

Conscious Sedation in Dentistry

Guidance Development Methodology

June 2017

Scottish Dental Clinical Effectiveness Programme

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NICE has accredited the process used by the **Scottish Dental Clinical Effectiveness Programme** to produce its Conscious Sedation in Dentistry guidance. Accreditation is valid for 5 years from 15 March 2016. More information on accreditation can be viewed at www.nice.org.uk/accreditation.

For further information about SDCEP's accreditation, visit www.sdcep.org.uk/how-we-work/nice-accreditation.

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1 Overview of the SDCEP Guidance Development Process

SDCEP first published Conscious Sedation in Dentistry in 2006 and a second edition of the guidance in 2012. In 2016, a Guidance Development Group (GDG) was convened to review and update the guidance in light of certain specific developments since 2012. These include publication of: *Safe Sedation Practice for Healthcare Procedures* by the Academy of Medical Royal Colleges (AoMRC) (2013) and *Standards for Conscious Sedation in the Provision of Dental Care: Report of the Intercollegiate Advisory Committee for Sedation in Dentistry (IACSD)* (2015), and an evidence update for the National Institute for Health and Clinical Excellence (NICE) Guideline: *Sedation in Children and Young People* (2012).¹⁻³

In accordance with SDCEP's guidance development process, the review of this guidance involved also searching for other sources of information and evidence including guidelines and systematic reviews, and appraisal of all eligible sources to assess their quality and to inform their utility as the basis for recommendations within this guidance.

The guidance development process that SDCEP follows has been accredited by NICE (National Institute for Health and Care Excellence; www.nice.org.uk/about/what-we-do/accreditation) and is as described in the SDCEP Guidance Development Process Manual (Version 1.3, February 2016). The review of *Conscious Sedation in Dentistry* followed SDCEP's standard guidance development process as outlined below, with the exception of the first step (topic proposal and selection) which is not relevant for an update:

- Topic proposal and selection;
- GDG selection;
- Scoping including horizon scanning literature review and baseline research on stakeholder attitudes to the topic and proposed guidance;
- Agreement on scope and key clinical questions;
- Preparation of draft guidance for consultation including:
 - Systematic literature review,
 - Evidence appraisal, synthesis and summary,
 - Considered judgements,
 - Formulating recommendations,
 - Grading recommendations;
- Open consultation and peer review;
- Review of consultation feedback and revision of the guidance and other related products;
- Final draft sign off;
- Design for publication;
- Dissemination and Implementation.

For further details of the standard process see the SDCEP Guidance Development Process Manual available at www.sdcep.org.uk/how-we-work/sdcep-guidance-development-process/. Consistent with SDCEP's standard guidance development methodology the update of *Conscious Sedation in Dentistry* aimed to be transparent, systematic and to adhere as far as possible to

international standards set out by the AGREE (Appraisal of Guidelines Research and Evaluation) Collaboration (www.agreetrust.org).

Specific details of the methodology used for the update of the *Conscious Sedation in Dentistry* guidance are presented either in the full guidance (www.sdcep.org.uk/published-guidance/sedation/) or in the following sections of this methodology document.

For further details, queries or requests for unpublished information, please contact SDCEP using the details provided on the front page of this document.

2 The Guidance Development Group

The following Guidance Development Group (GDG), comprising individuals from a range of branches of the dental and medical professions, with expertise and experience in dental sedation, along with patient representatives, was convened to update the guidance.

Vince Bissell (Chair)	Professor of Restorative Dentistry and Dental Education; Deputy Head of the Dental School, University of Glasgow
Mick Allen	Specialist in Special Care Dentistry, Newport; Post-graduate Sedation Tutor Wales Deanery
Lucy Burbridge	Consultant in Paediatric Dentistry, Newcastle Dental School; British Society for Paediatric Dentistry Representative
Francis Collier	Specialist in Special Care Dentistry, NHS Grampian.
Barry Corkey*	Specialist in Paediatric Dentistry, NHS Fife; Honorary Senior Lecturer, Edinburgh Dental Institute
Paul Coulthard	Professor of Oral and Maxillofacial Surgery; Head of School of Dentistry, University of Manchester
Giju George	Consultant Anaesthetist, Royal Liverpool and Broadgreen University Hospitals NHS Trust; Association of Dental Anaesthetists Representative
Abigail Heffernan	Consultant in Special Care Dentistry, Dundee Dental Hospital
Paul Howlett	General Dental Practitioner, Teesside
Dagmar Kerr	Patient Representative; Area Coordinator for Greater Glasgow & Clyde, Action for Sick Children Scotland
Karin Laidlaw*	Specialist Dental Nurse Tutor, NHS Education for Scotland, Edinburgh
Clare Ledingham	Specialist Paediatric Dentist, Liverpool Community Health NHS Trust; Honorary Secretary, BSPD
Simon Morrow	General Dental Practitioner, Ayrshire; Sedation Practice Inspector, NHS Ayrshire & Arran, NHS Greater Glasgow & Clyde, NHS Lanarkshire
Robin Smith	Patient Representative, Lothian
Peter Walker	Senior Dental Officer (Lead Sedationist), Stobhill Hospital, NHS Greater Glasgow & Clyde; NES Lecturer in Sedation; Honorary Clinical Sedation Teacher, University of Glasgow

*Members of GDG for 2006 and 2012 editions of this guidance

Scheduled meetings of the GDG took place as part of the guidance development process. The minutes of these meetings are available from SDCEP on request.

3 Scoping Research

Research to inform the scope and content of the updated guidance was carried out by SDCEP and their research collaborators TRiADS (Translation Research in a Dental Setting; www.triads.org.uk), following the TRiADS framework for translating guidance recommendations into practice.⁴

SDCEP carried out initial scoping work to gain an overview of the current provision of dental sedation and of sedation training across the UK, and to identify and understand possible issues arising in response to the *Standards for Conscious Sedation in the Provision of Dental Care* (2015) Report of the Intercollegiate Advisory Committee for Sedation in Dentistry (IACSD).² This involved semi-structured telephone interviews with more than 20 individuals across the UK involved in the provision of sedation or sedation training within the hospital, public/community dental service or general dental practice, or in other roles. Interviewees were invited to comment on the SDCEP *Conscious Sedation in Dentistry* (2012) guidance, on the IACSD Report and on the provision of dental sedation in general.

The IACSD shared with SDCEP much of the feedback it had received about the Report, along with the responses the IACSD provided to individuals. This and the responses provided as Frequently Asked Questions (FAQs) on the Royal College of Surgeons England Faculty of Dental Surgery website were also examined as part of the scoping. The report on the findings can be found in [Appendix 1](#). A number of the points initially raised in the scoping report were subsequently addressed through further discussions with the IACSD, new IACSD FAQ answers and other developments. These are described in the update to the scoping report found in [Appendix 1](#).

Patient experiences and views on dental sedation were obtained through telephone interviews conducted by TRiADS with patients, parents and carers. A report on this is available along with further information on the [TRiADS](#) website.

4 Clinical Questions

Clinical questions relevant to the scope of the guidance were drafted by the SDCEP Programme Development Team (PDT) based around the recommendations made in sections 2-9 of the SDCEP *Conscious Sedation in Dentistry* guidance 2nd Edition (2012). These formed the basis for the evidence summaries and considered judgements made by the GDG.

2 Preparation for Sedation

For patients undergoing dental treatment under sedation:

- 2.1 what factors should be assessed to determine the suitability of the use of sedation?
- 2.2 who should make the assessment and how should this be carried out and recorded?
- 2.3 how should consent be obtained for sedation?
- 2.4 what information should be provided to the patient before sedation?
- 2.5 what instructions should be given about eating and drinking before sedation?
- 2.6 what escort arrangements are required?
- 2.7 what facilities should be available?
- 2.8 what equipment should be available (for delivery of sedation, monitoring and management of complications)?
- 2.9 what staff are required for each sedation technique?

3 Conscious Sedation Techniques

For patients undergoing dental treatment under sedation:

- 3.1 which is the preferred (i.e. effective and safe) method of sedation (including drug, route)?
- 3.2 what alternative forms of sedation are acceptable and in what circumstances (e.g. indications, settings)?
- 3.3 what form of monitoring is required for each sedation technique to reduce the risk of and identify complications?

4 Conscious Sedation for Children

For child patients undergoing dental treatment under sedation:

- 4.1 which is the preferred (i.e. effective and safe) method of sedation (including drug)?
- 4.2 what alternative forms of sedation are acceptable and in what circumstances (e.g. indications, settings)?
- 4.3 what form of monitoring is required for each sedation technique to reduce the risk of and identify complications?

5 Conscious Sedation for Adults and Children with Special Care Needs

For patients with special care needs that affect provision of their dental care and who are undergoing dental treatment under sedation:

- 5.1 which is the preferred (i.e. effective and safe) method of sedation (including drug)?
- 5.2 what alternative forms of sedation are acceptable and in what circumstances (e.g. indications, settings)?
- 5.3 what form of monitoring is required for each sedation technique to reduce the risk of and identify complications?

6 Recovery and Discharge
For patients undergoing dental treatment under sedation: <ul style="list-style-type: none"> 6.1 when should monitoring stop? 6.2 what discharge criteria are required? 6.3 what aftercare instructions are required?
7 Records and Documentation
For patients undergoing dental treatment under sedation: <ul style="list-style-type: none"> 7.1 what records are required before, during and after treatment under sedation? 7.2 what information should be provided to patients/carers/escorts before and after sedation and in what format? 7.3 what additional information is required for child patients?
9 Training
9.1 What generic and specific skills and training are required for each member of the team and for each sedation technique?

5 Literature Search

The guiding principle for developing guidance within SDCEP is to first source existing guidelines, policy documents, legislation or other recommendations. Similarly, relevant systematic reviews are also identified. These documents are appraised for their quality of development, evidence base and applicability to the remit of the guidance under development. In the absence of these documents or when supplementary information is required, other published literature and unpublished work may be sought.

For this guidance, a comprehensive search of MEDLINE, EMBASE, CINAHL, the Cochrane Database of Systematic Reviews and the Cochrane Database of Abstracts of Reviews of Effects (DARE) was carried out on 12 April 2016 and of the National Guidelines Clearinghouse on 13 April 2016. No date limits were applied. Each database was queried with a combination of sedation and dental terms and 1252 records were retrieved in total. These literature searches were performed by the Trials Search Co-ordinator, Cochrane Oral Health Group. The details of the searches can be found in [Appendix 2](#).

Potentially eligible articles were identified from the list of titles and abstracts retrieved. This article selection was carried out independently in duplicate by researchers within SDCEP and the Cochrane Oral Health Group. An article was considered eligible if it met all of the following criteria:

1. The article was a systematic review or a guideline. For this purpose, an article would be included as a systematic review, if it included a methods section, a search of one or more

electronic databases and a table of included studies. An article was included as a guideline if it made recommendations for clinical practice.

- The article referred to sedation for the provision of dental care that is consistent with the agreed definition of conscious sedation (stated in Section 1.3 of SDCEP's *Conscious Sedation in Dentistry* (2012)).

The search results were also screened for any articles relevant to sedation training or patient views and preferences on dental sedation.

Full copies of all potentially eligible articles were retrieved and further checked against the criteria. Additional manual searching of other resources including NHS Evidence and BioMed Central for dental AND sedation, searching of specialist society websites and follow up of citations from relevant articles found through the systematic searching was also carried out. Other sources of evidence were identified by GDG members. A summary of the 13 guidelines and 7 systematic reviews appraised for this guidance can be found in [Appendix 3](#).

6 Evidence Appraisal and Synthesis

Eligible articles relevant for each of the clinical questions were identified. Precedence was given to the most recent articles, where of suitable quality, published in English. A reviewer assessed the full text of each article and extracted the information applicable to the clinical question. The evidence appraisal form for each of the relevant articles can be found in [Appendix 4](#).

For the development of this guidance SDCEP used the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach to assess and rate the quality of evidence presented in the systematic reviews (www.gradeworkinggroup.org). The GRADE framework is a widely accepted system for grading both the evidence and the recommendations, and is used internationally by other guideline producers.

After systematic consideration of a number of criteria, including the study types and potential risk of bias, a GRADE 'quality of evidence' rating was assigned to the evidence relevant to a clinical question. GRADE evidence ratings are defined by the GRADE working group as:

<i>High quality</i>	<i>We are very confident that the true effect lies close to that of the estimate of the effect.</i>
<i>Moderate quality</i>	<i>We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.</i>
<i>Low quality</i>	<i>Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.</i>
<i>Very low quality</i>	<i>We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.</i>

The GRADE evidence ratings for the outcomes from each of the systematic reviews are recorded in the summary table in [Appendix 3](#) and in the respective evidence appraisal forms ([Appendix 4](#)).

For guidelines, the AGREE II instrument was used to assess the methodological quality of the retrieved articles (www.agreerust.org). The AGREE II instrument is a simple and validated assessment tool that provides an overall quality score for each guideline and an indication of how reliable the guideline might be. Since relevant systematic reviews were lacking for many of the clinical questions, recommendations within the updated SDCEP guidance were informed to a greater extent by the guidelines. Consequently, for quality assurance, the guideline AGREE assessments were carried out independently in duplicate by reviewers from SDCEP and the Cochrane Oral Health Group. Where the scores for a given criterion differed by 2 or more, a third reviewer reconsidered the criterion and a moderated score was agreed and assigned. The overall moderated scores are recorded in the evidence appraisal forms in [Appendix 4](#). For clarity, methodological ratings for guidelines are also shown as one of four levels based on the AGREE scores (Very low: 1; Low:2/3; Moderate:4/5; High: 6/7). These methodological ratings are included in the summary table in [Appendix 3](#). The appraisal forms produced by the AGREE II tool used for assessing guidelines are available on request.

7 Considered Judgements and Development of Recommendations

The synthesised evidence from guidelines and systematic reviews for each clinical question was summarised ([Appendix 5](#)) and distributed to members of the GDG prior to meetings of the group to inform and facilitate the development of the recommendations in the guidance. The process for development of recommendations was informed by the GRADE approach, in that considered judgements were made for each clinical question based on the quality of evidence, the balance of risks and benefits, the values and preferences of patients, and the practicalities of the treatment or care. The impact of potential barriers to implementation of the recommendations, which were identified during guidance development and through stakeholder involvement and external consultation, was also considered.

According to GRADE the strength of a recommendation may be defined as:

<i>Strong for/or strong against</i>	<i>The guideline panel is confident that the desirable effects of an intervention outweigh its undesirable effects (strong recommendation for an intervention) or that the undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention). A strong recommendation implies that most or all individuals will be best served by the recommended course of action.</i>
<i>Weak for/or weak against (or conditional)</i>	<i>A weak recommendation is one for which the desirable effects probably outweigh the undesirable effects (weak recommendation</i>

	<p><i>for an intervention) or undesirable effects probably outweigh the desirable effects (weak recommendation against an intervention) but appreciable uncertainty exists.</i></p> <p><i>A weak recommendation implies that not all individuals will be best served by the recommended course of action.</i></p>
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The evidence summaries, GDG consideration of the criteria and the resulting outcomes for each recommendation are recorded in the Considered Judgement Forms (one for each clinical question) which can be found in [Appendix 5](#). Some of the recommendations were subject to further review and revisions by the group during the course of the guidance development process.

For the clinical questions underpinning this particular guidance, much of the evidence identified comprised other guidelines, most of which were themselves derived from expert opinion. Consequently, key recommendations informed by these guidelines were designated as based on expert opinion and since this is not recognised as a category of quality of evidence by GRADE, were not assigned a strength. Nonetheless, they are considered to be standard professional practice important for the provision of safe and effective care. Brief explanations of the basis for each recommendation are included in the guidance text.

8 Consultation and Peer Review

A wide range of individuals and organisations with an interest in this topic were given advance notice of open consultation on the draft guidance. The four-week open consultation period was initiated in January 2017 and notification of this was sent to a wide range of individuals and organisations across the UK with a particular interest in this topic, in addition to professional bodies and charities representing patient groups. During this period the consultation draft was available on the SDCEP website for comment with a consultation feedback form provided to facilitate the process. Implementation interviews with potential end-users of the guidance also took place at this time.

Topic experts, experienced sedationists and guidance/evidence appraisal methodologists were invited to contribute to targeted external peer review by providing feedback on the guidance, the recommendations and in particular the guidance development process used. The eight peer reviewers who provided feedback included two consultant anaesthetists, two consultants in special care dentistry, a consultant in paediatric dentistry, a consultant in dental public health, a general dental practitioner and an evidence-based dentistry methodologist. These peer reviewers were asked to declare any interests.

All comments received through the consultation and peer review process were reviewed, the feedback was considered by the GDG, and the guidance was amended accordingly prior to publication. The compiled feedback comments and GDG responses are available on request.

9 Updating guidance

A review of the context of this guidance (e.g. regulations, legislation, trends in working practices, evidence) will take place three years after publication and, if this has changed significantly, the guidance will be updated accordingly.

10 Conflicts of Interest

All contributors to SDCEP, including members of the GDG and external expert peer reviewers, are required to complete an SDCEP Declaration of Interests form to disclose relevant interests including financial conflicts of interest, such as receipt of fees for consulting with industry, and intellectual conflicts of interest, such as publication of original data bearing directly on a recommendation. These forms are held by SDCEP, updated yearly and are available on request. At the beginning of each group meeting during guidance development, participants are asked to confirm whether there are any changes to their Declaration of Interests.

Declared interests which could have potentially constituted a conflict of interest were considered by the SDCEP PDT, the GDG chair and the group to decide whether and how the extent of the individual's participation in the guidance development should be limited (e.g. exclusion from certain decisions or stages, or complete withdrawal).

Further information on SDCEP's approach to conflicts of interest is available in the [SDCEP Guidance Development Process Manual \(version 1.3, February 2016\)](#).

The Declarations of Interest forms for all individuals involved in the *Conscious Sedation in Dentistry* guidance update project are available on request. A summary of the declarations and the consideration of potential conflicts of interest and management decisions are provided in the following table.

Summary of Disclosures
<p>All of the GDG members, peer reviewers and members of the SDCEP PDT completed and returned the Declaration of Interests form. The Clinical Chair of the GDG had no declared interests.</p> <p>Professional roles in sedation provision, teaching or inspection through employment within non-commercial organisations were not considered to be a conflict of interests. A number of group members declared membership of committees or societies relevant to dental sedation, but this was also considered unlikely to lead to a conflict of interest.</p> <p>Four of the fifteen external GDG members disclosed direct financial interests relevant to the guidance topic which could potentially cause, or be perceived to cause, conflicts of interest.</p> <p>None of the SDCEP PDT members had any interests relevant to the guidance.</p>

GDG member	Details of interest(s) relevant to guidance
Francis Collier	1. Occasional fee paid sedation provision for other dental practices
Giju George	2. Private clinical work at Spire Liverpool Hospital and at Mellow Dental 3. Private sedation training for doctors, nurses and dentists (Mellow Dental)
Paul Howlett	4. Partner in Queensway Dental Clinic – private sedation provider
Simon Morrow	5. Practice Principal, Three Towns Dental Care – private sedation provider 6. Director of Scottish Sedation Training – private provider of sedation training.
Consideration of potential to cause conflict(s) of interest	
<p data-bbox="188 645 1369 707"><i>Are these interests likely in any way to affect the impartiality of the group member in his/her role in the guidance development e.g. in making recommendations?</i></p> <p data-bbox="188 719 1369 786">1, 2, 4, 5 It was considered that any recommendations made in the guidance would be unlikely to directly impact in a positive or negative way on income from private sedation provision.</p> <p data-bbox="188 797 1390 902">3, 6 Although recommendations made in the guidance may have an impact on the national standard of sedation training required by practitioners, no recommendations will be made which give preference to or disadvantage individual training providers.</p> <p data-bbox="188 913 1299 981">The declared interests are considered unlikely to cause (or be perceived to cause) a conflict of interests.</p>	
Decision on the management of the conflict(s) of interest	
<p data-bbox="188 1055 1321 1122"><i>Should the group member be excluded from any stages of guidance development or decisions, or be asked to withdraw from the process?</i></p> <p data-bbox="188 1133 1342 1238">Agreed with GDG chair at GDG meeting of 16 June 2016 that no action was required at this point. GDG members were notified that if at any point in the guidance development they felt that their impartiality could be affected, then they should contact SDCEP or the group chair to advise of this.</p> <p data-bbox="188 1249 1401 1317">Two of the peer reviewers also provide sedation training and/or sedation on a private basis. For the reasons discussed above, these interests were considered to be unlikely to cause a conflict of interests.</p>	

11 Equality Impact Assessment for the Guidance

The potential for any work carried out by SDCEP, within the Clinical Effectiveness workstream of NHS Education for Scotland (NES), to discriminate against or disadvantage any group of individuals has been considered through an [Equality Impact Assessment \(EQIA\)](http://www.nes.scot.nhs.uk/about-us/equality-and-diversity/equality-impact-assessments.aspx) published on the NES website (<http://www.nes.scot.nhs.uk/about-us/equality-and-diversity/equality-impact-assessments.aspx>).

The possibility of inequalities associated specifically with the *Conscious Sedation in Dentistry* guidance was considered at various stages during guidance development, in accordance with the EQIA. Potential issues were identified through discussions with guidance development group members, from interviews with practitioners and patients and from feedback from the external consultation.

Briefly, the issues identified mostly related to the potential for the guidance recommendations to disadvantage certain patient groups by affecting aspects of sedation service delivery. Examples include:

- patients in remote and rural locations if required to attend a pre-sedation assessment appointment;
- children in rural regions that do not have a paediatric specialist/consultant;
- ASA grade III/IV patients if they are automatically referred to another service for treatment;
- young children with acute trauma or sepsis who would normally have oral sedation but will now have to be referred for general anesthesia (because of requirements for advanced sedation);
- patients whose usual method of communication is not appropriate for use during sedation.

While the groups identified are not those specifically described by the legally protected characteristics defined in the Equality Act 2010, the issues were given full consideration by the GDG. The GDG agreed on the importance of balancing the need for equitable treatment with the need for patient safety, noting that in some cases the need to ensure patient safety and care would override potential discrimination in terms of access to treatment. Several of the recommendations made in the consultation draft of the guidance were reconsidered and revised to address the potential equality issues described.

Further details of the issues identified and specific actions taken or planned are recorded in an EQIA checklist which is available on request.

12 Acknowledgements

SDCEP would like to acknowledge Anne Littlewood, Anne-Marie Glenny, Tanya Walsh and Helen Worthington of the Cochrane Oral Health Group for performing literature searches and contributing to evidence selection and appraisals, and Colin Halliday, Jose Marshall and Karen Gordon, NHS Lothian, for advice on the learning outcomes listed in Appendix 2. SDCEP also wish to acknowledge representatives of the Intercollegiate Advisory Committee for Sedation in Dentistry (IACSD), David Craig, Richard Ibbetson, Kate Rivett and Anna-Maria Rollin for their feedback and other personal communications during the guidance development process. SDCEP is grateful to individuals who participated in interviews during scoping and consultation, to all those who provided feedback through consultation and to peer reviewers.

Appendix 1 – Scoping Report

Note that since the production of this scoping report a number of the points raised within it have been addressed through further discussions, new IACSD FAQ answers and other developments. These are summarised in an update at the end of the report.

Scoping Report May 2016

SDCEP agreed to update their *Conscious Sedation in Dentistry* guidance. The most significant development in the area of dental sedation since publication of SDCEP's guidance in 2012 has been the publication of the *Standards for Conscious Sedation in the Provision of Dental Care (2015) Report*² of the Intercollegiate Advisory Committee for Sedation in Dentistry (IACSD). To inform the guidance update, SDCEP carried out scoping work to gain an overview of the current provision of dental sedation and of sedation training across the UK and to identify and understand possible issues arising in response to the IACSD Report.

Semi-structured interviews with more than 20 individuals across the UK involved in the provision of sedation or sedation training within the hospital, public/community dental service or general dental practice, or in other roles, were carried out. Interviewees were invited to comment on the SDCEP *Conscious Sedation in Dentistry (2012)* guidance, on the IACSD Report and on the provision of dental sedation in general.

The IACSD shared with SDCEP some of the feedback received about the Report, along with the responses IACSD provided to individuals. This and the responses provided as [FAQs](#) on the Royal College of Surgeons England website were also examined as part of the scoping.

The findings are as follows. Please note that these are based on the opinions of individuals and may not reflect the views of all sedation providers and trainers.

General points:

SDCEP guidance:

For those familiar with this document, SDCEP's 2012 guidance was acknowledged as being clear, easy to use and well laid out. The inclusion of the basis for recommendations was valued by users (though some noted that the main recommendations were mandatory or based on expert opinion rather than evidence-based). Several of the interviewees suggested that the scope of the updated guidance should be widened to be more in line with the areas of sedation included in the IACSD Report e.g. to include more on alternative anxiety management strategies and advanced sedation techniques and to provide an increased range of patient information. Further suggestions made were to include more detailed information about life support, training, audit, consent and ASA levels.

IACSD Standards Report:

Regarding the IACSD Report, while some of the opinions and concerns differed across the dental service and between countries, there were also common themes identified. Many of the individuals interviewed were supportive of the Report and its aspirations for dental sedation. Particular areas that were acknowledged as improvements included the recommendations around more consistent validated training, those for ongoing CPD and for audit. A number of individuals were aware of the challenges in developing standards that are acceptable from both dental and medical perspectives.

General issues raised included uncertainty around some aspects of the Report, which has led to confusion about how to comply with the standards. This is causing difficulties in commissioning of sedation services. It was reported that the FAQs developed by the IACSD have gone some way towards addressing this, but that further elucidation would be beneficial for some aspects. A number of individuals advised that an indication of the basis (whether evidence-based, expert opinion, regulatory etc) for each of the standards set would aid acceptance and implementation of the IACSD Report.

Some individuals were concerned about the perceived lack of consideration given to possible barriers to implementation of the standards across the UK and the potential impact on sedation provision. That the standards were introduced with immediate effect from publication without time to make provision for complying with them, for example before the provision of approved training could be established, has exacerbated these concerns.

Specific points:

Several specific points relating to the IACSD Report were commonly identified. To a great extent these reflect the queries already communicated directly to the IACSD committee and which were contained in the feedback provided to SDCEP. These are outlined as follows:

Life support training

- Concerns around the requirement stated in the report for Immediate Life Support (ILS) or Paediatric Immediate Life Support (PILS) training for all members of the dental team was one of the most commonly identified issues.
- Access to suitable life support training and in particular paediatric life support training for dentists is reportedly very difficult.
- Responses provided by the IACSD to individual enquiries report that the Resuscitation Council UK have indicated that ILS and PILS courses may be adapted for the needs of dental sedation.
- The IACSD FAQs currently state that *"Practitioners must be able to provide age-appropriate immediate life support as defined by the main elements of the Resuscitation Council (UK) ILS/PILS training programmes. Alternative courses with equivalent content which are adapted to the needs of dental practice are acceptable: these might also include the management of common sedation, medical and dental emergencies."*
- It was generally felt that this FAQ response is useful. However, identifying which aspects of ILS and PILS would constitute life support training adapted for dental sedation and

who the IACSD consider to be suitable providers of this, would help implementation. Without this there is likely to be inconsistency across the country in levels of life support skills. This could cause issues around defensibility and potential negligence.

- Some have queried the necessity for ILS/PILS training for dental nurses who are assisting with only inhalation sedation, taking into consideration the practicalities (e.g. cost implications and lack of accessibility) of obtaining this training. It would be helpful if the IACSD could confirm the elements of life support training that are suited to these staff as part of life support training adapted for dental sedation.

Sedation training for dentists

- A current lack of availability of validated sedation training courses has been raised as a concern.
- Although there is some indication that training providers are developing suitably validated courses or are in the process of applying for IACSD accreditation, it is not clear when these will be available and if they will meet demand.
- IACSD acknowledged to individual queries that there may be a shortage of places on accredited courses in the short term.
- The suspension of the mentor list from the Dental Sedation Teachers Group (DSTG) and the Society for the Advancement of Anaesthesia in Dentistry (SAAD) is reported to be causing a shortage of mentors for supervised clinical practice to allow completion of training.
- The IACSD FAQs suggest that the criteria for suitability of mentors is still under consideration. A further update on this would be helpful.

Sedation training for nurses

- There appears to be some confusion about the appropriate training required for dental nurses new to sedation. The standards are interpreted by some to require that new dental nurses must complete a validated training course (along with supervised practice) prior to practicing sedation. An alternative interpretation is that in-house training and supervised practice are still acceptable, with the dental nurse encouraged to work towards certified training. It would be helpful if the IACSD could indicate the intended interpretation.
- The IACSD FAQs indicate that the National Examining Board for Nurses (NEBDN) *Certificate in Dental Sedation Nursing* (CDSN) is not mandatory but that all dental nurses should be encouraged to work towards this. It is possible that some have interpreted this to mean that validated training of any kind is not compulsory although it should be encouraged. It would be helpful if IACSD could confirm if this is the case.
- Considerable concern has been voiced about the availability and capacity of suitable courses, the cost implications and the length of time it will take to meet the requirements for practice. Significantly increased demand for training has already been noted. Because of the high turnover of dental nursing staff, it is expected that this will cause significant

staffing issues in both the short and longer term and particularly within the general dental service.

CPD

- While the clear statement on the requirement for 12 hours of verifiable CPD per 5 years is considered helpful, some individuals expressed concern about the current lack of availability of verifiable CPD opportunities for sedation.
- The IACSD FAQs and responses to individual queries clarify that although CPD should be verifiable, CPD and update courses do not need to be externally accredited.

Fasting

- The recommendation around fasting provided in the standards is considered by some to be open to varying interpretation. Those who interpret the standard as a requirement for fasting for conscious sedation queried the basis for this.

Monitoring

- A need for further clarity around intra-operative blood pressure monitoring has been raised by some as an issue.
- The IACSD FAQs reiterate that *"NIBP should be performed before and after sedation and at 'appropriate intervals' during the procedure"* with intervals *"determined following individual patient assessment"*.
- Some individuals have questioned the value of intra-operative BP monitoring in addition to clinical monitoring, for ASA I&II patients.
- Others would like further information on what is meant by *'appropriate intervals'* and at what level the BP should be of concern. Scenario based examples may be helpful.

Advanced sedation techniques

- A need has been indicated for further explanation around the terms:
 - *'a team having skills equivalent to those expected of a specialist/consultant in paediatric dentistry'*
 - *'a consultant in anaesthesia competent in sedation for dentistry'*
 - *'a facility equivalent to an NHS Acute Trust in England'*
 - *'equivalent range of skills and facilities to be found in an NHS Acute Trust'*
 relating to the clinical team and environment for advanced sedation provision for children and young people, and for advanced sedation in general.
- The IACSD FAQs suggest that demonstrating whether these descriptors are met may involve discussion with a professional indemnity organisation and external experts.
- The most current FAQs now provide some clarification of the definition of *'a facility equivalent to an NHS Acute Trust'*. Whether this updated FAQ addresses concerns on this point needs to be confirmed with relevant stakeholders.
- IACSD responses to individual queries indicate that the practitioner carrying out the treatment does not have to have validated paediatric consultant/specialist skills and that

the criteria could be met instead by establishing links with a suitable qualified individual through a clinical network. An FAQ that explains this would be helpful.

- Individuals have reported withdrawing the provision of advanced sedation in response to the standards, particularly because of an inability to meet these requirements as they have understood them (e.g. skills equivalent to those expected of a specialist/consultant in paediatric dentistry). Significant concerns have been expressed about the consequent impact on hospital services due to referrals, particularly in England. A further predicted impact is a greater number of children receiving general anaesthesia, if advanced sedation services are not developed in hospital services.

Maintaining competency

- Some individuals reported that the standards are very prescriptive about training requirements for staff new to sedation but unclear about requirements for maintaining competency for existing sedation providers i.e. how many cases of sedation should be carried out a year to remain competent.
- The IACSD FAQs suggest that an indemnity organisation should be consulted, rather than stating a number of cases.
- The IACSD responses to individual queries advise that the number of cases required to achieve competence might be a useful guide. The timescale for this is unclear.

Scoping Report Update May 2017

Several developments relating to the issues identified during scoping occurred during the course of the guidance development process. These developments included further clarification or information about the points and new initiatives. These informed the way in which some of the points were addressed in the guidance update.

Life Support Training

The IACSD confirmed the information presented in its FAQ i.e. that while all practitioners must be trained in life support that is age-appropriate and contextualised to the dental setting, it is not necessary to undertake a Resuscitation Council (UK) ILS/PILS training programme. The essential elements of the training are basic life support, the use of airway adjuncts and the use of an AED. The IACSD further noted that that all GDC registrants, irrespective of involvement in sedation, are required to be trained in dealing with medical emergencies including resuscitation and that elements listed are those recommended by the Resuscitation Council (UK) for all dental healthcare professionals.

Sedation training for dentists and nurses

The IACSD confirmed that the intention of the standards is that all healthcare professionals new to sedation, including dental sedation nurses, should undertake validated training and carry out supervised clinical practice prior to independent practice. The training can be specific for the sedation techniques that will be used.

At the time of this update, the IACSD had confirmed that more than 30 sedation training courses had been accredited. IACSD confirmed that 'in-house' training programmes can apply for accreditation. The IACSD also indicated that it intends to make public a list of accredited sedation training providers.

The IACSD has also launched a scheme to approve clinical supervisors for new trainees (<https://www.rcseng.ac.uk/dental-faculties/fds/publications-guidelines/standards-for-conscious-sedation-in-the-provision-of-dental-care-and-accreditation/application-for-supervisor-approval/>).

Advanced sedation techniques

Regarding '*skills equivalent to those expected of a specialist/consultant in paediatric dentistry*', a new FAQ was made available by the IACSD to explain how this could be demonstrated. Further communication clarified that these paediatric skills particularly relate to treatment planning and do not have to be provided by a single individual within the team. The term 'team' may include wider involvement, where the skills could be provided through contact between the sedation provider and a specialist/consultant in paediatric dentistry via professional networks (e.g. through peer review or annual audit). In regions where there is no local paediatric specialist or consultant, this contact could extend to other regions. These arrangements should be established in advance and evidence of them should be available for inspection. It is not yet clear who would assess compliance.

A new FAQ explaining the requirements for '*skills equivalent to those expected of a consultant in anaesthesia competent in sedation for dentistry*' for anaesthetists and medical and dental sedationists was also made available by the IACSD. Arrangements for assessing compliance with the requirements may be developed by the Royal Colleges.

Regarding the terms '*a facility equivalent to an NHS Acute Trust in England*' and '*equivalent range of skills and facilities to be found in an NHS Acute Trust*', the most recent FAQ indicated that this could include written protocols for managing collapse and adverse reactions, the timely transfer of a collapsed patient to a hospital with appropriate resuscitation facilities, the regular checking of emergency drugs and equipment, current immediate life support training and regular team-based participation in real-time emergency scenarios. Further communications clarified the intention that all of the elements described in the FAQ should be in place for dealing with an emergency for any patient, irrespective of the sedation technique.

Maintaining competency

Further discussion with IACSD around how sedation team members can demonstrate that they are suitably experienced clarified the difficulties in specifying a number of cases over a particular time period that would be appropriate for all healthcare professionals. An individual's level of experience will also be dependent on their accumulated experience, previous frequency of cases and the types of cases (e.g. technique, patient group, complexity) they were involved in.

Appendix 2 – Evidence Searches

SDCEP Sedation – Guidelines and systematic reviews Contact: Michele West Summary of Searches: April 2016 Searches carried out by Trials Search Coordinator, Cochrane Oral Health Group		
Database	Date of search	Records retrieved
Cochrane Database of Systematic Reviews	12 April 2016	76
DARE	12 April 2016	13
MEDLINE via OVID	12 April 2016	596
EMBASE via OVID	12 April 2016	1,079
CINAHL via EBSCO	12 April 2016	95
National Guideline Clearing House	13 April 2016	3
TOTAL RETRIEVED: 1,862 TOTAL AFTER DUPLICATES REMOVED: 1,252 (inc Clearinghouse)		

COCHRANE DATABASE OF SYSTEMATIC REVIEWS (CDSR) AND DATABASE OF ABSTRACTS OF REVIEWS OF EFFECTS (DARE) SEARCH STRATEGY

- #1 [mh Dentistry]
- #2 [mh "oral surgical procedures"]
- #3 (dental or dentist*):ti,ab
- #4 ((oral or periodont*) near/5 surg*):ti,ab
- #5 (pulpotom* or pulpect* or endodont* or "pulp cap*" or apicoectom* or apicectom* or gingivectom* or gingivoplast*):ti,ab
- #6 ((dental or teeth or tooth or molar*) near/5 (fill* or restor* or extract* or remov* or "cavity prep*" or caries or carious or decay* or scal* or polish* or "root plan*" or scrap* or "oral prophylaxis")):ti,ab
- #7 ("root canal" and (therap* or treat*)):ti,ab
- #8 (tooth near/3 replant*):ti,ab
- #9 ((dental or oral) near/2 (implant* or prosthetic*)):ti,ab
- #10 "root surface instrumentation":ti,ab
- #11 ((oral or mouth or dental) near/5 biops*):ti,ab
- #12 (crown* or bridge* or prosthodontic*):ti,ab
- #13 [mh ^"Dental anxiety"]
- #14 ((dental or dentist) and (fear* or anxiet* or phobia*)):ti,ab
- #15 ((special* near/3 (care or need*)) and (dentist* or dental)):ti,ab

- #16 [or #1-#15]
- #17 [mh ^"conscious sedation"]
- #18 [mh "hypnotics and sedatives"]
- #19 [mh "anti-anxiety agents"]
- #20 [mh ^ketamine]
- #21 (ketamine or ketaject or ketalar or ketamina or ketaminum or ketanest or Calipsol or Calypsol or Kalipsol or ketaset):ti,ab
- #22 [mh ^Propofol]
- #23 (propofol or anepol or anespro or anesvan or critifol or diprivan or disoprivan or disoprofol or dormofol or fresofol or gobbifol or hipnolam or hypro or "iv pro" or lipuro or "oleo lax" or plofed or profol or profolen or propofabb or propofil or propofolum or propogen or propolipid or propovan or propoven or provive or rapinivet or recofol or safol or trivam or troypofol or unifol or Aquafol or Ivofol):ti,ab
- #24 [mh ^midazolam]
- #25 (anquil or benzosed or buccolam or dalam or damizol or demizolam or doricum or dormicum or dormid or dormipron or dormire or dormitol or dormixal or dormonid or drimnorth or epistatus or flormidal or fulsed or "fused injection" or garen or gobbizolam or hipnazolam or hipnoz or hypnofast or hypnovel or ipnovel or midazolam or midazolamum or nocturna or setam or talentum or terap or versed):ti,ab
- #26 [mh ^Diazepam]
- #27 (diapam or diastat or diazemuls or diazepam or "methyl diazepam" or nervium or relanium or valium or Apaurin or Faustan or Relanium or Seduxen or Sibazon or Stesolid):ti,ab
- #28 [mh ^Fentanyl]
- #29 (abstral or actiq or duragesic or durogesic or fentanest or fentanil or fentanila or fentanilo or fentanyl or fentanyl or fentanylum or lazanda or nasalent or phentanyl or rapinyl or subsys or fentora or sublimaze):ti,ab
- #30 [mh ^"nitrous oxide"]
- #31 ("nitrous oxide" or "laughing gas" or "nitrogen protoxide"):ti,ab
- #32 (sevoflurane or sevorane or Ultane):ti,ab
- #33 [mh ^temazepam]
- #34 (euhypos or norkotral or normison or nortem or remestan or restoril or temaze or temazepam or temtabs or Dasuen or hydroxydiazepam or Levaxol or Methyloxazepam or Nocturne or Normitab or oxydiazepam or Planum or Signopam or Temaze):ti,ab
- #35 [mh ^benzodiazepines]
- #36 (benzodiazepine* or Triazolam or Halcion or Sonata or Zaleplon or Ativan or Lorazepam or Vistaril or hydroxyzine or Xanax):ti,ab
- #37 [mh ^"analgesics, opioid"]
- #38 (opioid* and sedat*):ti,ab
- #39 [mh ^"anesthesia, dental"]
- #40 (sedat* or aneshe* or anaeshe* or analges*):ti,ab
- #41 [or #17-#40]
- #42 #16 and #41

MEDLINE via OVID SEARCH STRATEGY

1. exp Dentistry/
2. exp Oral surgical procedures/
3. (dental or dentist\$.mp.
4. ((oral or periodont\$) adj5 surg\$.mp.
5. (pulpotom\$ or pulpect\$ or endodont\$ or "pulp cap\$" or apicoectom\$ or apicectom\$ or gingivectom\$ or gingivoplast\$.mp.
6. ((dental or teeth or tooth or molar\$) adj5 (fill\$ or restor\$ or extract\$ or remov\$ or "cavity prep\$" or caries or carious or decay\$ or scal\$ or polish\$ or "root plan\$" or scrap\$ or "oral prophylaxis")).mp.
7. ("root canal" and (therap\$ or treat\$)).mp.
8. (tooth adj3 replant\$.mp.
9. ((dental or oral) adj2 (implant\$ or prosthetic\$)).mp.
10. "root surface instrumentation".mp.
11. ((oral or mouth or dental) adj5 biops\$.mp.
12. (crown\$ or bridge\$ or prosthodontic\$.mp.
13. Dental anxiety/
14. ((dental or dentist) and (fear\$ or anxiet\$ or phobia\$)).mp.
15. ((special\$ adj3 (care or need\$)) and (dentist\$ or dental)).mp.
16. or/1-15
17. Conscious sedation/
18. exp "Hypnotics and sedatives"/
19. exp Anti-anxiety agents/
20. Ketamine/
21. (ketamine or ketaject or ketalar or ketamina or ketaminum or ketanest or Calipsol or Calypsol or Kalipsol or ketaset).ti,ab.
22. Propofol/
23. (propofol or anepol or anespro or anesvan or critifol or diprivan or disoprivan or disoprofol or dormofol or fresofol or gobbifol or hipnolam or hypro or "iv pro" or lipuro or "oleo lax" or plofed or profol or profolen or propofabb or propofil or propofolum or propogen or propolipid or propovan or propoven or provive or rapinovet or recofol or safol or trivam or troypofol or unifol or Aquafol or Ivofofol).ti,ab.
24. Midazolam/
25. (anquil or benzosed or buccolam or dalam or damizol or demizolam or doricum or dormicum or dormid or dormipron or dormire or dormitol or dormixal or dormonid or drimnorth or epistatus or flormidal or fulsed or "fused injection" or garen or gobbizolam or hipnazolam or hipnoz or hypnofast or hypnovel or ipnovel or midazolam or midazolamum or nocturna or setam or talentum or terap or versed).ti,ab.
26. Diazepam/
27. (diapam or diastat or diazemuls or diazepam or "methyl diazepam" or nervium or relanium or valium or Apaurin or Faustan or Relanium or Seduxen or Sibazon or Stesolid).ti,ab.
28. Fentanyl/

29. (abstral or actiq or duragesic or durogesic or fentanest or fentanil or fentanila or fentanilo or fentanyl or fentanyl or fentanylum or lazanda or nasalfent or phentanyl or rapinyl or subsys or fentora or sublimaze).ti,ab.
30. Nitrous oxide/
31. ("nitrous oxide" or "laughing gas" or "nitrogen protoxide").ti,ab.
32. (sevoflurane or sevorane or Ultane).ti,ab.
33. Temazepam/
34. (euhypnos or norkotral or normison or nortem or remestan or restoril or temaze or temazepam or temtabs or Dasuen or hydroxydiazepam or Levanxol or Methyloxazepam or Nocturne or Normitab or oxydiazepam or Planum or Signopam or Temaze).ti,ab.
35. Benzodiazepines/
36. (benzodiazepine\$ or Triazolam or Halcion or Sonata or Zaleplon or Ativan or Lorazepam or Vistaril or hydroxyzine or Xanax).ti,ab.
37. Analgesics, opioid/
38. (opioid\$ and sedat\$).ti,ab.
39. Anesthesia, dental/
40. (sedat\$ or anesthe\$ or anaesthe\$ or analges\$).ti,ab.
41. or/17-40
42. 16 and 41

Linked to the SIGN filter for identifying systematic reviews in MEDLINE Ovid,_source:

<http://www.sign.ac.uk/methodology/filters.html#systematic>

1. Meta-Analysis as Topic/
2. meta analy\$.tw.
3. metaanaly\$.tw.
4. Meta-Analysis/
5. (systematic adj (review\$1 or overview\$1)).tw.
6. exp Review Literature as Topic/
7. or/1-6
8. cochrane.ab.
9. embase.ab.
10. (psychlit or psyclit).ab.
11. (psychinfo or psycinfo).ab.
12. (cinahl or cinhal).ab.
13. science citation index.ab.
14. bids.ab.
15. cancerlit.ab.
16. or/8-15
17. reference list\$.ab.
18. bibliograph\$.ab.
19. hand-search\$.ab.
20. relevant journals.ab.
21. manual search\$.ab.
22. or/17-21
23. selection criteria.ab.

24. data extraction.ab.
25. 23 or 24
26. Review/
27. 25 and 26
28. Comment/
29. Letter/
30. Editorial/
31. animal/
32. human/
33. 31 not (31 and 32)
34. or/28-30,33
35. 7 or 16 or 22 or 27
36. 35 not 34

Linked to an adapted version of the CADTH filter for identifying guidelines in MEDLINE Ovid, source: <https://www.cadth.ca/resources/finding-evidence/strings-attached-cadths-database-search-filters#guide>

1. exp Clinical pathway/
2. exp Clinical protocol/
3. exp consensus/
4. exp consensus development conference/
5. exp consensus development conferences as topic/
6. critical pathways/
7. exp guideline/
8. guidelines as topic/
9. exp practice guideline/
10. practice guidelines as topic/
11. health planning guidelines/
12. exp treatment guidelines/
13. (guideline or practice guideline or consensus development conference or consensus development conference, NIH).pt.
14. (position statement\$ or policy statement\$ or practice parameter\$ or best practice\$).ti,ab,kf,kw.
15. (standards or guideline or guidelines or guidance\$).ti,kf,kw.
16. ((practice or treatment\$ or clinical) adj guideline\$).ab.
17. (CPG or CPGs).ti.
18. consensus\$.ti,kf,kw.
19. consensus\$.ab. /freq=2
20. ((critical or clinical or practice) adj2 (path or paths or pathway or pathways or protocol\$)).ti,ab,kf,kw.
21. recommendat\$.ti,kf,kw.
22. (care adj2 (standard or path or paths or pathway or pathways or map or maps or plan or plans)).ti,ab,kf,kw.
23. (algorithm\$ adj2 (screening or examination or test or tested or testing or assessment\$ or diagnosis or diagnoses or diagnosed or diagnosing)).ti,ab,kf,kw.

24. (algorithm\$ adj2 (pharmacotherap\$ or chemotherap\$ or chemotreatment\$ or therap\$ or treatment\$ or intervention\$)).ti,ab,kf,kw.
25. or/1-24

EMBASE via Ovid Search Strategy

1. exp Dentistry/
2. exp Oral surgery/
3. (dental or dentist\$).mp.
4. ((oral or periodont\$) adj5 surg\$).mp.
5. (pulpotom\$ or pulpect\$ or endodont\$ or "pulp cap\$" or apicoectom\$ or apicectom\$ or gingivectom\$ or gingivoplast\$).mp.
6. ((dental or teeth or tooth or molar\$) adj5 (fill\$ or restor\$ or extract\$ or remov\$ or "cavity prep\$" or caries or carious or decay\$ or scal\$ or polish\$ or "root plan\$" or scrap\$ or "oral prophylaxis\$")).mp.
7. ("root canal" and (therap\$ or treat\$)).mp.
8. (tooth adj3 replant\$).mp.
9. ((dental or oral) adj2 (implant\$ or prosthetic\$)).mp.
10. "root surface instrumentation".mp.
11. ((oral or mouth or dental) adj5 biops\$).mp.
12. (crown\$ or bridge\$ or prosthodontic\$).mp.
13. Dental anxiety/
14. ((dental or dentist) and (fear\$ or anxiet\$ or phobia\$)).mp.
15. ((special\$ adj3 (care or need\$)) and (dentist\$ or dental)).mp.
16. or/1-15
17. Conscious sedation/
18. exp "hypnotic sedative agent"/
19. exp Anti-anxiety agents/
20. Ketamine/
21. (ketamine or ketaject or ketalar or ketamina or ketaminum or ketanest or Calipsol or Calypsol or Kalipsol or ketaset).ti,ab.
22. Propofol/
23. (propofol or anepol or anespro or anesvan or critifol or diprivan or disoprivan or disoprofol or dormofol or fresofol or gobbifol or hipnolam or hypro or "iv pro" or lipuro or "oleo lax" or plofed or profol or profolen or propofabb or propofil or propofolum or propogen or propolipid or propovan or propoven or provive or rapinivet or recofol or safol or trivam or troypofol or unifol or Aquafol or Ivofol).ti,ab.
24. Midazolam/
25. (anquil or benzosed or buccolam or dalam or damizol or demizolam or doricum or dormicum or dormid or dormipron or dormire or dormitol or dormixal or dormonid or drimnorth or epistatus or flormidal or fulsed or "fused injection" or garen or gobbizolam or hipnazolam or hipnoz or hypnofast or hypnovel or ipnovel or midazolam or midazolamum or nocturna or setam or talentum or terap or versed).ti,ab.
26. Diazepam/
27. (diapam or diastat or diazemuls or diazepam or "methyl diazepam" or nervium or relanium or valium or Apaurin or Faustan or Relanium or Seduxen or Sibazon or

- Stesolid).ti,ab.
28. Fentanyl/
 29. (abstral or actiq or duragesic or durogesic or fentanest or fentanil or fentanila or fentanilo or fentanyl or fentanyl or fentanylum or lazanda or nasalfent or phentanyl or rapinyl or subsys or fentora or sublimaze).ti,ab.
 30. Nitrous oxide/
 31. ("nitrous oxide" or "laughing gas" or "nitrogen protoxide").ti,ab.
 32. (sevoflurane or sevorane or Ultane).ti,ab.
 33. Temazepam/
 34. (euhypnos or norkotral or normison or nortem or remestan or restoril or temaze or temazepam or temtabs or Dasuen or hydroxydiazepam or Levaxol or Methyloxazepam or Nocturne or Normitab or oxydiazepam or Planum or Signopam or Temaze).ti,ab.
 35. Benzodiazepine derivative/
 36. (benzodiazepine\$ or Triazolam or Halcion or Sonata or Zaleplon or Ativan or Lorazepam or Vistaril or hydroxyzine or Xanax).ti,ab.
 37. "narcotic analgesic agent"/
 38. (opioid\$ and sedat\$).ti,ab.
 39. Dental anesthesia/
 40. (sedat\$ or anesthe\$ or anaesthe\$ or analges\$).ti,ab.
 41. or/17-40
 42. 16 and 41

Linked to the SIGN filter for identifying systematic reviews in Embase Ovid, source:

<http://www.sign.ac.uk/methodology/filters.html#systematic>

1. exp Meta Analysis/
2. ((meta adj analy\$) or metaanalys\$).tw.
3. (systematic adj (review\$1 or overview\$1)).tw.
4. or/1-3
5. cancerlit.ab.
6. cochrane.ab.
7. embase.ab.
8. (psychlit or psyclit).ab.
9. (psychinfo or psycinfo).ab.
10. (cinahl or cinhal).ab.
11. science citation index.ab.
12. bids.ab.
13. or/5-12
14. reference lists.ab.
15. bibliograph\$.ab.
16. hand-search\$.ab.
17. manual search\$.ab.
18. relevant journals.ab.
19. or/14-18
20. data extraction.ab.
21. selection criteria.ab.

