

Writing A Faculty of Dental Surgery Clinical Guideline

INTRODUCTION

This guidance should be read by all those involved in authoring and/or reviewing Faculty of Dental Surgery (FDS) clinical guidelines.

The FDS is part of the Royal College of Surgeons of England (RCS). The College is a professional membership organisation and a registered charity with the stated aims of advancing surgical care and improving outcomes for patients. The FDS produces clinical guidelines as part of its contribution towards the overall fulfilment of the College's role and aims.

The body responsible for the creation and review of FDS clinical guidelines is the FDS Clinical Standards Committee (CSC). The CSC is made up of representatives from all of the dental specialties and members of the FDS Board, and includes a representative from both the Faculty of General Dental Practice (FGDP) who also represents dental care professionals and the College's Patient Liaison Group (PLG). Specialty representatives are normally nominated to serve by the individual specialist societies. Except for the PLG representative, all of the CSC Members are practising dental professionals and therefore potential end-users of the guidance.

IDENTIFYING A TOPIC

The CSC meets three times a year, in May September and December, at the Royal College of Surgeons of England in London. Guideline topics are either suggested by CSC members or emerge from CSC discussions. Topics normally address a perceived need among the profession either for guidance where none is present or for updated guidance in the light of new evidence. FDS clinical guidance is normally multi-specialty, requiring input from a minimum of two dental specialties.

If the consensus view is that a guideline is required, the Committee will agree a provisional clinical scope and target audience, which may be subject to revision as the guideline progresses.

Appendix 1 contains information in tabular form that the CSC may consider when selecting guideline topics.

IDENTIFYING THE AUTHORS

Each specialty's representative on the CSC will have the opportunity to register a stakeholder interest in the guideline, as will patient groups relevant to the guidance via the PLG.

The CSC will then identify the individuals who will comprise the Guideline Development Group (GDG) and write the guideline. The GDG may include members of the CSC, but this is not a requirement.

Normally one specialty will be identified as the lead specialty for that guideline, and its CSC representative will be tasked with taking the lead on that guideline or identifying an individual within that specialty who is recognised as having the skills and knowledge to be that guideline's lead author.

The guideline lead will then liaise with the appropriate specialty representatives on the CSC to identify and approach similarly appropriate consultants and/or specialists in those specialties to serve as the guideline's co-authors. If appropriate the various co-authors' areas of responsibility should be identified and communicated at this stage.

STAKEHOLDER INVOLVEMENT

The guideline development process involves stakeholders at relevant times within the process. This may include for example; involvement in the scoping, reviewing and/or piloting of the guideline. However, it is critical that they are invited to comment on, and to approve the final document, prior to its publication.

The stakeholders are chosen specifically for their appropriateness, experience and expertise. The target audience will have informed the original choice of stakeholders. More detail should be available on why and how these stakeholders were identified for this task and how they were enabled to contribute.

It is vital that there is patient and carer representation. This will enable the final guideline to reflect their valuable perspective.

EDITORIAL INDEPENDENCE

The Royal College of Surgeons of England is a registered charity and strenuously resists arrangements whereby commercial interests may be seen to influence the development of any of its guidelines. To this end, all stakeholders in the guideline development process are required to declare any conflicts of interest. Any sources of funding received towards the development of a guideline will be reported in the guideline.

Members of the CSC are required to complete an annual declaration of interests and to declare any interests in any of the matters on the agenda at the beginning of every meeting of the CSC.

All members of the GDG will be asked to complete and return to the Faculty a conflict of interest declaration form (See Appendix), which will be kept by the Faculty for a period of three years. This includes any trainees or similar who are contributing to the guideline, perhaps by undertaking a literature review, as part of their training. The GDG Lead must not have any conflicts of interest with the recommendations being set and in this situation must step down and a co-chair must stand in this instance

CSC members will be asked complete this form when presented with guidance for peer review.

Any conflicts of interest will be indicated at the end of the guideline

RESOURCES

The Faculty is aware that guideline authors will be contributing their time and expertise for free. In most cases GDG members will be communicating with one another via e-mail and telephone. Should the GDG deem a face-to-face meeting necessary, the FDS will bear the expenses and organise a meeting on Royal College premises if this is appropriate.

