HIGH RISK MEDICINES REGISTER

POLICY©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this document is to identify medicines which have been deemed to be at high risk of misadventure for the patients across SCHN.
- The acronym APINCH can be used to represent many high risk medicines:
  - Anti-infectives
  - Potassium and other electrolytes
  - Insulin
  - Narcotics/Opioids and sedative agents
  - Chemotherapeutic agents
  - Heparin and other anticoagulants
- Adverse events related to the use of high- risk medicines must be reported through the Incident Information Management System (IIMS).

CHANGE SUMMARY

- This policy includes changes to cover the introduction and use of the electronic medication management (eMM) system and automated dispensing cabinets (ADC).

READ ACKNOWLEDGEMENT

- All staff who prescribe, dispense or administer medications across SCHN are to read and acknowledge they understand the contents of this policy.

TABLE OF CONTENTS

This Policy/Procedure may be varied, withdrawn or replaced at any time. Compliance with this Policy/Procedure is mandatory.

1 Introduction

High-Risk Medicines are those that have a high risk of causing injury or harm if they are misused or used in error. Error rates with these medications are not necessarily higher than with any other medicines, but when problems occur, the consequences can be more significant.

In accordance with NSW Health Policy Directive PD2019_058 a Sydney Children's Hospitals Network (SCHN) high risk medicines policy and register has been developed. The medicines or groups of medicines outlined in this policy forms the SCHN High Risk Drugs Register. This is based on well-established high risk medicines in combination with a comprehensive review of the Network specific risks identified through the local incident reporting system. Medications included in the SCHN register include the following:

- Anti-infectives
- Potassium and electrolytes
- Insulin
- Narcotics and sedative agents
- Chemotherapeutic agents
- Heparin and other anticoagulants
- Paracetamol
- Neuromuscular Blocking agents

Staff across SCHN must comply with the requirements outlined in the NSW Health High Risk Medicines Management Policy. The requirements listed in this SCHN policy are in addition to the requirements of the NSW Health policy.

2 General Risk Mitigation Strategies

2.1 Safe Prescribing

Safe prescribing across SCHN is guided by

- Safe Prescribing-Practice Guideline-SCHN

The Paediatric National Inpatient Medication Chart (P-NIMC) is used throughout SCHN with the exception of areas where electronic prescribing has been implemented. The Australian Commission on Safety and Quality NIMC User guide should be used as a reference where clarification in sought.

An accurate patient weight must be documented on the P-NIMC for ALL patients, but this is especially important for patients prescribed high-risk medications. The following SCHN Practice Guidelines should be referred to for information about weights:

- Patient Weight for Use in Calculations – PICU/CICUt
- Height and Weight – Measurement in Infants, Children and Adolescents

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For those areas where eMM has been implemented, an accurate weight must also be documented in the electronic medical record (eMR). Dose adjustments must be considered when prescribing for patient groups such as overweight, obese or underweight patients as well as patients with existing clinical conditions that may affect drug metabolism and excretion.

The use of error prone abbreviations such as mcg, IU, U and od, and q is not tolerated as per The Australian Commission on Safety and Quality Recommendations for terminology, abbreviations and symbols guide. Regular Quality Use of Medicines (QUM) Indicator audits provide feedback on prescriber compliance.

Medication reconciliation processes, as outlined in Medication Reconciliation-Procedure SCHN, should be prioritised for these patients.

> If a medication order is difficult to read or the medication name, strength, form, dosage, frequency, route or date of prescribing is questionable, the nurse administering medications must contact the prescriber, and the order should be re-prescribed.
>
> **An illegible prescription is not a valid order.**

2.2 Medication Dispensing and Storage

Ward imprest lists are formally reviewed annually to rationalise the storage and accessibility of all high risk medicines to areas where they are necessary. This is conducted by the NUM and the ward pharmacist/pharmacy staff.

High-risk medications may be restricted to particular clinical areas, or may only be kept in pharmacy to minimise selection errors. The product range may be limited to reduce the risk of selection error.

2.3 Administration

All medications must be administered by appropriately trained staff within their defined scope of practice. As per NSW Health Policy Directive PD2019_058, an independent double check must be used for all high-risk medications, both staff members should complete checks alone and apart from each other, then compare results.

3 Anti-infectives

Antimicrobial prescribing and supply should be guided by Network and local hospital approved guidelines and with consideration local antimicrobial stewardship policies:

- SCH Policy – Antimicrobial Stewardship- SCH
- CHW Policy – Antimicrobial Stewardship – CHW

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3.1 Aminoglycosides

Aminoglycosides **(amikacin, gentamicin, tobramycin)** are dosed according to age, weight and renal function and are considered nephrotoxic and ototoxic. Limiting duration of therapy, careful guideline concordant dosing and monitoring of these agents is required to reduce the risk to patients while also maintaining efficacy. Under-dosing contributes to treatment failure and possible microbial resistance.

Aminoglycoside prescribing, administration and monitoring is discussed in the local policies:

- **At SCH** - Once Daily Gentamicin –SCH Practice Guideline

  Infectious Diseases approval is required for:

- amikacin (any duration)
- gentamicin (greater than 3 doses)
- **At CHW** - Aminoglycoside Dosing and Monitoring – CHW Practice Guideline

3.2 Amphotericin

There are several different formulations of intravenous amphotericin, each with different dosing and administration regimens.[1] Confusion between the different amphotericin formulations is frequently reported and has resulted in the death of a paediatric patient in 2011 in California.[2]

Confusion between the formulations of liposomal amphotericin B (Ambisome®), amphotericin B deoxycholate (Fungizone®) and amphotericin B lipid complex (Abelcet®) may result in errors, both in prescribing and administration.

A single formulation of amphotericin for intravenous administration – liposomal amphotericin (Ambisome®)- is available on the SCHN Formulary, limiting the risk of error associated with amphotericin.

Amphotericin dosing for empiric antifungal treatment of paediatric haematology, oncology and haematopoietic stem cell transplant patients should be guided by the SCHN Empiric Antifungal Treatment Guideline and the local electronic antimicrobial approval system.

3.3 Vancomycin

Supratherapeutic vancomycin levels can, in rare cases, cause nephrotoxicity and ototoxicity. Underdosing contributes to treatment failure and possible resistance. Monitoring of serum levels, with appropriate dose adjustment should be undertaken in all patients as per local hospital guidelines:

- **At SCH** - Vancomycin – SCH Practice Guideline
- **At CHW** – Vancomycin Dosing – CHW Practice Guideline

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4 Potassium and Other Electrolytes

4.1 Potassium

Intravenous potassium is a well-documented high risk medication posing an increased risk of harm where used in error. The causes of errors are multi-factorial and can be attributed to all stages of the medication management process, including storage and selection error. Wherever possible, pre-mixed standard bags should be used when potassium is prescribed.

All potassium use (storage, ordering, prescribing, dispensing, administration, monitoring and documentation of use) at SCHN must be in concordance with the requirements of local hospital guidelines:

- **At SCH** - Potassium Administration –SCH Practice Guideline
- **At CHW** – Potassium Administration – CHW Practice Guideline

Prescribing, supply and administration of intravenous potassium must also comply with NSW Health Individual High-Risk Medicine Management Standard: Potassium (intravenous) (page 19).

4.2 Low Sodium Content Fluids

There is a well-documented risk of hyponatraemia with the use of extremely-low sodium content fluids[3]. Increasingly, the published literature supports the use of higher sodium content, isotonic fluids to prevent hyponatraemia.[4-5] Use local fluid guidelines to guide fluid choice.

- **At SCH** – Intravenous Fluid and Electrolyte Therapy – SCH Practice Guideline
- **At CHW** – Intravenous Fluid Management – CHW Practice Guideline

Extremely low sodium containing fluids (0.225%, 0.22% and 0.18% sodium chloride) should only be used in neonates or under the direction of a specialist.

