National Institute for Health and Care Excellence

Draft for consultation

Advocacy services for adults with health and social care needs

NICE guideline: methods

NICE guideline TBC

Supplement 1: Methods

June 2022

Draft for Consultation

Evidence reviews were developed by the National Guideline Alliance hosted by 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.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive. All NICE guidance is subject to regular review and may be updated or withdrawn.

ISBN:

Contents

Development of the guideline

Remit

The National Institute for Health and Care Excellence (NICE) commissioned the National Guideline Alliance (NGA) to develop a new social care guideline on advocacy services for adults with health and social care needs.

What this guideline covers

Population

People with health and social care needs in all adult settings, including

- Those who have a legal right to an advocate
- Those who fund their own social care
- Young people under 18 who are accessing adult services

Key themes

- Identifying those who would benefit from advocacy
  - Who has a legal right to advocacy?
  - Who else would benefit from advocacy and how do we identify them?
- Facilitating advocacy
  - Improving access to advocacy (including addressing barriers)
  - Enabling and supporting effective advocacy (for example: time, approach, environment, including virtual and non-face-to-face services)
  - Information about effective advocacy and signposting to services
  - Monitoring services and collecting data for quality improvement
  - Planning and commissioning services for advocacy (including for those who do not have a legal right to advocacy)
  - Training and skills for practitioners who work with advocates
- Delivering advocacy
  - What does effective advocacy look like?
  - Partnership working and relationships with families and carers, commissioners and providers
  - Training, skills and support for advocates

The evidence reviews corresponding to each area of the key themes in the scope are summarised below.

Table 1: Index to evidence reviews

Evidence review	Scope area
[A] Who has a legal right to advocacy?	Who has a legal right to advocacy
[B] Who else would benefit from advocacy and how do we identify them?	Who would benefit from advocacy and how do we identify them?

Evidence review	Scope area
[C] Information about effective advocacy and signposting to services	Information about effective advocacy and signposting to services
[D] Improving access to advocacy	Improving access to advocacy (including addressing barriers)
[E] Enabling and supporting effective advocacy	Enabling and supporting effective advocacy (for example: time, approach, environment, including virtual and non-face-to-face services)
[F] What does effective advocacy look like?	What does effective advocacy look like?
[G] Partnership working and relationships with families and carers, commissioners and providers	Partnership working and relationships with families and carers, commissioners and providers
[H] Planning and commissioning services for advocacy	Planning and commissioning services for advocacy (including for those who do not have a legal right to advocacy)
[I] Training, skills and support for advocates	Training, skills and support for advocates
[J] Training and skills for practitioners who work with advocates	Training and skills for practitioners who work with advocates
[K] Monitoring services and collecting data for quality improvement	Monitoring services and collecting data for quality improvement

What this guideline does not cover

- Training courses to help people to advocate for themselves without third party support
- Deciding when to provide non-instructed advocacy (although the guideline will cover the provision of this service)
- Employment support advocacy
- Policy-based advocacy (including lobbying)
- Funding arrangements
- Legal decisions regarding mental capacity and mental health including assessing capacity

Methods

It was not anticipated that evidence reviews would identify significant new research on advocacy beyond that which has been identified in previous NICE guidelines (for example, the NICE guideline on decision-making and mental capacity). Therefore, new evidence reviews were not conducted for this guideline.

Recommendations on advocacy were identified from existing NICE guidelines and a call for evidence was issued to identify any key sources that may have been omitted from existing NICE guidelines. Statements relating to the key themes in the scope were drawn from the documents received and formal consensus methods were used to vote on these.

Recommendations were based on the statements, recommendations from existing NICE guidelines and the knowledge and experience of the guideline committee (see 'Developing recommendations' below).

Declarations of interest were recorded according to the NICE conflicts of interest policy.

Identifying recommendations from existing NICE guidelines

Searching for existing recommendations on advocacy

A targeted keyword search of existing published NICE recommendations was conducted to identify advocacy recommendations in existing NICE guidance.

