BTS
British Transplantation Society

The Voice of Transplantation in the UK

Guideline Development Policy

British Transplantation Society Guidelines

Revised Version May 2021

Contents

1. Introduction

1.1 Clinical Practice Guidelines and the British Transplantation Society

The Standards Committee was established by the British Transplantation Society (BTS) to prepare guidelines relating to transplantation in the UK. The Standards Committee reports to the Council of the BTS, which meets four times per year to overview the activities of its committees.

1.2 History of the British Transplantation Society guidelines

The BTS has produced guidelines on best practice in the field of solid organ transplantation since 1998. The intention of the guidelines is to promote best practice and facilitate clinical judgment, without being perceived as prescriptive. An archive of old guidelines is available on the Inactive Standards and Guidelines page of the BTS website: http://www.bts.org.uk/BTS/Guidelines_Standards/Archived/BTS/Guidelines_Standards/Archived_Guidelines.aspx?hkey=edb06bd8-746d-4889-89ab-561d3df73046

As much of the evidence to support the recommendations in guidelines comes from observational clinical studies rather than randomised controlled trials or systematic reviews, the modified GRADE (Grades of Recommendation, Assessment, Development and Evaluation) was introduced in 2009 to provide a transparent assessment of both the strength of recommendations and the levels of evidence. The use of GRADE has been adopted by national and international guideline development groups, e.g. Kidney Disease Improving Global Outcomes (KDIGO) and European Renal Best Practice (ERBP).

The main target audience for the BTS guidelines is the transplant community caring for patients with solid organ failure within the UK. The key professional groups include: medical staff (consultants, non-consultant career grade staff, specialty doctors and specialty trainees); nursing staff, especially specialist nurses working in transplantation and patient education; laboratory and technical staff, especially in the fields of immunology and tissue typing; transplant co-ordinators; medical statisticians; and all other health professionals caring for patients with organ failure for which transplantation may be an option (e.g. dieticians, pharmacists, social workers).

1.3 Aims and structure of the Guideline Development Policy

The main aims of this policy are to develop a reference tool for current and future authors of guidelines, and to summarise the guideline process for all users and appraisers of the guidelines, especially for members of the BTS, stakeholders, patients and sister agencies.

Based on the Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument (1), the subsequent sections of this policy document demonstrate that the Clinical Practice Guidelines of the BTS are:

• Produced to promote good transplant care and reduce the burden of chronic, irreversible organ disease

• Produced by transplant specialists and other healthcare professionals caring for patients with organ failure for the benefit of peer healthcare professionals, patients, and (to a lesser extent) the public
• Produced using a transparent, consistent, and reliable development process
• Designed to provide recommendations based and graded on the best available evidence
• Designed to provide recommendations – strong or weak – weighing up the cost, burden, and benefits of treatment or intervention
• Designed to provide audit measures for the guideline recommendations
• Recognised by other national and international guideline development groups

1.4 Review and update of the Guideline Development Policy

The document updates the first version of the Clinical Practice Guidelines published in November 2011. It is anticipated that further updates will occur every four years, this corresponding to the length of term of office of the Chair of the BTS Standards Committee.

2. Selection and planning of the guidelines

2.1 Selection criteria for clinical guidelines

The BTS Guidelines are produced in recognition of the need to identify markers of high quality of care and clinical practice, of equity of access, and of patient choice in the field of transplantation in the UK. The topics for guideline development are selected by the officers and Council of the BTS to cover areas of transplant assessment and management where sufficient evidence exists for a critical appraisal of the field and for appropriate recommendations to be made. Wherever possible, guidelines are designed to be consistent with and not overlap with guidelines produced by the Renal Association, NHSBT and NICE. However, it is recognised that differences of interpretation and emphasis may exist related to the different clinical and regulatory perspectives of these organisations. Where such differences exist, they are specifically highlighted.

