1. PURPOSE
This policy describes minimum standards to assure that sites, departments, and areas in Aurora Health Care that handle high risk medications have considered the risk of error associated with their use and have incorporated safeguards to minimize that risk. This policy augments provisions for the management of high alert medications that exist in other Aurora policies.

2. SCOPE
This policy applies to Aurora Health Care, Inc. and any entity or facility owned and controlled by Aurora Health Care.

3. DEFINITIONS

High alert medication: a drug that bears a heightened risk of causing significant patient harm when used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients.

Drugs which Aurora Health Care considers high alert medications are listed in Appendix A. Drugs included in this list are determined by the Aurora Medication Safety Committee based on national recommendations, review of internal and external event reports, and interdisciplinary feedback.

Independent verification: a procedure in which two individuals (may include a pharmacist, pharmacy technician, nurse, or physician) separately check - alone and apart from each other, then compare results - specified components of a given process. Barcode scanning may serve as independent verification of drug name and drug concentration or strength during preparation and administration.

4. POLICY

4.1 Aurora Health Care will maintain a list of medications [Appendix A] that have been designated as high alert medications within this organization.

4.2 The medication use process within Aurora Health Care will be designed to support the risk reduction strategies listed in Appendix B.

4.3 Independent verification of select products and components the medication use process is required as outlined in Appendix C and Appendix D.
5. PROCEDURE

5.1 The list of high alert medications [Appendix A] and risk reduction strategies [appendices B, C, and D] will be reviewed by the Aurora Medication Safety Committee no less frequently than on a biennial basis.

REFERENCES:


Institute for Safe Medication Practices. ISMP’s list of high alert medications in community/ambulatory healthcare.


Appendix A. High alert medications

- Antithrombotic agents including:
  - Heparin
  - Low molecular weight heparins (including enoxaparin, dalteparin)
  - Glycoprotein inhibitors (including ABCIXimab, eptifibatide, tirofiban)
  - Direct thrombin inhibitors (including argatroban, bivalirudin, dabigatran)
  - Thrombolytics (including alteplase, reteplase, tenecteplase)
  - Coumarin derivatives (including warfarin)
  - Factor Xa inhibitors (including apixaban, fondaparinux, rivaroxaban, edoxaban)
- Cardioplegic solutions
- Chemotherapy/antineoplastic agents
- Concentrated electrolytes for injection: sodium acetate (2 mEq/mL or greater), potassium acetate (2 mEq/mL or greater), sodium chloride (concentration greater than 0.9%), potassium chloride (2 mEq/mL or greater), potassium phosphate (3 mmol/mL or greater)
- Epidural and intrathecal medications
- Insulin
- Magnesium sulfate, continuous infusion
- Medications available in conventional and alternative formulations (e.g. liposomal, protein-bound, etc.)
- Narcotics/opiates
- Neuromuscular blocking agents
- Oxytocin
- Pramlintide
- Prostacyclines and analogs, inhaled and parenteral (including alprostadil, epoprostenol, treprostinil, iloprost)
- Sedatives (including benzodiazepines, barbiturates, dexametomidine, ketamine, etomidate, propofol)
- Sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers exceeding 100 mL
Appendix B. Actions to reduce risk with high alert medications

1. The following general safety procedures will be applied to the use of all high alert medications:

- Dose range alerts will be configured in computerized order entry systems and intravenous infusion pumps.
- A list of standardized concentrations of high alert medications administered by continuous intravenous infusion will be maintained by the Aurora Department of Pharmacy. Standardized concentrations will be limited to those necessary to provide patient care. These concentrations should be used whenever clinically feasible.
- Premixed solutions or solutions prepared by pharmacy should be used whenever possible.
- Any high alert medication infusion dispensed from pharmacy that is not a standardized concentration should bear a “NON-STANDARD CONCENTRATION” auxiliary label.
- High alert medications should be stored in a manner to minimize risk of a product selection error; such measures may include use of barcode scanning technology to verify product selection, physical segregation, or other mechanism to differentiate products (e.g. labeling storage bins or containers).
- Highly concentrated dosage forms will only be stocked in areas where it is absolutely necessary for patient care.
- Intravenous infusions of high alert medications will be administered via flow-controlled, programmable pumps using dose error reduction software (the only exception is small volume vesicants administered peripherally – infuse via gravity, only)
- An oral dosing device (e.g. oral syringe) with metric unit markings will be used for preparation and administration of oral/enteral liquid products requiring manipulation from manufacturer supplied dosing units (i.e. excludes unit dose cups when dose to be administered is dose supplied).
- Patient/family will be involved through education whenever appropriate/possible.
- Caregivers will observe any additional provisions as determined by the AHC Pharmacy & Therapeutics Committee to ensure safe use (e.g. utilization restrictions).
- Alaris infusion pumps – medication boluses should not be administered by programming an increased infusion rate. System Nursing Practice Council and the Aurora Medication Safety Committee determine which medications may be bolused directly from a continuous infusion. For these medications only, a “Bolus” option is available during pump programming.
2. The following safety principles will be applied to specific high alert medications

**Antithrombotics**
- Heparin will be stored in a distinct location from insulin, Hespan, and lidocaine.
- A protocol is available for reversal of over-anticoagulation with warfarin.

**Within medical centers**
- When verifying an order for a parenteral, therapeutic anticoagulant, the pharmacist will screen the patient’s medication profile for duplicate anticoagulation and appropriateness of dose based on indication prior to dispensing. Exception - heparin bolus and infusion may be initiated prior to pharmacist review, but require screening by prescribing physician and nurse for duplicate therapies. If indication is not readily apparent, the prescriber will be contacted for clarification.
- Order sets will be available for therapeutic use of formulary intravenous antithrombotics.
- All inpatients and patients cared for in the Emergency Department receiving therapeutic doses of heparin, enoxaparin, or fondaparinux, and those receiving oral anticoagulants (including warfarin, direct thrombin inhibitors, and factor Xa inhibitors) will have laboratory monitoring that at minimum, is compliant with minimum standards established by the Aurora Pharmacy and Therapeutics Committee.
- Capacity to view INR versus warfarin dose is available to all caregivers.

**Cardioplegic solutions**
- Preparation of cardioplegic solutions will be outsourced or limited to specially trained individuals.
- A prominent auxiliary label will be affixed to cardioplegic solutions prepared by pharmacy to reduce similarity of their appearance to other injectable solutions.

**Chemotherapy**
- Intravenous vinca alkaloids (vinblastine, vincristine, vinorelbine) will only be prepared and administered diluted an IV minibag.
- Vinca alkaloids products prepared by pharmacy will be labeled, “FATAL IF GIVEN INTRATHECALLY. IV USE ONLY” prior to dispensing.

**Concentrated electrolytes for injection**
- Should only be stocked in locations in which there is an accepted clinical indication for the product.
- Should be kept in a secure location, segregated from other medications.
- Products dispensed by pharmacy should bear a prominent auxiliary warning label.
- Access should be limited to qualified licensed professionals whose use of these agents is an acceptable standard of practice.
- Potassium injection must be adequately diluted prior to intravenous administration and never administered IV push.
Additional safeguards within facilities in which pharmacy is responsible for the distribution of medications:

- Concentrated electrolytes may only be stored outside of pharmacy if the pharmacy director ensures the following additional conditions are met:
  - The time delay associated with storing the concentrate in the pharmacy would be detrimental to patient care.
  - A conservative par level is established and pharmacy checks and restocks to the par level.
- Sodium chloride solutions for injection exceeding 0.9% will be dispensed only upon receipt of patient-specific order.

