

18 December 2009

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations

Action required by:

Directors of Clinical Governance

We recommend you also inform:

- Drug & Therapeutics Committees
- Sedation Committee
- Directors of Surgery
- Directors of Anaesthetics
- Directors of Intensive Care/Critical Care
- Directors of Pharmacy
- Directors of Emergency Department
- Area Directors of Nursing and Midwifery
- Day Surgery Unit Staff
- Intensive Care Nurses
- Emergency Department Clinicians and Nurses
- Nursing Unit Managers

Expert Reference Group

Content reviewed by:

- Statewide Medication Safety Committee
- NSW TAG
- ICCMU
- Emergency Care Taskforce
- GMCT
- Nursing and Midwifery Office
 Mental Health Drug & Alcohol Office
- Clinical Excellence
 Commission

Clinical Safety, Quality and

Governance Branch NSW Department of Health Tel. 02 9391 9200 Fax. 02 9391 9556 Email quality@doh.health.nsw.gov.au

Internet Website

http://www.health.nsw.gov.au/q uality/sabs

Intranet Website

http://internal.health.nsw.gov.au/qu ality/sabs/

Safety Notice 022/09

Safe use of Midazolam

Background

Midazolam is a short-acting benzodiazepine which works on the central nervous system as a sedative, hypnotic, anxiolytic and amnesic agent used in a variety of clinical situations. Improvement in the safe handling and use of Midazolam is recommended in NSW hospitals where dosing errors have resulted in over-sedation of some patients.

Contributing Factors

- Mistaken strength: Midazolam is produced by several manufacturers in two strengths of 1mg/mL and 5mg/mL in a variety of ampoule sizes for both intramuscular and intravenous injection. It is also administered by intranasal, oral, buccal, rectal and subcutaneous routes.
- Storage conditions in clinical areas: As Midazolam is stored as an S4D in small, often overstocked narcotic safes or emergency trolleys, there is increased potential for selection error to occur.
- Unclear communication related to use of Midazolam in emergency situations.

Strategies for reducing Midazolam related incidents

Storage

- Wherever possible, only one strength of Midazolam should be kept in each clinical area. The strength kept should be matched to the main clinical use of that area.
- All new and rotational staff must be aware of the strength of Midazolam kept and the reason why this is limited.
- If both strengths are requested to be kept together, ensure that ampoules of high strength Midazolam are not stored adjacent to low strength or clearly identify differences and limit ampoules to one size of each strength.
- Ampoules of high strength Midazolam are to be considered S4D in all hospitals and storage limited to S8 drug cupboards in clinical areas. These ampoules may also be stored in sealed Resuscitation or Emergency packs as indicated. Protocols
- Review therapeutic protocols to ensure use of Midazolam is clear and that risks are fully assessed particularly for elderly, frail and paediatric patients. Correct, individualised dose, selection, and potential for additive effects with other prescribed agents must be considered.
- Regular observations must be included for patients who have received Midazolam (in emergency and non-emergency situations) until full consciousness has been regained with a process in place for immediately escalating care for patients who clinically deteriorate.

Administration

- Ensure that all health care staff involved directly or participating in sedation techniques have prerequisite competencies required for their roles.
- Parenteral Midazolam should only be administered in areas where there is intubation and advanced airway management equipment and staff trained in their use.
- Where possible, only one type of infusion device should be used to administer Midazolam in each clinical setting.

Suggested Actions by Area Health Services:

- 1. Distribute this Safety Notice to all relevant clinical staff.
- 2. Undertake an evaluation to identify the appropriate use of Midazolam in clinical areas.
- 3. Keep only one strength of Midazolam in stock, where possible.
- 4. Where multiple strengths of Midazolam must be kept and stocked together, ensure they are stored in a way to prevent selection error.
- 5. Include safe use and handling of Midazolam administration in local guidelines with risk assessment where relevant for the elderly, frail and paediatric patients.
- 6. Ensure all clinicians have knowledge of local sedation policies and procedures.
- 7. In emergency situations, ensure communication regarding use and dosage of Midazolam is clear
- 8. Ensure staff are aware that further information on Midazolam is available via the CIAP website at http://www.ciap.health.nsw.gov.au or http://internal.health.nsw.gov.au



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Safe use of Midazolam

Emergency Use

- Communication of medicine orders in emergency situations should be clear and accurate. The generic drug name, dose and route of administration must be used.
- Patients given Midazolam in an emergency situation need close monitoring until full consciousness has been regained with a process in place for immediately escalating care for patients who clinically deteriorate.

Management of oversedation

- Oversedation with Midazolam can have severe consequences including death from respiratory depression. When oversedation occurs, it is important to ensure that the patient is closely monitored and treated with appropriate resuscitative measures. In non-emergency situations Midazolam should only be administered in clinical areas where there are appropriately skilled staff and advanced airway management equipment.
- In some cases, Flumazenil may be used to reverse the effects of Midazolam. Flumazenil has limited effectiveness and should only be used by clinicians aware of its limitations in terms of relative half-life and side effects.

Other Suggested strategies to reduce Sedation Management Incidents

- > All health care staff involved directly or participating in sedation techniques must have the competencies required including identification and management of patients who clinically deteriorate.
- Overall responsibility and evaluation of sedation management practices in each organisation should be assigned to the Drug and Therapeutic Committee and/or Sedation Committee or an appropriate senior clinician (e.g. an anaesthetist) nominated in smaller facilities.

References

- Medication Handling in NSW Public Hospitals Policy, Legislative requirements and policies on drug storage, supply, prescribing, dispensing and administration in NSW public hospitals. www.health.nsw.gov.au/policies/pd/2007/PD2007_077.html - 18k - Cached - 18 Oct 2007
- > Clinical Focus Report From Review of IIMS data. Use of Midazolam (Oct 2009)
- ANZCA/GESA/RACS PS9 document Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical or Surgical Procedures
- > Midazolam Hydrochloride. In: DRUGDEX® Evaluations Database. Micromedex 2009 Thomson Reuters.
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- Gan, T.J, Pharmacokinetic and Pharmacodynamic Characteristics of Medications Used for Moderate Sedation. Clinical Pharmacokinetics 2006, 45(9):855-869.
- National Patient Safety Agency. Rapid Response Report 2008/ RRR011 1074 Reducing the Risk of Overdose with Midazolam in Adults. 2008 <u>http://www.nrls.npsa.nhs.uk/resources/?entryid45=59896</u>
- National Patient Safety Agency. Rapid Response Report 2008/ RRR011 1074A- Reducing the Risk of Overdose with Midazolam in Adults - Supporting Information. 2008. http://www.nrls.npsa.nhs.uk/resources/?entryid45=59896)
- National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Taxonomy of Medication Errors 2008 (*http://www.nccmerp.org/pdf/taxo2001-07-31.pdf* - accessed 28 October 2009).
- Stowasser, D et al. Understanding the Medicines Management Pathway. J Pharm Pract Res 2004: 34: 293-6.