Methodology overview

2023 edition

NATIONAL CLINICAL GUIDELINE FOR STROKE

for the United Kingdom and Ireland

Methodology overview

This methodology overview explains the processes undertaken to produce the 2023 National Clinical Guideline for Stroke for the UK and Ireland. This was a substantial update, rather than a full update, of the 2016 edition.

The update followed the same process as adopted for the previous (fifth) edition in 2016, but the methodology has been updated and presented in a different format.

This methodology overview can be read in conjunction with the Guideline Development chapter which lists the seven distinct steps undertaken in developing the 2016 and 2023 editions. These steps are described in detail later in this overview.

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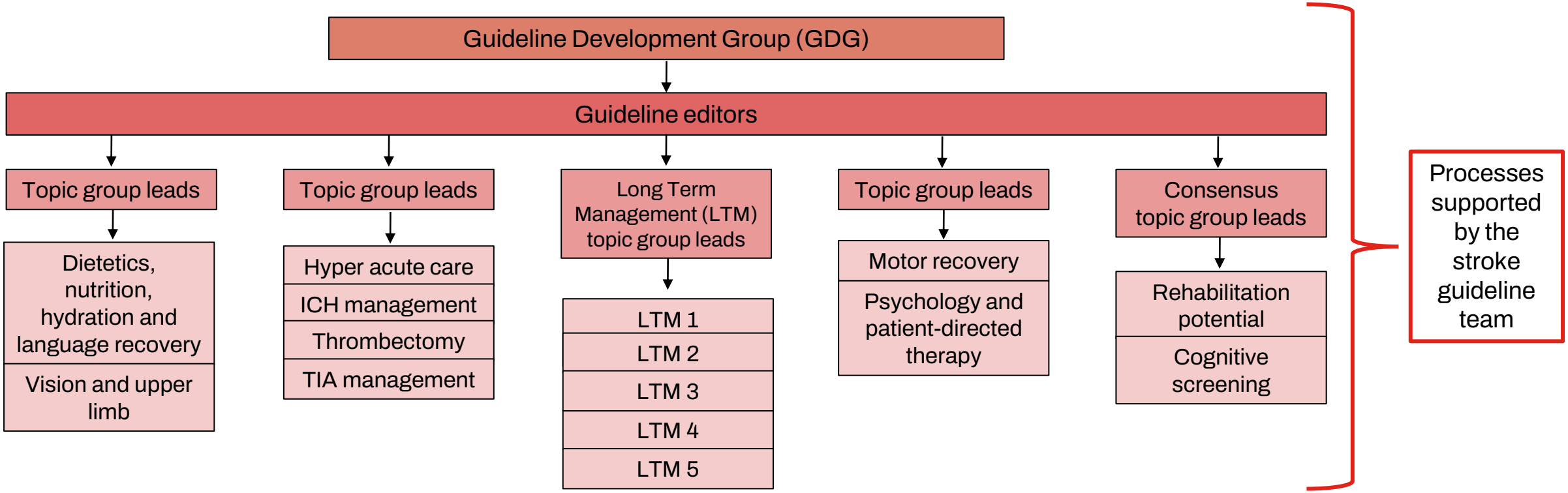
Roles and responsibilities

Guideline organisation structure

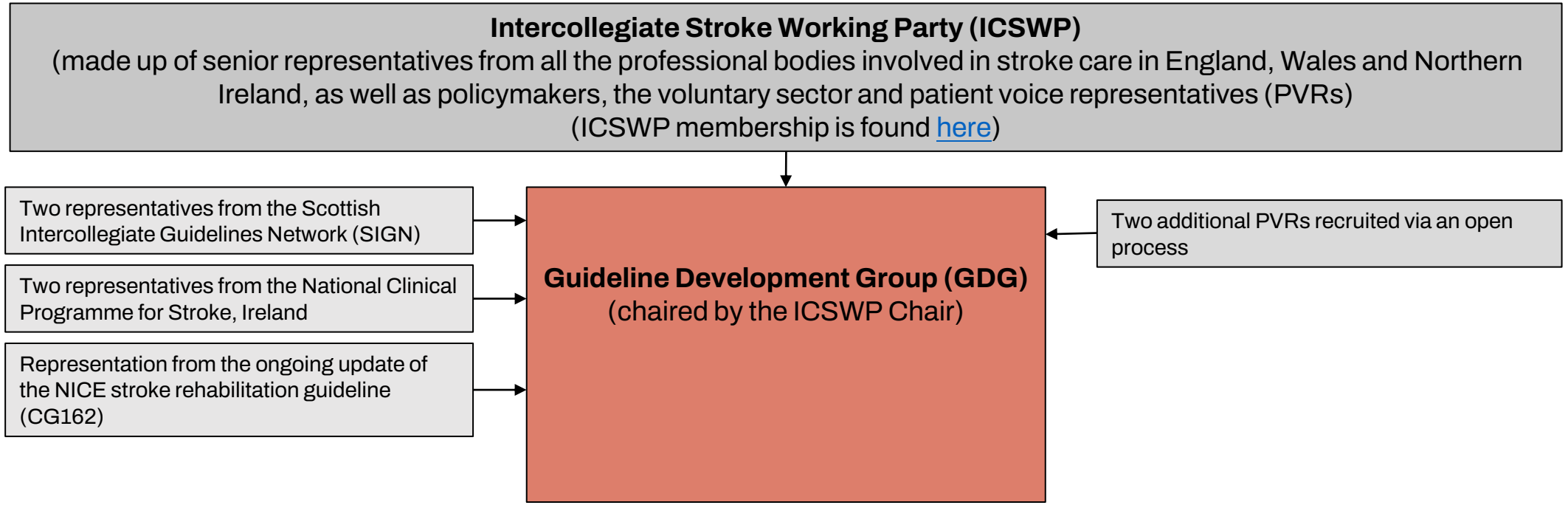


	Responsible for ownership of the guideline update: signs off updates to the guideline, ensures patient views are considered.
	Responsible for updates to individual chapters: coordinates topic groups, sign offs proposed guideline updates to submit to the GDG.
	Responsible for leading topic groups: selects papers for review with editors, coordinates evidence reviews, presents guideline updates to the
	Topic groups comprised of topic experts from UK & Ireland: reviews evidence, drafts guideline updates through consensus.

