National Institute for Health and Care Excellence

Draft for consultation

Safeguarding adults in care homes

Methods

NICE guideline tbc

Supplementary material A

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Draft for consultation

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

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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.

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Contents

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 safeguarding adults in care homes.

This guideline will also be used to develop the NICE quality standard for safeguarding adults in care homes.

What this guideline covers

Groups that are covered

Adults, aged 18 or over, who are accessing care and support in care homes that are registered with the Care Quality Commission.

Specific consideration will also be given to adults using care homes who:

- Have difficulty communicating or who do not communicate using speech (and may therefore find it harder to disclose abuse and neglect).
- May lack capacity to make certain decisions or choices.
- Have protected characteristics which may lead to assumptions about what is or isn't acceptable behaviour.

Key areas that are covered

- Identifying abuse in care homes.
- Identifying neglect in care homes.
- Managing safeguarding concerns about abuse and neglect.
- Supporting people directly affected.
- Multi-agency working and communication.
- Training and skills for safeguarding.
- Embedding learning in organisations to prevent abuse and neglect.

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

Methods

Introduction

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 – updated 2018).

Declarations of interest 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 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.

The review questions were based on the following frameworks:

- intervention reviews – using population, intervention, comparison and outcome (PICO)
- diagnostic reviews and reviews of prediction model accuracy – using population, diagnostic test (index test), reference standard and target condition (PIRT)
- qualitative reviews – using population, phenomenon of interest and context.

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 reviews corresponding to each question (or group of questions) are summarised in Table 1.

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

Evidence review	Review question	Type of review
[A] Signs and symptoms of abuse and neglect	• What indicators should alert people to abuse in care homes? • What indicators should alert people to neglect in care homes?	Diagnostic

Evidence review	Review question	Type of review
[B] Barriers and facilitators to identifying abuse and neglect in care homes	• What are the barriers and facilitators to identifying abuse in care homes? • What are the barriers and facilitators to identifying neglect in care homes?	Qualitative
[C] Tools to support recognition and reporting of safeguarding	• What tools and ways of working support effective or accurate recognition and reporting of safeguarding concerns in care homes?	Intervention
[D] Responding to and managing safeguarding concerns	• What approaches are effective in responding to and managing safeguarding concerns? • What is the acceptability of approaches for responding to and managing safeguarding concerns?	Mixed, quantitative (intervention) and qualitative
[E] Support and information needs	• What are the perceived support and information needs for all involved when a safeguarding concern is raised within a care home setting?	Qualitative
[F] Strategic partnership working	• What are the barriers and facilitators to effective strategic partnership working, information sharing and communication involving care homes, local authorities, Safeguarding Adults Boards and local health organisations?	Qualitative
[G] Multi agency working at the operational level	• What are the barriers and facilitators to effective multi-agency working at the individual operational level?	Qualitative
[H] Training models in safeguarding[1]	• What is the effectiveness of different models of training for safeguarding in care homes? • What is the acceptability of different models of training	Mixed, quantitative (intervention) and qualitative

Evidence review	Review question	Type of review
	for safeguarding in care homes?	
[l] Embedding organisational learning	• What is the effectiveness of approaches to embedding organisational learning about safeguarding in care homes in order to prevent abuse? • What is the acceptability of approaches to embedding organisational learning about safeguarding in care homes in order to prevent abuse? And what are the barriers and facilitators to embedding organisational learning about safeguarding in care homes in order to prevent abuse? • What is the effectiveness of approaches to embedding organisational learning about safeguarding in care homes in order to prevent neglect? • What is the acceptability of approaches to embedding organisational learning about safeguarding in care homes in order to prevent neglect And what are the barriers and facilitators to embedding organisational learning about safeguarding in care homes in order to prevent neglect?	Mixed, quantitative (intervention) and qualitative

[1] *Original economic analysis conducted*

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

- Supplement A (Methods; this document)
- Supplement B (NGA staff list).

Searching for evidence

Scoping search

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.

Systematic literature search

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

Databases were searched using subject headings, free-text terms and, where appropriate, study type filters. Where possible, searches were limited to retrieve studies published in English. All the searches were performed between December 2018 and September 2019 in the following databases: Applied Social Sciences Index and Abstracts (ASSIA), CINAHL, Cochrane Library, Embase, 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. Searches for grey literature were conducted in Health Management Information Consortium (HMIC), OpenGREY and PsycEXTRA across the guideline. For review question C, internet searches of websites to identify health and social care guidance were additionally undertaken to help optimise the retrieval of results.

