Guidelines on safe sedation practice for endoscopy.

Contents

For use in: Calderdale and Huddersfield NHS Trust.

Policy Statement: Guidelines on use of non-anaesthetic sedation in adult patients undergoing endoscopy procedures.

Scope of the policy: For use in adult patients only.

Statutory requirement: To be practiced by appropriately trained and experienced clinical staff.

Monitoring/Auditing arrangements: Assessment of adherence to the guidelines will be included in the endoscopy audit programme.

Summary of the consultation/development process:
The guidelines were compiled on behalf of and with the assistance of the CHT Endoscopy Users Group, by Dr. Sunil Sonwalkar (Consultant Gastroenterologist), Amanda Esmond (Nurse Endoscopist) and John Yorke (Chief Pharmacist) and were sent for comment to the staff highlighted below. It as also reviewed by Dr. Richard Johnson, Consultant Anaesthetist.

Distribution list and dissemination method (via Trust email to):
Clinical Director for Medicine
Consultant Gastroenterologists
Gastrointestinal Consultant Surgeons
Consultants in Acute Medicine
Gastroenterology Nurse Practitioners
Endoscopy Unit Managers
Nurse Manager
Endoscopy staff
Introduction:

Previously published UK reports showed that excessively large doses of benzodiazepines and opiates were being commonly used to sedate patients for gastrointestinal (GI) endoscopy. This unsafe practice has lead to avoidable morbidity and mortality.

Monitoring and safety guidelines for sedating patients have been issued in the past; particularly in light of a 1991 UK audit of over 14,000 patients undergoing an upper GI endoscopy. The 1991 audit, published in 1995, found that over 100 patients died within 30 days of the procedure. Several of these patients died as a result of being given too large a dose of either IV midazolam or diazepam. Similar cases of sedation-related deaths have been reported elsewhere. Previous guidelines have all stressed the importance of not exceeding the dose of IV benzodiazepine recommended by the manufacturer and of reducing the dose sufficiently in elderly, frail or at-risk patients. More recent audits of endoscopic procedures such as colonoscopy and Endoscopic Retrograde Cholangiopancreatography (ERCP) have shown improved use of pulse oximeters, supplemental oxygen and indwelling IV cannulae when compared with the earlier reports. Despite this, and a small reduction in the mean doses of sedative and analgesic drugs being employed in the more recent audits, there have been, once again, a number of reported sedation related cardiopulmonary deaths especially in elderly patients.

A 2004 report by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD), “Scoping our Practice”, found that there had been 1,818 deaths after therapeutic GI endoscopic procedures. NCEPOD advisors judged that the sedation given was inappropriate in 14% of cases, usually because an overdose of benzodiazepine had been administered.

The BSG, in its most recent guidelines on sedation and safety published in September 2003, made recommendations regarding dosage of midazolam and pethidine.

Need for updating local guidelines:

A document titled, ‘Safe Sedation Practice’, was issued in October 2005 for use in adult patients undergoing non-anaesthetic sedation in endoscopy at the Calderdale and Huddersfield NHS Trust (CHT).

Since, then there has been more evidence from large scale audits, NCEPOD and the BSG regarding sedation practice in endoscopy. Some recommendations from these will have to be incorporated to improve sedation related mortality and morbidity.

Reorganisation of the services across the trust has meant constant need for identifying differences in practice across the two sites and a strong desire to have common accepted standards to reduce risks. This has been an important issue in endoscopy due to the variation in practice regarding drawing up drugs and the types of drug vials used across the two sites.

A small audit of endoscopists working in the trust suggested that there was a desire for standardization of practice across the trust.
Evidence used:

The guidelines below have been mainly drawn from the

- The report of the Working Party on guidelines for Sedation by Non-anaesthetists, published by The Royal College of Surgeons of England, June 1993,

- Implementing and ensuring safe sedation practice for healthcare procedures in adults, the report of an intercollegiate working party chaired by the Royal College of Anaesthetists 2002.


- Hull and East Yorkshire Hospitals NHS Trust, ‘Guidelines on safe sedation and monitoring in Gastrointestinal Endoscopy.’

