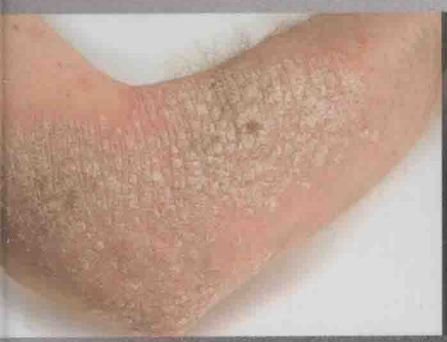
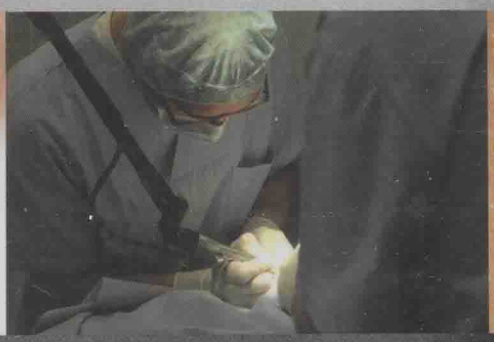
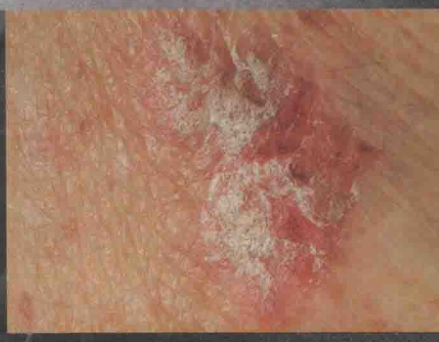
British Association of Dermatologists' Management Guidelines

Edited by
Neil Cox
John English

WILEY-BLACKWELL

British Association of Dermatologists' Management Guidelines

Edited by

Neil H. Cox BSc, MBChB, FRCP (Lond & Edin)
Consultant dermatologist
Cumberland Infirmary
Carlisle
UK

John S.C. English MBBS, FRCP
Consultant dermatologist
Nottingham University Hospital
Nottingham
UK

WILEY-BLACKWELL
A John Wiley & Sons, Ltd., Publication

Blackwell Publishing was acquired by John Wiley & Sons in February 2007. Blackwell's publishing program has been merged with Wiley's global Scientific, Technical and Medical business to form Wiley-Blackwell.

Registered office: John Wiley & Sons, Ltd, The Atrium, Southern Gate, Chichester, West Sussex, PO19 8SQ, UK

Editorial offices: 9600 Garsington Road, Oxford, OX4 2DQ, UK
The Atrium, Southern Gate, Chichester, West Sussex, PO19 8SQ, UK
111 River Street, Hoboken, NJ 07030-5774, USA

For details of our global editorial offices, for customer services and for information about how to apply for permission to reuse the copyright material in this book please see our website at www.wiley.com/wiley-blackwell

Library of Congress Cataloging-in-Publication Data

British Association of Dermatologists.
British Association of Dermatologists' management guidelines / edited by Neil H. Cox, John S.C. English.
p. ; cm.
Includes bibliographical references.
ISBN 978-1-4443-3552-1
1. Skin–Diseases–Treatment–Standards. 2. Dermatology–Standards–Great Britain. I. Cox, Neil H. II. English, John S. C. III. Title.
[DNLM: 1. Skin Diseases–therapy–Practice Guideline. 2. Dermatology–methods–Practice Guideline. WR 650 B862 2011]
RL110.B75 2011
616.5–dc22

2010024518

ISBN: 9780470654552

A catalogue record for this book is available from the British Library.

This book is published in the following electronic formats: ePDF 9781444329872; Wiley Online Library 9781444329865; ePub 9781444329889

Set in 9.25/11.5pt Minion by Aptara® Inc., New Delhi, India
Printed and bound in Singapore by Fabulous Printers Pte Ltd

1 2011

A tribute to Professor Neil H. Cox

Unfortunately, Neil died suddenly in December 2009. I had known Neil since the mid 1980s when we were both registrars in Glasgow with Professor Rona Mackie. Neil very quickly developed the high degree of skill in writing and editing dermatology papers and book chapters; to a level that I will never achieve. This book was one of his 'babies' as he had contributed more to the BAD guidelines than any other author and so knew them inside out. I hope I have done him and his guidelines justice in helping edit this compendium.

