NHS Improvement

Patient Safety Alert

Risk of death and severe harm from error with injectable phenytoin

9 November 2016

Alert reference number: NHS/PSA/W/2016/010

Warning Alert

Injectable phenytoin is used to slow and stabilise erratic electrical brain activity in, for example, status epilepticus, which is a life-threatening medical emergency. Phenytoin is a particularly complicated drug to use. It is recognised as a critical medicine by UK Medicine Information (UKMI).[1]

Phenytoin has a narrow therapeutic index, meaning that there is little difference between the effective dose and a larger dose that can cause harm. A loading dose, to quickly raise the amount of the drug in the body, is recommended for injectable phenytoin and guidance on patient safety issues has previously been issued.[2] Information on prescribing, preparation, administration and monitoring is available[3,4,5] and a decision should be taken locally on appropriate guidance for the use of phenytoin.

Injectable phenytoin is available in the strength of 50mg/mL and presented in a volume of 5mL. It may be administered undiluted or diluted only with sodium chloride 0.9%. Undiluted injectable phenytoin may be problematic to administer in small doses, for example, in paediatrics.

The NHS Improvement Patient Safety Team has been informed of two recent fatal incidents involving the use of injectable phenytoin in status epilepticus. A search for similar incidents submitted in the preceding three years to the National Reporting and Learning System (NRLS) revealed 2,200 patient safety incidents including two further deaths, five severe and 121 moderate harm incidents. A review of these incidents identified the following themes associated with errors:

- wrong weight estimated or patient not weighed
- failure to take account of existing phenytoin levels for loading dose
- supply issues and stock not available in clinical area
- misreading 100mg as 1,000mg and vice versa
- confusion around dilution and non-dilution of injectable phenytoin and failure to take account of the subsequent concentration
- wrong diluent used
- infused through the same line with an incompatible medicine
- failure to use an in-line filter
- wrong infusion rate
- loading dose continued for maintenance without dose change
- monitoring equipment not available
- failure to monitor the effectiveness of phenytoin and any toxic effects.

Use of injectable phenytoin is error-prone throughout the prescribing, preparation, administration and monitoring processes. Guidance exists to support safe use.[2,3,4,5]

This alert highlights the nature of errors reported. These suggest that the complexity of phenytoin use may be under-recognised. It asks providers to consider if more can be done to strengthen local guidance, training and teamwork related to the use of injectable phenytoin to reduce the risk of error.

Actions

Who: All organisations providing NHS-funded care where injectable phenytoin is prescribed, dispensed and/or administered.

When: To begin as soon as possible and to be completed by 21 December 2016.

1. Identify if the issues in this alert could occur in your organisation.
2. Consider if immediate action needs to be taken locally to improve the safe use of injectable phenytoin, and ensure an action plan to embed further improvement to patient safety is underway if required.
3. Circulate this alert to all relevant staff, including those with responsibilities for developing protocols, procedures, training and equipment required for the safe use of injectable phenytoin.
4. Share any learning from local investigations or locally developed resources via the Medication Safety Officers network or by emailing: patientsafety.enquiries@nhs.net

See page 2 for technical notes, supporting information and references

Alert reference number:	NHS/PSA/W/2016/010
	Warning Alert

Technical notes

Patient safety incident reporting

Extracted 30 August 2016. For dates 1 January 2013 to 31 July 2016 (based on the date the incident was reported to have occurred) with search terms IV, intravenous, infus* IV terms (inject, ampoule, bolus, epidural, intrathecal, subcut, parenteral, intramuscular, syringe, IM, SC, PC) and (phenytoin + brands) search strategy. All death, severe and moderate harm incidents, and two random samples of 100 each from no harm and low harm incidents.

References

1. UK Medicines Information - Medusa - the Injectable Medicines Guide. Consensus list high risk injectable medicines version 2 (November 2013) http://medusa.wales.nhs.uk/docs%5CNPSA20HighRiskConsensusList2013FinalRVJan14.pdf (accessed 8 November 2016).
2. National Patient Safety Agency. Rapid Response Report: Preventing fatalities from medication loading doses. (25 November 2010) www.nrls.npsa.nhs.uk/alerts/?entryid45=92305 (accessed 8 November 2016).
3. British National Formulary. Current information available on-line (accessed 8 November 2016).
4. Summary of Product Characteristics available by name www.medicines.org.uk/emc/about-the-emc (accessed 8 November 2016).
5. Health professionals can request access to the Medusa Injectable Medicines Guide website via http://medusa.wales.nhs.uk/?ID=4259ceba1cebe84c5c612057f5058dc0752. Once you have a log-in, use the Medusa search page to identify guidance on phenytoin.

Stakeholder engagement

- 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/)
- Specialist Pharmacy Services, United Kingdom Medicines Information
- Medication Safety Officer Network