Public Health England

Protecting and improving the nation's health

Delivering better oral health

Guideline development manual

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Foreword

Since 2007 when ‘Delivering better oral health’ (DBOH) was first published, it has provided key guidance for dental professionals on preventive advice and care for optimal oral health. In addition, it has been used to inform guidance for the wider health and social care workforce and the public. In 2014, Public Health England published the current version of the document, DBOH version 3, which has been well received and extensively used.

The publication of DBOH has led to to a range of positive changes that have increased the likelihood of people in England and Wales, across Europe and in other countries benefiting from improved oral health. The guideline has influenced toothpaste manufacturers to reformulate their products to more effectively prevent tooth decay. Guidance regarding the benefits of fluoride varnish for both children and adult’s teeth has led to a large increase in primary care teams applying fluoride varnish. Dental teams are using advice from DBOH in their interventions with patients, and the preventive advice underpins the Department of Health and Social Care’s dental contract reform programme. It was always intended that DBOH would be updated at appropriate intervals and that the process of updating would also be reviewed, to maintain the quality of the guideline.

Public Health England are now pleased to describe in this manual the methodology to develop the fourth version and future updates of DBOH and provide transparency of the review process. This manual has built on the work of previous iterations of DBOH, through the input of clinical stakeholders and key contributions from systematic review experts Cochrane Oral Health, and NICE-accredited clinical guidance development specialists the Scottish Dental Clinical Effectiveness Programme.

In common with clinical guidelines worldwide it has adopted the GRADE system to assess the certainty of the evidence and uses the AGREE II principles as a code of conduct for the guideline development process. A 3-tier structure has been established to share the key tasks and roles required to progress guideline updates and to ensure collaboration and accountability in the process.

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1.0 Background

'Delivering better oral health: an evidence-based toolkit for prevention' was first published in 2007 at the request of the Department of Health and Social Care (DHSC). It was the result of a collaboration between the British Association for the Study of Community Dentistry, DHSC and the National Health Service (NHS). This collaboration enabled the production of a document to support dental teams in a more preventive approach to dental care, based on current scientific evidence and best clinical practice. In recognition of the enormous amount of information and research available to practitioners, it was intended that 'Delivering better oral health' (DBOH) would provide a simple guide to the most relevant and high-quality evidence. It would explain the practical implications for dental teams, stating the evidence-based preventive advice and interventions that they should provide for all patients and the additional support they should give to those most at risk of the consequences of poor oral health.

DBOH was always intended to be a living document. It was first updated in 2009 (DBOH version 2), and after the Health and Social Care Act of 2012, Public Health England (PHE) took the lead role in its production, publishing the next revision in 2014 (version 3). In 2017, minor but significant revisions were made to DBOHv3[2] in response to changes in policy: the healthier eating section was revised to reflect the publication of the Scientific Advisory Committee on Nutrition's report Carbohydrates and Health (2015)[3], and the alcohol section was updated in line with the Chief Medical Officer's new guidelines on alcohol[4]. In addition, in response to feedback from dental teams, a summary of the oral health advice and care that should be given to adult and child patients was published in 2 'quick guides'[2].

In preparation for DBOH version 4, the guideline development process itself has been reviewed in discussion with colleagues from Cochrane Oral Health, the Scottish Dental Clinical Effectiveness Programme (SDCEP), the Centre for Evidence-based Dentistry and a number of other stakeholders. These groups have been instrumental in the development of this manual.

To assure the quality and transparency of the guideline development process, PHE aims to follow as closely as possible Appraisal of Guidelines for REsearch and Evaluation (AGREE II) principles[5].

