National Institute for Health and Care Excellence

Final confidential

Supporting adult carers

Supplement 1: Methods

NICE guideline

Development of the guideline and methods

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Final

Developed by the National Guideline Alliance part of the Royal College of Obstetricians and Gynaecologists

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

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Development of the guideline

Remit

The National Institute for Health and Care Excellence (NICE) commissioned the National Guideline Alliance (NGA) to develop a guideline about supporting adult carers.

This guideline will also be used to develop the NICE quality standard for supporting adult carers.

What this guideline covers

Groups that are covered

Adult carers, aged 18 or over, who provide unpaid care for 1 or more people aged 16 years or over with health and social care needs.

Specific consideration will also be given to the following carers:

- Older carers (including frail elderly)
- Those caring for more than 1 person
- Those who are also receiving care from the person they are caring for (mutual caring)
- Those caring at a distance or not living with the person they are caring for (remote carers).

Key areas that are covered

- Identifying carers as defined by the Care Act 2014 (including hidden carers).
- Providing information and advice for carers (for example, about personal budgeting, housing, planning and coordinating care, looking after their own health and self-care).
- Assessment of carers as defined by the Care Act 2014, including whole family assessments and planning for the caring role (including planning in a crisis).
- Support and advice to help adult carers to enter, remain in or return to work, education or training.
- Training carers to provide practical support to the person receiving care (including, training in managing medicines, personal care, moving and handling, use of aids and adaptations, use of digital and assistive technology).
- Providing practical social and community support interventions for carers, including supporting communication with health and social care professionals;

providing respite care and breaks from caring responsibilities; supporting access to local carers' groups and networks.

- Providing psychological and emotional support and interventions for carers.
- Providing support for carers who are caring for people at the end of life.
- Supporting carers during changes to the caring role, when caring needs fluctuate, when a person moves to another setting, or when a younger person being cared for enters adulthood.

For further details see the guideline scope on the NICE website.

What this guideline does not cover

Groups that are not covered

- People paid for providing care.
- People providing care as part of voluntary work.
- Young carers (aged 17 or under), except in relation to whole family assessments.
- Adults who care for children under 16 with health and social care needs, except in relation to whole family assessments.

The rationale for excluding these groups is outlined in the guideline scope on the NICE website.

Methods

Preamble

This section summarises methods used to identify and review the evidence, to consider cost effectiveness, and to develop guideline recommendations. This guideline was developed in accordance with methods described in Developing NICE guidelines: the manual (NICE 2014).

Until March 2018, declarations of interest were recorded and managed in accordance with NICE's 2014 conflicts of interest policy. From April 2018, declarations were recorded and managed in accordance with NICE's 2018 Policy on declaring and managing interests for NICE advisory committees.

Developing the review questions and outcomes

The 9 review questions considered in this guideline were based on the key areas identified in the guideline scope .They were drafted by the NGA technical team, and refined and validated by the guideline committee (see Table 1: Summary of review questions and index to evidence reports).

The review questions were based on the following frameworks:

- population, intervention (or issue of interest), comparison and outcome (or theme, for qualitative reviews or the qualitative component of mixed methods reviews) (PICO)

These frameworks guided the development of review protocols, the literature searching process, and critical appraisal and synthesis of evidence. They also facilitated development of recommendations by the committee.

Full literature searches, critical appraisal and evidence reviews were completed for all review questions.

The review questions and evidence reports corresponding to each question (or group of questions) are summarised in Table 1.

Table 1: Summary of review questions and index to evidence reports

Evidence report	Subtopic in scope	Review question	Type of review
[A]	Identifying carers as defined by the Ace Act 2014	What are the barriers and facilitators to (i) self-identification by carers and (ii) identification of carers by health and social care professionals?	Qualitative