22. 20 or 21
23. review.pt.
24. 22 and 23
25. letter.pt.
26. editorial.pt.
27. animal/
28. human/
29. 27 not (27 and 28)
30. or/25-26,29
31. 4 or 13 or 19 or 24
32. 31 not 30

Linked to an adapted version of the CADTH filter for identifying guidelines in Embase Ovid, source: <https://www.cadth.ca/resources/finding-evidence/strings-attached-cadths-database-search-filters#guide>

1. exp practice guideline/
2. consensus/
3. (guideline or practice guideline or consensus development conference or consensus development conference, NIH).pt.
4. (position statement\$ or policy statement\$ or practice parameter\$ or best practice\$).ti,ab,kf,kw.
5. (standards or guideline or guidelines or guidance\$).ti,kf,kw.
6. ((practice or treatment\$ or clinical) adj guideline\$).ab.
7. (CPG or CPGs).ti.
8. consensus\$.ti,kf,kw.
9. consensus\$.ab. /freq=2
10. ((critical or clinical or practice) adj2 (path or paths or pathway or pathways or protocol\$)).ti,ab,kf,kw.
11. recommendat\$.ti,kf,kw.
12. (care adj2 (standard or path or paths or pathway or pathways or map or maps or plan or plans)).ti,ab,kf,kw.
13. (algorithm\$ adj2 (screening or examination or test or tested or testing or assessment\$ or diagnosis or diagnoses or diagnosed or diagnosing)).ti,ab,kf,kw.
14. (algorithm\$ adj2 (pharmacotherap\$ or chemotherap\$ or chemotreatment\$ or therap\$ or treatment\$ or intervention\$)).ti,ab,kf,kw.
15. or/1-14

CINAHL via EBSCO Search Strategy

Limit to publication types: systematic reviews and guidelines

- S42 S16 and S41
- S41 S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33 or S34 or S35 or S36 or S37 or S38 or S39 or S40
- S40 (sedat* or anesthe* or anaesthe* or analges*)
- S39 (MH "anesthesia, dental")

- S38 (opioid* and sedat*)
- S37 (MH "analgesics, opioid")
- S36 (benzodiazepine* or Triazolam or Halcion or Sonata or Zaleplon or Ativan or Lorazepam or Vistaril or hydroxyzine or Xanax)
- S35 (MH "Antianxiety Agents, Benzodiazepine")
- S34 (euhypnos or norkotral or normison or nortem or remestan or restoril or temaze or temazepam or temtabs or Dasuen or hydroxydiazepam or Levanxol or Methyloxazepam or Nocturne or Normitab or oxydiazepam or Planum or Signopam or Temaze)
- S33 (MH "temazepam")
- S32 (sevoflurane or sevorane or Ultane)
- S31 ("nitrous oxide" or "laughing gas" or "nitrogen protoxide")
- S30 (MH "nitrous oxide")
- S29 (abstral or actiq or duragesic or durogesic or fentanest or fentanil or fentanila or fentanilo or fentanyl or fentanyl or fentanylum or lazanda or nasalfent or phentanyl or rapinyl or subsys or fentora or sublimaze)
- S28 (MH "Fentanyl")
- S27 (diapam or diastat or diazemuls or diazepam or "methyl diazepam" or nervium or relanium or valium or Apaurin or Faustan or Relanium or Seduxen or Sibazon or Stesolid)
- S26 (MH "Diazepam")
- S25 (anquil or benzosed or buccolam or dalam or damizol or demizolam or doricum or dormicum or dormid or dormipron or dormire or dormitol or dormixal or dormonid or drimnorth or epistatus or flormidal or fulsed or "fused injection" or garen or gobbizolam or hipnazolam or hipnoz or hypnofast or hypnovel or ipnovel or midazolam or midazolamum or nocturna or setam or talentum or terap or versed)
- S24 (MH "midazolam")
- S23 (propofol or anepol or anespro or anesvan or critifol or diprivan or disoprivan or disoprofol or dormofol or fresofol or gobbifol or hipnolam or hypro or "iv pro" or lipuro or "oleo lax" or plofed or profol or profolen or propofabb or propofil or propofolum or propogen or propolipid or propovan or propoven or provive or rapinovet or recofol or safol or trivam or troypofol or unifol or Aquafol or Ivofol)
- S22 (MH "Propofol")
- S21 (ketamine or ketaject or ketalar or ketamina or ketaminum or ketanest or Calipsol or Calypsol or Kalipsol or ketaset)
- S20 (MH "ketamine")
- S19 (MH "Antianxiety Agents+")
- S18 (MH "hypnotics and sedatives")
- S17 (MH "Conscious sedation")
- S16 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15
- S15 ((special* N3 (care or need*)) and (dentist* or dental))
- S14 ((dental or dentist) and (fear* or anxiet* or phobia*))
- S13 (MH "Dental anxiety")
- S12 ((oral or mouth or dental) N5 biops*)
- S11 (crown* or bridge* or prosthodontic*)
- S10 "root surface instrumentation"

- S9 ((dental or oral) N2 (implant* or prosthetic*))
- S8 (tooth N3 replant*)
- S7 ("root canal" and (therap* or treat*))
- S6 ((dental or teeth or tooth or molar*) N5 (fill* or restor* or extract* or remov* or "cavity prep*" or caries or carious or decay* or scal* or polish* or "root plan*" or scrap* or "oral prophylaxis"))
- S5 (pulpotom* or pulpect* or endodont* or "pulp cap*" or apicoectom* or apicectom* or gingivectom* or gingivoplast*)
- S4 ((oral or periodont*) N5 surg*)
- S3 (dental or dentist*)
- S2 (MH "Surgery, Oral+")
- S1 (MH "Dentistry+")

NATIONAL GUIDELINE CLEARINGHOUSE

Limit: Dentistry sedation

Search details prepared by:

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13 April 2016

Appendix 3 - Summary of Guidelines and Systematic Reviews

Ref No.	Title	Author/Source Country	Year	Relevant Patient Group Focus	Methodological Rating ^a (AGREE)
G1	Safe Sedation Practice for Healthcare Procedures. Standards and Guidance ¹	Academy of Medical Royal Colleges UK	2013	<ul style="list-style-type: none"> • All – not dental restricted • Most aspects of sedation provision 	Moderate
G2	Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students ⁵	American Dental Association (ADA) USA	2012 ^b	<ul style="list-style-type: none"> • All - dental • Dentist and undergraduate education 	Low
G3	Guidelines for the Use of Sedation and General Anaesthesia by Dentists ⁶	American Dental Association (ADA) USA	2012 ^b	<ul style="list-style-type: none"> • All - dental • Most aspects of sedation provision 	Low
G5	Guidelines on sedation and/or analgesia for diagnostic and interventional medical, dental or surgical procedures ⁷	Australian and New Zealand College of Anaesthetists (ANZCA) Aus/NZ	2014	<ul style="list-style-type: none"> • All – not dental restricted • Most aspects of sedation provision 	Low
G6	Standards for conscious sedation in dentistry: alternative techniques ⁸	Faculty of Dental Surgery, Royal College of Surgeons; Royal College of Anaesthetists UK	2007	<ul style="list-style-type: none"> • All - dental • Alternative (advanced) techniques 	Low

^a For clarity, methodological ratings for the guidelines appraised are shown as one of four levels based on the AGREE scores (Very low: 1; Low:2/3; Moderate:4/5; High: 6/7).

^b Updated in 2016; see Appendix 4 for further details.

G8	Guideline on use of nitrous oxide for pediatric dental patients ⁹	American Academy of Paediatric Dentistry (AAPD) USA	2013	<ul style="list-style-type: none"> • Children - dental • Most aspects of N2O inhalation sedation provision 	Low
G10	Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures ¹⁰	American Academies of Pediatrics (AAP) and Pediatric Dentistry (AAPD) USA	2011 ^a	<ul style="list-style-type: none"> • Children - dental • Most aspects of sedation provision 	Low
G12	Special Care Dentistry Association consensus statement on sedation, anesthesia, and alternative techniques for people with special needs. ¹¹	Glassman, P., A. Caputo, et al. _Special Care Dentistry Association Special care in dentistry USA	2009	<ul style="list-style-type: none"> • Special needs - dental • Justifying the decision to use sedation 	Low
G13	UK National Clinical Guidelines in Paediatric Dentistry. Managing anxious children: the use of conscious sedation in paediatric dentistry ¹²	Hosey, M. T. British Society for Paediatric Dentistry (2002). International journal of paediatric dentistry UK	2002	<ul style="list-style-type: none"> • Children - dental • Most aspects of sedation provision 	Moderate
G14	Standards for Conscious Sedation in the Provision of Dental Care. Report of the Intercollegiate Advisory Committee for Sedation in Dentistry (IACSD) ²	The dental faculties of the royal colleges and the Royal College of Anaesthetists UK	2015	<ul style="list-style-type: none"> • All - dental • All aspects of sedation provision 	Low

^a Updated in 2016; see Appendix 4 for further details.

G15	Sedation in under 19s: using sedation for diagnostic and therapeutic procedures ^{3,13}	National Institute for Health and Care Excellence (NICE) UK	2010 (updated 2012)	<ul style="list-style-type: none"> • Children – not dental restricted • All aspects of sedation provision 	High
G16	Standing Dental Advisory Committee Conscious Sedation in the Provision of Dental Care ¹⁴	Report of an Expert Group on Sedation for Dentistry Commissioned by the Department of Health UK	2003	<ul style="list-style-type: none"> • All - dental • Most aspects of sedation provision 	Low
G17	EAPD Guidelines on Sedation in Paediatric Dentistry ¹⁵	A.-L. Hallonsten, B. Jensen, M. Raadal, J. Veerkamp, M.T. Hosey, S. Poulsen; European Association of Paediatric Dentistry EU	2003	<ul style="list-style-type: none"> • Children – dental • Most aspects of sedation provision 	Low
Ref No.	Title	Author/Source	Year	Relevant Patient Group Focus	Evidence Quality (GRADE)
SR1	Sedation versus general anaesthesia for provision of dental treatment to patients younger than 18 years. ¹⁶	Ashley, P.F., CECS Williams, D.R. Moles, J. Parry. Cochrane Database of Systematic Reviews	2015	<ul style="list-style-type: none"> • Children – dental • Efficacy • Adverse events 	No qualifying evidence
SR2	The anxiolytic effect of midazolam in third molar extraction: a systematic review. ¹⁷	Chen, Q., L. Wang, et al. PLoS ONE	2015	<ul style="list-style-type: none"> • All - dental • Midazolam efficacy for anxiolysis • Adverse events 	Efficacy: Moderate
					Adverse events: Very low
SR5	Sedation of children undergoing dental treatment. ¹⁸	Lourenço-Matharu, L., P.F. Ashley, S. Furness. Cochrane Database of Systematic Reviews	2012	<ul style="list-style-type: none"> • Children - dental • Efficacy of various drugs for behaviour management. 	Oral Midazolam: Low
					N2O/O2: Very low
SR6	Inhalation sedation with nitrous oxide as an alternative to dental general anaesthesia for children. ¹⁹	Lyratzopoulos, G. and K. M. Blain. Journal of Public Health Medicine	2003	<ul style="list-style-type: none"> • Children – dental • Efficacy of N2O/O2 • Adverse events 	Low to Very low

SR7	Reported side effects of intravenous midazolam sedation when used in paediatric dentistry: a review. ²⁰	Papineni McIntosh A., P. F. Ashley et al. International Journal of Paediatric Dentistry	2015	<ul style="list-style-type: none"> • Children – dental • Intravenous midazolam – adverse events 	<p>Low to</p> <p>Very low</p>
SR8	Safety of oral midazolam sedation use in paediatric dentistry: a review. ²¹	Papineni, A., L. Lourenço-Matharu, et al. International Journal of Paediatric Dentistry	2014	<ul style="list-style-type: none"> • Children – dental • Oral midazolam – adverse events 	<p>Low to</p> <p>Very low</p>
SR9	A review of the use of intranasally administered midazolam in adults and its application in dentistry. ²²	Davies, D.J.H. Journal of Disability and Oral Health.	2015	<ul style="list-style-type: none"> • Adults – dental • Intranasal midazolam – efficacy • Adverse events 	<p>Efficacy:</p> <p>Low</p>

Appendix 4 – Evidence Appraisal Forms

Systematic Review SR1: Ashley et al., 2015

Systematic Review: Ashley PF, Williams CECS, Moles DR, Parry J. Sedation versus general anaesthesia for provision of dental treatment to patients younger than 18 years. Cochrane Database of Systematic Reviews 2015, Issue 9. Art. No.: CD006334. DOI:10.1002/14651858.CD006334.pub4.			Ref. No.: SR1 Reviewer(s): MW 300516
Aim of study: <i>is there a clearly focussed question?</i> To evaluate morbidity and effectiveness of sedation versus GA for provision of dental treatment to patients younger than 18 years. If data become available, to analyse the cost-effectiveness of different interventions. If data are not available, to obtain crude estimates of cost.			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
Children and adolescents undergoing dental treatment including fillings, removal of the nerve from a tooth and extraction of a tooth.	Sedative agents administered via any route by an anaesthetist, a dentist or another healthcare professional in any setting.	General anaesthesia administered via any route by an anaesthetist, a dentist or another healthcare professional in any setting.	Primary outcomes <ul style="list-style-type: none"> • *Mortality (if any). • *Completion of treatment: yes or no. • *Postoperative morbidity. Secondary outcomes <ul style="list-style-type: none"> • Cost to the participant. • Cost of the procedure. • Participant satisfaction. • Parental satisfaction. • Intraoperative morbidity.
Study Type:	Search Strategy:	Study selection:	No. of selectors: 2
<i>Appropriate study types?</i> RCTs <i>Correct components to address</i>	<i>Appropriate search terms?</i> provided in appendix	Yes,	Inclusion criteria: Planned to include randomized controlled clinical trials that compared sedative agents versus general anaesthesia in children and adolescents up to 18 years of age undergoing dental

<p>question? Yes <i>Study no.s:</i> none meeting criteria <i>Study sizes:</i></p>	<p><i>Appropriate databases?</i> CENTRAL, Medline, Embase, LILACS, Web of Science <i>Unpublished studies?</i> SIGLE <i>Follow up of citations?</i> n/a <i>Personal contact with experts?</i> Yes – to identify any unpublished work</p>	<p>treatment <i>Exclusion criteria:</i> Excluded complex surgical procedures and pseudo-randomized trials.</p>	
<p>Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i></p>			
<p><i>Randomisation: is it reported and appropriate?</i> No eligible studies</p>	<p><i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> No eligible studies</p>	<p><i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> No eligible studies</p>	
<p>Inconsistency: <i>Refers to unexplained heterogeneity in results.</i></p>	<p>Imprecision (random error):</p>	<p>Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i></p>	<p>Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i></p>
<p><i>Is heterogeneity analysis reported?</i> No eligible studies</p>	<p>No eligible studies</p>	<p>No eligible studies</p>	<p>No eligible studies</p>
<p>Meta-analysis:</p>		<p>Overall results (for each outcome): No. of data extractors: 0</p>	
<p><i>Was meta analysis conducted?</i> No eligible studies <i>Are results for individual studies shown?</i> <i>Was it reasonable to combine study results?</i> <i>Was an appropriate method used?</i> <i>Are reasons for variation in results discussed?</i></p>		<p><i>Is the effect substantial^a?</i> <i>Is there dose-response data^a?</i></p>	

<i>Would confounders affect overall result^a?</i>		
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?
Adverse events were to be considered as a primary outcome.	Cost effectiveness was to be considered	Patient satisfaction was to be considered as secondary outcome.
Reviewer’s comments:		GRADE evidence quality rating:
<p><i>Summary of main findings:</i> Authors found no randomized controlled trials (RCTs) comparing general anaesthesia (GA) versus sedation for providing dental care to children. Some publications compared any form of sedation versus GA using methods such as case control studies. Comments related to these studies were provided. The patients suitable for and the levels of dental treatment that can be provided with sedation or GA may not be equivalent. This may make RCTs unlikely. Although GA may be more expensive than sedation, treatment completion under sedation may require more visits.</p>		<p><i>Rating and brief explanation</i> No eligible studies to provide rating for. No recommendations made.</p>
<i>Applicability to SDCEP guidance</i>		
<p>SDCEP guidance themes: sedation technique ✓, patient selection X, records X, consent X, training X, monitoring X, fasting X, environment X, equipment X, staffing X, patient views ✓ (✓)= mentioned but not in detail.</p>		

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

Systematic Review SR2: Chen et al., 2015

Systematic Review: Chen, Q., Wang L, Ge L, Gao Y, Wang H (2015) The Anxiolytic Effect of Midazolam in Third Molar Extraction: A Systematic Review. PLoS ONE 10(4): e0121410. doi:10.1371/journal.pone.0121410			Ref. No.: SR2 Reviewer(s): MW 250516, DS 25.05.16
Aim of study: <i>is there a clearly focussed question?</i> To assess the efficacy of midazolam for anxiety control in third molar extraction surgery.			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
Anxious patient undergoing removal of third molar	midazolam	placebo or other anti-anxiety agents	1. *Efficacy – measured by assessment of anxiety levels using different methods 2. *Incidence of adverse events
Study Type:	Search Strategy:	Study selection:	No. of selectors: 2
<i>Appropriate study types?</i> RCTs <i>Correct components to address question?</i> Yes <i>Study no.s:</i> 10 <i>Study sizes:</i> see overall results below	<i>Appropriate search terms?</i> Yes, but could have included alternative names for midazolam <i>Appropriate databases?</i> Cochrane Library, CENTRAL, Medline, Embase, <i>Unpublished studies?</i> SIGLE <i>Follow up of citations?</i> yes <i>Personal contact with experts?</i> Not stated	<i>Inclusion criteria:</i> (1) Studies had to include dentally anxious outpatients who had undergone third molar extraction, regardless of gender or race; (2) published studies, including grey literature, had to be randomized, double-blind, and refer to midazolam's effect on dental anxiety compared with that of placebo or other anti-anxiety agents; (3) studies had to have outcome indices, including the patients' anxiety levels. <i>Exclusion criteria:</i> (1) Descriptive research such as reviews, case reports, and clinical observations were excluded, as were basic experiments; (2) studies including patients younger than 18 years old were excluded.	
Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i>			
<i>Randomisation:</i> <i>is it reported and</i>	<i>Blinding:</i> <i>consider whether blinding of patients or assessors would be important for outcomes</i>	<i>Other limitations:</i> <i>e.g. attrition bias (incomplete accounting of patients and outcome events),</i>	

<p><i>appropriate?</i> 7/10 used sequence generation 4/10 used allocation concealment (for another 4 it was unclear)</p>	<p><i>considered</i> 8/10 used blinding</p>	<p><i>reporting bias (selective outcome reporting), surrogate outcomes(?)</i> In 2/10 of the studies it was unclear whether outcome data was complete None of the studies was judged to have reporting bias Overall: 1/10 judged to have low risk of bias, 6/10 middle risk and 3/10 high risk.</p>	
<p>Inconsistency: <i>Refers to unexplained heterogeneity in results.</i></p>	<p>Imprecision (random error):</p>		<p>Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i></p> <p>Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i></p>
<p><i>Is heterogeneity analysis reported?</i> No formal analysis but noted that 1 study comparing midazolam with placebo had contradictory results (had high risk of bias)</p>	<p>Confidence intervals not reported</p>	<p>Midazolam was compared to placebo in some studies and to other drugs in other studies. Different routes of administration were included. Locations and settings of populations in individual studies not stated.</p>	<p>No assessment done.</p>
<p>Meta-analysis:</p>		<p>Overall results (for each outcome): No. of data extractors: 2</p>	
<p><i>Was meta analysis conducted?</i> No meta-analysis, because of different anxiety scales used to assess efficacy and variation in treatments and controls</p> <p><i>Are results for individual studies shown?</i> yes</p> <p><i>Was it reasonable to combine study results?</i> no</p> <p><i>Was an appropriate method used?</i> n/a</p> <p><i>Are reasons for variation in results discussed?</i> Yes – in that high risk of bias for 1</p>		<p>1. For 5/6 studies comparing midazolam (304 patients) with placebo (338), there was a statistically significant effect on anxiety relief. For 3 of these studies ES (effect size) calculations were done and all were >0.8 indicating effectiveness. 1 study (55 patients per group) indicated that propofol was more effective than midazolam. 1 study (20 patients per group) indicated that diazepam was more effective than midazolam or lorazepam. 2 studies (1192 patients in total) found that multidrug combinations were more effective than midazolam alone.</p>	

<p><i>contradictory study is discussed</i> <i>Would confounders affect overall result^a?</i></p>		<p>2. Reported that incidence of adverse events was no higher with midazolam than placebo – no further information provided. Some patients in groups taking fentanyl had respiratory depression</p> <p><i>Is the effect substantial^a?</i> <i>Is there dose-response data^a?</i></p>
<p>Adverse events:</p>	<p>Benefit/harm/cost considerations?</p>	<p>Values/preferences considerations?</p>
<p>Adverse events recorded for some studies e.g. drowsiness, lack of coordination, disorientation, and decreased saturation of blood oxygen. Diazepam caused pain on injection in some cases. Multidrug combinations including fentanyl led to respiratory depression in some cases.</p>	<p>Efficacy versus adverse events discussed</p>	<p>Not discussed</p>
<p>Reviewer’s comments:</p>		<p>GRADE evidence quality rating:</p>
<p><i>Summary of main findings:</i> The authors concluded that the selected studies provided evidence that midazolam is efficacious for anxiety control. The data on the other drugs and combinations is poorly reported, so it is difficult to rate the evidence quality for this. The data for adverse effects is poorly reported – it is not clear how many studies the data is from and there is no indication of the incidence rates.</p>		<p><i>Rating and brief explanation</i> Moderate quality For the comparison of midazolam versus placebo the evidence of effectiveness is judged to be moderate quality mainly because the included studies are RCTs with a moderate risk of bias. Very low quality There is little data presented on adverse effects</p>
<p><i>Applicability to SDCEP guidance</i> Studies only consider wisdom tooth extraction and not other dental procedures, but likely to be of relevance to wider range of dental treatments. Refers to ASA I&II patients only</p>		

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

<p>SDCEP guidance themes: sedation technique ✓, patient selection X, records X, consent X, training X, monitoring (✓), fasting X, environment X, equipment (✓), staffing X, patient views X (✓)= mentioned but not in detail.</p>	<p>and it is not clear which studies the data is taken from.</p>
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Systematic Review SR5: Lourenço-Matharu et al., 2012

Systematic Review: Lourenço-Matharu L, Ashley PF, Furness S. Sedation of children undergoing dental treatment. Cochrane Database of Systematic Reviews 2012, Issue 3. Art. No.: CD003877. DOI: 10.1002/14651858.CD003877.pub4.			Ref. No.: SR5 Reviewer(s): DS 01.06.16
Aim of study: <i>is there a clearly focussed question?</i> To evaluate the efficacy and relative efficacy of conscious sedation agents and dosages for behaviour management in paediatric dentistry.			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
Age of patients included in the trials ranged from 1 year to 16 years. Mean age (approximation) for all studies was 4.7 years. The mean number of participants was 78 (standard deviation (SD) = 124) with a total of 2810 subjects randomised in the 36 included trials.	Any sedative agent via any route of admission that can be administered by a dentist, anaesthetist, sedationist or dental auxiliary in an outpatient setting or dental office. <u>Vs placebo:</u> Oral midazolam Nitrous oxide/oxygen Chloral hydrate Meperidine <u>Vs different dosage:</u> Hydroxyzine Midazolam(intranasal) Midazolam(oral) <u>Vs other agents</u> Chloral hydrate/hydroxyzine Chloral hydrate/promethazine Ketamine Midazolam(oral) Midazolam(rectal)	Placebo (including no intervention) or alternative sedation agent or different dosage of the same agent.	Primary *Behaviour Secondary 1. *Completion of treatment (yes/no) 2. Postoperative anxiety 3. *Adverse events Behaviour was measured by a range of different indices; where possible these were combined to allow meta-analysis to be carried out. Behaviour for the procedure overall will be recorded; if this information is not available then behaviour at the time of injection will be used.

Sevoflurane			
Study Type:	Search Strategy:	Study selection:	No. of selectors: 2
<p><i>Appropriate study types?</i> Yes, RCTs</p> <p><i>Correct components to address question?</i> Yes</p> <p><i>Study no.s:</i> Thirty-six studies were included with a total of 2810 participants</p> <p><i>Study sizes:</i></p>	<p><i>Appropriate search terms?</i> Yes</p> <p><i>Appropriate databases?</i> Yes</p> <p>Electronic searches of MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Dissertation Abstracts, SIGLE, the WorldWideWeb (Google) and the Community of Science Database. Reference lists from relevant articles were scanned and the authors contacted to identify trials and obtain additional information.</p> <p>There were no language restrictions. Trials pre-1966 were not searched.</p> <p><i>Unpublished studies?</i> yes</p> <p><i>Follow up of citations?</i> yes</p> <p><i>Personal contact with experts?</i> yes</p>	<p><i>Inclusion criteria:</i></p> <p>Randomised controlled trials of conscious sedation comparing two or more drugs/techniques/placebo undertaken by the dentist or one of the dental team in children up to 16 years of age.</p> <p>Crossover trials were excluded.</p> <p>Studies where children were having complex surgical procedures were not included in this study.</p> <p>Studies that reported induction of deep sedation were excluded.</p>	
<p>Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i></p>			
<p><i>Randomisation: is it reported and appropriate?</i></p> <p>2/36 studies assessed as low risk of bias in sequence generation and allocation. Most studies at unclear risk of bias due to failure to report.</p>	<p><i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i></p> <p>Twenty (56%) trials were assessed as being at low risk of performance and detection biases. In six trials only the assessor was blind to the intervention, in three trials the operator and the outcome assessor was blinded, and in four trials there was no blinding.</p>	<p><i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i></p> <p>In many trials it was not possible to know if drop-out had occurred or not. 23 trials were at risk of attrition bias. Baseline demographics were poorly reported in seven trials.</p> <p>Overall: Of the 36 trials included in this review none were assessed as being at low risk of bias overall. Six trials (17%) were assessed as being at unclear risk of bias and in the remaining 30 trials (83%) at least one domain was assessed as being at high risk of bias.</p>	
<p>Inconsistency: <i>Refers to unexplained heterogeneity in results.</i></p>	<p>Imprecision (random error): <i>e.g. confidence intervals presented</i></p>	<p>Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i></p>	<p>Publication bias: <i>e.g. when intervention is new and not many studies available-may be biased for positive results</i></p>

<p><i>Is heterogeneity analysis reported?</i> Heterogeneity in the results of the trials was assessed where appropriate by inspection of a graphical display of the results and by formal tests of heterogeneity. Only in the case of oral midazolam vs placebo was it possible to calculate heterogeneity, which was considerable ($I^2 = 91\%$, $P < 0.00001$).</p>	<p>CI of SMD reported for Oral midazolam vs placebo 2.98 [1.58, 4.37] N2O vs placebo 0.69 [0.13, 1.26]</p>	<p>Intervention comparisons varied considerably between studies making an overall assessment of effect impossible. Studies from 13 countries, majority in USA. Eleven of the included studies reported the use of Papoose boards or Pedivrap to support or restrain children during the dental procedure. Treatment settings were unclear.</p>	<p>Search was thorough, so likely to have retrieved relevant publications. No assessment of publication bias presented.</p>
<p>Meta analysis:</p>		<p>Overall results (for each outcome): <i>Number of data extractors?</i> 2</p>	
<p><i>Was meta analysis conducted?</i> No <i>Are results for individual studies shown?</i> yes <i>Was it reasonable to combine study results?</i> No <i>Was an appropriate method used?</i> - <i>Are reasons for variation in results discussed?</i> Yes to an extent. Difficult to compare different scales. <i>Would confounders affect overall result^a?</i></p>		<p>Of the outcome measures proposed for this review (completion of treatment, difference in behaviour, difference in postoperative anxiety and adverse events), meaningful data could only be extracted on behaviour. Postoperative anxiety was rarely mentioned and in most of the studies almost all the participants completed treatment.</p> <p>There is weak evidence from five small clinically heterogeneous trials at high risk of bias, that the use of oral midazolam in doses between 0.25 mg/kg to 0.75 mg/kg is associated with more co-operative behaviour compared to placebo; standardised mean difference (SMD) favoured midazolam (SMD 2.98, 95% confidence interval (CI) 1.58 to 4.37, $P < 0.001$, $I^2 = 91\%$), which translates to an increase of approximately 1.8 points on the six-point Houpt behaviour scale.</p> <p>There is very weak evidence from two trials which could not be pooled that inhalational nitrous oxide is more effective than placebo.</p> <p><i>Is the effect substantial^a?</i> <i>Is there dose-response data^a?</i></p>	

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?
<p>Adverse events were recorded but this was not done in a uniform manner between studies. Vomiting and hiccupping was reported in the midazolam group of one trial using the highest dose of 0.75 mg/kg.</p> <p>There is insufficient evidence to support the effectiveness of either chloral hydrate or ketamine. However, chloral hydrate was associated with significant adverse effects, specifically airway issues especially when high doses (> 50 mg/kg) were combined with the use of inhalational nitrous oxide. Ketamine was also associated with significant adverse effects.</p>	Not discussed	Not discussed
Reviewer's comments:		GRADE evidence quality rating:
<p><i>Summary of main findings</i></p> <p>Of the 36 trials included in this review none were assessed as being at low risk of bias overall. Six trials (17%) were assessed as being at unclear risk of bias and in the remaining 30 trials (83%) at least one domain was assessed as being at high risk of bias.</p> <p>In general, reporting of the trials was poor with data such as method of sequence generation and allocation concealment frequently not reported. Participants were poorly described with important information such as gender or weight often missing. Sample size calculations were either not carried out or not reported, and it is likely that many of the trials lacked statistical power to detect a difference between intervention and control. Statistical methods used varied widely between studies even though outcome measures were sometimes similar. In some instances, these tests were arguably inappropriate for the types of data usually produced by these studies.</p> <p>Combining data from included studies to facilitate a meta-analysis was difficult. The enormous range of sedative agents used both in combination and singly, along with the wide range of outcome measures, precluded meta-analysis of homogenous groups of interventions.</p> <p>There is weak, but consistent evidence from five heterogeneous trials, that following administration of oral midazolam the behaviour of children was improved relative to placebo, with variations in the size of the benefit according to the dosage used. Where reported, adverse effects were few and minor. However, given the small number of studies (n = 5), participants (n = 182) and high risk of bias for all these papers, this conclusion must obviously be treated with some caution.</p> <p>There is very weak evidence from two trials that nitrous oxide inhalation was also more effective than placebo and no adverse effects were noted. This suggests that this may be an effective method for managing behaviour in children.</p> <p>One study showed that fasting made no difference to overall behaviour. One study noted no fasting pretreatment and no vomiting in either group receiving midazolam (intramuscular or intranasal).</p>		<p><i>Rating and brief explanation</i></p> <p>The review was thoroughly conducted but the evidence identified and included related to many diverse interventions which were of low quality.</p> <p>Behaviour with Oral Midazolam: Low quality</p> <p>Five heterogeneous RCTs, risk of bias high in three and unclear in two.</p> <p>Behaviour with Nitrous oxide/oxygen: Very low quality</p> <p>Two RCTs</p> <p>There was insufficient data to assess secondary outcomes for any interventions.</p> <ol style="list-style-type: none"> 1. Completion of treatment 2. Postoperative anxiety 3. Adverse events

<p><i>Applicability to SDCEP guidance</i></p> <p>Though most trials were carried out in other countries, and some also used restraint, the findings of this review are relevant to the provision of sedation in the UK.</p>	
<p>SDCEP guidance themes:</p> <p>sedation technique✓, patient selectionX, recordsX, consentX, trainingX, monitoringX, fasting(✓), environmentX, equipmentX, staffingX, patient viewsX</p> <p>(✓)= mentioned but not in detail.</p>	

Systematic Review SR6: Lyratzopoulos and Blain, 2003

Systematic Review: G. Lyratzopoulos and K. M. Blain (2003) Inhalation sedation with nitrous oxide as an alternative to dental general anaesthesia for children Journal of Public Health Medicine 25(4): 303-312. DOI: 10.1093/pubmed/fdg068			Ref. No.: SR6 Reviewer(s): MW 060616
Aim of study: <i>is there a clearly focussed question?</i> To carry out a systematic review of the literature on IHS as an alternative to DGA for children			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
Children judged untreatable without resort to DGA (dental general anaesthetic).	Inhalation sedation with nitrous oxide (N2O) and local anaesthesia.	DGA in 2 of the studies, no comparator for other studies.	<ol style="list-style-type: none"> 1. *Effectiveness (acceptance or completion of planned dental treatment under IHS) 2. Factors associated with IHS treatment failure 3. *Morbidity (i.e. side effects) 4. Mean time required per session 5. Treatment sessions required per patient 6. *User satisfaction 7. Cost Not all outcomes were reported in all studies.
Study Type:	Search Strategy:		Study selection:
<i>Appropriate study types?</i> 7 case series studies; 2 had comparators; no RCTs found <i>Correct components to address question? Yes</i> <i>Study no.s: 7</i> <i>Study sizes:</i> Each study had ≥20 cases; 1595	<i>Appropriate search terms?</i> Yes <i>Appropriate databases?</i> Medline, Embase, CINAHL, Cochrane Library (Limited to English language, human subjects, between 1975 and August 2002) Hand searching of International Journal of Paediatric Dentistry, Dental Community Health (1991-2000)		<i>Inclusion criteria:</i> <ul style="list-style-type: none"> • reported on dental treatment using IHS with nitrous oxide (supplemented by local anaesthesia); • reported on treatment of children; • contained evidence of level 3 or higher, according to the Scottish Intercollegiate Guidelines Network; • included patients referred for DGA by a dental practitioner or fulfilling explicit criteria suggesting that conventional dental treatment (i.e. with local anaesthesia alone) was impossible; • reported the rates of completion or acceptance of planned treatment among patients

<p>patients in total treated with IHS, 300 with DGA</p>	<p><i>Unpublished studies?</i> yes <i>Follow up of citations?</i> yes <i>Personal contact with experts?</i> yes</p>	<p>offered IHS</p> <p><i>Exclusion criteria:</i></p> <ul style="list-style-type: none"> • had no clear inclusion criteria for participating patients; • reported only effects of IHS on physiological parameters (such as heart rate and oxygen saturation) or only examined pharmacological safety; • included mainly other interventions, behavioural or medical, with or without IHS (e.g. hypnosis, behavioural management, administration of other oral, intravenous or inhaled agents); • reported on fewer than 20 cases; • included mainly adult patients or did not report results for children in subgroups; • were non-systematic reviews or letters; • were duplicate publications (wholly, or in part) of studies already included in the review. 	
<p>Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i></p>			
<p><i>Randomisation (selection bias): is it reported and appropriate (include sequence generation and allocation concealment if possible)?</i></p> <p>No randomisation in these studies (none of the studies were RCTs)</p> <p>There is the potential for further selection bias since patients were pre-selected for the studies and the criteria and numbers were not reported for some of the studies.</p> <p>i.e. does not give an accurate estimate of how many of the patients originally referred for DGA were then treated under IHS.</p>	<p><i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i></p> <p>None</p>	<p><i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i></p> <p>Of the comparator studies one had an unbalanced sex distribution between the two groups, and in the other study there was an imbalance in the mean number of teeth requiring extraction per patient favouring the IHS group.</p> <p>Overall risk of bias: High risk of bias because of potential selection bias.</p>	
<p>Inconsistency: <i>Refers to unexplained heterogeneity in results.</i></p>	<p>Imprecision (random error):</p>		<p>Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those</i></p> <p>Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i></p>

		<i>of interest</i>	
<p><i>Is heterogeneity analysis reported?</i></p> <p>No formal analysis but noted that: Studies differed in whether a comparator was included, in the type of dental treatment required (e.g. number of teeth extracted) and the outcomes reported.</p>	n/a	<p>The outcomes were compared between IHS and DGA in the 2 comparator studies and were just reported for IHS in the other studies.</p> <p>The settings varied with four studies conducted in teaching dental hospitals, one in a community clinic, one had a mixed community and tertiary setting, and the setting of one study was unclear.</p> <p>5 of the studies were UK based, 2 were Scandinavian.</p>	None identified other than studies limited to English language
Meta-analysis:		Overall results (for each outcome):	
		No. of data extractors: not stated	
<p><i>Was meta-analysis conducted?</i></p> <p>No, only a narrative description of the data, with ranges provided for the non-comparator studies</p> <p><i>Are results for individual studies shown?</i> Outcome data is stated in the text.</p> <p><i>Was it reasonable to combine study results?</i> no</p> <p><i>Was an appropriate method used?</i> n/a</p> <p><i>Are reasons for variation in results discussed?</i> There did not appear to be appreciable heterogeneity between study results</p> <p><i>Would confounders affect overall result^a?</i></p>		<ol style="list-style-type: none"> 1. In the two comparative studies, IHS and DGA were effective in 96.7% versus 100% and 83.4% versus 98.9% of children, respectively. In the other studies IHS treatment effectiveness ranged from 87% to 96.9% 2. Factors associated with IHS treatment failure were identified as younger age, more teeth needing to be extracted, poor previous attendance, higher anaesthetic risk status, immaturity and previous negative experience with dental treatment, history of psychiatric problems and the occurrence of side effects (data from 3 studies) 3. IHS was found to be similar or superior to DGA for morbidity, with only minor side effects reported, mainly nausea/vomiting and headache. In the other studies, only minor side effects associated with HIS are reported, mainly nausea/vomiting and headache, in 5–13% of patients (data from 1 comparator study and 3 of the others) 4. In the comparative studies the mean procedure time was 22.6 and 45.2 mins for IHS 	

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

		<p>compared with 6.8 and 7.4 minutes for DGA.</p> <p>In the other studies, mean procedure periods for IHS ranged from 22 to 44 mins. One study reported that 87.3% sessions required <40 minutes and 95.9% required <60 mins.</p> <p>5. In the comparative studies, the mean number of treatment sessions required to complete treatment with IHS were 1.0340 (orthodontic patients only) and 1.3541 sessions per patient. In non-comparative studies, a range of 1.24–2.09 sessions per patient was reported.</p> <p>6. In the comparative studies, IHS was found to be significantly better than DGA in terms of parental and children satisfaction. In the other study, high user satisfaction and preference of IHS over DGA, in patients with previous experience of DGA was found.</p> <p>7. Staffing costs for IHS were estimated to be cheaper by approximately one-third compared with DGA (other costs excluded; data from 1 comparative and 1 other study, carried out in dental teaching hospitals).</p> <p><i>Is the effect substantial^a?</i> no</p> <p><i>Is there dose-response data^a?</i> no</p>
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?
Side effects of sedation are one of the study outcomes reported. Those listed are considered to be minor and include nausea/vomiting and headache.	<p>The benefits of IHS are discussed i.e. the sedative effect of IHS is readily reversible and this form of sedation has a high safety record.</p> <p>The side effects are discussed as an outcome.</p> <p>Organisational barriers are discussed i.e. the length and number of sessions.</p> <p>Costs are a reported outcome and are discussed, with estimates of staff costs for IHS in a dental teaching hospital setting being 1/3 less than for DGA.</p>	Patient satisfaction with IHS and DGA are one of the reported outcomes.
Reviewer’s comments:		GRADE evidence quality rating:
<p><i>Summary of main findings:</i></p> <p>The reviewers conclude that evidence of a lower quality level (than RCTs) is suggestive that IHS can prevent the need for DGA in many children who would have otherwise required it. The proportion of such children may be between 45 and 64% of all children who would have otherwise required DGA (estimated from the 2 studies that reported the numbers of patients excluded from the studies).</p> <p>The % of effectiveness of IHS when only considering the patients selected for inclusion in the study can range from 83.4 to 96.9.</p>		<p><i>Rating and brief explanation</i></p> <p>Low to very low quality</p> <p>This is a well conducted systematic review. The evidence quality is judged to be low to very low for all outcomes because of the study types included (i.e. observational rather than RCTs)</p>

<p><i>Applicability to SDCEP guidance</i></p> <p>The evidence considered in this systematic review comes mostly from dental teaching hospital setting although it seems likely that the effectiveness of IHS in a primary care setting would be similar.</p>	<p>and the risk of selection bias.</p>
<p>SDCEP guidance themes:</p> <p>sedation technique ✓, patient selection ✓, records X, consent X, training X, monitoring X, fasting X, environment X, equipment X, staffing X, patient views ✓</p> <p>(✓)= mentioned but not in detail.</p>	

Systematic Review SR7: Papineni McIntosh et al., 2015

Systematic Review: Papineni McIntosh, A., P. F. Ashley, et al. (2015). Reported side effects of intravenous midazolam sedation when used in paediatric dentistry: a review. International Journal of Paediatric Dentistry 25: 153-164.			Ref. No.: SR7 Reviewer(s): MW 020616
Aim of study: <i>is there a clearly focussed question?</i> To review all available literature reporting the side effects of IV midazolam in children undergoing dental procedures.			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
Children and adolescents aged 0–16 years of age (including children with specific medical or behavioural problems) undergoing dental treatment.	IV midazolam	Other doses and routes of midazolam, other sedatives or placebo.	1. *Minor adverse reactions (defined as any reported adverse events that were non-life-threatening requiring minimal or no intervention). 2. *Significant adverse reactions (defined as potentially life-threatening adverse reactions. Examples were mortality, inability to maintain an airway or persistent desaturation not corrected by head movements.)
Study Type:	Search Strategy:	Study selection:	No. of selectors: 2
<i>Appropriate study types?</i> 5 RCTs (1 was a crossover study) 6 non-randomised studies <i>Correct components to address question? Yes</i> <i>Study no.s:</i> 5+6 <i>Study sizes:</i> RCTs had 10-94 patients in main treatment group i.e. IV midazolam alone (169 in total); non-randomised studies had 15-552 patients in treatment group (702 IV midazolam	<i>Appropriate search terms?</i> Yes – described in Tables 1&2 (The search for RCTs was modelled on that used by Cochrane review in 2005 – includes cross-over trials. The search for any other non-randomised studies used a combination of controlled vocabulary and free text terms based on the search strategy as described in Chapter 14 of the Cochrane Handbook). <i>Appropriate databases?</i> Medline, Embase, website search engine Handsearching of International Journal of Paediatric Dentistry, Pediatric Dentistry, Journal of	<i>Inclusion and exclusion criteria:</i> 1. Types of study subject: Children and adolescents aged 0–16 years of age (including children with specific medical or behavioural problems) undergoing dental treatment, regardless of baseline anxiety. 2. Types of interventions: Intravenous midazolam administered by a dentist, anaesthetist or sedationist in an outpatient setting or dental office. Studies that reported induction of deep sedation were excluded. Studies where a premedication was administered were excluded as reported side effects could not be attributed solely to IV midazolam. Studies which used nitrous oxide pre-operatively to aid cannulation were included, as nitrous oxide is rapidly eliminated from the lungs; however, studies where supplemental nitrous oxide was continued after cannulation were excluded. 3. Types of outcome measures: The primary outcome measure was the percentage prevalence of significant side effects per episode of treatment. The secondary outcome measure was the percentage prevalence of minor side effects per episode of treatment.	

treatment episodes in total)	American Dental Association, Anesthesia Progress (2000-11). Reference books and regulatory authorities <i>Unpublished studies?</i> Not stated <i>Follow up of citations?</i> yes <i>Personal contact with experts?</i> Yes		
Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i>			
<i>Randomisation (selection bias): is it reported and appropriate (include sequence generation and allocation concealment if possible)?</i> Not reported for individual studies	<i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Not reported for individual studies	<i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> 1/5 of the RCTs were crossover studies – some would argue that this design is inappropriate since the behaviour of children undergoing dental procedures and associated side effects could be influenced by the child's prior experience of dental treatment. Overall risk of bias: The overall risk of bias for the 5 RCTs was judged by the SR author to be high. For the 6 non-randomised studies, the overall risk of bias was judged by the SR author to be high; three (50%) were retrospective in nature and three (50%) were prospective case series.	
Inconsistency: <i>Refers to unexplained heterogeneity in results.</i>	Imprecision (random error):	Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i>	Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i>
<i>Is heterogeneity analysis reported?</i> No formal analysis but authors noted that: Reporting of side effects varied among the studies analysed. In some studies, no side effects were reported, and in others, up to 80% of patients experienced minor side effects. There was also found to be inconsistent description of individual side effects,	Confidence intervals not reported	IV midazolam was compared to placebo in some studies and to other doses, routes or other drugs in other studies. Although inclusion criteria should only allow studies carried out in outpatient settings, the settings for individual studies is not described. The locations included UK, Canada, India, China and Japan.	No assessment done.

making the categorisation of side effects difficult.			
Meta-analysis:		Overall results (for each outcome): No. of data extractors: 2	
<p><i>Was meta analysis conducted?</i> Only simple summary measures could be calculated due to the limited data available from some studies.</p> <p><i>Are results for individual studies shown?</i> yes</p> <p><i>Was it reasonable to combine study results?</i> Yes, for some</p> <p><i>Was an appropriate method used?</i> n/a</p> <p><i>Are reasons for variation in results discussed?</i> Yes – see heterogeneity above</p> <p><i>Would confounders affect overall result^a?</i></p>		<p>From the RCTs:</p> <ol style="list-style-type: none"> 1. Minor adverse events were: n = 33; 19.5% of cases, with paradoxical reactions* being the most commonly reported (n = 11, 6.5% of cases) 2. No significant events were reported. <p>From the non-RCTs:</p> <ol style="list-style-type: none"> 1. Minor adverse events were recorded (n = 118, 16.8% of cases), with paradoxical reactions* being the most commonly reported adverse event (n = 89, 12.7% of cases) 2. No significant adverse events were recorded. <p>The frequency of transient oxygen desaturation was 0% in RCT cases and 0.3% in non-RCT cases. This contrasts with the authors previous review on oral midazolam which found that 5.6% of RCT cases and 0.2% of non-RCT experienced transient desaturation.</p> <p>Data related to the effectiveness of the sedative were not collected.</p> <p>*Note that paradoxical reactions (e.g. agitation, vocalisation, body movement, crying and the patient being tearful) can be a result of under-sedation.</p> <p><i>Is the effect substantial^a?</i> no</p> <p><i>Is there dose-response data^a?</i> no</p>	
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?	
Adverse events are the main theme of this systematic review.	Potential harm from IV midazolam is the main theme of the review. The benefits of midazolam are discussed briefly i.e. midazolam is a short-	Mentioned that IV route might be less	

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

<p>Side effects of midazolam are listed in the British National Formulary for Children as cardiac arrest, heart rate changes, hypotension, convulsions, anaphylaxis, thrombosis, laryngospasm, bronchospasm, respiratory depression and respiratory arrest, gastrointestinal disturbances, dry mouth, hiccups, increased appetite, jaundice, drowsiness, confusion, ataxia, amnesia, headache, euphoria, hallucinations, dizziness, vertigo, involuntary movements, paradoxical excitement and aggression, dysarthria, urinary retention or incontinence, blood disorders, muscle weakness, visual disturbances including diplopia, salivation changes, skin reactions, injection site reactions with intravenous administration, and, with intranasal administration, burning sensation, lacrimation and irritation of nasal mucosa.</p> <p>The method of division of these side effects into minor and significant is subject to debate, as is the inclusion of certain side effects which may be classed as therapeutic, such as amnesia and drowsiness, which are listed alongside adverse side effects.</p>	<p>acting benzodiazepine which benefits from sedative, anterograde amnesia and anxiolytic effects.</p> <p>Other considerations:</p> <ul style="list-style-type: none"> • Disadvantages of the <u>oral</u> route of administration include the lack of titration, delay of onset and the absence of immediate IV access for a reversal agent or emergency medication (presumably benefits of IV midazolam would be the converse). • For conscious sedation in the UK, oral administration of midazolam is unlicensed, IV administration is licensed for use in children over 6 months of age. • The review reports that there has been an increase in the use of IV midazolam sedation in paediatric dental departments across the UK; however, many clinicians outside this environment do not routinely offer this service to children. Speculated that this may largely be due to the related training difficulties, as well as concern regarding the unpredictable reaction of children to midazolam, the acceptability of the intravenous route in children and apprehension of producing a deeper level of sedation than planned. 	<p>acceptable in children.</p>
<p>Reviewer’s comments:</p>		<p>GRADE evidence quality rating:</p>
<p><i>Summary of main findings:</i></p> <p>The reviewers conclude that of minor side effects associated with IV midazolam usage for behaviour management in children and adolescents requiring dental treatment, paradoxical reactions were the most common. No significant side effects were recorded (none reported from 871 treatments).</p> <p>A subset of the data suggests that incidences of transient oxygen desaturation seen might be lower with IV than oral midazolam (comparing with data from related review Papineni_2014). This may reflect the ability to titrate via the IV route. Other reasons are also discussed in the review.</p>		<p><i>Rating and brief explanation</i></p> <p>Low to very low quality</p> <p>The evidence on adverse effects of IV midazolam in children derived from the RCTs is judged to be of low quality. The risk of bias for all of these studies was high and 1 was a crossover study which may have had a confounding effect.</p>
<p><i>Applicability to SDCEP guidance</i></p> <p>In 4 of the 5 RCTs, the patients were ASA I or II. 3 of the 6 non-randomised studies included ASA I and II and 1 included patients up to ASA II.</p> <p>The evidence considered in this systematic review only refers to IV midazolam and only to children. Incidences of adverse events may differ in adults and with different drugs, doses and routes.</p> <p>According to the inclusion criteria the studies included should refer to IV midazolam administered by a dentist, anaesthetist, sedationist</p>		<p>The evidence from the observational studies is likely to be low or very low quality due to the study type and high risk of bias reported.</p>

<p>or dental auxiliary in an outpatient setting or dental office – presumably this could include hospital settings.</p>	
<p>SDCEP guidance themes: sedation technique✓, patient selection X, records X, consent X, training X, monitoring (✓), fasting (✓), environment X, equipment X, staffing X, patient views X (✓)= mentioned but not in detail.</p>	

Systematic Review SR8: Papineni et al., 2014

Systematic Review: Papineni, A., L. Lourenço-Matharu, et al. (2014). Safety of oral midazolam sedation use in paediatric dentistry: a review. International Journal of Paediatric Dentistry 24(1): 2-13 12.			Ref. No.: SR8 Reviewer(s): MW 010616
Aim of study: <i>is there a clearly focussed question?</i> To evaluate the side effects and other adverse outcomes following use of oral midazolam for behaviour management in paediatric dentistry			
Patient/Problem: <i>(target patients and actual participant characteristics)</i> Children and adolescents aged 0–18 years of age (including children with specific medical or behavioural problems) undergoing dental treatment.	Intervention or risk factors: Oral midazolam	Comparison: Other doses and routes of midazolam, other sedatives or placebo.	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i> 1. *Minor adverse reactions (defined as any reported adverse events that were non-life-threatening). 2. *Significant adverse reactions (defined as potentially life-threatening adverse reactions. Examples were mortality, inability to maintain an airway or desaturations not corrected by head movements.)
Study Type: <i>Appropriate study types?</i> 16 RCTs (7 were crossover) 11 non-randomised studies (authors argued that 'Analyses restricted to clinical trials may miss rare but significant outcomes (e.g. mortality); therefore, there is value in carrying out a separate review with a wider range of studies included such as cohort or case-control studies). <i>Correct components to address question?</i> Yes <i>Study no.s:</i> 16+11 <i>Study sizes:</i>	Search Strategy: <i>Appropriate search terms?</i> Yes – described in Figs 1&2 (The search for RCTs was modelled on that used by Cochrane review in 2005 – includes cross-over trials. The search for any other nonrandomized studies used a combination of controlled vocabulary and free text terms based on the search strategy as described in Chapter 14 of the Cochrane Handbook). <i>Appropriate databases?</i> Medline, Embase, website search engine Handsearching of International Journal of Paediatric Dentistry, Pediatric Dentistry, Journal of American Dental Association, Anesthesia Progress	Study selection: <i>Inclusion and exclusion criteria:</i> 1. Types of study subject: Children and adolescents aged 0–18 years of age (including children with specific medical or behavioural problems) undergoing dental treatment, regardless of baseline anxiety. 2. Types of interventions: Oral midazolam administered by a dentist, anaesthetist, sedationist or dental auxiliary in an outpatient setting or dental office. Studies that reported induction of deep sedation were excluded. Studies where oral midazolam was used as a premedication were excluded. Studies where supplemental nitrous oxide was given were excluded. 3. Types of outcome measures: The primary outcome measure was the percentage prevalence of significant side effects per episode of treatment. The secondary outcome measure was the percentage prevalence of minor side effects per episode of treatment.	No. of selectors: 2

<p>RCTs had 11-46 patients in main treatment group i.e. oral midazolam alone (486 in total); non-randomised studies had 15-579 patients in treatment group (2032 midazolam treatment episodes in total)</p>	<p>(2000-11). Reference books and regulatory authorities <i>Unpublished studies?</i> Not stated <i>Follow up of citations?</i> yes <i>Personal contact with experts?</i> Not stated</p>		
<p>Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i> Analysis of bias for the RCTs refers to Lourenco-Matharu et al Cochrane Review 2012 – some are included in 2005 or 2006 versions. However, sources of bias are only reported for 11 of the 16 RCTs.</p>			
<p><i>Randomisation (selection bias): is it reported and appropriate (include sequence generation and allocation concealment if possible)?</i> Although all 16 RCTs should have included randomisation, the method of sequence generation and allocation concealment are unclear or unknown (not assessed) for each i.e. unclear risk of selection bias for all studies.</p>	<p><i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> 7 of the 11 RCTs described in the other Cochrane reviews were double blinded. 1/11 didn't have blinding. For the other 8 studies blinding is unclear or unknown. Blinding may not be possible in some of these studies e.g. where comparing different kinds of sedation such as oral midazolam vs N2O.</p>	<p><i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> Only 2/11 of the RCTs assessed in the Cochrane reviews had a low risk of bias from incomplete outcome assessment. For 5/11 studies the risk was high and for the other studies the risk was unclear or is not known. 7 or the 11 RCTs assessed were free of selective reporting. For the others the risk is unknown. Only 3 of the 11 RCTs assessed were judged to be at low risk of other bias, for the others the risk is uncertain or unknown. 7/16 RCTs were crossover studies – some would argue that this design is inappropriate since the behaviour of children undergoing dental procedures and associated side effects could be influenced by the child's prior experience of dental treatment Overall risk of bias: None of the 11 studies assessed by Cochrane were judged as being at low risk of bias overall. For 5 of the studies at least one domain was assessed as being at high risk of bias. The rest were assessed as being at unclear risk of bias or the risk of bias is unknown (not assessed). The risk of bias for the 11 non-randomised studies was judged by the SR author to be high.</p>	
<p>Inconsistency: <i>Refers to unexplained heterogeneity in results.</i></p>	<p>Imprecision (random error):</p>	<p>Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i></p>	<p>Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i></p>

<p><i>Is heterogeneity analysis reported?</i> No formal analysis but noted that: Studies differed widely in the numbers of reported minor side effects; some reported none at all and others reported high proportions of patients (up to 50%) experiencing them. It is difficult to explain this solely in terms of dosage, patient age, or other factors; it may be that reporting itself was an issue.</p>	<p>Confidence intervals not reported</p>	<p>Oral midazolam was compared to placebo in some studies and to other doses, routes or other drugs in other studies.</p> <p>Locations and settings of populations in individual studies not stated.</p>	<p>No assessment done.</p>
<p>Meta-analysis:</p>		<p>Overall results (for each outcome): No. of data extractors: 2</p>	
<p><i>Was meta analysis conducted?</i> Only simple summary measures could be calculated due to the limited data available from some studies.</p> <p><i>Are results for individual studies shown?</i> yes</p> <p><i>Was it reasonable to combine study results?</i> Yes, for some</p> <p><i>Was an appropriate method used?</i> n/a</p> <p><i>Are reasons for variation in results discussed?</i> Yes – see heterogeneity above</p> <p><i>Would confounders affect overall result^a?</i></p>		<p>From the RCTs:</p> <ol style="list-style-type: none"> 1. Minor adverse events were more common than major (n = 68, 14% of cases), with nausea and vomiting being the most common side effect (n = 30, 6.2% of cases) 2. No significant side effects were reported. <p>From the non-RCTs:</p> <ol style="list-style-type: none"> 1. Minor adverse events were more common than major (n = 157, 8% of cases), with paradoxical reactions* being the most commonly reported side effect (n = 77, 3.8% of cases) 2. No significant side effects were recorded. <p>Data related to the effectiveness of the sedative were not collected.</p> <p>*Note that paradoxical reactions can be a result of under-sedation.</p>	

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

		<i>Is the effect substantial^a?</i>	no
		<i>Is there dose-response data^a?</i>	no
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?	
Adverse events are the main theme of this systematic review. Common side effects include transient desaturations, hiccough, nausea and vomiting, headache, vertigo, enuresis, hypersalivation, hallucinations, dizziness, diplopia and behavioural disinhibition (or paradoxical reaction). Severe side effects include cardiac arrest, heart rate changes, anaphylaxis, thrombosis, laryngospasm, bronchospasm, respiratory depression and respiratory arrest.	Potential harm from oral midazolam is the main theme of the review. The benefits of midazolam are discussed briefly i.e. can be administered orally, has anxiolytic and anterograde amnesic effects and is short acting.	Not discussed	
Reviewer’s comments:		GRADE evidence quality rating:	
<i>Summary of main findings:</i> The reviewers conclude that significant or major side effects associated with oral midazolam usage for behaviour management in children and adolescents requiring dental treatment appear to be rare (none reported from ~2500 treatments). Minor events are more common but determining precise figures was complicated by poor reporting (e.g. sometimes grouped together or not reported).		<i>Rating and brief explanation</i> Low to very low quality The evidence on adverse effects of oral midazolam in children derived from the RCTs is judged to be of low quality. The risk of bias for these studies was high or uncertain and nearly half were crossover studies which may have had a confounding effect. The evidence from the observational studies is likely to be low or very low quality due to the study type and high risk of bias reported.	
<i>Applicability to SDCEP guidance</i> The evidence considered in this systematic review only refers to oral midazolam and only to children. Incidences of adverse events may differ in adults and with different drugs, doses and routes. According to the inclusion criteria the studies included should refer to oral midazolam administered by a dentist, anaesthetist, sedationist or dental auxiliary in an outpatient setting or dental office – presumably this could include hospital settings.			
SDCEP guidance themes: sedation technique✓, patient selection X, records X, consent X, training X, monitoring (✓), fasting X, environment X, equipment X, staffing X, patient views X (✓)= mentioned but not in detail.			

