Introduction
High-alert medications are drugs that have an increased risk of causing significant patient harm when they are used incorrectly. Although mistakes may or may not be more common with high-alert drugs, the consequences are more devastating to patients.

Human fallibility along with the complex and high-risk nature of the healthcare system are recognized in the precautions recommended by the Institute for Safe Medication Practices Canada (ISMP Canada) to address the risks associated with high-alert medications.

Strategies for the safe use of high-alert medications may include safeguards such as automated or independent double checks to support the safe prescribing, preparation, dispensing and administration of high-alert drugs. Research shows that 95% of medication errors are discovered when people double check the work of others and double checks are more effective if they are performed independently. Other safeguards may include standardization, warnings, segregation and education.

Policy
1. The Hospital maintains a list of high-alert medications on the hospital Drug Formulary based on reports from the Canadian Medication Incident Reporting and Prevention System (CMIRPS) and the Institute for Safe Medication Practices Canada (ISMP Canada). The KHSC Lists (HDH site list and KGH site list) of High-Alert Medications are posted in the Drug Listings section of the Drug Formulary located on the KGH Intranet at: https://kghtoday.kgh.on.ca/pharmacy/publications-and-manuals/drug-formulary.

2. Safeguards are implemented to minimize the risks associated with the prescribing, preparation, dispensing and administration of high-alert medications throughout the hospital. Safeguards are listed for each high-alert medication on the KHSC Lists of High-Alert Medications.

Definitions
1. High-alert medications are drugs that bear a heightened risk of causing significant patient harm when used in error.
2. A safeguard is a measure implemented to reduce or eliminate the potential for a medication incident to occur.
3. An independent double check is a process in which a second Regulated Health Care Practitioner (RHCP) conducts an independent verification. Such verification can be performed in the presence or absence of the first RHCP. To maximize the independence of the double check, the first RHCP does not communicate the expected results to the second RHCP to avoid bias and reduce the visibility of the error.
4. An automated double check is a safeguard consisting of a verification process prompted by an automated device or technology (e.g. automated dispensing cabinet alerts, bar coding, programmable infusion pump alert).
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5. **Physical Alert:** A tactile alert to alert RHCPs within the medication storage area or at the patient’s side. These include but are not limited to:
   - Lidded medication storage container
   - Tamper proof security seals

6. **Visual Alerts:** Warning labels to alert RHCPs within the medication storage area or at the patient’s side. These include but are not limited to:
   - High-Alert
   - HYDROMorphone alert
   - Look-alike sound-alike alert

7. **Automated dispensing cabinet (ADC) alerts** (KGH site only) are informational messages, notifications, warnings, or sets of questions to alert the RHCP when accessing drugs from an ADC and include:
   - Drug specific warning alerts
   - Look-alike/sound-alike alerts
   - High-alert medication alerts
   - Witness required alerts (prompting for an independent double check)

8. **TALLman lettering** is a method used to assist in the differentiation of look-alike/sound-alike drug names through the application of uppercase lettering to certain sections of drug names to bring attention to the points of dissimilarity between confusable names.

**Procedure**

1. **Roles and Responsibilities**
   1.1 The Pharmaceuticals and Therapeutics Committee:
      1.1.1 Recommends drugs to be listed as high-alert in the Drug Formulary, based on the ISMP List of High-Alert Medications and relevant internal or national medication error reporting data.
   1.2 The Medication Safety Committee:
      1.2.1 Approves safeguards for the prescribing, storage, preparation, labeling, dispensing, and administration of identified high-alert medications including mandatory independent double checks for selected high-alert drugs;
      1.2.2 Updates the HDH site and KGH site high-alert medications lists (e.g. when medications are added to or removed from the Drug Formulary or when new safeguards are implemented).
      1.2.3 Coordinates staff education regarding the implementation of new safeguards as required;
      1.2.4 Conducts annual audits to monitor the management of high-alert medications and makes recommendations for improvement as necessary.
   1.3 RHCPs involved in medication practices:
      1.3.1 Participate in Hospital education programs about high-alert medications including Hospital orientation;
      1.3.2 Are responsible for recognizing medications identified as high-alert and comply with safeguards and implement independent double checks as required.
2. Prescribing High-Alert Medications
   2.1 Standardized order sets are used to initiate high-alert medications whenever possible to
   standardize practice and reduce the risk of prescribing errors, as per KGH Administrative
   Policy 11-046 Standardized Order Sets.
   2.2 Therapeutic goals are determined by the prescriber on a patient-specific basis as
   required.
   2.3 Verbal and telephone orders for high-alert medications are discouraged and are only
   accepted when the prescriber is unable to write the order or when a delay in ordering the
   medication would compromise patient care.
   2.3.1 Verbal and telephone orders for chemotherapy drugs are not accepted, unless
   the orders are to hold or discontinue chemotherapy.