Other studies referenced are documented at the end of the manuscript. Where possible the original wording of the documents has been retained but adapted to local working patterns based on local opinions.

Definition of Conscious Sedation:

Conscious sedation has been 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 should carry a margin of safety wide enough to render loss of consciousness unlikely.”

Royal College of Anaesthetists (2002)

Features of Conscious Sedation

- Minimally depressed consciousness
- Patient easily roused
- Protects own airway
- Maintains own breathing independently
- Responds to verbal commands
- Remains co-operative
End Point of Sedation - Conscious Sedation Scale

- Relaxed
- Restful
- Drowsy
- Appropriate response to commands
- Protective reflexes present
- Occasional vocalisation
- Pulse change <10%
- SaO₂ change <5%

What other levels of depressed consciousness can be produced by the same drugs?

Deep Sedation

- Not easily roused
- Partial loss of protective reflexes
- Partial or complete inability to protect airway (≤ GCS 9)
- No purposeful response to stimuli or commands

General Anaesthesia

- Controlled unconsciousness
- Loss of protective reflexes
- No response to physical stimuli or verbal command

It is inappropriate for practitioners to be operating at any level other than that of conscious sedation without a qualified anaesthetist and anaesthetic equipment in the same room as the patient.

The Practitioner operating at any level of sedation should have the competence to rescue the patient from a level deeper than that intended (i.e. be able to recover an inadequate airway, and to maintain adequate ventilation as required in basic life support). There are also specific reversal agents available and these will be discussed. The endoscopist is responsible for the health and safety of the patient throughout the procedure.

Monitoring during sedation for Endoscopy:
### In advance of the procedure

<table>
<thead>
<tr>
<th>Action</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>The patient and/or healthcare staff, should complete a ‘check-list’ to</td>
<td>Documents such as ICP, Clerking/admission</td>
</tr>
<tr>
<td>identify any risk factors.</td>
<td>notes can provide this information.</td>
</tr>
<tr>
<td>Patients must be provided with instructions on activities before and</td>
<td>The Trust Anaesthetic sheet would be a suitable checklist.</td>
</tr>
<tr>
<td>after the procedure.</td>
<td></td>
</tr>
<tr>
<td>Protocols must be in place for dealing with any intercurrent disease</td>
<td>The level of detail, and the need for further clinical examination or investigations, will</td>
</tr>
<tr>
<td>etc.</td>
<td>depend on the procedure and the patient’s general condition.</td>
</tr>
</tbody>
</table>

### During the Procedure

| Sedative drugs are usually administered by the oral or intravenous      | The specific technique used should be one defined by the relevant speciality consultants, |
| routes.                                                                | and drug doses should be adjusted to individual patient requirements.                     |
| When the intravenous route is used, secure venous access is mandatory   | Combinations of drugs, especially sedatives and opioids, should be employed with         |
| (Minimum 22 gauge blue venflon), specific antagonist drugs, if available,| particular caution.                                                                       |
| must be readily to hand.                                               |                                                                                           |
| A suitably trained Nurse, HCA or ODP must be present throughout the     | The opioid should be given first and allowed time to become maximally effective before     |
| procedure. They must have a defined responsibility for monitoring       | any sedative is added.                                                                     |
| patient safety and making a written record.                            |                                                                                           |
| Oxygen and devices for administering it by the nasal and facial routes,  | Oxygen should be administered if there is any concern that the oxygen saturation might     |
| must be available.                                                     | decrease below the resting figure, remembering that a reading below 90% is dangerous and |
|                                                                      | requires immediate intervention.                                                           |
| Appropriate resuscitation equipment must be immediately available with  | Each department will have equipment specific to the client group and procedures undertaken  |
| all staff being familiar with its use.                                 | as per Trust resuscitation policy December 2005.                                           |
|                                                                      | All patient trolleys should be capable of being tipped head down.                           |
Following the Procedure

| An appropriate level of clinical and instrumental monitoring should be continued until discharge criteria are met. | Clinical teams need to define the discharge criteria for their group of patients and ensure this information is readily available to all staff. |
| Instructions on aftercare are reinforced to the accompanying person. | The information needs to be verbalised to the accompanying person with written material for later reference. |

Handling Medicines in endoscopy:

Handling of medicines in Endoscopy departments can represent a significant risk because of the circumstances in which medicines are prescribed and prepared. It is important, therefore, that all staff involved with the use of medicines take every possible care in ensuring their safe use.