1.1 Purpose of this guideline development manual

The purpose of this manual is:

- to improve the quality of and standardise the process for updating DBOH by following as closely as possible AGREE II principles

- to be transparent regarding the guideline development process for updating DBOH

1.2 Overview of the guideline development process

The main stages in the development of DBOH updates are:

- planning - consider stakeholder feedback and agree the scope and key questions for each section, timescales and priorities for the work
- preparation - identify, select, appraise and summarise key evidence in tables and considered judgement forms
- participation - hold online and face-to-face meetings to discuss the evidence with topic experts and public representatives, and formulate recommendations and the content of narrative chapters
- publication - consult with all stakeholders on recommendations and narrative chapters, and finalise content prior to publication

The guideline development process can be seen as a flow chart in appendix 1.

The management structure for updating DBOH is comprised of a development oversight group (‘oversight group’), guideline working group (‘working group’) and 5 guideline development groups. The roles and responsibilities of the groups are described in the following sections.

1.3 DBOH development oversight group

The role of the oversight group is to provide strategic oversight of the entire process and ratification of the final publication, taking into consideration stakeholder views. The main responsibilities of the oversight group are to:

- agree the scope of the work and the structure and content of the updated version
- agree the process for the guideline update including the methodology for assessing the certainty of the evidence and strength of recommendations
- agree timelines and priorities with the working group
- sign off revised copies of summary tables (recommendations) and narrative chapters from the guideline development groups, including any proposed post consultation changes

1.4 DBOH guideline working group

The role of the working group is to undertake the day-to-day work of planning the project and finding, appraising and summarising the evidence on which recommendations will be based. The main responsibilities of the working group are to:

- define and agree, in conjunction with the oversight group, the scope of the work and the key questions
- propose timelines for the work and prioritise tasks
- propose chairpersons and members for the guideline development groups, for approval by the oversight group
- conduct evidence reviews in line with the agreed method and produce evidence tables and considered judgement forms for each of the key questions for the guideline development groups
- convene the guideline development groups and facilitate their work
- update the summary tables (recommendations) and narrative chapters as agreed with the guideline development groups and present to the oversight group for final sign off
- collate feedback from consultations and highlight to the relevant guideline development group where this may require discussion

1.5 DBOH guideline development groups

Guideline development groups are established for each of the 5 main sections of DBOH. Their membership includes key topic experts and a patient representative, and they are led by a chairperson nominated by the working group and approved by the oversight group. The role of the guideline development groups is to produce the recommendations and to decide aspects to be covered in the narrative chapters. Their main responsibilities are to:

- refine the scope and key questions along with the guideline working group before the literature searches are undertaken
- receive evidence tables and considered judgement forms from the guideline working group
- review summary tables (recommendations) and narrative sections of the current version of DBOH in light of the new evidence and recommend any revisions to the working group
- review suggested changes received in response to the draft consultation to consider if any amendments are required

The guideline development groups meet at the outset of the process by teleconference, and then face-to-face at a session facilitated by the working group, where the evidence tables and considered judgement forms are discussed and updated recommendations are agreed. If required, the group may meet via teleconference in response to consultation feedback and to consider any amendments needed. Appendix 2 details information for guideline development group members about their roles and responsibilities.

2.0 Stakeholder involvement

Stakeholders contribute to the process of developing DBOH, through the oversight, working and guideline development groups as well as through engagement with wider stakeholders and users of the guideline.

At the outset of the work views are sought on the previous version. For example, for DBOH v4, the views of wider stakeholders including members of the dental team (dentists, hygienists, therapist and dental nurses), dental consultants and specialists, dental specialist societies, dental academics, postgraduate dental deans, behavioural scientists, members of local government including directors of public health, health visitors and others were sought prior to the commencement of the work, through discussion at meetings and at 2 national stakeholder events. Industry partners were invited to attend an online webinar with a follow-up online survey to capture their views.

During the guideline development process, stakeholders have the opportunity to influence the document as members of the guideline development groups and at the final phase of consultation, stakeholder views are sought on the final draft document.

