include the costs of unpaid or informal care in cost-effectiveness analysis for health and public health interventions. However, the importance of informal care in contributing to publicly funded social care interventions (for example, care for older people) means that economic evaluation in social care should take account of the value of unpaid care associated with the services or interventions under evaluation. The inclusion

of unpaid care can have a significant impact on the potential cost effectiveness of social care interventions because unpaid care can be a substantial part of the care provided and therefore impacts on the outcomes of publicly funded services. It is recognised that there is no widely accepted method for valuing unpaid care, so any methods used should be justified and agreed with NICE before economic evaluation is undertaken, and consideration must be given to the sensitivity of results to the use of alternate methods. The issue is potentially complex, for example, some service users may pay privately to ensure additional 'quality' of care. In taking account of unpaid care, economic evaluation must be designed to ensure that the focus of the economic evaluation remains on assessing the cost effectiveness of publicly funded social care interventions and services.

Economic evaluation should also recognise that social care provided by the voluntary sector may be based on public-sector funding (grants to voluntary bodies, for example).

If appropriate, and with the agreement of NICE, results may also be presented from other perspectives. For example, an employer's perspective could be taken to show the business case for a social care intervention.

It is envisaged that the analytical difficulties involved in creating clear, transparent decision rules around what costs should or should not be considered, and for which interventions and outcomes, will be particularly problematic. These should be discussed with NICE before any economic evaluation is undertaken and an approach agreed.

7.2.4 Perspective on outcomes

The outcomes focus should be the effects on people for whom services are delivered. Effects on service users and carers (whether expressed in terms of health effects, social care quality of life, capability or wellbeing) are the intended outcomes of social care interventions and programmes.

Although holistic effects on service users, families and carers may represent the ideal perspective on outcomes, a pragmatic and flexible approach is needed to address different perspectives, recognising that improved outcomes for service users and carers may not always coincide.

The economic implications of alternative service outcomes could be the focus of some economic evaluations, and where appropriate, this should be agreed with NICE at the outset.

7.2.5 Type of economic evaluation

The approach to economic evaluation will be agreed with NICE at the outset. If possible, a cost-effectiveness analysis should be undertaken, with effects measured using a non-monetary outcome indicator. A cost–utility analysis, which allows effective comparisons across different decision problems, is the form of cost-effectiveness analysis usually preferred by NICE but the use of cost–utility analysis in social care economic evaluation will present methodological challenges because currently there is no accepted social care equivalent of the healthcare QALY.

If a cost-effectiveness analysis is not appropriate, or not possible, other validated methods such as cost–consequences or cost–benefit analysis may be used. The aim is to give the GDG an opportunity to consider the cost effectiveness of social care interventions and programmes across a complex arrangement of payers and providers. Cost–benefit analysis should only be used with NICE's agreement and should not conflict with NICE's social value judgements.

For social care topics, benefits may variously be identified in terms of health or social care-related quality of life, or in terms of capability. Evaluation related to quality of life may be undertaken in parallel with evaluation based on capability measures, where an intervention results in both types of outcome.

Cost–utility analysis

A cost–utility analysis is a form of cost-effectiveness analysis in which interventions producing different effects are expressed in terms of a common measure of outcome, such as QALYs.

NICE uses cost–utility analyses for technology appraisals and clinical guidelines and, if suitable data are available, for public health guidance. This ensures baseline comparability across the UK healthcare sector and across NICE's programmes. It also helps to prioritise which recommendations should be implemented locally. The same approach should be considered for social care economic evaluation if suitable data are available.

In healthcare and public health analysis, NICE compares the efficiency of alternative interventions using the QALY as the measure of outcome. A QALY is a measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. QALYs are calculated by estimating the years of life a

person can expect after a particular intervention and weighting each year with a quality of life score (on a 0 to 1 scale).

Box 11 Example of how a QALY is calculated in healthcare

Patient X has a serious, life-threatening condition.

- If he continues receiving standard treatment, he will live for 1 year, with a quality of life of 0.4 (0 or below = worst possible health, 1 = best possible health).
- If he receives the new drug, he will live for 1 year 3 months (1.25 years), with a quality of life of 0.6.

The new treatment is compared with standard care in terms of the QALYs gained:

- Standard treatment: 1 (year's extra life) × 0.4 = 0.4 QALY
- New treatment: 1.25 (1 year, 3 months extra life) × 0.6 = 0.75 QALY

The new treatment leads to 0.35 additional QALYs (that is: 0.75–0.4 QALY = 0.35 QALYs).

For social care economic evaluation, there is currently no commonly accepted measure of outcome like the QALY in health economics. However, various outcome measures for social care are emerging, ranging from social care-related quality of life to broader measures of capability and wellbeing. As economic methodology develops, these measures may allow cost–utility analysis on the basis of a social care equivalent of the QALY.

A pragmatic approach to cost–utility analysis for social care should use a measure of social care-related quality of life, but parallel work using capability and wellbeing measures should also be undertaken if possible. Specific consideration may be given to identifying the nature of effects, because health effects may be relevant to some social care guidance topics and may necessitate the use of health economic approaches for elements of the economic evaluation.

Other cost-effectiveness analysis

Cost–utility analysis is a form of cost-effectiveness analysis, but if data or evidence are not sufficient to support it, an alternative may be considered. Examples include using non-generic or intervention-specific measures.

A cost-effectiveness analysis could be modelled on a single well-conducted randomised controlled trial. Or it could use decision-analytic techniques to analyse probability, cost and outcome data from a variety of published sources.

Cost–consequences analysis

Cost–consequences analysis can measure both welfare and quality of life more broadly than the health-related quality of life measure encompassed in the EQ-5D instrument that NICE uses to estimate the QALY. It can take many other items into account that public sector bodies responsible for social care are likely to find important, including the trade-off between long-term goals and a paucity of short-run funding, and spill-over effects into other areas of public sector responsibility. The extent to which these effects are material for any particular analysis will depend on circumstances. The outcomes to be included in the cost–consequences analysis will depend on circumstances and should be discussed in advance with the NICE team.

Cost–benefit analysis

Cost–benefit analysis studies have been used sparingly at NICE in the past because cost–utility analysis studies have usually been adequate for interventions that involve health and healthcare alone. If cost–benefit studies occur in economic evaluation literature included in the evidence, NICE has used these studies. Cost–benefit analysis converts all benefits and costs that can be readily quantified into monetary terms. It sums the costs and benefits separately to arrive at either a net monetary benefit or a ratio of benefits to costs and consequently it usually operates with a societal perspective.

If a cost–benefit analysis is proposed, the economist and NICE should agree how benefits are to be valued in line with the reference case and general NICE economic evaluation principles.

These analyses could be used to:

- modify a decision based solely on cost–utility considerations
- explain to stakeholders and the public the additional costs and benefits for organisations outside the public social care sector.

There is often a trade-off between the range of new analyses that can be conducted and the complexity of each piece of analysis. Simple methods may be used if these provide the

GDG with sufficient information on which to base a decision. For example, if an intervention is associated with improved outcomes and fewer adverse effects, then a simple decision tree may provide a sufficiently reliable estimate of cost effectiveness. In other situations, a more complex approach may be warranted.

7.2.6 Time horizon

The time horizon should reflect all important differences in costs and outcomes, and the reasons for the time horizon used should be documented.

7.2.7 Measuring and valuing effects

The QALY is the measure of health effects preferred by NICE, based on patient-reported changes in health-related quality of life. The EQ-5D is the preferred measure of health-related quality of life in adults, with utility of changes being based on public preferences.

For social care economic evaluation, a flexible approach is needed, reflecting the nature of effects delivered by different social care interventions or programmes. If health effects are relevant, the EQ-5D-based QALY may be used. However, it is likely that broader, preference-weighted measures of social care outcomes, based on specific instruments, will be more appropriate.

Social care quality-of-life measures are being developed and NICE will consider using 'social care QALYs' if validated.

For example, the ASCOT (Adult Social Care Outcome Toolkit) set of instruments is used by the Department of Health in the Adult Social Care Outcomes Framework indicator on social care-related quality of life.

If a social care intervention is associated with both health and social care-related outcomes, it may be helpful for these elements to be presented separately, especially considering the emerging nature of social care economic evaluation.

Similarly, depending on the topic, and on the intended effects of social care interventions and programmes, the economic evaluation should also consider a parallel study of effects in terms of capability and wellbeing. For capability effects, use of the ICECAP (Investigating Choice Experiments for the Preferences of Older People – CAPability) instruments may be considered as part of the longer-term development of methodology.

In a field of emerging methodologies, and in the context of the variety of social care services, it is recognised that there is no single correct approach to measuring effects. The reference case, although referring to ASCOT-based social care quality of life in parallel with capability-based analysis based on ICECAP measures, should be approached with some flexibility, as long as decisions about the measurement of effects are clearly explained as part of economic evaluation reports.

Measurement of effects is as reported by service users or carers as relevant.

The source of preference data for valuing changes in quality of life and capability should be a representative sample of the UK public. However, if effects are expressed in terms of wellbeing, this must be valued by individual service users and carers.

7.2.8 Equity considerations

NICE healthcare and public health economic evaluation does not include equity weighting – a QALY normally has the same weight for all population groups.

It is important to recognise that social care provision may be means-tested, and that this affects the economic perspective in terms of who bears costs – the public sector or the service user or family. Economic evaluation should reflect the intentions of the social care system. Equity considerations relevant to specific topics, and how these were addressed in economic evaluation, must be reported.

Social care economic evaluation is unlikely to involve formal equity weighting at the outset. Economic analysis for presentation to the GDG may, however, be accompanied by a briefing on equity issues specific to social care (for example, using subgroup analysis). This approach would need to be agreed with NICE at the outset of economic evaluation.

7.2.9 Evidence on resource use and costs

Costs should relate to public sector resources (such as the NHS and personal social services) and be valued using relevant prices. Costs borne by service users and the value of unpaid care must also be included.

7.2.10 Discounting

The need to discount to a present value is widely accepted in economic evaluation,

although the specific rate is variable across jurisdictions and over time. NICE considers that it is usually appropriate to discount costs and health effects at the same rate. The annual rate of 3.5%, based on the recommendations of the UK Treasury for the discounting of costs, should be applied to both costs and effects.

Sensitivity analyses using rates of 1.5% for both costs and effects may be presented alongside the reference-case analysis.

7.2.11 Identifying and selecting model inputs

If existing models are being used, or are informing new analysis, the way these studies are adapted or used should be outlined clearly.

Additional searches may be needed, for example, if effectiveness searches do not provide the information needed for economic modelling, including:

- the relationship between short- and long-term outcomes
- quality of life
- resource use or costs.

It is not necessary to conduct formal, systematic literature searches for all the types of information required for economic modelling (although effectiveness data used in the modelling should be taken from the effectiveness reviews). For example, information on unit costs can be obtained from the Personal Social Services Research Unit report unit costs of health and social care or the Department of Health tariff. Information on costing can be found in the NICE Assessing cost impact: methods guide (2011) or from a costing analyst in the NICE implementation team. Some information about public services may be better obtained from national statistics or databases, rather than from literature studies.

7.2.12 Exploring uncertainty

Considerations of potential bias and limitations should be discussed by the GDG. Appropriate sensitivity analysis should be used (depending on the type of uncertainty) to explore the impact of potential sources of bias and uncertainty on the results of the economic analysis.

7.3 Economic evidence and guidance recommendations

For an economic evaluation to be useful, it must be taken into account in the guidance recommendations. The GDG should discuss cost effectiveness in parallel with general effectiveness when formulating recommendations (see section 9).

All economic analyses should be validated. The validation process should be outlined in the guidance. Useful and practical validation methods could include:

- systematic checking of model formulae and inputs by a second modeller
- sensitivity analysis
- ensuring that the model results are plausible and can be explained
- comparing end points from the model with source materials.

There should be the highest level of transparency in reporting methods and results.

In cost–utility analysis, if there is strong evidence that an intervention dominates the alternatives (that is, it is both more effective and less costly), then clearly it should be recommended. However, if an intervention is more effective but also more costly than another, then the incremental cost-effectiveness ratio (ICER) should be considered if possible. The ICER is the ratio of the difference in the mean costs of an intervention compared with the next best alternative (which could be no action or treatment) to the differences in the mean health outcomes. ICERs are expressed as cost (in £) per QALY gained.

If an intervention appears to be more effective than an alternative, the GDG must decide whether any increase in cost associated with the increase in effectiveness represents reasonable 'value for money'. In doing so, it should refer, as appropriate, to the principles outlined in Social value judgements: principles for the development of NICE guidance (second edition, 2008) (see section 1.2). Currently, no threshold has been established for social care and QALYs may not be an appropriate measure. So the GDG needs to make a judgement based on the economic evidence provided.

It is likely that over time, and as the methodology develops, indicative cost-effectiveness thresholds will be established for social care-related utility measures.

In using cost–consequences analysis, the GDG should ensure, where possible, that the different sets of consequences do not double-count costs or benefits. The way that the sets of consequences have been implicitly weighted should be recorded as openly, transparently and as accurately as possible. Cost–consequences analysis then requires the decision-maker to decide which interventions represent the best value, preferably using systematic and transparent process. Various tools are available to support this part of the process.

In using cost–benefit analysis, the GDG will need to take account of potential issues with the willingness to pay for a benefit in a cost–benefit analysis being the aggregation of individually elicited willingness to pay, as distinct from the willingness to pay of a public body (which may be exceeded).

Decisions about whether to recommend interventions should not be based on cost effectiveness alone. The GDG should also take into account other factors, such as the need to prevent discrimination and to promote equality. The GDG considers trade-offs between efficient and equitable allocations of resources. The issue of equity weighting in social care economic evaluation, and how any relevant means-testing in the social care system is addressed within the economic evaluation, is relevant to this.

These factors should be explained in the Evidence to recommendations section of the guidance (see section 9.2). If a structured social care question is not considered for further economic analysis, the GDG should still consider the likely cost effectiveness of the associated recommendations. This assessment may be based on published estimates of cost effectiveness if available or, if necessary, a qualitative judgement.

7.4 References and further reading

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Philips Z, Ginnelly L, Sculpher M et al. (2004) Review of good practice in decision-analytic modelling in health technology assessment. Health Technology Assessment 8: 1–158

Raftery J, editor (1999–2001) Economics notes series. British Medical Journal [online]

[3] Department of Health definition: personal social services describes care services for vulnerable people, including those with special needs because of old age or physical disability and children in need of care and protection. Examples are residential care homes for older people, home help and home care services, and social workers who provide help and support for a wide range of people.

8 Linking social care guidance to other NICE guidance

8.1 Other NICE guidance programmes

NICE currently produces the following types of guidance:

- Clinical guidelines, which focus on managing a particular disease or condition.
- Diagnostics guidance, which covers the efficacy and cost effectiveness of new diagnostic technologies.
- Interventional procedures guidance, which covers the safety and efficacy of interventional procedures used for diagnosis or treatment.
- Medical technologies guidance, which covers the efficacy and cost effectiveness of new or innovative medical technologies.
- Public health guidance, which deals with promoting good health and preventing ill health.
- Technology appraisal guidance, which focuses on the clinical and cost effectiveness of 1 or more technologies, such as new drugs, surgical procedures and medical devices.
- Quality standards, which provide a concise set of statements designed to drive and measure priority quality improvements within a particular area of care. Quality standards may span health, public health and social care.

The Centre for Clinical Practice develops clinical guidelines.

The Centre for Health Technology Evaluation develops technology appraisal, interventional procedures, medical technologies and diagnostics guidance.

The Centre for Public Health Excellence develops public health guidance.

Details of the development processes and methods for other programmes can be found on

the NICE website.

As the amount of NICE guidance increases, there will be more topics that span multiple work programmes at NICE. The scoping stage of social care guidance development should identify topics from other programmes that are relevant to the guidance being developed (see section 2). The mapping of the NICE pathway should also identify cross-links.

8.2 Avoiding duplication

If a new piece of work is commissioned in an area related to a published NICE clinical guideline or public health guidance, careful thought needs to be given to avoiding unnecessary duplication.

For example, the Department of Health or the NHS Commissioning Board may ask NICE to develop new combined guidance on both the clinical management of a condition and the associated social care service options.

A referral for combined guidance is managed jointly by the Health and Social Care Directorate and the Centre for Public Health Excellence or the Centre for Clinical Practice as appropriate.

9 Developing and wording guidance recommendations

9.1 General principles

Many users of social care guidance do not have time to read the full document and may want to focus only on the recommendations. It is therefore vital that recommendations are clear, can be understood by people who have not read the evidence reviews, and are based on the best available evidence. This section addresses key areas in developing guidance recommendations:

- interpreting the evidence to make recommendations
- wording the recommendations
- prioritising recommendations for future consideration in quality standard development
- formulating research recommendations.