Endoscopy nurses and endoscopists must be aware of the risks and causes of medication errors and must ensure that checking procedures are in place and adhered to, even for routine procedures. They must recognise that errors occur especially in situations of haste, distraction or fatigue. Sub optimal lighting frequently found within Endoscopy, needs to be recognised as a potential source for errors to be made.

Prescription of Medicines:

All medicines should be prescribed in accordance with the guidelines within the Medicine Code.

Medication required by patients prior to investigations is supplied against the instructions from the referring medical practitioner.

Nurse endoscopists either administer medication against a prescription written by a prescriber or in accordance with a Patient Group Direction.

The Endoscopist records the medication administered in endoscopy on the endoscopy report. Any medication required following the procedure is prescribed by the medical practitioner responsible for the patients care on the relevant prescription form. If the patient suffers an adverse event in the immediate post operative period then the endoscopist reviews the patient and takes the necessary action which is documented in the nursing care plan and on the report. This is also documented as an adverse event.

Preparation of Medicines:

Ideally, medicines should only be drawn up in to a syringe by the person who will administer the medicine, immediately before use. However, syringes may sometimes need to be prepared in advance. Where this is necessary each syringe must be clearly labelled with the approved name of the medicine and the strength of the medicine in mg/ml, or international units/ml, using the national standard labelling system.
Medicines for use in an emergency should be immediately available but stored in an area away from the immediate work area. Any syringes that are drawn up for use must be labelled and discarded as soon as that patient leaves the room.

Ampoule labels must be read and re-read before medicines are drawn up into a syringe. Errors are unlikely to be detected once the medicine is in the syringe. Lighting of the Endoscopy Suite is critical for all aspects of safety. Where technology requires reduced lighting, specific arrangements need to be made for selecting and checking medicines.

When a nurse prepares medications they must be checked by a second person before administration. All vials/ampoules should be kept until the end of the procedure—Thus ensuring all drugs administered are recorded. The check process must include a check of the actual syringe, any attached label and a check of all the original containers used.

As per Trust Policy single use containers of injectable products are for use in one patient only.

A snapshot audit of endoscopists within the trust suggested that most were happy to draw and administer their own drugs in keeping with the local medicines code. This practice however varied across the two sites. In keeping with the majority view and to avoid risk medicines (benzodiazepines & opiates only) should be drawn up by the administering endoscopists only. Other drugs used in endoscopy (therapeutic agents, buscopan, reversal agents, antibiotics, local anaesthetics, chromoscopic agents, EMR solutions etc.) will be drawn by the nursing team or the endoscopist if he is happy to do so.

The snapshot also suggested the following preferences:

1. Midazolam: Ideally 1mg/ml in a 5ml syringe so that 1 ml contains 1mg. A 5mg in 5ml Midazolam ampoule is now available trustwide and the suggestion is to draw this undiluted in a 5ml syringe to give a strength of 1mg/ml. (A 10ml syringe can be used to draw up to the 5ml mark).

2. Pethidine: Available as 50mgs in 1ml vial. Should be drawn up to the 1ml mark in a 2.5ml syringe so that 0.5mls contains 25mgs.

3. Fentanyl: Available as 100 micrograms in 2ml vial. Should be drawn up to the 2ml mark in a 2.5ml syringe so that 0.5mls contains 25micrograms.

Administration of Medicines:

Medicines may only be administered to an individual patient under the direction of a doctor or in accordance with a recognised and approved Patient Group Direction.