The final guideline will include a statement that the FDS is funded by its Fellows and Members and that no contributors or reviewers are paid for their work on a guideline, and nor is any payment provided in kind .

AIMS AND OBJECTIVES

Guidelines published by the CSC should be realistic and achievable, and relevant to modern practice in the context in which it is intended to be delivered. CSC guidelines are intended to bring about change and improve health outcomes, and should therefore be valid, reliable, clinically applicable, clinically flexible and clear

Table 1 Objective of Guidelines

To describe appropriate care based on the best available scientific evidence and broad consensus
To reduce inappropriate variation in practice
To provide a more rational basis for referral
To provide a focus for continuing education
To promote efficient use of resources
To enable setting and monitoring of standards including audit
To act as quality control with the aim of promoting clinical excellence
To highlight shortcomings of existing literature and suggest appropriate future research

The GDG should decide the overall objective of the guidance along with expected benefits from the guidance. Consideration must be given to the clinical, healthcare and/or social questions covered by the guidance along with the target audience. The GDG should aim to produce clear recommendations that are specific for the target audience to enable implementation.

The authors will first of all consider the scope and clinical questions that are to be addressed. Once identified these should be circulated to the CSC for comment and formal agreement. If there are any comments or objections these should be considered and appropriate changes made (or reasons provided for not so doing). When the scope has been agreed by the CSC the GDG should start its review of the evidence.

REVIEWING THE LITERATURE

To complete a comprehensive review of the evidence a systematic review of the literature must be carried out.

A systematic review aims to provide an exhaustive summary of current literature relevant to a research question. The first step of a systematic review is a thorough search of the literature for relevant papers.

The exact database(s) used will differ depending on the guideline being produced, however the literature review will make use of one or more of the more commonly used databases. The search should include a mix of databases from the following:

- Cochrane Database of Systematic Reviews (CDSR)
- Database of Abstracts of Reviews of Effects (DARE)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- Health Technology Assessment (HTA) database
- MEDLINE
- EMBASE
- NHS Evidence > Filter > Guidelines
- National Guidelines Clearing House
- PsycINFO (Psychology and Psychiatry)
- ASSIA (Applied Social Sciences Index and Abstracts)
- HMIC (Health Management Information consortium)

Each guideline should state why the particular database or search strategy was used.

If evidence is not forthcoming from a search of these databases then it may be necessary to include other sources of information for example expert opinion or proceedings of conferences.

The literature search will be undertaken by a member of the GDG or by an appropriate individual (e.g. trainee, information scientist, GDC-registered specialist) under the guidance of a member of the GDG.

Search terms will include subject headings. The search should take account of the fact that variations exist between databases, e.g. MeSH (Medical Subject headings) within Medline and Emtree within Embase, by using the following term types:

- free text, including synonyms, acronyms and abbreviations
- spelling variants
- old and new terminology
- brand and generic terms
- lay and medical terminology

For ease of searching the search should be limited to English language articles except where there is a lack of evidence reported in English.

Date limits for the search should be decided; these will depend on the topic being researched, and should be documented and explained in the search protocol.

Limits based on other criteria (eg age, setting, geography etc) may be applied as considered relevant and appropriate to the search and should be documented and explained.

The search will use filters to identify the following study types:

- Accredited guidelines
- Systematic reviews

- Randomised control trials (to be confirmed at the scoping stage)
- Diagnostic studies
- Observational studies

However should there be limited information available from these sources then it is acceptable to widen the search and include other available research, and supplementary search techniques. If there are questions that cannot be answered reliably with the available evidence then the searcher should add any identified uncertainties to the *NHS Evidence – UK Database of Uncertainties about the Effects of Treatments (DUETs)* and the uncertainties should be detailed in the guideline.

The details of the literature review, including the search strategy, databases searched and inclusion dates, will be recorded by the individual(s) undertaking the search. The GDG will retain this information and may add it as an appendix to the published guidance document. The GDG may also choose to list studies that were considered potentially relevant but were excluded from main data extraction, citing the reasons for the exclusion. It is accepted that the search may be an iterative process, but details of this need to be documented. All search strategies should be transparent and reproducible.

