USE OF MIDAZOLAM INJECTION IN ADULTS

This is a working document and any changes that become necessary to this policy must be notified in writing to the Medicine Management Group via the Chief Pharmacist, East Cheshire Trust

THIS POLICY MUST BE READILY ACCESSIBLE AT ALL TIMES AND AT THE POINT WHERE MIDAZOLAM IS USED.

The Medicines Management Group
Version 4: January 2017
Review: January 2020
<table>
<thead>
<tr>
<th><strong>Policy Title:</strong></th>
<th>Policy for the use of midazolam in adult patients</th>
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<tbody>
<tr>
<td><strong>Executive Summary:</strong></td>
<td>This policy provides guidance to all staff in East Cheshire NHS Trust in the use of midazolam. The policy aims to provide instruction for storage, security, prescribing and administration of medicines.</td>
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<td><strong>Supersedes:</strong></td>
<td>Version 3</td>
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<tr>
<td><strong>Description of Amendment(s):</strong></td>
<td>Restriction of prescribing for conscious sedation to senior doctors only</td>
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<td><strong>This policy will impact on:</strong></td>
<td>All health professionals involved in the prescribing, supply and administration of midazolam</td>
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<tr>
<td><strong>Financial Implications:</strong></td>
<td>None</td>
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<td><strong>Policy Area:</strong></td>
<td>Medicines Management</td>
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<td><strong>Document Reference:</strong></td>
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<td><strong>Effective Date:</strong></td>
<td>January 2017</td>
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<td><strong>Issued By:</strong></td>
<td>Chair of Medicines Management Group</td>
</tr>
<tr>
<td><strong>Review Date:</strong></td>
<td>January 2020</td>
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<tr>
<td><strong>Author:</strong></td>
<td>Clinical Pharmacy Services Manager</td>
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<tr>
<td><strong>Impact Assessment Date:</strong></td>
<td>November 2013</td>
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**APPROVAL RECORD**

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<tr>
<th><strong>Committees / Group</strong></th>
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<tr>
<td>Management – MMG</td>
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<tr>
<td>Consultant Advice to version 1</td>
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<tr>
<td>Dr James Willmott, Anaesthetist</td>
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<td>Dr Lutfi Sulaiman, Anaesthetist</td>
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<td>Dr Mark Nicol, Emergency Medicine</td>
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<td>Dr T Rimmer, Palliative Care</td>
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<td>Other (please specify)</td>
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Policy for the use of midazolam in adult patients – January 2017
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Index

1. Introduction 4
2. Aim 4
3. Roles and Responsibilities, competency requirements 4
4. Ordering and Storage of Midazolam Injection 5
5. General Anaesthesia and Conscious Sedation 6
6. Palliative Medicine 7
7. Documentation and Audit 8
8. References 9

Appendix 1: Therapeutic protocol for midazolam and flumazenil injection in conscious sedation.
Appendix 2: Safe sedation checklist
Appendix 3: Monitoring Pro Forma
Appendix 4: Discharge advice for patients following sedation
Appendix 5: Self certification of competence
Appendix 6: Risk Assessment
1. **INTRODUCTION**

   This policy has been developed in support of the National Patient Safety Rapid Response Report: NPSA/2008/RRR011, “Reducing Risk of Overdose with Midazolam Injection in Adults” available at [http://www.npsa.nhs.uk](http://www.npsa.nhs.uk)

   This policy applies to all healthcare professionals that are involved in the prescribing, administering and/or supply of midazolam injection for use in adults.

   This policy does not apply to the use of midazolam in children.

2. **AIM**

   The aim of this policy is to provide a safe system to manage the inherent risks to patients associated with the use of midazolam injection.

3. **ROLES AND RESPONSIBILITIES**

   All staff involved in the prescribing, administering or supply of midazolam injection must have the necessary work competencies to carry out their work safely, including how to manage complications.

   They must also be familiar with resuscitation methods and undergo periodic re-training. For more details about resuscitation please refer to the Trust’s Resuscitation Policy.

   All those responsible for the prescribing and administration of midazolam should ensure that they are competent to do so and any gaps in competence addressed to ensure that they undertake their duties safely. If this involves training then a record of the completed training must be made.

   Anaesthetists will be exempt from the need for regular training and documentation as conscious sedation is part of their normal clinical practice.

   Doctors and Nurses performing endoscopy and colonoscopy are accredited as part of their JAG training and those certified in this way, or who are trained and monitored using JAG standards will not require any further competency declaration.

   Other non-anaesthetic/JAG accredited staff administering midazolam must complete a Self-Certification for Competency in the Administration of Midazolam (see appendix 5). This should then be signed off by the lead Consultant within their speciality and kept in their portfolio. A copy should be forwarded Dr James Willmott – lead clinician for conscious sedation.

   Staff newly trained in conscious sedation administering midazolam should be supervised in practice until their lead consultant signs them off as competent to do so.

   Midazolam should not be prescribed or administered for conscious sedation by junior doctors, (FY1&2, ST1-4, with the exception of trainee Anaesthetists), unless under the direct supervision of a Consultant certified to administer midazolam.

   All staff involved in handling, prescribing and administering midazolam injection have a responsibility to ensure they read, understand and follow the Trust Policy for the Safe and Secure Handling of Medicines Policy. This policy is available on the Trust intranet.
All staff must be familiar with local written procedures and clinical protocols relating to the use of midazolam injection and adhere to them. For example, the protocol for the use of midazolam in the A&E department,

All critical incidents relating to midazolam injection must be reported to the risk management department at East Cheshire NHS Trust using a Datix report. This includes the administration of flumazenil as required by the NPSA.

4. ORDERING AND STORAGE OF MIDAZOLAM INJECTION

Midazolam is classed a schedule 3 control drug (CD). This means that all midazolam products must be stored in the CD cupboard.

Midazolam should be ordered from Pharmacy using a CD order book. The standard operating procedure for ordering and receiving CDs as outlined in the Trust Policy for the Safe and Secure Handling of Controlled Drugs should be followed. This policy is available on the Trust intranet.

Midazolam injection has been classified into and is available as:

- **High strength** - 5 mg/ml, 2 ml ampoules (10 mg/2 ml),
- 5 mg/ml, 10 ml ampoules (50 mg/10 ml),
- 2 mg/ml, 5 ml ampoules (10 mg/5 ml)
- **Low Strength** - 1 mg/ml, 2 ml ampoules (2 mg/2 ml)
- 5 ml ampoules (5 mg/5 ml)

The NPSA alert states that the storage and use of **high strength** midazolam injection should be restricted to general anaesthesia, intensive care, palliative medicine. In all other clinical areas (namely where midazolam is used for conscious sedation) only low strength midazolam injection should be used.

East Cheshire Trust has taken the view that palliative care patients may be admitted to any adult surgical or medical hospital ward and therefore high strength midazolam (10mg/2ml) is available in all adult wards areas. The risk assessment is attached. See appendix 6.

**ICU** will stock midazolam **10mg/5ml** as per their sedation policy.

**In theatres, ETU and Echocardiography the only midazolam preparation available is 1mg/ml.**

In the event of a paediatric intensive care transfer, the local guidelines stipulate that a morphine/ midazolam sedative should be used. In this instance, as a child may be sedated for some time and their circulating volumes are small a concentrated, (5mg/ml), preparation of midazolam is required to make up the syringe for transfer. As the child is almost always transferred from A&E, a stock of concentrated midazolam (10mg/2ml) is available in A&E but clearly labelled for paediatric use only, stored away from the dilute, (1mg/ml), midazolam and to be used only by an Anaesthetist or Paediatrician.

Pharmacy will apply a “High Strength Midazolam” sticker to all high strength midazolam products prior to distribution of the product to the ward.
5. **GENERAL ANAESTHESIA AND CONSCIOUS SEDATION**

Midazolam is widely used for general anaesthesia and conscious sedation in a number of procedures and settings. All healthcare staff participating in procedures requiring general anaesthesia and conscious sedation techniques must be trained to an appropriate level of knowledge, skills and competence in both delivering the technique and managing complications.

Use of a pro forma by clinicians is a proven tool to reduce clinical incidents associated with sedation - see example in appendix 2.

Resuscitation equipment and sedation reversing/antagonist drug (flumazenil) must be available in all areas where midazolam injection is administered and in the recovery area.

Patients receiving midazolam injection must have appropriate monitoring as follows:

- A suitably trained member of staff must have a specific responsibility for the exclusive monitoring of patient safety and must not be distracted by hands on involvement in the procedure (e.g. shoulder manipulation). Monitoring must continue from prior to administration of sedative until the procedure is complete AND the patient is spontaneously awake. Documentation of the monitored observations will be on a chart (appropriate for that clinical setting, see example appendix 3)

The level of clinical and instrumental monitoring will vary according to the clinical scenario and must be explicitly described by the clinician providing the sedation. This must then be communicated the healthcare professional(s) responsible for the patient’s recovery period. Typically this involves:

- Breathing: pulse oximeter; Respiratory rate
- Circulation: Blood pressure automated blood pressure monitoring to be set on automatic 3 lead ECG should be monitored especially in high risk patients e.g. patients aged 60 or over and those with cardiovascular problem of any age. A 12 lead ECG is often useful prior to sedation in the at risk groups. The ECG monitoring is not just for detecting rhythm disturbance but also for ST segment changes
- Disability: conscious level, sedation score (see appended chart 2 &3)

All sedated patients must have an indwelling intravenous cannula secured throughout the procedure and recovery period. A butterfly is inappropriate; and syringe and needle taped into a vein are not permissible.