The NGA team provided the following list of keywords to the NICE team to conduct the search:

- advoca*
- self-advocacy
- voice
- "independent support" or "independent-support"
- "third party support" or "third-party-support"
- intermediary
- champion
- empower*
- "mentor support" or "mentor-support"
- "peer support" or "peer-support"
- "crisis intervention" or "crisis-intervention"
- lobby or lobbying

An initial search was conducted in March 2020. A top-up search was conducted in March 2021 to identify additional recommendations from guidelines published since the initial search. The following, more focused, list of keywords was used for this search:

- advoca*
- voice
- intermediary
- champion
- empower*

Extraction of recommendations and thematic analysis

The identified recommendations were added to Microsoft Excel, along with a record of the guideline title and identifier and the year of publication.

Identified recommendations were screened and recommendations that did not mention advocacy were excluded.

Recommendations that mentioned advocacy were reviewed and either categorised into the pre-specified themes stated in the scope for this guideline or excluded if the concepts covered by the recommendations were not relevant to any of the key themes. Existing recommendations identified for each area of the scope are presented in appendix F of the relevant evidence report.

Call for evidence

A targeted call for evidence was conducted to identify any key sources that may have been omitted from existing NICE guidelines. This was issued directly to registered stakeholders and via the NICE website. The call for evidence lasted for 2 weeks.

The call for evidence asked for evidence or guidelines published since 2005, or unpublished information relating to research conducted since 2005, that covered:

- What effective advocacy looks like
- How to improve access to advocacy services
- Information and signposting to advocacy services
- Planning, commissioning and monitoring of advocacy services
- Advocacy services working with families and carers
- Training and skills for advocates

The following material was not considered as part of the call for evidence:

- promotional material
- unsubstantiated or non-evidence-based assertions of effectiveness
- opinion pieces or editorial reviews
- potentially unlawful or other inappropriate information

Additional evidence identified by the guideline committee

Following the call for evidence, the committee were presented with a summary of the responses received and asked to identify any further evidence they were aware of that was within the above parameters.

Inclusion/exclusion criteria

Inclusion and exclusion of documents received in response to the call for evidence or from the guideline committee was based on the following criteria:

Inclusion criteria

- UK-based
- National focus. For guidelines and policy documents this was interpreted as the policies/guidance applying nationally. For systematic reviews and primary research this was interpreted as studies having been conducted in the national context of the scope for this guideline (the English health and social care system)
- Conducted within the last 10 years (Note. a narrower date range was used than specified in the call for evidence due to the volume of documents received).

Exclusion criteria

- Publication not based on evidence
- Publication based on non-systematic review or case-studies
- No key findings or recommendations reported that were relevant to the key themes in the scope

A list of excluded documents for each area of the scope, including reasons for exclusion is presented in Appendix D of the corresponding evidence review.

Appraising the quality of evidence

Existing NICE guidelines

The quality of evidence underpinning recommendations from existing NICE guidelines was assessed as part of the development of the original guidelines, as outlined in their methods sections. However, as the quality of evidence is in part context-dependent, the overall quality of the guidelines was assessed for the purpose of this guideline using the second version of the Appraisal of Guidelines of Research and Evaluation (AGREE II) instrument (Brouwers 2010). Where guidelines have been updated, quality assessment was based on the information available for the version of the guideline that corresponded to the version that the relevant recommendation was identified from. Further, when developing recommendations (see 'Developing recommendations' below), the committee considered the original context for the recommendation and how this could be generalised to a new context.

AGREE II is intended for assessing the quality of systematically developed clinical practice guidelines, including assessments of methodological rigour and transparency. The tool assesses 6 domains (see Table 1): 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 a score for each domain, as well as an overall rating, is calculated (see the AGREE II for detailed instructions).

