Practice guideline development manual
Fourth edition
Royal College of Occupational Therapists
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- Occupational therapists’ use of occupation-focused practice in secure hospitals
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Practice guideline development manual
Fouth edition
Royal College of Occupational Therapists
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NICE has renewed accreditation of the process used by the Royal College of Occupational Therapists to produce its practice guidelines. The renewed accreditation is valid until 16 January 2023.

More information on NICE accreditation can be viewed at www.nice.org.uk/accreditation.
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Foreword

The current Royal College of Occupational Therapists (RCOT) guideline development programme was implemented in 2011 in order to support members in the production of high-quality, evidence-based practice guidelines. The process used to develop the guidelines was accredited by the National Institute for Health and Care Excellence (NICE) in 2013 and re-accreditation achieved until 2023.

The practice guidelines link to the RCOT Strategic intentions 2018–2023, in particular aims 1 ‘to position the profession, and our members, for the 21st century’ and 2 ‘to enhance the profile of the profession to a range of audiences’. RCOT practice guidelines define the best and most effective evidence-based practice for a specific area of occupational therapy, condition, population and/or set of circumstances.

As occupational therapists, we all have a duty to promote the profession, and practice guidelines help to raise the profile of occupational therapy nationally and assist with service improvement. A key aim of a practice guideline is to bring about positive change, both in the quality and consistency of practice and in the outcomes and experiences for people who access services and their carers. However, the publication of a guideline will not bring about changes on its own. To make change happen, consideration needs to be given to the scale of change that can be achieved realistically; even a small change can have a positive impact, especially if it involves an action that is repeated often. To help facilitate improvement, the quality of occupational therapy services can be audited, reviewed and monitored against the guideline recommendations.

Since the previous 2017 publication of this manual, there have been several amendments to the process to introduce an enhanced version of the existing NICE accredited process. Within the new guideline programme, topics will be selected that support a broader occupation-focused approach to practice and education. Selection will be driven equally by RCOT and national priorities, impact on the profession and informed by the quality of the evidence base. A revised selection process to establish membership of guideline development groups has been introduced that will draw on a wide range of expertise to contribute to the next phase of guideline development from 2020.

This comprehensive manual clearly articulates guideline development in a systematic process covering the scoping, development and publication through 15 steps. In addition, there are sections on the quality assurance process, implementation of guidelines into practice, and the importance of guideline review and updating. This manual has many tools to help you through the process of development. I endorse and recommend this manual to you, to assist in developing evidence-based practice guidelines to underpin your practice.

Professor Diane Cox
Chair of Council
Royal College of Occupational Therapists
The Royal College of Occupational Therapists (RCOT) is the professional body and voluntary membership organisation for occupational therapists throughout the United Kingdom. It is a subsidiary of and trading name for the British Association of Occupational Therapists (BAOT), which also acts as a trade union. RCOT sets the professional and educational standards for the occupational therapy profession and represents the profession at national and international levels. In addition, ten RCOT Specialist Sections support expert clinical practice.

RCOT is committed to supporting occupational therapists in developing evidence-based practice guidelines to underpin their practice. This manual will ensure that the practice guideline development process is not only tailored to the occupational therapy profession and its specific needs, but is also robust, rigorous and sustainable for the future.

Practice guidelines published by RCOT are publicly available from the RCOT website (www.rcot.co.uk).

**About this manual**

**Section 1  Introduction**

**Section 2 About practice guidelines**
This section defines practice guidelines and their characteristics, including legal implications. It is essential background reading to help occupational therapists understand how guidelines can support their practice.

**Section 3  RCOT guideline development**
This section will equip the reader with the basic knowledge and understanding required to get involved in developing guidelines. It provides a comprehensive guide to the different components and methodologies used to ensure a rigorous and robust practice guideline development process.

**Section 4  The quality assurance process**
Specific information about the quality assurance elements of the RCOT guideline development process are provided in this section.

**Section 5  Implementation of the guidelines**
Areas to consider to help implement guidelines effectively are outlined in this section.

**Section 6  Reviewing and updating guidelines**
This section provides information on monitoring the evidence to ensure a guideline remains safe for practice. It also covers the process involved in the five-year review and update of an RCOT practice guideline.

**Appendices**
The appendices contain additional supporting materials, including example forms and templates, which are used within the process.
About practice guidelines

Guidelines define the best and most effective practice for a specific area of occupational therapy, condition, population and/or set of circumstances. Guidelines are systematically developed recommendations based on high-quality research evidence (for example, randomised controlled trials, controlled clinical trials, quasi-randomised trials, systematic reviews, cohort or case-control and qualitative studies) and consensus of expert opinion. They assist occupational therapists in their decision-making about appropriate interventions and describe the profession’s contribution within a given care pathway. A guideline should always allow for professional or clinical judgement.

Key points: The value of occupational therapy practice guidelines

• To facilitate evidence-informed practice.
• To support business planning and commissioning by describing the unique contribution of occupational therapy.
• To improve the quality of occupational therapy services by facilitating audit against guideline recommendations.

2.1 Characteristics of high-quality practice guidelines

The framework that underpins RCOT’s guideline development process is based on the 25 criteria used by the National Institute for Health and Care Excellence (NICE) Accreditation Programme (NICE 2017, pp16–18). An accredited standard of guideline development provides assurance that the recommendations have been robustly developed, are fit for purpose, and that their application in practice will facilitate the delivery of improved outcomes.

Key points: Core elements of a quality guideline

• A clear scope and purpose concerned with the overall aim of the guideline, the specific health and social care questions, and the target population.
• Stakeholder involvement to ensure that the guideline represents the views of its intended users and those affected by the recommendations.
• Use of a rigorous and systematic process to appraise and synthesise the evidence and to develop recommendations, giving due consideration to benefits and risks.
• A clearly presented format, using unambiguous language appropriate to the specified target audience.
• Consideration of how to apply the guideline recommendations, including barriers, cost implications and approaches to support implementation.
• A transparent process that demonstrates editorial independence.
2.2 Practitioner responsibilities

The existence and use of guidelines do not remove the responsibility and duty of care placed on the occupational therapist.

Routine professional activity, such as record keeping, risk management and safeguarding confidentiality, is every practitioner’s responsibility. Adherence to current versions of regulatory and professional body requirements is assumed and therefore is not covered specifically in practice guidelines.

Practitioners are responsible for ensuring that the interpretation of guidelines is appropriate to the situation, taking into consideration people’s individual needs and local influences, as well as social and/or cultural practices. If the practitioner decides that it is appropriate to deviate from a practice guideline, this should be noted in the person’s care record, along with the rationale for the decision made. The final decision on the best intervention or action always depends upon the clinical reasoning and judgement of the professional, in shared decision-making with the person accessing services and the multidisciplinary team, as appropriate.
3ricot guideline development

All practice guidelines published by RCOT must follow the process accredited by NICE as described in this manual.

The guideline development process will adhere to RCOT’s Privacy policy (RCOT 2019) in line with the General Data Protection Regulation and Data Protection Act 2018.

3.1 Funding mechanisms for guideline development

As a membership organisation, the major source of funding for the Royal College of Occupational Therapists is obtained from membership subscriptions. Other sources of income are primarily advertising and events. A copy of RCOT’s statutory accounts is available from the website (https://www.rcot.co.uk/about-us/governance/statutory-accounts).

Occupational therapy practice guidelines are commonly developed by a group of members and stakeholders led by RCOT. Specific costs such as travel and subsistence expenses to attend meetings, photocopying and publishing costs are met by RCOT.

All funding sources must be declared in the published guideline.

3.2 Conflicts of interest

All individuals and organisations involved in developing practice guidelines must declare any conflicts of interest in relation to their intended or ongoing involvement in the guideline development process and associated activities. This statement is in line with the British Association and Royal College of Occupational Therapists’ Policy on conflicts of interest (RCOT 2018).

Key points: Conflicts of interest

This is identified as either a personal (of the person, their partner or close relatives) or a non-personal (of their department/employer/business) interest, which could have the potential to influence or affect their contribution to the development or the content of occupational therapy guidelines. Interests may be financial, non-financial, or commercial. Interests can be considered as either ‘specific’ to the guideline topic or meeting agenda (e.g. authorship of evidence being considered) or ‘non-specific’ (e.g. member of an RCOT Specialist Section or other professional body).

To ensure the credibility of the final guideline, there may be certain circumstances that would preclude an individual from being the Chair or Lead of a guideline development group. These would include the perception of competing interests or conflicts of loyalty where a person has a primary duty and loyalty to another organisation, or where a person has undue influence in a field of practice, education and/or research.
It is important that any relevant interests and/or associations, even though they may not be considered a direct conflict of interest, are highlighted, discussed and recorded. This applies to members of the guideline development group and all others who contribute to any specific elements/stages of the process: for example, external peer reviewers. Any change in interests during the course of the individual's involvement in the guideline development must also be reported and recorded.

A conflicts of interest declaration form (Appendix 1) must be completed by all involved and will be stored securely by RCOT in line with data retention guidance.