Full terms of reference are found here

Roles and responsibilities

Guideline development group composition



GDG characteristics:

a. Multidisciplinary, with all relevant clinical specialties represented alongside lay input
b. Relevant to current care practice, with a balance between members actively involved in day-to-day delivery of stroke care, topic experts, and patients and carers
c. Encompasses the range of skills and expertise required for the update
d. Geographically representative, including participants from across the UK and Ireland

Roles and responsibilities

Declarations of interest policy

The full NICE policy and guidance for declaring pecuniary and non-pecuniary interests is followed and can be found here. A summary is depicted on the next page.

Updating declarations of interest

For this guideline update, declarations of interest are requested and updated as follows:

a. GDG members: before every GDG meeting

b. Other guideline contributors (non GDG member topic group leads, non GDG topic group members): on appointment to a topic group, and annually thereafter.

The register of declarations of interests for all guideline contributors can be found here.

Roles and responsibilities

Declarations of interest questions (from NICE policy, used unamended)

Do you have a personal pecuniary interest?
In the last 12 months have you received, or do you plan to receive, a financial payment or other benefit from either the manufacturer or the owner of the product or service under consideration by NICE, or the industry or sector from which the product or service comes? This could include:

- holding a directorship, or other paid position
- carrying out consultancy or fee paid work
- having shareholdings or other beneficial interests
- receiving expenses and hospitality over and above what would be reasonably expected to attend meetings and conferences

→ **You must declare this interest.**
If the payment relates specifically to the product or service under consideration, you will have to withdraw.

Do you have a personal family interest?
In the last 12 months, has a member of your family received, or do they plan to receive, a financial payment or other benefit from the healthcare industry? This could include:

- holding a directorship, or other paid position
- carrying out consultancy or fee paid work
- having shareholdings or other beneficial interests
- receiving expenses and hospitality over and above what would be reasonably expected to attend meetings and conferences

→ **You must declare this interest.**
If the payment relates specifically to the product or service under consideration, you will have to withdraw.

Roles and responsibilities

Declarations of interest questions (from NICE policy, used unamended)

Do you have a non-personal pecuniary interest?

Do you have managerial responsibility for a department or organisation that has received a financial payment, or other benefit, in the last 12 months relating to either the product or service under consideration, or the manufacturer or the owner of the product or service. This could include:

- a grant or fellowship or other payment to sponsor a post, or contribute to the running costs of the department
- commissioning of research or other work
- contracts with, or grants from, NICE

or do you plan to receive such a payment or other benefit in the future?

→ **You must declare this interest.**

You will still be able to participate, unless the chair of the advisory body rules otherwise.

Do you have a personal non-pecuniary interest?

Have you expressed a clear opinion on the matter under consideration which has been:

- reached as a conclusion of a research project
- and/or expressed as a public statement?

Or are you part of a professional organisation or advocacy group with a direct interest in the matter under consideration?

Or is there another reason why people might think you could be biased when giving advice or considering the evidence?

→ **You must declare this interest.**

You will still be able to participate, unless the chair of the advisory body rules otherwise.

Seven development steps

The following steps are followed to ensure a thorough and rigorous process for updating the guideline. Details of each step follow.

Development of scope
Establish research questions, assign questions to topic groups, appoint topic group leads and members

Searching the scientific literature
Convert questions (PICOs) to search strategies, perform searches

Selection of studies for inclusion
Review abstracts and select papers for full evidence review

Assessment of the quality of evidence
Complete evidence tables, convene topic group evidence review meetings

Moving from evidence to recommendations
Assess evidence, draft recommendations, evidence to recommendations and implications, submit to GDG for review and sign off

Health economic considerations
Review specific papers for cost implications

External peer review and public consultation
Identify organisations and invite them to participate in peer review, review and respond to comments

Questions grouped together (one or two per topic group) and addressed in an evidence review cycle (approx. 10 weeks) culminating in submission of proposed amendments to the GDG.

Cycle repeated as necessary until all questions have been addressed and all amendments reviewed by the GDG.

See next page for example process for one question.

Example process for one question

NATIONAL CLINICAL GUIDELINE FOR STROKE
for the United Kingdom and Ireland

2 weeks | 4 weeks | 2 weeks | GDG meeting

1

Literature search for systematic reviews, meta-analyses, etc.

2

Literature search expanded where necessary for RCTs, observational studies, etc.

3

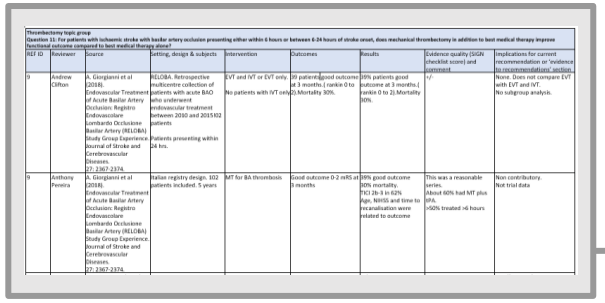
Abstract list sent to topic group lead & chapter editor

4

Abstract lists returned & cross-checked

	Autho	Ye	Title	R	Reviewer 1	Reviewer 2
3	H. K. Park	2021	Cilostazol versus aspirin in ischemic strok	Y	David Werring	Salim Elyas
8	K. Sakuta;	2021	Cerebral Microbleeds Load and Long-Teri	Y	Peter Kelly	Salim Elyas
9	N. Meng;	2020	Antiplatelet therapy may be safe in ischer	Y	Peter Kelly	David Werring
10	Y. Cheng;	2021	Use of anticoagulant therapy and cerebra	Y	Nicola Harding	Rustam Al-Shah
12	J. Aoki; Y.	2021	Microbleeds and clinical outcome in acut	Y	Salim Elyas	Nicola Harding

Topic group lead nominates 2 topic group members to review each selected paper



5

Empty **evidence tables**, **full** papers and evidence review checklists (with guidance on completing evidence tables) **sent out to 2 specified topic group members** per paper