These processes are at the heart of the work of the Guidance Development Group (GDG). However, they are not straightforward and it may not be easy for the GDG to reach agreement. Consensus techniques may need to be used (see section 3.5).

9.1.1 Challenges in formulating recommendations

There are many reasons why it can be difficult for a GDG to reach a decision about a recommendation. The evidence base is always imperfect, and so there is always a degree of judgement by the GDG. There may be very little, or no, good-quality evidence that directly addresses the review question the GDG has posed. In this situation, there are several options to consider:

- The GDG may wish to look at evidence that is likely to be more at risk of bias than the evidence they had hoped to find. This approach should be pursued only if there is reason to believe that it will help the GDG to formulate a recommendation.

- The GDG may wish to consider high-quality evidence in a related area, for example, in a largely similar service user group or for a closely related intervention. The GDG needs to make its approach explicit, stating the basis it has used for reviewing the data and the assumptions that have been made. This needs to include consideration of the plausibility of the assumptions. This approach is unlikely to be helpful if the evidence is derived from a question that is too different from the review question, or if the evidence is not of the highest quality.
- The GDG may consider basing a recommendation on its view of current most cost-effective practice. Formal consensus techniques may be used to elicit opinions from the GDG, although NICE does not recommend a particular approach. Importantly, it is not usually appropriate to involve stakeholders from outside the GDG in this process, because they will be offering opinions on recommendations without having seen the evidence considered by the GDG; in addition, stakeholders have not agreed to adhere to the principles underlying NICE's decisions on recommendations. This approach would also allow some stakeholders input to the decision-making process that other stakeholders do not have. GDGs should therefore be particularly cautious about using and interpreting the results of such exercises involving stakeholders outside the GDG, and should talk with NICE about any proposed use. NICE makes the final decision on whether such work with external stakeholders is warranted.

When formulating recommendations, there are likely to be instances when members of the GDG disagree about the content of the final guidance. Formal consensus methods can be used for agreeing the final recommendations (see section 3.5). Whatever the approach used, there should be a clear record of the proceedings and how areas of disagreement have been handled. This may be summarised in the guidance.

9.2 Interpreting the evidence to make recommendations

The GDG must decide what the evidence means in the context of the review questions and economic questions posed, and decide what recommendations can usefully be made to social care practitioners and other professionals.

The guidance should show clearly how the GDG moved from the evidence to the recommendation. This is done in a section called 'evidence to recommendations' so that it can be easily identified. A simple table can be used to show how the evidence was used to develop the recommendations, and should describe the relative value placed on

outcomes, benefits and harms, net benefits and resource use, and the overall quality of the evidence, as well as other considerations of the GDG.

This section may also be a useful way to integrate the findings from several evidence reviews that are related to the same recommendation or group of recommendations.

Underpinning this section is the concept of the 'strength' of a recommendation (Schunemann et al. 2003). This takes into account the quality of the evidence but is conceptually different.

Some recommendations are 'strong' in that the GDG believes that the vast majority of social care practitioners and other professionals and service users would choose a particular intervention if they considered the evidence in the same way as the GDG has. This is generally the case if the benefits clearly outweigh the harms for most people and the intervention is likely to be cost effective.

However, there is often a closer balance between benefits and harms, and some service users would not choose an intervention whereas others would. This may happen, for example, if some service users are particularly likely to benefit and others are not. In these circumstances, the recommendation is generally weaker, although it may be possible to make stronger recommendations for specific groups of service users.

For all recommendations, a general principle of NICE social care guidance is that service users should be informed of their options and be involved in decisions about their care. Service users may choose not to accept the advice to have the most cost-effective intervention. Or they may opt for an intervention that has the same or lower long-term benefits and personal social service costs if, for example, they feel that its associated harms are more tolerable.

There might be little evidence of differences in cost effectiveness between interventions. However, interventions that are not considered cost effective should not usually be offered to service users (see section 7.3) because the opportunity cost of that course of action has been judged to be too great (see section 7.1.2).

The concept of strength is reflected in the wording of the recommendation (see section 9.6.4). The GDG's view of the strength of a recommendation should be clear from its discussions, as reported in the guidance.

The following points need to be covered in the discussions and can also be used as a framework for reporting those discussions.

9.2.1 Relative value placed on the outcomes considered

Often, more outcome data are available than are actually used in decision-making. It is therefore important to have explicit discussion of which outcomes are considered important for decision-making (including considering the perspective of the decision-makers) when developing review protocols (see section 4.4), and of what relative importance was given to them. This might be done informally (for example, 'capacity was considered the most important outcome') or formally (for example, by the use of utility weights).

This discussion should be clearly separated from discussion of how this will play out when the evidence is reviewed, because there is potential to introduce bias if outcomes are selected on the basis of the results. An example of this would be choosing only outcomes for which there were statistically significant results.

It may be important to note outcomes that were not considered to be important for decision-making, and why (such as surrogate outcomes if longer-term, more relevant outcomes are available). If the same set of outcomes is used for a number of review questions, it might be more efficient to record this information once and then refer back to it.

9.2.2 Trade-off between benefits and harms

A key stage in moving from evidence to recommendations is weighing up the magnitude and importance of the benefits and harms of an intervention. This may be done qualitatively (for example, 'the evidence of a reduction in medicines errors in care homes outweighed a small increase in staff workload and resources') or quantitatively using a decision model.

9.2.3 Trade-off between net benefits and resource use

If there are net benefits from an intervention, there should be an explanation of how the implications of resource use were considered in determining cost effectiveness. Again, this may be informal, or may be more formal and include economic modelling. If there is no clear evidence of net benefit, cost and resource use could be discussed here.

9.2.4 Quality of the evidence

There should be discussion of how the presence, likely magnitude and direction of potential biases and uncertainty in the evidence have influenced the recommendation, and why. This should reflect the judgement on the quality of the evidence. Lower-quality evidence generally makes it more difficult to justify a strong recommendation, although there may be exceptions to this.

The discussion of uncertainty may include considering whether the uncertainty is sufficient to justify delaying making a recommendation to await further research, taking into account the potential harm of failing to make a clear recommendation.

9.2.5 Other considerations

If the 'evidence to recommendations' section combines consideration of several possible interventions, it may be useful to include discussion of the position of an intervention within a pathway of care or service model.

This section is also the appropriate place to note how the GDG's responsibilities under equalities legislation and NICE's equality scheme have been discharged in reaching the recommendations (see section 1.2). The GDG needs to consider whether:

- the evidence review has addressed areas identified in the scope as needing specific attention with regard to equalities issues
- criteria for access to an intervention might be discriminatory, for example, through membership of a particular group, or by using an assessment tool that might discriminate unlawfully
- people with disabilities might find it impossible or unreasonably difficult to receive an intervention
- guidance can be formulated to promote equalities, for example, by making access more likely for certain groups, or by tailoring the intervention to specific groups.

It may be useful to briefly talk about the extent of change in practice that will be needed to implement a recommendation, and the possible need for carefully controlled adoption with, for example, training programmes or demonstration projects.

9.3 Lack of evidence

If evidence of effectiveness is either lacking or too weak for reasonable conclusions to be reached, the GDG may recommend that particular interventions are used only in the context of research. Factors to be considered before issuing 'only in research' recommendations include the following:

- The intervention should have a reasonable prospect of providing benefits to service users in a cost-effective way.
- The necessary research can realistically be set up or is already planned, or service users are already being recruited.
- There is a real prospect that the research will be used when developing future NICE guidance.

9.4 Identifying effective interventions

The GDG should ensure that effective interventions strongly supported by the evidence are clearly identifiable. This will be fed into a future database.

9.5 Developing recommendations

As soon as members have discussed the findings of a NICE evidence review (or any expert testimony), the GDG should start drafting recommendations. This is an iterative process; the recommendations are likely to be revised several times before the wording is finalised.

First, the GDG should decide what it wants to recommend and which sectors (including which professionals within those sectors) should act on the recommendations.

In the early stages, it can be helpful to work in small groups. It may also help if a first draft of the recommendations is used as a starting point for discussion, based on the GDG's initial deliberations as a group. However they are developed, the draft recommendations should be clearly linked to evidence statements.

Some recommendations may be prioritised (see section 9.7).

If evidence on effectiveness or cost effectiveness is lacking or conflicting, the GDG may

decide that further research should be a condition for adoption.

Decisions can be made using a variety of approaches: discussion, informal or formal consensus or formal voting (for example, if members disagree). The proceedings should be recorded and a clear statement made about the factors that have been considered and the methods used to achieve consensus. This ensures the process is as transparent as possible.

A summary of the generic and specific issues considered and the key deliberations should be given in the 'Evidence to recommendations' section of the guidance (see section 9.2).

9.6 Wording of recommendations

9.6.1 General principles

Writing the recommendations is one of the most important steps in developing social care guidance. Many people read only the recommendations, so the wording must be concise, unambiguous and easy to translate into practice. Each recommendation, or bullet point within a recommendation, should contain only one main action.

The wording of recommendations should be agreed by the GDG and should:

- focus on the action that needs to be taken (action-oriented)
- include what readers need to know
- reflect the strength of the recommendation
- emphasise the involvement of the service user (and/or their carers if needed) in decisions
- be 'person-centred'
- use plain English where possible and avoid vague language
- follow NICE's standard advice on recommendations about waiting times and ineffective interventions.

The rest of this section explains these points in more detail. The lead editor for the guidance from NICE will advise on the wording of recommendations.

9.6.2 Focus on the action

Recommendations should begin with what needs to be done. When writing recommendations, keep in mind a reader who is saying, 'What does this mean for me?'. Recommendations should be as specific as possible about the exact intervention being recommended and the group of people for whom it is recommended (see also section 9.6.3).

Use direct instructions because they are clearer and easier to follow. Most recommendations should be worded in this way. Assume you are talking to the social care practitioner who is working with the service user or carer at the time.

Start with a verb describing what the reader should do, such as 'offer', 'measure', 'advise', 'discuss' or 'ask about' (see sections 9.6.4 and 9.6.5 for advice on the choice of verb).

Sometimes, it is clearer to start with details of the service user group or other details, particularly if recommending different actions for slightly different circumstances or to make the sentence structure simpler.

9.6.3 Include what readers need to know

Recommendations should contain enough information to be understood without reference to the evidence or other supporting material. But do not add unnecessary details, because recommendations are more likely to be followed if they are clear and concise.

- Define any specialised terminology that is used in the recommendations. Avoid using abbreviations unless your audience is likely to be more familiar with the abbreviation than with the term in full. If abbreviations are essential, define them at first mention and in a glossary. Do not use abbreviations for groups of people; for example, write 'people from black and minority ethnic backgrounds' rather than 'BMEs'.
- Define the intended audience for the recommendation. For some guidance topics, it may be necessary to group recommendations for specific practitioner or professional groups (for example, care home staff or social care commissioners).
- Define the target population if it is not obvious from the context. Often, it is necessary to define the population only in the first of a group of recommendations, if it is clear that the subsequent recommendations in that section relate to the same population.

- Define the setting(s) where the intervention is to be delivered if it is not obvious from the context.
- Include cross-references to other recommendations in the guidance if necessary to avoid the need to repeat information, such as components of the intervention or service.
- Do not include reasons justifying the recommendation unless this will increase the likelihood that it will be followed – for example, if it involves a change in usual practice or needs particular emphasis.

9.6.4 Reflect the strength of the recommendation

The description of the process of moving from evidence to recommendations in section 9.2 shows that some recommendations can be made with more certainty than others. This concept of the 'strength' of a recommendation should be reflected in the consistent wording of recommendations within and across social care guidance. There are 3 levels of certainty:

- recommendations for interventions that must (or must not) be used
- recommendations for interventions that should (or should not) be used
- recommendations for interventions that could be used.

The guidance document includes a standard section about how wording reflects the strength of recommendations.

Recommendations for interventions that must or must not be used

Recommendations that an intervention must or must not be used are usually included only if there is a legal duty to apply the recommendation, for example, to comply with health and safety regulations. In these instances, give a reference to supporting documents.

Occasionally, the consequences of not following a recommendation are so serious (for example, there is a high risk that the service user could be placed at significant risk) that using 'must' (or 'must not') is justified even if a legal requirement is not involved. Talk about this with the programme manager at NICE, and explain in the recommendation the reason for the use of 'must'.

If using 'must', word the recommendation in the passive voice ('an intervention must be used') because the distinction between 'should' and 'must' is lost if the recommendation is turned into a direct instruction.

Recommendations for interventions that should or should not be used

For recommendations on interventions that 'should' be used, the GDG is confident that, for most people, the intervention (or interventions) will do more good than harm, and will be cost effective.

Use direct instructions for recommendations of this type where possible, rather than using the word 'should'. Use verbs such as 'offer', 'refer', 'advise' and 'discuss'.

Use similar forms of words (for example, 'Do not offer...') for recommendations on interventions that should not be used because the GDG is confident that they will not be of sufficient benefit for most service users.

If an intervention is strongly recommended but there are 2 or more options with similar cost effectiveness, and the choice will depend on the service user's values and preferences, a 'should' recommendation can be:

- combined with a 'could' recommendation (see 'Recommendations for interventions that could be used), for example, by using wording such as 'Offer a choice of service A or service B' **or**
- followed by a 'could' recommendation, for example 'Offer rehabilitation. Consider service A or service B.'

Recommendations for interventions that could be used

For recommendations on interventions that 'could' be used, the GDG is confident that the intervention will do more good than harm for most service users, and will be cost effective. However, other options may be similarly cost effective, or some service users may opt for a less effective but cheaper intervention.

The choice of intervention, and whether to have the intervention at all, is therefore more likely to vary depending on a person's values and preferences, and so the social care practitioner should spend more time considering and discussing the options with the service user. It may be possible to make 'strong' recommendations for subgroups of

people with different values and preferences.

Use direct instructions for recommendations of this type where possible (see section 9.6.2), rather than using the word 'could'.

Use 'consider' to show that the recommendation is less strong than a 'should' recommendation.

Do not use 'consider offering', because of potential confusion with the wording of strong recommendations. Also, it might be misinterpreted to mean that a social care practitioner may consider offering an intervention without discussing it with the service user.

To minimise confusion, use 'consider' only to show the strength of a recommendation. Avoid other possible uses of 'consider'. For example, use 'be aware of', 'explore' or similar, rather than 'consider'. Use 'take other factors into account' or similar, instead of 'consider other factors'. 'Assess' and 'think about' are other possible alternatives to 'consider'.

9.6.5 Emphasise the service user's involvement

To emphasise the service user's role in decision-making (and, where appropriate, that of the carer, parent, guardian or advocate) and the need for them to consent to intervention, generally use verbs such as 'offer' and 'discuss' in recommendations, rather than 'prescribe' or 'give'. As described above, 'consider' is used for weaker recommendations; this implies that more discussion with the service user will be needed than a recommendation that uses, for example, 'offer'.

Use 'people' or 'service users' rather than 'individuals', 'cases' or 'subjects'. Where possible, use 'people' rather than 'patients' for people with mental health problems or chronic conditions.

9.6.6 Recommendations about person-centred care

The guidance document includes a standard section on person-centred care that covers informed consent and taking into account the service user's individual needs. Specific recommendations should not be made on points covered in this standard section guidance unless there are particular reasons to do so that relate to the guidance topic; for example, if there are issues relating to providing information, or to support needs, that are specific to the condition or needs covered by the guidance.

9.6.7 Use plain English

In general, follow the principles of effective writing as described in the 'Writing for NICE' booklet, available from Sola Odutola.

Avoid vague words and phrases, such as 'may' and 'can', or general statements such as 'is recommended', 'is useful/helpful', 'is needed' and 'service options include'. Instead, use an active verb that tells readers what they should do, and shows the strength of the recommendation.

Examples

- Instead of 'an intervention may be offered', say 'consider the intervention'.
- Instead of 'an intervention is recommended', say 'offer the intervention'.
- Instead of 'an intervention is helpful', say 'offer the intervention' or 'consider the intervention' (see section 9.6.4).

9.6.8 Recommendations on timeliness of care or services and ineffective interventions

Timeliness of care or services

Avoid giving targets for the timeliness of care or services. In some cases, a recommendation will need to specify a waiting time, referral time or time of intervention because this relates to the safety or effectiveness of an intervention. In this case, ensure that the evidence and reason for specifying the time is made clear in the evidence to recommendations section of the guidance.

Ineffective interventions

Recommend stopping ineffective interventions: state explicitly if particular care or services should not be carried out or should be stopped.

9.6.9 Using tables in recommendations

Do not use tables to summarise several actions in 1 recommendation. Such summaries

make it more difficult to link the recommended actions to the evidence summaries.

9.6.10 Example recommendations

Recommendations for social care should meet the key principles expected by NICE. They should (wherever possible) clearly detail: the intended audience for the recommendation; the intended population; the setting (if relevant); what specifically should be done; and, where relevant, what the time-frame is for doing it.