3 Preparation and Labeling of High-Alert Medications
   3.1 TALLman lettering is used to print look-alike/sound-alike high-alert drug names in the
   pharmacy information system drug catalog, on labels of patient specific medication and
   on unit dose medication packages prepared by Pharmacy, as well as on labels affixed
   to shelving units in drug storage areas.
   3.1.1 The KGH TALLman lettering drug list is posted in the Guidelines for writing
   Medication Orders section of the Drug Formulary located on the KGH Intranet at:
   3.1.2 TALLman lettering is used to document drug names in Policies & Procedures,
   Order Sets, Medical Directives, Delegated Controlled Acts and Dosage Charts
   3.1.2.1 Pharmacy is involved in the development of all Policies & Procedures,
   Order Sets, Medical Directives, Delegated Controlled Acts and Dosage
   Charts involving medication.

3.2 Pharmacy supplies pre-mixed parenteral solutions of high-alert drugs (either purchased
   commercially or compounded by Pharmacy) when possible and when applicable to the
   patient population.

3.3 Pharmacy compounded drugs are independently double checked prior to dispensing.

3.4 A “Note concentration” warning is included on patient specific labels for unusual
   concentrations of high-alert medications.

3.5 When RHCPs prepare parenteral solutions of high-alert drugs on patient care units,
   RHCPs follow the standard admixture procedures provided by the KHSC Parenteral
   Drug Therapy or the Neonatal Intensive Care Unit (NICU) Drug Manual to serve as a
   double check and document admixture on the orange “Medication added” label affixed to
   the infusion bag.
   3.5.1 When compounding a non-standard concentration, an independent double check
   is required. Both RHCPs involved in the independent double check initial the
   orange “Medication added” label affixed to the infusion bag.
   3.5.2 The label must include:
     • Patient name and hospital identification number
     • Date and time infusion prepared
     • Medication name and concentration
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- Name and credentials of RHCP who prepared medication

3.6 All intrathecal and epidural solutions are either prepared by the anesthesiologists or by Pharmacy.

3.7 All epidural solutions are labeled “For Epidural Infusion Only” and the epidural line is identified with yellow marking.

3.8 The RACE team and the pediatric and adult Critical Care teams may be exempted from the high alert medication safeguards requirements for preparation and labelling of high-alert medications administered parenterally in emergency situations when a delay in administration would compromise patient care.

4 Dispensing and Storage of High-Alert Medications in patient care areas

4.1 Access to high-alert drugs in patient care areas is limited to RHCPs authorized to dispense and administer medications.

4.2 The Medication Safety Committee determines the storage locations of high-alert drugs in selected patient care areas.

4.3 High-alert drugs are segregated from other medications in medication rooms and selected patient care areas when feasible.

4.4 The number of concentrations and volume options for high-alert medications stored in patient care areas are standardized and limited.

4.5 Multi-dose vials of high-alert drugs are reduced or eliminated when possible and are only located in selected patient care areas as determined by the Medication Safety Committee.

4.6 High-alert drugs used in emergency situations are stored in sealed trays (e.g. pediatric “code pink” and adult “code blue” cardiac arrest drug trays, neurological emergency drug tray) for use by trained RHCPs (e.g. RACE team, Critical Care Teams).

4.7 In the Operating Rooms, high-alert drugs are stored by Pharmacy in Anesthesia drug trays or packs restricted for use by anesthesiologists.

