Oral and Maxillofacial Surgery Departmental Guidelines for Provision of Oral Surgery Under IV Sedation at Kidderminster Treatment Centre

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Introduction

To promote the safe and effective selection and treatment of patients receiving IV sedation for Oral Surgery within the outpatient department at KTC

This guideline is for use by the following staff groups:

All clinical staff within the OMFS department.

Lead Clinician(s)

Mr Kieron McVeigh – Consultant Oral and Maxillofacial Surgeon & Clinical Lead
Dr Meera Thakar - Specialty Doctor in Oral Surgery
Dr Haimisha Mistry – Specialty Doctor in Oral Surgery

Approved by Medicines Safety Committee: 14th February 2024

Reviewed and approved at directorate governance meeting: 15th November 2023

This is the most current document and should be used until a revised version is in place: 3 years from approval date

Key amendments to this guideline

Date	Amendment	Approved by:
15/11/2023	Approved at Directorate Governance Meeting	OMFS and Dermatology Governance
14/02/2024	Approved at MSC	MSC

Oral and Maxillofacial Surgery Departmental Guidelines for Provision of Oral Surgery Under IV Sedation at Kidderminster Treatment Centre

Introduction

The Department of Oral and Maxillofacial Surgery provides a conscious sedation (intravenous midazolam) with local anaesthetic service for oral surgery procedures to meet the needs of the population served by Worcestershire Acute Hospitals NHS Trust. This service is run at the Oral and Maxillofacial Surgery Outpatients Department at Kidderminster Treatment Centre. Post treatment recovery facilities are provided on the Day Case Theatre Recovery suite. The service is consultant and middle grade (Specialty Doctor) led. However, junior trainees (Dental Core Trainees) will be involved in the supervised delivery of both sedation and surgery as this represents a valuable training opportunity. All junior staff will receive training on the delivery of safe sedation as part of the West Midlands Deanery study day programme and locally within the department.

Conscious Sedation

Conscious sedation can be 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.'

(**Standards for Conscious Sedation in the Provision of Dental Care - Report of Intercollegiate Advisory Committee for Sedation in Dentistry, 2015).**

The important clinical points emphasised in this definition are that the patient remains conscious and thus verbal communication and their laryngeal protective responses (including cough and swallowing reflexes) are maintained. In the UK the concept of "deep sedation' is categorised along with general anaesthesia and is not suitable or appropriate for the outpatient setting.

Methods of Conscious Sedation.

Conscious sedation can be achieved via a variety of techniques:

- Oral and transmucosal
- Inhalation
- Intravenous (via a variety of agents i.e., midazolam, propofol).

The only modality offered by the department is intravenous midazolam sedation. Inhalation sedation in particular for paediatric patients is offered by the Community Dental Services. Other forms of intravenous sedation including polypharmacy are administered where appropriate by the anaesthetic team in a theatre setting.

Preparation for Sedation Patient selection

On consulting a new patient on referral, it is the responsibility of the hospital clinician to assess the patient's suitability for conscious sedation. This is based upon the patient's individual needs, anxiety history, surgical complexity of the proposed treatment, background medical history and physiological status. Ultimately, careful assessment of these factors will more likely lead to the appropriate selection of cases with a safe and successful outcome for the patient. In some cases, alternative techniques, including local anaesthesia alone or even general anaesthesia may be more appropriate.

Reasons to consider IV sedation.

Patients selected for IV sedation in the outpatient setting most commonly fall into the following two categories:

1. Anxious or phobic patients who will not tolerate any procedure with local anaesthetic alone even of the proposed surgery is simple (for example – extraction of a single fully erupted tooth).
2. Patients who require moderately complex or prolonged surgery (for example – impacted wisdom teeth) with the aim of reducing the unpleasant stimuli associated with the procedure.

Some patients with a mild to moderate gag reflex may benefit from IV sedation.
However as IV sedation will suppress but not remove reflexes, more severe cases may benefit from general anaesthesia.
Patients with behavioural factors, learning disabilities or movement disorders impairing cooperation, are best treated under the care of the special care dentistry team. This led by Dr. Castle-Burrows (Consultant in Special Care Dentistry) who together with the anaesthetic team run a joint assessment clinic once a month at KTC.