Depending on the type of conflict, an individual may not be able to contribute to the guideline development process in whole or part. Appendix 2 provides detailed information on managing conflicts of interest within an occupational therapy guideline development group.

### 3.3 RCOT guideline development process

A guideline development group is expected to complete its project within 24 months, with work broken down into the following three stages, as shown in Figure 1:

**Scoping stage**   **Steps 1–2**
**Development stage**   **Steps 3–13**
**Publication stage**   **Steps 14–15**

<figure>
    <table>
        <tr>
            <td>1. Select potential guideline topic</td>
            <td>2. Conduct scoping search for high-quality evidence</td>
            <td>3. Establish the guideline development group</td>
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            <td>4. Develop the practice question</td>
            <td>5. Develop and agree guideline scope in consultation with stakeholders</td>
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            <td>13. Sign off final guideline</td>
            <td>14. Finalise guideline for publication</td>
            <td>15. Disseminate and implement the guideline</td>
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</figure>

*Figure 1  Flow chart showing key stages of guideline development*
After publication of the guideline, the process for monitoring the evidence, reviewing and updating must be followed, as outlined in section 6 of this manual.

3.4 Scoping stage (steps 1–2)

The purpose of the scoping stage is to:

• Select a topic for guideline development.
• Conduct a scoping search to confirm the potential of the existing evidence base.

3.4.1 Step 1: Select potential guideline topic
Topics for occupational therapy guidelines must support an occupation-based approach to practice and education. Topic selection will be driven equally by RCOT and national priorities, potential impact on the profession and the quality of the evidence base. Parties interested in developing national occupational therapy guidelines are encouraged to contact RCOT for discussion.

**Key questions to consider when selecting a topic**
RCOT uses these questions as a basis to inform its decision as to whether to support the development and publication of a practice guideline.

• Would a guideline in this topic area be of public benefit?
• What is the potential reach and impact of the guideline for occupational therapists?
• What is the potential reach and impact of the guideline for commissioners and service providers?
• Can the topic be clearly defined to avoid being too broad in scope?
• Is there sufficient high-quality evidence to support the development of a guideline in this topic area?

3.4.2 Step 2: Conduct scoping search
Before proceeding to a full guideline development project, a scoping search is carried out by the RCOT Library to determine whether enough high-level evidence exists to support production of a rigorous guideline. Scoping searches are brief searches of existing literature, designed to gain an overview of the range and depth of research that exists for a research area or, in this case, guideline topic (Pham et al 2014). They are used to determine the value and potential scope of undertaking a full systematic review and to identify gaps in the existing literature.

The RCOT scoping search is:

• A broad subject search on key relevant databases (for example, title, subject and abstract fields).
• Limited by high-level evidence terms (i.e. randomised controlled trial (RCT), meta-analyses, systematic reviews).
• Unrestricted by database limiters (except date).
Based on the quality and quantity of the existing high-level evidence, a decision will be made by RCOT as to whether the guideline development can proceed. In order to produce robust evidence-based recommendations, the guideline development project will proceed only where enough high-level evidence exists (for example, randomised controlled trials, controlled clinical trials, quasi-randomised trials, systematic reviews (qualitative and quantitative), cohort or case-control studies).

If high-level evidence does not exist, the results of the scoping search may be published as an evidence overview to identify gaps in the research.

3.5 Development stage (steps 3–13)

The purpose of the development stage is to:

- Establish the guideline development group.
- Develop the practice question.
- Develop and agree the guideline scope in consultation with stakeholders.
- Find the supporting evidence.
- Appraise and grade the evidence.
- Determine the strength and grade of recommendations.
- Write the draft guideline.
- Undertake peer review and stakeholder consultation.
- Amend the draft guideline.
- Complete AGREE evaluation by the RCOT Publications Group.
- Sign off the final guideline.

3.5.1 Step 3: Establish the guideline development group

Opportunities to get involved in guideline development are advertised through RCOT’s internal and external networks.

People with the appropriate expertise and knowledge in the topic will be invited to form a guideline development group (GDG). The group must be self-sufficient in terms of the skills required to develop the proposed guideline.

The core group should include people with the relevant skills:

- Project leadership (a GDG Chair to facilitate the process).
- Writing and editorial skills.
- Expert practitioners with the relevant experience.
- Evidence/research skills (for screening evidence and critical appraisal).
- Understanding of the guideline development process and/or applying guidelines in practice.
- Public contribution from people who have accessed occupational therapy services and their carers.
Ideally representation on the group should include all four UK nations, together with practice, research and education expertise to ensure that a balanced perspective can be brought to a project.

The guidelines will have greater credibility if the development group represents and/or engages with a wide range of appropriate stakeholders and those who will have some responsibility for implementing the recommendations. Not all contributors or stakeholders will necessarily need to be involved at all stages of the process or for the full term of the guideline development project. Some contributors can be co-opted as and when their relevant expertise is required.

RCOT provides project management and administrative support to the GDG via the Research and Development Manager, the Quality Programme Manager and the Research and Development Officer.

The group should adopt a consensus approach to decision-making. This involves participation and open discussion by all members, which should result in a decision that the group as a whole is able to support. The recommendation statements, for example, including assignment of the overall quality and strength grading, should be agreed using this decision-making process.

If a decision cannot be reached by consensus, the Chair will need to ask all members in attendance at the meeting to take a vote. Where a majority vote is not reached, the Chair or Vice-Chair (depending on any declared conflicts of interest) will have the deciding vote.

The method used to obtain agreement must be described in the guideline document, with the outcome of any voting decisions recorded in the meeting minutes.

**Key points: The guideline development group**

The following should also be considered:

- How many members are in the group? A core group of 8 occupational therapists allows sufficient breadth of expertise whilst remaining a manageable, functional group.
- Are those who will be influential in implementing and using the guideline represented in the group?
- Does the core group have access to individuals who will be able to support the appraisal process or provide other co-opted expertise/advice via a reference group?
- Do group members have access to academic libraries?
- Do all potential members have enough time available and support from their employer to actively engage with the project throughout its lifetime?
- How will an inclusive approach to participation be facilitated (for example, all voices being equally valued, accessible environments, teleconferencing)?

**3.5.2 Step 4: Develop the practice question**

The recommendations in a guideline should provide a response to a specific health or social care practice question. Specificity is important in developing questions that
address the requirements of the scope, and to ensure that the appropriate evidence can be identified and retrieved within a full literature search.

The formulation of a focused practice-based question using a specific framework is the key to finding high-quality evidence and also the key to making evidence-based decisions. Richardson et al (1995) introduced the PICO methodology to break down clinical questions into searchable keywords and identify the structural requirements for facilitating precise searches (i.e. containing an identifiable intervention and desired outcome).

The PICO mnemonic helps address these questions:

**P** – Patient or Problem: Who is the patient or patient group? What are the most important characteristics of the patient/population? What is the primary problem, disease, or co-existing condition? This needs to be defined in detail and include, for example, age, diversity and service context.

**I** – Intervention: What is the main intervention being considered? The intervention defines an action that would be used for this group or the context.

**C** – Comparison: What is the main comparison intervention? The comparison (or alternative intervention) describes another possible action or approach that could be taken and may be used within the question as a comparison. In occupational therapy there may not always be an alternative intervention or action to consider.

**O** – Outcome: What are the anticipated measures, improvements, or effects? The outcome should describe the desired/undesired or expected result of the intervention. It is important to highlight and consider the significance of the outcomes to the person/population and the potential improvement to their occupational performance.

### Key points: The PICO methodology

Questions should contain four key elements:

- The **Patient**, **Population** or **Problem/circumstance**.
- The **Intervention** under investigation or action.
- The **Comparison**, which is an alternative intervention or action.
- The desired **Outcome**.

(Richardson et al 1995, Huang et al 2006)

### 3.5.3 Step 5: Develop and agree the guideline scope in consultation with stakeholders

The scope sets the parameters of the guideline and describes what is to be included and excluded and is agreed in consultation with relevant stakeholders (see Appendix 3). The scope must include consideration of the potential health inequalities, and any social determinants of health, that may be appropriate to the guideline, i.e. best start in life for children; fair employment and good work for all; healthy standard of living for all; maximising individual capability and control over life; creating and developing healthy and sustainable places and communities; and strengthening the role and impact of ill-health prevention (Marmot 2010, p15).

Once developed, the draft is sent to stakeholder organisations for comment and amended in line with feedback received. Attention should be given to the accessibility of
the information sent to specific stakeholder groups. Following consultation, the amended scope is submitted to the RCOT Publications Group for consideration and approval (see section 4.2).

The scope for the production of the guideline is reviewed and ratified by the RCOT Publications Group (see section 4.2) and must include the key points shown below.

**Key points: Scope**

- The provisional guideline title.
- The health or social care question.
- The scope and overall objective of the guideline.
- How the guideline content will support an occupation-centred focus to practice.
- The intended audience(s).
- A description of the process that has been undertaken to establish that there is a demand for an occupational therapy practice guideline in this area.
- A copy of the scoping search strategy.
- An outline of key evidence that exists to support practice guideline development in this area, including relevant UK-wide documents/strategies/policy drivers or care pathways.
- An outline of the stakeholder activities undertaken in the development of the scope.
- Information about core guideline development group members and their skills.
- Any additional funding or support available from potential collaborators.

