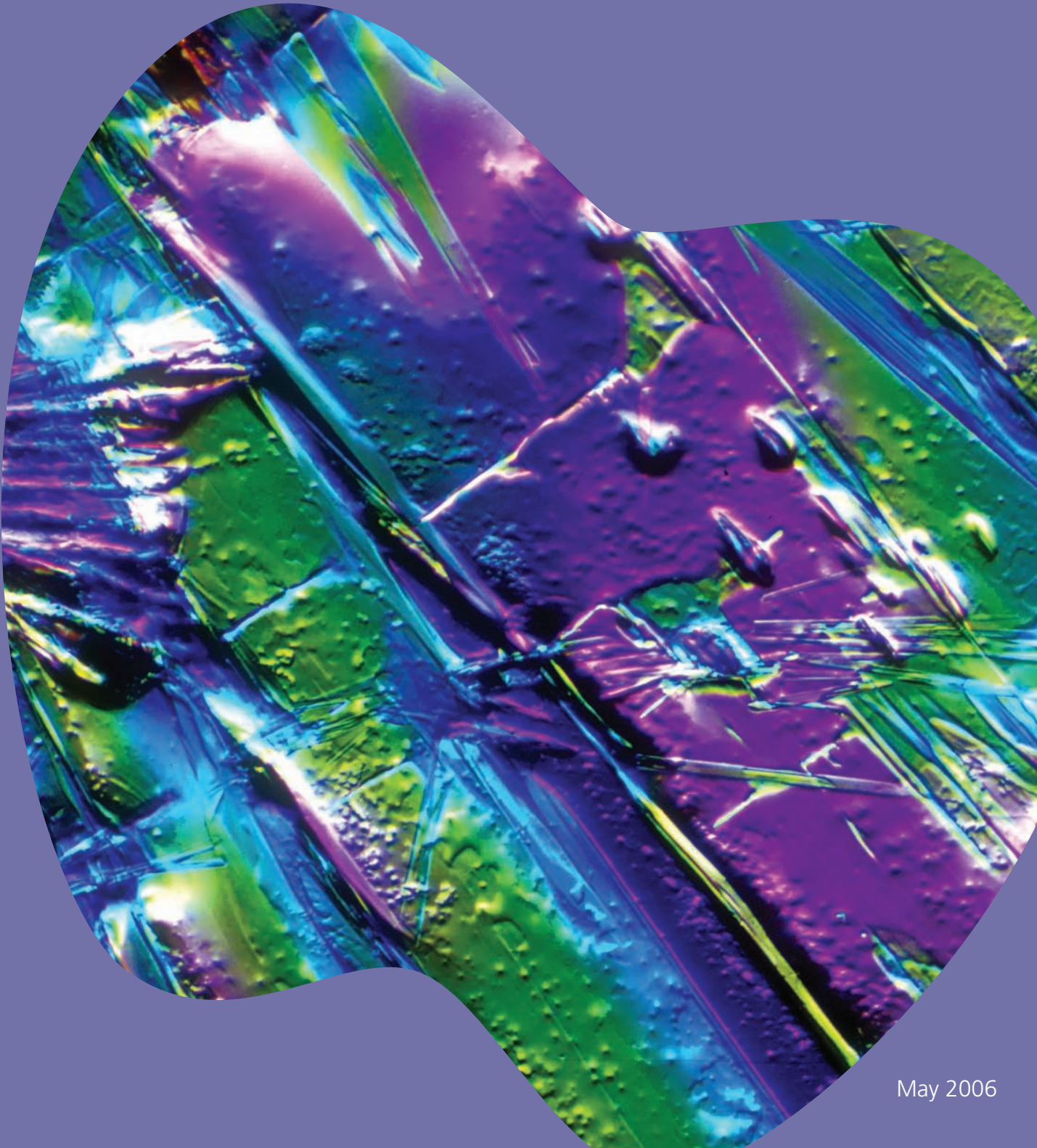


Conscious Sedation in Dentistry

Dental Clinical Guidance



The Scottish Dental Clinical Effectiveness Programme (CEP) is an initiative of the National Dental Advisory Committee (NDAC) and is supported by the Scottish Executive and NHS Education for Scotland. The Programme aims to provide user-friendly, evidence-based guidance for the dental profession in Scotland.

Scottish Dental CEP guidance is designed to help the dental team provide improved care for patients by bringing together, in a structured manner, the best available information that is relevant to priority areas in dentistry, and presenting this information in a form that can be interpreted easily and implemented.

'Supporting the dental team to provide quality patient care'



Conscious Sedation in Dentistry

Dental Clinical Guidance

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Conscious Sedation in Dentistry

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Summary

This summary outlines the areas where recommendations have been made within the guidance. The summary is not comprehensive and for a full appreciation of the recommendations and the basis for making them it is necessary to read all of the guidance. All of the recommendations in the guidance are considered important for the provision of high-quality dental care.

Referral [for full guidance refer to Section 2.1]

- Discuss alternative methods of anxiety management with the patient and ensure that dental care with sedation meets the agreed definition of conscious sedation (given in Section 1.3).

Assessment and Record Keeping [for full guidance refer to Sections 2.1, 2.2, 7]

- As part of a thorough assessment, discuss with the patient all aspects of their treatment using conscious sedation and also provide written instructions.
- Obtain the patient's written consent and maintain comprehensive and contemporaneous patient records.

Environment and Facilities [for full guidance refer to Section 2.3]

- Ensure that the environment for sedation is safe and that the correct equipment and drugs for each sedation technique used are provided.
- Ensure that equipment and drugs for dealing with medical emergencies or complications related to sedation are immediately available.

Training [for full guidance refer to Sections 2.3.4, 3.2, 3.4, 3.5.2, 4, 5, 9]

- Ensure all members of the dental team are correctly trained in the sedation techniques used, including monitoring of the patient during treatment and management of any sedation-related complications.
- For oral and transmucosal sedation, ensure that the sedationist is trained in other titratable techniques and skilled in performing venous cannulation.
- Ensure that the teams providing conscious sedation provide treatment for patient groups they are experienced in managing.

Conscious Sedation Techniques [for full guidance refer to Sections 2.3.3, 3.2, 3.3, 3.4]

- For inhalation sedation, ensure that a titrated dose of nitrous oxide is administered using dedicated purpose-designed equipment.
- Oral, transmucosal and intravenous sedation require pulse oximetry and blood-pressure monitoring.
- A titrated dose of midazolam is recommended for intravenous sedation.