The topics for guideline development are submitted to and approved by the Council of the BTS before the guideline development is initiated. It is recognised that super-specialisation and small patient numbers mean that some areas are not suited to formal guideline development. Areas which require specialist guideline development in collaboration with other societies first undergo approval by the Council of the BTS. While collaborative publications may have differences in style and format, such collaborations proceed through the same process of guideline development and peer review as those where the BTS is the sole sponsor. In addition, it is recognised that collaborating organisations will have their own, additional processes underpinning quality assurance.

The main objective of the BTS Guidelines is to improve clinical practice in transplantation services nationwide and it should be noted that NHSBT has reported progressive improvements in transplant outcomes in recent years.

2.2 Timelines for development of clinical guidelines

After the first draft has been prepared, each guideline (depending on complexity) requires 4-9 months for completion to allow for initial editorial assessment, author revision, a minimum of

four weeks of web-based consultation and feedback, the preparation of a penultimate draft, a second period of web-based consultation (if significant changes have been made), and the preparation of a final version to take account of feedback and endorsement of the final draft by the Council of the BTS.

The last date of the literature search performed in the preparation of clinical guidelines should be recorded in the guideline document. If significant new data become available from high quality studies during this process, the recommendations can be updated (section 2.3).

2.3 Updating of existing clinical guidelines

The dates of planned updates of existing guidelines should be published as part of the guidelines. These revisions will normally be at 3-5 yearly intervals, depending upon the perceived rate of change in the relevant fields.

If significant errors or omissions are identified after the date of final posting of a guideline, these may be corrected at the discretion of the President and Executive of the BTS and following discussion with the Chair of the Standards Committee. If such post-publication changes are made, appropriate version controls should be clearly posted on the website.

The authors of guidelines are asked to contact the Chair of the Standards Committee if they feel a guideline may need to be adjusted before the next planned date for revision. If a revision is subsequently undertaken, the final text will be referred to the Executive of the BTS for approval, before updating on the BTS website. Members of the Society and relevant stakeholders will be notified by email or e-newsletter of all such updates.

2.4 Composition and responsibilities of the guideline development group

The authors of each guideline have expertise, usually at the national level, in the sub-specialty field in which they have been invited to produce clinical guidelines. The authors are selected because of their expertise and track record of interest in the sub-speciality area, and their freedom from major conflicts of interest. It is recognised that potential conflicts may on occasion exist. Where present, these will always be declared at the start of the process of guideline development, and again in the guideline document. Major conflicts, such as ownership of significant stock in, or employment by a pharmaceutical company, will preclude authorship.

Each guideline has a minimum of two lead authors, who will usually invite colleagues with specialty knowledge and expertise to help produce the guideline. To ensure maximal acceptance of the guideline, members of the guideline development group are selected to represent an appropriate cross section of those transplant centres and specialties relevant to the guideline. In addition, at the start of the guideline process, members of the BTS are invited to apply to join the guideline development group through the monthly President's newsletter. We encourage and welcome involvement of trainees in the development of guidelines. In addition, we aim to have a multi-disciplinary team amongst the authorship to ensure we capture all aspects of clinical practice related to the guideline.

Patient representative involvement will be required from the outset for guideline development and at least two patient representatives will be invited to join the steering group for future guidelines. We also encourage involvement and take into account views of lay members.

All guidelines are reviewed by the Chair and other members of the BTS Standards Committee, with final sign off by the Council of the BTS. The involvement of a significant proportion of UK transplant specialists in the production of the guidelines promotes wider acceptance and credibility of the guidelines among peer professionals.

In the preparation and publication of the guidelines, members of the Standards Committee are responsible to the Chair, who in turn is responsible to the Executive and the Council of the BTS. The Chair of the Standards Committee is a member of the Council of the BTS and has a term of office of 4 years, with the option for the Executive to extend the post for 1 year to maintain continuity or complete work in progress.

2.5 Declaration of conflicts of interest

All authors are required to declare any potential conflicts of interest in the guideline document. The authors undertake that they have, nor expect to acquire, any financial gain from developing the recommendations in their guidelines. The majority of the Guideline Development Group must not have any potential conflicts. Any contributor that does not supply details of potential conflict of interest will be removed from authorship of the guideline and a note added to this effect.