Anxiety

Anxiety control is an important aspect of delivering any oral surgery service and conscious sedation represents one of the many possible options to achieve this. It is the responsibility of the referring practitioner to explore all other options for anxiety management and where possible manage patients in the primary care setting. The 'Modified Dental Anxiety Scale' (MDAS) can be a useful tool for assessing anxious patients.

Surgical Complexity.

In general, surgical complexity should be considered such that cases considered for IV sedation would be theoretically amenable to be carried out under local anaesthesia alone, with the IV sedation seen as an adjunct. IV sedation in the outpatient setting should not be viewed as a substitute for general anaesthesia.
Each sedation appointment is an hour in length and the proposed surgery should be possible to complete within 40 minutes. If it is anticipated that the surgery will exceed this timeframe, then consideration must be given to the appropriateness of conscious sedation as the technique of choice, or appropriate arrangements made to accommodate the time required (for example booking two visits or a double appointment).

Pre sedation assessment.

Medical / physiological factors.

All patients potentially benefiting from treatment under IV sedation are identified and assessed at the new patient consultation clinic. At this visit the following information is gathered following history taken and examination:

- Full medical history
- Drug and allergy history
- Previous experience of GA / sedation
- Pregnancy / breastfeeding status where applicable
- Dental history including anxiety history
- Social history - including home circumstances. Smoking /alcohol/ recreational drug use
- Height / Weight /BMI
- Observations: Blood pressure, pulse, oxygen saturation

- ASA status
- Venous access
- Airway assessment

Patient Suitability.

Patients meeting the following criteria are suitable for listing to receive treatment under IV sedation in the outpatient setting at Kidderminster Treatment Centre:

- **Age 16+ (No upper limit providing meet criteria)**
- **ASA I and II**
- **BMI <40**

To aid the process of patient selection reference is made to the patient's ASA (American Society of Anaesthesiologists) status.

ASA Classification (American Society of Anaesthesiologists).

ASA PS Classification	Definition	Examples, including, but not limited to:
ASA I [P1]	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use.
ASA II [P2]	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease.
ASA III [P3]	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA or CAD/stents.
ASA IV [P4]	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis.
ASA V [P5]	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction.
ASA VI [P6]	A declared brain-dead patient whose organs are being removed for donor purposes	

PATIENTS UNSUITABLE FOR LISTING FOR IV SEDATION AT KTC

- **ASA III and IV**

- **Severe / unstable cardiac disease:**
  MI < 6/12
  Unstable angina
  Pacemaker
  Implanted defibrillator

- **Undiagnosed / poorly managed hypertension – BP > 180/110**

- **Anaemia < 90g/L, sickle cell anaemia**

- **Severe / uncontrolled respiratory disease:**
  Unstable asthma
  Unstable COPD / Oxygen at home

- **Sleep apnoea +/- CPAP**

- **Severe hepatic / renal disease:**
  Transplant in last 6/12

- **Renal: Dialysis**
  GFR < 30, CKD III

- **Poorly controlled insulin dependent diabetes mellitus –**
  Hba1c > 8.5% or 69mmol/L in last 3/12 to refer to GP

- **Poorly controlled epilepsy (seizure < 6/12)**

- **Neuromuscular disease – inc. myasthenia gravis, MND /MS**

- **Pregnancy**

- **Severe learning difficulties - best referred under care of Special Care Dentistry team**

- **Alcohol / drug dependence**

The aforementioned criteria outline suitability for treatment specifically in the outpatient department / day case recovery setting as per KTC guidelines. In certain cases, patients not fulfilling criteria may undergo formal anaesthetic pre assessment with a view to delivery of sedation by an anaesthetist in theatre at WRH.

Consent

The risk and benefits of conscious sedation and surgery are discussed at the consultation appointment. The patient agrees to be listed for treatment but has time to consider the decision between consultation and treatment appointments. On the day of surgery informed verbal is regained and written consent is confirmed. A 'consent form 1' is completed.

Pre and Post-operative instructions

Verbal and written instructions are given to the patient on the day of consultation. An information sheet is available to hand out to patients. Pre-operative instructions are also included on the surgical appointment letter sent to patients. Post-operative instructions are reiterated on the day to patient and escort, verbally and in writing.

