

Updated guidance for writing a British Association of Dermatologists clinical guideline: the adoption of the GRADE methodology 2016

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C.H.S. declares the following: (i) BAD guideline development group lead for biologic therapy for psoriasis; (ii) NICE guideline development group chair for psoriasis: assessment and management (CG153); (iii) clinical research involving systemic therapy for psoriasis – Medical Research Council, Novartis UK, Pfizer UK, Regeneron Pharmaceuticals and Janssen-Cilag. No other conflicts of interest are declared.

This is an updated guidance for writing a British Association of Dermatologists (BAD) clinical guideline, prepared for the association's Clinical Standards Unit (CStU), which includes the Therapy & Guidelines subcommittee (T&G). Members of the CStU who have been involved are: P.M. McHenry (Chair, T&G), K. Gibbon, D.A. Buckley, T.A. Leslie, E.C. Mallon, S. Wakelin, R.Y.P. Hunasehally, M.J. Cork, G.A. Johnston, F.S. Worsnop, J. Natkunarajah, N. Chiang, S. Ungureanu, J. Donnelly (British National Formulary), C. Saunders (British Dermatological Nursing Group), A.G. Brain (BAD Clinical Standards Administrator), L.S. Exton (BAD Information Scientist), M.F. Mohd Mustapa (BAD Clinical Standards Manager).

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NICE has renewed accreditation of the process used by the British Association of Dermatologists to produce guidelines. The renewed accreditation is valid until 31 May 2021 and applies to guidance produced using the processes described here. The original accreditation term began on 12 May 2010. More information on accreditation can be viewed at www.nice.org.uk/accreditation.

1.0 Purpose and scope

The overall objective of this updated guideline development protocol is to describe the processes and methods for developing, maintaining, updating and disseminating the British Association of Dermatologists (BAD) evidence-based clinical guidelines, with reference to the Appraisal of Guidelines Research and Evaluation (AGREE II) instrument (www.agree-trust.org)¹ and the Grading of Recommendations Assessment, Development and Evaluation (GRADE).² This document supersedes the previous guidance.³

2.0 Stakeholder involvement and peer review

The draft protocol was circulated to the BAD membership for comments and peer-reviewed by the Therapy & Guidelines (T&G) subcommittee prior to publication.

3.0 Plans for review and/or revision

This guideline development protocol will be reviewed and updated every 5 years if deemed necessary, aligning it with the BAD's NICE Accreditation cycle.

4.0 Introduction

The BAD was established in 1920 and is a registered charity with the objectives of promoting and fostering Dermatology practice, teaching, training and research. The BAD works with the Department of Health, the National Institute for Health and Care Excellence (NICE), the Royal College of Physicians, patient groups and commissioners across the U.K. advising on best practice for dermatology care and on the provision of Dermatology services across all healthcare settings. It is funded by its members.

The BAD has been publishing evidence-based clinical guidelines in the *British Journal of Dermatology* (BJD) since the 1990s. They

are aimed at U.K. dermatologists, nurses and other relevant healthcare professionals providing clinical care for patients with skin conditions, patients and/or their carers. All BAD guidelines are based on the best available published evidence at the time of publication. However, it is well recognized that evidence in some areas may be lacking or of poor quality. Therefore, employing a robust methodology is important in developing guidance even when the evidence base is weak and this can be used to highlight areas where further research is required.

