Creating Clinical Guidelines:  
Our Protocol

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1. Introduction

a. British Society for Rheumatology’s aims and objectives in Guideline production.

The British Society for Rheumatology’s (BSR) main charitable aim is to improve the care of people with rheumatic diseases. Clinical guidelines promote optimum standards of care and are a key objective in achieving this aim.

b. Background

We promote excellence in the treatment of people with arthritis and musculoskeletal conditions and supports those delivering it. We have been at the forefront of the production of Guidelines in rheumatology for 25 years. Over the past 10 years, guideline methodology has evolved considerably. This document sets out how our Guidelines are produced and reviewed.

Since February 2013 British Society for Rheumatology’s guideline production processes have been accredited by NICE. NICE states that “Accreditation helps health and social care professionals identify the most robustly produced guidance available, enabling them to deliver high quality care”.

Everyone in a Guideline Working Group is involved in a major voluntary endeavour, investing considerable time and intellectual effort to mould the finished product. Group members are obliged to each other in aiming to deliver the process in timely fashion; the British Society for Rheumatology is grateful to all of them for their strenuous efforts.

c. Definition of a Guideline

‘A Guideline is a systematically developed statement that assists clinicians and patients in making decisions about appropriate treatment for specific conditions.’

Royal College of Physicians

Our Guidelines are intended as an aid to clinical judgement. Guidelines do not provide the answers to every clinical question. The ultimate decision about a particular clinical procedure or treatment will always depend on an individual patient’s condition, circumstances and wishes alongside the clinical assessment of their multi-disciplinary team (MDT).

d. Guideline Protocol

While this document aims to be comprehensive it cannot cover every issue that may arise in Guideline development. Circumstances not covered should be brought to the attention of the Chair of the Standard, Audit and Guidelines Working Group (SAGWG), [Terms of Reference in the Appendix] for advice and guidance.

This manual provides guidance to the Working Groups that develop and draft our Guidelines and draws on experience of previously produced clinical Guidelines and also the Royal College of Physicians (RCP) Guideline Development Handbook, from their Concise Guidelines Series. The British Society for Rheumatology strongly recommends that Working Groups also read the Appraisal of Guidelines for Research and Evaluation AGREE II instrument.
e. Roles in the development of our Guidelines

**Convenor:** The Convenor takes the lead managing and developing a Guideline Working Group. They may have made the original suggestion for a Guideline topic. They are formally approached by the SAGWG Chair and then agree to take on the role as formally described. They act as the main contact for the SAGWG Chair and the Secretariat. ‘Convenor’ is often used interchangeably with ‘Chair of the Guideline Working Group’ or ‘Guideline Working Group lead’. To ensure the Guideline Development Group remains on track, the Chair must have plans in place for a deputy, should they be required.

**The Guideline Working Group:** Sometimes called the Guideline Development Group this Group does the work in developing the scope, identifying the relevant questions, appraising the evidence and creating the recommendations. It consists of interested professionals/individuals and patient representatives from a variety of backgrounds which may include secondary care or primary care and AHP or nursing perspectives.

**Lead author:** The Working Group and Chair negotiate who will take the lead authorship roles and who will be named as authors in any publications. To ensure the writing remains on track, a deputy for the lead author or a joint lead author should also be identified, in case a lead author is side-lined for any reason.

**Lay/Patient Rep:** This describes patients, carers, lay representatives and those who represent and/or support patients in the voluntary sector. Their input ensures the Guideline reflects their patient concerns, especially the issues that may be overlooked by health professionals.

**Key stakeholders:** These are people outside the Working Group and often outside the Society who have an identified interest in the Guideline because they will use it or may be offered treatment based on it. Key stakeholders could be other clinicians in the speciality, clinicians outside it, other professional and third sector organisations and NHS bodies. Key stakeholders should help ensure robustness of the guideline through their involvement in the peer review process.

**Writing Group:** This is can be the whole Guideline Working Group membership or could be a subset whose contribution to the development of the guideline warrants naming them as authors on the published output.

**Peer review; internal, external and for publication.** Peer review is key to Guideline development. Detailed internal review is provided iteratively by SAGWG; other internal review by peers is through Clinical Affairs Committee (CAC) Exec. and Council. External peer reviewers are used to ensure transparency, independence and robustness. Finally, the *Rheumatology* journal also puts Guidelines through peer review for its standard publication processes.

**SAGWG:** The Standards, Audit and Guidelines Working Group oversees and directs all Guideline development on behalf of the British Society for Rheumatology. They are initial reviewers of any proposed final draft guidelines.

**SAGWG Chair:** This is SAGWG’s lead role, with authority for directing, overseeing and advising the Group.

**Embedded SAGWG member:** Each Guideline Working Group has a SAGWG member embedded in it. They will advise as appropriate on key aspects of the guideline development process.
British Society for Rheumatology Secretariat: The Secretariat is the back office organiser – teleconferences, monitoring and administrative oversight.

2. Process for identifying a topic for a Guideline

a. Call for Topics

A request to our membership for suggested Guideline topics for the following financial year is made through e-news, our website and open forum at our annual conference. A recommended format is given but there is no form. The regular annual deadline date is 31 August. This is so proposals can be considered at the September/October SAGWG meeting.

Recommendations on topics and Convenors are sent to the SAGWG for approval.

b. Criteria for selection of topic

A topic should normally meet one or more of the following criteria. Exceptionally, other topics will be considered on a case by case basis by SAGWG and the Clinical Affairs Committee (CAC).