Dr John S.C. English 2010

Introduction

It is with great pleasure that I introduce this compilation of the British Association of Dermatologists guidelines. I was an Honorary Secretary of the British Association of Dermatologists from 1996 to 2000 when the guidelines process was initially developed through the auspices of the then Drug and Therapeutics Committee. As described later in the book, we wanted the guidelines not only to represent best practice but also to reflect a consensus of views of British dermatologists. So we published draft documents in the BAD newsletter for a 3-month consultation before submission to the British Journal of Dermatology.

We hoped that the guidelines might act as a reference source for the development of dermatology education resources for healthcare practitioners, patients and the general public. Hence, when we developed our website they were made freely downloadable.

When I became President of the BAD some 10 years later, it was clear that the guideline process was a great success – a tribute to the innumerable clinicians who took part in their development. The editors of the BJD also told us that they were highly cited articles and reprints were requested internationally.

People enjoy access to information through many routes and it seemed to me that a compilation of the guidelines in a book would make the information available in another useful format.

The hard work of Neil Cox, in particular, along with John English has brought this to fruition. Reading it now, it seems not only a source for knowledge about the management of and therapies used in skin conditions but also an illustration of the evolution of the guidelines process over the last decade; a process in which Neil Cox was intimately involved.

Sadly, as Neil's last work it has also become a tribute to his memory.

I hope you find the book enjoyable and informative.

Dr Colin Holden BSc, MD, FRCP
Past President
British Association of Dermatologists

Preface

The guidelines contained in this publication have mostly been published in the *British Journal of Dermatology* within the last 10 years, and are all available online from the British Association of Dermatologists (BAD) website www.bad.org.uk. In preparing this compendium of the guidelines, we have been aware of three main factors.

Firstly, many of the guidelines have now been updated since they were first published. Most of the updates have given greater prominence to therapeutics, especially with regard to newer approaches, and to areas of controversy. By comparison, the initial versions generally 'set the scene' and contained more text about epidemiology and older treatments than in the updated versions. Therefore, many of these earlier versions still have value as review material, and we felt that references to these should be included.

Secondly, the whole process of assimilating, assessing and extrapolating evidence to be applied in clinical settings has been a rapidly changing field. This is discussed in more detail on pX. Although there is now a preferred style of citation of evidence and recommendations for BAD guidelines (see pX), the style differs somewhat between guidelines. This, in part, reflects styles in use at the time of writing as well as pragmatic issues such as ease of updating and of collaborating with other specialists to produce multidisciplinary guidelines. Additionally, some of the guidelines were produced as consensus documents (British Photodermatology Group) and have a different style.

Thirdly, no evidence is ever perfect, multiply replicated and applicable in all scenarios. Even with good evidence, the strength of a recommendation may vary between individuals who have assessed that evidence. External factors such as different healthcare systems or edicts by government bodies may influence recommendations. Newly emerging evidence needs to be put in context, and some evidence may create as many questions as it answers. Therefore, we have added some editorial comments about each guideline, and some details of recent evidence and of other guidelines and reviews, mostly by use of web addresses.

Finally, guidelines need to be useful. The BAD guidelines are written primarily for dermatologists and other specialists. They have been produced in summary format, capable of being copied and laminated for quick reference. They have also included other tools for the user, such as some suggested audit points. For this compendium, we have tried to extend this usefulness by adding guidelines that may be more applicable to primary care users (e.g. Clinical Knowledge Summaries (CKS) and reference material from the New Zealand DermNet). We have also included some guidance from bodies such as the UK National Health Service (NHS) and the UK National Institute for Health and Clinical Excellence (NICE), as well as material from other national dermatology bodies (such as the American Academy of Dermatology) and a variety of cancer organisations. We have also supplemented each topic, where applicable, with patient information resources that provide Patient Information Leaflets (PILs) or web-based information about specific conditions, prevention of disease, or about treatments.

Thus, for each guideline, in addition to reproducing the published version, we have included a web address for the guideline, some editorial comment, selected additional guidelines or other references for users, web details of the BAD's own PIL and details of additional patient-orientated sources of information.

