ACPGBI Framework for guideline development

Introduction

This document is a framework for development of future ACPGBI guidelines. It was developed by the ACPGBI guidelines subcommittee (Lisa Massey, Rebecca Fish, Nick Lees, Sree Mallappa, Lillian Reza, Adele Sayers, Phil Tozer and with thanks to Sarah Fitzgibbon). It was developed with reference to the Guidelines International Network (GIN) standards[1] and AGREE-II[2] and AGREE-S[3] tools or guideline quality assessment. An early draft was developed with reference to the UEG guideline development framework.[4]

ACPGBI guidelines will be funded by the Association with the process of topic selection for guideline development overseen by the guidelines subcommittee. We anticipate the selection of one or two topics for guideline development each year.

This document makes reference to the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach to guideline development. This approach is “a system for rating the quality of a body of evidence in systematic reviews and other evidence syntheses, such as health technology assessments, and guidelines and grading recommendations in health care”. More can be learnt about the GRADE approach from a series of published articles in the BMJ.[5]

1. **Topic selection**

   Guideline development in any form requires a significant amount of time and other resources. It is imperative therefore that topics for guideline development are carefully selected to reflect areas in which there is genuine need. Without a robust selection process and assessment of need, valuable time, expertise and financial resources will be wasted on developing guidelines which go unused. The need for a new guideline should be assessed in a stepwise fashion (see Figure 1 for summary). There will be patient and public involvement throughout the process.

   a. Longlisting to determine clinical need, which may arise due to:
      i. Development of new therapies or techniques.
      ii. Publication of new evidence.

iii. Identification of gaps in current knowledge/practice, including for rare conditions.
iv. A need to address health inequalities

Identification of such an unmet need may be achieved by submission of proposals from ACPGBI specialty subcommittees or individual members. This will be facilitated though a regular formalised submission call promoted annually or at an appropriate interval as determined by the ACPGBI guidelines committee.

b. Shortlisting of submitted proposals undertaken by the ACPGBI guidelines committee will include:
    i. Checking for any existing guidelines and whether these are up to date and relevant to the ACPGBI membership and our patients.
    ii. Assessing the body of available evidence to support development of a new guideline. This should be achieved through scoping searches. If it is determined that there is insufficient evidence to support production of a clinically useful formal guideline, the guidelines committee may recommend that an alternative form of guidance is developed e.g. consensus statement.
    iii. A standardised process for review of proposals with scoring criteria completed by at least two members of the guidelines committee.
c. Prioritisation of guidelines to take forward into development
    i. The number of new or updated guidelines that ACPGBI can support in a given cycle will be limited by availability of methodological support/expertise and funding considerations and should be determined ahead of each submission call by the ACPGBI guidelines subcommittee.
    ii. If more than the agreed number of guidelines satisfy the shortlisting criteria, a process of prioritisation should take place. This should take into account any specific time or funding considerations as well as the magnitude of the clinical need. This process will be undertaken by the guidelines committee with consideration of the results of recent surveys of the membership on priority topics for guideline development.

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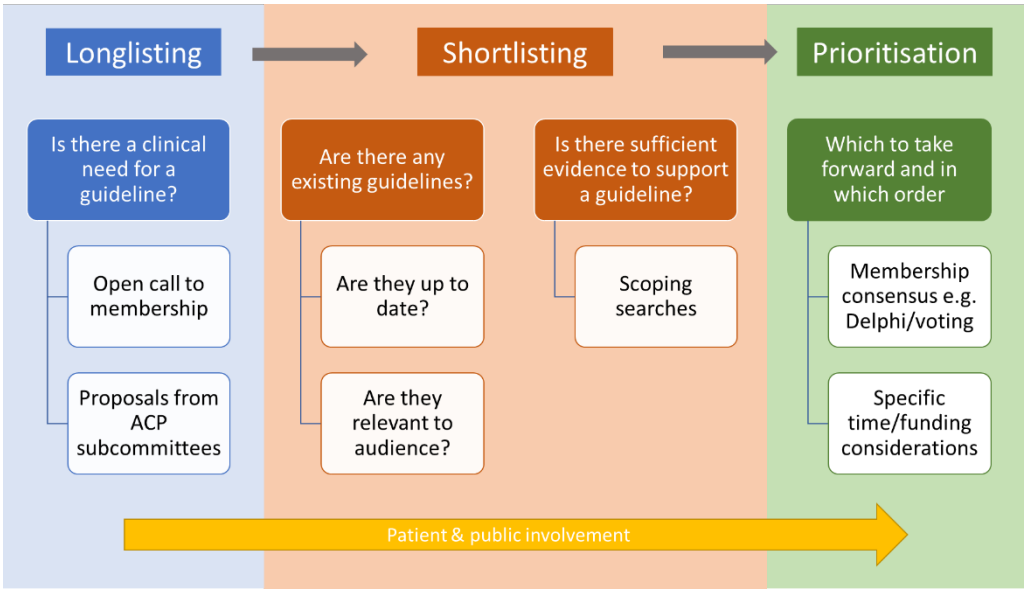

Figure 1: Guideline topic development

2. **Determining the most appropriate type of guidance**

   This could include guideline, rapid guideline and consensus statement. If there is poor quality or no evidence, then a high-quality guideline cannot be produced, and a consensus statement is more appropriate.

   a. Identify individuals to lead the work. There will be an open call for proposals for guidelines with proposals reviewed by the guidelines subcommittee. There is an expectation that individuals leading the projects have subject matter expertise as defined in section 4. Experience in guideline development is also desirable and where this is not the case a co-chair with guidelines expertise (formal training highly desirable) may be appropriate.

   b. A scoping literature search should be performed to identify the amount and quality of literature there is in the field.

   c. Project leads share findings of the scoping search with guidelines committee and agree on type of guidance to be developed and which reporting standards and methodology will apply e.g. GRADE methodology for guidelines[5], ACCORD for consensus statements[6], AGREE-II/AGREE-S reporting checklists for guidelines[2, 3].

3. **Defining scope**

   A protocol for the project, including a proposed timeline, is drawn up by the project leads. This is shared with members of the guidelines committee for input and assessment of resources and feasibility before embarking on the full project. It includes the following:

   a. Breadth and depth.
   b. What should and should not be covered considering target audience, patient population, healthcare setting, treatment/intervention, and clinical outcomes of interest.
   c. The scope should be based on gaps identified in the above that are a priority rather than aiming to be all inclusive. A well-defined, narrow scope is likely to produce a guideline that delivers on points that are clinically relevant in areas where uncertainty exists. For example, in patients with ileocolonic Crohn's disease requiring surgery, what lifestyle, dietary and medication interventions reduce the risks of perioperative complications?
   d. Potential collaborators and other stakeholders are identified at this stage. These could include other guideline-producing organisations with interests that include the topic. Agreements about funding, authorship and publication should be completed at the outset. If a potential collaborator has a guidelines committee then this would be our usual point of contact. It should be agreed at the outset what the role of the collaborator would be including funding, methodological expertise, members to contribute to the panel or review of the final recommendations. Any potential conflicts of interest should be identified and managed (detailed in section 5). Depending on the role(s) of the collaborator it may be appropriate that the guideline is presented as a joint venture, "with input from" or "endorsed by" the collaborator. Agreements about authorship and target journal are made at this point.
   e. A GANTT chart/project timeline including key points when the guidelines committee will be given updates. Project timeline should include dates for the following milestones:
      i. Formation of steering group
      ii. Development of PICO questions

iii. Formation of wider guideline development group
iv. Searching for evidence
v. Grading evidence
vi. Consensus meetings for development of recommendations
vii. Completion of first draft
viii. Submission to journal

We suggest updates should be given as a minimum after points ii, v and vii.

f. A clear plan of who will write the final guideline and authorship model.

4. Establishing working groups & formulating PICO questions

Three distinct groups will be required for guideline development. The roles and responsibilities of these groups are described below:

a. Steering group

This group should consist of the project lead, and up to four other members who will be responsible for performing an initial scoping search and defining the scope of the guideline. These members should be current members of ACPGBI. At least one member of the steering group should be a subject matter expert, another a methodologist, and another a patient. This group should identify potential collaborators for the guideline once scope has been defined. Stakeholder groups and the need for subject matter experts should be identified by the steering group. The overall progress of the guideline development group will be overseen by the steering group throughout the guideline development process until completion of the project. Members of the steering group will chair the GDG.

b. Guideline development group (GDG)

This group contains two separate cohorts, the evidence synthesis team and stakeholders.

i. Evidence synthesis team

This cohort should include members with methodological expertise whose role is to oversee the guideline development process and ensure methodological rigour. They will not have voting rights in the consensus process. They will help develop

the PICO (population/patient/problem, intervention, comparator, outcome) questions with the stakeholders. They will be responsible for performing a systematic search of the literature for the PICO questions, conducting GRADE assessment, and producing evidence--to-recommendation tables. This evidence synthesis team may consist of a methodologist and at least one other member, potentially many more for a larger guideline.