Syringes for midazolam injection given for conscious sedation, should only be prepared using low strength midazolam 1mg/ml. There should only be low concentration midazolam available in these areas.

All syringes should be labelled appropriately, including the saline flush

Best practice promotes use of different sized syringes especially where two or more drugs being administered are colourless or have same colour.

Oxygen should be given to all sedated patients prior to the onset of sedation and continued until the patient is ready to leave the recovery area.
The dose of midazolam injection must be titrated to the individual patient’s clinical needs, taking into account age, weight, concurrent medication, clinical condition(s), urgency of procedure and any concomitant alcohol consumed. Refer to Appendix 1 for the therapeutic protocol for midazolam in conscious sedation.

Adverse events occur more commonly when drug combinations are used, for example, midazolam with opioid drugs. Such drugs, used in combination, have synergistic effects and as a result, narrow the predictable margin of safety. Healthcare practitioners prescribing and administering multiple drugs during general anaesthesia and conscious sedation must have the necessary knowledge, skills and competencies to do so safely.

The dosage of midazolam and opioids should be kept to a minimum to achieve sedation and should be within the manufacturer’s guidelines (generally not more than 5 mg midazolam being required) **Opioids should, whenever possible, be given before midazolam** and their effect observed before proceeding.

The use of flumazenil injection for the reversal of the effects of midazolam in patients is potentially a surrogate of poor sedation technique, and therefore ALL cases where flumazenil has been needed will be logged onto DATIX to enable thorough case review.

6. **PALLIATIVE MEDICINE**

High strength midazolam injection (10mg/2ml) is used in palliative medicine. Midazolam is the Trust’s first line sedative for terminal agitation and is administered via the subcutaneous route as either a ‘stat’ dose, a ‘when required’ dose or in a continuous infusion.

For continuous subcutaneous infusion the dose range is normally 10-80mg over 24 hours although may be increased up to 120mg over 24 hours where appropriate on specialist advice. The initial dosage is normally 10mg/24 hours; this may be higher if the patient has been given and benefitted from more than 10mg of midazolam in the previous 24 hours. It should be monitored at least once a day, and increased incrementally according to patient’s needs.

Increases should be made at no less than 8 hours, unless there is a clear decision made – this must be recorded in the patient’s case record. Midazolam may also be prescribed ‘as needed’ subcutaneously; a “stat” dose for restlessness is 2.5-10mg, 3 hourly.

For sedation during haemorrhage, midazolam 10mg intramuscularly may be needed to be repeated at 30 minute intervals. Midazolam injection should only be prescribed by those healthcare professionals who have the necessary competences and are authorised to do so.

Midazolam may also be used for patients who have been taking regular anticonvulsant medication, and become unable to take their drugs orally. The usual starting dose is 20mg/24hours, again to be monitored at least daily.

To identify and reduce the risks associated with using high strength midazolam in clinical practice, a risk assessment should be undertaken in clinical areas/wards where high strength midazolam injection is used for palliative care purposes. See appendix 6.
Midazolam should be administered only by experienced healthcare professionals who have the necessary training and competences to do so. They must also be competent to manage any complications which arise as a result of using midazolam.

7. DOCUMENTATION & AUDIT

All clinical areas where sedation is being administered must use the consent form, operation form, sedation form and observation charts appropriate for that area.

All incidents involving midazolam and flumazenil reported to the Trust via the drug incident reporting system (Datix) will be collated and analysed on a regular basis. The following should be regarded as incidents: Apnoea, hypoxia, aspiration, hypotension, arrhythmia, acute cardiac ischaemia pre or post op, failure to regain conscious level in time frame expected, death.

