NHS
National Patient Safety Agency

Rapid Response Report

NPSA/2008/RRR011

From reporting to learning 9 December 2008

Reducing risk of overdose with midazolam injection in adults

Issue
Some adult patients are being overdosed with midazolam injection when used for conscious sedation. The presentation of high strength midazolam as 5mg/ml (2ml and 10ml ampoules) or 2mg/ml (5ml ampoule) exceeds the dose required for most patients. There is a risk that the entire contents of high strength ampoules are administered to the patient when only a fraction of this dose is required. Doses often exceed that required, are not titrated to the patient's individual needs, do not take into account concurrent medication (e.g. opioids) and may involve high risk groups for example, the frail or the elderly. There is frequent reliance on injectable flumazenil (antagonist/reversing agent) for reversal of sedation in patients that have been over sedated.

Patient Safety Incidents
The NPSA has received 498 midazolam patient safety incidents between November 2004 and November 2008 where the dose prescribed or administered to the patient was inappropriate. Three midazolam related incidents have resulted in death.

Incident data suggests that the reversing agent, flumazenil, is frequently used to treat inadvertent benzodiazepine overdose and, on occasion, no account is taken for the shorter half life of flumazenil (compared to midazolam) leading to residual re-sedation.

For IMMEDIATE ACTION by all organisations in the NHS and independent sector where midazolam is used for adult conscious sedation.

The deadline date for ACTION COMPLETE is 9 June 2009

An executive director, nominated by the Chief Executive, working with the lead pharmacist and relevant medical/nursing staff should:

011/1 Ensure that the storage and use of high strength midazolam (5mg/ml in 2ml and 10 ml ampoules; or 2mg/ml in 5ml ampoules) is restricted to general anaesthesia, intensive care, palliative medicine and clinical areas/situations where its use has been formally risk assessed, for example, where syringe drivers are used.

011/2 Ensure that in other clinical areas, storage and use of high strength midazolam, is replaced with low strength midazolam (1mg/ml in 2ml or 5ml ampoules).

011/3 Review therapeutic protocols to ensure that guidance on use of midazolam is clear and that the risks, particularly for the elderly or frail, are fully assessed.

011/4 Ensure that all healthcare practitioners involved directly or participating in sedation techniques have the necessary knowledge, skills and competences required.

011/5 Ensure that stocks of flumazenil are available where midazolam is used and that the use of flumazenil is regularly audited as a marker of excessive dosing of midazolam.

011/6 Ensure that sedation is covered by organisational policy and that overall responsibility is assigned to a senior clinician which, in most cases, will be an anaesthetist.

To help with implementation of this RRR:
Supporting information is available at www.npsa.nhs.uk/rrr including harm evidence and links to relevant guidelines/resources. Further queries to Linda Matthew, Senior Pharmacist c/o rrr@npsa.nhs.uk; telephone 020 7927 9890.

The NPSA has informed:
NHS organisations, independent sector, commissioners, regulators and relevant professional bodies.

Gateway Reference: 11015