Low sodium content fluids carry a cautionary statement “CAUTION – LOW SODIUM FLUID” to alert staff (see Figure 1, below). NSW Kids and Families recommend that extremely low sodium containing fluids (0.225%, 0.22% and 0.18% sodium chloride) are only stored in areas where neonatal patients are likely to be treated.[6]

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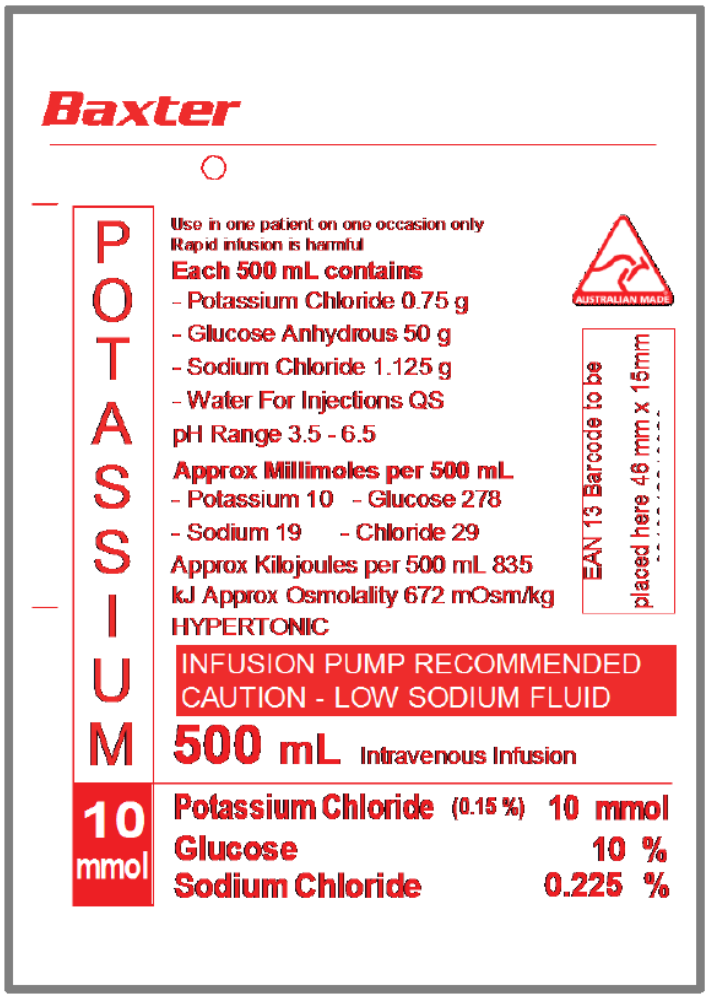

Figure 1: Example fluid bag label for low sodium content fluids.

4.3 Electrolytes

Concentrated intravenous electrolytes including calcium, phosphate, magnesium and 3% sodium chloride (hypertonic saline) pose a risk to patients when given in error. All use should be guided by local administration and prescribing guidelines:

- **At SCH** – SCH Injectable Guidelines

  Electrolyte Replacement Prescribing – SCH Practice Guideline

- **At CHW** – CHW Paediatric Injectable Medicines Handbook

As the appearance of 3% sodium chloride is similar to standard intravenous fluids, they are to be stored separately, in a container clearly marked “CAUTION: 3% sodium chloride – Hypertonic – On Specialist Recommendation Only” (Figure 2 below). Due to the risk of harm

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if used in error, 3% sodium chloride may only be kept in approved clinical areas such as Intensive Care Units, Emergency Departments, and other areas approved by the local Drug Committee.

Figure 2: Label required for intravenous 3% sodium chloride fluid bags

4.4 Oral and Rectal Bowel Cleansing Solutions

The inappropriate use of an oral bowel cleansing solution before surgery and/or an investigative procedure can cause harm or be fatal. Children and patients with contraindications for use are particularly at risk from these treatments.

Some products are well recognised to have the potential to cause dehydration and electrolyte disturbances; these include sodium picosulfate (eg- Picolax® or Picoprep®), phosphate (eg Fleet Phospho- Soda® and Fleet Enema®) and magnesium containing products. Alternative, less concentrated bowel cleansing preparations, such as macrogol containing products – Glycoprep®, should be used in high risk patients. These products are not without risk and high risk patients should always be monitored closely.[7]

Contraindications for the use of bowel cleansing solutions

- Patients with known or suspected gastrointestinal obstruction or perforation, ileus, gastric retention, acute intestinal or gastric ulcerative toxic colitis, or toxic megacolon
- Severe acute inflammatory disease
- Patients with severely reduced renal function
- Congestive heart failure
- Reduced levels of consciousness
- Hypersensitivity to any of the ingredients

Precautions

- Dehydration should be corrected before use
- Care should be taken in patients already receiving medicines which may be associated with hypokalaemia (such as diuretics or corticosteroids)
- Inadequate oral intake of water and electrolytes can create significant electrolyte deficiencies
- Bowel cleansing medicines may modify the absorption of regularly prescribed oral medications

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5 Insulin

Insulin is one of the top high risk medicines in the world, associated with errors in prescribing, dispensing, selection, calculation and administration. Errors in insulin therapy can cause serious harm and fatal incidents have been reported. Safeguards have been implemented across SCHN to prevent incidents and near misses:

- The term "units" must be written out in full
  - U and IU are error prone and should never be used.
- All wards across SCHN must only stock 50 unit insulin syringes.
  - Single doses exceeding 50 units must be confirmed with the prescriber.
- Products and doses should be confirmed with reliable sources and prescribed by *full name* **and** *strength*.

Extra caution should be taken at the point of administration to ensure correct item is selected. Diet, fasting state, exercise, previous blood sugar control should all be considered prior to prescribing and administration.

Refer to local policies regarding insulin management in various settings:

- **SCHN**
  - Diabetic Ketoacidosis Management Practice Guideline
  - Diabetes Management and Insulin Administration Practice Guideline for ordering, labelling, storage and administration of insulin
  - Diabetes Mellitus (Type 1): Inpatients using Insulin Pumps Practice Guideline
- **At SCH:**
  - Diabetic Children: Surgery and Fasting – SCH – Practice Guideline
- **At CHW**
  - Fasting and Surgery- Type 1 Diabetes Mellitus (T1DM) – CHW – Practice Guideline
  - Diabetes Management prescribing in eMM

6 Narcotics (Opioids) and other Sedatives

Incorrect dosing of opioids can lead to inadequate analgesia, excessive sedation and potentially lethal respiratory depression.

Narcotics (opioids) and sedatives include:

- HYDROmorphone, oxycodone, morphine
- Fentanyl, alfentanil, remifentanil and analgesic patches
- Benzodiazepines eg diazepam, midazolam, CLONazepam
- Thiopentone, propofol and other short term anaesthetics

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All narcotics and sedatives should be stored according to scheduling requirements and Medication Handling in NSW Health Facilities as well as local policies:

- **At SCH** – Medication: Administration & Handling (Non-Cytotoxic) – SCH Practice Guideline
- **At CHW** – Medication Management and Handling – CHW Practice Guideline

Prescription, administration and monitoring of intravenous opioids and narcotics should be guided by drug error reduction software (drug libraries) where applicable. Nursing staff must be accredited prior to administering intravenous opioids.

At SCH – Opioid Management - SCH

Education for prescribing and administration outside CICU available from: https://intranet.schn.health.nsw.gov.au/parenteral-analgesia-videos-sch

At CHW –Pain Management – CHW – Practice Guideline

Education on opioids and pain management at CHW are available from:

http://chw.schn.health.nsw.gov.au/ou/pain/resources/guides_and_in_service_packages/CHW_pain_prescription_chart_guide.pdf

http://chw.schn.health.nsw.gov.au/ou/pain/resources/BBraun_PCA_pump_-_in_service.pdf

http://chw.schn.health.nsw.gov.au/ou/pain/resources/guides_and_in_service_packages/oral_opioids_at_CHW.pdf

At SCH, liquid Schedule 8 and Schedule 4D medications are supplied with adaptor lids which must be used for measuring doses and when needed to perform volume checks. Dispensing cups and measuring straws must not be used.

At CHW, liquid Schedule 8 and Schedule 4D medications are supplied with bottle stoppers which must be used for measuring doses and when needed to perform volume checks. Dispensing cups and measuring straws must not be used.

6.1 Look Alike Sound Alike (LASA) Medicines

Due to the risk of sound alike narcotics (opioids) and sedatives, staff should take extra precautions to confirm the intended medication and formulation.

Selection errors may result due to similar names such as:

oxyCONTIN (oxycodone SR)	*and*	MS Contin (morphine SR)
oxyCONTIN	*and*	OxyNORM or Endone (oxycodone, immediate release)
paracetamol	*and*	propofol
morphine	*and*	HYDROmorphone

Tall Man lettering has been implemented across SCHN. Tall Man Lettering will be shown on LASA medications with a high risk of harm to patients if confused. Tall Man lettering should be present on:

- shelf labels, in pharmacy and in ward areas

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- inpatient pharmacy dispensing labels
- on-screen pharmacy dispensing program

6.2 Hydromorphone

HYDROmorphone is a potent opioid used to treat moderate to severe acute or chronic pain. HYDROmorphone is 5 to 7 times more potent than morphine. Because of its high potency, errors with HYDROmorphone may result in serious adverse patient outcomes. The commencement of HYDROmorphone in patients who are considered opioid naïve is hazardous and should not occur unless under specialist advice, and this use must be clearly documented in the patient's medical record.

Incidents involving confusion between morphine and HYDROmorphone have been reported, including fatal incidents involving inadvertent administration of HYDROmorphone instead of morphine.

Prescribing, supply and administration of HYDROmorphone must comply with the NSW Health Individual High-Risk Medicine Management Standard: Hydromorphone (page 10) and the actions outlined in NSW Health Safety Alert 001/17 Hydromorphone: High-risk medicine.

Hydromorphone is supplied in a brightly coloured bag that states "HYDROmorphone is 5 x more potent than morphine" and stored on separate shelf locations or Schedule 8 medication storage units where available.

Figure 3: HYDROmorphone label used throughout SCHN

Use is limited to Intensive Care, Oncology and Palliative care patients, with supervision by the Acute Pain Service. Prescribing requirements for HYDROmorphone are outlined in Opioid Management - SCH and Pain Management - CHW.

NOTE: Injectable Hydromorphone 10 mg in 1 mL is not routinely stored in clinical areas and HYDROmorphone 50 mg in 1 mL is not on the SCHN formulary. All HYDROmorphone dispensed to an individual patient must be returned to pharmacy at the earliest practicable time when no longer required. Where practicable, a pharmaceutical review should be performed prior to the administration of the first inpatient dose of HYDROmorphone.

There is a My Health Learning Course available on the Safe Use of HYDROmorphone. Whilst this course in not mandatory, it is strongly recommended staff undertake this module to ensure the safe use of HYRDROmorphone at every step in the patient journey.

7 Chemotherapeutic (Cytotoxic) agents

Chemotherapeutic agents must be prescribed, dispensed and administered according to local protocols:

- **At SCH** - Cytotoxic and Hazardous Drugs: Administration and Handling SCH Procedure
- **At CHW** – Hazardous and Cytotoxic Drugs: Administration and Handling CHW Procedure

Only staff specifically trained and experienced may prescribe, prepare, dispense or administer chemotherapeutic agents.

Intrathecal Administration

Wherever possible, intrathecal chemotherapy should be scheduled on different days to intravenous chemotherapy.

If chemotherapy is prescribed for intrathecal administration in the Operating Suite, only the intrathecal chemotherapy is to accompany the patient to the Operating Suite. No other chemotherapy including intravenous chemotherapy is to be sent.

7.1 Vincristine

Vincristine is a neurotoxic, anti-neoplastic drug of the vinca alkaloid group. Sentinel events associated with the inadvertent intrathecal administration of vincristine have been reported in both Australia and overseas. This error almost always results in central nervous system dysfunction and death. There are three known cases of intrathecal administration of vincristine in Australia, most recently occurring in a Sydney Hospital in 2003 - 2 cases resulted in death and 1 resulted in permanent quadriplegia.[7] Local risk mitigation strategies include avoiding the administration of vinca alkaloids on the same day as intrathecal chemotherapeutics.

Prescribing, supply and administration of vincristine must comply with the NSW Health Individual High-Risk Medicine Management Standard: Vincristine (page 22).

7.2 Other Vinca Alkaloids (vindesine, vinblastine, vinorelbine)

The intrathecal administration of other vinca alkaloids, such as vindesine, vinblastine and vinorelbine, has been associated with the same neurotoxicity and death as described above with vincristine.

- All vinca alkaloid preparations, including outer wraps, must be labelled with a prominent warning label “FOR INTRAVENOUS USE ONLY – CAN BE FATAL IF GIVEN BY OTHER ROUTES”. The outer wrap must also state, “Do not remove covering until moment of injection.”

7.3 Bortezomib

Bortezomib inhibits the activity of the 26S proteasome which prevents targeted proteolysis which can affect multiple signalling cascades within the cell. This disruption of normal homeostatic mechanisms can lead to cell death. Bortezomib is approved for use in multiple myeloma and is being studied in the treatment of many other cancers.[9]

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Bortezomib is administered as an intravenous infusion or subcutaneous injection. There have been several reports of death relating to accidental intrathecal administration of bortezomib.[9]

The following precautions should be taken when preparing bortezomib:

- All bortezomib preparations should be labelled with a prominent warning label “FOR INTRAVENOUS USE ONLY – CAN BE FATAL IF GIVEN BY OTHER ROUTES”. If bortezomib is to be given subcutaneously, replace INTRAVENOUS with SUBCUTANEOUS.
- Where possible, intrathecal chemotherapy should be given on a separate day to intravenous bortezomib.

7.4 Oral Methotrexate

Oral methotrexate is used in the treatment of autoimmune or inflammatory disorders such as juvenile rheumatoid arthritis and Crohn’s disease. Oral methotrexate is also used in the management of some leukaemias.

Oral methotrexate is administered as a **single dose once a week**. However, occasionally, in order to improve tolerance in some people, the total weekly dose is taken in 2 or 3 divided doses at 12 hourly intervals.

Catastrophic adverse events associated with methotrexate toxicity can occur following daily administration when weekly administration was indicated or intended.

Prescribing, supply and administration of oral methotrexate must comply with NSW Health Individual High-Risk Medicine Management Standard: Methotrexate (oral) (page 12). Forcing functions must be used across SCHN when prescribing weekly oral methotrexate on the Paediatric National Inpatient Medication Chart (P-NIMC) by stating the day of therapy, and crossing out the non-administration days. (See Figure 4)

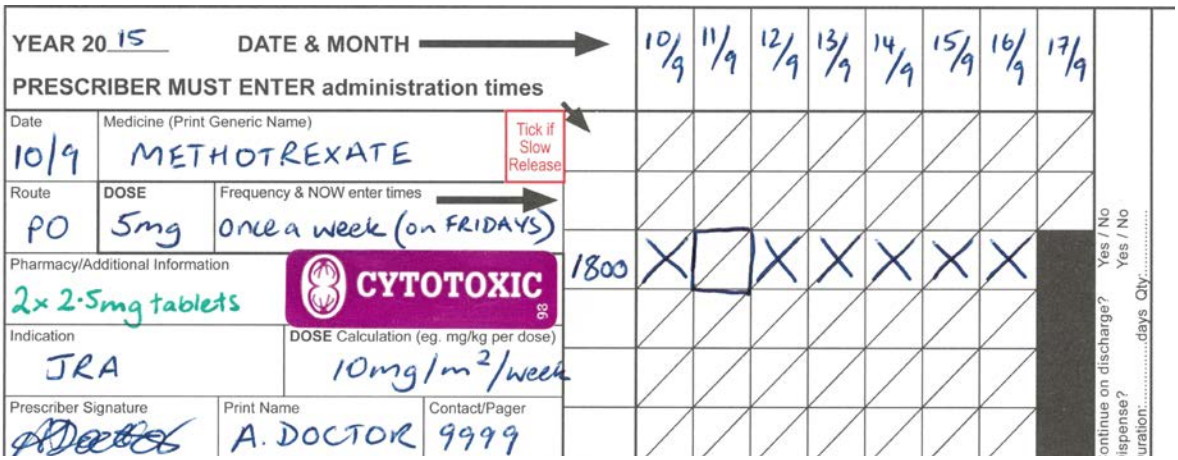

Figure 4: Correct charting of intermittent medication such as oral methotrexate

If prescribing of methotrexate is occurring in eMM, the above principles must be applied.

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7.5 Etoposide

Etoposide is available as the base drug Etoposide (Vepesid®) and the phosphate salt (Etopophos®). They contain different amounts of Etoposide and cannot be directly substituted. Confusion may result when prescribing or administering the medication and this can result in under or over dosing of the medication.[11]

Etoposide should be prescribed according to the number of milligrams of etoposide base required, as follows:

Etoposide (as the PHOSPHATE) x mg.

Where x is the number of milligrams of etoposide base required.

8 Heparin and other anticoagulants

Anticoagulant medicines have a narrow therapeutic index and over or under coagulation can result in significant adverse patient outcomes. The indication for anticoagulation and the therapeutic targets must be clearly documented by the prescriber.

Prescribing, supply and administration of anticoagulants must comply with NSW Health Individual High-Risk Medicine Management Standard: Anticoagulants (page 5).

8.1 Heparin

When prescribing heparin ensure that *units* is written in full. The use of u, U or IU is not acceptable as it can easily be mistaken for 0 or 4.

8.2 Warfarin

There are many significant drug interactions relating to the metabolism of warfarin. Be aware when commencing or ceasing medications, as this may precipitate change to INR and may require warfarin dose adjustment.

SCH Anticoagulant Policies

- For prevention and treatment of venous thromboembolism see Anticoagulant Therapy of Venous Thromboembolism (VTE) inc Heparin Administration - SCH including management with heparin, enoxaparin and warfarin.
- Enoxaparin Administration – SCH Drug Protocol

CHW Anticoagulant Policies

- Thromboprophylaxis in Surgical and Trauma Paediatric Patients – CHW Practice Guideline
- Enoxaparin – Low Molecular Weight Heparin – CHW Drug Protocol
- Heparin Infusion – CHW Drug Protocol
- Warfarin – CHW Drug Protocol

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9 Paracetamol

Paracetamol is the medication most frequently administered to children world-wide. It is a widely used analgesic and antipyretic agent and has a very long safety record when used in optimum dosage. However, it may be under or over-used in certain situations.

Paracetamol overdose may initially be asymptomatic and early assessment is recommended. Refer to the Paracetamol Overdose – Assessment and Management – SCHN Practice Guideline for further information.

Prescribing, supply and administration of paracetamol must comply with the NSW Health Individual High-Risk Medicine Management Standard: Paracetamol (page 17).

Intravenous paracetamol has been associated with errors attributed to concurrent use of oral paracetamol, dose calculation errors, non-adherence to labelling directions and tenfold errors due to confusion between 'mg' and 'mL'.[12]

Use of IV paracetamol is restricted and must be prescribed, dispensed, administered and monitored according to local policies:

SCH IV Paracetamol Policies

- Paracetamol –SCH Practice Guideline
- Intravenous Paracetamol Administration-SCH Drug Protocol

CHW IV Paracetamol Policies

- Pain Management – CHW – Practice Guideline (Section 41)

10 Neuromuscular Blocking Agents

Neuromuscular blocking agents such as pancuronium, vecuronium, rocuronium and cisatracurium, are used to produce skeletal (including respiratory) muscle relaxation. They are used to facilitate endotracheal intubation and control of the airway, to allow mechanical ventilation and to prevent reflex muscle contraction.[13]

Neuromuscular blocking agents are considered high-risk medicines because inadvertent use in patients without the availability of medical staff skilled in airway support can lead to respiratory arrest, permanent harm, or death.

Serious incidents have occurred involving inadvertent administration of a neuromuscular blocking agent to a patient instead of a sedative.

Prescribing, supply and administration of neuromuscular blocking agents must comply with NSW Health Individual High-Risk Medicine Management Standard: Neuromuscular Blocking Agents (page 16).

At SCH – Neuromuscular blocking agents are labelled and stored separate to other medications to prevent inadvertent administration.

At CHW – Neuromuscular blocking agents have warning labels applied to identify they are paralysing agents.

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11 Incident Management

Adverse incidents involving high risk medicines must be documented and reported into the Incident Information Management System (IIMS).

See SCHN Incident Management Policy for information on how to access IIMS.

Reported incidents involving high risk medicines are closely monitored and reported monthly by the SCHN Clinical Governance Unit.

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