PROCEDURE FOR INTRAVENOUS MAGNESIUM SULFATE READY-MADE PREFILLED SYRINGES FOR NEUROPROTECTION OF THE FETUS IN PRETERM LABOUR AND FOR THE TREATMENT/PREVENTION OF ECLAMPTIC SEIZURES.

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Target Audience:

People who need to know about this document in detail	All staff involved in the prescribing, administration and checking of IV magnesium sulfate.
People who need to have a broad understanding of this document	All staff involved in the prescribing, administration and checking of IV magnesium sulfate.
People who need to know that this document exists	All staff involved in the prescribing, administration and checking of IV magnesium sulfate.

Integrated Impact Assessment:

Equality Impact Assessment Date &	Date: 31/03/2022		
Outcome	Outcome: This procedure has been subject to		
	a full equality assessment and no impact has		
	been identified.		
Welsh Language Standard	No		
Date of approval by Equality Team:	(31/03/2022)		
Aligns to the following Wellbeing of	Provide high quality, evidence based,		
Future Generation Act Objective	and accessible care		



Disclaimer:

If the review date of this document has passed please ensure that the version you are using is the most up to date version either by contacting the author or CTM_Corporate_Governance@wales.nhs.uk

COMPONENTS:

A policy <u>must</u> contain the following components and must also be written to include the values and behaviours of the organisation wherever relevant:

It is accepted that for Clinical Policies and or other Written Control Documents (Procedures, Guidance etc.) the policy components below may not all be relevant.

For guidance on Clinical Policy Development please contact: CTM ClinicalPolicies@wales.nhs.uk

For guidance on Non Clinical Policy Development please contact: CTM Corporate Governance@wales.nhs.uk

Or visit the Policy Author Page on SharePoint:

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1.0 INTRODUCTION AND POLICY STATEMENT

The NPSA patient safety alert 20 in 2007 recommends that ready-made preparations should be used, when possible, to reduce the risk of calculation and preparation errors (NPSA, 2007).

Intravenous (IV) magnesium sulfate is a 'high risk' medicine, and concentrations can be expressed in several ways which increases the potential for confusion and dose error (Medusa, 2020) (NPSA, 2007) (SPS, 2018).

Magnesium sulfate is used for two indications within maternity; for neuroprotection of the fetus in preterm labour and in the prevention/treatment of eclamptic seizures.

Both indications involve an IV injection loading dose of 4g magnesium sulfate and an IV infusion maintenance dose of 1g per hour (length of maintenance infusion dependent on indication and individual patient's clinical need). The in-depth detail can be found in the CTMUHB guidelines below;

- Guidelines for the Management of Hypertensive Disorders in Pregnancy (MM205)
- Management of Preterm Labour Guideline (MM204).

The procedure will promote safe prescribing and administration of readymade IV magnesium sulfate prefilled syringes, and ensure uniformity of practice across hospitals within CTMUHB.

2.0 SCOPE OF POLICY

This procedure applies to all of maternity at Prince Charles Hospital (PCH) and Princess of Wales Hospital (POWH) within CTMUHB.

This procedure directs obstetric, midwifery, anaesthetic and medical staff on how to safely prescribe and/or administer IV ready-made magnesium sulfate prefilled syringes within maternity units at PCH and POWH, for the following indications;

- treatment/prevention of eclamptic seizures, and
- neuroprotection of the fetus in preterm labour.

3.0 AIM AND OBJECTIVES

To promote safe prescribing and administration of ready-made IV magnesium sulfate prefilled syringes.

To ensure uniformity of practice across hospitals within CTMUHB.

4.0 PURPOSE

This procedure is in response to an NPSA Patient safety alert (NPSA, 2007) and has been put in place to reduce the risk of harm in patients requiring IV magnesium sulfate; IV magnesium sulfate is safe and effective if used at the right dose and rate, but there have been instances where problems have caused serious harm and even death.

The purpose of this procedure is to provide guidance to obstetric, midwifery and anaesthetic staff, promoting safe prescribing and administration of ready-made IV magnesium sulfate prefilled syringes, and to ensure uniformity of practice across hospitals within CTMUHB.

