

## Lecture notes - Medico-Legal Aspects of Conscious Sedation

### ***Why We Need Guidelines***

Sedation techniques make many unpleasant healthcare procedures more acceptable to patients. But any drug which depresses the CNS has the potential to impair respiration, circulation or both and therefore have the potential to cause life threatening complications

Academy of Medical Royal Colleges 2001

### ***Why We Need Guidelines***

They give us advise to prevent unwanted complications.

To ensure the various techniques utilised continue to have a high level of safety and effectiveness

Ensure the highest possible standards for our patients – as patients rightly expect

Guide research and clinical governance

### ***The conscious sedation reports/guidelines :-***

#### ***General Dental Council - Nov 1998***

GDC take on board advise from specialist societies and Royal Colleges

They endorsed the need for Conscious sedation provision rather than GA as a demand led service

Nov 1998 GDC amended their ethical guidance on the standards re GA.

#### ***A CONSCIOUS DECISION - DEPARTMENT OF HEALTH - July 2000***

This document is a review of the use of general anaesthesia and conscious sedation in primary dental care.

It was a report by a group of people chaired by the Chief Medical and Dental Officers

The whole of dental profession had representation on the group

This was the start of removing GA from General Dental Practice and non hospital settings.

#### ***CONSCIOUS SEDATION Sept. 2001***

A referral guide for dental practitioners.

Produced by the Society for the Advancement of Anaesthesia in Dentistry and Dental Sedation Teachers Group.

Definition

Range of techniques

Reason for sedation

Reason for anxiety

Age

Medical History

Attitudes – Dental History

Social background

Treatment required

Responsibilities of referring Dentist

#### ***STANDARDS IN CONSCIOUS SEDATION FOR DENTISTRY – DOH HEALTH – Oct 2000***

##### **Main aim:-**

To ensure that general anaesthesia and conscious sedation are provided to the same professional standards wherever they are performed throughout the UK.

Contents

Education and training standards -

Consent



Environment for Sedation  
Equipment for IHS  
Equipment for IHS  
Patient Assessment  
Preparation of patient for CS

Records and documentation  
Aftercare  
Conscious sedation techniques  
Conscious Sedation for Children  
Complications

### ***CONSCIOUS SEDATION IN THE Provision of Dental Care - 2003***

Report of an Expert Group for Dentistry - Standing Dental Advisory Committee

Department of Health 2003

A Conscious Decision, the report of an expert group, chaired by the Chief Medical Officer and Chief Dental Officer, was published in 2000. This built on the recommendations of a number of previous working groups which emphasised that GA for dental treatment should only be used when there is no other method of pain and anxiety management appropriate for that patient. That report recommended that when a GA is considered necessary it should be provided in the safest way possible. This led to GA for dentistry being confined to a hospital setting where there is the immediate availability of a critical care facility.

The publication of "A Conscious Decision" resulted in a considerable reduction in the number of GA's being undertaken and a growing use of conscious sedation in both primary care and hospital settings. It is essential that where conscious sedation is carried out it is provided to the highest possible standards. Recognising the need for clarity about the appropriate standards for conscious sedation the Standing Dental Advisory Committee established an expert group to make recommendations on good practice. "Conscious Sedation in the Provision of Dental Care – 2003" - provides recommendations for all practitioners providing conscious sedation whether in primary care or in hospitals.

[www.advisorybodies.doh.gov.uk/sdac/conscious\\_sedationdec03](http://www.advisorybodies.doh.gov.uk/sdac/conscious_sedationdec03).

### ***STANDARDS IN CONSCIOUS SEDATION FOR DENTISTRY - 2003***

- Referring dentist and the sedationist must consider all pain and anxiety control options with patient
- Reason and justification for sedation
- Relevant dental history
- Med His
- Treatment required
- Single episode or full treatment
- Training and education – CPD
- Environment

### ***SCEP CONSCIOUS SEDATION IN DENTISTRY DENTAL CLINICAL GUIDANCE 2006, 2012 & 2017***

A Scottish Doc - Guidance on standards in relation to Conscious Sedation

Recommendations made in this guidance was developed assist in clinical decision making and each recommendation is considered to be important for the provision of high quality dental care

### ***STANDARDS FOR CONSCIOUS SEDATION IN DENTISTRY: ALTERNATIVE TECHNIQUES 2007***

A report from the Standing Committee on Sedation in Dentistry

The guidance is designed to improve practitioners with the information they need to ensure they provide conscious sedation services to specified standards in order to safeguard patients regardless of clinical setting