Systematic Review SR9: Davies, 2015

Systematic Review: Davies, D. H. J. (2015). A review of the use of intranasally administered midazolam in adults and its application in dentistry. Journal of Disability and Oral Health 16(3): 68-78.			Ref. No.: SR9 Reviewer(s): MW 250716
Aim of study: <i>is there a clearly focussed question?</i> Although not explicitly stated, the aim was to review evidence to evaluate the effectiveness and safety of intranasally delivered midazolam for its use for dental sedation.			
Patient/Problem: <i>(target patients and actual participant characteristics)</i> Adults aged 19-80+ years of age undergoing dental treatment. In some studies, patients had learning difficulties.	Intervention or risk factors: Intranasal midazolam (including by nasal drops, liquid or spray)	Comparison: Other doses and routes of midazolam, other sedatives or placebo.	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i> 1. Effectiveness of delivery method (e.g. liquid drops, spray etc) – measured by bioavailability and plasma concentration 2. Time taken for sedative effect 3. *Effectiveness (for dental treatment)# 4. *Side effects (not just from dental studies) #Only 4 studies were specific to the use of intranasal midazolam for dental treatment
Study Type: <i>Appropriate study types?</i> 25 studies met inclusion criteria; 13 RCTs, 9 controlled clinical trials, 3 comparative studies. Of these only 4 looked specifically at use for dental treatment (1 RCT). <i>Correct components to address question? Yes</i> <i>Study sizes:</i> No indication of numbers of participants in studies	Search Strategy: <i>Appropriate search terms?</i> Nasal/intranasal plus midazolam expanded terms (not limited to dental) Search limited to English language, ages from 19 to 80+, and comparative studies, controlled clinical trials, RCTs or meta-analysis. <i>Appropriate databases?</i> Medline, Embase, AMED, PubMed, Web of Science, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials. <i>Unpublished studies?</i> Not stated <i>Follow up of citations?</i> Not stated		Study selection: <i>Inclusion criteria:</i> Studies written in English on the sole use of intranasally administered midazolam on adults, that were meta-analyses, randomised controlled trials, systematic reviews, controlled clinical trials or comparative studies.
			No. of selectors: not stated

	<i>Personal contact with experts?</i>	Not stated	
Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i>			
<i>Randomisation (selection bias): is it reported and appropriate (include sequence generation and allocation concealment if possible)?</i> Not indicated	<i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Only mentioned for 1 study	<i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> Overall risk of bias: A level of bias risk was assigned to each study, but the basis for this was not described. Levels are assigned as low (15 studies) or high risk of bias (10 studies). 2 of the comparative studies were rated at low levels of risk of bias although if using GRADE, a lack of randomisation and blinding would be judged as a source of potential bias.	
Inconsistency: <i>Refers to unexplained heterogeneity in results.</i>	Imprecision (random error):	Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i>	Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i>
<i>Is heterogeneity analysis reported?</i> No formal analysis but author noted that different delivery methods, doses and formulations were used.	Confidence intervals not reported	Only 4 of the studies looked at outcomes for dental patients. In 2 of these, supplemental i.v. midazolam was also used for some patients. In some of the studies the patients had learning disabilities. Locations and settings of populations in individual studies not stated.	No assessment done.
Meta-analysis:		Overall results (for each outcome): No. of data extractors: not stated (presumably just the author)	
<i>Was meta-analysis conducted?</i> No, ranges of effects from studies relevant for a particular outcome were stated. <i>Are results for individual studies shown?</i> <i>Was it reasonable to combine study results?</i> <i>Was an appropriate method used?</i>	Yes, for some outcomes Possibly not since different delivery methods and doses were used and different studies focussed on different outcomes. n/a	1. Effectiveness of delivery method: The mean bioavailability of midazolam after intranasal delivery ranged from 50-85% (10 studies of varying quality likely to range from low to moderate) compared to 44% following oral administration (from 1 older study). Mean peak plasma concentration ranged from 28-257ug/ml (data from 14 studies, with 1 anomalous study excluded). 2. Time taken to reach maximum plasma concentration: ranged from 6.5-25mins; the	

<p><i>Are reasons for variation in results discussed?</i> Yes – different delivery methods, doses and formulations mentioned.</p> <p><i>Would confounders affect overall result^a?</i></p>	<p>longer times may be associated with the use of drops or solutions rather than spray.</p> <p>3. Effectiveness (for dental treatment): based on 4 studies (i) reduced anxiety with intranasal midazolam, although this study was likely to rate as low quality by GRADE (ii) improved patient compliance following intranasal midazolam compared to no treatment (RCT with low risk of bias therefore likely to be moderate quality by GRADE) (iii) in an audit of intranasal sedation (plus i.v. where required) for adult patients with learning disabilities, the patient was fully cooperative in 58% of episodes (222 in total) (minimal interference for 34%, 9% impossible to treat) – previously i.v. sedation alone had not been possible for the patients included in this audit (likely to be rated low quality evidence by GRADE). i.e. improved patient compliance compared to no treatment. (iv) in a related prospective audit, venous cannulation (for i.v. midazolam) was achieved following intranasal midazolam in 96% of treatment episodes (71% of patients in the audit had learning disabilities); likely to rate as low quality evidence</p> <p>4. Side effects (not just from dental studies): nasal burning and irritation, lacrimation, discomfort in the mouth, bad taste, sneezing, coughing, dry mouth, nausea and oxygen desaturation were reported adverse effects. Side effects were short-lived.</p> <p><i>Is the effect substantial^a?</i> no <i>Is there dose-response data^a?</i> no</p>	
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?
<p>Adverse events are reported.</p>	<p>The benefits of intranasal midazolam are discussed i.e. needle-free, patient friendly means of drug delivery. Side effects are also discussed and it is noted that most are short-lived and not severe. Oxygen desaturation was the most significant and could be addressed with supplemental oxygen.</p>	<p>Acceptability of intranasal midazolam as an alternative to intravenous routes is a main theme.</p>

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

Reviewer's comments:		GRADE evidence quality rating:
<p><i>Summary of main findings:</i></p> <p>The authors rated evidence quality and grades of recommendations according to SIGN criteria. Some of the risks of bias may have been underestimated compared to GRADE criteria e.g. only a low risk of bias was assigned to a study which lacked blinding of subjects and investigators, had no control group and was of a small size.</p> <p>There is insufficient comparator data to conclude whether intranasal midazolam has higher bioavailability or leads to higher peak plasma concentrations compared to that with other delivery routes. The authors suggest that intranasal delivery by spray is the most effective method and that the formulation might affect the time taken for absorption and consequently for the onset of the sedative effect.</p> <p>Low quality evidence suggests that intranasal midazolam can improve patient compliance with cannulation for supplemental i.v. midazolam, and/or compliance with dental treatment. It may be particularly useful for needle-phobic patients or those with learning difficulties who will not tolerate cannulation otherwise.</p> <p>Local and other side effects of intranasal midazolam were reported from some of the studies, although the levels of incidences are generally not stated. There is insufficient evidence to be able to draw a definitive conclusion about the safety of this route and how it compares to other options.</p>		<p><i>Rating and brief explanation</i></p> <p>Low quality (for effectiveness of intranasal midazolam)</p> <p>The evidence from the 4 studies suggesting that intranasal midazolam can reduce anxiety and increase patient compliance for dental treatment was rated according to SIGN criteria (2+, 1+, 2+, 2+). According to GRADE, the evidence is likely to rate as low quality overall, mainly because of the study types and some uncertainty over levels of risk of bias.</p>
<p><i>Applicability to SDCEP guidance</i></p> <p>As described above, only a subset of the studies included sedation for dental treatment. The evidence described for those studies is likely to be applicable to SDCEP guidance. The studies only included adult patients. The dental setting was not stated.</p>		
<p>SDCEP guidance themes:</p> <p>sedation technique✓, patient selection X, records X, consent X, training X, monitoring X, fasting X, environment X, equipment X, staffing X, patient views X</p> <p>(✓)= mentioned but not in detail.</p>		

Guideline G1: Academy of Medical Royal Colleges (AoMRC), 2013

Title: Safe Sedation Practice for Healthcare Procedures: Standards and Guidance		Ref. No.: G1 Reviewer(s): MW 050616 AGREE: G1moderated AGREE Appraisal
Authors/organisation: Academy of Medical Royal Colleges		
Date of publication/revision: 2013	Original version: 2001 These Standards and Guidance replace <i>Implementing and Ensuring Safe Sedation Practice for Healthcare Procedures in Adults</i> published by the AoMRC in 2001.	Source: http://www.aomrc.org.uk/index.php/publications/reports-a-guidance
Aim(s) of guidance: This document aims to give guidance for the safe use of conscious sedation techniques by healthcare professionals to facilitate diagnostic and therapeutic healthcare procedures. The report defines Fundamental Standards and Development Standards in safe sedation practice and recommends competency-based formal training for all healthcare professionals involved in sedation.		
Key recommendations: <i>relevant to SDCEP guidance</i>		
<u>Recommendations relevant to dental sedation are made on:</u> Pre-assessment Information and consent Fasting Patient management and choice of technique for conscious sedation Titration to effect Multiple drugs and anaesthetic drugs/infusions Use of antagonistic drugs Extremes of age		

Monitoring and the use of supplementary oxygen The team Discharge Record keeping Audit and quality assurance Educational and training standards - The guideline places emphasis on the importance of formal accredited competency-based training for all healthcare workers using sedation techniques.			
Geographical setting for guidance:	Healthcare setting for guidance: <i>users and patients</i>	Is guidance currently used?	
Guidelines developed in UK	Healthcare professional groups including doctors, dentists and nurses wishing to use sedation. Although not stated explicitly refers to all patients requiring sedation to facilitate diagnostic and therapeutic healthcare procedures. No age restriction made.	Likely	
Basis for recommendations: <i>e.g. published evidence, expert opinion etc.</i> <i>If evidence based, review evidence in sections below</i>			
The guideline makes reference to some evidence related to adverse events. This is mainly from audits and reports of observational studies and mostly refers to sedation for gastrointestinal endoscopy. The guideline reports that the Department of Health identified overdose of midazolam as of the top 10 'never events' for 2012/13. Recommendations appear to be based on other guidelines referenced (including other Royal College documents) or on expert opinion. There is no discussion of the strengths or weaknesses of the information supporting the guideline.			
Description of evidence for recommendations (if applicable):			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
Patients receiving sedation to facilitate diagnostic and therapeutic healthcare procedures	Sedation	Not known	Various indicators of adverse events e.g. over-dose of sedative, use or reversal agent
Study Type:	Search Strategy:		Study selection: No. of selectors: n/a
<i>Appropriate study types?</i> Includes audits and prospective	<i>Appropriate search terms?</i>	No search described	<i>Inclusion criteria:</i>

surveys of adverse events. <i>Correct components to address question?</i> Not known <i>Study sizes:</i> Not known	<i>Appropriate databases?</i> “ <i>Unpublished studies?</i> “ <i>Follow up of citations?</i> “ <i>Personal contact with experts?</i> “	No search described <i>Exclusion criteria:</i>
Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i>		
<i>Randomisation: is it reported and appropriate?</i> Not described	<i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Not described	<i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> Not described
Inconsistency: <i>Refers to unexplained heterogeneity in results.</i>	Imprecision (random error):	Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i>
Not described	Not described	The audit evidence discussed mainly refers to endoscopy.
Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i>		Not described
Meta-analysis: No. of data extractors: n/a		Overall results: <i>for each outcome or recommendation as applicable</i>
<i>Are results for individual studies shown?</i> no <i>Was it reasonable to combine study results?</i> n/a <i>Was an appropriate method used?</i>		There was very little data reported and most was descriptive. <i>Is the effect substantial^a?</i> <i>Is there dose-response data^a?</i>

<p><i>Are reasons for variation in results discussed?</i> None compared</p> <p><i>Would confounders affect overall result^a?</i></p>		
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?
<p>Adverse events (particularly for endoscopy) were discussed as the justification for the guideline.</p>	<p>The guideline acknowledges that: By relieving anxiety, reducing pain and providing amnesia, sedation techniques have the potential to render uncomfortable diagnostic and therapeutic procedures more acceptable for patients. However, it must be accepted that these techniques also have the potential to cause life-threatening complications.</p>	<p>Not mentioned</p>
Overall quality of guidance (AGREE II) and explanation:		Rating of recommendations: <i>Should the recommendations made be considered for SDCEP guidance?</i>
<p>Overall quality = 4/7 (moderate) AGREE appraisals available on request</p> <p>This is a moderate quality guideline. The recommendations appear to be based on other guidelines and expert opinion. There is some information presented on adverse events, mostly in endoscopy. There is no indication of a systematic search to source information to inform the recommendations was carried out and no consideration of the quality of the evidence cited to support the guideline.</p> <p>The strength of the recommendations is not explicitly stated (i.e. weak or strong) although the words 'should', 'do not', 'consider', 'ensure' etc are used to indicate strength.</p>		<p>The evidence was not appraised in any way. The audit reports and surveys on adverse events would be likely to be considered low to very low quality evidence if appraised using GRADE, because of the study type.</p> <p>The strength of the recommendations is not stated (i.e. weak or strong) although the words 'should', 'must', 'may be' etc could be used as indicators of strength.</p> <p>The recommendations relevant to dental sedation included in this guideline may be considered for supporting recommendations in the updated SDCEP guidance.</p>
Reviewer's comments:		

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

The information on adverse events may not have included sedation for dental procedures.

There are some recommendations made in the guideline that are specific to dentistry, particularly those referring to the number of sedation trained staff:

It is deemed acceptable in some specialties, e.g. dentistry, that, where conscious sedation is the target state, a second individual already responsible for monitoring the patient may assist the operator-sedationist with interruptible ancillary tasks of short duration, no third person being required.

SDCEP guidance themes:

sedation technique ✓, patient selection ✓, records ✓, consent ✓, training ✓, monitoring ✓, fasting ✓, environment ✓, equipment ✓, staffing ✓, patient views x

(✓)= mentioned but not in detail.

Guideline G2: American Dental Association (ADA), 2012a

Title: Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students		Ref. No.: G2 Reviewer(s): DS 02.06.16 AGREE: G2 moderated AGREE Appraisal
Authors/organisation: American Dental Association		
Date of publication/revision: 2012 Updated: Oct 2016 – see end of this appraisal form for details.	Original version:	Source: http://www.ada.org/en/member-center/oral-health-topics/anesthesia-and-sedation
Aim(s) of guidance: The intent of these guidelines is to provide direction for the teaching of pain control and sedation to dentists and can be applied at all levels of dental education from predoctoral through continuing education. They are designed to teach initial competency in pain control and minimal and moderate sedation techniques.		
Key recommendations: <i>relevant to SDCEP guidance</i>		
<ul style="list-style-type: none"> Experienced practitioners with a high degree of competency gained through a combination of instruction and experience are assumed to meet the educational criteria described. Aim to provide a consistent measure of acceptable predoctoral and continuing education but is not intended to fit every program into the same rigid educational mold. This is neither possible nor desirable. There must always be room for innovation and improvement. Includes an extensive list of definitions under headings: Methods of Anxiety and Pain Control (analgesia, conscious sedation, combination inhalation-enteral conscious sedation, local anaesthesia, minimal sedation, moderate sedation, titration, deep sedation, general anaesthesia); Routes of Administration (enteral, parenteral, transdermal, transmucosal, inhalation); Terms (qualified dentist, must/shall, should, may, continual, continuous, time-oriented anaesthesia record, immediately available); ASA Physical Status Classification. Educational Courses (Competency courses, update courses, survey courses, advanced education courses) Detailed recommendation describing the objectives, content and delivery of courses are provided under the following headings: <ul style="list-style-type: none"> Teaching Pain Control Recommendations General objectives; Curriculum Content; Sequence of Didactic and Clinical Instruction; Faculty; Facilities Teaching Administration of Minimal Sedation General objectives <u>Inhalation Sedation (Nitrous Oxide/Oxygen)</u> objectives and course content, duration (min 14 hours + clinical component); participant evaluation and documentation; faculty; facilities <u>Enteral and/or Combination Inhalation-enteral Minimal Sedation</u> objectives and course content, duration (min 16 hours + clinical experiences); participant evaluation and documentation; faculty; facilities Teaching Administration of Moderate Sedation General objectives; course content; <u>Enteral moderate sedation</u> course duration (min 24 hours plus management of at least 10 adult 		

case experiences, including 3 live patients + simulations/video); <u>Parenteral moderate sedation</u> course duration (min 60 hours plus management of at least 20 adult cases); participant evaluation and documentation; faculty; facilities			
Geographical setting for guidance:	Healthcare setting for guidance: <i>users and patients</i>	Is guidance currently used?	
Guidelines developed by American Society.	Not clearly stated.	Most recent therefore likely to be.	
Basis for recommendations: <i>e.g. published evidence, expert opinion etc.</i> <i>If evidence based, review evidence in sections below</i>			
The methodology used to develop this guideline is not presented. Only 10 references (mostly other guidelines) are listed as 'sources of information', but there is no indication of how these were identified or any assessment of quality. The recommendations are presented within bulleted lists.			
Description of evidence for recommendations (if applicable):			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
Not specified, but appears to relate to all patients including children and those with special needs	Sedation	N/A	
Study Type:	Search Strategy:	Study selection:	No. of selectors:
<i>Appropriate study types?</i>	<i>Appropriate search terms?</i> No <i>Appropriate databases?</i> No <i>Unpublished studies?</i> No <i>Follow up of citations?</i> No <i>Personal contact with experts?</i> No	<i>Inclusion criteria:</i> No details of study selection from search results are provided.	
Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i>			
<i>Randomisation: is it reported and appropriate?</i> Not described	<i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Not described	<i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> No details provided.	

<p>Inconsistency: Refers to unexplained heterogeneity in results.</p>	<p>Imprecision (random error):</p>	<p>Indirectness: consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</p>	<p>Publication bias: e.g. when intervention is new and not many studies available- may be biased for positive results</p>
<p>No heterogeneity analysis.</p>	<p>Not reported</p>	<p>Unclear</p>	<p>Publication bias is very likely.</p>
<p>Meta-analysis: No. of data extractors: not stated</p>		<p>Overall results: for each outcome or recommendation as applicable</p>	
<p>No meta-analysis performed Are results for individual studies shown? No Was it reasonable to combine study results? Was an appropriate method used? Are reasons for variation in results discussed? Would confounders affect overall result^a?</p>		<p>N/A Is the effect substantial^a? no Is there dose-response data^a? No</p>	
<p>Adverse events:</p>	<p>Benefit/harm/cost considerations?</p>	<p>Values/preferences considerations?</p>	
<p>Not discussed</p>	<p>Not specifically discussed. Cost considerations not mentioned.</p>	<p>Not discussed</p>	
<p>Overall quality of guidance (AGREE II) and explanation:</p>		<p>Rating of recommendations: Should the recommendations made be considered for SDCEP guidance?</p>	
<p>Overall quality = 2/7 (Low) AGREE appraisals available on request. This is a low quality guideline. The methodology used to develop this guideline appears</p>		<p>Due to the poor methodology employed, these recommendations should not be used as the basis for making recommendations in SDCEP guidance. However, if SDCEP guidance recommendations are consistent with these recommendations, this guideline could be cited as</p>	

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

to be very weak (i.e. not reported). Recommendations are relatively easy to find and are fairly unambiguous. The guideline is concise. There is no discussion of barriers, implementation, patient views etc.	such.
Reviewer's comments:	
<p>This is one of three ADA documents related to the provision of sedation. The guideline does not discuss choice of sedation technique.</p> <p>The absence of a reported methodology is a major weakness. The recommendations are fairly clear, unambiguous and likely to be consistent with practice in the UK with regard to minimal and moderate sedation only.</p> <p>It would not be appropriate to base recommendations for the UK on this guideline but it might be useful to cite it as verification of recommendations if they are consistent.</p>	
<p>SDCEP guidance themes: sedation techniqueX, patient selectionX, recordsX, consentX, training✓, monitoringX, fastingX, environmentX, equipmentX, staffing✓, patient viewsX (✓) indicated mentioned but not in detail.</p>	
2016 guideline update:	
<p>Relevant changes</p> <p>No longer includes children in the scope – refers to AAPD 2016 updated guideline (see appraisal form for G10).</p> <p>Only minimal and moderate sedation are defined.</p> <p>Maintenance of sedation equipment has been added to the course content.</p> <p>The sections covering teaching of enteral and parenteral moderate sedation have been combined.</p> <p>The update recommends that the course director should hold a current permit or license to administer moderate sedation (for teaching minimal sedation) or moderate or deep sedation and general anaesthesia (for teaching moderate sedation).</p> <p>Appraisal</p> <p>As for the 2012 version, the 2016 update does not describe the methodology used and there is no discussion of barriers, implementation or patient views. The recommendations are presented in a similar way to the 2012 version. Consequently, the 2016 update would also rate, using the AGREE II tool, as 2/7 (Low quality).</p>	

Guideline G3: American Dental Association (ADA), 2012b

Title: Guidelines for the Use of Sedation and General Anesthesia by Dentists		Ref. No.: G3 Reviewer(s): DS 02.06.16 AGREE: G3 moderated AGREE Appraisal
Authors/organisation: American Dental Association		
Date of publication/revision: 2012 Updated: Oct 2016 – see end of this appraisal form for details.	Original version:	Source: http://www.ada.org/en/member-center/oral-health-topics/anesthesia-and-sedation
Aim(s) of guidance: The purpose of these guidelines is to assist dentists in the delivery of safe and effective sedation and anesthesia.		
Key recommendations: <i>relevant to SDCEP guidance</i>		
<ul style="list-style-type: none"> Includes an extensive list of definitions under headings: Methods of Anxiety and Pain Control (analgesia, conscious sedation, combination inhalation-enteral conscious sedation, local anaesthesia, minimal sedation, moderate sedation, titration, deep sedation, general anaesthesia); Routes of Administration (enteral, parenteral, transdermal, transmucosal, inhalation); Terms (qualified dentist, must/shall, should, may, continual, continuous, time-oriented anaesthesia record, immediately available); ASA Physical Status Classification. Lists educational requirements (including life support training) for the dentist administering minimal sedation; moderate sedation; deep sedation or GA. Minimal Sedation recommendations related to: Patient evaluation; Pre-operative preparation; Personnel (including training) and Equipment Requirements; Monitoring (oxygenation; ventilation; circulation) and Documentation; Recovery and Discharge; Emergency Management; Management of Children. Moderate Sedation recommendations as for minimal sedation plus: equipment necessary to establish intravenous access must be available; enhanced staffing requirements for monitoring; monitoring of consciousness; enhanced documentation; additional procedures if a reversal agent has been used. Deep Sedation and GA recommendations as for moderate sedation plus: pre-op securing of an IV line; additional personnel; equipment for enhanced airway management and cardiac life support; monitoring of temperature; additional considerations for pediatric and special needs patients; additional emergency management measures. 		
Geographical setting for guidance:	Healthcare setting for guidance: <i>users and patients</i>	Is guidance currently used?
Guidelines developed by American Society.	Not clearly stated.	Most recent therefore likely to be.

Basis for recommendations: <i>e.g. published evidence, expert opinion etc.</i> <i>If evidence based, review evidence in sections below</i>			
The methodology used to develop this guideline is not presented. Only 9 references (mostly the same guidelines cited in G2) are listed as 'sources of information', but there is no indication of how these were identified or any assessment of quality. The recommendations are presented within bulleted lists.			
Description of evidence for recommendations (if applicable):			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
Not specified, but appears to relate to all patients including children and those with special needs	Sedation	<u>N/A</u>	
Study Type:	Search Strategy:	Study selection:	No. of selectors:
<i>Appropriate study types?</i>	<i>Appropriate search terms?</i> <i>Appropriate databases?</i> <i>Unpublished studies?</i> <i>Follow up of citations?</i> <i>Personal contact with experts?</i>	No No No No No	<i>Inclusion criteria:</i> No details of study selection from search results are provided.
Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i>			
<i>Randomisation: is it reported and appropriate?</i> Not described	<i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Not described	<i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> No details provided.	
Inconsistency: <i>Refers to unexplained heterogeneity in results.</i>	Imprecision (random error):	Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i>	Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i>
No heterogeneity analysis.	Not reported	Unclear	Publication bias is very likely.

Meta-analysis: No. of data extractors: not stated		Overall results: <i>for each outcome or recommendation as applicable</i>	
No meta-analysis performed <i>Are results for individual studies shown?</i> No <i>Was it reasonable to combine study results?</i> <i>Was an appropriate method used?</i> <i>Are reasons for variation in results discussed?</i> <i>Would confounders affect overall result^a?</i>		N/A <i>Is the effect substantial^a?</i> no <i>Is there dose-response data^a?</i> no	
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?	
Not discussed	Not specifically discussed. Cost considerations not mentioned.	Not discussed	
Overall quality of guidance (AGREE II) and explanation:		Rating of recommendations: <i>Should the recommendations made be considered for SDCEP guidance?</i>	
Overall quality = 2/7 (low) AGREE appraisals are available on request. This is a low quality guideline. The methodology used to develop this guideline appears to be very weak (i.e. not reported). Recommendations are relatively easy to find and are fairly unambiguous. The guideline is concise. There is no discussion of barriers, implementation, patient views etc.		Due to the poor methodology employed, these recommendations should not be used as the basis for making recommendations in SDCEP guidance. However, if SDCEP guidance recommendations are consistent with these recommendations, this guideline could be cited as such.	

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

Reviewer's comments:

This is one of three ADA documents related to the provision of sedation. The guideline does not discuss choice of sedation technique.

The absence of a reported methodology is a major weakness. The recommendations are fairly clear, unambiguous and likely to be consistent with practice in the UK with regard to minimal and moderate sedation only.

It would not be appropriate to base recommendations for the UK on this guideline but it might be useful to cite it as verification of recommendations if they are consistent.

SDCEP guidance themes: sedation techniqueX, patient selection✓, records✓, consent✓, training✓, monitoring✓, fasting(✓), environmentX, equipment✓, staffing✓, patient viewsX
(✓) indicated mentioned but not in detail.

2016 guideline update:**Relevant changes**

No longer includes children in the scope – refers to AAPD 2016 updated guideline (see appraisal form for G10).

Definitions have been amended and no longer include conscious sedation.

Some of the details of the recommendations for each level of sedation have been amended:

Minimal Sedation: baseline vital signs expanded to specify body weight, height, blood pressure, pulse rate and respiration rate (also body temperature when clinically indicated); documentation of equipment maintenance and pre-procedural checks have been added to equipment requirements; level of sedation has been added to monitoring.

Moderate Sedation: BMI now recommended as part of assessment; baseline vital signs expanded to specify body weight, height, blood pressure, pulse rate, respiration rate and oxygen saturation (also body temperature when clinically indicated); fasting instructions are now recommended in patient instructions; documentation of equipment maintenance, pre-procedural checks and the requirement for capnography equipment have been added; monitoring of end-tidal CO₂ has been added.

Deep Sedation or General Anaesthetic: these recommendations have also been updated but are not included in the scope of the SDCEP guidance.

Appraisal

As for the 2012 version, the 2016 update does not describe the methodology used and there is no discussion of barriers, implementation or patient views. The recommendations are presented in a similar way to the 2012 version. Consequently, the 2016 update would also rate, using the AGREE II tool, as 2/7 (Low quality).

Guideline G5: Australian and New Zealand College of Anaesthetists (ANZCA), 2014

Title: Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures		Ref. No.: G5 Reviewer(s): MW 010616 AGREE: G5 moderated AGREE Appraisal
Authors/organisation: Australian and New Zealand College of Anaesthetists (ANZCA), Faculty of Pain Medicine		
Date of publication/revision: 2014	Original version: Promulgated: (as P9) 1984 Reviewed: 1986, 1991, 1996, 2001, 2005, 2007, 2008, 2010, 2014	Source: http://www.anzca.edu.au/Documents/ps09-2014-guidelines-on-sedation-and-or-analgesia.pdf
Aim(s) of guidance: The aim is not very clearly stated but the implication is that it is to promote best practice in sedation for various procedures: This document is intended to apply wherever procedural sedation and/or analgesia for diagnostic and interventional medical, dental and surgical procedures are administered, but excludes situations where sedation is used for longer term management of patients such as in intensive care units or for psychiatrically disturbed patients. The Australian and New Zealand College of Anaesthetists (ANZCA) and all co-signing colleges/societies recognise that practitioners with diverse qualifications and training are administering a variety of medications to patients to allow such procedures to be performed. This document addresses pertinent issues for all practitioners involved in such activities. ANZCA's website states: <i>ANZCA's professional documents are crucial for promoting the safety and quality of patient care for those undergoing anaesthesia for surgical and other procedures.</i>		
Key recommendations: <i>relevant to SDCEP guidance</i>		
<u>Recommendations included in the text on:</u> Patient preparation (fasting recommendations are considered in separate guidelines PS15 and PS07) Patient assessment Staffing Facilities and equipment (including life support) Specialised equipment for inhalational sedation and/or analgesia Technique and monitoring Oxygenation Medications Documentation Recovery and discharge		

Training Audit			
Geographical setting for guidance:		Healthcare setting for guidance: <i>users and patients</i>	Is guidance currently used?
Guidelines developed in Australia but lists articles from other countries including UK guidelines.		Applicable for all patients where procedural sedation and/or analgesia for diagnostic and interventional medical, dental and surgical procedures are administered.	Don't know, but is regularly updated, so likely to be in use.
Basis for recommendations: <i>e.g. published evidence, expert opinion etc.</i> <i>If evidence based, review evidence in sections below</i>			
<p>The document is an update of a guideline produced in 1984 and revised 9 times since. The ANZCA <i>Policy for the Development and Review of Professional Documents</i> suggests that their <i>guidelines</i> should have a background paper which should include:</p> <p>2.8.1 A justification for the document (purpose and benefit).</p> <p>2.8.2 A concise review of the issues considered, with sufficient discussion to allow readers to understand the basis for and limitations of all recommendations.</p> <p>2.8.3 Documentation of literature search strategies and/or methods of expert consensus development.</p> <p>2.8.4 Lists of publications and other documents reviewed.</p> <p>2.8.5 Names of all those consulted or otherwise involved in document development.</p> <p>This would suggest that the guideline recommendations are based on systematically sourced evidence and expert consensus opinion. However, no details of the evidence (other than an unlinked list of references) are provided and there is no information on studies or their appraisal that may have been considered during development of recommendations.</p>			
Description of evidence for recommendations (if applicable):			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
Patients requiring procedural sedation and/or analgesia for diagnostic and interventional medical, dental and surgical procedures.	Sedation and/or analgesia	None made	Not stated but presumable includes effectiveness and safety.
Study Type:	Search Strategy:	Study selection:	No. of selectors:

<p><i>Appropriate study types?</i> The reference list includes some clinical studies.</p> <p><i>Correct components to address question?</i></p> <p><i>Study sizes:</i></p>	<p><i>Appropriate search terms?</i> unknown</p> <p><i>Appropriate databases?</i> unknown</p> <p><i>Unpublished studies?</i> unknown</p> <p><i>Follow up of citations?</i> unknown</p> <p><i>Personal contact with experts?</i> unknown</p>	<p><i>Inclusion criteria:</i> Not stated</p> <p><i>Exclusion criteria:</i> Not stated</p>	
<p>Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i></p>			
<p><i>Randomisation: is it reported and appropriate?</i> Study data not described</p>	<p><i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Study data not described</p>	<p><i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> Study data not described</p>	
<p>Inconsistency: <i>Refers to unexplained heterogeneity in results.</i></p>	<p>Imprecision (random error):</p>	<p>Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i></p>	<p>Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i></p>
<p>Study data not described</p>	<p>Study data not described</p>	<p>Study data not described</p>	<p>Study data not described</p>
<p>Meta-analysis: No. of data extractors: n/a</p>		<p>Overall results: <i>for each outcome or recommendation as applicable</i></p>	
<p><i>Are results for individual studies shown?</i> <i>Was it reasonable to combine study results?</i></p>		<p>No data presented</p>	

<p><i>Was an appropriate method used?</i> <i>Are reasons for variation in results discussed?</i> <i>Would confounders affect overall result^a?</i></p>		<p><i>Is the effect substantial^a?</i> <i>Is there dose-response data^a?</i></p>
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?
<p>Potential risks:</p> <p>2.2.1 Depression of protective airway reflexes and loss of airway patency.</p> <p>2.2.2 Depression of respiration.</p> <p>2.2.3 Depression of the cardiovascular system.</p> <p>2.2.4 Drug interactions or adverse reactions, including anaphylaxis.</p> <p>2.2.5 Unexpectedly high sensitivity to the drugs used for procedural sedation and/or analgesia which may result in unintentional loss of consciousness, and respiratory or cardiovascular depression.</p> <p>2.2.6 Individual variations in response to the drugs used, particularly in children, the elderly, and those with pre-existing disease.</p> <p>2.2.7 The possibility of deeper sedation or anaesthesia being used to</p>	<p>The aims and risks for procedural sedation are clearly described. The guideline indicates that the recommendations should be followed to ensure patient safety i.e. have taken the risks into consideration.</p> <p>Costs considerations related to any area of sedation provision are not mentioned.</p>	<p>None mentioned.</p>

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

<p>compensate for inadequate analgesia or local anaesthesia. 2.2.8 Risks inherent in the wide variety of procedures performed under procedural sedation and/or analgesia.</p>		
<p>Overall quality of guidance (AGREE II) and explanation:</p>		<p>Rating of recommendations: <i>Should the recommendations made be considered for SDCEP guidance?</i></p>
<p>Overall quality = 3/7 (low) AGREE appraisals are available on request. This is a fairly low quality guideline according to AGREE criteria. Although other documents on the ANZCA website suggest that appropriate methodology may be used e.g. evidence searching, expert involvement, consultation, conflict of interest, reviewing etc, specific details are not provided for the guideline so it is not clear that those methods were applied. The most significant concern with the guideline is the lack of provision of any link between the evidence and the recommendations.</p>		<p>There is no indication that the evidence has been formally appraised for quality and the basis for and strength of the recommendations is not stated. This guideline should not on its own be considered as a strong basis for informing recommendations in the updated SDCEP guidance.</p>
<p>Reviewer's comments:</p>		
<p>No clear link between recommendations and evidence or even expert opinion. If used, the individual recommendations (e.g. sedation and emergency drugs) should be checked for their applicability in the UK.</p>		
<p>SDCEP guidance themes: sedation technique ✓, patient selection ✓, records ✓, consent ✓, training ✓, monitoring ✓, fasting (✓), environment ✓, equipment ✓, staffing ✓, patient views x (✓)= mentioned but not in detail.</p>		

Guideline G6: Standing Committee on Sedation for Dentistry (SCSD), 2007

Title: Standards for Conscious Sedation in Dentistry: Alternative Techniques		Ref. No.: G6 Reviewer(s): MW 050616 AGREE: G6 moderated AGREE Appraisal
Authors/organisation: Standing Committee on Sedation for Dentistry (Intercollegiate Working Party of the Royal College of Anaesthetists and the Faculty of Dentistry of the Royal College of Surgeons of England).		
Date of publication/revision: 2007	Original version: Conscious Sedation in the Provision of Dental Care was published by the Standing Dental Advisory Committee (SDAC) in 2003. The 2007 standards are considered new additional guidance encompassing the use of alternative conscious sedation techniques. Together they have been designed to enable practitioners to take appropriate steps in the provision of a minimum standard for safe and effective patient care whatever the clinical setting.	Source: http://www.rcoa.ac.uk/system/files/PUB-SCSDAT.pdf
Aim(s) of guidance: The combined guidance is designed to provide practitioners with the information they need to ensure they provide conscious sedation services to the specified standards in order to safeguard patients regardless of the clinical setting. The standards set out in this guideline are the minimum requirements. The aim is to ensure that effective treatment given to patients is provided safely and that it is well within the competencies of the dentist / sedationist, dedicated sedationist and whole practice care team.		
Key recommendations: <i>relevant to SDCEP guidance</i>		
<u>Alternative techniques are defined as:</u> <ul style="list-style-type: none"> • Any form of conscious sedation for patients under the age of 12 years # other than nitrous oxide/oxygen inhalation sedation • benzodiazepine + any other intravenous agent with sedative effects for example: opioid, propofol, ketamine • propofol either alone or with any other agent for example: benzodiazepine, opioid, ketamine • inhalational sedation using any agent other than nitrous oxide / oxygen alone 		

<ul style="list-style-type: none"> combined (non-sequential) routes for example: intravenous + inhalational agent (except for the use of nitrous oxide / oxygen during cannulation) <p># It is recognised that the physical and mental development of individuals varies and may not necessarily correlate with the chronological age</p> <p><u>Recommendations are made on:</u></p> <p>Environment requirements including premises, drugs & equipment (sedation, monitoring, management of complications and resuscitation), the team (number of staff), the patient, documentation & protocols (including consent, patient and escort instructions).</p> <p>Qualification requirements (essential and desirable)</p> <p>Experience requirements (for entry into training in specific alternative techniques)</p>			
Geographical setting for guidance:	Healthcare setting for guidance: <i>users and patients</i>	Is guidance currently used?	
Guidelines developed in UK	Dental and medical practitioners including anaesthetists and their teams, who carry out alternative techniques of dental sedation (refers to any clinical setting). Although not stated explicitly, refers to all patients (including children) requiring alternative dental sedation techniques.	Possibly – may have been considered to have been superseded by IACSD 2015 report.	
<p>Basis for recommendations: <i>e.g. published evidence, expert opinion etc.</i></p> <p><i>If evidence based, review evidence in sections below</i></p>			
<p>It is not entirely clear whether the recommendations in this document are regarded as standards or guidance. The main section including 'recommendations/standards' on sedation is called 'Guidance on Standards'. The document is appraised here as a guideline although its focus may be more on quality assurance around the provision of alternative sedation techniques.</p> <p>Although not stated, it is assumed that the recommendations are based on expert opinion. The document refers to some other guidelines including the earlier AoMRC (2001), SDCAC (2003) and SDCEP (2006) documents. A group of 6 RCTs are cited as evidence that alternative techniques can be used by well trained and experienced teams (often involving anaesthetists as well as dentists) to provide conscious sedation. No further details of this evidence are given.</p> <p>There is no discussion of the strengths or weaknesses of any information supporting the guideline.</p>			
Description of evidence for recommendations (if applicable):			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
Patients requiring alternative sedation techniques for dental treatment.	Alternative sedation techniques	Not known	No details provided.

Study Type:	Search Strategy:		Study selection:	No. of selectors: n/a
Appropriate study types? Correct components to address question? Study sizes: No details provided.	Appropriate search terms? Appropriate databases? Unpublished studies? Follow up of citations? Personal contact with experts?	No search described " " " "	Inclusion criteria: No search described Exclusion criteria:	
Risk of bias/systematic error (study limitations that could cause systematic error): consider risk of bias for each important outcome				
Randomisation: is it reported and appropriate? Not described	Blinding: consider whether blinding of patients or assessors would be important for outcomes considered Not described	Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?) Not described		
Inconsistency: Refers to unexplained heterogeneity in results.	Imprecision (random error):	Indirectness: consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest	Publication bias: e.g. when intervention is new and not many studies available- may be biased for positive results	
Not described	Not described	Evidence not described.	No information on how information was sought.	
Meta-analysis: No. of data extractors: n/a			Overall results: for each outcome or recommendation as applicable	
Are results for individual studies shown? no Was it reasonable to combine study results? n/a Was an appropriate method used?			There was no data reported. Is the effect substantial ^a ? Is there dose-response data ^a ?	

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

<i>Are reasons for variation in results discussed?</i> None compared		
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?
Adverse events are not described.	Although safety is a key aim of the guideline, there is no discussion of specific benefits and risks or of cost considerations.	The only reference made to patient views is the statement that patients continue to report difficulty in gaining access to services for the assessment and appropriate control of pain and anxiety in dentistry including both conscious sedation and general anaesthesia.
Overall quality of guidance (AGREE II) and explanation:		Rating of recommendations: <i>Should the recommendations made be considered for SDCEP guidance?</i>
<p>Overall quality = 3/7 (low) AGREE appraisals are available on request.</p> <p>This report has a relatively low score because it fails to meet a number of AGREE criteria. This may be in part because its purpose may be more as guidance on achieving quality assurance around standards rather than as a clinical practice guideline.</p> <p>The recommendations provided in the document appear to be based on other guidelines and expert opinion. Although some RCTs are cited there is no indication that a systematic search was carried out to source the information to inform the recommendations and no consideration of the quality of the information used to support the guideline.</p>		It is not clear whether this document should be considered to be guidance or standards and whether mandatory. The focus seems to be on quality assurance although there are recommendations made for practice. Much of the detail of these is provided in the inspection checklist in Annex 3.
Reviewer's comments:		
The basis for the 'recommendations' provided in this document is not clear.		
<p>SDCEP guidance themes:</p> <p>sedation technique ✓, patient selection* ✓, records ✓, consent ✓, training ✓, monitoring ✓, fasting x, environment ✓, equipment ✓, staffing ✓, patient views x</p> <p>(✓)= mentioned but not in detail.</p> <p>Some of the information is referred to in the checklists in Annex 3.</p> <p>*indications and contraindications for oral/transmucosal midazolam are provided in Annex 4.</p>		

Guideline G8: American Academy of Pediatric Dentistry (AAPD), 2013

Title: Guideline on Use of Nitrous Oxide for Pediatric Dental Patients		Ref. No.: G8 Reviewer(s): MW 250516, DS 25.05.16 AGREE: G8 moderated AGREE Appraisal
Authors/organisation: Council on Clinical Affairs, American Academy of Pediatric Dentistry		
Date of publication/revision: 2013	Original version: 2005, updated 2009	Source: http://www.aapd.org/media/Policies_Guidelines/G_Nitrous.pdf
Aim(s) of guidance: To assist the dental profession in developing appropriate practices in the use of nitrous oxide/oxygen analgesia/anxiolysis for pediatric patients.		
Key recommendations: <i>relevant to SDCEP guidance</i>		
<u>Recommendations included in the text on:</u> Indications and contraindications for use of nitrous oxide/oxygen analgesia/anxiolysis Patient assessment Techniques of administration including dose and equipment Training in sedation and life support (no detail given) Monitoring Fasting Record keeping and patient information Emergency equipment Occupational safety		
Geographical setting for guidance:	Healthcare setting for guidance: <i>users and patients</i>	Is guidance currently used?
Guidelines developed by American association but include studies published outwith the USA.	Applicable for children (age not defined).	Not known, but is regularly updated, so likely to be in use.

		Healthcare setting not stated			
<p>Basis for recommendations: <i>e.g. published evidence, expert opinion etc.</i> <i>If evidence based, review evidence in sections below</i></p>					
<p>The document is an update of the previous guideline revised in 2009. The revision is based on a review of the current dental and medical literature related to nitrous oxide use. An electronic search was conducted using PubMed® with the following parameters: Terms: nitrous oxide, analgesia, anxiolysis, behavior management, and dental treatment; Fields: all; Limits: within the last 10 years, humans, English, and clinical trials. Forty articles met these criteria, and papers were added to the references from the previous document. When data did not appear sufficient or were inconclusive, recommendations were based upon expert and/or consensus opinion by experienced researchers and clinicians. Note: only some of the articles referred to were RCTs or SRs of primary studies (others included reviews and opinion articles) and there was no appraisal of the evidence documented.</p>					
<p>Description of evidence for recommendations (if applicable):</p>					
<p>Patient/Problem: <i>(target patients and actual participant characteristics)</i></p>		<p>Intervention or risk factors:</p>	<p>Comparison:</p>	<p>Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i></p>	
<p>Patient with indications for N2O sedation</p>		<p>N2O</p>	<p>None made</p>	<p>Not stated but inferred outcomes are:</p> <ol style="list-style-type: none"> 1. Effectiveness for analgesia/anxiolysis 2. Safety 3. Acceptability by children 4. Facilitation of dental treatment 5. Side effects 	
<p>Study Type:</p>		<p>Search Strategy:</p>		<p>Study selection:</p>	<p>No. of selectors:</p>
<p><i>Appropriate study types?</i> The 40 articles retrieved should have been clinical trials according to the search criteria, but the data from the studies is not presented. <i>Correct components to address question?</i> Study sizes:</p>		<p><i>Appropriate search terms?</i> basic <i>Appropriate databases?</i> Unpublished studies? Follow up of citations? Personal contact with experts? Nb search limited to studies in English, last 10 years and clinical trials</p>	<p>Yes although Pubmed only no Not stated Not stated</p>	<p><i>Inclusion criteria:</i> Not stated <i>Exclusion criteria:</i> Not stated</p>	
<p>Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i></p>					

<p><i>Randomisation: is it reported and appropriate?</i> Study data not described</p>	<p><i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Study data not described</p>	<p><i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> Study data not described. Limitations of search strategy is highly likely to have biased the results obtained.</p>	
<p>Inconsistency: <i>Refers to unexplained heterogeneity in results.</i></p>	<p>Imprecision (random error):</p>	<p>Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i></p>	<p>Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i></p>
<p>Study data not described</p>	<p>Study data not described</p>	<p>Not clear if studies were relevant to children.</p>	<p>Only considered articles in English and search was not extensive. Publication bias likely.</p>
<p>Meta-analysis: No. of data extractors: n/a</p>		<p>Overall results: <i>for each outcome or recommendation as applicable</i></p>	
<p>No meta-analysis performed, data not described. <i>Are results for individual studies shown?</i> <i>Was it reasonable to combine study results?</i> <i>Was an appropriate method used?</i> <i>Are reasons for variation in results discussed?</i> <i>Would confounders affect overall result^a?</i></p>		<p>None presented. <i>Is the effect substantial^a?</i> <i>Is there dose-response data^a?</i></p>	
<p>Adverse events:</p>	<p>Benefit/harm/cost considerations?</p>	<p>Values/preferences considerations?</p>	

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

<p>Nausea and vomiting listed as most common. Diffusion hypoxia can lead to headache and disorientation.</p>	<p>Safety and adverse effects are considered. The environmental impact of N2O use is discussed, as is occupational safety. Costs considerations related to any area of N2O sedation provision are not mentioned.</p>	<p>Patient experiences of N2O administration are discussed: Stated that Nitrous oxide generally is acceptable to children and can be titrated easily. Most children are enthusiastic about the administration of nitrous oxide/oxygen; many children report dreaming or being on a “space-ride”. For some patients, however, the feeling of “losing control” may be troubling and claustrophobic patients may find the nasal hood confining and unpleasant.</p>
<p>Overall quality of guidance (AGREE II) and explanation:</p>		<p>Rating of recommendations: <i>Should the recommendations made be considered for SDCEP guidance?</i></p>
<p>Overall quality = 3/7 (low) AGREE appraisals are available on request. This is a fairly low quality guideline according to AGREE criteria. Although some searching for evidence has been carried out, the studies are only referenced in the text with little or no reporting of the study details or data or assessment of the quality of the evidence. The recommendations are not clearly linked to the evidence or the underlying basis for each (e.g. expert opinion) indicated. There is no indication of evidence quality or recommendation strength. A number of other criteria for guideline quality are not met satisfactorily.</p>		<p>The authors do not use GRADE or an alternative and although the recommendations reference published articles retrieved by database searches, there is no indication that the evidence has been formally appraised for quality. There is no indication of the strength of the recommendations. There is not a strong basis for using these recommendations. However, if SDCEP guidance recommendations are consistent with these recommendations, this guideline could be cited as such.</p>
<p>Reviewer’s comments:</p>		
<p>The authors conclude that: When administered by trained personnel on carefully selected patients with appropriate equipment and technique, nitrous oxide is a safe and effective agent for providing pharmacological guidance of behavior in children. No clear link between recommendations and evidence. However, the authors state in methods that recommendations may be based on expert and/or consensus opinion. Very little detail is provided regarding recommendations for training. If used, the individual recommendations (e.g. for emergency equipment) should be checked for their applicability in the UK.</p>		
<p>SDCEP guidance themes: sedation technique ✓, patient selection ✓, records ✓, consent ✓, training (✓), monitoring ✓, fasting ✓, environment X, equipment ✓, staffing X, patient views ✓ (✓)= mentioned but not in detail.</p>		

Guideline G10: American Academy of Pediatric Dentistry (AAPD), 2011

Title: Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures		Ref. No.: G10 Reviewer(s): DS 01.06.16 AGREE: G10 moderated AGREE Appraisal
Authors/organisation: American Academy of Pediatrics and the American Academy of Pediatric Dentistry		
Date of publication/revision: 2011 Updated: 2016 – see end of this appraisal form for details.	Original version: 2006	Source: http://www.aapd.org/media/Policies_Guidelines/G_Sedation.pdf Update: http://www.aapd.org/media/Policies_Guidelines/G_Sedation1.pdf
Aim(s) of guidance: The purpose of this updated statement is to unify the guidelines for sedation used by medical and dental practitioners, add clarifications regarding monitoring modalities, provide new information from medical and dental literature, and suggest methods for further improvement in safety and outcomes.		
Key recommendations: <i>relevant to SDCEP guidance</i>		
<ul style="list-style-type: none"> • Defines terms including Minimal sedation and Moderate sedation (old terminology conscious sedation or sedation/analgesia): a drug-induced depression of consciousness during which patients respond purposefully to verbal commands (eg, open your eyes either alone or accompanied by light tactile stimulation—a light tap on the shoulder or face, not a sternal rub, Deep Sedation and General anesthesia). • It is beyond the scope of this document to specify which drugs are appropriate for which procedures; however, the selection of the fewest number of drugs and matching drug selection to the type and goal of the procedure are essential for safe practice. • Responsible person: The pediatric patient shall be accompanied to and from the treatment facility by a parent, legal guardian, or other responsible person. • Facilities: The practitioner who uses sedation must have immediately available facilities, personnel, and equipment to manage emergency and rescue situations. • Back-up emergency services: A protocol for access to back-up emergency services shall be clearly identified, with an outline of the procedures necessary for immediate use. • On-site monitoring and rescue equipment: An emergency cart or kit must be immediately accessible and contain equipment to provide the necessary age- and size-appropriate drugs and equipment to resuscitate a non-breathing and unconscious child. All equipment and drugs must be checked and maintained on a scheduled basis. Monitoring devices, e.g. ECG machines, pulse oximeters, end-tidal carbon dioxide monitors, and defibrillators (with size-appropriate defibrillator paddles), must have a safety and function check on a regular basis as required by local or state regulation. • Documentation before sedation: to include Informed consent; Instructions and information supplied to responsible person (see guideline for details); A 24-hour contact telephone number; Limitations of activities and appropriate dietary precautions. 		