Searches were run once for all reviews during development. The guideline committee and the NGA technical 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 A, B and C, 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 December 2019. Any studies added to the databases after December 2019 (including those published before December 2019 but not yet indexed) were not considered for inclusion.

Details of the search strategies, including the study-design filters used and databases searched, are provided in Appendix B of each evidence review.

Economic systematic literature search

Systematic literature searches were also undertaken to identify published economic evidence. Databases were searched using subject headings, free-text terms and, where appropriate, an economic evaluations search filter.

A single search, using the population search terms used in the evidence reviews, was conducted to identify economic evidence in the NHS Economic Evaluation Database (NHS EED) and HTA. Another single search, using the population search terms used in the evidence reviews combined with an economic evaluations search

filter, was conducted in Medline, Medline in Process and Embase. Where possible, searches were limited to studies published in English.

As with the general literature searches, the economic literature searches were updated at least 6–8 weeks in advance of the final committee meetings before consultation on the draft guideline; these updates were completed during December 2019.

Details of the search strategies, including the study-design filter used and databases searched, are provided in Appendix B of each evidence review.

Quality assurance

Search strategies were quality assured by cross-checking reference lists of relevant studies, analysing search strategies from published systematic reviews and asking members of the committee to highlight key studies. The principal search strategies for each search were also quality assured by a second information scientist using an adaptation of the PRESS 2015 Guideline Evidence-Based Checklist (McGowan 2016). In addition, all publications highlighted by stakeholders at the time of the consultation on the draft scope were considered for inclusion.

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 review).
- 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 review and in a more detailed evidence table (see Appendix E of each evidence review).
- Included studies were critically appraised using an appropriate checklist as specified in Developing NICE guidelines: the manual (NICE 2014 – updated 2018). 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 review 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) and complex review questions 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.

Systematic reviews with meta-analyses were considered to be the highest quality evidence that could be selected for inclusion.

For intervention reviews, or the intervention component of mixed methods reviews, randomised controlled trials (RCTs) were considered to be the most robust type of study design that could produce an unbiased estimate of intervention effects. However concerned as they were about a possible dearth of evidence for this topic the committee agreed to consider studies using an observational design. 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 considered the potential limitations of these data in their discussions.

In one of the intervention reviews (C) which was designed to locate effectiveness data about tools to support recognition and reporting of safeguarding concerns, the committee stated, a priori that they wished to also review the 'tools' themselves. This was partly owing to the fact that they did not expect to locate any data about the effectiveness of these tools but knowing they are already used in practice, the committee wanted to draw conclusions about the quality of the tools (or 'health and social care guidance documents') through a transparent review of the evidence retrieved from the systematic search for review question C and then use extracted data as a basis for recommendations about recognising and reporting safeguarding concerns. A detailed explanation of the approach taken to synthesising and critically appraising the health and social care guidance documents is given in evidence report C and elsewhere in this supplement under the heading 'analysis of health and social care guidance'.

For the diagnostic reviews, cohort and cross-sectional studies were prioritised for inclusion although in the event, none were located.

For qualitative reviews, or the qualitative component of mixed methods reviews, 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.

In terms of further inclusion/ exclusion criteria the committee adopted a step wise approach to a number of reviews, applying certain additional criteria, a priori, which related to study setting. This allowed them to balance the need to focus reviews and locate relevant data against their concerns about a potential paucity of evidence on which to draft recommendations. For example, for the quantitative reviews or the quantitative components of mixed methods reviews, the committee stated that if fewer than a certain number (detailed in each protocol) of UK studies were located then they would consider data from research conducted in Canada and Australia, and in high income countries (according to the World Bank) in Europe. This is because they felt that the care and support systems were sufficiently similar to the UK for effect size data to be transferable, although they reflected on any potential limitations of these data during their discussions. The committee did not wish to consider qualitative data from outside the UK because they felt that people's attitudes and views would be so closely tied to their experiences of care home policy and practice in the UK and to safeguarding legislation and cultural attitudes that transferring these subjective findings would be too unreliable.