Evidence report	Subtopic in scope	Review question	Type of review
[B]	Providing information and advice for carers	What are the views and experiences of adult carers, and of healthcare and related practitioners, regarding how information and advice about caring – including personal budgeting, legal issues, housing, planning and coordination care, or self-care – has been (and is) currently provided in the UK?	Qualitative
[C]	Assessment of carers as defined by the Care Act 2014	What is the acceptability of different tools or approaches for assessing the needs of carers?	Qualitative
[D]	Support and advice to help adult carers enter, remain in and return to work, education and training	What are the most effective, cost-effective and acceptable interventions, tools or approaches to support adult cares to enter, remain in and/ or return to (i) work (ii) education and (iii) training?	Mixed, quantitative (intervention) and qualitative
[E]	Training carers to provide practical support to the person receiving care	What skills and educational based interventions are effective, cost-effective and acceptable to carers for training them to provide practical support to the person receiving care?	Mixed, quantitative (intervention) and qualitative
[F]	Practical, social and community support for carers	What practical, social and community support interventions for adult carers are effective, cost-effective and acceptable to them?	Mixed, quantitative (intervention) and qualitative
[G]	Psychological and emotional support and interventions for carers	What psychological and emotional support interventions are effective, cost-effective and acceptable to adult carers for maintaining and/ or improving their health and wellbeing?	Mixed, quantitative (intervention) and qualitative
[H]	Support for carers caring for people at the end of life	What is the effectiveness, cost-effectiveness, and acceptability of interventions for supporting adult carers who are caring for people at the end of life, and	Mixed, quantitative (intervention) and qualitative

Evidence report	Subtopic in scope	Review question	Type of review
		after the person receiving care dies?	
[I]	Supporting carers during changes to the caring role	What is the effectiveness, cost-effectiveness, and acceptability of interventions for supporting adult carers during (i) changes to the setting in which care is provided, (ii) the transition of the person receiving care to adulthood and (iii) change of carer status or circumstances?	Mixed, quantitative (intervention) and qualitative

Additional information related to development of the guideline is contained in:

- Supplement 1 (Methods; this document)
- Supplement 2 (NGA technical team list).

Searching for evidence

Literature search

Systematic literature searches were undertaken to identify published evidence relevant to each review question.

Databases were searched using medical subject headings, free-text terms and study type filters where appropriate. Where possible, searches were restricted to retrieve articles published in English. All the searches were performed in November 2017 in the following databases: Applied Social Sciences Index and Abstracts (ASSIA), CINAHL, Cochrane Library, Embase, Health Management Information Consortium (HMIC), International Bibliography for Social Sciences (IBSS), Medline & Epub Ahead of Print, In-Process & other non-indexed citations, PsycINFO, Social Policy and Practice (SPP), Social Services Abstracts (SSA) and Sociological Abstracts. The guideline committee and reviewing team considered the review questions for which the searches might need to be updated, and after prioritising against a number of criteria, made a decision to selectively rerun the searches for review questions 1,3 and 4, which were performed at least 6–8 weeks in advance of the final guideline committee meetings before consultation on the draft guideline; these reruns were completed during January 2019. Any studies added to the databases after January 2019 (including those published before January 2019 but not yet indexed) were not considered for inclusion.

Search strategies were quality assured by cross-checking reference lists of relevant articles, analysing search strategies from other systematic reviews and asking members of the committee to highlight key studies. All search strategies were also quality assured by an information scientist who was not involved in developing the

primary search strategy. Details of the search strategies, including study-design filters applied and databases searched, are presented in Appendix B of each evidence report.

All publications highlighted by stakeholders at the time of the consultation on the draft scope were considered for inclusion. During the scoping phase, searches were conducted for relevant systematic reviews, guidance, policy and legislation and research and economic evidence on electronic databases and websites of organisations relevant to the topic.

Economic literature search

Systematic literature searches were also undertaken to identify published economic evidence. A broad search was conducted to identify economic evidence related to the topic in the Cochrane Central Register of Controlled Trials (CENTRAL). A broad search was also conducted to identify economic evidence related to the topic in the following databases with an economic search filter applied: Medline & Epub Ahead of Print, In-Process & other non-indexed citations, CENTRAL, Embase and PsycINFO. Where possible, the searches were restricted to retrieve articles published in English; studies published in languages other than English were not eligible for inclusion.

The search strategies for the economic literature search are included in SAC literature search appendices. The search was updated at least 6–8 weeks in advance of the final committee meetings before consultation on the draft guideline; these updates were completed during January 2019.

Reviewing evidence

Systematic review process

The evidence was reviewed in accordance with the following approach.

- Potentially relevant articles were identified from the search results for each review question by screening titles and abstracts. Full-text copies of the articles were then obtained.
- Full-text articles were reviewed against pre-specified inclusion and exclusion criteria in the review protocol (see Appendix A of each evidence report).
- Key information was extracted from each article on study methods and results, in accordance with factors specified in the review protocol. The information was presented in a summary table in the corresponding evidence report and in a more detailed evidence table (see Appendix E of each evidence report).
- Included studies were critically appraised using an appropriate checklist as specified in Developing NICE guidelines: the manual (NICE 2014). Further detail on appraisal of the evidence is provided below.