**Stakeholder involvement** is integral to the development of high-quality practice guidelines for occupational therapists. It is important to establish early in the process how a range of stakeholders, including people who access services and their carers, will be involved.

**Stakeholders are defined as follows:**

*Professional organisations and bodies*: e.g. other Allied Health Professions (AHPs), and other medical organisations, charitable or third sector organisations, commissioners or service providers.

*Public contributors*: i.e. individuals or organisations representing people who access services or carers.

*People who access services and their carers*: i.e. people who engage with or have accessed occupational therapy services and those who care for them.

*Occupational therapists* who will use the guideline.

Occupational therapy is delivered in a wide range of services and environments and therefore the most appropriate approach to involvement of any individual stakeholder will be influenced by service delivery configurations, professional networks, and the knowledge and experience of individuals and organisations in the topic field. It is
unlikely that all potential stakeholders will be able to or wish to be involved either in the guideline development group or in all stages of the guideline development process.

**Key points: Stakeholder involvement**

There is no one single model of stakeholder involvement that will suit all guideline development projects. Decisions on the approach to engagement must be justified and documented.

The following should be considered:

- Who are the key stakeholders that should be invited to be members of the guideline development group or an associated reference group? The aim should be to include the most appropriate stakeholder representatives.

- What level of involvement will each stakeholder have? For example, contributing to the scoping process; full member of the guideline development group; co-opted expert opinion at specific stages; reviewing document drafts; external peer review; providing a foreword; or co-badging the published guideline.

- Expectations of involvement should be discussed and agreed with the invited stakeholders before the process begins.

- All stakeholders must be informed of the RCOT Privacy policy (RCOT 2019) in line with the General Data Protection Regulation and Data Protection Act 2018.

- The RCOT policy for reimbursement of expenses should be explained.

- Key stakeholders must have the opportunity to influence the development of the scope (that is, what is to be included within and excluded from the guideline).

- Key stakeholders must be consulted on the full draft of the guideline document.

3.5.4 Step 6: Find the supporting evidence

Developing an evidence-based guideline requires a systematic approach to the search and the review of the literature. Woolf et al (2012) suggest that this is a critical stage of guideline development which should include defining the types of evidence and information that will be relevant, and by what criteria that evidence will be evaluated.

As described in section 4.4 of the 2018 NICE guideline development manual, recommendations are formed from a range of evidence, including:

- Scientific evidence: These findings may be quantitative or qualitative, and may come from a range of study types, including systematic reviews, randomised controlled trials (RCTs), cohort studies, cross-sectional studies and surveys of the views and experiences of people using health and social care services.

- Colloquial [anecdotal] evidence: This can complement scientific evidence or provide missing information on context. It can come from expert testimony, from members of the GDG, from a reference group of people using services, or from stakeholders. Colloquial [anecdotal] evidence includes values (including political judgement), practical considerations (such as resources, professional experience or expertise and habits or traditions, the experience of people using services) and the interests of specific groups (views of lobbyists and pressure groups).

- Other evidence: For example, reports, audits or service evaluation.
RCOT guidelines are based on high-level evidence wherever possible to ensure that robust recommendations can be formulated to guide occupational therapy practice.

### Key points: Types of scientific evidence that RCOT considers

The range of evidence to be appraised may include:

- Meta-analysis.
- Systematic reviews.
- Qualitative evidence synthesis.
- Randomised controlled trials.
- Controlled clinical trials.
- Cohort or case-control studies.
- Non-randomised experimental research single study designs.
- Qualitative research studies.
- Cost effectiveness/economic evaluation studies.

The RCOT Library and Information Service will undertake the literature search to identify the evidence above using the following platforms and databases:

- EBSCOhost platform: CINAHL, MEDLINE.

The librarians will also select other databases and resources to search as appropriate to the guideline topic. Other specialist databases may include OTDBASE, OT SEARCH, OTseeker, Cochrane Library, NICE and SIGN guidelines and the RCOT’s occupational therapy library catalogue.

### Key points: The search strategy should:

- Align with the research question identified for the guideline.
- Detail the appropriate search concepts (for example, interpretation of international terminology, settings, inclusion and exclusion criteria).
- Include the exact search terms to be used, including keywords and subject headings (thesaurus terms) with any truncation or variant spellings. Fields searched should also be included where relevant.
- Include the Boolean operators used and the combinations of terms searched.
- Clearly identify any filters or limiters used, including any date or language restrictions.
- Record the resources and databases and relevant platforms searched, including the date the search was carried out.

The search strategy and process must be recorded to a level of detail that will enable the search to be replicated. This means that another guideline development group could
repeat the process by the same method and should reach the same conclusions. The strategy, search terms (including Boolean operators and database syntaxes), date the search was run and outcomes of the search must be made explicit in the guideline document to avoid misinterpretation.

Should a third party run a search in the development of an RCOT guideline, the detailed strategy, search histories and result files must be submitted to RCOT.

RCOT will retain all full search histories and results for the lifespan of the guideline.

3.5.5 Step 7: Appraise and grade the evidence
Specific inclusion and exclusion criteria must be developed prior to screening the results of the literature search. These criteria must be specified within the guideline document. The search results are screened and reviewed against the defined criteria to enable the most appropriate sources of evidence to be appraised. It may be possible to identify the appropriate evidence to be included from the abstracts, but where there is uncertainty, the full paper will be required for screening.

The process of appraisal aims to assess the methodological rigour and potential bias of any evidence. Different types of research have specific interpretations of rigour; therefore, it is important that the correct appraisal tools are used for the various types of research. There is a variety of appraisal tools available. RCOT uses either the McMaster University Critical Review Forms or the Critical Appraisal Skills Programme (CASP) tools as standard. Both these resources provide frameworks that can be used to appraise different types of studies. They can be accessed, subject to copyright requirements, via the McMaster University or CASP UK websites respectively (see Appendix 4). Details of the tool(s) used must be recorded in the guideline.

Normally two guideline development group members should carry out an independent appraisal of each study. Any differences in assessment or assignment of level of quality should be discussed between the two appraisers and, if necessary, reviewed by a third person or the guideline development group to reach an agreed decision.

A PRISMA flow diagram (Moher et al 2009) should be produced to record the number of articles identified, and decisions made regarding inclusion/exclusion, at each stage of the article search, screening and appraisal process.

Articles excluded from critical appraisal, particularly those that just fall short of inclusion criteria, should be recorded with a brief rationale. This may be documented within the main text of the guideline or as an appendix if there are many excluded papers.

Evidence tables must be used for summarising information and recording decisions made about each study appraised. These tables are included as an appendix in published guidelines (see Appendix 5).
Key points: Appraising the evidence

General principles to consider when reviewing the evidence:

- Normally the articles should be screened independently by at least two reviewers.
- The evidence must meet all of the inclusion criteria.
- The evidence should enable the guideline development group to assess both the benefits and the risks of any actions or interventions.
- The guideline development group should consider evidence of the cost effectiveness of any interventions or actions. This may include a cost/benefit analysis and/or comparison to other interventions.
- Evidence tables should be completed to record decisions made (see Appendices 5 and 6).
- A PRISMA flow diagram (Moher et al 2009) should be generated to record the final numbers of papers considered.

RCOT has adopted elements of the GRADE system (Grading of Recommendations Assessment, Development and Evaluation, http://www.gradeworkinggroup.org/) for evaluation of quality and strength of evidence and the subsequent decision about the strength of a guideline recommendation.

The design of a study provides the underpinning framework for determining quality, acknowledging that, in general, stronger evidence is provided by randomised controlled trials (RCTs) compared with observational studies, and that rigorous observational studies provide stronger evidence than uncontrolled case series. Expert opinion is included in this grading system.

Under the GRADE categorisation, RCTs and systematic reviews constitute high-quality evidence, and observational studies without special strengths or important limitations constitute low-quality evidence. All other evidence constitutes very low-quality evidence (GRADE Working Group 2004).

Following appraisal, quality of the available evidence for a given outcome should be given an initial grading in one of the following categories:

- Randomised trial/systematic review = high.
- Observational study = low.
- Any other evidence = very low.

Limitations in the design of a study and its implementation may, however, bias the estimates of the treatment effect. If there are serious limitations, then downgrading of the quality of the evidence should be considered by the guideline development group.
Table 1 Upgrading and downgrading quality

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<thead>
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<th>Decrease grade if</th>
<th>Increase grade if</th>
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<tbody>
<tr>
<td>• Serious or very serious limitation to study quality.</td>
<td>• Magnitude of the treatment effect is very large and consistent.</td>
</tr>
<tr>
<td>• Important inconsistencies in results.</td>
<td>• Evidence of a large dose–response relationship.</td>
</tr>
<tr>
<td>• Some or major uncertainty about directness of the evidence.</td>
<td>• All plausible confounders/biases would have decreased the magnitude of an apparent treatment effect.</td>
</tr>
<tr>
<td>• Imprecise or sparse data (relatively few participants and/or events).</td>
<td>Only studies with no major threats to validity should be upgraded.</td>
</tr>
<tr>
<td>• High probability of reporting bias.</td>
<td></td>
</tr>
</tbody>
</table>

*Each quality criterion can reduce the quality by one or, if very serious, by two levels.*

*Only studies with no major threats to validity should be upgraded.*

Depending on the various factors detailed in Table 1, the initial grading may potentially be increased or decreased. Evidence will ultimately be graded in one of four categories from high to very low, as defined in Table 2 (see page 16). To facilitate ease of identification, RCOT uses an alphabetical reference for this grading from A (high) to D (very low).