The first iteration of the BAD's guideline development protocol, which was an outline of the process involved, was published in 1999 in the *BJD*.⁴ This was updated in 2004 as an in-house document, with the third update published in 2009 in the *BJD*;³ this version secured the BAD's NICE Accreditation attainment in 2010.⁵

The alphanumerical grading systems used previously by the BAD³ for classifying the quality of evidence and strength of recommendation relied on the premise of the study design determining the strength of recommendations made. It is now recognized that this approach is inadequate, as other elements must be considered (see section 8.5.3).⁶ GRADE, which was developed by a widely representative group of international guideline developers, is now recognized as the gold-standard methodology used for developing systematic reviews and clinical guidelines.² Unlike other evidence classification systems, the GRADE approach considers the quality of the evidence on an outcome level, and across the body of evidence for each pairwise comparison (e.g. intervention vs. comparator/control). GRADE considers these elements explicitly and provides a framework by which the quality of the evidence is assessed. There is a comprehensive set of criteria for downgrading and upgrading the quality of evidence ratings, clearly separating the quality of evidence from the strength of recommendations. Crucially, it guides users through a transparent process of moving from evidence to recommendations, with set criteria to aid the guideline development group (GDG) in formulating a recommendation and determining its strength, with clear and pragmatic interpretation of strong vs. weak recommendations for clinicians, patients and policy makers. It also evaluates the importance of outcomes of alternative clinical interventions or management strategies and acknowledges patient values and preferences. GRADE has been adopted by the World Health Organization, Cochrane Collaboration, NICE, Scottish Intercollegiate Guidelines Network and over 100 other international organizations.² It has been used to develop new and update existing BAD guidelines since September 2013.

5.0 Funding

All BAD guideline development is funded by the BAD.

6.0 Commissioning and proposing topics for clinical guidelines

The T&G subcommittee commissions guidelines based on a preferred list of topics that is reviewed and updated as necessary.

Topics for guideline development can be proposed by the T&G subcommittee, the BAD membership, patient groups or other relevant organizations. The T&G subcommittee is responsible for the selection, approval and prioritization of the topics.

The key principles underlying the selection of any BAD clinical guideline topic are that they involve all relevant stakeholders including patients, the topic must be pertinent and potentially fill important gaps in the evidence base for treating patients with skin disease. All BAD clinical guidelines should be independent, evidence-based, with clear recommendations, disseminated appropriately and updated in a timely way.

7.0 Guideline development group membership

Once a guideline topic has been approved, posts for the GDG will be advertised with expressions of interest sought for the lead, subject to eligibility based on the BAD's policy for declaring conflicts of interest (COIs) for guideline authors (see section 7.2); the T&G subcommittee will decide on the most appropriate person to lead the project. The lead will identify prospective GDG members (subject to COI compliance) with support from the T&G subcommittee and Clinical Standards Unit (CStU), if required.

All relevant stakeholders should be represented in the GDG. This should be at least five clinicians, including specialists and generalists. Where GDG members are recognized experts from other subspecialties, the CStU may seek official approval of their representation on the GDG from the respective professional bodies. Ideally, two patient representatives should be invited to join the GDG, drawn from relevant patient support or advocacy groups, or individual clinicians' cohorts of patients. Additional specialists may be co-opted to provide expertise in particular areas without necessarily joining the GDG. The GDG may also co-opt additional people to support the guideline development work (e.g. trainees or specialist registrars); these and relevant BAD members of staff or external persons providing guidance, technical support and assistance with guideline development will be included in the GDG membership as part of the technical team.

Only clinical members of the GDG will have voting rights; therefore, this would exclude the technical team, including co-opted trainees, unless they had been selected to join the GDG right from the beginning due to specific experience and/or expertise.

7.1 Authorship

The principles for authorship as set out below fulfil the following requirements:

- 1 The need to recognize the contribution of individuals who have contributed to all aspects of the guideline development; and
- 2 Compliance with NICE Accreditation criteria.

The guideline lead is defined as the GDG member who will be the first named author for the publication; meetings may

be chaired by another member of the GDG, including a BAD member of staff, if appropriate. The order of the authorship may be decided at the early stages of the guideline development.

7.2 Conflicts of interest policy for British Association of Dermatologists guideline authors

To ensure the independence of BAD clinical guidelines all GDG members are required to read the policy document for declaring COIs, which can be found on the BAD website – www.bad.org.uk/healthcare-professionals/clinical-standards – and complete the online declaration form for evaluation by the T&G subcommittee and the CStU. The conditions and exclusions are highlighted in the Supplementary Information (Data S1).