We hope that these measures will increase the utility of the guidelines beyond the original presentation.

We thank all guideline authors for their dedication to this project, and to current and previous members of the BAD's Therapy Guidelines and Audit Subcommittee who have overseen the production of guidelines throughout the last decade.

N.H. Cox & J.S.C. English
Editors 2009

Background to the British Association of Dermatologists clinical guidelines

The British Association of Dermatologists (BAD) started its programme of writing guidelines over 10 years ago, with impetus from Professors Hywel Williams and Chris Griffiths and the Therapy Guidelines and Audit Subcommittee of the BAD. The process of developing national guidelines began for various reasons, at least partly because of a realisation that many guidelines were being developed by local groups of dermatologists (or others), with varying quality and sometimes with significant input or endorsement from pharmaceutical manufacturers, and it was felt that a national approach, independent from external influence, and produced in a way that would have broad consultation amongst members of the Association, would be preferable. There was also external impetus in that the Royal College of Physicians (RCP) of London wanted all specialist societies to generate some national audit criteria, and it was felt that the strongest suggestions would be achieved by basing them on evidence-based national guidelines.

The guidelines writing and consultation process had some key features [1], some of which have altered with time. The initial plan was to write guidelines 'by dermatologists, for dermatologists' (but with the knowledge that at least some parts of these guidelines would be applicable to primary care and to other disciplines). The guidelines were to be prepared by small groups, including some clinicians working out with academic centres; they would include an evaluation of the strength of the available evidence, and recommendations would be made together with suggestions for possible audit. All draft versions, once approved by the Therapy Guidelines and Audit Subcommittee, which was central to this process, would be circulated to the membership of the Association for a 3-month consultation period, inviting any comments and, thus, acting as a peer review as well as giving a sense of ownership of the guidelines to all members of the BAD. Some aspects have changed slightly over the years, as described below, but the basic aims and methods remain unchanged, and a valuable resource has been built up by clinicians who have put much time and effort into this process.

Although the original aim was primarily to produce disease-related guidelines, it became apparent that there was also a need for guidelines on specific treatments; this has led to guidelines on systemic therapies such as azathioprine and biological agents for psoriasis. One of the major changes that took place over the years was in relation to authorship. In some cases, additional authors were included (for example, because of experience in performing a Cochrane review of a subject), or because of the breadth of some topics; for example, guidelines on biological agents needed to take into consideration the needs for a register of use of such agents and to include authors who would be involved with such a register. Recognising the value of unified guidelines on topics that spanned different specialties led to multidisciplinary guidelines, initially for melanoma (involving the BAD and members of the Melanoma Study Group) and later for Squamous Cell Carcinoma (with Plastic Surgery). An even broader group has been involved with revised Melanoma guidelines, and guidelines for monitoring of isotretinoin have taken a further step by having a lay member representing the relevant (acne) patient support group. Perhaps, the greatest change, and the main subject of the following discussion, has been changes in expectations for guidelines in terms of their validity, independence from any conflicts of interest and in the explicit links between available evidence and the recommendations that are made.

Fairly rapidly, writing guidelines evolved into a 'business', the most pertinent parts of this culture being the production of definitions of what a guideline represents, issues around the legal position of guidelines and the evolution of 'guidelines for guidelines' that dictated certain content aspects, stringency requirements for evidence to be viewed as valid, systems for grading of evidence and the strength of the recommendations that could be drawn from such evidence. The process that had been adopted by the BAD had acknowledged that there were areas of

'normal established practice' that were not supported by high-quality evidence, that there were many areas lacking head-to-head comparisons of treatment, that evaluation of successful treatment was often subjective, and that lack of formal evidence did not necessarily preclude recommending a treatment. Therefore, the link between quality of evidence initially used in the BAD guidelines (stratified in a manner similar to that used by the US Task Force on Preventative Care Guidelines) and the recommendations that were made allowed less easily measurable factors to be taken into consideration. The subsequent shift in expectations for production of guidelines, described below, meant that the recommendations of a guideline would be more tightly limited by the validity of the available evidence on which it was based.