- Summaries of evidence by outcome – or by qualitative theme – were presented in the corresponding evidence report and discussed by the committee. In mixed methods reviews quantitative (intervention) evidence was presented first, followed by related qualitative data.

Review questions selected as high priorities for economic analysis (and those selected as medium priorities and where economic analysis could influence recommendations) were subject to dual screening and study selection through a 10% random sample of articles. Any discrepancies were resolved by discussion between the first and second reviewers or by reference to a third (senior) reviewer. For the remaining review questions, internal (NGA) quality assurance processes included consideration of the outcomes of screening, study selection and data extraction and the committee reviewed the results of study selection and data extraction. The review protocol for each question specifies whether dual screening and study selection was undertaken for that particular question.

Drafts of all evidence reviews were checked by a senior reviewer.

Type of studies and inclusion/exclusion criteria

Inclusion and exclusion of studies was based on criteria specified in the corresponding review protocol.

For the mixed methods reviews quantitative (intervention), qualitative and cost-effectiveness studies were considered for inclusion and for the qualitative reviews, only qualitative studies were considered. Systematic reviews with meta-analyses or meta-syntheses were considered to be the highest quality evidence that could be selected for inclusion.

A step wise approach was set out a priori, which allowed for the committee to focus reviews by applying certain additional inclusion criteria relating to study design, setting or publication date. They agreed to do so for the quantitative (intervention) components of all mixed method review questions, because they wished to prioritise the most relevant effectiveness data as a basis for drafting recommendations. For example, for intervention components of mixed methods reviews, randomised controlled trials (RCTs) were prioritised for inclusion because they are considered to be the most robust type of study design that could produce an unbiased estimate of intervention effects. Where there was no evidence from RCTs (as in the original search for review question 4), non-RCTs and/or observational studies were considered for inclusion. Where data from observational studies were included, results for each outcome were presented separately for each study and meta-analysis was not conducted.

The committee also agreed to exclude studies conducted in the US because they agreed that the nature of the health and welfare systems might undermine the applicability of findings to the UK context. The committee also chose to apply more recent publication cut-off dates to the review questions that they thought would be

particularly influenced by policy and practice changes introduced by the Care Act 2014. Questions to which this applied were the quantitative components of the reviews about providing practical and community support to carers, providing psychological support to carers and providing support during changes to the caring role. .

For qualitative reviews or the qualitative components of mixed methods reviews, the committee agreed a more inclusive approach and only introduced a more recent publication date cut-off for the review about identifying carers for the same reasons as with 6, 7 and 9 explained above. In terms of study design, studies using focus groups, structured interviews or semi-structured interviews were considered for inclusion. Where qualitative evidence was sought, data from surveys or other types of questionnaire were considered for inclusion only if they provided data from open-ended questions, but not if they reported only quantitative data.

The committee was consulted about any uncertainty regarding inclusion or exclusion of studies. A list of excluded studies for each review question, including reasons for exclusion is presented in Appendix D of the corresponding evidence report.

Narrative reviews, posters, letters, editorials, comment articles, unpublished studies and studies published in languages other than English were excluded. Conference abstracts were generally not considered for inclusion.

Methods of combining evidence

When planning reviews (through preparation of protocols), the following approaches for data synthesis were discussed and agreed with the committee.

Data synthesis for intervention components

Meta-analysis of results from RCTs was not carried out because there were no quantitative components (of the mixed methods reviews) with multiple studies reporting the same intervention. Results were presented individually for each study.

Data synthesis for qualitative components and qualitative reviews

The main aim of qualitative data synthesis in this guideline was to describe the acceptability of interventions for supporting carers, in the context of mixed methods reviews. The exceptions were the reviews about identifying carers, providing information to carers and assessing carers' needs where qualitative data alone were used to understand barriers and facilitators and views and lived experiences. Whenever studies identified a qualitative theme, this was extracted and then themes common across studies within a review were categorised, synthesised and tabulated. This included information on how many studies had contributed to each theme identified by the NGA technical team.