- **Dietary precautions:** Children receiving sedation for elective procedures should generally follow the same fasting guidelines as before general anesthesia (because the absolute risk of aspiration during procedural sedation is not yet known) –details are provided in the guideline; for emergency procedures in children who have not fasted, the risks of sedation and the possibility of aspiration must be balanced against the benefits of performing the procedure promptly.
- **Documentation at the time of sedation:** 1) Pre-sedation health evaluation (see guideline for extensive details); 2) Prescriptions for sedation
- **Documentation during treatment:** The patient’s chart shall contain a time-based record that includes the name, route, site, time, dosage, and patient effect of administered drugs (see guideline for details). Adverse events and their treatment shall be documented.
- **Documentation after treatment:** The time and condition of the child at discharge from the treatment area or facility shall be documented; this should include documentation that the child’s level of consciousness and oxygen saturation in room air have returned to a state that is safe for discharge by recognized criteria.
- **Continuous quality improvement:** each facility should maintain records that track adverse events and examine these for assessment of risk reduction and improvement in patient satisfaction.
- **Preparation and setting up for sedation procedures:** use a systematic approach e.g. SOARME acronym.
- **Minimal sedation:** Children who have received minimal sedation generally will not require more than observation and intermittent assessment of their level of sedation.
- **Moderate sedation:** The drugs and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness highly unlikely. The practitioner responsible for the treatment of the patient and/or the administration of drugs for sedation must be competent to use such techniques, to provide the level of monitoring provided in this guideline, and to manage complications of these techniques (ie, to be able to rescue the patient). Because the level of intended sedation may be exceeded, the practitioner must be sufficiently skilled to provide rescue should the child progress to a level of deep sedation. The practitioner must be trained in, and capable of providing, at the minimum, bag-valve-mask ventilation so as to be able to oxygenate a child who develops airway obstruction or apnea. Training in, and maintenance of, advanced pediatric airway skills is required; regular skills reinforcement is strongly encouraged.
Support personnel The use of moderate sedation shall include provision of a person, in addition to the practitioner, whose responsibility is to monitor appropriate physiologic parameters and to assist in any supportive or resuscitation measures, if required. This individual may also be responsible for assisting with interruptible patient-related tasks of short duration. This individual must be trained in and capable of providing pediatric basic life support.
Monitoring and documentation: baseline vital signs if possible; during the procedure documentation of the name, route, site, time of administration, and dosage of all drugs administered. There shall be continuous monitoring of oxygen saturation and heart rate and intermittent recording of respiratory rate and blood pressure; these should be re-corded in a time-based record. The child’s head position should be checked frequently to ensure airway patency.
After the procedure: The child who has received moderate sedation must be observed in a suitably equipped recovery facility [eg, the facility must have functioning suction apparatus as well as the capacity to deliver more than 90 percent oxygen and positive-pressure ventilation (eg, bag and mask with oxygen capacity as described previously)]. The patient’s vital signs should be recorded at specific intervals. If the patient is not fully alert, oxygen saturation and heart rate monitoring shall be used continuously until appropriate discharge criteria are met.
- **Deep sedation:** There must be one person available whose only responsibility is to constantly observe the patient’s vital signs, airway, patency, and adequacy of ventilation and to either administer drugs or direct their administration. At least one individual must be present who is trained in, and capable of, providing advanced pediatric life support, and who is skilled in airway management and cardiopulmonary resuscitation; training in pediatric advanced life support is required. Additional equipment: an electrocardiographic monitor and a defibrillator for use in pediatric patients. Monitoring as for moderate sedation with vital signs, including oxygen saturation and heartrate documented at least every five minutes in a time-based record. Post-sedation care as for moderate sedation.
- **Special considerations:** To ensure that the patient will not receive an excessive dose of local anesthetic, the maximum allowable safe dosage (ie, mg/kg) should be calculated before administration. It is essential that any oximeter probe is positioned properly. The use of expired carbon dioxide monitoring devices (capnography) is encouraged for sedated children, particularly in situations where other means of assessing the adequacy of ventilation are limited. Familiarity with various adjuncts to airway management and resuscitation and intraosseous needles, training with patient simulators, is encouraged.

<ul style="list-style-type: none"> • Nitrous oxide: Inhalation sedation/analgesia equipment that delivers nitrous oxide must have the capacity of delivering 100 percent and never less than 25 percent oxygen concentration at a flow rate appropriate to the size of the patient. Equipment that delivers variable ratios of nitrous oxide to oxygen and that has a delivery system that covers the mouth and nose must be used in conjunction with a calibrated and functional oxygen analyzer. The use of nitrous oxide for minimal sedation is defined as the administration of nitrous oxide (50 percent or less) with the balance as oxygen, without any other sedative, narcotic, or other depressant drug before or concurrent with the nitrous oxide to an otherwise healthy patient in ASA class I or II. The patient is able to maintain verbal communication throughout the procedure. If nitrous oxide in oxygen is combined with other sedating medications, such as chloral hydrate, midazolam, or an opioid, or if nitrous oxide is used in concentrations greater than 50 percent, the likelihood for moderate or deep sedation increases. • Appendices provide recommended discharge criteria; ASA Physical Classification; Drugs that may be needed to rescue a sedated patient; emergency equipment. 			
Geographical setting for guidance:		Healthcare setting for guidance: <i>users and patients</i>	Is guidance currently used?
Guidelines developed by American Society but include studies published in journals outside of the US.		This guideline is intended for all venues in which sedation for a procedure might be performed (hospital, surgical center, freestanding imaging facility, dental facility, or private office).	Most recent therefore likely to be in use.
<p>Basis for recommendations: <i>e.g. published evidence, expert opinion etc.</i> <i>If evidence based, review evidence in sections below</i></p>			
The methodology used to develop this guideline is not presented. Over 200 references are cited, but there is no indication of how these were identified or any assessment of quality. The recommendations are presented in narrative form.			
Description of evidence for recommendations (if applicable):			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
Children up to age 21 years specified	Sedation	<u>N/A</u>	Not identified.
Study Type:	Search Strategy:		Study selection: No. of selectors:
<p><i>Appropriate study types?</i> No details of studies are provided but it appears all study and article types may have been included.</p>	<p><i>Appropriate search terms?</i> No</p> <p><i>Appropriate databases?</i> No</p> <p><i>Unpublished studies?</i> No</p> <p><i>Follow up of citations?</i> No</p>		<p><i>Inclusion criteria:</i> No details of study selection from search results are provided.</p>

	Personal contact with experts?	No	
Risk of bias/systematic error (study limitations that could cause systematic error): consider risk of bias for each important outcome			
<i>Randomisation: is it reported and appropriate?</i> Risk of bias and other limitations are not explicitly considered for each study.	<i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Not described	<i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> No details provided.	
Inconsistency: Refers to unexplained heterogeneity in results.	Imprecision (random error):	Indirectness: consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest	Publication bias: e.g. when intervention is new and not many studies available- may be biased for positive results
No heterogeneity analysis.	Not reported.	Unclear if study selection focussed on studies of child patients.	Search was limited therefore publication bias is very likely.
Meta-analysis: No. of data extractors: not stated		Overall results: for each outcome or recommendation as applicable	
No meta-analysis performed <i>Are results for individual studies shown?</i> No <i>Was it reasonable to combine study results?</i> <i>Was an appropriate method used?</i> <i>Are reasons for variation in results discussed?</i> <i>Would confounders affect overall result^a?</i>		N/A <i>Is the effect substantial^a?</i> no <i>Is there dose-response data^a?</i> no	

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

Adverse events:		Benefit/harm/cost considerations?	Values/preferences considerations?
<p>Discussed: Desaturation, apnea, laryngospasm, the need for airway interventions including jaw thrust, positive pressure ventilation, prolonged sedation, unanticipated use of reversal agents, unintended or prolonged hospital admission, and unsatisfactory sedation/analgesia/anxiolysis.</p> <p>Hypoventilation, airway obstruction, and cardiopulmonary impairment are listed as potential adverse events.</p>		<p>Not specifically discussed.</p> <p>States that Nitrous oxide in oxygen with varying concentrations has been successfully used for many years to provide analgesia for a variety of painful procedures in children.</p> <p>Cost considerations not mentioned.</p>	<p>Not discussed</p>
Overall quality of guidance (AGREE II) and explanation:		Rating of recommendations: <i>Should the recommendations made be considered for SDCEP guidance?</i>	
<p>Overall quality = 2/7 (low) AGREE appraisals are available on request.</p> <p>This is a low quality guideline. The methodology used to develop this guideline appears to be weak (i.e. not reported). Recommendations are relatively easy to find and are fairly unambiguous. The guideline is concise. There is no discussion of barriers, implementation, patient views etc.</p>		<p>Due to the poor methodology employed, these recommendations should not be used as the basis for making recommendations in SDCEP guidance. However, if SDCEP guidance recommendations are consistent with these recommendations, this guideline could be cited as such.</p>	
Reviewer's comments:			
<p>This is an update of a guideline first published in 2005 that was written to unify guidelines for sedation used by medical and dental practitioners. It consequently superseded other publications (e.g. AAPD Guideline on elective use of minimal, moderate and deep sedation and general anesthesia for pediatric dental patients, 2005).</p> <p>The absence of a reported methodology is a weakness. Although in narrative form, the recommendations are fairly clear, unambiguous and likely to be consistent with practice in the UK with regard to minimal and moderate sedation only.</p> <p>It would not be appropriate to base recommendations for the UK on this guideline but it might be useful to cite it as verification of recommendations if they are consistent.</p>			
<p>SDCEP guidance themes: sedation technique✓, patient selection✓, records✓, consent✓, training✓, monitoring✓, fasting✓, environment✓, equipment✓, staffing✓, patient viewsX</p> <p>(✓) = mentioned but not in detail.</p>			

2016 guideline update:**Relevant changes**

New title: Guideline for Monitoring and Management of Pediatric Patients *Before, During and After Sedation for Diagnostic and Therapeutic Procedures*

Source: http://www.aapd.org/media/Policies_Guidelines/G_Sedation1.pdf

Updated Aim: The purpose of this updated report is to unify the guidelines for sedation used by medical and dental practitioners; to add clarifications regarding monitoring modalities, *particularly regarding continuous expired carbon dioxide measurement*; to provide updated information from the medical and dental literature; and to suggest methods for further improvement in safety and outcomes. to add clarifications regarding monitoring modalities, particularly regarding continuous expired carbon dioxide measurement; to provide updated information from the medical and dental literature; and to suggest methods for further improvement in safety and outcomes.

Scope: previously the guideline stated that it applied to children up to age 21 years – not stated in update

Updated recommendations:

On-site monitoring and rescue equipment: the update now provides a list of equipment required and states that emergency life support equipment must allow for life support of the patient until transported to an emergency facility.

Documentation at the time of sedation: assessment guidance is more extensive in update including more detail on relevant medical history and inclusion of measurement of oxygen saturation in addition to heart rate, blood pressure, respiratory rate and temperature).

Documentation during treatment: Capnography has been added in update: The patient's chart shall contain documentation at the time of treatment that the patient's level of consciousness and responsiveness, heart rate, blood pressure, respiratory rate, *expired carbon dioxide values*, and oxygen saturation were monitored. Standard vital signs should be further documented at appropriate intervals during recovery until the patient attains predetermined discharge criteria.

Continuous quality improvement: Update adds requirement to track significant interventions.

Moderate Sedation: The update provides further details for the practitioner on rescue and indicates that skills reinforcement should include with simulation. The update stipulates that the support personnel should be trained in advanced airway skills (previously only required paediatric basic life support). Capnography is now recommended for moderate sedation (required for deep sedation) and monitoring parameters should be recorded every 10 minutes.

Deep Sedation: The update provides further details, but this is not included in the scope of the SDCEP guidance.

Appraisal

As for the 2011 version, the 2016 update does not describe the methodology used and there is no discussion of barriers, implementation or patient views. Almost 500 references are cited for the update but there is no description of how the search was carried out or any discussion of the evidence quality. The recommendations are presented in a similar way to the 2011 version. As a result, the 2016 update would also rate, using the AGREE II tool, as 2/7 (Low quality).

Guideline G12: Glassman et al., 2009

Title: Special Care Dentistry Association consensus statement on sedation, anesthesia, and alternative techniques for people with special needs		Ref. No.: G12 Reviewer(s): DS 02.06.16 AGREE: G12 moderated AGREE Appraisal
Authors/organisation: Glassman, P., A. Caputo, et al. (2009). "Special Care Dentistry Association consensus statement on sedation, anesthesia, and alternative techniques for people with special needs." <i>Special care in dentistry</i> 29 (1): 2-8.		
Date of publication/revision: 2009	Original version:	Source: http://www.scdonline.org/?page=SCDAJournal http://onlinelibrary.wiley.com/doi/10.1111/j.1754-4505.2008.00055.x/abstract
Aim(s) of guidance: This consensus statement is not intended to duplicate the many existing guidelines that focus on training, techniques, and equipment needed to provide anesthesia and sedation services. The purpose of this consensus statement is to focus on the decision-making process for choosing a method of treatment or combination of methods to facilitate dental treatment. It is meant to assist oral health professionals and other interested parties in planning and carrying out oral health treatment for people with special needs (PSN).		
Key recommendations: <i>relevant to SDCEP guidance</i>		
<ul style="list-style-type: none"> Includes a description of the modalities listed below that can be used to help individuals with special needs receive dental treatment services, with a discussion of the advantages and disadvantages of each modality. Also included is information about combinations of modalities and frequency of administration. The definitions for anesthesia and sedation used here are from the American Dental Association's <i>Guidelines for the Use of Sedation and General Anesthesia by Dentists</i> General anesthesia delivered in hospitals, surgical centers, and dental offices Sedation—ranging from minimal sedation to deep sedation Behavioral support Physical support Psychological support Social support Prevention strategies Describes levels of sedation. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected. A more thorough description and comparison of various techniques for delivering sedation are contained in other articles. As with general anesthesia, sedation is generally available for dental treatment 		

<p>in hospitals or surgical centers. Dental and other anesthesiologists are available in certain areas to provide sedation in a dental office. In addition, some dentists are trained and equipped to provide sedation services in their offices in conjunction with dental treatment. Moderate and particularly minimal sedation require less training, less equipment, and less stringent licensing than deep sedation or general anesthesia and therefore are available in a larger number of dental offices.</p> <ul style="list-style-type: none"> • Sedation, particularly moderate and minimal sedation, is easier to arrange and generally less expensive than deep sedation or general anesthesia. This procedure generally has a lower risk of side effects than do deep sedation or general anesthesia. • Discusses impact of financing on oral health treatment decisions • Discusses impact of education on oral health treatment decisions 				
Geographical setting for guidance:		Healthcare setting for guidance: <i>users and patients</i>	Is guidance currently used?	
Guidelines developed by an American society		Not clearly stated.	Most recent therefore likely to be	
<p>Basis for recommendations: <i>e.g. published evidence, expert opinion etc.</i> <i>If evidence based, review evidence in sections below</i></p>				
<p>This consensus statement is the result of a consensus development process within the SCDA. In June 2006, a <i>Consensus Conference on Anesthesia, Sedation, and Alternative Techniques for Providing Dental Treatment for People with Special Needs</i> was held in conjunction with the SCDA's annual meeting. The conference was sponsored and organized by the American Association of Hospital Dentists, a component organization of the SCDA. Ten individuals were recruited to form a consensus development committee. Each member of the committee performed a literature review and prepared a background article on a subject related to the topic of the conference. During the conference, the authors presented the background articles as well as a draft of this statement. Input was solicited from the audience at the conference as well as from other association members. Given the fact that other associations with guidelines in this area were revising their guidelines, some time was spent after the conference assessing those newly released guidelines and making appropriate alterations to the SCDA's consensus statement. The committee considered all the input and revised the statement accordingly. This consensus statement was presented to the Special Care Dentistry Board of Directors and was approved in May 2008.</p>				
Description of evidence for recommendations (if applicable):				
Patient/Problem: <i>(target patients and actual participant characteristics)</i>		Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
<p>1 Individuals with cognitive impairment or emotional conditions who have difficulty understanding what is expected in a dental treatment situation.</p> <p>2 Patients whose fear about receiving dental treatment prevents them from receiving the needed treatment.</p> <p>3 Patients who are unable to sit in a dental chair or remain still enough to have dental procedures performed.</p> <p>4 Patients who have extensive dental needs that would require extended dental</p>		Sedation	<u>N/A</u>	Not identified

<p>treatment over a prolonged period of time.</p> <p>5 Patients who require dental procedures that cannot easily be performed with local anesthesia because of an inability to achieve adequate local anesthesia for that procedure.</p> <p>6 Individuals with complex medical problems who require intra- and peri-operative monitoring.</p> <p>7 Individuals with complex medical problems (e.g., severe hypertension and cardiac or respiratory disease) whose physiologic state will be more safely controlled in a sedated or anesthetized state.</p>						
Study Type:		Search Strategy:		Study selection:	No. of selectors:	
<p><i>Appropriate study types?</i> Not discussed</p>		<p><i>Appropriate search terms?</i> No</p> <p><i>Appropriate databases?</i> No</p> <p><i>Unpublished studies?</i> No</p> <p><i>Follow up of citations?</i> No</p> <p><i>Personal contact with experts?</i> No</p>		<p><i>Inclusion criteria:</i> No details of study selection from search results are provided.</p>		
<p>Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i></p>						
<p><i>Randomisation: is it reported and appropriate?</i> Not described</p>		<p><i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Not described</p>		<p><i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> No details provided.</p>		
<p>Inconsistency: <i>Refers to unexplained heterogeneity in results.</i></p>		<p>Imprecision (random error):</p>		<p>Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i></p>		
<p>No heterogeneity analysis.</p>		<p>Not reported</p>		<p>Unclear</p>		
<p>Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i></p>		<p>Publication bias is very likely.</p>				
<p>Meta-analysis: No. of data extractors: not stated</p>		<p>Overall results: <i>for each outcome or recommendation as applicable</i></p>				

No meta-analysis performed <i>Are results for individual studies shown?</i> No <i>Was it reasonable to combine study results?</i> <i>Was an appropriate method used?</i> <i>Are reasons for variation in results discussed?</i> <i>Would confounders affect overall result^a?</i>		N/A <i>Is the effect substantial^a?</i> no <i>Is there dose-response data^a?</i> no
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?
Not discussed	Not specifically discussed. Cost considerations not mentioned.	Not discussed
Overall quality of guidance (AGREE II) and explanation:		Rating of recommendations: <i>Should the recommendations made be considered for SDCEP guidance?</i>
Overall quality = 2/7 (low) AGREE appraisals available on request. This is a low quality guideline. The methodology used to develop this guideline appears to be weak. Recommendations are not easy to find and vague. There is some discussion of barriers and implementation.		Due to the poor methodology employed, these recommendations should not be used as the basis for making recommendations in SDCEP guidance. However, if SDCEP guidance recommendations are consistent with these recommendations, this guideline could be cited as such.
Reviewer’s comments:		
This is a consensus statement from SCDA rather than a guideline as such. Although broad statements are made about preferred approaches to care, these are not recommendations and there is limited evidence to support them. The methodology is reported but is generally weak. The recommendations are not particularly obvious and are vague. They may be consistent with practice in the UK with regard to minimal and moderate sedation only. It would not be appropriate to base recommendations for the UK on this guideline but it might be useful to cite it as verification of recommendations if they are consistent.		

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

SDCEP guidance themes: sedation techniqueX, patient selection✓, recordsX, consentX, trainingX, monitoringX, fastingX, environmentX, equipmentX, staffing(✓,) patient viewsX
(✓) = mentioned but not in detail.

Guideline G13: Hosey, 2002

Title: UK National Clinical Guidelines in Paediatric Dentistry Managing anxious children: the use of conscious sedation in paediatric dentistry		Ref. No.: G13 Reviewer(s): DS 03.06.16 AGREE: G13 moderated AGREE Appraisal
Authors/organisation: Hosey, M. (2002). International Journal of Paediatric Dentistry / the British Paedodontic Society [and] the International Association of Dentistry for Children 12(5): 359-372.		
Date of publication/revision: 2002	Original version: 1997	Source: https://www.rcseng.ac.uk/fds/publications-clinical-guidelines/clinical_guidelines/documents/paed_sedation.pdf
Aim(s) of guidance: The intention is to encourage improvement in clinical practice and to stimulate research and clinical audit in areas where scientific evidence is inadequate. Also states: "It is hoped that this guideline will be an adjunct to clinical judgement and careful treatment planning within both primary dental care and specialist paediatric dentistry practice"		
Key recommendations: <i>relevant to SDCEP guidance</i>		
Notes: The Poswillo Report clearly stated that conscious sedation should involve the administration of a single drug. In the light of the paucity of evidence to the converse, and in the interest of the safety and well-being of child dental patients, this guideline will apply this principle to children's dentistry in the UK. Defines conscious sedation as per GDC.		
<ul style="list-style-type: none"> • Goals of paediatric conscious sedation: promote welfare and safety; facilitate care; behaviour management; promote positive psychological response to treatment; safe discharge Grade C • Patient Assessment: to include full medical and dental history. Grade C • Fitness for CS: ASA1 or II for GDS, CDS, specialist paediatric practice; otherwise hospital. Grade C • Patient Information and Consent: informed consent essential; explanation of alternatives; written pre- and post-operative instruction in advance. Grade C • Escort: escort required; qualified member of staff always present; seditionist chaperones at all times. Grade C • Fasting: Not required for N2O, though might recommend light meal only 2 hrs prior to CS. Other forms of sedation: No solids within 6 hrs; No milk within 4 hours; No clear fluid within 2 hours. Grade C • Documentatiuon: must include staff names; treatment plan, consent, radiographs, reason; treatment performed with drug, concentration, dosage, route, duration; monitors used and readings; time-based record, where appropriate. Grade C • Staff training: dentists must undergo recognised initial training and regularly update; dental nurse should be appropriately trained, CDSN from NEBDN encouraged. Grade C 		

<ul style="list-style-type: none"> • Choice of sedative agent: <p>Nitrous oxide: recommendations on indications (A, B&C), contra-indications (B&C), nitrous oxide pollution (C) other inhalation agents (C).</p> <p>Diazepam and Temazepam: can be used though can be unpredictable in children (B) routes either rectal diazepam (B), intravenous diazepam (C)</p> <p>Midazolam: generally for anxious adults or adolescents (B); routes: oral and intra-nasal not recommended outwith hospital (C); rectal (A) but only in hospital with qualified anaesthetist (C); intramuscular not recommended (C). Reversal with Flumazenil is not recommended (B).</p> <p>Opioids and other agents: not recommended outwith hospital (C).</p> • Routes of administration Inhalation is the recommended route for paediatric dentistry (C); is not reliable(B), requires dedicated equipment with close fitting scavenging nasal hood (C) <ul style="list-style-type: none"> Oral: sedative to be administered on site, child accompanied at all times, and monitored clinically and electronically (C). Intravenous: not recommended for pre-cooperative children; single drug sedation e.g. midazolam, recommended for adolescents; suitably trained staff required, minimum of clinical monitoring and pulse oximetry, <u>in a hospital facility for children below 14 years.</u> (C) Rectal: not recommended (C) Intramuscular: not recommended (C) • Polypharmacy: not recommended (B) • Complications: highlights possibility of respiratory depression, nausea, hypoxia, hyperactivity and unintentional, loss of consciousness. (C) • Monitoring: Alert clinical monitoring is essential at all times; appropriately trained staff and monitoring essential for desaturation; electronic monitoring not required for N2O; minimum of pulse oximetry for other types of sedation (C). • General anaesthesia: preferred for pre-cooperative children (C) • Recommendations are supplemented with extensive explanatory notes. Reference to drug dosage is specifically excluded (except N2O). 			
Geographical setting for guidance:		Healthcare setting for guidance: <i>users and patients</i>	Is guidance currently used?
Guideline developed for UK specialist societies.		GDS, CDS, specialist paediatric practice; otherwise hospital	Unclear. Not listed on BSPD website. Still available on Royal College FDS website.
Basis for recommendations: <i>e.g. published evidence, expert opinion etc.</i> <i>If evidence based, review evidence in sections below</i>			
The methodology described is consensus of opinion of current best clinical practice. The guideline has been circulated to all consultants in paediatric dentistry in the UK, to the Council of the BSPD, and to people of related specialties recognized to have expertise in the subject. The final version of the guideline is produced from a combination of this input and thorough review of published literature. Uses SIGN grading system (ABC) for recommendations, implying that there has been some appraisal of the evidence.			
Description of evidence for recommendations (if applicable):			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>

Healthy anxious children; discussion of the sedation of medically compromised children or those with a learning disability is not included.	Sedation	N/A	Not explicitly discussed.	
Study Type:	Search Strategy:		Study selection:	No. of selectors:
<i>Appropriate study types?</i>	<i>Appropriate search terms?</i>	No	<i>Inclusion criteria:</i> No details of study selection from search results are provided.	
	<i>Appropriate databases?</i>	No		
	<i>Unpublished studies?</i>	No		
	<i>Follow up of citations?</i>	No		
	<i>Personal contact with experts?</i>	No		
Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i>				
<i>Randomisation: is it reported and appropriate?</i> Not described	<i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Not described		<i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> No details provided.	
Inconsistency: <i>Refers to unexplained heterogeneity in results.</i>	Imprecision (random error):	Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i>		Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i>
No heterogeneity analysis.	Not reported	Unclear		Publication bias is very likely.
Meta-analysis: No. of data extractors: not stated		Overall results: <i>for each outcome or recommendation as applicable</i>		
No meta-analysis performed <i>Are results for individual studies shown?</i> No <i>Was it reasonable to combine study results?</i> <i>Was an appropriate method used?</i>		N/A <i>Is the effect substantial^a?</i> no <i>Is there dose-response data^a?</i> no		

<i>Are reasons for variation in results discussed?</i>		
<i>Would confounders affect overall result^a?</i>		
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?
Highlights possibility of respiratory depression, nausea, hypoxia, hyperactivity and unintentional, loss of consciousness, but not linked to individual interventions.	Not specifically discussed. Cost considerations not mentioned.	Not discussed
Overall quality of guidance (AGREE II) and explanation:		Rating of recommendations: <i>Should the recommendations made be considered for SDCEP guidance?</i>
<p>Overall quality = 4/7 (moderate) AGREE appraisals are available on request.</p> <p>Although aspects of the methodology are lacking, this is a relatively well-structured and well developed guideline that is informed by evidence and has been through a consensus process to arrive at recommendations that are generally accepted for the UK.</p>		Recommendations are clear and there is some link with evidence (using the SIGN system of the time). Given that the guideline is from 2002, it could be a useful source to inform current clinical recommendations, though more up-to-date evidence would be desirable.
Reviewer's comments:		
The recommendations in this guideline, though now nearly 15 years old, are still likely to be relevant to current clinical practice. It is not clear if this guideline is still in general use.		
<p>SDCEP guidance themes: sedation technique✓, patient selection✓, records✓, consent(✓), training✓, monitoring✓, fasting✓, environment X, equipment✓, staffing✓, patient viewsX</p> <p>(✓) = mentioned but not in detail.</p>		

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

Guideline G14: Intercollegiate Advisory Committee for Sedation in Dentistry (IACSD), 2015

Title: Standards for Conscious Sedation in the Provision of Dental Care: Report of the Intercollegiate Advisory Committee for Sedation in Dentistry		Ref. No.: G14 Reviewer(s): DS 03.06.16 AGREE: G14 moderated AGREE Appraisal
Authors/organisation: Intercollegiate Advisory Committee for Sedation in Dentistry (The dental faculties of the Royal Colleges of Surgeons and the Royal College of Anaesthetists)		
Date of publication/revision: 2015	Original version:	Source: https://www.rcseng.ac.uk/dental-faculties/fds/publications-guidelines/standards-for-conscious-sedation-in-the-provision-of-dental-care-and-accreditation/
Aim(s) of guidance: States "This report creates a national standard for the use of conscious sedation in the delivery of dental care. "		
Key recommendations: <i>relevant to SDCEP guidance</i>		
<p>Introduction defines conscious sedation as per previous documents, with the addition of "patient..is able to both understand and respond to verbal commands <u>either alone or accompanied by a light tactile stimulus</u>".</p> <p>Options for care: It is essential that all options are considered and explained to the patient (and, where appropriate, the carer) before a decision is reached.</p> <ul style="list-style-type: none"> • A practitioner must make a careful, thorough assessment of the patient and his or her needs before deciding that the use of conscious sedation is indicated. • The treatment plan must be agreed with the patient and any carer; ideally, this should be done in advance of the procedure. • An individual is considered to be a child until puberty is reached. Such patients require a sedation team member with paediatric resuscitation skills. • Any child under 12 years with complex oral health needs or who cannot be managed with either BM/LA or LA/inhalation sedation OR any young person aged 12-16 years with complex oral needs or who cannot be managed with either BM/LA or LA/inhalation sedation or LA/midazolam (all routes) should be referred to a team with the skills equivalent to those expected of a specialist/consultant paediatric dentist and a consultant in anaesthesia competent in sedation for dentistry for assessment and treatment in a facility equivalent to an NHS Acute Trust in England. This would include care provided by a managed clinical network or a recognised care pathway. • When referring a patient, clear referrals must be made, the guidance described by the Dental Sedation Teachers Group should be followed and the responsibilities described by the General Dental Council (GDC) in the UK must be met. <p>Preparation for sedation: Valid consent is necessary for all patients receiving dental care under conscious sedation and this must be confirmed in writing, as specified in relevant national legislation.</p> <ul style="list-style-type: none"> • <u>Valid consent</u> should be obtained prior to the day of treatment and must also be <u>re-confirmed</u> on the actual day of treatment. 		

- **Patient information:** Written information for adult and child patients, those with parental responsibility, carers and escorts must be supplied. It must include the range of techniques suitable for the individual and contact details, including for out-of-hours emergency advice and services. Instructions on the practical arrangements pre-and post-op, including responsibilities of the escort. A separate sheet with escort instructions is required. Additional information is specified to be provided for child patients.
- **Fasting:** Views for fasting prior to sedation are described without a clear recommendation. However, it is reasonable to interpret from the report that, as recommended in NICE guidance, fasting is not necessary for conscious sedation as defined for dentistry. Clinicians who choose to sedate patients without fasting should be prepared to justify this choice.

Clinical environment for sedation

The physical environment, supporting facilities and equipment must be appropriate for the delivery of dental care under sedation.

- All centres providing conscious sedation for the delivery of dental care should be inspected to determine that the necessary standards are in place
- The correct equipment must be available in treatment and recovery areas, and be proper maintenance documented for inspection.
- There must be access for emergency services and patient transfer.

Nature of the clinical team for sedation

All members of the care team must have the relevant knowledge and skills for the technique being used, as defined by their scope of practice and competencies.

- Clinical skills are underpinned by validated education and training while knowledge and continuing competence must be maintained through appropriate continuing professional development.
- The clinical team required for each technique are described in detail, including level of education and training, necessary life support skills

Techniques for sedation

The selection of a technique must be appropriate for the individual patient and not chosen simply for operator or sedationist convenience or at the insistence of a third party. The practitioner providing the sedation must be trained and competent in the technique used, and each individual in the team caring for the patient must also have the necessary validated skills.

- **Essential principles include:** The simplest and safest technique that is likely to be effective should be used. Titrating a drug/drugs to effect is critical to safely achieving a recognised sedation endpoint. As a general rule, single drugs are easier to titrate to effect and safer than sequential administration of two or more drugs. Specific considerations that limit the use of multiple/anaesthetic drug techniques.
- **Specific sedation techniques:** For all conscious sedation techniques other than inhalation sedation with nitrous oxide/oxygen, competence in cannulation is mandatory.

Standard techniques

- **Oral sedation** must only be administered in the place where the dental treatment is provided and must only be carried out by practitioners who are already competent in intravenous sedation. Midazolam is now considered the first choice agent for oral sedation. Oral techniques are not titratable and should only be used when titratable sedation techniques are inappropriate.
- **Inhalation sedation:** a titrated dose of nitrous oxide in oxygen is the first choice inhalation sedation technique.
- **Intravenous sedation:** a titrated intravenous dose of midazolam is usually the first choice intravenous sedation technique.
- **Intranasal sedation:** e.g. Midazolam, these techniques are not titratable and should only be used when titratable sedation techniques are inappropriate.

Advanced techniques

- **Intravenous sedation:** opioid (usually fentanyl) and midazolam; ketamine. Midazolam and propofol requires a dedicated sedationist
- **Patient controlled sedation:** midazolam, propofol.
- **Targeted-controlled infusion sedation:** propofol. These techniques require the presence of a dedicated sedationist.

- Inhalation sedation: Sevoflurane in O2 or N2O/O2 requires a dedicated sedationist.

Peri-operative care

- Monitoring The sedationist or another appropriate person who has capability within his or her scope of practice must monitor the patient throughout the procedure and will wish to confirm at regular intervals that the patient is conscious. If this level of sedation is exceeded, the team caring for the patient must have the appropriate skills to manage the situation. There must be a written contemporaneous record of the monitoring of the patient that is in accordance with the clinical sedation technique used. Clinical and instrumental monitoring relevant to the patient's medical status and the clinical setting must be used. For inhalation sedation with nitrous oxide, clinical monitoring will usually suffice. As a minimum for all other techniques, monitoring should include pulse oximetry as well as non-invasive blood pressure monitoring preoperatively, at appropriate intervals during the procedure and post-operatively. All members of the clinical team must be capable of monitoring the condition of the patient. Monitoring requirements for each technique are tabulated.
- Complications It is essential that the team delivering care is able to recognise medical, dental or sedation-related adverse events and manage them appropriately and safely. The dentist is responsible for complications resulting from medical or dental emergencies; sedationist for complications resulting from sedation or medical emergencies; dentist, dental hygienist and therapist, sedationist and dental nurse must be competent in life support. There must be clearly defined roles, rehearsal and evidence of scenario-based team training. The provider of dental care and the provider of the sedation service must be able to maintain life support for a patient until such time as the emergency services are able to attend.
- Recovery, discharge and aftercare: The presence of a suitable third party to take responsibility for the patient at the time of discharge is an essential requirement for sedation using anything other than inhalation sedation with nitrous oxide/oxygen in adults. Children under 16 years of age require an escort for inhalation sedation. During recovery, the patient must be supervised; a trained member of the dental team must be responsible for the patient and monitor the individual throughout this period. The decision to discharge the patient is the responsibility of the sedationist, with each patient being assessed on an individual basis. See also Patient information above. Discharge criteria listed.

Clinical Governance and audit

Conscious sedation procedures must be the subject of robust and regular audit in which all members of the team take part. The focus must be an ongoing review of procedures and processes with analysis of outcomes and modifications made to procedures and techniques as necessary.

- Records of the audit process and outcomes from them must be maintained and be available for inspection.
- Sedation teams must maintain high quality full clinical records and a written or electronic clinical log. Each clinical team must maintain continuous and contemporaneous records of the number and types of sedation cases performed as well as the rate of any complications that may have arisen.
- This report recommends the use of a national system for recording adverse clinical incidents by all dentists, doctors and healthcare professionals who provide or directly support sedation for the delivery of dental care.

Education and training

All members of the delivery and care team must have undertaken appropriate validated education and training and demonstrated an acceptable level of competence by means of a robust assessment process. Courses that are solely didactic and skills-based without supervised clinical practice, assessment and external quality assurance do not constitute sufficient training for unsupervised practice in those clinical techniques.

- It is the responsibility of individual team members to ensure that relevant continuing professional development to maintain knowledge, skills and competence is undertaken at appropriate intervals.
- For revalidation in a sedation technique, a practitioner (all team members) must undergo a minimum of 12 hours of continuing professional development every 5 years that are relevant to the techniques practised.
- Educational courses intended to provide training in clinical delivery of conscious sedation and to prepare the team for independent practice must be assessed, be externally quality assured and incorporate supervised clinical practice. Syllabuses for education and training of the dental team are described in Appendix 1 of the report.

Geographical setting for guidance:	Healthcare setting for guidance: <i>users and patients</i>	Is guidance currently used?	
Report is developed for UK.	The standards apply to all who practise conscious sedation techniques, whether they are dentists, doctors, nurses or dental care professionals.	Yes.	
Basis for recommendations: <i>e.g. published evidence, expert opinion etc.</i> <i>If evidence based, review evidence in sections below</i>			
This is a report of an expert working group. Although titled at Standards, the report describes the content as recommendations (e.g. on p3), clinical guidance as stated in this report (p33) and guidance (p87). Consequently, it can be regarded like a guideline for the purposes of appraisal. The method used to formulate recommendations is not stated nor is the basis for the recommendations (e.g. expert opinion, evidence-based). References that inform some recommendations are cited in the text. There is no assessment of evidence presented.			
Description of evidence for recommendations (if applicable):			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
Implied from listed issues to consider: anxiety, a pronounced gag reflex, a traumatic procedure, the level of patient co-operation, the nature of the clinical care required and the time needed to deliver treatment. The use of conscious sedation may be indicated for special care patients, certain medical indications or difficult clinical situations.	Sedation	<u>N/A</u>	Not explicitly stated.
Study Type:	Search Strategy:		Study selection: No. of selectors:
<i>Appropriate study types?</i>	<i>Appropriate search terms?</i>	No	<i>Inclusion criteria:</i> No details of study selection from search results are provided.
	<i>Appropriate databases?</i>	No	
	<i>Unpublished studies?</i>	No	
	<i>Follow up of citations?</i>	No	
	<i>Personal contact with experts?</i>	No	

Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i>			
<i>Randomisation: is it reported and appropriate?</i> Not described	<i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Not described	<i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> No details provided.	
Inconsistency: <i>Refers to unexplained heterogeneity in results.</i>	Imprecision (random error):	Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i>	Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i>
No heterogeneity analysis.	Not reported	Unclear	Publication bias is very likely.
Meta-analysis: No. of data extractors: not stated		Overall results: <i>for each outcome or recommendation as applicable</i>	
No meta-analysis performed <i>Are results for individual studies shown?</i> No <i>Was it reasonable to combine study results?</i> <i>Was an appropriate method used?</i> <i>Are reasons for variation in results discussed?</i> <i>Would confounders affect overall result^a?</i>		N/A <i>Is the effect substantial^a?</i> no <i>Is there dose-response data^a?</i> no	
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?	

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

Not discussed.	States: It is recognised that some of the recommendations of this report will have far-reaching consequences. Implementation may have significant implications for providers and for those who commission dental clinical services but safety of patients is our priority.	Not discussed
Overall quality of guidance (AGREE II) and explanation:		Rating of recommendations: <i>Should the recommendations made be considered for SDCEP guidance?</i>
<p>Overall quality = 3/7 (low) AGREE appraisals are available on request.</p> <p>This is a recent report of an expert working group convened on behalf of the Royal Colleges and therefore should be an authoritative source to inform guidance recommendations. Although titled at Standards, the report describes the content as recommendations (e.g. on p3) and as guidance (p87). Consequently, it can be regarded as a guideline for the purposes of appraisal.</p> <p>The structure of the document does not make for easy reading. Recommendations are embedded within narrative, sometimes in several sections, and so can be difficult to identify. The methodology used is apparently weak (not reported) with no discussion of the evidence base, assessment of quality or the basis of recommendations.</p>		<p>The presentation of recommendations does not follow a consistent, clear format and the rationale for recommendations is not presented. It is unclear to what extent evidence, the balance of risks and benefits, the practicalities, and practitioner perspectives or patient values have been taken into account. While some recommendations are clear and unambiguous, others are much less so and open to alternative interpretation which may or may not have been intended. IACSD have provided some further information on certain points in the form of “Frequently Asked Questions” via their web page.</p> <p>Further clarification of many of the recommendations in this report will be necessary to determine how these should be reflected within the SDCEP guidance.</p>
Reviewer’s comments:		
<p>This report has been available since April 2015. There is comprehensive coverage of conscious sedation issues and it is likely that some practitioners will be adapting their practice towards complying with this report, which may include ceasing sedation provision. Although the far-reaching implications of the recommendations are recognised in the report, little by way of advice and/or tools is provided to support putting the recommendations into practice.</p> <p><i>Additional information:</i></p> <p>The IACSD provides guidance and standards for members of its contributing Royal Colleges that may also be relevant to others. As a recent authoritative source, this report should be important in informing current and future practice. Several factors have contributed to potential end-users having difficulties implementing the recommendations in this report. These include: lack of clarity in the text leading to doubt or misinterpretation (it has been necessary for the IACSD to provide answers to numerous FAQs online as a means of addressing this); unexplained underlying methodology; the absence, before publication, of wide consultation or engagement with stakeholders responsible for the organisation and delivery of care. Implementation of new standards would ideally involve an associated impact assessment and implementation plan in each of the UK nations.</p>		
<p>SDCEP guidance themes: sedation technique✓, patient selection✓, records✓, consent✓, training✓, monitoring✓, fasting✓, environment✓, equipment✓, staffing✓, patient viewsX (✓) = mentioned but not in detail.</p>		

Guideline G15: National Institute for Health and Care Excellence (NICE), 2010

Title: Sedation in under 19s: using sedation for diagnostic and therapeutic procedures		Ref. No.: G15 Reviewer(s): MW 030616 AGREE: G15 moderated AGREE Appraisal
Authors/organisation: National Institute for Health and Care Excellence (NICE)		
Date of publication/revision: 2010 Evidence update carried out in 2012 https://www.nice.org.uk/guidance/CG112/documents/cg112-sedation-in-children-and-young-people-evidence-update2 Guidance rated as static in 2014	Original version: 2010	Source: www.nice.org.uk/guidance/cg112 See full guideline for methods https://www.nice.org.uk/guidance/cg112/evidence/full-guideline-136287325
Aim(s) of guidance: The guideline offers best practice advice on the care of children and young people under the age of 19 undergoing sedation for diagnostic or therapeutic procedures. The aim of this guideline is to provide recommendations to both improve the effectiveness and safety of all types of procedural sedation and to reduce current variations in standards of care.		
Key recommendations: <i>relevant to SDCEP guidance</i>		
<u>Recommendations relevant to dental sedation are made on:</u> Pre-sedation assessment, communication, patient information and consent Fasting Psychological preparation Personnel and training Discharge criteria Clinical environment and monitoring Painful procedures Dental procedures The dental specific recommendations are:		

<p>Recommendation 35 For a child or young person who cannot tolerate a dental procedure with local anaesthesia alone, to achieve conscious sedation consider: - nitrous oxide (in oxygen) or - midazolam. If these sedation techniques are not suitable or sufficient, refer to a specialist team for an alternative sedation technique.</p>			
<p>Geographical setting for guidance:</p>	<p>Healthcare setting for guidance: <i>users and patients</i></p>		<p>Is guidance currently used?</p>
<p>Guidelines developed in UK</p>	<p>Hospital settings, including inpatients, outpatients, radiology and emergency departments. Primary care, including dental and medical general practice settings. Infants, children and young people (under 19 years) receiving sedation by any technique for painful or non-painful diagnostic or therapeutic procedures including dental surgery and minor operations carried out under local anaesthesia.</p>		<p>Yes</p>
<p>Basis for recommendations: <i>e.g. published evidence, expert opinion etc.</i> <i>If evidence based, review evidence in sections below</i></p>			
<p>The guideline is based on evidence and/or expert consensus opinion, depending on the clinical question. These questions and the methods used to formulate the recommendations are summarised in a table on pages 34-37 of the full guideline. A description of the evidence and the GDG considerations around the questions are given in sections 4 and 6 of the full guideline. Evidence was sought for the recommendations on:</p> <ul style="list-style-type: none"> • Fasting • Psychological preparation • Efficacy and safety of the various drugs used for sedation i.e. midazolam, ketamine, chloral hydrate, nitrous oxide, opioids, propofol, sevoflurane, triclofos sodium • Sedation sparing <p>Where evidence was sought to address a particular question, RCTs were identified first, then observational studies if insufficient evidence from RCTs. Drug efficacy outcome data was only taken from RCTs. Observational studies were sought for data on serious adverse events (since these are rarer).</p>			
<p>Description of evidence for recommendations (if applicable):</p>			
<p>Patient/Problem: <i>(target patients and actual participant characteristics)</i></p>	<p>Intervention or risk factors:</p>	<p>Comparison:</p>	<p>Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i></p>

<p>Infants, children and young people (under 19 years) receiving sedation.</p>	<p>Dependent on clinical question</p>	<p>Dependent on clinical question</p>	<p><u>Primary outcome:</u> Successful completion of diagnostic or therapeutic procedure</p> <ul style="list-style-type: none"> • measured as the number of patients for whom the diagnostic or therapeutic procedure was carried out and completed. <p><u>Secondary outcomes:</u> Behavioural ratings including:</p> <ul style="list-style-type: none"> • pain as assessed by the patient or parent or other observer using validated pain scales e.g. Visual Analogue Scale (VAS), Children’s Hospital of Eastern Ontario Pain Scale (CHEOPS), Faces Pain Scale (FPS). • distress and/or anxiety as assessed by the patient or parent or other observer using validated scales e.g. Visual Analogue Scale (VAS), Observation Scale of Behavioral Distress (OSBD). • patient or parent satisfaction including preference <p>Sedation timing including</p> <ul style="list-style-type: none"> • length of induction: time from administration of sedation drug to initiation of procedure • recovery: time from completion of procedure to recovery criteria being met or recovery to pre-sedation state • duration of procedure • total: time from administration of intervention to when patient has been transferred to the recovery area or has been discharged <p>Adverse events:</p> <ul style="list-style-type: none"> • Aspiration • Respiratory intervention, including: <ul style="list-style-type: none"> o oral-pharyngeal airway o endotracheal intubation o assisted ventilation • Cardiac arrest requiring either/or: <ul style="list-style-type: none"> o external cardiac massage
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			<ul style="list-style-type: none"> o defibrillation • Oxygen desaturation <90% • Vomiting
Study Type:	Search Strategy:		Study selection: No. of selectors: 2
<p><i>Appropriate study types?</i> Searches were carried out for systematic reviews and RCTs, with additional literature review of observational studies for some data e.g. on serious adverse events.</p> <p><i>Correct components to address question?</i> Yes</p> <p><i>Study sizes:</i> Only RCTs with n≥20 in each arm were included. The largest available cohort studies were included for drug safety reviews.</p>	<p><i>Appropriate search terms?</i> yes</p> <p><i>Appropriate databases?</i> yes</p> <p><i>Unpublished studies?</i> not clear</p> <p><i>Follow up of citations?</i> no</p> <p><i>Personal contact with experts?</i> unknown</p>	<p><i>Inclusion criteria:</i> The articles were sifted using an inclusion criteria form, but these criteria were not found in the full guideline or appendices. Included articles would have been systematic reviews, RCTs or observational studies based around the various drugs etc.</p> <p><i>Exclusion criteria:</i> Non-English language studies and abstracts were not reviewed.</p>	
Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i>			
<p><i>Randomisation: is it reported and appropriate?</i> Described for each RCT in the characteristics of included studies tables in Appendix D.</p>	<p><i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Described for each RCT in the characteristics of included studies tables in Appendix D.</p>	<p><i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> Described for each RCT in the characteristics of included studies tables in Appendix D. Risk of bias for each study outcome is recorded in the evidence profiles for the drugs in section 6 of the full guideline.</p>	
Inconsistency: <i>Refers to unexplained heterogeneity in results.</i>	Imprecision (random error):	Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those</i>	Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i>

		<i>of interest</i>	
Risk of bias for each study outcome is recorded in the evidence profiles for the drugs in section 6 of the full guideline.	Risk of bias for each study outcome is recorded in the evidence profiles for the drugs in section 6 of the full guideline.	Only some of the evidence relates to sedation for dental procedures.	Risk of bias for each study outcome is recorded in the evidence profiles for the drugs in section 6 of the full guideline.
Meta-analysis: No. of data extractors: n/a		Overall results: <i>for each outcome or recommendation as applicable</i>	
<p>Meta-analyses for RCTs were performed where drug interventions and comparisons and outcomes were sufficiently homogenous, and studies were combined regardless of dose, duration of intervention, procedure (within painful and non-painful groups), setting (e.g. dentistry, accidents and emergencies) and age.</p> <p><i>Are results for individual studies shown?</i> yes</p> <p><i>Was it reasonable to combine study results?</i> sometimes</p> <p><i>Was an appropriate method used?</i></p> <p><i>Are reasons for variation in results discussed?</i></p> <p><i>Would confounders affect overall result^a?</i></p>		<p>The outcome data from the studies considered is provided in sections 4 (for fasting and psychological preparation) and 6 (for drug efficacy and safety) of the full guideline.</p> <p>The essential evidence from each drug review relevant to dental procedures was extracted and is presented in a summary of evidence for dental procedures (section 6.12.5.1 of full guideline) – the primary outcome for this was completion of procedure.</p> <p>Note. The success rate of nitrous oxide in the paediatric dental setting was reported as only approximately 50% - may be higher if patients are pre-selected.</p> <p><i>Is the effect substantial^a?</i></p> <p><i>Is there dose-response data^a?</i></p>	
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?	
Adverse events were considered in the secondary outcomes and were a key consideration for the recommendations on the different drugs.	<p>The benefits (efficacy) and risks (adverse events) are considered for each of the drugs.</p> <p>Health economic analysis was carried for some of the clinical questions e.g. for dental procedures either nitrous oxide or midazolam were shown to be the lowest cost sedation techniques (see section 6.12.5.2 of full</p>	<p>One of the secondary outcome measures for evidence appraisal was patient or parent satisfaction including preference.</p> <p>Literature regarding parental and children’s desire for information was identified and reviewed (section 5 of full</p>	

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

	guideline).	guideline). A survey was carried out with 63 child sedation patients at Alder Hey Children’s NHS Foundation Trust. None were having sedation for dental treatment.
Overall quality of guidance (AGREE II) and explanation:		Rating of recommendations: <i>Should the recommendations made be considered for SDCEP guidance?</i>
<p>Overall quality = 7/7 (high) AGREE appraisals are available on request.</p> <p>This is a high quality NICE accredited guideline which meets all of the AGREE criteria. The evidence, where available, is systematically identified and appraised according to GRADE. Benefits and harms along with cost analysis are taken into consideration when forming the recommendations.</p> <p>The strength of the recommendations is not explicitly stated (i.e. weak or strong) although the words ‘should’, ‘do not’, ‘consider’, ‘ensure’ etc are used to indicate strength.</p>	<p>Where evidence was considered it was formally appraised for quality using GRADE:</p> <p>The outcomes of interest in each RCT were evaluated using a GRADE evidence profile. It was considered that research from non RCT observational studies is subject to the usual limitations of observational work, including dependence on the quality of medical record documentation and potential for bias secondary to non randomisation, and un-blinded participants. In these studies (for adverse events), there were no interventions or comparisons but merely data collection of events. The datasets were generally large, and were expected to provide more information on a range of adverse events than the small RCTs available for review. Due to these limitations, they were assigned a very low quality rating based on the GRADE scheme.</p> <p>The recommendations were based on consideration of the body of evidence, where applicable, or on expert consensus.</p> <p>The recommendations relevant to dental sedation included in this guideline should be considered for informing recommendations in the updated SDCEP guidance.</p>	
Reviewer’s comments:		
<p>The conclusions from the evidence to recommendations section for dental procedures (section 6.12.5.3) are:</p> <p>Moderate sedation maintaining verbal contact (conscious sedation) with intravenous midazolam, is considered to be effective for selected children and young people who are cooperative, and younger children who can tolerate a nasal mask can be managed with nitrous oxide.</p> <p>In the past, if these were not effective, anaesthesia has often been the only alternative. The GDG agreed that additional sedation techniques could be effective for patients who cannot be managed by midazolam or nitrous oxide. If demand is high, alternative sedation techniques would be necessary. The common concern is that additional sedation drugs, especially in combination, may not be predictable enough for widespread use. Sevoflurane and propofol for example may only be safe enough for use by specialist sedation teams.</p> <p>The GDG agreed that there were potential important economic advantages of avoiding hospital based anaesthesia services. Economic modelling showed midazolam or nitrous oxide to be the lowest cost strategies in suitably selected patients. The training of dental sedation teams was regarded as crucial.</p> <p>An evidence update was carried out in 2012 which included new evidence relevant to dental sedation. However, the existing recommendations were not changed.</p> <p>Note that: Midazolam is used in UK clinical practice for sedating children and young people up to the age of 18. At the time of publication (December 2010) midazolam did not have UK marketing authorisation for oral or buccal administration, or for children younger than 6 months.</p>		

Midazolam did not have UK marketing authorisation for use for procedural sedation in children under 6 months at the time of publication of the Evidence Update (2012). However, the BNFc includes dosing advice for children from 1 month.

Although the guideline only applies to paediatric patients, the recommendations in some areas are likely to be applicable to all patients. The guideline covers sedation for different types of procedures, not just dental and the evidence for drug efficacy and safety is combined irrespective of the setting/procedure. However, the dental specific evidence is also summarised in section 6.12.5.3 Table 1.

SDCEP guidance themes:

sedation technique ✓, patient selection ✓, records ✓, consent ✓, training ✓, monitoring ✓, fasting ✓, environment ✓, equipment ✓, staffing ✓, patient views ✓

(✓)= mentioned but not in detail.

Guideline G16: Standing Dental Advisory Committee (SDAC), 2003

Title: Conscious Sedation in the Provision of Dental Care: Report of an Expert Group on Sedation for Dentistry		Ref. No.: G16 Reviewer(s): DS 03.06.16 AGREE: G16 moderated AGREE Appraisal
Authors/organisation: Standing Dental Advisory Committee, report Commissioned by Department of Health		
Date of publication/revision: 2003	Original version: (largely based on SAAD 2000)	Source: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069257
Aim(s) of guidance: <p>States: The following recommendations are designed to fully endorse and build upon the generic guidance and lay down specific guidance for the practice of <i>Conscious Sedation</i> in the provision of dental care.</p> <p>The guidelines aim to promote good clinical practice with the techniques referred to being appropriate for use by an operator-sedationist where the practitioner carrying out the dental treatment also administers the <i>Conscious Sedation</i> supported at all times by an appropriately trained assistant. Their purpose is to ensure that the various techniques utilised continue to have a high level of safety and effectiveness. It is hoped that they will assist colleagues to attain and maintain the high clinical standards which all patients rightly expect.</p>		
Key recommendations: <i>relevant to SDCEP guidance</i>		
<ul style="list-style-type: none"> • Defines conscious sedation as per GDC. • Educational and Training Standards: ALL members of the dental sedation team must have received appropriate supervised theoretical, practical and clinical training before undertaking independent practice. Theory must cover all aspects of this document. Training in use of drug and equipment prior to clinical training; training in management of complications and regularly rehearsed life support techniques. • Clinical Training: Supervised hands-on education, training and experience must be acquired by practitioners administering sedation and by their assistants for EACH <i>Conscious Sedation</i> technique used. This may be provided in a variety of settings. The method and timespan allowed for acquisition of this supervised practice may vary depending upon local and individual circumstances. • Provision of Education and Training: This may be provided in-house and/or in more formal courses. Those arranging such training for their staff have a duty to ensure that the quality of training and trainers is appropriate and that all theoretical and practical training is documented. Peer reviewed assessment should occur at least once a year. • Environment for Sedation: ambulance access to building; large enough treatment and recovery areas, operating chair capable of head down tilt position • Equipment for N2O/O2 inhalation sedation: dedicated purpose designed machines incapable of delivering hypoxic mixture; adequate scavenging. • Equipment for intravenous sedation: all equipment available in the treatment area including antagonist drugs; Supplemental O2 immediately available with back-up supply. • Indications for Conscious Sedation: anxious or phobic patients, those with movement disorder or with physical and/or mental disability; for unpleasant procedures; to avoid GA. 		