6

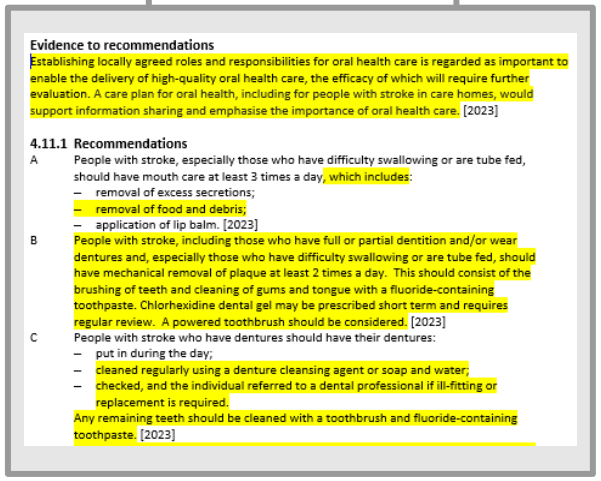
Completed **evidence tables returned**

7

Topic group evidence review meeting to discuss changes to guideline text

8

Topic group lead presents changes to recommendations and evidence to recommendations **to GDG**



Evidence to recommendations

Establishing locally agreed roles and responsibilities for oral health care is regarded as important to enable the delivery of high-quality oral health care, the efficacy of which will require further evaluation. A care plan for oral health, including for people with stroke in care homes, would support information sharing and emphasise the importance of oral health care. [2023]

4.11.1 Recommendations

A People with stroke, especially those who have difficulty swallowing or are tube fed, should have mouth care at least 3 times a day, which includes:
- removal of excess secretions;
- removal of food and debris;
- application of lip balm. [2023]

B People with stroke, including those who have full or partial dentition and/or wear dentures and, especially those who have difficulty swallowing or are tube fed, should have mechanical removal of plaque at least 2 times a day. This should consist of the brushing of teeth and cleaning of gums and tongue with a fluoride-containing toothpaste. Chlorhexidine dental gel may be prescribed short term and requires regular review. A powered toothbrush should be considered. [2023]

C People with stroke who have dentures should have their dentures:
- put in during the day;
- cleaned regularly using a denture cleansing agent or soap and water;
- checked, and the individual referred to a dental professional if ill-fitting or replacement is required.

Any remaining teeth should be cleaned with a toothbrush and fluoride-containing toothpaste. [2023]

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Development of scope

Scoping exercise

The scoping exercise (Scope document found here) produces 59 research questions. In addition, three consensus questions are agreed by editors and the GDG where formal literature searching of a narrowly defined research question does not adequately encompass the clinical implications of the topic.

Assigning questions to topic groups

The final research questions and consensus questions are structured using the 'Population, Intervention, Control, Outcome' (PICO) format. Each question is assigned to an appropriate topic group according to the scope. The topic group lead, with support from their editor, is responsible for taking on these questions and working through the evidence review process, and is responsible for keeping to the scope of their questions.

Appointing topic group leads and members

Editors propose topic group leads and this is agreed by the GDG. Topic group leads are specialists in the subject area of the topic and appointments are from across the UK and Ireland.

Topic group leads propose topic group members and this is agreed by editors. Topic group members are experts drawn from a wide range of specialist societies and interested parties such as clinicians, physicians, academics and therapists. PVR's are appointed to topic groups for specific questions with particular patient/carer considerations, and appointments are from across the UK and Ireland.

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Searching the scientific literature

Searching process

A literature search is undertaken for each individual question to identify studies that help to answer the question and provide evidence that is robust enough to allow recommendations to be made. Literature searching is coordinated by the stroke guideline team, and carried out by the stroke guideline team and SIGN.

1. Initial searches are undertaken and linked to search strategies. These initial searches look for guidelines, systematic reviews, and meta-analyses only and cover the following databases:
    a. Cochrane Database of Systematic Reviews (CDSR)
    b. MEDLINE
    c. Embase

1. The output of these searches is reviewed to identify areas relating to each question not covered by the results of the initial search. A second search is undertaken by filtering the search strategies to include randomised controlled trials (RCTs) and observational studies, and cover the following databases (where appropriate):
    a. MEDLINE (via OVID)
    b. Embase (via OVID)
    c. AMED (via OVID)
    d. PsycInfo (via OVID)
    e. CINAHL

Searching the scientific literature

Screening search results

All search results are screened by the stroke guideline team and inappropriate or irrelevant studies are excluded. Editors and topic group leads may review initial abstract lists and advise on applying search limits or filters, particularly where searches produce an unmanageably high output. SIGN have developed pre-tested strategies that identify higher quality evidence from vast amounts of literature indexed in databases, which can be applied. Abstract lists include a report generated by the stroke guideline team to inform decisions.

Q47: What is the best treatment for post-stroke depression?

Search strategies									Date of search: 09/03/2022
Embase <1974 to 2022 March 09>			Ovid MEDLINE(R) ALL <1946 to March 09, 2022>			AMED (Allied and Complementary Medicine) <1985 to March 2022>			After deduplication, n=1320 abstracts identified from initial search of Medline/EMBASE. 33 from AMED. 104 included in final abstract list.
									Reasons for exclusion from abstract list:
1	stroke.mp.	505624	1	stroke.mp.	335610	1	stroke.mp.	9786	review articles, conference abstracts, consensus statements, case reports, case series, study protocols
2	exp *Stroke/	100019	2	exp *Stroke/	119643	2	exp stroke/	4080	abstracts where population not human, adult (16+), stroke patients
3	exp Cerebral Hem	158482	3	exp Cerebral Hem	36123	3	exp Cerebral hem	84	abstracts where N<30
4	(stroke or strokes	462832	4	(stroke or strokes	290387	4	(stroke or strokes	9949	abstracts describing patterns of antidepressant intervention use / consultation use for depression
5	((cerebro$ or bra	56573	5	((cerebro$ or bra	38907	5	((cerebro$ or bra	616	abstracts investigating prevalence / neural or clinical correlates of / risk factors for assessment of / depression
6	cerebral infarct$.	30721	6	cerebral infarct$.	35478	6	brain attack$.ti,a	6	abstracts investigating pathomechanism of depression
7	cerebrovascular a	246351	7	cerebrovascular a	5051	7	or/1-6	10456	abstracts investigating depression in carers of stroke patients

Full details of search strategies and SIGN search filters used are found here.

Searching the scientific literature

Grey literature

Not all sources relevant to this edition of the guideline are will be found in publication databases. Grey literature is defined by the Cochrane Handbook for Systematic Reviews of Interventions as ‘literature that is not formally published in sources such as books or journal articles’.