8.0 Guideline development process and outputs

All BAD guidelines should be comprehensive and up-to-date at the point of publication. Recommendations are based on evidence drawn from a systematic review of the literature pertaining to the clinical questions identified. This involves employing a comprehensive search strategy to identify all available evidence, followed by data extraction, data syntheses, appraisal and grading of the evidence, as well as formulating and grading the recommendations, according to the GRADE methodology. The full guideline produced may be detailed and lengthy; therefore, in order to provide concise guidance to which healthcare professionals can refer quickly in the clinical setting, a summary of the recommendations should be produced. All BAD GDGs are expected to produce a set of guidelines featuring:

- 1 A review of the literature which may include, if applicable, the disease definition, natural history, clinical presentation, epidemiology, aetiology, diagnosis and investigation, differential diagnosis and prognosis for a skin condition;
- 2 Systematic reviews for the key clinical questions being addressed in the guideline, covering different treatment options, where applicable;
- 3 A summary of all recommendations for quick reference, featured in the manuscript or published separately as an executive summary;
- 4 Discussion on any organizational or financial barriers in implementing the recommendations;
- 5 An algorithm of management strategy, if appropriate;
- 6 Recommended audit points and a set of audit standards that can be used as a basis for undertaking a BAD national audit (www.bad.org.uk/healthcare-professionals/clinical-standards/clinical-audits);
- 7 Research recommendations for areas of uncertainties; and
- 8 A Patient Information Leaflet or an updated version if one exists already; GDGs would be best placed to undertake this, having reviewed the latest evidence for the guideline.

Coordination of each step of the developmental process will be carried out by a designated member of the CStU.

8.1 Purpose and scope

The purpose and scope of the guidelines should be discussed at the outset. It is essential that all relevant stakeholders are considered in the process, with due consideration given to patients and subgroups (for example, children and young people, those planning conception, people with comorbidities, etc.).

Any specific exclusion should be considered and stated explicitly.

8.2 Clinical questions and PICO

GDGs should specify key clinical questions to form the basis of the guideline using the PICO method; this is a technique used in evidence-based medicine to frame and answer a clinical question:

- P Patient/population
- I Intervention
- C Comparator/control (if applicable)
- O Outcome

This is the method used by GRADE and should help the GDG to focus on the pertinent clinical issues. Systematic review protocols may help in pooling together the common P, I, C, O strands from the clinical questions; these protocols will be used as the template for any bespoke data extraction proforma produced (see section 8.4).

8.3 Literature searches and selection strategy

The CStU will prepare an initial literature search strategy before the first meeting in collaboration with the GDG lead, with revisions made following discussion at the first meeting. The CStU will run the searches across multiple databases (e.g. PubMed, MEDLINE, Embase, Cochrane Library, and if appropriate, CINAHL, LILACS and AMED), and collate and de-duplicate the results. Targeted literature searches for specific sections or PICO questions may be warranted in some instances.

A top-up literature search will be carried out just before or during the consultation period for the draft guideline. This is to ensure that the guidelines are as current as possible at the point of publication. The date of the last literature searches carried out for any guideline should be stated in the guideline manuscript and supporting materials.

8.3.1 Selection criteria

A set of selection criteria should be agreed upon by the GDG before the searches are carried out as part of the literature search strategy discussions. It may be appropriate to decide on

a threshold for the number of patients in included studies; such selection criteria will be featured in the systematic review protocol. Further information on the selection of identified literature is featured in the online Supplementary Information (Data S1).

8.4 Data extraction and synthesis

As part of the systematic approach to reviewing the evidence, relevant data across multiple studies will be extracted and then pooled appropriately. These data will be synthesized by the CStU in the systematic review software package RevMan (Review Manager, The Cochrane Collaboration) to produce summaries, forest plots and meta-analyses (where appropriate). Calculations will include the treatment effects (e.g. risk ratios, RR), weighting of each study, and indication of the heterogeneity and imprecision in any pooled set of data to help inform the GDG when formulating recommendations at later stages.