- Is the burden/importance of the condition/health care intervention large enough to warrant guideline development?
- Is there uncertainty or controversy about the relative effectiveness of the available clinical strategies for the condition(s) for which a guideline is proposed? Please provide some examples/assessment of this uncertainty.
- Is there perceived or documented variation in practice in the management of a given condition or use of a particular health care intervention?
- Is there sufficient scientific evidence of good quality to allow development of a guideline?
- Are there existing guidelines on the proposed topic? If a guideline were to be developed, assuming appropriate dissemination, do you believe that it would make a significant impact on clinical decision-making/clinical outcomes and/or reduce practice variation?

3. Managing the Guideline Development process

a. Structure, process and outputs/outcomes phasing

Guideline development is a linear process. The structure phase e.g. finalising Working Group membership, completing ‘ Declarations of Interest’ or defining authorship has to be accomplished prior to commencement of the main body of development work. The process phase takes up the bulk of Working Groups’ activities. The outputs/outcomes phase is the objective.

b. Setting a timetable

It is most important to maintain momentum for timely Guideline production. Strenuous efforts to avoid timetable overruns are required from the guideline working group.
NICE says ‘The development time for Guidelines is usually between 12 and 27 months (from the start of scoping to publication), depending on the size and scope of the topic.’ We have adopted this timescale as the ideal aim. Since we do not have the resources of NICE there is a 15% contingency of extra timing (c.4 months) to accommodate reasonable delays, whilst keeping the timetable clearly in focus.

To avoid problems with missed deadlines we allow Guideline Working Groups to set their own timetable, within reach of the 27 month ideal. The starting date will be recorded and the deadline immediately calculated. Progress updates will be requested c.4 -6 monthly. These report forms will remind the Chair of the Guideline Working Group of the deadlines. We will collect monitoring data in the office and have a clear visual and comparative overview of progress.

c. Advice on timetabling (see Fig.1 page 8);

British Society for Rheumatology is keen that Guidelines emerge in a timely fashion. The embedded SAGWG member is there to help and anything they say about deadlines will be based on experience, not any intention to criticise.

It is important for the guideline lead to monitor factors that may impact on timelines and to have plans for keeping a Guideline Working Groups on track. Pregnancy or job changes are common life events and they are not expected to impact on timelines as there should always be time to implement cover arrangements and redistribution of work as required.

After the main body of work from each Working Group is complete, the peer review and consultation phases always consume far more additional time than anyone expects. Once a Guideline has been submitted to the Rheumatology journal, time is then needed for formatting and then peer review for publication. By then the Guideline Working Group has no influence on the timetable except if they are slow to make revisions requested by the journal.

The lead author should expect to be asked to make a series of responses to feedback and/or suggested amendments, in an iterative process within a compressed time frame. These consultation phases are included within the expected timetable.

Guideline Groups who are falling significantly behind their own timetable are encouraged to notify SAGWG and to seek help at the earliest opportunity. We do not run a blame culture and seeks only to keep a Guideline on track and with appropriate justification a revised timetable can be negotiated with SAGWG. Working Groups must act on the lead advice from SAGWG.

A major timetable change can only be negotiated formally once, out of respect for the whole Group endeavour. If a Guideline Working Group continues to fail to meet deadlines we will step in and put a Guideline into ‘special measures’. The British Society for Rheumatology may need to disband the Group and re-convene another one given that it is a condition of NICE accreditation that Guidelines emerge in a timely fashion.

Some Guidelines have a large scope from the outset. Working Groups should keep in mind how they will manage this, especially in the drafting phase.

The lead author has responsibility for making sure that the Guideline follows the format detailed from page 16 onwards and in Rheumatology journal’s ‘Instructions to Authors’. These must be read before
commencing writing up the Guideline for publication. Deadlines risk being missed when authors don’t achieve the word limit. Authors must meet the limit of 3,500 words for the Executive Summary. There is no leeway or special pleading.

d. Monitoring progress

Progress updates will be obtained from the Working Group lead, ahead of the biannual SAGWG meeting and c. 4-6 monthly or as required, in the interim. The chair of SAGWG should be informed at an early stage of any delays and may advise on remedial action. Significant delays beyond the literature search stage of development may require the evidence base to be searched again.

**STRUCTURE PHASE:**

**4. Composition of Guideline Working Group**

a. Selection of the Guideline workgroup lead/Convener

The Convenor will be selected by SAGWG based on an in-depth expertise of the Guideline subject. They have responsibility for developing a good understanding of the Guideline development process managing the Guideline Working Group and ensuring the timely delivery of the Guideline.

The chair of SAGWG makes informal contact with the proposed Convenor and informs The Secretariat of the name of the Convenor who has agreed to co-ordinate a Working Group.

A formal letter providing the information needed to oversee the group and produce the Guideline is sent by the Secretariat. Convenors formally accept their appointment and confirm they understand the budgetary limits and Secretariat role by completing a ‘Confirmation of Appointment’ form prior to starting work on the guideline.

b. Other recommendations on Guideline Working Group membership

Convenors are responsible for approaching volunteers to sit on the Guideline Working Group. An uneven number of Working Group members avoids any consensus votes resulting in a deadlock. All Working Groups should include an allied health professional member of BSR, a lay/patient representative, experts and non-experts in the topic being addressed by the guideline. In addition, trainees, primary care and other clinician representation should be used as appropriate to the topic under consideration.

c. Embedded SAGWG member

There will be an embedded SAGWG member in each Guideline Working Group. This is to allow oversight and guidance through the process by an experienced hand, whilst also providing a direct conduit back to the main SAGWG committee. Should the Guideline Working Group get into difficulties meeting deadlines the SAGWG member can advise the group and should notify SAGWG as a priority.
Fig. 1 NEW Guideline Development Timeline

NICE: ‘The development time for guidelines is usually between 12 and 27 months - from the start of scoping, to publication - depending on the size and scope of the topic.’