In the case of specific questions where literature searching does not identify good quality evidence, topic group members are asked to identify and submit good quality grey literature, which is then reviewed. This can include:

a. Government reports
b. Conference proceedings
c. Unpublished clinical trials
d. Public health guidance
e. Other guidelines
f. Study protocols
g. Consensus statements

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Selecting studies for inclusion

Abstract lists

Abstract lists are created in the format below.

	A	B	C	D	E	F	G	H	I	J	K
1	A	Abstract	Author	Yea	Title	Journa	Vo	Issue	Pages	Review Y/N	If Y, reason for reviewing
2	1	The aim of the present guideline is to	N. F. Chi;	2022	2021 Taiwan Stroke Society Guidelines of blood pressure control for isc	Journal of					
3	2	The Recurrent Stroke Prevention Clini	K. Kitagaw	2022	Intensive or standard blood pressure control in patients with a history c	Hypertens	45	4	591-601		
4	3	Background: Blood pressure control h	G. Arling;	2022	Blood Pressure Trajectories and Outcomes for Veterans Presenting at V	American					
5	4	Background: Guidelines recommend l	S. Shihab;	2022	Influence of Baseline Diastolic Blood Pressure on the Effects of Intensiv	Hypertens	79	4	785-793		
6	5	Objective: To update the recommend	M. Rodrig	2021	Stroke prevention in patients with arterial hypertension: Recommendat	Neurologi	36	6	462-471		
7	6	To investigate the optimal blood pres	M. He; B.	2021	Focus on blood pressure levels and variability in the early phase of acut	Journal of	23	12	2089-2099		
8	7	Importance: Low diastolic blood pres	A. J. Foy;	2021	Association between Baseline Diastolic Blood Pressure and the Efficacy	JAMA Net	4	10	e2128980		
9	8	Background: Intensive blood pressure	S. Basu; J.	2017	Benefit and harm of intensive blood pressure treatment: Derivation and	PLoS Med	14	10	e1002410		
10	9	'Covert' cerebral small vessel disease	J. M. Ware	2021	ESO Guideline on covert cerebral small vessel disease	European	6	2	CXI-CLXII		

The editor and topic group lead return their lists with papers to be selected for review clearly marked. The stroke guideline team highlights discrepancies between the selections and requests that a final decision is made by the topic group lead.

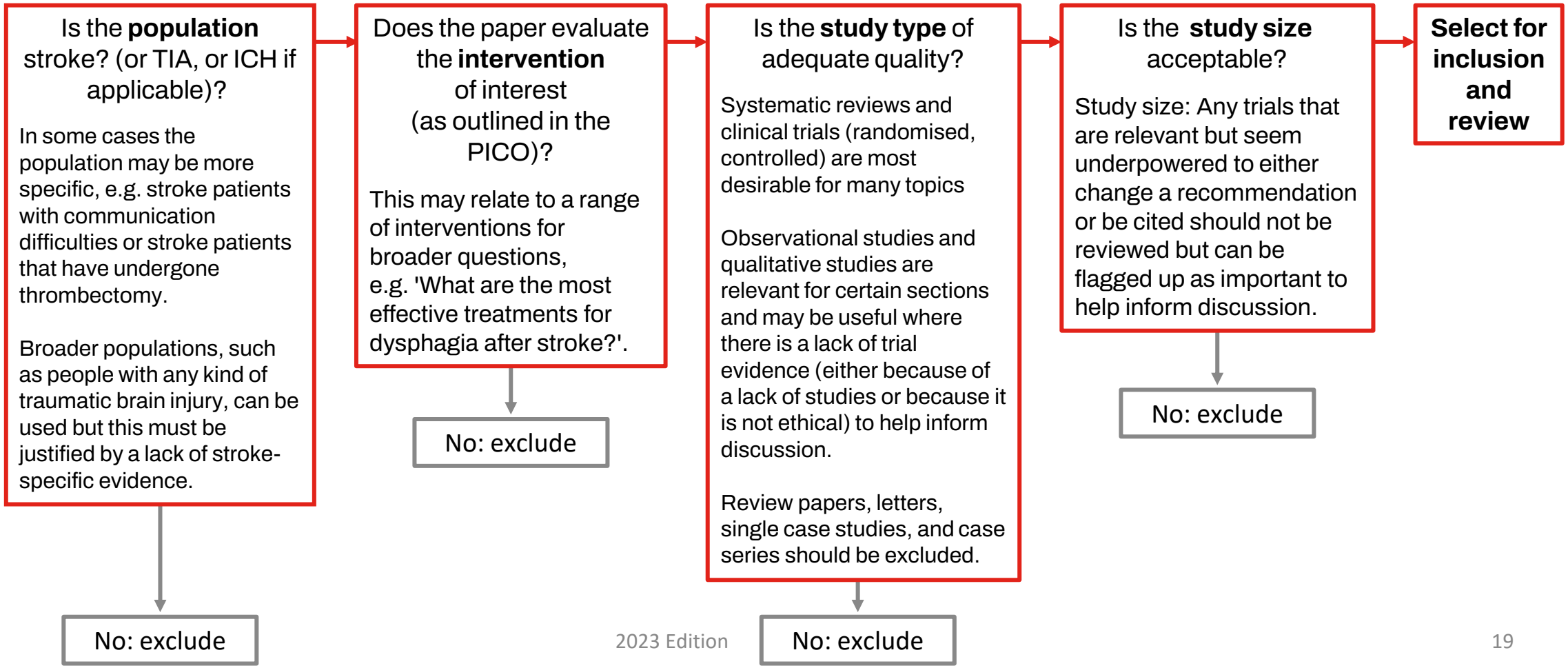
Double reviewing

The topic group lead assigns each paper to two topic group members for review. In contrast to the full update in 2016, the 2023 guideline update focuses only on research questions likely to change recommendations. Therefore all papers are double reviewed, and any discrepancies in the assessment of the quality of evidence are fully discussed within the topic group. Where papers are only selected to provide context to discussion, a single reviewer is appropriate to summarise the contents for the topic group.