Aftercare [for full guidance refer to Sections 2.2.7, 6]

- Monitor patients throughout the recovery period until they are discharged by the sedationist into the care of a responsible adult escort who has also been given written post-operative instructions. An escort might not be required after nitrous oxide inhalation sedation.

Recommendations and Levels of Evidence





All the recommendations made in this guidance have been developed to assist in clinical decision-making and each recommendation is considered to be important for the provision of high-quality dental care.

The recommendations are based on:

- current legislation and professional regulations;
- consensus of the Guidance Development Group after critical evaluation of the available body of evidence;
- consensus of the Guidance Development Group after considering expert opinion.

The following system for presenting recommendations has been developed for use by the Scottish Dental Clinical Effectiveness Programme. The system is based on proposals of the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) group and existing systems as used by SIGN (Scottish Intercollegiate Guidelines Network) and NICE (National Institute for Health and Clinical Excellence)¹⁻³.

Symbols in the left-hand margin of the guidance represent the basis for the recommendations as described below and not their clinical importance.

Symbol	Basis for Recommendation
	These recommendations are legal or professional regulatory requirements and are therefore considered to be mandatory.
	These recommendations are supported by strong evidence with limited bias (Level 1++/1+/2++/2+)*.
	These recommendations are supported by weak evidence with some potential for bias (Level 2+/- 3)*.
	These recommendations are based on a consensus of expert opinion (Level 4).

* Level 2+ studies are regarded as strong evidence when the study designs are appropriate to address the question being considered. By contrast, level 2+ studies are regarded as weak evidence when they are not the most appropriate design: for example, when evaluating different therapies.

The system we have developed for presenting recommendations has been revised in response to feedback received in the consultation phase of developing this guidance. This system will be kept under review.

Recommendations and Levels of Evidence

Evidence used to support recommendations has been assigned a level according to its quality as detailed below. This scheme was developed by SIGN¹. Levels of evidence are indicated in the right-hand margin of the guidance.

Level of Evidence	Type of Evidence
1++	High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias.
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias.
1–	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias.
2++	High-quality systematic reviews of case–control or cohort studies. High-quality case–control or cohort studies with a very low risk of confounding, bias or chance, and a high probability that the relationship is causal.
2+	Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance, and a moderate probability that the relationship is causal.
2–	Case–control or cohort studies with a high risk of confounding, bias or chance, and a significant risk that the relationship is not causal.
3	Non-analytic studies (e.g. case reports, case series).
4	Expert opinion.

1 Introduction

The provision of adequate anxiety control is an integral part of the practice of dentistry. The General Dental Council has indicated that this is both a right for the patient and a duty placed on the dentist.

All patients deserve appropriate anxiety control for any dental procedure; in order to be appropriate the methods used must be considered for the individual patient having a specific treatment. A 'one size fits all' approach is inappropriate. A range of options is required.

It is important that a wide margin of safety between conscious sedation and the unconscious state provided by general anaesthesia is maintained. In conscious sedation, verbal contact and protective reflexes are maintained, whereas in general anaesthesia these are lost.

The area of conscious sedation has attracted more reports than any other area of the practice of dentistry⁴⁻¹⁰. Many of these reports have relied entirely on expert opinion, whereas others have quoted extensively from evidence obtained from other countries where the definition of sedation is different from that in the UK.

Since 1998 there has been a sea change in the provision of pain and anxiety management in dentistry in the UK. This has resulted in an increased emphasis on the safe provision of conscious sedation instead of a reliance on general anaesthesia that is demand led. General anaesthesia should be provided only in response to clinical need. The publication of '*A Conscious Decision*' in 2000⁶ resulted in the cessation of general anaesthesia for dentistry in the primary care setting. This took effect in April 2001 in Scotland.

The present guidance has been produced by a group of professionals with a particular interest and experience in dental sedation. The group was convened under the auspices of the Scottish Dental Clinical Effectiveness Programme and followed a structured process as described in Section 11 – Guidance Development. The guidance is an evolution of the report by a subgroup of the Standing Dental Advisory Committee (SDAC)^{11†} and extends the advice for dentistry provided in Guideline 58⁹ prepared by the Scottish Intercollegiate Guideline Network (SIGN). We gratefully acknowledge the work of both these organisations. The guidance aims to identify good practice and the level of supporting evidence that informs the recommendations made. The Guidance Development Group has searched for evidence, focussing on areas of contention or evolving practice. In many areas, despite thorough searching, there is not evidence to support the recommendations. In such cases we have indicated this in the document.

The many mandatory recommendations in this document reflect the fact that much of the practice of conscious sedation is dictated by legislation or professional regulations.

† The General Dental Council supports the guidance within the SDAC report '*Conscious Sedation in the Provision of Dental Care*' and expects dental professionals to follow it¹². Therefore, the SDAC report has been regarded as professional regulations when formulating recommendations within this guidance.

1 Introduction

1.1 Remit of the Guidance

This guidance aims to promote good clinical practice through recommendations for the provision of conscious sedation in dentistry that is both safe and effective. It is not a recipe book for sedation and therefore does not include details of drug dosages. Similarly, adequate pain control is an important element of good dental practice but is outside the remit of this guidance.

This guidance is applicable to all patients receiving conscious sedation to facilitate the provision of any type of dental treatment whether it is delivered in a dental practice, in a community dental service clinic or in a hospital setting. It also includes the provision of conscious sedation for dental treatment provided on a domiciliary basis.

Specifically excluded from this guidance are patients who require assisted ventilation, intensive care sedation, premedication for general anaesthesia, post-operative analgesia, sedation in palliative care, night sedation and sedation in the home setting other than for the provision of dental treatment on a domiciliary basis.

1.2 Principles of Good Sedation Practice

Good sedation practice requires practitioners to consider the range of non-pharmacological and pharmacological methods of anxiety management in treatment planning for individual patients.

It is essential that conscious sedation is provided to the highest possible standards, respecting the rights of patients as individuals.

The provision of safe and effective conscious sedation requires both regulation and, more importantly, education of the profession and patients.

1.3 Definition of Conscious Sedation

The following definition is accepted by the National Dental Advisory Committee, General Dental Council, Standing Dental Advisory Committee and the Dental Sedation Teachers Group^{6,8,11,13-15}:

A technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used to provide conscious sedation for dental treatment should carry a margin of safety wide enough to render loss of consciousness unlikely.