For most of the reviews, regardless of study type, the committee favoured a publication cut-off date of 2008. They linked this with the Mental Capacity Act 2005, which came into force in 2007 and which is fundamental to safeguarding activity in England and Wales. The committee wanted to ensure that the data on which their recommendations are based were generated since the implementation of the Act. The only exception to this decision was for review B in which a year 2000 cut-off date was adopted. This date is associated with the publication of the 'No Secrets' guidance on protecting vulnerable adults from abuse, although it was later repealed by the Care Act 2014, which contains replacements and mandatory requirements around adult safeguarding. The committee felt 2000 was the key time point from which barriers and facilitators were likely to have remained more or less unchanged and would therefore still be relevant to current practice. Where barriers or facilitators were reported in pre 2014 studies, the committee were able, through their own expertise, to judge whether they were subsequently addressed by the Care Act and how to reflect this in recommendations.

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 review.

Narrative reviews, posters, letters, editorials, comment articles, unpublished studies and studies published in languages other than English were excluded. Conference abstracts were not considered for inclusion because conference abstracts typically do not have sufficient information to allow for full critical appraisal.

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 and intervention reviews

Pairwise meta-analysis

Meta-analysis of results from RCTs or non-randomised comparative studies was not possible in any of the mixed methods reviews because of differences in populations, interventions, comparisons or methods. Results were presented individually for each study.

When evidence was based on studies that reported descriptive data or medians with interquartile ranges or p values, this information was included in the corresponding GRADE tables (see below) without calculating relative or absolute effects. Consequently, certain aspects of quality assessment such as imprecision of the effect estimate could not be assessed as per standard methods for this type of evidence and subjective ratings were considered instead.

Analysis of health and social care guidance

In review C, an intervention question, no quantitative research evidence was identified. According to the protocol, health and social care guidance documents were therefore included on the basis of the committee's opinion that these would provide the 'next best' available source of evidence. Relevant data were extracted from each guidance document which comprised advice about how to recognise and report safeguarding concerns in care homes. Concepts relating to different types of abuse and neglect were identified, given an overall 'median' AGREE II rating (see below) and presented to the committee in evidence statements for use as a basis for recommendations about recognising and reporting safeguarding concerns. Further details about the process of combining and assessing evidence from health and social care guidance are provided in evidence report C.

Data synthesis for qualitative components and qualitative reviews

Where possible, a meta-synthesis was conducted to combine evidence from qualitative studies. Whenever studies identified a qualitative theme relevant to the protocol, this was extracted and the main characteristics were summarised. When all themes had been extracted from studies, common concepts were categorised 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 new 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 (D, H and I), the NGA technical team synthesised and presented the data from quantitative and qualitative studies separately but in the same committee meeting and where data were available, organised around the protocol interventions. The committee integrated these mixed data through their discussions and interpretation of the results. Their interpretation of the relationship between the quantitative and qualitative data is described in the committee's discussion of the evidence section of all the mixed methods reviews.

Appraising the quality of evidence

Intervention studies

GRADE methodology for intervention reviews

For intervention reviews and intervention components, the evidence for outcomes from included RCTs and comparative non-randomised studies was evaluated and presented using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology developed by the international GRADE working group. When before and after studies were included in reviews, they were analysed where possible using modifications of the GRADE principles intended for RCTs.

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 and any meta-analysis results. 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 and non-randomised studies assessed by ROBINS-I start as 'high' quality evidence, other non-randomised

and before and after studies start 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 non-randomised 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')	This refers to limitations in study design or implementation that reduce the internal validity of the evidence
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 few participants or few events of interest, resulting in wide confidence intervals that cross minimally 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
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

Overall quality grading	Description
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 – updated 2018).

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 2019).

For systematic reviews of RCTs the AMSTAR checklist was used and for systematic reviews of other study types the ROBIS checklist was used (see Appendix H in Developing NICE guidelines: the manual (NICE 2014 – updated 2018).

For non-randomised studies the ROBINS-I checklist was used (see Appendix H in Developing NICE guidelines: the manual (NICE 2014 – updated 2018).

Assessing inconsistency in intervention reviews

Inconsistency refers to unexplained heterogeneity in results of meta-analysis. When estimates of treatment effect vary widely across studies (that is, there is heterogeneity or variability in results), this suggests true differences in underlying effects. Inconsistency is, thus, only truly applicable when statistical meta-analysis is conducted (that is, results from different studies are pooled). When outcomes were derived from a single study the rating ‘no serious inconsistency’ was used when assessing this domain, as per GRADE methodology (Santesso 2016).

