The Regulation and Quality Improvement Authority

FOLLOW- UP REVIEW OF INTRAVENOUS SEDATION USE IN GENERAL DENTAL PRACTICE

December 2010

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Section 1: 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 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, RQIA has developed a planned programme of clinical and social care governance reviews within the health and social care services and will also carry out commissioned reviews at the request of the DHSSPS.

Section 2: 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 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 is a range of techniques for providing conscious sedation:

- intravenous sedation using Midazolam
- inhalation sedation using nitrous oxide and oxygen
- oral sedation using 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[*]. Using appropriate doses 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.

[*] 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

Section 3: Context for the Review

3.1 Previous Review

As part of its planned programme of reviews in 2009, RQIA undertook a review of intravenous sedation use in general dental practice. This review included

- an assessment of the process employed by HSC Boards, as commissioners of dental services, to monitor the safety and quality of intravenous sedation provision
- self-assessment questionnaires sent to all practices identified as carrying out dental treatment using intravenous sedation
- validation visits to a sample of 10 dental practices

The review was completed in January 2009. It outlined serious deficiencies in two of the practices visited. Following the review, information was shared with the HSC Board and board representatives then carried out a series of visits to the identified practices, ensuring compliance with all necessary standards.

As a result of the review RQIA was asked by DHSSPS to carry out a further follow-up review of dental sedation use in general dental practice.

3.2 Standards Used

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 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.

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. It also emphasised that 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

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

[2] Conscious sedation in the provision of dental care. Standing Dental Advisory Committee. DOH 2003.

of having the appropriate equipment and drugs and ensuring that equipment is properly maintained.

Standards for Dental Professionals, the ethical guidance produced by the General Dental Council [3] states "We support the recommendations set out in the Department of Health (England) publication A Conscious Decision - a review of the use of general anaesthesia and conscious sedation in primary dental care (July 2000) and associated letters of advice from Chief Dental Officers in England, Northern Ireland, Scotland and Wales."

The guidance also states" We also support the guidance set out in Conscious Sedation in the Provision of Dental Care (November 2003), a Standing Dental Advisory Committee report of an expert group on sedation for dentistry, which the Department of Health asked for. We expect dental professionals to follow this guidance."

All dental professionals in Northern Ireland are registered with the General Dental Council and so are expected to follow the recommendations set out in A Conscious Decision and the guidance in Conscious Sedation in the Provision of Dental care.

In December 2008 the National Patient Safety Agency (NPSA) produced a Rapid Response Report entitled Reducing the Risk of Overdose with Midazolam Injection in Adults. Although aimed mainly at Midazolam use in secondary care it made recommendations that were relevant in the primary care setting. This report was issued by DHSSPS on 31 December 2008 and again all dental professionals in Northern Ireland are expected to follow its recommendations.

The following pieces of guidance also exist but do not apply in Northern Ireland.

A second report of an expert working group of the Standing Dental Advisory Committee was published in September 2005.[4] It 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,[5] 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.

[3] Standards for Dental Professionals. www.gdc-uk.org
[4] Second report of an expert working group of the standing dental advisory committee. DOH Sept 2005
[5] conscious sedation in dentistry. Dental clinical guidance. SDCEP. May 2006

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".

3.3 Role of 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)

Private dental treatment is provided to patients who:

- make arrangements with dental practitioners outside the health service, who are wholly private dental practitioners
- make arrangements with dental practitioners who carry out a mixture of private and health service work

The HSC Board is responsible for ensuring the delivery of dental services at a local level by general dental practitioners who are contracted to the health and social care board to provide general dental services. They are not employed by the board but are independent contractors who have undertaken to provide health service dental treatment. Although dental practitioners are independent contractors, the HSC Board still has a responsibility to ensure that all treatment provided in the General Dental Service is of sufficient quality.