Recording of the appropriate information in tabular form may help, especially when the literature search is to be carried out by someone other than a member of the GDG.;

Literature Search	
Search Title	
Research Question	
Inclusion criteria (& reasons)	
Intervention	
Comparators	
Outcomes	
Search period (Year range)	
Exclusion criteria (& reasons)	
Types of studies to be included	
Other useful information	

A preliminary review of the search output should be done to remove any items of literature that are irrelevant, be it due to content or inappropriate study design. Abstracts may then be examined and further studies discarded if they do not meet the inclusion criteria. The above stages could be carried out by an information scientist/technologist/manager. However, if there is any doubt then the decision should be deferred to the GDG.

Further reviewing & sifting should now be carried out by members of the GDG and clinical judgement used to reject any other studies that do not fit the criteria.

Once the final group of studies has been identified the full text versions will be acquired to allow the evidence to be assessed as to its quality and evaluated.

The methodology used in each study should be assessed to ensure its validity and to ensure there is no bias in the results reported and the conclusions drawn. Information on how this is carried out should be included in the guidelines

In order to keep a record of key characteristics of the studies included an evidence table may be produced. Items to include:

Bibliographic reference	author(s), year, article title, journal, volume, pages
Study type	E.g. randomised controlled trial, and cohort or case-control studies.
Patient numbers	total number of patients included in the study, including number of patients in each arm of the study, with inclusion and exclusion criteria. Also record the numbers of patients who started and completed the study.
Patient characteristics	characteristics relevant to the area of interest: age, sex, ethnic origin, comorbidity, disease status, community- or hospital-based.
Intervention	treatment, procedure or test studied. If important for the study, specify duration of treatment. For diagnostic studies the intervention is the diagnostic test plus associated treatment studied.
Comparison	placebo or alternative treatment. For diagnostic studies, comparison of the test is with another test and treatment strategy.
Length of follow up	length of time that patients take part in the study for, from first staging treatment until either a pre-specified end-point (for example, death, specified length of disease-free remission) or the end of the data-gathering phase is reached. If the study is stopped earlier than originally planned for any reason, this should be noted here.
Outcome measures	list all outcome measures defined in the review protocol, including associated harms. For
Effect size	raw data from the study that allow analyses such as absolute risk reduction and relative risk (reduction), number needed to treat, number needed to harm, odds ratios, as required. Confidence intervals should be given whenever possible.
Funding source	Funding organisation & role of funding organisations
Other relevant information	Eg flaws, additional questions or issues

The strengths and limitations of the body of evidence should be assessed and recorded and any areas of uncertainty acknowledged .

The GRADE (Grading of Recommendations Assessment, Development and Evaluation) method should be used for systematically assessing the strengths and limitations of the evidence base, and details of this should be included within the guideline, normally as an appendix. The GRADE approach has been used in the development of NICE clinical guidelines since 2009 (<http://www.nice.org.uk/article/PMG6/chapter/6-Reviewing-the-evidence>).

Details of the GRADE system are included in Appendix 2.

PRODUCING RECOMMENDATIONS

After reviewing all of the evidence a formal consensus process (eg Delphi) should be used to arrive at recommendations. The exact method of carrying this out should be recorded. This may not be included in the final guideline but could be added as an appendix.

If there is disagreement within the GDG about the recommendations to be drawn from the evidence then a face to face meeting between those holding the conflicting views chaired by the GDG Lead or other suitable person (eg Dean of FDS or Chair of CSC) should occur. Any final disagreements about the recommendations to be drawn from the evidence must be documented in the guideline.

The health benefits and side effects and risks will be considered in formulating recommendations. For example: Eg survival, quality of life, adverse effects, harms and symptoms management or a discussion comparing one treatment option to another will be considered prior to formulating recommendations.

WRITING THE GUIDELINE

Co- authors write draft review guidelines based on their specific area of expertise and responsibility. These are then circulated to the GDG for comments and amendments before being peer reviewed.

The aims and objectives should be clearly stated at the commencement of the guideline.