1. Methodology selection
2. Scope of guideline defined; Key or PICO(T) questions
3. Literature search
4. Evidence assessment, formulating and grading of recommendations

2nd Year
5. Drafting of guideline and key recommendations
6. Development of audit tool
7. Piloting of audit tool
8. Out for SAGWG Peer Review; ALLOW TIME FOR AMENDMENTS

3rd Year
9. Out for external Stakeholders’ Peer Review; ALLOW TIME FOR AMENDMENTS
10. Two week’s public consultation for end users; ALLOW TIME FOR AMENDMENTS
11. FINAL Draft
12. Approval by Chair of Clinical Affairs Committee; BSR Executive Committee; BSR Council.
13. Submit to Rheumatology 3,500 word limit on paper version of Exec. Summary. It will be peer reviewed again.

***PUBLICATION***

Often happen at the same time

Timing from here is not under GWG control

C.2.5 months
d. Lay/patient input

‘Lay/patient’ is used as a generic term to describe patients, carers, lay representatives and those who represent and/or support patients in the voluntary sector. Their input in Guideline development is important to ensure that the Guideline reflects patients’ needs and concerns, especially the issues that may be overlooked by health professionals. A Guideline Working Group should include at least one lay/patient representative.

5. Prior to starting work on the Guideline

a. Confirmation of the Working Group membership and Guideline authorship

The Chair of the Guideline Group will confirm the members of the group who will constitute the “writing committee” for the Guideline and inform the Secretariat of the full list of participants on the Working Group and their affiliations prior to commencing any work on the guideline.

Authorship should be agreed as early as possible and be made clear to all members of the group to avoid misunderstanding at a later date. While it is likely that for some Guidelines the number of named authors may be 2 or 3, for others the list of named authors may run to 10 or more.

b. Declarations of Interest

Declarations of Interest are vital to transparency. You could come across them in three distinct contexts which intersect at Guideline production.

1. You will be asked to sign one annually if you are a member of any of the Society’s Committees.
2. You will also be asked to sign another one, annually, as a member of a Guideline Working Group. Its form meets NICE requirements. It is similar to but not identical to the general Society from.
3. You will be asked to sign another one if you are named as an author of a Guideline accepted for publication by *Rheumatology*. The journal’s ‘Statement of Interests’ relates solely to their publication process and is totally separate from our governance. It will cover the previous two years.

These repeat signings are inelegant but currently unfixable. They should only take a few minutes to complete.

The Working Group Chair is responsible for forwarding completed Declaration of Interests Statements to the Secretariat prior to commencing work on the Guideline. They should cover all Working Group members and any other individuals who will be contributing to the Guideline development process. ‘Declaration of Interest’ Statements will also be obtained by the SAGWG chair for all SAGWG members, peer reviewers and any other individuals outside the Working Group who are involved in the peer review process or in producing the recommendations.

NICE requires that ‘Declarations of Interests’ are completed annually, by every member, of every Guideline Working Group. There are a great many of which the Secretariat have to keep track. Please be prompt in completing and returning them when asked.

When submitting Dols use the email address doi@rheumatology.org.uk
The Working Group Chair must raise any potential conflicts of interest for any member of the Working Group with the Secretariat and the Chair of SAGWG before work on the Guideline is undertaken.

c. Stakeholder identification and notification

The Working Group Chair is required to identify, record and then notify the SAGWG Chair of key stakeholders relevant to their Guideline prior to commencing work on the guideline.

d. Training needs of Guideline Working Group members

Where a Chair or members of a Guideline Working Group have identified a gap in their skills or knowledge re Guideline development this should be discussed with the Secretariat. Peer support will be offered as required.

e. Budget

The Society has a policy on Working with Industry and publishes annual accounts.

Guidelines remain fully independent throughout their development. The British Society for Rheumatology neither seeks nor accepts industry funding for their production.

The budget for the production of the Guideline should be agreed with the Secretariat before work begins. In general the maximum budget allowed is £2,000 which should cover:

- Guideline Working Group meeting costs (room hire, refreshments etc.)
- Travel costs for group members to attend meetings
- Cost of obtaining copies of papers that cannot otherwise be acquired through group members’ own library access
- Cost of production of drawings/figures for inclusion in the final Guideline document.
- Dissemination/publicity costs - to be agreed with the Secretariat before they are incurred.

Cochrane reviews and other searches requiring funding will only be considered on a case by case basis and will generally not usually be funded.

f) Reviewer identification

Guideline working groups will be asked to suggest experts and non-experts in the topic being addressed by the guidelines that could be approached to review the finalised guideline as part of the peer review process

**PROCESS PHASE:**

**6. Development of the Guideline**

The Standard, Audit and Guidelines Working Group will assess the Guideline so they can recommend endorsement of it by BSR. They have used the AGREE II (Appraisal of Guidelines for Research and
Evaluation in Europe: [www.agreetrust.org](http://www.agreetrust.org) instrument and the RCP Concise Guidance to Good Practice for this. The Guideline should be developed with these criteria in mind.

a. Selecting the methodology

Our Guidelines are based on the best available evidence. There are several methodologies for critically appraising the evidence base but we prefer you to use the Scottish Intercollegiate Guidelines Network: (SIGN) [http://www.sign.ac.uk/methodological-principles.html](http://www.sign.ac.uk/methodological-principles.html) and its incorporation of the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system for grading evidence.

The method used must be specifically identified and referenced in the published Guideline. This will assist in future updates as well as providing the rationale for the current guideline’s recommendations.