<p>Each exposure to conscious sedation must be justified.</p> <ul style="list-style-type: none"> • Responsibilities of the referring dentist: discussion of alternatives and assurance that conscious sedation provided to agreed definition. • Patient Assessment and Selection: A thorough medical, dental and social history should be taken and recorded prior to each course of treatment. • Contraindications: few contraindications – special care is required in the assessment and treatment of children and elderly patients. • Preparation of patients: Patients must receive careful instructions and written valid consent must be obtained; Fasting is not normally required however some authorities recommend the same fasting requirements as for general anaesthesia. A responsible adult escort must accompany the patient home and assume responsibility for the rest of the day (Escort may not be required for N2O/O2 sedation). Details of potential complications and emergency contact details provided. • Consent: valid informed consent is required. Written pre- and post-operative instructions given. • Records and Documentation: Accurate comprehensive contemporaneous records are required – details listed. • Aftercare: Recovery: A member of the dental team must supervise and monitor the patient throughout this period. Discharge: sedationist is responsible. • Conscious Sedation Techniques: Inhalation, oral and intravenous are usually sufficient, using the simplest for the requirements. Monitoring. Must include clinical monitoring (all staff capable) and also pulse oximetry and blood pressure for intravenous. Inhalation sedation – use a titrated dose of N2O/O2. First choice for children. Intravenous sedation – standard technique if use of a titrated dose of a single drug, e.g. benzodiazepine. Only required for a minority of children. Oral/Intranasal/Transmucosal sedation: oral premedication with a low dose sedative may be prescribed. • Complications: the whole dental team must be trained in management of complications with a focus on risk awareness, risk control and risk containment. It is vitally important for the whole team to be prepared and that it rehearses the routine regularly. • Clinical Governance: evidence of sedation-relevant CPD and personal clinical audit is required. 			
Geographical setting for guidance:		Healthcare setting for guidance: <i>users and patients</i>	Is guidance currently used?
Report is developed for UK.		All practitioners providing <i>Conscious Sedation</i> for the provision of dental care in general dental practice, community and hospital settings	Unclear. Only available on website as an archive.
<p>Basis for recommendations: <i>e.g. published evidence, expert opinion etc.</i> <i>If evidence based, review evidence in sections below</i></p>			
<p>This is a report of an expert working group. There are 39 references cited throughout the main text. However, it is not clear how these sources were identified or their quality assessed. The report includes recommendations, though it is unclear if all or some are mandatory.</p>			
Description of evidence for recommendations (if applicable):			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>

Anxious or phobic patients, those with movement disorder or with physical and/or mental disability; for unpleasant procedures; to avoid GA.	Sedation	N/A	Not identified	
Study Type:	Search Strategy:		Study selection:	No. of selectors:
<i>Appropriate study types?</i>	<i>Appropriate search terms?</i>	Not stated	<i>Inclusion criteria:</i> No description of search or details of study selection from search results provided.	
	<i>Appropriate databases?</i>	Not stated		
	<i>Unpublished studies?</i>	Not stated		
	<i>Follow up of citations?</i>	Not stated		
	<i>Personal contact with experts?</i>	Not stated		
Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i>				
<i>Randomisation: is it reported and appropriate?</i> Not described	<i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Not described		<i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> No details provided.	
Inconsistency: <i>Refers to unexplained heterogeneity in results.</i>	Imprecision (random error):	Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i>		Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i>
No heterogeneity analysis.	Not reported	Unclear		Publication bias is very likely.
Meta-analysis: No. of data extractors: not stated		Overall results: <i>for each outcome or recommendation as applicable</i>		
No meta-analysis performed <i>Are results for individual studies shown?</i> No <i>Was it reasonable to combine study results?</i> <i>Was an appropriate method used?</i>		Studies not described. <i>Is the effect substantial^a?</i> no <i>Is there dose-response data^a?</i> no		

<p><i>Are reasons for variation in results discussed?</i> <i>Would confounders affect overall result^a?</i></p>		
Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?
Not discussed	Not specifically discussed. Cost considerations not mentioned.	Not discussed
Overall quality of guidance (AGREE II) and explanation:		Rating of recommendations: <i>Should the recommendations made be considered for SDCEP guidance?</i>
<p>Overall quality = 3/7 (low) AGREE appraisals available on request. The methodology is weak (or not reported) with unclear stakeholder involvement, a lack of systematic searching and appraisal of evidence or use in informing recommendations, no discussion of barriers or implementation and unclear editorial independence. Recommendations are clear and easily found.</p>		<p>There is comprehensive coverage of conscious sedation issues and this report has been the basis for practice for many years in the UK.</p>
Reviewer's comments:		
<p>SDCEP guidance themes: sedation technique✓, patient selection✓, records✓, consent✓, training✓, monitoring✓, fasting✓, environmentX, equipment✓, staffing✓, patient viewsX (✓) = mentioned but not in detail.</p>		

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

Guideline G17: European Association of Paediatric Dentistry (EAPD), 2003

Title: EAPD Guidelines on Sedation in Paediatric Dentistry.		Ref. No.: G17 Reviewer(s): DS 07.06.16 AGREE: G17 moderated AGREE Appraisal
Authors/organisation: A.-L. Hallonsten, B. Jensen, M. Raadal, J. Veerkamp, M.T. Hosey, S. Poulsen on behalf of the European Academy of Paediatric Dentistry		
Date of publication/revision: 2003 (adopted 2005)	Original version:	Source: http://www.eapd.gr/8B927172.en.aspx
Aim(s) of guidance: States: "In recognition of the expanding need for both the elective and emergency use of sedative agents and the importance of delivering painless treatment to children, guidelines for the use of sedative agents among children are important."		
Key recommendations: <i>relevant to SDCEP guidance</i>		
<ul style="list-style-type: none"> • Staffing: These guidelines are only dealing with conscious sedation. This implies that the dentist should be able to act as his/her own sedationist without the presence of an anaesthesiologist, provided that these guidelines are followed. • Patient assessment must include a full medical and dental history as well as a social history. Each patient must be classified according to the ASA Physical Status Classification System (6). Patients who are ASA Class I or Class II may be considered candidates for conscious sedation as outpatients. Patients in ASA Class III and Class IV represents special problems and require individual consideration and shall be treated in a hospital environment, involving the assistance of medical doctors when appropriate. • Indications and contraindications When identifying children in need of conscious sedation it is useful to make a combined judgement of the following two groups of factors. Children with low coping ability: Behaviour management problems; Dental fear and anxiety; odontophobia; Mental retardation; General disorders, psychiatric conditions; Treatment need: Emergency treatment; Moderate to large and complicated treatment needs. • Patient monitoring Paediatric dental patients under conscious sedation must be monitored continuously clinically, as this is the most important element in patient monitoring. <u>Clinical monitoring</u> includes: Response by the patient to physical stimulation and verbal command, Observing breathing, Movements of the thorax, Passage of the air stream, Respiratory frequency, Observing skin colour. The use of <u>pulse oximetry</u> has been widely discussed. In the case of conscious sedation, oxygen desaturation (<i>i.e.</i> below 95%) is probably rare. Pulsoximetry is not deemed required for conscious sedation with nitrous oxide/oxygen sedation, but is preferable in benzodiazepine sedation. It is however vital that the staff are adequately trained in the use of clinical monitoring, and if used the management of electronic monitoring. When pulse oximetry is used, more than 3 out of four of the alarms may be false positives due to movement artefacts, sensor displacement or other reasons. Young children especially may react with increased anxiety to the placement of the 		

pulsoximeter.

- **Patient information - Written and oral information, consent, escort**

Pre- and postoperative instructions in writing must be given in advance of the procedure to the child and the parent or guardian. Informed consent shall follow the legislation of the country. An adult who is well known to the child should always escort them to and from treatment. In the context of school dental clinics and the use of nitrous oxide/oxygen sedation, schoolchildren can after parents' consent get treatment without the presents of an adult escort, provided the parents have consented.

- **Fasting** rules vary slightly between the European countries. Prior to conscious sedation it is recommended, that the child shall be fasted according to the following rules: No clear liquids 2-3 hours before sedation; No solid foods or non-clear liquids 4 hours before sedation. Clear liquids are non-fruity juice, water, tea, and coffee. All milk products (non-clear liquids) are considered as solid foods. Children under school age shall drink sugar containing clear liquid up to 2 hours before treatment in order to avoid low blood sugar. For the emergency patient, where proper fasting has not been assured, the increased risk of sedation must be weighed against the benefits of the treatment, and the lightest effective sedation should be used. If possible, such patients may benefit from delaying the procedure.

- **Discharge** Before discharge, children should be alert and oriented (or have returned to an age-appropriate base line). A responsible adult must be present to observe the child for complications after discharge, and to control that the child sits with the head in an upright position to facilitate breathing. In the situation of an outpatient child and if the responsible adult is driving a car to the home, another adult must be present if the child is young. The adult must be given written and oral instructions on: Appropriate diet, Medications, Management of possible postoperative bleeding, Level of activity.

- **Documentation and records** It is recommended that the documentation includes:

Medical history including prescribed medication, Previous dental history, Previous conscious sedations and general anaesthesia, Indication for the use of conscious sedation, Pre-sedation assessment, Written instructions provided pre- and post-operatively, Presence of an accompanying responsible adult, Arrangements for suitable post-operative transportation and supervision, Compliance with pre-treatment instructions, The course of the treatment (Monitoring, Dose, and route of administration of sedative drugs, Dental treatment performed, Sedation evaluation (sedation scale), Accept of sedation and treatment (behavioural scale), Complications), Post-sedation assessment and time of discharge home

- **Safety for the staff** Inhalation sedation requires special scavenging equipment to ensure safety for the personal in the operating room. Dental staff must follow strict indications for the use of nitrous oxide, only use nitrous oxide delivery systems with an efficient scavenging system, have appropriate technique for disconnection of the delivery system, and have methods for testing the integrity of the breathing system.

- **Education and Training:** Training of paediatric dentists in sedation should include theoretical training as well as practical training. EAPD Guidelines for postgraduate training in paediatric dentistry should be followed in developing appropriate training programmes in sedation. Theoretical training should cover all the subjects referred to in the present document. Practical training should include knowledge of the drugs and equipment used for conscious sedation, and must be completed before the clinical training. Knowledge of management of complications due to conscious sedation is essential. Training and experience should be regularly updated and maintained.

Documented, contemporaneous supervised hands-on experience must be acquired for each conscious sedation technique used. The minimum number of documented supervised cases completed should be no less than those specified by appropriate authorities.

Dental auxiliary personnel assisting during conscious sedation sessions shall also have appropriate but shorter training.

All clinical staff require theory and practical training in basic life support. Basic life support must conform to contemporary guidelines issued by national authorities and dental associations.

Training can be through informal courses where clinical training is included or in theoretical courses with clinical demonstrations in combinations with clinics where conscious sedation is regularly performed for hands-on supervision.

Those arranging such training have a duty to ensure that the quality of training and trainers is appropriate and that all theoretical and practical training is documented.

- **Drugs** used for paediatric dental sedation includes inhalation agents where the gas is delivered through a specially designed machine and the patient inhales the gas through a

nasal hood (mainly nitrous oxide), benzodiazepines and other agents with sedative properties.

Nitrous oxide when administered to patients for inhalation must be given in a mixture with oxygen (30% or more) to safeguard the patient's oxygen supply; has a rapid onset, a fast recovery (both within minutes) and is a poor anaesthetic.

Benzodiazepines (BZD) are a group of drugs, which have the following effects: anxiolysis, sedation/hypnosis, skeletal muscular relaxation, anterograde amnesia, respiratory depression and an anticonvulsive effect. A combination of nitrous oxide/oxygen and BZD may be used for conscious sedation, as there is an additive effect of the nitrous oxide to the BZD sedative effect. In these cases, more strict fasting rules should be followed. Among the different benzodiazepines available, midazolam and diazepam are the most suitable for use in paediatric dentistry.

Other agents with sedative properties The efficacy of fentanyl and pethidine is questionable and the associated risks may outweigh their benefit and some are only recommended in some countries for use in hospital settings and by qualified anaesthetists. The use of propofol and ketamine in paediatric dentistry is still experimental and requires the assistance of or has to be administered by a qualified anaesthesiologist.

- **Nitrous oxide/oxygen** has been shown to be an effective anxiolytic and sedative inhalation agent for conscious sedation during dental treatment and is recommended as the preferred drug.
- Indications: Nitrous oxide/oxygen sedation is useful in children 4 years and older and can be used in patients with a strong gagging reflex, which makes dental treatment impossible, as well as in patients with muscular tone disorders such as cerebral palsy, in order to avoid unintentional movements. Patients belonging to ASA Class III and Class IV can be treated with the help of nitrous oxide/oxygen sedation provided other indications are present, but treatment of these patients must be restricted to hospital settings, where an anaesthesiologist can be present.

Contraindications: Pre-co-operative children, Patients with upper airway problems as common cold, tonsillitis or nasal blockage, Patients with sinusitis or recent ENT operations (within 14 days), Patients in bleomycin chemotherapy, Psychotic patients, Patients with porphyria.

Side effects of nitrous oxide are over sedation, nausea, vomiting, dysphoria, sweating, restlessness, panics, headache, nightmare, tinnitus and urinary incontinence

Delivery The gas mixture shall contain a maximum 50 % nitrous oxide. Nitrous oxide/oxygen sedation and local anaesthesia is an alternative to general anaesthesia. Only dedicated dental nitrous oxide/oxygen delivery systems must be used. The system must contain fail-safe device (*i.e.* if the oxygen pressure falls, the supply of nitrous oxide automatically stops), flow-meter for individual set of gas flow and nitrous oxide concentration, emergency air-valve, non re-breathing, tubes with low breathing resistance, and an effective scavenging device for exhaled and excess gas. The use of rubber dam improves the effect of the sedation and reduces atmospheric pollution. Dental operators should ensure that they comply with national guidelines in respect to nitrous oxide pollution and gas safety.

- **Midazolam** is now the standard BZD agent for conscious sedation during dental treatment in children. After oral administration the peak plasma concentration is reached within 20 minutes, faster via the rectal route in about 10 min. After 45 minutes the sedative effect wears off. The elimination half time is 2 hours, which facilitates a fast recovery.

Indications: see general indications for conscious sedation.

Contraindications: Midazolam must not be given to the following groups of children: under the age of one year; with any form of acute disease; with neuromuscular diseases as myasthenia gravis; with allergy to BZD; with sleep apnoea; with liver dysfunction; with hepatic dysfunction.

Clinical considerations: All drugs in use in the treatment area must be clearly labelled and each drug should be given according to accepted recommendations.

Routes: Oral midazolam can be administered in tablet form (available in some countries) or as a sweetened mixture for delivery either via a drinking cup or drawn into a needleless syringe and deposited in the retromolar area. Transmucosal administration of midazolam has the advantage of depositing the drug directly into the systemic circulation. Rectal sedation utilises this transmucosal approach. Rectal administration requires syringes and a rectal applicator. In some countries, rectal administration is uncommon due to cultural attitude. Despite this rectal administration of midazolam has a good evidence base. In some countries doctors keep away from rectal administration due to a negative opinion of the public. Midazolam should be administered at the clinic. Doses provided.

- **Diazepam** has a long elimination half-life, 24-48 hours, and active metabolites. The clinical action develops within an hour after oral tablet administration. Because of a pronounced distribution, the time of clinical effect is rather short. Inherited metabolic deficiencies occur in some individuals, with a risk of prolonged effect. Diazepam is highly effective in

<p>reducing preoperative anxiety, and useful for sleep disturbances prior to treatment. <u>Routes:</u> Oral administration of tablets can be given either as a single dose 1 hour before treatment, or fractionated, with half the dose taken on the night before, and the remaining half 1 hour prior to treatment. Tablets can be crushed and mixed in sweetened drink in to facilitate administration. Doses provided.</p> <ul style="list-style-type: none"> • Appendices with ASA Classification; Sedation scale according to Wilton. 			
Geographical setting for guidance:		Healthcare setting for guidance: <i>users and patients</i>	Is guidance currently used?
Guidelines developed for use in European countries.		Not stated	Possibly. Still available on EAPD website, despite being over 10 years since adopted.
<p>Basis for recommendations: <i>e.g. published evidence, expert opinion etc.</i> <i>If evidence based, review evidence in sections below</i></p>			
<p>During the development of the guidelines it became clear, that very few RCTs had been performed in the area of sedation of children for dental care. Thus, the present guidelines had to be based on lower levels of evidence, such as guidelines developed by other professional organisations, as well as clinical experience. One of the obvious recommendations therefore is, that there is a need for well-controlled clinical studies on sedation of children for dental care.</p> <p>41 references are listed and cited throughout the text. There is no methodology described and therefore it is impossible to know whether there was a systematic search for evidence and whether there was any assessment of quality. It is therefore assumed that the recommendations are based on expert opinion, informed by evidence listed.</p> <p>A distinction is made between the use of 'must' or 'shall' (imperative) and 'may' or 'could' (freedom to follow suggested or reasonable alternative), which might be regarded as relating to strength of recommendation.</p>			
Description of evidence for recommendations (if applicable):			
Patient/Problem: <i>(target patients and actual participant characteristics)</i>	Intervention or risk factors:	Comparison:	Outcomes: <i>note with * those which are critical/important (from patient perspective) for the guidance recommendation</i>
Children: All patients below the age of 18 years, as defined by the UN Convention on the Rights of the Child	Sedation	N/A	Not identified.
Study Type:	Search Strategy:		Study selection: No. of selectors:
<i>Appropriate study types?</i>	<i>Appropriate search terms?</i>	No	<i>Inclusion criteria:</i> No description of search or details of study selection from search results provided.
	<i>Appropriate databases?</i>	No	
	<i>Unpublished studies?</i>	No	
	<i>Follow up of citations?</i>	No	

	Personal contact with experts?	No	
Risk of bias/systematic error (study limitations that could cause systematic error): <i>consider risk of bias for each important outcome</i>			
<i>Randomisation: is it reported and appropriate?</i> Not described	<i>Blinding: consider whether blinding of patients or assessors would be important for outcomes considered</i> Not described	<i>Other limitations: e.g. attrition bias (incomplete accounting of patients and outcome events), reporting bias (selective outcome reporting), surrogate outcomes(?)</i> No details provided.	
Inconsistency: <i>Refers to unexplained heterogeneity in results.</i>	Imprecision (random error):	Indirectness: <i>consider i) whether interventions of interest were compared directly or not; ii) whether population characteristics or settings differ from those of interest</i>	Publication bias: <i>e.g. when intervention is new and not many studies available- may be biased for positive results</i>
No heterogeneity analysis.	Not reported	Unclear	Publication bias is very likely.
Meta-analysis: No. of data extractors: not stated		Overall results: <i>for each outcome or recommendation as applicable</i>	
No meta-analysis performed <i>Are results for individual studies shown? No</i> <i>Was it reasonable to combine study results?</i> <i>Was an appropriate method used?</i> <i>Are reasons for variation in results discussed?</i> <i>Would confounders affect overall result^a?</i>		The results of the studies are not reported. <i>Is the effect substantial¹?</i> <i>Is there dose-response data¹?</i>	

^a This is only relevant for observational studies (automatically start at low quality) where none of the quality criteria need to be downgraded, and allows for the possibility of upgrading. Not relevant for RCTs where quality starts at high.

Adverse events:	Benefit/harm/cost considerations?	Values/preferences considerations?
Side effects highlighted (see above).	Not specifically discussed. Safety issues with inhalation mentioned (see above). Cost considerations not mentioned.	Not discussed.
Overall quality of guidance (AGREE II) and explanation:		Rating of recommendations: <i>Should the recommendations made be considered for SDCEP guidance?</i>
<p>Overall quality = 2/7 (low) AGREE appraisals available on request.</p> <p>This is a low quality guideline. Although the recommendations are reasonably clear, some are less easy to find and there is no indication that the evidence quality has been considered. Several aspects of the methodology are lacking.</p>		<p>Recommendations are fairly easy to find and supported by references, although how that was identified is not clear. Given that it is from 2003, it could be a useful source to inform current clinical recommendations, though more up-to-date evidence would be desirable.</p>
Reviewer's comments:		
<p>The recommendations in this guideline, though now 13 years old, are still likely to be relevant to current clinical practice. It is not clear if this guideline is still in general use.</p>		
<p>SDCEP guidance themes: sedation technique✓, patient selection✓, records✓, consent✓, training✓, monitoring✓, fasting✓, environment X, equipment✓, staffing✓, patient viewsX (✓) = mentioned but not in detail.</p>		

Appendix 5 – Considered Judgement Forms

Preparation for Sedation (Clinical Questions 2.1-2.9)

<p>Question 2.1:</p> <p>For patients undergoing dental treatment under sedation: what factors should be assessed to determine the suitability of the use of sedation?</p>	<p>Appraisal refs:</p> <p>G1, G3, G5, G6, G8, G10, G12, G13, G14, G15, G16, G17</p>
<p>1. Summary of evidence</p> <p>G1: Recommends pre-operative assessment and preparation of patients, focusing on medical, social and psychological assessment and evaluation of risk, taking into consideration the limitations of the setting. (Risk factors may include heart disease, cerebrovascular disease, lung disease, liver failure, anaemia, shock and morbid obesity and sick and/or elderly patients may have significant co-morbidity.)</p> <p>Pre-assessment should, wherever possible, include consultation of previous records. An important consideration is the ability to rescue a patient who becomes inadvertently over-sedated and, where necessary, maintain an airway and establish satisfactory ventilation and oxygenation.</p> <p>G3: For ASA I and II, patient evaluation assessment must take place prior to sedation, comprising review of current medical history and medication use. ASA III or IV, may require consultation with primary care physician or specialist.</p> <p>G5: All patients should be assessed before procedural sedation and/or analgesia. Assessment should include: Details of the current problem, co-existing and past medical and surgical history, history of previous sedation and anaesthesia, current medications (including non-prescribed medications), allergies, fasting status, the presence of false, damaged or loose teeth, or other evidence of potential airway problems, and the patient's exercise tolerance or functional status; Examination of the airway, respiratory and cardiovascular status, and other systems as indicated by the history, including that relevant to the current problem; Results of relevant investigations.</p> <p>This assessment should identify those patients at increased risk of cardiovascular, respiratory or airway compromise during procedural sedation and/or analgesia, as in such cases, an anaesthetist, or other trained and credentialed medical practitioner within his/her scope of practice, should be present to care for the patient. These patients include all children less than 2 years of age, the elderly, those with severely limiting heart, cerebrovascular, lung, liver or renal disease, morbid obesity, significant obstructive sleep apnoea, known or suspected difficult endotracheal intubation, acute gastrointestinal bleeding particularly with cardiovascular compromise or shock, severe anaemia, the potential for aspiration of stomach contents (which may necessitate endotracheal intubation), previous adverse events due to sedation, analgesia or anaesthesia, and patients in ASA Grades P 4-5 (see appendix 1 and ANZCA professional document <i>PS07 Recommendations for the Pre-Anaesthesia Consultation</i>).</p>	

G6: For alternative techniques: The Patient requirements: medical and dental history, age, ASA, weight, psychological status, social aspects, proposed dental procedure.

Indications for oral and transmucosal sedation with midazolam:

Oral or intranasal sedation should only be used where it is not possible to use one of the titratable techniques. For example: where intravenous cannulation cannot be achieved due to patient phobia, learning difficulties or other disabilities; where inhalation sedation with nitrous oxide does not provide sufficient relaxation or the patient has been assessed as being too anxious for this to be successful

Contraindications: where it is more appropriate to use one of the titratable techniques (e.g. intravenous or inhalation sedation). It is thus the third choice technique; where cannulation is difficult or impossible due to the anatomy of the patient or where there is a history of failed cannulation (which is not simply the result of patient anxiety); where the sedationist is inexperienced at cannulation.

G8: Review of patient's medical history prior to decision to use N₂O/O₂, including allergies, medications, diseases etc, previous hospitalization, recent illnesses. Consult medical specialists for patients with significant underlying medical conditions.

G10: The health evaluation should include: Age and weight. Health history, including: 1) allergies and previous allergic or adverse drug reactions, 2) medication/drug history, including dosage, time, route, and site of administration for prescription, over-the-counter, herbal, or illicit drugs, 3) relevant diseases, physical abnormalities, and neurologic impairment that might increase the potential for airway obstruction, such as a history of snoring or obstructive sleep apnea, 4) pregnancy status, 5) a summary of previous relevant hospitalizations, 6) history of sedation or general anesthesia and any complications or unexpected responses, and 7) relevant family history, particularly related to anesthesia. Review of systems with a special focus on abnormalities of cardiac, pulmonary, renal, or hepatic function that might alter the child's expected responses to sedating/analgesic medications. Vital signs, including heart rate, blood pressure, respiratory rate, and temperature (for some children who are very upset or non-cooperative, this may not be possible and a note should be written to document this occurrence). Physical examination, including a focused evaluation of the airway (tonsillar hypertrophy, abnormal anatomy e.g. mandibular hypoplasia) to determine whether there is an increased risk of airway obstruction. Physical status evaluation [ASA classification]. Name, address, and telephone number of the child's medical home.

G12: lists indications for sedation and factors to consider: health history, current medical and physical status (refers to ASA status), likelihood of success, time and effort required, cost, risks, social environment and support available, availability of various treatment modalities, urgency.

G13: Assessment to include full medical and dental history before decision to use sedation (*SIGN Grade C, no references cited*)

G14: To facilitate the provision of high quality dental care, conscious sedation is just one option for the control of anxiety. The decision to use a particular (behaviour management) approach must be based on a full assessment in respect of healthcare history, psychological needs and overall management. The use of conscious sedation may be indicated for special

care patients, certain medical indications or difficult clinical situations.

G15: Establish suitability by assessing: current medical condition and any surgical problems; weight (growth assessment); past medical problems (including any associated with previous sedation or anaesthesia); current and previous medication (including any allergies); physical status (including the airway); psychological and developmental status. Seek advice from a specialist before delivering sedation: if there is concern about a potential airway or breathing problem; for ASA III or greater; for infants, including neonates. *(based on consensus expert opinion)*

For an elective procedure, consider referring to a mental health specialist children or young people who are severely anxious or who have a learning disability.

Choose the most suitable sedation technique based on all the following factors: what the procedure involves; target level of sedation; contraindications; side effects; patient (or parent or carer) preference. *(based on consensus expert opinion)*

G16: Patient Assessment and Selection: A thorough medical, dental and social history should be taken and recorded prior to each course of treatment – takes into account specific factors such as age, state of health social circumstances and special needs. A provisional treatment plan should be formulated following the taking of a history, dental examination and assessment of the patient's general fitness. Assessment of general appearance, skin colour, pulse and respiration is important in the selection of appropriate treatment for each patient. Accurate measurement of blood pressure is an essential part of risk assessment for intravenous sedation. ASA Physical Status classification should be determined and recorded. Only patients in ASA classes I and II should normally be considered suitable for sedation as outpatients. Patients in ASA class III should be referred to an appropriate secondary care unit.

G17: General Indications: When identifying children in need of conscious sedation it is useful to make a combined judgement of the following two groups of factors.

Children with low coping ability: Behaviour management problems; Dental fear and anxiety, odontophobia; Mental retardation;

General disorders, psychiatric conditions; Treatment need: Emergency treatment; Moderate to large and complicated treatment need.

Nitrous oxide/oxygen sedation is useful in children 4 years and older and can be used in patients with a strong gagging reflex, which makes dental treatment impossible, as well as in patients with muscular tone disorders such as cerebral palsy, in order to avoid unintentional movements. Patients belonging to ASA Class III and Class IV can be treated with the help of nitrous oxide/oxygen sedation provided other indications are present, but treatment of these patients must be restricted to hospital settings, where an anaesthesiologist can be present.

Contraindications: Pre-co-operative children, Patients with upper airway problems as common cold, tonsillitis or nasal blockage Patients with sinusitis or recent ENT operations (within 14 days), Patients in bleomycin chemotherapy, Psychotic patients, Patients with porphyria.

Midazolam Indications: see general indications for conscious sedation. Contraindications: Midazolam must not be given to the following groups of children: under the age of one year; with any form of acute disease; with neuromuscular diseases as myasthenia gravis; with

allergy to BZD; with sleep apnoea; with liver dysfunction; with hepatic dysfunction.

2. Quality, quantity and consistency of evidence

Eleven guidelines methodologically rated high (G15), moderate (G1, G13) or low (G3, G5, G6, G10, G12, G14, G16, G17) provide recommendations related to factors to be assessed to determine the suitability for use of sedation, which are based on expert opinion of best practice. These factors relate to patient-specific factors and indications for sedation. The level of detail provided about factors that influence the decision to use sedation varies significantly.

Patient – specific factors. All eleven guidelines recommend assessment of medical history (some list details) and several specify assessment of the physical condition of the patient (G1, G6, G10, G12, G16) and cite assessing ASA status, and significant medical conditions (G1, G5, G8, G10, G15), which might warrant referral to a specialist or secondary care.

A variety of other patient factors are specifically mentioned including: Personal details (G10); social history (G1, G6, G16), dental history (G6, G13, G16), age (G6, G10), weight (G6, G10, G15), proposed dental procedure/problem (G6, G16), medication, vital signs (G10, G16), airway (G1, G5, G10, G15). G12 also lists: likelihood of success, time and effort required, cost, risks, social environment and support available, availability of various treatment modalities, urgency.

Indications for sedation.

The highly rated guideline G15 states: Choose the most suitable sedation technique based on all the following factors: what the procedure involves; target level of sedation; contraindications; side effects; patient (or parent or carer) preference.

G6 states: Oral or intranasal sedation should only be used where it is not possible to use one of the titratable techniques.

G12, which is specifically focused on special dental care, lists:

1. Individuals with cognitive impairment or emotional conditions who have difficulty understanding what is expected in a dental treatment situation.
2. Patients whose fear about receiving dental treatment prevents them from receiving the needed treatment.
3. Patients who are unable to sit in a dental chair or remain still enough to have dental procedures performed.
4. Patients who have extensive dental needs that would require extended dental treatment over a prolonged period of time.
5. Patients who require dental procedures that cannot easily be performed with local anaesthesia because of an inability to achieve adequate local anaesthesia for that procedure.
6. Individuals with complex medical problems who require intra- and perioperative monitoring.
7. Individuals with complex medical problems (e.g., severe hypertension and cardiac or respiratory disease) whose physiologic state will be more safely controlled in a sedated or anesthetized state.

G14 notes: The use of conscious sedation may be indicated for special care patients, certain medical indications or difficult clinical situations.

G17 lists: Children with low coping ability: Behaviour management problems; Dental fear and anxiety, odontophobia; Mental retardation; General disorders, psychiatric conditions; Treatment need: Emergency treatment; Moderate to large and complicated treatment need.

Also states: N₂O/O₂ is useful for children: 4 years and over; with strong gagging reflex; with muscular tone disorders.

3. Subgroup considerations

It may be difficult to carry out all aspects of a full assessment (e.g. oral examination) for some patients e.g. young or very anxious children or patients with additional needs. Adaptation of the process might be required in these cases.

Patients who are not ASA I or II i.e. it is likely that patients that are ASA III or above will not be treated in a primary care setting.

Patients with significant medical conditions (e.g. cardiovascular, respiratory problems, airway concerns).

Consider support for children with additional needs to enable sedation in preference to GA i.e. ways of helping children to cope.

The location of the assessment and treatment facilities may be important for some groups e.g. those with long travel times.

4. Balance of effects

There is agreement about the importance of thoroughly assessing the patient and the purpose of the sedation technique being considered, to ensure that the correct decision is made for the individual patient.

5. Generalisability and applicability

Many of the guidelines cited are from the UK and are generally consistent with those from other countries. The assessment should be tailored to the individual patient and their needs.

6. Values and preferences

Patient/carer preference, as identified by a patient representative, is that assessment of children should be carried out by staff experienced with that age group and should involve play workers.

The importance of patient specific risk assessment was also identified.

7. Acceptability

It is likely that patients would expect a thorough assessment and a decision about sedation that is specific to their individual needs.

8. Feasibility

Assessment is standard practice for provision of dental healthcare.

9. Other factors

The group agreed that ideally assessment should take place on a separate visit prior to treatment, but acknowledged that there are circumstances in which this might not be feasible, e.g. urgent care. Also, the location might influence how and where assessment is carried out.

10. Recommendation for guidance

Summary of group's judgements:

There was overall agreement within the sources identified about the principles of assessment for conscious sedation, with some variation regarding the detail.

The GDG agreed that ideally, patient assessment for elective procedures should take place at a visit prior to the treatment visit. There are exceptional circumstances when assessment on the day of the visit may be necessary (e.g. patient in acute pain, trauma). The possibility of alternative approaches to enable 'remote' assessment (e.g. by telephone) was considered but it was agreed that a number of aspects of the assessment can only be completed with the patient present.

As assessment is to inform the decision to sedate as well as the method of sedation, the GDG was keen to emphasise the importance of exploring the use of behaviour management strategies either instead of or as an adjunct to sedation.

The GDG agreed that the patient's history taking should include anxiety and sedation history and that drug use should more explicitly identify illicit or recreational drugs. It was agreed to include the latest version of the ASA status table as an appendix.

For sedation other than inhalation with nitrous oxide/oxygen, the GDG agreed that blood pressure monitoring during the assessment is essential (except for children) and that other monitoring should be recommended, specifically pulse oximetry and heart rate, since these help to inform the suitability of the patient for sedation.

The GDG agreed that it should be emphasised that effective treatment planning may reduce the need for future treatment with sedation.

Regarding indications for sedation, there was agreement that the emphasis should be on the patient's need for sedation rather than the desire for sedation, i.e. on each occasion, the need for sedation should be re-assessed. Slight amendments to indications for sedation were agreed, to extend these to behavioural conditions.

Recommendations and clinical advice:

The key recommendation on assessment should indicate that a full assessment of the patient should be carried out to inform the need for sedation and the technique selected.

In line with the guidelines considered here, the aspects of assessment to be included are those already listed in Appendix 2 of SDCEP's *Conscious Sedation in Dentistry* guidance (2012), with the inclusion of prescribed and non-prescribed drugs in the medical history.

Information on indications for sedation should be provided and emphasis given to consideration of non-pharmacological behaviour management techniques. The guidance should also include the other points made in this section.

Basis for Key Recommendation: Expert opinion.

This key recommendation is informed by several recent guidelines and is consistent with current standard professional practice. Because the recommendation was mainly informed by other guidelines it is designated as based on expert opinion and is not assigned a strength.

Post-consultation revisions:

The advice on the need for a separate assessment visit prior to the day of sedation was revised after consultation. The GDG agreed that thorough assessment is best achieved at a separate appointment prior to the patient's treatment under sedation to allow the clinician sufficient time to obtain and fully consider all of the required information and, for consent purposes, to give the patient time to consider options without concerns about receiving treatment the same day. However, they also acknowledged that there may be some circumstances, other than for emergency treatment, where alternative arrangements could be justifiable provided they meet the criteria for thorough assessment and valid consent. These circumstances might include patient factors affecting attendance at a separate appointment, for example, geographical location, mobility, cost, childcare issues etc, which were identified as potential equality issues.

11. Additional Information

The 2016 update of guideline G10 recommends that vital signs measured at assessment should include oxygen saturation (unless not possible for children who are upset or noncooperative).

<p>Question 2.2: For patients undergoing dental treatment under sedation:</p> <p>who should make the assessment and how should this be carried out and recorded?</p>	<p>Appraisal refs: G14, G15</p>
<p>1. Summary of evidence</p> <p>G14: Assessor is the practitioner.</p> <p>G15: Assessor to be suitably trained healthcare professional. <i>(based on consensus expert opinion)</i></p>	
<p>2. Quality, quantity and consistency of evidence</p> <p>Two guidelines, including the highly rated G15, make recommendations, which are based on expert opinion of best practice. Terminology differs in G14 and G15.</p> <p>Is it important to state who makes the assessment of suitability for sedation and if so, what unambiguous term can be used to specify who this should be?</p>	
<p>3. Subgroup considerations</p> <p>Are there certain patients for whom assessment might be carried out, even in part, by a different individual (e.g. the need for two visits in remote locations)?</p>	
<p>4. Balance of effects</p> <p>There is a high risk that patient safety and treatment will be compromised if the practitioner responsible for patient assessment is not one who has the appropriate knowledge and skills to be able to judge whether and what kind of sedation would be suitable for the patient to allow the dental treatment required.</p>	
<p>5. Generalisability and applicability</p> <p>Both guidelines cited are from UK. G14 covers all patients, G15 children and young people.</p>	
<p>6. Values and preferences</p> <p>It is likely that patient expectation would be that the assessment would be carried out by someone with the appropriate training. This was confirmed by a patient representative.</p>	
<p>7. Acceptability</p> <p>It is likely that responsibility for patient assessment for sedation being that of the sedationist would be the expectation.</p>	
<p>8. Feasibility</p> <p>Again, are there certain patients (e.g. the need for two visits in remote locations) for whom assessment might be carried out, even in part, by a different individual.</p>	

9. Other factors

Guideline G14 states:

A practitioner must therefore make a careful, thorough assessment of the patient and his or her needs before deciding that the use of conscious sedation is indicated. (p8)

A sub-committee of representatives of IACSD (Intercollegiate Advisory Committee for Sedation in Dentistry) provided further explanation of their intention for the term 'practitioner' in the context of assessment as used in their guideline (G14):

Patient assessment should be carried out by both the referring dentist and sedationist. The referring practitioner ensures that referral for sedation is the appropriate option, and that the patient understands this, and may be less knowledgeable about sedation than the sedationist. The sedationist who assesses the patient ensures that the most appropriate sedation technique is used. In some cases, sedation may be delivered by another sedationist who did not carry out the assessment.

10. Recommendation for guidance

Summary of group's judgements:

This question was included because it had become apparent that there is some doubt about roles and responsibilities relating to assessment. G15 (NICE guideline) included this as a clinical question, and G14 (IACSD Report) is unclear about who carries out the assessment, stating 'A practitioner'. Consequently, clear guidance would be beneficial.

Considering the information above, and in their own expert opinion, the GDG agreed that the ultimate responsibility for the sedated patient lies with the sedationist. It is acceptable for a sedation trained practitioner to assess the patient and a different sedationist (in the same facility) to carry out the sedation. It may be acceptable for members of the clinical team, other than the sedationist, to carry out some aspects of the assessment (e.g. measuring blood pressure) provided they are suitably trained. Any decision making regarding sedation would be the responsibility of the sedationist.

The GDG agreed that the guidance should be worded to emphasise the roles of the referrer (assesses the need for sedation and identifies that patient treatment need is beyond their competence) and the clinical team (sedationist has ultimate responsibility), with careful consistent use of terminology. This might require an explanation of what is meant by the 'team'.

It might also be appropriate to include text to encompass establishing the need for sedation and justification of the decision to use sedation.

Recommendations and clinical advice:

The advice that the assessment for sedation is ultimately the responsibility of the sedationist, and that the assessor(s) should be appropriately trained, should be contained within the section on patient assessment (see Question 2.1) and as such will not be included in a separate key recommendation.

As indicated above, the responsibilities of the referring dentist and sedationist should be more clearly stated to emphasise their roles in assessment of the patient.

Basis for Key Recommendation: see Question 2.1.

11. Additional Information

See Question 7.1 for aspects of the assessment to record in the patient's notes.

<p>Question 2.3: For patients undergoing dental treatment under sedation:</p> <p>how should consent be obtained for sedation?</p>	<p>Appraisal refs:</p> <p>G1, G3, G5, G8, G10, G13, G14, G15, G16, G17</p>
<p>1. Summary of evidence</p> <p>G1: Valid consent is an essential preliminary to sedation. (Department of Health guidance available) Information should be provided at an appropriate time (not at the last moment) when there is a chance to have a discussion and for the patient to be able to ask questions, understand the choices and risks before making a decision to sedate. Risks and benefits must be clearly explained and proper distinction should be made between average risk and personalised risk. Alternatives to sedation (typically general anaesthesia or local anaesthesia with behavioural techniques) should be clearly explained.</p> <p>G3: The patient, parent, guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.</p> <p>G5: Informed consent for sedation and/or analgesia and for the procedure should be obtained from the patient, or a person entitled to give consent on behalf of the patient, according to applicable legislation (see ANZCA professional document <i>PS26 Guidelines on Consent for Anaesthesia or Sedation</i>).</p> <p>G8: Informed consent must be obtained from the parent and documented in the patient's record prior to administration of nitrous oxide/oxygen.</p> <p>G10: The patient record shall document that appropriate informed consent was obtained according to local, state, and institutional requirements.</p> <p>G13: Informed consent for a course of dental treatment under conscious sedation must be obtained from each parent/guardian, and the child, where appropriate, prior to the conscious sedation appointment. (<i>SIGN Grade C, no references cited</i>)</p> <p>G14: Valid consent should be obtained in writing prior to the day of treatment and must also be re-confirmed on the actual day of treatment. Further description of the consent considerations is provided (capacity to consent, consent for and by children).</p> <p>G15: Obtain and document informed consent for sedation. (<i>based on consensus expert opinion</i>)</p> <p>G16: Specific written valid consent must be obtained for all patients who are to receive treatment under sedation.</p> <p>G17: Informed consent shall follow the legislation of the country.</p>	
<p>2. Quality, quantity and consistency of evidence</p> <p>Ten guidelines methodologically rated high (G15), moderate (G1, G13) or low (G3, G5, G10, G12, G14, G16, G17), provide recommendations on the obtaining of consent for sedation, which are based on expert opinion of best practice.</p>	

Seven guidelines state that informed written consent must be obtained (G3, G5, G8, G10, G13, G15, G17), three that valid written consent must be obtained (G1, G14, G16).

G1, G13 and G14 state that consent should be obtained at an appointment prior to the procedure and G14 states that this should be reconfirmed on the day of the procedure.

G1 states as part of gaining consent, alternative options and risks, including personal risks should be discussed. G14 describes other aspects of consent including capacity and consent on behalf of and by children.

The narrative that accompanies the recommendations in G15 describes the factors to be discussed with the child or young person and/or their parent guardian when obtaining valid consent, including involvement of the child in the discussion, choices of sedation techniques (or no sedation or general anaesthesia) risks, side effects and the patient's ability to cope with discomfort or anxiety

G5, G8 and G13 state that consent should be obtained from the responsible person/parent.

3. Subgroup considerations

Special considerations are required for patients who are unable to give consent for their treatment. The legal position may differ across the UK.

4. Balance of effects

5. Generalisability and applicability

Several of the cited guidelines are from the UK.

6. Values and preferences

Even if they are unable to give consent legally, it is important, where their level of understanding allows, to include patients in the discussions about their treatment and to allow them to confirm that they are content to proceed.

The information provided to inform consent should be appropriate for the patient's age and learning ability.

7. Acceptability

Obtaining valid consent is standard practice for provision of dental healthcare.

8. Feasibility

Obtaining valid consent is standard practice for provision of dental healthcare. Written consent for sedation is a GDC requirement.

9. Other factors

General Dental Council Standard 3.1 states:

You must obtain valid consent before starting treatment, explaining all the relevant options

and the possible costs.

3.1.6 You must obtain written consent where treatment involves conscious sedation or general anaesthetic.

Further explanation of the consent process is provided, including that:

- it is the discussions that take place with the patient that determine whether the consent is valid.
- you must provide patients with sufficient information and give them a reasonable amount of time to consider that information in order to make a decision.
- you must check and document that patients have understood the information you have given.

10. Recommendation for guidance

Summary of group’s judgements:

Ideally consent should be obtained on a different day from the procedure, particularly given the anxious nature of most of these patients, and should involve both verbal and written explanation of the procedure. A patient cannot give consent after premedication. Those who are unable to give consent should still be involved in discussions and extra information or information in different formats may be required.

Valid written consent should be obtained according to the GDC standards, prior to the treatment. Appropriate patient information must be provided to facilitate this. As consent is an ongoing process it is important to reconfirm consent on the day of the procedure and record this in the patient’s notes.

Basis for Recommendation:

Obtaining consent is a mandatory requirement. As such, this should be standard practice and consequently requirements for obtaining consent do not constitute a key recommendation in this guidance.

Post-consultation revisions:

The guidance on consent was amended to clarify that the consent process should begin at a separate appointment prior to the procedure, so that the patient has time to fully consider the information and options. This amendment also allows for the consent process to be completed on the day of treatment, for example where it is necessary to accommodate changes in the treatment plan.

Reference to the recent development in the law on obtaining informed consent, following the Montgomery v Lanarkshire Health Board case was added.

11. Additional Information

<p>Questions 2.4: For patients undergoing dental treatment under sedation:</p> <p>what information should be provided to the patient before sedation?</p>	<p>Appraisal refs: G1, G3, G5, G8, G10, G13, G14, G15, G16, G17</p>
<p>1. Summary of evidence</p> <p>G1: Psychological preparation of patients, especially children and their carers is an important part of preparation for sedation. Certain patient groups will require additional bespoke information for example children, pregnant and lactating women.</p> <p>G3: Pre-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.</p> <p>G5: The proceduralist or other suitable person should provide the patient, or their carer, with written information, where possible, which includes the nature and risks of the procedure, preparation instructions (including the importance of fasting – see ANZCA professional document <i>PS15 Guidelines for the Perioperative Care of Patients Selected for Day Care Surgery</i>), and what to expect during the immediate and longer term recovery period, including after discharge.</p> <p>G8: The practitioner should provide instructions to the parent regarding pre-treatment dietary precautions, if indicated.</p> <p>G10: The practitioner shall provide verbal and/or written instructions to the responsible person. Information shall include objectives of the sedation and anticipated changes in behavior during and after sedation. Special instructions shall be given to the adult responsible for infants and toddlers who will be transported home in a car safety seat.</p> <p>G13: In advance of the procedure, the child and their parent or guardian must be given clear and comprehensive pre- and postoperative instructions in writing. <i>(SIGN Grade C, no references cited)</i></p> <p>G14: Patient information: Written information for adult and child patients, those with parental responsibility, carers and escorts must be supplied for use in conjunction with pre-operative assessment and face-to-face discussions and explanations. It must include the range of techniques suitable for the individual and contact details, including for out-of-hours emergency advice and services. Instructions on the practical arrangements pre-and post-op, including responsibilities of the escort. A separate sheet with escort instructions is required. Additional information is specified to be provided for child patients.</p> <p>G15: To enable the child or young person and their parents or carers to make an informed decision, offer them verbal and written information on all of the following: proposed sedation technique; the alternatives to sedation; associated risks and benefits. <i>(based on consensus expert opinion)</i></p> <p>Ensure that the child or young person is prepared psychologically for sedation by offering information about: the procedure; what the child or young person should do and what the healthcare professional will do; the sensations associated with the procedure (for example, a sharp scratch or numbness); how to cope with the procedure. <i>(based on consensus expert</i></p>	

opinion)

Ensure that the information is appropriate for the developmental stage of the child or young person and check that the child or young person has understood the information.

Offer parents and carers the opportunity to be present during sedation if appropriate. If a parent or carer decides to be present, offer them advice about their role during the procedure. *(based on consensus expert opinion)*

G16: Patients must receive careful verbal and written instructions regarding conscious sedation effects and their responsibilities both before and immediately after it. The patient and escort should be provided with details of postoperative risks, pain control and management of possible complications. Adequate information regarding aftercare arrangements and emergency contact must also be provided.

G17: Pre- and postoperative instructions in writing must be given in advance of the procedure to the child and the parent or guardian.

2. Quality, quantity and consistency of evidence

Ten guidelines rated methodologically high (G15), moderate (G1, G13) and low (G3, G5, G8, G10, G14, G16, G17) provide recommendations about pre-sedation patient information.

G5 and G13 state that instructions should be written while G10, G14, G15, and G16 state that pre-operative instructions should be verbal and written.

Instructions should be given to: patient/child (G1, G3, G5, G13, G14, G16), parent/guardian/care giver (G3, G5, G10, G13, G14, G16), responsible person/escort (G3, G14, G17). G14 states that the patient must receive a separate sheet describing the responsibilities of the escort and G1 and G14 state that for children, separate age appropriate information regarding the sedation procedure should also be provided.

The methodologically highly rated G15 states that pre-operative instructions should be age-appropriate, checked for understanding and include: proposed sedation technique; the alternatives to sedation; associated risks and benefits; the procedure; what the child or young person (and parent/carer, if present) should do and what the healthcare professional will do; the sensations associated with the procedure (for example, a sharp scratch or numbness); how to cope with the procedure.

Other recommendations include: the range of techniques, preparation instructions, behaviour after the procedure, special instructions for post-op transport of children home, complications procedures, 24-hour contact number.

G14 devotes two sections to patient information and provides several examples of information for patients.

Also see Questions 6.3 (What aftercare instructions are required) and 7.2 (What information should be provided to patients/carers/escorts before and after sedation and in what format).

3. Subgroup considerations

G14 recommends additional, age-appropriate instructions to be given to children and their parents/guardians/care givers and provides examples.

Special consideration is required to ensure that information is appropriate for the patient

group (e.g. children, patients with additional support needs).
<p>4. Balance of effects</p> <p>The consensus is that providing patient information is essential. Not providing suitable information will compromise the validity of consent and risks the patient being unprepared for their sedation appointment.</p>
<p>5. Generalisability and applicability</p> <p>There is general agreement that it is essential to provide pre-operative instructions and this should not present any practical difficulties.</p>
<p>6. Values and preferences</p> <p>G15 summarises evidence about parental desire for pre-operative information. In one study 96% of parents wished to receive comprehensive information concerning their child's anaesthetic, including possible complications. In a second study, over 90% of parents reported that discussion of anaesthetic risks was desirable and understood. In a third study, 87% of parents wanted to know the risk of death after anesthesia, though understandably, several parents did not want this discussed in front of the child. Finally, in a review of six studies the authors concluded that parents want detailed information about the specifics of anaesthetic procedures, risks and personnel roles.</p> <p>G15 also examined evidence about children's desire for information. Only one study is reported in which the vast majority of children (n=143) aged 7-17 years had a desire for comprehensive information about their surgery, including information about pain and anaesthesia, procedural information and information about potential complications.</p> <p>Feedback from the patient & parent scoping interviews carried out by TRiADS (www.triads.org.uk) indicates that patients expect to receive information verbally which is then backed up in a written form consistently using the same terminology. This should include a description of what being sedated will feel like for the patient and how it is possible to experience a sense of 'loss of time' whilst being sedated. Nervous or anxious patients often reported finding it difficult to retain verbal information. Some patients asked that the clinicians be mindful of the fact that although it is routine for them, it could be the first time for the patient or parent.</p> <p>Individual patient feedback indicated that too much information can increase anxiety for some patients.</p>
<p>7. Acceptability</p> <p>It is likely that most patients would accept pre-sedation instructions, in an appropriate format.</p>
<p>8. Feasibility</p> <p>There should be few practical difficulties in providing patient information. Provision of examples/templates will assist in ensuring that the instructions provided contain the required information. Consideration should be given to how patient information will be printed in the</p>

healthcare setting to ensure that it is compatible with available printers and of a suitably professional quality. Reference to additional information on the internet if desired is a means of limiting the amount of printed material supplied.

It may be difficult in some cases to ensure that the patient escort receives information in advance of the sedation appointment, if, for example, they are not present at the assessment appointment.

9. Other factors

Consideration should be given to when and how instructions are provided, for maximum effectiveness. For example, if there is a significant period of time between the assessment and sedation appointments,

Consideration should also be given to what is the appropriate amount and level of patient information i.e. providing sufficient information without overburdening the patient/carer. Following recommended use of the patient information examples provided in G14 could mean that, for example, an adult patient having intravenous sedation is provided with at least 4 documents.

10. Recommendation for guidance

Summary of group's judgements:

The GDG agreed on the importance of providing consistent pre- and post-sedation information both verbally and in writing and the need for additional communication formats for some patients with additional support needs. It was agreed to refer to the examples of patient information provided in the IACSD report (G14) in the first instance, though these are not in a format that sedation practices could easily use without modification.

Recommendations and clinical advice:

The key recommendation for pre- and post-sedation information should indicate that the patient (also carer and/or escort) should receive consistent verbal and written instructions in advance of sedation. The information should be specific to the patient's needs and should include details of what to expect from the sedation, the need for an adult escort, their responsibilities before and after sedation, advice about fasting and post-treatment analgesia. Contact details for the care provider and for out-of-hour services should be provided.

Locally appropriate information (e.g. directions and an image of the sedation facility) might be particularly helpful for some patient groups..

Basis for Key Recommendation: Expert opinion

This key recommendation is informed by several recent guidelines and is consistent with current standard professional practice. Because the recommendation was mainly informed by other guidelines it is designated as based on expert opinion and is not assigned a strength.

11. Additional Information

The IACSD agreed that the patient information examples contained within their online report could be made available as word documents to facilitate use.