Although future clinical trials were increasingly expected to meet validity criteria, notably those of the CONSORT statement (Consolidated Standards of Reporting Trials) [2], these criteria were proposed some years after the start of the BAD guidelines production process. Whilst they set a new level of expectation for clinical trials, these criteria could not necessarily discredit the conclusions of historical studies where descriptions of trial design were not always recorded to the new level of detail that CONSORT advised. Furthermore, those performing clinical trials needed to be educated in application of these new standards [3, 4] before these standards could become the norm. Whilst many older trials were undoubtedly suboptimal as a basis for evidence in guidelines, the opposite also applied in some instances; some good-quality trials used selected patients, often excluding older patients or those with co-morbidities, and thus, only truly represented a minority of subjects with a particular condition.

As guidelines for guidelines developed further, more objective methods to quantify the validity of guidelines were constructed; the most relevant to the BAD (as it was adopted by the RCP) was the AGREE instrument [5, 6], in which a scoring system for guidelines was suggested based on various aspects such as applicability, stakeholder involvement (in our case, consultation with the membership), robustness of searches for evidence, clear links between strength of evidence and the recommendations, through to statements about editorial independence from any funding bodies or other conflicts on interest and inclusion of 'user tools' (in our case, summary tables and lists of possible audit points). Guidelines for guidelines started to force a direct link between the grading of evidence and the strength of recommendation. Whilst the BAD guidelines were actually complying with many of the suggestions and thus 'scoring points' (for example, there was no extrinsic funding and there was a consultation process with potential users – the membership of the BAD), space constraints precluded stating all of these points in every guideline. A further publication was produced to explain how many of these 'new' recommendations were already being addressed [7], and the two references outlining the BAD guidelines process [1, 7] were added to subsequent guidelines so that institutions that wished to score guidelines could access the 'process' issues behind each of the BAD guidelines. More recently, large organisations have revisited the issue of guidelines for guidelines in deciding the key components that they wish to see in their own guidelines; the World Health Organization, for example, published a series of 16 articles on guideline development including comparisons of different guidelines for guidelines [8] and how they wished their own guidelines to be structured [9].

More explicit links between quality of evidence and the therapeutic recommendations that could be made have gradually became more widely used [10–12] and were summarised for BAD guidelines authors by Dr Tony Ormerod in 2004 [13]. This publication includes a summary of how to rank evidence, and to make recommendations, that is more rigid than that used in previous BAD guidelines, but more robust (this advice is currently being updated). However, even at this time changes were still being suggested; one study of six systems used by 51 organisations involved in clinical practice guidelines suggested that all of them had important shortcomings [14]. A new scheme for assessing the level of evidence and strength of recommendations was used in the BAD guideline on biological agents for psoriasis, recognising that some recommendations could only be given a low 'D' rating due to lack of evidence, but that such evidence may still be very important (for example, formal consensus of experts would fall into this category) [15]. Yet it remains difficult to apply guidance on how to mix research evidence, expert opinion and patient experience, and how to formalise a consensus recommendation that remains an inevitable element of most guidelines [16].

What does this mean for the reader of the present book? First, it should be appreciated that the main stakeholder group for most of the guidelines is dermatologists, although some guidelines have been written in collaboration with other specialists involved with treatment of a specific disorder. Second, the link between quality of evidence and strength of recommendation has not only involved a subjective component (for example, even if informally, most guidelines have taken costs, availability and convenience into account when making therapeutic

recommendations), but has also altered in format with time as new recommendations for writing guidelines have been incorporated. Finally, many of the guidelines may not 'score' well on guideline appraisal systems unless the separate publications documenting the guideline process [1, 7] are also taken into consideration. For this reason, some of the guidelines presented here are formal updated versions of previous publications; in other instances, where rewriting a full guideline with a more modern evidence-recommendation summary would have been unlikely to lead to fundamentally different advice, authors have had an opportunity to add new information or to adjust evidence or recommendation grading in order to ensure that the conclusions are currently applicable.