General Dental Services Regulations[6] 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 two to three year programme. There is a regional inspection protocol, but the only references to sedation are in respect of emergency equipment and basic life support training, which are relevant to all practices, regardless of whether or not they provide any form of sedation.

3.4 Private Dentistry

The amount of private dentistry carried out in Northern Ireland is increasing, yet the number of purely private dental practices remains 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.

Private dentistry in Northern Ireland is not currently regulated, though a recommendation from the initial RQIA report on intravenous sedation use in general dental practice proposed that "DHSSPS should implement a process for the regulation of private dentistry." Following the publication of the initial report, DHSSPS has taken the decision that RQIA will regulate all dental practices that have any private component. It is anticipated that this process will be initiated in 2010, following a change in legislation.

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

Section 4: The Review Team

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

The membership of the review team was as follows:

- Barry Corkey BDS MSc MMSc. Senior Lecturer University of Edinburgh, Associate Specialist NHS Fife
- Vicky Adams BDS BMedSci MFDS Dip Cons Sed. Oral Surgery Dept School of Dentistry Royal Group of Hospitals
- Dr Rina James MBBS DA FCARCSI. Consultant Anaesthetist Royal Group of Hospitals
- Miss Elizabeth Duffin OBE. Lay Reviewer
- Hall Graham BDS FDSRCPS MSc. Head of Primary Care RQIA

Section 5: The Review Methodology

The methodology has three key elements:

- identification of practices
- self- assessment to those practices not included in the first review
- validation visits to dental practices by a review team

5.1 Identification of Practices

A database was developed, which included all general dental practices in Northern Ireland (both general dental services and private), using data from the Business Services Organisation (BSO) and other information as to where completely private dental practices are situated.

A questionnaire was sent to all practices asking if they provided intravenous sedation. If no response was received from a practice a follow-up phone call(s) was made and a 100% return was achieved.

A definitive list was then created of all practices in Northern Ireland that carried out intravenous sedation.

5.2 Self-Assessment

As part of the initial RQIA review of intravenous sedation use in general dental practice a self assessment proforma (Appendix 1), based on guidance regarding standards of treatment had been constructed. This questionnaire was then sent to practices that had not been included in the initial review.

Returned questionnaires and questionnaires from the initial review formed the basis for visits to practices.

5.3 Review Visits

Forty five practices were identified as providing treatment using intravenous sedation (excluding 10 that had been visited as part of the initial review). Questionnaires were sent to 14 practices which had not been included in the initial review and replies were received from 13 of these practices. All questions included in the questionnaire were validated during review visits which took place during November and December 2009.

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

In December 2008 the National Patient Safety Agency (NPSA), produced a Rapid Response Report entitled Reducing the Risk of Overdose with Midazolam Injection in Adults (issued by DHSSPS on 31 December 2008). Although aimed mainly at Midazolam use in secondary care it made recommendations that were still relevant in the primary care setting. It recommended that:

- high strength Midazolam is replaced with low strength Midazolam (1mg/ml in 2ml or 5ml ampoules)
- therapeutic protocols are reviewed to ensure that guidance on the use of Midazolam is clear and that the risks for the elderly or frail are fully assessed
- stocks of Flumazenil* are available where Midazolam is used and the use of Flumazenil is regularly audited as a marker of excessive dosing of Midazolam
- all healthcare practitioners involved directly or participating in sedation techniques have the necessary skills, knowledge and competencies required

Compliance with these recommendations would also be assessed by the review team.

Following the review visit, each practice was provided with feedback from the review team, highlighting areas of good practice and outlining any concerns and areas where improvements might be made.

A letter summarising the recommendations was subsequently sent to each practice. 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 taking immediate remedial action in line with RQIA's escalation policy.

In the future monitoring of dental practices by the appropriate regulator will ensure that dental treatment using intravenous sedation continues to be provided safely.

A table summarising recommendations made to practices is provided at Appendix 2.