<p>Question 2.5: For patients undergoing dental treatment under sedation:</p> <p>what instructions should patients be given about eating and drinking before sedation?</p>	<p>Appraisal refs: G1, G3, G8, G10, G13, G14, G15, G16, G17</p>
<p>1. Summary of evidence</p> <p>G1: As for G14, fasting recommendations that apply to conscious sedation refer to those stated in NICE guidance for children G15 (see below). For other levels of sedation, the 2-4-6 fasting rule is recommended. As for G14, clinicians who choose to sedate patients without fasting should be prepared to justify this choice.</p> <p>G3: Preoperative dietary restrictions must be considered based on the sedative technique prescribed.</p> <p>G8: Fasting is not required for patients undergoing nitrous oxide analgesia/anxiolysis, though only a light meal two hours before may be recommended.</p> <p>G10: Children receiving sedation for elective procedures should generally follow the same fasting guidelines as before general anaesthesia (because the absolute risk of aspiration during procedural sedation is not yet known) – details are provided in the guideline (2-4-6 rule); for emergency procedures in children who have not fasted, the risks of sedation and the possibility of aspiration must be balanced against the benefits of performing the procedure promptly.</p> <p>G13: Fasting: Not required for N₂O, though might recommend light meal only 2 hrs prior to conscious sedation. For other forms of sedation: No solids within 6 hrs; No milk within 4 hours; No clear fluid within 2 hours. (<i>SIGN Grade C, no references cited</i>)</p> <p>G14: Views for fasting prior to sedation are described without a clear recommendation. However, it may be reasonable to interpret from the report that, as recommended in NICE guidance (G15), fasting is not necessary for conscious sedation as defined for dentistry (i.e. where verbal contact will be maintained). Clinicians who choose to sedate patients without fasting should be prepared to justify this choice.</p> <p>G15: Before starting sedation, confirm and record the time of last food and fluid intake in the healthcare record. Fasting is not needed for: minimal sedation; sedation with nitrous oxide (in oxygen); moderate sedation during which the child or young person will maintain verbal contact with the healthcare professional (<i>low quality evidence</i>). For an emergency procedure in a child or young person who has not fasted, base the decision to proceed with sedation on the urgency of the procedure and the target depth of sedation.</p> <p>Apply the 2-4-6 fasting rule (2 hours for clear fluids 4 hours for breast milk 6 hours for solids) for elective procedures using any for deep sedation and moderate sedation during which the child or young person might not maintain verbal contact with the healthcare professional.</p> <p>G16: Fasting is not normally required; however, some authorities recommend the same fasting requirements as for general anaesthesia.</p> <p>G17: Fasting rules vary slightly between the European countries. Prior to conscious sedation it is recommended, that the child shall be fasted according to the following rules: No clear liquids 2-3 hours before sedation; No solid foods or non-clear liquids 4 hours before</p>	

sedation. Clear liquids are non-fruity juice, water, tea, and coffee. All milk products (non-clear liquids) are considered as solid foods. Children under school age shall drink sugar containing clear liquid up to 2 hours before treatment in order to avoid low blood sugar. For the emergency patient, where proper fasting has not been assured, the increased risk of sedation must be weighted against the benefits of the treatment, and the lightest effective sedation should be used. If possible, such patients may benefit from delaying the procedure.

SR5: One included study showed that fasting made no difference to overall behaviour. One included study noted no fasting pre-treatment and no vomiting in either group receiving midazolam (intramuscular or intranasal).

2. Quality, quantity and consistency of evidence

Nine guidelines rated methodologically high (G15), moderate (G1, G13) and low (G3, G8, G10, G14, G16, G17) provide recommendations and one systematic review reports studies that commented on fasting before conscious sedation.

G15 states very clearly that fasting is not needed for sedation with N₂O/O₂ or for moderate sedation where the child or young person will maintain verbal contact, i.e. includes conscious sedation as defined for dentistry. This is based on low quality evidence from one RCT (no significant difference +/- fasting before dental treatment) and several observational studies showing no association between vomiting or other adverse events and pre-sedation fasting time, and a GDG discussion of avoidance of unnecessary fasting where there are no safety concerns. For other forms of sedation the 2-4-6 fasting rule is recommended.

Three other guidelines state or imply that fasting is not necessary prior to conscious sedation (G1, G14, G16) and two indicate that fasting is not needed specifically for N₂O/O₂ sedation (G8, G13), though both recommend a light meal only before sedation.

The evidence from the studies reported in SR5 is consistent with guideline recommendations not to fast before conscious sedation for dental treatment.

Two guidelines (G1 and G14) state the need for clinicians to justify their choice to sedate without fasting.

3. Subgroup considerations

Consideration should be given to procedures for emergency/urgent cases, any medical or physical conditions or age that may influence the decision about pre-sedation fasting.

4. Balance of effects

In studies cited in G15 and SR5, no significant adverse effects of not fasting before sedation were reported.

For conscious sedation where verbal contact is maintained, it is unlikely that protective reflexes will be lost and therefore the risk of aspiration is low. For some patients, fasting can have adverse effects.

The balance of risks will change where there is a significant risk of aspiration and it would be appropriate to consider fasting in these situations.

5. Generalisability and applicability

Several of the cited guidelines are from the UK.

6. Values and preferences

A survey of patient attitudes towards fasting prior to intravenous sedation for dental treatment found that 79% of patients experienced at least one adverse symptom after fasting, with a quarter indicating that the fasting process made them feel more nervous about their sedation appointment.²³

It was reported in the patient & parent scoping interviews carried out by TRiADS (www.triads.org.uk) that avoiding food and drink was more challenging for appointments in the afternoon especially for children/adults with additional needs.

7. Acceptability

SDCEP guidance has recommended since 2006 that there is no need for patients to fast before conscious sedation.

8. Feasibility

A requirement for fasting may lead to more cancelled appointments if patients who have failed to do this cannot be sedated.

9. Other factors

Several of the cited sources state the importance of recording the advice given about fasting and confirming and recording the last food and fluid intake prior to sedation.

10. Recommendation for guidance

Summary of group's judgements:

Taking into consideration all factors including the available evidence, the balance of risks of adverse events and for the avoidance of unnecessary fasting, the group agreed that for conscious sedation using standard techniques, fasting should not usually be necessary. However, for some advanced techniques, the chance of deeper than intended sedation may be greater and therefore there is a greater risk that protective reflexes could be lost and a greater risk of aspiration. Certain medical conditions and patient history might also indicate a higher risk of aspiration. Where this is a significant risk, fasting using the 2-4-6 rule may be appropriate (2 hours for clear fluids; 4 hours for breast milk; 6 hours for solids).

Recommendations and clinical advice:

The judgements above should be reflected in the key recommendation in relation to conscious sedation for dental treatment.

Patients who do not need to fast should be advised that they can eat and drink on the day of their sedation appointment, avoiding large meals and alcoholic drinks. It was agreed that there should be a record in the patient's notes about the information given to the patient regarding fasting and a record of their food and drink intake on the day of sedation. Some patients may be advised to fast, so their food and drink intake should be recorded. Even when a patient does not need to fast it is important that their food and drink intake is

recorded to ensure that they have complied with the advice to avoid large meals and alcohol. In addition, recording this information is important for the auditing of fasting/not-fasting versus outcomes. The group acknowledged that there may be some patients or circumstances (e.g. where a significant risk of vomiting and/or aspiration) where it would be appropriate to consider fasting.

The group agreed that, in line with the recommendations made by NICE (G15), which are quoted by AoMRC (G1) and IACSD (G14), the key recommendation should indicate that for conscious sedation where verbal contact will be maintained the patient does not need to fast unless there are specific indications to do so.

Post-consultation revisions:

The key recommendation was revised after further consideration by the GDG, to recommend that advice should be provided to the patient about whether to fast or not based on an individual assessment of the patient and the nature of the sedation and dental procedure. As before the guidance also advises that, for conscious sedation, if there are no indications for fasting the patient can be advised that they can eat and drink on the day of the appointment.

The GDG considered that there should be more emphasis on judgement based on individual patient assessment. This was already the intention of the recommendation in the consultation draft, which reflected the low quality evidence, although this may not have been sufficiently clear to users. Hence, the guidance now indicates that the risk of aspiration and other factors should be assessed in each case and fasting advice provided accordingly. The advice provided and justification should be recorded. The GDG acknowledged that whether a patient is advised to fast or not may also be influenced by local policies or patient or clinician preference. The group agreed that this should be a conditional recommendation. Although it is supported by evidence, this evidence is limited and of low quality. Not all practitioners or patients would choose to follow the recommendation given all the available information. The balance of risks of fasting versus not fasting is dependent on the individual circumstances in each case and the sedationist should use their clinical judgement to assess these when advising the patient. The justification for the advice given should be recorded.

Basis for Key Recommendation: Expert opinion; Low quality evidence

The recommendation reflects the importance of making an individual judgement for each patient as advocated by current guidelines (G1 and G14) and is consistent with the evidence based recommendations made by NICE (G15). The evidence regarding fasting before dental sedation is of low quality and, depending on the circumstances, it may or may not be appropriate for the patient to modify food and drink intake before sedation. Thus, the principle of basing fasting advice on individual judgement for each patient is informed by expert opinion, while low quality evidence supports the option of not fasting for conscious sedation where there are no indications to do so.

11. Additional Information

The 2016 update of guideline G3 recommends that for minimal sedation, preoperative dietary restrictions must be considered based on the sedative technique prescribed, while for moderate sedation, it is recommended that pre-operative fasting instructions are given, based on the ASA Summary of Fasting and Pharmacologic Recommendations (i.e. the 2-4-6 rule).

<p>Question 2.6: For patients undergoing dental treatment under sedation: what escort arrangements are required?</p>	<p>Appraisal refs: G1, G3, G10, G13, G14, G16, G17</p>
<p>1. Summary of evidence</p> <p>G1: Patients meeting discharge criteria following sedation who go on to be sent home should be discharged into the care of a suitable third party. No further details.</p> <p>G3: Escort mentioned but no details of requirements.</p> <p>G10: The pediatric patient shall be accompanied to and from the treatment facility by a parent, legal guardian, or other responsible person. It is preferable to have two or more adults accompany children who are still in car safety seats if transportation to and from a treatment facility is provided by one of the adults.</p> <p>G13: A parent, legal guardian or other responsible adult must accompany the child to and from the treatment facility. Also a qualified member of staff always to be present; sedationist chaperoned at all times. (<i>SIGN Grade C, no references cited</i>)</p> <p>G14: The presence of a suitable third party to take responsibility for the patient at the time of discharge is an essential requirement for sedation using anything other than inhalation sedation with nitrous oxide/oxygen in adults. Children under 16 years of age require an escort for inhalation sedation.</p> <p>G16: A responsible adult escort must accompany the patient home and assume responsibility for the rest of the day (Escort may not be required for adult N₂O/O₂ sedation).</p> <p>G17: An adult who is well known to the child should always escort them to and from treatment. In the context of school dental clinics and the use of nitrous oxide/oxygen sedation schoolchildren can, after parent's consent, get treatment without the presence of an adult escort, provided the parents have consented.</p>	
<p>2. Quality, quantity and consistency of evidence</p> <p>Seven guidelines rated methodologically moderate (G1, G13) and low (G3, G10, G14, G16, G17) provide recommendations about the patient's escort, a responsible person to accompany the patient to and from the treatment facility.</p> <p>G1 and G3 provide little detail.</p> <p>G14 and G16 indicate that for N₂O/O₂ inhalation sedation, only children under 16 require to have an escort. For other sedation techniques, all patients require an escort.</p> <p>G10, G13 and G17 are specifically about paediatric sedation. G13 states that a qualified member of staff must always be present and the sedationist chaperoned. For younger children, G10 suggests that two responsible adults are required if one will be driving the patient home.</p>	
<p>3. Subgroup considerations</p> <p>Consideration of extra requirements for younger children and for patients only receiving N₂O/O₂ sedation.</p>	

Some patients may need more than one escort/carer.
<p>4. Balance of effects</p> <p>There are potential risks if a patient was to leave a facility unaccompanied having received sedation, due to after-effects. In the case of inhalation sedation with N₂O/O₂ the risks would be minimal because of the rapid reversal of its effects.</p>
<p>5. Generalisability and applicability</p> <p>Several of the cited guidelines are from the UK and so recommendations should be relevant.</p>
<p>6. Values and preferences</p> <p>None identified.</p>
<p>7. Acceptability</p> <p>The need for an adult escort is currently standard practice.</p>
<p>8. Feasibility</p> <p>Some provision may be required if a patient is unable to identify an escort (e.g. lives alone or is homeless).</p> <p>The clinical team will need to be able to assess the suitability of an escort for taking responsibility for the patient after sedation.</p>
<p>9. Other factors</p> <p>In some instances, the escort taking the patient home may not be the person responsible for supervising the patient for the rest of the day (e.g. when returning a resident to a care facility). Consideration should be given to ensuring that the appropriate escort information is passed on.</p>
<p>10. Recommendation for guidance</p> <p>Summary of group's judgements:</p> <p>The GDG noted that an escort may not be the same person for the duration of their responsibility for the patient and that this should be acknowledged within the guidance. In some circumstances, unusual escort arrangements might exist, e.g. prisoners, residents in care homes. This is one reason why specific written information for the escort supplied to the patient prior to the procedure is necessary. The GDG was keen to advise avoidance of use of public transport after sedation, if possible, and the extra escort responsibilities when this is not possible.</p> <p>The GDG further noted that there may be circumstances where an adult patient having inhalation sedation with N₂O/O₂ would need an escort, and that the sedationist should assess the need for this and advise accordingly.</p>

Recommendations and clinical advice:

The GDG agreed that there was no reason to deviate from the current recommended practice of requiring an adult escort for patients having conscious sedation, except if by inhalation of N₂O/O₂. This should be covered in the key recommendation. Children and young people should have an escort after any sedation technique.

Basis for Key Recommendation: Expert opinion

This key recommendation is informed by several recent guidelines and is consistent with current standard professional practice.

11. Additional Information

<p>Question 2.7: For patients undergoing dental treatment under sedation:</p> <p>what facilities should be available?</p>	<p>Appraisal refs:</p> <p>G1, G5, G6, G8, G10, G14, G16</p>
<p>1. Summary of evidence</p> <p>G1: Where multiple drug/anaesthetic drug techniques are used, the sedation team should have immediate access to the same range of skills and facilities as would be found in an acute NHS Trust, for the prompt recognition and immediate management of adverse events.</p> <p>Where anaesthetic drug techniques (with or without opioid) are used, trained personnel must be immediately available to assist with the resuscitation of a collapsed patient so that the patient’s airway, breathing and circulation are supported fully without delay.</p> <p>G5: The procedure must be performed in a location which is of an adequate size, and is staffed and equipped to deal with a cardiopulmonary emergency. These facilities and equipment must be sufficient and appropriate for the age and condition of the patient so that, if required, basic life support may be maintained until more specialised help, equipment and drugs become available. At a minimum this must include: Adequate room to perform resuscitation should this prove necessary; Appropriate lighting; An operating table, trolley or chair which can be tilted head down readily is preferable but not mandatory; An adequate suction source, catheters and hand piece; A supply of oxygen and suitable devices for the administration of oxygen to a spontaneously breathing patient; A means of inflating the lungs with oxygen (for example, a self-inflating bag and mask) together with ready access to a range of equipment for advanced airway management (for example, masks, oropharyngeal airways, laryngeal mask airways, laryngoscopes, endotracheal tubes); Appropriate drugs for cardiopulmonary resuscitation and a range of intravenous equipment and fluids including drugs for reversal of benzodiazepines and opioids (see appendix 2); A pulse oximeter; A sphygmomanometer or other device for measuring blood pressure; Ready access to an electrocardiograph (ECG) and a defibrillator; A means of summoning emergency assistance; Within the facility there should be access to devices for measuring expired carbon dioxide; Adequate access throughout the facility to allow the patient to be transported easily and safely; A clinical emergency response plan to manage potential clinical deterioration.</p> <p>G6: For alternative sedation techniques: Premises must comply with the standards required for the practice of dentistry but the following require further consideration: waiting area, surgery, recovery facilities.</p> <p>G8: All newly installed facilities for delivering nitrous oxide/oxygen must be checked for proper gas delivery and fail-safe function prior to use.</p> <p>G10: The practitioner who uses sedation must have immediately available facilities, personnel, and equipment to manage emergency and rescue situations. A protocol for access to back-up emergency services shall be clearly identified, with an outline of the procedures necessary for immediate use. For nonhospital facilities, a protocol for ready access to ambulance service and immediate activation of the emergency medical system for life-threatening complications must be established and maintained.</p> <p>Newly constructed or reconstructed treatment facilities, especially those with piped-in</p>	

nitrous oxide and oxygen, must have appropriate state or local inspections to certify proper function of inhalation sedation/analgesia systems before any delivery of patient care.

G14: The physical environment, supporting facilities and equipment must be appropriate for the delivery of dental care under sedation. All centres providing conscious sedation for the delivery of dental care should be inspected to determine that the necessary standards are in place. The correct equipment must be available in treatment and recovery areas, and proper maintenance documented for inspection. There must be access for emergency services and patient transfer. Circumstances in which sedation must only be performed in a facility equivalent to an NHS Trust in England are specified: Any child under 12 years with complex oral health needs or who cannot be managed with either behavioural management techniques (BM)/local analgesia (LA) or LA/inhalation sedation OR any young person aged 12-16 years with complex oral needs or who cannot be managed with either BM/LA or LA/inhalation sedation or LA/midazolam (all routes) OR for any patient where multiple drugs or anaesthetic drugs are used for conscious sedation.

G16: Unimpeded ambulance access to building; large enough treatment and recovery areas, operating chair capable of head down tilt position.

2. Quality, quantity and consistency of evidence

Seven guidelines rated methodologically moderate (G1) and low (G5, G6, G8, G10, G14, G16) provide recommendations about the facilities for sedation. Note there is overlap between requirements for facilities and equipment (Question 2.8).

G14 states that the physical environment, supporting facilities and equipment must be appropriate for the delivery of dental care under sedation, with documented maintenance of the equipment located in treatment and recovery areas, and inspection of facilities. G6 states that premises must comply with standards required for the practice of dentistry.

Room and access: G5 states the room must be of a size adequate for management of cardiopulmonary emergencies and specifies adequate lighting, preferably a head-down tilt chair (also stated in G16), suction, oxygen supply and other equipment that must be available for managing emergencies/complications. G5, G14 and G16 state that there must be access for emergency services/ambulance and patient transfer.

G5 and G10 state the need for an emergency response plan/protocol.

G6 emphasises the need for a suitable waiting area and recovery facilities.

G8 and G10 state a requirement for inspection of inhalation sedation equipment, including piped-in N₂O and O₂ delivery.

G1 and G14 state that where multiple drugs or anaesthetic drugs are used, there should be immediate access to the skills and facilities found in an NHS Trust. G14 additionally states that these skills and facilities are required for:

i) sedation of any child under 12 years with complex oral health needs or who cannot be managed with either behaviour management (BM)/local analgesia (LA) or LA/inhalation sedation OR

ii) any young person aged 12-16 years with complex oral needs or who cannot be managed with either BM/LA or LA/inhalation sedation or LA/midazolam (all routes).

3. Subgroup considerations

Consideration should be given to whether additional facilities are required for anything other than standard techniques for children, young people and adults and if so, what these requirements would be.

4. Balance of effects

The careful consideration of facilities is required to reasonably mitigate the risks associated with each sedation technique.

5. Generalisability and applicability

Several of the cited guidelines are from the UK.

6. Values and preferences

Patients may prefer to be treated locally.

7. Acceptability

It would be generally accepted that the facilities should be as required to deliver sedation safely and to manage any complications. The risks of the procedure(s) for the patients being treated should dictate the minimum requirements for the facilities.

8. Feasibility

Requirements for facilities might preclude some providers from being able to deliver sedation for some (or all) patient groups.

9. Other factors

The IACSD provided further explanation of 'a facility equivalent to an NHS Acute Trust in England' as used in their guideline (G14), in the form of a FAQ response:

How can I demonstrate that my practice facilities are equivalent to those of an 'NHS Acute Trust in England' (Options for Care, page 9)?

You must be able to provide evidence that in the event of a patient collapse you have the knowledge, skills and facilities to offer the same quality of immediate care as would be expected in an NHS Acute Trust. Evidence might include written protocols for managing collapse and adverse reactions, the timely transfer of a collapsed patient to a hospital with appropriate resuscitation facilities and the regular checking of emergency drugs and equipment. Current immediate life support (see FAQ 16) certificates and records of regular team-based participation in real-time emergency scenarios would also be appropriate. The SAAD Safe Sedation Practice Scheme (www.saad.org.uk) covers some of these elements. The checklist used by SAAD inspectors is available for download and may be used for self-assessment. It is not the responsibility of IACSD to assess evidence.

www.rcseng.ac.uk/dental-faculties/fds/publications-guidelines/standards-for-conscious-sedation-in-the-provision-of-dental-care-and-accreditation/faq/.

10. Recommendation for guidance

Summary of group's judgements:

Recommendations and clinical advice:

The GDG agreed that the recommendations made should emphasise that the environment needs to be suited to both the forms of sedation being provided and to the patients being cared for.

A quality assurance process should be in place for all providers of sedation. Sedation practice inspections exist in Scotland and are desirable for providers elsewhere. In England, quality assurance is the responsibility of commissioners of services. The SAAD Safe Sedation Practice Scheme is a useful means of assuring quality. The difficulties in assuring quality in wholly private facilities were acknowledged.

The GDG agreed that the details of facility requirements should reflect those advocated in current guidelines. There is a risk of adverse events associated with all sedation techniques and a key aspect of sedation facilities, equipment and staff is that they should be as required to ensure the effective management of sedation related complications and other emergencies. This should include advance, regularly rehearsed protocols for immediately managing such situations, as described in the IACSD FAQ in Section 9 above, and the necessary knowledge and skills, including in life support. There should be adequate access for emergency services.

Personal communication with IACSD representatives clarified that the elements included in their FAQ on facilities describe the standard of requirements that should be in place for dealing with an emergency for any patient, irrespective of the sedation technique.

The GDG agreed that facilities would be included in an overarching key recommendation for sedation environment to cover facilities, equipment (Question 2.8) and staffing (Question 2.9), and to indicate that these should all be suited to the sedation techniques used and patients treated. Further details will be provided in the relevant guidance sub-sections.

Basis for Key Recommendation: Expert opinion (for recommendation for sedation environment)

The key recommendation reflects a principle that is longstanding professional practice. The details of the advice provided on facilities should reflect currently advocated practice as discussed above.

11. Additional Information

<p>Questions 2.8: For patients undergoing dental treatment under sedation:</p> <p>what equipment should be available (for delivery of sedation, monitoring and management of complications)?</p>	<p>Appraisal refs:</p> <p>G1, G3, G5, G6, G8, G10, G13, G14, G16, G17</p>
<p>1. Summary of evidence</p> <p>G1: Staffing and equipment must meet the needs of both the technique (including monitoring) and its possible complications. Resuscitation equipment must be checked, maintained and include all the drugs necessary for life support.</p> <p>G3: A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.</p> <p>When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm. An appropriate scavenging system must be available if gases other than oxygen or air are used. The equipment necessary to establish intravenous access must be available for moderate sedation.</p> <p>G5: When inhalational agents such as nitrous oxide or methoxyflurane are being used to provide sedation and/or analgesia, risks of chronic exposure should be considered, and the following special requirements must be satisfied: There must be the capacity for the administration of 100 per cent oxygen; Installation and maintenance of any piped gas system must comply with relevant standards. Servicing of such piped gases must occur on a regular basis and at least annually; An appropriate method for scavenging of expired gases within the room must be in use.</p> <p>When nitrous oxide is used: The patient breathing circuit should be of lightweight construction, should have a reservoir bag for inspired gases, and must provide low resistance to normal gas flows; There must be a non-return valve or other mechanism (such as a T-piece flow connection) to prevent re-breathing; Gas flow rates must be adequate and the circuit must include an anti-hypoxic device; There must be a low gas flow alarm except when a demand-flow system is used; When methoxyflurane is used, the facility should have a guideline for the recognition and emergency management of malignant hyperthermia.</p> <p>Facilities and equipment must be sufficient and appropriate for the age and condition of the patient so that, if required, basic life support may be maintained until more specialised help, equipment and drugs become available. At a minimum this must include: Adequate room to perform resuscitation should this prove necessary; Appropriate lighting; An operating table, trolley or chair which can be tilted head down readily is preferable but not mandatory; An adequate suction source, catheters and hand piece; A supply of oxygen and suitable devices for the administration of oxygen to a spontaneously breathing patient; A means of inflating the lungs with oxygen (for example, a self-inflating bag and mask) together with ready access to a range of equipment for advanced airway management (for example, masks, oropharyngeal airways, laryngeal mask airways, laryngoscopes, endotracheal tubes); Appropriate drugs for cardiopulmonary resuscitation and a range of intravenous equipment and fluids including drugs for reversal of benzodiazepines and opioids (see appendix 2); A</p>	

pulse oximeter; A sphygmomanometer or other device for measuring blood pressure; Ready access to an electrocardiograph (ECG) and a defibrillator; A means of summoning emergency assistance; Within the facility there should be access to devices for measuring expired carbon dioxide; Adequate access throughout the facility to allow the patient to be transported easily and safely; A clinical emergency response plan to manage potential clinical deterioration.

G6: For alternative techniques: Drugs & equipment should be appropriate for the techniques utilised. These include those required for: sedation, monitoring, the management of complications and resuscitation.

G8: Inhalation equipment must have the capacity for delivering 100 percent, and never less than 30 percent, oxygen concentration at a flow rate appropriate to the child's size. Additionally, inhalation equipment must have a fail-safe system that is checked and calibrated regularly according to the practitioner's state laws and regulations. Selection of an appropriately sized nasal hood should be made. The equipment must have an appropriate scavenging system to minimize room air contamination and occupational risk.

G10: Inhalation sedation/analgesia equipment that delivers nitrous oxide must have the capacity of delivering 100 percent and never less than 25 percent oxygen concentration at a flow rate appropriate to the size of the patient. Equipment that delivers variable ratios of nitrous oxide to oxygen and that has a delivery system that covers the mouth and nose must be used in conjunction with a calibrated and functional oxygen analyzer. An emergency cart or kit must be immediately accessible (details provided).

G14: The correct equipment must be available in treatment and recovery areas, and formal maintenance documented for inspection. All necessary equipment and drugs must be available to support recovery and to manage any complications that may arise.

G16: For N₂O/O₂ inhalation sedation: dedicated purpose designed machines incapable of delivering hypoxic mixture; adequate scavenging. For intravenous sedation: all equipment for the technique available in the treatment area including antagonist drugs; supplemental O₂ immediately available with back-up supply. All equipment must be regularly maintained and appropriate records kept.

G17: Only dedicated dental nitrous oxide/oxygen delivery systems must be used. The system must contain fail-safe device (*i.e.* if the oxygen pressure falls, the supply of nitrous oxide automatically stops), flow-meter for individual set of gas flow and nitrous oxide concentration, emergency air-valve, non re-breathing, tubes with low breathing resistance, and an effective scavenging device for exhaled and excess gas. The use of rubber dam improves the effect of the sedation and reduces atmospheric pollution. Dental operators should ensure that they comply with national guidelines in respect to nitrous oxide pollution and gas safety.

Pulsoximetry is not deemed required for conscious sedation with nitrous oxide/oxygen sedation, but is preferable in benzodiazepin sedation.

2. Quality, quantity and consistency of evidence

Nine guidelines rated methodologically moderate (G1) and low (G3, G5, G6, G8, G10, G14, G16, G17) provide recommendations on equipment that should be available. The level of detail provided varies.

G1, G6 and G16 state that equipment must be suitable for the technique (sedation and monitoring) and possible complications. G14 states that the correct equipment must be available in the treatment and recovery areas and formal maintenance documented for inspection.

Details of specification for equipment for N₂O/O₂ inhalation sedation varies but common items include: cannot deliver a hypoxic mixture (G16) / <30% oxygen (G3, G8) / <25% oxygen (G10) and capable of delivering 100% oxygen (G3, G5, G8, G10); have a fail-safe system that is checked and calibrated (G3, G8, G17). There must be adequate scavenging (G3, G5, G8, G16, G17). Equipment must be maintained and records kept (G5, G16).

For intravenous sedation, G16 states that all equipment for delivery of sedation should be in the treatment area, including antagonist drugs.

Resuscitation equipment must be available, checked and maintained (G1, G10, G16). G5 provides an extensive list of such equipment and states that equipment should be appropriate for all ages and conditions of patients being treated. G14 states that all necessary equipment and drugs must be available to support recovery and to manage any complications that may arise.

Supplemental oxygen must be available (G3) with back-up supply (G16 for intravenous sedation).

3. Subgroup considerations

Equipment requirements for delivery of sedation, monitoring and management of complications differs depending on the technique. GDG to consider level of detail required.

4. Balance of effects

Having the correct equipment available for sedation and for dealing with complications is essential for the safe provision of sedation.

5. Generalisability and applicability

Several of the guidelines cited are from the UK, although some are from other countries that may be subject to different regulations regarding equipment.

6. Values and preferences

None identified.

7. Acceptability

Some equipment that could be recommended will not currently be available in all practices. Cost considerations may affect acceptability.

8. Feasibility

See above.

9. Other factors

The equipment and drugs required for dealing with medical emergencies in a dental practice are described in the National Dental Advisory Committee (NDAC)'s *Emergency Drugs and Equipment in Primary Dental Care* (2015), SDCEP's *Drug Prescribing in Dentistry* (3rd Ed) guidance and *Practice Support Manual* and the *British National Formulary* (BNF).²⁴⁻²⁷ The NDAC document also lists additional emergency equipment for sedation practices including pulse oximeter, blood pressure monitor and nasal cannula set for administering supplemental oxygen.

The Resuscitation Council (UK) *Quality Standards for Primary Dental Care*²⁸ state that '*All clinical dental areas should have immediate access (within the first minutes of a cardiorespiratory arrest) to oxygen, resuscitation equipment for airway management including suction, and an automated external defibrillator (AED).*'

10. Recommendation for guidance

Summary of group's judgements:

Recommendations and clinical advice:

The GDG agreed that the information on equipment for the delivery and monitoring of sedation for the management of medical and sedation-related complications as presented in the 2nd edition of SDCEP's guidance on sedation was appropriate and in line with that recommended in other current UK guidelines. References to resources that list emergency drugs, equipment and relevant regulations should be updated.

The GDG noted that practices should have documentation of COSHH and risk assessments, maintenance records and evidence of regular checking of drugs and equipment. Reversal agents appropriate to the sedation drugs being used must be available with staff trained in their use.

A key recommendation at the start of the section on *Environment for Sedation* will encompass facilities, equipment and staffing (see Question 2.7) therefore there is not a key recommendation specifically for equipment.

Basis for Key Recommendation: see Question 2.7

11. Additional Information

The 2016 update of guideline G3 added that there should be documentation of compliance with manufacturers' recommended maintenance of equipment and pre-procedural checks of equipment performed. The update also states that equipment for capnography must be available for moderate sedation.

<p>Questions 2.9: For patients undergoing dental treatment under sedation:</p> <p>what staff are required for each sedation technique?</p>	<p>Appraisal refs:</p> <p>G1, G3, G5, G6, G8, G10, G13, G14, G15, G17</p>
<p>1. Summary of evidence</p> <p>G1: It is deemed acceptable in some specialties, e.g. dentistry, that, where conscious sedation is the target state, a second individual already responsible for monitoring the patient may assist the operator-sedationist with interruptible ancillary tasks of short duration, no third person being required.</p> <p>G3: At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.</p> <p>G5: Except for techniques such as inhaled nitrous oxide, inhaled methoxyflurane or low dose oral sedation, there must be a minimum of three appropriately trained staff present, the proceduralist, the practitioner administering sedation and monitoring the patient, and at least one additional staff member to provide assistance to the proceduralist and/or the practitioner providing sedation as required.</p> <p>The assistant to the practitioner administering sedation must be exclusively available to that practitioner at induction of and emergence from sedation, and during the procedure as required. If general anaesthesia is intended, and especially in emergency situations where endotracheal intubation is planned, a person to specifically assist the anaesthetist, or other trained and credentialed medical practitioner within his/her scope of practice, is required throughout the procedure (see ANZCA professional document <i>PS08 Recommendations on the Assistant for the Anaesthetist</i>).</p> <p>A medical or dental practitioner who is skilled in airway management and cardiopulmonary resuscitation, relevant to the patient's age and condition, must be present whenever procedural sedation and/or analgesia are administered.</p> <p>In situations other than those when an anaesthetist, or other trained and credentialed medical practitioner within his/her scope of practice, must be present, administration of sedation and/or analgesia and monitoring of the patient should be performed by another practitioner working with the proceduralist and whose training complies with the requirements outlined in section 13. If such an appropriately trained medical or dental practitioner is not present solely to administer sedation and/or analgesia and monitor the patient, there must be another health practitioner present during the procedure, who is trained in observation and monitoring of sedated patients and in resuscitation. The <i>primary</i> responsibility of this other practitioner is to monitor the level of consciousness and cardiorespiratory status of the patient. This practitioner must be immediately available to manage the patient should there be any need. This person may, if appropriately trained, administer sedative and/or analgesic drugs under the direct supervision of the proceduralist, who must have advanced life support skills and training. Propofol, thiopentone and other anaesthetic agents must not be used in these circumstances. If loss of consciousness, airway obstruction or cardiorespiratory insufficiency occur at any time, all staff must devote their entire attention to treating and monitoring the patient until recovery, or until such time as another medical or dental practitioner becomes available to take responsibility for the</p>	

patient's care.

G6: For alternative techniques: The Team includes operator/sedationist; dedicated sedationist; dental care professionals (DCPs); recovery personnel; support staff. Each patient must be attended by at least two appropriately trained and experienced members of the conscious sedation team.

A dedicated sedationist is required for the administration of any technique requiring the continuous IV infusion of a drug or drugs OR when three or more sedative drugs are used in combination regardless of the route. Operator/sedationist using such techniques MUST be able to demonstrate appropriate training in the use of the specific method, expertise in its use and also provide audit records of its safe administration in that clinical setting.

Where a dentist works with a dedicated sedationist either employed by the dentist or employed by a third party there must be a formal or contractual responsibility for the treating dentist to clarify the responsibilities and accountability of each member of the dental team involved with each patient during preparation, sedation, recovery and discharge.

G8: The practitioner who utilizes nitrous oxide/oxygen analgesia/anxiolysis for a pediatric dental patient shall possess appropriate training and skills and have available the proper facilities, personnel, and equipment to manage any reasonably foreseeable emergency.

G10: The practitioner who uses sedation must have immediately available facilities, personnel, and equipment to manage emergency and rescue situations. The use of moderate sedation shall include provision of a person, in addition to the practitioner, whose responsibility is to monitor appropriate physiologic parameters and to assist in any supportive or resuscitation measures, if required. This individual may also be responsible for assisting with interruptible patient-related tasks of short duration. This individual must be trained in and capable of providing pediatric basic life support.

G13: It is vital that adequately trained staff and the appropriate monitoring facilities are available to alert the operator if the patient undergoes desaturation. The sedationist should be chaperoned at all times by another member of staff. (*SIGN Grade C, no references cited*)

G14: The sedationist or another appropriate person who has capability within his or her scope of practice must monitor the patient throughout the procedure and will wish to confirm at regular intervals that the patient is conscious.

Clinical and electro-mechanical monitoring and contemporaneous recording at appropriate intervals intra-operatively is recommended for all but N₂O/O₂ sedation. During recovery, the patient must be supervised; a trained member of the dental team must be responsible for the patient and monitor the individual throughout this period.

Basic techniques can be delivered by operator-sedationist. Most advanced techniques require a dedicated sedationist. What are normally considered to be operator-sedationist techniques may sometimes be more effective and/or safer when the sedation is provided by a dedicated sedationist and a separate operator, for example when: the patient is medically compromised, has a physical disability or is emotionally challenging; either the operator or the sedationist is relatively inexperienced; the patient has a history of being particularly difficult to manage; the dental procedure is complex or prolonged; patients are at the extremes of age.

G15: Ensure that both the following will be available during sedation: a healthcare

professional and assistant trained (see section on personnel and training) in delivering and monitoring sedation in children and young people; immediate access to resuscitation and monitoring equipment (see section on clinical environment and monitoring). (*expert opinion*)

G17: These guidelines are only dealing with conscious sedation. This implies that the dentist should be able to act as his/her own sedationist without the presence of an anaesthesiologist, provided that these guidelines are followed.

2. Quality, quantity and consistency of evidence

Ten guidelines rated methodologically high (G15), moderate (G1, G13) and low (G1, G3, G5, G6, G8, G10, G14, G17) provide recommendations on staff requirements.

Some guidelines are not specific in indicating the number of staff required, stating that adequate personnel (or similar) are available to manage emergencies (G5, G8, G13).

Most others recommend that for conscious sedation in dentistry, a suitably trained operator/sedationist may be assisted by one other member of staff carrying out short, interruptible, patient-related tasks, who is trained in monitoring of the patient and in assisting in the event of complications (G1, G3, G14, G15, G17).

Exceptions to this are: G6 states that a dedicated sedationist is required for techniques that require continuous intravenous infusion or where three or more sedative drugs are used. G14 states that most advanced techniques require a dedicated sedationist. G14 also lists several circumstances in which it is desirable to have a dedicated sedationist for normally operator-sedationist techniques. G5 states that for certain techniques including N₂O/O₂ sedation, a minimum of three members of staff must be present.

G14 states that clinical and electro-mechanical monitoring and contemporaneous recording at appropriate intervals intra-operatively is recommended for all but N₂O/O₂ sedation. It is unclear if this means that for some techniques a third person is required, depending on the expected frequency of monitoring.

G14 states that a member of staff capable of monitoring must supervise the patient during recovery and up until discharge. G13 states that the sedationist should be chaperoned at all times.

G5 provides an appendix that clearly indicates the staff required in various sedation scenarios.

3. Subgroup considerations

Consider circumstances when operator/sedationist plus trained assistant is not sufficient

4. Balance of effects

To ensure patient safety there must be sufficient staff members present who have the correct skills and knowledge to deliver the sedation, monitor the patient and recognise and manage complications.

5. Generalisability and applicability

Several of the guidelines cited are from the UK.

6. Values and preferences

None identified.

7. Acceptability

See below.

8. Feasibility

Requirements for staffing might preclude some providers from being able to deliver sedation for some (or all) patient groups.

9. Other factors

It is important to indicate the level of training each member of staff must have to fulfill each role in order to provide a clear recommendation about staff requirements in various situations.

A query was raised in regard to the IACSD report (G14) and staffing:

Staff required for each technique:

The report states that *'There must be a written contemporaneous record of the clinical and electro-mechanical monitoring of physiological systems required for specific sedation techniques.'* (p30)

Depending on the extent of this, this might require a third team member.

IACSD representatives confirmed that contemporaneous recording includes recording at the end of the procedure and therefore a third member of the team is not required for recording during the procedure.

10. Recommendation for guidance**Summary of group's judgements:**

Recommendations and clinical advice:

The GDG agreed that, in line with previous SDCEP sedation guidance (2012) and with others including AoMRC (G1), IACSD (G14) and NICE (G15), the guidance should recommend that when providing conscious sedation for dental treatment, an operator-sedationist and an assistant, both of whom should be trained in the sedation techniques used, would normally be sufficient. Dental hygienists and therapists can deliver N₂O/O₂ inhalation sedation as operator-sedationists according to their GDC scope of practice. For most advanced techniques and certain patient circumstances, a dedicated sedationist should deliver the sedation. The IACSD report (G14) provides details of these and the GDG agreed that it would be reasonable to reflect these in the guidance. Additional staff skills will be required for sedation of children and young people (see Question 4.2).

The GDG agreed that additional explanation of the various team scenarios and roles and responsibilities of members of staff in each case should be provided. A table or infogram could be included in the guidance to clarify these. The required skills, knowledge and

training are considered in more detail in Question 9.

A key recommendation at the start of the section on *Environment for Sedation* will encompass facilities, equipment and staffing (see Question 2.7) therefore there is not a key recommendation specifically for staffing.

Basis for Key Recommendation: see Question 2.7

Post-consultation revisions:

Consultation feedback indicated that while some consultees thought that the staffing infographic was helpful others did not or found it confusing. Because of this, the GDG agreed on balance to remove it from the guidance.

11. Additional Information

The 2016 update of guideline G10 revised the recommendation for support personnel for moderate sedation to indicate that they should be trained in and capable of providing advanced airway skills (e.g. PALS), rather than paediatric basic life support as recommended previously.

Conscious Sedation Techniques (Clinical Questions 3.1-3.3)

<p>Question 3.1:</p> <p>For adult patients undergoing dental treatment under sedation: which is the preferred (i.e. effective and safe) method of sedation (including drug and route)?</p>	<p>Appraisal refs:</p> <p>G1, G6, G14, G15, G16 SR2, SR9</p>
<p>1. Summary of evidence</p> <p>G1: No one sedation technique is suitable for all patients or procedures. Adopting the principle of minimum intervention, the simplest and safest effective technique, based on patient assessment and clinical need, should be used.</p> <p>For those patients requiring conscious sedation for dentistry, the majority of procedures can be undertaken using inhalational sedation (N₂O/O₂), or sedation using a benzodiazepine (midazolam) as a single drug. Analgesia for painful procedures is provided by means of effective local anaesthesia in conjunction with behavioural management strategies.</p> <p>The use of oral sedation may have a limited role. However, titration to effect with oral dosing is not possible and bioavailability is variable, resulting in an unpredictable response. When administering intravenous conscious sedation, the initial drug dose should be determined by careful pre-assessment of the patient and any relevant history, and this dose must have taken full effect before any additional dose is given. The use of fixed doses or boluses is unacceptable. Subsequent doses, if necessary, should be carefully titrated to achieve the desired effect. Safe sedation demands knowledge of each drug's time of onset, peak effect and duration of action. In principle, titrating a drug/ drugs to optimal effect is critical to safely achieving a recognised sedation endpoint, thereby avoiding inadvertent over-sedation or general anaesthesia.</p> <p>When the intravenous route is used, secure venous access should be maintained throughout the procedure and into the recovery period, and specific antagonist drugs (i.e. naloxone and flumazenil) must be to hand.</p> <p>For localised procedures, e.g. dental or minor procedures, effective local anaesthetic techniques must be used, once adequate sedation is achieved.</p> <p>G6: Standard techniques are: Inhalational sedation using nitrous oxide/oxygen; Intravenous sedation using midazolam alone; Oral/transmucosal benzodiazepine* provided adequate competence in intravenous techniques has been demonstrated.</p> <p>*The transmucosal administration of conscious sedation is regarded by some sedationist as falling within the category of standard techniques. Nevertheless, it is essential that strict protocols are in place.</p> <p>G8, G13: see Section 4 Children</p> <p>G14: The simplest and safest technique that is likely to be effective should be used. Titrating a drug/drugs to effect is critical to safely achieving a recognised sedation endpoint. A titrated dose of nitrous oxide in oxygen is the first choice inhalation sedation technique. A titrated intravenous dose of midazolam is usually the first choice intravenous sedation</p>	

technique. Oral and intranasal sedation techniques are not titratable and should only be used when titratable sedation techniques are inappropriate.

The 'basic' techniques all have an excellent safety record and are of proven efficacy for a wide range of patients. The vast majority of patients (probably >95%) may be managed using one of these simple and cost-effective techniques, which are suitable for use by an appropriately trained and experienced operator-sedationist.

Also see Section 4 Children

G15: see Section 4 Children

G16: The three standard techniques of inhalation, oral and intravenous sedation employed in dentistry are effective and adequate for the vast majority of patients. The simplest technique to match the requirements should be used. The only currently recommended technique for inhalation sedation is a titrated dose of nitrous oxide with oxygen and it is absolutely essential to ensure that a hypoxic mixture cannot be administered. The standard technique for intravenous sedation is the use of a titrated dose of a single drug; for example the current use of a benzodiazepine.

Also see Section 4 Children

G17: see Section 4 Children

SR2: Moderate quality evidence that midazolam by various routes is effective for use for anxiety control during third molar extraction and very low quality evidence that adverse events are not increased. It can also be used with other intravenous drugs to obtain better sedative effects, but the patient's respiratory function must be monitored closely, because multidrug sedation is also more risky. Although all patients were having 3rd molar extractions, the focus of review was on anxiety therefore likely to be of relevance to wider range of dental treatments.

SR5: see Section 4 Children

SR9: Low quality evidence supports the use of intranasal midazolam to reduce anxiety and to improve patient acceptance of cannulation and dental treatment.

2. Quality, quantity and consistency of evidence

Four guidelines rated methodologically moderate (G1) and low (G6, G14, G16) provide recommendations and two systematic reviews (SR2, SR9) are relevant to the preferred method for sedation. In addition, 3 guidelines and five systematic reviews specifically relate to the sedation of children (G8, G13, G15, G17, SR1, SR5, SR6, SR7, SR8) – see Question 4.1.

General recommendations are that the simplest and safest, effective titratable technique is the preferred option (G1, G14, G16).

N₂O/O₂ is the preferred inhalation sedation technique (G1, G6, G14, G16).

For intravenous sedation, midazolam alone (G1, G6, G14) or 'a benzodiazepine' (G16) are stated as the preferred option.

Oral sedation is less favoured because of inability to titrate to effect (G1). G6 states that sedation with oral/transmucosal benzodiazepine requires competence in intravenous

techniques, while G14 states that for all conscious sedation techniques other than inhalation sedation with nitrous oxide/oxygen, competence in cannulation is mandatory.

G1 states for intravenous sedation, venous access must be maintained through recovery and antagonist drugs must be available.

SR2 provides moderate quality evidence supporting that midazolam is effective in alleviating anxiety. SR9 describes low quality evidence of efficacy to support the use of transmucosal midazolam in situations where intravenous methods might not be suitable. In both systematic reviews the quality of evidence on adverse effects for the technique(s) is very low quality at best.

In addition, 3 guidelines and five systematic reviews specifically relate to the sedation of children (G8, G13, G15, G17, SR1, SR5, SR6, SR7, SR8) – see Question 4.1. In general, these guidelines consistently identify nitrous oxide or midazolam as suitable effective and safe sedation techniques for children. Some recommend that nitrous oxide should be the first choice, with midazolam indicated for adolescents. The evidence provided in the systematic reviews supports their use.

3. Subgroup considerations

It may be helpful to specify preferred techniques for any specific patient group (other than children).

4. Balance of effects

The effectiveness of each sedation technique versus the risk and severity of adverse events is of key importance in deciding whether to recommend a particular technique. Much of the evidence regarding these comes from substantial clinical experience over many years rather than from high quality studies.

5. Generalisability and applicability

The evidence discussed above relates to techniques considered 'basic' or 'standard' for adults in the UK and may not be generalisable to children. For information specifically relating to the choice of techniques for children see Question 4.1.

6. Values and preferences

For practical reasons (e.g. implications for staff, equipment required), some providers of sedation may have a preference for the techniques they use.

Feedback from the patient & parent scoping interviews carried out by TRiADS (www.triads.org.uk) indicates that patients trust their clinician to make the appropriate choice of sedation on their behalf and often only seek reassurance that the method of sedation selected will be effective.

See additional information under Question 4.1.

7. Acceptability

The techniques discussed are already considered acceptable practice.

8. Feasibility

There are equipment and training implications for different techniques which could affect the feasibility of a given recommended technique for some sedation facilities.

9. Other factors

G1 and G14 note that: Midazolam over-sedation is defined as a 'never event' by the Department of Health and reporting of these incidents to the National Reporting and Learning System and to the body commissioning this care is mandatory.

10. Recommendation for guidance

Summary of group's judgements:

Consistent with other guidelines and according to the principles of minimal intervention, the GDG agreed that the sedation technique chosen should be the simplest and safest that is likely to be effective for the patient. As is current practice, the first choice standard inhalation sedation technique should be N₂O/O₂ and for intravenous sedation, single drug midazolam. Where these titratable techniques are likely to be unsuitable (e.g. for some patients with additional support needs or because of needle-phobia), the oral or transmucosal routes for delivery of midazolam are acceptable standard techniques (advanced for children). The effectiveness of each of these techniques for adults is supported by limited evidence.

Recommendations and clinical advice:

Advice on the use of low dose oral premedication will be included in the section on preparation for sedation, rather than in the section on sedation techniques to emphasise the distinction between this and sedation techniques. The GDG also agreed that it would be useful to include that inhalation sedation is one means of facilitating cannulation for intravenous sedation.

The overarching key recommendation for all conscious sedation techniques should indicate that, irrespective of whether standard or advanced, the most suitable technique should be used in each individual case and should be provided by staff who are specifically trained and experienced in the technique and working in an appropriate environment.

Basis for Key Recommendation: Expert opinion

The recommendation is informed by several recent guidelines and reflects current professional practice and as such, should be designated as based on expert opinion.

A further key recommendation specifically referring to the use of standard techniques should emphasise the principle discussed above, that the simplest and safest technique (i.e. a standard technique) should be used unless it is unlikely to be effective. The guidance should also be clear that when deciding on a technique for a patient (see assessment section), it is preferable to use a carefully chosen technique most suitable for that patient from the outset rather than progress through a range of techniques likely to fail i.e. if none of the standard techniques is judged likely to be effective for a particular patient then it would be justifiable to select an advanced technique (delivered by appropriately trained staff in the correct setting, by referral if necessary) instead of a standard technique.

Basis for Key Recommendation for standard techniques: Expert opinion; Low quality evidence

The use of a standard technique as the first choice where possible is largely informed by the principle of minimal intervention advocated in recent guidelines and is consistent with current professional practice. There is also some evidence of varying but overall low quality that supports the use of midazolam (SR2, SR9) and a significant body of clinical experience in the use of standard techniques that supports the recommendation to use them. However, there is a lack of evidence comparing the efficacy and safety of standard versus advanced techniques to inform the preference for a standard technique as a first choice.

11. Additional Information

<p>Question 3.2:</p> <p>For patients undergoing dental treatment under sedation: what alternative forms of sedation are acceptable and in what circumstances (e.g. indications, settings)?</p>	<p>Appraisal refs: G1, G5, G6, G14, G16</p>
<p>1. Summary of evidence</p> <p>G1: Multiple drug/anaesthetic drug techniques should only be considered where there is a clear clinical justification, having excluded simpler techniques.</p> <p>A small number of patients may require the use of systemic analgesia to facilitate administration of local anaesthesia, for example, if multi-quadrant dental treatment is planned. For these patients it may be appropriate to administer a single dose of a short-acting opioid, e.g. fentanyl, waiting a period of time for it to take full effect and only then titrating midazolam to effect. Due to the unpredictability of titrating multiple drugs to effect, the addition of a subsequent dose of opioid should be avoided.</p> <p>Benzodiazepines may be up to eight times more potent following prior administration of an opioid and so must be titrated with care.</p> <p>There should be no reliance on systemic analgesia to undertake the procedure itself. If the procedure cannot be undertaken satisfactorily with local analgesia it would be appropriate to abandon the procedure and consider an alternative technique of pain and anxiety management.</p> <p>Anaesthetic drugs, e.g. propofol, possess a narrow therapeutic index and reduced margins of safety, increasing the likelihood of adverse events.</p> <p>G5: Reliable venous access should be in place for all procedural sedation and/or analgesia except when low doses of inhaled or oral agents are used. This may not be practical in some patients receiving non-intravenous sedation (for example, small children, intellectually disabled patients).</p> <p>The most common intravenous agents used are benzodiazepines (such as midazolam) for sedation and opioids (such as fentanyl) for analgesia. Because there is usually synergism between such drugs, even small doses of these drugs may result in loss of consciousness in some patients.</p> <p>Intravenous anaesthetic agents such as propofol must only be used by a second medical or dental practitioner trained in their use because of the risk of unintentional loss of consciousness. These agents must not be administered by the proceduralist.</p> <p>G6: Alternative techniques include: any form of conscious sedation for patients under the age of 12 years* other than nitrous oxide/oxygen inhalation sedation; benzodiazepine + any other intravenous agent with sedative effects for example: opioid, propofol, ketamine; propofol either alone or with any other agent for example: benzodiazepine, opioid, ketamine; inhalational sedation using any agent other than nitrous oxide/oxygen alone; combined (non-sequential) routes for example: intravenous + inhalational agent (except for the use of nitrous oxide / oxygen during cannulation).</p>	

* It is recognised that the physical and mental development of individuals varies and may not necessarily correlate with the chronological age.

G13: see Section 4 Children

G14: Most advanced techniques require a dedicated sedationist and immediate access to the equivalent range of skills and facilities to be found in an NHS Acute Trust.

Also see Section 4 Children

G15: see Section 4 Children

G16: Continuous infusion of a drug or drugs used in combination may be appropriate in specially selected circumstances. However, it is particularly emphasised that their administration must be restricted to an experienced practitioner and team fully trained in their use working in an appropriate environment.

Also see Section 4 Children

2. Quality, quantity and consistency of evidence

Five guidelines rated methodologically moderate (G1) and low (G5, G6, G14, G16) provide recommendations relating to acceptable alternative (advanced) forms of sedation.

G6 identifies the range of alternative techniques using drugs including opioids (such as fentanyl), alone or in combination with a benzodiazepine (e.g. midazolam) and anaesthetic drugs (e.g. propofol). G14 states that most advanced techniques require a dedicated sedationist and immediate access to the equivalent range of skills and facilities in an acute NHS Trust, while G16 states that advanced techniques must only be carried out by a fully trained and experienced practitioner and team working in an appropriate environment.

In addition, 4 guidelines specifically relate to alternative forms of sedation for children (G13, G14, G15, G16). – see Question 4.2. Collectively, alternative techniques for children are only indicated in a minority of cases and require additional skills, experience and facilities.

3. Subgroup considerations

G1 mentions the type of patients/conditions that might merit the use of alternative techniques. It may be helpful to include this type of guidance.

Some patient groups might require a dedicated sedationist.

4. Balance of effects

The effectiveness of each sedation technique and the risk and severity of adverse events are of key importance in deciding whether to recommend a particular technique. There is a lack of research evidence to inform the choice of advanced technique for an individual patient.

5. Generalisability and applicability

Several of the guidelines are from the UK.

6. Values and preferences

Feedback from the patient & parent scoping interviews carried out by TRiADS

www.triads.org.uk) suggests that patients want to have the sedation that they believe will minimise their anxiety, nervousness and fears.