- A nurse can administer medicines in accordance with the Trust Medicine Code.
- Nurses can administer prescribed intravenous medicines and infusions after completing the Trust intravenous medicines training and being assessed as competent in their work place, whilst working to departmental protocols.
• Good practice states that for intravenous medicines and infusions two practitioners should check the preparation and administration. The medicines administered are recorded on the endoscopy reports.

**All endoscopists to follow the trust ANTT guidance when handling/administering medicines.**

**Risk Management:**

Risk assessments must be carried out in connection with the medicine and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

A risk assessment should be undertaken on each occasion when a new product or procedure is introduced in Endoscopy.

If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. The risks must be documented on the departments risk register and staff must have undertaken the necessary training to minimise risks.

There will be emergency situations when drugs will have to be drawn up and/or administered by the person not performing the endoscopy in view of patient safety.

**Drugs used in endoscopy:**

**What drugs/combinations are commonly used?**

• Pharyngeal anaesthesia (non sedating).
• Benzodiazepine sedation.
• Opiate analgesia plus Benzodiazepine sedation (Intravenous Sedo-analgesia).

**Pharyngeal anaesthesia (non sedating):**

- **Lidocaine 10% (Xylocaine throat spray)**
  - 10 mg/dose, 10 doses in adults(max 20) by local spray to the pharynx to suppress the gag reflex.

**Avoid:**
- If intravenous sedo-analgesia is used
- If prolonged sedation likely
- Excessive number of sprays, which may suppress cough reflex
- In patients with likely to have excess secretions (patients with dysphagia or gastric outlet obstruction)

**Benzodiazepine sedation intravenously: Midazolam**

Midazolam binds to stereo specific benzodiazepine receptors on the postsynaptic GABA neuron at several sites within the central nervous system, including the limbic system and reticular formation. Enhancement of the inhibitory effect of GABA on neuronal excitability
results by increased neuronal membrane permeability to chloride ions. This shift in chloride ions results in hyper polarization (a less excitable state) and stabilization. Midazolam has been found to cross the placenta. It also enters breast milk. Midazolam causes anterograde amnesia. Paradoxical reactions, including hyperactive or aggressive behaviour have been reported. Midazolam has no analgesic, antidepressant, or antipsychotic properties.

- First choice in sedation for upper or lower intestinal endoscopy.
- Moderately rapid onset of action (1-2 min)
- Compared to diazepam emulsion injection (Diazemuls), 3 times more potent, shorter half-life (1.5-4.5h) has greater amnesiac effect.
- Potentiates effects of opiates and so must be used carefully in smaller doses, with an up to four fold decrease in total dose used. (see below in section on how sedation should be given)

### Benzodiazepine side effects:

Any drug that depresses the central nervous system has the potential to impair respiration, circulation or both.

<table>
<thead>
<tr>
<th>CNS</th>
<th>CV / Respiratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agitation</td>
<td>Mean arterial pressure ↓</td>
</tr>
<tr>
<td>Restlessness</td>
<td>Cardiac output ↓</td>
</tr>
<tr>
<td>Hallucinations</td>
<td>Stroke volume ↓</td>
</tr>
<tr>
<td>Dizziness</td>
<td>Vasc. resistance ↑</td>
</tr>
<tr>
<td>Headaches</td>
<td>Respiratory depression</td>
</tr>
<tr>
<td>Amnesia (50-75% adults)</td>
<td>Respiratory arrest</td>
</tr>
</tbody>
</table>

### Opiate analgesia intravenously:

#### Pethidine

It binds to opiate receptors in the CNS, causing inhibition of ascending pain pathways and altering the perception of pain. It produces generalized CNS depression.

- Longer acting, useful in prolonged procedures (eg ERCP)
- Good analgesic effect
- Can cause nausea and vomiting

#### Fentanyl

Fentanyl binds with stereo specific receptors at many sites within the CNS, and increases pain threshold, alters pain reception, and inhibits ascending pain pathways.

- Rapid onset of action.
- Short duration of action (20 minutes)
- More marked respiratory depression
- Potentiates the effects of Benzodiazepines up to 8 times
How should sedation be given?