Selecting studies for inclusion

Screening abstract lists

It is reasonable for editors and topic group leads to exclude papers where they fail to meet the following criteria:



Selecting studies for inclusion

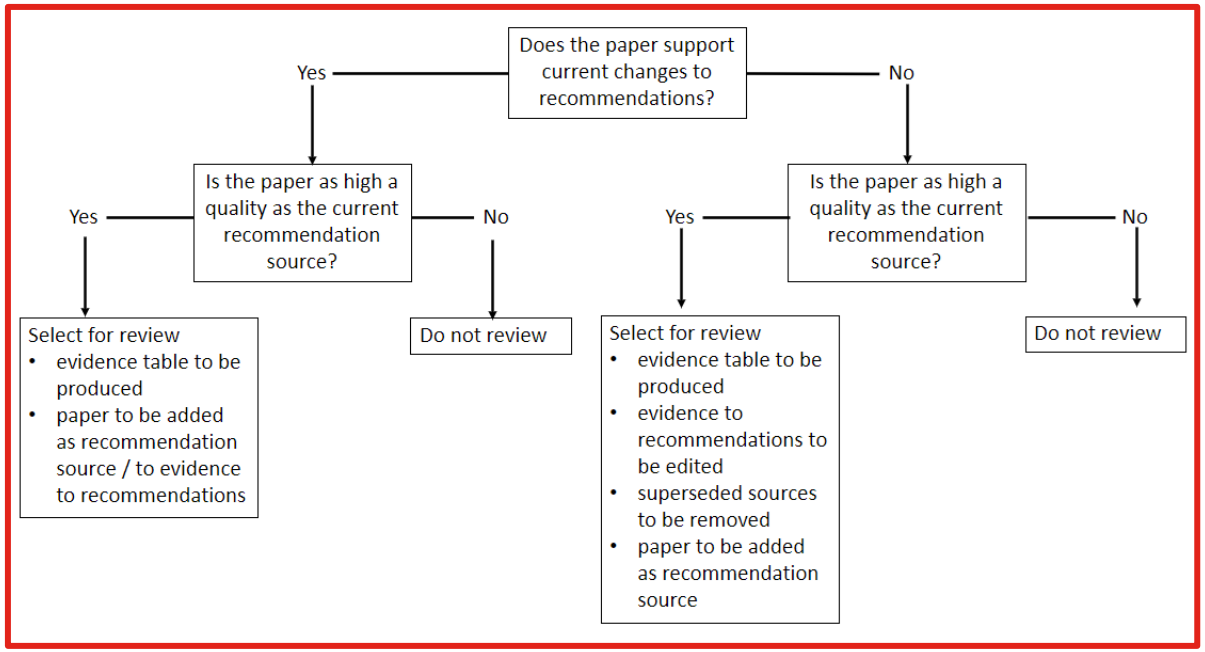
Sifting search re-run abstract lists and assessing the quality of research

Literature searches are re-run shortly before the draft guideline is issued for peer review and public consultation. This ensures that the most recently published papers are not missed. The search method is the same as before.

Topic group leads and editors sift abstracts and apply the same evidentiary standard as previously; only papers of a high a quality as the sources already identified are considered for full evidence review.

Evidence review follows the normal process.

Topic groups only convene where the evidence suggests there should be a significant change to recommendations that have already been drafted. Amendments are submitted to the GDG in the normal way.



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Identify organisations and invite them to participate in peer review, review and respond to comments

Assessment of the quality of the evidence

Evidence tables

Evidence tables are created in the format below. Completed evidence tables are found here.

The stroke guideline team asks reviewers to complete an evidence table. Reviewers receive:

- An empty evidence table
- PDF copies of the papers they have been allocated to review
- A link to SIGN checklists (see next page).

The stroke guideline team reviews returned tables to ensure they are completed appropriately, and collates all completed table entries into one collated evidence table to circulate to the topic group.

Thrombectomy topic group
Question 3: For patients with ischaemic stroke with anterior circulation large vessel occlusion from 6-24 hours from last seen well, does mechanical thrombectomy plus best medical therapy improve functional outcome compared to best medical therapy alone?

REF ID	Reviewer	Source	Setting, design & subjects	Intervention	Outcomes	Results	Evidence quality (SIGN checklist score) and comment	Implications for current recommendation or 'evidence to recommendations' section
4	Reviewer #1 name	G. W. Albers et al (2018). Thrombectomy for stroke at 6 to 16 hours with selection by perfusion imaging. New England Journal of Medicine. 378: 8. 708-718.						
4	Reviewer #2 name	G. W. Albers et al (2018). Thrombectomy for stroke at 6 to 16 hours with selection by perfusion imaging. New England Journal of Medicine. 378: 8. 708-718.						
10	Reviewer #1 name	P. Bhuva et al (2020). Noncontrast Computed Tomography Alberta Stroke Program Early CT Score May Modify Intra-Arterial Treatment Effect in DAWN. Stroke. 2404-2412.						
10	Reviewer #2 name	P. Bhuva et al (2020). Noncontrast Computed Tomography Alberta Stroke Program Early CT Score May Modify Intra-Arterial Treatment Effect in DAWN. Stroke. 2404-2412.						

Assessment of the quality of the evidence

Reviewing evidence and completing evidence tables

Evidence tables have the following columns for reviewers to complete.

Source	This is the study reference – first author + year of publication.
Setting, design and subjects	**Setting** should describe the country of study and, if relevant to the question, any other detail related to location (developed/non-developed, public/private healthcare system, urban/rural). **Design** refers to study design: MA (meta-analysis), SR (systematic review), Cochrane SR, RCT (randomised controlled trial [mark quasi-randomised studies separately with an *]), CCT (controlled clinical trial), case-control, cohort, etc. If known, should also state if RCT is a cross-over or parallel group or an equivalence trial. **Subjects** refers to the patients studied. Should give the total number (n=?). If an MA and/or SR then should give the number of studies and the total number of patients (if known). If relevant, should describe the population studied (e.g. acute, long-term, all stroke patients or only with a specific condition) and population demographics (age, sex, ethnicity, other socioeconomic factors) where available.
Intervention	Should describe the intervention(s) being evaluated (including dose, mode of delivery). Should give not only the new/experimental intervention but also the routine or control and the numbers in each group, e.g. “randomised to 25 µg intrathecal baclofen (n=xx) **or** matching placebo (n=xx)”, or “task-specific training (n=xx) **or** local standard therapy (n=xx)”, or “trained volunteer (n=xx) **or** no treatment (n=xx)”.
Outcomes	Should describe the main therapy outcome being evaluated and the time points covered by the study. Give the actual measure, or main domains. If multiple, then should at least give the primary outcome measured. e.g. “mean morning serum cortisol, measured every day for 60 days”.