7. Acceptability

The alternative techniques considered are already used in sedation practice in some parts of the UK.

8. Feasibility

There are equipment, facility, staffing and training implications for different techniques which could affect the feasibility of a given recommended technique for some sedation facilities.

9. Other factors

IACSD indicate in their report (G14) that where multiple drugs or anaesthetic drugs are used the sedation team must have immediate access to the equivalent range of skills and facilities to be found in an NHS Acute Trust. Further information about this is provided in a response to a FAQ. See question 2.7 (facilities) for further details.

10. Recommendation for guidance

Summary of group's judgements:

The GDG preferred the use of the term 'advanced' rather than 'alternative' for these techniques to more clearly convey that they are potentially riskier than standard techniques, since they involve drug combinations and anaesthetic drugs and are not simply equivalent alternatives. Drug combinations have less predictable effects than single sedatives, and the anaesthetic drugs and infusions used for sedation have narrower therapeutic indices. Consequently, advanced sedation techniques are likely to have reduced margins of safety and this should be taken into consideration in the recommendations. More detailed advice will be needed to cover all the advanced techniques and the staffing and facility implications.

Recommendations and clinical advice:

There should be emphasis in the guidance on the need for providers of advanced sedation techniques to have the appropriate training and experience of these techniques for the patient groups being treated. The GDG agreed that as indicated in G14, a dedicated sedationist should be advised for most advanced techniques. There may be further staffing requirements for children having advanced sedation (see Questions 4.1 and 4.2).

There is a lack of synthesised evidence on the efficacy and safety of advanced techniques for conscious sedation to inform any recommendations for preferred techniques. The GDG agreed that the key recommendation for advanced techniques should mirror that made for standard techniques, in that advanced techniques should only be used if it is clear that the clinical needs of the patient are not suited to using a standard technique. The use of an advanced technique should be justified.

Basis for Key Recommendation: Expert opinion

This is based on consideration of the additional risks associated with advanced techniques and is informed by several recent guidelines. Consequently, the recommendation should be

designated as being based on expert opinion.

11. Additional Information

<p>Question 3.3:</p> <p>For patients undergoing dental treatment under sedation: what form of monitoring is required for each sedation technique to reduce the risk of and identify complications?</p>	<p>Appraisal refs:</p> <p>G1, G3, G5, G14, G16</p> <p>SR2</p>
<p>1. Summary of evidence</p> <p>G1: Clinical and instrumental monitoring to a degree relevant to the patient’s medical status and the sedation method, must be used.</p> <p>For minimal sedation/anoxiolysis: dictated by co-morbidity. For conscious sedation: verbal responsiveness, oxygen saturation, NIBP (use of ECG and ETCO₂ are Developmental Standards).</p> <p>Existing guidance for patients undergoing anaesthesia identifies the need for pulse oximetry, ECG and automated non-invasive blood pressure monitoring. If verbal communication is lost the patient requires the same level of care as for general anaesthesia.</p> <p>Where conscious sedation is used and continuous verbal contact with the patient maintained, ECG monitoring is not essential.</p> <p>Oxygen, via nasal cannulae, should usually be administered from the commencement of sedation, through to readiness for discharge from recovery, particularly for patients with relevant medical conditions, where multiple drug techniques or anaesthetic drugs are used, or deeper levels of sedation administered.</p> <p>Currently, oxygen administration is not administered in fit patients undergoing brief, simple procedures and its use in this group should be considered a Developmental Standard.</p> <p>Where not already in use, as a fundamental standard, capnography for patients receiving sedation should be considered a Developmental Standard.</p> <p>Monitoring should be continued into the recovery period.</p> <p>G3: A qualified dentist administering moderate sedation must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. When active treatment concludes and the patient recovers to a minimally sedated level a qualified auxiliary may be directed by the dentist to remain with the patient and continue to monitor them as explained in the guidelines until they are discharged from the facility. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility.</p> <p>For minimal sedation, monitoring should include: consciousness, oxygenation, circulation, ventilation. For moderate sedation, ventilation and pulse oximetry is essential.</p> <p>G5: Monitoring of the depth of sedation, typically by assessing the patient’s response to verbal commands or stimulation must be routine. Loss of patient response to stimulation or verbal commands indicates that loss of airway reflexes, respiratory and/or cardiovascular depression are likely, and sedation should be lightened accordingly. Monitoring of verbal response may be difficult in some patients for example, small children, patients with intellectual disabilities or language difficulties).</p> <p>All patients undergoing procedural sedation and/or analgesia must be monitored</p>	

continuously with pulse oximetry and this equipment must alarm when appropriate limits are transgressed. In all patients there must be regular monitoring of pulse rate, oxygen saturation and blood pressure throughout the procedure. Monitoring prior to commencement of sedation may not be practical in some patients (for example, small children, patients with intellectual disabilities). According to the clinical status of the patient, other monitors such as ECG or capnography may be required

G8, G10, G13: See Section 4 Children

G14: The sedationist or another appropriate person who has capability within his or her scope of practice must monitor the patient throughout the procedure and will wish to confirm at regular intervals that the patient is conscious. If this level of sedation is exceeded, the team caring for the patient must have the appropriate skills to manage the situation. There must be a written contemporaneous record of the monitoring of the patient that is in accordance with the clinical sedation technique used. Clinical and instrumental monitoring relevant to the patient's medical status and the clinical setting must be used. For inhalation sedation with nitrous oxide, clinical monitoring will usually suffice. As a minimum for all other techniques, monitoring should include pulse oximetry as well as non-invasive blood pressure monitoring preoperatively, at appropriate intervals during the procedure and post-operatively. All members of the clinical team must be capable of monitoring the condition of the patient. Monitoring requirements for each technique are tabulated for ASA grade I/II patients receiving conscious sedation for dental treatment. Clinical monitoring involves checking the level of consciousness/depth of sedation, airway patency, respiration (rate and depth), skin colour, capillary refill, pulse rate, rhythm and volume while non-invasive blood pressure (NIBP) monitoring also records heart rate. NIBP is not essential in children. Intra-operative measurements may be useful in longer cases. Pulse oximetry provides a visual display and audible indication of arterial oxygen saturation as well as heart rate and rhythm. Audible alarms must not be silenced. Routine use of capnography for ASA I and II dental patients is not recommended.

Also see Section 4 Children

G15: see Section 4 Children

G16: Stringent clinical monitoring and appropriate recording of the level of responsiveness, airway, respiration, pulse and colour is of particular importance throughout *Conscious Sedation* procedures of all types and for each patient. All members of the clinical team must be capable of monitoring the condition of the patient. For intravenous sedation this must include the appropriate use of pulse oximetry and blood pressure monitoring. During inhalation sedation clinical monitoring of the patient without additional electronic devices is generally adequate.

G17: see Section 4 Children

SR2: For patient safety, continuously monitor the patient's respiratory function, coupled with the practitioner's experience and training, along with the equipment and drugs necessary to manage this complication. Capnography can provide non-invasive monitoring of ventilation and detect apnoea during sedation.

2. Quality, quantity and consistency of evidence

Five guidelines rated methodologically moderate (G1) and low (G2, G5, G14, G16) provide

recommendations relating to monitoring required for sedation and one systematic review provides comments on monitoring.

In addition, 5 guidelines specifically relate to the monitoring required for sedation of children (G8, G10, G13, G15, G17) – see Question 4.3 (Section 2).

G1 states that clinical and instrumental monitoring to a degree relevant to the patient's medical status and the sedation method, must be used and G14 and G16 state that a written contemporaneous record of this must be maintained. The sedationist or other suitably qualified member of the team must monitor the patient throughout the procedure (G5, G14) but all members of the team must be capable of doing so (G14, G16).

G5 states the requirement for regular monitoring of the depth of sedation, pulse rate, oxygen saturation and blood pressure throughout the procedure.

G14 and G16 state that for N₂O/O₂ inhalation sedation, clinical monitoring (details provided in G14 and G16) is sufficient. For other techniques, the minimum requirement is additionally pulse oximetry, non-invasive blood pressure (NIBP), before during (at appropriate intervals) and after the procedure (G14). G14 states NIBP is not essential in children, though it is unclear which techniques this refers to. G14 states that intra-operative measurements may be useful in longer cases but it is unclear if this implies it is not useful or necessary in shorter cases, nor what constitutes a longer case.

Although SR2 suggests that use of capnography might be beneficial, G14 states that it is not currently recommended for ASA I & II patients. G1 also states that ECG is not essential for conscious sedation.

3. Subgroup considerations

It is important to make a clear distinction between the extent of monitoring required for different techniques and patient groups.

4. Balance of effects

Effective monitoring is essential for the recognition of sedation related complications. The necessity of the type of monitoring should be linked to the risk. For example, it might not be necessary to monitor blood pressure for patients having inhalation sedation with nitrous oxide/oxygen, or for children where it might increase anxiety and prevent completion of the treatment.

5. Generalisability and applicability

Not all forms of monitoring are suitable for all techniques e.g. measuring oxygen saturation when a patient is receiving nitrous oxide with oxygen is not meaningful.

6. Values and preferences

Although no patient preferences about monitoring were identified, it seems likely that some patients (e.g. children and patients with additional support needs) may find some forms of monitoring upsetting.

7. Acceptability

There could be difficulties with some monitoring of certain patients e.g. before sedation.

8. Feasibility

If a second appropriately trained person is assisting an operator/sedationist, contemporaneous recording of monitoring carried out during the procedure might be difficult or necessitate a third member of the team. Discussion with IACSD committee members confirmed that recording of monitoring data immediately after treatment would be considered contemporaneous. Therefore, an additional member of staff to specifically record monitoring is not required.

Some forms of additional monitoring, if recommended, could have financial implications in terms of cost of the equipment (e.g. capnography).

9. Other factors

G1: Failure to monitor oxygen saturation during sedation is also a 'never event' and must be reported to the National Reporting and Learning System and to the body commissioning this care.

10. Recommendation for guidance

Summary of group's judgements:

The GDG agreed that all of the advice on monitoring should be merged into one section, including what, how and when to monitor and any special conditions e.g. monitoring for children or other sub-groups. (see Questions. 2.8, 4.3, 5.3 and 6.1).

The components of clinical monitoring need to be defined, for example as in G14. The GDG agreed that not all aspects of clinical monitoring will be required at every point throughout the procedure and that it will be dependent on the clinical situation and patient status.

The types and frequency of monitoring should reflect the patient condition and the risks associated with the sedation technique being used (see Section 4 above).

Recommendations and clinical advice:

There is a lack of reported evidence relating to monitoring and the GDG agreed that the clinical advice in the guidance should be consistent with that in current guidelines. Clinical monitoring is sufficient for inhalation sedation with nitrous oxide/oxygen. For all other sedation techniques, monitoring should also include pulse oximetry and blood pressure monitoring. For children, it may not be essential to take blood pressure measurements and would be justifiable not to if it was likely to result in failure of the sedation appointment.

Since capnography is currently described as a developmental standard in G1 and is not recommended for ASA grade I and II patients in G14, the GDG agreed that it would not be recommended for use for conscious sedation for healthy patients.

The GDG agreed that the overarching principle for monitoring is that it is carried out by an appropriately trained member of staff and that the monitoring is suited to the clinical conditions i.e. the patient and the sedation technique being used. This should be reflected in the key recommendation.

Basis for Key Recommendation: Expert opinion

This is informed by several recent guidelines and is consistent with current standard professional practice. Consequently, this recommendation should be designated as based on expert opinion.

11. Additional Information

The 2016 update of guideline G3 recommends that end-tidal CO₂ is measured to monitor ventilation for patients having moderate sedation.

Conscious Sedation for Children (Clinical Questions 4.1-4.3)

<p>Question 4.1:</p> <p>For child patients undergoing dental treatment under sedation: which is the preferred (i.e. effective and safe) method of sedation (including drug and route)?</p>	<p>Appraisal refs:</p> <p>G1, G8, G13, G14, G15, G16, G17</p> <p>SR1, SR5, SR6, SR7, SR8</p>
<p>1. Summary of evidence</p> <p>In addition to the information summarised in the tables for Question 3.1 (for all patient groups) and 4.2 (alternative techniques for children):</p> <p>G1: Refers to NICE guidance (G15).</p> <p>G8: Nitrous oxide is generally acceptable to children and can be titrated easily. Most children are enthusiastic about the administration of nitrous oxide/oxygen.</p> <p>G13: Inhalation sedation is the recommended route for conscious sedation for paediatric dentistry. Nitrous oxide inhalation sedation should be offered to children with mild to moderate anxiety to enable them to accept dental treatment better and to facilitate coping across sequential visits. <i>(SIGN Grade A, 11 studies cited)</i></p> <p>Midazolam is generally reserved for anxious adolescent or adult dental patients. <i>(SIGN Grade B, no references cited)</i></p> <p>G14: The simplest and safest technique that is likely to be effective should be used. For children under 12 years of age, only nitrous oxide/oxygen is considered to be 'basic'. The 'basic' techniques all have an excellent safety record and are of proven efficacy for a wide range of patients.</p> <p>For a young person aged 12-16 years, basic sedation includes nitrous oxide/oxygen inhalation sedation and midazolam (all routes). <i>Inferred (p27), not stated as such.</i></p> <p>G15: Choose the most suitable sedation technique based on all the following factors: what the procedure involves; target level of sedation; contraindications; side effects; patient (or parent or carer) preference.</p> <p>For a child or young person who cannot tolerate a dental procedure with local anaesthesia alone, to achieve conscious sedation consider: nitrous oxide (in oxygen) or midazolam <i>(Moderate to very low quality evidence).</i></p> <p>G16: Nitrous oxide/oxygen should be the first choice for paediatric dental patients.</p> <p>G17: Nitrous oxide/oxygen has been shown to be an effective anxiolytic and sedative inhalation agent for conscious sedation during dental treatment and is recommended as the preferred drug.</p> <p>SR1: No randomized controlled trials (RCTs) comparing general anaesthesia (GA) versus sedation for providing dental care to children were found.</p>	

SR5: There is weak, but consistent evidence from five heterogeneous trials, that following administration of oral midazolam the behaviour of children was improved relative to placebo, with variations in the size of the benefit according to the dosage used. Where reported, adverse effects were few and minor. However, given the small number of studies (n = 5), participants (n = 182) and high risk of bias for all these papers, this conclusion must obviously be treated with some caution.

There is very weak evidence from two trials that nitrous oxide inhalation was also more effective than placebo and no adverse effects were noted. This suggests that this may be an effective method for managing behaviour in children.

SR6: There is low to very low quality evidence from 7 case series studies that suggests that inhalation sedation with nitrous oxide can prevent the need for GA in children who would otherwise have required it for dental treatment. The proportion of such children may be between 45 and 64% of all children referred for dental GA. The effectiveness of inhalation sedation in terms of completing/acceptance of planned treatment could be as high as 83-97% of selected subgroups of children. Inhalation sedation is suggested to be particularly suitable for orthodontic treatment for older children and for children requiring no more than 4 extractions, although this is inferred rather than directly addressed by the evidence. Reported side effects were minor and infrequent.

SR7: Minor side effects associated with IV midazolam usage in children and adolescents requiring dental treatment have been reported in 19.5% (data from 5 RCTs) and 16.8% (data from 6 observational studies) of cases with paradoxical reactions being the most common. No significant side effects were recorded (871 treatments). A subset of the data reports transient oxygen desaturation at 0% in RCTs and 0.3% of cases in other studies i.e. lower than for oral route (see SR8 below). This may reflect the ability to titrate via the IV route. The evidence for these outcomes is judged to be low to very low quality.

SR8: Low to very low quality evidence from 16 RCTs and 11 observational studies suggests that significant or major side effects associated with oral midazolam usage in children and adolescents requiring dental treatment are rare (none reported from ~2500 treatments). Minor adverse events (primarily nausea, vomiting and paradoxical reactions) were more common (14% of cases in RCTs; 8% of cases in observational studies). Transient desaturation was reported in 5.6% of cases in the RCTs and 0.2% of cases in the other studies, supporting the need for adequate monitoring.

2. Quality, quantity and consistency of evidence

Six guidelines with low (G8, G14, G16, G17), moderate (G13) or high (G15) methodological ratings made recommendations about sedation of children with nitrous oxide or midazolam. Four of these (G13, G14, G16, G17) indicated that inhalation with nitrous oxide is the preferred technique for children. Three (G13, G14, G15) provided further recommendations for midazolam, with G13 and G14 indicating that midazolam may be useful for adolescents and G15 recommending either technique for a child or young person.

One systematic review (SR5) provides supporting evidence that nitrous oxide is more effective than placebo and safe, although the evidence quality for this is judged to be very low. A second (SR6) provides very low quality evidence that nitrous oxide can be effective and safe for children who were otherwise referred for GA.

Low quality evidence reviewed in SR5 suggests that oral midazolam is more effective than placebo and safe. SR7 and SR8 provide low to very low quality evidence that IV and oral midazolam, respectively, are safe in children.

In general, the guidelines consistently identify nitrous oxide or midazolam as suitable effective and safe sedation techniques for children. Some recommend that nitrous oxide should be the first choice, with midazolam indicated for adolescents. The evidence provided in the systematic reviews supports their use.

3. Subgroup considerations

Sedation by nitrous oxide inhalation is the only technique considered as basic/standard for children (under 12 years old; G14). All other techniques for this age group would be considered advanced/alternative. For young people (12-16 years old), any techniques other than nitrous oxide inhalation or midazolam (by any route) may be considered advanced. Recommendations made in the guidance about the sedation techniques for children should reflect the different care options (e.g. required staff, setting, monitoring, life support) that may result from this distinction.

Consideration should be given to the additional treatment planning skills and experience that may be required for the management of children with complex oral needs. G14 recommends that skills equivalent to those expected of a specialist/consultant in paediatric dentistry are available.

4. Balance of effects

The effectiveness of each sedation technique and the risk and severity of adverse events for each age group are of key importance in deciding whether to recommend a particular technique.

5. Generalisability and applicability

Although some of the guidelines and studies included in the systematic reviews originated in other countries, the recommendations and conclusions are consistent with the UK based articles.

6. Values and preferences

In the 2 comparative studies assessed in SR6, inhalation sedation was found to be significantly better than dental GA in terms of parental and children satisfaction. In another study, high user satisfaction and preference of inhalation sedation over GA was found in patients with previous experience of dental GA. However, this evidence is considered to be of low to very low quality.

7. Acceptability

The intravenous route may be less acceptable for younger children.

8. Feasibility

Nitrous oxide versus general anaesthetic:

Studies have reported that procedures took 3-6 times longer with inhalation sedation than dental GA (SR6; low to very low quality). Staffing costs for inhalation sedation were estimated to be cheaper by approximately one-third compared with dental GA (carried out in dental teaching hospitals). Note however, that although GA may be more expensive than sedation, treatment completion under sedation may require more visits.

Costs for different techniques:

Health economic analysis suggested that for dental procedures, either nitrous oxide or midazolam are the lowest cost sedation techniques (G15).

Environment/staff required:

The sedation technique used for a particular age range (i.e. basic versus advanced) may have implications in terms of staff, setting, monitoring and life support required.

9. Other factors

10. Recommendation for guidance

Summary of group's judgements:

The GDG agreed that sedation for children and young people should be included in a separate section and that the age ranges should be defined in the guidance. These would be <12 years old for a child and 12 up to 16 years old for a young person, in accordance with the IACSD Report (G14) and Resuscitation Council UK. The techniques that are considered basic/standard and advanced for each age group should be defined at the start of the guidance.

It was proposed that advice on providing a child friendly environment is included in the guidance. It was also suggested that emphasis should be put on considering behavioural management techniques for children to avoid the need for sedation.

Recommendations and clinical advice:

The recommendations and clinical advice discussed in Questions 3.1, 3.2 and 3.3 should also apply to the conscious sedation of children and young people.

Informed by the low quality evidence described in the systematic reviews and by the guidelines, which were based on expert opinion, the GDG agreed that N₂O/O₂ should be the first choice of technique for children and N₂O/O₂ or midazolam the first choice techniques for young people.

For sedation of children and young people, the clinical staff should have appropriate training and experience of sedating the specific age group. Life support training for all members of the team treating children or young people should include life support of the age ranges being treated. The GDG agreed that additional skills and experience in paediatric dentistry would be required for effective treatment planning and management of children and young people with complex oral health needs (see Question 4.2 for more details).

The GDG agreed that the key recommendation for conscious sedation techniques in children and young people should reflect these requirements and indicate that the staffing,

equipment and facilities should be appropriate for the patient age and sedation technique.

Basis for Key Recommendation: Expert opinion

This is based on consideration of the importance of both the additional skills required to manage these patient groups and of an appropriate environment, and is informed by several recent guidelines.

11. Additional Information

Question 4.2:

For child patients undergoing dental treatment under sedation: what alternative forms of sedation are acceptable and in what circumstances (e.g. indications, settings)?

Appraisal refs:

G6, G13, G14, G15,
G16, G17

1. Summary of evidence

G6: Alternative techniques include: any form of conscious sedation for patients under the age of 12 years other than nitrous oxide/oxygen inhalation sedation. It is recognised that the physical and mental development of individuals varies and may not necessarily correlate with the chronological age.

G13: The use of multiple drugs increases the risk of complication and is not recommended. *(SIGN Grade B, 4 studies cited, very low quality)*

G14: Any child under 12 years with complex oral health needs or who cannot be managed with either behaviour management (BM)/Local analgesia(LA) or LA/inhalation sedation OR any young person aged 12-16 years with complex oral needs or who cannot be managed with either BM/LA or LA/inhalation sedation or LA/midazolam (all routes) should be referred to a team with the skills equivalent to those expected of a specialist/consultant paediatric dentist and a consultant in anaesthesia competent in sedation for dentistry for assessment and treatment in a facility equivalent to an NHS Acute Trust in England. This would include care provided by a managed clinical network or a recognised care pathway.

G15: If N₂O/O₂ inhalation sedation or midazolam sedation techniques are not suitable or sufficient, refer to a specialist team for an alternative sedation technique *(Moderate to very low quality evidence)*.

G16: Intravenous sedation for children is only appropriate in a minority of cases. Its use may be indicated in older children for whom inhalational sedation has been unsuccessful.

Oral/intranasal/transmucosal sedation techniques are not in general use for dentistry at present. As for adults they should only be administered under appropriate circumstances by a practitioner experienced in their use.

G17: Midazolam is now the standard BZD agent for conscious sedation during dental treatment in children

2. Quality, quantity and consistency of evidence

Six guidelines rated methodologically high (G15), moderate (G13) or low (G6, G14, G16, G17) provide recommendations about advanced forms of sedation for children.

G6 defines anything other than N₂O/O₂ inhalation sedation in children under 12 years to be an advanced technique, as does G14. Additionally, G14 defines anything else other than midazolam for children 12-16 years to be an advanced technique, and importantly, states that advanced techniques must be carried out by a team with the skills equivalent to those expected of a specialist/consultant paediatric dentist and of a consultant anaesthetist in a facility the equivalent of an NHS Acute Trust in England. G15 states that in such cases, refer to a specialist team, but does not specify the environment or skills required.

G16 states that intravenous sedation for children is only suited to a minority of cases, e.g. when inhalation sedation has been unsuccessful, and must be provided by an experienced practitioner. G13 states that use of multiple drugs in children is not recommended.

Collectively, advanced techniques for children are only indicated in a minority of cases and require additional skills, experience and facilities.

3. Subgroup considerations

It may be useful to specify indications for the use of advanced sedation techniques for children (e.g. where nitrous oxide is unlikely to be effective for the patient and treatment required, or for the avoidance of a general anaesthetic).

4. Balance of effects

The effectiveness of each sedation technique and the risk and severity of adverse events are of key importance in deciding whether to recommend a particular technique.

5. Generalisability and applicability

Several of the guidelines are from the UK.

6. Values and preferences

Sedation is likely to be preferable for children and parents to GA (see Question 4.1) and therefore it is important that there is provision for the minority of cases for which advanced techniques are indicated.

7. Acceptability

8. Feasibility

Being clear about the environment and skills required for the delivery of such techniques, and alternative ways in which this might be achieved, is important for the planning of services.

The requirement for specialist skills and facilities is likely to limit the availability of advanced

sedation techniques for children and might lead to an increased number requiring GA for dental care.

9. Other factors

IACSD provide further explanation of 'a team having skills equivalent to those expected of a specialist/consultant in paediatric dentistry' and 'a consultant in anaesthesia competent in sedation for dentistry' in responses to FAQs:

How can I show that I have 'skills equivalent to those expected of a specialist/consultant in paediatric dentistry' (Options for Care, page 8)?

You must be able to provide evidence that the person leading the team possesses the knowledge and skills which will ensure that treatment planning and care under conscious sedation will be delivered to the same standard as would be expected of a specialist. Evidence might include training (including CPD, postgraduate qualifications, clinical attachments, honorary NHS appointments etc.) and documented experience appropriate to the age group/s to be treated. A good record of experience would include dated (but anonymised) patient data including age, ASA status, sedation technique, monitoring, dental treatment, recovery, outcome, adverse incidents and a summary of the number of sedation cases managed per year. The training and experience of other members of the sedation team, any support available from a local peer, consultant or MCN and the equipment and facilities available might also be relevant. The SAAD Safe Sedation Practice Scheme covers some of these elements. The checklist used by SAAD inspectors is available for download and may be used for self-assessment. Written support from specialist/consultant who is familiar with your experience might also be helpful. The syllabuses in Appendix 1 define the knowledge and skills required of the whole team for a variety of techniques and age groups.

How can I show that I have 'skills equivalent to those expected of a consultant in anaesthesia competent in sedation for dentistry' (Options for Care, page 8)?

If you are an anaesthetist (i.e. on the GMC Specialist Register in anaesthetics) wishing to commence providing dental conscious sedation for children and young people you must be able to demonstrate training and experience in paediatric anaesthesia to a standard equivalent to that detailed in the paediatric section of the RCoA curriculum and acquisition of the competencies outlined in the RCoA dental sedation curriculum (IACSD Ref 34).

If you are an anaesthetist already engaged in the provision of dental conscious sedation for children and young people you must be able to demonstrate that you possess the necessary competencies for safe independent sedation practice. Formal appraisal/revalidation for this activity would include demonstration of appropriate paediatric anaesthetic training and experience, possession of the necessary paediatric dental sedation competencies (IACSD Ref 34), ongoing experience (logbook of sedation activity), evidence of appropriate continuing professional development, participation in audit of practice and outcomes and documentation of any complaints.

If you are a medical or dental practitioner you must be able to provide evidence that you possess the knowledge and skills which will ensure that conscious sedation will be delivered to the same standard as would be expected of a specialist in anaesthesia (see above) who is competent in sedation for dentistry. This includes competence in age-appropriate 'rescue' procedures in the event of cardio-respiratory complications associated with a deeper level of

sedation than intended. However, you are not expected to possess broader anaesthetic skills which are not directly relevant to the administration of dental conscious sedation or its complications. Evidence might include formal appraisal/revalidation, training (including CPD, postgraduate qualifications, clinical attachments, honorary NHS appointments etc.) and documented experience appropriate to the age group/s to be treated. A satisfactory record of experience would include dated (but anonymised) patient data including age, ASA status, sedation technique, monitoring, dental treatment, recovery, outcome, adverse incidents and a summary of the number of sedation cases managed per year. The training and experience of other members of the sedation team, support available from a local peer, specialist anaesthetist or MCN and the equipment and facilities available might also be relevant. The SAAD Safe Sedation Practice Scheme covers some of these elements. The checklist used by SAAD inspectors is available for download and may be used for self-assessment. Written support from a specialist anaesthetist who is familiar with your experience might also be helpful. The syllabuses in Appendix 1 define the knowledge and skills required of the whole team for a variety of techniques and age groups.

www.rcseng.ac.uk/dental-faculties/fds/publications-guidelines/standards-for-conscious-sedation-in-the-provision-of-dental-care-and-accreditation/faq/.

10. Recommendation for guidance

Summary of group's judgements:

There is a lack of reported synthesised evidence on the efficacy and safety of advanced sedation techniques for children. As for adults, advanced sedation techniques should only be used for children and young people when standard techniques are not suitable to meet their clinical needs and would only be appropriate in a minority of cases. Their use must be justified.

Recommendations and clinical advice:

To be consistent with currently advocated practice (G14), the GDG agreed that the team responsible for sedating children using an advanced technique (i.e. anything other than inhalation of nitrous oxide for children and other than nitrous oxide or midazolam for young people) should include the skills and knowledge equivalent to that expected of a specialist/consultant in paediatric dentistry. This would also be the case for children and young people with complex oral health needs irrespective of the sedation technique. These skills could be from an individual(s) within the immediate team or could be accessed through wider networks. In either case the aim would be to ensure effective treatment planning for the patient and to minimize unnecessary repeat sedation episodes. The GDG also agreed that it would be appropriate for the sedationist to have the skills equivalent to those expected of a consultant in anaesthesia competent in sedation for dentistry delivering advanced sedation techniques for children and young people.

The facility requirements for any sedation technique are discussed in Question 2.7.

The key recommendation for sedation for children and young people applies to all sedation techniques (see Question 4.1) and there is no key recommendation specifically for advanced techniques.

Post-consultation revisions:

Significant concerns were raised by numerous consultees regarding 'the skills equivalent to those expected of a specialist/consultant in paediatric dentistry'. Senior experienced dental practitioners were unsure about whether and how they could demonstrate these skills. Furthermore, accessing a specialist/consultant in paediatric dentistry, even via remote mechanisms, was reported to be currently unworkable in many areas and unlikely to change. This may be particularly problematic when treating children and young people with complex oral health needs, because of the level of demand in some settings. These significant implementation barriers were considered carefully by the GDG and revisions made to this section of the guidance with the aim of encouraging high quality patient care while maintaining access to care. In line with the principles put forward in G14, the guidance upholds the requirement for effective treatment planning for this patient group.

Consequently, the GDG agreed to:

- explain and further emphasise the importance of treatment planning for these patients;
- revise the advice on the management of a child or young person having an advanced sedation technique, or with complex oral health needs, to focus on the need for effective treatment planning and the practitioner's duty to decide if they are competent to do this, or whether input from a more experienced colleague (likely to be a specialist or consultant in paediatric dentistry) is required. This is in line with the fundamental principle that all healthcare professionals should be working within their level of competency for a particular situation;
- Advocate that teams providing advanced sedation for children and young people work within a managed clinical network.

11. Additional Information

<p>Question 4.3:</p> <p>For child patients undergoing dental treatment under sedation: what form of monitoring is required for each sedation technique to reduce the risk of and identify complications?</p>	<p>Appraisal refs:</p> <p>G8, G10, G13, G14, G15, G17</p>
<p>1. Summary of evidence</p> <p>G8: During nitrous oxide/oxygen analgesia/anxiolysis, continual clinical observation of the patient’s responsiveness, color, and respiratory rate and rhythm must be performed. Spoken responses provide an indication that the patient is breathing. If any other pharmacologic agent is used in addition to nitrous oxide/oxygen and a local anesthetic, monitoring guidelines for the appropriate level of sedation must be followed.</p> <p>G10: For moderate sedation:</p> <p><u>Baseline.</u> Before administration of sedative medications, a baseline determination of vital signs shall be documented. For some children who are very upset or non-cooperative, this may not be possible and a note should be written to document this happenstance.</p> <p><u>During the procedure.</u> The practitioner shall document the name, route, site, time of administration, and dosage of all drugs administered. There shall be continuous monitoring of oxygen saturation and heart rate and intermittent recording of respiratory rate and blood pressure; these should be recorded in a time-based record. A functioning suction apparatus must be present.</p> <p><u>After the procedure.</u> The child who has received moderate sedation must be observed in a suitably equipped recovery facility [eg, the facility must have functioning suction apparatus as well as the capacity to deliver more than 90 percent oxygen and positive-pressure ventilation (eg, bag and mask with oxygen capacity as described previously)]. The patient’s vital signs should be recorded at specific intervals. If the patient is not fully alert, oxygen saturation and heart rate monitoring shall be used continuously until appropriate discharge criteria are met. Because sedation medications with a long half-life may delay the patient’s complete return to baseline or pose the risk of re sedation, some patients might benefit from a longer period of less-intense observation (e.g. a step-down observation area where multiple patients can be observed simultaneously) before discharge from medical supervision. A recently described and simple evaluation tool may be the ability of the infant or child to remain awake for at least 20 minutes when placed in a quiet environment. Patients who have received reversal agents, such as flumazenil or naloxone, will also require a longer period of observation, because the duration of the drugs administered may exceed the duration of the antagonist, which can lead to re sedation.</p> <p>G13: Alert clinical monitoring is essential at all times. It is vital that adequately trained staff and the appropriate monitoring facilities are available to alert the operator if the patient undergoes desaturation. Electronic monitoring is not required in nitrous oxide inhalation sedation. A <i>minimum</i> of pulse oximetry is an essential requirement for all other types of sedation. (SIGN Grade C, 1 reference cited)</p> <p>G14: Non-invasive blood pressure (NIBP) monitoring also records heart rate and is not essential in children. <i>Not clear whether this applies to ALL sedation techniques in children – see Tables 1&2 in G14.</i></p>	

G15: For moderate sedation excluding with nitrous oxide alone (in oxygen) continuously monitor, interpret and respond to changes in all of the following: depth of sedation; respiration; oxygen saturation; heart rate; pain; coping; distress. (*expert opinion*)

G17: Paediatric dental patients under conscious sedation must be monitored continuously clinically, as this is the most important element in patient monitoring. Clinical monitoring includes: Response by the patient to Physical stimulation and Verbal command, Observing breathing, Movements of the thorax, Passage of the air stream, Respiratory frequency, Observing skin colour. The use of pulse oximetry has been widely discussed. In the case of conscious sedation, oxygen desaturation (i.e. below 95%) is probably rare. Pulse-oximetry is not deemed required for conscious sedation with nitrous oxide/oxygen sedation, but is preferable in benzodiazepin sedation. It is however vital that the staff are adequately trained in the use of clinical monitoring, and if used the management of electronic monitoring.

2. Quality, quantity and consistency of evidence

Six guidelines rated methodologically high (G15), moderate (G13) or low (G8, G10, G14, G17) provide recommendations on monitoring for sedation specifically of children.

All guidelines agree that clinical monitoring is essential for all forms of sedation. G8, G10 and G17 provide details.

G10 describes monitoring and recording required before (vital signs), during (sedation details, O₂ saturation, heart rate, and periodically respiratory rate and blood pressure) and after moderate sedation until discharge criteria are met (vital signs, O₂ saturation, heart rate).

Electronic monitoring is not required for N₂O/O₂ inhalation sedation in children (G13, G15, G17)

For anything other than N₂O/O₂inhalation sedation, pulse oximetry is recommended (G13, G17). G15 recommends continuous monitoring of depth of sedation, respiration, heart rate, pain, coping and distress. Consistent with this, G14 states that NIBP monitoring is not essential for children but is unclear about which methods this applies to.

G10 notes that some child patients might require a longer period of observation before discharge due to potential re-sedation.

3. Subgroup considerations

Some child groups may require additional monitoring e.g. depending on medical status.

4. Balance of effects

See Question 3.3, section 4.

5. Generalisability and applicability

Several of the guidelines are from the UK.

6. Values and preferences

Although no patient preferences about monitoring were identified, it seems likely that some patients (e.g. children and patients with additional support needs) may find some forms of

monitoring upsetting.
<p>7. Acceptability</p> <p>Some children might dislike some forms of monitoring.</p>
<p>8. Feasibility</p> <p>See above.</p>
<p>9. Other factors</p>
<p>10. Recommendation for guidance</p> <p>Summary of group’s judgements:</p> <p>Advice relating to monitoring for children and young people will be included in the section for all patients (see Question 3.3). In line with other guidelines, clinical monitoring and pulse oximetry should be required for children and young people for all techniques other than inhalation of nitrous oxide/oxygen, for which clinical monitoring is sufficient. For children, it may not be essential to take blood pressure measurements and would be justifiable not to if it was likely to result in failure of the sedation appointment (see Question 3.3).</p> <p>There is no key recommendation specifically for monitoring for children and young people.</p>
<p>11. Additional Information</p> <p>The 2016 update of guideline G10 advises that during moderate sedation, in addition to continuous monitoring of oxygen saturation and heart rate, monitoring of ventilation by (1) capnography (preferred) or (2) amplified, audible pretracheal stethoscope (e.g., Bluetooth™ technology) or precordial stethoscope is strongly recommended. If bi-directional verbal communication is not appropriate or not possible, monitoring of ventilation by capnography (preferred), amplified, audible pretracheal stethoscope, or precordial stethoscope is required. The update recommends that these measurements i.e. heart rate, respiratory rate, blood pressure, oxygen saturation, and expired carbon dioxide values are recorded, at minimum, every 10 minutes in a time-based record.</p>

Conscious Sedation for Adults and Children with Special Care Needs (Clinical Questions 5.1-5.3)

<p>Question 5.1: For patients with special care needs that affect provision of their dental care and who are undergoing dental treatment under sedation:</p> <p>which is the preferred (i.e. effective and safe) method of sedation (including drug, route)?</p>	<p>Appraisal refs: G1, G13, G14, G16, G17</p>
<p>1. Summary of evidence</p> <p>G1: Elderly patients are more sensitive to many drugs than younger patients. It is well established that the doses of midazolam and opioid they require is usually half or less than those required for younger patients. Subsequent incremental doses should also be reduced. It is important therefore to reduce the dose sufficiently in the elderly, frail or at-risk patients.</p> <p>G13: Those (children) who are not in these categories (ASA I or II) requiring conscious sedation should be treated in a hospital environment with due consideration to their individual needs and medical condition, involving the assistance of medical colleagues where appropriate. <i>(SIGN Grade C, no references cited)</i></p> <p>G14: Intranasal (midazolam) sedation is one of a group of routes of administration referred to as transmucosal sedation. These techniques have become more popular in recent years, especially in special care dentistry. As with oral sedation, these techniques are not titratable and should only be used when titratable sedation techniques are inappropriate.</p> <p>G16: Patients in ASA class III should be referred to an appropriate secondary care unit.</p> <p>G17: Patients in ASA Class III and Class IV represents special problems and require individual consideration and shall be treated in a hospital environment, involving the assistance of medical doctors when appropriate.</p>	
<p>2. Quality, quantity and consistency of evidence</p> <p>Five guidelines of low (G14, G16, G17), moderate (G1, G13) or high methodological quality (G15) provide recommendations related to the provision of sedation for patients with special care needs, G1 concerning reducing midazolam or opioid doses for elderly, frail or at risk patients, and G13, G16 and G17 recommending treatment of ASA III+ patients in a hospital setting. G14 notes that use of intranasal midazolam should only be considered when titratable drugs are unsuitable.</p> <p>Although a guideline specifically about special care dentistry, G12 did not include specific recommendations about the provision of sedation for patients with special needs.</p>	
<p>3. Subgroup considerations</p> <p>The most appropriate sedation technique to use will depend on the individual needs of any special care patient e.g. age, physical status, learning ability.</p>	
<p>4. Balance of effects</p>	

The benefits of each sedation technique considered should be weighed up against the risks for the individual patient.

5. Generalisability and applicability

The guidelines identified provide recommendations for different special care situations which would not be applicable in every case.

6. Values and preferences

Feedback from the patient & parent scoping interviews carried out by TRiADS (www.triads.org.uk) indicates that patients trust their clinician to make the appropriate choice of sedation on their behalf and often only seek reassurance that the method of sedation selected will be effective.

7. Acceptability

Will depend on the sedation techniques recommended for each patient group.

8. Feasibility

See above.

9. Other factors

10. Recommendation for guidance

Summary of group's judgements:

The GDG felt that it was difficult to define this group as it may include patients that would be considered for special care dental treatment, but who would not necessarily be considered special or additional needs patients according to social or educational definitions e.g. elderly patients, highly anxious patients, patients with a high BMI or specific medical conditions. The group could include patients with learning difficulties or difficulties with cooperation. Because of the variation in the needs of this patient group it was not considered feasible to make specific recommendations on preferred sedation techniques. It was agreed that rather than having a separate section for patients with special care needs, specific advice, special conditions or treatment options would be included in the main sections on sedation techniques for adults or children and young people.

The GDG also agreed to include a section in the guidance (under assessment for sedation) about individualisation of treatment/treatment planning considerations for person-centred care, based on factors such as those indicated above (elderly, high BMI, physical status etc). This section should make the progression from assessment to outcome to treatment plan clearer. Discussion on adaptations to treatment to suit the needs of the patient should be included here.

Recommendations and clinical advice:

A dedicated sedationist may be required for special care patients depending on their

individual needs. There is some low quality evidence that supports the use of oral or transmucosal sedation for adults including those with additional support needs (see Question 3.1). Non-verbal means of communication may be required for some patients.

Post-consultation revisions:

The GDG agreed that further guidance on referral of ASA grade III/IV patients should be provided. It was considered clear that ASA grade IV patients should only be treated under sedation in secondary care. There should be more flexibility around where to treat ASA grade III patients, since this will depend on various factors including the technique used, the suitability of the environment in terms of skills etc and patient stability. It was agreed that it was not possible to specify criteria for when to refer ASA grade III patients or what sedation techniques to provide and that this should be judged by the assessing clinician on an individual basis. This advice should be provided in the section on assessment.

11. Additional Information

<p>Question 5.2: For patients with special care needs that affect provision of their dental care and who are undergoing dental treatment under sedation:</p> <p>what alternative forms of sedation are acceptable and in what circumstances (e.g. indications, settings)?</p>	Appraisal refs:
<p>1. Summary of evidence</p> <p>See Question 5.1, otherwise, none of the included sources has other specific recommendations on alternative techniques for patients with special needs.</p>	
<p>2. Quality, quantity and consistency of evidence</p> <p>There is a lack of information specifically about advanced sedation techniques for special care patients.</p>	
<p>3. Subgroup considerations</p> <p>See Question 5.1.</p>	
<p>4. Balance of effects</p> <p>See Question 5.1.</p>	
<p>5. Generalisability and applicability</p> <p>See Question 5.1.</p>	
<p>6. Values and preferences</p> <p>See Question 5.1.</p>	
<p>7. Acceptability</p> <p>See Question 5.1.</p>	
<p>8. Feasibility</p> <p>See Question 5.1.</p>	
<p>9. Other factors</p>	
<p>10. Recommendation for guidance</p> <p>Summary of group’s judgements:</p> <p>Refer to Question 5.1 (Section 10)</p> <p>Any recommendations or clinical advice on standard or advanced techniques for special care</p>	

patients are to be included in the main sections on sedation techniques for adults or children and young people.

11. Additional Information

<p>Question 5.3: For patients with special care needs that affect provision of their dental care and who are undergoing dental treatment under sedation:</p> <p>what form of monitoring is required for each sedation technique to reduce the risk of and identify complications?</p>	<p>Appraisal refs: G14</p>
<p>1. Summary of evidence</p> <p>G14: states that additional monitoring (e.g. end-tidal or transcutaneous capnography, electrocardiography) may be appropriate for ASA grade III/IV patients, particularly those with chronic lung disease.</p>	
<p>2. Quality, quantity and consistency of evidence</p>	
<p>3. Subgroup considerations</p> <p>Some special care patient groups may require additional monitoring e.g. depending on medical status.</p>	
<p>4. Balance of effects</p> <p>See Question 3.3.</p>	
<p>5. Generalisability and applicability</p> <p>See Question 3.3.</p>	
<p>6. Values and preferences</p> <p>See Question 3.3.</p>	
<p>7. Acceptability</p> <p>See Question 3.3.</p>	
<p>8. Feasibility</p> <p>See Question 3.3.</p>	
<p>9. Other factors</p>	
<p>10. Recommendation for guidance</p> <p>Summary of group’s judgements:</p> <p>The recommendations for monitoring for all patients (see Question 3.3) also apply to those</p>	

with special care needs. Additional monitoring e.g. ECG or capnography may appropriate for some patients depending on their physical status.

The guidance should note that there may be difficulties in carrying out pre-sedation monitoring for some patients.

11. Additional Information

Recovery and Discharge (Clinical Questions 6.1-6.3)

<p>Question 6.1: For patients undergoing dental treatment under sedation: when should monitoring stop?</p>	<p>Appraisal refs: G1, G3, G5, G10, G14, G15, G16</p>
<p>1. Summary of evidence</p> <p>G1: Monitoring should be continued into the recovery period.</p> <p>G3: The qualified dentist or appropriately trained clinical staff must monitor the patient during recovery until the patient is ready for discharge by the dentist. The qualified dentist must determine and document that level of consciousness; oxygenation, ventilation and circulation are satisfactory for discharge.</p> <p>When active treatment concludes and the patient recovers to a minimally sedated level a qualified auxiliary may be directed by the dentist to remain with the patient and continue to monitor them as explained in the guidelines until they are discharged from the facility. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility.</p> <p>If a pharmacological reversal agent is administered before discharge criteria have been met, the patient must be monitored for a longer period than usual before discharge, since re-sedation may occur once the effects of the reversal agent have waned.</p> <p>G5: Recovery should take place under appropriate supervision in a properly equipped and staffed area which may be the area where the procedure was performed. If the recovery area is not where the procedure occurred, then there must be adequate and safe patient transfer facilities available. Adequate staffing and facilities must be available in the recovery area for managing patients who have become unconscious or who have suffered complications during the procedure.</p> <p>G10: Consideration for a longer period of observation shall be given if the responsible person's ability to observe the child is limited (e.g. only one adult who also has to drive). Another indication for prolonged observation would be a child with an anatomic airway problem or a severe underlying medical condition, or where a reversal agent has been administered.</p> <p>G14: During recovery, the patient must be supervised; a trained member of the dental team must be responsible for the patient and monitor the individual throughout this period. All necessary equipment and drugs must be available to support recovery and to manage any complications that may arise.</p> <p>G15: After the procedure, continue monitoring until the child or young person: has a patent airway; shows protective airway and breathing reflexes; is haemodynamically stable; is easily roused. (<i>expert opinion</i>)</p> <p>G16: A member of the dental team must supervise and monitor the patient throughout this period and both equipment and drugs for dealing with medical emergencies must be immediately to hand. The practitioner must be available to see the patient urgently in the</p>	

event of any problems arising.

2. Quality, quantity and consistency of evidence

Guidelines of low (G3, G5, G10, G14, G16), moderate (G1) and high (G15) methodological ratings provide recommendations relating to the recovery period. Only four (G1, G14, G15, G16) provide specific details about when it is appropriate to stop monitoring the patient. G1, G14 and G16 recommend that the patient is monitored throughout recovery. Referring to children, G15 provides more details indicating that the patient should be monitored until they have a patent airway; show protective airway and breathing reflexes; are haemodynamically stable; are easily roused.

Additional points relevant to responsible staff and facilities required for recovery, made by the other guidelines include that:

- recovery should take place under appropriate supervision in a properly equipped and staffed area (G5).
- a trained member of the dental team must be responsible for the patient and all necessary equipment and drugs must be available to support recovery and to manage any complications that may arise (G14).
- a member of the dental team must supervise and monitor the patient and both equipment and drugs for dealing with medical emergencies must be immediately to hand. The practitioner must be available to see the patient urgently in the event of any problems arising (G15).
- a qualified auxiliary may be directed by the dentist to monitor the patient (during recovery) until discharge; the dentist must not leave the facility before then (G3).

For information on criteria for indicating when the patient has recovered sufficiently for discharge, see Question 6.2.

3. Subgroup considerations

Children: prolonged monitoring of recovery might be required if the child has an anatomic airway problem or a severe underlying medical condition, or if the responsible person has to drive in addition to observing the child (G10).

Patients who have had a reversal agent: prolonged monitoring of recovery might be required in case of re-sedation when the effects of the agent wear off (G3, G10).

4. Balance of effects

Appropriate monitoring and care of patients until suitably recovered is an important safety consideration. Early discharge is likely to carry risk.

5. Generalisability and applicability

It seems likely that the recommendations identified relating to recovery would be generally applicable, irrespective of their source of origin.

6. Values and preferences

Information on patient preferences about when monitoring should stop was not found.

However, regarding the recovery period, the preference for a private recovery area, separate from the incoming patients waiting room, was identified.

7. Acceptability

It seems likely that practitioners and patients would find it acceptable to have monitoring throughout the recovery period.

8. Feasibility

There could be issues around having sufficient space for a private recovery area if separate from the treatment area.

Consideration could be given to whether members of the clinical team, other than the sedationist, could carry out aspects of the discharge process e.g. BP measurement, providing information, removal of cannula etc, if appropriately trained to do so.

The requirement for monitoring equipment (e.g. for pulse oximetry) in both the treatment and recovery areas could be a perceived barrier to monitoring during recovery.

9. Other factors

10. Recommendation for guidance

Summary of group's judgements:

The GDG agreed that the recommendations and advice relating to monitoring during recovery should be presented together with those on discharge and on post-sedation instructions (see Questions 6.2 and 6.3) in one section of the guidance.

Recommendations and clinical advice:

It was noted that there is a lack of reported evidence to inform recommendations relating to recovery and discharge. The guidelines considered above are fairly consistent in the points that they make and the GDG agreed that the recommendations in the guidance should reflect these.

The recovery area may be the treatment area or a separate area. In either case, an appropriately trained member of staff is required to carry out the monitoring, and the equipment required for monitoring and for managing sedation-related complications and emergencies should be immediately available. It is considered good practice that the recovery area is separate from the waiting room for other patients.

G14 proposes a 2-stage recovery process (Stage1: unable to walk to recovery; Stage 2: ambulant with escort) with different levels of monitoring for each stage (Table 2, p31). The GDG felt that this distinction was unnecessary and that the patient should be monitored as during sedation until fully recovered. This would normally include clinical observations, pulse oximetry and blood pressure (except for inhalation sedation with nitrous oxide/oxygen), as described in Question 3.3.

The group agreed that monitoring should stop when the patient has met the discharge criteria. Discharge criteria are considered in Question 6.2. The GDG agreed that those listed

in G14 were consistent with other guidelines and suitable for use. It was also agreed that the sedationist would ultimately be responsible for the decision to discharge the patient.

Post-operative instructions are considered in Question 6.3.

The GDG agreed that the key recommendation for recovery and discharge should indicate that the patient should be monitored throughout the recovery period until discharged into the care of an escort who has been given post-operative instructions. Further details, including those described above, will be included in the guidance in the recovery and discharge section and elsewhere (e.g. monitoring, escort, post-sedation instructions).

Post-consultation revisions:

At consultation, it was noted that (adult) patients having inhalation sedation with nitrous oxide/oxygen would not usually be discharged into the care of an escort. Consequently, the key recommendation was amended slightly to indicate that the patient should be monitored continuously until assessed as fit for discharge. Further advice on escort and post-sedation instructions will be provided elsewhere in the section on discharge.

Basis for Key Recommendation: Expert opinion

The recommendation is informed by several recent guidelines and is consistent with current standard professional practice.

11. Additional Information

<p>Question 6.2: For patients undergoing dental treatment under sedation: what discharge criteria are required?</p>	<p>Appraisal refs: G1, G3, G8, G10, G14, G15, G16, G17</p>
<p>1. Summary of evidence</p> <p>G1: Discharge criteria are as follows:</p> <ul style="list-style-type: none"> • The patient has returned to their baseline level of consciousness. • Vital signs are within normal limits for that patient. • Respiratory status is not compromised. • Pain and discomfort have been addressed. • If there is a requirement to discharge the patient prior to meeting these criteria, they should be transferred to an appropriate clinical environment with continuation of peri-procedure monitoring standards. • Patients meeting discharge criteria following sedation who go on to be discharged home should be discharged into the care of a suitable third party. • Verbal and written instructions should be given. <p>G3: The qualified dentist must determine and document that level of consciousness; oxygenation, ventilation and circulation are satisfactory for discharge. Post-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.</p> <p>G8: The patient must return to pre-treatment responsiveness before discharge.</p> <p>G10: 1. Cardiovascular function and airway patency are satisfactory and stable. 2. The patient is easily arousable, and protective reflexes are intact. 3. The patient can talk (if age appropriate). 4. The patient can sit up unaided (if age appropriate). 5. For a very young or handicapped child incapable of the usually expected responses, the pre-sedation level of responsiveness or a level as close as possible to the normal level for that child should be achieved. 6. The state of hydration is adequate.</p> <p>G14: The decision to discharge the patient is the responsibility of the sedationist, with each patient being assessed on an individual basis. Discharge criteria include:</p> <ol style="list-style-type: none"> 1. The patient is orientated in time, place and person. 2. Vital signs are stable and within normal limits for the patient. Respiratory status is not compromised. 3. Pain and discomfort have been addressed. 4. Where relevant, haemostasis has been observed. 5. The cannula, where inserted, has been removed. 6. The responsible escort is present and arrangements have been made for supervision as advised by the sedationist. 7. Written and verbal postoperative instructions appropriate for both the sedation and the dental treatment have been given to the patient and escort/carer. 8. Advice has been given regarding precautions in the post-sedation period. This must be related to the dental treatment and the use of any local analgesia, the type of sedation and their duration. The precautions should include not drinking alcohol, operating machinery, driving or making important decisions for a specified period of time. 	

9. Arrangements for postoperative analgesia have been made where appropriate.

10. Arrangements are in place for out-of-hours advice.

G15: Ensure that all of the following criteria are met before the child or young person is discharged: vital signs (usually body temperature, heart rate, blood pressure and respiratory rate) have returned to normal levels; the child or young person is awake (or returned to baseline level of consciousness) and there is no risk of further reduced level of consciousness nausea, vomiting and pain have been adequately managed. (*expert opinion*)

G16: The decision to discharge a patient into the care of the escort following any type of sedation must be the responsibility of the sedationist. After assessment the patient must be discharged to the care of a competent adult. The patient should be able to walk unaided without stumbling or feeling unstable before being allowed to leave professional supervision. Where a cannula has been inserted for the administration of intravenous sedation it is preferable that it be removed at this stage. Adult patients who have received nitrous oxide and oxygen inhalation sedation may leave unaccompanied at the discretion of the sedationist.

