Association of Coloproctology of Great Britain & Ireland Advice on Production of Clinical Guidelines and Position Statements

Michael Davies (Multidisciplinary Clinical Committee Chair) **January 2021**

- **Introduction**

The Multidisciplinary Clinical Committee (MCC) of the Association of Coloproctology of Great Britain and Ireland (ACPGBI) and its various sub-committees commission guidelines on the management of various aspects of colorectal surgery with the underlying ethos to improve the care of patients with colorectal disease. There is a need to ensure the highest level of quality when producing these guidelines, to ensure that they are compliant with NICE standards of guideline development.

Any member of the ACPGBI who wishes to produce or update guidelines should use this document as a template to ensure this highest level of quality. Occasionally the ACPGBI will commission Position Statements, similar to full guidelines but without the same level of methodological vigour. This may be the case when a rapid response is required and would normally be followed by a full guideline project.

- **Commissioning**

It is intended that each subcommittee of the Multidisciplinary committee will consider topics relevant to their committee for update or development. If a specific topic is identified by one of the subcommittees, this should be ratified through the Chair of the MCC. On occasions a specific need for a Guideline will be identified through individual members or the Executive itself, or a topic will fall outside the structure of the MCC subcommittees. In these circumstances the Chair of the MCC will consider such a proposal and identify an appropriate individual or team to take the topic forward.

A guideline should make an important contribution to the care of patients with colorectal disease. Where possible collaboration with other relevant organisations both within the UK and abroad should be considered in order to improve relevance and avoid duplication.

- **The Guideline Team**

Guidelines should be developed by a named team and this should typically be 5-10 individuals who have a specialist knowledge in the area covered by the guideline. There should also be a broad range of individuals representing the disciplines relevant to the topic. These include for instance clinicians from other specialties, nurses and trainees. There should also be patient representation, preferably at least 2 patients with experience of the condition being analysed. Knowledge of current Guideline Methodolology should be held by members within the Guideline Team. Ideally the Chair of the team should be an elected individual from the relevant sub-committee. When the topic falls outside the direct remit of the sub-committees an individual will be appointed by the Chair of the MCC after ratification through the Executive. The role of the other members will include some who will review the literature and others who will form the writing committee. The team may wish to divide up and concentrate on particular sections of the proposed subject. In such cases it is imperative that an overall editing team maintains consistency of the document in the final draft. The members of the team will be unpaid.

- **Patient Representation**

Patient Representation by two or more lay members is essential on the guideline team who should have a personal experience of the area of the guidelines or can represent the patient group affected by conditions covered by the guidelines, based on their experience of colorectal disease. Lay members would usually be identified through the Patient Liaison Group (PLG). The PLG may seek appropriate individuals through umbrella organisations or charities or by approaching appropriate patients under the care of the guideline team members. On rare occasions an advert may be required.

The patients or carers' views should be adequately considered and where appropriate incorporated in the guidelines. Patients or carers will receive the same material support as the other members and every effort should be made to have any technical language simplified and explained. They should be included in the authorship. Patients are responsible for writing a lay summary to accompany the guidelines.

- **Conflicts of Interest**

All members of the guideline team and any outside individuals or groups having direct input into the guidelines should complete a Declaration of Conflicts of Interest (COI) Form (Appendix 1) at both the start of the process and at the completion of the document. Conflicts of Interest include those that may lead to financial or non-financial benefit for that individual, partner or immediate family within 12 months of initiation of the project.

The COI form of the Chair will be reviewed by the Chair of the MCC (or if she/he is conflicted, by another member of the MCC). The COI form of the other members of the team will be reviewed by the Chair of the working team. If a Conflict of Interest is identified for a specific section of the guidelines, the individual may withdraw from making recommendations on that section and continue on the team. If the individual is completely conflicted she/he may be asked to withdraw from the team completely. In such cases careful discussion should occur within the MCC. All such decisions should be documented and available for external review.

- **Initial Proposal for Guideline Submission Template (see Appendix 2)**

An initial proposal for any guidelines should be submitted to the MCC for ratification. This proposal should include:

- The Objective of the Guideline
- The Target Population. This may be all patients or limited by age or to a specific special subset of patients.
- The Target Users. This will commonly be colorectal surgeons but may include other members of the multidisciplinary team, gastroenterologists and primary care physicians. In these cases, the relevant disciplines should be included in the team.
- The Main Clinical Questions including interventions and comparators as well as appropriate outcomes.
- Use of Appropriate Criteria including AGREE II (or validated surgical equivalent if that is developed) and GRADE assessment.