ii. *Stakeholders*

This cohort should consist of people who may be affected by the recommendations of the guideline. Stakeholders should be clinicians from the multidisciplinary team managing the condition of interest (e.g. consultant surgeons, physicians, radiologists, general practitioners, nurses and other allied health professionals), subject matter experts and patients. There should be at least two members from each stakeholder group. The stakeholders should be limited to no more than 20 members. They will be involved in the development of the PICO questions and will have voting rights at the consensus meeting which will establish the final recommendations for the PICO questions.

c. *Selection of members*

The project lead, on behalf of the steering group, should define essential and desirable criteria for selection of members with the guidelines subcommittee. There should be an open call for applications to the various working groups outlined above. The call for applications will be made as an open call through the ACPGBI newsletter and other relevant associations for the recruitment of subject matter experts. If an organisation has a guidelines committee then they should be approached, if not we would ask them to identify their own route (preferably via an open call).

d. *EDI in selection of members*

The guidelines subcommittee will audit the selection of members to ensure compliance with the principles of EDI, as well as appropriate numbers in

the Evidence Synthesis and Stakeholder cohorts. When selecting between applicants for each cohort, an equitable balance of gender, age, geography and practice setting should be sought, where possible. Some guidelines may require specific additional EDI considerations e.g. sexual orientation.

e. *Subject matter experts*

There is no agreed definition of subject matter expertise. In general, a subject matter expert is more than simply a practitioner, even an experienced or well-regarded one. They should demonstrate “reflective practice” which is implied by publications, a high-volume relevant practice and other markers of esteem (national or international) in the relevant area. Involvement in committees or other guidelines would not alone denote an expert, nor would expertise in an adjacent field. This definition remains subjective, but any published guideline would need to justify its own rationale and appointments.

The criteria for selection of patient partners should focus on their lived experience and they may be considered “experts by experience”.

f. *External reviewers*

The steering group should identify one or two external reviewers to review the protocol, consider existing guidance and recommend changes early in the guideline development process. The final manuscript should also be reviewed by the external reviewer(s) prior to submission for publication. The guidelines subcommittee may be able to suggest suitable external reviewers.

5. Managing conflicts of interest

It is critical to address potential conflicts of interest (COIs) at the outset of forming a working group. All participants must submit a comprehensive declaration of interest (DOI) before their involvement is approved. These declarations should be inclusive of financial, intellectual, academic, clinical, and public interests to maintain transparency, adhering to ACPGBI policy on declaration of interest.

a. It is the responsibility of the steering group to meticulously examine each participant's DOI to ascertain whether any disclosed interests could potentially hinder their impartiality in the work process.
b. As the work progresses, it is possible for COIs to evolve or new ones to surface. Consequently, it is recommended to periodically reassess COIs at predetermined intervals, such as biannually or at significant milestones within the project timeline. A feasible method for maintaining current declarations is to have participants reaffirm their DOI by signing an updated draft of their original declaration. Any modifications to a DOI should receive the steering group's re-endorsement.
c. Determining what constitutes a significant COI, particularly concerning industry funding, requires careful consideration. Direct involvement with a company, such as employment, consultancy, paid speaking engagements, or share ownership in a company related to the guideline, should be flagged as potential COIs.
d. The Chair of the Guideline Development Group should have no COI relevant to the guideline topic. COI from other members of the Guideline Development Group will be reviewed by the Chair. These COIs do not necessary preclude the individual's involvement in the guideline but may require management, for example withdrawal from voting and/or discussion on specific recommendations.
e. A detailed published disclosure to be provided on the funding source, the role of sponsors and any financial or other support provided towards guideline development.
f. In instances where the complexity of COIs warrants external input, seeking the expertise of the guidelines subcommittee may be beneficial. Ultimately, all disclosed interests must be transparently reported in the final version of the guideline document.