Examples are provided below of social care recommendations from a variety of sources and after these, we have suggested rewording to ensure that the recommendations meet the key principles expected by NICE for social care guidance. The reworded recommendations are solely to illustrate the principles and are not NICE guidance.

The NICE clinical guideline Dementia: supporting people with dementia and their carers in health and social care recommends:

'Health and social care staff should identify the specific needs of people with dementia and their carers arising from ill health, physical disability, sensory impairment, communication difficulties, problems with nutrition, poor oral health and learning disabilities. Care plans should record and address these needs.' [Recommendation 1.1.1.4]

To meet the requirements for NICE social care recommendations, this could be reworded as:

'Within 4 weeks of initial diagnosis, identify the specific needs of people with dementia and their carers arising from ill health, physical disability, sensory impairment, communication difficulties, problems with nutrition, poor oral health and learning disabilities. Record all specific needs and how they will be addressed in the care plan.'

All recommendations for health and social care staff could then be presented together.

The Social Care Institute for Excellence's guide on Mental health service transitions for young people (accredited by NICE) states:

'It is vital that young people are fully involved in planning their transition. Planning should start in good time – at least six months in advance.'

To meet the requirements for NICE social care recommendations, this could be reworded as:

'Discuss the transition to adult services and ensure that the young person feels fully involved. Start planning at least 6 months before the discharge from child and adolescent mental health services (CAMHS).'

9.7 Prioritising recommendations

NICE's social care guidance may cover large areas of social care. The GDG identifies a subset of these recommendations as priorities to consider for quality standard development.

Prioritised recommendations are usually those that are likely to do at least 1 of the following:

- have a large effect on outcomes that are important to service users
- have a large effect on reducing variation in care and outcomes
- set challenging but achievable expectations of social care services
- focus on key areas for quality improvement
- include actions that are measurable
- lead to more efficient use of public resources
- promote service user choice
- promote equality.

In addition, the GDG should try to identify recommendations that are particularly likely to benefit from adoption support. Criteria overlap with those above, but include whether a recommendation:

- relates to an intervention that is not part of routine service provision
- will need changes in service delivery
- will need retraining of staff or the development of new skills and competencies

- highlights the need for practice to change
- affects, and needs to be implemented across, a number of agencies or settings (complex interactions)
- may be viewed as contentious, or difficult to implement for other reasons.

There should be a clear record of which criteria were considered particularly important by the GDG for each prioritised recommendation. This should be reported in a short paragraph in the guidance.

9.8 Formulating research recommendations

The GDG is likely to identify areas in which there are uncertainties or specific gaps in the evidence base, or for which robust evidence is lacking. NICE has published a Research recommendations process and methods guide, which details the approach to be used across NICE's guidance producing programmes to identify key uncertainties and associated research recommendations.

For standard social care guidance in which there may be many hundreds of uncertainties or gaps, it is not possible to document each in detail. Although GDGs could write research recommendations for dealing with each uncertainty or gap, this is not likely to be feasible. Therefore, the GDG should select key research recommendations to include in the guidance. Further information about how these should be derived can be found in the Research recommendation process and methods guide.

9.9 Further reading

Brown P, Brunnhuber K, Chalkidou K et al. (2006) How to formulate research recommendations. British Medical Journal 333: 804–6

10 Writing social care guidance and the role of the NICE editors

At the end of guidance development, the final guidance is published and the recommendations are incorporated into NICE Pathways.

This section describes the structure and content of guidance, and the role of the NICE editors.

10.1 Guidance structure

The guidance contains all the recommendations, together with details of the methods used and the evidence underpinning the recommendations. It should specify the date of publication of the version of the guidance manual that was used for developing the guidance.

The structure and format of the guidance should follow the template for social care guidance. The content is likely to include the following, but the exact structure will change as the digital approach to publication develops:

- Sections or appendices containing:
  - Guidance Development Group (GDG) membership
  - a list of all the recommendations
  - a list of all the research recommendations
  - the scheduled date for review of the guidance
- A short overview section discussing the need for the guidance, its aim, scope and expected audience and a section on service user-centred care.
- A short methods section that cross-refers to the social care guidance manual wherever possible and makes clear where and why there have been any deviations from the methods described in the manual.

- If relevant to the guidance, an epidemiology section consisting of a formal review of epidemiology data, including data from disease registries. It should not include general background or 'scene-setting'.
- Sections dealing with the review questions and the evidence that led to the recommendations, each with the following content:
  - The review question(s) in PICO (population, intervention, comparator[s] and outcome), SPICE (setting, perspective, intervention or phenomenon of interest, comparison, evaluation) or similar format (see section 4)
  - A brief introduction to the review question.
  - The evidence review, including a summary of economic studies.
  - The meta-analysis (if this has been done for the review question).
  - The economic evidence review.
  - Evidence statements (short text summaries of the evidence on effectiveness and cost effectiveness).
  - An 'evidence to recommendations' discussion: a structured summary of GDG discussions on the trade-off between benefits and harms, and consideration of economic evidence, in relation to policy, making clear the justification for the recommendations (see section 9.2).
  - The recommendations.
  - The research recommendations (if applicable).
- References.
- Glossary and abbreviations (see section 10.2.3).

- Appendices, which should include:
  - a list of the contributors
  - declarations of interest
  - a link to the scope on the NICE website
  - review questions and tables by PICO (population, intervention, comparator and outcome), SPICE (setting, perspective, intervention or phenomenon of interest, comparison, evaluation), or similar framework
  - review protocols
  - details of search strategies (see sections 5.2–5.4)
  - summary of numbers of studies identified
  - excluded studies
  - evidence tables
  - forest plots
  - full data extraction tables
  - full economic report
  - reasons for prioritisation of research recommendations (see section 9.8)
  - if the guidance is an update (see section 14), a table in the draft version summarising the proposed changes to the original recommendations.
  - anything else specific to the guidance, such as questionnaires, charts or examples of software.

10.2 Style

The guidance should be written in a style that can be understood by non-specialist social care practitioners and by anyone who has a good knowledge of the guidance topic but is not a trained social care practitioner (for example, a service user who has a good knowledge of the service options).

10.2.1 Bulleted lists

Bulleted lists are a useful way of:

- simplifying and clarifying a series of points
- dealing with repetition
- dealing with complex paragraph structures.

A bulleted list should be used rather than a numbered list, unless there is a good reason to use numbers (for example, to show the order in which steps should be carried out or to indicate a grading system). This is because a numbered list can imply a ranking or preference that may not be intended.

10.2.2 Tables and figures

Tables and figures should be numbered sequentially and should be cited in the text. Information provided in a table or figure should not be repeated in the text.

Tables or figures from another source may be reproduced only if written permission has been obtained, usually from the publisher. It must be stated in the guidance that such permission has been received.

10.2.3 Abbreviations

Abbreviations should be used sparingly, and in accordance with the NICE style guide. If a term appears only a few times it is usually better not to abbreviate it. However, if general readers will be more familiar with the abbreviation, or if the full term is long, the abbreviation may be used throughout the guidance. All abbreviated terms should be defined at first use. The guidance may be downloaded in sections, so abbreviations should be redefined at first use in each section. A list of abbreviations should be included in the guidance.

10.3 The role of the NICE editors

The products are edited at key stages to ensure that:

- they conform to the NICE house style and format

- the recommendations are unambiguous
- the information is clear and appropriate for the intended audience.

The NICE editor will also lead on developing the NICE pathway (see below).

10.4 Incorporating recommendations into NICE Pathways

NICE Pathways are a practical online resource for health and social care professionals. The recommendations from each piece of social care guidance are presented in a pathway consisting of interactive topic-based diagrams, or added to an existing pathway on a closely related topic. The pathway contains all the recommendations from the guidance, as well as any other NICE guidance that is directly relevant to the topic (for example, clinical or public health guidance and quality standards). It also contains links to adoption (implementation) tools and to related NICE guidance and pathways. The NICE editor will lead on this stage of development.

10.4.1 Involvement of the Guidance Development Group with the NICE pathway

During the guidance development process, each GDG is asked to nominate 2 or 3 members to work closely with the lead editor on the NICE pathway. The role of the nominees is to:

- attend an editorial meeting
- gather the views of GDG members on key issues concerning the NICE pathway
- check for accuracy, answer queries and check revisions on behalf of the GDG.

11 The consultation process and dealing with stakeholder comments

Consultation with stakeholders, which lasts 6 weeks for standard social care guidance, is an integral part of the NICE guidance development process. Comments received from stakeholders are a vital part of the quality-assurance and peer-review processes, and it is important that they are addressed appropriately. This section describes the principles of responding to stakeholder comments following consultation.

This section also includes information on what to expect during the consultation process, and the circumstances in which a second consultation may be needed.

11.1 Consultation on the guidance

This section describes what to expect during the consultation phase.

11.1.1 Stakeholders

The draft version of the guidance is published on the NICE website for consultation. Registered stakeholders are informed by NICE that it is available.

11.1.2 External expert review

NICE does not routinely commission peer review from external experts, but occasionally additional external review of part or all of a social care guidance topic may be arranged. Experts may include social care practitioners, those commissioning care, healthcare professionals or people who can represent the perspective of service users and carers. These external reviewers should be named in the final guidance.

External expert review may take place during guidance development or at the consultation stage. If it occurs during development, the process and comments remain confidential with only the list of experts published in the final guidance. Comments from external expert witnesses during guidance development should be discussed by the whole Guidance Development Group (GDG).

If external expert witnesses comment during consultation, their comments are responded to in the same way as comments from registered stakeholders and are published in the guidance consultation table on the NICE website under 'external expert witnesses'. All external expert witnesses are required to complete a declaration of interests form (see section 3.2.1).

11.1.3 NICE staff

NICE staff also comment on the consultation draft of the guidance, before and during the consultation. These staff include NICE's Public Involvement Programme lead, implementation adviser and the lead editor for the guidance, as well as technical advisers, the programme manager and the Health and Social Care Directorate lead for the guidance.

11.2 Principles of responding to stakeholder comments

This section describes how to respond to comments received from stakeholders about the draft guidance. The same principles apply when responding to comments on the draft scope (see section 2.6.1).

11.2.1 Responding to comments

Most comments are received from registered stakeholders. These comments, and the responses to them, are sent to stakeholders with the advance copy of the guidance, and are posted on the NICE website when the guidance is published (see section 12.1).

Comments received from non-registered stakeholders, and comments received after the deadline for submission, are not considered and are not responded to; such comments will be returned to the sender.

11.2.2 Format of comments

The following key points should be taken into account when responding to comments from stakeholders:

- Each comment must be acknowledged and answered as fully and as factually as possible.

- If changes are made to the scope or guidance as a result of the comment, this must be made clear in the response. If no changes have been made, it should be made clear why not.
- For draft guidance, responses to comments and changes to the guidance must be agreed with the GDG before publication.

11.3 Considering a second consultation

In exceptional circumstances, the Health and Social Care Directorate director may consider the need for a further 4-week stakeholder consultation after the standard consultation. This additional consultation may be needed if either:

- information or data that would significantly alter the guidance were omitted from the first draft, **or**
- evidence was misinterpreted in the draft and the amended interpretation significantly alters the guidance.

NICE makes the final decision on whether to hold a second consultation.

12 Finalising and publishing the guidance

12.1 Final steps

12.1.1 After consultation

Once the consultation period has ended, the Guidance Development Group (GDG) meets to consider any changes needed to the guidance in response to the stakeholder comments received. Once the changes have been agreed, modifications are made to the guidance. The revised versions are then sent to NICE.

12.1.2 Signing off the guidance versions

After review by NICE and liaison with the NICE Collaborating Centre for Social Care (NCCSC) to address any outstanding issues, all guidance versions are signed off:

- The guidance is signed off by NICE's Guidance Executive.
- NICE pathways are signed off by the Health and Social Care Directorate lead for the guidance.

12.1.3 Releasing an advance copy to stakeholders

An advance copy of the final guidance and responses to stakeholder comments made during the public consultation is sent to registered stakeholders 2 weeks before the publication date. This information is confidential until the guidance is published. This step allows stakeholders to prepare for publication, but it is not an opportunity to comment further on the guidance.

12.1.4 Publication

The guidance and adoption tools are published at the same time (see section 13).

12.2 Launching and promoting the guidance

Members of the NCCSC and GDG work with NICE to promote awareness of the guidance, both at the point of launch and afterwards.

12.2.1 The press launch

NICE's communications lead will discuss with the NCCSC and GDG the most appropriate launch strategy for each piece of guidance. This may range from a press conference with the national press and media to a more targeted approach aimed at specialist or trade press.

If there is likely to be substantial media interest, a press conference is held 1 or 2 days before publication, usually at NICE's offices. This form of briefing allows for a more structured and considered exchange of information, where any potentially controversial aspects of the guidance can be explained and contextualised. It also provides journalists with an opportunity to interview people involved in development of the guidance and other commentators, and to prepare articles or broadcast pieces in advance.

Information provided to the media is confidential until the launch date for the guidance.

NICE's communications lead also ensures that relevant stakeholder organisations, such as practitioner and service user or carer organisations, are involved in the launch, if appropriate.

All GDG members are encouraged to provide details of case studies that can be used to illustrate some of the recommendations, because these are a good way of creating media interest.

The aim of the press briefing is to communicate key messages about the guidance to the press and media. The NCCSC or GDG may like to arrange separate events at which social care practitioners or providers can learn more about the guidance, or to showcase the guidance directly to peers. In such cases, the communications team at NICE should be involved at the earliest possible opportunity (see section 12.2).

12.2.2 Reaching the target audience

NICE welcomes input from GDG members on how to identify groups of social care

practitioners or providers and specialists who should be sent details of the guidance and adoption support tools. GDG members may also be able to identify other ways of raising awareness of the guidance and adoption support tools – for example, via newsletters, websites or training programmes of organisations they are affiliated to (particularly for service user and carer organisations), or by suggesting relevant conferences at which the guidance can be promoted.

13 Adoption (implementation) support for social care guidance

The aim of NICE adoption support is to encourage and promote the uptake of NICE guidance. Priorities identified by the Guidance Development Group (GDG), recommendations identified as having significant resource implications or resulting in a change in practice, and information from stakeholder consultation help determine the focus of adoption support work for social care guidance.

Support may include the provision of practical tools and a range of activities to promote uptake. Tailored tools may need developing for social care services users, particularly given that some of them may commission their own care, either independently or through budgets.

Adoption tools are produced by the NICE Collaborating Centre for Social Care (NCCSC) working alongside the implementation programme at NICE. Further details are available on the NICE website.

14 Updating published social care guidance and correcting errors

Social care guidance developed by NICE is published with the expectation that it will be reviewed and updated as necessary. Any decision by NICE to update guidance must balance the need to reflect changes in the evidence against the need for stability, because frequent changes to guidance recommendations would make adoption difficult. This section describes the process and methods for reviewing the need to update NICE social care guidance and for producing updated guidance.

When scheduling updates of guidance into its work programme, NICE prioritises topics for updated guidance and topics for new guidance according to the need for new guidance. The relative priorities are communicated to guidance developers through the NICE business planning process.

This section also describes the process for correcting errors that are identified after publication of guidance.

14.1 Reviewing the need to update published guidance

14.1.1 Routine updates

After publication of social care guidance, NICE collects information that might affect the timing or content of a subsequent update. This may include any queries or comments received by NICE or the NICE Collaborating Centre for Social Care (NCCSC) after publication, and evidence submitted by researchers or other stakeholders.

NICE and the NCCSC do not actively seek new evidence, unless it is acknowledged in the guidance that new information is likely to emerge before the 3-year scheduled review that may result in the need for an exceptional update or amendment (see section 14.1.2).

A formal review of the need to update guidance is undertaken by NICE 3 years after its publication.

14.1.2 Exceptional updates

Exceptionally, significant new evidence may emerge that necessitates an update of guidance before the formal planned review. This might be a single piece of evidence, an accumulation of evidence or other published NICE guidance (such as other social care guidance or clinical guidelines). This evidence must be sufficiently robust to make it likely that:

- 1 or more recommendations in the guidance will need updating in a way that will change practice significantly **or**
- service user safety or safeguarding issues need to be addressed **or**
- important new areas need to be included in the guidance.

Examples of such evidence include significant data from randomised controlled trials or major changes in costs. Exceptional updates may also be triggered if an error is identified in the guidance after publication (see section 14.2).

Determining the need for an exceptional update

The Health and Social Care Directorate advises NICE's Guidance Executive on the following questions:

- Is the update necessary?
- Is there any other evidence (published, unpublished or from ongoing studies) that is relevant to the newly identified evidence?
- Which recommendations need to be reviewed in the light of the new evidence?

The Guidance Executive then decides on the need for an update based on the answers to these questions. If an exceptional update is necessary, the Health and Social Care Directorate commissions the NCCSC to carry out the work. Stakeholders are informed at this point by NICE.

