Advice on the production of clinical guidelines and consensus statements

The Multidisciplinary Clinical Committee (MCC) of the Association of Coloproctology of Great Britain and Ireland (ACPGBI) commissions guidelines on the management of various colorectal disorders in order to improve the standard of practice of colorectal surgery and guide clinicians.

Commissioning

Most guidelines are commissioned by the MCC. Subjects for guidelines may however be proposed by any member of ACPGBI, external bodies and other speciality associations. All potential subjects need to be agreed by ACPGBI council and executive committees however following discussion by the MCC.

Guidelines are usually commissioned because of a perceived need for greater clarity and consensus in the recommended management of a colorectal condition. The need usually arises following important advances in treatment and understanding. This treatment needs to be incorporated into clinical practice for the benefit of patients.

Guidelines need to make an important contribution to clinical practice. It may well be that a guideline is on a subject already considered and the new guideline essentially makes the previous guideline redundant. It is important that existing guidelines as produced by ACPGBI are regularly updated.

Guideline development group and initial submission

Guidelines need to be the product of several individuals who are recognised authorities in the area to be considered. It is anticipated that no less than four and no more than eight authors would be involved.

The practice of self-selected individual surgeons opining on certain areas of interest is no longer acceptable practice. The formulation of the guidelines will be driven by a Guidelines Development Group (GDG) which will include a writing committee and others representing a range of relevant expertise. It is envisaged that a clinician whose everyday practice would be influenced by the guidelines actually contributes to the guidelines. The GDG should ideally be multidisciplinary, and may include other specialities, trainees and other healthcare professionals. The guidelines produced should be ratified by the Patient Liaison Group of ACPGBI. Ideally a patient representative should sit on the GDG.

A Guideline Development Group chairperson should be designated. The chairperson should also be the lead author and along with at least some members of the GDG should be identified by the MCC on the basis of having the relevant expertise. The GDG chairperson may choose to co-opt other individuals to the writing group. In certain situations the whole membership of ACPGBI may be contacted and applications considered. The final decision on membership will rest with the chair of the MCC.

All members of the GDG must complete a declaration of Conflict of Interest form (COI) (Appendix 1). Where an individual is found to have a possible conflict of interest with a particular section of the guideline the individual may continue to be involved in the overall process but withdraw their involvement from that specific area. In some cases a Conflict of Interest may preclude an individual's membership of the Guideline Development Group. Decisions in regard to these issues will be made by the chair of the MCC in consultation with the chair of the Guideline Development Group and in extreme circumstances with the President of ACPGBI.

Any initial guideline/consensus statement proposal should be drafted to the chair of the MCC for consideration in consultation with counsel and executive committee of ACPGBI. The proposal for the guidelines should include:

a) The overall objective of the guideline.
b) The target users. The guidelines are intended primarily to aid clinicians and so the target audience should include all healthcare professionals who contribute to clinical management of that condition. This may include both primary and secondary care physicians, nursing and Allied Health professionals and other specialities (gastroenterology, oncology, radiology, etc….)
c) The main clinical question to be addressed.

Assuming the subject is approved by ACPGBI Executive and Council, then the Chair of the GDG will write to the editorial team of *Colorectal Disease* Journal informing them of the proposed activity, and confirming that the journal isn't in the process of publishing similar statements from other organisations.

Non-commissioned guidelines

As stated, any individual with a particular interest in a topic may submit a proposal for a guideline to the Multidisciplinary Clinical Committee for consideration.

If approved commissioned and non-commissioned guidelines will be treated identically.

Development of guidelines

Guideline development must take account of all relevant stakeholder views and preferences including professional groups, patients and carers, in this regard the GDG should conduct a consultation, exercise and prior to its first meeting should share the draft proposal with 1) relevant profession organisations who might be influenced by the guidelines, 2) the Patient Liaison Group of the ACPGBI. All replies must be seriously considered by the GDG and when appropriate incorporated into the initial guideline proposal. The final submission template should be submitted to the chair of the MCC. It should include 1) the member list of the GDG, 2) the proposal as modified in the light of any consultation with other stakeholders.

The GDG will then develop the specific questions to be addressed relating to the optimal management of the condition in question.

The questions are best grouped into clinical sections. One option that maybe used but not exclusively so is PICO (Patients, Interventions, Controls, Outcomes) system and will be used for critical components predefined as precisely as possible. The larger section will relate directly to management and may be divided into subgroups. This should have sections on epidemiology, clinical manifestations, diagnosis, health economics and health service organisation which are encouraged though not specifically required.

The evidence of search for each clinical section should be systematic, comprehensive, transparent and reproducible strategy to search for evidence on which management recommendations will be based. The

overall search strategy should be decided by the GDG as a whole and described in adequate detail including which electronic databases were consulted, the time period covered, and the key words used.

It maybe necessary to include studies of suboptimal quality if they constitute best available evidence. Their flaws however need to be highlighted.

When published evidence of a specific point is incomplete or unavailable anecdotal evidence may be used that needs to be acknowledged as such.

It is good practice to repeat the search prior to publication of the guideline to ensure that it is entirely up to date.