In some respects, although arguably subjective rather than rigorous (and making assumptions of behalf of patients), our original avoidance of an automatic extrapolation from strength of evidence to grade of recommendation has been vindicated, as current developments in guideline recognise that other factors such as values and preferences of patients, and wise use of resources, are pertinent in making recommendations. The need to consider costs (resource utilisation) in guidelines was recognised some years ago [17]. Thus, for example, guidelines produced by the National Institute for Clinical Excellence (NICE) in the UK [18] include formal cost-benefit analyses – but these include guidelines that are written as much for healthcare commissioners as for clinicians, some that are specific to individual treatments and some that are sufficiently broad-ranging that they are very large and less 'user-friendly' for easy reference than the BAD guidelines. At the time of writing, the recommendations of the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group have been reviewed in detail and are likely to be adopted as the 'gold standard' for guideline production [19–23], having been and endorsed by many guideline-producing organisations [24]. Obviously, the wide consultation and high costs of some of these measures (such as performing cost-benefit analyses) will have a major impact on the ability of specialty groups to write comparable guidelines; some will feel that succinct guidelines, as currently produced by the BAD, are more suitable for application in clinical situations.

As allude to above, in order to allow simultaneous publication of guidelines that were produced in a staged manner over a period of years, including some that have been formally updated but retained their original evidence and recommendation hierarchies, we have published this group of guidelines largely in the format in which they were originally published. All were subject to methodologies, consultation processes and compliance with reasonably accepted guideline-writing criteria that applied at the time of writing and, as discussed, we have incorporated some updates within this structure. Where appropriate, the editors have added details of other guideline or systematic review resources for additional reading or for comparison. Especially in areas of imminent or rapid change, we have included comments on new data that have become apparent during the proof stages; where necessary for expedient publication, this may be 'stand-alone' rather than integrated within the prose. Finally, we have used our discretion to add an editorial comment in situations where there are issues of inadequate or conflicting evidence or opinion, either within or between guidelines.

This remains a process of evolution; Drs Bell and Omerod discuss the present aspirations of the BAD for its guideline author in pXIV.

Finally, neither this nor any other compendium of guidelines can ever be and remain both comprehensive and up-to-date. We advise readers to supplement these guidelines with additional web resources and textbooks that include guidelines, systematic reviews or other forms of evidence-based medicine [18, 25–29], as well as with guidelines aimed at other user groups. The latter include, in the UK, the Clinical Knowledge Summaries – previously known as PRODIGY guidelines – which contain disease-orientated, evidence-based information for primary care, produced by the Sowerby Centre for Health Informatics at Newcastle (Schin; http://www.schin.co.uk); these include guidelines on several dermatological topics, many with input from authors of guidelines in this book [30]. Guidelines available on websites based in other countries may also be useful [31, 32], and the National Guideline Clearinghouse [33] keeps a database of guidelines that fulfil their specific criteria (although there are not many dermatological guidelines included at present). For those wishing to assess in more detail the evidence that contributes to guidelines, issues about how to find evidence, hierarchy of evidence, systematic reviews and appraisal of studies can be found in standard texts [25, 34].

N.H. Cox & J.S.C. English
Editors 2009

REFERENCES

1 Griffiths CEM. The British Association of Dermatologists guidelines for the management of skin disease. *Br J Dermatol* 1999; 141: 396–7.