* Flumazenil is an antagonist drug which counteracts the sedative effects of benzodiazepines including Midazolam

Section 6 Validation of Self Assessment

The following table summarises the questions posed in the self-assessment and also from information obtained during practice visits, validation of information supplied in the questionnaires.

Summary of validation of self-assessments

Question	Number of practices N=45
Is a thorough written medical, dental and social history obtained for each patient?	45
Is written consent obtained for all sedation patients?	45
Is a single titrated dose of Midazolam only used in each case?	45
Are drugs administered by titration to a recognised end point?	45
Is a pulse oximeter always used during sedation?	45
Are all patients specifically assessed for fitness to discharge?	45
Are arrangements made for all sedation patients to have a responsible adult as escort following treatment?	45
Is Flumazenil available and in date?	45
Do patients receive detailed written and verbal instructions prior to treatment?	43
Are all patients supplied with written post-operative instructions?	43
Are all staff involved in sedation trained in basic life support?	42
Is a second person **always** present during treatment?	41
Does the practice operate on an operator-sedationist basis?	41
Is all emergency equipment (excluding defibrillator) suggested in the British Resuscitation Guidelines available?	41
Have staff received training in the management of medical emergencies?	39
Are all patients recovering from sedation appropriately protected and monitored in adequate recovery facilities?	36
Are emergency drugs available and in date?	36
Are patients always assessed for suitability at a separate visit?	33
Is equipment serviced according to manufacturer's guidelines?	28
Is a defibrillator present in the practice?	22
Has relevant, externally validated and up- to- date training been undertaken by the sedationist?	20
Have all dental nurses who assist with sedation had training in sedation techniques, either external or practice based?	18
Is a contemporaneous record kept of the administration of sedation?	12
Does the practice operate with a separate operator and sedationist?	4
Does the practice treat children (under16) using intravenous sedation?	2
Which grades of patient does the practice treat - ASAI, II, III, IV (see page 12)	All practices only treat ASA I and II

Section 7: Summary of Recommendations made to Practices

Following each visit, areas of good practice and areas where improvements needed to be made were highlighted. Recommendations were made verbally to each practitioner and this was followed up with written confirmation of the individual recommendations that had been made.

The following tables summarise the guidelines/standards that each practice has to meet, the findings of the review team in relation to each guideline/standard and a summation of the individual recommendations that were made to each practice in relation to each guideline/standard.

The individual recommendations have been clustered into four areas:

1) recommendations arising from the NPSA Rapid Response Report
2) the sedation process
3) record keeping
4) dealing with medical emergencies

The standards and guidance used during the inspection process were:

1) A Conscious Decision - a review of the use of general anaesthesia and conscious sedation in primary dental care
2) Conscious Sedation in the Provision of Dental Care
3) NPSA Rapid Response Report - Reducing the Risk of Overdose with Midazolam Injection in Adults

1. NPSA Rapid Response Report

Guideline/standard	Review team finding
High strength Midazolam is replaced with low strength Midazolam (1mg/ml in 2ml or 5ml ampoules).	12 practices not yet routinely using the lower strength of Midazolam.
Recommendation 1: Practices not already doing so must use the lower strength Midazolam.	

The use of low strength Midazolam was recommended as a means of ensuring that doses are kept as low as possible, while still achieving the desired therapeutic effect. There had been some difficulty initially for all practices, obtaining the appropriate strength, but these problems had now been overcome. Any practices not using the desired dilution were informed verbally and in writing that they must comply with this recommendation.

Guideline/standard	Review team finding
Therapeutic protocols are reviewed to ensure that guidance on the use of Midazolam is clear and that the risks for the elderly or frail are fully assessed.	All practices only treat ASA I or ASA II patients. The very elderly or the very frail are never treated using intravenous sedation*
Recommendation : None.	

