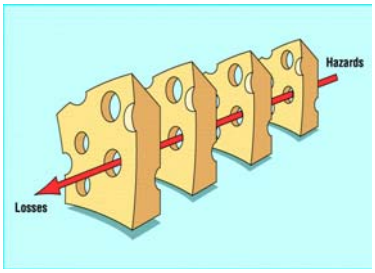

Medicines Governance Project

SAFETY MEMO 4

From: Medicines Governance Pharmacists,
Tracey Boyce Kathryn King Barbara Milliken
Sharon O'Donnell Jillian Redpath Lisa Smith

To:
Directors of Pharmaceutical Services / Trust Pharmacy Managers
Dr N Morrow, Chief Pharmacist, DHSSPSNI } For information
Directors of Pharmacy, HSS Boards

7th August 2003

RE: Administration of intravenous IV phenytoin injection

Various medication incidents related to the incorrect administration of IV phenytoin have been reported via the incident reporting systems in Northern Ireland hospitals.

As you will be aware the rapid administration of IV phenytoin may lead to cardiac arrhythmias, respiratory depression and/or hypotension. In addition, due to its low aqueous solubility, dilution in sodium chloride 0.9% gives an increased risk of precipitate formation in the infusion bag, thus requiring the use of an inline filter during administration.

The instructions for the administration of IV phenytoin are clearly described on the products SPC. There appears, however to be a lack of awareness of this information at ward level and of the risks involved in the incorrect administration of the product.

To clarify the two correct methods of administering IV phenytoin, the Medicines Governance Project Team have prepared the enclosed administration summary sheet.

If suitable 0.22-micron inline filters are not available already in the hospital, filters can be obtained in boxes of 50, from Macartney Surgical Ltd., at a cost of £3.68/filter.

Many hospitals will already be aware of, and have dealt with, this issue. However it is advised that HPSS Trusts review the information available to clinical areas regarding the use of IV phenytoin injection.

Tracey Boyce, Team Leader

On behalf of the Medicines Governance team

Enc

ADMINISTRATION OF INTRAVENOUS PHENYTOIN INJECTION

There are two recommended methods for intravenous administration of phenytoin:

Method 1

Undiluted by slow IV injection into a large vein, via a large gauge needle or IV catheter (≥ 20 gauge), at a rate not exceeding 50mg/minute in adults. In neonates and children the drug should be administered at a rate not exceeding 1 – 3mg/kg/minute.[1,2]

Risk

- Rapid administration may lead to cardiac arrhythmias, respiratory depression and/or hypotension.[3]
- Local administration reactions in peripheral veins are possible.[4]

In areas where the undiluted administration method is used, staff should be made aware of the need to:-

- Use a large gauge needle or IV catheter ≥ 20 gauge
- Not exceed maximum rate of administration 50mg/minute (adults) and 1-3 mg/kg/minute (neonates and children)
- Use a rate controlled infusion device as appropriate
- Precede and follow each injection with a saline flush, through the same needle or catheter, to prevent local venous irritation
- Monitor for infusion reactions

Method 2

Diluted in 50 – 100ml of sodium chloride 0.9%.The final concentration must not exceed 10mg/ml.The administration rate should not exceed 50mg/minute in adults and 1-3mg/kg/minute in neonates and children. The administration must be completed within 1 hour and an in-line filter 0.22 - 0.5 micron must be used. The drug must be given by a rate controlled infusion device. [1,2]

Risk

- As phenytoin has poor aqueous solubility, the dilution increases the likelihood of precipitation occurring.
- Local administration reactions in peripheral veins are possible but less likely.[4]

In areas where the dilution administration method is used, staff should be aware of the need to:-

- Use the prepared infusion immediately on dilution
- Watch closely for precipitate formation
- Not exceed final concentration 10mg/ml
- Use an in-line filter 0.22 – 0.5 micron
- Not exceed maximum rate of administration 50mg/minute (adults) and 1-3mg/kg/minute (neonates and children)
- Use a rate controlled infusion device
- Precede and follow each injection with a saline flush, through the same needle or catheter, to prevent local venous irritation
- Complete administration of infusion within 1 hour

NB: Both methods require continuous monitoring of ECG and blood pressure. This information should be used in conjunction with the current Summary of Product Characteristics and advice from the Pharmacy Department.

References:

(1) BNF 45 March 2003
(2) Product Technical Information. Phenytoin Injection 50 mg/ml. Mayne Pharma
(3) UCL Injectable Drug Administration Guide 1998
(4) Anderson G et al. Incidence of Intravenous Site Reactions in Neurotrauma patients receiving Valproate or Phenytoin. The Annals of Pharmacotherapy 2000; 34; 697-702.