The Regulation and Quality Improvement Authority

Review of intravenous sedation use in General Dental Practice

May 2009

informing and improving health and social care
www.rqia.org.uk

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1.0 The Roles and Responsibilities of the Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) is a non-departmental public body, established with powers granted under the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003. It is sponsored by the Department of Health, Social Services and Public Safety (DHSSPS), with overall responsibility for assessing and reporting on the availability and quality of health and social care services in Northern Ireland and encouraging improvements in the quality of those services.

The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 places a statutory duty of quality on Health and Social Care (HSC) organisations and requires the RQIA to encourage continuous improvement in the quality of care and services throughout all sectors in Northern Ireland.

In order to fulfill its statutory responsibilities, the RQIA has developed a planned programme of clinical and social care governance reviews within the HPSS and will also carry out commissioned reviews at the request of the DHSSPS.

As part of this planned programme the RQIA decided to undertake a review of intravenous sedation use in general dental practice, which would include assessment of the process employed by HSS Boards, as commissioners of dental services, to monitor the safety and quality of intravenous sedation provision.

2.0 Background

Pain and anxiety management for patients is of paramount importance in dentistry and is both a right for the patient and a duty placed on the dentist.

Most dental patients are able to accept dental treatment with local anaesthesia and sympathetic management alone. Some, however, require additional help from a range of techniques which include conscious sedation.

Reasons for carrying out dental treatment under sedation are

- to treat anxious or phobic patients who would otherwise be denied access to dentistry
- to enable an unpleasant or a lengthy procedure to be carried out without distress to the patient
- to avoid the need for a general anaesthetic

Conscious sedation is defined as *"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".

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.

There are a range of techniques for providing conscious sedation

- intravenous sedation with Midazolam
- inhalation sedation with nitrous oxide and oxygen
- oral sedation with benzodiazepines

This review focuses on the use of intravenous sedation in general dental practice. In this process a drug, usually Midazolam* is administered intravenously by means of a cannula*. This drug does not actually induce sleep, the patient remains conscious at all times and should be able to follow instructions from the dentist. The process produces a state of relaxation, allowing the administration of a local anaesthetic and enabling patients to tolerate unpleasant or lengthy procedures.

3.0 Context for the Review

"*A Conscious Decision,*[1]*"* the report of an expert group under the joint chairmanship of the Chief Medical Officer Sir Liam Donaldson and the Chief Dental Officer Mr Robin Wild in 2000, recommended that when a general anaesthetic is considered necessary for dental treatment, it should be carried out in a hospital setting where there is the immediate availability of a critical care facility.

The report went on to say that "*conscious sedation should be available as an alternative to general anaesthesia but that high standards must be attained. These should include appropriate undergraduate and postgraduate training, appropriate arrangements for patient assessment, consent and patient escorts, high standards of resuscitation training and the use of dedicated assistants".*

In Northern Ireland, as a result of *"A Conscious Decision"*, all general anaesthetics in general dental practice effectively ended on 31 December 2001. As a consequence there has been a growing use of conscious sedation in primary dental care settings and it is essential that where it is carried out, it is provided to the highest possible standards.

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* short acting benzodiazepine derivative with a short elimination half life

* a very thin needle encased in a soft plastic tube - when the needle is removed from the vein it leaves the plastic tube behind allowing venous access throughout the treatment

[1] A conscious decision. A review of the use of general anaesthesia and conscious sedation in primary dental care. DOH July 2000

Presently, however there are no specific Northern Ireland standards or guidance for provision of intravenous sedation in general dental practice.

"Conscious sedation in the provision of dental care,[2]" a report of an expert group on sedation in dentistry provided guidelines building on generic guidance provided in "*A Conscious Decision,"* and laid down specific guidance for the practice of conscious sedation in dentistry.

The report emphasised the importance of both theoretical and practical training. Continuous update and clinical audit for the whole dental team as part of the clinical governance framework are essential for ensuring the delivery of a high quality service. It also emphasised the necessity of having the appropriate equipment and drugs and ensuring that equipment was properly maintained.

A second report of an expert working group of the Standing Dental Advisory Committee in September 2005[3] concluded that there was an urgent need for a robust system of regular inspection and monitoring of clinical teams providing pain and anxiety control services, and of the environment in which they are administered. They also noted that there was existing documentation that could be suitably adjusted to match local requirements to assist such a process of inspection and monitoring.

In May 2006 the Scottish Dental Clinical Effectiveness Programme produced *"Conscious Sedation in Dentistry. Dental Clinical Guidance,[4]"* which aimed to promote good clinical practice through recommendations for the provision of conscious sedation in dentistry that is both safe and effective.

The Scottish guidance resulted from careful consideration of current legislation, professional regulations, available evidence and expert opinion. The expert group considered that *"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 the guidance should be fully documented in the patient's case notes at the time the relevant decision is made".*

3.1 Role of HSS Boards (HSC Board)

Intravenous sedation is delivered in a number of settings in the public and private sectors. In the public sector Health Service dental treatment is provided by dental practitioners who are self employed, working to a scale of fees through the General Dental Services (GDS) of the Health Service.

[2] Conscious sedation in the provision of dental care. Standing Dental Advisory Committee. DOH 2003.
[3] Second report of an expert working group of the standing dental advisory committee. DOH Sept 2005
[4] Conscious sedation in dentistry. Dental clinical guidance. SDCEP. May 2006

Private dental treatment is provided to patients who:

1) make arrangements with dental practitioners outside the Health Service, who are wholly private dental practitioners.
2) make arrangements with dental practitioners who carry out a mixture of private and Health Service work

HSS Boards (HSC Board) are responsible for ensuring the delivery of dental services at a local level by general dental practitioners who have entered into arrangements with the Boards to provide general dental services. They are not employed by Boards but are independent contractors who have undertaken to provide health service dental treatment. Although dental practitioners are independent contractors HSS Boards still have a responsibility to ensure that all treatment provided in the General Dental Services is of a sufficient quality.

General Dental Services Regulations[5] require*" that a dentist admit to his/her premises (upon receipt of reasonable notice), a Dental Officer, or authorised person representing the Board for the purposes of inspecting the premises".* There are no set time limits for inspections but they are generally carried out as part of a rolling 2-3 year programme. There is a regional inspection protocol, but the only questions that relate to sedation are regarding emergency equipment and Basic Life Support Training, which are relevant to all practices, regardless of whether or not they provide any form of sedation.

3.2 Private Dentistry

The amount of private dentistry being carried out in Northern Ireland has been increasing yet the number of purely "private" dental practices is relatively small. Most practices offer a mixture of private and health service dentistry and as such are subject to the assurance processes that apply to the public sector.

Currently however, dental practices in Northern Ireland that are wholly private are not subject to any clinical regulatory or monitoring processes.

4.0 The Review Team

RQIA review teams are multidisciplinary, and include both health and social care professionals (peer reviewers) and members of the public (lay reviewers). Review teams are managed and supported by RQIA project managers and project administrators.

Lay reviewers come from a range of backgrounds across Northern Ireland. Each plays a vital role in review teams, bringing new insights and providing a

[5] General Dental Services Regulations (NI) Schedule 2

lay person's perspective on all aspects of the provision of health and social care services.

The membership of the review team can be found in Appendix 2.

5.0 The Review Process

The review process has three key elements:

- self assessment
- pre-visit analysis
- validation visits by a review team.

5.1 Development of Self Assessment Tool

Self assessment as a technique is used widely in health and social care regulation, accreditation and licensing across the UK and internationally.

For the purposes of this review the Central Services Agency was initially asked to identify all practices that had submitted a claim for treatment carried out under intravenous sedation in the financial year 2007/2008.

Based on CSA data 77 practices were identified as having made an NHS claim with the range of numbers of patients treated being from 1 to1488. The total number of NHS claims made in the 2007/2008 financial year was 5822.

A self assessment proforma (Appendix1),based on guidance regarding standards of treatment contained in the documents *"Conscious Sedation in the Provision of Dental Care"* and *"Conscious Sedation in Dentistry Dental Clinical Guidance",* was constructed and sent to all practices identified by the Central Services Agency. There was a 100% return of self assessments (return date 7 November 2008) and based on these returns 41 practices were identified as carrying out dental treatment under intravenous sedation at the time of the survey. A number of practices either no longer carried out treatment using sedation or had made a claim in error which brought the number of practices involved from 77 to 41.

HSS Boards, specifically Directors of Dental Services, were asked to outline how the quality and safety of intravenous sedation use in general dental practice is assured.

5.2 Pre-visit Analysis of Self Assessment

Self assessment proformas returned from dental practices and replies from HSS Boards were analysed by RQIA project managers prior to validation

visits to practices. Self assessment information was entered into a Microsoft Access database to allow for easier interrogation of data. All information was collated to provide a framework which was then used by the review team during validation visits.

5.3 Review Visits

A stratified random sample of the 41 practices identified as carrying out treatment under intravenous sedation was chosen, based on numbers of patients treated, and the HSS Board area the practice was in. Ten practices were identified, 4 from EHSSB, 3 from NHSSB, 2 from SHSSB and 1 from WHSSB and these were visited by the RQIA review team over a three day period, 19-21 January 2009.

Based on the initial analysis, the review team used a semi-structured interview schedule exploring issues identified from the self assessment.

Following the review visit, feedback from the review team was supplied to each practice, highlighting any areas of good practice and also outlining any concerns and areas where improvements might be made. In cases where concerns were considered to be minor, discussing these with practitioners at the time of the visit was considered to be adequate. More serious concerns would be dealt with by passing these on to the relevant Board Dental Director for action.

5.4 The Report

Following the review visits to dental practices a report was drafted that was sent to the review team for comment.

The report will be made available to the general pubic in print, at www.rqia.org.uk and in other formats on request.

6.0 Summary of HSS Board Replies

Northern Health and Social Services Board

The NHSSB reply pointed out that the General Dental Council expects all dentists to practice within their own competency levels. While specialist lists have been developed for many areas of dental practice this has not yet occurred for sedation, but, as ethical professionals, dentists are expected to recognise the limits of their skills and at all times work within those boundaries. The practise of sedation, therefore, relies in part on self regulation.

The NHSSB outlined the following procedures used to assure the quality and safety of intravenous sedation in general dental practice.

1) Practice Inspections - all dental practices in the Board area are inspected every three years. Included in the inspection is a requirement that practices have appropriate drugs and resuscitation equipment.
2) Quality Assurance Returns - annual quality assurance returns from all practices that undertake health service dentistry ask respondents to confirm that all treatment is carried out to a satisfactory standard (including sedation).
3) Interviews for new contract holders - all applicants who wish to join the Board's dental list receive a structured interview. Applicants are asked if they plan to use sedation and whether they are aware of the ethical and medico-legal issues that are involved in the use of sedation.
4) CSA Quarterly Database - the Board's probity officer analyses dental payment data. The database is interrogated in relation to the number of sedation claims per dentist, per patient and per course of treatment. While the probity officer is looking for outliers that may suggest inappropriate claims, there is a strong overlap with quality of care.
5) Record Card Checks - record cards are examined and incidental findings regarding sedation are noted and followed up.
6) Serious Adverse Incident Reporting - in 2005 and 2008 all NHSSB practice principals were informed in writing of their obligation to report SAI's (including those arising from IV sedation).
7) Defibrillators - in 2007 the Board purchased an AED[*] for the two specialist oral surgery practices in the area who undertake the vast majority of the dental sedations carried out in the NHSSB area.
8) CPR funding - for most of the last five years the Board has provided practices with funding for CPR training.

Western Health and Social Services Board

1) The WHSSB practice visitor applies the regional document developed by all Boards in relation to health and safety issues in general practice premises (usually once every 18 months to two years).
2) The WHSSB probity officer will, when practitioners appear as outliers, review their notes which will include medical histories, consent and detail of notes. The same officer will also carry out claim to record checks routinely for all practitioners.

Southern Health and Social Services Board

1) The SHSSB undertakes practice visits biannually at which stage practices detail their provision of IV sedation.
2) CPR training has been funded on an annual basis from 1997-2008 and for practices delivering sedation, additional sessions covering defibrillation were provided.

[*] Automated External Defibrillator

3) In 2005 a general dental practitioner experienced in intravenous sedation, undertook a two visit exercise for each practice which delivers sedation. Visit one involved checking equipment and observing practise while the second covered training for all members of the team. This proved to be a valuable exercise but unfortunately the practitioner has retired and his expertise has been lost to the Board.
4) The complaints officer of SHSSB liaises closely with primary care regarding areas of concern which have been raised through the complaints process. In the event of problems associated with sedation being raised, these would be addressed as a matter of urgency.

Eastern Health and Social Services Board

1) General monitoring - the EHSSB has undertaken two successive 3-year cycles of practice inspection visits involving all GDS practices operating within its area. The current inspection protocol is relatively high level covering multiple aspects of general dental practice. In relation to IV sedation the process records whether this is provided by the practice and also records any relevant qualifications gained by members of the practice team. Of further relevance to the process the protocol also records details of emergency drugs and equipment and the last date of CPR training for each practice. While not in a position to give detailed expert advice the Board officer will highlight any deficiencies to the practice principal.
2) Routine scrutiny of dental records may identify anomalies in sedation treatments, and these are dealt with by dental officers.
3) For many years on an annual basis the Board has centrally organised and funded provision of on -site basic life support training for all staff in every GDS practice within its area.
4) In 2004 the Board organised and funded two advanced life support training sessions for all staff from practices providing IV sedation.
5) The Board has funded 2/3 of course fee costs to support 12 dental nurses from GDS practices to obtain the additional qualification in dental sedation.
6) The Board has approved funding to assist several GDPs with some of the costs associated with studying for a Diploma in Sedation from Newcastle University.

The Director of Dental Services in his reply concluded, *" IV sedation is one of the very few areas within general dental practice where patients' lives are at significant risk if proper standards of provision are not maintained on a consistent basis. As indicated by the above, the Board's ongoing oversight of IV sedation provision within its area is largely subsumed within its overall general monitoring process for the GDS as a whole. Arguably this does not subject this aspect of service provision to the degree of scrutiny it should warrant.*

Given this situation, I would welcome this review by the RQIA and hope that it will provide authoritative guidance on the level of monitoring that will be appropriate for this aspect of the GDS in the future. The review is particularly timely given the RPA changes that are about to be implemented, creating new organisations with a regional remit that will be receptive to, and well placed to effectively deliver on any recommendations that are forthcoming in this regard".

7.0 Summary of Self Assessment Returns

41 practices were identified as carrying out treatment using intravenous sedation and the numbers of patients treated in each practice ranged from 5 to 2000.

Practices were asked to provide details of numbers of adults and numbers of children treated in the previous year, using IV sedation, both NHS and privately. In total 11,720 patients were treated which compares with the figure of 5,484 supplied by the CSA as to number of NHS treatments carried out. This indicates that a significant amount of sedation is now carried out privately.

Figures 1 and 2 illustrate the numbers of children and adults treated per practice

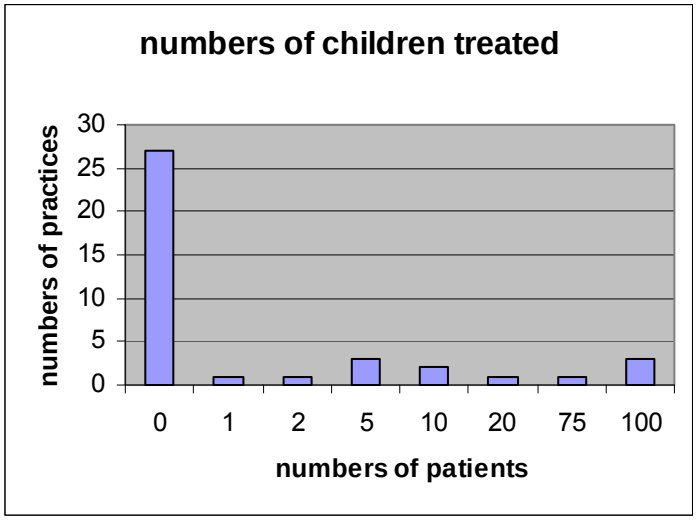

Figure 1. Practice reported numbers of children treated per practice

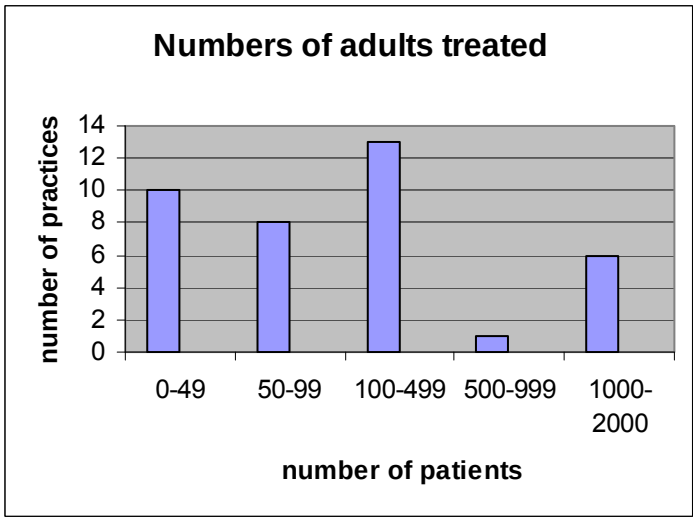

Figure 2. Practice reported numbers of adults treated per practice

The following table summarises the number of practices in each Board area who treat patients using intravenous sedation.