Table 2: AGREE II domains

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

Call for evidence and evidence identified by the guideline committee

Assessing methodological limitations in guidelines

Methodological limitations in guidelines from the call for evidence or identified by the guideline committee were also assessed using AGREE II. As described above, AGREE II is intended for assessing the quality of clinical practice guidelines; however, the documents included were broader than clinical practice guidelines, for example guidelines from government and social care organisations and, therefore, they were not developed to meet the standards set by AGREE II. Despite this, AGREE II was considered to be the best available tool for use in the context of NICE guideline development to support a systematic appraisal of the way in which the included guidance documents were developed.

Assessing methodological limitations in systematic reviews

Methodological limitations in systematic reviews were assessed using the Risk of Bias in Systematic Reviews (ROBIS) tool (Whiting, 2016; see appendix H in Developing NICE guidelines: the manual). The tool assesses concerns with the review process in 4 domains (see Table 2): study eligibility criteria, identification and selection of studies, data collection and study appraisal, and synthesis and findings. Within each domain there is a set of signalling questions, each of which is answered with yes, probably yes, probably no, no, or no information. The level of concern about each domain is then summarised with low, high or unclear concerns, before an overall rating of risk of bias in the review, which is either low, high or unclear.. The overall rating of risk of bias in the review was not considered to purely be a 'count' of the individual domain ratings, therefore no strict cut-offs were used to equate a certain level or number of domain ratings with a particular overall assessment. Judgements about the overall risk of bias in reviews were also influenced by considerations about the extent to which the domain concerns were acknowledged by authors and would be likely to undermine confidence in the review findings.

Table 3: ROBIS domains

Domain	Description
Study eligibility criteria	This domain assesses whether eligibility criteria were clear and appropriate and whether there was evidence that objectives and eligibility criteria were pre-specified
Identification and selection of studies	This domain assesses whether methods of study identification and selection were appropriate and whether efforts were made to minimise errors in selection
Data collection and study appraisal	This domain assesses whether data was extracted from studies appropriately, if appropriate tools were used to assess methodological quality and whether efforts were made to minimise errors in data collection and study appraisal
Synthesis and findings	This domain assesses whether data synthesis was appropriate and followed a pre-specified plan and whether the findings were robust

ROBIS in intended for assessing the quality of systematic reviews. However, the documents assessed using this tool included reviews that were not intended by the authors to be systematic. Therefore, they were not developed to meet the standards of systematic reviews assessed by ROBIS. Despite this, ROBIS was considered to be the best available tool for use in the context of NICE guideline development to support a systematic appraisal of the way in which the included review documents were developed.

Assessing methodological limitations in qualitative studies

Methodological limitations in qualitative studies were assessed using the Critical Appraisal Skills Programme (CASP) checklist (CASP Programme 2018) for qualitative studies (see appendix H in Developing NICE guidelines: the manual). Data from the qualitative studies were used to inform statements rather than to underpin a thematic synthesis and development of review findings, so GRADE-CERQual methodology could not be applied. This is because GRADE-CERQual is intended for use assessing the confidence of evidence from reviews of qualitative research rather than the quality of an individual study or study findings.

The CASP tool assesses methodological limitations across 10 areas (see Table 3): aims of the research, appropriateness of using qualitative methodology, research design, recruitment strategy, data collection, relationship between researcher and participants, ethical considerations, data analysis, findings, and value of research.

Table 4: CASP qualitative checklist domains

Domain	Description
Aims of the research	This domain assesses whether the aims, importance and relevance of the study were described clearly
Appropriateness of using qualitative methodology	This domain assesses whether qualitative research methods were appropriate for investigating the research question, for example, does the study aim to interpret or illuminate actions or subjective experiences
Research design	This domain assesses whether the study approach has been documented clearly and

