National Patient Safety Alert

NHS

Risk of death from unintended administration of sodium nitrite

Date of issue:	06 August 2020	Reference no:	NatPSA/2020/004/NHSPS

This alert is for action by: **All acute trusts** (children and adult)

This is a safety critical and straightforward National Patient Safety Alert. Implementation should be co-ordinated by Chief Pharmacist/Director of Medicines Optimisation, or equivalent role, with oversight by an executive leader.

Explanation of identified safety issue:

Sodium nitrite has one licensed indication: as an antidote to cyanide poisoning. The Royal College of Emergency Medicine (RCEM) and National Poisons Information Service (NPIS) guideline[1,2] recommends that it should be "immediately available in the emergency department".

Sodium nitrite can cause significant side effects, including methaemoglobinaemia and nitric oxide induced vasodilation; with Toxbase[3] categorising it as 'highly toxic'.

Historically, sodium nitrite 30mg/ml has been an unlicensed product supplied in ampoules by 'Specials' manufacturers.[4] However a licensed product, supplied as a vial, has been available since 2016.

Our regular review of the National Reporting and Learning System (NRLS) identified two incidents where unlicensed sodium nitrite was inadvertently administered to premature babies instead of sodium bicarbonate 4.2%: one very premature baby died soon after this incident occurred and the other died after a period of neonatal intensive care.

Sodium bicarbonate 4.2% is used to correct acidosis and for neonatal units is supplied as an unlicensed product by 'Specials' manufacturers. Packaging and labelling of these ampoules look like the unlicensed sodium nitrite ampoules. As only emergency departments require sodium nitrite, mis-selection errors in other areas are likely to be due to inadvertent supply of sodium nitrite rather than sodium bicarbonate. This error may not be identified by ward staff before the wrong drug is administered.

A review of the NRLS identified two further incidents where licensed sodium nitrite injection was inadvertently administered instead of sodium nitroprusside, which is used to treat hypertension. This indicates that even with the more distinct labelling and packaging of the licensed version of sodium nitrite, there is risk of mis-selection.

Actions required

Actions to be completed by as soon as possible and no later than 06 November 2020

1. **Check**: as soon as possible physically check all clinical areas to ensure sodium nitrite injection has not been inadvertently supplied.
2. **Remove:** sodium nitrite injection from all clinical areas where kept as stock, except Emergency Departments, and update ward stock lists.
3. **Replace** all unlicensed sodium nitrite ampoules in Emergency Departments, with licensed sodium nitrite vials (see Note A).
4. **Destroy**: all unlicensed sodium nitrite ampoules (see Note A).
5. **Within pharmacy**: change procedures and storage policies to ensure:
   a. all 'specialist antidotes' (see Note B) are stored in automated dispensing cabinets/systems **or**
   b. 'specialist antidotes' are stored in a separate area within pharmacy specifically designated for antidotes only and separate from the main stock; those requiring refrigeration should be segregated from other medicines in the medication fridge and clearly identified as antidotes **and**
   c. if 'specialist antidotes' are kept in the emergency/out-of-hours medicine cupboards, they should be segregated from other medicines and clearly identified as antidotes.
6. **Within Emergency Departments**: change procedures and storage policies to ensure all 'specialist antidotes' (see Note B) are stored in a separate, designated location that is clearly marked for antidote storage only; those requiring refrigeration should be segregated from other medicines in the medication fridge and clearly identified as antidotes.

For further detail, resources and supporting materials see: https://www.england.nhs.uk/2020/08/risk-of-death-from-unintended-administration-of-sodium-nitrite

Additional information:

Notes

A. Unlicensed stock of sodium nitrite ampoules should be replaced as soon as is feasible. We are aware however that there may be limited stock of licensed sodium nitrite 300mg in 10ml vials and are working with the manufacturer and designated wholesaler of the licensed product to ensure additional stock is made available; in the short-term this maybe imported stock of sodium nitrite vials which are distinct in terms of labelling/packaging from the ampoules. In the interim, Regional Pharmacy Procurement Specialists in England, and colleagues in the devolved nations, will oversee the ordering and supply of this medicine within localities.
   If you are unable to obtain replacement vials by the 'Action Complete' date of this Alert, you should notify your Regional Pharmacy Procurement Specialist and do not record the Alert as 'Completed' until licensed stock is obtained. We will ensure publications of Alert compliance clearly flag this relates to circumstances beyond your control and ensure CQC is aware.
B. For the purposes of this alert, a 'specialist antidote' is defined as one that is on the RCEM/NPIS list[1] and is only used in Emergency Departments as a specific antidote, eg sodium nitrite injection.

Links to broader medication safety work

Work is planned to look at the larger issue of how 'Specials' are packaged and labelled, and there will be engagement with the Medicines Safety Officer network to consider if there is learning from this National Patient Safety Alert that may be applicable to other antidotes on the RCEM/NPIS list.[1]

Patient safety incident data

The NRLS was searched for incidents with an incident date of 01 May 2018 or later, if uploaded by 10 May 2020, containing reference to 'sodium nitrite', and again for incidents reported with an incident date of 01 Jan 2017 or later, if uploaded by 15 May 2020, containing reference to other commonly used antidotes ('dicobalt', 'cyanokit', 'sodium thiosulfate', 'anti-viper venom', 'fomepizole' and 'sodium nitrite'). Identified confusions between drugs included:

- sodium bicarbonate 4.2% ampoules and sodium nitrite 300mg/10ml ampoules (2 incidents)
- sodium nitroprusside 50mg vials and sodium nitrite 300mg/10ml vials (2 incidents)
- sodium bicarbonate 4.2% ampoules and sodium phenylbutyrate 1g ampoules (1 incident)

Other than the two premature babies, the other incidents did not appear to result in significant harm; although potentially severe harm or death could occur.

References

1. Royal College of Emergency Medicine and National Poisons Information Service Guideline on Antidote Availability for Emergency Departments, January 2017: https://www.rcem.ac.uk/docs/College%20Guidelines/RCEM%20NPIS%20Antidote%20Guideline%20List.pdf
2. Royal College of Emergency Medicine and National Poisons Information Service Guideline on Antidote Availability for Emergency Departments, Appendix 1, January 2017: https://www.rcem.ac.uk/docs/College%20Guidelines/RCEM%20NPIS%20Antidote%20Guideline%20Appx%201.pdf
3. Toxbase - https://www.toxbase.org/
4. Association of Pharmaceutical Specials Manufacturers - https://apsm-uk.com/

Stakeholder engagement

1. National Patient Safety Response Advisory Panel (for a list of members and organisations represented on the panel, see improvement.nhs.uk/resources/patient-safety-alerts/)
2. Faculty of Intensive Care Medicine
3. Medicines Supply Team – Department of Health and Social Care

We thank the staff in those organisations reporting the incidents for their active and helpful engagement.

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and straightforward National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the Chief Pharmacist or equivalent role, to co-ordinate the implementation of this National Patient Safety Alert, copying in their nominated executive leader (or equivalent role in organisations without executive boards).