The aim of an exceptional update is to be responsive to new evidence, so it is imperative that changes to recommendations are published quickly. The process for developing exceptional updates should be the same as that for conducting a routine update (see section 14.1.1).

14.2 Correcting errors in published social care guidance

Measures are in place throughout the development of social care guidance to ensure that errors in the collection, synthesis, interpretation or presentation of the evidence are avoided as far as possible. However, on rare occasions, errors may be found after publication of the guidance.

These errors may not always warrant changes to the guidance, in which case they will be logged for consideration when the guidance is reviewed for updating. If an error is found, the following criteria and process will be used to determine whether changes are necessary.

14.2.1 Criteria and process for a correction

Published social care guidance will be changed or corrected if an error:

- puts service users at risk, or affects their care or provision of services **or**
- damages NICE's reputation **or**
- significantly affects the meaning of the recommendation.

If it is necessary to correct an error in a published guidance, the internal policy for dealing with errors is followed. The person or organisation who reported the error is contacted in writing and the rationale for the decisions and actions taken is explained to them.

The guidance and (if needed) adoption tools are corrected, and the changes are highlighted on the guidance's home page on the NICE website Depending on the nature and significance of the error and the time since publication of the guidance, stakeholders may also be notified by email. .

14.3 Further reading

Shojania et al. (2007) Updating systematic reviews. Technical Review, Number 16, Agency for Healthcare Research and Quality publication no. 07–0087

Appendix A Agreements and advice for Guidance Development Group members

A1 Code of conduct for Guidance Development Group (GDG) members and others who attend GDG meetings

A1.1 Key principles of development

NICE's social care guidance development process:

- involves and consults with organisations that represent the interests of service users, carers, practitioners, providers, commissioners, researchers and the voluntary sector.
- uses robust and transparent methodologies
- produces guidance that is based on the best available evidence, and is clearly explained.

GDGs should ensure that social care guidance cross-refers to, or incorporates, any relevant recommendations from NICE's other guidance programmes (for example public health guidance, clinical guidelines), and should also take into account recommendations from appropriate national service frameworks (NSFs). Each GDG should ensure that its guidance is developed in line with these requirements. It should also follow the principles set out in Social value judgements: principles for the development of NICE guidance (second edition) and adhere to the NICE equality scheme.

A1.2 Status of GDG members

Members are appointed to a GDG either by virtue of their relevant experience (as in the case of service user and carer members, and social care practitioner members) or because they have specific technical skills (as in the case of systematic reviewers and health economists). If members are from stakeholder organisations, NICE and the GDG assume that these members bring this perspective to the group, but do not represent their

organisations. GDG members are appointed for the duration of the development process for a social care guidance topic.

People appointed to the GDG are co-authors of the guidance. They will respect the rights of NICE both to publish the final guidance documents and to receive notification of associated publications, as described in contracts with the NICE Collaborating Centre (NCC).

A1.3 Mutual undertaking

NICE, usually through its NCC, undertakes to:

- ensure that the GDG is properly resourced to produce the guidance
- provide all members of the GDG with equal access to available resources and to the evidence used in the development of the guidance
- offer appropriate training to GDG members to enable them to play a full part in the development of the guidance
- provide technical support during the development of the guidance.

GDG members undertake to:

- make sufficient time available to attend meetings and properly inform the development of the guidance through their personal and professional knowledge and, where appropriate, their organisation's perspective
- provide the GDG, and subsequently (and only after failure to resolve the issue within the GDG) the NCC and NICE, with the opportunity to consider and resolve concerns or disagreements about either the process or the detail of the emerging guidance
- contribute positively to the work of the group and the development of the guidance.

A1.4 Transparency

NICE believes that its guidance will be enhanced if those who are intended to benefit from it and those who have the responsibility for implementing it have had the opportunity to be involved in its development.

For GDGs to operate successfully, they need to be able to develop and debate issues within the group before exposing them to wider comment. There is therefore a need for arrangements that protect the confidentiality of documents and discussions.

In order to provide the environment described above, NICE expects GDG members:

- to be aware that the Guidance Executive and Senior Management Team at NICE will not comment on the development of a guidance in progress, other than in the context of the formal consultation exercises
- to regard the views expressed by individual members of the GDG as confidential
- to regard the documents used and discussions held by the GDG as confidential to the group until public consultation, as stipulated in the 'Confidentiality acknowledgement and undertaking' agreement (see appendix A2)
- not to discuss commercial-in-confidence data outside the GDG
- to respect the confidentiality of documents supporting a published or unpublished technology appraisal and guidance in development if such documents are received by the GDG
- to respect the confidentiality of documents relating to other unpublished NICE guidance (such as interventional procedures, medical technologies, clinical guidelines or public health guidance) if such documents are received by the GDG.

GDG members are also expected to adhere to NICE's policy for declaring conflicts of interest.

A2 Participation in NICE guidance: confidentiality acknowledgement and undertaking

Please complete the sections below and return by email to: [insert NCC email]

If email is not possible, please return by fax to: [insert NCC fax no.]

This agreement covers all those who have sight of documents, or are party to discussions, relating to guidance before public consultation. This includes members of the Guidance Development Group (GDG), invited external experts, observers and participants in

consensus exercises. Staff of the NICE Collaborating Centre (NCC) are covered by the contract between NICE and the NCC.

1) I undertake to NICE that I shall:

(a) keep all confidential information strictly confidential

(b) not use any confidential information for any purpose other than participating in the deliberations of the GDG (for GDG members and external experts)

(c) not disclose any confidential information to any third party without the prior written consent of NICE

(d) not disclose the deliberations of a GDG to any other person without the explicit consent of the Chair of the GDG and the Director of the NCC.

2) The undertakings set out in paragraph 1 above ('the undertakings') shall not apply to the use or disclosure of information that:

(a) at or after the time of disclosure or acquisition is in the public domain in the form supplied otherwise than through a breach of any of the undertakings; or

(b) was lawfully within my possession before its disclosure to me by NICE, provided that the source of such information was not bound by, or subject to, a confidentiality agreement with NICE; or

(c) I am required to disclose by any court of competent jurisdiction or any government agency lawfully requesting the same, provided that I notify NICE in advance of such disclosure; or

(d) is approved for release by prior written authorisation from NICE.

Signed .....Date .....

Print name .....

Data Protection. The personal data submitted on this form will be used by the National Institute for Health and Care Excellence for work on its Guidance Programmes and will be

held on the NICE's databases for future reference and in accordance with the Data Protection Act 1998.

Appendix B Methodology checklist: systematic reviews and meta-analyses

Appendices B–G include checklists for those study designs that are expected to be used in the evidence reviews for NICE social care guidance. Other checklists can found in the NICE clinical guidelines manual and Methods for the development of NICE public health guidance.

Checklist

Study identification *Include author, title, reference, year of publication*			
Guidance topic:	**Review question no:**		
Checklist completed by:			
SCREENING QUESTIONS			
In a well-conducted, relevant systematic review:	***Circle or highlight one option for each question***		
1 The review addresses an appropriate and clearly focused question that is relevant to the review question	Yes	No	Unclear
2 The review collects the type of studies you consider relevant to the guidance review question	Yes	No	Unclear
3 The literature search is sufficiently rigorous to identify all the relevant studies	Yes	No	Unclear
4 Study quality is assessed and reported	Yes	No	Unclear
5 An adequate description of the methodology used is included, and the methods used are appropriate to the question	Yes	No	Unclear
6**Overall assessment of internal validity. Are the results internally valid?** Rate the review for internal validity below (for further information see notes on using the methodology checklist)			

++	+	-
Comments:		
Overall assessment of external validity – Are the results externally valid (i.e. generalisable to the whole source population)? Consider participants, interventions, settings, comparisons and outcomes. 7 Rate the review for external validity below (for further information see notes on use of the methodology checklist)		
++	+	-

If the review does not meet some or all of these criteria, it may still be useful as a source of references, but should not be relied upon on its own to address a review question.

If you have insufficient information on the design or quality of individual studies, you should use the checklists for studies on interventions (see appendices C, D and E) to appraise each study. Each study should appear as a separate entry in the evidence table (see appendix H); the review should not appear in the evidence table.

If you plan to use the review as a whole, you will need to complete a row in an evidence table for the systematic review and input the results into an evidence profile as appropriate.

Notes on use of Methodology checklist: systematic reviews and meta-analyses

A systematic review uses explicit and systematic methods to identify, appraise and summarise the literature according to predetermined criteria. If the methods and criteria used to do this are not described or are not sufficiently detailed, it is not possible to make a thorough evaluation of the quality of the review.

The terms 'systematic review' and 'meta-analysis' are often used interchangeably. The term 'meta-analysis' is often used incorrectly to describe a systematic review that has used quantitative methods to summarise the results. However, it should be noted that meta-analysis refers only to the statistical techniques used to combine studies; thus not all meta-analyses are systematic reviews.

This checklist is intended for use with systematic reviews of questions about interventions. It can potentially be used for any other types of question, although it has been designed primarily for this purpose.

The aim of this checklist is to consider the suitability of the systematic review to answer a guidance review question. This assessment has 2 aspects: firstly, whether the question addressed by the review (in terms of the populations, interventions, comparisons and outcomes [PICO] or setting, perspective, intervention, comparison, evaluation [SPICE]) is appropriate to answer the review question addressed by the guidance, and secondly, whether the methodology used for the review is sufficiently robust to permit a valid conclusion.

For each question in this section, you should indicate whether or not it has been addressed in the review. Choose 'unclear' if this aspect of the review process was ignored, or is not described in the report.

1 The review addresses an appropriate and clearly focused question that is relevant to the guidance review question

If the question addressed by the systematic review is not clearly stated, it will be difficult to determine whether the review is adequate to answer the guidance review question. If the question is not clear, the systematic review is unlikely to be a good one because it is difficult to be systematic in addressing an unclear question. The review report should give a clear description of the population considered, the interventions, settings, comparators, and outcomes evaluated. Inclusion and exclusion criteria should be clearly described. Outcomes considered should be clearly described within the methodology, including a precise definition and acceptable methods of measuring. The appropriateness of the question addressed in the systematic review for answering the guidance review question can be determined by comparing these components. If the review does not consider all of the outcomes that are judged to be important to your guidance review question, you may still be able to use the outcome data but may need to review the individual studies to obtain other outcome data.

2 The review collects the type of studies you consider relevant to the guidance review question

You should be clear about the characteristics of studies that you consider will adequately address your guidance review question. These may relate to minimum design or quality

characteristics. Systematic reviews should report the types of studies they sought, including any inclusion/exclusion criteria used. You can use this information to quickly assess the review's suitability for your purpose.

3 The literature search is sufficiently rigorous to identify all the relevant studies

Systematic and rigorous searches can help to minimise publication biases and identify as many relevant data as possible. Exact search terms depend on the review question, and you will need to make a judgment on the appropriateness and comprehensiveness of the sources searched for relevant data, which will depend on the aim of the systematic review. The dates on which the searches were carried out should be given in the review. Good-quality reviews will also attempt to identify relevant studies by hand searching of key journals and examining reference lists of retrieved studies for further references.

If the methods used to locate studies are not clearly reported, it will be difficult to determine whether the review is likely to have missed important relevant studies. Ideally, the search strategy used should be reported in sufficient detail that the process could be replicated.

Any restrictions applied to the search (such as language or year of publication) should also be reported. You should consider how these might have influenced the findings of the review.

Advice from the information specialist (and/or other members of the Guidance Development Group) working on the guidance may be useful to determine whether any important search terms have been omitted.

If the search described in the review is judged to be inadequate to identify all relevant studies, it may be possible to expand the search by including additional databases or extra search terms within the search strategy, or by updating the search to identify more recently published studies. Any additional studies identified by this expanded search should be appraised for quality using the appropriate NICE checklist (see appendices C–G). They should appear individually in separate rows in an evidence table.

4 Study quality is assessed and reported

The inclusion of poor-quality studies within a review can result in biased estimates of

effect. A well-conducted systematic review should have used clear criteria to assess whether individual studies had been appropriately designed and conducted, before deciding whether to include or exclude them. These criteria should be clearly described and should be reported for each study included. The quality appraisal checklists in appendices C–G, as appropriate for the type of question and study design, can be used as a guide to the types of quality criteria that should be considered.

If there is no indication of such a quality assessment, the review is unlikely to be reliable enough to be used in formulating guidance recommendations. It may be necessary to obtain and quality appraise the individual studies as part of your review.

5 An adequate description of the methodology used is included, and the methods used are appropriate to the question

In common with primary research, the approach used to analyse the data should be described and justified where appropriate. This may include the choice of statistical test used to analyse the outcome data, approaches to dealing with heterogeneity, and methods of analysis and synthesis.

6 Overall assessment of internal validity

Rate the review for internal validity according to the list below:

++ All or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter

+ Some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter

– Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter

7 Overall assessment of external validity

Rate the external validity of the review (also using ++, +, –). This is the extent to which the findings for the study participants apply to the whole source population (the population they were chosen from). If the review is of an 'intervention', then it should be assessed to see whether it would be feasible in settings other than that initially investigated, if

restricted by setting, for example.

Appendix C Methodology checklist: randomised controlled trials

Appendices B–G include checklists for those study designs that are expected to be used in the evidence reviews for NICE social care guidance. Other checklists can found in the NICE clinical guidelines manual and Methods for the development of NICE public health guidance.

Checklist

Study identification Include author, title, reference, year of publication					
Guidance topic:	**Review question no:**				
Checklist completed by:					
		Circle or highlight 1 option for each question			
A. Selection bias (systematic differences between the comparison groups)					
A1	An appropriate method of randomisation was used to allocate participants to intervention groups (which would have balanced any confounding factors equally across groups)	Yes	No	Unclear	N/A
A2	There was adequate concealment of allocation (such that investigators, social care practitioners, healthcare professionals and participants cannot influence enrolment or allocation to groups)	Yes	No	Unclear	N/A

A3	The groups were comparable at baseline, including all major confounding factors	Yes	No	Unclear	N/A
Based on your answers to the above, in your opinion was selection bias present? If so, what is the likely direction of its effect?					
Low risk of bias	Unclear/unknown risk	High risk of bias			
Likely direction of effect:					
B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)					
B1	The comparison groups received the same care and support apart from the intervention(s) studied	Yes	No	Unclear	N/A
B2	Participants receiving care and support were kept 'blind' to intervention allocation	Yes	No	Unclear	N/A
B3	Individuals administering care and support were kept 'blind' to intervention allocation	Yes	No	Unclear	N/A
Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?					
Low risk of bias	Unclear/unknown risk	High risk of bias			

Likely direction of effect: . .					
C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)					
C1	All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up)	Yes	No	Unclear	N/A
C2	a. How many participants did not complete the intervention in each group?				
	b. The groups were comparable for intervention completion (that is, there were no important or systematic differences between groups in terms of those who did not complete the intervention)	Yes	No	Unclear	N/A
C3	a. For how many participants in each group were no outcome data available? .				
	b. The groups were comparable with respect to the availability of outcome data (that is, there were no important or systematic differences between groups in terms of those for whom outcome data were not available).	Yes	No	Unclear	N/A
Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect? . . .					
Low risk of bias	Unclear/unknown risk	High risk of bias			

Likely direction of effect:					
D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)					
D1	The study had an appropriate length of follow-up	Yes	No	Unclear	N/A
D2	The study used a precise definition of outcome	Yes	No	Unclear	N/A
D3	A valid and reliable method was used to determine the outcome	Yes	No	Unclear	N/A
D4	Investigators were kept 'blind' to participants' exposure to the intervention	Yes	No	Unclear	N/A
D5	Investigators were kept 'blind' to other important confounding factors	Yes	No	Unclear	N/A
Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect? . .					
Low risk of bias	Unclear/unknown risk	High risk of bias			
Likely direction of effect:					
E. Overall assessment of internal validity. Are the study results internally valid? Rate the study for internal validity below (for further information see notes on using the methodology checklist)					
++	+	–			
Comments:					

F. Overall assessment of external validity – Are the study results externally valid (i.e. generalisable to the whole source population)? Consider participants, interventions, settings, comparisons and outcomes. Rate the study for external validity below (for further information see notes on use of the methodology checklist)		
++	+	–

Notes on use of Methodology checklist: randomised controlled trials

The studies covered by this checklist are designed to answer questions about the relative effects of social care interventions, such as task-centred interventions, crisis interventions or psychosocial interventions. Please note some of the items on this checklist may need to be filled in individually for different outcomes reported by the study. It is therefore important that the systematic reviewer has a clear idea of what the important outcomes are **before** appraising a study. You are likely to need input from the Guidance Development Group in defining the important outcomes.

Checklist items are worded so that a 'yes' response always indicates that the study has been designed/conducted in such a way as to minimise the risk of bias for that item. An 'unclear' response to a question may arise when the item is not reported or not clearly reported. 'N/A' should be used when a randomised controlled trial cannot give an answer of 'yes' no matter how well it has been done.