1 Introduction

- **It is of fundamental importance that the level of sedation must be such that the patient remains conscious, and is able to both understand and respond to verbal commands.** If a patient is unable to respond to verbal contact when fully conscious, the normal method of communicating with them must be maintained.
- The definition describes the **state** of conscious sedation, and does not attempt to prescribe **how** it is achieved. Specifically, it is acknowledged that a number of techniques involving the use of one or more drugs administered via different routes will fulfil this definition provided that there is an adequate margin of safety.
- Any technique resulting in the loss of consciousness is defined as general anaesthesia, and in the UK 'deep sedation'^{9,16} is considered within this category¹³.

1.4 Statement of Intent

This guidance has resulted from a careful consideration of current legislation, professional regulations, the available evidence and expert opinion. It should be taken into account when making decisions about a particular clinical procedure or treatment plan in discussion with the patient and/or guardian or carer. As guidance, it does not override the individual responsibility of the health professional to make decisions appropriate to the individual patient. However, it is advised that significant departures from this guidance should be fully documented in the patient's case notes at the time the relevant decision is made.

2 Preparation for Sedation

2.1 Responsibilities of the Referring Dentist

Re

Having discussed alternative methods of pain and anxiety management with the patient, referring practitioners must satisfy themselves that the care ultimately offered on referral is *conscious sedation* according to the agreed definition (Section 1.3)¹¹.

4

It is the duty of both the referring practitioner and the dentist providing treatment with sedation to encourage the patient to seek continuing dental care.

2.2 Responsibilities of the Treating Dentist

Re

The dentist providing treatment with sedation should keep the referring practitioner informed of treatment plans and treatment provided.

4

2.2.1 Patient Assessment and Selection

Rm

Patient assessment must be carried out, preferably at a separate visit to the patient's treatment under sedation. Careful and thorough assessment of the patient is necessary to ensure correct decisions are made regarding the planning of treatment¹¹.

4

All relevant anxiety management techniques including, where necessary, general anaesthesia must be explored with the patient to ensure that when conscious sedation is required the most suitable form is selected on each occasion and administered in the correct environment¹¹.

Re

It is not a requirement to fail in a technique before advancing to another technique. Due consideration should be given to a patient's American Society of Anaesthesiologists (ASA) physical status¹⁷ when determining where the sedation is provided¹¹.

2.2.2 History

Rm

A thorough medical, dental and social history must be taken to ensure that the conscious sedation technique chosen is the most appropriate to enable treatment to be carried out for each individual¹¹.

4

2 Preparation for Sedation

2.2.3 Examination and Treatment Planning

Whenever possible an oral examination and treatment planning should be undertaken as part of the assessment.



Recording of blood pressure is part of the assessment process for all patients having intravenous¹¹, oral or transmucosal sedation[‡], unless lack of patient compliance renders pre-sedation measurement impossible.

4

The ASA status must be determined and recorded.

2.2.4 Consent

Consent should follow the principles set out in current guidance¹⁸.



Written consent must be obtained prior to the administration of sedative drugs unless the patient is unable to complete a consent form¹¹.

4

In the case of people aged 16 years and over who are unable to fully understand the nature and implications of the proposed treatment because of mental incapacity, the medical code of practice of '*Adults with Incapacity (Scotland) Act (2000): Part 5*' must be followed¹⁹.

Up-to-date advice may be obtained from your defence organisation.

2.2.5 Pre- and Post-sedation Instructions



In advance of the procedure, patients must receive careful verbal and written instructions regarding the effects of their proposed sedation and their responsibilities both before and immediately after treatment¹¹.

4

Sample pre- and post-operative instructions are provided in Appendix 1.

[‡] As oral and transmucosal sedation may achieve the same target state as intravenous sedation using the same pharmacological agents, the same standards of care apply for all of these techniques.

2 Preparation for Sedation

2.2.6 Fasting

There is insufficient evidence to inform the debate about whether fasting prior to treatment contributes to patient safety for conscious sedation in dentistry.

R_e

Fasting for conscious sedation is not required unless there is a specific indication. Patients should be advised to eat normally on the day of their appointment avoiding alcoholic drinks and large meals.

4

2.2.7 Escort

R_m

A responsible adult escort must accompany the patient home after treatment under conscious sedation and remain with them as a minimum for the rest of the day¹¹.

However, an adult who receives only nitrous oxide/oxygen inhalation sedation does not normally require an escort.

4

2.3 Facilities and Staff

It is anticipated that regular independent inspections of all facilities in Scotland that provide conscious sedation for dentistry will be introduced as part of a quality assurance programme²⁰.

2.3.1 Environment

R_m

Conscious sedation for dentistry must be carried out in an environment that is fit for the purpose. Such an environment should include staff, facilities and equipment that are appropriate to the form(s) of conscious sedation practised. Contemporaneous records of all related operational procedures must be kept, including COSHH assessments, risk assessments and maintenance records and/or agreements²¹⁻²³.

4

2 Preparation for Sedation

2.3.2 Facilities

Treatment and recovery areas must be large enough to enable adequate access for the dental care team¹¹.

R_m

All equipment and drugs recommended for treating medical emergencies and sedation-related complications must be immediately available. The equipment must be in working order and the drugs must be within their expiry date¹¹.

4

The recovery facility may be a dedicated recovery area or the treatment area. It must be equipped to facilitate the management of any sedation-related complication¹¹.

2.3.3 Equipment

Inhalation Sedation with Nitrous Oxide

Dedicated, purpose-designed machines for the administration of inhalation sedation for dentistry must be used. Such machines must conform to current British Standards and be maintained according to manufacturers' guidance with regular, documented servicing¹¹.

R_m

Gas cylinders must be stored safely with regard to current regulations and secured to prevent injury^{11,21}.

4

Scavenging of waste gases must be active and sufficient to fully conform to current COSHH standards^{11,21,22}.

R_e

Pulse oximetry is not routinely required for inhalation sedation.

Intravenous, Oral and Transmucosal Sedation[‡]

All the necessary equipment for the administration of intravenous sedation, including sedation and appropriate antagonist drugs, cannulae and labels, must be available in the treatment area¹¹.

R_m

Calibrated and appropriately maintained equipment is required for all intravenous infusion techniques¹¹.