The Chair of a Guideline Development Group must not have any significant conflict of interest related to the guideline under development. In addition, the Chair of the BTS Standards Committee must not have any significant conflict of interest. If any perceived conflict of interest exists, the Chair of the Standards Committee must pass editorial control of the guideline to the Vice Chair of the Standards Committee or to a nominee of the Executive of the BTS.

2.6 Funding of guideline development

The BTS was founded in 1972, is registered in England & Wales as Company 4691176, and is registered as charity number 1098584.

BTS Guidelines are not funded by any external organisation, commercial company or charity. Although the BTS does admit corporate members, such members have no influence on the development of guidelines. The authors of each guideline are selected for their expertise in their sub-specialty area and because they are free of major conflicts of interest with major commercial providers of transplant technology, disposables, and drugs.

The BTS Standards Committee receives no funding apart from that dispensed from the BTS Executive to cover the cost of meetings and secretarial expenses required for the process of guideline development.

3. Guideline development process

The BTS guidelines are developed using, as appropriate, the principles of a defined methodology based on five core principles:

• Development is carried out by nationally recognised experts in the field of the guidelines who are free of overt conflicts of interest
• The expert group performs a systematic review to identify and critically appraise the evidence

• Recommendations using the GRADE system are explicitly linked to the supporting evidence
• Recommendations take account of equality issues, financial and resource implications, and patient choice and lifestyle
• Recommendations are open to minimum of one, and usually two rounds of peer review by the full membership of the BTS, stakeholders, patients and interested members of the public before being submitted for approval by the Council of the BTS

3.1 Selection criteria of topics within guidelines

Each guideline proposal is approved by the Council of the BTS prior to beginning the process of development. The current guidelines cover areas relating to solid organ transplantation, with the main aims of reducing morbidity and mortality in patients with organ failure and addressing idiosyncratic differences in the utilisation of drug management and other interventions between transplant units.

The selection of key issues for each guideline is based on clinical priorities, the expert authors' knowledge of the available literature, the range of treatments and interventions in the field, and outcomes which are important to patients. On this basis, a number of criteria are used by the authors of each guideline to decide which areas merit inclusion:

• Areas of variation in clinical practice
• Areas of variation in patient outcome
• The availability of resources to provide high quality patient care
• The existence of interventions, procedures, and drug management which influence patient morbidity and/or mortality
• Issues relating to patient safety and the avoidance of preventable complications

The definition of the target population and interventions is an essential component in the development of the guideline recommendations. Application of these principles is readily achieved using the **PICO** framework:

• The **patients** or **population of interest** are patients with organ failure for whom transplantation may be an option, potential organ donors, and other transplant-related specialists working in the field. These criteria identify patients for inclusion in literature reviews that are designed to generate patient subgroup-specific recommendations in the range of BTS guidelines. The BTS guidelines usually apply equally to adolescents and adults in the context of transplantation; some guidelines will contain specific areas and recommendations related to paediatric transplantation.

The guidelines are careful not to make recommendations that may prejudice clinical care based on gender, age, ethnicity, or socioeconomic status. No patients' groups are excluded.

• The **interventions** in the guidelines for patients with transplantation related issues are readily identified from the literature to generate intervention-specific recommendations: different drug treatments for clinical conditions; complications related to transplantation (e.g. immunosuppression, organ preservation, cancer, infection); and different forms of solid organ transplantation (e.g. living donation, donation after circulatory death, donation after brain death; renal, cardiothoracic, liver, etc).

• The **comparisons** in the guidelines are mainly with placebo/no treatment or comparisons between different treatment options, e.g. drug treatments or types of transplantation. Some guidelines consider differences in diagnostic techniques e.g. for antibody identification, or organisational issues e.g. organ allocation.

• Hard **outcomes** such as patient mortality, morbidity, hospitalisation and complication rates are preferred in developing recommendations, but it is recognised that many studies in transplantation only report surrogate outcomes.