5.0 PRINCIPLES

This procedure directs doctors, independent prescribers and midwives on how to safely prescribe and/or administer the readymade IV magnesium sulfate prefilled syringes on maternity at PCH and POWH, within CTMUHB.

6.0 READY-MADE PREFILLED SYRINGE CONTENT'S

Pre-filled syringes of magnesium sulfate are available as follows;

- Magnesium sulfate 4g in 20mL sodium chloride 0.9% prefilled syringe.

This is a 20% w/v preparation, and used for the *loading dose*.

- Magnesium sulfate 5g in 50mL sodium chloride 0.9% prefilled syringe.

This is a 10% w/v preparation, and used for the *maintenance* dose.

Although the prefilled syringes are of different size and volume, there are no distinguishing features on the syringes to differentiate between the different strengths of the loading and maintenance syringes.

The syringes will have necessary drug information stickers attached, and thorough checking on selection is essential to prevent picking errors.

7.0 PROCEDURE

7.1 Dose and Indication.

7.1.1 Prophylaxis/ Treatment of Eclamptic Seizures using Ready-Made Magnesium Sulfate Prefilled Syringes: Dosage and Administration Regimen.

If a woman has severe hypertension or severe pre-eclampsia has or previously had an eclamptic fit, give intravenous magnesium sulfate.

Consider giving intravenous magnesium sulfate to women with severe pre-eclampsia if birth is planned within 24 hours.

Consider the need for magnesium sulfate treatment, if 1 or more of the following features of severe pre-eclampsia is present:

- Ongoing or recurring severe headaches
- Visual scotomata
- Nausea or vomiting
- Epigastric pain
- Oliquria and severe hypertension
- Progressive deterioration in laboratory blood tests (such as rising creatinine or liver transaminases, or falling platelet count) (CTMUHB, 2020).

Please refer to **CTMUHB Guidelines for the Management of Hypertension in Pregnancy (MM205)** (CTMUHB, 2020) for the full guidance information.

Loading dose*

Prefilled syringe contents:

4g of magnesium sulfate in 20mL of sodium chloride 0.9% (0.2g in 1mL).

This is a 20% w/v preparation.

Dose and directions:

4g to be given slowly as an IV injection over 5 to 15 minutes.

Can be administered IV via infusion pump at a rate of 240mL/hour to 80mL/hour, i.e., 5 to 15minutes.

Loading dose is followed by maintenance dose (see below).

Maintenance dose*

Prefilled syringe contents:

5g of magnesium sulfate in 50mL of sodium chloride 0.9% (0.1g in 1mL).

This is a 10% w/v preparation.

Dose and directions:

To be administered IV at a rate of 1g/hour for 24 hours, or continued for 24 hours after the last eclamptic seizure.

Give IV via infusion pump at a rate of 10mL/hour.

Recurrent seizures*

Prefilled syringe contents:

4g of magnesium sulfate in 20mL of sodium chloride 0.9% (0.2g in 1mL).

This is a 20% w/v preparation.

Dose and directions:

Recurrent seizures should be treated with a further loading dose of 2g slowly as an IV injection over 5 to 15 minutes. **N.B. only administer 2g (10ml) of the prefilled syringe.**

Can be administered IV via infusion pump at a rate of 120mL/hour to 40mL/hour, i.e., 5 to 15 minutes.

*See Appendix one for magnesium sulfate regimen using ampoules IF prefilled syringe unavailable.

Please refer to **CTMUHB Guidelines for the Management of Hypertension in Pregnancy (MM205)** (CTMUHB, 2020) for guidance on seizure treatment/ prophylaxis in women who are oliguric from the outset, as the maintenance dose is normally omitted until urine output normalises.

7.1.2 Neuroprotection of Fetus in Preterm Labour using Ready-Made Magnesium Sulfate Prefilled Syringes: Dosage and Administration Regimen.

Offer IV magnesium sulfate up to 29+6 weeks and consider it up to 33+6 weeks for neuroprotection in case of planned early delivery however, urgent delivery should not be delayed (CTMUHB, 2021).

If the infusion is solely given for neuroprotection of the fetus, the infusion should be discontinued at birth (CTMUHB, 2020).