Clinicians must make best use of e-coding for their clinical area e.g. in A&E Extramed CRIS has sedation as a treatment code. This can then inform appraisal and revalidation.
8. References


Hameln pharmaceuticals. Summary of product characteristics, midazolam 1mg/1ml. 2 December 2008. Available at: http://emc.medicines.org.uk/medicine/21331/spc/midazolam+1mg+ml%2c+solution+for+injection+(hameln)/

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J Accid Emerg Med 1999;16:120-122 doi:10.1136/emj.16.2.120. A risk management audit: are we complying with the national guidelines for sedation by non-anaesthetists? M F Nicol Available at: http://emj.bmj.com/content/16/2/120.abstract


APPENDIX 1
THERAPEUTIC PROTOCOL FOR MIDAZOLAM AND FLUMAZENIL INJECTION IN CONSCIOUS SEDATION

A. MIDAZOLAM
Midazolam is a potent sedative agent that requires titration and slow administration. It should not be administered by rapid or single bolus injection. Syringes of midazolam injection should only be prepared using low strength i.e. 2mg in 2ml or 5mg in 5ml ampoules.

IV MIDAZOLAM DOSING IN CONSCIOUS SEDATION
In adults, the intravenous injection of midazolam should be given slowly at a rate of approximately 1mg in 30 seconds.

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

In adults over the age of 60 years, debilitated or chronically ill patients, the initial dose must be reduced to 0.5–1 mg and given 5 to 10 minutes before the beginning of the procedure. Further doses of 0.5 to 1 mg may be given as necessary. Since in these patients the peak effect may be reached less rapidly, additional midazolam should be titrated very slowly and carefully. A total dose greater than 3.5 mg is usually not necessary. (Unless for use in palliative care-PLEASE REFER TO SECTION 6 PALLIATIVE MEDICINE FOR MIDAZOLAM DOSING IN PALLIATIVE CARE)

When combining midazolam and opioids, the dosage should be kept to a minimum to achieve sedation and should be within the manufacturer’s guidelines. (Generally not more that 5 mg of midazolam being required) In elderly patients there should be a sensible pause after the initial dose is administered to observe effect. Opioids should, whenever possible, be given before midazolam and their effects observed before proceeding.

Pharmacological Properties
The onset of sedation varies amongst individuals depending on their physical status and the nature of infusion (ie speed of administration, total dose). The onset of action is approximately 2 minutes after the injection. Maximum effect is observed between 5 to 10 minutes after injection.

Midazolam has an elimination half life of 1.5 to 2.5 hours in adults. In patients over the age of 60 years, this may be prolonged up to 4 times.

Contraindications
The use of midazolam is contraindicated in patients with known hypersensitivity to benzodiazepines or to any component of the product. Use of midazolam for conscious sedation is contraindicated in patients with respiratory failure or acute respiratory depression.

Special warnings and precautions for use
Special caution is required for the indication of conscious sedation in patients with impaired respiratory function. Midazolam, as with other benzodiazepines, should be avoided in patients with a medical history of alcohol or drug abuse.

Pregnancy and Lactation
Insufficient data are available on midazolam to assess its safety during pregnancy. Midazolam passes in low quantities into breast milk. Nursing mothers should be advised to discontinue breast feeding for 24 hours following administration of midazolam.
Effects
It is well recognised that midazolam causes amnesia, and the patients should be warned about this during consent process.

Adverse Effects
See 7.2.2 Midazolam

Fitness for discharge
Patients should be given a sedation advice leaflet (and their NOKin /carer should be involved as appropriate) in understanding the DO NOTs after procedure as they have legal ramifications:
do NOT drink alcohol for 24hr
do NOT drive or operate machinery,
do NOT sign legally important documents for 24hr after receiving sedation.

Monitoring
See paragraph on monitoring 5.3.2

Other requirements
All sedated patients must have a flexible (not “butterfly”) intravenous cannula in situ throughout the procedure and recovery period. Oxygen should be given to all sedated patients throughout the procedure and recovery period, which means from before sedative administration to readiness for discharge from recovery.

Overdose:
Symptoms: The symptoms of overdose are mainly an intensification of the pharmacological effects; drowsiness, mental confusion, lethargy and muscle relaxation or paradoxical excitation. More serious signs would be
Breathing: apnoea,
Circulation: hypotension,
Disability: apnea, coma and death.

Treatment: In most cases monitoring of vital functions only is required. Flumazenil is indicated for the complete or partial reversal of the central sedative effects of benzodiazepines. It may therefore be used in reversal of midazolam sedation.
B. FLUMAZENIL
Flumazenil is a benzodiazepine antagonist. In the UK it is licensed for the complete and partial reversal of the central sedative effect of benzodiazepines. It may therefore be used in anaesthesia and intensive care in the following situations:
- Termination of general anaesthesia induced and/or maintained with benzodiazepines.
- Reversal of benzodiazepine sedation in short diagnostic and therapeutic procedures.
- For the specific reversal of the central effects of benzodiazepines, to allow return to spontaneous respiration and consciousness, in patients in intensive care.