Board area	Number of practices
EHSSB	21
NHSSB	10
SHSSB	8
WHSSB	2

Table 1. Number of practices in each Board area that carry out sedation.

The following table summarises the answers to a selection of questions from the self assessment.

Question	No of practices		
	y	n	n/r *
Q2 Does the practice operate on an operator-sedationist basis?	37	3	1
Q3 Does the practice treat children (under 16 years) under intravenous sedation and how many are treated annually?	12	27	2
Q6 Which grades of patient would you feel confident to treat•			
Treat ASA I +II	40	0	1
Treat ASA III	4	36	1
Treat ASA IV	0	40	1
Q8 Is a thorough written, medical , dental and social history obtained for each patient and recorded in the patient notes?	40	0	1
Q9 Is written consent obtained for all sedation patients?	40	0	1
Q11, Q22 Do patients receive detailed written and verbal pre and post -op instructions?	37	2	2
Q14 Is a single titrated dose of Midazolam only used in each case?	39	1	1
Q12 Has relevant, externally validated and up to date training been undertaken by the sedationist?	35	2	4
Q13 Have all dental nurses who assist with sedation had training, either external or practice based?	34	3	4
Q14 Is a pulse oximeter always used during sedation?	40	0	1
Q28 Is all emergency equipment suggested in the British Resuscitation Council Guidelines available?	37	2	2
Q30 Have staff received training in the management of medical emergencies including the use of defibrillators and emergency drugs?	24	15	2
Q29 Is a defibrillator available in the practice?	17	23	1
Q27 Are all staff involved in sedation trained in basic life support?	40	0	1

* yes/no/no return

• ASA I -Healthy patient
ASA II - Mild systemic disease with no functional limitation for example controlled hypertension
ASA III - Severe systemic disease with no functional limitation for example chronic obstructive pulmonary disease
ASA IV - Severe systemic disease that is a constant threat to life for example unstable angina

Table 2. Summary of self assessments
The self assessment asked practitioners to provide details of training undergone by the dentist and also by dental nurses participating in the procedure. The following tables summarise responses to these questions.

Type of training	Number of dentists
SAAD Course*	19
Newcastle Diploma**	2
NIMDTA Training course***	10
No recognised postgraduate training	4
Incomplete return	6

Table 3. Dentist training

*The Society for the Advancement of Anaesthesia in Dentistry (SAAD) provides a 2 day course which is completely theoretical. They note that practitioners completing their course are strongly advised to gain further practical and clinical experience, under the guidance of a practitioner experienced in the use of conscious sedation techniques.

**Newcastle University provides a training programme leading to a Postgraduate Diploma in Conscious Sedation in Dentistry. This takes the form of 9 didactic teaching days of lectures and seminars plus 14 half days of hands-on clinical training in sedation techniques which are spaced evenly over a full academic year.

***The Medical and Dental Training Agency provides a 1 day induction or refresher training course.

The review team found variation in the type of training courses which had been attended by dentists. Because of a lack of standardisation of training and also in the absence of standards there was some confusion among dentists regarding which type of course they should attend.

The above table indicates that four practitioners had not attended any postgraduate training courses. Of these four, two were no longer carrying out sedation and one brought in an outside medical practitioner to provide sedation. The last practitioner had extensive undergraduate experience and also experience gained as a house officer in a large teaching hospital. The practitioner was however advised by the review team to attend a further postgraduate training course.

Question 12 of the self assessment asked, "Has relevant, externally validated and up to date training been undertaken by the sedationist?"

The question then went on to ask dentists to "provide details of training to include original/most recent training".

The question did not specifically ask practitioners to provide the date of last training leading to a number of incomplete replies.

However the replies that were received indicated variation in the length of time elapsed since attending a postgraduate course.

The review team also found variation in the length of time that had elapsed since practitioners had attended a postgraduate course but practitioners indicated that there was no local guidance on appropriateness of, or timescales for training.

Year of last training	Number of practices
2000	2
2001	0
2002	0
2003	5
2004	3
2005	1
2006	4
2007	4
2008	3
No postgraduate training	4
Incomplete return	15

Table 4. Date of last training.

Type of training	Number of practices
National sedation qualification	14
In house training	22
SAAD	3
Incomplete	2

Table 5. Dental nurse training.

8.0 Summary of Practice Visits

Ten practices were identified through a process of random selection. These practices were then visited by an RQIA review team who explored in depth, issues raised by the self assessment.

Practice 1

Profile	Mostly NHS
Number of patients treated using intravenous sedation	4/5 per adults per year 0 children
Dentist training	SAAD course 2003
Dental nurse training	1 nurse national sedation qualification
Issues arising	• no checking of expiry dates for emergency drugs • Flumazenil* expired 2007 • no blood pressure monitoring • no bag and mask to supply positive pressure ventilation if required • no defibrillator
Recommendations	• has to improve recording of o medical/dental/social history o monitoring BP/Pulse/oxygen saturation • BP recorded at assessment and sedation visits • check all drugs for expiry dates and record checks • should have all appropriate emergency equipment including a defibrillator

* Used as an antidote in the case of sedation overdose. All practices should have in date supplies of Flumazenil to reverse the effects of sedation in case of emergency.