**Epidural/intrathecal agents**

- Tubing without any side injection ports will be used for all epidural and intrathecal lines.
- All epidural infusions prepared/dispensed from pharmacy will bear an “EPIDURAL” auxiliary label on both sides of bag.
- All intrathecal products prepared/dispensed from pharmacy will bear an intrathecal auxiliary label.

**Insulin**

- Use of insulin pens is prohibited within AHC hospitals and clinics with limited exceptions described by the Aurora Pharmacy & Therapeutics Committee (e.g. use of appropriately labeled, tamper-evident, patient-specific U-500 insulin pens in medical centers).

Applicable to inpatients, patients being treated in a medical center clinic, and patients being treated in an AHC emergency department:

- To ensure single patient use, insulin U-500 pens must be immediately discarded (needles in sharps container, pen device in black medication waste) upon order discontinuation or patient discharge. Used U-500 insulin pens should never be returned to pharmacy.
- All insulin infusions will bear a prominent “INSULIN” auxiliary label on both sides of bag.
- All doses of long-acting insulin (e.g. glargine, detemir) will be prepared in prefilled syringes by pharmacy.
- Standard insulin dilution(s) will be designated to prepare neonatal insulin doses.
- Administration of insulin doses should be separated from administration of other medications such that insulin is scanned (where available), prepared as necessary, and administered before proceeding to the next medication.

**Medications available in conventional and alternative (liposomal, protein-bound, etc.) formulations**

- Conventional and alternative dosage forms of products will be segregated from one another in storage.
- Designation of liposomal or protein-bound formulation will be included for all liposomal and protein-bound dosage forms on labels and computerized systems/eMAR.
Narcotics/opiates

- Morphine and HYDROMorphone will be physically segregated from one another in drug storage areas.

Additional safeguards within facilities in which pharmacy is responsible for the distribution of medications:

- Oral liquid opioids available in floor stock will be limited to a single concentration and volume for each drug stocked (conventional concentration will be stocked unless patient population justifies use of concentrated solutions).

Neuromuscular blocking agents

- Floor stock restricted to areas designated to provide critical care.
- Bedside attendance of licensed practitioner who is competent to provide intubation and airway management during initial administration is required.
- Storage will be segregated from all other medications by one of the following mechanisms: storage in a sealed box (e.g. with breakaway lock), storage in lock-lidded compartment of an automated dispensing cabinet, storage in a lidded container in the refrigerator, or storage in another secure, isolated storage area within pharmacy. While segregating products by one of the aforementioned methods is considered best practice, in procedural areas such as the operating room, physical segregation (e.g. stock segregated by dividers in anesthesia dispensing system) along with provider verification of correct drug selection is acceptable.
- Storage containers should bear an appropriate warning label identifying contents as paralyzing agents.
- Products dispensed from pharmacy (including vials, syringes, and infusion bags) should bear prominent, colored labeling that notes, “Warning: paralyzing agent – causes respiratory arrest”.

Prostacyclines and analogs, inhaled and parenteral

- All inhalational agents will be dispensed from pharmacy labeled, “For respiratory use only”.
- Respiratory therapy is responsible for placing and verifying every shift that, “For respiratory use only” stickers are affixed to the following: epoprostensol inhalation container, administration pump, administration tubing just below drip chamber, administration tubing just prior to connection to leur-lock, over connection site where terminal end of administration set connects to nebulizer.
- Inpatient administration of intravenous infusions will be converted to Aurora Health Care pumps whenever possible.

Sedatives

- Oral liquid sedatives available in floor stock will be limited to a single concentration and volume for each drug stocked.
- Age- and size-appropriate resuscitation equipment and reversal agents will be available wherever sedatives are administered or monitored (excluding end of life care).
Sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers exceeding 100 mL

- All containers of sterile water exceeding 100 mL dispensed by pharmacy will bear an auxiliary label, “NOT FOR INTRAVENOUS USE” prior to dispensing.
- Sterile water without additives will never be stocked/dispensed for direct parenteral administration (exception: sterile water used for reconstitution of dantrolene).
- Parenteral solutions compounded from sterile water should only be administered with additives sufficient such that final solution osmolarity is at least 154 mOsm/mL.
- To prevent inadvertent mixup with other fluids, use of one liter bags of sterile water for injection, irrigation, and inhalation will be limited to circumstances precluding the use of available alternatives (vials, other bag sizes of sterile water).