Pre-operative

- There is no requirement to fast prior to the procedure
- All prescribed medication to be taken as normal unless instructed otherwise.
- The patient must arrange to be accompanied by a responsible adult to collect them from the recovery ward at time of discharge and transport them home (avoiding public transport)
- Loose comfortable clothing should be worn
- Nail varnish including acrylic / shellac /gel nails should be avoided.
- Young people aged 16-17 should be made aware will be treated on adult list and recovered in the adult day care recovery area.

Post-Operative

For 24 hours following the sedation the patient should not:

- Return to work
- Be left unaccompanied
- Drive a motor vehicle
- Consume alcohol or recreational drugs
- Operate machinery or household appliances
- Have sole responsibility of supervising children
- Sign important or legal documents

Delivery of Sedation Facilities

Conscious sedation is delivered in one of the treatment (oral surgery) surgeries within the Oral and Maxillofacial Outpatients Department at Kidderminster Treatment Centre. The surgery is of sufficient size to accommodate the extended team required for safe and efficient practice. It also allows for easy wheel chair access to facilitate patient transfer to the recovery ward. The surgery is fully equipped with all necessary equipment including suction facilities and supplemental oxygen for delivery via nasal cannula or face mask if required. There is immediate access to full resuscitation equipment (including a defibrillator and emergency drugs) via a connecting door between the department and the adjacent Minor Injuries Unit.

Staffing

The treatment sessions are largely led by middle grade specialty doctors and delivered in conjunction with junior staff to facilitate their training. There are two dedicated nurses at each clinic. One nurse is responsible for looking after the patient and aiding the operator / seditionist in the observation and monitoring of the patient. The second nurse acts as a runner. In situations where a junior clinician does not attend the list, the first nurse should act as scrub nurse. The primary responsibility of the second nurse is to then look after the patient. Both nurses will escort the patient to the recovery ward following completion of the procedure.

All nursing staff have completed appropriate conscious sedation qualifications. All members of the clinical team will have completed mandatory training in the management of medical emergencies, BLS - basic life support and also ILS training (immediate life support).

Confirmation of patient details and treatment plan

At the start of the appointment, prior to the delivery of sedation, all team members will Introduce themselves to the patient and confirm the patient's details and treatment plan. The details of the proposed treatment are displayed on a wall mounted dry wipe board and any relevant radiographs are clearly displayed. All equipment is checked at the start of the list. A standardised checklist based on the WHO surgical checklist used in the operating theatres is completed. This includes pause to confirm the correct site of surgery.

Drugs and Monitoring Midazolam

At the start of each clinic checks are performed to ensure all drugs are within their expiry date. All injectable substances on being drawn up into a syringe are to be are to be immediately labelled using the pre-printed adhesive labels available in surgery. Conscious sedation is achieved with a single injectable drug, midazolam, given intravenously. This drug is supplied to the department by pharmacy in the following format:

• 1mg/ml in 5ml ampoule (total 5mg midazolam)

Midazolam is a controlled drug class 3 schedule 3, meaning as per trust policy it is not required to be in a controlled drugs cabinet or recorded in a controlled drugs register. Within the department, midazolam is kept in a locked cabinet when not in use.

Midazolam is a water soluble benzodiazepine with a rapid onset of action. It is a GABA A receptor agonist, enhancing the inhibitory effect of GABA. Thus, it prolongs the time taken for repolarisation of a neurone following depolarisation after an electrical impulse. This results in the following properties and effects which are utilised for sedation:

Properties of midazolam:

• Sedative
• Anxiolytic
• Amnesic - anterograde amnesic properties which will limit the patient's recollection of unpleasant experiences.
• Muscle relaxant
• Anti-convulsant

Midazolam does not have analgesic properties, therefore local anaesthetic is also administered prior to starting the surgical procedure.

Midazolam is metabolised through oxidation in the liver, with an approximate elimination half-life of 2 hours. The active metabolite alpha hydroxymidazolam has a further half-life of

1.25 hours which can lead to some degree of 'rebound' sedation and slower recovery.