Domain	Description
	if it was justified, for example, based on a theoretical framework
Recruitment strategy	This domain assesses the procedure and reasons for the method of selecting participants and whether reasons for non-participation are discussed
Data collection	This domain assesses the documentation and justification of the method of data collection (in-depth interviews, semi-structured interviews, focus groups or observations). It also assesses where interviews took place, what form the data took (e.g., tape recordings, written notes) and data saturation
Relationship between researcher and participants	This domain assesses who conducted any interviews, any potential biases they might have and how these might have influenced the research questions or data collection. The assessment should include consideration of how the researcher responded to events during the study
Ethical considerations	This domain assesses whether ethical approval was obtained and ethical standards maintained, including issues of informed consent, confidentiality and the effect of the study on participants
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 whether contradictory data are taken into account and whether the researcher considered their own biases during analysis and selection of data for presentation also forms part of this assessment
Findings	This domain assesses whether findings are credible, reported explicitly and discussed in the context of the original research question. It also assesses if findings for and against the researchers' arguments are discussed
Value of research	This domain assesses if the researchers discuss the generalisability of findings, the contribution they make to existing knowledge and directions for future research

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Formal consensus

Formal consensus was used to agree statements that were used to inform recommendations (see 'New guideline recommendations based on formal consensus' below for more information). Formal consensus was carried out using the nominal group technique (Murphy 1998). This is a structured method focusing on the opinions of individuals within a group. Due to this focus on individuals, it is referred to as a 'nominal group' technique. It usually involves anonymous voting with an opportunity to provide comments and follows an iterative process in which options with low agreement are eliminated and options with high agreement are retained. Using the comments that individuals provided, options with medium agreement are revised and then considered in a second round of voting.

Details of the nominal group technique as used in this guideline

Responses to the call for evidence and additional evidence identified by the guideline committee provided the source material for the formal consensus process. The NGA technical team assessed each document against the inclusion and exclusion criteria (see 'Inclusion/exclusion criteria' above) and the relevant quality appraisal tool (see 'Appraising the quality of evidence' above). Relevant findings and recommendations were then extracted for each of the key themes specified in the scope. These findings and recommendations were then turned into statements for use in the formal consensus process. Statements were edited to collate concepts reported from multiple sources and to ensure each statement addressed a single, discrete issue but otherwise reflected information as presented in the source material

The formal consensus exercise was conducted over email. Statements were sent to the committee in a questionnaire format. All committee members were invited to take part in the formal consensus exercise, excluding the chair and a minimum response rate of 60% of committee members was required. Committee members were asked to rate each statement based on their personal opinion of what they believed 'best practice' would be. The statements were rated using a 9-point Likert scale, where 1 represents 'strongly disagree', 5 represents 'neither agree nor disagree', and 9 represents 'strongly agree'; 7 was the threshold for agreement with a statement. Instead of rating the statement, participants could also record, with an 'X', if they believed they had insufficient knowledge to provide a rating. A further alternative response option was 'C', which indicated that the committee member felt they had a conflict of interest stemming from their involvement in or authorship of documents that were used to generate that statement. This meant that the number of people providing an actual rating (1-9) could potentially vary for each statement depending on people's perceived level of relevant knowledge or perceived conflict of interests. Where people did not rate a statement due to a conflict of interest they nevertheless participated in the meeting where the results of the voting and related recommendations were discussed so that they could respond to questions from other members of the committee, for example in relation to the documents on which statements were based (see the register of interests for more information). Finally the committee was also given the opportunity to provide written comments about each statement regarding suggestions for revision or need for clarification.

Once this first round of consensus had been conducted, the NGA technical team calculated overall percentage agreement for each individual statement and presented the results to the committee. Statements with 80% or greater agreement were

retained and carried forward to committee discussions (see 'Developing recommendations' below). Statements with 60% to 80% agreement were redrafted by the NGA technical team (taking into account comments from the committee) unless there were minor addressable issues that could be dealt with when developing recommendations, in which case the statement was carried forward to committee discussions. Where this happened, it is indicated in appendix G of the individual reviews. Those with less than 60% agreement were discarded unless there were obvious and addressable issues identified from any comments or raised by members of the committee during presentation of the results, in which case the statement was redrafted. Clarification on written comments and additional information from the committee was sought by the NGA technical team, as needed, to inform the redrafting of statements.

Redrafted statements underwent a second round of rating using the same process as described above. Following the second round of rating, all statements were either carried forward to committee discussions (using the same criteria as for round 1) or discarded. No further redrafting of statements was undertaken.

