Standards of Care Committee

Guideline Production Manual

1 Introduction

1.1 Background

The British Society for Allergy and Clinical Immunology (BSACI) has charitable status with its major objective to improve the management of allergies and related diseases of the immune system in the United Kingdom, through education, training and research. The production and dissemination of evidence-based guidelines provides guidance for optimal standards of care and fulfils an important part of this objective. The BSACI also leads on national audits to assess changes in clinical care.

In 2004 BSACI set up the Standards of Care Committee to develop guidelines for use in secondary care by both adult physicians and paediatricians practising allergy. By 2017 thirteen guidelines have been published in a major international journal of Allergy and Immunology. The process of guideline development was informed by the AGREE instrument (Appraisal of guidelines for research and evaluation) and the SIGN (Scottish Intercollegiate Guidelines Network) 50 guideline developer's handbook and has been continually adapted and refined. The Standards of Care Committee were awarded NICE accreditation of their guideline writing processes in 2013, and this was reviewed / renewed in 2018.

This document describes the principles, policies and processes that should be followed in the development of BSACI guidelines. Issues that are not covered in this document, but are thought to be important for improving this development process should be brought to the attention of the Chair of the Standards of Care Committee. The writing of this manual has been informed by the British Thoracic Society's Guideline production manual (2012), the NHS/NICE guidelines manual Draft 2012 and the NICE accreditation renewal process manual (August 2017).

1.2. General Principles

The production of guidelines is the responsibility of the BSACI Standards of Care Committee (SOCC). Appendix 1 contains the constitution of the SOCC.

BSACI guidance is produced by Guideline Writing Groups selected and approved by the BSACI Standards of Care Committee. The work of the SOCC and Guideline groups is supported by the BSACI Research officer who is a staff member of BSACI Head office. The work undertaken by the SOCC, the guideline group members and the lay person(s)

representatives is on an honorary basis although expenses to attend meetings are funded by the Society. The Society does not seek external funding for the production of its guidelines.

BSACI guidelines are based on the best available evidence. It is however recognised that evidence in some areas may be sparse or of poor quality. It is thus important that robust methodology is used to develop guidance even in areas where the evidence base is weak. Guidance for good practice for these topics is often much needed, and can also serve to highlight areas for future research. BSACI guidelines aim to adhere to the AGREE criteria (www.agreecollaboration.org).

BSACI guidelines are designed to give guidance in the United Kingdom. Special considerations are therefore given to drugs available within the NHS. The ethnic diversity within the UK should be considered by providing guidance on specific needs or risks within ethnic groups.

2 Initiation of the Guideline process

2.1. Topic, scope and preparation of a new guideline

The intended users of BSACI guidelines are health practitioners with a special interest in Allergy and Immunology. Suggestions for new guideline topics are made on the BSACI website and topics can be submitted to the SOCC. Any submissions will be discussed at one of the four SOCC meetings each year and evaluated for clinical need, appropriateness, timeliness, feasibility and available evidence with SOCC membership deciding whether to approve the proposal.

The following steps should be taken in preparation of the development of a new guideline.

1. A guideline Lead is proposed by the Chair of the SOCC, in consultation with SOCC. The Chair and members of the writing group are usually BSACI members and may be simultaneously members of the SOCC. The proposed lead should have specialist expertise in the area of the guideline topic and is formally invited by the SOCC Chair. Once appointed the guideline lead will be informed about the process of guideline development (appendix 4) timelines, future meetings and usual template of BSACI guidelines (appendix 3). The lead is expected to ensure quality of input from all group members, adhere to the BSACI policy for declaration of interest and manage declarations of interest and potential conflicts of interest of group members, lead draft write ups, attend SOCC meetings when the guideline is an agenda item, keep SOCC updated on the guideline progress and undertake activities to promote the guideline implementation after guideline publication. The lead is accountable for delivering the draft guideline to SOCC within an agreed timeframe.
2. The guideline lead, in consultation with the SOCC chair, assembles a writing group, usually consisting of 5-10 individuals. Members of the writing group will be recognised experts in the guideline subject. A minimum of two representatives from patient organisations (from Allergy UK and /or Anaphylaxis Campaign) will be part of the guideline writing group throughout the guideline production process (including scoping and development of recommendations). Both patient organisations have sufficiently large membership to provide lay members. In the unlikely event that a lay member

cannot be identified within the patient organisations, the BSACI SOCC will invite lay people who have fulfilled this role on previous guidelines. The guideline lead should confirm that the writing group have sufficient time available to devote to the project. The writing group is a separate body to the SOCC, but may contain SOCC members.