Dosing and method of administration
Flumazenil is for slow intravenous injection or infusion. It should only be administered under the supervision of an experienced physician. It may be used concurrently with other resuscitative procedures.

Adults:
The recommended initial dose is 200 micrograms administered intravenously over 15 seconds. If the desired level of consciousness is not obtained within 60 seconds a further dose of 100 micrograms can be injected and repeated at 60-second intervals where necessary, up to a maximum total dose of 1 mg (or 2mg in intensive care). The usual dose required is 300-600 micrograms.

If drowsiness recurs, an intravenous infusion of 100-400 micrograms per hour may be employed. The rate of infusion should be individually adjusted to achieve the desired level of arousal.

Elderly:
No specific data are available on the use of flumazenil in the elderly, but it should be remembered that this population is more sensitive to the effects of benzodiazepines and should be treated with due caution.

Patients with renal or hepatic impairment:
In patients with impaired hepatic function, the elimination of flumazenil may be delayed and therefore careful titration of dosage is recommended. No dosage adjustments are required in patients with renal impairment.

Contraindications
Flumazenil is contra-indicated in patients with known hypersensitivity to flumazenil, benzodiazepines or any of the excipients.

Flumazenil is contra-indicated in patients who have been given a benzodiazepine for control of a potentially life-threatening condition (e.g. control of intracranial pressure or status epilepticus). It should not be used in patients treated with tricyclic antidepressant drugs, epileptogenic drugs (i.e. drugs that increase the risk of epileptic seizures such as clozapine and cyclosporin), or patients with ECG abnormalities (QRS or QT prolongation).

Special warnings and precautions for use
In view of the short duration of action of flumazenil and the possible need for repeat doses, the patient should remain under close observation until all possible central benzodiazepine effects have subsided.

Panic attacks have been reported after the use of flumazenil in patients with a history of panic disorder.

Policy for the use of midazolam in adult patients – January 2017
Due to the increased frequency of benzodiazepine tolerance and dependence in patients with alcoholism and other drug dependencies, flumazenil should be used with caution in this population.

**Pregnancy and lactation**
Emergency use of flumazenil during pregnancy and lactation is not contraindicated. It is not known whether flumazenil is excreted in human milk. For this reason, breastfeeding should be interrupted for 24 hours when flumazenil is used during lactation.

**Adverse effects**
Patients who have received flumazenil to reverse the effects of benzodiazepine sedation should be warned not to drive, to operate machinery or to engage in other activities demanding physical or mental exertion for at least 24 hours, since the effect of the benzodiazepine may return.

**Pharmacological properties**
Flumazenil is mainly eliminated through hepatic metabolism. Elimination is rapid and has a short half life of 40 to 80 minutes which is largely unaffected by age.
Every area where procedural sedation conducted on a regular basis should consider a proforma such as but not necessarily identical to the following

### SAFE SEDATION CHECKLIST
for procedural sedation in adults

**Pre-operative Assessment**
- Age > 65 yrs
- H/o Co-morbid diseases (HTN, DM, MI, COPD etc)
- Obesity (BMI>30)
- H/o Sleep apnoea
- SpO2, BP, PR, pain score recorded
- Axillary nerve sensation (if applicable) and Pulse check on injured side
- Routine 12 lead ECG for >65 yr. old, or co-morbidity
- Consent obtained (ideally written)

**Equipment**
- Monitor (3 lead ECG, HR, BP, SpO2%)
- Supplementary oxygen provided
- Table capable of holding xray cartridge
- Table capable of Head down tilt
- Resuscitation equipment available
- Nurse available to monitor

**Monitoring**
- IV Cannula secured
- Monitoring at 5 min intervals

**Drugs**
- Consider different sized syringes for colourless drugs to avoid drug error
- IV opiates given for analgesia
  - Drug: 
  - Dose: 
  - Time:
- IV Sedative
  - Drug: 
  - Dose: 
  - Time:
- Inhalation Nitrous Oxide
- Antagonists available out of the cupboard (Naloxone and Flumazenil)

**Level of sedation**
- Verbal responsiveness
- Airway patent

**Discharge criteria**
- A: Airway patent
- B: Oxygen saturation >95%
- C: Haemodynamically stable
- D: Spontaneously alert
- D: Pain controlled
- Nausea and vomiting

Policy for the use of midazolam in adult patients – January 2017
Policy for the use of midazolam in adult patients – January 2017

Every area where procedural sedation conducted should have patient information leaflet available.
### APPENDIX 3

Date: 

What procedure is being performed: 