- Confirm that there is no recently published or guideline in progress with associated Colorectal Societies / Associations on the clinical area covered in the proposed Guideline.

- **Financial support**

Whilst it is imperative that members of any guideline team are unfunded there will be financial support available for meetings and travel reimbursement. Patients may require funding and in such cases the team should follow INVOLVE guidelines. Additional fees for searches, methodological support and publication fees may be provided after discussion through the MCC and at Executive level. All funding should be declared in the published guideline.

- **Development of the Guidelines:**

    - **AGREE II**

Guidelines should be developed in accordance with the principles laid down by the Appraisal of Guidelines for Research & Evaluation Instrument (AGREE II) instrument. AGREE II is a checklist to ensure transparency and clarity of reporting of practice guidelines. The topic should be registered with the AGREE II website at the start of the project and the instrument utilised. It is recognised that the AGREE II instrument may not be completely appropriate for surgical guidelines and a more specific instrument is under development. When this instrument becomes available it should be used in addition to the AGREE II instrument or in preference only when such an instrument is recognised by NICE. It is expected that a completed AGREE II checklist will be provided as an appendix or supplement to all future ACPGBI guidelines. .

- **Stakeholder views**

Guideline development must take into account all relevant stakeholder views and preferences including professional groups, patients or carers. The team should conduct a consultation exercise and, prior to the first meeting, should share a draft proposal with;

- Relevant professional organisations (eg BSG, AUGIS, Primary Care, RCN)
- International colleagues to ensure no duplication or identify collaboration (eg ESCP, ASCRS, CCSANZ)
- Charities representing patients (eg IA)
- The Patient Liaison Group of the ACPGBI (if not represented through the lay members of the team)

Replies must be taken into consideration and, where appropriate, incorporated into the Secondary Guideline Proposal (Appendix 3). This proposal should also include the final team member list with signed COI forms from all members and be again submitted to the MCC for consideration.

- **Clinical Questions**

Once the final proposal has been ratified the team should develop the specific clinical questions to be addressed. The aim is for these questions to be as extensive as possible and should be relevant to the

recent published literature. Where other good quality guidance overlaps this should be referred to rather than being duplicated in detail.

Ideally the clinical questions should be in the form of a PICO process (Participants, Interventions, Comparators and Outcomes). The majority of the work will concern management but other sections may cover, epidemiology, clinical manifestations, diagnosis, health economics and service provision. It may be beneficial to allocate various sections to specific individuals.

- **Evidence Search**

Guidelines should include a thorough, objective and reproducible search of a range of sources to gather evidence on which management strategies can be based. The overall strategy should be decided by the guideline team and described in adequate detail, if necessary in an appendix. A search should include;

- Electronic databases (eg MEDLINE, Embase, CENTRAL)

- The time period covered and justification of this period

-The search terms used including key words derived from the clinical question set.

It is desirable to include;

- A search through specialist bibliographic databases where relevant (e.g. CINAHL for nursing related topics)
- A hand search of relevant journals
- Ongoing studies and trial registries (e.g. www.ClinicalTrials.gov, https://www.isrctn.com/)
- A grey literature search (e.g. http://opengrey.eu/)

Electronic resources should be available to all members of the guideline team and the libraries generated by the keywords should be stored to allow excluded references to be traced.

At least two members of the guideline team should then assess each article identified, preferably in the context of PICO above. Initial exclusion is based on title alone with subsequent assessment on abstract, then full article. Further consideration should be based on methodological quality. Any disagreements should be discussed and if necessary the Chair should arbitrate. The team may wish to consider utilising electronic services to help with the sorting and selecting. Funding may be available to pay for e.g. Covidence.

If there are knowledge gaps for certain clinical questions, it may be necessary to include articles of suboptimal quality but the methodological flaws should be highlighted. If knowledge gaps are still present then statements based on clinical experience and patient views may be incorporated but this needs to be made clear in any recommendation.

Shortly before publication the search should be repeated to identify important new evidence.

- **Study summary and interpretation and grading of the evidence**

The evidence for each clinical question should be systematically reviewed and summarised. Categorisation of evidence into systematic reviews, randomised controlled studies, cohort studies,

case-control studies and others is helpful. The GRADE system should be utilised. (https://gdt.gradepro.org/app/handbook/handbook.html#h.z014s19g02b2). Tables 5.1-5.3 of the handbook are particularly helpful to guide assessment. Overall the approach used to grade the evidence should include

- A GRADE definition of the quality of evidence
- Criteria for assessing the quality of evidence (risk of bias, directness of evidence, consistency and precision of results, risk of publication bias, magnitude of effect, dose-response gradient, influence of confounding)
- Quality of evidence for each outcome (high, moderate, low, very low)
- Summaries of evidence (tables or narrative)
- Criteria for strength of recommendation (weak or strong)
- Transparency of decisions about strength of recommendations

Constructions of tables based on the PICO system is encouraged and can be included into an appendix.