Practice 2

Profile	Mixed NHS/Private
Number of patients treated using intravenous sedation	100 adults per year 0 children
Dentist training	NIMDTA 2004
Dental nurse training	2 nurses NIMDTA training 2004
Issues arising	• no defibrillator • blood pressure not noted and recorded before discharge • no recording of emergency drugs being checked for expiry dates
Recommendations	• should have all appropriate emergency equipment including a defibrillator • blood pressure should be monitored and recorded at assessment visit and at beginning and end of sedation • emergency drugs checks should be recorded

Practice 3

Profile	Mostly NHS
Number of patients treated using intravenous sedation	>1000 adults per year Few children
Dentist training	2 dentists SAAD course. Third dentist no formal training
Dental nurse training	No formalised training - carried out "in house" no record of what training consists of.
Issues arising	• dosages of more than 10mg used • cannula not used • Midazolam stored in a locked cupboard sited in patient toilet • records illegible and almost no recording of monitoring and discharge. • unclear post op care instructions. • one dentist has no formal postgraduate training

	• no formal training for dental nurses • consent forms do not include a description of dental treatment. • no training in medical emergencies • only 1 ampoule of Flumazenil available
Recommendations	• More cautious use of Midazolam and justification for frequently using >10mg dosages • to use a cannula and leave in place to ensure venous access rather than just a butterfly • although Midazolam is in a locked cupboard, it should not be situated in the patient toilet • records must be legible and contain information on monitoring and discharge • patient instructions re transport home and post op care should be clearer • all dentists must have attended postgraduate training in use of sedation • consideration should be given to providing an opportunity for dental nurses to access formal training. • consent forms should be amended to include a description of treatment to be carried out • training in medical emergencies should be provided • all emergency drugs including Flumanezil should be checked regularly

Practice 4

Profile	Specialist Oral Surgery Practice
Number of patients treated using Intravenous Sedation	1400 adults per year 75 children
Dentist training	First dentist Diploma in sedation (Newcastle University) 2007 Second dentist SAAD training, doing diploma in 2009 Third dentist SAAD/Armed forces training
Dental nurse training	3 nurses have national sedation qualification 2 nurses doing course/exam
Issues arising	None

Practice 5

Profile	Specialist Oral Surgery Practice
Number of patients treated using Intravenous Sedation	2000 adults per year Few children
Dentist training	1 dentist medically qualified/diploma in sedation Newcastle University I dentist about to do Diploma 1 dentist 25 years experience
Dental nurse training	All nurses national sedation qualification
Issues raised	None

Practice 6

Profile	Mixed NHS/Private
Number of patients treated using Intravenous Sedation	1000+ adults per year No under 16s
Dentist training	SAAD course 2005, NIMDTA update 2008
Dental nurse training	1 nurse national sedation qualification, the rest trained "in house"
Issues raised	BP not recorded at assessment visit
Recommendations	In future BP to be monitored at assessment visit as well as treatment visit

Practice 7

Profile	Private
Number of patients treated using Intravenous sedation	50 adults per year 0 children
Dentist training	SAAD training 2006
Dental nurse training	2 nurses national sedation qualification
Issues raised	No defibrillator
Recommendations	• should have all recommended emergency equipment including a defibrillator

Practice 8

Profile	Private
Number of patients treated using Intravenous sedation	20-30 adults per year 0 children
Dentist training	NIMDTA update training 2006
Dental nurse training	1 nurse update training " In house" training provided (not documented)
Issues arising	• no defibrillator • no written medical history • no formal training for dental nurses and no documentation of "in house " training.
Recommendations	• should have all recommended emergency equipment including a defibrillator • should have a detailed written medical history • should consider formal training for dental nurses and also document any "in house" training

Practice 9

Profile	Mostly NHS
Number of patients treated using intravenous sedation	1000+ adults >100 children
Dentist training	1 dentist NIMDTA update 1 dentist no formal training
Dental nurse training	No formal training "in house" training. Not documented
Issues arising	• large number of children treated under sedation • lack of formal training for dentists • lack of formal training for dental nurses • BP not monitored sufficiently • cannula not used • Midazolam already drawn up in syringes • Midazolam stored in an unlocked drawer • 10mg/2ml Midazolam used • records not detailed enough • no training in medical emergencies • dosages of >10mg Midazolam being used • no defibrillator • no written pre and post-op instructions provided
Recommendations	• caution with IV sedation for children. Should have child specific training • all dentists who carry out sedation should have formal training • consideration should be given to formal training for dental nurses • BP should be checked at assessment visit and at least twice at sedation visit • a cannula should be used to administer Midazolam and remain in place throughout treatment and recovery • Midazolam should not be drawn up until just before use

	• Midzolam should not be stored in an unlocked drawer • more dilute Midazolam, 10mg in 5ml or 10mg in 10ml should be used • more detailed records of drugs, monitoring, recovery and discharge to be kept • training in dealing with medical emergencies should be provided for all staff • more cautious use of Midazolam - dosages should be limited to 10mg max and reasons for using >10mg recorded • all recommended emergency equipment including a defibrillator should be available • written pre and post -op instructions should be made available to patients

Practice 10

Profile	Private
Number of patients treated using Intravenous Sedation	120 adults 0 children
Dentist training	NIMDTA training 2003. Unclear about other dentists in the practice.
Dental nurse training	2 nurses national qualification, 1 nurse doing exam
Issues raised	• a 5mg bolus of Midazolam is given initially • a Cannula is not used in all cases • post op instructions are not consistent • not all dentists had received formal training in sedation • no defibrillator present • no staff training in medical emergencies
Recommendations	• avoid giving a 5ml bolus but begin with 1-2 mg • a cannula should be used in all

	cases to maintain access • post -op instructions should be consistent • all recommended emergency equipment should be available • training in dealing with medical emergencies should be provided for all staff

Following each practice visit, verbal feedback was given to practitioners, highlighting any areas of good practice but also outlining any concerns and areas where improvements might be made.