In qualitative synthesis, a theme being reported more than other themes across included studies does not necessarily mean that the theme is more important than other themes. The aim of qualitative research is to identify new perspectives on a particular topic. Study types and populations in qualitative research can differ widely, meaning that themes identified by just one or a few studies can provide important information on a given topic

Themes from individual studies were integrated into a wider context and, when possible, overarching categories of themes with sub-themes were identified. Themes were derived from data presented in individual studies. When themes were extracted from 1 primary study only, theme names used in the guideline mirrored those in the source study. However, when themes were based on evidence from multiple studies, the theme names were assigned by the NGA technical team. The names of overarching categories of themes were also assigned by the NGA technical team.

Emerging themes were placed into a thematic map representing the relationship between themes and overarching categories and shown in the main body of each evidence review. The purpose of such a map is to show relationships between overarching categories and associated themes.

Synthesis of quantitative and qualitative data

For the mixed methods reviews, the NGA technical team presented the data from quantitative and qualitative studies together, organised around the protocol interventions (where data were available). The committee completed the synthesis of these mixed data through their discussions of the evidence. Their interpretation of the relationship between the quantitative and qualitative data is described in the committee discussion of the evidence section of all the mixed methods reviews.

Appraising the quality of evidence

Intervention studies

GRADE methodology for intervention reviews

For the intervention components of reviews, the evidence for outcomes from included RCTs and comparative observational studies was evaluated and presented using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology developed by the international GRADE working group.

When GRADE was applied, software developed by the GRADE working group (GRADEpro) was used to assess the quality of each outcome, taking account of individual study quality factors. Results were presented in GRADE profiles (GRADE tables).

The selection of outcomes for each review question was agreed during development of the associated review protocol in discussion with the committee. The evidence for

each outcome was examined separately for the quality elements summarised in Table 2. Criteria considered in the rating of these elements are discussed below. Each element was graded using the quality ratings summarised in Table 3. Footnotes to GRADE tables were used to record reasons for grading a particular quality element as having a 'serious' or 'very serious' quality issue. The ratings for each component were combined to obtain an overall assessment of quality for each outcome as described in Table 4.

The initial quality rating was based on the study design: RCTs start as 'high' quality evidence and observational studies as 'low' quality evidence. The rating was then modified according to the assessment of each quality element (Table 2). Each quality element considered to have a 'serious' or 'very serious' quality issue was downgraded by 1 or 2 levels respectively (for example, evidence starting as 'high' quality was downgraded to 'moderate' or 'low' quality). In addition, there was a possibility to upgrade evidence from observational studies (provided the evidence for that outcome had not previously been downgraded) if there was a large magnitude of effect, a dose–response gradient, or if all plausible confounding would reduce a demonstrated effect or suggest a spurious effect when results showed no effect.

Table 2: Summary of quality elements in GRADE for intervention reviews

Quality element	Description
Risk of bias ('Study limitations')	Limitations in study design and implementation may bias estimates of treatment effect. High risk of bias for the majority of the evidence reduces confidence in the estimated effect
Inconsistency	This refers to unexplained heterogeneity in the results
Indirectness	This refers to differences in study populations, interventions, comparators or outcomes between the available evidence and inclusion criteria specified in the review protocol
Imprecision	This occurs when a study has relatively few participants or few events of interest, resulting in wide confidence intervals around estimates of effect that include clinically important thresholds
Publication bias	This refers to systematic under- or over-estimation of the underlying benefit or harm resulting from selective publication of study results

Table 3: GRADE quality ratings (by quality element)

Quality issues	Description
None or not serious	No serious issues with the evidence for the quality element under consideration
Serious	Issues with the evidence sufficient to downgrade by 1 level for the quality element under consideration

Quality issues	Description
Very serious	Issues with the evidence sufficient to downgrade by 2 levels for the quality element under consideration

Table 4: Overall quality of the evidence in GRADE (by outcome)

Overall quality grading	Description
High	Further research is very unlikely to change the level of confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on the level of confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on the level of confidence in the estimate of effect and is likely to change the estimate
Very low	The estimate of effect is very uncertain

Assessing risk of bias in intervention reviews

Bias is a systematic error, or consistent deviation from the truth in results obtained. When a risk of bias is present the true effect can be either under- or over-estimated.

Risk of bias in RCTs was assessed using the Cochrane risk of bias tool (see Appendix H in Developing NICE guidelines: the manual; NICE 2014).

The Cochrane risk of bias tool assesses the following possible sources of bias:

- selection bias
- performance bias
- attrition bias
- detection bias
- reporting bias.

A study with a poor methodological design does not automatically imply high risk of bias; the bias is considered individually for each outcome and it is assessed whether the chosen design and methodology will impact on the estimation of the intervention effect.

More details about the Cochrane risk of bias tool can be found in Section 8 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011).

For systematic reviews of RCTs the AMSTAR checklist was used and for systematic reviews of other study types the Cochrane ROBIS checklist was used (see Appendix H in Developing NICE guidelines: the manual; NICE 2014).

For observational studies the Newcastle-Ottawa checklist was used (see Appendix H in Developing NICE guidelines: the manual; NICE 2014).

Assessing inconsistency in intervention reviews

Inconsistency refers to unexplained heterogeneity in results of meta-analysis. However, as explained above, the data for all outcomes in this guideline were derived from single studies. This being the case, the rating 'no serious inconsistency' was used when assessing this domain for every outcome, as per GRADE methodology (Santesso 2016).

Inconsistency was assessed by visually inspecting forest plots and observing whether there was considerable heterogeneity in the results of the meta-analysis. This was assessed by calculating the I-squared statistic for the meta-analysis with an I-squared value of more than 50% indicating considerable heterogeneity. When considerable heterogeneity was observed, possible reasons were explored and subgroup analyses were performed as pre-specified in the review protocol if possible.

When no plausible explanation for the heterogeneity could be found, the quality of the evidence was downgraded in GRADE for inconsistency.

Assessing indirectness in intervention reviews

Directness refers to the extent to which populations, interventions, comparisons and outcomes reported in the evidence are similar to those defined in the inclusion criteria for the review and was assessed by comparing the PICO elements in the studies to the PICO defined in the review protocol. Indirectness is important when such differences are expected to contribute to a difference in effect size, or may affect the balance of benefits and harms considered for an intervention.

Assessing imprecision and clinical importance in intervention reviews

Imprecision in GRADE methodology refers to uncertainty around the effect estimate and whether or not there is a clinically important difference between interventions (that is, whether the evidence clearly supports a particular recommendation or appears to be consistent with several candidate recommendations). In the context of this guideline the concept of clinical importance refers more broadly to importance in the overall health and social care context. Therefore, imprecision differs from other aspects of evidence quality because it is not concerned with whether the point estimate is accurate or correct (has internal or external validity). Instead, it is concerned with uncertainty about what the point estimate actually represents. This uncertainty is reflected in the width of the confidence interval (CI).

The 95% CI is defined as the range of values within which the population value will fall on 95% of repeated samples, were the procedure to be repeated. The larger the study, the smaller the 95% CI will be and the more certain the effect estimate.

Imprecision was assessed in the guideline evidence reviews by considering whether the width of the 95% CI of the effect estimate was relevant to decision making, considering each outcome independently. This is illustrated in Figure 1, which considers a positive outcome for the comparison of treatment 'A' versus treatment

'B'. Three decision-making zones can be differentiated, bounded by the thresholds for clinical importance (minimally important differences; MIDs) for benefit and harm. The MID for harm for a positive outcome means the threshold at which treatment A is less effective than treatment B by an amount that is clinically important to people with the condition of interest (favours B).

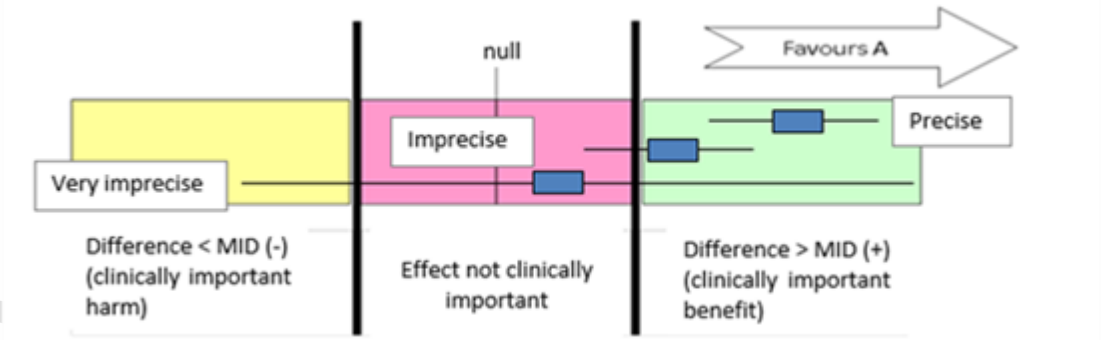
When the CI of the effect estimate is wholly contained in 1 of the 3 zones there is no uncertainty about the size and direction of effect, therefore, the effect estimate is considered precise; that is, there is no imprecision.