- **Recommendations**

Recommendations on each section should be drafted by the section leads. These should be linked to each corresponding evidence summary. The guideline team should discuss each recommendation in detail with the process used to reach consensus described in detail in the methodology:

-It is preferable to follow a formal Delphi technique to reach consensus.

-If disagreement persists then the Chair may seek resolution with either a formal vote or a survey of relevant stakeholders.

-Recommendations should if possible be categorised as strong or weak as per the GRADE system.

-Where the guideline team's strength of recommendation is unanimous the wording 'we recommend' should be used. Where the decision is the majority and the recommendation is weak the wording 'we suggest' should be used.

- It is possible to have low quality evidence but a strong recommendation if it is clinically important and universally agreed.

- It is possible to have more than one management recommendation if the evidence for each is of similar efficacy. In this situation clinician or patient opinion may influence the recommendation. This should be documented.

- **Implementation of Guidelines**

The ACPGBI is keen on assessing implementation. Where possible tools to implement the guidance and methods to assess implementation should be included in the Guideline Document. Examples include algorithms of care, checklists and key performance indicators allowing subsequent audit or Quality Improvement Project. Feedback from members of the ACPGBI and other stakeholders should be encouraged, before submission for formal publication.

- **Cost and Service Implications**

Whilst a full economic analysis is beyond the scope of most standard guidelines, some assessment of the cost effectiveness should be considered if data is available.

- **Patient Summary**

A patient lay summary should be included to enable clear understanding of the guidelines for individuals who do not have knowledge of technical terms. Assessments of plain English such as the Gunning-Fog Index may be useful.

- **Research Recommendations**

A list of research recommendations should be included based on identified and clinically relevant knowledge gaps. These can be drawn from sources including: i) meta-analysis of multiple studies suggesting benefit or harm that has not been proven in a large randomised trial, ii) cohort studies showing benefit (or harm) from treatment practice that has not been demonstrated in a well designed randomised trial, iii) conflicting randomised trial results, where the research team can identify methodological aspects of trials that require attention to definitively answer the question, iv) absence of data on cost effectiveness, qualitative aspects, or implementation data.

- **Format of the Guidelines**

Guidelines should preferably be submitted to Colorectal Disease for consideration of publication. (Completed Guidelines should be submitted to the MCC for review prior to submission for publication).

The following outline structure should be followed:

- Title
- Acknowledgements
- Guideline team: list of members, qualifications and positions.
- Abstract
- Executive summary to include purpose, patient group, target users and concise summary
- Patient summary
- Date of previous guidelines
- Background
- Objective
- Methodology
- Evidence summary linked to recommendations (highlighted with grade of evidence and strength of recommendation with idea of degree of agreement.
- Algorithm of care
- Factors for aiding assessment of implementation (Key performance indicators etc)
- Cost-benefit analysis where possible or appropriate
- Implications for practice
- Implications for research
- Any declared conflicts of interest

- References- numbered, Vancouver style. 1-200
- Planned review date
- Appendices include Final Submission Template (Appendix 3), Search Criteria, GRADE Tables and Outcomes of Delphi Discussion, as well as the AGREE II template.

- **Authorship**

Authorship of ACPGBI Guidelines will be detailed using the following formatting:

- Authorship will be using a corporate authorship model (e.g. ACPGBI (name of guideline) Guideline Group.
- Credit Taxonomy will be used to detail contributions of guideline authors.

- **Review Prior to Publication**

The completed guidelines should be submitted to the MCC who will then approach 2 members of the committee to act as referees to check the guidelines have maintained the appropriate standards for publication. It is also placed on the ACPGBI website for 4 weeks and comments invited from members. A summary of feedback is presented to the guideline team Chair and appropriate amendments made and replies constructed. Once completed the guidelines are submitted to the editor of colorectal disease for publication pending peer review.

- **Promotion**

Advice will be sought from Colorectal Disease as to how best to publicise the document. Open access will be sought through either author affiliation or through the ACPGBI and any collaborators. Stakeholders will also be encouraged to promote through their own processes.

- **Review and Updating**

There should be a specific statement regarding planned review with a rolling programme of updates coordinated by the MCC. Updating should ordinarily be considered a minimum of every 5 years.