Where relevant systematic reviews exist (e.g. Cochrane reviews) it would be sufficient to cite these as the basis for making recommendations, provided that:

- 1 The methodology indicates a systematic approach to producing the review (an assessment checklist will be provided). N.B. data from more recent trials not included in the systematic review will need to be extracted and synthesized.
- 2 The outcomes listed in the systematic review match (all or in part) those that the GDG had set for the guideline.

N.B. outcomes reported in individual trials which match those that the GDG had set but not included in the systematic reviews will need to be extracted and synthesized.

8.5 GRADE

GRADE is outcome-centric and therefore necessitates the use of the PICO method.

8.5.1 Defining outcomes

The GDG should identify all possible outcomes of interest for the topic and of importance to patients, and rank them as outlined in Figure 1.^{7,8}

Those outcomes ascertained as being critical for decision making would determine the overall quality of the evidence. A maximum of seven outcomes per systematic review is recommended.

8.5.2 Grading the quality of evidence

The quality of evidence indicates the extent to which the reader can be confident that an estimate of a treatment effect is adequate to support a particular recommendation. GRADE utilizes a system for classifying the quality of evidence that is easier for guideline users to understand than previous numerical ratings. The quality of evidence is described as being high, moderate, low or very low as defined in Table 1.^{9,10}

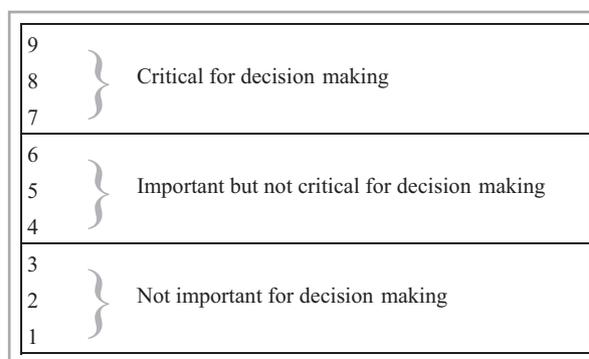


Fig 1. Scale showing the ranked importance of outcomes.

Table 1 Quality of evidence defined

Quality	Definition
High	Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low	Any estimate of effect is very uncertain

Unlike previous systems where each study was assessed and graded individually, GRADE takes a different approach (Fig. S1; see Supporting Information). The quality of evidence is assessed *per comparison* (intervention vs. comparator/control), *per outcome* and then across all the studies (i.e. for the body of evidence) that report that comparison and that outcome.

Evidence based on randomized controlled trials would be graded initially as high quality, but confidence in the trials may be decreased due to one or more of the following five factors:^{7,9,10}

- 1 Study limitation/risk of bias;¹¹
- 2 Inconsistency of the pooled results;¹²
- 3 Indirectness of the evidence;¹³
- 4 Imprecision of the pooled results;¹⁴
- 5 Reporting/publication bias.¹⁵

The GDG should be vigilant with regard to these potential negative factors, i.e. those that would reduce their confidence in the quality of the evidence. For each of the factors the GDG would need to determine (i) if there is a problem, (ii) whether the problem matters and (iii) if so, by how much does it matter.

Further information on these factors is featured in the Supplementary Information (Data S1) and the Cochrane Handbook for Systematic Reviews of Interventions.¹⁶

A quality rating would then be obtained for each outcome where problems with any of the five factors would lead to downgrading.

Observational studies would start with 'low' quality ratings due to inherent selection bias. However, *upgrading* may be possible in unusual circumstances, but only if the evidence has not been downgraded already, due to study limitation/risk of bias, inconsistency and imprecision.¹⁷ Factors that may upgrade observational studies are in cases where:

- 1 The magnitude of the treatment effect is large (RR > 2 or RR < 0.5) or very large (RR > 5 or RR < 0.2);
- 2 There is evidence of a dose–response relationship;
- 3 All plausible confounders or biases behave in the opposite direction to what might be expected.

