Clinical Practice Guidelines - Information Sheet for Guideline Developers

Guideline Development Process

Guideline Programme Team This programme holds editorial control of the guideline. The clinical lead will invite the chair to take on the task of the guideline update/development. The programme manager facilitates the Guideline Developers throughout the process. Offers guidance regards template, assists to meet target timelines and coordinates review by relevant groups.

Specific to the writing group
The writing development group is multidisciplinary in its composition and includes representation from all relevant areas.
Chair. The role of the Chair is crucial to ensure that the guideline developers group functions efficiently and meets its aims. They are responsible for including other relevant team members and overseeing the progress of the document and liaising with the other developers.
Guideline Developers The group members must make a full commitment to the tasks involved and be prepared to consult with colleagues in order to consider the widest possible range of views whilst at all times maintaining confidentiality around the content of discussions within the group.
Meetings held – if held, some record is suggested
Any Stakeholders should be acknowledged

Conflict of interest

Minimising conflicts of interest in guideline development and ensuring appropriate management is critical to ensuring public and healthcare professionals' confidence in the clinical guideline. Conflicts of interest may arise if members of the guideline development group have financial or academic interests in, or work closely with pharmaceutical companies, medical equipment or other commercial companies. These relationships may have an influence on Guideline Developers members. All potential conflicts of interest, including those beyond the commercial sector, should be declared at the start of the development process.

Defining the Role of Authors and Contributors

The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Scope

The purpose of the scope for the CPG is to provide the following:

- Background epidemiology relevant to the condition or disease.
- Clear outline of the aspects of care that the guideline will cover in terms of:
    - the population to be included or excluded,
    - the healthcare setting,
    - the interventions and treatments to be included and excluded.
- Overview of the clinical questions to be addressed

Clinical Questions

The clinical questions define the areas to be examined within the guideline and provide the framework for the systematic review of the available evidence.

Clinical questions within CPGs cover a wide range of areas including, identifying women at risk of a particular condition or outcome, diagnosis, optimal care and follow-up, including the role of specific interventions and multidisciplinary team composition. In addition, there is often the need to address communication needs, service delivery, user experience, resources and training. The range and type of questions posed will depend on the scope and the subject area (RCOG).[1]

Where applicable, clinical questions should be broken down into PICO (T) format - Population, Intervention, Comparison, Outcome, (Time). The clinical questions should be clear, unambiguous, focused and concise (NCEC, 2013).[2]

P Patient/populations: Which patients or populations are we interested in? Are there any subgroups that need to be considered?
I Intervention: Which policy, treatment or procedure should be used?
C Comparison(s): What is/are the main alternative(s) to compare with the intervention?
O Outcome(s): What are the important outcomes for the patient, including risks, benefits and side effects?
T Timeframe (optional)

Literature search strategy

In drafting the literature review, guideline developers are encouraged to incorporate systematic reviews, randomized clinical trials, and prospective studies as evidence to support the recommendations for each clinical question. The quality of this evidence is assessed by the author for each outcome according to criteria such as study design, risk of bias, and effect size during manuscript development and by the guideline programme team during review.
A summary of evidence table may later be created to display the quality of evidence supporting the recommendation for each clinical question and provide transparency in the recommendation making process. You may choose to access other useful sources during your

literature search besides those mentioned below for example Clinical Guidelines from other countries. If so, please reference appropriately so as to avoid plagiarism.

Please include:-

- Details of the strategy used to search for evidence.
- Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, CINAHL)
- Time periods searched (e.g., January 1, 2004 to March 31, 2008)
- Search terms used (e.g., text words, indexing terms, subheadings)
- Inclusion and Exclusion criteria

Appraisal of evidence

Guideline developers are encouraged to appraise all evidence for validity and applicability to the setting using a systematic method and to record results. This means describing the strengths and limitations of the evidence, as well as considering from the perspective of the individual studies and the body of evidence aggregated across all the studies.

Therefore, guideline developers should critically appraise the quality, validity and relevance of all evidence gathered as part of the search. As a first step, studies can be categorised according to the 'hierarchy of evidence' (e.g.) meta-analyses and systematic reviews (Cochrane) are a higher level of evidence than randomised controlled trials, which are a higher level of evidence than Cohort or Case-Control Studies (NCEC, 2013). [2]

When considering the strengths & limitations of the evidence it can be useful to add:-

- Study design(s)
- Study methodology limitations
- Appropriateness/relevance of primary and secondary outcomes considered
- Consistency of results across studies
- Direction of results across studies
- Magnitude of benefit versus magnitude of harm
- Applicability to practice context

AGREE II process

The potential benefits of guidelines are only as good as the quality of the guidelines themselves. Appropriate methodologies and rigorous strategies in the guideline development process are important for the successful implementation of the resulting recommendations. The Appraisal of Guidelines for REsearch & Evaluation (AGREE) Instrument was developed to address the issue of variability in guideline quality. To that end, the AGREE instrument is a tool that assesses the methodological rigour and transparency in which a guideline is developed. The original AGREE instrument was refined, which resulted in the AGREE II Instrument. [3]

The purpose of the AGREE II, is to provide a framework to:
1. Assess the quality of guidelines;
2. Provide a methodological strategy for the development of guidelines; and
3. Inform what information and how information ought to be reported in guidelines.
Guidelines should be reviewed by the guideline developers using the AGREE II tool, and this will form part of the process of guideline review by the programme team and EAG as well.

