



CLINICAL GUIDELINE

Intravenous Midazolam Administration for Conscious Sedation

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Important Note:

The online version of this document is the only version that is maintained. Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Background: Sedation is an important skill to allow procedures to take place in both primary and secondary care settings and is provided by many different medical and dental practitioners. Avoidable morbidity and mortality still occurs however and therefore it is vital to have some universal standards.

Staff: Staff should be suitably trained in the administration of sedative agents including the required monitoring and resuscitation of the patient. Staff should only use sedative drugs that they are familiar with and it is recognised that they should also be trained in Basic Life Support as a minimum. Higher levels of training are desirable. It is also recognised that administration of procedural sedation requires two trained personnel as a minimum.

Patient Selection: Patients should be assessed prior to receiving sedation with respect to comorbidities and concurrent medication to allow an informed decision about the safety of sedation. High risk cases may require the assistance of an anaesthetist. Appropriate fasting should be observed prior to elective cases. In general it is recognised that patients with an American Society of Anaesthetists (ASA) grading of three or greater require to be sedated in a secondary care setting. It is appreciated that it is possible for such patients to be looked after in primary care dependent upon the skills, knowledge and experience of the sedationist and the current stability of the patient's condition.

Equipment: Areas where sedation is administered should have the following equipment immediately available: a supply of piped or cylinder oxygen, suction, facilities to hand ventilate the patient, emergency drugs including appropriate reversal agents, a defibrillator and appropriate airway adjuncts. Beds and trolleys must be capable of being tipped head down.

Monitoring: Appropriate monitoring facilities should be available when midazolam is administered. Pulse oximetry and Non Invasive Blood Pressure (NIBP) must always be used. ECG monitoring should be available but is not essential during conscious sedation in ASA 1 or 2 patients. Pulse oximetry, NIBP and ECG should be used as standard in high risk patients (ASA 3 and above). Capnography should be used where ventilation cannot be directly observed, e.g MRI, CT, where multiple drugs are used or where pre-assessment highlights increased clinical risk. In any area, there should be a nominated member of staff to monitor and record the patient's physiological variables, including conscious level. If verbal contact is lost, then the patient needs a level of care equal to that of general anaesthesia and as such requires an anaesthetist to be called.

Drugs and Dosing: Staff should only use drugs with which they are familiar. A single agent will suffice in most cases. If an opioid is required for analgesia, it should be administered first before a lower dose of midazolam is given. Oxygen should always be available but may not always be necessary. In some cases oxygen may be detrimental e.g. patients with chronic respiratory disease and hypercapnia. Midazolam doses should reflect age, weight and comorbidities as per the manufacturer's recommendations. Reversal agents should **not** be used to hasten recovery to allow earlier discharge but should be available for emergency use. If a reversal agent is required, the patient should be monitored for at least 4 hours post reversal dose and a datix form should be completed for audit purposes.

Agents such as propofol and ketamine should not be used for conscious sedation by anyone who has not had sufficient anaesthetic training and experience.

Recovery and discharge: Patient monitoring and oxygen therapy should continue during recovery with adequate staff present and resuscitation equipment available. If patients need airway support, are suffering from cardiovascular instability or are unable to communicate, they will need a one-to-one nursing ratio. Discharge criteria relating to their clinical condition and home circumstances should be met prior to discharge.

Background

Midazolam is a sedative agent commonly used to alleviate anxiety and ensure patient comfort and cooperation during potentially uncomfortable procedures such as endoscopy and colonoscopy. The vast majority of time, midazolam is used safely and effectively, however, a National Patient Safety Agency (NPSA) Rapid Response Report in 2008 highlighted that 498 incidents had been reported to them over a four year period where an inappropriate dose had been administered¹. Three patient deaths had occurred as a result of these errors. This echoed a National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report in 2004 which suggested that 14% of the 1818 deaths related to GI endoscopy that had been reported to it had received inappropriate sedation². Both these publications recommend that local guidelines should be developed to aid the safe use of sedation and of midazolam in particular.

These guidelines refer to the use of midazolam for *Conscious Sedation* which 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.”

If a patient is unable to respond to verbal contact when fully conscious an alternative effective means of communication or interaction must be sought and maintained.

Any technique resulting in the loss of consciousness is defined as general anaesthesia and in the UK deep sedation requires the same level of care as general anaesthesia. The drugs and techniques used to provide conscious sedation should carry a margin of safety, wide enough to render loss of consciousness unlikely.

These guidelines have been developed by summarising the content of several national documents from a variety of specialties. Although there are many areas of agreement, there may be small differences in management between individual procedures and specialties. As such the reader is advised to use this document in combination with any relevant national guidance particular to their individual specialty or procedure. Examples of such guidance can be found in the references.