*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

Guideline/standard	Review team finding
Stocks of Flumazenil are available where Midazolam is used and the use of Flumazenil is regularly audited as a marker of excessive dosing of Midazolam.	Flumazenil is readily available in all practices. To date only two practices have ever had to use it.
Recommendation : None.	

All practices have Flumazenil available in the practice and in only two practices has it ever been used. As the antagonist drug is almost never used, this indicates that appropriate doses of Midazolam are being administered in dental practices.

Guideline/standard	Review team finding
All healthcare practitioners involved directly or participating in sedation techniques have the necessary skills, knowledge and competencies required.	In 25 of the 45 practices dentists had not attended training within a three to four year period. In 27 of the 45 practices dental nurses had not attended training within a three to four year period.
Recommendation 2 Practices should ensure that all dentists and dental nurses participating in sedation that have not attended update training in the last three to four years should access appropriate training at the earliest opportunity.	

All guidance emphasises the importance of appropriate training for both dentist and dental nurses but none state a timescale for updated training. It is good practice that update training is undertaken every three to four years. Training for dental nurses can be carried out in-house but it must be demonstrated that it meets the required standard and be documented. In 25 practices visited, dentists had not updated their training within the recommended three to four year period and in 27 practices dental nurses had either had no training within the three to four year period or had in-house training that had not been documented. It is recommended to practices that they should attend training as soon as possible.

2. Sedation Process

Guideline/standard	Review team finding
A cannula should be used to obtain venous access in all cases.	Thirteen practices did not use a cannula routinely or used a butterfly in difficult cases.
Recommendation 3 A cannula must be used in all cases.	

All practices used a single drug, Midazolam, and were aware of the need for a slowly titrated dose according to individual patient's needs. It is good practice that a cannula should be used to obtain venous access instead of a butterfly. This is due to the small chance of cutting out or blockage occurring with a butterfly, resulting in loss of venous access. The drawback is that cannulas are more difficult to use. However all practices still using butterflies, even occasionally, were informed that they must use a cannula at all times.

Guideline/standard	Review team finding
Dose of Midazolam should not usually exceed 10mg.	Seven practices very occasionally exceed this dose.
Recommendation 4 Only in exceptional circumstances should a dose of 10mg Midazolam be exceeded. If this occurs the rationale for doing so should be carefully documented.	

It is good practice that the dose of Midazolam is kept below 10mg. It is also accepted that each patient is different and reactions to the drug can vary widely depending on body mass, social and medical history etc. All practices were informed that if the level of 10mg is exceeded then the rationale for doing so should be carefully documented.

Guideline/standard	Review team finding
Presence of a chaperone.	In four practices, occasionally a dentist or a dental nurse may be left alone with a sedated patient.
Recommendation 5 All practices must have a robust system to ensure that at no time is either a dentist or dental nurse left alone with a sedated patient.	

On no occasions should either a dentist or a dental nurse be left alone with a sedated patient. All practices are aware of the need for a chaperone at all times. However, in a few cases it emerged that occasionally either dentist or dental nurse might leave the surgery, albeit for a very short time. These practices were informed that if someone had to leave the room they should have a system in place that another member of staff should immediately take their place.

Guideline/standard	Review team finding
Storage of Midazolam.	In 4 practices Midazolam was not being stored securely when not being used.
Recommendation 6 Practices should ensure that Midazolam is stored in a lockable drawer or cupboard.	

Midazolam is a schedule 3 controlled drug and though conditions for its use are not stringent it is good practice for stocks to be locked away when not in use. A recommendation was made to those practices that did not store Midazolam securely that they should do so as soon as possible.

Guideline/standard	Review team finding
Treatment of young people under 16 years of age.	Two practices use sedation for young people under 16 years of age in a significant number of cases.
Recommendation 7 Practices must document the rationale behind the decision to use intravenous sedation in young people under 16 years of age and demonstrate that all treatment options had been discussed.	