Assessment of the quality of the evidence

Reviewing evidence and completing evidence tables

Results	Should try to provide the main data. Should avoid "no effect"; use "no differences detected between groups". Should give as much detail as possible – "10% more independent at 6 months post-stroke" or "25% of patients had improved gait by 2 months, 39% by 6 months" are more informative than "positive effect".
Evidence quality (SIGN checklist score) and comment	**Quality** Checklists assess the methodological quality of a paper and hence the quality of the evidence provided by the paper. The checklists allow reviewers to provide a quality score in the evidence table: ++ high quality + Acceptable - Low quality 0 Reject Reviewers should complete the appropriate checklist according to the study type, and where the checklists cannot be used (e.g. grey literature), reviewers should give a brief judgement of their assessment of the study/paper quality (e.g. "Pre-publication report of large scale cohort study with important implications"). **Comment** allows the highlight of any bias, limitations, concerns, strengths etc. Always make some comment. (e.g. "Discrepancy between Barthel and mRS findings hard to explain. Not clear if reviewers blinded or whether assessor agreement investigated."). Please also note the study's sources of funding here if a potential source bias (e.g. for a question regarding oral health, "study funded by toothpaste company"). Make sure your comments are evidence based and unbiassed. SIGN checklists can be downloaded from https://www.sign.ac.uk/what-we-do/methodology/checklists/.
Implications	Should describe the main therapy outcome being evaluated and the time points covered by the study. Should give the actual measure, or main domains. If multiple, then should at least give the primary outcome measured. e.g. "mean morning serum cortisol, measured every day for 60 days". **Note that this column is not included in the final evidence tables for publication**, but is used to inform topic group discussion.

Assessment of the quality of the evidence

Evidence review meeting process

The topic group lead chairs the evidence review meeting. The meeting follows this agenda:

1. A familiarisation with the question to be discussed, and reminder of the PICO.
2. A summary from all reviewers of the papers reviewed with reference to the collated evidence table.
3. Discussion of the evidence base as a whole (using the considered judgement prompts, see next page) and whether the evidence base is strong enough to change the existing recommendations / evidence to recommendations / implications sections of the guideline. Reviewers consider whether the existing guideline evidence is still the strongest or consider if it needs to be updated?
4. What any new recommendations should say (using guidance for drafting recommendations, see later page) or how existing recommendations should be amended, along with amendments to evidence to recommendations and implications sections of the guideline. Due to time constraints, the meeting focuses on reaching consensus (exact wording of recommendations can be edited after the meeting).
5. The following is also to be noted about any changes to recommendations:
    a. If there is any overlap with other sections of the guideline (e.g. a goal setting recommendation may overlap between acute and long-term management chapters).
    b. Which issues are likely to require considerable debate at the subsequent GDG meeting.

Assessment of the quality of the evidence

Use of considered judgements

Evidence review meetings enable topic groups to discuss whether or not the evidence reviewed (as documented in the completed evidence table) is strong enough to amend the wording of a guideline recommendation and the evidence to recommendations section of the guideline. Topic groups consider these judgement prompts:

Quality of evidence base	Review the quality, volume, reliability, and consistency of the evidence base.
Study populations	Are the studies directly relevant to the stroke population/subgroup of the stroke population? Should any of the common comorbidities be taken into account, or did the study population have comorbidities?
Limitations and bias	Are there concerns about all studies coming from the same research group? Funded by industry? Publication bias? Use of indirect outcomes?
Benefits and harms / outcomes	Consider results of trials or balance of outcomes (an intervention may improve one outcome, but not another which is considered to be more important, e.g. short-term vs long-term). For example benefit: 1 MA reported a small, positive benefit associated with Drug X in the reduction of condition Y compared to placebo (XX et al, 2018); harm: Drug X was associated with an increased risk of renal events, including calculi, compared to placebo (XX et al, 2020).
Impact on patients	Would the results be acceptable to patients? e.g. is it an intervention that would require someone to attend a clinic regularly (accessibility, willingness to do so), or is it an intervention that is well tolerated, easy to use/participate in and acceptable to patients? Does it have any other benefits, e.g. regular contact with a healthcare professional/opportunity to build relationship?
Feasibility	Are the interventions/action implementable in England, Wales, Northern Ireland, Scotland, and Ireland? Consider existing advice for clinicians, cost effectiveness, financial & human resource implications.

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Moving from evidence to recommendations

Achieving a consensus in a topic group

In most cases, topic groups make decisions through a process of informal consensus. The topic group lead ensures all members are able to present their views, that assumptions can be debated and that the discussions are open and constructive.

The topic group lead needs to allow sufficient time for all members to express their views, and should check that all members agree to endorse any amendments to guideline text (including topic group members who did not attend an evidence review meeting).

Moving from evidence to recommendations

Consensus recommendations

In some cases there is little or no evidence to determine what recommendation should be made. In this case recommendations are developed by consensus. Recommendations are developed by consensus under two circumstances and a different process is followed in each case:

1. Where formal literature searching delivers evidence which is scanty or of unacceptable quality:
    a. Evidence is assessed by the topic group members following standard practice
    b. Draft recommendations are agreed by consensus of the topic group
    c. Draft recommendations are reviewed and agreed by the GDG following standard practice (source listed as 'Guideline Development Group consensus').
2. Where formal literature searching of a narrowly defined research question would not adequately encompass the clinical implications of the topic:
    a. A specialist consensus topic group is formed to discuss the topic. Consensus topic group membership includes at least two PVR's as well as representation from across the UK and Ireland from a broad range of professions.
    b. Key literature, policy documents, and guidelines relevant to the question are identified by the editor, the consensus topic group lead and members of the consensus topic group and distributed to the group as suggested background reading before the meeting. There are no evidence tables.
    c. A consensus topic group meeting is held to discuss the possibility of amending guideline text on the topic.
    d. Topic groups working on research questions which are relevant to the consensus topic area receive the draft recommendations and evidence to recommendations text for review (e.g. for a consensus topic area from the Recovery & Rehabilitation chapter, the draft will be circulated to members of all topic groups addressing questions relating to Recovery & Rehabilitation chapter content).
    e. The draft amendments to guideline text are presented to the GDG in the normal way.