4

Supplemental oxygen, and the equipment and skills required to deliver supplemental oxygen to the patient, must be immediately available¹¹.

Calibrated and appropriately maintained pulse-oximeter and blood-pressure monitors must be available for use as indicated¹¹.

[‡] As oral and transmucosal sedation may achieve the same target state as intravenous sedation using the same pharmacological agents, the same standards of care apply for all of these techniques.

2 Preparation for Sedation

2.3.4 Staffing

All members of the team providing treatment under conscious sedation must have received appropriate theoretical training (Section 9) as well as supervised practical and clinical training before undertaking independent clinical practice¹⁴.

All members of the dental team must be trained in the management of complications related to conscious sedation in addition to the standard requirement for proficiency in life-support techniques and the management of medical emergencies¹¹.



A dentist who assumes the dual responsibility of sedating the patient as well as providing dental treatment must be assisted by a second appropriately trained person. This person must be present throughout and be capable of monitoring the clinical condition of the patient and assisting the dentist in the event of a complication. The second appropriately trained person may receive their theoretical and practical training in-house if the training is fully documented and of appropriate quality¹¹.

4

Where a second dental or medical practitioner is providing conscious sedation for a patient, the dental team must be capable of assisting the sedationist in the event of a complication¹¹.

A member of sedation-trained staff must supervise the patient until they are fit for discharge¹¹.



Staff should be acutely aware of chaperoning issues with sedated patients. A member of staff must not be alone with a sedated patient at any time.

3 Conscious Sedation Techniques

This section is generally applicable to all patients. Additional guidance for the conscious sedation of children is given in Section 4. Additional guidance for the conscious sedation of adults and children with special needs is given in Section 5.

3.1 Indications for Conscious Sedation

Indications for the use of conscious sedation as an adjunct to patient management include patients with:

- dental anxiety and phobia;
- prolonged or traumatic dental procedures;
- medical conditions potentially aggravated by stress;
- medical conditions affecting the patient's ability to cooperate;
- special needs.

4

3.2 Monitoring

All members of the clinical team must be capable of monitoring the condition of the patient¹¹.

R_m

Monitoring for intravenous¹¹, oral and transmucosal sedation must include the appropriate use of pulse oximetry and blood-pressure monitoring^{11‡}.

During nitrous oxide inhalation sedation, clinical monitoring of the patient without additional electronic devices is generally adequate.

R_e

Additional electromechanical monitoring may be indicated, for example, when treating patients with significant degrees of cardiovascular disease.

4

3.3 Inhalation Sedation

The success of the technique depends on appropriate titration of nitrous oxide to the individual patient's response and is supported by behaviour management techniques. Dedicated inhalation sedation machines will not allow hypoxic levels of sedation.

R_e

The recommended technique for inhalation sedation is the use of a titrated dose of nitrous oxide with oxygen.

4

‡ As oral and transmucosal sedation may achieve the same target state as intravenous sedation using the same pharmacological agents, the same standards of care apply for all of these techniques.

3 Conscious Sedation Techniques

3.4 Intravenous Sedation

Intravenous sedation is commonly achieved by the injection of a single drug. In addition, there are a number of other techniques published in the literature and practised by some healthcare professionals. These include the use of combinations of sedative drugs or intravenous sedative(s) in combination with either inhalation or oral sedation. A range of these techniques have been used successfully within randomised controlled trials to provide conscious sedation of dental patients²⁴⁻³⁸. However, as a result of limitations in the design of many studies comparing sedative regimens and the variety of sedative drugs and the outcome measures used in these studies, it is not possible to make evidence-based recommendations about the choice of these combinations of intravenous sedative techniques.

1—

Similarly, the use of continuous infusions has also been shown to provide conscious sedation in a safe and effective manner in several randomised controlled trials^{31,34,39-53}. Again, there is currently insufficient evidence to recommend the use of any particular intravenous infusion drug regimen.

1—

The success of intravenous sedation is directly related to titration of the dose according to the individual patient's needs and therefore the use of fixed doses or bolus techniques is unacceptable¹¹.

R_e

Intravenous access by way of a cannula should be maintained until discharge.

R_e

The recommended technique for intravenous sedation is the use of a titrated dose of midazolam.

R_m

Sedation using multiple intravenous drugs, intravenous drugs in combination with oral or inhalation sedation, or infusion of short-acting agents might be appropriate in certain circumstances.

It is particularly emphasized that sedation using multiple intravenous drugs, intravenous drugs in combination with oral or inhalation sedation, or infusion of short-acting agents must be restricted to a fully trained and experienced practitioner and team working in an appropriate environment²³.

4

3 Conscious Sedation Techniques

3.5 Oral and Transmucosal Sedation

3.5.1 Oral Premedication

The role of oral premedication is to aid the patient's anxiety management before treatment, and is not as a definitive sedation technique.

Re

Oral premedication with a low dose of benzodiazepine may be prescribed to assist with sleep the night before treatment or to aid an anxious patient's journey under close supervision for treatment.

4

Re

Patients who are to receive oral premedication must receive appropriate pre- and post-operative instructions.

3.5.2 Oral and Transmucosal Sedation

Sedation may be achieved through the oral or transmucosal (e.g. intranasal) administration of a benzodiazepine. The pharmacokinetic characteristics of midazolam make it the preferred choice^{54,55} and in several small randomised controlled trials midazolam delivered orally or intranasally has been found to provide conscious sedation for dental patients that is both safe and effective^{31,56-72}.

1-

These techniques should be used when the titratable techniques (inhalation and intravenous sedation) are deemed to be inappropriate. The state of conscious sedation might be as deep as that produced by the intravenous administration of drugs, but it is approached in a less-controlled manner.

Re

Practitioners who use oral or transmucosal sedation techniques must be trained in the use of the other titratable sedation techniques and be competent in the skill of venous cannulation in addition to being experienced in the sedative technique that is used.

4

Rm

Special procedures must be followed for the off-licence use of agents for oral or transmucosal sedation^{11,73,74}.

4 Conscious Sedation for Children

This section of the guidance must be considered in conjunction with the preceding sections and is generally applicable to children under 16 years of age, of normal physical and mental development.

R_m

Conscious sedation for children must be provided only by those who are trained and experienced in sedating children and where the appropriate equipment and facilities are available¹¹.