This checklist is designed to assess the internal and external validity of the study. Internal validity implies that the differences observed between groups of participants allocated to different interventions may (apart from the possibility of random error) be attributed to the intervention under investigation. Biases are characteristics that are likely to make estimates of effect differ systematically from the truth. External validity assesses the extent to which the findings for the study participants apply to the whole 'source population' (that is, the population they were chosen from).

The checklist contains 5 sections (A–E) on internal validity. Sections A–D each address potential sources of bias. At the end of each section you are asked to give your opinion on whether bias is present and to estimate the likely direction of this bias – that is, whether you think it will have increased or decreased the effect size reported by the study. It will

not always be possible to determine the direction of bias, but thinking this through can help greatly in interpreting results. In section E you are asked to give an overall assessment of the internal validity of the study (using ++, +, –). Section F then requires you to assess and rate the external validity of the study.

A: Selection bias

Selection bias may be introduced into a study when there are systematic differences between the participants in the different intervention groups. As a result, the differences in the outcome observed may be explained by pre-existing differences between the groups rather than because of the intervention itself. For example, if the people in one group are in poorer health or have higher levels of need, then they may be more likely to have a bad outcome than those in the other group, regardless of the effect of the intervention. The intervention groups should be similar at the start of the study – the only difference between the groups should be the intervention received.

Randomisation

There are 2 aspects to randomisation:

- generation of the random allocation sequence that results in groups that differ only randomly
- allocation concealment, so that both the participant and the investigator are unaware of which group the next participant will be allocated to when entering the study.

A1. An appropriate method of randomisation was used to allocate participants to intervention groups

If an appropriate method of randomisation has been used, each participant should have an equal chance of ending up in any of the intervention groups. Examples of random allocation sequences include random numbers generated by computer, tables of random numbers, and drawing of lots or envelopes. Any method of allocation used should be judged as to its potential for bias.

There are some more complicated ways of allocating people to intervention groups that minimise the differences between groups, such as block randomisation and minimisation. Although these are not truly random, they are usually considered to be adequate for the

purpose. If a study does not report the method of randomisation used, this should be scored as 'unclear'.

A2. There was adequate concealment of allocation

If investigators are aware of the allocation group for the next participant being enrolled in the study, there is potential for participants to be enrolled in an order that results in imbalances in important characteristics. For example, a social care practitioner (or healthcare professional where appropriate) might feel that participants who are more unwell or who have a higher level of need are likely to do better on a new, experimental, intervention and be tempted to enrol such participants when they know they will be allocated to that group. This would result in the participants in the intervention group being, on average, more unwell. Concealment of intervention group may not always be feasible, but concealment of allocation up until the point of enrolment in the study should always be possible.

The information presented within the paper should provide some assurance that allocations were not known until at least the point of enrolment. Centralised allocation, computerised allocation systems and the use of coded identical containers are all regarded as adequate methods of concealment. Sealed envelopes can be considered as adequate concealment if the envelopes are serially numbered and opaque, and allocation is performed by a third party. Poor methods of allocation concealment include alternation, or the use of case record numbers, date of birth or day of the week.

If the method of allocation concealment used is regarded as poor, or relatively easy to subvert, the study must be given a lower quality rating. If a study does not report any concealment approach, this should be scored as 'unclear'.

A3. The groups were comparable at baseline, including all major confounding factors

Studies may report the distributions of potential confounding factors in the comparison groups, or important differences in the distribution of these factors may be noted.

Formal tests comparing the groups are problematic – failure to detect a difference does not mean that a difference does not exist, and multiple comparisons of factors may falsely detect some differences that are not real.

Social care practitioner (or healthcare professional where appropriate) input may be required to determine whether all likely confounders have been considered. Confounding factors may differ according to outcome, so you will need to consider potential confounding factors for all of the outcomes that are of interest to your review.

B: Performance bias

Performance bias refers to systematic differences between the comparison groups in the care and support provided to the participants, other than the intervention under investigation.

This may consist of additional care, support, or advice, or even simply a belief about the effects of an intervention. If performance bias is present, it can be difficult to attribute any observed effect to the experimental intervention rather than to the other factors.

B1. The comparison groups received the same care apart from the intervention(s) studied

There should be no differences between the intervention groups apart from the intervention(s) received. If some participants received additional care or support (known as 'co-intervention'), this intervention is a potential confounding factor that may compromise the results.

Blinding

Blinding (also known as masking) refers to the process of withholding information about intervention allocation from those involved in the study who could potentially be influenced by this information. This can include participants, investigators, those administering care and support and those involved in data collection and analysis. If people are aware of the intervention allocation ('unblinded'), this can bias the results of studies, either intentionally or unintentionally, through the use of other effective co-interventions, decisions about withdrawal, differential reporting of symptoms or influencing concordance with the intervention. Blinding of those assessing outcomes is covered in section D on detection bias.

Blinding of participants and carers is not always possible, particularly in studies of non-drug interventions used in social care, and so performance bias may be a particular issue in these studies. It is important to think about the likely size and direction of bias caused

by failure to blind.

The terms 'single blind', 'double blind' and even 'triple blind' are sometimes used in studies. Unfortunately, they are not always used consistently. Commonly, when a study is described as 'single blind', only the participants are blind to their group allocation. When both participants and investigators are blind to group allocation, the study is often described as 'double blind'. It is preferable to record exactly who was blinded, if reported, to avoid misunderstanding.

B2. Participants receiving care and support were kept 'blind' to intervention allocation

The knowledge of assignment to a particular intervention group may affect outcomes, such as a study participant's reporting of symptoms, self-use of other known interventions or even dropping out of the study.

B3. Individuals administering care and support were kept 'blind' to intervention allocation

If individuals who are administering the intervention and/or other care and support to the participant are aware of intervention allocation, they may treat participants receiving one intervention differently from those receiving the comparison intervention; for example, by offering additional co-interventions.

C: Attrition bias

Attrition refers to the loss of participants during the course of a study. Attrition bias occurs when there are systematic differences between the comparison groups with respect to participants lost, or differences between participants lost to the study and those who remain. Attrition can occur at any point after participants have been allocated to their intervention groups. As such, it includes participants who are excluded after allocation (and may indicate a violation of eligibility criteria), those who do not complete intervention (whether or not they continue measurement) and those who do not complete outcome measurement (regardless of whether or not intervention was completed). Consideration should be given to why participants dropped out, as well as how many. Participants who dropped out of a study may differ in some significant way from those who remained as part of the study throughout. Drop-out rates and reasons for dropping out should be similar across all intervention groups. The proportion of participants excluded after

allocation should be stated in the study report, and the possibility of attrition bias considered within the analysis; however, these are not always reported.

C1. All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up)

If the comparison groups are followed up for different lengths of time, then more events are likely to occur in the group followed up for longer, distorting the comparison. This may be overcome by adjusting the denominator to take the time into account.

C2a. How many participants did not complete intervention in each group?

A very high number of participants dropping out of a study should give concern. The drop-out rate may be expected to be higher in studies conducted over a longer period of time. The drop-out rate includes people who did not even start the intervention; that is, they were excluded from the study after allocation to intervention groups.

C2b. The groups were comparable for intervention completion (that is, there were no important or systematic differences between groups in terms of those who did not complete the intervention)

If there are systematic differences between groups in terms of those who did not complete the intervention, consider both why participants dropped out and whether any systematic differences in those who dropped out may be related to the outcome under study, such as potential confounders. Systematic differences between groups in terms of those who dropped out may also result in intervention groups that are no longer comparable with respect to potential confounding factors.

C3a. For how many participants in each group were no outcome data available?

A very high number of participants for whom no outcome data were available should give concern.

C3b. The groups were comparable with respect to the availability of outcome data (that is, there were no important or systematic differences between groups in terms of those for whom outcome data were not available)

If there are systematic differences between groups in terms of those for whom no outcome data were available, consider both why the outcome data were not available and whether there are any systematic differences between participants for whom outcome data were and were not available.

D: Detection bias (this section should be completed individually for each important relevant outcome)

The way outcomes are assessed needs to be standardised for the comparison groups; failure to 'blind' people who are assessing outcomes can also lead to bias, particularly with subjective outcomes. Most studies report results for more than 1 outcome, and it is possible that detection bias may be present in a study for some, but not all, outcomes. It is therefore recommended that this section is completed individually for each important outcome that is relevant to the guidance review question under study. To avoid biasing your review, you should identify the relevant outcomes **before** considering the results of the study. Social care practitioner (or healthcare professional where appropriate) input may be required to identify the most important outcomes for a review.

D1. The study had an appropriate length of follow-up

The follow-up of participants after intervention should be of an adequate length to identify the outcome of interest. This is particularly important when different outcomes of interest occur early and late after an intervention. A study that is too short will give an unbalanced assessment of the intervention. For events occurring later, a short study will give an imprecise estimate of the effect, which may or may not also be biased. For example, a late-occurring side effect will not be detected in the intervention arm if the study is too short.

D2. The study used a precise definition of outcome

D3. A valid and reliable method was used to determine the outcome

The outcome under study should be well defined. It should be clear how the investigators determined whether participants experienced, or did not experience, the outcome. The

same methods for defining and measuring outcomes should be used for all participants in the study. Often there may be more than 1 way of measuring an outcome (for example, questionnaires, reporting of symptoms and functioning). The method of measurement should be valid (that is, it measures what it claims to measure) and reliable (that is, it measures something consistently).

D4. Investigators were kept 'blind' to participants' exposure to the intervention

D5. Investigators were kept 'blind' to other important confounding factors

In this context the 'investigators' are the individuals who are involved in making the decision about whether a participant has experienced the outcome under study. Investigators can introduce bias through differences in measurement and recording of outcomes, and making biased assessments of a participant's outcome based on the collected data. The degree to which lack of blinding can introduce bias will vary depending on the method of measuring an outcome, but will be greater for more subjective outcomes, such as reporting of pain or quality of life.

E. Overall assessment of internal validity

Rate the study for internal validity according to the list below:

++ All or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter

+ Some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter

– Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter

F. Overall assessment of external validity

Rate the external validity of the study (also using ++, +, –). This is the extent to which the findings for the study participants apply to the whole source population (the population they were chosen from). This may also involve an assessment of the extent to which, if the study were replicated in a different setting but with similar population parameters, the

results would have been the same or similar. If the study includes an 'intervention', then it should be assessed to see whether it would be feasible in settings other than that initially investigated.

Appendix D Methodology checklist: cohort studies

Appendices B–G include checklists for those study designs that are expected to be used in the evidence reviews for NICE social care guidance. Other checklists can found in the NICE clinical guidelines manual and Methods for the development of NICE public health guidance.

Checklist

Study identification Include author, title, reference, year of publication					
Guidance topic:	**Review question no:**				
Checklist completed by:					
		Circle or highlight 1 option for each question:			
A. Selection bias (systematic differences between the comparison groups)					
A1	The method of allocation to intervention groups was unrelated to potential confounding factors (that is, the reason for participant allocation to intervention groups is not expected to affect the outcome[s] under study)	Yes	No	Unclear	N/A
A2	Attempts were made within the design or analysis to balance the comparison groups for potential confounders	Yes	No	Unclear	N/A
A3	The groups were comparable at baseline, including all major confounding factors	Yes	No	Unclear	N/A
Based on your answers to the above, in your opinion was selection bias present? If so, what is the likely direction of its effect?					
Low risk of bias	Unclear/unknown risk	High risk of bias			

Likely direction of effect: .					
B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)					
B1	The comparison groups received the same care and support apart from the intervention(s) studied	Yes	No	Unclear	N/A
B2	Participants receiving care and support were kept 'blind' to intervention allocation	Yes	No	Unclear	N/A
B3	Individuals administering care and support were kept 'blind' to intervention allocation	Yes	No	Unclear	N/A
Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?					
Low risk of bias	Unclear/unknown risk	High risk of bias			
Likely direction of effect: . .					
C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)					
C1	All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up)	Yes	No	Unclear	N/A
C2	a. How many participants did not complete the intervention in each group?				
	b. The groups were comparable for intervention completion (that is, there were no important or systematic differences between groups in terms of those who did not complete the intervention)	Yes	No	Unclear	N/A
C3	a. For how many participants in each group were no outcome data available?				

	b. The groups were comparable with respect to the availability of outcome data (that is, there were no important or systematic differences between groups in terms of those for whom outcome data were not available)	Yes	No	Unclear	N/A

Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?		
Low risk of bias	Unclear/unknown risk	High risk of bias
Likely direction of effect:		

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)					
D1	The study had an appropriate length of follow-up	Yes	No	Unclear	N/A
D2	The study used a precise definition of outcome	Yes	No	Unclear	N/A
D3	A valid and reliable method was used to determine the outcome	Yes	No	Unclear	N/A
D4	Investigators were kept 'blind' to participants' exposure to the intervention	Yes	No	Unclear	N/A
D5	Investigators were kept 'blind' to other important confounding factors	Yes	No	Unclear	N/A

Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?		
Low risk of bias	Unclear/unknown risk	High risk of bias
Likely direction of effect:		

E. Overall assessment of internal validity. Are the study results internally valid? Rate the study for internal validity below (for further information see notes on using the methodology checklist)		
++	+	–
Comments:		
F. Overall assessment of external validity – Are the study results externally valid (i.e. generalisable to the source population)? Consider participants, interventions, settings, comparisons and outcomes. Rate the study for external validity below (for further information see notes on use of the methodology checklist)		
++	+	–
Comments:		

Notes on use of Methodology checklist: cohort studies

Cohort studies are designed to answer questions about the relative effects of interventions, using an observational design. Such studies usually study 2 or more groups of people – cohorts – with similar characteristics. One group receives an intervention, is exposed to a risk factor or has a particular symptom and the other group does not. The study follows their progress over time and records what happens.

Please note some of the items on this checklist may need to be filled in individually for different outcomes reported by the study. It is therefore important that the systematic reviewer has a clear idea of what the important outcomes are **before** appraising a study. You are likely to need input from the Guidance Development Group in defining the important outcomes.

Checklist items are worded so that a 'yes' response always indicates that the study has been designed/conducted in such a way as to minimise the risk of bias for that item. An 'unclear' response to a question may arise when the item is not reported or is not reported clearly. 'N/A' should be used when a cohort study cannot give an answer of 'yes' no matter how well it has been done.

This checklist is designed to assess the internal and external validity of the study. Internal validity implies that the differences observed between groups of participants allocated to different interventions may (apart from the possibility of random error) be attributed to the intervention under investigation. Biases are characteristics that are likely to make estimates of effect differ systematically from the truth. External validity assesses the extent to which the findings for the study participants apply to the whole 'source population' (that is, the population they were chosen from)

This checklist contains 5 sections (A–E) on internal validity. Sections A–D each address a potential source of bias . At the end of each section you are asked to give your opinion on whether bias is present, and to estimate the likely direction of this bias – whether you think it will have increased or decreased the effect size reported by the study. It will not always be possible to determine the direction of bias, but thinking this through can help greatly in interpreting results. In section E you are asked to give an overall assessment of the internal validity of the study (using ++, −). Section F then requires you to assess and rate the external validity of the study (also using ++, +, −).

A: Selection bias

Selection bias can be introduced into a study when there are systematic differences between the participants in the different intervention groups. As a result, the differences in the outcome observed may be explained by pre-existing differences between the groups rather than because of the intervention itself. For example, if the people in one group are in poorer health or have higher levels of need , then they may be more likely to have a bad outcome than those in the other group, regardless of the effect of the intervention. The intervention groups should be similar at the start of the study – the only difference between the groups should be in terms of the intervention received.

The main difference between randomised trials and non-randomised studies is the potential susceptibility of the latter to selection bias. Randomisation should ensure that, apart from the intervention received, the intervention groups differ only because of random variation. However, care needs to be taken in the design and analysis of non-randomised studies to take account of potential confounding factors. There are 2 main ways of accounting for potential confounding factors in non-randomised studies. Firstly, participants can be allocated to intervention groups to ensure that the groups are equal with respect to the known confounders. Secondly, statistical techniques can be used within the analysis to take into account known differences between groups. Neither of these approaches is able to address unknown or unmeasurable confounding factors, and it

is important to remember that measurement of known confounders is subject to error. Therefore, considerable judgement is needed to assess the internal validity of non-randomised studies; social care practitioner (or healthcare professional where appropriate) input may be needed to identify potential confounding factors that should be taken into consideration.

A1. The method of allocation to intervention groups was unrelated to potential confounding factors

In non-randomised studies, there will usually be a reason why participants are allocated to the intervention groups (often as a result of social care practitioner and/or service user choice). If this reason is linked to the outcome under study, this can result in confounding by indication (where the decision to treat is influenced by some factor that is related in turn to the intervention outcome). For example, if the participants who are the most ill or have the highest level of need are selected for the intervention, then the intervention group may experience worse outcomes because of this difference between the groups at baseline. It will not always be possible to determine from the report of a study which factors influenced the allocation of participants to intervention groups.