Additional safeguards within facilities in which pharmacy is responsible for the distribution of medications:

- In the absence of situations precluding the use of alternative products (e.g. shortages), one liter bags of sterile water should not be stocked or purchased. Within hospitals and hospital outpatient departments, in such circumstances, one liter bags of sterile water should only be ordered by pharmacy.
Appendix C. High alert medications requiring independent verification during PREPARATION

For select drugs, independent verification of select components the medication use process is required.
- In accordance with national safety recommendations, use of independent verification is selectively applied to certain components of the medication use process for judiciously selected (not all) high alert medications in order to maximize impact of this strategy. Drugs requiring independent verification are determined by the System Medication Safety Committee in conjunction with the Pharmacy Leadership Council and System Nursing Practice Council based on elements that may include the nature of the drug, the complexity and/or vulnerability of processes surrounding preparation or use of the drug, external recommendations, and review of internal data.

The following requirements apply to the preparation of high alert medications by caregivers other than qualified licensed independent practitioners.

A. Drugs that are not prepared by qualified pharmacy caregivers
- Within pharmacy, safeguards include scanning on preparation and final verification by a licensed pharmacist

<table>
<thead>
<tr>
<th>Drug/product</th>
<th>Components of independent verification - PREPARATION</th>
</tr>
</thead>
</table>
| Compounded heparin admixtures | Verify the following against the medication label or actual order:  
  - Drug name  
  - Drug concentration or strength  
  - Drug dose/volume added to admixture  
  - Diluent and diluent volume  
  - Final concentration of admixture and/or final dose/volume prepared |
| Insulin drips |                                |
| Thrombolytics (excludes aliquots for catheter clearance) |                                |