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 importance in intervention reviews

Imprecision in GRADE methodology refers to uncertainty around the effect estimate and whether or not there is an important difference between interventions (that is, whether the evidence clearly supports a particular recommendation or appears to be consistent with several candidate recommendations). 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 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 two treatments. Three decision-making zones can be differentiated, bounded by the thresholds for minimal importance (minimally important differences; MIDs) for benefit and harm.

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.

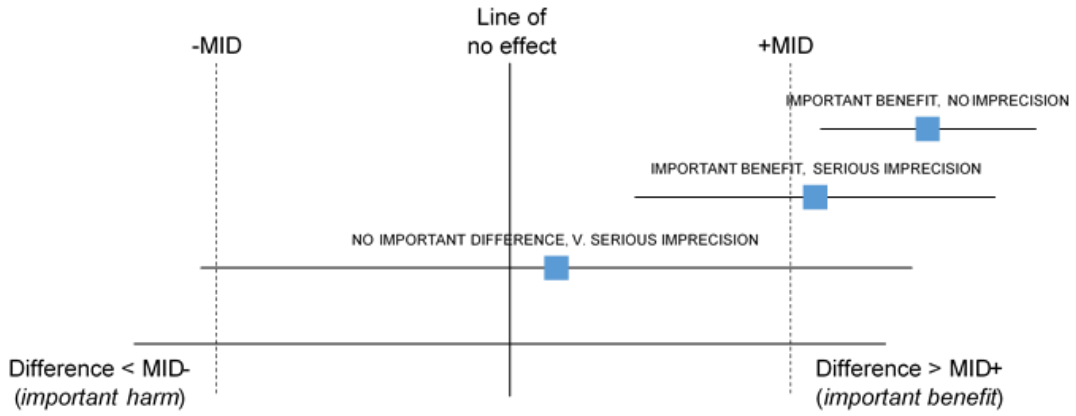
When the CI crosses 2 zones, it is uncertain in which zone the true value of the effect estimate lies and therefore there is uncertainty over which decision to make. The CI is consistent with 2 possible decisions, therefore, the effect estimate is considered to be imprecise in the GRADE analysis and 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 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, an important zone, requires the guideline committee to estimate an MID or to say whether they would make different decisions for the 2 confidence limits.

Finally, for outcomes where insufficient information was provided for systematic definition of importance (for example those without confidence intervals or measures of variance), imprecision was assessed on the basis of sample size and the committee subjectively considered the importance of each individual finding.

Figure 1: Assessment of imprecision and 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 important in practice 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

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 considering 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 . 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 .

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
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 methodological limitations in qualitative reviews

Methodological limitations in qualitative studies were assessed using the Critical Appraisal Skills Programme (CASP) checklist for qualitative studies (see appendix H in Developing NICE guidelines: the manual (NICE 2014 – updated 2018). Overall methodological limitations were derived by assessing the methodological limitations across the 6 domains summarised in Table .

Table 8: Methodological limitations 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 importance in qualitative reviews

For themes stemming from qualitative findings, 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.

Appraising the quality of health and social care guidance

Assessing quality of guidelines

Health and social care guidance documents were included in review C and used as a basis for drafting recommendations about recognising and reporting safeguarding concerns. Relevant guidance documents were assessed for quality using the AGREE

II instrument (Table). The tool assesses 6 domains: scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability and editorial independence.

Within each domain there is a set of questions, each of which is scored using a 7-point scale (1 – 'strongly disagree' to 7 – 'strongly agree'). Each section is rated and then an overall score for that domain is calculated. Two reviewers independently rated all identified guidelines using this method (see the AGREE II for detailed instructions). Further details about the process of combining and assessing evidence from health and social care guidance are provided in evidence report C.