This type of grading system has an association with quantitative medical research, where large-scale randomised controlled trials are more frequently undertaken. The nature of occupational therapy research is much broader and therefore high-quality qualitative research must also be considered.

CERQual is a grading tool used to evaluate findings from qualitative evidence syntheses and to systemise the process of assessing the evidence. Work on CERQual is evolving; however, it may be appropriate to consider using this approach within the RCOT guideline development process (Lewin et al 2018).
Table 2 GRAGE quality of evidence grading

<table>
<thead>
<tr>
<th>Quality of evidence</th>
<th>RCOT grading for quality of evidence</th>
<th>Characteristics</th>
<th>Confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Grade A</td>
<td>Based on consistent results from well-performed randomised controlled trials and/or systematic reviews, or overwhelming evidence of an alternative source, e.g. well-executed observational studies with strong effects.</td>
<td>True effect lies close to that of the estimate of the effect. Further research is very unlikely to change confidence in the estimate of the effect.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Grade B</td>
<td>Based on randomised controlled trials and/or systematic reviews where there are serious flaws in conduct, inconsistency, indirectness, imprecise estimates, reporting bias or some other combination of these limitations, or from other study designs with special strengths.</td>
<td>True effect likely to be close to the estimate of the effect, but there is a possibility that there could be a substantial difference. Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.</td>
</tr>
<tr>
<td>Low</td>
<td>Grade C</td>
<td>Based on observational evidence, or from controlled trials or systematic reviews with several very serious limitations.</td>
<td>True effect may be substantially different from the estimate of the effect. Further research is very likely to have an important impact on confidence in the estimate of the effect and is likely to change the estimate.</td>
</tr>
<tr>
<td>Very Low</td>
<td>Grade D</td>
<td>Based on case studies or expert opinion.</td>
<td>Any estimate of effect is very uncertain and may be far from the true effect.</td>
</tr>
</tbody>
</table>
3.5.6 Step 8: Determine strength and grade of recommendations

Once the methodological quality of each piece of evidence has been assessed, it can then be evaluated to judge its potential contribution to the development of the guideline recommendations. The highest quality evidence identified should be synthesised and used to formulate the recommendations.

Where a number of items of evidence are supporting an identified outcome and subsequent recommendation, an overall quality of evidence rating should be determined as follows:

- If the outcomes of individual studies point in the same direction towards either benefit or harm, then the highest grade of evidence should determine the overall grade of the recommendation.
- If the outcomes of individual studies point in different directions towards both benefit and harm, the lowest grade of evidence should determine the overall grade of the recommendation. For example, evidence to support the use of hand and wrist orthoses shows that some orthoses relieve pain and some cause pain.
- If there are several studies that consistently show the balance of benefits and harm to be uncertain, then the lowest grade of evidence should determine the grade of the recommendation. For example, evidence to support the use of hand and wrist orthoses shows that some orthoses relieve pain but reduce function.

Any recommendation that has an element of risk within it should be assessed as to whether there is a need for some positive risk taking within the occupational therapy process (RCOT 2018). Risk management considerations may then form part of the recommendation.

When developing recommendations, any limitations within the guideline development process should be explained and documented: for example, a poor response from identified stakeholders, or limitations of search or evidence findings (which may include applicability for culture or context).

Determining the strength and overall grading of recommendations is the second element of the GRADE system. Two categories are used to reflect the strength: strong or conditional. Assigning a recommendation as either strong or conditional provides the guideline user with a clear indication of the level of confidence.

The overall grade of a recommendation is defined in a guideline document by a numerical, then alphabetical, grade to reflect the strength and quality of evidence, e.g. 1A – Strong, high-quality; 2C – Conditional, low-quality.

The strength of grade assigned will reflect the characteristics shown in Table 3 (see page 18).
Table 3 Strength of grade

<table>
<thead>
<tr>
<th>Strength</th>
<th>Grade</th>
<th>Benefits and risks</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong</td>
<td>1</td>
<td>‘It is recommended . . .’</td>
<td>Benefits appear to outweigh the risks (or vice versa) for the majority of the target group. Most people would want to, or should, receive this course of intervention or action.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits appear to outweigh the risks (or vice versa) for the majority of the target group. Most people would want to, or should, receive this course of intervention or action.</td>
<td></td>
</tr>
<tr>
<td>Conditional</td>
<td>2</td>
<td>‘It is suggested . . .’</td>
<td>Risks and benefits are more closely balanced, or there is more uncertainty in likely values and preferences of people who access services. The majority of people would want this intervention, but not all, and, therefore, they should be supported to arrive at a decision for intervention consistent with the benefits, and their values and preferences.</td>
</tr>
</tbody>
</table>

(Based on Guyatt et al 2008)

How a recommendation is developed must be documented. The record must include key information about the evidence used to form the basis of that recommendation, and the overall allocation of quality of evidence and strength. Any judgement by the guideline development group should be documented as part of this decision-making process (see Appendix 6). The information recorded should be summarised within the main guideline text to ensure there is a clear association with and logical development from the appraisal of the evidence and the recommendation.

Key points: Developing a recommendation

The guideline development group should consider a number of factors:

- Volume, strength, quality and consistency of evidence.
- Grading of the quality of the evidence.
- Uncertainty about the likely benefit or risk, or variability in, values and preferences about this intervention compared with alternatives (view of guideline development group).
- Importance of the outcome.
- Risks and benefits associated with the intervention, including any risk management strategies, side-effects/contra-indications.
- Confidence that the benefits or desirable effects of the intervention outweigh the risks or undesirable effects, and vice versa.
**Key points: Writing a recommendation statement**

Recommendations should:

- State the specific clinical, healthcare, social or other circumstances.
- Make explicit links between the recommendation and the evidence on which it is based, for example reflecting the language used in the supporting evidence.
- Be objective, clear, unambiguous and precise in describing the desired activity/procedure.
- Not incorporate personal or subjective opinion.
- Be transparent and take account of any potential for bias.

### 3.5.7 Step 9: Write the draft guideline

The editorial role is important to ensure that the guideline meets all requirements relating to content, style and format, and to ensure that the language is clear, specific and unambiguous. As such, a designated Editorial Lead is required. This role can be undertaken either by a member of the guideline development group or by RCOT. In both cases any potential conflict of interest must be declared and recorded. Editorial support provided by RCOT does not include determining the nature and content of the recommendations. These decisions are the responsibility of the guideline development group.

**Key points: Factors to consider when writing the guideline**

When writing the guideline, it is important to remember that:

- Guidelines should be tailored to meet the needs of the primary audience(s) and, where appropriate, alternative formats should be made available.
- Attention should be given to the language used to write the guideline, ensuring it is professional and appropriate to the target audience(s):
  - Use a jargon-free, plain English style – write concisely and clearly.
  - Use the active rather than passive voice where possible.
  - Use positive presentations of ethnicity, gender, age and physical characteristics.
  - Ensure that all definitions and terminology used are current.
  - If third party material is being used as a source of information, it must be fully referenced within the document.
- Guidelines should be structured in a logical and methodical way, ensuring that all stages of the process are included and documented accurately (Appendix 7).
- Key recommendations should be presented at the beginning of the guideline document.
- Where gaps in the evidence or research priorities are identified, these should be included in the guideline to inform future research.
- It is essential that any potential organisational, resourcing or financial barriers that may exist and could affect implementation (NICE 2015) are documented.
3.5.8 Step 10: Peer review and stakeholder consultation
Stakeholder consultation and peer review are important stages of guideline development in order to provide an external view on the accuracy of content, and potential applicability and relevance to current practice. Review may be provided by individuals or groups. Essentially this review stage represents a ‘field test’, and should be carried out using a full draft of the guideline document. See section 4.3.1.

3.5.9 Step 11: Amend the draft guideline
Following peer review and stakeholder consultation, the guideline development group will need to factor in the time for review of feedback and the incorporation of amendments. See section 4.3.1.

3.5.10 Step 12: AGREE evaluation by RCOT Publications Group
Practice guidelines are assessed by the RCOT Publications Group against the Appraisal of guidelines, research and evaluation (AGREE) II instrument (AGREE Next Steps Consortium 2013). See section 4.3.2.

3.5.11 Step 13: Sign off final guideline
Following the RCOT Publications Group evaluation of the guideline, the final review and sign-off are given by the RCOT Assistant Directors (Professional Practice; Education and Research). Following this, a full reference check is carried out by the RCOT Library. The guideline then proceeds to the publication stage.