Using the above methodology, the authors for each guideline are able to identify subject areas that they wish to address, and which allow evidence-based recommendations to be formulated.

3.2 Systematic literature review

The authors of each guideline are selected because of their expertise and track record of interest in the sub-speciality area, and their freedom from overt conflicts of interest (see section 2.4).

The authors will have followed the literature in their field for many years prior to preparing their guideline. The BTS do not have the resources to commission and conduct formal evidence reviews, but the authors conduct their own systematic search of the literature published in English just prior to preparing their guideline. The dates covered by these systematic literature searches should be stated clearly in each guideline or in an appendix, usually with specific details of the search strategy and search terms used. This will involve, as a minimum, a search on Pubmed and/or Medline using key search terms documenting the relevant literature for the subjects within the guideline, as well as a review of the Cochrane Library database and Clinical Trials database. Articles not available in English or only available in abstract form, letters, case reports, editorials or review articles are excluded.

The authors also review other transplant guidelines – such as clinical practice guidelines issued by other national and international societies such as the American Society for Transplantation (AST), the American Society for Transplant Surgeons (ASTS), Kidney Disease Improving Global Outcomes (KDIGO), and guidelines relevant to the topic such as those published by NICE.

3.3 Selection and evaluation of the evidence

The expert authors assess articles for relevance to the guideline, eligibility for inclusion in the evidence base for that guideline, and methodological quality. Articles are considered of particular relevance if they are describing prospective randomised or quasi-randomised trials, controlled trials, meta-analyses of several trials, Cochrane systematic reviews, or systematic reviews.

The guideline producers consider all relevant randomised controlled trials, systematic reviews and meta-analyses in preparing recommendations and the supporting evidence for these recommendations. In many areas of transplantation, the number of such high-quality publications is relatively low compared with other specialties, and much of the evidence is based on observational studies. In general, the guideline authors do not exclude this evidence given that the GRADE system provides a transparent means of expressing the strength or weakness of recommendations for best practice, even when the supporting evidence is limited.

In such circumstances, the recommendations are explicitly qualified by an appropriate low grading of the level of evidence (grade C or D).

3.4 Grading the guideline recommendations

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group has developed an approach to grading evidence that moves away from initial reliance on study design to consider the overall quality of evidence across outcomes. The GRADE system was developed by an international group of guideline developers and methodologists to maximise the usefulness of clinical practice guidelines in the management of typical patients (2-8).

The advantages of the modified GRADE system are:

1. The grading system is explicit and transparent

The grading system provides an informative, transparent summary for clinicians, patients and policy-makers by combining an explicit evaluation of the strength of the recommendation with a judgment of the quality of the evidence for each recommendation.

2. The two-level grading system of recommendations is simple

A Grade 1 recommendation is a strong recommendation to do (or not do) something where the benefits clearly outweigh the risks (or vice versa) for most, if not all patients. A Grade 2 recommendation is a weaker recommendation, where the risks and benefits are more closely balanced or are more uncertain. Two grading levels facilitate a clear interpretation of the implications of strong and weak recommendations. Explicit recommendations are made on the basis of the trade-offs between the benefits on the one hand, and risks, burden, and costs on the other.

3. Standard wording is used to indicate the strength of each recommendation

It is desirable to provide clinicians with a standard terminology to aid the interpretation of the strength of recommendations. When making a strong recommendation, guideline authors are encouraged to use ‘We recommend...’, and when making a weak recommendation authors should use ‘We suggest...’. The use of the active voice attributes responsibility for the recommendations to the guideline authors and their supporting organisation.

4. Explicit methodology is used to describe the quality of evidence

Grade A evidence means high quality evidence that comes from consistent results from well-performed randomised controlled trials, or overwhelming evidence of another sort (such as well-executed observational studies with very strong effects).

Grade B evidence means moderate quality evidence from randomised trials that suffer from serious flaws in conduct, inconsistency, indirectness, imprecise estimates, reporting bias, or some combination of these limitations, or from other study designs with special strength.