Please refer to **CTMUHB Guidelines for the Management of Preterm Labour (MM204)** (CTMUHB, 2021) for the full guidance information.

Loading	
dose*	

Prefilled syringe contents:

4g of magnesium sulfate in 20mL of sodium chloride 0.9% (0.2g in 1mL).

This is a 20% w/v preparation.

Dose and directions:

4g to be given slowly as an IV bolus injection over 15 minutes (ideally given 4 hours prior to delivery).

Can be administered IV via infusion pump at a rate of 80mL/hour.

Maintenance dose*

Prefilled syringe contents:

5g of magnesium sulfate in 50mL of sodium chloride 0.9% (0.1g in 1mL).

This is a 10% w/v preparation.

Dose and directions:

To be administered IV at a rate of 1g/hour until the birth or for 24 hours (whichever is sooner).

Give IV via infusion pump at a rate of 10mL/hour.

*See Appendix one for magnesium sulfate regimen using ampoules IF prefilled syringe unavailable.

7.2 Contraindications.

- Hypersensitivity to magnesium
- Heart block or myocardial damage
- Renal failure (hepatic coma if there is a risk of renal failure)
- Myasthenia gravis (CTMUHB, 2021).

Please refer to the BNF (www.bnf.nice.org.uk) or Summary of Product Characteristics (www.medicines.org.uk) for a full list of contraindications.

7.3 Cautions.

- Interaction with antihypertensive agents especially calcium channel blockers
- Magnesium sulfate is associated with a transient (30 40 minutes) and usually mild reduction in BP, but this may be profound if nifedipine is also being given. Therefore, hydralazine given IV is a preferable antihypertensive.
- Magnesium sulfate may be associated with reduction in variability of fetal heart rate
- Magnesium sulfate acts in synergy with neuromuscular blocking agents (if suxamethonium is given, fasciculations may not be visible)
- Any woman requiring IV magnesium sulfate infusion should be reviewed by an anaesthetist to consider the need for placement of an arterial line (CTMUHB, 2021)
- Renal impairment; there is an increased risk of magnesium toxicity.
- Cardiac disease (CTMUHB, 2021).

Please refer to the BNF (www.bnf.nice.org.uk) or Summary of Product Characteristics (www.medicines.org.uk) for a full list of cautions.

7.4 Interactions with other Medication.

Please refer to the BNF (www.bnf.nice.org.uk) or Summary of Product Characteristics (www.medicines.org.uk) for interactions.

7.5 Side-effects.

- Nausea and vomiting
- Blurred vision
- Drowsiness and confusion
- Slurred speech
- Respiratory depression
- Muscle weakness (CTMUHB, 2021)

Minor side-effects should quickly resolve when treatment is stopped (eMC, 2019).

Signs of toxicity may include muscle weakness (due to neuromuscular blockade), decreased deep tendon reflexes and respiratory depression. **Urgent medical review is needed.**

Please refer to the BNF (www.bnf.nice.org.uk) or Summary of Product Characteristics (www.medicines.org.uk) for a full list of side-effects.

7.6 Monitoring Requirements.

Monitor closely for clinical signs of magnesium toxicity; pulse, blood pressure, respiratory rate and deep tendon reflexes must be recorded. Any signs of magnesium toxicity needs an urgent medical review.

- For hypertensive disorders monitor:
 - Blood pressure every fifteen minutes for initial loading dose and then as per Obstetric plan based on blood pressure thereafter
 - Continuous pulse oximetry
 - One hourly urine output
 - One hourly respiratory rate
 - Four hourly deep tendon reflexes
 - Renal function as clinically indicated.
- Management of preterm labour guidelines (MM204) states to monitor for signs of magnesium sulfate toxicity at least every four hours by recording pulse, blood pressure, respiratory rate and deep tendon flexes.

If a woman has or develops oliguria or other signs of renal failure monitor more frequently for magnesium toxicity and consider if dose reduction of magnesium sulphate is clinically necessary. Please refer to the BNF (www.bnf.nice.org.uk) or Summary of Product Characteristics (www.medicines.org.uk) for additional monitoring information.