Position Statements

The ACPGBI will occasionally commission Position Statements. These are brief statements addressing novel or topical subjects where the Association feels it needs to clarify a position and give clear advice where possible to the membership.

They are often limited to expert opinion based on the best available evidence. They should be submitted to Executive through the MCC inviting comments from all members of Executive. Following approval and amendment the statement may be submitted for publication in Colorectal Disease or added to the website and disseminated to the membership.

This Advice on Production of Clinical Guidelines and Position Statements Document should be reviewed annually.

Appendix 1: ACPGBI Guideline Development Group

Declaration of Conflict of Interest Form

I ……. as an invited member of the ACPGBI……. Guideline Development Group have set out my interests below.

	NATURE OF INTEREST	Please give details of the interest and whether it applies to yourself or, where appropriate, a member of your immediate family, connected persons or some other close, personal connection.
1.	Current employment and any previous employment in which you continue to have a financial interest.	
2.	Appointments (voluntary or otherwise) eg trusteeships, directorships, local authority membership, tribunals etc.	
3.	Membership of any professional bodies, special interest groups or mutual support organisations.	
4.	Investments in unlisted companies, partnerships and other forms of business, major shareholdings (1% of issued capital) and beneficial interests.	
5.	Gifts of hospitality offered to you by external bodies and whether this was accepted or declined in the last 12 months.	

6.	Do you use, or care for a user of the organisation's services?	
7.	Any contractual relationship with ACPGBI or its subsidiaries (beyond membership).	
8.	Any suspension from normal duties.	
9.	Any other conflicts not covered by the above.	

To the best of my knowledge, the above information is complete and correct. I undertake to update as necessary the information provided, and to review the accuracy of the information on an annual basis. I give my consent for it to be used for the purposes described in the Declaration of Interests policy.

Signed: Date:

Print Name:

Position:

Professional Organisation Member (if relevant):

APPENDIX 2: Initial proposal for guideline- Submission Template

(Refer to ACPGBI guidelines advice document)

1. **Applicant:**

Name	Qualifications	Position

2. **Contact details:**

Address	Telephone / Fax	Email

3. **Co-applicants:**

Name	Qualifications	Position

4. **Title of guideline:** (a provisional title may be provided at this stage)

5. **Brief outline of the area the guideline will be covering:**

6. **Clearly state the overall objective of guideline:**

7. **<u>Clearly state the clinical questions to be answered by the guideline and reason why the guideline is being produced:</u>** (e.g., health benefits arising from the guideline, absence of previous guidelines on this area or previous guidelines out of date)

8. **<u>Scope of guideline:</u>**

Who are the target users?	**Describe the patient group / target population covered by the guideline**

Appendix 3: - Secondary proposal for guideline- Submission Template

(Refer to ACPGBI guidelines advice document)

1. **Lead author / applicant:**

Name	Qualifications	Position

2. **Contact details:**

Address	Telephone / Fax	Email

3. **Co-authors:**

Name	Qualifications	Position

4. **Title of guideline:**

5. **Brief outline of the area the guideline will be covering:**

6. **Clearly state the overall objective of guideline:**

7. **<u>Clearly state the clinical questions to be answered by the guideline and reason why the guideline is being produced:</u>** (e.g., health benefits arising from the guideline, absence of previous guidelines on this area or previous guidelines out of date)

8. **<u>Scope of guideline:</u>**

Who are the target users?	**Describe the patient group / target population covered by the guideline**

9. **<u>Guideline Development Team:</u>**

Name of team member:	**Representing (group / discipline)**:

10. **<u>Time scale:</u>**

Start date:	**(Anticipated) Finish date:**

11. **<u>Editorial independence:</u>** Commercial sponsorship is discouraged and usually not acceptable. Any conflicts of interest for must be listed and COI forms submitted for all members.

12. **<u>Guideline methodology:</u>**

Details of systematic methods that will be used to search for evidence:	
Databases to be searched	

Principal search terms	

Use of GRADE?

Describe the methods that will be used to formulate recommendations: Recommendations should arise from and be explicitly linked to the corresponding evidence summary. If recommendations are based on expert opinion describe any formal consensus technique and specify methods for resolving areas of disagreement e.g. the guideline team will meet and vote on strength of recommendations using GRADE.

How will the cost implications and/or cost effectiveness of the advice be assessed?

Describe how patient /user views will be incorporated other than by inclusion on the team:

13. <u>Review of guideline:</u>

What are the planned procedures for updating the guideline? (The schedule for review is usually 5 years but may be sooner for rapidly developing topics, e.g., which Specialist Section /Committee will review the guideline and when.)