Grade C evidence means low quality evidence from observational evidence, or from controlled trials with several very serious limitations.

Grade D evidence is based only on case studies or expert opinion.

5. Ability to upgrade and downgrade the quality of evidence

The use of GRADE allows the reviewer to appraise all relevant study data and to upgrade or downgrade the overall quality of evidence. In general, randomised controlled trials = high initial grade; observational studies = low initial grade; other evidence = very low initial grade.

The grade may be reduced if the study has limitations, if there is inconsistency between studies, surrogate but no direct patient outcomes, or bias.

The grade may be increased if confounders may have significantly reduced the observed effects, there is a strong association without plausible confounders, or there is a large dose-response effect.

The review of critical appraisal tools for use by specialist medical societies conducted by NHS Plus and the Clinical Effectiveness Forum of Royal College of Physicians of London gave support to the use of GRADE in producing guidelines (9). An extract from its Executive summary states: "SIGN, GRADE, GATE and NSF use different methods for grading evidence and recommendations. SIGN uses a '++', '+', '-' system to grade evidence; GRADE uses a 'high', 'moderate', 'low' or 'very low' system; GATE has no pre-defined grading levels; and NSF has a mixture of letters, numbers and words to grade evidence. To grade recommendations, SIGN uses an 'A', 'B', 'C', 'D' system, GRADE uses 'strong' and 'weak' levels; GATE is used to assist the development of recommendations rather than being a prescribed system and so has no levels of grading; and NSF uses an 'A', 'B', 'C' system
to grade recommendations.

Each system has strengths and weaknesses depending on the field of research and study design for which it is used. A matrix has been developed to show these strengths and weaknesses and to suggest the most appropriate system to use for the type of study being assessed. Based on the research conducted for this report, SIGN or GRADE have been deemed the more appropriate systems for assessing studies in therapy research; GRADE or
NSF have been deemed the more appropriate systems for assessing diagnostic or screening studies; GRADE has been deemed the more appropriate system for causation studies; and NSF has been deemed the more appropriate system for prognosis, psychometric, qualitative and behavioural studies."

Most guideline organisations have recognised the need for a standard grading scheme and the GRADE system has been adopted by many leading organisations including NICE, SIGN, BMJ, and WHO, KDOQI and European Renal Best Practice. UpToDate started using this system in 2006.

For the above reasons, effective from 2009, the BTS has elected to use the GRADE system in all guideline revisions and new guidelines on the basis that this grading system:

- Provides an estimate of both the quality of evidence and strength of recommendation
- Permits the development of guidelines in the absence of randomised clinical trials
- Promotes harmonisation of national and international guidelines (e.g. with NICE, KDIGO)

3.5 Forming the guideline recommendations

The guidelines are intended to:
• Provide clear advice and guidance on effective clinical practice
• Identify audit measures for review and monitoring
• Support staff in improving transplant services
• Promote patient safety and the implementation of clinical governance

The expert authors review all the available evidence in a topic area to make draft recommendations with a supporting rationale. Explicit recommendations are made on the basis of GRADE by assessing trade-offs between the health/patient benefit on the one hand, and risks, burden, and costs on the other. The recommendations are written with an emphasis on using standard, consistent and up-to-date terminology to avoid ambiguity. This terminology is well established and familiar to the main target audience. The recommendations are formulated to be clear, concise and able to be interpreted separately from their supporting rationale. This is usually reinforced by the publication of an executive summary of the recommendations to serve as a quick reference guide.

The guideline authors ensure that the balance between health benefits and risks/harm is in favour of the former before producing recommendations to follow a specified management; and vice-versa.

The tabulated format with numbering of the subjects and guideline recommendations has been designed to make the guidelines user friendly.

The prevalence of organ failure and the need for transplantation is higher in ethnic subgroups of the population e.g. Asian, Afro-Caribbean. However, the guidelines apply equally to all patient groups regardless of race, religion, disability, gender, or age, except where distinction is justified on clinical grounds, e.g. taking account of the risks of over-immunosuppression in the elderly, or of specific long-term adverse effects when treating the young.

The BTS guidelines attempt to harmonise with other international guidelines whenever appropriate to the UK healthcare system. However, the guidelines stand-alone where differences of opinion or interpretation exist, or where international guidelines are not directly applicable to the UK.

3.6 Resource implications of the guideline recommendations

As with other areas of medicine, the practice of transplantation is limited by resource considerations, as it demands a relatively high level of healthcare resource and finance. An even more important issue is the shortage of donor organs, which is a particular and unique constraint upon the development of transplant services.

It is recognised that funding issues are primarily dealt with by NICE and that the BTS does not have the resources to commission independent analyses of cost-effectiveness. However, while guideline authors should draft and agree the recommendations based primarily on clinical effectiveness, the use and cost-effectiveness of resources should also be taken into account, particularly with regard to the use of donor organs. The authors should produce recommendations to follow management which on balance favours health gain/patient benefit over risk/harm where there is evidence of clinical effectiveness. Conversely, the authors should

not produce recommendations where there is significant doubt about the evidence of clinical benefit or cost effectiveness; where further evidence is required, it is appropriate that this be highlighted and that the lack of evidence should be highlighted in the GRADE scoring.

In addition to financial issues, organisational barriers to the implementation of guidelines should be highlighted, where relevant.

4. Format of the guidelines

4.1 Layout of guidelines

Guidelines will include the following:

Title page
Contents page
Introduction (including search methods)
Summary of recommendations
Main body of text
References
Authors' declarations of conflicts of interest

4.2 Introduction

In the introduction, the guideline authors should indicate the background and rationale for the development of the guideline. Links to prior versions of the guideline and to the guidelines of other national and international guideline development groups should be described when appropriate.

The search strategy should be described in the introduction, together with the methods and dates of search. Where appropriate, harmonisation with the recommendations of other national or international guidelines should be acknowledged. The method of grading the strength of recommendations and level of supporting evidence should be described and referenced.

4.3 Summary of recommendations

A summary of the guideline recommendations should be provided for ease of review by the user. This section should be readily available for printing separately from the full guideline and serve as a quick reference guide.

The guideline should be divided into subsection headings and the headings should be in bold font to identify clearly the specific clinical or healthcare circumstances that apply to the recommendations. The headings and subheadings should be tabulated numerically for ease of reference and clarity of presentation.

Where appropriate, guidelines should contain audit measures to assist with implementation of the guidelines, promote improvement in the quality of care, and allow comparative audit. The audit measures should be measurable, achievable, and serve as evidence-based criteria for continuing quality improvement.

4.4 Main body of text

This should provide the rationale and chain of logic for the guideline recommendations. The rationale and references should be described separately after each recommendation or subgroup of recommendations to allow for ease of updating and editing. The body of text should provide support for the grading of the recommendations.

4.5 Acknowledgements and declarations of interest

Significant contributions to the guideline from clinicians, clinical scientists, patients and other stakeholders should be acknowledged. All authors should provide declarations of conflicts of interest.

4.7 Electronic publication on the BTS website

Most guidelines should be published electronically rather than printed. This approach enables more rapid publication, promotes dissemination of the guidelines, and cuts down on paper use.

The guidelines pages on the BTS website are paginated to be user friendly, with separation of active guidelines on the main guidelines page, and out-of-date guidelines on the 'Inactive guidelines' page.

5. Consultation and peer review of the guidelines

The consultation and peer review process during the preparation of the BTS guidelines has been agreed by the BTS Standards Committee and the Council of the BTS.

External peer review, validation, and pre-testing of the recommendations within the guidelines are achieved by inviting feedback from the membership of the BTS on both the first and final drafts of the recommendations, and also at meetings of relevant experts specifically convened for this purpose. In addition, for most guidelines, independent external peer review is sought at the stage of the initial draft. This review may be from transplant professionals within the UK transplant community or – where appropriate – external advisors are invited to provide an international perspective.