General Points on Sedation:

- Midazolam <75 years maximum 5 mgs; >75 years maximum 2mgs, given incrementally
- Excessive dose may cause deep sedation risking respiratory depression, agitation and aggression.
- End point of sedation in alcoholics and in drug users are uncertain and the dosage of sedative may need to be paradoxically less.

Individually Titrated Benzodiazepine Dose

1. Start sedating with Midazolam 2–2.5 mg IV or half of the recommended dose based on body weight over approx. 60sec (elderly 1mg IV).
2. Allow 2 min to act and assess effectiveness.
3. Add increments of 0.5-1 mg IV until endpoint reached (Elderly 0.5 mg IV).
4. ‘Top-up’ if needed with prolonged procedure (25% of initial dose)

Intravenous Sedo-analgesia

- In the case of Pethidine, the BSG has suggested an average dose of no more than 25 mg in a patient over the age of 75 years of age and no more than 50 mg for a fit young adult.(<age of 75 years)

  **BSG guidelines 2003**

- Opiates and Benzodiazepines are highly synergistic in terms of both efficacy and side effects
- Lower doses of each are required when used in combination.
1. Start intravenous sedo-analgesia by giving opiate first: either Fentanyl 25-100 microgram IV (avoid in Elderly >75 years) or Pethidine 25-50 mg IV (for the elderly 25mg IV).
2. Follow this by smaller than usual titrated dose of either Midazolam 1-3 mg IV.

When and how to reverse the effects of sedatives and analgesics?

**When to reverse**

- Deep sedation
- Slow recovery after procedure (especially elderly, or after sedo-analgesia)
• Significant co-morbidity (eg respiratory compromise) in patients undergoing an emergency endoscopy unless there is immediate recovery
• Risk of aspiration
• Patients occasionally become restless or even violent following sedation. This situation can sometimes be salvaged by reversing the sedation, which may allow the endoscopy to proceed.

This guidance pertains mainly to gastroscopies, colonoscopies and flexible sigmoidoscopies. Other procedures (like ERCP) might need higher sedation doses in some cases. For the use of sedation and analgesia there will also be other exceptions in certain cases based on clinical needs as assessed by the endoscopist. This guidance does recognise this and is within the scope of the guidance.

How to reverse

Reverse Benzodiazepines with Flumazenil

2. Then a further 100 microgram IV at 60 sec intervals.
3. Usual dose range 300-600 microgram IV (max. total 1 mg).
   • Rapid onset, short half life (20 min).
   • Side effects:
     • Agitation
     • BP
     • PR ▲
     • Seizures
     • Angina

Reverse Opiates with Naloxone

1. Give Naloxone 100-200 microgram IV aliquots.
2. Further increments 100-200 microgram IV every 2 min if poor response.
   • Rapid onset, short half life (20 min).
   • Side effects:
     • Agitation
     • BP ▲
     • PR ▲
     • Angina

Proposed Audit pathways and standards of care:

Suggested indicators:
Lead consultants (Preferably a Gastroenterologist and an Anaesthetist) appointed.

Audit
- Percent patients who have undergone an assessment prior to sedation.
- Percent patients requiring the use of reversal agents.
- Percent patients where procedure abandoned due to inadequate sedation
- Percent patients with an uncomplicated recovery (without medical intervention in the recovery area and without delayed discharge or admission to a ward).
- Percent patients who meet standard criteria for discharge after day case surgery before they are discharged.

Audit percent patients with:
1. Dedicated intravenous access
2. Continuous monitoring of heart rate and pulse oximetry (SpO2)
3. Supplementary oxygen
4. Continual care during the procedure and recovery from a person trained in resuscitation and unconnected with the actual procedure.

**Proposed standard or target for best practice:**

All hospitals should have lead consultants appointed.

100% patients should have the four factors listed above.

0% patients should require reversal of sedative or opioid.

< 5% of procedures should be abandoned due to inadequate sedation.

100% patients should have an uncomplicated recovery.

100% patients should meet standard criteria for discharge after day case surgery before they are discharged.

**Consider a safe sedation course for all endoscopists.**