The overall quality rating of the body of evidence, per comparison, is determined by the lowest quality of evidence for any of the critical outcomes for that comparison.

A GRADE evidence summary table, which displays the quality of assessments, study features and summary of findings (including the pooled estimate of effect for each outcome across included studies), will help with decision making.^{18,19}

8.5.3 Formulating recommendations and grading the strength

The following should be in place when formulating recommendations at a GDG meeting:

- 1 A quorum is achieved, i.e. at least 50% of appointed members are present and able to vote.
- 2 The presence of at least one patient or patient representative; if quorum is achieved *draft* recommendations may be formulated in their absence, then agreed upon with the patient or patient representative.
- 3 BAD members of staff or other guideline technical support personnel do not:
 - contribute towards the quorum of the GDG
 - contribute to the development of recommendations during meetings
 - hold voting rights.

A strong recommendation for an intervention in specific circumstances indicates the extent to which the reader can be confident that the intervention has more desirable effects than undesirable ones. GDGs should evaluate four elements which form the framework in determining the strength of recommendations:^{20,21}

- 1 A balance between desirable and undesirable effects;
- 2 The quality of the body of evidence;
- 3 Any variability or uncertainty in patient values and preferences; and
- 4 Costs, in terms of resource allocation.

Desirable effects might include:

- 1 reduction in morbidity and mortality
- 2 improvement in the quality of life
- 3 reduction in the burden of treatment
- 4 reduction in resource expenditures.

Undesirable effects might include adverse effects having a deleterious impact on:

- 1 morbidity
- 2 mortality
- 3 quality of life
- 4 costs, i.e. an increase in resource expenditures.

GRADE utilizes a binary system for classifying the strength of recommendations, providing unequivocal direction to clinicians, policy makers and patients.^{20,22} The recommendations are described simply as being strong or weak:

→ **Strong**, i.e. unconditional, where:

- Desirable effects of an intervention clearly outweigh the undesirable effects (or clearly do not);
- There is a high-quality body of evidence with large, precise effects;
- There is low variability or uncertainty in patient values and preferences; and
- There is low resource allocation.

→ **Weak**, i.e. conditional, where:

- Desirable effects of an intervention are not clearly greater or smaller than undesirable effects;
- There is a low-quality body of evidence with imprecise estimates;
- Variability or uncertainty in patient values and preferences; and
- There is high resource allocation.

The implications of strong and weak recommendations are highlighted in Figure 2.

It would be possible to have the scenarios in Table 2, where the strength of a recommendation does not always follow the quality of the evidence.

A template for 'Linking the Evidence To the Recommendations' (LETR), factoring in the aforementioned four elements, will be used at meetings where recommendations are formulated. Evidence statements/summaries, recommendations and their grading will be produced 'live' during the meeting following discussion of the synthesized evidence, providing a transparent trail. Where disagreement exists concerning setting the strength of recommendations, following evaluation of the four elements, it may be appropriate for core GDG members (see section 7.0) to vote in order to reach an informal consensus. In such cases, the result of the vote may be indicated in the guideline for that recommendation. Also, a vote may be appropriate in the third scenario in Table 2, in which case the result reached by such recommendation should be accompanied by a clear explanation in the narrative for the GDG's decision.

Recommendations to use specific interventions only in the setting of a clinical study, i.e. a research recommendation, may be appropriate, e.g. in cases where the evidence is lacking.