G17: Before discharge, children should be alert and oriented (or have returned to an age-appropriate base line). A responsible adult must be present to observe the child for complications after discharge, and to control that the child sits with the head in an upright position to facilitate breathing. In the situation of an outpatient child and if the responsible adult is driving a car to the home another adult must be present if the child is young.

2. Quality, quantity and consistency of evidence

Guidelines that provide specific details of discharge criteria are G3, G8, G10, G14, G16, G17 (low methodological rating), G1 (moderate) and G15 (high). These criteria are fairly consistent between the guidelines.

The criteria include:

- The patient has returned to their baseline level of consciousness and responsiveness (G1, G3, G8, G10, G14, G15, G17)
- Vital signs are within normal limits for that patient (G1, G3, G10, G14, G15)
- Respiratory status is not compromised (G1, G3, G10, G14, G15)
- Pain and discomfort have been addressed (G1, G14, G15)
- The patient can walk unaided (G16) and talk (G10).
- If there is a requirement to discharge the patient prior to meeting these criteria, they should be transferred to an appropriate clinical environment with continuation of peri-procedure monitoring standards (G1)
- The cannula, where inserted, has been removed (G14, G16)
- Patients meeting discharge criteria should be discharged into the care of a suitable third party (G1, G3, G14, G16, G17) to whom written instructions have been provided (G3, G14)
- Verbal and written instructions have been given (G1, G3, G14)

According to G3, G14 and G16 the practitioner/sedationist has the responsibility for discharge of the patient.

G10 (paediatric) states an additional criterion that the patient's state of hydration is adequate. G14 indicates that haemostasis should have been achieved.

<p>3. Subgroup considerations</p> <p>See Qu 6.1</p>
<p>4. Balance of effects</p> <p>Appropriate monitoring and care of patients until suitably recovered is an important safety consideration. Early discharge is likely to carry risk.</p>
<p>5. Generalisability and applicability</p> <p>The criteria listed should be widely applicable.</p>
<p>6. Values and preferences</p> <p>See Qu 6.1</p>
<p>7. Acceptability</p> <p>It seems likely that practitioners and patients would find the discharge criteria acceptable.</p>
<p>8. Feasibility</p> <p>See above.</p>
<p>9. Other factors</p>
<p>10. Recommendation for guidance</p> <p>Summary of group’s judgements:</p> <p>The GDG agreed that the recommendations and advice relating to discharge criteria should be presented together with those on monitoring during recovery and on post-sedation instructions (see Questions 6.1) in one section of the guidance. The discharge criteria listed in the IACSD report are generally consistent with the other guidelines and suitable for referring to.</p> <p>The key recommendation covering recovery and discharge is discussed in Question 6.1.</p>
<p>11. Additional Information</p>

<p>Question 6.3: For patients undergoing dental treatment under sedation: what aftercare instructions are required?</p>	<p>Appraisal refs: G1, G3, G5, G10, G13, G14, G16, G17</p>
<p>1. Summary of evidence</p> <p>G1: Verbal and written instructions should be given after treatment.</p> <p>G3: Post-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.</p> <p>G5: The patient should be discharged into the care of a responsible adult to whom written instructions should be given, including advice about eating and drinking, pain relief, and resumption of normal activities, as well as about making legally-binding decisions, driving, or operating machinery.</p> <p>G10: The practitioner shall provide verbal and/or written instructions to the responsible person. Information shall include objectives of the sedation and anticipated changes in behaviour during and after sedation. Special instructions shall be given to the adult responsible for infants and toddlers who will be transported home in a car safety seat regarding the need to carefully observe the child’s head position so as to avoid airway obstruction. Transportation by car safety seat poses a particular risk for infants who have received medications known to have a long half-life, such as chloral hydrate, intramuscular pentobarbital, or phenothiazine.</p> <p>A 24-hour telephone number for the practitioner or his or her associates shall be provided to all patients and their families.</p> <p>Instructions shall include limitations of activities and appropriate dietary precautions.</p> <p>G13: In advance of the procedure, the child and their parent or guardian must be given clear and comprehensive pre- and post-operative instructions in writing. (<i>SIGN Grade C, 1 reference cited</i>)</p> <p>G14: Verbal and written instructions for the post-operative period must be provided for both the patient and the responsible adult escort. Examples of the written instructions are provided. They must include the post-operative risks, pain control and possible postoperative complications together with the aftercare arrangements and emergency contacts.</p> <p>G16: The patient and escort should be provided with details of postoperative risks, pain control and management of possible complications. Adequate information regarding aftercare arrangements and emergency contact must also be provided.</p> <p>G17: The adult must be given written and oral instructions on: Appropriate diet, Medications, Management of possible postoperative bleeding, Level of activity.</p>	
<p>2. Quality, quantity and consistency of evidence</p> <p>Eight guidelines (methodological rating: low for G3, G5, G10, G14, G16, G17; moderate for G1, G13) make recommendations on aftercare instructions based on expert opinion of best</p>	

practice. G1, G3 and G13 provide no details.

G5 and G13 state that instructions should be written while G1, G3, G10, G14, and G17 state that post-operative instructions should be verbal and written. G13 clearly states that this advice should be provided pre-operatively. G16 does not specify how instructions should be provided.

Instructions should be given to: patient/child (G3, G13, G14, G16), parent/guardian/care giver (G3, G13, G17), responsible person/escort (G3, G5, G10, G14, G16)

G14 and G16 both recommend that post-operative instructions should include: post-operative risks, pain control and possible postoperative complications together with the aftercare arrangements and emergency contacts.

Other recommendations include: 24-hour contact number, special instructions for post-op transport of children home, limitations of activities, dietary advice, medications, management of possible postoperative bleeding, limiting level of activity/resumption of normal activities, about making legally-binding decisions, driving, or operating machinery.

G14 provides several examples of instructions for patients.

Also see Questions 2.4 (What information should be provided to the patient before sedation and 7.2 (What information should be provided to patients/carers/escorts before and after sedation and in what format).

3. Subgroup considerations

G14 recommends additional, age-appropriate instructions to be given to children and their parents/guardians/care givers and provides examples.

Special consideration is required to ensure that information is appropriate for the patient group (e.g. children, patients with additional support needs).

4. Balance of effects

The consensus is that providing patient information is essential. Most recommend that this is both verbal and written. Consideration should be given to when instructions are provided.

5. Generalisability and applicability

Irrespective of the origin of the guidelines, there is general agreement that it is essential to provide post-operative instructions.

6. Values and preferences

In some instances, the escort taking the patient home may not be the person responsible for supervising the patient for the rest of the day (e.g. when returning a resident to a care facility). Patient & parent scoping interviews carried out by TRiADS (www.triads.org.uk) indicated that in these circumstances it would be preferable to have written escort information that could be passed on the next responsible carer. It was also indicated that escorts would like information about whether the patient should take their prescribed medications as usual.

7. Acceptability

It is likely that most patients would find it helpful to receive the appropriate information about aftercare and that practitioners would find it acceptable to provide post-operative instructions.

8. Feasibility

There should be few practical difficulties in providing aftercare instructions. Provision of examples/templates will assist in ensuring that the instructions provided contain the required information. Consideration should be given to how patient information will be printed in the healthcare setting to ensure that it is compatible with available printers and of a suitably professional quality. Reference to additional information on the internet if desired is a means of limiting the amount of printed material supplied.

9. Other factors

Consideration should be given to what is the appropriate amount and level of patient information i.e. providing sufficient without overburdening the patients/carer.

10. Recommendation for guidance

Summary of group's judgements:

The GDG agreed that advice relating to post-sedation instructions should be presented together with that on monitoring during recovery and on discharge criteria (see Questions 6.1 and 6.2) in one section of the guidance.

Recommendations and clinical advice:

There is general agreement between the guidelines listed for this question and for Questions 2.4 and 7.2. Taking these and the other factors listed into consideration, the GDG agreed that patient, carer and escorts should be provided with written details of escort responsibilities post-operative risks and possible complications, analgesia and aftercare advice and restrictions on post-sedation activities. Contact details for the care provider and out-of-hours emergency contacts should be included. It should be emphasised that the information must be appropriate for the patient, taking into consideration factors such as age and learning ability

The GDG agreed to refer to the examples of patient information provided with the IACSD report (G14) in the first instance, though these are not in a format that sedation practices could easily use without modification.

The key recommendation covering recovery and discharge is discussed in Question 6.1.

The key recommendation covering pre- and post-sedation instructions is discussed in Question 2.4.

11. Additional Information

Records and Documentation (Clinical Questions 7.1-7.3)

<p>Question 7.1: For patients undergoing dental treatment under sedation:</p> <p>what records are required before, during and after treatment under sedation?</p>	<p>Appraisal refs:</p> <p>G1, G3, G5, G6, G8, G10, G13, G14, G15, G16, G17</p>
<p>1. Summary of evidence</p> <p>G1: Patient evaluation, consent, data from monitoring during and after sedation and readiness for discharge should be documented.</p> <p>G3: For minimal and moderate sedation: Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics and monitored physiological parameters. Pulse oximetry and end-tidal CO₂ measurements (if taken), heart rate, respiratory rate and blood pressure must be recorded continually.</p> <p>G5: The clinical record should include the names of staff performing sedation and/or analgesia, with documentation of the history, examination and investigation findings. A written record of the dosages of drugs and the timing of their administration must be kept as a part of the patient's records. Such entries should be made as near to the time of administration of the drugs as possible. This record should also note the regular readings from the monitored variables, including those in the recovery phase, details of any major resuscitation or rescue interventions, complications, etc., and should contain other information as indicated in ANZCA professional document <i>PS06 Recommendations on the Recording of an Episode of Anaesthesia Care</i>.</p> <p>G6: For alternative techniques: Documentation and protocols must comply with contemporary clinical governance standards for the practice of dentistry but the following require additional consideration: assessment and preparation, written valid consent, technical procedure and recovery, written instructions for patient and escort.</p> <p>G8: Informed consent must be obtained from the parent and documented in the patient's record prior to administration of nitrous oxide/oxygen.</p> <p>In addition, the patient's record should include indication for use of nitrous oxide/oxygen inhalation, nitrous oxide dosage (i.e. percent nitrous oxide/oxygen and/or flow rate), duration of the procedure, and post treatment oxygenation procedure.</p> <p>G10: <u>Before sedation:</u> Documentation shall include, but not be limited to: 1. Informed consent. 2. Instructions and information provided to the responsible person.</p> <p><u>At the time of sedation:</u> Health evaluation (see Question 2.1 Preparation for sedation); prescriptions for sedation.</p> <p><u>During treatment:</u> The patient's chart shall contain a time-based record that includes the name, route, site, time, dosage, and patient effect of administered drugs. Before sedation, a "time out" should be performed to confirm the patient's name, procedure to be performed, and site of the procedure. During administration, the inspired concentrations of oxygen and</p>	

inhalation sedation agents and the duration of their administration shall be documented. Before drug administrations, special attention must be paid to calculation of dosage (i.e. mg/kg). The patient's chart shall contain documentation at the time of treatment that the patient's level of consciousness and responsiveness, heart rate, blood pressure, respiratory rate, and oxygen saturation were monitored until the patient attained predetermined discharge criteria (see Appendix A). A variety of sedation scoring systems are available and may aid this process. Adverse events and their treatment shall be documented.

After treatment: The time and condition of the child at discharge from the treatment area or facility shall be documented; this should include documentation that the child's level of consciousness and oxygen saturation in room air have returned to a state that is safe for discharge by recognised criteria. Because some sedation medications are known to have a long half-life and may delay a patient's complete return to baseline or pose the risk of re-sedation, some patients might benefit from a longer period of less-intense observation (e.g. a step-down observation area) before discharge from medical supervision. Several scales to evaluate recovery have been devised and validated. A recently described and simple evaluation tool may be the ability of the infant or child to remain awake for at least 20 minutes when placed in a quiet environment.

G13: The notes must: Include the name and signature of the operator together with the name(s) of the assistants. Contain a clear treatment plan, completed medical history and consent form, appropriate radiographs and briefly give an account of the reason for the need for sedation. Document the operative treatment that was performed, the name of the drug, concentration and batch number (if appropriate), dosage, route and duration of sedation. State which monitors were used (as appropriate) together with their readings. Include a time-based record where appropriate. (*SIGN Grade C, no references cited*)

G14: Advice given on eating and drinking must be recorded in the patient's clinical records. There must be a written contemporaneous record of the monitoring of the patient that is in accordance with the clinical sedation technique used.

Records of the maintenance of equipment must be retained and made available for subsequent formal inspections.

Records of the audit process and outcomes from them must be maintained and be available for inspection.

Sedation teams must maintain high quality full clinical records and a written or electronic clinical log. Each clinical team must maintain continuous and contemporaneous records of the number and types of sedation cases performed as well as the rate of any complications that may have arisen.

G15: Ensure that data from continuous monitoring during sedation are clearly documented in the healthcare record. (*expert opinion*)

G16: Accurate and contemporaneous entries on the clinical records should be kept. It is recommended that the documentation includes: A fully recorded medical history including prescribed and self-prescribed medication [alcohol / tobacco / drugs]; a previous dental history; a previous conscious sedation / general anaesthetic history; the reason for selection of conscious sedation on each occasion that it is planned; a pre-sedation assessment; any individual patient requirements; written instructions provided pre- and post-operatively; the

presence of an accompanying responsible adult; arrangements for suitable post-operative transport and supervision; compliance with the pre-treatment instructions; written consent for conscious sedation; written consent for the planned dental treatment; any changes in the recorded medical history or medication; the treatment procedure: Monitoring, Dose, Dental treatment details; post-sedation assessment and time of discharge home.

G17: It is recommended that the documentation includes: Medical history including prescribed medication, Previous dental history, Previous conscious sedations and general anaesthesia, Indication for the use of conscious sedation, Pre-sedation assessment, Written instructions provided pre- and post-operatively, Presence of an accompanying responsible adult, Arrangements for suitable post-operative transportation and supervision, Compliance with pre-treatment instructions, The course of the treatment [Monitoring, Dose, and route of administration of sedative drugs, Dental treatment performed, Sedation evaluation (sedation scale), Accept of sedation and treatment (behavioural scale), Complications], Post-sedation assessment and time of discharge home.

2. Quality, quantity and consistency of evidence

Eleven guidelines make specific recommendations about what should be documented in clinical records for sedation. These are G3, G5, G6, G8, G10, G14, G16, G17 (low methodological rating), G1, G13 (moderate) and G15 (high). It is likely that this information is based on expert opinion. Although not all of the guidelines cover all aspects, there is reasonable agreement about the inclusion of the following:

Records relating to before sedation:

- medical history, dental history, previous sedation or anaesthesia
- treatment plan
- choice of sedation technique and reason
- any individual patient requirements
- pre-assessment results
- information provided to patient (including advice about eating and drinking before sedation)
- written consent from the patient (or parent, if appropriate) for treatment and sedation
- at the visit for sedation – changes to medical history, confirmation of consent, compliance with instructions including whether escort present (if required) and time of last food/drink

Records relating to during sedation:

- contemporaneous records of monitoring
- sedation drug, route, dose, time of administration, duration
- completion of treatment (i.e. effectiveness of sedation)
- any complications

Records relating to after sedation:

- contemporaneous records of monitoring during recovery
- pre-discharge assessment, time of discharge
- written information provided to patient and escort

Two of the guidelines (G5, G13) also indicated that the sedation staff names should be

<p>included. One (G13) identified that drug batch number should be recorded.</p> <p>Other records recommended by G14 include those for maintenance of equipment, records of the audit process and outcomes, and written or electronic logs for each clinical team (number and types of sedation cases performed, rate of any complications that may have arisen).</p>
<p>3. Subgroup considerations</p> <p>None identified.</p>
<p>4. Balance of effects</p> <p>Record keeping is considered essential.</p>
<p>5. Generalisability and applicability</p> <p>It is unlikely that the information to be recorded would vary significantly between countries.</p>
<p>6. Values and preferences</p> <p>None identified</p>
<p>7. Acceptability</p> <p>No issues about acceptability were identified.</p>
<p>8. Feasibility</p> <p>A possible impact if there is a requirement for contemporaneous recording of monitoring during sedation, is that this could require a third member of staff to be present during sedation. Discussion with IACSD committee members confirmed that recording of monitoring data immediately after treatment would be considered contemporaneous. Therefore, an additional member of staff to specifically record monitoring is not required.</p>
<p>9. Other factors</p>
<p>10. Recommendation for guidance</p> <p>Summary of group’s judgements:</p> <p>As would be expected, there is a lack of reported evidence on what should be recorded, therefore the GDG judgements were based on the records recommended in other expert opinion based guidelines, which generally reflect current professional practice.</p> <p>There is no key recommendation for records and documentation. Specific records are indicated at relevant points within the guidance and a list of required details to be included in patient records, that are consistent with those stated in other guidelines, is included in an appendix.</p> <p>The GDG specifically considered the issue of how often patient monitoring data should be recorded and agreed that it was not helpful to indicate a particular frequency for recording</p>

data, particularly for continuous observations. This will depend on the clinical situation and the guidance should advise that the most important time to record monitoring data is when any significant event occurs.

11. Additional Information

The 2016 update of guideline G10 added that expired carbon dioxide levels should be recorded in the documentation relating to treatment.

<p>Question 7.2: For patients undergoing dental treatment under sedation:</p> <p>what information should be provided to patients/carers/escorts before and after sedation and in what format?</p>	<p>Appraisal refs:</p> <p>G1, G3, G5, G8, G10, G13, G14, G15, G16, G17</p>
<p>1. Summary of evidence</p> <p>G1: Verbal and written instructions should be given after treatment.</p> <p>G3: Pre-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.</p> <p>G5: The proceduralist or other suitable person should provide the patient, or their carer, with written information, where possible, which includes the nature and risks of the procedure, preparation instructions (including the importance of fasting – see ANZCA professional document <i>PS15 Guidelines for the Perioperative Care of Patients Selected for Day Care Surgery</i>), and what to expect during the immediate and longer term recovery period, including after discharge.</p> <p>G8: The practitioner should provide instructions to the parent regarding pre-treatment dietary precautions, if indicated.</p> <p>G10: Before sedation: The practitioner shall provide verbal and/or written instructions to the responsible person. Information shall include objectives of the sedation and anticipated changes in behavior during and after sedation. Special instructions shall be given to the adult responsible for infants and toddlers who will be transported home in a car safety seat regarding the need to carefully observe the child’s head position so as to avoid airway obstruction. Transportation by car safety seat poses a particular risk for infants who have received medications known to have a long half-life, such as chloral hydrate, intramuscular pentobarbital, or phenothiazine.</p> <p>A 24-hour telephone number for the practitioner or his or her associates shall be provided to all patients and their families.</p> <p>Instructions shall include limitations of activities and appropriate dietary precautions.</p> <p>G13: In advance of the procedure, the child and their parent or guardian must be given clear and comprehensive pre- and postoperative instructions in writing. (<i>SIGN Grade C, 1 reference cited</i>)</p> <p>G14: Written information for adult and child patients, those with parental responsibility, carers and escorts must be supplied. This is to be used in conjunction with the clinical pre-operative assessment and face-to-face discussions and explanation. It must include the range of techniques appropriate for both the relief of anxiety and the behaviour management appropriate for the dental treatment needs of the individual.</p> <p>Adult patients will receive written information at the pre-operative visit. For child patients receiving sedation, information in written form for both the child and those with parental responsibility and carers will be supplied at the time of the clinical assessment.</p> <p>Information regarding the sedation technique should contain a description of the sedation procedure that has been suggested and recommended as the most appropriate management technique for the individual patient, including its benefits, risks and</p>	

alternatives. The information must also include relevant contact details of the care provider as well as the out-of-hours contact details for emergency advice and services. Instructions for the pre- and postoperative periods must be suitable for each age group of patients and their escorts and carers. *Further details of patient information for adults and young people and for children are supplied.*

Clear information must be provided that prepares patients for dental treatment under sedation. This information should explain the procedure, the pharmacological process, and the benefits and risks associated with the selected form of sedation. It should be imparted as part of a face-to-face explanation to the patient at the time of clinical preoperative assessment and must then be supported by the provision of written information. Best practice in the process of consent dictates that this information should be provided prior to the day of the procedure. In addition, information must be provided for patient escorts.

Verbal and written instructions for the post-operative period must be provided for both the patient and the responsible adult escort. Examples of the written instructions are provided. They must include the post-operative risks, pain control and possible postoperative complications together with the aftercare arrangements and emergency contacts.

A separate sheet with escort instructions is required. Additional information is specified to be provided for child patients.

G16: Patients during preparation for *Conscious Sedation* must receive careful verbal and written instructions regarding its effects and their responsibilities both before and immediately after it. The patient and escort should be provided with details of postoperative risks, pain control and management of possible complications. Adequate information regarding aftercare arrangements and emergency contact must also be provided.

G17: Pre- and postoperative instructions in writing must be given in advance of the procedure to the child and the parent or guardian.

2. Quality, quantity and consistency of evidence

Ten guidelines of low (G3, G5, G8, G10, G14, G16, G17), moderate (G1, G13) or high (G15) methodological rating provide recommendations about the information that should be provided to patients and/or carers before and/or after sedation. Nine of these indicated which format should be used, stating that written information should be provided. Several specify that the information should be given both verbally and in writing (G1, G3, G10, G14, G15, G16).

The range of information includes:

Before sedation:

- information on the recommended sedation technique e.g. aims and effects of the sedation and what to expect, benefits, risks, alternatives
- fasting instructions
- post-operative instructions (to be provided in advance of treatment)

Also see Question 2.4 (What information should be provided to the patient before sedation).

After sedation:

- post-operative risks, possible postoperative complications and pain relief

- limitations of activity/resumption of normal activities (e.g. driving, operating machinery, decision making)
- contact details and out of hours emergency contacts

Also see Question 6.3 (What aftercare instructions are required).

A number of the guidelines agree that written information should also be provided to the parent, carer or responsible person and to the escort.

G14 provides a comprehensive range of examples of patient information, suitable for different techniques, for adult patients and children and for parents/carers and escorts.

3. Subgroup considerations

Age and ability appropriate information may be required.

Special instructions could be given to the adult responsible for infants and toddlers who will be transported home in a car safety seat regarding the need to carefully observe the child's head position so as to avoid airway obstruction (G10; although particularly referring to drugs with a long half-life). Two adults might be required.

4. Balance of effects

The consensus is that providing patient information is essential. Most recommend that this is both verbal and written. Consideration should be given to when instructions are provided.

5. Generalisability and applicability

There is general agreement from the various guidelines identified, irrespective of where they originated, that it is essential to provide both pre- and post-treatment information to patients.

6. Values and preferences

See Questions 2.4 and 6.3.

7. Acceptability

See Questions 2.4 and 6.3.

8. Feasibility

See Questions 2.4 and 6.3.

9. Other factors

Consideration should be given to what is the appropriate amount and level of patient information i.e. providing sufficient information without overburdening the patient/carers.

Following recommended use of the patient information examples provided in G14 could mean that, for example, an adult patient having intravenous sedation is provided with at least 4 documents.

10. Recommendation for guidance**Summary of group’s judgements:**

For the GDG’s considered judgements on patient information to be provided before and after the sedation appointment, see Questions 2.4 (What information should be provided to the patient before sedation and 6.3 (What aftercare instructions are required).

The GDG acknowledged the comprehensive array of patient information examples provided in the IACSD report (G14), though these are not in a format that sedation practices could easily use without modification. However, given the resources that would be required to produce new versions, the GDG agreed to signpost users to these examples.

The key recommendation covering pre- and post-sedation instructions is discussed in Question 2.4.

11. Additional Information

<p>Question 7.3: For patients undergoing dental treatment under sedation:</p> <p>what additional information is required for child patients?</p>	<p>Appraisal refs: G1, G14, G15, G17</p>
<p>1. Summary of evidence</p> <p>G1: Psychological preparation of patients, especially children and their carers is an important part of preparation for sedation. Certain patient groups will require additional bespoke information, for example children, pregnant and lactating women.</p> <p>G14: For paediatric dentistry, information for those with parental responsibility and carers is also required, together with age appropriate information for the child or older adolescent. <i>Further details of patient information for adults and young people and for children are supplied.</i></p> <p>G15: Ensure that the information is appropriate for the developmental stage of the child or young person and check that the child or young person has understood the information.</p> <p>G17: Pre- and postoperative instructions in writing must be given in advance of the procedure to the child and the parent or guardian.</p>	
<p>2. Quality, quantity and consistency of evidence</p> <p>Several of the guidelines referenced in Questions 2.4, 6.3 and 7.2 are specific to sedation for children, and generic information recommended for patients of any age including children is described in those sections.</p> <p>G14, G17 (low) and G15 (high methodological rating) recommend that information should also be provided in an age appropriate format for children and young people and G14 provides examples. G1 agrees that bespoke information may be required for children.</p>	
<p>3. Subgroup considerations</p> <p>Consideration may have to be given to further subgroups within the child age range i.e. young children. For written instructions, pictures may be required rather than text.</p>	
<p>4. Balance of effects</p> <p>Consideration should be given to whether any information to be provided to a child is likely to cause more concern than reassurance.</p>	
<p>5. Generalisability and applicability</p> <p>Advice about children appropriate information should be generally applicable.</p>	
<p>6. Values and preferences</p> <p>See Question 2.4</p>	
<p>7. Acceptability</p> <p>Parents or carers may wish to be aware of information prior to it being given to children or</p>	

patients with learning disabilities to check its suitability.

8. Feasibility

See Question 2.4

9. Other factors

See Question 2.4

10. Recommendation for guidance

Summary of group's judgements:

See considered judgement tables for Questions 2.4, 6.3 and 7.2 which all relate to patient information and specify that the information should be appropriate for the patient's age and learning ability.

The GDG agreed to refer to the examples of patient information provided with the IACSD report (G14), which includes examples intended for children.

The key recommendation covering pre- and post-sedation instructions is discussed in Question 2.4.

11. Additional Information

Training (Clinical Question 9.1)

<p>Question 9.1: What generic and specific skills and training are required for each member of the team and for each sedation technique?</p>	<p>Appraisal refs: G1, G2, G3, G5, G6, G8, G10, G13, G14, G15, G16, G17</p>
<p>1. Summary of evidence</p> <p>G1: Irrespective of educational background, the competencies required for safe sedation and, crucially, rescue from sedation-related adverse events, must be the same. There must be one standard for all, but the educational requirements and pathways to attain a common standard will vary for different disciplines.</p> <p>It is the responsibility of all disciplines using sedation techniques to ensure that their trainees receive accredited training in the use of these techniques, to a clearly defined national standard.</p> <p>Specific training relevant to children is required.</p> <p>Addressing the training needs requires that the necessary competencies for the safe and appropriate administration of sedation and prompt recognition and treatment of sedation-related complications, be defined and specified within approved postgraduate training curricula. Trainees who will be expected to use conscious sedation techniques within their sphere of practice on obtaining their Certificate of Completion of Training (CCT), must demonstrate acquisition of the necessary competencies at Annual Review of Competency Progression (ARCP), or through an equivalent process. An exemplar core curriculum with required competencies is provided in the guideline appendix.</p> <p>Those continuing to be actively involved in administering sedation must be able to demonstrate continued competency through maintenance of an appropriate level of experience, and ongoing participation in relevant life-long learning/CPD programmes, now necessary for revalidation.</p> <p><u>Life support:</u></p> <p>BLS (RCUK defined) with basic airway manoeuvres for minimal sedation/anxiolysis; ILS (RCUK defined) with competency in the use of basic airway manoeuvres, airway adjuncts, supraglottic devices and bag and mask ventilation for moderate sedation/analgesia (conscious sedation).</p> <p>The management of sedation-related complications and medical emergencies should be regularly rehearsed as a team.</p> <p>G2: Experienced practitioners with a high degree of competency gained through a combination of instruction and experience are assumed to meet the educational criteria described. Guideline aims to provide a consistent measure of acceptable predoctoral and continuing education but is not intended to fit every program into the same rigid educational mold. This is neither possible nor desirable. There must always be room for innovation and improvement.</p> <p>Teaching Administration of Minimal Sedation: General objectives are listed. Inhalation Sedation (Nitrous Oxide/Oxygen) objectives and course content are listed, duration (min 14</p>	

hours + clinical component); Enteral and/or Combination Inhalation-enteral Minimal Sedation objectives and course content, duration (min 16 hours + clinical experiences); details provided of participant evaluation and documentation; faculty; facilities.

Teaching Administration of Moderate Sedation course objectives and content are listed; Enteral moderate sedation course duration (min 24 hours plus management of at least 10 adult case experiences, including 3 live patients + simulations/video); Parenteral moderate sedation course duration (min 60 hours plus management of at least 20 adult cases); details provided of participant evaluation and documentation; faculty; facilities

G3: For all levels of sedation, the practitioner must have the training, skills, drugs and equipment to identify and manage deeper than intended sedation until either assistance arrives (emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complications.

To administer moderate sedation, the dentist must have successfully completed:

- a. A comprehensive training program in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students at the time training was commenced, or
- b. An advanced education program accredited by the ADA Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage moderate sedation commensurate with these guidelines; and
- c. 1) A current certification in Basic Life Support for Healthcare Providers and 2) Either current certification in Advanced Cardiac Life Support (ACLS) or completion of an appropriate dental sedation/anesthesia emergency management course on the same recertification cycle that is required for ACLS.

Administration of moderate sedation by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support for Healthcare Providers.

G5: Non-anaesthetist practitioners wishing to provide low dose analgesia should have received adequate supervised training in the technique to be used. Those medical or dental practitioners wishing to provide procedural sedation and/or analgesia should have received a minimum of three months full time equivalent supervised training in procedural sedation and/or analgesia and anaesthesia or similar approved course. They should participate in a process of in-training and competency assessment. Training should include completion of a crisis resource management simulation centre course.

There are non-anaesthetist medical or dental practitioners who have had many years of experience in procedural sedation and/or analgesia, yet may not have had a period of formal supervised training as described. Such longstanding clinical experience may be deemed equivalent to a formal period of training as described. Credentialing, training and clinical support of such medical or dental practitioners should be achieved by close cooperation with nominated anaesthetists, or for remote or rural practitioners with anaesthetists in a major centre particularly when intravenous or intramuscular sedation is practiced.

Regular certification in cardiopulmonary resuscitation relevant to the clinician's practice, and evidence of relevant continuing professional development, are required for credentialing.

Medical, dental or healthcare facilities are responsible for the safe administration of sedation

within their institutions. This responsibility includes establishing the scope of practice and credentialing of practitioners administering sedation. Institutions must ensure that such practitioners are trained, and that their scope of practice remains valid with relevant ongoing professional development.

G6: Qualification and training requirements for the sedationist should acknowledge differences in educational and training backgrounds.

Essential: Primary registrable dental qualification OR Primary registrable medical qualification; Appropriate knowledge, skills, attitude, behaviour and aptitude in the field of conscious sedation; training in standard sedation techniques; compliance with GMC/GDC CPD recommendations for conscious sedation; compliance with contemporary standards; evidence of training (even for anaesthetists) in specific alternative sedation techniques in an appropriate environment; evidence of annual team training in Immediate Life Support or equivalent.

It is clear that, for a medical graduate, a period of training in anaesthesia would provide much of the requirement. For sedation in another clinical setting (first trimester termination of pregnancy) satisfactory completion of two years' training in anaesthesia has been recommended.

Desirable: postgraduate dental qualifications (e.g.: MFDS/MFGDP, MSc/Dip in sedation); trainer in conscious sedation; postgraduate medical qualifications (e.g.: FRCA).

For entry to training in specific alternative techniques, practitioners must have: documented experience of the relevant intravenous or inhalational standard techniques (at least 100 cases over last 2 years); not less than 4 years post-registration experience in the United Kingdom as a dental or medical practitioner.

Oral and intranasal sedation must only be administered by those: who are trained and experienced in intravenous sedation; who are competent at intravenous cannulation; who are competent in the management of sedation related complications; who have evidence of training in these techniques.

G8: Nitrous oxide/oxygen must be administered only by appropriately licensed individuals, or under the direct supervision thereof, according to state law. The practitioner responsible for the treatment of the patient and/or the administration of analgesic/anticholinergic agents must be trained in the use of such agents and techniques and appropriate emergency response.

Training and certification in basic life support are required for all clinical personnel. These individuals should participate in periodic review of the office's emergency protocol, the emergency drug cart, and simulated exercises to assure proper emergency management response.

G10: The practitioner responsible for the treatment of the patient and/or the administration of drugs for sedation must be competent to use such techniques, to provide the level of monitoring provided in this guideline, and to manage complications of these techniques (ie, to be able to rescue the patient). Because the level of intended sedation may be exceeded, the practitioner must be sufficiently skilled to provide rescue should the child progress to a level of deep sedation. The practitioner must be trained in, and capable of providing, at the minimum, bag-valve-mask ventilation so as to be able to oxygenate a child who develops

airway obstruction or apnea. Training in, and maintenance of, advanced paediatric airway skills is required; regular skills reinforcement is strongly encouraged.

G13: The dental team must undergo appropriate training on a regular basis as determined by competent authorities. It is essential that primary care dentists who sedate children undergo training that is recognized by appropriate authorities and that their clinical skill and knowledge relating to paediatric conscious sedation, including local anaesthesia, behavioural management and the provision of operative dental care for children, is regularly updated. The dental nurse should be appropriately trained in sedation techniques. Attainment of the Certificate in Dental Sedation Nursing (CDSN) from the National Examining Board for Dental Nurses (NEBDN) is encouraged. Specialist paediatric dentists are expected to have acquired the necessary skills and competency for nitrous oxide inhalation conscious sedation, but such individuals are still obliged to update themselves regularly and to adhere to national and regional policy and procedure. (*SIGN Grade C, no references cited*)

G14: All members of the care team must have the relevant knowledge and skills for the technique being used, as defined by their scope of practice and competencies. Clinical skills are underpinned by validated education and training while knowledge and continuing competence must be maintained through appropriate continuing professional development. For revalidation in a sedation technique, a practitioner (all team members) must undergo a minimum of 12 hours of CPD every 5 years that are relevant to the techniques practised.

For all conscious sedation techniques other than inhalation sedation with nitrous oxide/oxygen, competence in cannulation is mandatory

All members of the delivery and care team must have undertaken appropriate validated education and training and demonstrated an acceptable level of competence by means of a robust assessment process. Educational courses intended to provide training in clinical delivery of conscious sedation and to prepare the team for independent practice must be assessed, be externally quality assured and incorporate supervised clinical practice. Syllabuses for education and training of the dental team are described in Appendix 1 of the report and include the ability to perform ILS/PILS and recognise and manage sedation-related complication.

Dental sedation nurses must be trained and experienced in the sedation technique used (NEBDN CDSN or equivalent; CDSN encouraged).

Transition arrangements are described and recommended for experienced practitioners to maintain a service to patients.

It is essential that the team delivering care is able to recognise medical, dental or sedation-related adverse events and manage them appropriately and safely. The dentist is responsible for complications resulting from medical or dental emergencies; sedationist for complications resulting from sedation or medical emergencies; dentist, dental hygienist and therapist, sedationist and dental nurse must be competent in life support. There must be clearly defined roles, rehearsal and evidence of scenario-based team training. The provider of dental care and the provider of the sedation service must be able to maintain life support for a patient until such time as the emergency services are able to attend.

All team members must have the necessary life support skills (ILS/PILS for all sedation techniques).

G15: Healthcare professionals delivering sedation should have knowledge and understanding of and competency in: sedation drug pharmacology and applied physiology; assessment of children and young people; monitoring; recovery care; complications and their immediate management, including paediatric life support.

Healthcare professionals delivering sedation should have practical experience of: effectively delivering the chosen sedation technique and managing complications; observing clinical signs (for example airway patency, breathing rate and depth, pulse, pallor and cyanosis, and depth of sedation); using monitoring equipment.

Ensure that members of the sedation team have the following life support skills: Minimal (including sedation with N₂O/O₂ and conscious sedation in dentistry): all members Basic LS; Moderate: all members Basis plus at least one member Intermediate LS.

Ensure that a healthcare professional trained in delivering anaesthetic agents is available to administer: sevoflurane, propofol, opioids combined with ketamine.

Healthcare professionals delivering sedation should have documented up-to-date evidence of competency including: satisfactory completion of a theoretical training course covering the principles of sedation practice; a comprehensive record of practical experience of sedation techniques (including details of: sedation in children and young people performed under supervision; successful completion of work-based assessments).

Training may be delivered by Trusts, Universities, Royal Colleges or other independent providers but the responsibility for ensuring that healthcare professionals have undergone appropriate training should lie with the local NHS Trust providing sedation services.

Each healthcare professional and their team delivering sedation should ensure they update their knowledge and skills through programmes designed for continuing professional development. (*expert opinion*)

G16: Educational and Training Standards: ALL members of the dental sedation team must have received appropriate supervised theoretical, practical and clinical training before undertaking independent practice. Theory must cover all aspects of this document. Training in use of drug and equipment prior to clinical training; training in management of complications and regularly rehearsed life support techniques.

Clinical Training: Supervised hands-on education, training and experience must be acquired by practitioners administering sedation and by their assistants for EACH Conscious Sedation technique used. This may be provided in a variety of settings. The method and timespan allowed for acquisition of this supervised practice may vary depending upon local and individual circumstances.

Provision of Education and Training: This may be provided in-house and/or in more formal courses. Those arranging such training for their staff have a duty to ensure that the quality of training and trainers is appropriate and that all theoretical and practical training is documented. Peer reviewed assessment should occur at least once a year.

G17: Training of paediatric dentists in sedation should include theoretical training as well as practical training. EAPD Guidelines for postgraduate training in paediatric dentistry should be followed in developing appropriate training programmes in sedation.

Theoretical training should cover all the subjects referred to in the present document.

Practical training should include knowledge of the drugs and equipment used for conscious sedation, and must be completed before the clinical training. Knowledge of management of complications due to conscious sedation is essential. Training and experience should be regularly updated and maintained.

Documented, contemporaneous supervised hands-on experience must be acquired for each conscious sedation technique used. The minimum number of documented supervised cases completed should be no less than those specified by appropriate authorities.

Dental auxiliary personnel assisting during conscious sedation sessions shall also have appropriate but shorter training.

All clinical staff requires theory and practical training in basic life support. Basic life support must conform to contemporary guidelines issued by national authorities and dental associations.

Training can be through informal courses where clinical training is included or in theoretical courses with clinical demonstrations in combinations with clinics where conscious sedation is regularly performed for hands-on supervision. Those arranging such training have a duty to ensure that the quality of training and trainers is appropriate and that all theoretical and practical training is documented.

2. Quality, quantity and consistency of evidence

There is a lack of available evidence about sedation training and the training recommendations made in the various guidelines are necessarily informed by expert opinion.

12 of the guidelines with low (G2, G3, G5, G6, G8, G10, G14, G16, G17), moderate (G1, G13) and high (G15) methodological ratings provided information on sedation training. Points from these have been further summarised below to highlight the recommendations that specify what training they consider appropriate for each sedation technique, sedation team member and patient group and whether they indicate that training should be formal/validated.

Generic skills

As would be expected, all of the guidelines indicate that appropriate training, experience and competency is required for the provision of dental sedation. Staff should have practical experience in the techniques used, in monitoring and in managing complications.

Specific skills

Some of the guidelines (G1, G6, G14, G15) indicate that additional specific training/skills are required e.g. for alternative/advanced techniques and/or paediatric patients. G15 recommends that a healthcare professional trained in delivering anaesthetic agents is available to administer sevoflurane, propofol, opioids combined with ketamine.

Staff specific training

Two of the guidelines provide specific details of requirements for dental sedation nurses (G13, G14). Both indicate that attainment of the NEBDN CSDN certificate (or equivalent; G14) should be encouraged.

Training Curricula

Sedation training curricula and learning objectives have been developed by various expert groups, societies and organisations specialising in dental and/or sedation training. Examples of curricula are also provided with some of the guidelines (G1, G2, G14, G17). Some of the curricula available are specific for particular sedation techniques (basic or advanced), team members (dentist, hygienist/therapist or nurse) or patient group (children, young people and adults). The most recent curricula developed for the UK include:

- The Independent Expert Group on Training Standards for Sedation in Dentistry (IEGTSSD) documents (www.saad.org.uk/documents):
 - A Guide to Maintaining Professional Standards in Conscious Sedation for Dentistry, 2011;
 - Advanced Conscious Sedation Techniques for Adult Dental Patients Training Syllabus, 2011;
 - Advanced Conscious Sedation Techniques for Paediatric Patients Training Syllabus, 2011
- G1: Safe Sedation Practice for Healthcare Procedures, Standards and Guidance, 2013:
 - Exemplar core curriculum for the safe use of conscious sedation
- G14: Standards for Conscious Sedation in the Provision of Dental Care, 2015:
 - Syllabus 1: Dentists: Basic conscious sedation techniques for children, young people and adults
 - Syllabus 2: Dentists: Advanced conscious sedation for young people and adults
 - Syllabus 3: Dentists: Advanced conscious sedation for children
 - Syllabus 4: Dental hygienists and therapists: Inhalation sedation
 - Syllabus 5: Dental nurses: Assisting during conscious sedation

Accepted standard of training/assessment

Five of the guidelines (G1, G3, G5, G13, G14) stipulate that sedation training should be delivered by an approved provider. Others recommend that training should meet criteria described in the guidelines and/or indicate that in-house training would be suitable. The most recent UK guidelines (G1, G14) recommend that externally validated/accredited training should now be required.

CPD

Several of the guidelines (G1, G2, G5, G14, G15, G17) recommend that competency should be maintained through appropriate sedation experience and CPD training, although they do not provide further details. G14 specifies 12 hours of verifiable CPD per 5 years.

Life support training

Most of the guidelines highlight the need for the team members to have life support training and skills and it is accepted that they should be able to recognise and manage complications until emergency services can attend. Several of the guidelines (G1, G3, G6, G8, G10, G14, G15, G17) provide to various extents more specific details on the level of training/skills required for sedation techniques, team members and patient groups.

These are as follows:

Minimal sedation/anxiolysis

G1: RC(UK) defined BLS with basic airway manoeuvres (all patients)

G3: Basic Life Support for Healthcare Providers

G15: Minimal (including sedation with N₂O/O₂ and conscious sedation in dentistry): all members Basic Life Support (children and young people)

Moderate/conscious sedation

G1: RC(UK) defined ILS with basic airway manoeuvres, airway adjuncts, supraglottic devices and bag and mask ventilation (all patients)

G3: Basic Life Support for Healthcare Providers (USA) and Advanced Cardiac Life Support (ACLS) (all patients)

G8: Basic Life Support (USA) training is required for all clinical personnel (nitrous oxide; children)

G10: The practitioner must be trained in, and capable of providing, at the minimum, bag-valve-mask ventilation so as to be able to oxygenate a child who develops airway obstruction or apnea. Training in, and maintenance of, advanced pediatric airway skills is required (USA) (children).

G14: ILS/PILS for all team members (adults/children)

G15: Basis life support (all members) plus at least one member with intermediate life support (children and young people).

G17: Theory and practical training in basic life support for all staff. Basic life support must conform to contemporary guidelines issued by national authorities and dental associations. (children)

Advanced/Alternative techniques

G6: Annual team training in Immediate Life Support or equivalent.

G14: ILS/PILS for all team members (adults/children).

Deep Sedation

G15: Basic life support (all members) plus at least one member with advanced life support (children and young people).

There are inconsistencies between the recommendations in terms of which team members these requirements apply to. It is specified within guideline G14 that RC(UK)PILS is a requirement for all paediatric sedation team members, although it is indicated elsewhere in the document (p8) that the patient needs a member of the team to be PILS trained, suggesting that this would be sufficient. The NICE guidance for sedation of children and young people (G15) also indicates that is sufficient for one member of the team to have more advanced life support training, with the rest of the team having basic life support training.

3. Subgroup considerations

It may be appropriate for different team members to undergo different sedation training i.e. different courses for dentists, dental nurses and dental hygienists/therapists (as is already the case). Training recommendations could refer to courses tailored for different sedation techniques e.g. *SQA Inhalation Sedation for Dental Nurses* and *Intravenous Sedation for*

Dental Nurses courses.

G1 states that 'passing along the sedation continuum from minimal through moderate to deep sedation, and ultimately to general anaesthesia, increasing depression of physiological systems is seen. The likelihood of adverse events increases, which if not managed promptly, and effectively, may progress to poor outcomes. Increasing depth of sedation is, therefore, accompanied by an escalation in the level of competency required to ensure safe sedation practice'. The converse is that lower levels of competency may be appropriate for decreasing depth of sedation e.g. inhalation sedation with nitrous oxide.

4. Balance of effects

Appropriate training is considered essential for patient safety, but there may be a balance between the stringency of training requirements (e.g. the need for external accreditation) and the risk of a negative impact on sedation provision for patients.

5. Generalisability and applicability

Authorities who can accredit training may vary between countries. The content of training courses e.g. for life support may also vary.

6. Values and preferences

Patients have an expectation that their healthcare providers will be properly trained.

7. Acceptability

Validated training is widely acknowledged as valuable to ensure a consistent standard.

8. Feasibility

Concern has been raised about the lack of validated/accredited training course places available for sedation staff and the time it might take to get staff trained if in-house training is not an acceptable route. There could be a substantial impact on the availability of trained staff and therefore on sedation provision.

9. Other factors

Life Support Training:

In response to queries about life support training, IACSD provided further explanation and clarification of this aspect of their report (G14) through personal communication and the FAQ response provided on the Royal College of Surgeons website (www.rcseng.ac.uk/dental-faculties/fds/publications-guidelines/standards-for-conscious-sedation-in-the-provision-of-dental-care-and-accreditation/faq/).

FAQ: *What level of life support training does the sedation team need?*

Practitioners must be able to provide age-appropriate immediate life support as defined by the main elements of the Resuscitation Council (UK) ILS and PILS training programmes. It is not essential to undertake a Resuscitation Council (UK) accredited ILS/PILS course. Alternative courses with equivalent content which are adapted to the needs of dental practice are

acceptable: these might also include the management of common sedation, medical and dental emergencies.

IACSD confirmed that the key elements of life support training required are those to ensure competency in Basic Life Support (BLS), the use of an Automatic External Defibrillator (AED) and the use of airway adjuncts. Importantly the training should be appropriate for the age groups of the patients to be treated and contextualised to the dental setting. There should be an emphasis on regular team training. These requirements are consistent with the Resuscitation Council (UK)'s *Primary Dental Care - Quality Standards for CPR*²⁸

CPD:

IACSD confirmed via another FAQ response that '*CPD and update courses offering only knowledge and skills training do not need external accreditation*'.

Use of equipment for delivering nitrous oxide/oxygen:

Concern has been raised about training relating to the safe use of equipment, particularly for N₂O delivery. The main concerns are about the hygiene of nose-masks etc and the risks to staff of released N₂O. The extent to which these are addressed in existing curricula and/or practice inspections should be considered.

10. Recommendation for guidance

Summary of group's judgements:

As stated above (Section 2), there is a lack of available evidence about sedation training, and so the training recommendations are necessarily informed by expert opinion.

Training Syllabuses

The GDG agreed that the guidance should refer to the dental sedation training syllabuses described in the IACSD report (G14), which are based on the earlier syllabuses developed by sedation specialist bodies IEGTSSD and SAAD.

Training validation

The majority of the GDG members agreed that to ensure that staff are appropriately trained to deliver sedation safely, there should be a requirement for validated training for all dental sedation team members (i.e. dentist/sedationist, sedation nurse, dental hygienist/therapist). Training should be delivered by a recognised training provider (e.g. NES, university, deanery) or IACSD accredited, for quality assurance and be based on the syllabuses in the IACSD report. There was concern raised about the implications of this, particularly for dental nurses. The GDG acknowledged the potential difficulties in accessing accredited training and resulting impact on sedation services and made suggestions for interim arrangements (see below).

It was indicated that the agreed training requirements, which are in line with those stated in the IACSD report, need to be clearly defined in the guidance recommendations to avoid any misunderstanding and should, for clarity, be structured around team members new to sedation and team members already providing sedation.

Maintaining competency

The GDG considered whether guidance on a level of sedation cases required to maintain

competency could be provided (e.g. how many cases of sedation should be carried out a year to remain competent). It was decided that it would be inappropriate to do so because of the variation in individual circumstances (e.g. levels of previous experience, different sedation techniques and patient groups and opportunity for practice).

CPD

The IACSD report recommends 12 hours of sedation related CPD every 5 years and indicates that this should be verifiable (according to existing mechanisms) but does not have to be accredited. This level of CPD is in line with that recommended by the IEGTSSD in *A Guide to Maintaining Professional Standards in Conscious Sedation for Dentistry*, 2011

(www.saad.org.uk/documents/). The GDG agreed that while some stakeholders report difficulty in accessing CPD, this was a reasonable level to recommend.

Professional development courses for managing e.g. difficult children, patients using non-verbal communication etc could be signposted in the guidance. Some aspects are included as learning outcomes in existing training courses (e.g. for nurses).

Team members already practising sedation

The GDG agreed that the guidance should recommend that experienced clinical team members already carrying out sedation could continue to do so without having to complete validated training, although they should comply with the requirements stipulated in the IACSD report (G14, p87):

1. *Sedation practitioners should maintain a log in either written or electronic form of all sedation cases undertaken, with comprehensive details of patient type, baseline vital signs, sedation agent used/route/dose/reversals/untoward incidents etc.*
2. *Sedation practitioners and their clinical teams must undertake the similar, validated* continuing professional development required for those following the pathway of training recommended in this report.*
3. *Sedation practitioners must undertake sedation based audit and reflection frequently and regularly in each location sedation is provided.*
4. *Sedation practitioners and their clinical teams must be competent in the appropriate 'rescue' skills described in this report for the techniques of conscious sedation that are practised.*
5. *Sedation practitioners must meet the requirements for the environment and equipment and the patient pathway checklist described in Section 1: Care pathways.*
6. *Sedation practitioners in primary care should ensure that appropriate clinical governance is in place to comply with the standards set in this report.*

The records for points 1–6 above should be available to those who commission or carry responsibility for NHS provision of conscious sedation for dentistry. These requirements also apply to those practising conscious sedation for dentistry outwith the NHS.

* Note that the use of the term 'validated' here is incorrect and should be replaced with 'verifiable'. CPD does not need external accreditation (see Section 9 above).

These requirements should apply to dental nurses and hygienists/therapists, as well as dentists and other dental sedationists.

Team members new to sedation

All team members new to sedation (including dentists, dental nurses and dental hygienist/therapists) should complete training appropriate to the sedation techniques used, via a validated course including those accredited by IACSD or delivered by a recognised

authority. Providers of in-house training may apply for IACSD accreditation for their programme.

Interim arrangements

According to the IACSD report, April 2015 defines the cut off for those already providing sedation and the start of the requirement for validated training. However, this date has not been accepted by the UK CDOs. In recognition of the difficulties around accessing approved training and clinical supervision, particularly for dental nurses, the GDG suggested that interim arrangements should be recommended. One suggestion was that those providing in-house or other forms of training should be able to continue, as long as the training is in line with the syllabuses described in the IACSD report and an application for IACSD accreditation has been submitted. Another suggestion was to simply have a delay after publication of the guidance before the requirement for validated training come into force. The period of time to which these interim arrangements should apply may be informed by further investigation of the availability of approved training and supervisors. Deaneries or equivalent recognised authorities should be encouraged to help with training provision.

Although the GDG acknowledged that these suggestions might help with difficulties in implementing the training recommendations in the short-term, they agreed that it would not be appropriate to include such interim recommendations in the guidance but they could inform any related implementation plan.

Life Support Training

In light of the further clarification provided by IACSD regarding life support (see Section 9 above), the GDG agreed to make recommendations based on this information. Essentially the requirements should be for life support training that includes basic life support, use of AEDs and airway management, is age-appropriate and suitable for the dental setting and for all team members.

Managing sedation-related complications

After further consideration the GDG agreed that an individual section on the management of sedation-related complications should be included in the guidance. This a key safety issue in the provision of sedation and specific training may not be included as part of life support training. While members of the dental sedation team will have been trained in the recognition and management of sedation-related complications, members of the wider clinical team may not have undergone formal validated sedation training. The recognition and management of sedation-related complications and other emergencies should be a team responsibility and so the whole clinical team should participate in regular scenario-based training. The roles and responsibilities of each team member should be established in advance.

Key recommendation:

The overarching key recommendation for training should indicate that all members of the dental sedation team have the knowledge and skills to safely and effectively deliver the sedation technique used. This should be linked to the details provided in the training sections that follow the recommendation.

Basis for Key Recommendation: Expert opinion

The recommendation reflects the critical importance for patient safety of the correct training

of staff involved in the provision of dental sedation and is consistent with currently advocated professional practice.

Post-consultation revisions:

On reconsideration of the guidance relating to experienced members of the dental sedation team, the GDG agreed that most of the elements described under the 'transitional arrangements' in the IACSD report should apply to all members of the sedation team, including those who were newly trained. Consequently, a new section on maintaining knowledge and skills was added that applies to both staff new to sedation and experienced members of the sedation team. The GDG agreed that this section would include advice on maintaining a log of cases, CPD, audit and reflection and maintaining competence in managing complications.

To highlight the importance of training and practice in the management of sedation related complications, a further key recommendation was added to the training section. The GDG agreed that this recommendation should advise that the clinical team together should be competent in the recognition and management of sedation related complications.

Basis for Key Recommendation: Expert opinion

The recommendation reflects the critical importance for patient safety of training in the management of sedation-related complications, which is consistent with current standard professional practice.

11. Additional Information

During the guidance development period, there were developments relating to the availability of validated training. These included that a significant number of training programmes, including some for 'in-house' training had gained IACSD accreditation. In addition, IACSD made available a scheme for approving clinical supervisors of newly trained providers of sedation who are gaining experience prior to independent practice.

References

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