Two out of 45 practices sedated a significant number of young people under the age of 16. Intravenous sedation for this age group is not in itself dangerous, but a young person's reaction is less predictable than that of an adult and is dependent on the body mass and maturity levels of the patient. The practitioners involved were asked to ensure that the training they had received was adequate to use this technique for this group of patients. Practices should carefully document the rationale behind the decision to use this form of treatment and also provide evidence that all treatment options had been discussed.

Guideline/standard	Review team finding
Patients should be kept for at least 1 hour following the last administration of Midazolam and be accompanied by a suitably qualified person.	Nine practices occasionally did not keep patients for the required time or did not have a suitable qualified person present at all times.
Recommendation 8 Practices should comply with guidance on recovery.	

No practice would consider using intravenous sedation for a patient unless there was another responsible adult to accompany them home. It is also recommended that patients be kept in the practice for an hour following the last dose of Midazolam and that they be accompanied by a suitably qualified person during the recovery period. In the majority of cases the patient is recovered in the dental surgery and both dentist and dental nurse are present throughout. Occasionally a separate recovery room is used and it was emphasised to these practices that a suitably qualified dental nurse should be present to monitor the patient throughout the recovery period.

3. Record Keeping

Guideline/standard	Review team finding
Clinical notes should record • BP before during and after a procedure and times noted • dose of Midazolam, batch number and expiry date of each ampoule • a range of recordings for oxygen saturations and pulse with times • time of the last dose of Midazolam • time of discharge • clear written instructions should be provided for both patient and escort following a procedure.	Thirty three practices were recording insufficient information in clinical notes regarding the sedation process.
Recommendation 9 Practices should comply with guidance on record keeping.	

The most frequent recommendation made to practices concerned record keeping. It is important that practitioners keep a comprehensive and contemporaneous record of the sedation process. All practices used a pulse oximiter and take blood pressure readings. All practices provided evidence of written consent and clear written medical histories and most provided written instructions for booth patient and escort. The most frequent recommendation concerned monitoring of sedation, in that monitoring was being done but not sufficiently recorded. In a few cases only verbal instructions were given to the escort and a recommendation was made that these should be written.

4. Dealing with Medical Emergencies

Guideline/standard	Review team finding
A full range of emergency drugs should be available and in date.	In nine practices, one or more emergency drugs were out of date.
Recommendation 10 All practices must immediately replace any out of date emergency drugs and have a robust system to check that all emergency drugs remain in date.	

All practices should have a full range of emergency drugs, as recommended in UK Resuscitation Council guidance and these should be stored together in a purposely designed emergency drug storage container and be in date. In nine practices one or more emergency drugs were out of date. Practitioners were instructed to rectify this immediately and develop a system to ensure that it did not happen again.

Guideline/standard	Review team finding
Oxygen cylinders must be fully replenished and be easily accessible.	In two practices oxygen cylinders were almost empty. In two practices oxygen cylinders were past their expiry date. In one practice it took more than five minutes to locate the oxygen cylinder.
Recommendation 11 Practices must immediately replace oxygen cylinders where necessary and in the future have a system in place for checking cylinders.	

All practices should have a full range of emergency equipment as recommended in UK Resuscitation Council guidance, which includes an oxygen cylinder which should be regularly checked. In two practices the oxygen cylinders were almost empty and in two cases the cylinder was past its expiry date. The practices were told to take immediate steps to address these deficiencies.

Guideline/standard	Review team finding
Training in medical emergencies.	In three practices it had been more than a year since training had been carried out. In three practices training had not involved dealing with medical emergencies.
Recommendation 12 Practices using intravenous sedation must carry out yearly basic life support training which includes dealing with medical emergencies.	

All practices should have yearly basic life support training but in practices using intravenous sedation it is recommended that this training be extended to include dealing with medical emergencies. In three practices this training was overdue, though only by a matter of weeks, and in three other practices training had not included dealing with medical emergencies. Again, it was recommended to these practices that this training should be organised as soon as possible.