The BAD will use the standardized wording for recommendation statements adopted by NICE,²³ so that they are clearly identifiable, unambiguous and specific. The LETR template

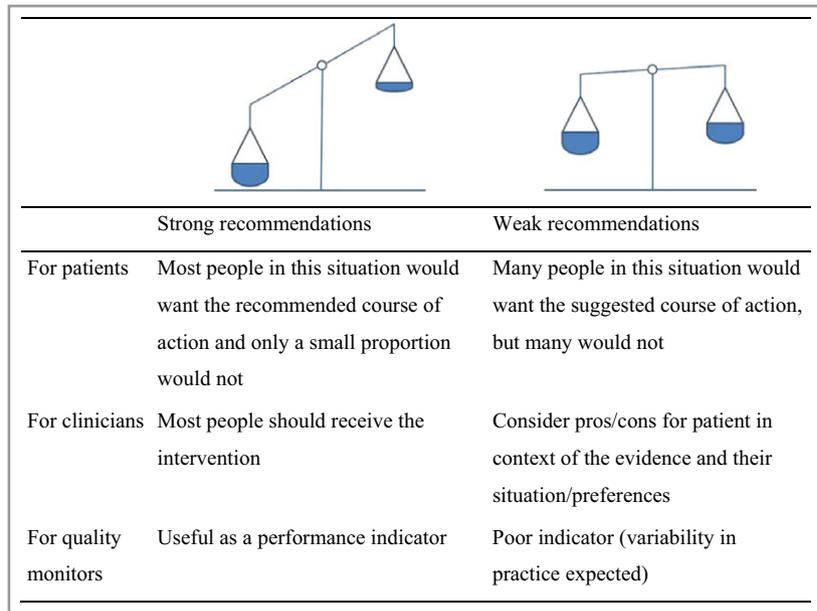


Fig 2. Implications of strong and weak recommendations.

Table 2 Recommendation scenarios

Quality of evidence	Benefit vs. harm	Recommendation	Rationale
High	Similar	Weak	Lack of agreement in the evidence
High	Benefit > harm; acceptable costs	Strong	Agreement in the evidence
Low/very low	Irrelevant	Strong	GDG unanimity, fully aware of limitations in the evidence

GDG, guideline development group.

contains a brief guidance for ease of reference at meetings. Additionally, GDGs may use appropriate symbols to help the end-user identify the strength of recommendations more conveniently.

- 1 strong ‘OFFER... ↑↑’ or
- 2 strong ‘DO NOT OFFER... ↓↓’
- 3 weak ‘CONSIDER... ↑’

8.6 Standard format of British Association of Dermatologists guidelines and collation of draft sections

The CStU has a standard structural template for all BAD guidelines, which will be circulated with the agenda of the first meeting for modification to suit the specific topic. The template includes items and sections that are required for inclusion as part of the NICE Accreditation requirements and criteria. There is also an in-house formatting style for the

finalized draft when it is distributed to members and stakeholders for consultation. All references included in BAD guidelines will follow the standard BJD citation format. The CStU will collate all draft sections into the template and house style, edit the manuscript and carry out citations using the reference management software package EndNote (Thomson Reuters Corporation). The year of publication for the guideline should be featured in the title, and the anticipated year for review in the section ‘Plans for guideline revision’.

8.7 Consultation, peer review and sign-off

All draft BAD guidelines will be peer-reviewed by the T&G subcommittee; comments from the committee will be fed back to the GDG, with appropriate amendments made before the draft is amended and circulated to all relevant groups for consultation.

The consultation will be open to all relevant stakeholders including, but not limited to, members of the BAD, British Dermatological Nursing Group, Primary Care Dermatological Society and suitable patient groups, for a period of up to 1 month. Comments will be collated by the CStU and fed back to the GDG for review alongside any new evidence identified from any top-up literature searches. Ordinarily, changes to a recommendation would be made only if evidence of high quality had been identified (for a recommendation based previously on evidence of lower quality) indicating better trade-offs between clinical benefit and harm, with little or no difference in cost implications or patients’ preferences.

The amended version will be reviewed again by the T&G subcommittee for sign-off, with any final comments fed back to the GDG, prior to submission to the BJD.