6. Budget and Timeline

A budget should be drawn up for the costs of guideline development. The sources of funding should be clearly stated in the final guideline document, including any financial support received during the development process. For

ACPGBI guidelines funding will come directly from the Association with the expectation that the target journal for publication will be Colorectal Disease.

a. Estimated costs for each step of guideline development should be outlined. Proposals will be asked to include a budget template. These costs will include a budget for a methodologist and may include costs for a guideline development platform, methodology software such as GRADEPro and expenses.
b. Many members of the guideline development group will work as volunteers with no payment or reimbursement for their time. Statisticians and methodologists will require payment for any work done, as may other members of the evidence synthesis team. Financial support in the form of travel reimbursement will be available for attendance at guideline panel meetings in line with the ACPGBI expenses policy.
c. A clear policy on payment to patient partners should be outlined prior to their involvement so that they know in advance what is being offered and are able to make an informed decision about their involvement.
d. Additional costs for searches, methodological support, publication fees and training panel members should be included in the initial proposal. All funding should be declared in the published guideline.
e. Address the timeline and timetable for the completion of guideline development milestones and completion of the guideline at each meeting with strict adherence to target dates for completion of guideline development milestones. Realistically, high-quality guidelines may take 12 to 36 months to complete. The ACPGBI guidelines project timeline template should be completed at the time a proposal is received. The guidelines subcommittee will work with groups to understand and support where possible the meeting of these milestones. In instances where inadequate progress is made despite this support then funding may be withdrawn.

7. Patient and public involvement (PPI)

Patient involvement should be present from the outset, including evidence that the topic is relevant to patient care and PPI involvement in the guideline proposal.

We encourage patient partners being part of the project steering group and they are an essential part of the GDG with input into the discussions and the final recommendations including the acceptability of these to patients. The published guideline should be reviewed with patients and the public to produce a lay version and/or summary (see section 13).

8. Evidence search

a. A search protocol should be developed with the help of a methodologist. This should include details on methods for locating, selecting and synthesising evidence, in addition to outlining database selection, setting inclusion/exclusion criteria, and detailing how results will be assessed/documented.
b. It should be determined who within the group will develop the search strategies, perform the searches and select the evidence (e.g. a working group within the development group, whether some/all it will be outsourced to an external agency. If an external agency used, this should be agreed on in the budget beforehand and the contract agreed with ACPGBI).
c. When selecting evidence, the most commonly used approach is a step-by-step iterative approach by levels of evidence in order e.g. systematic reviews followed by RCTs etc.
d. If existing systematic reviews are found, these should be appraised using a validated tool (e.g. AMSTAR 2[7]) to ensure they are of adequate quality and therefore appropriate for use within the guideline. If not of adequate quality, or the review requires updating, then the next level of evidence should be used and a new systematic review conducted. These decisions are best taken in collaboration with a methodologist.
e. Pivotal studies should be included when filtering evidence e.g. by date.
f. All evidence identified in the search should be screened by at least two working group members. Evidence should be screened in a stepwise approach (e.g. screening of titles, screening of abstracts, then screening of manuscript). Both reviewers should agree that the final manuscripts meet the pre-defined inclusion criteria. If there is no agreement, then consensus with a third working group member should be sought. Results (including

details on the evidence excluded) should be summarised in an evidence table with key references, short explanatory text and level of evidence. The Preferred Reporting Items for Systematic reviews and Meta-Analyses[8] (PRISMA) or Methodological Expectations of Cochrane Intervention Reviews[9] (MECIR) frameworks should be used.

g. Methods for identifying additional evidence and unpublished data and handling and appraising this evidence will be handled and appraised should be established (e.g. expert opinion).
h. All searches, including search strategy and details on selection of evidence must be documented and published to ensure that methods are explicit and transparent.

9. Summarising and grading of evidence

Evidence should be summarised using a concise summary (e.g. evidence tables) of the best available evidence for each important outcome. This should include anticipated benefits, harms, resources, quality of evidence rating and a summary of the relative and absolute results/estimate of effect for each outcome. Further detail on evidence tables can be found within the GRADE Handbook.[5]

a. Methodological support should be sought by the working group for development of the evidence tables and grading of evidence. Training on guideline methodology include evidence tables should be undertaken by members of the GDG. This could include formal training from e.g. InGuide or online courses such as the one offered by UEG or training from the guideline methodologist.
b. The quality of evidence for each important outcome, including the judgements made in appraising the quality, should be documented to ensure they are transparent and explicit.