When the formal consensus process started, there were 12 committee members appointed. Therefore, there were 12 committee members eligible for voting for round 1 the below scope areas (which were the first to go through this process):

- Who has a legal right to advocacy?
- Who else would benefit from advocacy and how do we identify them?
- Training and skills for practitioners who work with advocates

An additional committee member was appointed between the first and second round of voting for the above areas; therefore 13 committee members were eligible for voting during round 2. For all remaining scope areas, there were 13 committee members eligible for voting in both round 1 and round 2 as the additional committee member was appointed before any rating of the statements occurred.

Reviewing economic evidence

It was not anticipated that the call for evidence would identify economic evidence beyond that which has been identified in previous NICE guidelines. Therefore, economic evidence reviews were not conducted for this guideline. Economic evidence from the call for evidence would have been considered if it was within the scope of the guideline.

Appraising the quality of economic evidence

No formal appraisal of economic evidence was undertaken but where economic evidence was identified this was presented to the committee by an economist. Whilst formal appraisal was not undertaken, the conclusions of the evidence were presented and discussed with consideration of the economic evaluations checklist specified in Developing NICE guidelines: the manual. Where identified economic evidence was considered by the committee this was recorded in 'The committee's discussion of the evidence'.

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 healthcare resources. Economic evaluations aim to integrate data on healthcare benefits (ideally in terms of quality-adjusted life-years; QALYs) with the costs of different 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 on NHS, local authority or Third Sector finances and so need special attention.

The guideline committee highlighted recommendations where implementation could lead to a significant resource impact. These recommendations were considered for economic modelling where such work was feasible and could potentially lead to adaptation or reinforcement of the recommendation.

The following recommendations or broad areas covering multiple recommendations were prioritised for economic modelling by the committee:

- Training for advocates

The methods and results of the de novo economic analyses are reported in Appendix H of the relevant evidence report. When economic analysis was not prioritised, the committee made a qualitative judgement regarding cost effectiveness by considering expected differences in resource use and costs between options, alongside effectiveness evidence.

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 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 committee's discussion of the evidence' section of the relevant evidence reviews.

Details of the cost effectiveness analyses undertaken for the guideline are presented in appendix I of the relevant evidence reviews.

Other sources of evidence

External experts (expert witness)

In addition to the sources of evidence used for this guideline described above, testimony from expert witnesses was also used as a basis for recommendations, namely as a means of addressing key themes in the scope that were not adequately covered by recommendations from existing NICE guidelines or statements generated for the formal consensus process. Expert witnesses are not members of the committee, they do not have voting rights and they are not involved in the final decisions or influence the wording of recommendations.

An equality impact assessment that was undertaken for the guideline highlighted that people from Black, Asian and Minority Ethnic communities can face disparity in access and discrimination in health and social care services, and are underrepresented in those accessing advocacy services. However, there was a paucity of existing NICE recommendations addressing this. The formal consensus process did result in some statements relating to culturally appropriate advocacy but in discussions with the committee it was agreed that there was not enough detail from the statements in order to fully address this issue. Therefore, the committee agreed to invite expert witnesses to provide testimony about specific approaches for overcoming barriers to accessing advocacy services for people from Black, Asian and Minority Ethnic communities, as well as addressing stigma, discrimination and unconscious bias in advocacy services. The expert witnesses presented testimony directly to the committee, as opposed to using this as an additional source of material for generating statements to be used in the formal consensus process, due to the time required for the formal consensus process.

The two expert witnesses submitted a written testimony in response to a brief drafted by the NGA technical team, and then presented this testimony to the committee and answered questions. The committee used the testimony to refine and expand recommendations about culturally appropriate advocacy and cultural competence that were made following the formal consensus exercise (see ‘Developing recommendations’ below). The written testimony is provided in appendix H of evidence review F and how this impacted recommendations is documented under the heading ‘The committee’s discussion of the evidence’ in relevant evidence reviews.