3.6 Publication stage (steps 14–15)

3.6.1 Step 14: Finalise guideline for publication
This stage includes copy-editing, design, typesetting and proofreading. The RCOT Publications Manager liaises with the guideline development group to resolve any queries arising from the copy-edit and to check and finalise proofs.

Secure storage of any data and documents that have been generated during the development of the guideline must be carried out at this stage. This should include, for example, the full search strategy and findings, recommendation decision tables and conflicts of interest forms.

3.6.2 Step 15: Disseminate and implement the guideline
A range of implementation tools is developed (see section 5). All RCOT practice guidelines are publicly available from the website, together with the implementation and audit tools.

To ensure the guideline reaches all those for whom it is intended, RCOT will assist in the promotion and distribution of the guideline in discussion with the GDG.
4 The quality assurance process

RCOT has established a clear and rigorous guideline development process. Quality assurance is integral to this process and is carried out through a series of checks by the RCOT Publications Group.

The terms of reference for the RCOT Publications Group are available in Appendix 8 and outline membership of the group.

The RCOT guideline quality assurance process has four stages:

• Developing the search strategy.
• Review of the draft scope.
• Evaluation of the draft guideline.
• RCOT sign-off.

4.1 Developing the search strategy

To ensure quality in search strategy development for the guideline, preliminary work involves consulting with topic experts to identify key articles. These articles serve as a check against which to test the search strategy. They also help in identifying alternative key terms and subject headings. Text mining applications, such as PubMed PubReMiner, MeSH on Demand and Yale MeSH Analyzer, may also be used for keyword and subject heading development. These factors contribute to quality assuring a comprehensive search strategy.

Before the searches are undertaken, the search strategies, usually for the OVID and EBSCOHOST platforms, are checked by another member of the Library team. These checks are based on the PRESS Peer Review of Electronic Search Strategies (McGowan et al 2016). The following are reviewed as a minimum on the main platforms: alignment of the search strategy to the research question identified; appropriateness of Boolean operator placement and use; use of bracket (parenthesis) in organisation of the search; use of subject headings if included; use, inclusion and appropriateness of text words (keywords), spelling, syntax and search line combinations.

Search strategies for review and updates of guidelines are also subject to the same quality checks.

4.2 Review of the draft scope

Following stakeholder consultation, the draft scope is amended and submitted to the RCOT Publications Group. Stakeholder comments and the guideline development group's responses, along with a detailed project plan, are also provided for review.

The RCOT Publications Group approves the draft scope through discussion and may suggest amendments required in line with the NICE accredited process. On approval of the scope, the development stage commences.
4.3 Evaluation of the draft guideline

All new and updated guidelines follow the same process for evaluation and ratification.

4.3.1 Peer review and stakeholder consultation

The guideline development group is required to seek peer review of the draft guideline document via open consultation with relevant members/occupational therapists.

Following agreement of the complete draft guideline, a minimum of two external peer reviewers will be invited to review the guideline. These individuals should have the relevant experience and be acknowledged experts in the topic and/or in guideline development. All peer reviewers must be asked to declare any conflict of interest. A proforma is used to gather critical appraisal of both the presentation and content of the draft guideline from peer reviewers. A period of one month should be allowed for peer review responses.

A draft guideline consultation will also take place with key stakeholders, as outlined in the scope.

Feedback received from peer review and consultation should be reviewed by the GDG, responses agreed and documented, and the guideline amended accordingly.

At this stage the GDG should also apply for any external endorsements, approaches in relation to writing a foreword, permission to co-badge, etc.

4.3.2 AGREE evaluation

Practice guidelines are assessed by the RCOT Publications Group against the Appraisal of guidelines, research and evaluation (AGREE) II instrument (AGREE Next Steps Consortium 2013).

The AGREE II instrument provides a framework for this assessment against six different aspects or domains: scope and purpose; stakeholder involvement; rigour of development; clarity and presentation; applicability; and editorial independence. These domains and their associated criteria are also compatible with the NICE Accreditation scheme requirements (NICE 2017, pp16–18).

4.4 RCOT sign-off

Following the RCOT Publications Group evaluation of the guideline, the final review and sign-off are given by the RCOT Assistant Directors (Professional Practice; Education and Research). Following this, a full reference check is carried out by the RCOT Library. The guideline then proceeds to the publication stage.
5 Implementation of guidelines

The purpose of a practice guideline is to bring about positive change, both in the quality and consistency of practice and in the outcomes and experiences for those accessing services. The publication of the guideline document in itself will not bring about the desired change; it has to become part of everyday practice. Awareness and knowledge of what needs to change, and why, are vital first steps in enabling change to occur (NICE 2007).

The implementation of any guideline needs to be an active process. Multiple approaches are likely to be more effective than a single one. Implementation can benefit from having influential people sponsoring or supporting the document. However, the ongoing use of a guideline will be determined by the degree to which it actually assists commissioners, service providers and occupational therapists in decision-making and problem-solving.

Implementation strategies to support guideline uptake are important (Shekelle et al 2012) and can be enhanced by the relationship with those responsible for dissemination and implementation. RCOT works with its Specialist Sections and wider networks to incorporate strategies such as multiple formats and channels for dissemination; development of educational resources; and use of data collection tools (such as simple audit templates).

5.1 Selecting implementation techniques and support tools

Implementation will need to take place at a local level, taking into account the context of that setting, including identification and discussion of the potential organisational and financial barriers to implementation detailed in the guideline document. The guideline development group should give consideration to how the guideline may be implemented by occupational therapists and develop support tools to facilitate its use.

The Royal College of Occupational Therapists will co-ordinate the production of a set of implementation resources for each guideline, available for download from the RCOT website.

Occupational therapists should use the guideline recommendations to evaluate their individual and/or service delivery as part of their evidence-based practice activities, in line with the requirements of the Health and Care Professions Council (HCPC 2016, 2013) and the Royal College of Occupational Therapists (COT 2017, 2015).

Bringing the guideline to the attention of the relevant clinical governance/audit department, or equivalent, is also recommended, particularly as they may have established mechanisms or strategies for implementation and may be able to provide support and audit. A guideline should also be brought to the attention of managers, commissioners and service providers.
Key points: Implementation support tools

Implementation resources produced for each guideline may include:

• Quick reference and implementation guide, which provides the recommendations and key information in a concise, easy-to-use format. It includes practical tips to support the translation of recommendations into practice.

• Audit form with defined criteria and data collection guidance.

• Continuing professional development/knowledge transfer resource: an interactive resource that can be tailored for local use. The resource can be used for group or self-directed learning, or for raising awareness of the guideline at multidisciplinary meetings and study days/events.
To ensure a guideline remains safe for practice, it is essential to include regular monitoring of the evidence following publication.

All RCOT guidelines are subject to a five-year review and update where applicable.

6.1 Annual monitoring of evidence

An alert system must be in place to highlight new evidence pertinent to the guideline scope post-publication. An annual evidence monitoring search is carried out by the RCOT Library to identify any new high-level evidence relevant to the guideline topic. New evidence must be screened by the GDG to establish its impact on the recommendations. Where any new evidence is found to be significant, a decision must be made as to whether the guideline requires updating to ensure continued safe practice. Normally, screening and subsequent decisions should be completed within three months of the search being undertaken.

6.2 Five-year review and update

Published guidelines must be reviewed to include new evidence pertinent to the guideline scope post-publication. This is crucial to ensure that the recommendations remain applicable, accurate, safe and relevant to practice. RCOT recommends that practice guidelines should be updated within a maximum period of five years from publication or, if agreed, withdrawn. The scheduled review period may need to be revisited, however, if significant new evidence becomes available via the annual monitoring that could have an impact on the validity or appropriateness of the recommendations in a guideline. The formal five-year review should commence approximately three years from publication of the first edition, so that any revised publication is available at the five-year point.

The search strategy carried out for the original guideline must be replicated, subject to database upgrades, to ensure consistency between editions.

RCOT keeps an overview of all published guidelines and the scheduled review dates. The review should be carried out by a group with similar expertise to the original guideline development group members.
Key questions that the review group must consider are:

- Is there any new high-level evidence relevant to the original guideline scope?
- What impact does the new evidence have on the existing guideline recommendations?
- Would the new evidence indicate the need for additional recommendations?
- If no new high-level evidence exists, does the guideline still provide best available evidence to inform practice?
- Can the guideline be confidently followed as safe practice?

6.3 Guideline requires updating

If a guideline requires updating, the process will follow the main guideline development process as outlined in this manual.

All review projects should include:

- Literature search which, subject to any database refinement, should replicate the original guideline search strategy. Relevant amendments to the publication date range will capture new articles added to the databases.
- Identification and appraisal of new high-level evidence.
- Consideration of new evidence that reinforces existing recommendations.
- Consideration of new evidence that contradicts or undermines the existing recommendations.
- Consideration of any relevant feedback and comments received since the publication of the guideline.
- Consideration of any original material that is no longer appropriate and how this might need to be superseded or withdrawn.
- Development of new recommendations where indicated by new evidence.