Side Effects / Oversedation effects

Midazolam is a CNS depressant and can have synergistic effects with other depressants such as alcohol, barbiturates and opioids. Effects of over sedation (particularly through rapid or bolus administration) include:

- Respiratory depression / arrest
- Cardiovascular depression / cardiac arrest (primary or secondary to respiratory)
- Decreased level of consciousness
- Loss of response to verbal commands
- Loss of reflexes
- Oversedation risk - care at extremes of age
- Some patients may be prone to fantasy - chaperone should always be present
- Tolerance to repeated use of drug

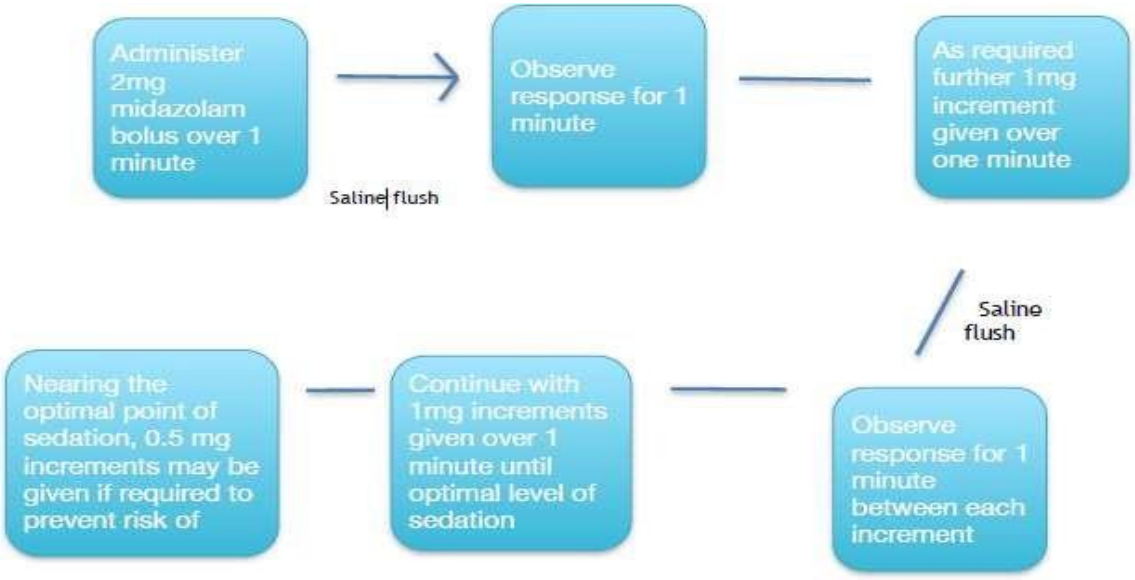
Administration of midazolam

Midazolam is administered via an intravenous cannula. Ideally this is placed in the dorsum of the hand for access, or in the antecubital fossa, with care of anatomy. It is not possible predict the quantity of midazolam required for patients and so it is imperative that careful, incremental titration of the drug is performed rather than bolus delivery.

Titration refers to the process of delivering small increments of the drug whilst observing the clinical response until sedation is deemed adequate. It is also preferable that once sedation has been achieved the treatment is completed during the period of sedation to avoid repeated dosing of midazolam during the procedure, as this can prolong recovery. The intravenous cannula is left in situ for transfer to the recovery ward and removed immediately prior to discharge.