When the CI crosses 2 zones, it is uncertain in which zone the true value of the effect estimate lies and therefore there is uncertainty over which decision to make. The CI is consistent with 2 possible decisions, therefore, the effect estimate is considered to be imprecise in the GRADE analysis and the evidence is downgraded by 1 level ('serious imprecision').

When the CI crosses all 3 zones, the effect estimate is considered to be very imprecise because the CI is consistent with 3 possible clinical decisions and there is therefore a considerable lack of confidence in the results. The evidence is therefore downgraded by 2 levels in the GRADE analysis ('very serious imprecision').

Implicitly, assessing whether a CI is in, or partially in, a clinically important zone, requires the guideline committee to estimate an MID or to say whether they would make different decisions for the 2 confidence limits.

Figure 1: Assessment of imprecision and clinical importance in intervention reviews using GRADE



MID, minimally important difference

Defining minimally important differences for intervention reviews

The use of MIDs is not very well established in social care research. In this context, the approach taken for this guideline to defining MIDs was firstly for the technical team to search for published and validated MIDs. Where none could be located, the agreement with the committee, described in the protocols, was to apply the line of no statistically significant effect. That is, any statistically significant change was

considered to be clinically important and in that case, there was no imprecision. If there was no statistically significant change, the effect estimate was considered to have serious imprecision.

Qualitative reviews

Adapted GRADE-CERQual methodology for qualitative reviews

For qualitative reviews an adapted GRADE Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual) approach (Lewin 2015) was used. In this approach the quality of evidence is considered according to themes in the evidence. The themes may have been identified in the primary studies or they may have been identified by synthesising the reports of a number of studies. Quality elements assessed using GRADE-CERQual are listed and defined in Table 5. Each element was graded using the levels of concern summarised in Table 6. The ratings for each component were combined (as with other types of evidence) to obtain an overall assessment of quality for each theme as described in Table 7.

Table 5: Adaptation of GRADE quality elements for qualitative reviews

Quality element	Description
Risk of bias ('Methodological limitations')	Limitations in study design and implementation may bias interpretation of qualitative themes identified. High risk of bias for the majority of the evidence reduces confidence in review findings. Qualitative studies are not usually randomised and therefore would not be downgraded for study design from the outset (they start as high quality)
Relevance (or applicability) of evidence	This refers to the extent to which the evidence supporting the review findings is applicable to the context specified in the review question
Coherence of findings	This refers to the extent to which review findings are well grounded in data from the contributing primary studies and provide a credible explanation for patterns identified in the evidence
Adequacy of data (theme saturation or sufficiency)	This corresponds to a similar concept in primary qualitative research, that is, whether a theoretical point of theme saturation was achieved, at which point no further citations or observations would provide more insight or suggest a different interpretation of the particular theme. Individual studies that may have contributed to a theme or sub-theme may have been conducted in a manner that by design would have not reached theoretical saturation at an individual study level

Table 6: CERQual levels of concern (by quality element)

Level of concern	Definition
None or very minor concerns	Unlikely to reduce confidence in the review finding
Minor concerns	May reduce confidence in the review finding

Level of concern	Definition
Moderate concerns	Will probably reduce confidence in the review finding
Serious concerns	Very likely to reduce confidence in the review finding

Table 7: Overall confidence in the evidence in CERQual (by review finding)

Overall confidence level	Definition
High	It is highly likely that the review finding is a reasonable representation of the phenomenon of interest
Moderate	It is likely that the review finding is a reasonable representation of the phenomenon of interest
Low	It is possible that the review finding is a reasonable representation of the phenomenon of interest
Very low	It is unclear whether the review finding is a reasonable representation of the phenomenon of interest

Assessing risk of bias in qualitative reviews

The risk of bias in qualitative studies was assessed using the Critical Appraisal Skills Programme (CASP) checklist for qualitative studies (see Appendix H in Developing NICE guidelines: the manual; NICE 2014). The overall risk of bias was derived by assessing the risk of bias across the 6 domains summarised in Table 8.