Safe practice for both standard and alternative techniques ( IVS <12 years of age, Benzodiazepine + and other IV agent, propofol +/- any other agent, IHS + any other agents, combined routes - IHS + IVS) relies on 3 key areas:

- Qualifications and training
- Environment and patient selection
- Experience and CPD

### ***DP RISK MANAGEMENT MODULE - CONSCIOUS SEDATION***

*Cover the following topics:-*

Nervous patients	Supervision
Consent	Record management
Side effects	Supporting staff
Chaperone	Training
Recovery	Amnesia

### ***STANDARDS FOR CONSCIOUS SEDATION IN PROVISION OF DENTAL CARE***

May 2015

This report creates a national standard which applies to all who provide conscious sedation for dentistry - First section provides core information

Divides into 5 key areas:-

- Care pathways
- Clinical sedation techniques
- Peri-operative care
- Patient information
- Education and training

### **Main Changes**

- Management of children
- Monitoring
- Education and training requirements

***These standards are presently not approved by DH&SSP in NI***

***DENTAL PROTECTION ADVISE RE STANDARDS IN CONSCIOUS SEDATION IN PRIMARY CARE 2015***

***SCEP CONSCIOUS SEDATION IN DENTISTRY DENTAL CLINICAL GUIDANCE - 2017***

***In Conclusion:-***

## **CONSCIOUS SEDATION**

If a GDP provide CS he/she must provide similar standards as required for GA regarding in relation to:-  
patient assessment  
consent  
patient escorts

### **Patient Assessment**

All options for care must be discussed prior to referring or arranging treatment under sedation.

Patients may require different support services at different points in their dental care

### **Assessment/Preparation for Sedation**

Consent for treatment under conscious sedation is necessary for all patients and **must** be confirmed in **writing**

**Consent** should be obtained on a **separate day** to treatment except where immediate treatment is in the best interests of the patient

**Consent** must be **re-confirmed on the day of treatment**

### **Assessment visit/Preparation for sedation**

Written information about the sedation must be supplied at the assessment visit  
For children it is advised that information for both the child and the parent is provided

Information should include:-

- Description of the sedation procedure
- Risks, benefits and alternatives
- How the patient is likely to feel
- Contact details and out of hours information

### **Clinical Sedation Team**

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

### **Techniques of Sedation**

Adopt the principle of minimum intervention based on robust patient assessment and clinical need

Safe sedation demands knowledge of time of onset, peak effect and duration of action of drug  
Whichever technique is used there must be clear clinical justification

### **The clinical environment**

The environment must be appropriate for the needs and safety of patients, carers and staff  
Have main waiting room and recovery separate  
Access for emergency services to building/surgery  
Have a chair that can be placed head down tilt position

Check list at: [www.saad.org.uk/safeppractice2015](http://www.saad.org.uk/safeppractice2015)

### **A sedation practice**

- Must have a written recognised sedation protocol
- IHS should be administered to a recognised sedation end point
- Must apply recognised discharge criteria
- Emergency contact information
- Escort on discretion of sedationist

### **Must provide:**

- CPR for all staff incl. airway adjuncts
- Dedicated Clinical Assistants
- Emergency equipment

as required for GA

### **Resuscitation**

- Medical emergency could occur at any time.
- A dentist must ensure that all members of the dental team are properly trained.
- Training should practice simulated routines for resuscitation.
- All training must be documented.

Be assisted by a second appropriately trained person throughout who is capable of monitoring the clinical condition of the patient and assisting if there is a complication!

### **Responsibilities, Education and Skills**

When dentists both sedate and provide treatment they must:

- Have had relevant training
- Have a commitment to continuous post-grad training
- Ensure that the techniques and drugs are the most appropriate

### **Clinical Governance**

Requirement of good practice:-

All professional clinicians should work with colleagues to monitor and maintain awareness of the quality and care they provide.