This type of consensus question is included in the scope found here.

Moving from evidence to recommendations

Characteristics of recommendations to consider

Recommendations are phrased as follows:

a. The correct target population and their condition (e.g. ‘People with stroke’, or ‘Patients with acute spontaneous intracerebral haemorrhage with a systolic BP 150-220mmHg’), or the situation (e.g. ‘A stroke rehabilitation unit’).
b. The recommended course of action (‘should’, ‘should not’, ‘should be considered’, ‘may be considered’. (See next page for wording relating to the strength of recommendations).
c. The action or intervention recommended (e.g. what, who, where, how).
d. Any qualifying statements.

Recommendations are linked and ordered where necessary, e.g. a recommendation concerning assessment will be followed by recommendations that specify who does this, how often it is done and where it is done.

Moving from evidence to recommendations

Strength of the wording of recommendations

Topic groups follow the house style which determines the strength of a recommendation:

STRONG

- If there is sufficient evidence with low risk of bias, and all other factors are positive (or negative) or if there is consensus amongst the topic group that the intervention 'should' be used (for 'GDG consensus' recommendations).
- If the topic group is very certain that benefits do, or do not, outweigh risks and burdens.

"Patients with condition X **should** be treated with Y"

"Patients **should not** be treated with Z except as part of a clinical trial, or when all other treatments have failed."

CONDITIONAL

- If there is doubt about the reliability of the evidence or for other reasons, e.g. potential adverse effects / patient acceptability, or if there is consensus amongst the topic group that the intervention 'should/may be considered' (for 'GDG consensus' recommendations).

"Patients with condition X **should be considered for** treatment Y", where all patients should be considered for Y.

"Patients with condition X **may be considered for** treatment Y", where there is no obligation to consider all patients for Y (to be used sparingly).

As a rule, readers can assume that if an action or intervention is not specifically mentioned in the guideline, then it is not recommended and should not be offered to people with stroke other than as part of a research trial.

Moving from evidence to recommendations

Wording of evidence to recommendations and implications sections

It is appropriate to include an evidence to recommendations section in almost all sections of the guideline. Particular attention is given to it in instances when:

a. A recommendation is fully or partially derived by consensus.
b. The evidence is not particularly strong.
c. The evidence is not stroke specific.
d. The evidence is conflicting.

The evidence to recommendations text adheres to the following:

a. A relatively short section, usually of no more than 200 words, but if the topic is particularly complex then it may need to be longer.
b. It should state the question and briefly the relevance.
c. It should include which patients have been included in the research and therefore to whom the recommendation may be most relevant.
d. It should include a statement about the strength of the evidence on which the recommendation is made or why no recommendation could be made. This is the opportunity to cite the lower level evidence, e.g. small RCTs, case series, single case studies.
e. It should cite the key reference(s) that were used to formulate the recommendation.
f. It should highlight areas where there is insufficient evidence and where research would be valuable.

Moving from evidence to recommendations

Updating list of sources

Editors also finalise the sources list, ensuring it is updated where appropriate, adhering to the following format:

1. All recommendations have at least one source assigned to them.
2. All sources are mentioned in the evidence to recommendations text.
3. Sources that have been superseded are removed.

Highlighting changes to guideline text

Editors sign off changes to recommendations, evidence to recommendations and implications sections of the guideline that have been agreed by topic groups, and highlight the following for the GDG's attention:

1. New sections of text.
2. Text that has been updated (insertions/amendments).
3. Text which the topic group has reviewed against the literature but decided not to update.

Moving from evidence to recommendations

Prior to GDG meetings

The following paperwork relating to each question is circulated one week before a GDG meeting:

1. Completed evidence table.
2. Document with relevant guideline text, including highlights to new or amended text to the recommendations and sources, evidence to recommendations and implications.
3. Any relevant amendments to guideline text that have already been submitted and approved by the GDG, which may now be superseded.

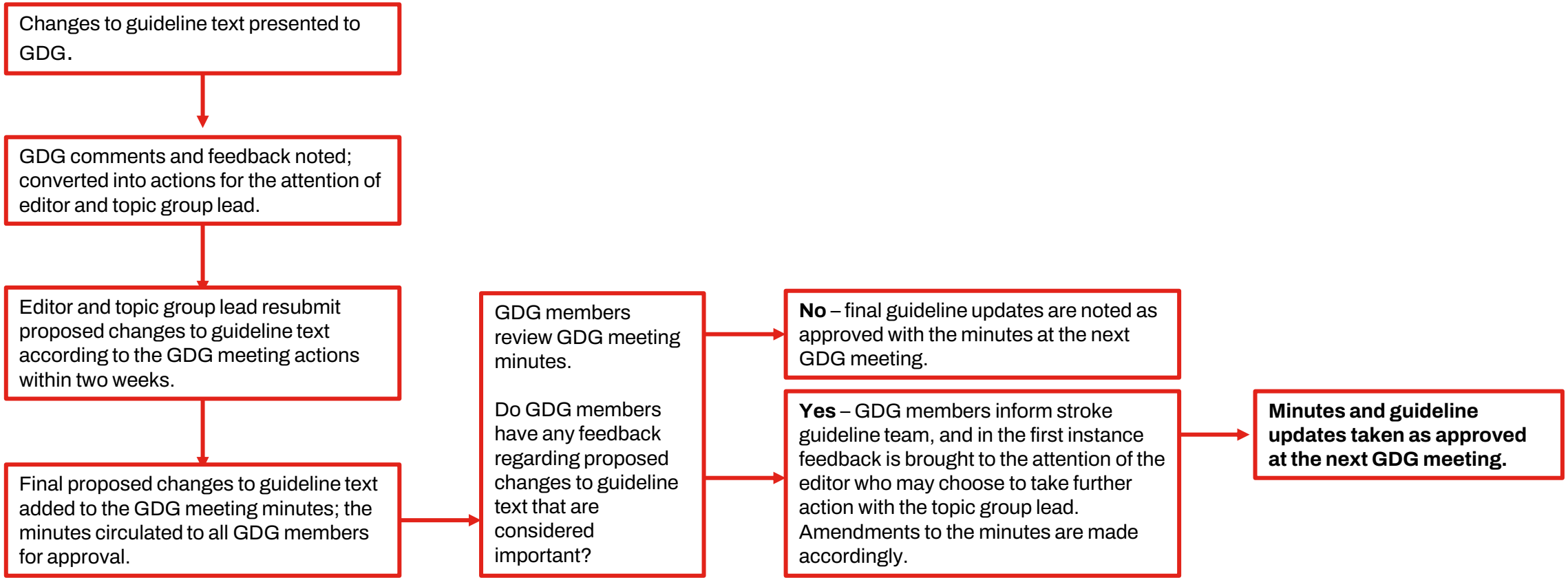
At GDG meetings

Agenda timeslots are allocated to each question, during which topic group leads present the following:

