British Society for Surgery of the Hand (BSSH) Evidence for Surgical Treatment (B.E.S.T.)

Process Manual

1st Edition (12th version, November 2016)

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1. Contents

2. Contributors

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3. Acronyms Used

BSSH	British Society for Surgery of the Hand
BEST	British Society for Surgery of the Hand Evidence for Surgical Treatment
UK	United Kingdom
NHS	National Health Service
GP	General Practitioner
AGREE II	Appraisal of Guidelines, Research and Evaluation Instrument II
NICE	National Institute for Health and Care Excellence
GDG	Guidance Development Group
PICO	Patient, Intervention, Comparison, Outcome
CENTRAL	Cochrane Central Register of Controlled Trials

4. Introduction & Purpose

4.1. Background

4.1.1. The British Society for Surgery of the Hand (BSSH) aims to produce guidance to standardise and optimise the treatment of common hand conditions by hand surgeons. The platform for delivering this is the BSSH Evidence for Surgical Treatment (BEST) document. This manual describes the standardised processes by which BEST documents are produced.

4.1.2. BEST documents will evaluate the evidence describing treatment options for hand conditions that might be delivered by hand surgeons. Where possible, care pathways and recommendations will be made using evidence. Other treatment modalities available for hand conditions, but not delivered by hand surgeons will be considered but will not be central to BEST documents. An example would be the use of radiotherapy in the prevention or treatment of Dupuytren's disease.

4.1.3. BEST documents are intended for use as an aid to clinical decision-making. Specific circumstances affecting individual cases may mean that deviation from BEST guidance is appropriate. Ultimately only that patient and the healthcare professionals providing his/her clinical care can reach this.

4.1.4. Oversight responsibility for BEST documents remains with BSSH Council, supported by the BSSH Research Committee, as indicated in this process manual.

4.1.5. Members of the BSSH Research Committee are required to provide a current declaration of interests at all meetings of the committee.

4.2. Scope, Aims & Objectives

4.2.1. BEST will be produced for clinical guidance targeted for use in the United Kingdom (UK) National Health Service (NHS). Where appropriate, recommendations will be made with reference to this, with particular attention to how the implementation of recommendations can be facilitated.

4.2.2. The anticipated users of the main BEST document are UK healthcare professionals and patients. The former include hand surgeons, other orthopaedic and plastic surgeons, general practitioners (GPs), hand therapists, nursing staff and clinical commissioning groups [see Appendix 1, AGREE II item 6].

4.2.3. The anticipated users for quick guide implementation aids (comprising single A4 sheet summaries of guidance

recommendations) include all the above, as well as NHS patients, their relatives and carers, and members of the UK public.

4.2.4. It is accepted that healthcare professionals working outside the UK NHS may also use high quality clinical guidance based on systematic review of evidence.

4.2.5. The questions that BEST documents may attempt to answer are:

- Which patients should be referred to hand surgeons?
- Which treatments are superior to other treatments?
- Which treatments are more cost-effective than other treatments?
- What treatments should be offered to patients?
- At what clinical stage should different treatments be offered to patients?
- What outcomes can be expected from particular treatments?
- What future research might be beneficial in clarifying optimal treatment?

4.2.6. Not all topics will have sufficient evidence available to answer all of these questions. Acknowledgement of limitations of the existing evidence will be made when appropriate [see Appendix 1, AGREE II item 9]. However, identification of future research needs as part of the guidance development process will encourage the appropriate development of the evidence base.

4.3. Principles underpinning BEST document development

4.3.1. The processes employed by BSSH for BEST document development are based on the criteria specified in the Appraisal of Guidelines, Research and Evaluation (AGREE II) instrument (1) [see Appendix 1], and the application of this instrument in the National Institute for Health and Care Excellence (NICE) Accreditation process (2). The AGREE II instrument comprises 23 individual items. The particular AGREE II items that the processes specified in this manual address are referenced throughout.

4.3.2. All funding for the routine development of BEST documents will be provided by BSSH. If a guidance document is developed in collaboration with another organisation, then division of the cost of development between BSSH and the collaborating body will be established at the outset of the development process. No other external funding will be routinely sought or accepted for the development or implementation of BEST Guidance document and funding will not be conditional on editorial input. Instead, it will be based on estimated costing of the work streams required, which will be provided by the GDG. A summary of the BSSH's financial information will be displayed on the BEST webpage within the public domain of the BSSH website. [see Appendix 1, AGREE II item 22].

4.3.3. Occasionally, the systematic review conducted as part of the BEST document development process will be performed as part of additional research work, e.g. towards a higher research degree by a member of the Guidance Development Group. If that person is supported financially, e.g. by research grants, then all sources of finance will be declared in their Declaration of Interests [see Appendix 2]. If the funding body that has provided the financial support is considered to have potentially influenced the design, conduct or outcome of the systematic review, then this systematic review will be discarded and a new systematic review designed and implemented for the BEST document development. The impact of the potential influence of the funding body on the prospective GDG member will be assessed in the same manner as other conflicts of interest, as described in paragraph 5.5.8.

5. BEST Guidance Development Process

5.1. Topic Identification & Selection

5.1.1. BSSH Research Committee is responsible for approving topics for the development of BEST guidance. All topics will be approved prior to initiating the development process.