2.1 Guideline development groups

For each topic, a multidisciplinary guideline development group that includes health professionals (with a particular expertise or experience in the subject area) and a public/patient representative is convened to review and develop the guidance as outlined in Section 1.5 above. Guideline development group members represent a diverse range of professional roles, including a clinical or dental public health chairperson, academic topic experts, members of the dental team (for example, dentist, dental nurse, hygienist, therapist), public health and dental public health representatives. Dental team members are key as they represent end-users of the guideline and individuals who will be aware of the challenges of a given topic. The membership of the working, oversight and guideline development groups will be listed in an appendix in the relevant section of DBOH.

2.2 Equality and diversity

In terms of DBOH content, equality and diversity issues are considered during the preparatory engagement with stakeholders, the scoping of each topic area, face-to-face guideline development group meetings, and the final consultation. Particular attention is paid to those likely to require different dental and oral health care and advice compared to the majority, for example, pregnant women, children and adults with disabilities and older adults living in long-term residential care. Where potential issues are identified as

of concern for a particular subgroup of patients or guideline users, the content may be amended or added to as appropriate to address these.

In terms of the DBOH development process, accessibility is considered for attendance at face-to-face meetings, with modifications put in place where necessary and feasible. Patient representatives are provided with a travel and subsistence allowance to facilitate attendance.

2.3 Declarations of interests

All members of the oversight group, working group and guideline development groups are asked to complete a declaration of interests form on an annual basis to describe any potential interest, whether financial or non-financial (appendix 3). In addition, at the start of each development or oversight group meeting, participants are asked to confirm their declared interests and whether there are any changes to their interests since the last meeting. If the declaration of interest of a working group member changes during the course of the guideline update, they should alert the chairperson of the group at the earliest opportunity. Respondents to the final consultation on the draft publication are asked to declare any financial or non-financial interests.

Prior to approving the chairpersons of the guideline development groups, their declaration of interest form is reviewed by the chairperson and vice chairperson of the oversight group; any conflict of interest identified would make them ineligible to chair the group. Once appointed, the chairpersons of the guideline development groups review members declared interests and any that they believe may be a conflict of interest, are raised with the chairperson or vice chairperson of the oversight group. Where it is agreed that an interest constitutes a potential conflict, management options are considered. These options include the member contributing only as an expert without decision-making powers or being excluded from part or all the development process. The member should be informed of these discussions and decisions should be confirmed prior to the face-to-face meeting. All declarations of interest and decisions about potential conflicts of interest are recorded by the chairperson or vice chairperson of the oversight group.

3.0 Defining the scope

For each topic, the working group produce a provisional scope, and key questions. This is presented to the guideline development group, with whom the working group refine and agree it via teleconference. The working group draft the final scope and it is approved by the oversight group before literature searches begin. The resulting questions are used to develop appropriate search strategies.

4.0 Literature review

For each topic, a transparent and systematic evidence search is undertaken to supplement evidence identified in earlier versions of DBOH. In order to minimise duplication of effort and to use resources efficiently, the working group focuses on identifying existing high quality systematic reviews and guidelines and, as appropriate, policy documents or legislation. The search does not aim to identify and synthesise primary studies, unless there is a clear gap in secondary sources of evidence.

Comprehensive searches of electronic sources are undertaken, including Medline, the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, NICE Evidence and Epistemonikos. Further searching for relevant guidelines/recommendations produced by key organisations such as the National Institute for Health and Care Excellence, Scottish Dental Clinical Effectiveness Programme, American Dental Association, Scottish Intercollegiate Guidelines Network and World Health Organisation is also undertaken. The search for each topic is run from the date of the search in the last version of DBOH onwards, unless a clear need for a broader/narrower search period can be identified by the relevant guideline development group. Unless resources allow, only articles published in English are considered.