We recognise that in some areas evidence may be sparse or of poor quality. It is important to ensure that robust methodology is used to develop guidance even where the evidence base is weak. Guidance for good practice for these topics is often much needed and can also serve to highlight areas where further research is required.

b. Defining the scope of the Guideline and key questions

In line with the AGREE II criteria, each Guideline should explicitly state the clinical questions to be addressed, and the patient population/target audience for the Guideline. These questions should be agreed as early as possible as they require formal SAGWG approval before further major work on the guideline is undertaken.

Working Groups should break down the Guideline remit into a series of structured key questions. The process for selecting the key objectives and questions should be recorded and retained in meeting minutes and a brief outline of the process should be included in the Guidelines. Those involved in developing the key questions should also be recorded.

Systems such as the PICOT format should be considered by Working Groups as appropriate. If PICOT is not used then an outline of why should be given in the Guideline, including details of the system chosen:

- **Patients** or population to which the question applies
- **Intervention** (or diagnostic test, exposure, risk factor, etc.) being considered in relation to these patients
- **Comparison(s)** to be made between those receiving the intervention and another group who do not receive the intervention
- **Outcome(s)** to be used to establish the size of any effect caused by the intervention
- **Timeframe** (optional)
The Patients or population to be covered by the literature searches is largely defined by the presence of the particular condition that the Guideline will cover. Which age groups are covered and which are excluded must be specified.

Any ethnic or social groups that have particular needs in relation to the topic under review will be considered. Exclusion of any group from the population covered by the Guideline should be identified when setting the key questions, and reasons given for their exclusion.

The Interventions (which in this context includes diagnostic tests, risk factors, risk exposure) must be specified clearly and precisely. The only exception is in drug therapy where drug classes should be used in preference to specific agents unless there is a clear reason for focusing on a named agent.

Comparisons between placebo / no treatment, other available therapies or existing standards of care should be undertaken as appropriate.

Outcomes that will influence the views of Guideline group members as to how effective a particular intervention might be should be identified at the start. For some questions there will be a wide range of outcomes used in the literature. If useful comparisons are to be made across studies it must be made clear which of these outcomes are important. Outcomes used should be objective and directly related to patient outcomes. It is also important to include outcomes that are important to patients and not focus entirely on clinical outcomes. Outcomes should include potential serious untoward effects of interventions.

The Timeframe covered by the question, where long term efficacy and safety data of interventions are important.

The questions identified in this way will then form the basis of the literature search.

Guideline Working Groups should draw up as concise a list of key questions as possible.

Once key questions have been formulated these will be forwarded to the SAGWG for consideration and approval. Through this process key stakeholders are able to feedback comments to the Working Group at an early stage in Guideline development. Should any other key stakeholders be identified by the Working Group they will also have the opportunity to review the key questions at this stage.

Areas specifically excluded by the Guideline should also be itemised.

c. Developing search strategies and record keeping

Our Guidelines should be based on a systematic review of the best available evidence, undertaken by the Guideline Working Group. Systematic literature searches should be undertaken for all key questions identified agreed during the scoping process.

Systematic review is defined as ‘an efficient scientific technique to identify and summarise evidence on the effectiveness of interventions and to allow the generalisability and consistency of research findings to be assessed and data inconsistencies to be explored’. For some Guidelines the evidence base will be sparse.

The search strategy should be fit for purpose and should be documented in detail and retained by the Working Group. This can assist in the subsequent decisions to revise a guideline. Re-running it will
bring up new evidence which might have emerged or show that it has not - thus dictating the size of any revision task. Details of the databases used, dates searches were completed, search terms and the criteria for inclusion and exclusion of literature should be summarised in the Guidelines. The search strategy should ensure maximum coverage of studies that include:

- Systematic reviews
- Randomised controlled trials
- Observational studies
- Diagnostic studies

Where high quality, directly relevant Guidelines exist within the scope of the new Guideline, reference can be made to the existing Guidelines rather than repeating work that has already been completed. However, reference to all such existing Guidelines can only be made following up to date literature searches. This ensures that there is no new evidence that would alter any recommendations. That acceptable methodology has been used in developing the guidelines is shown with use of the AGREE II instrument.

d. Reviewing the evidence

The literature search will produce a long list of potential sources of evidence. Each reference must then be assessed to ensure its relevance and validity. The Guideline Working Group members should review the evidence, bearing in mind the AGREE II criteria, and record the relevance or not, of the abstracts identified through the searches.

It is suggested that this is best performed by dividing the literature into sections and allocating at least two Working Group members to each section/set of literature to ensure that each paper is read by at least two people. Criteria should be formulated to ensure that this process is carried out uniformly across the Working Group, and could include, for example:

- Does this study address the clinical question?
- Has the appropriate study type been used to produce the best evidence to answer the clinical question?

Non-English abstracts should be considered, provided there is an English translation available. It is not usual to provide translations of non-English papers unless a compelling case can be made. The Working Group should consult the Secretariat if such an issue arises.

Abstracts may be considered, particularly if there is limited information on the related topic, but appropriate weighting must then be given to any linked evidence. Abstracts are low quality evidence so will often be rejected automatically in the search process.

Studies often record side effects, harmful effects and risks of effects of interventions under scrutiny but these are rarely primary outcome measures. Where suitable, these secondary outcomes may be considered to inform recommendations with appropriate weighting of evidence.

Working Group members are encouraged to make full use of their NHS/university library resources to obtain full copies of the papers remaining within copyright rules at all times. Where Groups encounter difficulty in obtaining copies of papers, the Secretariat can offer advice and assistance.
e. Grading the evidence, formulating and grading recommendations

When all relevant papers have been obtained and the non-relevant excluded, Working Group members are required to grade the evidence.

The quality of the evidence should be appraised using GRADE methodology as described via SIGN50.