Stop magnesium sulfate infusion if:

- Urine output <100mL in four hours
- Deep reflexes are absent after five hours (not due to regional block)
- Respiratory rate <12 breaths per min
- Oxygen saturation <90% (CTMUHB, 2021).

7.7 Patient Unlicensed Medicines Record.

As magnesium sulfate ready-made prefilled syringes are unlicensed, patient details (name and hospital number) and date of use **must** be recorded on an *Unlicensed Medicines Reconciliation Record* (see Appendix three).

Midwives must complete the necessary details on the record form.

Completed forms must be returned to the pharmacy department.

7.8 Storage.

There are no specific storage directions; ready-made magnesium sulfate prefilled syringes should be stored at ambient temperatures below 25°C.

Please ensure adequate separation of the different strengths of magnesium sulfate ready-made prefilled syringes, as agreed locally within each unit.

The prefilled syringes are readily available on the labour wards and theatres as stock. There will also be one loading dose prefilled syringe (4g in 20mL) located in the preeclampsia toxaemia (PET) emergency boxes.

7.9 Expiry.

The *B.Braun Medical Ltd.* ready-made magnesium sulfate prefilled syringes are an unlicensed product and once manufactured have an expiry of 60 days.

Midwives are accountable to complete all necessary stock and expiry date checks.

7.10 Availability of Magnesium Sulfate.

The midwifery team must check ward stock expiry dates and stock levels regularly, as it's the responsibility of the midwifery team to reorder magnesium sulfate ready-made prefilled syringes from the hospital pharmacy department.

Pharmacy must be contacted no later than 10 days prior to needing replenishment of stock, to give ample time for reordering and delivery from the manufacturer.

7.11 Pharmacokinetic Properties of Magnesium Sulfate.

When given intravenously, magnesium sulfate has an immediate onset of action, and its duration of activity is about 30mins.

The major excretory pathway is renal and parenteral loads are rapidly eliminated in this way. In renal impairment, there may be accumulation of magnesium (eMC, 2019).

7.12 IV Magnesium Sulfate Compatibility with other IV Medications.

Magnesium sulfate IV may have to run alongside other IV medications.

Infusions compatible with magnesium sulfate (it is assumed that medicines meet close to the vascular access device) include;

- aciclovir (Medusa, 2020)
- benzylpenicillin (IBM Micromedex, 2022)
- co-trimoxazole (Medusa, 2020)
- Hartmann's (compound sodium lactate solution) (Medusa, 2020)
- gentamicin (Medusa, 2020)
- hydralazine (IBM Micromedex, 2022)
- insulin (soluble) (Medusa, 2020)
- labetalol (Medusa, 2020)
- metronidazole (Medusa, 2020)
- OXYTOCIN (IBM Micromedex, 2022)
- sodium chloride 0.9% (IBM Micromedex, 2022)
- vancomycin (Medusa, 2020)

Please note, this list is not exhaustive. For further information please consider referring to:

- Medusa Injectable Medicines guide (https://medusa.wales.nhs.uk/Home.asp), or
- Micromedex IV Compatibility Checker (https://www.micromedexsolutions.com/micromedex2/librarian/ssl/true/PFDefaultActionId/evidencexpert.FindIVCompatibility).

Please contact pharmacy for further advice if necessary.

7.13 Magnesium Levels.

It is the clinical discretion of senior physicians if magnesium levels are necessary; levels are not routinely required for these dosing regimens.

Levels may be necessary in certain clinical situations, such as in patients with renal impairment, when toxicity is suspected or during uncontrolled eclamptic seizures.

8.0 ANTIDOTE

The antidote for magnesium sulfate toxicity is 10ml of calcium gluconate 10% (1g) intravenously over 10 minutes.

Please refer to the BNF (www.bnf.nice.org.uk) or Summary of Product Characteristics (www.medicines.org.uk) for a full list of contraindications, cautions, interactions, side-effects and monitoring requirements.

8.1 Calcium Gluconate Administration.

IV injection undiluted

Calcium gluconate can be given as a slow IV injection in an emergency; 10mL of calcium gluconate 10% slowly IV over 10 minutes (CTMUHB, 2021).

