NICE National Institute for Health and Care Excellence

Guidance producer:	**British Transplantation Society**
Guidance product:	**Clinical guidelines**
Date:	**3 March 2017**
Version:	**1.2**

Final Accreditation Report

Contents

Introduction 3

Accreditation recommendation 3

Background to the guidance producer 3

Summary 3

Implementation 6

Appendix A: NICE Accreditation analysis 7

Appendix B: Bibliography 23

Appendix C: NICE Accreditation Advisory Committee, external advisers and NICE Accreditation team 23

Introduction

The NICE Accreditation Programme recognises organisations that demonstrate high standards in producing health or social care guidance. Users of the accredited guidance can therefore have high confidence in the quality of the information. Organisations may publicly display a seal of approval called an Accreditation Mark for 5 years after their processes have been accredited. The process for accrediting producers of guidance and recommendations for practice is described in the process manual.

Accreditation recommendation

NICE has renewed accreditation of the process used by the **British Transplantation Society** to produce **clinical guidelines**. The renewed accreditation is valid until **25 January 2022** and applies to guidance produced using the processes described in **BTS Guideline Development Policy, Revised: 14 January 2016**. The original accreditation term began on **25 January 2012**.

Background to the guidance producer

The British Transplantation Society (BTS) was formed in 1971. Membership is open to all professionals working in the field of transplantation. Membership is multi-disciplinary and includes clinicians from a range of specialties including scientists, professionals working in histocompatibility and immunogenetics, nurses, donor coordinators, ethicists and professions allied to medicine.

The aim of the society is to progress the study of the biological and clinical problems of tissue and organ transplantation. The society also addresses the social implications of transplantation.

The BTS's overall vision is to be the national professional authority on transplantation. It represents the disciplines of the transplantation community and develops scientific, clinical and ethical practice for the benefit of patients.

In 1986, a Supervisory Committee on Organ Transplantation was created, following publication by the BTS of its ‘Recommendations concerning the use of living unrelated donors in the United Kingdom’.

The Standards Committee appeared in 1998, at a time when outcomes were uniformly improving, with little significant variation between centres. A Government-supported campaign for ‘Evidence-Based Medicine' was being implemented around this time. Members in general welcomed the drawing up of BTS guidelines, both as a source of reliable information and as a form of protection. The first guidelines appeared in 1998 and continue to be produced sometimes in association with other societies.

The financial support (since 1982) of corporate members and the achievement (in 1988) of charitable status has allowed the society to award research fellowships, travelling fellowships and bursaries.

Summary

The Accreditation Advisory Committee considered that the processes used by the British Transplantation Society (BTS) to produce Clinical guidelines demonstrated compliance with 23 of the 25 criteria for accreditation.

The scope and purpose of the guidance is clear. The overall objectives, questions addressed, target population and intended users are all clearly stated. The recommendations are provided in reference to specific circumstances and where relevant, links to supporting evidence is provided.

The process includes relevant stakeholder groups throughout the development process as members of the guideline development groups (GDGs). Intended users are also represented in the process.

The guidelines are produced from systematic, transparent search methods with defined inclusion and exclusion criteria. The strengths and limitations of the evidence are considered, alongside risks and benefits, when developing recommendations. The method for arriving at recommendations is clear. There are processes for regular and unscheduled review of the guidelines.

The content and format of the guidance is suitable for the specified target audience. Organisational and financial barriers are considered during development of guidelines and processes are in place to monitor the use of the guidance.

Overall, the standards development process is editorially independent. Funding mechanisms are transparent. Interests are declared and managed according to a policy that applies to all those involved in all aspects of the development of the guidelines. The possibility of bias in the process is accounted for.

A recommendation to improve the process used to produce clinical guidelines is to:

- ensure the recently developed process to include patient or patient representatives on the guideline development group is implemented into all new and updated guidelines produced.

Professor Martin Underwood

Chair, Accreditation Advisory Committee

March 2017

Implementation

Following accreditation, guidance from the accredited producer will be identified on NICE Evidence Search by the Accreditation Mark. The accredited guidance producer is also granted a royalty-free, worldwide licence to use the NICE Accreditation Mark in accordance with the Conditions and Terms of Use. Providing these conditions are met, a guidance producer's accreditation will last for a further 5 years from the expiry of the previous accreditation term. Guidance already produced under the previous accreditation decision continues to be accredited.