The searches are undertaken utilising searches developed by an information specialist. Members of the guideline working group are responsible for screening the search results, independently and in duplicate, to identify systematic reviews and guidelines that address the topic covered. Disagreements in screening may be shared with the oversight group for arbitration if consensus cannot be reached. Included documents are judged for their quality and applicability to the topic under development. Where several high quality systematic reviews and guidelines covering the same topic are identified, the most up-to-date document of the highest quality is used. No attempt is made to appraise all systematic reviews and guidelines addressing a given topic. Should the guideline development groups identify additional systematic reviews or guidelines they believe are relevant, these will be considered.

Identified documents are assessed using the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach for assessing the level of certainty of the evidence[6]. Where a GRADE assessment has been undertaken, repeat assessments are not undertaken unless justified. The working group is responsible for undertaking assessment of the identified evidence and producing evidence tables (see example in appendix 4). The evidence tables provide a summary of the results and conclusions of the review, guideline or policy document, and an assessment of the evidence certainty. The working group draws on these to prepare a considered judgement form for the guideline development groups. For each intervention or statement of advice the considered judgement form will include a short description of

the quality and quantity of the body of evidence and any proposed recommendations for consideration by the guideline development group.

5.0 Formulating recommendations

The final evidence tables and draft considered judgement forms, provide an overview of the synthesised evidence for each clinical question, they are distributed to all members of the relevant guideline development groups in advance of the face-to-face meeting. The evidence tables and considered judgement forms are used to facilitate the discussion and agreement of the clinical recommendations at the meeting.

The development of recommendations also follows the GRADE[7] approach, which considers several factors when determining the strength of recommendations:

- the magnitude of effect of the interventions on important outcomes
- confidence in those estimates
- estimates of typical values and preferences
- variability of values and preferences
- resource use

The guideline development group review the evidence tables, consider the factors listed above and, with the working group, draft or approve potential recommendations and decide the associated strength of the recommendation (strong, conditional, no recommendation, recommendation for research only, good practice). For transparency, all recommendations are linked to the supporting evidence.

Guideline development group recommendations are reached by consensus or, where agreement is not reached, through use of a voting system. All group members' views are important. Where there is disagreement or conflict, this is recorded and, where necessary, highlighted to the oversight group.

6.0 Consultation on the draft guideline

To enable wider input into the development of the guideline, a consultation draft is circulated to all stakeholders involved in the process. Stakeholders are notified of the consultation period and invited to comment by completing a feedback form. This feedback is collated and discussed by the working group: individual comments are reviewed, common themes identified, and proposed responses drafted. Where

necessary, the guideline development group discuss and approve or amend these and pass any revisions to the draft guideline to the oversight group for final sign off prior to publication.

7.0 Endorsement

The development of DBOH is led by PHE and supported by the DHSC, NHS England and specialist society the British Association for the Study of Community Dentistry. Previous versions have been adopted by the Welsh government as Welsh guidance and endorsed by the European Platform for Better Oral Health in Europe as good practice. As each new version is developed, PHE seek to continue to maintain and support these relationships. DBOH is developed by a steering group with representations from key organisations, specialist societies, academic institutions and the wider dental workforce. Key organisations are asked to comment on the draft guideline at the consultation stage and to endorse it.

8.0 Presentation

DBOH has previously been published electronically on the gov.uk website, with free access to all, and under crown copyright. Several versions are available: a full version of the toolkit, which includes summary guidance tables and narrative chapters; the summary tables alone (these are often printed and laminated by dental teams to display in surgeries); 2 quick guides with summary guidance for children and adults.

New formats may be proposed during each iteration, for example, summary flow charts, patient versions and hyperlinks in digital versions. Decisions about appropriate formats are made based on policy, technological developments and stakeholder feedback, with any changes or additions being agreed by the oversight group.

9.0 Communication and dissemination

The PHE communications team supports the launch of new versions by developing a communications plan in collaboration with partner communications leads. All members of the oversight group, working group and guideline development groups are asked to circulate DBOH through their networks and link to the document from their websites.