The main audience for whom the guidance has been written, should be clearly stated.

If various sections are intended for different audiences, this should also be clarified at the beginning of the document, with an indication of the change in intended readership at the start of each section.

During the peer review stage, representatives of each audience group should have the opportunity to read the sections of relevance to them and be encouraged to identify any ambiguous, unclear or difficult narrative.

In some cases a separate patient information leaflet (PIL) should be considered if there is perceived benefit to the audience.

Authors are also encouraged to refer to the guides provided by the *Plain English Campaign* at <http://www.plainenglish.co.uk/free-guides.html>

Authors are requested where possible, to divide the substantive part of the guideline into three sections:

- literature review
- concise clinical guideline

- a patient information leaflet (PIL) (if appropriate)

The cover of an FDS clinical guideline will present the following information:

- guideline title
- logo/name of sponsoring body (Faculty of Dental Surgery of the Royal College of Surgeons of England) and any associate bodies (most likely specialty societies)
- authors
- date of literature search
- date of publication
- date of last update
- date of expiry
- date of commencement of next review

PRESENTING RECOMMENDATIONS

Recommendations should be specific, unambiguous and clearly identifiable. Visual tools, such as tables, flowcharts and colour-coding of sections should be considered. Guidance should be concise, with a view to being used in a clinical setting.

Where an issue can be addressed in different ways within a specific area, all of the options should be stated. These may be broken down into the specific circumstances as to when one option may be preferred over another, with a link to the evidence base. It must be made clear what set of circumstances each and every recommendation applies to.

In some instances if the evidence is not clear cut and there is uncertainty or disagreement over the best care options, this uncertainty should be stated in the guidance with supporting evidence.

SUPPORT TOOLS

A guideline should, where appropriate, include support tools to aid implementation of the guideline's recommendations. These should be listed in the guideline's contents page. Such tools might include:

- summary document and quick reference guide
- algorithms
- information on development of the validation procedures and implementation tools
- information leaflets, including easy read versions for people with a sensory impairment or disability
- information on how the guidance can be adapted for delivery in all settings (e.g. domiciliary setting or hospital ward) and its recommendations disseminated therein
- guidance on access to other useful tools and resources, including websites and apps
- appendices and resources
- outcomes from the pilot and learning outcomes from the guideline

PEER REVIEW

Following production of a draft of the guidelines they must undergo a process of external review. The primary reason for this may vary between different guidelines but include improving quality, gathering feedback, assessing applicability and disseminating evidence.

Once a draft guideline has been produced it will normally first of all be reviewed by the specialty organisations whose representatives have authored the draft guideline. The dental specialty organisations that the CSC represents create and revise their own single-specialty guidelines. Their professional input should always be sought at the first stage of the peer review process. Comments will be fed back to the authors and the guideline amended appropriately.

The draft guideline will then be peer reviewed by the CSC as a whole. This will ensure that every dental specialty has a chance to comment. Each specialty representatives will circulate the guideline to their specialty organisation. The FGDP and PLG will also be invited to comment.

All comments will be fed back to the guideline authors so that any necessary amendments can be incorporated into a final draft.

The final draft will then be reviewed by the CSC.

PUBLICATION

If and when final approval is given by the CSC, the guideline will then be formatted by the RCS Publications Department to produce a final PDF document. A printed version will only be available if specific funding has been provided for the purpose by a specialty society or other interested body.

DISSEMINATION

To disseminate the guideline the FDS will:

- publish the guideline on its Clinical Guidelines webpage
- copy the guideline and weblink to the relevant specialty societies
- copy the guideline and weblink to its Regional and Specialty Advisors across the UK
- publicise the document in its monthly Faculty Bulletin
- send a copy to NICE for publication on its website and inclusion in its search database
- send a copy to the British Dental Journal
- publicise the guideline via the FDS Twitter Feed

EVALUATING AND UPDATING

Any guideline that is produced would need to be evaluated; the various components of the evaluation of clinical practice guidelines are shown below:

1. an assessment of awareness of the guideline;
2. an assessment of whether or not clinical practice has changed in line with the guidelines' recommendations;
3. an assessment of whether or not health outcomes have changed;

4. an assessment of the guidelines' impact on patients' and clinicians' knowledge and understanding

These rely on auditing and assessing the guidelines in use within the health service and by health service providers and it is not envisaged that this would be the focus of guideline producers. Any published data based on guideline evaluation would be used when reviewing data for updating guidelines.