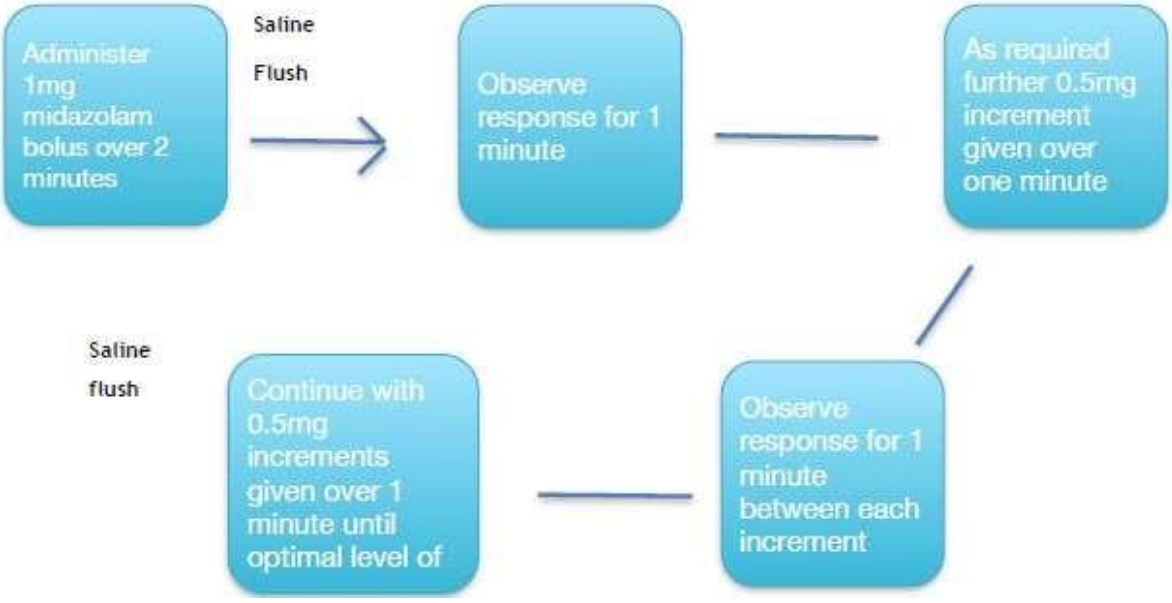
Titration of midazolam

ASA I & II Age 16-60



- The cannula should be flushed with saline between each increment.

ASA I & II Age 60+ MODIFICATION



Patients below age 16, and those ASA III + also require care with administration and titration of midazolam, but these groups would not be treated in the outpatient setting.

'Maximum' dose midazolam

As stated, the dose of midazolam is very much titrated to the individual needs of each patient. However, the BNF advises for the purpose of conscious sedation for a procedure, a maximum dose of 7.5mg per course for adult patients, reduced to 3.5mg for 'elderly' patients. On occasion the clinician may decide a higher dose is required and clinically justified. On balance, however, the majority of patients can be treated successfully within the use of one 5ml vial of 1mg/1ml midazolam, and doses over 10mg are rarely indicated. Midazolam should always be titrated incrementally to the patient's response whilst monitoring the patient's vital signs both with equipment and clinically.

Monitoring

Blood pressure, pulse and oxygen saturation are recorded at the start of the procedure. Similar observations should be available for comparison on the booking form completed at the consultation / pre-assessment appointment. The clinician will make an assessment regarding suitably to proceed as per guidelines previously described. The potential effects of anxiety and the individual medical history of the patient are also taken into account. During the procedure, continuous pulse oximetry monitoring should be performed throughout. Alarms should be set for pulse below 50 or above 120 bpm and oxygen saturation below 95%. Blood pressure is not routinely measured again during the procedure. However, should there be any clinical concerns, particularly with regards to oversedation, or the procedure is prolonged, it should be reviewed.
Observations are repeated at the end of the procedure prior to the patient being moved to the recovery area. All observations taken should be documented, together with the time at which taken, on a 'NEWS 2' chart (National Early Warning Scores), as per trust practice.