There needs to be a study, interpretation and grading of the evidence into analysis, randomised controlled trials, controlled studies, case reports and anecdotal evidence. The grade system is suggested for this process as described below:

Level of evidence		Grade of recommendation	
I	Evidence obtained from a single randomized controlled trial or from a systematic review or meta-analysis of randomized controlled trials	A	Evidence of type I or consistent findings from type IIa, IIb or III
IIa	Evidence obtained from at least one well-designed controlled study without randomisation	B	Evidence of type IIa, IIb or III and generally consistent findings.
IIb	Evidence obtained from at least one other well designed quasi-experimental study.	C	Evidence of type IIa,IIb or III but inconsistent findings.
III	Evidence obtained from well-designed nonexperimental descriptive studies, correlation studies and case studies.	D	Little or no systemic evidence
IV	Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities, case reports.	GP	Recommended good practice based on the clinical experience of the expert group and other professionals.

The strengths and limitations of the body of evidence should be clearly described. There should be discussion if needed of risk, of bias, consistency, applicability and relevance of study end points, the magnitude of the effect and any dose response relationships.

Construction tables based on the PICO system is encouraged incorporating end points of several similar studies. If extensive these tables maybe incorporated into an appendix. The guidelines should refer to any unpublished work on relevant patient experiences.

Formulation of recommendations

a) Recommendations should be specific and unambiguous.
b) Recommendations themselves are drafted by section leads. The GDG as a whole must then discuss all recommendations in detail including their potential health benefits, risks and side effects.
c) Different grades of evidence may be available in response to the varying clinical questions. If the evidence is not conclusive discussions will take place within the GDG in order to reach consensus. If this is not possible a Delphi exercise may be performed. GDG are encouraged to categorise the recommendations.
d) The GDG are encouraged to categorise the recommendations.
e) More than one management option may be recommended if the evidence suggests that each is of similar efficacy.

The cost and service implications of implementing the guidelines and the potential facilitators and organisation barriers to doing so should also be considered, however, a full economic analysis is not expected.

Guidelines should include a statement as to how the implementation of the guideline will be assessed. Specific criteria which can be audited should be specified and where possible evidence based standards of care should also be specified.

List of recommendations for further research in the area in question should also be detailed.

Format

The following outline structure is suggested:

1. Authors, i.e. members of the Clinical Development Group.
2. Summary.

3. Date of previous guideline time period covered by previous literacy search.
4. Background where a guideline is necessary and particular issues surrounding it.
5. Objectives.
6. The development process for the guidelines including discussion and methodology and the search terms used.
7. Summary, e.g. epidemiology, prevention, clinical presentation, diagnosis and management.
8. Findings and recommendations should be in specific paragraphs in bold text within the main body of the work.
9. Any declared conflicts of interest and acknowledges, reference and appendices.

Review of guidelines prior to publication

The guidelines should be submitted to the editor of *Colorectal Disease* for peer review and potential publication in the first instance. Assuming satisfactory peer review is obtained then guidelines would be published in *Colorectal Disease* and also on the ACPGBI website. The final decision on publication in *Colorectal Disease* rests with the Editorial team of *Colorectal Disease*. If for whatever reason *Colorectal Disease* declines to publish the guidelines/consensus statement, then they may be submitted to other journals, as being representative of the position of ACPGBI.

Reviewing and updating the guidelines

The guidelines are the responsibility of the multidisciplinary clinical committee and may be reviewed at the latest every 7 years though it is not anticipated the guideline will be formally revised within 3 years unless a major change in clinical practice as a result of new work.

Declaring conflicts of interest

Members of the Guideline Development Group and others having a direct input into the guidelines should complete a “declaration of conflict of interest” form before becoming involved in the process. If an individual is conflicted within a specific area of the guideline then they may be withdrawn from this

specific area though contribute to the overall guideline. The COI may ultimately preclude the individual from contributing to the guidelines in its entirety. This decision is taken by the lead of the GDG though further advice may be sought from the chair of the MCC if required. Conflict of interest is defined as any arrangement in the past 12 months which constitutes current significant benefit to the individual, partner of that individual or their immediate family and includes for example financial benefits over £500 and membership of any organisation which is related to the guidelines. Completed COI forms should be submitted to the Chairman of the MCC.

Charles Maxwell-Armstrong

Chairman MCC June 2016

APPENDIX 1 DECLARATION OF CONFLICT OF INTEREST

TITLE OF GUIDELINE:

Do you or your partner or any immediate family member have any commercial interest in any companies that are or could be involved in the production of the above named guideline?

YES/NO If YES – detail involvement below

Does your department or unit receive financial support from any commercial organisations that are or could be involved in the above named guideline?

YES/NO If YES- detail involvement below

Are you a consultant to or a member of any national body, charity or pressure group whose work is related to the above named guideline?

YES/NO If YES – detail involvement below

Do you receive editorial fees for commissioned articles for publication or are you paid for editorial work for any publication related to the above named guideline?

YES/NO If YES – detail involvement below

Do you or your department hold a patent (existing or pending) related to the above named guideline?

YES/NO If YES – detail involvement below

NAME DATE

SIGNATURE

Completed COI forms should be returned to the Secretary of ACPGBI