A2. Attempts were made within the design or analysis to balance the comparison groups for potential confounders

This represents an attempt when designing the study to ensure that the groups are similar in terms of known confounding factors, in order to optimise comparability between the intervention groups. For example, in a matched design, the controls are deliberately chosen to be equivalent to the intervention group for any potential confounding variables, such as age and sex.

An alternative approach is to use statistical techniques to adjust for known confounding factors in the analysis.

A3. The groups were comparable at baseline, including all major confounding factors

Studies may report the distributions of potential confounding factors in the comparison groups, or important differences in these factors may be noted.

Formal tests comparing the groups are problematic – failure to detect a difference does

not mean that a difference does not exist, and multiple comparisons of factors may falsely detect some differences that are not real.

Social care practitioner (or healthcare professional where appropriate) input may be needed to determine whether all likely confounders have been considered. Confounding factors may differ according to outcome, so you will need to consider potential confounding factors for each of the outcomes that are of interest to your review.

B: Performance bias

Performance bias refers to systematic differences in the care provided to the participants in the comparison groups, other than the intervention under investigation.

This may consist of additional care, support, or advice, or even simply a belief about the effects of an intervention. If performance bias is present, it can be difficult to attribute any observed effect to the intervention rather than to the other factors.

Performance bias can be more difficult to determine in non-randomised studies than in randomised studies, because the latter are likely to have been better planned and executed according to strict protocols that specify standardised interventions and care. It may be particularly difficult to determine performance bias for retrospective studies, where there is usually no control over standardisation.

B1. The comparison groups received the same care apart from the intervention(s) studied

There should be no differences between the intervention groups apart from the intervention(s) received. If some participants received additional care or support (known as 'co-intervention'), this intervention is a potential confounding factor that may compromise the results.

Blinding

Blinding (also known as masking) refers to the process of withholding information about intervention allocation or exposure status from those involved in the study who could potentially be influenced by this information. This can include participants, investigators, those administering care and support, and those involved in data collection and analysis. If people are aware of the intervention allocation or exposure status ('unblinded'), this can

bias the results of studies, either intentionally or unintentionally, through the use of other effective co-interventions, decisions about withdrawal, differential reporting of symptoms or influencing concordance with the intervention. Blinding of those assessing outcomes is covered in section D on detection bias.

Blinding of participants and carers is not always possible, particularly in studies of non-drug interventions used in social care, and so performance bias may be a particular issue in these studies. It is important to think about the likely size and direction of bias caused by failure to blind.

The terms 'single blind', 'double blind' and even 'triple blind' are sometimes used in studies. Unfortunately, they are not always used consistently. Commonly, when a study is described as 'single blind', only the participants are blind to their group allocation. When both participants and investigators are blind to group allocation the study is often described as 'double blind'. It is preferable to record exactly who was blinded, if reported, to avoid misunderstanding.

B2. Participants receiving care were kept 'blind' to intervention allocation

The knowledge of assignment to a particular intervention group may affect outcomes such as a study participant's reporting of symptoms, self-use of other known interventions or even dropping out of the study.

B3. Individuals administering care were kept 'blind' to intervention allocation

If individuals who are administering the intervention and/or other care and support to the participant are aware of intervention allocation, they may treat participants receiving one intervention differently from those receiving the comparison intervention; for example, by offering additional co-interventions.

C: Attrition bias

Attrition refers to the loss of participants during the course of a study. Attrition bias occurs when there are systematic differences between the comparison groups with respect to participants lost, or differences between the participants lost to the study and those who remain. Attrition can occur at any point after participants have been allocated to their intervention groups. As such, it includes participants who are excluded after allocation (and may indicate a violation of eligibility criteria), those who do not complete intervention

(whether or not they continue measurement) and those who do not complete outcome measurement (regardless of whether or not the intervention was completed). Consideration should be given to why participants dropped out, as well as how many. Participants who dropped out of a study may differ in some significant way from those who remained as part of the study throughout. Drop-out rates and reasons for dropping out should be similar across all intervention groups. The proportion of participants excluded after allocation should be stated in the study report and the possibility of attrition bias considered within the analysis; however, these are not always reported.

C1. All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up)

If the comparison groups are followed up for different lengths of time, then more events are likely to occur in the group followed up for longer, distorting the comparison. This may be overcome by adjusting the denominator to take the time into account; for example by using person-years.

C2a. How many participants did not complete intervention in each group?

A very high number of participants dropping out of a study should give concern. The drop-out rate may be expected to be higher in studies conducted over a longer period of time. The drop-out rate includes people who did not even start the intervention; that is, they were excluded from the study after allocation to intervention groups.

C2b. The groups were comparable for intervention completion (that is, there were no important or systematic differences between groups in terms of those who did not complete the intervention)

If there are systematic differences between groups in terms of those who did not complete the intervention, consider both why participants dropped out and whether any systematic differences in those who dropped out may be related to the outcome under study, such as potential confounders. Systematic differences between groups in terms of those who dropped out may also result in intervention groups that are no longer comparable with respect to potential confounding factors.

C3a. For how many participants in each group were no outcome data available?

A very high number of participants for whom no outcome data were available should give concern.

C3b. The groups were comparable with respect to the availability of outcome data (that is, there were no important or systematic differences between groups in terms of those for whom outcome data were not available)

If there are systematic differences between groups in terms of those for whom no outcome data were available, consider both why the outcome data were not available and whether there are any systematic differences between participants for whom outcome data were and were not available.

D: Detection bias (this section should be completed individually for each important relevant outcome)

The way outcomes are assessed needs to be standardised for the comparison groups; failure to 'blind' people who are assessing the outcomes can also lead to bias, particularly with subjective outcomes. Most studies report results for more than 1 outcome, and it is possible that detection bias may be present for some, but not all, outcomes. It is therefore recommended that this section is completed individually for each important outcome that is relevant to the guidance review question under study. To avoid biasing your review, you should identify the relevant outcomes **before** considering the results of the study. Social care practitioner (or healthcare professional where appropriate) input may be required to identify the most important outcomes for a review.

D1. The study had an appropriate length of follow-up

The follow-up of participants after intervention should be of an adequate length to identify the outcome of interest. This is particularly important when different outcomes of interest occur early and late after an intervention. A study that is too short will give an unbalanced assessment of the intervention. For events occurring later, a short study will give an imprecise estimate of the effect, which may or may not also be biased. For example, a late-occurring side effect will not be detected in the intervention arm if the study is too short.

D2. The study used a precise definition of outcome

D3. A valid and reliable method was used to determine the outcome

The outcome under study should be well defined and it should be clear how the investigators determined whether participants experienced, or did not experience, the outcome. The same methods for defining and measuring outcomes should be used for all participants in the study. Often there may be more than 1 way of measuring an outcome (for example, questionnaires, reporting of symptoms and functioning). The method of measurement should be valid (that is, it measures what it claims to measure) and reliable (that is, it measures something consistently).

D4. Investigators were kept 'blind' to participants' exposure to the intervention

D5. Investigators were kept 'blind' to other important confounding factors

In this context the 'investigators' are the individuals who are involved in making the decision about whether a participant has experienced the outcome under study. Investigators can introduce bias through differences in measurement and recording of outcomes, and making biased assessments of a participant's outcome based on the collected data. The degree to which lack of blinding can introduce bias will vary depending on the method of measuring an outcome, but will be greater for more subjective outcomes, such as reporting of pain or quality of life.

E. Overall assessment of internal validity

Rate the study for internal validity according to the list below:

++ All or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter

+ Some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter

Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter

F. Overall assessment of external validity

Rate the external validity of the study (also using ++, +, –). This is the extent to which the findings for the study participants apply to the whole source population (the population they were chosen from). This may also involve an assessment of the extent to which, if the study were replicated in a different setting but with similar population parameters, the results would have been the same or similar. If the study includes an 'intervention', then it should be assessed to see whether it would be feasible in settings other than that initially investigated.

Appendix E Methodology checklist: case–control studies

Appendices B–G include checklists for those study designs that are expected to be used in the evidence reviews for NICE social care guidance. Other checklists can found in the NICE clinical guidelines manual and Methods for the development of NICE public health guidance.

Checklist

Study identification Include author, title, reference, year of publication			
Guidance topic:		**Review question no:**	
Checklist completed by:			
Section 1: Internal validity			
		Circle or highlight 1 option for each question	
1.1	The study addresses an appropriate and clearly focused question.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
Selection of participants			
1.2	The cases and controls are taken from comparable populations	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable

1.3	The same exclusion criteria are used for both cases and controls	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.4	What was the participation rate for each group (cases and controls)?	Cases: Controls:	
1.5	Participants and non-participants are compared to establish their similarities or differences	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.6	Cases are clearly defined and differentiated from controls	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.7	It is clearly established that controls are not cases	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
Assessment			
1.8	Measures were taken to prevent knowledge of primary exposure from influencing case ascertainment	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable

1.9	Exposure status is measured in a standard, valid and reliable way	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
Confounding factors			
1.10	The main potential confounders are identified and taken into account in the design and analysis	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
Statistical analysis			
1.11	Have confidence intervals been provided?		

1.12 Overall assessment of internal validity. Are the study results internally valid?

Rate the study for internal validity below (for further information see notes on using the methodology checklist)

++	+	–
Comments:		

Section 2: Overall assessment of external validity. Are the study results externally valid (i.e. generalisable to the source population)?

Consider participants, interventions, settings, comparisons and outcomes. Rate the study for external validity below (for further information see notes on use of the methodology checklist)

++	+	–
Comments:		

Section 3: Description of the study (This information is required for evidence tables to facilitate cross-study comparisons. Please complete all sections for which information is available.) *Please print clearly*		
3.1	How many people participated in the study?	*List the numbers of cases and controls separately.* . . . .
3.2	What are the main characteristics of the study population?	*Include all characteristics used to identify both cases and controls – for example, age, sex, social class, level of need.* . . . .
3.3	What environmental or prognostic factor is being investigated?	. . . .
3.4	What comparisons are made?	*Normally only 1 factor will be compared, but in some cases the extent of exposure may be stratified. Note all comparisons here.* . . . .

3.5	For how long are participants followed up?	*This is the length of time over which participant histories are tracked in the study.* . . . .
3.6	What outcome measure(s) is/are used?	*List all outcomes that are used to assess the impact of the chosen environmental or prognostic factor.* . . . . .
3.7	What size of effect is identified?	*Effect size should be expressed as an odds ratio. If any other measures are included, note them as well. Include p-values and any confidence intervals that are provided.* . . . .
3.8	How was the study funded?	*List all sources of funding quoted in the article, whether government, voluntary sector or industry.* . . . .
3.9	Does this study help to answer your guidance review question?	*Summarise the main conclusions of the study and indicate how it relates to the review question.* . . . .

Notes on use of the Methodology checklist: case–control studies

Case–control studies are designed to answer questions of the type 'What are the factors that caused this event?'. They involve comparison of individuals who have an outcome with other individuals from the same population who do not have the outcome. These studies start after the outcome of an event, and can be used to assess multiple causes of a single event. They are generally used to assess the causes of a new problem but they may also be useful for the evaluation of population-based interventions. .

The questions in **section 1** are aimed at establishing the internal validity of the study under review – that is, making sure that it has been carried out carefully, and that any link between events and outcomes is clearly established. Each question covers an aspect of methodology that has been shown to make a significant difference to the conclusions of a study. In question 1.12 you are, based on the results from the study checklist, asked to provide an overall assessment of the internal validity of the study.

In section 2 you are then asked to rate the external validity of the study (also using ++, +, –). External validity assesses the extent to which the findings for the study participants apply to the whole 'source population' (that is, the population they were chosen from).

Case–control studies need to be designed very carefully – the complexity of their design is often not appreciated by investigators, and so many poor-quality studies are conducted. The questions in this checklist are designed to identify the main features that should be present in a well-designed study. There are few criteria that should, alone and unsupported, lead to rejection of a study. However, if a study fails to address or report on more than 1 or 2 of the questions in the checklist you should consider whether to reject the study

For each question in this section you should choose 1 of the following categories to indicate how well it has been addressed in the study:

- well covered
- adequately addressed
- poorly addressed
- not addressed (not mentioned, or this aspect of study design was ignored)

- not reported (mentioned, but with insufficient detail to allow assessment to be made)
- not applicable.

Question

1.1 The study addresses an appropriate and clearly focused question

Unless a clear and well-defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer.

Selection of participants

1.2 The cases and controls are taken from comparable populations

Study participants may be selected from the target population (all individuals to which the results of the study could be applied), from the source population (a defined subset of the target population from which participants are selected) or from a pool of eligible people (a clearly defined and counted group selected from the source population). A study that does not include clear definitions of the source population may be rejected.

1.3 The same exclusion criteria are used for both cases and controls

All selection and exclusion criteria should be applied equally to cases and controls. Failure to do so may introduce a significant degree of bias into the results of the study.

1.4 What was the participation rate for each group (cases and controls)?

Differences between the eligible population and the study participants are important because they may influence the validity of the study. A participation rate can be calculated by dividing the number of study participants by the number of people who are eligible to participate. It is more useful if it is calculated separately for cases and controls. If the participation rate is low, or there is a large difference in rate between cases and controls, the study results may be invalid because of differences between participants and non-participants. In these circumstances the study should be downgraded, and rejected if the differences are very large.

1.5 Participants and non-participants are compared to establish their similarities or differences

Even if participation rates are comparable and acceptable, it is still possible that the participants selected to act as cases or controls may differ from other members of the source population in some significant way. A well-conducted case–control study will look at samples of those not participating among the source population to ensure that the participants are a truly representative sample.

1.6 Cases are clearly defined and differentiated from controls

The method of selection of cases is of critical importance to the validity of the study. Investigators have to be certain that cases are truly cases, but must balance this with the need to ensure that the cases admitted into the study are representative of the eligible population. The issues involved in case selection are complex, and should ideally be evaluated by someone with a good understanding of the design of case–control studies. If there is no information on how cases were selected it is probably safest to reject the study as a source of evidence.

1.7 It is clearly established that controls are not cases

Just as it is important to be sure that cases are true cases, it is important to be sure that controls do not have the outcome under investigation. Controls should be chosen so that information on exposure status can be obtained or assessed in a similar way to that used for the selection of cases. If the methods of control selection are not described, the study may be rejected. If different methods of selection are used for cases and controls, the study should be evaluated by someone with a good understanding of the design of case–control studies.

Assessment

1.8 Measures were taken to prevent knowledge of primary exposure from influencing case ascertainment

If there is a possibility that case ascertainment was influenced by knowledge of exposure status, assessment of any association is likely to be biased. A well-conducted study should take this into account in the design of the study.

1.9 Exposure status is measured in a standard, valid and reliable way

The inclusion of evidence from other sources or previous studies that demonstrate the validity and reliability of the assessment methods, or the fact that the measurement method is a recognised procedure, should increase confidence in study quality.

Confounding factors

1.10 The main potential confounders are identified and taken into account in the design and analysis

Confounding is the distortion of a link between exposure and outcome by another factor that is associated with both exposure and outcome. The possible presence of confounding factors is one of the principal reasons why observational studies are not more highly rated as a source of evidence. The report of the study should indicate which potential confounders have been considered, and how they have been assessed or accounted for in the analysis. Social care practitioner (or healthcare professional where appropriate) judgement should be used to consider whether all likely confounders have been taken into account. If the measures used to address the potential effects of confounders are considered inadequate, the study should be downgraded or rejected, depending on how serious the risk of confounding is considered to be. A study that does not address the possibility of confounding should be rejected.

Statistical analysis

1.11 Have confidence intervals been provided?

Confidence intervals are the preferred method for indicating the precision of statistical results, and can be used to differentiate between an inconclusive study and a study that shows no effect. Studies that report a single value with no assessment of precision should be treated with caution.

Internal validity

1.12 Overall assessment of internal validity

Rate the study for internal validity according to the list below:

++ All or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter

+ Some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter

– Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter

External validity

Section 2 of the checklist asks you to rate the external validity of the study (also using ++, +, –). External validity assesses the extent to which the findings for the study participants apply to the whole 'source population' (that is, the population they were chosen from). This may also involve an assessment of the extent to which, if the study were replicated in a different setting but with similar population parameters, the results would have been the same or similar. If the study includes an 'intervention', then it should be assessed to see whether it would be feasible in settings other than that initially investigated.

Section 3 of the checklist asks you to summarise key points about the study that will be added to an evidence table (see appendix H) in the next stage of the process.

Appendix F Methodology checklist: economic evaluations

Appendices B–G include checklists for those study designs that are expected to be used in the evidence reviews for NICE social care guidance. Other checklists can found in the NICE clinical guidelines manual and Methods for the development of NICE public health guidance..

This checklist is designed to determine whether an economic evaluation provides evidence that is useful to inform the decision-making of the Guidance Development Group (GDG) (see chapter 7). It is not intended to judge the quality of the study or the quality of reporting.