B. Drugs prepared throughout the organization

<table>
<thead>
<tr>
<th>Drug/product</th>
<th>Components of independent verification - PREPARATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Custom cardioplegic solution prepared from base ingredients by pharmacy</td>
<td>Verify via laboratory assessment that pH, potassium, osmolarity, and glucose are all within 5% expected value</td>
</tr>
<tr>
<td>Custom dialysate solution prepared from base ingredients by pharmacy (e.g. custom CRRT)</td>
<td>Laboratory assessment of sodium concentration</td>
</tr>
<tr>
<td>Drug/product</td>
<td>Components of independent verification - PREPARATION</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Chemotherapy requiring compounding/manipulation of original dosage form</td>
<td>Refer to AHC Chemotherapy Checking Competency for additional detail.</td>
</tr>
<tr>
<td></td>
<td>Prior to final preparation, verify the following (as applicable):</td>
</tr>
<tr>
<td></td>
<td>• Drug name and strength or concentration of product matches medication label or actual order</td>
</tr>
<tr>
<td></td>
<td>• Diluent and diluent volume matches label or compounding instructions</td>
</tr>
<tr>
<td></td>
<td>• Product concentration based on diluent used matches medication label or actual order</td>
</tr>
<tr>
<td></td>
<td>• Drug volume drawn up in syringe matches medication label or actual order</td>
</tr>
<tr>
<td></td>
<td>• Final diluent bag and volume matches medication label or actual order</td>
</tr>
<tr>
<td></td>
<td>○ Removed overfill that is drawn up in a syringe matches medication label or compounding instructions</td>
</tr>
<tr>
<td></td>
<td>• Final concentration matches medication label or actual order</td>
</tr>
<tr>
<td></td>
<td>• Tubing matches label or actual order</td>
</tr>
<tr>
<td></td>
<td>• Final product bears appropriate auxiliary labels</td>
</tr>
<tr>
<td>All compounded oral and parenteral high-alert medications prepared for pediatric patients</td>
<td>Verify (if applicable):</td>
</tr>
<tr>
<td></td>
<td>• Drug name and strength or concentration against medication label or actual order</td>
</tr>
<tr>
<td></td>
<td>• Diluent and diluent volume against medication label, actual order, or AHC compounding instructions</td>
</tr>
<tr>
<td></td>
<td>• Dose/volume of drug used against label/actual order</td>
</tr>
<tr>
<td></td>
<td>• Final concentration of admixture and/or final dose/volume prepared</td>
</tr>
<tr>
<td>Non-standard concentrations of high alert medications prepared for continuous infusion</td>
<td>Verify (if applicable):</td>
</tr>
<tr>
<td></td>
<td>• Drug name and strength or concentration against medication label or actual order</td>
</tr>
<tr>
<td></td>
<td>• Diluent and diluent volume against medication label, actual order, or AHC compounding instructions</td>
</tr>
<tr>
<td></td>
<td>• Dose/volume of drug used against medication label or actual order</td>
</tr>
<tr>
<td></td>
<td>• Final concentration of admixture and/or final dose/volume prepared</td>
</tr>
<tr>
<td></td>
<td>• Final product bears “NON-STANDARD CONCENTRATION” auxiliary label</td>
</tr>
<tr>
<td>High alert medications compounded for neuraxial administration (epidural, intraventricular, intrathecal)</td>
<td>Verify (if applicable):</td>
</tr>
<tr>
<td></td>
<td>• Drug name and strength or concentration against medication label or actual order</td>
</tr>
<tr>
<td></td>
<td>• Diluent and diluent volume against medication label, actual order, or AHC compounding instructions</td>
</tr>
<tr>
<td></td>
<td>• Dose/volume of drug used against medication label or actual order</td>
</tr>
<tr>
<td></td>
<td>• Final concentration of admixture and/or final dose/volume prepared</td>
</tr>
<tr>
<td></td>
<td>• Final product bears appropriate auxiliary labels</td>
</tr>
</tbody>
</table>
Appendix D. High alert medications requiring independent verification prior to ADMINISTRATION

For select drugs, independent verification of select components the medication use process is required.

- In accordance with national safety recommendations, use of independent verification is selectively applied to certain components of the medication use process for judiciously selected (not all) high alert medications in order to maximize impact of this strategy. Drugs requiring independent verification are determined by the System Medication Safety Committee in conjunction with the Pharmacy Leadership Council and System Nursing Practice Council based on elements that may include the nature of the drug, the complexity and/or vulnerability of processes surrounding preparation or use of the drug, external recommendations, and review of internal data.

The following requirements apply to the administration of high alert medications by caregivers other than qualified licensed independent practitioners.

<table>
<thead>
<tr>
<th>Drug/product</th>
<th>Components of independent verification - ADMINISTRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemotherapy</td>
<td>Components per AHC Chemotherapy/Biotherapy Administration of Anti-Cancer Agents Policy No. 2025</td>
</tr>
<tr>
<td>Patient controlled analgesia</td>
<td>Verify the following upon initiation, syringe change, and any change in dose (including basal rate)</td>
</tr>
<tr>
<td></td>
<td>• Drug name and concentration on product and medication label match that programmed on pump</td>
</tr>
<tr>
<td></td>
<td>• PCA dose, lockout, and basal rate (if ordered) programmed on pump match actual order</td>
</tr>
<tr>
<td>All high alert medications administered to pediatric patients</td>
<td>• Verify product label against actual order (drug name, dose, volume, route, and duration)</td>
</tr>
<tr>
<td></td>
<td>• For intravenous infusions - verify pump settings against label or actual order (drug name, dose, volume, duration)</td>
</tr>
</tbody>
</table>