For studies relevant to a particular question, a checklist is prepared and the data relevant to the evidence review and Guideline development is extracted into evidence tables. Checklist pro formas are available from the SIGN website. This data commonly includes: the study author, year, design, quality, objective, population, setting, sample size, follow-up, and definitions and results of clinically relevant outcomes. Evidence tables are developed for each key question. Data are extracted by one or more authors and disagreements are resolved by the remaining authors. Systematic reviews may also be included in a Guideline if there are a large number of relevant reviews available in the literature. A level of evidence should be assigned to each paper and designated as: high (++++ or A); moderate (+++ or B); low (++ or C); or very low (+ or D). Low and very low levels of evidence may be combined into category C. RCTs start as high quality and observational trials begin as low quality. Further detail is given in quality of supporting evidence section below.

The grading of evidence is then made on the basis of an objective assessment of the design and quality of each study and a considered judgement on the consistency, clinical relevance and external validity of the whole body of evidence. These factors can decrease or increase grade of evidence. For instance, grade of evidence would be reduced if there are serious limitations of study quality or important inconsistencies. Guideline recommendations are thus graded, to differentiate between those based on strong evidence and those based on weak evidence.

Where there is a lack of evidence on a particular question, the Guideline Working Group should be clear about how a consensus has been reached in formulating a recommendation.

In grading the recommendations the Working Group should consider the following aspects:

- volume of the body of evidence;
- applicability of the obtained evidence to the defined target audience of the Guideline;
- generalisability of the evidence to the target population of the Guideline;
- level of consistency in the evidence obtained to support recommendations;
- health benefits, side effects and risks;
- implications of recommendations on clinical practice in terms of resources and skilled expertise.

If deadlock occurs when trying to agree recommendations, the Chair of the Guideline Working Group, as an expert in the area, casts the deciding vote. Deadlock can be avoided by having an uneven number of Working Group members.

While our Guidelines explicitly exclude consideration of cost-benefit analysis, Groups must include a consideration of cost implications and cost-effectiveness issues where literature exists that is appropriate to the topic.

f. Presentation of Recommendations
There has to be an explicit link between the recommendations and supporting evidence.

**Strength of Recommendation SoR**

A strong (designated as 1) recommendation may be made where the working group are very certain that based on available evidence the benefits clearly outweigh the risks, or vice versa, for nearly all patients. A weak (designated as 2) recommendation is made either when risks and benefits are more closely balanced or where they are more uncertain.

**Quality of supporting evidence**

Assessment of evidence quality in GRADE reflects confidence in the estimates of benefits, harms and burdens. We recommend the use of three/four levels (C and D can be combined in C) by using A, B, C or D for a high, moderate or low/very low quality of evidence.

*High quality* is where further research is very unlikely to change the confidence in the estimate of effect. High-quality evidence typically comes from well-performed randomised controlled trials or other overwhelming evidence such as well-executed observational studies with very large effects.

*Moderate quality* is where further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Moderate-quality evidence typically comes from randomised trials with important limitations, or from other study designs with special strength.

*Low quality* is where further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate. Low-quality evidence typically comes from observational studies or from controlled trials with very serious limitations.

*Very low-quality* evidence typically comes from non-systematic observations, biologic reasoning or observational studies with serious limitations.

**Level of Agreement/Consensus Scores**

The **Level of Agreement** across the Working Group must be clearly indicated e.g. Consensus by simple majority voting via show of hands expressed as a percentage. ‘Consensus’ or ‘Strength of Agreement’ scores can be obtained using a scale of 1 (no agreement) to 10 (complete agreement) and there should be at least 80% guideline working group member agreement on the wording of each recommendation. The presentation of the average score for each recommendation is preferred to the median Level of Agreement score to avoid the situation where near complete agreement is presented as 100% across all relevant recommendations.

**Sample text to explain this:**

“This guideline was developed in line with BSR’s Guidelines Protocol using Royal College of Physicians (RCP), Scottish Intercollegiate Guidelines Network (SIGN) and AGREE II methodology to determine level of evidence and strength of evidence. A core panel within the GWG convened on [number] occasions to review evidence, resolve disagreements and determine recommendations.”
A draft document was then circulated to the full GWG for review. Each suggested recommendation in the final document was evaluated by all members and subjected to a vote relating to strength of agreement on (e.g.) a scale of 1 [no agreement] to 10 [complete agreement].”

The strength of agreement from across the GWG could be presented for each recommendation as a percentage e.g. 100% would imply all responses were 10/10.

Therefore, accompanying each recommendation statement should be detailed in parentheses, reflecting assessment of three separate things:

a. **the Strength of Recommendation,**
b. **the quality of supporting evidence/Level of Evidence** and
c. **the Level of Agreement/Consensus Score** with the recommendation across the Working Group.

e.g. A recommendation followed by Grade 1B 85% means that a strong recommendation was made based on working group assessment of benefits versus risks, of moderate quality evidence that was supported by most of the Group

g. **Developing audit tools and key standards of care**

Audit tools, linked to clearly identified standards of care, need to be provided as an appendix to the Guideline. This will enable users to assess the effectiveness of implementation.

Ideally, audit tools are piloted prior to incorporation into the final draft of the Guideline.

### 7. Drafting the Guideline

a. **Lead author**

A lead and back-up author should be nominated, to undertake the majority of the writing and revising of a Guideline. This does not need to be the Guideline Working Group Chair or Convenor as writing a guideline is a good learning opportunity for other members of the working group. As early- or mid-career clinicians may not yet have acquired multiple external commitments they are more likely to have the flexibility in their workload to be lead author and, crucially, be timely in delivery. A Working Group could choose to nominate a lead author and a senior editor – the lead author doing the bulk of the writing but with a senior colleague as editor with ‘oversight’.

b. **Template**

The Journal team have a template for standardising the presentation of Guidelines as much as possible. This template will assist in the speedy progress of guidelines through the publication process. When you are ready to write up ask the Secretariat for it if you do not have it.