R_e

The child's response to their environment and to interventions may vary, influenced by such factors as their degree of cognitive ability and cooperation and the influence of their medical history on the proposed treatment. Corresponding adaptations in treatment protocols may be required: for example, pre-operative recording of physiological data or intra-oral examination may not be possible. In such cases, reasons for deviations from standard practice should be recorded.

4

A recent Cochrane systematic review found evidence for a variety of techniques that have been used successfully to provide conscious sedation for children in a manner that is safe and effective⁷⁵. On the basis of the available evidence, it was not possible to reach a definitive conclusion about which drug or method of conscious sedation is the most effective.

1+

4.1 Inhalation Sedation

R_e

Nitrous oxide/oxygen is usually the technique of choice for conscious sedation of paediatric dental patients¹¹.

4

4.2 Intravenous Sedation

Few randomised controlled trials were found in which intravenous sedation of paediatric dental patients has been reported as a safe and effective technique^{24,76}.

1-

R_m

Intravenous sedation for children must be provided only by those who are trained in these techniques for patients of this age group^{9,11}.

4

R_e

Intravenous sedation for children is appropriate in a minority of cases.

If practical, a topical anaesthetic should be used prior to venous cannulation.

4 Conscious Sedation for Children

4.3 Oral and Transmucosal Sedation

Most of the randomised controlled trials using oral and transmucosal sedation have concerned the sedation of children, and in these studies have been safe and effective^{56-59,62-67,70-72}. These techniques should be used when the titratable techniques (inhalation and intravenous sedation) are deemed to be inappropriate.

1—
4



Oral and transmucosal sedation is appropriate in a minority of cases.

4

5 Conscious Sedation for Adults and Children with Special Needs

This section of the guidance must be considered in conjunction with the preceding sections and is generally applicable to adults and children whose disabilities affect the provision of their dental care.

R_e

Conscious sedation for such patients must be provided only by those who are experienced in sedating people with special needs and where the appropriate equipment and facilities are available.

R_e

The patient's response to their environment and to interventions may vary, influenced by such factors as their degree of cognitive ability and cooperation and the influence of their medical history on the proposed treatment. Corresponding adaptations in treatment protocols may be required: for example, pre-operative recording of physiological data or intra-oral examination may not be possible. In such cases, reasons for deviations from standard practice should be recorded.

4

It can be difficult to judge the level of sedation in patients who are unable to respond well to verbal communication. This is not a reason to deepen the sedation to an unacceptable level.

R_m

In the case of patients who are unable to respond to verbal contact when fully conscious, the normal method of communicating with them must be maintained¹¹.

4

6 Aftercare

6.1 Recovery

Recovery from sedation is a progressive step-down from completion of treatment, through to the patient's discharge into the care of a responsible adult escort.

R_m

A trained member of the dental team must be responsible for and monitor the patient throughout this period, and both equipment and drugs for dealing with sedation complications must be immediately to hand. The sedationist must be available to see the patient urgently in the event of any problems arising^{11,23}.

4

6.2 Discharge

R_e

All patients must be individually assessed for their suitability for discharge and should be allowed to leave only when they have returned to a normal level of responsiveness and orientation for age and mental status and can walk unaided (if appropriate).

R_m

Where a cannula has been inserted, it should be left *in situ* until the patient is assessed as fit for discharge¹¹.

4

The decision to discharge a patient following any type of sedation must be the responsibility of the sedationist¹¹.

6.3 Aftercare Instructions

R_e

The patient and escort should be provided with written details of post-operative risks, pain control and management of possible complications. Information regarding aftercare arrangements and emergency contacts must also be provided.

4

Sample pre- and post-operative instructions are provided in Appendix 1.

7 Records and Documentation

For each patient, a detailed record of the pre-sedation assessment, the visit for conscious sedation, the treatment procedure and the recovery should be kept.



Comprehensive and contemporaneous clinical records must be maintained for every patient and provide evidence to support the formal consent process¹².

4

Further details of the information that should be recorded are given in Appendix 2.

8 Clinical Governance

It is a requirement of clinical governance and fundamental good practice that all clinicians work to monitor and constantly strive to improve the quality of care they and their teams provide to patients.

Re

Those involved in sedation practice should seek to regularly audit their practice. There should be a system of local protocols for the care and management of complications. There should be a positive environment of training for the whole dental team. Clinical governance and audit procedures should include all patient groups being managed by the dental team. All sedation practices should carry out adverse-event analysis.

4

Re

All facilities that provide conscious sedation for dentistry should undergo regular independent inspections as part of a quality assurance programme²³.

4

9 Training in Conscious Sedation for the Dental Team

9.1 Sedation Training for Dentists

9.1.1 Intravenous Midazolam and Inhaled Nitrous Oxide

The standards for training in conscious sedation can be found in *'Training in Conscious Sedation for Dentistry'*¹⁴. This document details the training required for a dentist to practise intravenous sedation with midazolam and inhalation sedation with nitrous oxide/oxygen. The training includes supervised clinical practice in the techniques.

4



All those who provide sedation using these techniques must be trained in accordance with these standards.

9.1.2 Training for Other Techniques

The training of sedationists to use techniques other than intravenous administration of midazolam and inhalation using nitrous oxide is less well established.

Oral and Intranasal Sedation

The recommendations of the Dental Sedation Teachers Group (DSTG) state *'that the use of oral and intranasal sedation techniques by practitioners who are already competent in intravenous sedation requires very little additional training'*¹⁴. Although that training has not been detailed, it must include supervised clinical practice.

Other Techniques

Postgraduate courses will vary in the range of conscious sedation techniques covered. Any course should include revision of the core sedation curriculum in addition to covering any additional pharmacology and clinical techniques.

Supervised clinical practice involving the whole dental team is an integral part of all training in conscious sedation. Such supervised practice should be assessed by those providing the course or appropriately trained and experienced assessors.

9.2 Sedation Training for Other Sedationists



Any professional providing conscious sedation for dentistry should be trained to the same standards as dental practitioners who provide conscious sedation for dentistry. The professional background of the sedationist cannot be used as a reason to avoid training.

4

9 Training in Conscious Sedation for the Dental Team

9.3 Sedation Training for Dental Care Professionals

9.3.1 Dental Nurses

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Dental nurses who assist with conscious sedation for dentistry should be trained to the standards of the Certificate on Dental Sedation Nursing as awarded by the National Examining Board for Dental Nurses¹¹.

The holding of the certificate is the ideal, but a dental nurse may be an appropriate assistant provided she/he has undergone a course of training that covers the syllabus.