Developing recommendations

For all recommendations, the committee considered the balance between potential benefits and harms and the economic costs or implications compared with the economic benefits, as well as current practice, person’s preferences and equality issues, based on the statements, recommendations from existing NCIE guidelines, and their expert knowledge and experience.

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.

Additional information relevant to developing recommendations based on the different approaches used for this guideline are described in the sections below.

Adopting and adapting existing NICE recommendations

Existing recommendations for each area of the scope were presented to the guideline committee along with information about which guideline the recommendation came from and a brief summary of the evidence underpinning the recommendation. Where existing recommendations addressed a number of concepts within one recommendation, only those relevant to advocacy were presented to the committee. Moreover, there were a number of existing recommendations under the key themes of 'Who else would benefit from advocacy and how do we identify them?' and 'Information about effective advocacy and signposting to services' that covered the same action for different populations and were all based on informal consensus. These recommendations were combined prior to presentation to the guideline committee to avoid repetition and streamline discussions.

For each recommendation (or group of recommendations in the event of recommendations being combined), the committee discussed whether the recommendation should be adopted (included in the current guideline exactly as it appears in the original guideline), adapted (modified for use in the current guideline), or discarded (not used in the current guideline but remain as it appears in the original guideline). Many of the existing NICE guidelines have a narrower focus in terms of population than the current guideline. Therefore, as part of this process the committee considered whether existing recommendations could be generalised to the broader context of this guideline, taking into account the population and underpinning evidence for the recommendation in the original guideline. Adaptations to recommendations included broadening the population or context of the original recommendation and editorial changes or changes to presentation to collate related recommendations and avoid repetition. Reasons for discarding recommendations included avoiding repetition, the need for the recommendation being superseded by other recommendations made in the current guideline, and the population or context being too specific. The action taken for each identified relevant existing NICE recommendation is presented in appendix F within each evidence review, alongside justification for the action, the underpinning evidence as documented in the original NICE guideline, and the final recommendation agreed for this guideline. Where recommendations have been adapted, additional information on how and why the recommendation was adapted is documented under the heading 'The committee's discussion of the evidence' within each evidence review.

New guideline recommendations based on formal consensus

The statements carried forward to the committee discussion did not form recommendations themselves; rather they were used as the basis to inform recommendations. The statements were considered by the committee in a similar way to how evidence from traditional evidence reviews would be considered and 'The committee's discussion of the evidence' section of each evidence reviews documents how the committee supplemented the statements with their expertise and experience to arrive at the recommendations.

Not all of the statements that were carried forward to committee discussion were used to inform recommendations. As with the recommendations from existing NICE

guidelines, some statements were not used to inform a recommendation as the concept covered by the statement was already addressed by another recommendation. Moreover, some statements did not provide enough information to inform a specific action that would address the issue covered by the statement or the action required was outside the remit of NICE guidelines. The NGA technical team reviewed the statements to highlight those that may fall into these categories prior to presenting the statements for each key area of the scope to the guideline committee. However, the committee were given the opportunity to review and discuss these statements alongside the remaining statements for each area. If any statements were not used to inform recommendations following discussion with the guideline committee, this was also documented under the heading 'The committee's discussion of the evidence' within each evidence review.

New guideline recommendations based on informal consensus

The committee identified a number of gaps in relation to key themes in the scope that they agreed were not adequately covered by recommendations made following the above processes. In these instances the committee drafted recommendations based on their expertise and experience alone. Such recommendations still required consideration of the factors outlined above (potential benefits, harms and costs) but did not follow a formal process for reaching consensus on the recommendation. As with the other recommendations, the main considerations specific to each recommendation are outlined under the heading 'The committee's discussion of the evidence' within each evidence review.

Research recommendations

The committee considered making recommendations for future research in areas where there were a lack of existing NICE recommendations or statements generated for the formal consensus process or if statements indicated a need for further research. For further details refer to Developing NICE guidelines: the manual and NICE's Research recommendations process and methods guide.

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.

Funding

The NGA was commissioned by NICE to develop this guideline.

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