There will be two versions of the Guideline.
• **Full Guideline.** This is only published in its entirety online, formerly as supplementary material but now, since 2017, as e-pages. It is accessible via both the Society’s and Rheumatology websites.

• **Executive Summary** derived from the Full Guideline. This is the version that is published in print. The limit is 3,500 words. It also appears online.

The template mostly relates to the Executive Summary but also includes advice for the Full Guideline.

**The Executive Summary of a guideline consists of the following:**

- Word limit: 3,500 words (excluding the abstract and references).
- Tables/Figures: A maximum of 6 tables and figures.
- References: 50 or fewer
- Key words: Up to 10

c. Format and headings

Text should be unambiguous and clearly state that this protocol has been followed. Any diversions from the protocol must be highlighted with an accompanying explanation.

The Guideline should include clear recommendations, preferably in the order *question – evidence recommendations followed by*

- the *grade of evidence* supporting each recommendation.
- an explicit *level of evidence* linking the recommendations and supporting evidence
- and a consensus score showing the *level of agreement* on the strength of the recommendation within the Group

Guideline Groups should include a consideration of cost implications and cost-effectiveness issues linked with their recommendations where appropriate literature exists.

The lead author must make sure that the final guideline submitted to the Society meets all the requirements of this protocol and for Rheumatology (see ‘Instructions to Authors’).

The following headings are the likely content. Headings are open to change depending on the nature of the Guideline but are typical of the areas the template (see b.) covers.

1. **Full Guideline**

Links to the full Guideline will be published on our website and should contain the following sections and attachments/appendices:

2. **Executive Summary**

See 7b, above. An executive summary of the Guideline must be provided. The summary should include the key features of the Guideline. In particular it should contain:

1. Scope and purpose of the Guideline
   - Need for Guideline
   - Objectives of Guideline
2. Key recommendations from the Guidelines

3. Key references

The full Guideline will contain, as appropriate for the topic of the Guideline, full details on:

III. Guideline protocol

All Guidelines should include the following statement: ‘This Guideline was developed in line with the British Society for Rheumatology’s Guidelines Protocol’.

IV. Scope and Purpose

- Background to disease
- Need for Guideline
- Objectives of Guideline
- Target audience
- The areas the Guideline does not cover

V. Stakeholder Involvement

- Names and affiliations of representatives on the working party
- List of stakeholder groups involved in their development.

VI. Rigour of Development

- Statement of scope of literature search and strategy employed
- Statement of methods used to formulate the recommendations (levels of evidence)
- Statement of any limits of search and search dates
- Statement of when Guideline will be updated

VII. Guideline Itself

- Eligibility criteria
- Exclusion criteria
- Algorithm of Guideline
- Assessment of disease and response to treatment
- Criteria for withdrawal of therapy
- Monitoring of treatment

VIII. Applicability and Utility
A statement of potential organisational barriers to implementation including, where appropriate, cost implications for implementation of the Guideline and some comment on potential cost savings and hence cost effectiveness needs to be made.

A mechanism for auditing compliance with the Guideline, linked with clearly identified key standards of care needs to be incorporated

IX. Acknowledgements

All those who participated in the review process and contributed written comments, excepting named authors, should be acknowledged.

X. Authors and Affiliations

The Guideline will list the senior author (lead author or Convenor) first and then all other authors (either alphabetically or in order of degree of involvement) together with their affiliations as part of the title page (see ‘Instructions to Authors’ below).

The authorship of our Guideline should be given in the following form:


XI. Conflicts of Interest

A statement should be included in each Guideline when published to confirm that the Guideline Working Group members adhered to our policy for the Declaration of Interests, and where appropriate specific interests should be declared. An example of such a statement is given below:

“All members of the Guideline Working Group made declarations of interest in line with British Society for Rheumatology Policy. The full list of Declarations of Interests is given in an Appendix in the online version of the Full Guideline.”

XII. References

The Guideline should be fully referenced and the references should appear in the text in square brackets and numbered sequentially in order of appearance (see ‘Instructions to Authors’ below).

XIII. Appendices

Audit tools linked to key identified standards of care need to be included. Any tools to facilitate implementation, e.g. a pocket guide or flow chart, should also be developed where appropriate

8. Peer review, public consultation and approval

These are three distinct phases:

- Peer review by SAGWG and expert external peer reviewers
- Public or ‘open’ consultation via the website
• Approval by any endorsing bodies

a. Peer review

The final draft Guideline should be submitted to the Secretariat so it can conduct the peer review stage. This consists of consultation with SAGWG members and external reviewers. Guideline leads should have identified potential reviewers at the outset of guideline development.

‘Declaration of Interest’ statements will be obtained for all SAGWG members, peer reviewers and any other individuals outside the working group that were involved in the peer review process.

All comments from SAGWG and reviewers will be collated on a form and fed back to the Chair of the Guideline Working Group. In turn, they should then make a clear response to each comment on the same form, which should then be returned to the Chair of SAGWG and Secretariat within c.4 weeks.

The Chair will review the proposed responses and approve it or advise on any conflicting or unclear comments, as appropriate. The Draft Guideline should now be amended in line with the comments. Any amendments made by the Chair of the Working Group should be agreed with the guideline working group and should not override the evidence.