10.0 Implementation

Implementation of DBOH is a crucial area, which is highlighted repeatedly as an important issue at stakeholder events. Whilst there are many examples of good practice of the implementation of the guidance, translation into practice is unpredictable and can be slow. In view of this, an important part of the guideline development process is to assess the barriers and facilitators to implementation and draw on contemporary evidence regarding guideline implementation to translate findings into practice.

11.0 Updating the guideline

Periodically PHE will consider whether DBOH remains current or requires amendment. A review of the published guideline may be triggered in response to significant changes in policy or research findings and the oversight group will determine the level of urgency. The extent of revision and method of dissemination will be informed by the significance and nature of the update; for example, a notice posted on gov.uk may be sufficient to advise of minor amendments, but more substantive changes may warrant a new edition being published online.

References

1. Scottish Dental Clinical Effectiveness Programme (2019) Guidance Development Process Manual (Version 2). Available from: www.sdcep.org.uk/how-we-work/sdcep-guidance-development-process/

2. Public Health England (2014) Delivering better oral health: an evidence-based toolkit for prevention. Available from: www.gov.uk/government/publications/delivering-better-oral-health-an-evidence-based-toolkit-for-prevention

3.Scientific Advisory Committee on Nutrition (2015) Carbohydrates and Health. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/445503/SACN_Carbohydrates_and_Health.pdf

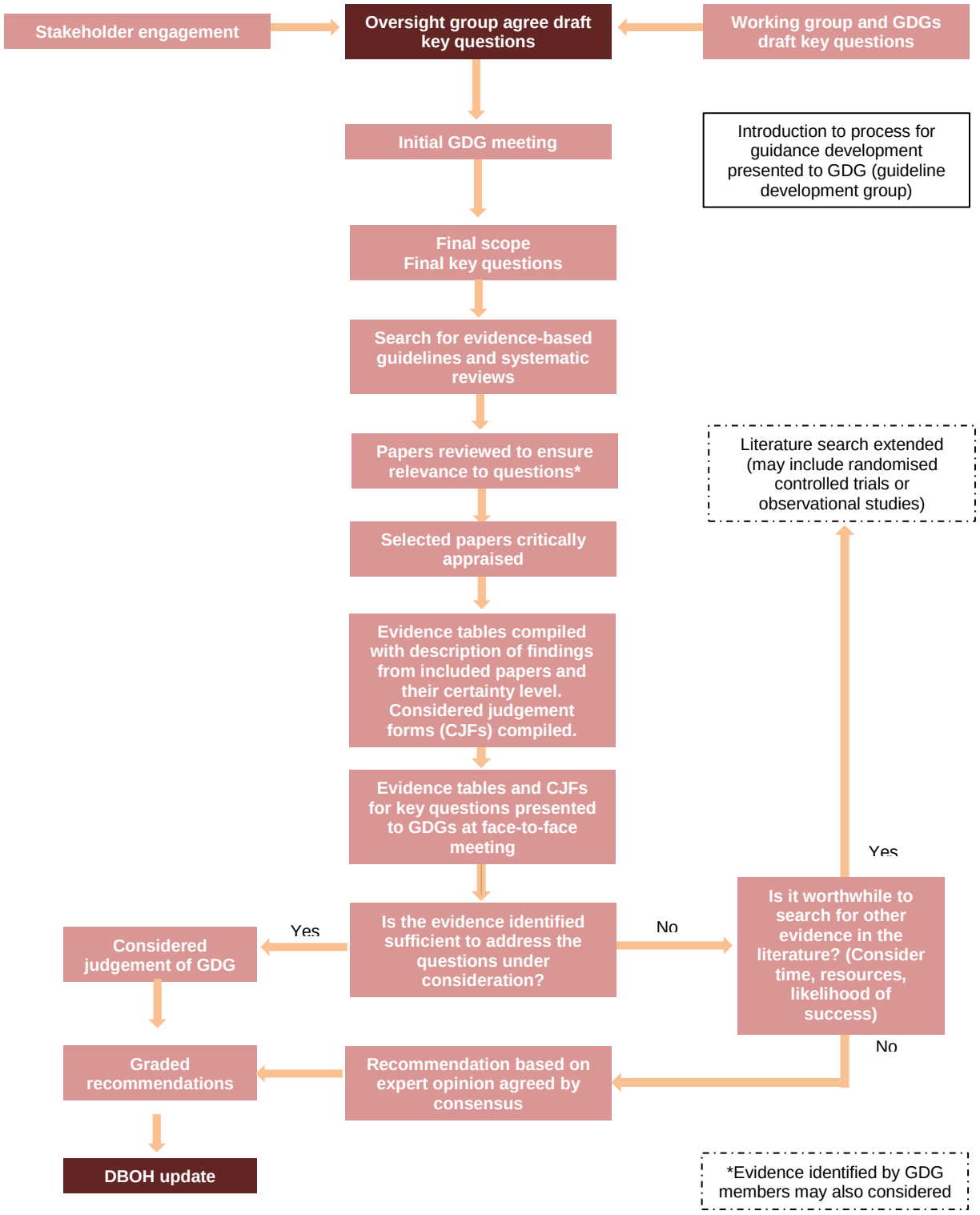
4. Department of Health (2016) UK Chief Medical Officers' Low Risk Drinking Guidelines. Available from: www.gov.uk/government/publications/alcohol-consumption-advice-on-low-risk-drinking