Name of practitioner sedating 

Name practitioner doing procedure 

Name of nurse /assistant 

Location where sedation performed 

<table>
<thead>
<tr>
<th>Time (s)</th>
<th>Sedative given</th>
<th>Other drug given</th>
<th>Knife to skin or start time</th>
<th>O2 l/min</th>
<th>SpO2</th>
<th>RRate</th>
<th>PR</th>
<th>ECG rhythm</th>
<th>Bp systolic</th>
<th>Bp diastolic</th>
<th>Conscious level</th>
<th>AVPU</th>
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End time

Detail any of the following morbidity:
- Aspiration
- Hypoxia
- Vomit
- Other

Policy for the use of midazolam in adult patients – January 2017
16
APPENDIX 4

Discharge advice for patients following sedation

Sedation can impair your reflexes and Judgement

1. You should arrange for a responsible, able-bodied adult to collect you from hospital. You may make your own taxi arrangements if a car is not available.

2. You must have a responsible, able-bodied adult in attendance at home for 24 hours following general anaesthesia and sedation.

3. You should try to spend a restful evening and maintain a gentle level of activity. You will probably feel quite drowsy.

4. The drugs we give to relax you could make you clumsy, slow and forgetful for about 24-48 hours.

   For 48 hours after your treatment:
   - Do not make important decisions i.e. sign any legally binding documents
   - Do not use machinery or electrical items at work or home e.g. including kettles/ hot saucepans
   - Do not drink alcohol or take sleeping tablets
   - Do not work at heights (including climbing a ladder or onto a chair)
   - Do not drive for 48 hours unless your procedure states differently.

If you experience any chest pain or shortness of breath after discharge home, please contact the department or return as soon as possible.

Please show this information to the person who is looking after you.
**ECNHST Self Certification for Competency in the Administration of Midazolam**

I, the undersigned, do declare that I have read the East Cheshire NHS Trust guidelines of the administration of midazolam for the purposes of conscious sedation.

I consider myself competent to administer midazolam, with or without the concomitant administration of a suitable opiate, under these guidelines for the purposes of conscious sedation.

Signed. .................................................................Date:.........................

Name. .................................................................

Grade. .................................................................

Consultant Counter signatory  .................................................................

Date……………………………………………………………………………………
APPENDIX 6

East Cheshire NHS Trust Risk Assessment

Assessment of: NPSA/2008/RRR011 Reducing the risk of overdose with midazolam injection in adults
Assessment date: January 2010, December 2016
Assessor(s): Elisabeth Street/ Julie Whitehead

Date for review: December 2019

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<th>Likelihood</th>
<th>Impact</th>
<th>Risk Rating</th>
<th>Plan/Controls</th>
</tr>
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<tbody>
<tr>
<td>1 High Strength midazolam is available in ward areas for use in palliative care</td>
<td>Patients Clinical staff working in wards and departments where high dose midazolam is stored</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>Midazolam is treated as a controlled drug and stocked in the locked controlled drug cabinet. Full CD records are maintained at ward level.</td>
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<td>patients. This is required for the Care of the Dying Pathway. There is potential for this drug to be used inappropriately.</td>
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<td>Flumazenil is stocked in all areas where midazolam is used.</td>
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<td>The Use of Midazolam injection policy is available on Trust intranet.</td>
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<td>All high strength midazolam boxes are labelled with 'High Strength Midazolam' sticker.</td>
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<td>3/12 pharmacy CD audits identify where high dose midazolam is stocked and checks flumazenil available on these wards.</td>
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<td>Annual review by pharmacy of flumazenil stock usage report for each ward using ipharmacy crystal reports.</td>
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<td></td>
<td>Review of all drug incident forms relating to midazolam overdose/ flumazenil use and action plan to ensure practitioners receive additional training when necessary.</td>
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</tbody>
</table>

Policy for the use of midazolam in adult patients – January 2017
Equality Analysis (Impact assessment)

Equality Analysis (Impact assessment)

1. What is being assessed?

The Trust policy for use of midazolam in adults

Details of person responsible for completing the assessment:

• Name: Elisabeth Street
• Position: Clinical Pharmacy Services Manager
• Team/service: Pharmacy

State main purpose or aim of the policy, procedure, proposal, strategy or service:

• This policy has been developed in support of the National Patient Safety Rapid Response Report: NPSA/2008/RRR011, “Reducing Risk of overdose with midazolam injection in adults” available at http://www.npsa.nhs.uk
• This policy applies to all healthcare professionals that are involved in the prescribing, administering and/or supply of midazolam injection for use in adults.
• This policy does not apply to the use of midazolam injection in children.