The amended Draft Guideline should be returned to the Secretariat within c.4 weeks. Authors must use Track Changes when making alterations in response to SAGWG or other peers’ feedback. If the submitted documents are not in the required format, incomplete, or changes not clearly tracked in re-submissions they will be returned without review, for correction. SAGWG has to clearly see what has changed and make sure all changes are as they expected.

Thus, the overall timeline for responding to the Peer Review process and arriving at a revised draft guideline is 8 weeks.

b. Public consultation to obtain ‘end user’ comments

Following peer review, the Secretariat publishes the formatted draft Guideline on the Society’s website, clearly watermarked as DRAFT; the Open Consultation period is 4 weeks. Both members and non-members are notified through e-news that the Guideline is available for review and comments must be made by the four week deadline.

In addition, feedback is sought from key external stakeholders.

Comments from the Open Consultation are collated and fed back to the Chair of the Guideline Working Group. Generally, there are far fewer comments than there are at the Peer Review stage. The Working Group lead should send the form containing a response to every comment back to the Chair of SAGWG as soon as possible and within 3-4 weeks of receiving them. Revisions to the draft should then be agreed in consultation with the guideline working group. The Chair of the Working Group must not make amendments without reference to the Group. Any revision must not override the evidence. Just as after the Peer Review phase, please use Track Changes. If the submitted documents are not in the required format, incomplete, or changes not clearly tracked in re-submissions they will be returned without review for correction.
The revised Draft Guideline documents should then be re-submitted to the Secretariat as a clean version and also as a ‘Tracked Changes’ version.

c. Approval

Any stakeholder organisations endorsing the Guidelines will be sent a copy of the final draft Guideline prior to publication with a request to confirm endorsement where appropriate.

The final draft is sent to the Chairs of SAGWG and CAC for approval before submission; and to BSR Executive and Council ‘for information’. The final Guideline is published once *Rheumatology* review has been completed and publication achieved.

**OUTPUTS/OUTCOMES PHASE:**

9. Publication in *Rheumatology*

a. Permission to publish

After endorsement we will seek to publish the executive summary in the print and online version of *Rheumatology*. It will also publish the full Guideline as e-pages in the online version.

It is the responsibility of the lead author to submit these Guidelines to *Rheumatology* for publication. This must not be done until British Society for Rheumatology Secretariat has given permission. Whilst authors contributing to the guideline own the authorship rights, the Society owns the copyright for all material within the guidelines. The names of the Convenor and Working Group members will be included in the paper.

b. Submission for publication

The Guideline should be submitted to *Rheumatology* by the lead author or Convenor using their online submission system under the manuscript type ‘Guidelines’. The Guideline should consist of:

- A title page giving the full title, author names and affiliations, and details of the lead or corresponding author.
- A double-spaced word document (.doc or .rtf format only).

The Journal’s peer reviewers and editors will process the guideline with access to the anonymised comments and author responses at both the Peer Review and Open Consultation phases. This process assists in speeding up the peer review process within the journal’s own publication mechanism.

c. Post acceptance for publication

Disclosures Statements

The journal *Rheumatology* uses disclosures statements which are particular to them and entirely separate from the Society’s ‘disclosures of interests’ filed by all G/L Working Group membership at the beginning of the development process and by the Society’s committee members more generally.
The Journal’s system forms part of their publication process. The format meets the recommendations of the World Association of Medical Editors and the Committee of Publication Ethics which the Journal has to fulfil. Previous guideline authors have been dismayed to discover this extra layer of form filling during the last stages of preparing their Guideline for publication. Unfortunately, it cannot be avoided. Knowing to expect it might alleviate some of the pain.

These forms are mandatory. They must be completed and returned to ensure the publication process advances. The Guidelines manuscript is not publishable until the disclosures statements from the whole Working Group are received. Collecting disclosures statements at one time point ensures they are up-to-date and cover a uniform period of time for all authors. The statements cover the previous 2 years.

The author disclosure form is in two parts.

- An authorship statement
- A conflict of interest statement

The blank e-form is sent out by the Editorial Office to the author who designated him/herself as the contact – usually the lead author for the Guideline. It is the responsibility of the contact author to distribute the form to Working Group members, accompanied by a firm direction to fill it in. It may help to mention that tardiness in doing so will inevitably delay publication.

Each author listed on the manuscript must fill one in and submit it using the email address registered to their account on the journal’s submission system (ScholarOne Manuscripts). The contact author is not expected to collect completed forms and pass them back to the Editorial Office. The forms are electronic and go directly. Forms cannot be filled in by any author on behalf of any other author.

The Editorial Office will inform the contact author of any missing forms that must be chased up.

Guideline authors must provide the editorial office with all requested information. The submitting author is responsible for ensuring that all the required forms are sent.

A signed ‘licence to publish’ form must be submitted to the journal by the lead author on behalf of all the authors.

The manuscript is sent ‘to production’ from the Editorial Office at BSR to the journal’s publication team at Oxford University Press for final typesetting. Lead Authors will be asked to sign a licence agreement to cover ‘open access’ requirements. All our Guidelines are published free of charge. When asked, select ‘standard licence’.

The final Guideline is posted on our website once Rheumatology review has been completed and publication achieved.

10. Dissemination, added value and feedback

a. Dissemination to professionals
Guidelines have to be disseminated before they can be used. Once published in *Rheumatology* they remain accessible via links on our website. There are Guideline sessions at the Society’s Annual Conference and there may be launch events. Distribution via multi-disciplinary professional networks is key and social media also has a role. Wherever possible, new guidelines will be presented at conference.

