The Association of Coloproctology of Great Britain and Ireland

Terms of Reference for ACPGBI Guidelines Committee

Background:

- The production of guidelines is a fundamental role of the ACPGBI: Guidelines underpin modern clinical practice and its governance. It is essential that ACPGBI produces robust and evidence-based guidelines to support its members and the wider clinical community.

- Guidelines provide an additional role in supporting the development and relevance of the Association's own journal, Colorectal Disease.
  The journal's editor Neil Smart has noted that in the 2 leading colorectal journals that published guidelines differing impacts are felt on the journals at present.
  Colorectal Disease (CODI) – 0% of top 10 / 9% of top 100 cited papers 2016-2020
  Diseases of the Colon and Rectum (DCR) – 50% of top 10 / 15% of top 100 cited papers 2016-2020

- The requirements for Guideline Development have significantly changed in recent years and there has been a "step-change" in the methodology with use of AGREE II, AGREE-S and GRADE. This has increased the volume and complexity of work required to produce a guideline and many Colorectal Specialists are unfamiliar with this methodology. An ACPGBI Guidelines Committee will be established to lead and support ACPGBI guideline development.

- **Purpose and Objectives of the ACPGBI Guidelines Committee:**

The Committee has several roles (Ref: Roles of ACPGBI Guidelines Committee) and their work will be undertaken within a Guideline Development Framework (Ref: Process for Delivering ACPGBI Guidelines).

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Royal College of Surgeons of England / 35-43 Lincoln's Inn Fields / London WC2A 3PE / Telephone: **+44 (0)20 7973 0307** / **+44 (0)20 7973 0373**
Email: admin@acpgbi.org.uk

A) Roles of the ACPGBI Guidelines Committee:

1. **Develop a Guideline Development Framework.**

   This will be an initial role for the committee to guide ongoing activity.

2. **Select areas for ACPGBI Guideline Development:**

   a. *Define areas where guidelines are required.*
   b. *Review of published evidence.*
   c. *Prioritisation of areas for guideline development.*

3. **Define requirement of the membership eg Guideline or Consensus Statement:**

   a. *The type of guidance will be determined by the Guideline Committee based on evaluation of the quality of published literature using the Guideline Development Framework.*
   b. *The Guidelines Committee may require external specialist input to support this process (Subject Area & Methodology).*
   c. *Consider whether the guideline would benefit from joint development with other professional bodies eg. JAG, ESCP, ASGBI.*

4. **Support Selected Guideline Development:**

   a. *Selection of Guideline Development Group and Chair.*
   b. *Define meeting process.*
   c. *Methodological support – engage expert and / or provide expertise (PICO / Recommendations / Delphi / Grading).*
   d. *Support guideline writing.*

5. **Review of New (External) or Existing Guidelines:**

   a. *New (from External Organisations) – initiate contextualisation process.*
   b. *Existing – initiate update process.*

6. **Communication:**

   a. *Provision of regular updates on Guideline activity to Executive and Council.*
   b. *Communication to allied organisations re potential joint guidelines.*
   c. *External communication of new guidelines (Website, Publication, Twitter etc).*

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B) Process for Delivering ACPGBI Guidelines:

- **Guideline development framework**

The ACPGBI should have its own framework for guideline development. This should use the AGREE-S framework as its basis, but this should be enhanced with a greater emphasis according to our own priorities including patient involvement, EDI, and subject matter expertise. This will minimise bias in panel selection and will delineate a clear process of development enabling those who wish to take part in guideline creation to expand their skills and experience.