Monitoring of plasma calcium and ECG monitoring is recommended (Medusa, 2021).

Calcium gluconate undiluted has a high osmolarity and may cause venous irritation and tissue damage in cases of extravasation. If a central venous access device is unavailable, administer via a large peripheral vein, monitoring insertion site closely using a recognised phlebitis scoring tool. Resite cannula at first signs of inflammation (Medusa, 2021).

IV infusion diluted

If preferred, dilute 10mL of 10% calcium gluconate in 50mL sodium chloride 0.9% and give over 10 minutes (CTMUHB, 2020).

Please refer to Medusa (injectable medicines guide) for further administration detail.

9.0 TRAINING IMPLICATIONS

It is the responsibility of the maternity leads to ensure that all required staff working within the maternity sector are aware of this procedure for the safe use of the magnesium sulfate ready-made IV prefilled syringes across CTMUHB.

10.0 REVIEW, MONITORING and AUDIT ARRANGEMENTS

10.1 Review and Audit.

The prescribing and administration of IV magnesium sulfate will be subject to regular audit and review.

10.2 Monitoring Implementation.

Magnesium sulfate DATIX incidents for maternity will be monitored.

The prescribing and administration of IV magnesium sulfate will be subject to regular audit and review.

11.0 RESPONSIBILITIES

11.1 Prescribing.

The responsibility of prescribing lies with the doctor or independent prescriber.

11.2 Administration.

The responsibility for administration lies with the health professional administering the magnesium sulfate.

11.3 Ordering of Stock.

The responsibility for ordering the ready-made magnesium sulfate prefilled syringes lies with the midwives.

Orders are to be placed with pharmacy at least 10 days prior to ward stock running out or expiring.

It is the responsibility of the pharmacy department procurement team to source the ready-made magnesium sulfate prefilled syringes from the manufacturer.

11.4 Policy and Procedures.

The responsibility for the review and updating of this document and associated procedures lies with the author / service manager.

12.0 NON-CONFORMANCE

Everyone involved in the prescribing, administration and checking of IV magnesium sulfate prefilled syringes must comply with this procedure.

Deviations from it may cause harm to the patient and the fetus.

13.0 EQUALITY IMPACT ASSESSMENT STATEMENT

This procedure has been subject to a full equality assessment and no impact has been identified.

14.0 PRIVACY IMPACT ASSESSMENT STATEMENT

A privacy impact assessment is not required for this procedure.

15.0 EQUALITY IMPACT ASSESSMENT STATEMENT

This policy has been screened for relevance to Equality. No potential negative impact has been identified.

Statement approved by a member of the Equality team (CTM_Equality@wales.nhs.uk) on 31/03/2022.

16.0 RELATED POLICIES

- CTMUHB Guidelines for the Management of Hypertensive
 Disorders in Pregnancy (MM205). (<a href="http://ctuhb-intranet/Policies/layouts/15/WopiFrame.aspx?sourcedoc={01E0 0962-D03E-4AD4-A09B-B661113E6B8C}&file=Management%20of%20Hypertensive%20 Disorders%20in%20Pregnancy%20Guideline.docx&action=default)
- CTMUHB Management of Preterm Labour Guideline (MM204).
 http://ctuhb-intranet/Policies/layouts/15/WopiFrame.aspx?sourcedoc={A1FE6F6F-0D83-4396-BACB-CD0AA5AF1F0D}&file=Preterm%20labour%20Guideline.docx&action=default
- CTMUHB Procedure for the supply of Unlicensed and Off Label Medicines (<a href="http://ctuhb-intranet/Policies/layouts/15/WopiFrame.aspx?sourcedoc=%7BDCF1DD23-5155-4857-B271-AB9159CA8F9C%7D&file=Unlicensed%20Medicines%20Policy.docx&action=default&DefaultItemOpen=1).

17.0 INFORMATION, INSTRUCTION AND TRAINING

Senior midwives, Catrin Rees and Dawn Apsee, will be responsible for communicating the change to midwifery staff across the health board.