1. A summary of the topic group discussion regarding the question, and key papers that underpin the amendments.
2. The proposed amendments to the guideline text, and reasoning behind the wording of any recommendations.
3. Any further information relevant in how the topic group reached its consensus, and any statements as agreed by the topic group that may be accepted as controversial.
4. The stroke guideline team records any subsequent actions for the topic group lead and editor following discussion and questions from the GDG.

Moving from evidence to recommendations

Process for obtaining final GDG approval of guideline updates



Seven development steps

Development of scope
Establish research questions, assign questions to topic groups, appoint topic group leads and members

Searching the scientific literature
Convert questions (PICOs) to search strategies, perform searches

Selection of studies for inclusion
Review abstracts and select papers for full evidence review

Assessment of the quality of evidence
Complete evidence tables, convene topic group evidence review meetings

Moving from evidence to recommendations
Assess evidence, draft recommendations, evidence to recommendations and implications, submit to GDG for review and sign off

Health economic considerations
Review specific papers for cost implications

External peer review and public consultation
Identify organisations and invite them to participate in peer review, review and respond to comments

Health economic considerations

Health economist input

Although a cost-benefit analysis of interventions is not included in the scope of the guideline, questions that have significant resource and financial implications can benefit from health economic considerations. An editor or topic group may invite a health economist to participate in the evidence review process, which can include:

a. Reviewing abstracts for specific papers that include a cost-benefit analysis.
b. Fully reviewing specific papers and completing evidence tables.
c. Supporting other topic group members in accurately summarising relevant health economic sections of papers.
d. Actively participating in discussions in topic group evidence review meetings.
e. Providing advice in the drafting of guideline updates.

Financial barriers to implementation of recommendations can be highlighted in the implications sections of the guideline.

Seven development steps

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External peer review and public consultation (see Peer Review and Public Consultation document here, see Peer Review Report here)
Identify organisations and invite them to participate in peer review, review and respond to comments

External peer review and public consultation

Survey hosting and supporting documentation

A peer review survey and a public consultation survey are published online by Health Improvement Scotland.

The following documentation is published for reviewers:

1. National Clinical Guideline for Stroke 2023 consultation document which highlights the following guideline sections for review:
    i. New guideline sections.
    ii. Guideline text that has been updated.
    iii. Guideline text that has been reviewed against the literature as part of the scope for this guideline update, but has not been updated through lack of evidence.
2. Bibliography.
3. The scope of the guideline update.
4. List of people involved in developing the updated guideline.
5. List of organisations invited to peer review *(to be used to advise individuals to submit comments through an organisation invited to peer review with which they have an affiliation).*

External peer review and public consultation

Peer review

The following peer review approach was developed for the 2023 edition to give the draft guideline maximum exposure to qualified review.

1. Specific organisations are invited to peer review:
    a. Those which are represented at the ICSWP and GDG.
    b. National patient and carer organisations.
    c. Professional societies and royal colleges.
    d. Public sector and charitable sector providers and commissioners (national).
    e. Government departments and national statutory agencies.
2. One single collated response per organisation is invited.
3. All peer reviewers must submit declarations of interest on behalf of their organisation
4. GDG members may coordinate responses on behalf of an organisation but not actively take part in peer review. Topic group members may contribute to their organisation's collated response but should recuse themselves from reviewing areas that were within scope of their topic group's questions.
5. The GDG responds to all peer review comments. All peer review comments are published, with declarations of interests and the GDG's response.

External peer review and public consultation

Public consultation

Non-peer reviewers also have the opportunity to review the draft guideline update. The following public consultation approach aims to maximise exposure of the draft to corrections and adjustments:

1. Public consultation is open to anyone who wishes to comment.
2. Individuals are initially asked to submit comments through an organisation with which they have an affiliation. Where there is no affiliation, it is then appropriate for individuals to submit a public consultation response.
3. All public consultees must submit personal declarations of interest.
4. Public consultation comments are considered but are not responded to or published, unless a particularly important point is raised that is not covered by the peer review.

Publication

Post peer review and public consultation guideline amendments

Where comments require potential changes to guideline text, editors consult with topic group leads and topic groups. Where new evidence has been identified through peer review, topic group leads and editors follow the same evidentiary standard as previously; only papers of as high a quality as the sources already identified are considered for full evidence review.

Evidence review follows the normal process, with topic group leads assigning two reviewers and the topic groups convening where the evidence suggests there should be a significant change to recommendations. Proposed guideline text amendments are submitted to the GDG in the normal way.

Post peer review and public consultation final GDG sign off

The final GDG sign off takes place at the next GDG meeting. All proposed guideline text amendments based on peer review comments are considered. On approval, the GDG has completed its responsibilities regarding approval of the updated guideline.

Publication

Endorsement

The final updated guideline is reviewed by the chief decision-making bodies of the following organisations: the Royal College of Physicians, the Scottish Intercollegiate Guidelines Network (SIGN), and the Royal College of Physicians of Ireland. Their agreement means that the guideline is endorsed for use in clinical practice in the UK and Ireland.

The guideline is published with the endorsing organisation logos on www.strokeguideline.org.

Publication

Plain language summary

A plain language summary of the guideline is produced for people affected by stroke (people with stroke and their families, friends and carers). This is titled 'Care after stroke or transient ischaemic attack: What, when, and why?'

The plain language summary is:

a. A summary of the main points of relevance to people affected by stroke that derive from the guideline update.
b. Produced by the PVR's on the GDG, supported by another GDG member and the stroke guideline team.
c. Reviewed by patient organisations from across the UK and Ireland prior to publication.
d. Produced in a format which is easily accessible and is helpful for people with aphasia.
e. Produced in print, as a PDF and online.