5. AGREE Next Steps Consortium (2017). The AGREE II Instrument. Available from: www.agreetrust.org

6. GRADE Working Group (2016). GRADE. Available from: www.gradeworkinggroup.org/#

7. Andrews et al (2013). GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. Journal of Clinical Epidemiology, 66 (7), 726-735. Available from: www.sciencedirect.com/science/article/abs/pii/S0895435613000541

Appendix 1: Process for the development of DBOH substantive updates



Appendix 2: Information for guideline development group members

The guideline development group (GDG) is responsible for agreeing the content of the summary tables (recommendations) and the narrative chapters of DBOH. To achieve this, GDG members work with the working group and one another under the leadership of an appointed chairperson. This may involve:

- applying professional experience such as general, community or hospital practice, dental public health, academia or health service management
- drawing on personal experience, for example, as a patient with a relevant disease condition or as a carer
- sharing research knowledge and experience on the topic

Responsibilities of the chairperson:

- agree membership of GDG
- address any conflicts of interest
- chair GDG meetings
- provide clinical/public health leadership for group discussions
- encourage all members of the GDG to share their views
- read and approve minutes of GDG meetings
- liaise effectively with the chairpersons of the oversight and working groups
- attend oversight group, guideline development group and working group meetings, where necessary

Responsibilities of GDG members:

- attend all GDG meetings: preliminary teleconference meetings, full-day face-to-face meeting and follow-up (if required)
- participate in group discussion and decision-making during GDG meetings, including identification of key issues, agreement of the scope and key questions and changes or revisions to the summary tables and narrative
- read documentation provided between guideline development group meetings
- bring to the attention of the group any relevant publications or ongoing work
- read drafts of the guideline and provide constructive criticism and suggestions for improvement
- respond to email correspondence and work with the oversight group and working group between meetings, as appropriate
- adhere to deadlines set at guideline development group meetings or provided by the oversight group and working group
- promote DBOH after publication, as appropriate
- maintain confidentiality as requested

Appendix 3: Declaration of interests

Members of the Delivering better oral health (DBOH) oversight group, guideline working group and guideline development groups, are required to complete and sign the following declaration of interest form annually. Please return to the chairperson of your group. Any interest that is judged to be a potential conflict of interest will be discussed and dealt with in accordance with the guidance in this manual and Public Health England policy. Individuals with a conflict of interest are ineligible to chair a guideline development group.