These guidelines are not applicable for the use of midazolam for control of symptoms in palliative care patients – alternative guidelines are available for care of these patients.

There are six main areas where recommendations are made: staff, patient selection, equipment, monitoring, drugs and dosing, and recovery and discharge

Staff

Staff involved in the administration or monitoring of patients receiving sedation should be knowledgeable of the pharmacology of the drugs that are administered, the dose, predicted onset time and time to peak effect of the drugs they administer and the potential for synergism between agents¹⁻⁵. They should only use defined methods of sedation for which they have received formal training. They should also be appropriately trained in resuscitation^{4,5}. In specialties with regular exposure to sedation, trainees should have sedation training monitored as part of their ongoing Annual Review of Competence Progression (ARCP). Career grade staff should be able to demonstrate continued experience in the practice of sedation and appropriate ongoing CPD^{3,4}.

As a bare minimum, there must be two members of staff present whenever midazolam is administered. One of these must be at least Basic Life Support (BLS) certified^{3,4,5,6}, with Immediate or Advanced Life Support certification being highly desirable.

It is essential to have an appropriately trained second person monitoring the patient at all times when a single operator/sedationist is working. A third trained person available is good practice for all but the simplest procedures performed on fit (ASA 1 or 2) patients.

Patient Selection

Patients should be assessed prior to commencing sedation with regard to the following factors:

- Chronic health status especially cardiorespiratory disease,
- Age and body habitus,
- Relevant concurrent medication (such as opioids or other sedative agents).

A dedicated sedationist rather than an operator/sedationist should be employed in the following situations

- Medically compromised patient, physical disability or **emotionally challenging**.
- Extremities of age
- Inexperienced sedationist or operator
- Complex or prolonged procedure
- Previous difficulty managing the patient under sedation

Patients should be graded according to the American Society of Anaesthesiologist (ASA) physical status classification system

ASA1	Normal Healthy Patient	Non smoker, no medications
ASA 2	Patient with mild systemic disease	Smoker, controlled hypertension, asthma, diabetes. No substantive functional limitations
ASA 3	Patient with severe systemic disease	Multiple co-morbidities, morbid obesity, poorly controlled diabetes. Substantive functional limitations
ASA 4	Patient with severe disease that is a constant threat to life	Recent MI (<3 months) Severe heart failure, long term home oxygen
ASA 5	Moribund patient not expected to survive without operation	Ruptured aortic aneurysm Intercranial bleed.

Patients ASA III and above may require the assistance of an appropriately trained anaesthetist in a hospital setting and this should be considered. It is of course important to note that in the Covid 19 pandemic there has been an increased need to treat these patients out with secondary care. ASA IV patients should only be sedated in a secondary care setting.

Patients should have a drug history assessed for potential interactions with their usual medication and to assess allergy status. There are a number of drugs which can affect the half-life and plasma concentration of midazolam. Certain antifungals, antibiotics, anticonvulsants, antivirals, antiemetics, calcium channel blockers, statins and herbal medicines have all been implicated in altering the pharmacokinetics of midazolam though this list is not exhaustive. The British National Formulary (BNF) and the manufacturer's data sheet should therefore be consulted for an up to date list of potential interactions.

Please note: In an overdose situation, an increase in the terminal half-life of midazolam (due to an interacting drug) may alter the efficacy of flumazenil and necessitate extended monitoring.

In some circumstances, local anaesthetic techniques may reduce the need for sedation and this should always be considered prior to embarking on a sedative technique. If both local anaesthetic and sedation are used, caution should be exercised and a smaller sedative dose considered.

All elective patients should observe standard fasting guidelines as appropriate to the relevant specialties national guidance prior to sedation (see Appendix 2). If there are no guidelines for the practitioners specialty, fasting should be as per the Association of Anaesthetists of Great Britain and Ireland recommendations (no solid food, milk or carbonated drinks for six hours preoperatively and no clear fluids for two hours preoperatively). These guidelines should only be deviated from after the relative risks and benefits have been considered – e.g. endoscopy for ongoing haemorrhage.

Equipment

Sedation should only be administered in an environment with suitable resuscitation facilities including:

- a supply of piped or cylinder oxygen, suction
- facilities to hand ventilate patients (e.g. self-inflating bag and suitable face masks),
- emergency drugs including:
 - flumazenil (*Anexate*®)
 - naloxone (*Narcan*®) if opioids are to be used,
 - resuscitation drugs (such as adrenaline and atropine)
- a defibrillator
- appropriate airway adjuncts relevant to the skills available such as oral and nasal airways, laryngeal mask airways, and endotracheal tubes and laryngoscopes if a relevantly trained practitioner is available
- beds and trolleys should only be used if they can be tipped head down ^{3,4,5}.