The framework should include the following areas:

1) *Choice of guideline development group members*
2) *Drafting of the protocol/proposal (including AGREE-II and AGREE-S)*
3) *Managing conflicts of interest*
4) *Outcome selection: There should be a prioritisation of outcomes. This consists of not only voting on the importance of outcomes, but also setting minimal important differences per outcome, as described by GRADE working group.*
5) *Formulating the questions and development of PICOs*
6) *Evidence retrieval, including development of a framework that will outline steps for reviewing systematic reviews, to avoid using poor-quality reviews as a basis for recommendations. If no good quality review exists, then a new systematic review may be commissioned, which is detailed in the WHO handbook for guideline development.*
7) *Evidence assessment (GRADE)*
8) *Development of recommendations*
9) *Guideline writing*
10) *Guideline implementation, adaptation (including potential barriers) and monitoring/evaluation.*
11) *Setting a date for updating the guideline*

- **Framework for identifying and selecting topics for guideline development.**

Without a robust selection process and assessment of need, valuable time, expertise and financial resources will be wasted on developing guidelines which go unused.
In assessing the need for a guideline, consideration needs to be given to three broad questions in a stepwise fashion, only progressing to the next stage if the answer at each stage is yes (see figure 1).
Following a robust and transparent framework for identifying and selecting areas for guideline development ensures that:

1. *The initial longlisting is broad and inclusive minimizing the potential for important areas to be overlooked.*
2. *Potential for waste/duplication is minimized.*
3. *The wider ACPGBI membership are engaged early increasing awareness of and confidence in any guidelines produced and subsequent good uptake/utilisation.*

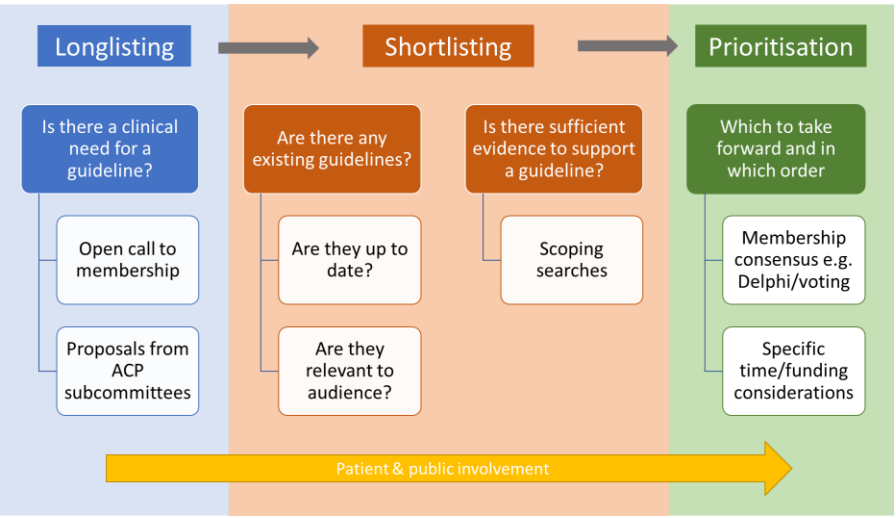

Figure 1: Framework for identifying and selecting areas for guideline development.

- **Format of Guidance Produced:**

The Guideline committee can decide upon the format of the guideline and whether the topic is suitable for a guideline or a 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. The Accurate Consensus reporting document (ACCORD) from the Equator network (Enhancing the Quality and Transparency of health research) is due to be published in 2023. This guidance should help ensure a degree of methodological rigour when producing consensus statements.

- **Updating Guidance:**

There will be a need to update older guidelines. This work will need to be prioritised alongside the development of new guidelines. Updating guidelines that have been conducted with more transparent methods should be easier when updating search strategies and including new evidence. The process for updating should be clearly outlined in the ACPGBI Guideline protocol and the guideline.

1) *The timing of guideline updates may be different depending on guideline type; a rapid guideline or consensus statement could be updated more frequently than a standard guideline (e.g 3-5yrs). If new evidence is available, then the guidelines should be updated sooner.*
2) *For standard guidelines, it is also not always necessary to update the whole guideline, (unless it has not been subject to the current standards of Methodology). The focus should be on areas where there is new evidence available.*
3) *Periodic searches, using the guidelines search strategy should be conducted, to highlight new evidence. This lies within the remit of the Guideline committee.*

- **Guideline Development Groups Structure:**

Guideline development groups (GDGs) should have a Chair, a methodology expert, a number of subject matter experts and a number of stakeholder representatives. GDGs should number around 12-16 members, but this may vary according to the nature of the guideline work being undertaken.

- **The Chair's role** is to lead the GDG, monitor costs, report to the Guideline Committee, and organise meetings, voting, dissemination and reporting. Inguide level 3 training would certainly be valuable as something to aspire to in time but is not a prerequisite. Methodological experience, Inguide level 1 training and subject matter interest demonstrated by publication or committee membership will be required by the chair. A co-chair may sometimes be valuable.

- **The methodologist's role** is to maintain the methodological integrity of the guideline, according to the framework in use, advising and supporting the actual method being employed. They should have Inguide level 2 or equivalent training and may be supervising a trainee methodologist in addition.

- **The Subject matter experts' role** is to provide interpretation of the evidence and voting in expert consensus processes. Subject matter experts would ideally have or be working towards level 1 Inguide training or equivalent. Defining subject matter experts is difficult and this should be based on publication, tertiary practice and evidence of reflective practice, rather than committee or administrative experience alone. They might come from any professional group (surgeons, nurses, gastroenterologists etc.) and any hospital setting (DGH, teaching hospital etc.). Around 6-10 subject matter experts may be appropriate, depending on the nature of the guideline and subject.

- **Stakeholder representatives** are crucial to ensure that the guidance produced is relevant to patients and across the range of HCPs using them, including any combination of colorectal surgeons (including from DGH and teaching hospital settings), specialist nurses, gastroenterologists, AHPs and GPs, for example.

- **Higher trainees** may be involved in guideline development groups as part of their own training or academic work. In this setting, they will be invested in undertaking a substantial portion of the work required in evidence identification/assessment, and data extraction and may attend GDG panel meetings.

- **GDGs should demonstrate:** active engagement & representation with equality, diversity & inclusion (EDI).

- **ACPGBI Guideline Committee Strategy:**

The ACPGI Guidelines Committee should define a strategy for a 5-year period. This should recognise the need to develop the training of individuals in guideline methodology. This strategy should be consistent with the Strategy Document currently in production for the whole Association.

The strategic directions should include:

- **Development of an ACPGBI framework for guideline development** and the appointment of the GDG members
- **Prioritisation and planning of defined areas for guideline development** over a rolling period of 2 years, so that the output is always current and relevant to the needs of the general membership of the ACPGBI.
- **Development of methodological expertise within the ACPGI:**
    - *Training for specific methodologists to the level of the current contracted expertise*
    - *Training for a small group to a level of leadership of GDGs*
    - *Training for a large group of individuals to a level of GDG panellist*
    - *Individuals should be selected based on application.*

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- **Identification of subject matter expertise within the ACPGBI.** This may be difficult to achieve, and it would be useful for the Association to delineate a benchmark for expertise, which might have wider application beyond guideline work.
- **Development of a trainee group** to create a source of trained guideline panellists which might undertake subprojects of SR writing and grading of existing SRs to gain relevant skills in reviewing and statistical analysis.
- **Development of Guideline / Research Fellowships** – this could be part of a longer-term strategy once there is some maturity of experience within the guideline committee.
- **Guideline methodology sessions and courses** could also be developed and offered at the national meeting.

Membership & Structure of ACPGBI Guideline Committee
The membership of the ACPGBI Guidelines Committee will consist of the following:

- *6 elected members including a mixture of stakeholders (Academic Experience, DGH Type Experience)*
- *Trainee Representative*
- *Patient Representative*
- *Nursing Representative*

Membership will be for a 3-year period (renewable by application for re-election for a maximum of 6 years). Members will need to have received or will require training in Guideline Methodology. The elected members may be augmented with additional temporary external members where specialist expert input is required including Subject Matter Expertise and Methodology Expertise, (incl. Statistician etc.). Editorial advice may also be sought ay an early stage in the development process.

Accountability:
The chair of the subcommittee will report to the Chair of the MCC.

Meetings:
The guideline group will meet regularly to evaluate new guideline proposals and update regarding current guideline development. Individual members will be required to attend Guideline Development Meetings more frequently as required.

Reimbursement of expenses:

The ACPGBI will reimburse reasonable day travel expenses and second-class rail fares. Overnight accommodation and subsistence will be covered if required.

- **Costs of ACPGBI Guideline Development**

The ACPGBI Guideline Taskforce (2023) undertook a detailed evaluation of the potential costs of guideline development. The following costs were identified:

- **Methodologist** as a consultant. If we decide to train surgeon methodologists this would only be an early cost. They will attend all guideline meetings and be available for consultation. They can provide consultation for two guidelines at a time only. This does not include providing training for GDG members.
- **Training GDG:**
    - **To level 1 with INGUIDE (Option 1)** – £1500-£2000 per guideline

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  - **To Level 1 with Professor Jos Kleijnen (Option 2)** – £2000 for an 8 hour session for an unlimited number of members. He will include objectives covered in INGUIDE level 1 but he will also expand on topics as necessary and tailor it to our needs.
  - **Additional training -** INGUIDE level 2 for each guideline and an additional member being trained to level 3 - £1944 - £2679 per guideline.

- **Patient representatives' costs -** ACPGBI should cover transport and overnight accommodation (where necessary) for face-to-face meetings. There is also an argument that they should be paid for their time.

- **Costs associated with GDG panel meetings** – it is possible to conduct meetings virtually, but other guideline-producing groups often have at least one face-to-face meeting. This could be attached to e.g. the annual conference to reduce additional travel and/or accommodation costs.

- **Publishing costs** – not defined (Open Access)

- **Research fellow (s) –** Experience from within the taskforce indicated the need for at least 1 or 2 individuals, who are required to undertake a substantial quantity of work in the production of guidelines (incl. Literature Search, Evaluation of Literature, Grading, Guideline Writing). This is often best achieved through employing a Research Fellow working on the topic area, who can submit the guideline development as part of their thesis. The Research Fellow would need to be provided by a member of the Guideline Development Committee for a guideline, since the cost of this would exceed available funding from the ACPGBI. The ACPGBI could however contribute to Guideline Methodology Training).

- **Cost effectiveness analysis (COA**) in guidelines- probably not required for ACP guidelines unless performed in partnership with NICE/funding bodies. Specialist associations are usually not expected to perform COAs for recommendations and in instances where they have in the past, it is usually through engagement and partnership with local funding decision makers or NICE. From discussions with Jos Kleijnen, the cost of performing a COA using KSR evidence will depend on the number of recommendations being assessed and can cost an additional £40,000 - £50,000. NICE guidelines usually have a budget of £250,000-£300,000 per guideline, and normally limit COAs to 1-2 recommendations due to the costs associated with producing these in the absence of appropriate evidence).

- **Summary of costs of producing guidelines:**
  From the above, it is estimated that an ACP guideline will cost approximately £15,000 to produce with the help of research fellows under the supervision of a methodologist.
  Generally, the cost of a guideline depends on the scope of the guideline and the number of recommendations that a guideline is expecting to produce. For perspective, if we commissioned KSR evidence to produce a guideline then they would perform the literature search for systematic reviews and RCTs, data extraction, ROBIS assessments, GRADE, and evidence tables. They normally estimate £40,000 per guideline for this work as each recommendation costs £3000 to produce. Depending on the scope of the guideline, this estimate can increase. This estimate also does not include producing new systematic reviews or performing additional meta-analysis. It only involves a pragmatic approach to evidence, where any available high level (existing systematic reviews, RCTs) evidence is extracted to produce recommendations.

References:

1. AGREE II : www.agreetrust.org/agreeii
2. AGREE-S: www.agree-s.org
3. GRADE: www.gradeworkinggroup.org

Michael Davies, Graham Branagan, Jared Torkington. October 2023