The aim of this policy is to provide a safe system to manage the inherent risks to patients associated with the use of midazolam injection.

2. Consideration of Data and Research

To carry out the equality analysis you will need to consider information about the people who use the service and the staff that provide it. 2.1 Give details of RELEVANT information available that gives you an understanding of who will be affected by this document

The population of Cheshire as at the 2005 mid year figures (Cohesia Report 2008) is 684,400.

Age:
17.8% (30,500) of the population in Cheshire East is over 65 compared with 15.9% nationally. This results in a high “old age” dependency ratio, i.e. low numbers of working-age people supporting a high non-working dependant older population. The percentage of “older” or “frail” old is also considerably higher, with 2.3% (8,200) persons 85 and over compared to 2.1% nationally.

Cheshire East has the fastest growing older population in the North West. By 2016, the population aged 65+ will increase by 29.0% (8,845) and the population aged 85+ by 41.5% (3,403).

This will have an impact on the number of patients being managed by ECT and the complexity of the health and social care issues that the older person is experiencing. In addition the staffing profile of ECT will change to include an increasing number of staff over 65 in the workforce.
**Race:**
The 2005 mid year estimate (Cohesia Report 2008) show that the majority of the population in Cheshire (94.6%) is White British, with 5.4% non White British. The Cheshire 2007-10 Local Area Agreement identified that minority ethnic communities account for around 3% of the population. Issues for BME communities include lack of knowledge of services, access to services, access to translation/interpretation, cultural differences, family values. Many people from BME communities experience poverty, poor housing and unemployment which make it difficult for them to lead healthier lives. 4180 migrant workers registered in Cheshire in 2006/07 and comparison to the mid-year population estimates for Cheshire in 2005 strongly suggests that Cheshire’s migrant worker population is larger than every individual BME group other than the White-Other White group.

Gypsies and travellers – at the last count (July 2006) the highest number was recorded in the Borough of Congleton (125). 42% of gypsies and travellers report limiting long term illness compared to 18% of the settled population, with an average life expectancy 10-12 years less than settled population. 18% of gypsy and traveller mothers have experienced the death of a child compared to 1% in the settled population.

**Disability:**
There are over 10 million disabled people in Britain, of whom 5 million are over state pension age. Nearly 1 in 5 people of working age (7 million, or 18.6%) in Great Britain have a disability. Hearing loss: 1 in 4 has a hearing problem. Sight problems: There are 2 million people with sight problems in the UK. Learning disabilities: There is quite a high proportion of people with learning disabilities in the local area due to there being a number of residential homes/institutions in the area. Problems encountered can be lack of staff awareness, communication issues, information requirements.

**Dementia**
Approximately six in 100 people aged over 65 develop dementia and this rises to around 20 in 100 people aged 85 or over. Dementia affects 750,000 people in the UK.

**Carers**
Around 6 million people (11 per cent of the population aged 5+) provided unpaid care in the UK in April 2001. While 45% of carers were aged between 45 and 64, a number of the very young and very old also provided care. By 2037, it is anticipated that the number of carers will increase to 9 million.

**Gender**
On average in Cheshire, 49% of the population are male and 51% are female

Transgender: No local data available, national trends show:

1/12,000 males, transgender from male to female
1/33,000 females, transgender from female to male

Specific issues around access to services, specific services for men or women, and ‘single sex’ facilities. In terms of the transgender population, GIRES (Gender Identity Research and Education Society ) gives an estimate of 600 per 100,000. If these figures were applied to the Cheshire East community based on the 2005 mid year estimates, there may be around 2,100 trans people in the area.

**Religion/Belief**
In the Cheshire East area:

- Christian - 80%
- Sikh - 0.05%
- Buddhists - 0.16%
- Other religion -
- 0.15%

Policy for the use of midazolam in adult patients – January 2017
The Muslim population has the highest levels of ill health amongst faith groups – this includes higher smoking rates amongst men and higher rates of coronary heart disease and diabetes.

**Sexual Orientation**
Lesbians, gay men and bi sexual people (LGB) make up to 5-7% of the UK population (Dept of Trade and Industry, 2003). 13% of Gay men and 31% Lesbian women are parents (Morgan and Bell, First Out: Report of the findings of Beyond the Barriers national survey of LGB people)

The experience and health needs of gay men and women will differ. However, both groups are likely to experience discrimination, higher levels of mental ill health and barriers to accessing health care

National Health Inequalities data shows that lesbian, gay, bisexual and transgender (LGBT) people are e 2001 census showed:
significantly more likely to smoke, to have higher levels of alcohol use and to have used a range of recreational drugs than heterosexual people. They are also at greater risk of deliberate self-harm.
Although most LGBT people do not experience poor mental health, research suggests that some are at higher risk of mental health disorder, suicidal behaviour and substance misuse

2.2 Evidence of complaints on grounds of discrimination: (Are there any complaints or concerns raised either from patients or staff (grievance) relating to the policy, procedure, proposal, strategy or service or its effects on different groups?)

