

Writing a British Association of Dermatologists clinical guideline: an update on the process and guidance for authors

This advice is aimed at the authors of British Association of Dermatologists (BAD) guidelines.

The idea for developing a new topic for a BAD guideline usually comes from a member of the BAD, but could come from patient representatives or other organizations such as the Royal College of Physicians (RCP).

The intention is that a guideline will be comprehensive and up-to-date, aimed at dermatologists and nurses working in clinical dermatological practice.

Before proceeding, the topic must be agreed by the Therapy and Guidelines Subcommittee (T&G).

Authorship

If the topic suggestion is from a BAD member, they may be involved in writing the guideline. As a bare minimum, authorship should consist of three clinicians with an interest in the area and ideally representing both teaching hospital and district general hospital practices; for consensus-based recommendations a larger group is more effective. The lead author will identify their coauthors with support from the T&G if necessary. Depending on the guideline topic, nursing and patient representatives may be invited to join the guideline development group (GDG) or alternatively they may be involved at the peer review stage. For conditions managed by more than one specialty, the other specialties should be represented in the GDG (e.g. malignant melanoma) and some such guidelines may be developed in collaboration with another body (e.g. RCP for vitiligo). The group can also include specialist registrars for whom involvement in producing a guideline is a worthwhile educational objective.

The process

Over recent years the guideline process has evolved to become increasingly complex with a rigorous methodology, and the amount of work involved should not be underestimated. The first step in the guideline process is identifying the scope and clinical questions that are going to be addressed. It is best if the topic has a limited focus with carefully identified questions. The framework of PICO (Patients, Interventions, Comparators and Outcomes) can assist in focusing the questions. Recommendations are based on evidence drawn from a systematic review of the literature pertaining to these questions. This involves employing a comprehensive search strategy to

identify all available evidence, followed by appraisal of the papers and grading of the evidence.

As a result of this comprehensive process there has been a tendency for the most recently produced guidelines to be detailed and lengthy, thereby moving away from one of the original aims to produce concise guidance which the clinician can refer to quickly in the clinical setting. The policy of producing a laminated version for use in the clinic has become difficult to implement. In addition, it is important that the BAD continues to expand the range of patient information leaflets (PILs) and these should concur with information given in guidelines.

Consequently, authors of future guidelines will be encouraged to produce three documents in parallel:

1. A review of the literature (for a guideline update this would be limited to publications since the original was produced) in which a clear synthesis of evidence shows the strength of evidence supporting an intervention and whether the literature agrees or disagrees. Relevant harms and crude relative costs should also be considered where important.
2. A concise clinical guideline, which is clearly linked to the evidence, for use in the dermatology clinic.
3. Relevant PILs in the standard BAD format.

All three documents would be subjected to the usual peer review process and the first two would subsequently be published in the *British Journal of Dermatology* (BJD).

The concise guideline provides a focus for defining the recommendations, would be suitable for publication in a book of BAD guidelines and would be amenable to adaptation for use by other professionals such as general practitioners and pharmacists.

With each guideline, authors should consider audit points arising from their recommendations. The National Institute for Health and Clinical Excellence (NICE) Technical Manual devotes a chapter to this. Authors would also be well placed to contribute to the Database of Uncertainties about Effects of Treatments (DUETs, Appendix 1).

Peer review

Once a draft BAD guideline has been produced, it is first peer reviewed by all members of the T&G, which includes representatives from the British Dermatological Nursing Group and the British National Formulary. If they have not been involved directly as authors, members of any relevant patient support groups will be invited to review the guideline at this stage.

Comments will be fed back to the authors, appropriate amendments made and the final draft approved by the T&G before being published in the BAD Newsletter. There then follows a consultation period during which the entire membership is invited to return comments. These are collated by the Chair of the T&G and fed back to the authors for final amendments to be made. A final draft is then reviewed by the T&G prior to publication in the *BJD* and on the BAD website. There is the facility for abridging the paper guideline if there are extensive tables and reproducing these on the BAD website. The steps involved in producing a guideline are summarized in Appendix 2.

British Association of Dermatologists support for guideline authors

In addition to changes that have evolved in the process of guideline development, there are ever-increasing demands on members' time, and the BAD recognizes that authors provide their time and expertise free of charge and should be supported as much as possible. The following support will be available:

Two meetings of the GDG will be offered at Willan House, one at commencement of the process for identifying questions and dividing responsibilities for sections between members, and the other towards the end for pulling the draft document together. Members' travel expenses will be reimbursed and lunch will be provided and a member of the T&G will attend to support and provide consistency.

The T&G administrator/information scientist will organize, attend and record minutes of the meetings and will subsequently play a major role in performing the literature review and supporting the authors with appraisal of papers, grading of evidence (Appendix 3) and production of evidence tables. Members of the T&G will be available for advice and support at all stages in the process.