Table 8: Risk of bias in qualitative studies

Aim and appropriateness of qualitative evidence	This domain assesses whether the aims and relevance of the study were described clearly and whether qualitative research methods were appropriate for investigating the research question
Rigour in study design or validity of theoretical approach	This domain assesses whether the study approach was documented clearly and whether it was based on a theoretical framework (such as ethnography or grounded theory). This does not necessarily mean that the framework has to be stated explicitly, but a detailed description ensuring transparency and reproducibility should be provided
Sample selection	This domain assesses the background, the procedure and reasons for the method of

	selecting participants. The assessment should include consideration of any relationship between the researcher and the participants, and how this might have influenced the findings
Data collection	This domain assesses the documentation of the method of data collection (in-depth interviews, semi-structured interviews, focus groups or observations). It also assesses who conducted any interviews, how long they lasted and where they took place
Data analysis	This domain assesses whether sufficient detail was documented for the analytical process and whether it was in accordance with the theoretical approach. For example, if a thematic analysis was used, the assessment would focus on the description of the approach used to generate themes. Consideration of data saturation would also form part of this assessment (it could be reported directly or it might be inferred from the citations documented that more themes could be found)
Results	This domain assesses any reasoning accompanying reporting of results (for example, whether a theoretical proposal or framework is provided)

Assessing relevance of evidence in qualitative reviews

Relevance (applicability) of findings in qualitative research is the equivalent of indirectness for quantitative outcomes, and refers to how closely the aims and context of studies contributing to a theme reflect the objectives outlined in the guideline review protocol.

Assessing coherence of findings in qualitative reviews

For qualitative research, a similar concept to inconsistency is coherence, which refers to the way findings within themes are described and whether they make sense. This concept was used in the quality assessment across studies for individual themes. This does not mean that contradictory evidence was automatically downgraded, but that it was highlighted and presented, and that reasoning was provided. Provided the themes, or components of themes, from individual studies fit into a theoretical framework, they do not necessarily have to reflect the same perspective. It should, however, be possible to explain these by differences in context (for example, the views of healthcare professionals might not be the same as those of family members, but they could contribute to the same overarching themes).

Assessing adequacy of data in qualitative reviews

Adequacy of data (theme saturation or sufficiency) corresponds to a similar concept in primary qualitative research in which consideration is made of whether a theoretical point of theme saturation was achieved, meaning that no further citations or observations would provide more insight or suggest a different interpretation of the theme concerned. As noted above, it is not equivalent to the number of studies contributing to a theme, but rather to the depth of evidence and whether sufficient quotations or observations were provided to underpin the findings.

Assessing clinical importance in qualitative reviews

For themes stemming from qualitative findings, clinical importance was agreed by the committee taking account of the generalisability of the context from which the theme was derived and whether it was sufficiently convincing to support or warrant a change in current practice, as well as the quality of the evidence.

Evidence statements

Evidence statements are presented in the main body of each evidence report. They summarise key features in the available evidence. The wording reflects the certainty or uncertainty in the estimate of effect (quantitative evidence) or review finding (qualitative evidence). In the mixed methods reviews evidence statements are presented by intervention and then by outcome or theme, starting with the quantitative evidence and then providing the associated qualitative statements. In this way, the quantitative and qualitative evidence was brought together for the committee's consideration but this is not presented as a formal technique for synthesis of mixed methods data.

The evidence statements for both quantitative and qualitative findings encompass the following features:

- the quality of the evidence
- the numbers of studies and participants for the outcome concerned (quantitative evidence) or that contributed to themes (qualitative evidence)
- a brief description of the participants
- a brief description of the intervention (particularly mode of delivery)
- where relevant, an indication of the direction of effect (for example, if an intervention is beneficial or harmful compared with another, or whether there is no difference between the tested interventions)
- where relevant, whether or not the estimate of effect is clinically important.

Reviewing economic evidence

Inclusion and exclusion of economic studies

A global economic literature search was undertaken for the provision of support for adult carers to cover all 9 review questions in the guideline.

Titles and abstracts of articles identified through the economic literature searches were independently assessed for inclusion using the predefined eligibility criteria listed in Table 9.