5.1 Consensus process for grading of the recommendations

Based upon the GRADE instrument, the authors of the guidelines aim to reach a consensus on the strength of recommendation (1 or 2) and level of supporting evidence (A – D), as described in section 3.4. The recommendations for the first draft result from a collective decision reached by informal discussion by the expert authors, and whenever necessary with
input from the Chair of the BTS Standards Committee. The number of expert authors of each guideline is too small to support formal consensus methods such as the Delphi technique or nominal-group technique, but a wider consensus is subsequently achieved as a result of peer review of both the first and final drafts of the guidelines by fellow professionals, stakeholders, and patients. Changes to the grading of the recommendations may be considered after feedback from the first and final drafts of the guidelines.

In the rare event that a consensus of opinion cannot be achieved, areas of disagreement will be referred to the Chair of the BTS Standards Committee who will discuss these areas with the

Executive of the BTS and, taking these views into account, will have the final say on the format and content of the subsequent guideline.

5.2 Peer review of the first draft of the guideline

The first draft of the guideline is subject to peer review by the membership of the BTS and invited stakeholders. The membership of the BTS exceeds 750 and includes the majority of the consultants and specialists working in the field of transplantation in the UK. The main steps in peer review of the first draft are:

1. The first draft of new or updated guidelines is placed on the guidelines page of the BTS website with a request for comments to be sent by email to the Chair of the BTS Standards Committee within a 4-6 week timeline.

2. At the same time, all BTS members (as well as committee members) are informed about this by email by the BTS Secretary via a notice in the monthly BTS newsletter, or by separate email.

3. External peer review is invited from selected UK or international experts who have not been involved in generating the draft document.

4. Lead authors also ask other key stakeholders, including patient representatives, to comment on the first draft.

5. Lead authors consider the comments from BTS members and other stakeholders and use these to generate a further draft.

6. The lead authors send this draft, the summary of comments received and key changes to the Chair of the Standards Committee within four weeks of the deadline for receipt of comments on the first draft.

5.3 Peer review of the final draft of the guideline

The Chair of the Standards Committee reviews the revised document and, if changes and comments received are minor, passes the document to the BTS Council for final approval. If more substantive comments/changes are made, the Chair arranges for the revised draft to undergo a second round of peer review by the membership of the BTS and invited stakeholders. The key steps in peer review of the second draft are:

1. The revised first draft of new or updated guidelines is placed on the guidelines page of the BTS website with a request for comments to be sent by email to the Chair of the Standards Committee within a four week timeline.

2. At the same time, all BTS members (as well as committee members) are informed about this by email by the BTS Secretary via a notice in the monthly BTS newsletter, or by separate email.

3. The revised first draft and summary of comments/key changes is circulated to all members of the Standards Committee. Members are asked to review the revised draft in detail and give feedback to the lead authors and Chair of the Standards Committee within four weeks.

4. The authors of each guideline invite stakeholders and patients to provide feedback on the drafts. If patient feedback influences the final guidelines, this is acknowledged, for instance by putting patient acknowledgements at the end of the guideline.

5. After incorporating feedback and comments on the revised first draft, the authors of the guideline submit the final version to the Chair of the Standards Committee for final editing.

5.4 Approval of the final version by the BTS Council

The Chair puts forward the final edited version of the guideline for review and endorsement by the Council of the BTS at one of the four annual meetings of the Council, or by email correspondence. Once approved, the final version is published and locked in the main guidelines page of the BTS website with a notice of the date of e-publication. The timeline to complete the two stage peer review process is at least three months for each guideline.

All of the current guidelines have the date of completion and the date for planned updating of the guideline clearly identified. If important new information from high quality studies becomes available (for instance a major RCT is published in between planned updates), the electronic website format permits recommendations to be changed, when appropriate and endorsed by the Council of the BTS, and subject to appropriate version control on the website.

