Supporting information for the PReCePT Programme

In use safety of intravenous magnesium sulfate

- Intravenous magnesium sulfate is a ‘high risk’ medicine. Used appropriately it can save lives, but used incorrectly it can cause serious harm or death. Over three years (2010-2012) 1,025 incidents relating to ‘magnesium’ were identified with 5 reported as death or severe harm. Magnesium concentrations can be expressed in several ways which increases the potential for confusion and dosage error.

- Magnesium sulfate should not be administered by the intravenous route at a concentration higher than 20%w/v. Safety reviews have recommended that ready-to-use magnesium sulfate products are used wherever possible. However, in some parts of the country it remains common practice for clinical staff to dilute viscous, high strength (50%w/v) magnesium products in potentially pressured situations prior to use, with the resulting risk of errors in dose calculation, measurement and mixing.

- The PReCePT Programme aims to increase use of magnesium sulfate in maternity care for very premature deliveries to reduce the risk of cerebral palsy. The standard magnesium sulfate dosage regimen for eclampsia and for PReCePT is the same ie 4g as a loading dose, then 1g per hour maintenance for up to 24 hours. The following information is intended to support organisations in deciding which magnesium products are most appropriate for local use in maternity care.

Quality and safety

When available a licensed medicine should be used in preference to an unlicensed product. A product that is ready-for-use and does not require dilution [eg 20%w/v or less] is preferred to one that needs manipulation before administration. This avoids potential dilution errors and significant staff time being diverted away from direct patient care. However, before any changes to current maternity practice are made, it is vital that a full assessment of local circumstances has been made. Factors to be considered should include:

- Is more than one strength of injectable magnesium sulfate going to be available in the clinical area at any time?
- Have all relevant staff been included in the decision making process about which products will be used?
- What alternative product would be made available if there was a shortage of the preferred product?
- What actions must be taken before, during and after implementation of any product change (eg leadership, supporting resources, rapid feedback, incident reporting)?

Products and supply

Ready to use 20%w/v magnesium sulfate ampoules were first licensed in the UK in March 2018 (Synchrony Pharma Limited) and may soon be available from other suppliers. Previously only 10% and 50% strengths were available as licensed products. A 20% strength unlicensed product has been in use in some areas. The Synchrony 20% product is only supplied in 10ml ampoules. The ampoules are in boxes of 10 with a shelf life of 3 years.

(NB The licensed indications for the new Synchrony product, in common with other magnesium IV injectables, are magnesium deficiency and eclampsia. The licensing process is such that a product specifically licensed for
neuroprotection in preterm births is very unlikely to be produced. The view of the Medicines & Healthcare products Regulatory Agency (MHRA) is that the 'off label' use of a licensed product is generally preferable to using an unlicensed product.)

*Costs (exc VAT) need to be confirmed by local medicines procurement specialists; the table below gives an indication of costs. The 50% products are deliberately not included because of the safety risk and staff resource required for dose preparation prior to use.

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Product Name</th>
<th>Pack Size</th>
<th>Cost estimate* per pack (x10)</th>
<th>Cost estimate* for 4g loading dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synchrony</td>
<td>Magnesium Sulfate 20% w/v solution for infusion</td>
<td>10 x 10ml ampoules</td>
<td>£58.00</td>
<td>£11.60 (2 amps)</td>
</tr>
<tr>
<td>Various suppliers</td>
<td>Magnesium Sulfate 10% w/v solution for infusion</td>
<td>10 x 10ml ampoules</td>
<td>£35.00</td>
<td>£14.00 (4 amps)</td>
</tr>
</tbody>
</table>

Key references
1. Reducing the risk of errors with IV magnesium sulfate. Wessex Academic Health Science Network 2013
2. Medicines Q&As. Magnesium sulfate injection: converting between millimoles, milligrams and percentage w/v. UKMI 2016

ADDITIONAL WARNING DEMO SA BRAND IV MAGNESIUM SULFATE

We are aware of several recent serious dose errors with DEMO SA magnesium sulfate injection 10% and 50%. The main label states the % w/v magnesium sulfate concentration ie 10g in 100ml for the 10% product or 50g in 100ml for the 50% product. However, the information in smaller print does not give the concentration of magnesium sulfate in mg per ml. Instead it gives the concentration of magnesium ions in mg per ml, which is very different from magnesium sulfate. Prescribing/dose information in the BNF is for magnesium sulfate and confusing magnesium ions with magnesium sulfate has resulted in 10 fold dosing errors. The company and the MHRA are aware of the problem and are revising the package labelling.

All organisations are advised to check which magnesium sulfate products are currently stocked in all areas and action additional local safety strategies to avoid patient harm.