Literature Review

The HSE National Framework for developing PPPGs has a guidance manual section, where agreed templates for CPG documents are set out. [4]

This includes:-

1. It is important that the document is accessible to users in terms of layout and language.
2. Recommendations from the National Adult Literacy Agency (NALA) should be followed:

- Type of Font – NALA approve Verdana, Calibri, and Arial (choose one)
- Type size – Headings 12 Bold and Text 12
- Align the text throughout the document
- Use single line spacing
- Use double spacing between paragraphs
- Section Headings – boldface typed
- Every entry in a guideline must be numbered
- Paragraphs are structured so that each main subheading represents a separate heading
- Each subheading is represented by equal indentation
- Abbreviations should be kept to a minimum
- Definitions for all terms used in the text must be included
- When working with draft documents ensure a draft number and date is identified clearly on the cover page

In this section Guideline Developers make reference to:

- What was the role of each developer in the literature review process
- Who conducted the review of the literature
- Who reviewed the final documents selected
- What evidence is available to answer the clinical questions
- What is the quality of evidence
- Is the evidence applicable to the Irish setting
- Why literature was used or omitted

Recommendations

The guideline developers should identify a set of recommendations to be listed at the beginning of the guideline. These will consist of recommendations the developers have identified to be prioritised for implementation to improve patient outcomes.

For recommendations to change practice, they need to be specific to populations, settings and or circumstances and be easy to understand. Ideally, recommendations need to reflect considerations of both benefits and harms/side effects/risks.

Guideline developers should describe the methods used to formulate the recommendations and how final decisions were reached. This includes specifying any areas of disagreement and the methods used to resolve them.

How the guideline development group linked and used the evidence to inform the final recommendations must be clear – this can be assisted by linking the recommendations to evidence tables and / or the evidence summaries in the literature review.

Grading of Recommendations Assessment, Development, and Evaluation (GRADE) is a recognized and standardized process used to rate the quality of supporting evidence and determine the strength of recommendations. This process helps to inform the key stages in guidance development process: the formulation of clinical questions, review of the evidence, and grading of recommendations. While we acknowledge that for this particular work an extensive GRADE approach is not possible, we do recommend using the suggested language set out in the GRADE table when making your recommendations.

The table gives examples of how this can be applied in practice, in terms of hierarchy of statements and language used in the CPG. GRADE table

Other considerations

Guideline developers are likely to identify potential resource implications of implementing the CPG, including the need for staff education and training, protected time or clinical space. These should be included in the CPG and will be considered by the programme team and EAG.

An important outcome of the guideline development process is in highlighting gaps in the evidence base. Ideally, CPGs should have a section listing the guideline development group's recommendations for future research.

A plan for dissemination of each CPG will be developed by the guideline programme team to ensure effective communication and collaboration with all stakeholders once the final guideline is published. The guideline developers may wish to be involved in this process.

Auditable Standards

Development, dissemination and implementation of a guideline should be monitored and evaluated through clinical audit. Guideline developers should present key review criteria and standards for monitoring and audit.

"Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated

against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements."[5]

The terms 'standard' and 'criteria' often lead to confusion as these terms have been used differently by various professional groups and writers across healthcare. For some, a standard is a statement of best practice. For others, a standard is the performance level or target for expected compliance (usually expressed as a percentage). [6]

The approach taken by the guideline programme team is consistent with the approach taken by the Health Service Executive when specifying standards. [6–8]
A standard describes and defines the quality of care to be achieved. Standard criteria are explicit statements representing elements of care which need to be achieved in order for that standard to be reached. Criteria may relate to process (e.g. decision, interventions, and communications), structure (staffing, space, skills) or outcomes (expected outcomes of care).

References

All references used in the CPG should be listed. The preferred citation format is the Vancouver style (https://libguides.ucd.ie/vancouverstyle). The Vancouver style places full details of references at the end of a paper in the form of a numbered list. Superscript numbers are used for In-Text-Citations. The list of references should appear at the end of the CPG in the order which they were cited in the document. An additional bibliography will also be used at the end of every CPG – the guideline developers may have some general texts, reference manuals or standards to add to this section.

References for this guideline developer information sheet

1. Royal College of Obstetricians and Gynaecologists. Developing a Green-top Guideline Guidance for developers [Internet]. 2020. Available from: https://www.rcog.org.uk/en/guidelines-research-services/guidelines/clinical-governance-advice-1a/
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3. Brouwers MC, Hanna S, University M, Kho CM, Canada Littlejohns OP, College London K, et al. AGREE II PUBLICATION [Internet]. 2017. Available from: www.agreetrust.org
4. Health Service Executive Ireland. Quality Improvement Division., National Clinical Strategy and Programmes Division. HSE national framework for developing policies, procedures, protocols and guidelines (PPPGs) [Internet]. 2016. Available from: https://www.hse.ie/eng/about/who/qid/use-of-improvement-methods/nationalframeworkdevelopingpolicies/
5. Commission on Patient Safety and Quality Assurance., Madden D, Ireland. Department of Health and Children. Building a culture of patient safety : report of the Commission on Patient Safety and Quality Assurance ; [chair: Deirdre Madden]. Stationery Office; 2008. 228.
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7. Clinical Audit Criteria and Guidance Working group. Healthcare Audit Criteria and Guidance [Internet]. 2008. Available from: https://www.hse.ie/eng/about/who/qid/evidence-for-improvement/clinical-audit/
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Bibliography for this guideline developer information sheet

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Scottish Intercollegiate Guidelines Network (SIGN). A guideline developer's handbook. Edinburgh: SIGN; 2019. (SIGN publication no. 50). [November 2019]. Available from URL: http://www.sign.ac.uk

Society of Maternal-Fetal Medicine. SMFM Clinical Practice Guidelines Development Process [Internet]. Available from: https://www.smfm.org/publications