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9.3.2 Dental Hygienists and Therapists

Dental hygienists and therapists may provide treatment for sedated patients provided that they have undergone adequate training, including supervised clinical practice.

R_m

The General Dental Council's guidance on the presence of other members of the dental team must be followed⁷⁷.

9.4 Continuing Professional Development

Evidence of active participation in continuing professional development (CPD) is a statutory requirement for all registered dentists⁷⁸. It will shortly be a requirement for all dental care professionals (DCPs).

R_e

For those involved in sedation, part of their annual CPD should relate to this aspect of their practice and should include all of the patient groups that they manage.

4

10 Recommendations for Future Research

In a recent systematic review of paediatric dental sedation, the authors found that the overall quality of studies was disappointing, with poor reporting frequently the main problem⁷⁵. In addition, the variety of drug regimens compared and outcome measures used within the included studies made it impossible to aggregate the data reported or to conduct a meta-analysis. Consequently, these authors were unable to reach a definitive conclusion about the most effective sedation method for anxious children. They made detailed recommendations for future studies assessing sedative agents.

Similarly, we found that the vast majority of publications concerned with conscious sedation in dentistry were not reported well enough to enable a reliable judgement to be made about how the trials had been conducted and the validity of their results. Future reporting of clinical trials should adhere to the CONSORT (Consolidated Standards of Reporting Trials) statement⁷⁹. Moreover, consideration of these recommendations at the outset may also improve trial design.

There are several factors specifically related to the investigation of conscious sedation that should be clearly stated in the reports of all studies, including:

- Details of the sample and how the sample size was determined.
- A precise description of the sedative procedure, including the use of supplementary nitrous oxide inhalation sedation.
- Whether physical intervention was used, because some methods are not acceptable practice in the UK.
- Whether conscious sedation or deep sedation was employed, because deep sedation is not permitted in the UK.
- An account of all adverse effects. Even if none was observed, this should be stated.

Clinical sedation techniques require to be research led. Evaluation of the literature illustrates that a range of techniques have been applied successfully for the sedation of dental patients. However, there is a need for high-quality randomised controlled trials carried out within an appropriate governance framework to improve the evidence base in the following areas:

- Fasting before conscious sedation.
- Conscious sedation of paediatric dental patients.
- Dental conscious sedation using combinations of drugs.
- Dental conscious sedation using continuous infusion.
- The choice of sedation method for dental patients.
- Cognitive and behavioural effects of conscious sedation.
- The interaction of pharmacological and non-pharmacological anxiety management techniques.

11 Guidance Development

11.1 The National Dental Advisory Committee and the Scottish Dental Clinical Effectiveness Programme

The National Dental Advisory Committee (NDAC) comprises representatives of all branches of the dental profession and acts in an advisory capacity to the Chief Dental Officer. It considers issues that are of national importance in Scottish dentistry and also provides feedback to other bodies within the Scottish Executive on related, relevant healthcare matters. Periodically, sub-groups of the NDAC have produced publications, including *'Emergency Dental Drugs'*, *'Clinical Governance in Dental Primary Care'* and *'Dental Practice Advisors in Scotland'*.

To give a structured approach to providing clinical guidance for the dental profession, the Scottish Dental Clinical Effectiveness Programme (CEP) was established in 2004 under the direction of the NDAC. The aim of this initiative is to provide user-friendly, evidence-based guidance in priority areas for dental healthcare in Scotland. Scottish Dental CEP guidance is designed to assist the dental team and to improve patient care by presenting advice and recommendations that are based on the best available information, thereby facilitating evidence-based practice and assisting in compliance with the ever-changing regulatory framework of healthcare provision.

Most practitioners will be familiar with the term 'clinical guidelines' defined as *'systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances'*⁸⁰. Several organisations are devoted to developing high-quality clinical guidelines in the UK, notably SIGN and NICE. These organisations consider topics from throughout medicine and use development processes structured towards thoroughly evaluating a wealth of evidence to inform their recommendations. The Scottish Dental CEP, with its focus on pressing issues within dentistry, should complement the work of these organisations.

Within the Scottish Dental CEP, the term 'clinical guidance' is used. This is for several reasons. Firstly, it is recognised that currently within many areas of dentistry there is a lack of the type of high-quality scientific evidence that usually informs the recommendations within conventional clinical guidelines. Despite this, there is some research evidence and a wealth of expertise and specialist knowledge within dentistry upon which to draw in order to make recommendations. Secondly, in some areas, there exists documentation including legislation, policies and guidelines that are not in a readily accessible format. A key aim of the Programme is to evaluate this type of information and to translate it into a form that members of the dental profession will find useful. Finally, the term clinical guidance reflects the fact that the guidance currently under development within the Programme takes a variety of forms, including not only clinical guidelines but also patient care pathways and a manual to support the running of primary dental practices.

The methodology used to develop Scottish Dental CEP guidance mirrors that used to develop high-quality guidelines. It aims to be transparent and systematic and to adhere as far as possible to international standards set out by the Appraisal of Guidelines Research and Evaluation (AGREE) Collaboration (www.agreecollaboration.org/).

11 Guidance Development

11.2 The Guidance Development Group

The Guidance Development Group comprised individuals from all branches of the dental profession that have a role in dental sedation.

Dr Nigel Robb (Chairman)	Senior Lecturer in Sedation in Relation to Dentistry and Honorary Consultant in Restorative Dentistry, University of Glasgow Dental School
Mr Barry Corkey	Senior Community Dentist and Specialist in Paediatric Dentistry, Community Dental Service, Fife
Dr Tom Cripps	Consultant Anaesthetist and Associate Medical Director (Clinical Governance), Borders General Hospital, Melrose
Dr Chris Deery	Consultant in Paediatric Dentistry, Edinburgh Dental Institute
Dr Jason Leitch	Clinical Lecturer in Sedation and Oral Surgery, University of Glasgow Dental School
Mrs Karin Laidlaw	Senior Community Dental Nurse, Special Care and Sedation, Lothian Salaried Primary Care Dental Service
Mrs Avril Macpherson	Senior Community Dentist, Special Care and Sedation, Lothian Salaried Primary Care Dental Service
Mr Harry Robertson	General Dental Practitioner with a special interest in pain and anxiety management, Paisley

Declarations of interests were made by all members of the Guidance Development Group and recorded. Details are available on request.