No- none aware of

2.3 Does the information gathered from 2.1 – 2.3 indicate any negative impact as a result of this document?

No

3. Assessment of Impact
Now that you have looked at the purpose, etc. of the policy, procedure, proposal, strategy or service (part 1) and looked at the data and research you have (part 2), this section asks you to assess the impact of the policy, procedure, proposal, strategy or service on each of the strands listed below.

**RACE:**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, racial groups differently? Yes □  No  X

Explain your response: __. Applies to all patients within the scope of the policy following completion of the relevant assessments. Where a person’s first language is not English, staff will follow the Trust’s interpretation and translation policy.

**GENDER (INCLUDING TRANSGENDER):**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, different gender groups differently? Yes □  No  X

Policy for the use of midazolam in adult patients – January 2017
**Explain your response**: Applies to all patients within the scope of the policy following completion of the relevant assessments. The Trust has a transgender policy and staff will be mindful of this.

**DISABILITY**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, disabled people differently?  Yes ☐ No x

**Explain your response**: Applies to all patients within the scope of the policy following completion of the relevant assessments. Use of an interpreter may be employed where necessary for Deaf patients or deaf blind. The Trust is also implementing Signtranslate which is an online BSL interpretation system using a webcam, which may help with communication with patients and carers. Information can be provided in a variety of formats such as large print, audio, Braille and easy read. For patients with learning disabilities, picture communication books are available in ward communication boxes and staff have access to learning disabilities awareness training including Makaton.

**AGE:**
From the evidence available does the **policy, procedure, proposal, strategy or service**, affect, or have the potential to affect, age groups differently?  Yes ☐ No x

**Explain your response**: Applies to all patients within the scope of the policy following completion of the relevant assessments.

**LESBIAN, GAY, BISEXUAL:**
From the evidence available does the **policy, procedure, proposal, strategy or service** affect, or have the potential to affect, lesbian, gay or bisexual groups differently?  Yes ☐ No x

**Explain your response**: Applies to all patients within the scope of the policy following completion of the relevant assessments.

**RELIGION/BELIEF:**
From the evidence available does the **policy, procedure, proposal, strategy or service** affect, or have the potential to affect, religious belief groups differently?  Yes ☐ No x

**Explain your response**: Applies to all patients within the scope of the policy following completion of the relevant assessments. For patients of Muslim faith, then all drugs administered will be checked with the pharmacy for porcine content.

**CARERS:**
From the evidence available does the **policy, procedure, proposal, strategy or service** affect, or have the potential to affect, carers differently?  Yes ☐ No x

**Explain your response**: Patient consent would be sought unless life threatening situation.

Policy for the use of midazolam in adult patients – January 2017

23
OTHER: EG Pregnant women, people in civil partnerships, human rights issues.
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect any other groups differently?  Υes □  No x

Explain your response: Applies to all patients within the scope of the policy following completion of the relevant assessments. Appropriate risk assessment would need to be completed for any pregnant or breastfeeding lady prior to administration of midazolam.

4. Safeguarding Assessment - CHILDREN
   a. Is there a direct or indirect impact upon children?  Yes □  No x
   b. If yes please describe the nature and level of the impact (consideration to be given to all children; children in a specific group or area, or individual children. As well as consideration of impact now or in the future; competing / conflicting impact between different groups of children and young people:
   c. If no please describe why there is considered to be no impact / significant impact on children.
      This policy only relates to use of midazolam in adult patients

5. Relevant consultation
   Having identified key groups, how have you consulted with them to find out their views and that the made sure that the policy, procedure, proposal, strategy or service will affect them in the way that you intend? Have you spoken to staff groups, charities, national organisations etc?
      Policy applies to all patient groups equally.

6. Date completed:  7/11/13  Review Date: Nov 2016

7. Any actions identified: Have you identified any work which you will need to do in the future to ensure that the document has no adverse impact?

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<thead>
<tr>
<th>Action</th>
<th>Lead</th>
<th>Date to be Achieved</th>
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8. Approval – At this point, you should forward the template to the Trust Equality and Diversity Lead lynbailey@nhs.net

Approved by Trust Equality and Diversity Lead: 

Date: 12 Nov 13

Policy for the use of midazolam in adult patients – January 2017

24