In ward areas, it would be more suitable to use designated treatment rooms rather than the bedside to perform procedures to allow sufficient room for monitoring equipment and additional staff.

Monitoring

Full monitoring should be immediately available in every area where intravenous sedation is administered.

Midazolam should never be administered without adequate patient monitoring. Pulse oximetry should be used in every patient receiving sedation alongside automated non-invasive blood pressure (NIBP) monitoring. ECG monitoring should be immediately available in hospital environments. If capnography monitoring is available and appropriate to be used in the procedure, its use is advised³. ECG and blood pressure monitoring should be used as standard in high risk patients^{3,4,5}. An exception to this is areas where midazolam is administered to carefully selected ASA 1 and 2 patients only, such where only pulse oximetry and NIBP monitoring is considered necessary. This monitoring should be continued during recovery until discharge criteria have been met. There should be a nominated member of staff to monitor and record the patient's conscious level, respiratory rate and measured variables^{2,3,4,6}.

The AVPU score is a useful guide in this regard, with a target of keeping patients conscious level either “A” or “V” (*appendix 1*).

Drugs and dosing

Clinicians should only use drugs with which they are familiar and have been trained to administer^{4,5}. In most cases, a single agent will be sufficient and is far safer than using a combined technique of a sedative agent with an opioid as these drugs often display synergistic effects^{3,5}. If pain is an issue, then the opioid should be administered first and given time to take effect before a lower dose of a sedative agent is administered. Intravenous access must be secured throughout the procedure. Doses of drugs should be considered more carefully and reduced in the elderly and those with significant co-morbidities.

A patient drug history must be obtained in order to assess for potential interactions with their usual medication and to assess allergy status. There are a number of drugs which can affect the half-life and plasma concentration of midazolam. Certain antifungals, antibiotics, anticonvulsants, antivirals, antiemetics, calcium channel blockers, statins and herbal medicines have all been implicated in altering the pharmacokinetics of midazolam though this list is not exhaustive. The British National Formulary (BNF) and the manufacturer’s data sheet should therefore be consulted for an up to date list of potential interactions.

Oxygen

All hospital patients receiving sedation should be assessed for the need for oxygen therapy. In the vast majority of cases the use of oxygen is safe and should be considered as a default position, but in some cases it may not be necessary or even detrimental to the patient (e.g. Chronic Respiratory Disease with raised CO₂ on blood gases). Pulse oximetry should be used in all cases and oxygen therapy should be immediately to hand if not being used electively^{3,4,5,6}.

Midazolam (Intravenous)

Only the 1mg/ml strength of midazolam injection should be used for conscious sedation.

Healthy Adults – **Initially 2–2.5 mg, to be administered 5–10 minutes before procedure at a rate of approximately 2 mg/minute, increased in steps of 1 mg if required, usual total dose is 3.5–5 mg; maximum 7.5 mg per course.**⁷ IV midazolam doses above 7.5mg are considered off label. If higher doses are used this is a clinical decision made by an experienced practitioner and must be justified and documented in the patient notes.

Elderly or Unwell Adults – **Initially 0.5–1 mg, to be administered 5–10 minutes before procedure at a rate of approximately 2 mg/minute, increased in steps of 0.5–1 mg if required; maximum 3.5 mg per course.**⁷

Midazolam overdose may be treated with flumazenil (*Anexate*[®]). An initial bolus dose of 200 micrograms should be administered, with repeated doses of 100 micrograms given at one minute intervals until a suitable response has occurred⁸. It should be noted, however, that flumazenil has an elimination half life of 40-80 minutes compared to midazolam's half life of 90-150 minutes which may result in the patient becoming re-sedated after the flumazenil has worn off. This is especially important in the elderly where the half-life of midazolam can be prolonged fourfold, whereas flumazenil's remains unchanged¹.

As flumazenil can precipitate seizures, caution should be exercised in patients with the following⁹

- Epilepsy
- A medical condition known to lower the seizure threshold (e.g. intracranial space occupying lesion)
- Chronic use of a benzodiazepine

Flumazenil should never be used “routinely” to allow quicker recovery from a deeper level of sedation, or to hasten a patient’s discharge home. If flumazenil is used, patients should be monitored for at least four hours to ensure the effects of midazolam have worn off.

The use of flumazenil when midazolam has been used for conscious sedation should be reported via the Datix reporting system for ongoing learning and audit purposes and any other local reporting systems.