11 Guidance Development

Members of the Guidance Development Group serve on the following committees:

Association of Dental Anaesthetists

Council of the Society for the Advancement of Anaesthesia and Dentistry (SAAD)

Dental Anaesthesiology Research Group of the International Association for Dental Research

Dental Sedation Teachers Group (DSTG)

European Federation for the Advancement of Anaesthesia in Dentistry

National Examining Board of Dental Nurses

The General Dental Council – Fitness to Practise Panel

The National Dental Advisory Committee (NDAC)

The Standing Dental Advisory Committee (SDAC)

Members of the Guidance Development Group have also been involved in the development of the following:

A Conscious Decision, Department of Health

Advanced Sedation Techniques, DSTG

Emergency Dental Drugs, NDAC

Implementing and Ensuring Safe Sedation Practice for Healthcare Procedures in Adults,
The UK Academy of Medical Royal Colleges and Their Faculties

Sedation in Dentistry, DSTG

Standards in Conscious Sedation for Dentistry, SAAD

The Competent Graduate, DSTG

The Scottish Dental Clinical Effectiveness Programme is funded by the Scottish Executive Health Department and is a collaboration with NHS Education for Scotland. The views and interests of these organisations have not influenced the recommendations within this guidance document.

11 Guidance Development

11.3 Guidance Development Methodology

The guiding principle for developing guidance within the Scottish Dental Clinical Effectiveness Programme is to first source existing guidelines, policy documents, legislation or other recommendations. Similarly, relevant systematic reviews are also initially identified. These documents are appraised for their quality of development, evidence base and applicability to the remit of the guidance under development. Where appropriate, to supplement this information, key questions are formulated by the Guidance Development Group and these are used as the basis for designing systematic literature database search strategies to identify further research evidence that may address these questions, using unpublished work where relevant.

The following internet sites were searched for guidelines related to sedation in dentistry: The New Zealand Guidelines Group, The Canadian Collaboration on Clinical Practice Guidelines in Dentistry, The National Guidelines Clearinghouse, the FDI World Dental Federation and the National Electronic Library for Health Guideline Finder. A Medline search for guidelines was also conducted. Systematic reviews within the Cochrane Library were identified.

To address key questions, systematic searches of Medline, Embase and the Cochrane Library were conducted and the results combined. The results of these searches were supplemented by material known to members of the Guidance Development Group. The titles and abstracts of the identified references were screened for relevance independently by two researchers who were not members of the Guidance Development Group. Disagreement about the inclusion of specific individual references for further consideration was resolved by discussion and if necessary the opinion of a third researcher was sought.

Included references were appraised and data abstracted independently by two researchers using a specifically designed data abstraction form. This information was then checked for inconsistencies, which were resolved by discussion, and used to construct evidence tables. The evidence tables were presented to the Guidance Development Group to inform their decision-making and their recommendations related to the key question under consideration.

Levels of evidence were assigned by two researchers who were not members of the Guidance Development Group. Formulation of each recommendation was achieved by consensus reached through discussion, drawing on the broad range of interest and experience of sedation related to dentistry within the membership of the Guidance Development Group.

Consultation and peer review were conducted prior to publication. A draft of the guidance was the subject of discussion at the Dental Sedation Teachers Group annual symposium in April 2004. Subsequently, approximately one hundred copies were distributed throughout the UK to a range of professional organisations and individuals with an interest in dental sedation, and comments requested. In addition, all dentists in Scotland who recently claimed NHS allowance for treatment with sedation were invited to comment. The consultation draft was also made available on our website: www.scottishdental.org/cep. All comments received through this consultation were considered and the guidance amended accordingly prior to peer review. Further amendments were made in response to comments from peer reviewers before publication.

11 Guidance Development

An assessment of the potential impact of this guidance on equality target groups has been conducted⁸¹.

Further information about the methodology used to develop this guidance is available on our website: www.scottishdental.org/cep.

11.4 Review and Updating

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

11 Guidance Development

11.5 Steering Group

A Steering Group oversees all the activities of the Scottish Dental Clinical Effectiveness Programme and includes representatives of each Guidance Development Group and the Dental Institutions in Scotland.

Prof. Jeremy Bagg (Chairman)	Chairman of the National Dental Advisory Committee; Head of Glasgow Dental School, University of Glasgow
Dr Jan Clarkson	Director, Scottish Dental Clinical Effectiveness Programme; Programme Director, Dental Health Services Research Unit, University of Dundee
Mr Graham Ball	Consultant in Dental Public Health, Fife
Dr Dafydd Evans	Senior Lecturer and Consultant in Paediatric Dentistry, Dundee Dental Hospital and School, University of Dundee
Mrs Mary McCann	Deputy Chief Dental Officer
Prof. Nigel Pitts	Director, Dental Health Services Research Unit, University of Dundee
Mr Derek Richards	Specialist Advisor to the Programme Development Team; Consultant in Dental Public Health, Forth Valley; Director of the Centre for Evidence-Based Dentistry, Oxford
Dr Nigel Robb	Senior Lecturer in Sedation in Relation to Dentistry, University of Glasgow Dental School
Miss Alice Miller	General Dental Practitioner, Duns, Borders
Mr Alan Whittet	General Dental Practitioner, Longniddry, Lothian
Prof. David Wray	Professor of Oral Medicine, University of Glasgow Dental School
Prof. Richard Ibbetson	Director, Edinburgh Postgraduate Dental Institute, University of Edinburgh
Prof. William Saunders	Dean of the Dental School, University of Dundee

11.6 Programme Development Team

The Programme Development Team provides project management and administrative support and is responsible for the methodology of guidance development, literature and information searching, retrieval and appraisal.

Dr Douglas Stirling	Research Manager
Dr Gillian MacKenzie	Researcher
Mrs Linda Young	Researcher
Mrs Jill Farnham	Administrator
Miss Emma Hart	Administrator

Appendix 1

Sample Pre- and Post-operative Instructions for Patients Requiring Dental Treatment Under Conscious Sedation

Note that arrangements should be in place to make instructions available to all patients, including those who are unable to understand English. This may include providing instructions in other languages or allowing additional time to discuss treatment with the patient and/or carer.