5.1.2. Topics may be referred to the Research Committee for consideration for BEST guidance development by different routes. These include:

- referral by BSSH members, including Research Committee members
- referral by other specialty associations or professional bodies
- referral by members of the public

5.1.3. All referrals made to the Research Committee from outwith the Research Committee will involve completion of Appendix 3 by the referring individual or organisation. This will not be required for referrals from within the Research Committee, where such discussions will be contained within the minutes for Committee meetings.

5.1.4. For externally referred topics, the topic will be circulated to all members of BSSH's Research Committee. Research Committee members will complete an Evaluation form [see Appendix 4]. A

minimum of one completed Evaluation form will be received. The Chair of BSSH's Research Committee will collate the Evaluation forms and complete the appropriate section based on the majority opinion of the Committee. The Evaluation decision will be ratified by a majority vote of the Research Committee members.

5.1.5. Once a topic for the development of a BEST guidance document is approved, a Guidance Development Group (GDG) lead will be identified. If a member of the Research Committee volunteers, they will be considered for the role. Otherwise, a call will be made to BSSH full members to volunteer to lead the GDG. Volunteers from outwith the Research Committee will answer the questions in Appendix 5 so that the committee has the information required to consider their application.

5.1.6. Applications to lead the Guidance Development Group will be considered by BSSH Research Committee members. The Research Committee Chair, supported by a majority vote of the Committee if required, will select the prospective GDG lead. The Chair of the Research Committee will request that the prospective GDG lead complete a statement of Declaration of Interests [see Appendix 2]. The Research Committee Chair will present the prospective candidate and any conflicts of interest for review by BSSH Council. BSSH Council will approve the appointment of the GDG lead. Following this, the GDG lead will be invited to produce a BEST Development Proposal. The GDG

lead will complete an up-to-date Declaration of Interests prior to the publication of the document, and this will be reviewed by the Chair of the Research Committee.

5.1.7. Up-to-date paperwork will be stored by BSSH until the BEST document is revised (typically 5 years after publication) [see Appendix 1, AGREE II item 23].

5.2. Guidance Development Group (GDG) Lead Role

5.2.1. The GDG lead will be responsible for:

1. Taking receipt of topic selection from BSSH Council
2. Assembling a GDG for the production of the BEST document on a particular topic
3. Producing a BEST Development Proposal
4. Ensuring the timely delivery of the stages of BEST document production
5. Providing written progress updates to the Research Committee on a quarterly basis

5.2.2. It is anticipated that a BSSH member will only act as GDG lead for one BEST document development process at a time. However, the GDG lead may also contribute to other BEST document development processes as a GDG Member at the same time, should they choose to

do so without compromising their commitment to each individual project. Once a GDG lead has completed the development of a BEST document, they may then serve as GDG lead for the development of another document covering a different topic should they choose to volunteer to do so, and be appointed by BSSH Council.

5.3. BEST Development Proposal

5.3.1. The selected GDG lead will submit a proposal for the development of a BEST document on the selected topic to BSSH Research Committee.

5.3.2. The BEST Development Proposal may include details such as:

- Provisional aims and objectives of the BEST document
- Provisional target population for the BEST document
- Relevant stakeholder groups (see 5.4.) to the particular topic
- List potential GDG members and completed Application form [Appendix 5] for them if the GDG lead believes that further examination of their suitability is required by the Research Committee
- A personal specification (comprising essential and desirable skills) for lay/patient members of the particular GDG
- Further GDG member positions for which the GDG lead has been unable to identify suitable candidates
- Estimated timeframe for the delivery of the final BEST document

- Estimation of anticipated costs of development, including
    - GDG meeting and transport expenses
    - Literature search and access costs
    - Illustration costs
    - Implementation costs

5.3.3. The expected timeframe for the delivery of a completed draft of the BEST document for review is ideally within 3 years of the approval of GDG lead.

5.3.4. BSSH Research Committee will consider the BEST Development Proposal, and either request revision and or approve the Proposal. Once approved, the GDG lead will initiate the development of the BEST document proper.

5.4. Stakeholder Groups

5.4.1. It is recognised that the implementation of a clinical guidance document will affect different groups from within the multidisciplinary team, and also patients. Any group likely to be significantly affected by the implementation of a guidance document will be considered for involvement as a stakeholder group. Consideration of stakeholder groups will take place for each BEST document development process [see Appendix 1, AGREE II item 4].

5.4.2. Some groups are likely to be stakeholders for all topics that BEST documents might cover. These groups will be considered as 'core stakeholders'. They include hand surgeons (plastics and/or orthopaedics), surgical trainees, hand therapists, and patients. These core stakeholders will be represented on all BEST document GDGs.

5.4.3. Other 'special stakeholders', may be relevant to particular topics. Special stakeholders will be invited to participate in BEST GDGs on relevant topics.

5.4.4. Involvement of representatives from special stakeholder groups may involve participation as members of the GDG, or may involve invitation to peer review the draft guidance, or both.

5.4.5. The specific role of representatives of special stakeholder groups for a topic will be determined by the GDG lead. Their role will also include representing the views of commissioners of healthcare.

5.4.6. Organisations representing stakeholder groups will be invited to peer review draft BEST documents, irrespective of whether a representative of their organisation has been a member of the GDG or not, with a deadline for comments.