The nature, strengths and weaknesses of new evidence identified will influence the extent of the updating process. Where there are significant changes in recommendations, then early engagement of stakeholders and people who access services will be required.

If there are any new or amended recommendations indicated as a result of a review, consultation with stakeholders, including people who access services and end users, should be undertaken, together with external peer review (see section 4.3.1).

The updated guideline must be submitted to the RCOT Publications Group for evaluation (see section 4.3.2).
The updated guideline document should include:

- Details of the review/updating process followed, with relevant sections of the document amended, including any minor refinements to the search strategy due to database upgrades.
- Clear annotation to identify where new recommendations have been included or existing recommendations have been revised or withdrawn.
- Date of review.

Implementation tools must be updated in line with any changes made to the guideline and its recommendations.

All RCOT guidelines will be automatically withdrawn 10 years after the original publication date.

6.4 Guideline does not require updating

Where a review indicates that the existing guideline remains valid (i.e. no new relevant high-level evidence has been identified and the recommendations remain safe and effective practice), then the outcome will be that the guideline should be reprinted without further amendment.

The reprint must include:

- A statement in the section on ‘Updating the guideline’: This guideline was reviewed in 20XX in line with the Practice guideline development manual (20XX) requirements. No new relevant high-level evidence was identified. The review development group has assessed that the guideline and its recommendations continue to define the best available evidence to support effective and safe practice.
- Date of review.

Guidelines that have been reviewed as scheduled, but in which the content remains unchanged, will be available for up to 10 years from the original date of publication and then withdrawn.
Appendix 1: Conflicts of interest declaration form

Practice guideline development conflicts of interest declaration

<table>
<thead>
<tr>
<th>Guideline title:</th>
</tr>
</thead>
</table>

The Royal College of Occupational Therapists (RCOT) values your involvement in the development of practice guidelines for occupational therapists. To ensure that the guideline developed cannot be found to be biased, you must consider whether you may have any interests that may potentially conflict with the role you will be taking in the guideline development.

A conflict of interest is identified as either a personal (of the person, their partner or close relatives) or non-personal (of their department/employer/business) interest that could have the potential to influence or affect an individual’s ability to act in the best interests of RCOT. Interests can be considered as either ‘specific’ or ‘non-specific’ in relation to the matter under discussion.

For example, if a GDG member is also a member of an RCOT Specialist Section, they may have some potential ‘non-specific’ conflict of interest by virtue of their professional interests (e.g. membership of clinical forums or specialist professional organisations) and expertise (e.g. practice specialists, researchers). Some individuals, by virtue of the relatively small pool of experts, may have more ‘specific’ conflicts (e.g. author of evidence).

To ensure the credibility of the final guideline, there may be certain circumstances that would preclude an individual from being the Chair or Lead of a GDG. These would include the perception of competing interests or conflicts of loyalty where a person has a primary duty and loyalty to another organisation, or where a person has undue influence in a particular field of practice, education and/or research.

<table>
<thead>
<tr>
<th>Type of interest</th>
<th>Description of interest (if you have no interests in a category, state ‘none’)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Involvement in research and published evidence in relation to the guideline topic.</td>
<td>Nature of involvement and associated dates</td>
</tr>
<tr>
<td>Involvement in the development of guidelines within this topic area for another organisation.</td>
<td>Name of organisation, nature of involvement and associated dates</td>
</tr>
</tbody>
</table>
## Appendix 1: Conflicts of interest declaration form

<table>
<thead>
<tr>
<th>Type of interest</th>
<th>Description of interest (if you have no interests in a category, state ‘none’)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordinary membership of professional bodies, RCOT Specialist Sections, committees, charities, voluntary bodies, etc.</td>
<td>Name of body</td>
</tr>
<tr>
<td>Office held in professional bodies, Specialist Sections, committees, charities, voluntary bodies, etc.</td>
<td>Name of body and nature of office held</td>
</tr>
<tr>
<td>Consultancies, research or other positions with any commercial companies with interests in the guideline topic area or which might potentially benefit financially or otherwise from the guideline recommendations.</td>
<td>Name of companies and position(s) and associated dates</td>
</tr>
<tr>
<td>Other relevant interests that could lead to a perception of bias when giving opinions at any stage during the guideline development process.</td>
<td></td>
</tr>
</tbody>
</table>

I hereby declare the above is an accurate declaration of my interests in relation to my current and anticipated involvement in the development of the above guideline:

Signature: ..............................................................................................................................................

Name (please print): ............................................................................................................................ Date: ................................

Job title: .................................................................................................................... Employer: ............................................................................................

A copy of the RCOT's Conflicts of interest policy can be accessed via the website at: https://www.rcot.co.uk/about-us/governance/council-and-boards/royal-college-occupational-therapists-council. Details specific to guideline development are included in the Practice guideline development manual, available at: https://www.rcot.co.uk/practice-resources/rcot-practice-guidelines
Appendix 2: Management of conflicts of interest

Establishing whether GDG members have any conflict of interest currently, or anticipated over the project timeline, enables the appropriate management of any interests during the guideline development.

If a GDG member is also a member of an RCOT Specialist Section, they may have some potential ‘non-specific’ conflict of interest by virtue of their professional interests (e.g. membership of clinical forums or specialist professional organisations) and expertise (e.g. practice specialists, researchers). Some individuals, by virtue of the relatively small pool of experts, may have more ‘specific’ conflicts (e.g. author of evidence).

To ensure the credibility of the final guideline, there may be certain circumstances that would preclude an individual from being the Chair or Lead of a GDG. These would include the perception of competing interests or conflicts of loyalty where a person has a primary duty and loyalty to another organisation, or where a person has undue influence in a particular field of practice, education and/or research.

Management of conflicts of interest: checklist

1. A conflicts of interest form must be completed by the Project Lead/GDG Chair and submitted to RCOT for review to ensure that there are no particular interests that may preclude the individual from leading the project.

2. A conflicts of interest form must be completed by all invited or volunteering core guideline group members prior to commencement of or involvement in the guideline activity. Forms are reviewed by RCOT to ensure that there is no specific conflict of interest which would preclude membership.

3. The guideline scope form (Appendix 3) must include details of any potential conflicts of interest identified regarding the group's members. This will be reviewed as part of the submission to the RCOT Publications Group. Where any concern is raised, clarification will be sought.

4. Declarations of interest must be included as a standard agenda item for every GDG meeting. Group members must declare any conflicts in relation to the matters under discussion on the agenda for that meeting, or any changes since last completing the declaration form.

5. Where an interest is declared at a meeting, then it should be clarified if it relates directly to the matter under discussion. If the interest is not relevant, then, following declaration, participation should be possible. Where the interest is relevant, the GDG Chair, with the consensus of the rest of the GDG members, will determine the most appropriate action to manage that conflict, i.e.:
   • Group member remains in the meeting but does not participate in discussion or any decision-making, OR
   • Group member remains in the meeting, participates in the discussion but not in the decision-making, OR
Appendix 2: Management of conflicts of interest

- Group member withdraws from the meeting during the item under discussion and whilst any decision is made (action normally appropriate for any personal financial interest).

If the conflict is with the Chair, then the nominated Vice-Chair will lead the meeting, or agenda item, in line with one of the three options above.

6. Declarations of interest and actions taken to manage any conflict must be recorded in the meeting minutes.

7. A new conflicts of interest form will be completed annually by core group members in line with the RCOT’s Conflicts of interest policy.

8. All abstracts for screening must be checked prior to allocation to ensure authors do not screen their own work.

9. All evidence for critical appraisal must be checked prior to allocation to ensure no authors appraise their own publications.

10. All co-opted members and peer reviewers will be asked to complete a conflicts of interest form.

11. Individuals participating in any guideline consultation activity will be asked to declare any conflicts of interest in writing, or if participating in a face-to-face consultation group activity, verbal declarations will be recorded by the group facilitator.

12. A clear statement outlining conflicts of interest, and declarations made, must be included within all published guidelines.

All completed conflicts of interest forms are retained by the Royal College of Occupational Therapists for the lifetime of the guideline, i.e. 10 years. Forms are securely stored in line with RCOT’s Privacy policy (RCOT 2019).
This form should be completed by the Guideline Development Group (GDG) Chair in consultation with members of the GDG and RCOT. It should be sent to stakeholders and amended prior to submission to the RCOT Publications Group for consideration and approval.