Guideline/standard	Review team finding
Defibrillator.	Twenty three practices did not have a defibrillator.
Recommendation 13 Practices should consider purchase of a defibrillator as recommended in UK Resuscitation Council Guidance.	

The UK Resuscitation Council Guidance sets out minimum standards for medical emergency and resuscitation equipment. These minimum standards recommend the provision of an automated external defibrillator (AED) in all dental practices, irrespective of whether or not sedation is carried out. In Northern Ireland it has been left to individual practitioners as to whether or not they followed this guidance.

A recommendation was made to all practices that they should give serious consideration to the purchase of a defibrillator**.**

Guideline/standard	review team finding
Defibrillator training.	Two practices had purchased a defibrillator but had not had training in its use.
Recommendation 14 Practices with a defibrillator should include training in its use in their annual medical emergency training.	

Guideline/standard	Review team finding
Equipment servicing.	Seventeen practices were unaware that pulse oximeters and BP monitors could be serviced, and should be serviced yearly.
Recommendation 15 All practices should ensure that equipment used in sedation is serviced yearly.	

Conscious Sedation in Dentistry - Dental Clinical Guidance recommends that "calibrated and appropriately maintained pulse-oximeter and blood pressure monitors must be available for use as indicated".

All practices had pulse-oximeters and blood pressure monitors but in 17 practices they were unaware of the need to have this equipment serviced yearly.

Guideline/standard	Review Team Finding
Adverse Incidents.	No practice reported an adverse incident relating to intravenous sedation.
Recommendation None.	

Section 8: Follow Up Visits

In two practices, due to deficiencies identified, immediate follow up was considered to be necessary. The following tables summarise the issues identified in the two practices and also follow-up action that was taken and timescales.

Practice 1

Issue identified	First follow-up (24 hrs)	Second follow-up (2 weeks)
Emergency drugs out-of-date.	Full range of emergency drugs in date. System for checking in place.	
Midazolam in syringes in a drawer.	Syringes removed and practice stopped.	
Not routinely using cannulas.		All dentists using cannulas.
Hygienist monitoring sedated patient.	Stopped.	
Oxygen cylinder almost empty.		New oxygen cylinders present.
Only one pulse oximeter in practice.		2 new pulse oximeters purchased.
No system to ensure chaperone at all times.	System now in place.	
Written instructions for both patient and escort.		Written instructions present for both patient and escort.
Records - not all information being recorded.		Records examined and all necessary information is now being recorded.
Flumazenil readily available in surgery where sedation taking place.	Flumazenil in each surgery.	
Training for dentists and dental nurses.		Dentists attending course in Feb 2010. Attending SAAD[7] course later in 2010. Learning to be cascaded to dental nurses who would attend next available course.
Defibrillator not present in the practice.		Defibrillator purchased. Training in medical emergencies arranged, to include training in use of a defibrillator.

[7] Society for the Advancement of Anaesthesia in Dentistry

Practice 2

Issue identified	Follow-up (1 week)
Emergency drugs insufficient and most out-of-date.	All recommended emergency drugs present and in date. System in place to ensure checking in future.
Oxygen cylinder out of date and took five minutes to find.	Oxygen cylinder replaced and accessible.
Insufficient emergency equipment.	All recommended emergency equipment present.
Life support training did not include dealing with medical emergencies.	Life support training including dealing with medical emergencies and also in use of emergency equipment arranged.
Training for dentist and dental nurse.	Training course arranged for February 2010. In house training for dental nurse would now be documented and formal training arranged at the first opportunity.
Not routinely using cannulas.	Arrangements made for mentoring by another practice to include use of cannulas.
Written instructions to both patient and escort.	Written instructions now given to both patient and escort.
Records - not all necessary information being recorded.	All necessary information now being recorded.
No system to ensure chaperone at all times.	System to prevent either dentist or dental nurse being left alone with a sedated patient now in place.
Defibrillator not present in practice.	Defibrillator purchased and training organised.