Senior midwives have advised the robust training and education will include:

- Lunch and learn sessions
- Drop-in sessions on the unit
- Posters throughout the units
- Communication on various communication channels, including social media pages and what's app groups
- Communication in shift handover
- Education during PROMPT training sessions

Ongoing Midwife refresher sessions will be provided during the periodic PROMPT sessions.

The Consultant Anaesthetist involved agreed to communicate change to anaesthetic and obstetric staff across the health board.

The communication, training and education will be health board wide. Attendance registers of the education and training provided will be kept.

Pharmacy communication will be led by CTMUHB lead pharmacist for maternity and neonates.

18.0 REFERENCES

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APPENDIX ONE: Magnesium Sulfate Ampoules.

Ampoules should only be used if ready-made prefilled syringes are unavailable.

Ampoules can be ordered from pharmacy during opening hours or obtained as per hospitals local agreement when pharmacy is closed.

Be aware there are **three different strengths** of ampoules.

Please see flow chart for guidance;

LOADING DOSE

40mL of 10% magnesium

sulfate solution (4g).

This makes 4g in 40mL.

Give as an IV bolus over 5-15 minutes (at a rate of 480-160mL/hour) depending on indication+

MAINTENANCE DOSE

100mL of 10% magnesium sulfate solution (10g).

This makes 10g in 100mL

Administer IV via infusion pump at 10mL/hour.

RECURRENT SEIZURE DOSE

20mL of 10% magnesium sulfate solution (2g).

This makes 2g in 20mL.

Give as IV bolus over 5 minutes (at a rate of 240mL/hour).

LOADING DOSE

20mL of 20% magnesium sulfate solution (4g).

This makes 4g in 20mL.

Give as an IV bolus over 5-15 minutes (at a rate of 240-80mL/hour) depending on indication+

MAINTENANCE DOSE

50mL of 20% magnesium sulfate solution (10g).

This makes 10g in 50mL.

Administer IV via infusion pump at 5mL/hour.

RECURRENT SEIZURE DOSE

10mL of 20% magnesium sulfate solution (2g).

This makes 2g in 10mL.

Give as IV bolus over 5 minutes (at a rate of 120mL/hour).

LOADING DOSE

*ALWAYS dilute before use

Draw up 8mL of 50% magnesium sulfate solution (4g) and make up to 20mL with sodium chloride 0.9%.

This makes 4g in 20mL (of a 20% solution).

Give as an IV bolus over 5-15 minutes (at a rate of 240-80mL/hour) depending on indication⁺

MAINTENANCE DOSE

Draw up 20mL of 50% magnesium sulfate solution (10g) and make up to 50mL with sodium chloride 0.9%.

This makes 10g in 50mL (of a 20% solution).

Administer IV via infusion pump at 5mL/hour.

RECURRENT SEIZURE DOSE

Draw up 4mL of **50%** magnesium sulfate solution (2g) and make up to 10mL with sodium chloride 0.9%.

This makes 2g in 10mL (of a 20% solution).

Give as IV bolus over 5 minutes (at a rate of 120mL/hour).

APPENDIX TWO: Magnesium Conversion Table (mmol, % w/v and g/mL).

Magnesium Sulfate Concentration (% w/v and g/mL)	Magnesium Sulfate (g / mL)	Magnesium Ions (mmol / mL)
10% w/v (0.1g in 1mL)	2g in 20mL	8mmol in 20mL
	4g in 40mL	16mmol in 40mL
	10g in 100mL	40mmol in 100mL
20% w/v (0.2g in 1mL)	2g in 10mL	8mmol in 10mL
	4g in 20mL	16mmol in 20mL
	10g in 50mL	40mmol in 50mL
	2g in 4mL	8mmol in 4mL
50% w/v (0.5g in 1mL)	4g in 8mL	16mmol in 8mL
	10g in 20mL	40mmol in 20mL

APPENDIX THREE: Unlicensed Medicine Reconciliation Record

(CTMUHB, 2022).

Batch number: [



Expiry:

UNLICENSED MEDICINE RECONCILIATION RECORD

	L			
Product & Manufacturer:				Unit size:
Date	Patient name and hospital number	No. of dose units used	Balance	Staff Signature

Completed form must be returned to pharmacy department and retained for 5 years from last issue.