The finalized BJD-submitted guideline will be peer-reviewed, and reviewers may include healthcare professionals based overseas, as a final quality-control measure. Jointly

badged guidelines with other medical subspecialties and simultaneous publication in multiple journals may be appropriate and will be considered on a case-by-case basis by the T&G subcommittee.

8.8 Updating published guidelines

All published BAD guidelines should be updated every 5 years or more frequently if deemed necessary, e.g. for topics where development is fast moving. The CStU will contact the GDG leads of published guidelines on the second anniversary of publication to ascertain the need to start the updating process then, or to defer by up to 2 years. The GDG lead may request for the original literature search strategy to be re-run to provide information on studies published since the last set of searches were carried out, and assist with the decision on whether to start the updating process.

The original GDG members will be approached by the CStU to determine if they would be prepared to undertake the work and produce an update. If none of the original GDG members are available, the T&G subcommittee will propose a new lead for the CStU to approach, which may involve advertising to the BAD membership.

If a guideline is not updated then it should be removed from the main guidelines' page of the website as potentially it could be misleading, and placed in the guidelines archive area of the BAD website, indicating it is not going to be updated.

In certain topics where development is fast moving, the GDG or lead may request an annual review of the literature, limiting such review to high-quality studies only. A decision could then be made by the GDG whether to update the guideline on the basis of this review or to issue a statement that the new evidence identified and reviewed would not materially affect any of the recommendations in the guideline. In any case, once a guideline is published, subsequently published Cochrane reviews in the same clinical area may be linked and used to determine if relevant recommendations in the guideline would need to be updated.

The same level of support will be offered by the CStU for the updating process, and the same requirements and processes also apply.

8.9 Other considerations

As guideline methodology evolves, the CStU will monitor and consider new developments and approaches, for example, the process of adapting other guidelines according to the ADAPTE method,²⁴ and moving away from 'traditional' guidelines, which attempt to cover all eventualities, towards more focused guidelines that aim to answer specific clinical questions.

8.10 Limitations of all guidelines

All clinical guidelines would have been prepared from the best evidence available, and the results of any future studies may require some of the recommendations to be changed. Under certain circumstances, it may be necessary to deviate from the

recommendations. Failure to adhere to any BAD guidelines should not necessarily be considered as an act of negligence, nor should adherence to the recommendations constitute a defence against a claim of negligence. These standard limitations are reiterated in all BAD guidelines.

9.0 Timelines and summary of steps

A realistic timeline for each guideline will be discussed and decided at the first meeting. However, pressures and demands on GDG members could result in the agreed timeline being unachievable; therefore, regular communication with the CStU and the GDG lead is essential to minimize delays.

The CStU will also employ a reminder strategy:

- 1 Regular e-mail reminders, which will vary in frequency depending on the stage of development;
- 2 An amended timeline will be set as soon as possible after any missed milestones and circulated to the entire GDG.

A brief outline of the entire process, using a 2-year timeline, is provided below as a guide (Fig. S2; see Supporting Information):

- 1 Pre-first meeting (up to 6 months);
- 2 First meeting (day 1);
- 3 Post-first meeting (~ 8 months);
- 4 Second meeting (within 8–10 months of first meeting);
- 5 Post-second meeting (~ 2 months);
- 6 Third meeting (within 2–3 months of second meeting);
- 7 Post-third meeting/pre-consultation (3–5 months);
- 8 Consultation (1 month);
- 9 Post-consultation/pre-BJD (1–2 months);
- 10 BJD peer review (~ 3 months).

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's website:

Data S1. Information regarding Conflicts of Interest; Meetings; Selection of identified literature and retrieval of papers; and GRADE-ing the quality of evidence.

Fig. S1. Comparison of the evidence grading approaches for four studies evaluating the same intervention and comparator/control.

Fig. S2. Flow diagram covering the major stages of a British Association of Dermatologists guideline development (reference to the relevant sections in the main article in brackets).