Note: In view of the findings of the follow-up visit at one week in relation to compliance with the standards, a second follow-up visit was not undertaken.

Section 9: Conclusions

The initial RQIA review of intravenous sedation use in general dental practice was completed in January 2009 and made the following 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 required standard.
2) DHSSPS and the Northern Ireland Medical and Dental Training Agency (NIMDTA) should carry out a review focusing on the availability, appropriateness and standardisation of intravenous sedation training.
3) Boards must ensure that all dentists who carry out treatment using intravenous sedation are practising in line with the NPSA rapid response report Reducing the Risk of Overdose with Midazolam Injection in Adults.
4) Boards 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 AEDs.
5) Boards 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 review 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.

Having now inspected all dental practices that provide treatment using intravenous sedation it is considered that all of the above recommendations are still relevant.

The most common issue reported by dentists in both the initial review and also in the follow up review was access to appropriate training for both dentists and dental nurses. Compared to the overall number of dentists in Northern Ireland, only a small number actually provide treatment under intravenous sedation. These dentists will be at different stages in their careers and will have different training needs. This creates difficulties for providers of training, in that what is appropriate for an inexperienced practitioner is not appropriate for a practitioner with experience in this area.

Practitioners considered that a possible solution might be formation of one or more sedation peer review groups (as outlined in recommendation 7 from the initial review).
These peer review groups would not need to meet more than once a year, and would be a forum for sharing good practice. They would provide a vehicle where less experienced practitioners may learn from more experienced colleagues and more experienced practitioners from each other. It would also be possible, perhaps through this group to arrange for mentoring of practitioners wishing to undertake sedation for the first time. This would allow them to achieve the recommended hands-on training which, at present, is difficult to access.

One additional issue noted by many practitioners is where to refer patients who require sedation but are not suitable for treatment in general practice. It is possible for patients needing oral surgery work, such as extraction of wisdom teeth and other difficult extractions to obtain treatment in the School of Dentistry in the Royal Group of Hospitals. However, for those patients needing conservation work, such as fillings and crown and bridge work, this facility is not available.

A follow up recommendation to the first report would therefore be

Recommendation
The provision of a service to allow for the referral of patients needing sedation who require treatment other than for oral surgery should be considered.

Intravenous sedation as carried out in general dental practice is a valuable and effective procedure allowing a large cohort of patients to access dental treatment that would not be available elsewhere. Where guidelines on training, competency and technique are followed it is also a very safe procedure.

RQIA's two reviews examining intravenous sedation use in general dental practice have raised awareness among dental practitioners as to what their responsibilities are in relation to intravenous sedation and what they must do to ensure safe practice.

RQIA will, in the near future, assume responsibility for the regulation of private dentistry. At this point RQIA can ensure that as part of its inspection process, intravenous sedation use in general dental practice remains safe and effective.

Appendices

Appendix 1 - Questionnaire

INTRAVENOUS SEDATION IN GENERAL DENTAL PRACTICE
2009

Self Assessment

PLEASE ENSURE THIS DOCUMENT IS RETURNED NO LATER THAN

16 OCTOBER 2009

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

31 Is a second person **always** present during treatment? yes☐ no☐

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. Recommendations made to Practices

The recommendations made to each practice are summarised in the table below.

RECOMMENDATION	NUMBER OF PRACTICES
Records	33
Training for dental nurse	27
Training for dentist	25
Defibrillator	23
Equipment servicing	17
Use of cannula	13
Use of 5mg/5ml Midazolam	12
Recovery	9
Patient and escort instructions	9
Emergency drugs in date	9
Doses of Midazolam below 10mg	7
Life support training/medical emergencies	6
Chaperone	4
Midazolam in locked cupboard	4
Oxygen cylinders	4
Defibrillator training	3
Flumazenil use	2
Sedation for under 16s	2