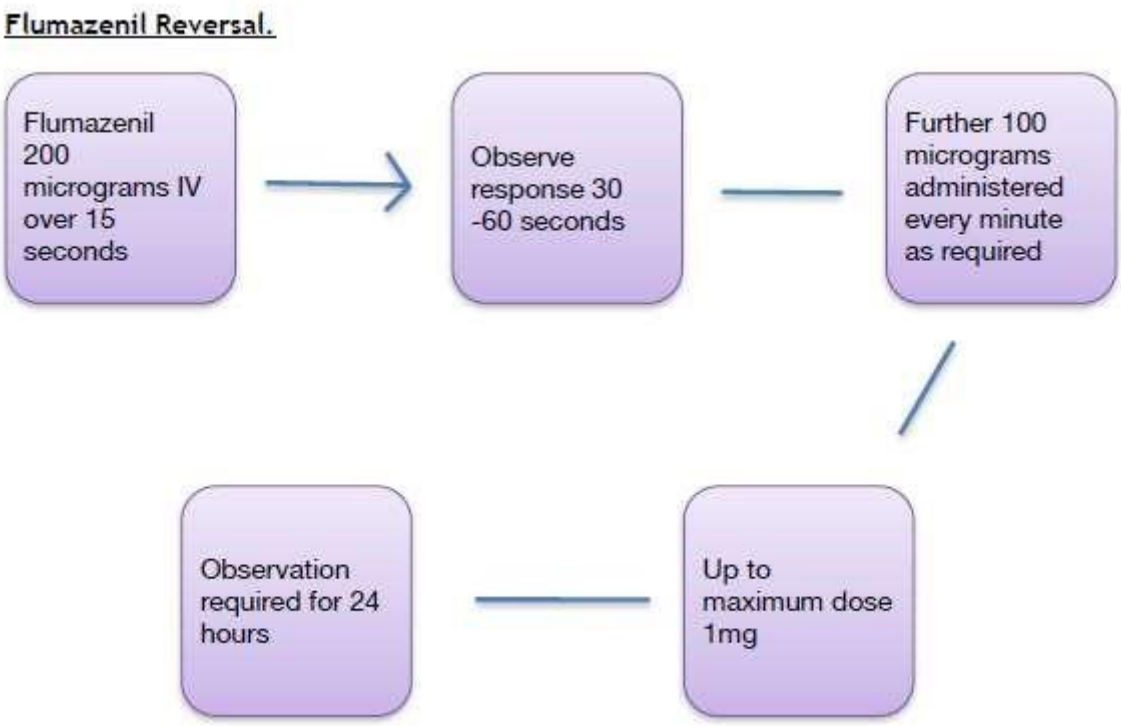
Oxygen

Supplemental oxygen is available in the surgery for delivery by nasal cannula during the procedure. Oxygen should be checked as part of equipment at the beginning of the list. It is not routinely required for every case. If the oxygen saturation, as monitored by pulse oximetry, falls 95% or below, supplemental oxygen at 2-4 litres / minute is administered. Further to this, should oxygen levels fall below 90%, reversal of sedation should be considered.

Flumazenil

If, despite taking the precautions detailed above, the patient is excessively sedated (indicated by oxygen desaturation, reduced level of consciousness, falling blood pressure or loss of gag reflexes) then a short acting reversal agent is immediately available. Flumazenil is a competitive antagonist at the GABA receptor and is supplied in 5 ml ampoules at a concentration of 100 micrograms/ml (total 500 micrograms) and is administered at a rate of 200 micrograms (2ml) over 15 seconds, then 100 micrograms (1ml) every minute as required. The BNF advises a usual dose of 300-600 micrograms with a maximum dose of 1mg for the purposes of sedation reversal. However, the clinical response of the patient should be main factor when administering the reversal agent, again with particular care with elderly patients.
As the reversal effects are short acting, apparent re-sedation may occur and the patient will require careful monitoring for 24 hours following the procedure.

The reversal agent should not be routinely used, and only drawn up if required. The intent of successful sedation is a natural recovery from the agent. Any episode of flumazenil use should be reported through the 'Datix' system.



Medical Emergencies

All members of the team are trained in the immediate management of medical emergencies or an arrest situation (BLS and ILS trained). Should a medical emergency arise, the procedure should be stopped as safely as possible. The operator and assistant should make an assessment of the patient via the 'ABCDE' pathway as per ILS protocol. The third team member should call for help from colleagues on the clinic and summon the emergency drugs trolley located in the minor injuries clinic directly adjacent through double doors to the OMFS department. In addition, there is a 'RMO' (resident medical officer) on call at Kidderminster Treatment Centre via 2222. Theatres may also be contacted to request assistance from an available anaesthetist. It should be noted at KTC there is not a designated 'crash team'. In the event of a cardiac arrest or peri-arrest situation the operator should be alerted swiftly as an ambulance will be required to attend from Worcester.
Following a medical emergency, once the patient is stabilised, appropriate follow-on care should be arranged in consultation with the medical team.