In most cases these areas for improvement were not serious enough to warrant major concern and the review team felt that they had been adequately dealt with by the feedback provided at the time of the visit.

However in two cases the review team felt that there were sufficient concerns to warrant further action. The relevant Board Dental Director has been made aware both via discussion and in writing of the concerns of the review team, asked to address these concerns and supply RQIA with the results of any action taken by the Board.

9.0 Conclusions

The document "*Conscious sedation in the provision of dental care,"* a report of an expert group on sedation for dentistry stated that *"the effective management of pain and anxiety is of paramount importance for patients requiring dental care, and conscious sedation is a fundamental component of this. Competently provided conscious sedation is safe, valuable and effective.*

"A high level of competence based on a solid foundation of theoretical and practical supervised training, progressive updating of skills and continuing experience is the key to safe practice.

"Education and training standards must ensure that ALL members of the dental team providing treatment under conscious sedation have received appropriate supervised theoretical, practical and clinical training before undertaking independent practice.

"Retention and improvement of knowledge and skills relies upon regular updating by means of appropriate refresher courses and a programme of continuing peer-reviewed assessment as a routine practice activity. The interval at which updated training is required will depend upon local circumstances but must be documented. Peer reviewed assessment should occur at least once a year."

The need for adequate training, and standards for use of sedation, is also emphasised in the 2007 report from the Standing Committee on Sedation for Dentistry, *"Standards for Conscious Sedation in Dentistry: Alternative Techniques*[6]*"* which notes that there remains disquiet about safety and quality standards in the provision of conscious sedation for dental care. The report provides guidance on standards for alternative more advanced sedation techniques but many of these standards also apply to single drug use.

During practice visits, most dentists told the review team that they felt the lack of specific Northern Ireland guidance led to them being unclear as to what standard they had to reach in relation to intravenous sedation. Some dentists were aware of the 2003 Department of Health guidance and also Scottish guidance, but some were not.

Recommendation 1. As a matter of urgency The DHSSPS should develop Northern Ireland standards/guidance for the provision of conscious sedation in dental practice or make it clear to practitioners that another guidance document is taken as the required standard.

In every set of guidance researched, the competence of the operator is emphasised as a vital safety factor. One of the themes that emerged from the

[6] Standards for Conscious Sedation in Dentistry: Alternative Techniques. A report from the Standing Committee on Sedation for Dentistry.

self assessments and also from practice visits is that there is great variation in the training that has been undertaken by both dentists and dental nurses. The review team felt this was an issue that would need to be addressed. During practice visits it was stressed by dentists that there were few courses available in Northern Ireland, and there was some confusion as to whether courses supplied by NIMDTA were designed as starter courses for beginners, or refresher courses for those dentists who had already received more comprehensive training.

The 2003 report of an expert group on sedation for dentistry suggests that "*Education and training standards must ensure that ALL members of the dental team providing treatment under conscious sedation have received appropriate supervised theoretical, practical and clinical training before undertaking independent practice."*

Training involving practical as well as theoretical elements is not readily available and difficult to access in Northern Ireland.

Some dentists suggested to the review team that the lack of exposure to intravenous sedation as undergraduates contributed to variation in practice and also did not encourage newly qualified dentists to get involved in the procedure.

Recommendation 2 - DHSSPS/NIMDTA should carry out a review focusing on the availability, appropriateness and standardisation of intravenous sedation training.

Midazolam is widely used for conscious sedation in a number of procedures and settings. As well as dental treatment uses include endoscopic procedures, minor surgery in acute settings and a range of procedures in community hospitals.

A National Patient Safety Agency (NPSA) Rapid Response Report - "*Reducing the risk of overdose with Midazolam injection in adults* [7]"was published in December 2008. It was designed to give guidance on using low strength Midazolam ampoules instead of high strength ampoules thus reducing the risk of overdose.

As well as giving this advice the report also suggests that organisations should

- review therapeutic protocols to ensure that guidance on the use of Midazolam is clear and that the risks, particularly for the elderly or frail, are fully assessed
- ensure that all healthcare practitioners involved directly or participating in sedation techniques have the necessary knowledge, skills and competences required

[7] Rapid Response Report: NPSA/2008/RRR011: Reducing risk of overdose with Midazolam injection in adults. December 2008

- ensure that stocks of Flumazenil are available where Midazolam is used and that the use of Flumazenil is regularly audited as a marker of excessive dosing of Midazolam
- ensure that sedation is covered by organisational policy, and that overall responsibility is assigned to a senior clinician which, in most cases, will be an anaesthetist

The National Patient Safety Agency has received 498 Midazolam related patient safety incidents between November 2004 and November 2008 where the dose prescribed or administered to the patient was inappropriate. Three Midazolam related incidents have resulted in death.

The majority of these incidents occurred in the acute sector and two involved dentistry. However the differences in reporting cultures between the primary and secondary care sectors partly explains these figures.

Recommendation 3 - Boards (HSC Board) must ensure that all dentists who carry out treatment using intravenous sedation are practising in line with the NPSA safety bulletin" Reducing the risk of overdose with Midazolam injection in adults".