Intravenous, Oral and Transmucosal Sedation

- Patients should eat normally on the day of their appointment and must avoid alcoholic drinks.
- Patients should take routine medication as normal unless advised not to by the treating dentist or anaesthetist.
- A responsible adult escort must accompany the patient to their appointment and escort them home after treatment under conscious sedation. Arrangements must be made to ensure the patient is supervised for a minimum of the rest of the day. It is essential that the escort gives attention to the patient and therefore should not be responsible for children, elderly and/or dependent relatives.
- Wherever possible there should be arrangements in place for the patient and escort to travel home by private car or taxi rather than public transport. If this is impossible, the escort must be made fully aware of the added responsibilities of caring for the patient during the journey home. If either the patient or the escort appears to be unwilling or unable to comply with these requirements conscious sedation should not be administered.
- Sensible clothing is advised, avoiding tight sleeves and high-heeled shoes.
- For the remainder of the day, patients must not:
 - return to work;
 - drive a car or other vehicle;
 - consume alcohol;
 - operate machinery (including kitchen equipment);
 - climb heights (e.g. ladders, scaffolding);
 - be in charge of other people;
 - make important decisions (e.g. signing legal documents).
- Patients who are trying to conceive, are pregnant or are breast-feeding must inform their dentist in advance of their appointment.

If you have any concerns after you have left the dental surgery, please do not hesitate to contact the dental practice on (insert telephone number).

Appendix 1

Sample Pre- and Post-operative Instructions for Patients Requiring Dental Treatment Under Conscious Sedation

Nitrous Oxide/Oxygen Inhalation Sedation

- Patients should eat normally on the day of their appointment avoiding alcoholic drinks.
- Routine medication should be taken as normal.
- Children must be accompanied to their appointments by a responsible parent or guardian who is able to give consent. Adults should be accompanied to their first appointment by a responsible adult escort but may be permitted to attend subsequent appointments unaccompanied at the discretion of the treating dentist.
- Unaccompanied adult patients who have received nitrous oxide/oxygen inhalation sedation must adopt caution before driving, operating machinery or signing legal documents and may be asked to remain in the clinic for up to 30 minutes after treatment is complete.
- Sensible clothing is advised, avoiding tight sleeves and high-heeled shoes.
- Patients who are trying to conceive or who are pregnant must inform their dentist in advance of their appointment.

If you have any concerns after you have left the dental surgery, please do not hesitate to contact the dental practice on (insert telephone number).

Appendix 2

Patient Records and Documentation

It is recommended that the documentation for each patient includes details of:

The Pre-sedation Assessment

- A fully recorded medical history.
- Blood pressure.
- Weight, if recorded.
- ASA status.
- A dental history.
- A conscious sedation and general anaesthetic history.
- Dental treatment plan.
- The selected conscious sedation technique.
- Any individual patient requirements.
- Provision of pre- and post-operative written instructions provided before treatment.
- Written consent for conscious sedation and dental treatment.

The Visit for Dental Treatment Under Conscious Sedation

- The presence of an accompanying responsible adult escort (if required).
- Arrangements for suitable post-operative transport and supervision (if required).
- Compliance with the pre-treatment instructions.
- Presence of written consent for the procedure.
- Any changes in the recorded medical history or medication.

The Treatment Procedure

- Dose, route and time(s) of administration of drugs.
- Comprehensive details of clinical and electromechanical monitoring.
- Personnel present in surgery.
- Patient reaction and success of sedation.
- Dental treatment provided.

Recovery

- Monitoring – appropriate details of all observations and measurements throughout.
- Pre-discharge assessment by sedationist – appropriate discharge criteria met.
- Written post-operative instructions given and explained to patient and escort.
- Time of discharge.

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Conscious Sedation in Dentistry – Summary

This summary outlines the areas where recommendations have been made within the guidance. The summary is not comprehensive and for a full appreciation of the recommendations and the basis for making them it is necessary to read all of the guidance. All of the recommendations in the guidance are considered important for the provision of high-quality dental care.

Referral [for full guidance refer to Section 2.1]

- Discuss alternative methods of anxiety management with the patient and ensure that dental care with sedation meets the agreed definition of conscious sedation (given in Section 1.3).

Assessment and Record Keeping [for full guidance refer to Sections 2.1, 2.2, 7]

- As part of a thorough assessment, discuss with the patient all aspects of their treatment using conscious sedation and also provide written instructions.
- Obtain the patient's written consent and maintain comprehensive and contemporaneous patient records.

Environment and Facilities [for full guidance refer to Section 2.3]

- Ensure that the environment for sedation is safe and that the correct equipment and drugs for each sedation technique used are provided.
- Ensure that equipment and drugs for dealing with medical emergencies or complications related to sedation are immediately available.

Training [for full guidance refer to Sections 2.3.4, 3.2, 3.4, 3.5.2, 4, 5, 9]

- Ensure all members of the dental team are correctly trained in the sedation techniques used, including monitoring of the patient during treatment and management of any sedation-related complications.
- For oral and transmucosal sedation, ensure that the sedationist is trained in other titratable techniques and skilled in performing venous cannulation.
- Ensure that the teams providing conscious sedation provide treatment for patient groups they are experienced in managing.

Conscious Sedation Techniques [for full guidance refer to Sections 2.3.3, 3.2, 3.3, 3.4]

- For inhalation sedation, ensure that a titrated dose of nitrous oxide is administered using dedicated purpose-designed equipment.
- Oral, transmucosal and intravenous sedation require pulse oximetry and blood-pressure monitoring.
- A titrated dose of midazolam is recommended for intravenous sedation.

Aftercare [for full guidance refer to Sections 2.2.7, 6]

- Monitor patients throughout the recovery period until they are discharged by the sedationist into the care of a responsible adult escort who has also been given written post-operative instructions. An escort might not be required after nitrous oxide inhalation sedation.



The Scottish Dental Clinical Effectiveness Programme (CEP) is an initiative of the National Dental Advisory Committee (NDAC) and is supported by the Scottish Executive and NHS Education for Scotland. The Programme aims to provide user-friendly, evidence-based guidance for the dental profession in Scotland.

Scottish Dental CEP guidance is designed to help the dental team provide improved care for patients by bringing together, in a structured manner, the best available information that is relevant to priority areas in dentistry, and presenting this information in a form that can be interpreted easily and implemented.

Conscious Sedation in Dentistry is the first of several guidance initiatives of the Scottish Dental CEP. Other initiatives include clinical guidance in areas such as decontamination, patient care pathways and drug prescribing, and will facilitate evidence-based practice and assist in compliance with the ever-changing regulatory framework of healthcare provision.

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