Table 9: Inclusion and exclusion criteria for systematic reviews of economic evaluations

Inclusion criteria
Intervention or comparators in accordance with the guideline scope
Study population in accordance with the guideline scope
Full economic evaluations (cost-utility, cost-effectiveness, cost-benefit or cost-consequence analyses) assessing both costs and outcomes associated with interventions of interest
Exclusion criteria
Abstracts containing insufficient methodological details
Cost-of-illness type studies

Once the screening of titles and abstracts was completed, full-text copies of potentially relevant articles were requested for detailed assessment. Inclusion and exclusion criteria were applied to articles obtained as full-text copies.

Details of economic evidence study selection, lists of excluded studies, economic evidence tables, the results of quality assessment of economic evidence (see below) and economic evidence profiles are presented in each of the evidence reports.

Appraising the quality of economic evidence

The quality of economic evidence was assessed using the economic evaluations checklist specified in Developing NICE guidelines: the manual (NICE 2014). See the evidence reports for further details.

Economic modelling

The aims of the economic input to the guideline were to inform the guideline committee of potential economic issues to ensure that recommendations represented a cost effective use of resources. Economic evaluations aim to integrate data on health and social care benefits with the costs of different care options. In addition, the economic input aimed to identify areas of high resource impact; these are

recommendations which (while cost effective) might have a large impact for commissioners of health and social care and so need special attention.

For the provision of support for adult carers, the guideline committee prioritised the following review questions where it was thought that economic considerations would be particularly important in formulating recommendations.

- What are the most effective and cost-effective interventions, tools or approaches to support adult carers to enter, remain in, and/or return to (i) work, (ii) education, and (iii) training?
- What practical, social and community support interventions for adult carers are effective, cost effective, and acceptable to them?
- What psychological and emotional support interventions are effective, cost effective and acceptable to adult carers for maintaining and/or improving their health and wellbeing?

Original economic modelling was not undertaken for the review question about practical, social and community support interventions for adult carers as there was included economic evidence and a lack of effectiveness data to undertake new modelling.

Original economic modelling was not undertaken for the review question about psychological and emotional support interventions as there were a number of included economic studies and insufficient effectiveness data to inform new modelling.

Although effectiveness evidence was not identified from the effectiveness review for the question about tools or approaches to support adult carers to enter, remain in, and/or return to work, education, and training, some grey literature was found that allowed a relationship between hours of caring and the probability of being in work to be estimated. Therefore, this data was used to undertake new economic modelling of the cost effectiveness of replacement care for adult carers not working due to caring.

Cost effectiveness criteria

NICE's report Social value judgements: principles for the development of NICE guidance sets out the principles that committees should consider when judging whether an intervention offers good value for money. In general, an intervention was considered to be cost effective if any of the following criteria applied (provided that the estimate was considered plausible):

- the intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more effective compared with all the other relevant alternative strategies)
- the intervention cost less than £20,000 per quality adjusted life year (QALY) gained compared with the next best strategy

- the intervention provided important benefits at an acceptable additional cost when compared with the next best strategy.

The committee's considerations of cost effectiveness are discussed explicitly under the heading 'Cost effectiveness and resource use' in the relevant evidence reports.

Details of the cost effectiveness analyses undertaken for the guideline are presented in Appendix J of the evidence reports.

Developing recommendations

Guideline recommendations

Recommendations were drafted on the basis of the committee's interpretation of the available evidence, taking account of the balance of benefits, harms, acceptability and costs between different courses of action. When evidence was of poor quality, conflicting or absent, the committee drafted recommendations based on their expert opinion. The considerations for making consensus-based recommendations include the balance between potential benefits and harms, the economic costs or implications compared with the economic benefits, current practices, legislation and statutory guidance, recommendations made in other relevant guidelines, carers' preferences and equality issues.

The main considerations specific to each recommendation are outlined under the heading 'The committee's discussion of the evidence' within each evidence report.

For further details refer to Developing NICE guidelines: the manual (NICE 2014).

Research recommendations

When areas were identified for which evidence was lacking, the committee considered making recommendations for future research. For further details refer to Developing NICE guidelines: the manual (NICE 2014).

Validation process

This guideline was subject to a 6-week public consultation and feedback process. All comments received from registered stakeholders were responded to in writing and posted on the NICE website at publication. For further details refer to Developing NICE guidelines: the manual (NICE 2014). [The details in this paragraph will apply at publication]

Updating the guideline

Following publication, NICE will undertake a surveillance review to determine whether the evidence base has progressed sufficiently to consider altering the

guideline recommendations and warrant an update. For further details refer to Developing NICE guidelines: the manual (NICE 2014).

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