5.4.7. Organisations representing stakeholder groups will be identified and contacted to confirm willingness to participate in BEST document development in the specified role.

5.5. GDG Member Recruitment

5.5.1. GDG membership will comprise representatives from core stakeholder groups, and from special stakeholder groups, at the GDG lead's discretion.

5.5.2. All GDGs will have at least one lay and/or patient member [see Appendix 1, AGREE II item 5].

5.5.3. Lay/patient members of the GDG will be individuals who are currently undergoing, or have previously undergone, treatment of the clinical topic condition, or their carers or close family members. Lay/patient members will be recruited from different sources. There will be at least one lay/patient GDG member, though preferably two will be sought. The GDG Lead will identify volunteers. Ideally, these volunteers will not be current or previous patients treated by the GDG lead him- or herself, nor should they be current or previous patients of other GDG members. In the rare event that no suitable candidates can be identified by the GDG lead or other GDG members, assistance will be requested from The Royal College of Surgeons' Patient Liaison Group. If this is not possible for a particular topic, then the GDG lead

will identify suitable lay GDG members by arranging open advertising in NHS clinic waiting areas placed in at least two different NHS Trust locations. These locations will not include places in which the GDG lead normally practices him/herself, to minimise bias in the recruitment process.

5.5.4. Prior to committing to the GDG, prospective lay/patient members should understand the specific roles that they will be expected to fulfil within the GDG. Whilst lay/patient members will not be able to, or be expected to, represent all viewpoints held by the general public, they should endeavour to reflect upon opinions and priorities of patients in general, to the best of their ability. The specific skills required for a lay/patient member of a particular GDG will be determined by the GDG lead, and will be documented in a personal specification comprising essential and desirable criteria. Support to develop lay/patient members' understanding will be arranged in a bespoke fashion to meet the needs of the individual and the contribution required of them. This may involve discussion with bodies such as the Royal College of Surgeons' Patient Liaison Group. Additionally, copies of supporting documentation, such as this Process Manual, will be made available to all members. Specific focus on the roles of lay/patient members will be incorporated into GDG member training (see 5.6.). All prospective lay/patient members will be encouraged to access the training materials freely available from The Cochrane Collaboration: http://training.cochrane.org/consumers.

5.5.5. Systematic review methodologists and statisticians may be included in the GDG at the discretion of the GDG lead, depending on the expertise of the other GDG members with respect to systematic review and meta-analysis. Where this support will incur a cost, BSSH Council should approve the expense prior to the engagement of the statistician, and ideally these costs will have been identified as part of the BEST Development Proposal.

5.5.6. The GDG lead will identify prospective GDG members where possible. If this is not possible (e.g. if the GDG lead does not have suitable contacts within particular stakeholder groups), this will have been identified in the BEST Development Proposal, allowing the Research Committee to assist in identifying suitable candidates.

5.5.7. Prospective members will be issued a formal invitation by the GDG lead explaining the topic of the guidance, Conflict of Interests policy, and Expenses policy.

5.5.8. All GDG members will complete and sign a paper copy of the Declaration of Interests statement (see Appendix 2). This will be reviewed by the GDG lead, and if required, be referred to the Research Committee for further review when a potential conflict of interests is present and a clear plan of action cannot be formulated by the GDG lead. If necessary, this will then be referred to BSSH Council by the

Chair of the Research Committee. If no referral is made, then the GDG Lead will assume responsibility for the outcome of the Declarations of Interest [see Appendix 1, AGREE II item 23].

5.5.9. A conflict of interests that might prevent a prospective GDG member from being able to appraise the evidence relevant to the topic in an objective manner may result in prospective member being excluded from taking up a position within the GDG. For example, a prospective member who has received, or continues to receive, consultancy fees or royalties from a company producing a technology relevant to the topic may be excluded from becoming a GDG member, if it is believed that this conflict would unduly influence the individual's contributions to the project.

5.5.10. Prior to publishing the document, all GDG members and document authors will complete up-to-date Declarations of Interest covering the whole period of work on the document. Copies of these final Declaration of Interests statements will be stored by BSSH administrative services based at The Royal College of Surgeons of England, London, until the BEST document is revised (typically 5 years after publication). Copies of the documents will be made available upon written request to the BSSH.

5.5.11. Confirmed members of the GDG will proceed to Training.

5.6. GDG Member Training & Introductory Sessions

5.6.1. If GDG members express a desire for training, introductory sessions will be arranged by the GDG lead or the Research Committee.

5.6.2. Introductory sessions will be lead by the Chairman of the BSSH Research Committee, or a nominated deputy with appropriate knowledge and expertise.

5.6.3. Prior to any introductory sessions, GDG members will be directed to access to this Process Manual, Accreditation pages of NICE's website, NHS Evidence, and the AGREE II Instrument.

5.6.4. Once any introductory sessions have been completed to the satisfaction of all parties concerned, then the GDG will effectively begin to work on the project. Meetings will be arranged either face-to-face, or by other means, at the discretion of the GDG lead, in response to the needs of the project and the GDG members. The above materials will be reviewed and the GDG Lead will discuss the BEST Development Proposal. GDG members will be given the opportunity to ensure that they understand the processes for BEST document development, and the principles underpinning them.