Identified questions will first be approved by the T&G. A realistic timeline for the guideline development will be sought from the authors and a date for the second meeting set at the first. Guidelines which take too long to develop risk being out of date by the time they are published.

Support will also be provided for guideline updates with a single meeting at Willan House offered where substantial changes to the original document are required. The information scientist will perform a re-run of the original literature search prior to the meeting.

Procedures for updating

Once a guideline is published, the process does not stop. Guidelines should be updated if any new evidence significantly changes the conclusion. Otherwise they need to be reviewed after 5 years and the originally defined search strategy should be re-run to obtain the last 5 years of evidence. Authors are approached by the T&G to undertake this work and produce an updated guideline. This, after the usual peer

review process, would appear in the *BJD* and the text on the website, including the PIL if necessary, would be updated with a renewed date for currency. If original authors are unable to undertake an update it is the responsibility of members of the T&G to seek alternative authors or to perform the task themselves. If the updated literature search reveals that a guideline needs no changes the T&G can authorize a new use-by date of 5 years; however, if a guideline is not updated then it should be removed from the website as potentially it could be misleading.

Appendix 1. Useful resources

Helpful skills in producing guidelines are a grounding in evidence-based medicine and systematic review. Training in these areas is available to Cochrane reviewers (<http://www.cochrane.org/resources/training.htm> and <http://www.cochrane.org/admin/manual.htm>).

Parts 1 and 2 of the following publication provide an invaluable resource: Williams H, Bigby M, Diepgen T, Herxheimer A, Naldi L, Rzany B (editors). *Evidence Based Dermatology*. London: BMJ Publishing Group, 2003.

Examples of best practice are to be found on the NICE (<http://www.nice.org.uk/page.aspx?o=201982>) and the Scottish Intercollegiate Guidelines Network (<http://www.sign.ac.uk/methodology/index.html>) guideline websites and currently the BAD adopts their approach to evidence tables and grading of the evidence (Appendix 3).

From the outset it useful to be aware of the AGREE instrument (Appendix 4) which is a widely used guideline scoring instrument to rate the quality of the guideline (<http://www.agreecollaboration.org/1/agreeguide/>).

Current BAD guidelines are published in the *BJD* and are recognized internationally. They also appear on the BAD website and are linked in with the National Electronic Library for Health (<http://www.library.nhs.uk/>). They should also meet the selective criteria of the U.S. National Guideline Clearinghouse (NGC) (<http://www.guideline.gov/>), increasing the audience and benefits of the guideline. Those guidelines that go on to the NGC site have further utility for producing summaries, comparisons and palmtop downloads.

Criteria for a DUETs (<http://www.library.nhs.uk/DUETS>) uncertainty are as follows: (i) an up-to-date systematic review has shown that there is an uncertainty over treatment effects; (ii) existing systematic reviews are out of date; (iii) there is no relevant systematic review.

There are many patient organizations under the umbrella of the skin care campaign (<http://www.skincarecampaign.org/>) that can assist in guideline development or review as stakeholders.

Appendix 2. Summary of steps involved in producing a guideline

- 1 Title suggestion approved by the T&G
- 2 Lead author and coauthors identified

3 Initial meeting to identify questions, and to produce a scope, a search strategy and selection criteria. Allocation of sections/tasks to GDG members. Timeline and date of second meeting agreed

4 Scope and questions approved by the T&G

5 Data extraction: literature search performed by BAD information scientist (IS) and identified titles and abstracts forwarded to relevant section author

6 Authors with assistance of IS systematically sift and discard those that are irrelevant and scrutinize remaining papers to assess if they meet selection criteria. IS documents the selection process

7 Critical appraisal of the quality of remaining studies by at least two authors against tick lists with a third arbiter for disagreements

8 IS synthesizes the data from eligible studies and produces evidence tables with quantitative pooling of data if appropriate

9 Evidence tables circulated to all authors for comments

10 Getting from synthesis of evidence to a recommendation is not straightforward. There needs to be a dialogue between GDG members at this stage. The process should take into account the body of evidence, i.e. not just one paper

11 Section authors write draft review, concise guideline and PIL and identify potential audit points and DUETs

12 Second meeting to present a synthesis of data, review draft recommendations and establish consensus and implications for practice. IS will summarize recommendations

13 Draft documents collated by authors and IS and finalized

14 Review by T&G, comments fed back to authors and amendments made

15 Publication in BAD Newsletter for wide consultation

16 Redrafting in light of received comments

17 Review by T&G

18 Publication in BJD, BAD website and other sites, e.g. NGC

19 Five-year review: authors contacted by T&G. Literature search re-run by IS. If needed, updated guideline and PIL subjected to usual peer review process. If no update needed, renew web-based document with 5-year expiry date

20 Alternatively, publish updated guideline in BJD and on the website

Appendix 3. Levels of evidence and grades of recommendation (from Scottish Intercollegiate Guidelines Network)

The older format used in previous guidelines is updated in the light of advances in the methods of guideline development.