Intravenous sedation as carried out in general dental practice is a safe, valuable and effective procedure as long as guidelines on training, competency and technique are followed.

Of the 41 practices 37 only use the technique to treat ASA I or ASA II patients so in general, healthy patients are being treated which reduces the risk of the procedure.

Analysis of self assessments showed that 38 practices used a single drug, Midazolam, but it was concerning that the remaining three were unsure of which drug was used because a separate sedationist was employed. It is felt that adverse events occur more frequently when drug combinations are used and the use of multiple drugs during intravenous sedation presents additional training requirements.

The NPSA report suggests guidelines on appropriate doses of Midazolam to be used:

"In adults, the intravenous injection of Midazolam should be given slowly at a rate of approximately 1mg in 30 seconds.

"In adults below the age of 60 the initial dose is 2-2.5 mg given 5-10 minutes before the beginning of the procedure. Further doses of 1mg may be given as necessary. Mean total doses have been found to range from 3.5-7.5 mg. A total dose of greater than 5mg is usually not necessary.

"In adults above the age of 60, debilitated or chronically ill patients, the initial dose must be reduced to 0.5-1.0 mg and given 5-10 minutes before the beginning of the procedure. Further doses of 0.5-1.0mg may be given as

necessary. Since in these patients the peak effect may be reached less rapidly, additional Midazolam should be titrated very slowly and carefully. A total dose greater than 3.5mg is usually not necessary".

During practice visits it was clear that there was great variation in the dosages of Midazolam that were considered to be appropriate. It is considered that dentists must be able to justify giving doses in excess of 10mg. In certain practices doses of greater than 10 mg seemed to be given frequently. In two practices a larger initial bolus than is recommended was given and in some practices butterflies were used instead of the recommended cannula and in one case neither was used. It is recommended that intravenous access is maintained throughout the procedure and during recovery, and the only reliable way to achieve this is by using a cannula.

Midazolam is a Schedule Three controlled drug and it is good practice that supplies of the drug should be kept in a locked cabinet in a secure part of the surgery. In one practice supplies of Midazolam were kept in a locked cabinet but the cabinet was situated in the patient toilet which is not considered to be a secure location. In another practice syringes of Midazolam had been prepared and were kept in an unlocked drawer in the surgery with easy access for patients, cleaning staff etc.

The review team felt that the variation in dosages of Midazolam and also storage of midazolam were important safety issues. These in future would need to be addressed by appropriate training and also by increased monitoring of the procedure by the commissioners of the service.

As a result of findings from practice visits the RQIA passed on concerns to the appropriate commissioning Board.

All practices had provided training for their staff in basic life support but fewer had provided training in dealing with medical emergencies which is recommended in the 2003 guidance.

The UK Resuscitation council in their 2006 guidance[8] to all dental practitioners recommends that *"all clinical areas should have immediate access to an automated external defibrillator (AED)."*

17 out of the 41 practices providing dental treatment using intravenous sedation have a defibrillator. This is an individual decision for all practices but they should be aware of the Resuscitation Council guidance and carry out a risk assessment for their practice. They must also be aware that if they decide not to have a defibrillator in their practice they are less able to deal with an emergency than they might be.

[8] Medical Emergencies and Resuscitation. Standards for clinical practice and training for dental practitioners and dental care professionals in general dental practice. British Resuscitation Council. July 2008.

Recommendation 4 - Boards (HSC Board) should ensure that all practices carrying out treatment using intravenous sedation should have training in dealing with medical emergencies. Practices should also have access to an appropriate range of emergency equipment including AED's.

HSS Boards have a statutory duty to ensure that all treatment carried out on their behalf is of a sufficient quality. Boards also, under dental regulations have the right to inspect practices who have a contract to provide general dental services on their behalf. Each Board carries out a rolling programme of practice inspections, usually every 2-3 years. The inspection protocol checks the practices' obligations in relation to health and safety, radiation safety and cross infection/decontamination. Apart from checking on emergency drugs, emergency equipment and date of last CPR training the protocol does not go into depth on how those practices providing intravenous sedation for their patients carry out the procedure.

Recommendation 5 - Boards (HSC Board) should develop a specific inspection protocol for dental practices that treat patients using intravenous sedation and carry out a separate, specific inspection of these practices.

As indicated earlier in the report, on analysis of self assessments a total of 11,720 patients were treated using intravenous sedation. CSA figures show the number of Health Service claims to be 5,840 so there is a substantial proportion of treatment using sedation that is carried out privately.

If the Boards develop a process of inspection this would only include those practices that carry out treatment on the NHS. Those practices only providing sedation privately would not be subject to this inspection process.

Recommendation 6 - DHSSPS should implement a process for the regulation of private dentistry.

It was clear from the practice visits that although there were some areas of concern there were also some areas of good practice such as a system to track each ampoule of Midazolam which is used in the practice and also some excellent examples of written pre and post -op instructions and consent forms. Another example is where a practice has arranged a contract with their local hospital for calibration of the instruments involved in sedation. These examples however have been developed in isolation and there is no mechanism for sharing of good practice.

Recommendation 7 - Consideration should be given to the formation of a sedation "peer group" perhaps through the peer review and clinical audit system.

The DHSSPS has been in negotiations since 2006 to develop a bespoke dental contract for Northern Ireland. There is a commitment to test the new contract in pilot sites beginning in October 2009 with evaluation starting in

October 2010. Pending successful evaluation it is hoped to roll out the new contract in April 2011.

The new contract has at its basis, the recommendations arising from the Primary Dental Care Strategy and with local commissioning of services as one of its key aims, will allow for much more flexible arrangements than the present contract.