1. **OVERVIEW**

<table>
<thead>
<tr>
<th>1.1 Provisional practice guideline title:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>1.2 Please outline the practice question, guideline topic and its proposed overall objective.</th>
</tr>
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<tbody>
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<td></td>
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</table>

<table>
<thead>
<tr>
<th>1.3 Please describe how the topic will support occupation-focused practice.</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>1.4 How will potential health inequalities and social determinants be considered within the guideline?</th>
</tr>
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<td></td>
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</table>

<table>
<thead>
<tr>
<th>1.5 How will the guideline address diversity of the target population?</th>
</tr>
</thead>
</table>
2. **RATIONALE**

<table>
<thead>
<tr>
<th>2.1 (a)</th>
<th>Who would this guideline be relevant to? Who is/are your intended audience(s)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b)</td>
<td>Who else might be interested in this guideline?</td>
</tr>
</tbody>
</table>

| 2.2 | Describe the process that has been undertaken to establish that there is a demand for occupational therapy practice guidelines in this particular area. |

<table>
<thead>
<tr>
<th>2.3 (a)</th>
<th>Please provide an outline of key evidence that exists to support practice guideline development in this area.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b)</td>
<td>Please provide a copy of the scoping search strategy that was undertaken to support this guideline development.</td>
</tr>
</tbody>
</table>

| 2.4 | Will the document be relevant UK-wide? |

| 2.5 | Will the proposed guideline link to any national documents, strategies, policies or care pathways? *Please specify.* |
3. **STAKEHOLDER ENGAGEMENT**

3.1 (a) Please provide a list of stakeholders you have liaised with in the development of the scope.

(b) Will any of the stakeholder organisations be represented on the guideline development group? *If so, please specify.*

3.2 Detail the expressions of interest received from occupational therapists with regard to membership of the guideline development group.

4. **GUIDELINE DEVELOPMENT GROUP – SKILL MIX**

4.1 Please provide the names of the core guideline development group members against the following individual backgrounds/skills:

- Expert practitioner
- Experience in developing professional documentation or writing skills (*this role is supported by an RCOT Research and Development Officer*)
- Research experience (*including critical appraisal*)
- Project management experience (*this role is supported by an RCOT Research and Development Officer*)
- Experience of accessing occupational therapy services
- Other stakeholder(s) (*please state*).

Please provide the names of those responsible for the following roles:

- Project Lead/GDG Chair
- Deputy Project Lead/GDG Vice-Chair
- Editorial Lead.
4.2 Are there any potential conflicts of interest to be declared by members of the GDG? If yes, please clearly state all those identified.

5. SUPPORT AND FUNDING

Please attach details of any secured funding.

5.1 If funding or support is available from potential collaborators, how will this be agreed and managed?

Please state how much funding has been secured and submit written evidence with this form.

All funding sources must be acknowledged and declared in the final guideline to ensure transparency.

Scope form prepared and submitted by:

Name ................................................................. Date .....................................................
GDG Chair

For RCOT use only: Date

<table>
<thead>
<tr>
<th>a) Scope approved</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>b) Decision deferred – request for further information</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

Scope approved by:

Name ................................................................. Date .....................................................
Chair RCOT Publications Group

Name ................................................................. Date .....................................................
RCOT Assistant Director – Education and Research

Name ................................................................. Date .....................................................
RCOT Assistant Director – Professional Practice
Appendix 4: Appraisal tools

Different types of appraisal tools are tailored for different study types to help the reviewer to appraise the evidence against areas which typically include the following: study purpose; literature review; design and its appropriateness; biases; sample/recruitment; intervention; data collection; data analysis; results/outcomes; ethical considerations; overall rigour; drop-outs; conclusions and practice implications.

A range of appraisal tools is available; RCOT uses either:

1. McMaster University evidence appraisal framework
   The McMaster University framework has a specific occupational therapy focus and two tools with comprehensive guidance notes for:
   • Quantitative review (Law et al 1998).
   • Qualitative review (Letts et al 2007).

   The tools can be accessed, subject to copyright requirements, via the McMaster University website: http://srs-mcmaster.ca/research/evidence-based-practice-research-group/

2. Critical Appraisal Skills Programme (CASP)
   CASP has critical appraisal tools available for:
   • Systematic reviews.
   • Randomised controlled trials.
   • Qualitative research.
   • Economic evaluation studies.
   • Cohort studies.
   • Case-control studies.
   • Diagnostic test studies.

   These tools are copyright of CASP UK and are available at: http://www.casp-uk.net/

   Details of the tool(s) used and the relevant acknowledgement must be recorded in the guideline document.
Appendix 5: Evidence tables template

<table>
<thead>
<tr>
<th>Source</th>
<th>Design and participants</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
<th>Quality and comment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
## Appendix 6: Recommendation decision table template

<table>
<thead>
<tr>
<th>Key question/outcome</th>
<th>Strength of recommendation (1 or 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommendation statement</strong>&lt;br&gt;Detail the recommendation that the guideline development group makes from the evidence. Define strength of recommendation (1 = strong – ‘It is recommended ....’&lt;br&gt;Or 2 = conditional – ‘It is suggested .....’)&lt;br&gt;</td>
<td></td>
</tr>
<tr>
<td><strong>Quality of evidence statement</strong>&lt;br&gt;Summary of the synthesis of the evidence relating to the key question and overall evidence level (A = High, B = Moderate, C = Low, D = Very low)&lt;br&gt;</td>
<td>Overall quality of evidence level&lt;br&gt;</td>
</tr>
<tr>
<td><strong>Evidence table references</strong>&lt;br&gt;</td>
<td></td>
</tr>
<tr>
<td><strong>Quality and volume of evidence</strong>&lt;br&gt;Are there any issues concerning the quantity of evidence available on this topic, its methodological quality and consistency?&lt;br&gt;</td>
<td></td>
</tr>
<tr>
<td><strong>Generalisability</strong>&lt;br&gt;How reasonable is it to generalise from the results of the studies used as evidence to the target population for this guideline?&lt;br&gt;</td>
<td></td>
</tr>
<tr>
<td><strong>Applicability</strong>&lt;br&gt;To what extent is the evidence directly applicable to occupational therapy in the UK?&lt;br&gt;</td>
<td></td>
</tr>
<tr>
<td><strong>Impact</strong>&lt;br&gt;Due consideration should be given to the following: magnitude of the effect, potential harm, benefits and risks, financial barriers, organisational barriers, and any issues related to health inequalities or social determinants of health.&lt;br&gt;</td>
<td></td>
</tr>
<tr>
<td><strong>Other factors</strong> considered by the guideline development group and any variance of opinion.&lt;br&gt;</td>
<td></td>
</tr>
</tbody>
</table>

Adapted from the ‘Considered Judgement Proforma’ (SIGN 2014) with permission from the Scottish Intercollegiate Guidelines Network.
Appendix 7: Guideline document template

A published guideline should normally include the following components, although the order in which the content appears may vary. Additional appendices to those listed below may be appropriate.

Contents

Foreword(s)

Introduction
  • Practice requirement for the guideline.
  • Topic identification process.
  • Reference to national context and any other relevant publications.
  • Context of service delivery/background to health conditions.
  • Consideration of the health inequalities and socioeconomic influences.

Key recommendations for implementation
  • This provides a summary of the guideline recommendations and their grading of quality and strength.

Occupational therapy role
  • The role of occupational therapy in the guideline topic area.

Objective of the guideline
  • Overall objective of the guideline.

Guideline scope
  • Practice, healthcare or social questions covered by the guideline.
  • Population and target audience to whom the guideline applies.

Guideline recommendations and supporting evidence
  • These detail the evidence identified, quality of evidence, any discussion and interpretation, and subsequent recommendations.
  • These include presentation of different options for management or intervention as appropriate.
  • Reference is made to specific clinical, healthcare or social circumstances in which the guideline applies.
  • Recommendations must consider/discuss the health benefits, side-effects and any risk issues associated, and potential impact.
Appendix 7: Guideline document template

Perspectives from people who access services and their carers
- May include views on the recommendations and/or anonymised quotes from consultation feedback.

Implementation of the guideline
- Includes details of any support tools, audit and review criteria.
- Discusses the potential organisational and financial barriers for the application of the recommendations.

Recommendations for future research
- Identifies the gaps in the evidence base and potential areas for further research.

Guideline development process
- Guideline development group (how established, membership).
- Stakeholder involvement.
- Involvement from people who access services and their carers (how involved and in what aspects).
- External peer review and consultation (details of how this has taken place).
- Conflicts of interest.
- Declaration of funding for the guideline development.
- RCOT appraisal and ratification process.

Guideline methodology
- Guideline question(s).
- Literature search strategy and results (includes date of search).
- Criteria for inclusion and exclusion of evidence.
- Strengths and limitations of body of evidence and any uncertainty.
- Describes method used to arrive at recommendations (including any consensus activity).
- Identifies any limitations of the guideline and any potential bias in the conclusions or recommendations.

Updating the guideline
- Details when and how the guideline will be updated, with proposed date of review stated.
- When updating an existing guideline, the review process should be described fully in the second edition.
- Implementation tools should be updated to reflect any new or updated recommendations.
Appendices

Guideline development group and review groups
• Lists those involved in the guideline development and review group where appropriate.

Acknowledgements
• Details any other relevant contributors, stakeholders (including people who access services and their carers), peer reviewers, etc.

Conflicts of interest declarations (states any conflict of interest declared by guideline development group members, reviewers or stakeholders).

Literature search strategy

Evidence tables

Glossary and abbreviations

References
Appendix 8: The RCOT Publications Group terms of reference

Terms of Reference
RCOT Publications Group

Responsible to: RCOT Council (via the Professional Practice Business Report)

1. ROLES

1.1 Strategic: To provide a quality assurance role in reviewing proposals and drafts produced by the Royal College of Occupational Therapists’ Specialist Sections, Regional and other groups that wish to publish practice documents in collaboration with the Royal College of Occupational Therapists (RCOT).