Guidelines should be reviewed after five years. However they may be reviewed earlier if there is new significant new evidence emerges that might change the conclusions. The original search strategy should be rerun to obtain the evidence that has emerged since the guideline was last published or reviewed.

If the original authors are unable to undertake an update the CSC will identify reviewers as though the guideline were a new undertaking.

If no changes are required a review date will be put on the front of the document stating that the document has been reviewed and that no changes have been found necessary. The key dates on the front of the document will be amended accordingly.

APPENDIX 1

Table 1: Suggested Criteria for Selecting Guideline Topics

There must be a clear problem that may be resolved by the development and dissemination of the guideline on what is the most appropriate practice. For example, the problem could relate to the extent of the health burden, cost, or variations in practice
The risk benefits of implementing guidelines. For example, impact on patient safety, patient outcome, patient experience equity of access and resource.
The areas of clinical uncertainty as evidenced by wide variation in practice or outcomes
The conditions where effective treatment is proven and where mortality or morbidity can be reduced.
The evidence of effective practice on which to base the guideline recommendations
The GDG must decide on the best way forward that will address clinical need without avoiding duplication and waste of resources
The clinical priority areas for NHS England, local CQUIN

Table 2: Summary of Key principles to consider when developing guidelines

Focus on outcomes. Outcome measures can range from survival rates to quality-of-life attributes.
Utilise the best available evidence and include a statement about the strength of their recommendations. Ideally recommendations must be based on the highest level of evidence, but this may be difficult to achieve in some instances e.g. public health and social science interventions.
When turning the evidence whatever level, quality, relevance or strength into a clinically useful recommendation, judgement and experience of the group developing the guidelines is required.
Be flexible and adaptable to varying local conditions, consider risk-benefits of implementing
Include different target populations; consider geographic and clinical settings, taking into account costs and constraints.
Make provision for accommodating the different values and preferences of patients e.g. when choosing between treatment options.
Once developed and implemented, disseminate to all target audiences.
Following implementation, evaluate impact of guidelines.
Revise regularly

APPENDIX 2

The *GRADE* (Grading of Recommendations Assessment, Development and Evaluation) approach to assessing the quality of evidence

GRADE is a system developed by an international working group for rating the quality of evidence across outcomes in systematic reviews and guidelines; it does not rate the quality of individual studies. *GRADE* can also be used to grade the strength of recommendations in guidelines.

In order to apply *GRADE*, the evidence must clearly specify the relevant setting, population, intervention, comparator(s) and outcomes.

Before starting an evidence review the GDG should apply an initial rating to the importance of outcomes in order to identify which outcomes of interest are both 'critical' to decision-making and 'important' to patients. This rating should be confirmed or, if absolutely necessary, revised after completing the evidence review.

The following features are assessed for the evidence found for each 'critical' and each 'important' outcome from a systematic review:

- study limitations (risk of bias): assessing the 'internal validity' of the evidence;
- inconsistency: assessing heterogeneity or variability in the estimates of treatment effect across studies;
- indirectness: assessing the degree of differences between the population;
- intervention, comparator for the intervention and outcome of interest;
- imprecision (random error): assessing the extent to which confidence in the effect estimate is adequate to support a particular decision;
- publication bias: assessing the degree of selective publication of studies.

Other considerations (for observational studies only):

- effect size
- effect of all plausible confounding
- evidence of a dose–response relationship.

The quality of evidence is classified as high, moderate, low or very low (see *GRADE* website for definitions)

NB - The approach taken by NICE differs from the standard *GRADE* system in two ways:

- It also integrates a review of the quality of cost-effectiveness studies.
- It has no 'overall summary' labels for the quality of the evidence across all outcomes or for the strength of a recommendation, but uses the wording of recommendations to reflect the strength of the recommendation

APPENDIX 3

Stages of FDS Guideline Development



REFERENCES

GRADE

Guyatt et al. J Clinical Epidemiology 64 (2011) 380 – 382

Followed by a series of 8 articles in J of Clin Epidemiology 64 (2011)

THIS SECTION TO BE COMPLETED ONCE TEXT IS FINALISED.

ACRONYMS

CSC Clinical Standards Committee

FDS Faculty of Dental Surgery

FGDP Faculty of General Dental Practice

GDC Guideline Development Group

PLG Patient Liaison Group

RCS Royal College of Surgeons

APPENDIX 4

Conflict of Interest Guidance

1. Introduction

- 1.1 The Royal College of Surgeons of England works to avoid actual and potential conflicts of interest where possible.
- 1.2 The purpose of this document and the attached declaration is to promote transparency and accountability in the work of The Faculty of Dental Surgery of the Royal College of Surgeons and associated Surgical Speciality Associations involved in development of dental clinical guidance and to take steps to avoid any conflict of interest arising as a result of any individual's personal circumstances or membership of, or association with, other organisations.
- 1.3 Individuals involved in the work of the developing and reviewing clinical guidelines are asked to complete the declaration below. Declaring a conflict of interest does not imply that the individual has been influenced by his or her secondary interest. It is intended to make interests (financial or otherwise) more transparent and to allow others participating in the work to have knowledge of the interest when considering the individual's contribution.

2 How to identify a conflict

- 2.1 A conflict of interest is any situation in which an Individual's personal interests or interests they owe to another organisation and those of the clinical guideline arise simultaneously or appear to clash.
- 2.2 When deciding if an interest is relevant, individuals must consider if there is a risk that the interest could be perceived as biasing their decisions in relation to the work of the development of the particular guideline. If there is any doubt whether to register an interest they should consult the Faculty Secretariat for guidance.

When to declare a conflict

- 2.3 Members of the Faculty's Clinical Standards Committee will be asked to declare all conflicts of interest on appointment and then at the start of each peer review process for each individual guideline. The information provided will be held at the College for a period of five years.
- 2.4 Individuals will also be asked to declare at the beginning of each meeting any private interest they have which relates to an item which is due to be discussed. Their involvement in further discussions on that item will be at the discretion of the Chair.
- 2.5 Declarations of interest and any subsequent withdrawal from discussions will be recorded in the minutes.
- 2.6 All Members of a Guideline Development Group will be asked to declare all conflicts of interest on appointment.

FACULTY OF DENTAL SURGERY

This completed form should be returned to the College to hjohnstone@rcseng.ac.uk.

CONFLICT OF INTEREST DECLARATION

Full Name:

Title/Position:

1. Have you at any time accepted income or gifts from an organisation which might be perceived in any way to gain or lose from your involvement in the work of the Clinical Standards Committee/Guideline Development Group?* (Tick any that apply and add details)

	Delete As Appropriate	If YES Please Specify
Funds for a member of staff	YES/NO	
Fees for consultancy	YES/NO	
Funds for research	YES/NO	
Fees for speaking at meeting/symposium	YES/NO	
Sponsorship for attending a meeting	YES/NO	

2. Have you at any time been employed by an organisation which, it may be reasonable to assume, might in any way gain or lose from your involvement in the work of the Clinical Standards Committee/Guideline Development Group?*

Delete As Appropriate	If YES Please Specify
YES/NO	

3. Do you hold stocks or shares, patents (planned, pending or issued) or receive royalties from an organisation which, it may be reasonable to assume, might in any way gain or lose from your involvement in the work of the the Clinical Standards Committee/ Guideline Development Group?*

Delete As Appropriate	If YES Please Specify
YES/NO	

4. Do you have any other competing financial interests (including personal partner/close family member interests)?

Delete As Appropriate	If YES Please Specify
YES/NO	

5. Do you have any other interests not covered by the above categories? (e.g. Trusteeships, governorships, board level memberships of other positions of influence/authority)

Signature:

Date:

The College will not use information on this form for any other purpose than the register. The register will be kept in manual and computer form in accordance with the Data Protection Act 1998.

*delete as appropriate