Recommendation 8 - Although not recognised as a speciality by the General Dental Council, DHSSPS should consider, under new contractual arrangements only awarding contracts for the provision of intravenous sedation to those practices that can demonstrate that they meet appropriate standards.

10.0 Summary of Recommendations

1) As a matter of urgency the DHSSPS should develop Northern Ireland standards/guidance for the provision of conscious sedation in dental practice or make it clear to practitioners that another guidance document is taken as the expected standard.-
2) DHSSPS/NIMDTA should carry out a review focusing on the availability, appropriateness and standardisation of intravenous sedation training.
3) Boards (HSC Board) must ensure that all dentists who carry out treatment using intravenous sedation are practising in line with the NPSA safety bulletin "Reducing the risk of overdose with Midazolam injection in adults".
4) Boards (HSC Board) should ensure that all practices carrying out treatment using intravenous sedation have training in dealing with medical emergencies. Practices should also have access to an appropriate range of emergency equipment including AED's.
5) Boards (HSC Board) should develop a specific inspection protocol for dental practices that treat patients using intravenous sedation and carry out a separate, specific inspection of these practices.
6) DHSSPS should implement a process for the regulation of private dentistry.
7) Consideration should be given to the formation of a "sedation peer group" perhaps through the peer review and clinical audit system.
8) Although not recognised as a speciality by the GDC, DHSSPS should consider under new contractual arrangements only awarding contracts for the provision of intravenous sedation to those practices that can demonstrate that they meet appropriate standards.

APPENDIX 1

INTRAVENOUS SEDATION IN GENERAL DENTAL PRACTICE

2008

Self Assessment

PLEASE ENSURE THIS DOCUMENT IS RETURNED NO LATER THAN

7th NOVEMBER 2008

GENERAL INFORMATION

1. Does the practice use intravenous sedation for dental treatment? yes☐ no☐

   if no, do not proceed. Please return the self assessment in envelope provided.

2. Does the practice operate on an operator- sedationist basis? yes☐ no☐

3. Does the practice operate with a separate operator and sedationist? yes☐ no☐

If yes, please supply details of separate sedationist

4.

How many adults (defined as 16+ years) are treated under intravenous sedation annually?*	

5.

How many children (defined as under 16 years)are treated under intravenous sedation annually?*	

6. Which grades of patient would you feel confident to treat (please circle)?**

ASA I
ASA II
ASA III
ASA IV

PREPARATION FOR SEDATION

7. Are patients assessed for suitability at a preceding visit? yes☐ no☐

8. Is a thorough, written, medical, dental and social history obtained for each patient and recorded in the patient notes? yes☐ no☐

* *NHS and Private*

** *ASA I - Healthy patient*
ASA II - Mild systemic disease with no functional limitation for example controlled hypertension
ASA III - Severe systemic disease with no functional limitation for example chronic obstructive pulmonary disease
ASA IV - Severe systemic disease that is a constant threat to life for example unstable angina

9. Is written consent obtained for all sedation patients? yes☐ no☐

10. Are all options for anxiety and pain control explored with the patient as part of the consent process? yes☐ no☐

11. Do patients receive detailed written and verbal instructions prior to their treatment ? yes☐ no☐

TRAINING FOR THE DENTAL TEAM

12. Has relevant, externally validated and up to date training been undertaken by the sedationist? yes☐ no☐

Please provide details of training to include original /most recent training

13. Have all DCPs who assist with sedation had training , either external or practice based? yes☐ no☐

Please supply details of training

SEDATION PRACTICE

14. Is a single titrated dose of midazolam only used in each case? yes☐ no☐

If no please list drug/drugs used

15. Are drugs administered by titration to a recognised sedation end point? yes☐ no☐

16. Is a pulse oximeter always used during sedation? yes☐ no☐

17. Is all equipment serviced according to manufacturers guidelines? yes☐ no☐

18. Is a service record kept for all equipment? yes☐ no☐

19. Are all patients recovering from sedation appropriately protected and monitored in adequate recovery facilities? yes☐ no☐

Please indicate facilities available for recovery

20. Please indicate arrangements in place for monitoring of recovery of patients?

21. Are all patients specifically assessed for fitness to discharge? yes☐ no☐

22. Are all sedation patients provided with written post-operative instructions? yes☐ no☐

23. Are arrangements made for all sedation patients to have a responsible adult as an escort following treatment? yes☐ no☐

24. Is a contemporaneous record kept of the administration of sedation? yes☐ no☐

DEALING WITH EMERGENCIES

25. Is Flumenazil available and in date? yes☐ no☐

26. Are emergency drugs readily available and in date? yes☐ no☐

27. Are all staff involved in sedation trained in basic life support? yes☐ no☐

If yes please note date of most recent staff training	

28. Is all emergency equipment suggested in the British Resuscitation Guidelines available? yes☐ no☐

29. Is a defibrillator available in the practice? yes☐ no☐

30. Have staff received training in the management of medical emergencies including use of defibrillators and emergency drugs? yes☐ no☐

Please supply details of training

Any further comments on any aspects of the sedation process.

Please complete by providing name, practice address and e-mail address for ease of communication

Name _____

Practice Address _____

_____

_____

_____

E-Mail _____

Signature _____

APPENDIX 2 - Membership of Review Team

Mr Barry Corkey BDS MSc MMedSc	**Associate Specialist and Assistant Clinical Director,NHS Fife and Edinburgh Postgraduate Dental Institute**
Miss Elizabeth Duffin OBE	**Lay Reviewer**
Mr Hall Graham BDS FDSRCPS MSc	**Head of Primary Care Review RQIA**
Mr Sean Brown	**Project Manager RQIA**