6. Dissemination and implementation of the guidelines

6.1 Notification of e-publication of the final version

The membership of the BTS is notified in the monthly e-newsletter when the final version of a guideline is posted on the main guidelines page on the website. These guidelines are available through the BTS website:
http://www.bts.org.uk/BTS/Guidelines_Standards/BTS/Guidelines_Standards/Current_Guidelines.aspx?hkey=94dd25f6-8a90-444a-9563-d3a0c01553e6

6.2 Listing of the guidelines by NHS Evidence

After being published and locked on the BTS website, BTS guidelines will be listed by NHS Evidence in its database of approved guidelines. This is dependent upon periodic review of the quality of guideline development.

6.3 Use of audit measures for national audit

Implementation of the BTS guidelines is promoted by audit of performance measures related to key recommendations within the guidelines. The authors of guidelines aim to identify audit measures to serve as evidence-based criteria for continuing quality improvement.

The audit measures may be used for local and regional audit, and some of the audit measures are used as performance indicators in national audit. This approach helps ensure that implementation of the recommendations covered by national audit is high. For organ donation rates and organ allocation, for example, some of the established audit measures are used as performance indicators by NHSBT and have been used to compare the performance of

transplant units across the UK (see http://www.odt.nhs.uk/uk-transplantregistry/). Similarly, outcome data for transplantation have been incorporated into organ-specific reports from national Societies and Registries, e.g. The Renal Registry for renal transplantation (see https://www.karger.com/Article/FullText/504851, The 21st UK Renal Registry Annual Report: A summary of Analyses of Adult Data in 2017)

6.4 Dissemination and implementation initiatives

Several initiatives have been introduced to improve dissemination and implementation of the BTS guidelines:

1. Each guideline has a summary of recommendations. This section can be readily downloaded from the website as a concise summary of the recommendations without needing to read, download, or print the entire guideline document.

2. All the BTS Guidelines are freely available on an open access area of the BTS website, from which copies may be downloaded at no cost.

3. Presentations on the guidelines have been promoted at Continuing Medical Education meetings, e.g. an early draft of the Living Liver Donor guidelines was presented for discussion at the Living Donor Forum in October 2014. The updated guidelines will also be publicised through social media platforms such as Twitter using the BTS Society's account.

4. Review articles summarising the guidelines are encouraged, e.g. summaries of the guidelines relating to Diagnosis and Treatment of Cytomegalovirus in Solid Organ Transplantation, Living Donor Kidney Transplantation, Transplantation from Donors with Deceased Circulatory Death, and the Management of the Failing Graft have been published in Transplantation.

7. References

1. The AGREE Collaboration. Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument. www.agreecollaboration.org

2. Atkins D, Best D, Briss PA, et al; GRADE Working Group. Grading quality of evidence and strength of recommendations. BMJ 2004; 328: 1490

3. Guyatt G, Gutterman D, Baumann MH, et al. Grading strength of recommendations and quality of evidence in clinical guidelines: report from an American college of chest physicians task force. Chest 2006; 129: 174- 81

4. Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008; 336: 924-6

5. Guyatt GH, Oxman AD, Kunz R, et al. GRADE: Incorporating considerations of resources use into grading recommendations. BMJ 2008; 336: 1170-3

6. Guyatt GH, Oxman AD, Kunz R, et al. GRADE: going from evidence to recommendations. BMJ 2008; 336: 1049-51

7. Jaeschke R, Guyatt GH, Dellinger P, et al. Use of GRADE grid to reach decisions on clinical practice guidelines when consensus is elusive. BMJ 2008; 337: 327-30

8. Uhlig K, MacLeod A, Craig J, et al. Grading evidence and recommendations for clinical practice guidelines in nephrology. A position statement from Kidney Disease: Improving Global Outcomes (KDIGO). Kidney Int 2006; 70: 2058-65

9. Baker A, Madan I, Young K, Potter J. A review of critical appraisal tools for use by specialist medical societies. NHS Plus and the Clinical Effectiveness Forum of Royal College of Physicians of London 2008