Active participation in clinical audit is an essential feature of clinical governance.  
Hence Conscious Sedation procedures must be the subject of robust and regular audit and peer review

Critical incidents must be reported according to local and national policy  
Reporting through Safe Anaesthesia Liaison Group (SALG) is recommended

***[www.aagbi.org/safety/salg](http://www.aagbi.org/safety/salg)***

### ***STANDARDS IN CONSCIOUS SEDATION IN THE PROVISION OF DENTAL CARE – 2015***

Although these standards are not approved by DH&SSP in NI we have to inform you about its content. You need to familiarize yourself with the contents of it to answer SO 5 Ethical Dilemma ROC

**The document creates a national standard for CS in dentistry and replaces previous documents**

**This document divided into sections:-**

1. Care Pathways - Options for care
2. Preparation for Sedation – Consent, patient information etc.
3. Clinical environment
4. The team
5. Clinical sedation Techniques
6. Perioperative care - monitoring complications, Recovery, discharge and aftercare
7. Clinical Governance and audit
8. Education and Training

**Main Changes :-**

- Management of children
- Monitoring
- Education and training requirements

**1. CARE PATHWAYS**

Patients should receive the appropriate support for care at the right time and in the right place.  
Care pathways need to be determined locally  
Professionals should have access to necessary support services for their patients

**2. CLINICAL SEDATION TECHNIQUES**

**Sedation techniques Children**

Patients who have not yet reached puberty are physiologically immature and hence a sedation team member require to have paediatric resuscitation skills.

The guidelines define the age of a child as being an individual of under 12 years of age

The first choice of sedation technique is Inhalation sedation with N<sub>2</sub>O/O<sub>2</sub>

Any child under 12yrs with complex needs or any child under 12yrs who cannot be managed with either;

- A) Behavioural management/LA
- B) LA plus inhalation sedation

Should be referred to a team having skills equivalent to those expected of a specialist/consultant in paediatric dentistry

A consultant in anaesthesia competent in sedation for dentistry  
Treated in a facility equivalent to an NHS Acute Trust

Any young person aged 12-16 with complex needs or any young person aged 12-16 who cannot be managed with either;

- A) Behavioural management/LA
- B) LA plus inhalation sedation
- C) LA and midazolam (all routes)

Should be referred to a team having skills equivalent to those expected of a specialist/consultant in paediatric dentistry

A consultant in anaesthesia competent in sedation for dentistry  
Treated in a facility equivalent to an NHS Acute Trust

### **3. PERI-OPERATIVE CARE - PATIENT INFORMATION - PRE-OP, INTRA-OP, POST-OP -**

Full and comprehensive information must be provided for patients, parents and carers in verbal and written form

Information should explain:

- The procedure
- The pharmacological process
- The benefits and risks
- Pre and post operative care/ instructions

Example are provided in the Standard Document and can be reproduced with acknowledgement to the document

#### **Adults and Young People**

Information should be provided to the patients and the patients escort

**Children** -Separate age appropriate information should be provided.

Learning disability or English not first language consideration must be given to these groups in line with local policy

### **4 CLINICAL MONITORING -**

**Clinical monitoring** of patient – required for all sedation techniques

**BP** - All sedation techniques except N2O/O2 inhalation sedation

**Pulse Oximetry** - All sedation techniques except N2O/O2 inhalation sedation

### **5. FASTING**

Continues to be the subject of significant discussion

Airway reflexes are assumed to be maintained during moderate and minimal sedation however it is important to consider inadvertent over sedation

Careful consideration on a case-by-case basis of the patients co-morbidities and the nature of the procedure is important to evaluate the risks of aspiration

### **6. CLINICAL ENVIRONMENT**

All centers providing conscious sedation should be inspected to determine that the necessary standards are in place

Clinical setting must permit access for emergency services

Check list at: [www.saad.org.uk/safeppractice2015](http://www.saad.org.uk/safeppractice2015)

### **7. EDUCATION AND TRAINING**

All members of the sedation team must have carried out appropriate validated education and training

Educational courses providing training in clinical delivery of conscious sedation must be:-

- Validated
- Externally quality assured
- Incorporate supervised clinical practice

Courses should be provided by nationally recognised institutions and bodies  
Teachers must be appropriately experienced in techniques they are teaching  
Courses designed to lead to independent practice require accreditation

**“Revalidation”**

A practitioner must undergo a minimum of 12 hours  
of CPD in a 5 year cycle relevant to the technique practiced

**EDUCATION AND TRAINING cont/-**

Healthcare professionals should not provide conscious sedation for dental patients without the training described in the standards.

Experienced practitioners currently providing conscious sedation for dentistry who have not received the formal postgraduate training as described can continue to provide conscious sedation services, under ‘grandfathering’ arrangements, assuming they comply with the guidance laid down in the standards.