1.2 Governance: To ensure that all practice publications maintain a style and quality that support the professional and public standing of the RCOT.

2. RESPONSIBILITIES

2.1 To review practice publication proposals, incorporating planned new work by RCOT Specialist Sections, new work in response to professional or national developments, and the review of published documents.

2.2 To support the development of agreed new work, through the provision of information, advice, templates and critical appraisal.

2.3 To ensure that proposals and draft manuscripts are assessed against RCOT's agreed evaluation criteria and, where applicable, NICE accreditation criteria.

2.4 To ensure that all publications are appropriate to the readership, whether UK-wide or country-specific.

2.5 To support a consistent, reliable and timely publication process within RCOT.

2.6 To encourage and support collaborative multiprofessional development of publications that are relevant to allied health professions.

2.7 To ensure that information about the group and meeting dates are available on the RCOT website, together with associated materials and briefings, to support members in the development of publications.

2.8 To involve and inform RCOT members, Council, Boards and Committees, and external interest groups, in the development of publications, as appropriate.

2.9 To report work progress and outcomes to the RCOT Council via the Professional Practice Business Report and the Quality Programme Manager.

2.10 The Chair and Quality Programme Manager will ensure that the UK RCOT Specialist Section Forum and relevant groups are informed of, and involved in, any publication issues of general interest and act as a communication link as required.
Appendix 8: The RCOT Publications Group terms of reference

3. **MEMBERSHIP**

3.1 The membership will comprise:

3.1.1 **RCOT Officers (3):**
- Quality Programme Manager (Professional Practice)
- Research and Development Manager (Education and Research)
- Publications Manager (Communications and Marketing)

3.1.2 **Occupational Therapy Practitioners/Managers (5):**
Five representatives from a range of health and social care backgrounds, with an interest in, and experience of, the production of professional documentation to support evidence-based practice.

3.1.3 **Public Contributors (2):**
Two public participants with an interest in occupational therapy and improving health and social care.

3.1.4 **Co-opted Member:**
One occupational therapist working in an educational/academic setting, with an interest in, and experience of, the production of professional documentation to support evidence-based practice.

3.1.5 **Experts** (usually 1 or 2), with relevant knowledge and/or experience, may be co-opted to the group for the time taken to develop a particular publication.

4. **RULES**

4.1 A membership term will be three years. Vacancies will be advertised nationally.

4.2 The post of Chair will be held by an RCOT member, elected from the group. The Chair may delegate some tasks and authority to the appropriate RCOT Officers in order to progress the work of the group.

4.3 The Chair may be invited to attend RCOT Board meetings when the agenda indicates it is necessary.

4.4 The Chair will be supported by a Vice-Chair, also an RCOT member, elected from the group.

4.5 The posts of Chair and Vice-Chair will not exceed their term of office. The out-going Vice-Chair will normally become the subsequent Chair.

4.6 A quorum shall be four members, one of whom must be the Chair or Vice-Chair.

4.7 The group members who are occupational therapists must be members of RCOT.

4.8 Any member who fails to attend two consecutive meetings in any one Council year without providing a good reason, which is accepted by the group, may be deemed to have resigned. The Chair reserves the right to request further explanation or resignation where absence affects the business of the group.

4.9 When any member completes a term of office, one year should normally lapse before the member is eligible to apply and be considered for a further term of office.

5. **MEETINGS**

5.1 The RCOT Publications Group meets twice a year at the Royal College of Occupational Therapists’ offices in London. The meetings are held in two sessions. The first session looks at public-facing documents; the second session concentrates on membership materials.
5.2 Group members will be required to undertake review of document submissions outside of the meetings.

6. **ADMINISTRATION AND SUPPORT**

6.1 The administration of the group will be carried out by a member of RCOT headquarters staff.

7. **REVIEW DATE**

7.1 Terms of reference to be reviewed every three years.

**Conflicts of Interest**

Group members should declare any conflicts of interest at the beginning of an RCOT Publications Group meeting or before the discussion of the item itself. These declarations and the actions that follow will be recorded in the minutes. RCOT’s Policy on conflicts of interest is available at: https://www.rcot.co.uk/about-us/governance/council-and-boards/royal-college-occupational-therapists-council
Appendix 9: Guideline development group responsibilities

The primary purpose of an RCOT guideline development group (GDG) is to develop an occupational therapy-specific practice guideline following the process described in the NICE accredited *Practice guideline development manual*. RCOT members with the appropriate expertise and skills are invited to form a GDG. Depending on the guideline topic, the GDG may also include representatives from the relevant RCOT Specialist Sections, other occupational therapists with relevant experience, an RCOT Professional Adviser, and representation from the public, people who access occupational therapy services and/or their carers. The GDG is supported by RCOT officers including: the Research and Development Manager, the Research and Development Officer and the Quality Programme Manager.

1. **The GDG Chair and Vice-Chair are expected to:**
   - Lead the GDG with support from RCOT.
   - Agree each GDG member’s specific role and responsibility within the group.
   - Ensure that the development process, as described in the *Practice guideline development manual* is followed and evident in the final guideline.
   - Encourage all GDG members to contribute their point of view to discussions during GDG meetings and ensure the opportunity for input from all members.
   - Complete and update, as necessary, all conflicts of interest forms and adhere to guidance on conflict management [see Appendices 1 and 2].
   - In liaison with RCOT officers, ensure that an agenda and minutes, recording all decisions and actions, are produced and agreed for each GDG meeting.
   - Adhere to any relevant research governance/project ethics requirements.
   - Lead the write-up of the draft guideline following the guideline document template [see Appendix 7].
   - Lead the group in considering and addressing stakeholder comments on the draft guideline.
   - Agree and implement a plan with GDG members for arranging peer review of the draft guideline.
   - Agree and implement an action plan for engaging and consulting with stakeholders, and for approaching external organisation(s) regarding the provision of a foreword and/or endorsement of the final document.
   - Provide progress reports to the RCOT Publications Group as required.
Appendix 9: Guideline development group responsibilities

- Respond to all RCOT Publications Group communications within the designated timeframes.
- Support the dissemination and implementation of the guideline – be a champion for the guideline and undertake activities to promote its implementation, such as presenting at professional conferences and participating in the production of publishing guideline-related articles.
- Undertake timely review post-publication of new evidence generated by annual monitoring searches.

2. All GDG members are expected to:

- Complete a declaration of conflicts of interest form before the project commences.
- Submit and update declarations of interest and potential conflicts of interest on a regular basis.
- Adhere to the process as described in the Practice guideline development manual.
- Adhere to RCOT's Privacy policy (RCOT 2019) in line with the General Data Protection Regulation and Data Protection Act 2018.
- Notify RCOT of any risk to the scheduled action plan, e.g. any change in membership of group, slippage to timescales, etc.
- Communicate with relevant RCOT Specialist Sections/regional groups and/or other professional bodies regarding stakeholder involvement in the guideline development.
- Attend all GDG meetings and read papers in advance of meetings.
- Input positively to meetings and value all contributions.
- Participate in guideline development training as appropriate.
- Wherever possible, work within agreed timelines for each phase of the guideline development project.
- Work with RCOT officers and group members to formulate practice questions for review, review evidence tables and agree draft recommendations.
- Participate in the preparation and review of the draft guideline.
- Work with other group members and RCOT officers to write and edit draft sections of the guideline.
- Work with other group members to consider and address stakeholder comments on the draft guideline.
- Support the dissemination and implementation of the guideline – be a champion for the guideline and undertake activities to promote its implementation, such as presenting at professional conferences and participating in the production of publishing guideline-related articles.
- Undertake timely review post-publication of new evidence generated by annual monitoring searches.
Appendix 9: Guideline development group responsibilities

3. **Copyright responsibility**

   As a GDG member, articles will be sent to you for appraisal. They will be obtained for you from the British Library via the RCOT Library under the terms of the College’s CLA business licence.

   The articles are only to be used for the purposes of appraisal for this guideline. Under copyright law and supplementary licence regulations, only one copy of each article is permitted for each member of the guideline group. Once you have printed/ saved the article, please delete any articles sent to you via email, including the article as an attachment.

   Due to copyright licence terms, articles are only for appraisal purposes for you and for the guideline and must not be forwarded to anyone else.

4. **Guideline authorship**

   RCOT will own the copyright and be named as the primary author of the guideline and all GDG members will be acknowledged as contributors in the published guideline. The expectations and requirements for all GDG members to contribute as authors to the guideline should be made clear at the first meeting of the guideline group.
References


Royal College of Occupational Therapists (2019) *Privacy policy*. London: RCOT. Available at: [https://www.rcot.co.uk/privacy-policy](https://www.rcot.co.uk/privacy-policy)


All websites in these references were accessed on 13.01.2020.
Practice guideline development manual

Fourth edition

This manual describes the NICE accredited process used by the Royal College of Occupational Therapists to develop practice guidelines. It offers a guide to producing high-quality evidence-based guidelines for occupational therapists.