NAME		**POSITION**	
ORGANISATION			
I declare: (please tick) ☐ **Financial interest** ☐ **Non-financial interest** ☐ **No interest**			

I declare the following interests that may be considered to have a bearing on my position in developing DBOH (use a continuation sheet if necessary).

1.	
2.	
3.	
SIGNATURE	
DATE	
Comments:	

SIGNATURE OF CHAIR	
DATE	
The section below is to be completed by chair/vice chair of the oversight group	
Is this a conflict of interest?	**Yes ☐ No ☐**
Action agreed	
SIGNATURE OF CHAIR/VICE CHAIR (DEVELOPMENT OVERSIGHT GROUP)	

Appendix 4: Sample evidence table (fluoride varnish)

Marinho VCC, Worthington HV, Walsh T, Clarkson JE. **Fluoride varnishes for preventing dental caries in children and adolescents.** Cochrane Database of Systematic Reviews **2013**, Issue 7. Art. No.: CD002279. DOI: 10.1002/14651858.CD002279.pub2
www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD002279.pub2/full

Population and setting	**Intervention or risk factors**	**Comparison**	**Outcomes**
Children and adolescents	Fluoride varnish at any concentration (ppm F), amount or duration of application. However, frequency of application should have been at least once a year	Placebo or no treatment	Caries increment in primary (dmfs/t) and secondary dentition (DMFS/T) measured at dentinal level of diagnosis. Preventive fraction (PF) was primary outcome (that is the difference in mean caries increments between the treatment and control groups expressed as a percentage of the mean increment in the control group) Other outcomes: tooth loss, dental pain, specific adverse effects (oral allergic reactions, mucosal irritation, adverse symptoms such as nausea, gagging, vomiting), use of health service resources (such as visits to dental care units, length of dental treatment time)
Included studies	**Additional information**		
22 randomised controlled trials	13 trials contributed data to permanent tooth surfaces 10 trials contributed data to primary tooth surfaces The second question was a secondary objective, to examine whether the effect of fluoride varnish is influenced by fluoride concentration or frequency of use. This was examined by meta-regression investigating heterogeneity for the primary objective. 18 of 22 trials had fluoride dose of 22,600 ppm F. Fluoride application was twice a year in 17 out of 22 trials, 4 times per year in 3 trials. In addition, the review found that effect of varnish applied in populations with different levels of caries risk and exposure		

	to other sources of fluoride (e.g. fluoridated water)

Overall results	**GRADE evidence certainty rating**
Caries Permanent tooth surfaces PF: 43% (95% confidence interval (CI) 30% to 57%) Primary tooth surfaces PF: 37% (95% CI 24% to 51%)	**Moderate**[1]
Fluoride concentration or frequency of application No significant association between fluoride dose or frequency of application with caries was found. Most trials compared 2.26% fluoride varnish applied twice a year, making comparisons between different concentrations and frequency of application difficult.	**Very low**[2]

GRADE rating explanation

1. The certainty of the evidence was downgraded twice due to considerable heterogeneity, and several trials being at high risk of bias; however, the body of evidence showed a consistent, large clinically important effect and was upgraded to moderate certainty.
2. Indirect comparison, only a few trials were included in one group with limited power to detect differences.

OVERALL SUMMARY

There is moderate certainty evidence that fluoride varnish prevents caries in both the permanent and primary dentition.
There is insufficient evidence to support the use of any specific concentration of fluoride varnish or frequency of use, although this must be at least once per year.
There is very low certainty evidence that the effect of varnish did not vary when applied in populations with different levels of caries risk and exposure to other sources of fluoride.

Notes
A review by Mishra et al (2017) included 17 RCTs and other observational studies. Qualitative synthesis reported PF between 5% to 63% for early childhood caries (www.ncbi.nlm.nih.gov/pubmed/28702057).