Documentation

For each patient it is essential that clear and legible documentation is completed.
A 'sedation paperwork pack' is available for printing from 'CLIP'. This includes co morbidity details, pre-operative checklist, WHO checklist, NEWS 2 observation chart and operation notes including dosage of midazolam administered together with drug batch number and expiry date.
Contemporaneous notes of the procedure carried out and any complications should be legibly recorded. It is also useful to record response to sedation for future reference. A 'TTO' sheet is also completed on discharge. 'Over the counter' analgesia is not prescribed but on occasion stronger analgesia or antibiotics may need to be prescribed.

Recovery and Discharge

Once escorted to the discharge ward a verbal handover is given to the ward nursing staff including details of the treatment, drug dosages and details of who will be collecting the patient and escorting them home. All clinical notes and discharge documentation will have been completed in the surgery prior to transfer and are handed over.
The operating clinician should review any patients remaining on recovery at the end of morning and afternoon sessions. The operating clinician remains available for consultation should the recovery staff have any concerns, until all routine patients have been discharged.

Patients are deemed fit for discharge as per day care second stage recovery guidance. The patient should be fully awake, responsive to verbal commands and taking oral fluids. Ideally, the patient should have eaten, but often this may be limited immediately following oral surgery. In addition, the patient should pass urine, again this may not always be the case given the relatively short time frame of between admission and discharge for oral surgery under IV sedation. This should not necessarily delay discharge, providing there are no other clinical concerns or issues from previous medical history.
Patients should have a responsible adult escort present to collect them on discharge and accompany home via private transport. A responsible adult should remain with the patient for 24 hours post administration of the last dose of midazolam sedation.

In the event of a patient needing admission following a complication, or a returning patient, any concerns out of hours will be directed to the on call maxillofacial team based at Worcestershire Royal Hospital. Patients are provided with written instructions giving advice on management of post- operative symptoms and clear advice as to what to do if they have concerns. Contact numbers are given for the department and the out of hours on call service.

Clinical Governance and Audit

As part of clinical governance, the department engages in regular audit activities of conscious sedation practice. Any adverse events are recorded on 'Datix'. Such events should be analysed and discussed at the departmental clinical governance meetings to identify potential problems and prevent further events.

Flumazenil use should be regularly audited and any such use recorded via 'Datix'. All team members remain up to date with BLS and ILS training, together with attendance of dental / oral surgery sedation specific courses as appropriate to maintain continuing professional development requirement.

References

These guidelines have been created with reference to the following documents:

- **Standards for Conscious Sedation in the Provision of Dental Care - Report of the Intercollegiate Advisory Committee for Sedation in Dentistry (2015)** - The dental faculties of the Royal Colleges of Surgeons & the Royal College of Anaesthetists •
- **Guidelines for the Provision of Anaesthesia Services (GPAS) Chapter 19 - Guidance on the Provision of Sedation Services (2016)** - The Royal College of Anaesthetists
- Worcestershire Acute Hospital Trust - Department of Anaesthetics - Day case Surgery Guidelines - available on intranet
- FLOWER, R.J., HENDERSON G., RANG H.P. and RITTER J.M., 2015. *Rang and Dale's Pharmacology.* 8th ed. London: Churchill Livingstone •

BNF - British National Formulary -NICE https://bnf.nice.org
MedPolSOP14 Reducing Risk of Overdose With Midazolam Injections in Adults

Contribution List

This key document has been circulated to the following individuals for consultation;

Designation
Trust Sedation Committee
Dr David Whitelock – Consultant Anaesthetist
Mr Keith Hinton – Pharmacist

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Trust Sedation Committee

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**		
	□ Race	No	
	□ Ethnic origins (including gypsies and travellers)	No	
	□ Nationality	No	
	□ Gender	No	
	□ Culture	No	
	□ Religion or belief	No	
	□ Sexual orientation including lesbian, gay and bisexual people	No	
	□ Age	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	No	
4.	**Is the impact of the policy/guidance likely to be negative?**	No	
5.	**If so can the impact be avoided?**	No	
6.	**What alternatives are there to achieving the policy/guidance without the impact?**	No	
7.	**Can we reduce the impact by taking different action?**	No	

If you have identified a potential discriminatory impact of this key document, please refer it to Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Human Resources.

Worcestershire Acute Hospitals NHS Trust

WAHT-

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	**Yes/No**
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval.