NEONATAL MEDICATION GUIDELINE	
Phenytoin Sodium	
Scope (Staff):	Nursing, Medical and Pharmacy Staff
Scope (Area):	KEMH NICU, PCH NICU, NETS WA
This document should be read in conjunction with the Disclaimer.	

Quick Links

Dose	Preparation & Administration	Side Effects & Interactions	Monitoring

Restrictions

Formulary: Highly Restricted

Requires Neonatologist or Neurologist approval before commencing

HIGH RISK Medication ⚠

An overdose can be rapidly fatal. Increases in doses must be in small increments (10%) because metabolism of phenytoin is saturable and rate-limited. Small dosage adjustments may result in large changes in free serum phenytoin levels

Description

Anticonvulsant

Presentation

Ampoule: 50mg/mL – phenytoin sodium (2mL or 5mL volumes)

Oral solution: 100mg/5mL

Storage

Store at room temperature, below 25°C

Protect from light

Contraindications

Hypersensitivity to phenytoin or any components of the formulation

Acute porphyrias

Sinus bradycardia, sinoatrial clock, second and third degree atrioventricular block, Stokes-

Adams Syndrome – IV phenytoin contraindicated

Dose

Formulations of phenytoin are available as phenytoin base or phenytoin sodium. Doses below are prescribed as phenytoin sodium

100mg phenytoin sodium = 90mg phenytoin base

Consider concentration monitoring when changing from a product containing phenytoin to another product containing phenytoin sodium (and vice versa); adjust dosage as necessary

Control of seizures unresponsive to first line therapy

IV/Oral:

Loading dose: 15 – 20 mg/kg

Maintenance dose: 2 – 4 mg/kg/dose every 12 hours

Maximum: 8 mg/kg/dose every 8 to 12 hours after 1 week of age

Dose Adjustment

Dosage should be individualised based upon clinical response and serum concentration

Renal & Hepatic Impairment:

Dose adjustment may be required in severe hepatic and renal impairment

Preparation

IV

Can be used undiluted at a concentration of **50mg/mL**

Note: diluted phenytoin may precipitate over time, inspect solutions for infusions carefully. Do not use if precipitation or haziness occurs

Dilute 1mL (50mg) of phenytoin sodium to a final volume of 10mL with Sodium Chloride 0.9%

Concentration = 50mg/10mL = **5mg/mL**

Administration

IV

Flush the line with Sodium Chloride 0.9% before and after administration

Administer into a large vein where possible through a large gauge catheter

Diluted phenytoin may precipitate – it is recommended to infuse through a 0.22 micron filter

The rate of intravenous phenytoin administration should not exceed 1 – 3 mg/kg/minute or 50mg/minute, whichever is slower

Faster infusions increase the risk of severe hypotension and cardiac arrhythmias

Careful cardiac monitoring is needed during and after administering intravenous phenytoin – see *Monitoring* section

Compatible Fluids

Sodium Chloride 0.9%

Y-Site Compatibility

Refer to KEMH Neonatal Medication Guideline: Y-Site IV Compatibility in Neonates

Side Effects

Common: CNS depression, bradycardia, hypotension, feed intolerance, can cause vein irritation and tissue necrosis

Serious: cardiovascular collapse, rash, blood dyscrasias

Interactions

Incompatible with Glucose 5%

Do not mix with any other medication or fluids

Monitoring

Monitor electrocardiogram, blood pressure, and respiratory function continuously during infusion, and for 15 minutes to 1 hour after infusion. Observe IV site for extravasation. Follow serum concentration closely

Drug levels

Sampling time: Just before next dose (trough)

Phenytoin elimination half-life is variable and steady-state may not yet be reached (can take up to 7 – 10 days) in the initial serum samples

Take initial concentration **48 hours** after loading dose and then weekly if continued on phenytoin therapy

Therapeutic range *in the first week*:

6 – 15 microgram/mL (highly variable)

Therapeutic range *after steady state*:

10 – 20 microgram/mL due to changes in protein binding

Comments

Oral absorption is poor, varying response seen in the first week of life

A small change in dosage may result in a disproportionately large change in phenytoin concentration due to saturation of its hepatic metabolism

Use with caution in infants who have received lidocaine – increased risk of cardiotoxicity

Related Policies, Procedures & Guidelines

CAHS Clinical Practice Guidelines:

Neonatal Seizures

NETSWA: Seizures

Medication Administration: Intramuscular, Subcutaneous, Intravascular

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NSQHS Standards Applicable:	☒ Std 1: Clinical Governance ☐ Std 2: Partnering with Consumers ☒ Std 3: Preventing and Controlling Healthcare Associated Infection ☒ Std 4: Medication Safety	☐ Std 5: Comprehensive Care ☐ Std 6: Communicating for Safety ☐ Std 7: Blood Management ☒ Std 8: Recognising and Responding to Acute Deterioration

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