Accredited guidance producers must take reasonable steps to ensure the accredited processes are followed when generating the type of evidence for which they are accredited. Accredited guidance producers should have quality assurance mechanisms in place and must inform NICE accreditation within 30 days if any significant change is made to a process.

Figure 1: The NICE Accreditation Mark

Appendix A: NICE Accreditation analysis

The Accreditation Advisory Committee considered the following analysis of the guidance producer's compliance with NICE Accreditation criteria, which covers 6 discrete domains. The full analysis leading to the accreditation decision is shown below.

	Criterion	Evidence for meeting the criterion	Accreditation decision
Scope and purpose	**Does the guidance producer have a policy in place and adhered to that requires them to explicitly detail:**		
	1.1 Overall objective	The process document[1] states that the overall aims of the guidelines are to promote best practice and facilitate clinical judgment. Both example guidelines state their specific objectives[2,3.]	Criterion met
	1.2 The clinical, healthcare or social questions covered	The process document[1] states that guidelines should be produced using a transparent, consistent and reliable process. The target population and interventions are defined using a patient, intervention, comparison and outcome (PICO) framework which is an important part of developing recommendations. Clinical questions are specified in the guideline examples[2,3].	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	1.3 Population and/or target audience to whom the guidance applies	The process document[1] defines the primary target audience as the transplant community managing patients with solid organ failure within the UK. It includes medical, nursing, laboratory and technical staff and support workers such as transplant co-ordinators. Most guidelines apply to both adolescents and adults and some guidelines make recommendations specific to paediatric transplantation. The intended patient population and target audience are stated in both guidelines[2,3].	Criterion met
	1.4 Guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	The process document[1] states that the recommendations are formulated to be clear, concise and able to be interpreted separately from their supporting rationale. Both guideline examples[2,3] include clear recommendations in reference to specific clinical circumstances.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
Stakeholder involvement	**Does the guidance producer have a policy in place and adhered to that means it includes:**		
	2.1 Individuals from all relevant stakeholder groups, including patient groups, in developing guidance	The process document[1] states that GDG authors are selected due to their expert knowledge in sub-specialty areas, who may then decide to invite additional specialists to help write and review content. Lead authors ask key stakeholders including patient representatives, when appropriate, to comment on the first draft. If substantial changes are made in light of comments from BTS members, patient representatives and other stakeholders a second draft is produced. Both example guidelines provide the names, discipline/area of expertise and employing institution of the clinicians that form the GDG but neither guideline[2,3] includes lay or patient involvement on GDGs. The process has recently been updated and the developments in involving patients, lay people (donors) and their representatives (charities) in the forthcoming Living Donor Kidney Transplantation guideline[4] is now underway, which is a welcomed development. However the example guidelines[2,3] did not incorporate patient or lay involvement and the Living Donor Kidney Transplantation guideline is not yet published.	Not fully met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	2.2 Patient and service user representatives and seeks patient views and preferences in developing guidance	The process document[1] states that patients' and their representatives, lay people and stakeholders can comment on the first draft and final draft where it is produced. The guidance producer is starting to implement the involvement of patient and lay involvement by recruiting delegates from these groups onto GDGs for future guidelines developed or updated. The example guidelines[2,3] have not incorporated patient or lay involvement and the Living Donor Kidney Transplantation guideline[4] is not yet published.	Not fully met
	2.3 Representative intended users in developing guidance.	The process document[1] states that the intended users of the guidelines are represented by their GDGs and vary depending on the nature of the guideline. To ensure acceptance of the guideline, members of the GDG are selected to represent a good cross section of clinicians at transplant centres and specialties relevant to the guideline. It is clear that the professional members forming GDGs represent the intended users of both example guidelines[2,3] in terms of professional role and level of expertise.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
Rigour of development	**Does the guidance producer have a clear policy in place that:**		
	3.1 Requires the guidance producer to use systematic methods to search for evidence and provide details of the search strategy	The process document[1] states that the expert group performs a full systematic literature search to identify all available evidence. Search date parameters should also be specified. PubMed and/or Medline, Cochrane library and Clinical trials databases should be queried as an absolute minimum. Details of the search strategy should be defined in the introduction section of guidelines. Both example guidelines[2,3] confirmed the date parameters from the search along with the keywords used. An example search strategy that was used to identify the evidence base for the revised Living Kidney Donor Guideline[4] was supplied by the guidance producer. This search was developed in Ovid Medline which was then adapted for Embase, Cochrane library and EconLit.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	3.2	Requires the guidance producers to state the criteria and reasons for inclusion or exclusion of evidence identified by the evidence review	The process document[1] states that articles not written in English or only available in abstract form, as letters, case reports, editorials or review articles are excluded. The GDG examine the evidence base of articles and look for relevance, and consider their methodological quality. Evidence that is particularly relevant includes prospective randomised or quasi-randomised trials, controlled trials, meta-analyses, or Cochrane systematic reviews. The number of high quality publications is low, and much of the evidence is based on observational studies. Both example guidelines[2,3] confirm the types of studies included, limited to those in the English language. The Living Kidney Donor Guideline[4] searches were restricted to articles in English from the year 2000 onwards.	Criterion met
	3.3	Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty	The process document[1] states that authors should identify relevant randomised controlled trials, systematic reviews and meta-analyses to support recommendations when available. The guideline examples[2,3] describe the strengths and limitations of the evidence base and state when evidence is inconclusive. GRADE is used to appraise studies and the grading of evidence may be reduced if the study has limitations, or if there is inconsistency between studies or bias is present.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	3.4	Describes the method used to arrive at recommendations (for example, a voting system or formal consensus techniques like Delphi consensus)	The process document[1] states that recommendations are formulated using the GRADE system. The number of expert authors is too small to support formal consensus methods such as Delphi. A wider consensus is achieved via the peer review process, which incorporates first and final drafts of the guidelines, by fellow professionals, stakeholders, and patients. When consensus of opinion is not possible, areas of disagreement are referred to the Chair of the BTS Standards Committee who discusses the issue with the Executive of the BTS who will make the final decision on the format and content of the guideline. Both guideline examples[2,3] state that the GRADE system is used to rate the strength of evidence and the strength of recommendations. Recommendations are made even when the evidence is weak as this is an evolving field.	Criterion met
	3.5	Requires the guidance producers to consider the health benefits against the side effects and risks in formulating recommendations	The process document[1] states that where there is evidence of clinical effectiveness authors should produce recommendations which support health gain and patient benefit over harm or risk. Authors should not produce recommendations where there is significant uncertainty regarding evidence of clinical benefit or cost-effectiveness. Where further evidence is required this should be highlighted and reflected in the GRADE scoring. Both guideline examples[2,3] state the health benefits, side effects and risks of treatment or management recommendations where this is useful.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	3.6 Describes the processes of external peer review	The process document[1] confirms that all relevant stakeholders, patient representatives and the full membership of the society (which includes the majority of UK specialists working in the transplantation specialty) are notified by email about first drafts of new or updated guidelines and invited to comment. Selected UK or international experts who have not been involved in generating the draft document are also invited to take part in external peer review. If greater changes are requested the revised draft undergoes a second round of peer review (for four weeks) by the BTS members and its stakeholders before being finalised. The timeframe to complete a two stage peer review process takes a minimum of three months for each guideline. The guideline examples[2,3] state they were available for public consultation/peer review via the BTS website and provide details of stakeholders and experts who made comments or requested changes.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	3.7 Describes the process of updating guidance and maintaining and improving guidance quality	The process document[1] describes the policy for scheduled and unscheduled updates. Scheduled updates should take place at 3-5 year intervals depending on the rate of change within the sub-specialty. The policy for unscheduled updates states that if important new information becomes available between planned updates, authors should contact the Chair of the Standards Committee initially and if approval is given recommendations can be changed online. The BTS Executive members along with relevant stakeholders should be notified. To maintain and improve guideline quality errors or omissions identified after a guideline is published can be rectified on the judgement of the BTS President and Executive of the BTS after discussion with the Chair of the Standards Committee and notified via version control on the website. Guideline examples[2,3] list the changes that have occurred over the lifetime of each guideline and state due dates for revision (after 4 years).	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
Clarity and presentation	**Does the guidance producer ensure that:**		
	4.1 Recommendations are specific, unambiguous and clearly identifiable	The process document[1] states that standard terminology is used to assist interpretation of the strength of the recommendations. Strong recommendations should use the term 'We recommend...' while weak recommendations should use 'We suggest...' Recommendations should be written using consistent, clear and concise terminology which is well established and familiar to the target audience and therefore avoids ambiguity and is user friendly. A standard layout for guidelines is suggested, further ensuing consistency. Both example guidelines[2,3] contain recommendations which are easily identifiable and are specific and in context. Recommendations are made across clinical, management, infrastructure, commissioning and auditing areas. Executive summaries of recommendations are near the start of each document for ease of reference, making them clearly identifiable.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	4.2	Different options for the management of the condition or options for intervention are clearly presented	The process document[1] states that the comparisons in the guidelines are mainly with placebo/no treatment or comparisons between different treatment options and that some guidelines consider differences in diagnostic techniques. Both guideline examples[2,3] present different clinical or management options when relevant. Where evidence is vague, uncertainty about the best treatment or management option can be present and this is highlighted in guidelines.	Criterion met
	4.3	The date of search, the date of publication or last update and the proposed date for review are clearly stated	The Process document[1] states that the dates of literature searching should be shown in guidelines or in an appendix along with the date that the guideline was last updated. The date of planned review should also be provided. Both guideline examples[2,3] show the dates of search completion, last update, and planned revision.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	4.4 The content of the guidance is suitable for the specified target audience. If patients or service users are part of this audience, the language should be appropriate.	The process document[1] defines the target audience as professionals from the transplant community caring for patients with solid organ failure within the UK. It is clear that the content and style of the guideline examples[2,3] is aimed at professionals working in the transplantation field. A list of abbreviations is included in both example guidelines which would assist the lay and professional reader alike.	Criterion met
Applicability	**Does the guidance producer routinely consider:**		
	5.1 Publishing support tools to aid implementation of guidance	The process document[1] confirms that support tools such as quick reference guides and executive summaries reinforce the recommendations as they can be downloaded from the BTS website and printed out independently from the main guideline and used as an aid to implementation. Both example guidelines[2,3] include supporting information as and when required. Both guidelines provide tables and figures to highlight parts of their content. These tables and figures can be considered as support tools to aid implementation.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	5.2 Discussion of potential organisational and financial barriers in applying its recommendations	The process document[1] states that the specialty of transplantation is limited by resource issues, as it is healthcare resource intensive and therefore financially expensive. A shortage of donor organs is an exclusive restriction upon the development of transplant services. The process document[1] advises that authors of guidelines should agree recommendations based primarily on clinical effectiveness but should be aware that cost-effectiveness and the use of scarce resources should also be considered. Both example guidelines[2,3] consider barriers that impede or complicate the adoption of their recommendations from an organisational and financial standpoint where necessary. Both guidelines include discussions about the shortage of suitable donor organs preventing implementation of recommendations. Where new tests require less expensive equipment to achieve an equivalent diagnosis this is emphasised.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	5.3 Review criteria for monitoring and/or audit purposes within each product.	The process document[1] states that when appropriate, implementation of the guidelines should be promoted via audit or monitoring. Authors of guidelines should aim to identify audit measures to act as criteria for ongoing quality improvement in local, regional and national audit. Outcome data has been included in organ specific reports for the UK Renal registry for renal transplantation (part of the Renal Association). The Renal registry monitors quality of care indicators and comparative data which is used for audit and benchmarking, planning, research and clinical governance. Both guideline examples[2,3] direct users to monitor specific treatments, drug use or disease episodes against benchmark outcome data. In both guidelines there are parameters to audit against.	Criterion met
Editorial independence	**Does the guidance producer:**		
	6.1 Ensure editorial independence from the funding body	The process document[1] states that the BTS is a charity, and that guidelines are funded internally. Authors are recruited entirely for their expert knowledge of the subject area. It is clear that the example guidelines[2,3] are developed by multidisciplinary professionals working across the specialty and the authoring process includes robust stakeholder consultation and peer review.	Criterion met

	Criterion		Evidence for meeting the criterion	Accreditation decision
	6.2	Demonstrate transparency about the funding mechanisms for its guidance	The process document[1] explains that the guidelines were developed without external funding. The BTS Standards Committee only receives money from the BTS Executive to cover the cost of meetings and administration expenses. The funding mechanism is transparent.	Criterion met
	6.3	Record and state any potential conflicts of interest of individuals involved in developing the recommendations	The process document[1] requires that the Chair of a GDG must not have any significant conflict of interest related to the guideline under development. In addition, the majority of the GDG must not have any potential conflicts. Any contributor that does not supply details of potential conflicts of interest is removed from authorship of the guideline and a note is added to explain this. Clinicians, clinical scientists, patients and other stakeholders who have made contributions to the guideline should be acknowledged and authors should complete a declaration of conflicts of interest. Both example guidelines[2,3] list the declarations of interest of the authors and state that editors, authors and contributors have worked to the standards detailed in the process document.	Criterion met

	Criterion	Evidence for meeting the criterion	Accreditation decision
	6.4 Take account of any potential for bias in the conclusions or recommendations of the guidance	The robust peer review process[1] and strong assessment process for assessing the strengths and weaknesses of the evidence base helps to minimise bias.	Criterion met

Documents referenced above:

1. BTS Guideline Development Policy, Revised: 14 January 2016
2. Guidelines for antibody incompatible transplantation (3rd Edition), draft December 2015
3. UK guidelines for kidney and pancreas transplantation in patients with HIV (2nd Edition), March 2015.
4. Living Donor Kidney Transplantation guideline (not published but in development when assessed)

Appendix B: Bibliography

Appendix B lists the additional information taken into account in the analysis and considered by the committee.

Document name	Description	Location
BTS Guideline Development Policy, Revised: 14 January 2016	Process document	https://bts.org.uk/guidelines-standards/
Guidelines for antibody incompatible transplantation (3rd Edition), draft December 2015	Guideline example	https://bts.org.uk/guidelines-standards/
UK guidelines for kidney and pancreas transplantation in patients with HIV (2nd Edition), March 2015.	Guideline example	https://bts.org.uk/guidelines-standards/
Living Donor Kidney Transplantation guideline	Unpublished , in progress Guideline example	Supplied (selected chapters)

Appendix C: NICE Accreditation Advisory Committee, external advisers and NICE Accreditation team

NICE Accreditation Advisory Committee

The NICE Accreditation Advisory Committee operates as a standing advisory committee of the Board of the National Institute for Health and Care Excellence (NICE). The Committee provides advice to NICE on a framework for accrediting sources of evidence that should be recognised as trusted sources of information for the NHS. The Chair of the Committee is appointed by the NICE Board and the meetings are conducted by the chair or in his/her absence the vice chair. The current Chair is Martin Underwood. A full list of the Accreditation Advisory Committee membership is available on the NICE website. Members are appointed for a period of 3 years. This may be extended by mutual agreement for a further 3 years, up to a maximum term of office of 10 years.

The decisions of the Committee are arrived at by a consensus of the members present. The quorum is set at 50% of committee membership. The Committee submits its recommendations to the NICE Publications executive which acts under delegated powers of the NICE Board in considering and approving its recommendations.

Committee members are asked to declare any interests in the guidance producer to be accredited. If it is considered that there is a conflict of interest, the member(s) is excluded from participating further in the discussions. Committee members who took part in the discussions for this accreditation decision are listed below.

Title	Name	Surname	Role	Organisation
Dr	Adrian	Brown	Principal Screening Advisor (formerly)	Public Health England (formerly)
Mr	Richard	Brownhill	Independent health care improvement manager	Royal Bolton Hospitals Trust
Ms	Ailsa	Donnelly	Lay member	N/A
Ms	Joyce	Epstein	Lay Member	N/A

Dr	Elvira	Garcia	Consultant in Public Health Medicine - Health Protection Lead	NHS Ayrshire & Arran
Mrs	Diana	Gordon	Company Director	DRG Consultants
Ms	Barbara	Graham	Service Manager	Health Improvement Team, NHS National Services Scotland
Ms	Angela	Green	Lead clinical research therapist	Hull and East Yorkshire Hospitals NHS Trust
Dr	Steve	Hajioff	Director of Public Health	Hillingdon Borough Council
Prof	Donal	O'Donoghue	Consultant Renal Physician	Salford Royal NHS Foundation Trust
Dr	Mahendra	Patel	Principal Enterprise Fellow (Senior Academic Pharmacist)	University of Huddersfield
Ms	Mandy	Sainty	Research and Development Manager	College of Occupational Therapists
Mr	Duncan	Service	Evidence Manager	Scottish Intercollegiate Guidelines Network
Dr	Sara	Twaddle	Director of Evidence	Healthcare Improvement Scotland
Prof	Martin	Underwood	Professor of Primary Care Research, Director of Warwick Clinical Trials Unit	The University of Warwick
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