An outline of the systematic review is proposed by the writing group at a face to face meeting, usually at BSACI headquarters. The literature is identified according to an explicit search strategy with pre-defined inclusion and exclusion criteria. At this meeting the guideline group identify a series of structured questions using the PICOT (Population, Intervention, Comparison, Outcome and Timeframe) format. The responsibility for writing each section is allocated amongst the writing group, by the lead at this meeting, and a deadline should be agreed between the authors for delivery of a first draft to SOCC for discussion.

3. The systematic literature review begins by defining key search terms, dates, inclusion and exclusion criteria driven by the PICOT questions identified in 3). Other literature can also be collected where evidence is not driven by PICOT questions, e.g. epidemiology. The search should include systematic reviews, randomised controlled trials and observational studies. All references are reviewed by the writing group to ensure relevance and validity, and accordance with inclusion / exclusion criteria. Usually the literature is divided into sections and at least two guideline group members assess the literature.

   Once the search is complete and validated, the evidence is graded and assessed using SIGN or GRADE systems, by the writing group. Recommendations based on the evidence are made for each PICOT question. Based on the evidence and recommendations, the writing group begins to develop the executive summary and main text. The guideline introduction will include the aim(s) of the guideline, intended users, description of the target population, inclusion / exclusion criteria for evidence, search strategy methodology, date of searches (which will also appear in the guideline appendix), 5 year renewal statement and the declaration of interests of the guideline group members as well as all stakeholders. The composition of the writing group, (including lay membership) will be stated.

   The writing group builds and then submits a first draft of the guideline, including results of the literature search to SOCC for review. The guideline lead is co-opted onto SOCC for the duration of the guideline review process. An iterative review process is undertaken at SOCC, in consultation with the guideline lead, and members of the writing group. They are invited to attend SOCC meetings at times when the guideline is an agenda item for discussion.

4 When the guideline is considered to be in a suitably advanced draft state by SOCC, the guideline undergoes a peer consultation process with the BSACI membership via the BSACI website.

5 The comments raised in 4) are tabulated and considered by the SOCC; appropriate changes are included in the manuscript. A final draft is prepared.

6 The final draft guideline is submitted to Clinical and Experimental Allergy for publication.

3 Composition of the Guideline group

The members of the writing group should consist of health-care providers with specialist knowledge and expertise in the guideline topic. They should be drawn appropriately from various aspects of the clinical management, e.g. adult and paediatric consultants, GPs, nurses, dieticians, physiotherapists, immunologists, specialist trainees. Guideline group members may or may not be members of the BSACI. A minimum of two patient group representatives are appointed for each guideline and form part of the guideline writing group. They are involved in all aspects of the guideline production.

The Lead of the writing group formally invites the group members and agrees the work on the various sections.

The Lead of the writing group confirms the members of the 'writing group' for the guideline who will be named as authors. Named authors will need to have written at least one section or given substantial input to the final guideline. This will be agreed at the outset.

Appointed guideline group members as well as the SOCC chairman and all SOCC members are required to complete a declaration of interests and declare all conflicts of interests and sign the agreement to confidentiality (see appendix 2). The Chair of the SOCC and the Lead of the guideline group are responsible for scrutinising the declarations of interest to avoid any conflicts of interest on the guideline. At all times, the BSACI conflicts of interest policy for committees is followed. All declaration of interest forms are kept at the BSACI head office and made available for inspection on request.

4 Guideline preparation

Literature/Evidence

BSACI guidelines focus on providing clinical guidance on patient management based on the best available evidence obtained by using expert knowledge of the literature and systematic reviews. The following essential principles of systematic reviews should be adhered to:

The literature is

- Identified according to an explicit search strategy of which an abbreviated form is published in the final guideline.