Opioids

Morphine, pethidine and fentanyl may all be used to relieve procedural pain. All these drugs increase the risk of respiratory depression with midazolam. It takes approximately 10 minutes for IV pethidine, and 30 minutes for IV morphine to reach peak effect⁹ and so unless a sufficient time is left before midazolam is administered, significant respiratory depression can occur. IV Fentanyl is more rapidly acting with its peak effect being reached in approximately 2 minutes⁹. However, it is extremely potent and there is a significant risk of respiratory depression when used in conjunction with midazolam. All of these agents should only be used with midazolam in trained hands in a well monitored and controlled environment.

Opioid induced respiratory depression can be treated with naloxone (*Narcan*[®]) 100-200 micrograms followed by a further 100 micrograms every 2 minutes¹⁰. In keeping with flumazenil, naloxone's duration of action (approximately 20mins) is significantly shorter than the corresponding duration of action for the opioids discussed above (approximately 30 minutes for fentanyl, and 240 minutes for morphine and pethidine¹⁰)

If either flumazenil or naloxone is used to treat an overly sedated patient, the patient should remain in hospital for at least four hours after the administration to ensure the sedative or analgesic agent has worn off.

Other agents

Agents such as ketamine and propofol should not be used for conscious sedation by anyone without sufficient anaesthetic training and experience^{3,5}. These drugs are anaesthetic agents with a narrow therapeutic index and their use is out with the scope of these guidelines.

Recovery and discharge

Monitoring and oxygen therapy (if required) should be continued during the recovery period⁵. There should be adequate staff to monitor patients during this time and access to resuscitation equipment.

It should be noted that a patient's conscious level may deepen once an uncomfortable stimulus is removed and respiratory depression may only be apparent during this time.

Patients should only be discharged once the following criteria have been met:

- Are conscious and orientated,
- Are cardiovascularly stable
- Are able to eat and drink
- Will be accompanied by a responsible adult who will remain with them for at least 12 hours
- Are given clear written instructions on whom to contact in case of complications
- Are advised not to drive, sign legal documents, operate machinery or consume alcohol for 24 hours following administration of sedative drugs^{5,6}.

References

1. National Patient Safety Agency. "Reducing Risk of Overdose with Midazolam Injection in Adults" NPSA/2008/RRR011. December 2008 Available from <http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=59896>
2. NCEPOD. "Scoping our Practice"2004. Available from www.ncepod.org.uk
3. Academy of Medical Royal Colleges "Safe Sedation Practice for Healthcare Procedures: Standards and Guidance", www.aomrc.org.uk October 2013
4. Intercollegiate Advisory Committee for Sedation in Dentistry. "Standards for Conscious Sedation in the Provision of Dental Care" 2015
5. British Society of Gastroenterology Endoscopy Section Committee Working Party. "Recommendations for Standards of Sedation and Patient Monitoring during Gastrointestinal Endoscopy". September 2003
6. Royal College of Radiologists. "Safe Sedation, Analgesia and Anaesthesia within the Radiology Department" 2003
7. <https://bnf.nice.org.uk/drugs/midazolam/#indications-and-do>
8. Roche Pharmaceuticals. Summary of Product Characteristics, *Anexate 0.1mg/ml*. 15th June 2011
9. Sasada & Smith. "Drugs in Anaesthesia and Intensive Care", 2nd Edition Oxford University Press 1997
10. Hameln Pharmaceuticals. Summary of Product Characteristics, *Naloxone 400mcg/ml*. 15th June 2008

Additional resources

RCOA. "Guidance on Provision of Anaesthetic Services, Chapter 19 Guidance on Provision of Sedation Services" 2016 www.rcoa.ac.uk/system/files/GPAS-2016-19-SEDATION.pdf

Du rand IA et al: "British Thoracic Society Guideline for Diagnostic Flexible Bronchoscopy in Adults"; *Thorax* 2013;**68**: i1-i44

Appendix 1: Scoring systems used in the guidelines

1. AVPU scoring

Score	Description
A –Alert	A fully awake patient
V – Voice	The patient responds to a vocal stimuli
P- Pain	The patient only responds to a painful stimuli
U – Unresponsive	The patient does not respond to any stimuli

Appendix 2: Fasting Guidelines

Specialty	Clear fluid, water, black tea or coffee		Solids (including milky drinks)
Dentistry	2 hours pre-procedure		6 hours pre-procedure
Upper GI Endoscopy	2 hours pre-procedure		6 hours pre-procedure
Radiology	2 hours pre-procedure		6 hours pre-procedure
Anaesthetics	2 hours pre- procedure		6 hours pre-procedure

Please note: In radiology and anaesthetics, chewing gum is allowable up to 2 hours pre-procedure as long as it is not swallowed...