5.6.5. The GDG Lead will confirm the authors of the final BEST document prior to completion of the project. All GDG members will be

acknowledged by name in the document introduction. However, not, all GDG members will necessarily contribute to the writing of the document and thus may not be named authors of the document. All GDG members (and their occupations and conflicts of interest) will be listed in the BEST document (see 5.10.4.). This will include lay/patient members. Where individuals have been unable to participate in the project, or to complete their contributions in an accurate and timely manner, the GDG lead may elect to request that they step down from the group. If they have not contributed to the process adequately or to the final product, they will not be named as an author or contributor.

5.6.6. If during the guideline development process, it is identified that input from specific individuals out with the GDG will be beneficial in authoring the guideline document, then such individuals can be included as guideline authors at the GDG lead's discretion. The specific role of authors who are not GDG member will be described in the guideline document and they will complete a Declaration of Interests form (Appendix 2). Others who contribute to the guideline may be acknowledged separately from the authors, at the GDG lead's discretion.

5.6.7. The scope, aims, objectives and target population set out in the BEST Development Proposal will be discussed by the GDG. This will conclude in the generation of specific and detailed lists of the objectives for the final BEST document, in the form of the particular

clinical questions that the guidance will set out to answer, and the population groups that they apply to. Exclusions will be established and clearly listed [see Appendix 1, AGREE II items 1,2,3].

5.6.8. Target population selection and exclusions may apply to patients of particular age groups, e.g. children, or particular focus may need to be applied to specific socioeconomic groups, e.g. manual workers, or patients of specific ethnic origins of relevance to the topic [see Appendix 1, AGREE II item 3]. When exclusions are made, the reason for doing so will be documented.

5.6.9. The GDG Lead will allocate specific roles for individual GDG members. This will include performing the literature searching, and extracting appropriate study data.

5.6.10. All GDG members, including lay/patient members, will complete a declaration of adequacy of training (Appendix 6). These will be collated by the GDG lead who then arrange further training for individual GDG members as required. Depending on the GDG members and the tasks allocated, this may be completed prior to introductory sessions, prior to starting the project, or after being allocated tasks that the member is comfortable to complete.

5.7. Systematic Review Strategy

5.7.1. The identification of suitable studies to inform the development of BEST documents will involve a formal systematic review of the evidence, the methodology of which will be clearly documented in the final document [see Appendix 1, AGREE II items 7,8].

5.7.2. Developing BEST documents for specific topics will require particular search strategies. Responsibility for the design of an appropriate search strategy remains with the GDG Lead. However, several principles will be adhered to for all BEST documents.

5.7.3. The PICO (Patient, Intervention, Comparison, Outcome) formula is a widely used tool to guide the formulation of appropriate clinical questions. This approach is encouraged when developing questions to be answered by BEST documents. A concise list of questions to be answered in the BEST document will be generated using this technique and approved by the GDG Lead.

5.7.4. A search strategy will be developed using the guidance described in The Cochrane Handbook for Systematic Reviews of Interventions (3). The search strategy employed will be documented in the BEST document.

5.7.5. Search strategies will be designed to identify the highest quality evidence available for the topic. This might include meta-analysis,

systematic review, randomised controlled trials and/or observational studies.

5.7.6. The following databases will be searched, as a minimum:

- The Cochrane Library
- Cochrane Central Register of Controlled Trials (CENTRAL)
- OvidMEDLINE (1948 – current date)
- EMBASE (1980 – current date)

(All of these resources can be accessed by NHS employees through the NHS Evidence website.)

5.7.7. Additional resources may also be searched, at the discretion of the GDG lead. If other resources are used, this will be recorded in the document. Grey literature searching is encouraged, and searches for grey literature should be stated as such. Grey literature for BEST documents may include national audits and similar data sources. When such sources are used, their methodological quality will be appraised, and whether their findings have been subjected to a peer review or other quality assurance process will be appraised.

5.7.8. Wherever possible, GDG members will perform searches and obtain relevant papers, using NHS Evidence, or access to resources from their own affiliated institutions, within the limitations of copyright law.

5.7.9. Where GDG members are not able to perform aspects of the literature searches themselves, the issue should be referred to the Research Committee via the GDG Lead.

5.7.10. Search strategies, and resources used will be recorded in the BEST document.

5.7.11. The search results will be de-duplicated. Each reference's abstract will be screened for relevance based upon specific documented inclusion/exclusion criteria established by the GDG Lead [see Appendix 1, AGREE II item 8]. These criteria will be particular to the individual BEST document, and the clinical question that it aims to address.

5.7.12. Two separate GDG members will screen all abstracts independently, with details kept of which references are included and which are excluded. Where inconsistencies between the screening members arise, or where there is uncertainty regarding inclusion/exclusion of a reference, it will be referred to the GDG Lead for a third and final opinion.

5.7.13. Articles with abstracts in languages other than English will be considered when an English translation of the abstract can be obtained.

5.7.14. If references cannot be obtained through the resources specified in 5.7.8, this will be referred to BSSH administrative staff to identify alternatives sources of the article.

5.8. Evidence Synthesis

5.8.1. Evidence will be appraised and recommendations assigned an evidence level following The Scottish Intercollegiate Guidelines Network's (SIGN) system, as described in SIGN 50: A Guideline Developer's Handbook (4) or preferably using GRADE (5) [see Appendix 1, AGREE II item 9]. One of these systems should be chosen and used throughout the document.

5.8.2. In keeping with guidance, the evidence level assigned represents the quality of the studies rather than the importance of its recommendation.

5.8.3. Appraisal of evidence in studies will be performed in keeping with SIGN's or GRADE's recommendations (4). All recommendations in the final BEST document should incorporate a statement referring to the quality of the evidence on which they are made.

5.8.4. Where existing clinical guidance from other providers is identified, only guidance produced through a NICE Accredited process will be used to inform BEST document development. It is anticipated that there will be

little guidance from other producers of relevance to the niche area of hand surgery.

5.8.5. If appropriate, evidence tables comprising details of studies relevant to the questions formulated by the GDG (see 5.7.3.) will be produced in keeping with SIGN or GRADE guidance (4). These will incorporate e.g. evidence of adverse effects, risks and side effects in addition to benefits, such that a balanced interpretation of the evidence is possible when formulating recommendations [see Appendix 1, AGREE II item 11].

5.9. Recommendation Formulation

5.9.1. All GDG members will review evidence tables, to allow recommendation synthesis by informal consensus at a face-to-face meeting or virtual meeting using telecommunications, as assessed by the GDG lead [see Appendix 1, AGREE I item 10]. Additionally, the strength of the recommendation will be graded depending upon the volume, quality and applicability of the evidence underpinning it, using the guidance provided by SIGN for this process (4) [see Appendix 1, AGREE II item 12]. When consensus of GDG members cannot be reached at a face-to-face/virtual meeting, an anonymous vote will be triggered by the GDG lead during the meeting. Where this fails to achieve a majority vote, the GDG lead will have the casting vote.

5.9.2. Recommendations will be made within the body of the document following the evidence table of relevance, so that links between the evidence and the recommendation can be easily and clearly identified [see Appendix 1, AGREE II item12].

5.9.3. When consensus is not reached, or where the evidence is deemed lacking, Delphi consensus will be considered to formulate the recommendation. In doing so, the viewpoints of all stakeholder group representatives will be weighted equally. When recommendations are reached in this manner due to a paucity of evidence, this will be clearly acknowledged in the BEST document, in addition to being reflected in the grading of the strength of the recommendation [see Appendix 1, AGREE II item 9].

5.9.4. 'Good Practice Point' recommendations may be made for important points that all GDG members agree contribute to high quality care, in keeping with guidance provided by SIGN (4). These points will be clearly identifiable as separate entities from evidence-based recommendations. Good practice points will not be subject to grading, unlike evidence-based recommendations.

5.9.5. Good practice points may provide advice to clarify practicalities of implementing evidence-based recommendation [see Appendix 1, AGREE II item 19].

5.9.6. The wording of recommendations will be considered and agreed upon by GDG members, to ensure clarity, specificity and to avoid ambiguity [see Appendix 1, AGREE II item 15].

5.9.7. The GDG will identify audit indicators from the recommendations and good practice points made, wherever possible. These will comprise aspects of practice that the GDG members consider to be unanimously important for the delivery of high quality clinical care. They will be listed in an appendix at the end of the BEST document [see Appendix 1, AGREE II item 21].

5.9.8. If possible, evidence describing cost-utility analyses will be included in the recommendation synthesis process, so that GDG members are aware of resource implications of the recommendations [see Appendix 1, AGREE II item 20]. However, it is acknowledged that limited high quality data describing cost-utility of hand surgery interventions is likely to be currently available.

5.9.9. In addition to recommendations regarding a treatment option, alternative treatment options will be discussed in the BEST document [see Appendix 1, AGREE II item 16]. Where the evidence describing alternative options has been investigated as part of the question (typically as the 'Comparison' in the PICO formula for the question, see 5.7.3.), this may be briefly discussed. Where the evidence describing alternative treatments has not been thoroughly and robustly identified as part of the systematic

review, this will be clearly acknowledged in the document and no recommendation made regarding alternative treatment options made within the document.

5.9.10. Once all recommendations have been made and graded, and good practice points identified, key recommendations to be highlighted will be identified by consensus of GDG members [see Appendix 1, AGREE II item 17].

5.10. Document Structure

5.10.1. BEST documents will be laid out using a common structure to ensure clarity of presentation and standardisation.

5.10.2. Key recommendations will be highlighted separately from the body of text of the document [see Appendix 1, AGREE II item 17].

5.10.3. The level of evidence will be discussed alongside each key recommendation.

5.10.4. A quick guide implementation aid will also be produced as a support tool. This will include algorithms and be written in a bullet-point style.

5.10.5. Any potential bias in the recommendations, e.g. resulting from of interest will be discussed in the clinical practice recommendations section and the conflicts of interest section.

5.11. Internal/External Review Process

5.11.1. Once the authors have completed and approved a draft of the BEST document, all GDG members will be invited to review this and provide comments.

5.11.2. If considered appropriate, the GDG members will compose a section describing anticipated facilitators and barriers to the implementation of the recommendations, and advice that might facilitate implementation based on the discussions held during recommendation synthesis [see Appendix 1, AGREE II item 18].

5.11.3. When all GDG members' comments have been addressed by the authors and the anticipated facilitators and barriers section has been added, the draft BEST document will be submitted to the Research Committee and BSSH Council for peer review from out with the GDG. Any GDG member who is also a member of the Research Committee or Council will abstain from this Research Committee review. BSSH Research Committee members and BSSH Council members are subjected to processes for the management of conflicts of interest. This involves providing a written

declaration of conflicts of interest when joining the committee/council and providing verbal statements of conflicts of interest at the start of meetings of the committee/council. Any declared conflicts are then acted upon by the Chair of the Research Committee/President respectively, based on the specific nature of the conflict declared. For example, conflicted individuals may be asked to abstain from votes on relevant issues or from participating in specific activities where an undue risk of bias may be present. A summary of this process will be displayed on the BEST webpage within the public domain of the BSSH website. Members of either group with relevant conflicts of interest will have their involvement in the internal review managed by the respective lead of the group (Research Committee Chair or BSSH President).

5.11.4. After internal review comments made by the Research Committee and Council have been received, the guideline authors will consider comments and make adjustments to the draft if appropriate.

5.11.5. After internal review, the revised draft guidance will be sent for expert review to the organisations representing stakeholder groups, such as those who were contacted initially in the development process and consented to participate (see 5.4.7.) [see Appendix 1, AGREE II item 13]. Comments will be received on the form in Appendix 7.

5.11.6. The internally reviewed draft will also be posted on the BSSH website and to allow for public consultation. The public may submit comments by

email using the form in Appendix 7. For guideline topics for which no specific patient representative group can be identified as a stakeholder organisation for external review, public consultation will allow for the views of the public and patients to be further incorporated into the guideline.

5.11.7. Closing dates will be set for comments from Research Committee review, and from reviews external to BSSH (organisations representing stakeholder group reviews, and public consultation). The GDG lead will take receipt of feedback proformas and will revise the draft document with the author group to generate a proof BEST document.

5.11.8. The format on the document will be guided by the template in Appendix 8.

5.11.9. The final proof document will be submitted to BSSH Council. BSSH Council may request final revision of the proof BEST document, and resubmission.

5.11.10. Once BSSH Council grants final approval, the final BEST document will be published. Responsibility for proof reading the document prior to its publication at this stage remains with the named authors.

5.12. Publication

5.12.1. The published BEST document will be made available as a downloadable PDF file or similar from the BSSH website.

5.12.2. A copy of the published BEST document will be sent to all relevant organisations representing stakeholder groups, irrespective of whether they participated in the development of the document.

5.13. Support Tools & Aids to Implementation

5.13.1. The published BEST document will be available free of charge through the BSSH's website (www.bssh.ac.uk).

5.13.2. Where possible and appropriate, the summary at the end of the BEST document will incorporate a treatment algorithm [see Appendix 1, AGREE II item 19].

5.13.3. If a treatment algorithm is developed, it will be included in a "Quick Reference Guide" as an appendix within the BEST document. The quick reference guide will comprise of a single page of A4 paper with the guideline title, algorithm and key recommendations, such that this could be printed out as a stand-alone item, e.g. to be fixed to the wall in clinic rooms, to support the use of the guideline.

5.13.4. The quick reference guide will be available free of charge from the BSSH website. This will be based on key recommendations and any algorithms produced.

5.14. Review and Update Process

5.14.1. BEST documents will be valid for five years from the date of publication, at which point they will expire. A review of the BEST document will be triggered two years after the publication of the document, such that it is completed within the five-year lifespan of the original document [see Appendix 1, AGREE II item14].

5.14.2. The BEST document will display the publication date and expiry date.

5.14.3. BSSH Council may trigger a review process earlier than scheduled if alerted to a significant and practice-altering change in the evidence-base either by direct contact to the BSSH Council from a member of the clinical community, or through the surveillance process described in 5.14.3.

5.14.4. The review process will be conducted in a similar to the development of new BEST document.

5.14.5. If BSSH Council considers that changes in the evidence base are so significant as to render the existing BEST document unsafe, then the document will be withdrawn.

5.14.6. Following the completion of the BEST document, the GDG lead will be asked to provide written comments on this process itself to the Chair of the Research Committee.

5.14.7. Administrative staff at the BSSH will store the written comments provided by all GDG leads. The Chair of the Research Committee will commission an update of the process manual if significant changes are suggested by a GDG lead, or after five years without review.

5.14.8. The BEST Process and Process Manual itself will be reviewed and if necessary revised every 3 years.

5.15. Monitoring the impact of guidance

5.15.1. The number of downloads of the BEST document from the BSSH website will be analysed on a 6 monthly basis, to allow this to be discussed at The BSSH Research Committee meetings (which currently take place 6 monthly).

5.15.2. An electronic survey of BSSH members will be conducted 1 year after the publication of the BEST document to analyse uptake, implementation and to support strategies to improve implementation that will be considered at the BSSH Research Committee meeting following the completion of the survey.

Appendix 1: AGREE II Instrument

This comprises 23 items separated into 6 domains (1):

Domain 1: Scope and Purpose

1. The overall objective(s) of the guideline is (are) specifically described.

2. The health question(s) covered by the guideline is (are) specifically described.

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

Domain 2: Stakeholder Involvement

4. The guideline development group includes individuals from all relevant professional groups.

5. The views and preferences of the target population (patients, public, etc.) have been sought.

6. The target users of the guideline are clearly defined.

Domain 3: Rigour of Development

7. Systematic methods were used to search for evidence.

8. The criteria for selecting the evidence are clearly described.

9. The strengths and limitations of the body of evidence are clearly described.

10. The methods for formulating the recommendations are clearly described.

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

12. There is an explicit link between the recommendations and the supporting evidence.

13. The guideline has been externally reviewed by experts prior to its publication.

14. A procedure for updating the guideline is provided.

Domain 4: Clarity of Presentation

15. The recommendations are specific and unambiguous.

16. The different options for management of the condition or health issue are clearly presented.

17. Key recommendations are easily identifiable.

Domain 5: Applicability

18. The guideline describes facilitators and barriers to its application.

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

20. The potential resource implications of applying the recommendations have been considered.

21. The guideline presents monitoring and/or auditing criteria.

Domain 6: Editorial Independence

22. The views of the funding body have not influenced the content of the guideline.

23. Competing interests of guideline development group members have been recorded and addressed.

Appendix 2: Declaration of Interests

The Declaration of Interests is based on that described by The British Orthopaedic Association (6):

I hereby declare the following interests in the healthcare industry within the three years prior to the date of signature:

1. Personal Pecuniary Interest

This includes direct financial benefit provided to the individual. This includes direct employment, honoraria and consultancy fees from relevant bodies. Personal pecuniary interests may require the individual to be excluded from participation in a Guidance Development Group completely, or may require them to be excluded from recommendation synthesis, when the recommendation concerned pertains to the source of the pecuniary interest.

Description (if you have no interests in this category, state 'none')

2. Family Pecuniary Interest

This includes direct financial benefit provided to relatives of the individual. This includes direct employment, honoraria and consultancy fees from relevant bodies. Personal pecuniary interests may require the individual to be excluded from participation in a Guidance Development Group completely, or may require them to be excluded from recommendation synthesis, when the recommendation concerned pertains to the source of the pecuniary interest. If deemed to be minor

and not of influence, then interest will be noted in the BEST document, but may not require exclusion from participation.

Description (if you have no interests in this category, state 'none')

3. Non-personal Pecuniary Interest

This includes indirect financial benefit to the individual or organisations that they are associated with. For example, the provision of research funding to the department in which the individual works, or the reimbursement of travel/subsistence expenses to the individual's department. Non-personal pecuniary interests may require the individual to be excluded from participation in a Guidance Development Group completely, or may require them to be excluded from recommendation synthesis, when the recommendation concerned pertains to the source of the pecuniary interest. If deemed to be minor and not of influence, then interest will be noted in the BEST document, but may not require exclusion from participation.
Description (if you have no interests in this category, state 'none')

SIGNATURE & NAME: _____DATE: _____

It is stressed that it is vital for the transparency and acceptability of the BEST document that all potential conflicts of interest are declared, even if considered minor. Decisions regarding conflicts of interest will be made in keeping with the protocols specified in the BEST Process Manual. Decisions made regarding conflicts of interests are final.

Appendix 3: Topic Referral

All referrals of topics must have the following questions answered by the referring individual or organisation:

1. What is the clinical topic to be addressed?
2. Who is the individual/organisation supporting the proposal?
3. Is there variation in clinical practice surrounding the condition within the NHS?
4. How might implementation of a clinical guideline improve patient outcomes in the NHS?
5. Which potential stakeholder groups may need to be included in guideline development?
6. Does existing clinical guidance exist describing this topic?
7. Is high quality evidence available describing the topic? (Particularly meta-analysis, systematic review, randomised controlled trials)

Appendix 4: Research Committee Evaluation of Referred Topics

1. Title of referred topic

2. Does clinical guidance exist for this topic? [Yes, No, Unsure]

3. If so, is adequate? (E.g. produced by a NICE Accredited developer)

4. Estimate of size of clinical need of topic: (prevalence, mortality, morbidity, cost of treatment) [Grade A-E, A being greatest need]

Research Committee Lead Section:

1. Range of Estimates of clinical need from Committee members:

2. Research Committee Evaluation Decision:

    a. Proceed to presentation to BSSH Council

    b. Reject referral

3. Comments on decision

Appendix 5: Volunteering to participate in a BEST Guidance Development Group

1. Name

2. Current post

3. Brief explanation of previous experience of systematic review or guidance development

4. Brief explanation of clinical experience of topic

5. Confirmation of awareness of the requirements of participation in a Guidance Development Group, as detailed in The BEST Process Manual (including time commitment and Conflict of Interests policy)

Appendix 6: GDG member declaration of training adequacy

All GDG members will complete this declaration upon completing the introductory sessions. Further training as required will be arranged by the GDG lead on an individualised basis.

BEST Document Title:

GDG Member Name and occupation:

Introductory sessions attended (dates and locations):

Background materials accessed to date:

I am confident that I have adequate knowledge and understanding of the guidance development PROCESS to participate in the development of this BEST document:

YES ☐ **NO** ☐

I am confident that I have adequate knowledge of the CLINICAL TOPIC AND QUESTIONS TO BE ANSWERED to participate in the development of this BEST document:

YES ☐ **NO** ☐

Name & Signature of GDG member: **Date:**

TO BE COMPLETED BY GDG LEAD:

Further training required for this GDG member:

Plan of action:

Name & Signature of GDG lead: **Date:**

Appendix 7: Feedback proforma for draft guidance review

The British Society for Surgery of the Hand is grateful for all comments received pertaining to BSSH Evidence for Surgical Treatment (BEST) Clinical Guidance. Please provide comments using this proforma.

Title of BEST document reviewed:

Date comments made:

Name of individual/organisation providing feedback:

Does the individual/organisation (or its members) providing comments have any potential conflict of interests relating to the content of this document?:

(This may include, for example, potential financial benefit/loss personally, or to close family members or organisations resulting from recommendations made in the document, or being affected personally by the recommendations of the document, or having close family, friends or organisation members who might be affected by the recommendations of the document)

Please provide details of potential conflicts of interests:

(IF THIS SECTION IS NOT COMPLETED, OR IS INCOMPLETELY COMPLETED, ALL COMMENTS PROVIDED BY THIS INDIVIDUAL/ORGANISATION WILL BE DISREGARDED. All comments will be interpreted in light of potential conflicts of interest)

Comments on processes used to generate recommendations:

Comments on recommendations:

TO BE COMPLETED BY BSSH:

Date of receipt of comments:

Guidance Development Group Lead Response to comments:

Action by GDG Lead resulting from comments:

Appendix 8: BEST Document Template

British Society for Surgery of the Hand Evidence for Surgical Treatment (BEST)

Topic: *Enter title*

Date of publication: *(to be entered by BSSH Research Committee Lead)*

Date of anticipated review: *(date of publication + 5 years)*

Authors:
Authors of document, not necessarily all GDG members

Guideline Development Group:
Names, job title and roles/stakeholder group represented for all GDG members including authors and other members

Funding sources used: *If any*

Collaborating organisations:
Those who contributed to guideline development (not external review), if any

Conflicts of interest: *GDG members' and Authors' conflicts of interest*

Disclaimer:
e.g.
This document reflects a consensus view of the British Society for Surgery of the Hand Research Committee and Council, based on a systematic and transparent review of evidence. All users of this document must ensure that they consider the entirety of the document when using it, that the recommendations within this guideline are not mandatory, and that clinical judgement and that patient-centred decision making for all individual patients is the highest priority. Users are reminded of their individual duties and responsibilities, professional or otherwise, to use this guideline responsibly and that no content within this guideline overrides these duties and responsibilities.

Process:
e.g.
This document has been produced by systematic reviews, with the interpretation and development of recommendations achieved by consensus of the GDG members.

Overall objective:

Anticipated users:

Target Population:

Questions discussed in this BEST:

(delete as applicable):

- Which patients should be referred to hand surgeons?
- Which treatments are superior to other treatments?
- Which treatments are more cost-effective than other treatments?
- What treatments should be offered to patients?
- At what clinical stage should different treatments be offered to patients?
- What outcomes can be expected from particular treatments?
- What future research might be beneficial in clarifying optimal treatment?

Questions not discussed in this BEST:
(delete as applicable):

- Which patients should be referred to hand surgeons?
- Which treatments are superior to other treatments?
- Which treatments are more cost-effective than other treatments?
- What treatments should be offered to patients?
- At what clinical stage should different treatments be offered to patients?
- What outcomes can be expected from particular treatments?
- What future research might be beneficial in clarifying optimal treatment?

Inclusion & exclusion criteria
Who this guideline applies to. E.g. children, adults elderly, etc

Plain Language Summary
Summary of the document written using language that an intelligent lay person would understand

Introduction
Summary of problem as per a scientific paper

Methods
As per a scientific paper

Systematic review results
As per a scientific paper

Systematic review overview discussion:
As per a scientific paper

Clinical practice recommendations:
Recommendations with reference to quality of evidence supporting the recommendation

Good practice points:
Suggested good practice points that may not be supported by existing evidence, but that are unanimously agreed upon by GDG. The nature of these recommendations should be stated, e.g. "It was considered a good practice point that … should be considered for all cases, although this was based on consensus of expert opinion rather than other evidence"

Clinical audit indicators:
Suggested metrics that could be assessed in clinical practice audits

Resource Implications:
Impact of implementing the recommendations on existing services

Facilitators and barriers to implementation:
Any suggestions that may support implementation of the recommendations

Future research recommendations:
Suggestions for future research to answer important areas of unresolved uncertainty

Stakeholders invited to provide external review:

Timeline of guideline:
Date topic identified:
Date GDG lead appointed:
Date draft supplied by GDG authors:
Date Internal review completed:
Dates of public consultation:
Date external review completed:
Date published:

Appendix 1: PRISMA flow chart for systematic review:

Appendix 2: Evidence Summary Table(s):

Appendix 3: Key clinical practice recommendations table

Appendix 4: Patient flow algorithm:

Appendix 5: Support Tool: Quick reference guide:

Appendix 6: Characteristics of included studies

Appendix 7: Quality of evidence assessment of included studies

Appendix 8: Included study references

Appendix 9: Excluded study references

Appendix 10: Other references

References

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