Checklist

Study identification Include author, title, reference, year of publication		
Guidance topic:		Question no:
Checklist completed by:		
Section 1: Applicability (relevance to specific review question(s) and the NICE reference case as described in the NICE social care guidance manual) This checklist should be used first to filter out irrelevant studies.	**Yes/ partly/no/ unclear/ NA**	**Comments**
1.1 Is the study population appropriate for the review question?		
1.2 Are the interventions appropriate for the review question?		
1.3 Is the social care system in which the study was conducted sufficiently similar to the current UK social care context?		
1.4 Are the perspective(s) clearly stated and what are they?		

1.5 Are all direct effects on individuals included, and are all other effects included where they are material?		
1.6 Are all future costs and outcomes discounted appropriately?		
1.7 How is the value of effects expressed?		
1.8 Are costs and outcomes from other sectors (including the value of unpaid care, where relevant) fully and appropriately measured and valued?		
1.9**Overall judgement:** Directly applicable/partially applicable/not applicable There is no need to use section 2 of the checklist if the study is considered 'not applicable'.		
Other comments:		
Section 2: Study limitations (the level of methodological quality) This checklist should be used once it has been decided that the study is sufficiently applicable to the context of the social care guidance[1].	**Yes/ partly/no/ unclear/ NA**	**Comments**
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?		
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?		
2.3 Are all important and relevant outcomes included?		
2.4 Are the estimates of baseline outcomes from the best available source?		
2.5 Are the estimates of relative intervention effects from the best available source?		
2.6 Are all important and relevant costs included?		
2.7 Are the estimates of resource use from the best available source?		
2.8 Are the unit costs of resources from the best available source?		

2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?		
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?		
2.11 Is there any potential conflict of interest?		
2.12**Overall assessment:** Minor limitations/potentially serious limitations/very serious limitations		
Other comments:		
[a] The items and notes in this checklist have been developed from guidance in NICE's Guide to the methods of technology appraisal; Evers S, Goossens M, de Vet H et al. (2005) Criteria list for assessment of methodological quality of economic evaluations – CHEC. International Journal of Technology Assessment in Health Care 21:240–5; and Philips Z, Ginnelly L, Sculpher M et al. (2004) Review of guidelines for good practice in decision-analytic modelling in health technology assessment. Health Technology Assessment 8.		

Notes on use of the Methodology checklist: economic evaluations

For all questions:

- answer 'yes' if the study fully meets the criterion
- answer 'partly' if the study largely meets the criterion but differs in some important respect
- answer 'no' if the study deviates substantively from the criterion
- answer 'unclear' if the report provides insufficient information to judge whether the study complies with the criterion
- answer 'NA (not applicable)' if the criterion is not relevant in a particular instance.

For 'partly' or 'no' responses, use the comments column to explain how the study deviates from the criterion.

Section 1: Applicability

1.1 Is the study population appropriate for the review question?

The study population should be defined as precisely as possible and should be in line with that specified in the guidance scope and any related review protocols.

This includes consideration of appropriate subgroups that require special attention. For many interventions, the capacity to benefit will differ for participants with differing characteristics. This should be explored separately for each relevant subgroup as part of the base-case analysis by the provision of estimates of effectiveness and cost effectiveness. The characteristics of participants or communities in each subgroup should be clearly defined and, ideally, should be identified on the basis of an a priori expectation of differential effectiveness or cost effectiveness as a result of biologically, sociologically or economically plausible known mechanisms, social characteristics or other clearly justified factors.

Answer 'yes' if the study population is fully in line with that in the review question(s) and if the study differentiates appropriately between important subgroups. Answer 'partly' if the study population is similar to that in the review question(s) but: (i) it differs in some important respects; or (ii) the study fails to differentiate between important subgroups. Answer 'no' if the study population is substantively different from that in the review question(s).

1.2 Are the interventions and services appropriate for the review question?

All relevant alternatives should be included, as specified in the guidance scope and any related review protocols. These should include routine and best practice in UK social care, existing NICE guidance and other feasible options.

Answer 'yes' if the analysis includes all options considered relevant for the review question, even if it also includes other options that are not relevant. Answer 'partly' if the analysis omits 1 or more relevant options but still contains comparisons likely to be useful for the guidance. Answer 'no' if the analysis does not contain any relevant comparisons.

1.3 Is the social care system in which the study was conducted sufficiently similar to the current UK social care context?

This relates to the overall structure of the social care system within which the interventions were delivered. For example, an intervention might be delivered on a residential basis in one country whereas in the UK it would be provided in the community. This might significantly influence the use of resources and costs, thus limiting the applicability of the results to a UK setting. In addition, old UK studies may be severely limited in terms of their relevance to current practice.

Answer 'yes' if the study was conducted within the UK and is sufficiently recent to reflect current practice. For non-UK or older UK studies, answer 'partly' if differences in the setting are unlikely to substantively change the cost-effectiveness estimates. Answer 'no' if the setting is so different that the results are unlikely to be applicable in the current social care context.

1.4 Are the perspectives clearly stated, and what are they?

The decision-making perspective of an economic evaluation determines the range of costs that should be included in the analysis. For social care guidance, one perspective that will usually be used is that of the public sector organisations (such as local authorities) delivering the interventions. Sometimes costs will be borne and benefits will accrue outside the public sector. When they are borne or accrue predominantly by other public sectors agencies, it will also be appropriate to use a public sector perspective. For social care topics the importance of the value of unpaid care in contributing to outcomes may be an important element of the cost perspective. In topics where interventions have a material effect on employment, the perspective may also need to reflect that. Where cost effectiveness using a narrower perspective is clearly established, however, the requirement to embrace a wider perspective is much reduced. Answer 'yes' if the study clearly and correctly states the perspective used, and whether that perspective is appropriate. Answer 'partly' if the perspective stated is not the perspective used. Answer 'no' if the study does not state the perspective or that the perspective is not appropriate.

1.5 Are all direct effects on individuals included, and are all other effects included where they are material?

For a personal social services (PSS) (and where appropriate, an NHS perspective), outcomes should include all direct effects, whether for individuals directly affected or,

when relevant, other people (often other family members or carers). This is consistent with an objective of maximising benefits from available public sector resources. Any significant characteristics of social care provision that have a value to people that is independent of any direct effect on outcomes should be noted. These characteristics include the convenience with which social care is provided and the level of information available for service users and carers.

Where the perspective is wider (a public sector perspective), outcomes may, where relevant, include not just the individuals directly targeted but also their families, friends and the community in general.

If a wider public sector perspective is used, answer 'yes' if the measure of outcome excludes effects that are not directly related to the social care intervention (or if such effects can be excluded from the results). Answer 'partly' if the analysis from a public sector perspective includes some non-social care effects but these are small and unlikely to change the cost-effectiveness results. Answer 'no' if the analysis incorrectly includes or excludes significant non-social care effects that are likely to change the cost-effectiveness results for a particular perspective.

If a societal perspective is used, answer 'yes' if the measure of outcome includes non-social care effects. Answer 'partly' if the analysis includes some non-social care effects but these are small and unlikely to change the cost-effectiveness results. Answer 'no' if the analysis incorrectly includes or excludes significant non-social care effects that are likely to change the cost-effectiveness results for a particular perspective.

1.6 Are all future costs and outcomes discounted appropriately?

The need to discount to a present value is widely accepted in economic evaluation, although the specific rate is variable across jurisdictions and over time. NICE considers that it is usually appropriate to discount costs and health effects at the same rate. The annual rate of 3.5%, based on the recommendations of the UK Treasury for the discounting of costs, should be applied to both costs and effects. Sensitivity analyses using rates of 1.5% for both costs and effects may be presented alongside the reference-case analysis.

Answer 'yes' if both costs and effects are discounted at 3.5% per year (or at another rate considered appropriate). Answer 'partly' if costs and health effects are discounted at a rate similar to the rate considered appropriate (for example, costs and effects are both

discounted at 3% per year where the appropriate rate is 3.5%). Answer 'no' if costs and/or health effects are not discounted, or if they are discounted at a rate (or rates) different from the rate considered appropriate (for example, 5% for both costs and effects, or 6% for costs and 1.5% for effects where the appropriate rate is 3.5%). Note in the comments column what discount rates have been used. If all costs and health effects accrue within a short time (roughly a year), answer 'NA'.

1.7 How is the value of effects expressed?

The QALY is a measure of a person's length of life weighted by a valuation of their health-related quality of life (HRQoL) over that period. For social care, the QALY may not be the most appropriate measure of effects; other measures based on social care-related quality of life or capability may be used.

Answer 'yes' if the effectiveness of the intervention is measured using QALYs or an appropriate social care-related equivalent; answer 'no' if not. Use the comments column to describe the measure of effects used. There may be circumstances when such measures cannot be obtained or where the underlying assumptions are considered inappropriate. In such situations answer 'no', but consider retaining the study for appraisal. Similarly, answer 'no' but retain the study for appraisal if it does not include appropriate measures of effects but is still thought to be useful for GDG decision-making: for example, if the evidence indicates that an intervention might be dominant, and estimates of the relative costs of the interventions from a cost-minimisation study are likely to be useful. When economic evaluations not using appropriate measures of effects are retained for full critical appraisal, use the comments column to note why.

1.8 Are costs and outcomes from other sectors (including the value of unpaid care, where relevant) fully and appropriately measured and valued?

Studies in social care often include costs accruing to other sectors of the economy or benefits gained by these sectors. Not all of these benefits can be translated into measures of effects (for example, the ability to return to work earlier). **Answer 'yes' if all the costs and all the benefits have been included, if they are appropriately measured and if they are appropriately valued. Answer 'partly' if omissions are not material and answer 'no' if some major cost or benefit is omitted, is improperly measured or improperly valued. Use the comments column to** describe costs and outcomes relating to other sectors or unpaid care.

1.9 Overall judgement

Classify the applicability of the economic evaluation to the social care guidance, the current social care situation and the context for NICE guidance as 1 of the following:

- **Directly applicable** – the study meets all applicability criteria, or fails to meet 1 or more applicability criteria but this is unlikely to change the conclusions about cost effectiveness.
- **Partially applicable** – the study fails to meet 1 or more of the applicability criteria, and this could change the conclusions about cost effectiveness.
- **Not applicable** – the study fails to meet 1 or more of the applicability criteria, and this is likely to change the conclusions about cost effectiveness. Such studies would usually be excluded from further consideration and there is no need to continue with the rest of the checklist.

Section 2: Study limitations

2.1 Does the model structure adequately reflect the nature of the topic under evaluation?

This relates to the choice of model and its structural elements (including cycle length in discrete time models, if appropriate). Model type and its structural aspects should be consistent with a coherent theory of the social care needs under evaluation. The selection of care pathways, whether individual states or branches in a decision tree, should be based on the underlying biological, sociological or economic processes of the topic under study and the potential impact (benefits and adverse consequences) of the intervention(s) of interest.

Answer 'yes' if the model design and assumptions appropriately reflect the health condition and intervention(s) of interest. Answer 'partly' if there are aspects of the model design or assumptions that do not fully reflect the health condition or intervention(s) but these are unlikely to change the cost-effectiveness results. Answer 'no' if the model omits some important aspect of the health condition or intervention(s) and this is likely to change the cost-effectiveness results. Answer 'NA' for economic evaluations based on data from a study which do not extrapolate intervention outcomes or costs beyond the study context or follow-up period.

2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?

The time horizon is the period of analysis of the study: the length of follow-up for participants in a trial-based evaluation, or the period of time over which the costs and outcomes for a cohort are tracked in a modelling study. This time horizon should always be the same for costs and outcomes, and should be long enough to include all relevant costs and outcomes relating to the intervention. A time horizon shorter than lifetime could be justified if there is no differential mortality effect between options, and the differences in costs, social care-related quality of life or other relevant outcomes relate to a relatively short period.

Answer 'yes' if the time horizon is sufficient to include all relevant costs and outcomes. Answer 'partly' if the time horizon may omit some relevant costs and outcomes but these are unlikely to change the cost-effectiveness results. Answer 'no' if the time horizon omits important costs and outcomes and this is likely to change the cost-effectiveness results.

2.3 Are all important and relevant outcomes included?

All relevant outcomes should include direct social care or other effects relating to harms from the intervention as well as any potential benefits.

Answer 'yes' if the analysis includes all relevant and important harms and benefits. Answer 'partly' if the analysis omits some harms or benefits but these would be unlikely to change the cost-effectiveness results. Answer 'no' if the analysis omits important harms and/or benefits that would be likely to change the cost-effectiveness results.

2.4 Are the estimates of baseline outcomes from the best available source?

The sources and methods for eliciting baseline probabilities should be described clearly. These data can be based on 'natural history' (outcomes in the absence of intervention), sourced from cohort studies. Baseline probabilities may also be derived from the control arms of experimental studies. Sometimes it may be necessary to rely on expert opinion for particular parameters.

Answer 'yes' if the estimates of baseline health outcomes reflect the best available evidence as identified from a recent well-conducted systematic review of the literature. Answer 'partly' if the estimates are not derived from a systematic review but are likely to

reflect outcomes for the relevant group of people in England (for example, if they are derived from a large UK-relevant cohort study). Answer 'no' if the estimates are unlikely to reflect outcomes for the relevant group of people in England.

2.5 Are the estimates of relative intervention effects from the best available source?

Evidence on outcomes should be obtained from a systematic review, defined as the systematic location, inclusion, appraisal and synthesis of evidence to obtain a reliable and valid overview of the data relating to a clearly formulated question.

Synthesis of outcome data through meta-analysis is appropriate provided that there are sufficient relevant and valid data obtained using comparable measures of outcome.

Head-to-head randomised controlled trials (RCTs) provide the most valid evidence of the effects of interventions. However, such evidence may not always be available. Therefore, data from non-randomised studies may be required to supplement RCT data. Any potential bias arising from the design of the studies used in the assessment should be explored and documented.

When assessing multiple interventions that have not been compared within a single RCT, data from a series of pairwise head-to-head RCTs should be presented. Consideration should also be given to presenting a combined analysis using a mixed treatment comparison framework if it is considered to add information that is not available from the head-to-head comparison.

The principles of good practice for standard meta-analyses should also be followed in mixed and indirect treatment comparisons.

The methods and assumptions that are used to extrapolate short-term results to final outcomes should be clearly presented.

Answer 'yes' if the estimates of the effect of intervention appropriately reflect all relevant studies of the best available quality, as identified through a recent well-conducted systematic review of the literature. Answer 'partly' if the estimates of the effect of intervention are not derived from a systematic review but are similar in magnitude to the best available estimates (for example, if the economic evaluation is based on a single large study with effects similar to pooled estimates from all relevant studies). Answer 'no' if the

estimates of the effect of intervention are likely to differ substantively from the best available estimates.

2.6 Are all important and relevant costs included?

Costs related to the topic of interest and incurred in additional years of life gained as a result of intervention should be included in the base-case analysis. Costs that are considered to be unrelated to the topic or intervention of interest should be excluded. If introduction of the intervention requires additional infrastructure to be put in place, consideration should be given to including such costs in the analysis.

Answer 'yes' if all important and relevant resource use and costs are included given the perspective and the research question in the economic study under consideration. Answer 'partly' if some relevant resource items are omitted but these are unlikely to affect the cost-effectiveness results. Answer 'no' if important resource items are omitted and these are likely to affect the cost-effectiveness results.

2.7 Are the estimates of resource use from the best available source?

It is important to quantify the effect of the interventions on resource use in terms of physical units (for example, days in care or contacts with social care practitioners) and valuing those effects in monetary terms using appropriate prices and unit costs. Evidence on resource use should be identified systematically. When expert opinion is used as a source of information, any formal methods used to elicit these data should be clearly reported.

Answer 'yes' if the estimates of resource use appropriately reflect all relevant evidence sources of the best available quality, as identified through a recent well-conducted systematic review of the literature. Answer 'partly' if the estimates of resource use are not derived from a systematic review but are similar in magnitude to the best available estimates. Answer 'no' if the estimates of resource use are likely to differ substantively from the best available estimates.

2.8 Are the unit costs of resources from the best available source?

Resources should be valued using the prices relevant to the agencies that deliver the interventions. A first point of reference in identifying costs and prices should be any current official listing published by relevant government departments.

When the acquisition price paid for a resource differs from the public list price, the public list price should be used in the base-case analysis. Sensitivity analysis should assess the implications of variations from this price. When cost data are taken from the literature, the methods used to identify the sources should be defined. When several alternative sources are available, a justification for the costs chosen should be provided and discrepancies between the sources explained. When appropriate, sensitivity analysis should have been undertaken to assess the implications for results of using alternative data sources.

Answer 'yes' if resources are valued using up-to-date prices relevant to the appropriate sectors. Answer 'partly' if the valuations of some resource items differ from current relevant unit costs but this is unlikely to change the cost-effectiveness results. Answer 'no' if the valuations of some resource items differ substantively from current relevant unit costs and this is likely to change the cost-effectiveness results.