Table 9: Assessing quality of guidelines

Domain	Description
Scope and purpose	Assesses the aim of the guideline, the specific health questions, and the target population
Stakeholder involvement	Assesses the extent to which the guideline involved the appropriate stakeholders, and whether it represents the views of intended users
Rigour of development	Assesses the methods used to gather and synthesise the evidence and to construct the recommendations
Clarity of presentation	Assesses the language, format and structure of the guideline
Applicability	Assesses likely barriers and facilitators of implementation, uptake and resource implications of the guideline
Editorial independence	Assesses the likelihood of the recommendations being biased and potential conflict of interests

Evidence statements

In line with Developing NICE guidelines: the manual (NICE 2014 – updated 2018) evidence statements were only included in reviews where neither GRADE nor GRADE-CERQual were used to synthesise and appraise the quality of evidence. The report to which this applied was C, where evidence statements were used to summarise key features in the available health and social care guidance. The wording of the evidence statements reflects the quality of the summarised evidence. Evidence statements are presented by theme and subtheme, and encompass the following features:

- the quality of the evidence, reflecting the AGREE II assessment
- the numbers of guidance documents that contributed to the theme
- the type of abuse or neglect to which the theme refers.

Reviewing economic evidence

A global economic literature search was undertaken for the provision of support for adult carers to cover all 18 review questions in the guideline.

Inclusion and exclusion of economic studies

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

Table 10: 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
Poster presentations and abstracts in conference proceedings
Non-English language papers
Abstracts containing insufficient methodological details

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.

Lists of included economic studies with their evidence tables, as well as studies excluded after obtaining full text with reasons for exclusion, are provided in Appendix H and Appendix L, respectively, of the relevant evidence reports. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) for the search of economic evaluations is presented in Appendix G of each Evidence Review Report.

Appraising the quality of economic evidence

The applicability and quality of economic evaluations in this guideline were appraised using the methodology checklist reported in Developing NICE guidelines: the manual (NICE 2014 – updated 2018), Appendix H, for all studies that met the inclusion criteria.

The methodological assessment of economic studies considered in this guideline has been summarised in economic evidence profiles that were developed for each review question for which economic evidence was available. All studies that fully or partially met the applicability and quality criteria described in the methodology checklist were considered during the guideline development process.

Economic profiles of all economic studies that were considered during guideline development, including de novo economic analyses undertaken for this guideline, are provided in Appendix I of the respective Evidence Review Reports.

Economic modelling

The aims of the economic input to the guideline were to inform the guideline committee of potential economic issues related safeguarding adults in care homes in order 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, as these need to be supported by robust evidence on cost effectiveness.

Areas for economic modelling were prioritised by the committee. The rationale for prioritising review questions for economic modelling was set out in an economic plan agreed between NICE, the committee, and members of the NGA technical team. Economic modelling was undertaken in areas with likely major resource implications, where the current extent of uncertainty over cost effectiveness was significant and economic analysis was expected to reduce this uncertainty. The following economic questions were selected as key issues that were addressed by economic modelling:

- Tools and ways of working for effective recognition and reporting of safeguarding concerns in care homes
- Effective approaches to responding to safeguarding concerns in care homes
- Effectiveness and acceptability of different models of training for safeguarding in care homes
- Effectiveness and acceptability of approaches to embed organisational learning about safeguarding in care homes in order to prevent abuse and neglect.

No original economic modelling was undertaken for the review question about approaches to responding to safeguarding concerns in care homes as review did not find any quantitative evidence on which an economic model could be based.

No original economic modelling was undertaken for the review question about tools and ways of working for effective recognition and reporting of safeguarding concerns in care homes as there was no comparative data on the effectiveness of different tools on which an economic model could be based.

No original economic modelling was undertaken for the review question about embedding organisational learning about safeguarding in care homes as the review did not find any quantitative evidence on which an economic model could be based.

Quantitative evidence was not found on training models and modes of training. However, a hypothetical “what-if” model was developed to support the research recommendation the committee made with respect to a comparison of face-to-face training and e-learning approaches for safeguarding training for adults in care homes (evidence report H).

Cost effectiveness criteria

NICE’s report The NICE Principles 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 committee's considerations of cost effectiveness are discussed explicitly under the heading 'The committee's discussion of the evidence, Cost effectiveness and resource use' in the relevant evidence reviews.

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 and costs between different courses of action. When effectiveness and economic 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, recommendations made in other relevant guidelines, person's 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 review.

For further details refer to Developing NICE guidelines: the manual (NICE 2014 – updated 2018).

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 – updated 2018).

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 – updated 2018).

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 – updated 2018).

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