- Selected according to defined inclusion and exclusion criteria and publish these criteria
- Evaluated against consistent methodological standards, e.g. the systematic reference searches should be run with appropriate key words provided by the Guideline group. The selection of keywords may be informed by a series of structured key questions using the PICOT format.
    - **P**atients or population to which the question applies
    - **I**ntervention (or diagnostic test, exposure, risk factor, etc.) being considered in relation to these patients
    - **C**omparison(s) to be made between those receiving the intervention and another group who do not receive the intervention
    - **O**utcome(s) to be used to establish the size of any effect caused by the intervention
    - **T**imeframe (optional)

Appendix 5 outlines support for literature acquirement. The SOCC encourages guideline writers to draw up evidence tables in order to present the evidence in a clear and transparent manner, and to facilitate later updating of guidelines (Evidence table template, see appendix 7). Whenever possible the evidence should be graded (Appendix 6 shows Grades of Evidence and Grades of recommendations adopted by the BSACI). Appropriate references should support all key recommendations made. An advanced draft should be presented to the SOCC who scrutinises the guideline for clarity, clinical applicability and the evidence presented. Literature search dates are noted in the guideline drafts. The final search strategy for each guideline is attached as an appendix 8 to the final guideline published guideline document.

Where evidence is lacking recommendations should be agreed by consensus after detailed discussion. If consensus cannot be achieved the group may make a decision by vote with the chair of the SOCC providing the pivotal vote if necessary.

Lack of evidence should be noted in recommendations for future research at the end of each guideline.

The formulation of management recommendations should evaluate the risks versus health benefits. If various treatment options are available the least risky option should be recommended or comparative risks documented. Financial and organisational barriers are discussed and should be taken into account in the final recommendations.

Support tools

Most BSACI guidelines include patient information on the topic of the guideline. This information is intended to be handed to patients usually within the context of a consultation. The guideline writing group should strive to use clear, unambiguous language free of jargon and free of difficult to understand medical terms in the patient information section. These Patient Information Leaflets are available on the BSACI website.

Lay/patient input

Patient views and experiences should inform the guideline and thus each guideline has a minimum of two patient representatives provided by Allergy UK and / or Anaphylaxis Campaign as part of the guideline writing group and are involved in all aspects of the guideline production. Specific information is sought to:

- Ensure that key questions are informed by issues that matter to patients (this is sought at the earliest stage in guideline production – the kick-off meeting when deciding PICOT questions.
- Identify areas where patients' preferences and choices may need to be acknowledged in the guideline
- Prepare any patient information literature which may be required identifying sources of further information
- Ensure that the guideline is sensitively and appropriately worded

Patient group representatives are required to complete a declaration of interests and declare any conflicts of interest and sign the agreement to confidentiality.

Stakeholder input/BSACI member consultation

The final draft of the guideline is placed on the members' only webpages of the BSACI website (www.bsaci.org) for consultation for 4-6 weeks. All BSACI members are invited by email to participate in sending comments and feedback on the guideline to the SOCC. All comments are collected and individually assessed. Suggested changes are discussed by the SOCC and the chair of the guideline group and implemented where appropriate and evidence is available. Where appropriate, expert advice is sought from other interested parties (e.g. Dermatologists, Endocrinologists, Gastroenterologists, Dieticians, etc.).

Publication of BSACI guidelines

All BSACI guidelines are submitted for peer-review before publication by an appropriate journal (usually *Clinical and Experimental Allergy*). Reviewers are selected by the journal editor and stay anonymous throughout the process. This adds a further layer of scrutiny by experts in the field who are commonly drawn from an international panel.

5 Confidentiality Agreement and Declaration of Interests

All SOCC members including the chair as well as experts or lay people consulted and contributing to any guideline development shall fill in a declaration of interest upon their appointment. The declaration of interest shall be updated at each SOCC or writing group meeting thereafter and updated reactively throughout the year as new conflicts of interest arise. The Chair cannot have any conflict of interest in relation to the guidelines under consideration. Conflicts of interest declarations will be kept at BSACI head office and made available for inspection on request (each guideline will contain a statement in the introduction indicating that such declarations are available on request).

6 Process for Review/updating of existing guidelines

Updates/revisions to existing Guidelines are considered by the SOCC (and the chair of the guidelines group) on a regular basis with the intention that existing guidelines are updated every 5-6 years (or sooner if the evidence base for the guideline is known to have changed). Updates may be triggered by substantial new management (drug) developments and/or other new guidelines with specific recommendations that challenge previous BSACI recommendations. If no significant additional evidence is available, the SOCC may decide to confirm the validity of the existing guideline for a further period and review the guideline again in 1-2 years' time. The BSACI organises an annual meeting, where clinical and scientific studies are presented and discussed. Guideline leads and expert groups are encouraged to monitor changes of patient management with regards to their published guideline on a yearly basis and raise update alerts with the chair of the SOCC when necessary.