2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?

An appropriate incremental analysis is one that compares the expected costs and outcomes of one intervention with the expected costs and outcomes of the next-best non-dominated alternative.

Standard decision rules should be followed when combining costs and effects, and should reflect any situation where there is dominance or extended dominance. When there is a trade-off between costs and effects, the results should be presented as an incremental cost-effectiveness ratio (ICER): the ratio of the difference in mean costs to the difference in mean outcomes of a technology compared with the next best alternative. Where benefits are expressed as QALYs, in addition to ICERs, expected net monetary or health benefits can be presented using values placed on a QALY gained of £20,000 and £30,000. However, it may not be possible to place such values on other measures of benefits that are used in social care economic evaluation.

For cost-consequences analyses, appropriate incremental analysis can only be done by selecting one of the consequences as the primary measure of effectiveness, providing the consequences are independent of one another.

Answer 'yes' if appropriate incremental results are presented, or if data are presented that allow the reader to calculate the incremental results. Answer 'no' if: (i) simple ratios of costs to effects are presented for each alternative compared with a standard intervention;

or (ii) if options subject to simple or extended dominance are not excluded from the incremental analyses.

2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?

There are a number of potential selection biases and uncertainties in any evaluation (trial- or model-based) and these should be identified and quantified where possible. There are 3 types of bias or uncertainty to consider:

- Structural uncertainty – for example in relation to the categorisation of different states of capability/wellbeing/health and the representation of different pathways of care. These structural assumptions should be clearly documented and the evidence and rationale to support them provided. The impact of structural uncertainty on estimates of cost effectiveness should be explored by separate analyses of a representative range of plausible scenarios.
- Source of values to inform parameter estimates – the implications of different estimates of key parameters (such as estimates of relative effectiveness) must be reflected in sensitivity analyses (for example, through the inclusion of alternative scenarios). Inputs must be fully justified, and uncertainty explored by sensitivity analysis using alternative input values.
- Parameter precision – uncertainty around the mean capability/wellbeing/health and cost inputs in the model. Distributions should be assigned to characterise the uncertainty associated with the (precision of) mean parameter values. Probabilistic sensitivity analysis is preferred, as this enables the uncertainty associated with parameters to be simultaneously reflected in the results of the model. In non-linear decision models – when there is not a straight-line relationship between inputs and outputs of a model (such as Markov models) – probabilistic methods provide the best estimates of mean costs and outcomes. Simple decision trees are usually linear. The mean value, distribution around the mean, and the source and rationale for the supporting evidence should be clearly described for each parameter included in the model. Evidence about the extent of correlation between individual parameters should be considered carefully and reflected in the probabilistic analysis. Assumptions made about the correlations should be clearly presented.

Answer 'yes' if an extensive sensitivity analysis was undertaken that explored all key uncertainties in the economic evaluation. Answer 'partly' if the sensitivity analysis failed to

explore some important uncertainties in the economic evaluation. Answer 'no' if the sensitivity analysis was very limited and omitted consideration of a number of important uncertainties, or if the range of values or distributions around parameters considered in the sensitivity analysis were not reported.

2.11 Is there any potential conflict of interest?

The British Medical Journal (BMJ) defines competing interests for its authors as follows: "A competing interest exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It may arise for the authors of a BMJ article when they have a financial interest that may influence, probably without their knowing, their interpretation of their results or those of others."

Whenever a potential financial conflict of interest is possible, this should be declared.

Answer 'yes' if the authors declare that they have no financial conflicts of interest. Answer 'no' if clear financial conflicts of interest are declared or apparent (for example, from the stated affiliation of the authors). Answer 'unclear' if the article does not indicate whether or not there are financial conflicts of interest.

2.12 Overall assessment

The overall methodological study quality of the economic evaluation should be classified as 1 of the following:

- **Minor limitations** – the study meets all quality criteria, or fails to meet 1 or more quality criteria but this is unlikely to change the conclusions about cost effectiveness.
- **Potentially serious limitations** – the study fails to meet 1 or more quality criteria, and this could change the conclusions about cost effectiveness.
- **Very serious limitations** – the study fails to meet 1 or more quality criteria, and this is highly likely to change the conclusions about cost effectiveness. Such studies should usually be excluded from further consideration.

Supporting references

National Institute for Health and Clinical Excellence (2008) Social value judgements: principles for the development of NICE guidance (second edition). London: National Institute for Health and Clinical Excellence

Philips Z, Ginnelly L, Sculpher M et al. (2004) Review of guidelines for good practice in decision-analytic modelling in health technology assessment. Health Technology Assessment 8 (36)

Evers, S, Goossens M, de Vet H et al. (2005) Criteria list for assessment of methodological quality of economic evaluations: consensus on health economic criteria. International Journal of Technology Assessment in Health Care 21: 240–5

These documents are available from the NICE website.

Appendix G Methodology checklist: qualitative studies

Appendices B–G include checklists for those study designs that are expected to be used in the evidence reviews for NICE social care guidance. Other checklists can found in the NICE clinical guidelines manual and Methods for the development of NICE public health guidance..

This checklist is based on checklists from:

- Spencer L. Ritchie J, Lewis J et al. (2003) Quality in qualitative evaluation: a framework for assessing research evidence. London: Government Chief Social Researcher's Office
- Public Health Resource Unit England (2006) Critical Appraisal Skills Programme (CASP) – making sense of evidence: 10 questions to help you make sense of qualitative research
- National Training and Research Appraisal Group (NTRAG); contact: info@ntrag.co.uk
- British Sociological Association (BSA)

Checklist

Study identification Include author, title, reference, year of publication	
Guidance topic:	**Key research question/aim:** .
Checklist completed by:	

	Circle or highlight 1 option for each question	
Section 1: theoretical approach		
1.1**Is a qualitative approach appropriate?** *For example:* Does the research question seek to understand processes or structures, or illuminate subjective experiences or meanings (in social care this would apply to how care and support is organised and service user or carer experience)? Or could a quantitative approach better have addressed the research question?	Appropriate Inappropriate Not sure	Comments:
1.2**Is the study clear in what it seeks to do?** *For example:* Is the purpose of the study discussed – aims/objectives/ research question(s)? Are the values/assumptions/theory underpinning the purpose of the study discussed?	Clear Unclear Mixed	Comments:
Section 2: study design		
2.1**How defensible/rigorous is the research design/ methodology?** *For example:* Are there clear accounts of the rationale/justification for the sampling, data collection and data analysis techniques used?	Defensible Not defensible Not sure	Comments:
Section 3: data collection		

3.1**How well was the data collection carried out?** *For example:* Are the data collection methods clearly described? Were the data collected appropriate to address the research question?	Appropriate Inappropriate Not sure/ inadequately reported	Comments:
Section 4: validity		
4.1**Is the context clearly described?** *For example:* Are the characteristics of the participants and settings clearly defined? Were observations made in a variety of circumstances and from a range of respondents? Was context bias considered (that is, did the authors consider the influence of the setting where the study took place)?	Clear Unclear Not sure	Comments:
4.2 **Were the methods reliable?** *For example:* Were data collected by more than 1 method? Were other studies considered with discussion about similar/different results?	Reliable Unreliable Not sure	Comments:
Section 5: analysis		
5.1 **Are the data 'rich'?** *For example:* How well are the contexts of the data described? Has the diversity of perspective and content been explored? Has the detail of the data that were collected been demonstrated? Are responses compared and contrasted across groups/ sites?	Rich Poor Not sure/not reported	Comments:

5.2 **Is the analysis reliable?** *For example:* Did more than 1 researcher theme and code transcripts/ data? If so, how were differences resolved? Were negative/discrepant results addressed or ignored? Is it clear how the themes and concepts were derived from the data?	Reliable Unreliable Not sure/not reported	Comments:
5.3 **Are the findings convincing?** *For example:* Are the findings clearly presented? Are the findings internally coherent (that is, are the results credible in relation to the study question)? Are extracts from the original data included (for example, direct quotes from participants)? Are the data appropriately referenced so that the sources of the extracts can be identified? Is the reporting clear and coherent?	Convincing Not convincing Not sure	Comments:
5.4 **Are the conclusions adequate?** *For example:* How clear are the links between data, interpretation and conclusions? Are the conclusions plausible and coherent? Have alternative explanations been explored and discounted? Are the implications of the research clearly defined? Is there adequate discussion of any limitations encountered?	Adequate Inadequate Not sure	Comments:
Section 6: ethics		

6.1 **Was the study approved by an ethics committee?**	Yes No Not sure/not reported/not applicable	Comments:
6.2 **Is the role of the researcher clearly described?** *For example:* Has the relationship between the researcher and the participants been adequately described? Is how the research was explained and presented to the participants described?	Clear Not clear Not sure/not reported	Comments:
Section 7: Overall assessment		
As far as can be ascertained from the paper, how well was the study conducted (see guidance notes)	++ + –	Comments

After completion of quality appraisal using the checklist, the included studies can be presented in a 'Quality of the included studies' table, which summarises the quality of each study under the main criteria of population, methods and analysis, and also the relevance of the study to the population being considered in the guidance.

Notes on use of Methodology checklist: qualitative studies

The studies covered by this checklist are those that collect and analyse qualitative data – usually (but not exclusively) textual (written), spoken or observational data. Qualitative data are occasionally collected using structured questionnaires (for example, as thematically organised free-text comments) but such research needs to be scrutinised carefully because it may not meet acceptable quality criteria for consideration as a qualitative study.

There is considerable debate over which quality criteria should be used to assess qualitative studies. Quality in qualitative research can be assessed using the same broad concepts of validity (or trustworthiness) used for quantitative research, but these need to

be put in a different contextual framework to take into account the aims of qualitative research. This checklist is based on the broadly accepted principles that characterise qualitative research and that may affect its validity; it is concerned with adequate reporting of key factors that affect the quality of qualitative research studies. The questions in the checklist are framed to encompass the variety of ways in which qualitative research is conducted. Care must be taken to apply the checklist in a way that matches the research methodology.

The following notes provide suggestions for completing the checklist. A list of publications on qualitative research is provided at the end of these notes for further reading on this topic.

Note that the sub-questions given as examples under each question in the checklist are intended to highlight some of the key issues to be considered for that question – they are not intended to be exhaustive. Please add any additional considerations in the comments box.

Section 1: theoretical approach

This section deals with the underlying theory and principles applied to the research.

1.1 Is a qualitative approach appropriate?

A qualitative approach can be judged to be appropriate when the research sets out to investigate phenomena that are not easy to quantify or measure accurately, or where such measurement would be arbitrary and inexact.

Qualitative research in social care settings often measure:

- personal experiences (for example, of a service, intervention or package of care)
- processes (for example, action research, practitioner or service user views on assessments of social care and support needs)
- personal values and beliefs (for example, about need, disability and dignity)
- interactions and relationships (for example between service users and social workers or between service users and personal carers)

- service evaluations (for example, what was good or bad about service user or carer experiences of a re-ablement package).

If clear numerical measures could reasonably have been put in place, then consider whether a quantitative approach may have been more appropriate.

1.2 Is the study clear in what it seeks to do?

The design of qualitative research tends to be 'theory generative' rather than 'theory testing'; it is therefore unlikely that a research question will be found in the form of a hypothesis or null hypothesis in the way that you would expect in traditional quantitative research. Nevertheless, what the study is investigating should still be set out early and clearly. The research question should be set in context, with a summary of the background literature and the study's underpinning values and assumptions.

Section 2: study design

This section considers the robustness of the design of the research project.

2.1 How defensible/rigorous is the research design/methodology?

There are a large number of qualitative methodologies, and a tendency in many studies to 'mix' aspects of different methodologies or to use a generic qualitative method. From a qualitative perspective, this should not compromise the quality of the study if the research design captures appropriate data and has an appropriate plan of analysis for the subject under investigation.

Sampling in qualitative research can be purposive. Qualitative research is not experimental and does not purport to be generalisable, and therefore does not require a large or random sample. People are usually 'chosen' for qualitative research based on being key informers. The choice of sample and sampling method should be described, ideally including any shortcomings of the sample.

Section 3: data collection

3.1 How well was the data collection carried out?

Assess whether the methods of data collection are described with details of the following:

- how the data were collected
- how the data were recorded and transcribed (if verbal data)
- how the data were stored
- what records were kept of the data collection.

Were these appropriate methods of data collection to use, given the aims of the research?

Section 4: validity

Assessing the validity of qualitative research is very different from assessing that of quantitative research. Qualitative research is much more focused on demonstrating the causes of bias rather than eliminating them. The report should include sections discussing the reflexive position of the researcher (their 'role' in the research), the context in which the research was conducted and the reliability of the actual data.

4.1 Is the context clearly described?

It is important when gauging the validity of qualitative data to consider whether the data are plausible and realistic. To make an accurate assessment of this, it is important to describe the context of the research in terms of the physical context (for example, care home, day centre, school) and who else was there (for example, participants are likely to position themselves very differently, and thus to respond very differently, in a discussion with parents present compared with a discussion with peers present). The participants should be described in enough detail to allow some insight into their life and situation and any potential context bias considered by the authors (that is, interpretation of the influence of the setting).

4.2 Were the methods reliable?

It is important that the method used to collect the data is appropriate for the research question and that the data generated map well to the aims of the study. Ideally, more than 1 method should have been used to collect data.

Section 5: analysis

Qualitative data analysis is very different from quantitative analysis. This does not mean

that it should not be systematic and rigorous; however, systematisation and rigour require different methods of assessment.

5.1 Are the data 'rich'?

Qualitative researchers use the adjective 'rich' to describe data that are in-depth, convincing, compelling and detailed enough that they can provide some insight into the research participants' experience. It is also important to know the 'context' of the data – where they came from, what prompted them, what they pertain to, and so on.

5.2 Is the analysis reliable?

The analysis of data can be made more reliable by the researchers putting checks in place. Sections of data should be coded by another researcher or, as a minimum, a second researcher should check the coding for consistency. Participants may also verify the transcripts of their interview (or other data collection, if appropriate). Negative or discrepant results should be highlighted and discussed.

5.3 Are the findings convincing?

The results of the research should be convincing or credible. Findings should be presented clearly and organised logically and the authors should consider and explain any contradictions. Extracts from original data should be included where possible to give a fuller sense of the findings. These data should be appropriately referenced – although you would expect data to be anonymised, they still need to be referenced in relevant ways (for example, if sex differences were important, then you would expect extracts to be marked male or female).

5.4 Are the conclusions adequate?

This section is self explanatory.

Section 6: ethics

6.1 Was the study approved by an ethics committee?

All qualitative research involves ethical considerations, and these should be considered

within any research report. Ideally there should be a full discussion of ethics, although this is rare because of space constraints in peer-reviewed journals. Any qualitative research should be approved by a research ethics committee, and this should be stated in the report so that it is clear that every care was taken to protect research participants.

6.2 Is the role of the researcher clearly described?

The researcher should have considered their role in the research; for example, as a reader, interviewer or observer. This is often referred to as 'reflexivity'. The 'status' of the researcher can profoundly affect the data. For example, a middle-aged woman and an 18-year-old man may get different responses to questions about care, support needs and dignity when interviewing a group of older women. It is important to consider age, gender, ethnicity and 'insider' status (such as whether the interviewer or researcher is part of the group being researched or has the same condition or disability). The researcher can also profoundly influence the data by use of questions, opinions, judgements and so on, so it is important to know what the researcher's position is in this regard, and how the researcher introduced and talked about the research with the participants.

Section 7: overall assessment

Grade the study according to the list below:

++ All or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter

+ Some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter

– Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter

Most qualitative studies by their very nature will not be generalisable. However, where there is reason to suppose the results would have broader applicability they should be assessed for external validity. Qualitative studies that are rated for external validity should be prefixed with 'EV' (external validity).

Further reading

Barbour RS (2001) Checklists for improving rigour in qualitative research: a case of the tail wagging the dog? British Medical Journal 322: 1115–7

Daly J, Willis K, Small R et al. (2007) A hierarchy of evidence for assessing qualitative health research. Journal of Clinical Epidemiology 60: 43–9

Mays N, Pope C (2000) Assessing quality in qualitative research. British Medical Journal 320: 50–2

Miller G, Dingwall R, editors (1997) Context and method in qualitative research. London: Sage

Shaw I, Gould N (2001) Qualitative research in social work. London: Sage

Appendix H Examples of evidence tables

Appendix H is available as a separate PDF. It includes examples of evidence tables for those study designs that are expected to be used in the evidence reviews for NICE social care guidance. Other evidence tables can found in the NICE clinical guidelines manual and Methods for the development of NICE public health guidance..

About this manual

About this document

This document describes the methods used in the development of NICE social care guidance. It will be updated as described in section 1.9.

Nothing in this document shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

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