The published studies selected from the search should be assessed for their methodological rigour against a number of criteria. Checklists may be used to assess the selected studies; these are available in Appendix C–I of the NICE Technical Manual. The overall assessment of each study is graded using a code ‘++’, ‘+’ or ‘–’, based on the extent to which the potential biases have been minimized, as in the Table.

Levels of evidence

Level of evidence	Type of evidence
1++	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1–	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias ^a
2++	High-quality systematic reviews of case-control or cohort studies High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2–	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal ^a
3	Nonanalytical studies (for example, case reports, case series)
4	Expert opinion, formal consensus

RCT, randomized controlled trial. ^aStudies with a level of evidence ‘–’ should not be used as a basis for making a recommendation.

Grades of recommendation

Once a level of evidence has been derived and evidence tables drawn up levels of recommendation can be derived. These are the conclusion of the guideline and it is important that they stand out and stand alone. Often they can be highlighted in a box or a table. The level of the recommendation is determined by the level of evidence although the usefulness of a classification system based solely on this has been questioned because it does not take into consideration the importance of the recommendation in changing practice and it may be that more sophisticated derivations of strength of recommendation will appear in future.

Class	Evidence
A	<ul style="list-style-type: none"> At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population, or A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results
B	<ul style="list-style-type: none"> Evidence drawn from a NICE technology appraisal A body of evidence including studies rated as 2++, directly applicable to the target population and demonstrating overall consistency of results, or Extrapolated evidence from studies rated as 1++ or 1+

Class	Evidence
C	<ul style="list-style-type: none"> • A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results, or • Extrapolated evidence from studies rated as 2++
D	<ul style="list-style-type: none"> • Evidence level 3 or 4, or • Extrapolated evidence from studies rated as 2+, or • Formal consensus
D (GPP)	<ul style="list-style-type: none"> • A good practice point (GPP) is a recommendation for best practice based on the experience of the guideline development group

NICE, National Institute for Health and Clinical Excellence; RCT, randomized controlled trial.

Appendix 4. AGREE and National Guideline Clearinghouse (NGC) criteria

AGREE criteria

Scope and purpose

- 1 The overall objective(s) of the guideline should be specifically described
- 2 The clinical question(s) covered by the guideline should be specifically described
- 3 The patients to whom the guideline is meant to apply should be specifically described

Stakeholder involvement

- 4 The GDG should include individuals from all the relevant professional groups
- 5 The patients' views and preferences should be sought
- 6 The target users of the guideline should be clearly defined
- 7 The guideline should be piloted among end users

Rigour of development

- 8 Systematic methods should be used to search for evidence
- 9 The criteria for selecting the evidence should be clearly described
- 10 The methods used for formulating the recommendations should be clearly described
- 11 The health benefits, side-effects and risks should be considered in formulating the recommendations
- 12 There should be an explicit link between the recommendations and the supporting evidence
- 13 The guideline should be externally reviewed by experts prior to publication
- 14 A procedure for updating the guideline should be provided

Clarity and presentation

- 15 The recommendations should be specific and unambiguous
- 16 The different options for diagnosis and/or treatment of the condition should be clearly presented
- 17 Key recommendations should be easily identifiable
- 18 The guideline should be supported with tools for application

Applicability

- 19 The potential organizational barriers in applying the recommendations should be discussed
- 20 The potential cost implications of applying the recommendations should be considered
- 21 The guideline should present key review criteria for monitoring and audit purposes

Editorial independence

- 22 The guideline should be editorially independent from the funding body
- 23 Conflicts of interest of guideline development members should be recorded

Criteria for inclusion of clinical practice guidelines in NGC

- 1 The clinical practice guideline contains systematically developed statements that include recommendations, strategies, or information that assists physicians and/or other health care practitioners and patients make decisions about appropriate health care for specific clinical circumstances.
- 2 The clinical practice guideline was produced under the auspices of medical specialty associations; relevant professional societies, public or private organizations, government agencies at the Federal, State, or local level; or health care organizations or plans. A clinical practice guideline developed and issued by an individual not officially sponsored or supported by one of the above types of organizations does not meet the inclusion criteria for NGC.
- 3 Corroborating documentation can be produced and verified that a systematic literature search and review of existing scientific evidence published in peer reviewed journals was performed during the guideline development. A guideline is not excluded from NGC if corroborating documentation can be produced and verified detailing specific gaps in scientific evidence for some of the guideline's recommendations.
- 4 The full text guideline is available upon request in print or electronic format (for free or for a fee), in the English language. The guideline is current and the most recent version produced. Documented evidence can be produced or verified that the guideline was developed, reviewed, or revised within the last 5 years.

H.K. BELL (Chair) and A.D. ORMEROD (Immediate Past Chair)
BAD Therapy and Guidelines Subcommittee, September 2008.