7 Implementation of BSACI guidelines

All BSACI guidelines are made available for internet download on the BSACI website for BSACI members and on the publishing journal website (with free access) for other interested health care providers. Education and Training with specific reference to BSACI guidelines is provided at the annual BSACI conference and regionally in workshops organised by BSACI members. The Guideline Lead develops basic Power Point slides as aides for these workshops and these are also available on the BSACI website. The executive summary, tables and algorithms are usually included in order to convey the main messages from each guideline. Other dissemination aides may be produced, such as posters highlighting the main points of a guideline. These may be published as a pull out in the BSACI's quarterly Newsletter to BSACI members and also disseminated at allergy workshops and educational training events. The BSACI supports 10-12 regional training workshops each year and a national audit programme to assess the implementation of its guidelines and to monitor changes in practice.

8 References

1. AGREE II (Appraisal of guidelines for research and evaluation), 2009 www.agreetrust.org
2. SIGN (Scottish Intercollegiate Guidelines Network) 50: A guideline Developer's handbook (2008, revised 2011)
3. British Thoracic Society Standards of Care Committee Guideline Production Manual 1 July 2012
4. National Institute for Health and Clinical Excellence – 'The guidelines manual' Draft March 2012
5. NHS evidence accreditation (https://www.evidence.nhs.uk/accreditation/)

Appendix list:

Appendix 1: SOCC constitution

Appendix 2: Declaration of interest form

Appendix 3: Template of BSACI guidelines

Appendix 4: BSACI guideline development

Appendix 5: Support for literature acquirement to guideline group

Appendix 6: Grading the Evidence and the Recommendation

Appendix 7: BSACI evidence table for intervention studies

Appendix 8: Search strategy results

Appendix 1

Constitution

The Standards of Care Committee (SOCC)

Title and Objects:

1. The title of the Committee is: Standards of Care Committee (SOCC) of the British Society for Allergy and Clinical Immunology (BSACI)

2. The application process for membership and the chair of the committee should be fair and transparent. The composition of SOCC should guarantee a good spread of expertise and include a representative from primary care as well as a specialist trainee.

3. The objects of the Committee are to
    a. Develop guidelines for the management of patients with allergies
    b. Ensure that all guideline development conforms to the highest standards of this process as set out by leading organisations of the profession (e.g. Royal College of Physicians (RCP), Scottish Intercollegiate Guidelines Network (SIGN), etc.). As such this process shall consider and as far as possible implement best available clinical evidence, involvement of specialists, general practitioners and paediatricians; involvement of patients and the inclusion of a BSACI members based consultation process.
    c. Ensure publication of such guidelines by suitable means
    d. Update guidelines at suitable intervals to ensure that new discoveries and findings inform the guidelines
    e. Develop and implement systems of audit of performance of the structure, process and outcome of care

In order to put these objects into practice, SOCC members will meet 4-5 times per year.

The BSACI supports the work of SOCC by means of expense payments as well as through research assistance and secretarial and organisational support.

Standards of Care Committee Chair

Suggestions for applicants for the Chair of the Standards of Care Committee shall be made to the BSACI president. The Chair shall be appointed by the president and approved by the executive committee for a term of 3 years. Re-appointment shall be possible for a maximum of a further 3 years. After a total of six years chairing the committee, no future re-appointment shall be possible. The Chair shall be an ex-officio member of the BSACI council. The chair of the SOCC group should complete the declaration of interest form and declare any conflicts of interest on the guidelines under production by SOCC.

Standards of Care Committee Members

The members shall be appointed by the Chair of the Committee for a term of three years. Re-appointment may be possible at the discretion of the chair for second three year term and in special circumstances with the approval of the committee for longer where a member with particular expertise/experience is needed.

Suggestions/applications for membership of the Standards of Care Committee shall be considered by the Chair of SOCC in consultation with SOCC members during meetings of the committee and outcomes minuted.

Members with a poor record of attendance at SOCC meetings over a 12 month period may be replaced at the discretion of the chair.

Only Ordinary or Honorary Members of the Association shall be eligible to serve as Chair or as members of the Standards of Care Committee.

Guideline development – other experts/Guideline leads/New members

Suggestions for new SOCC members/Guideline leads/other experts may come from several different sources:

- Recommendation by the SOCC Chair or other members of SOCC
- Recommendation by other sub-committees of BSACI
- Canvassing the BSACI membership for volunteers
- Unsolicited suggestions from individual BSACI members

Once a suggestion for membership has been received it will be considered by the SOCC Chair, bearing in mind the existing mix of specialities represented, and expertise already on SOCC. The SOCC Chair may then invite the candidate for an informal interview with themselves and the BSACI Scientific Officer (unless they are already well known to both). Then a final decision will be made about whether an offer of membership is to be made.

Any consultant in such a capacity shall have to sign a confidentiality agreement and fill in a declaration of interest (see further details below). The composition of the SOCC is published on the BSACI website.

Confidentiality Agreement and Declaration of Interests

All SOCC members including the chair as well as experts or lay people consulted and contributing to any guideline development shall sign a confidentiality agreement and fill in a declaration of interest upon their appointment. The declaration of interest shall be updated at each SOCC meeting, thereafter and updated reactively throughout the year as new conflicts of interest arise. The Chair cannot have any conflict of interest in relation to the guidelines under consideration. Conflicts of interest declarations are held at the BSACI head office and will be made available for inspection on request.

Appendix 2

Declarations of Interest of BSACI Committee Members and patient management guideline producers concerning Pharmaceutical industry & commercial sponsorship

Date

To all members of BSACI Council, Executive, sub-committees and working groups

It is important to ensure any potential conflicts of interest of those members involved in the BSACI Council and Executive Committee, sub-committees/working groups are detailed and if necessary addressed.

As a result the BSACI have decided to assemble a register of interest. These interests are divided into two categories; here we have given some examples of interest in each category:

- Personal – any fees (over £250) paid directly to you for: presenting at conferences, travel, expenses, various grants, writing literature, attending meeting/conferences, and shares.
- Non Personal – funds/fees that are made to your department for salaries, research, equipment, education.

Please refer to the BSACI Conflicts of Interest Policy Document for description of conflicts to be declared. With your signature on the form you acknowledge that you have read this document and you affirm that the information you give is a true indication of interests.

I would be grateful if you could complete the attached form and return it to the BSACI at Studio 16 Cloisters House, 8 Battersea Park Road, London SW8 4BG no later than Date (usually at the beginning of a calendar year)

Yours sincerely

BSACI Secretary

British Society for Allergy and Clinical Immunology

Declaration of Interest Form for the period of

1st January – 31st December (previous year)

Please read the BSACI policy document on Conflicts of Interest and then complete all sections on this form and return it to BSACI, Studio 16 Cloisters House, 8 Battersea Park Road, London SW8 4BG even if you have nothing to declare.

Full name:_____

Please tell us all the BSACI Committees/Groups you are a member of:

_____

I have no conflict of interest ☐

Personal Benefits

This section includes payment/fees (over £250) eg: for lectures, advisory committees or consultancy services, either on a regular or irregular basis from which you will personally benefit. Benefits in kind should also be registered.

Company	Reason for payment	Completed at the end of Dec (previous year) or to be continued.
		Please continue on the following pages

Personal Travel Grants/Expenses for Conferences etc.

Company	Reason for the benefit

Personal Shares

Company Shares	Shares still held at 31st December previous year

Non-Personal Interests

For funds/fees that are made to your department for salaries, research, equipment, education etc. Also includes benefits in kind and fees for your own work if you do not benefit personally.

Company	Reason for support	Completed at the end of December 31st previous year or continuing?

Other potential conflicts of interest

Commercial interests of spouse/partner and membership of relevant outside agencies, organizations, including pressure groups etc.

Company	Reason for support	Completed at the end of December 31st previous year or continuing?

Additional interests for present year

Please list activities which you are sure will take place.

Company	Reason for support

I have read the BSACI policy document on Conflicts of Interest and declare that the information I have given is a true indication of interests.

SIGNATURE: ……

PRINT NAME:……

DATE: ……

Please return this by date (beginning of the year) to:

BSACI office
Studio 16, Cloisters House
8 Battersea Park Road
London
SW8 4BG

Would members of guideline development expert groups and those of the following four BSACI committees please also sign the **confidentiality agreement** (next page), unless they have done this previously: **BSACI Council, Standards of Care Committee (SOCC); BSACI Paediatric subcommittee (PAG), Primary Care Group**

Annex 2

British Society for Allergy and Clinical Immunology

Confidentiality Agreement

This agreement covers all those who have sight of documents, or are party to discussions, relating to the development of guidelines before public consultation. This includes Standards of Care Committee members, BSACI Trustees and other members of BSACI Committees, especially those involved with guideline development, and BSACI staff and associates.

1. I undertake to BSACI that I shall:
    a. Keep all confidential information strictly confidential
    b. Not use any confidential information for any purpose other than participating in the deliberations of any BSACI Committee
    c. Not disclose any confidential information to any commercial industrial party without the prior written consent of BSACI and in the event that such disclosure is permitted I shall ensure that such party is fully aware of and agrees to be bound by these undertakings
    d. Not disclose the deliberations of any BSACI guideline Committee to any other person without the explicit consent of the Chair of the Committee.
2. The undertakings set out in paragraph 1 above ('the undertakings') shall not apply to the use or disclosure of information that:
    a. At or after the time of disclosure or acquisition is in the public domain in the form supplied otherwise than through a breach of any of the undertakings, or
    b. Was lawfully within my possession before its disclosure to me by the BSACI or the Standards of Care Committee or any other guideline committee provided that the source of such information was not bound by, or subject to, a confidentiality agreement with BSACI; or
    c. I am required to disclosure by any court of competent jurisdiction or any government agency lawfully requesting the same, provided that BSACI is notified in advance of such disclosure; or
    d. Is approved for release by prior written authorisation from BSACI.

Signed ……..Date……

Print name…….

Appendix 3 – Template for BSACI guidelines (headings)

Not all headings may be appropriate, highlighted in bold are those usually included

Title: 'BSACI guidelines for the management of ……'

Authors

Keywords

Summary (about 300 words)

Introduction

Aim of the guideline, intended users, description of the target population, inclusion/exclusion criteria for evidence, search strategy methodology, date of searches, 5 year renewal statement and the composition of the writing group including lay membership will be stated. There will be a statement to say that DOIs will be available on request. The search strategy will be added to guideline document as appendix 8.

Executive Summary (usually bullet points)