Links have been established with MGP [multi-media best practice publishers] to allow promotion of specific aspects of any new guideline that are relevant to primary care.

b. Wider publicity and media

Occasionally there is wider public interest in a Guideline than exists simply within the medical speciality; Guidelines about pregnancy, for example. Our marketing team will assist with publicity for all Guidelines and be aware of any extended PR value in any particular subject. They will develop a relevant Communications Plan. Working Group members may be invited to make themselves available for interviews or quotes at regional or national level for health specific media.

c. Collating research questions

The British Society for Rheumatology can add further value to the creation of Guidelines. There are often areas for further clinical research identified as a result of appraising the evidence base. Defined areas of uncertainty in rheumatological practice should be brought to the attention of the Secretariat’s research team to ensure their capture and that the Society’s Research Committee is informed.

d. Care of lay member

We hope that lay/patient members of Guideline Working Groups have a good experience of working within them. Working Group Chairs should pay particular attention to thanking them for their contribution, asking for feedback on how they felt about the experience, what advice they might give to lay members in the future and what, with hindsight, they wished they had known at the outset.

e. Feedback from Working Group membership and Leads

The British Society for Rheumatology relies on the voluntary contribution of its membership to deliver the guideline process. Confidential feedback on Guideline development will be sought via the Secretariat in order to monitor Working Group members’ experience of processes, communication and the collaborative ethos. If we are aware of recurring issues that might have an adverse impact on participation in developing other guidelines in the future we can address them.

11. Implementation, Audit and review and updating of existing Guidelines

a. Monitoring of Guideline use
This process will be on-going. Downloads are the easiest way of assessing the popularity of our Guidelines, though this metric is a proxy measure of their use rather than a direct measure. These are reported on at all SAGWG meetings and are available to Convenors on request.

b. Use of audit tools and standards

Guidelines are required to contain audit tools, if possible linked to key standards of care which will assist end users in assessing their compliance with the guideline.

c. Impact of our Guidelines

Whilst audit is of considerable re-assurance that a Guideline is in use, impact can be still be difficult to assess. We will occasionally scan the published literature for references to our guidelines. For example the following publication, showing the impact of a guideline, was recently identified. Can the publication of guidelines change the management of early rheumatoid arthritis? An interrupted time series analysis from the United Kingdom. A Judge et al. *Rheumatology* published 4 August 2015, 10.1093/rheumatology/kev268

d. Process for Review and Updating of Existing Guidelines

SAGWG considers updates/revisions to existing Guidelines annually. Existing Guidelines are updated c. every 3-4 years.

The Chair of the Guideline Group will have ongoing responsibility for notifying the Chair of SAGWG if the evidence base changes and the guideline requires an earlier update. Other rheumatology professionals, members or previous contributors to a Guideline Working Group can also notify the Chair of SAGWG if they believe the evidence base has shifted significantly. When an existing Guideline is selected for updating, the Chair of SAGWG asks the Chair of the previous Guideline Working Group (or another nominated individual) to review the Guideline and advise whether any modification, minor modification or a major re-write is needed.

It is sometimes obvious to clinicians if there has been a large shift in the evidence base and a major re-write is required. However, smaller shifts or no shifts in the evidence base might be more difficult to define confidently without exploratory work. If there is uncertainty, two clinicians, if possible members of the original Working Group, will be invited to perform a literature search using the same strategy as used previously and independently grading the findings for relevance. Should no revision be then required, a statement to that effect will be posted on our website.

For minor modifications a timescale should be agreed with the chair of SAGWG. (Fig.2 Page 25 for outline) The revised Guideline may go through the peer review, open consultation and approval processes, as described on pages 17-18. However, minor changes may not result in publication in *Rheumatology* but could just be communicated via a Letter in the journal. For major re-writes, the Convenor of a Working Group will be sought and the protocol for a new Guideline followed.
Fig. 2 Minor Revision of Guideline

Development Timeline c.15 months

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<thead>
<tr>
<th>START DATE</th>
<th>1. Methodology revise and update</th>
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<tr>
<td></td>
<td>2. Scope of guideline checked; Key or PICO(T) questions</td>
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<td>3. Literature search</td>
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<td>4. Evidence assessment, formulating and grading of NEW recommendations; identification of unchanged recommendations</td>
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<td></td>
<td>5. Re-drafting of revised guideline and key recommendations</td>
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<td>6. Development of audit tool</td>
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<td>7. Piloting of audit tool</td>
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<td>8. Out for SAGWG Peer Review; <em>ALLOW TIME FOR AMENDMENTS</em></td>
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<td>9. Out for external Stakeholders’ Peer Review; <em>ALLOW TIME FOR AMENDMENTS</em></td>
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<td>2nd Year</td>
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<td>10. Two weeks’ public consultation for end users; <em>ALLOW TIME FOR AMENDMENTS</em></td>
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<td>11. FINAL Draft</td>
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<td>12. Approval by Chair of Clinical Affairs Committee; Sent FYI to BSR Executive Committee; BSR Council.</td>
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<td></td>
<td>13. Submit to Rheumatology [possibly as Letter rather than a new publication]</td>
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***PUBLICATION***

3 months
12. Production of Joint Guidelines and endorsement of externally produced Guidelines

The Society may be invited by other organisations/groups to produce a joint Guideline.

SAGWG will consider proposals for the production of joint Guidelines but they will require that the methodology follows this protocol and specify the way in which BSR representation is achieved.

From time to time, we are requested to endorse a non-BSR Guideline. This will be considered only if the Guideline development process has current NICE accreditation.

For Guidelines meeting this criterion, a copy of the request is sent to the chairs of the SAGWG and CAC for discussion. If they recommend that the Society should endorse the Guideline then it goes to Council for formal endorsement.

Appendices

1. Terms of Reference of SAGWG
2. ‘Declaration of Interests’ Statement
3. ‘Instructions to Authors’ for Journal Publication
4. ‘Working with Industry’ policy