10. Developing and writing recommendations including evidence to decision framework

a. Apply an evidence to decision framework (e.g. GRADE) outlining the factors to be considered to arrive at a recommendation, taking note of those factors that will influence the direction and strength of the final

recommendation (e.g. quality of evidence, balance between desirable and undesirable effects, resource use, equity, implementation considerations etc). Draft recommendations should be developed by the GDG based on the evidence tables. Final recommendations should be established by consensus by the stakeholders in the GDG. In the absence of unanimous agreement, a formal consensus process should be used e.g. Delphi. The protocol should outline the consensus process and threshold (usually 80% agreement, not less than 70% agreement) for achieving consensus.

b. Developing guidelines using consensus methods when evidence is lacking:
    i. Where there is a lack of evidence to support superiority of an intervention, the GDG may choose not to make a recommendation (and state that further research is required), or the GDG may suggest that as there are no significant differences in efficacy, either intervention is acceptable. The GDG may also choose to make a recommendation based on expert opinion and indirect evidence. GRADE methodology may support the production of Good Practice Statements in these cases. Voting on “expert consensus” recommendations must be undertaken by subject matter experts. Other committee members (including patient partners) should remain vocal members of the GDG, providing advice, context and methodological expertise as relevant to their role.
    ii. Where a consensus process has been used to develop recommendations, the ACCORD guidance[6] should be followed and reported. If a guideline contains both evidence-derived recommendations and recommendations developed by consensus methodology in the absence of adequate evidence, both ACCORD and AGREE-II/AGREE-S reporting checklists[2, 3] should be used accordingly and the guideline should clearly state which methodology has been used for each recommendation.
c. Make provisions for formulating research recommendations and decide where to report them in the final document (e.g. in the guideline appendix,

suggesting specific research questions, or specific patient-important outcomes that need to be measured)

d. Formulate each recommendation with a clear summary of the rationale for each recommendation. This should include transparent details about judgments that were made by the group and highlight the explicit link between the recommendation and the supporting evidence.
e. Select a method for rating the strength of the formulated recommendations, so that the guideline group's confidence in that recommendation is clear. There should be standardised wording used in each recommendation to ensure clarity and consistency throughout the guideline, avoiding the use of vague and nonspecific wording within recommendations. The exact wording to be used, based on the strength of the recommendation should be made clear within the final guideline. For example, as advised by the GRADE working group:
    i. For strong recommendations the phrases "we recommend" or "clinicians should"
    ii. For weak recommendations "we suggest" or "clinicians might"
f. Recommendations must be written in a way that is actionable and contain sufficient information, so that guideline readers do not need to refer to any other material in order to understand the recommendation.

11. Writing the guidelines

a. A standardised format for reporting the guideline should be used, with use of a specific structure, headings and content.
b. Decide who will be responsible for writing the final guideline (see section 3).
c. Ensure that the quality of evidence and strength of recommendation is reported in proximity to the recommendation statement.
d. There must be a review of the final draft of the guideline by all members of the guideline development group, whilst ensuring there is sufficient opportunity for feedback, editing and revisions by all group members.
e. Review of the final guideline must be sought from the guideline development group.

12. Final manuscript

a. The final manuscript should include a background outlining the scope of the guideline, patient/population studied, healthcare setting and the intended audience. The methodology should state the role of the steering group, evidence synthesis group and guideline panel. The process used to develop recommendations should be clearly outlined and any deviations from the protocol should be explained. The manuscript should present each PICO question with recommendations followed by the relevant GRADE and evidence to recommendations tables.

b. A summary of recommendations should be included for quick review.

c. There should be a reference made in the methodology to the protocol and where it may be accessed (ACPGBI website or formal publication).

d. The manuscript should include a section on implementation of the guideline. The group should consider challenges to implementation of the recommendations. These challenges may be resource limitations, availability of trained personnel/expertise, and variation in practice due to cultural differences.

e. A suggested timeframe for updating the guideline should be included.

f. The AGREE-II/AGREE-S appraisal instrument[2, 3] should be completed and included with the manuscript to demonstrate adherence to the standards set by the tool kit. In the case of a consensus statement the ACCORD checklist[6] should be used.

13. Guideline implementation

Strategies to increase implementation should be considered early and prior to publication. Publication should be on an open access platform. Short versions, patient versions/mobile/app versions /translation can all be considered. Inform relevant patient groups and policy makers that new guidelines have been published. This work will include:

a. Liaising with the ACPGBI Patient Liaison Group to co-produce lay versions/summary.

b. Developing a dedicated section on the ACPGBI website for guidelines.

c. Planning promotion of awareness of new guidelines before publication, including via national and international meetings and social media.

14. Guideline updates

a. The steering group should reconvene at pre-determined intervals to assess the need for update; the steering group may nominate/form a designated working group for this.

b. The need for an existing guideline to be updated should follow the same process for long-listing, short-listing and prioritization as described in section 1.

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