**Accreditation may be done through:**

- Universities
- Health Education England
- NHS Education Scotland
- Wales Deanery
- NI Medical and Dental Training Agency
- Schools of Anaesthesia
- NEBDN (for DCP courses)
- IACSD (for privately run courses)

Recognises that some of the guidance will have far-reaching consequences  
Emphasises that patient safety is the priority

These standards are not approved by DH&SSP in NI

***As well as adhering to current guidelines we need to consider medico-legally the following:-***

**GENERAL DENTAL COUNCIL**

Maintaining Standards (November 2000)  
superseded by Standards Guidance (May 2005)  
Superseded by Standards (Nov 2013)

**GDC \_ LAW ETHICS & PROFESSIONALISM**

- ✓ Be able to keep clinical records
- ✓ Know about their role in obtaining consent
- ✓ Know their duty of care





- ✓ Know a patient's rights
- ✓ Know the permitted duties of dental professional
- ✓ Know the regulatory function of GDC

### **GDC - Pain and Anxiety Control**

Duty and Expectations

Dentists have a duty to provide adequate and appropriate pain and anxiety control.

Failure of responsibilities with regards to pain and anxiety control may lead to a charge of serious professional misconduct

### **GDC - Pain and Anxiety Control**

Behavioral Management

Local Anaesthesia

Mainstay of pain control.

Duty to use appropriate & effective method

Technique relates to medical history and pharmacological properties of LA agent

Conscious Sedation (HIS/IVS)

General Anaesthesia

### **MEDICO-LEGAL ASPECTS WITHIN DENTAL PRACTICE**

1. Accountability
2. Consent
3. Confidentiality
4. Negligence
5. Assault
6. Documentation

#### **1. Accountability**

Being personally answerable to the law of the land for all your actions or omissions (including what you write or don't write, what advice you give or don't give) while fulfilling your role/contract as a dentist/PCD

Rosemary Wilson 2008

#### **2. Consent**

The principle of consent is:-

Autonomy  
Capacity  
Information

Principle of autonomy ultimately override beneficence (what dentists thinks best) in all but the most extreme circumstances.

### **Dental Protection Shared Decision Making 2015**

**According to Dental Protection:-**

70% of litigation is related to poor communication

27% of surgical claims are related to poor explanation of the procedure to the patient

95% of patients wants more information



96% want to be offered choices and asked their opinion

**Written consent** is compulsory!

It should be signed by a parent/

guardian, dated and filed with the patient's record

### 3. Negligence

Clinicians have a legal duty of care to patients

A clinician is not considered, in law, to be negligent if he/she has acted in accordance with the law and the practice he/she does is accepted as proper by a responsible body of qualified persons skilled in that particular art.

Actions alleging negligence include diagnosis, treatment and advice

#### How to avoid Negligence

Appropriately trained staff

Appropriate equipment

Patient assessment

Accurate patient records, legible, comprehensive, dated and signed (DNA)

All pre and post operative instructions: verbal and written

Written informed consent

### 4. Assault

All dental practices carry the possibility of legal action for assault

#### Civil Assault

Treatment without valid consent

#### Common Assault

Any unauthorised hands-on procedure

#### Indecent Assault

Usually made by female patient against male dentist or occasionally sexual abuse of young patients

Patients must be chaperoned as the perception of sedated patients is altered

### 5. Record Keeping – Clinical notes

Must provide written, contemporaneous record of clinical and electro-mechanical monitoring

Computer-held records

#### Must include:-

Treatment plan

Reason for sedation

Medical history +/- BP reading

Consent

Name + signature of operator

Name of assistant



Dosage of drug

Treatment given

Duration of sedation

Monitors:-

Pulsoximeter/BP not required for IHS (NI/UK)

**But** is required for Intravenous Sedation

Any deviations from standard practice should be recorded, including reasons!

### **Handwriting and clinical notes**

Beware of illegible handwriting!

GDP prescribed Amoxil

Pharmacist dispensed Daonil

Patient suffered brain damage

Court stated GDP's handwriting was 'very poor'

Awarded £119,302

Pharmacist 75% - bad hand writing 25%

### **Retention of Patients Records**

According to "Good Management, Good Records DHSS &PS 2004"-

### **CHILDREN**

Until 25<sup>th</sup> birthday or 26<sup>th</sup> if 17 at conclusion of treatment or 8 years after treatment completion

### **ADULT**

20 years after conclusion of treatment

DP as above for children but for adults 12 years after the completion of treatment.

BDA advise: Adults 11 years, children 11 years or up to 25 whichever is longer (2008 BDA news)

### **IN SUMMARY**

**ADHERE to present GUIDELINES**

**Remember written CONSENT for treatment but as well sedation**

**Take detail MEDICAL HISTORY**

**RECORD KEEPING**

**Keep up to date**

**12 hrs CDP in every 5yr cycle**