2 http://www.consort-statement.org
3 Cox NH, Williams HC. Can you COPE with CONSORT? *Br J Dermatol* 2000; 142: 1–3.
4 Ormerod AD. CONSORT your submissions: an update for authors. *Br J Dermatol* 2001: 145: 378–9.
5 The AGREE Collaboration. Guideline development in Europe: an international comparison. *Int J Technol Assess Healthcare* 2000; 16: 1036–46.
6 Appraisal of Guidelines for Research and Evaluation AGREE Instrument. London: St George's Medical School, 2001 (http://www.agreecollaboration.org/1/agreeguide).
7 Cox NH, Williams HC. The British Association of Dermatologists therapeutic guidelines: can we AGREE? *Br J Dermatol* 2003; 148: 621–5.
8 Oxman AD, Schünemann HJ, Freitheim A; WHO advisory committee on health research. Improving the use of research evidence in guideline development: 1. Guidelines for guidelines. *Health Res Policy Syst* 2006; 4: 13.
9 Oxman AD, Schünemann HJ, Freitheim A. Improving the use of research evidence in guideline development: 14. Reporting guidelines. *Health Res Policy Syst* 2006; 4: 26.
10 Harbour R, Miller J, for the Scottish Intercollegiate Guidelines Network Grading Review Group. A new system for grading recommendations in evidence based guidelines. *Br Med J* 2001; 323: 334–6.
11 http://www.sign.ac.uk/methodology/index.html
12 http://www.nice.org.uk/nhsevidence/
13 Ormerod AD. How to go about writing a clinical guideline for the B.A.D. http://www.bad.org.uk//site/622/default.aspx.
14 Atkins D, Eccles M, Flottorp S, *et al.* Systems for grading the quality of evidence and the strength of recommendations I: critical appraisal of existing approaches. The GRADE Working Group. *BMC Health Serv Res* 2004; 4: 38.
15 Ormerod AD. Recommendations in British Association of Dermatologists guidelines. *Br J Dermatol* 2005; 153: 477–8.
16 Rycroft-Malone J. Formal consensus: the development of a national clinical guideline. *Qual Health Care* 2001; 10: 202–3.
17 Atkins D, Best D, Briss PA, *et al.* Grading quality of evidence and strength of recommendations. *Br Med J* 2004; 328: 1490.
18 www.nice.org.uk
19 Guyatt GH, Oxman AD, Vist GE, *et al*, for the GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *Br Med J* 2008; 336: 924–6.
20 Guyatt GH, Oxman AD, Vist GE, *et al*, for the GRADE Working Group. GRADE: what is "quality of evidence" and why is it important to clinicians? *Br Med J* 2008; 336: 995–8.
21 Guyatt GH, Oxman AD, Kunz R, *et al*, for the GRADE Working Group. GRADE: going from evidence to recommendations. *Br Med J* 2008; 336: 1049–51.
22 Schünermann AHJ, Oxman AD, Brozek J, *et al*, for the GRADE Working Group. GRADE: grading quality of evidence and strength of recommendations for diagnostic tests and strategies. *Br Med J* 2008; 336: 1106–10.
23 Guyatt GH, Oxman AD, Kunz R, *et al*, for the GRADE Working Group. GRADE: incorporating considerations of resources use into recommendations. *Br Med J* 2008; 336: 1170–73.
24 Kunz R, Djulbegovic B, Schünemann HJ, Stanulla M, Muti P, Guyatt G. Misconceptions, challenges, uncertainty, and progress in guideline recommendations. *Semin Hematol* 2008; 45: 167–75.
25 Williams HC, Bigby M, Diepgen T, Herxheimer, Naldi L, Rzany B (eds). *Evidence-Based Dermatology, 2nd edn.* Oxford: BMJ Books/Blackwell Publishing, 2008.
26 http://www.blackwellpublishing.com/medicine/bmj/dermatology/default.asp
27 Cochrane Skin Group. http://www.csg.cochrane.org.
28 Cochrane Library. http://www.thecochranelibrary.org.
29 NHS National Library for Health. http://www.library.nhs.uk.
30 NHS Clinical Knowledge. http://www.cks.nhs.uk/home.
31 New Zealand Dermatology Guidelines. http://www.dermnetnz.org.
32 American Academy of Dermatology guidelines. http://www.aad.org/research/guidelines/index.html.
33 National Guideline Clearinghouse. http://www.jcaai.org.
34 Bigby M, Williams HC. *Evidence-based dermatology.* In: Burns DA, Breathnach SM, Cox NH, Griffiths CEM (eds). *Rook's Textbook of Dermatology, 8th edn.* Oxford: Blackwell Science, 2010, p 7.1–7.23.

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. [a]Studies 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	• 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 • Evidence drawn from a NICE technology appraisal
B	• 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	• 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	• Evidence level 3 or 4, or • Extrapolated evidence from studies rated as 2+, or • Formal consensus
D (GPP)	• 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.

http://www.bad.org.uk/Portals/_Bad/Guidelines/Clinical%20Guidelines/How%20to%20go%20about%20writing%20a%20BAD%20Clinical%20Guideline%20-%20BJD%20paper.pdf

REFERENCE

1 Bell HK, Omerod AD. Writing a British Association of Dermatologists clinical guideline: an update on the process and guidance for authors. *Brit J Dermatol* 2009; 160: 725–8.

Contents