Definition

Background and epidemiology

Aetiology

Clinical Classification or Clinical patterns

Mechanisms or risk factors

Prognosis

Diagnosis (including examinations, investigations) – with algorithms

Treatment in Adults – with algorithms

Treatment in Children – with algorithms

Treatment in pregnancy and breastfeeding

Economic considerations for implementation of guidelines

Co-morbid associations

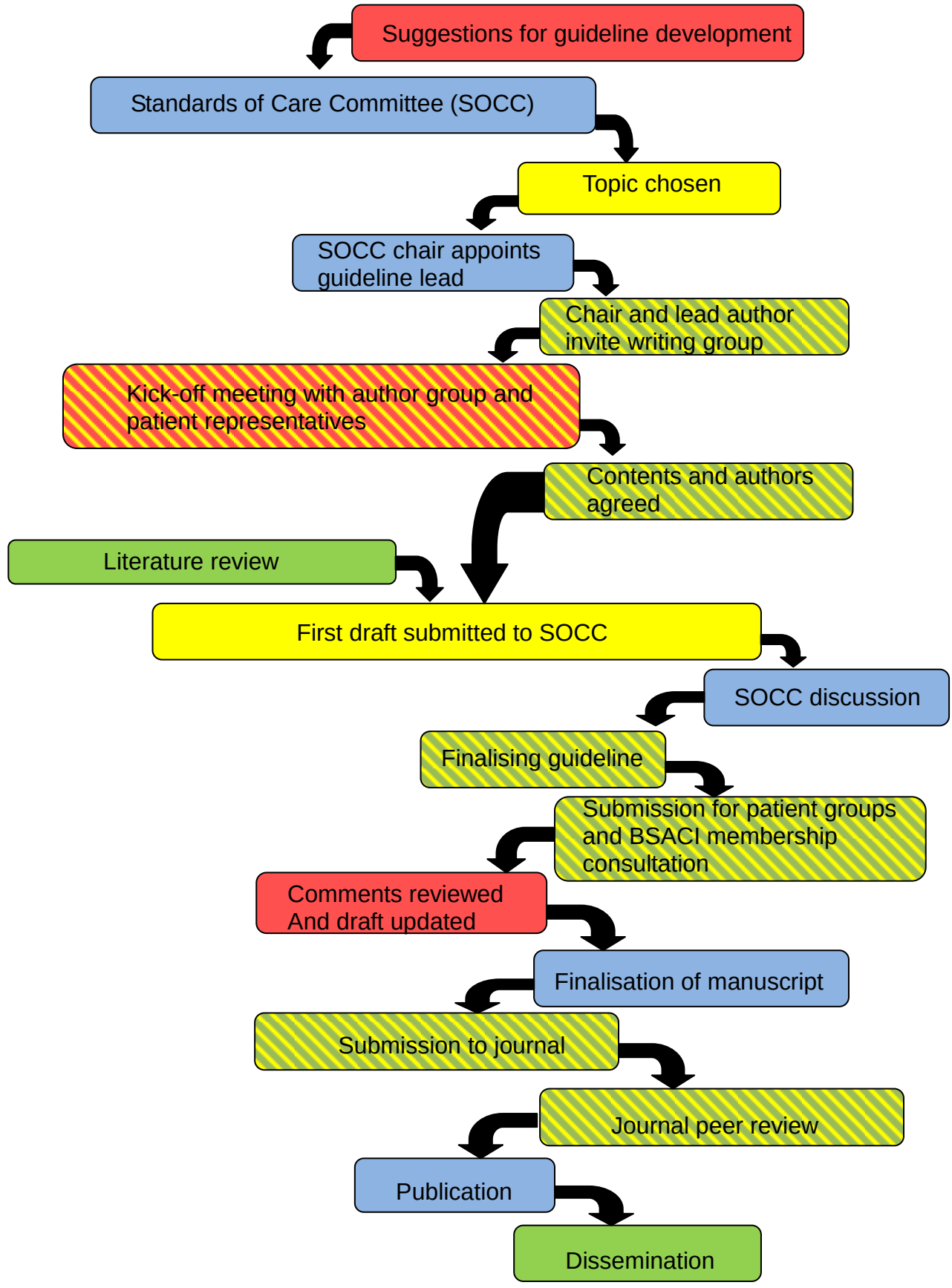
Prevention

Future Research

Acknowledgements

References

Appendix 4: BSACI guideline development



Appendix 5 - Support for literature acquirement to guideline group

1) Literature searches

Guideline group members may employ libraries within their institutions to carry out literature searches. Where this is not available the BSACI research officer may be asked to carry out literature searches. The main databases used are provided by the Royal College of Medicine including Embase and Medline. Additional databases used are the Cochrane databases of systematic reviews, PubMed (ncbi), NHS Evidence, the US national guidelines clearinghouse.

2) Obtaining copies of papers

A first scan through the reference list provided by the search may be undertaken by any guideline group member or by the BSACI research officer to focus relevant literature for the guideline. One or two members of the writing team of the guideline will then further evaluate abstracts and generate a list of references for which full papers are required. Copies of papers may be obtained from:

- Journals/books held as personal copies by guideline group members
- Individual member's institutional library (or electronic library) subscriptions.
- Request to the corresponding author of the published material

The BSACI research officer can assist with ordering copies of journal articles that are otherwise difficult to obtain.

3) Managing data

The BSACI research officer assists in compiling a database of references that are relevant to the guideline. She/he holds the central copy of Endnote and assists with the in-manuscript citation formation.

Appendix 6 – Grading the Evidence and the Recommendation (SIGN)

Level of evidence	**Definition**
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, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort or studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

Grade of recommendation	Type of Evidence
A	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; *or* A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population,
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+
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+
E (is not contained in SIGN)	Recommended best practice based on the clinical experience of the guideline development group

Appendix 7: BSACI evidence table for intervention studies (amended from the original SIGN evidence table format)

Question (Purpose of the guideline):

Bibliographic citation	Study type	Ev lev	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow up	Outcome measures	Effect size	Source of funding	Has the study provided answers to the original question? Weakness/limitation	ci-ted Y/N