4.8 In KGH site patient care areas, ADCs are used to provide directed access to high-alert drugs:

4.8.1 Look-alike and sound-alike drugs and different concentrations of the same drug are located in separate ADC drawers;

4.8.2 Locked lidded ADC bins are used to segregate and restrict access of selected high-alert drugs (e.g. opioids, potassium phosphate for injection, potassium chloride for injection concentrate, sodium chloride for injection hypertonic and other concentrated electrolytes) to ensure only one medication is available for retrieval when accessed on the patient’s profile;

4.8.3 Refrigerated high-alert drugs are located in a separate lidded container with a “High-Alert” label affixed on the lid (e.g. neuromuscular blocking agents);

4.8.4 ADCs are programmed with automated dispensing alerts for selected high-alert drugs (e.g. HYDROMorphone alert).

4.9 In HDH site patient care areas and KGH site locations not equipped with an ADC:

4.9.1 High-alert medications are separated from other medications (e.g. in a separate box/drawer within medication storage area);
4.9.2 Storage bins are affixed with a “High-Alert” label.
4.9.3 Specific medications have additional multi-sensory alerts:
   - Lidded boxes
   - Tamper proof seals
4.9.4 Look-alike, sound-alike products are segregated and labeled.

5 Administration of High-Alert Medications
5.1 Automated double checks are implemented to support the safe administration of high-alert drugs to patients.
5.1.1 Programmable infusion pumps with guardrails (soft and hard dose limits) and automated pump alerts are used for the parenteral administration of high-alert medication infusions (as per Administrative Policy 11-210 Smart Parenteral Infusion Devices).
5.1.2 High-alert medications administered as an intravenous infusion are administered using standardized concentrations.
   5.1.2.1 If a concentration other than the standardized concentration is required, the prescriber must order the concentration and the nurse highlights on the infusion bag and medication administration record.
5.1.3 At KGH site, ADC automated double checks are programmed for high-alert medications. ADC alerts display on the ADC screen once the drug is selected for removal and require the user's action (to continue or cancel item) before a medication can be retrieved. The removal of a high-alert drug may trigger more than one ADC alert and alerts can be combined. ADCs alerts include:
   - **Drug specific warning alert**
     When the user selects to remove a specific medication from the ADC, a warning is displayed on the ADC screen (e.g. HYDROmorphine alert displaying message: “ALERT – you are accessing HYDROmorphine (Dilauid®)").
   - **Look-alike sound-alike alert**
     When the user selects to remove a high-alert medication listed on the KGH TALLman lettering drug list from the ADC, a warning is displayed on the ADC screen indicating “ALERT – look-alike/sound-alike medication.”
   - **High-alert medication alert**
     When the user selects to remove a high-alert medication from the ADC, a warning is displayed on the ADC screen indicating “HIGH ALERT,” (e.g. concentrated electrolyte alert, high-dose format heparin product alert, high-dose format opioid alert, neuromuscular blocking agent alert).
   - **Witness required alert**
     Once the user confirms the above request, the ADC may prompt for an independent double-check with message: “WITNESS REQUIRED” appearing on the ADC screen. The ADC double-check function requires
that a second user logs in the ADC to witness and confirm the removal of the high-alert medication.

5.2 Independent Double Checks are required for selected high-alert drugs prior to administration to support safe patient care.

5.2.1 Only RHCPs who have medication administration within the scope of their practice (e.g. nurses (RN, RPN), nurse practitioners, physicians, pharmacists, respiratory therapists) can perform an independent double check. Students are not permitted to perform independent double checks.

5.2.2 At KGH site, high-alert drugs stored in ADCs and flagged with an alert stating “Independent double check required by two Regulated Health Care Professionals” require that the second RHPC who confirms the removal of the drug from the ADC complete an independent double check.

5.2.3 At HDH site, high-alert drugs are flagged with a high-alert sticker prompting RHCPs to complete an independent double check.

5.2.4 Independent double checks may not be required when high-alert drugs are administered by RHCPs in emergency situations where the delay required for implementing the independent double check could harm the patient.

5.3 The process for conducting an independent double check is as follows:

5.3.1 The RHCP caring for the patient prepares to administer the medication according to the patient care orders.

5.3.2 Medication-specific policies and procedures and Hospital drug information resources are consulted as necessary. Pharmacists are available at all times for consultation regarding medication preparation and administration.

5.3.3 The preparation includes verification of the correct:

- Patient
- Medication
- Dose
- Route or site
- Time
- Concentration, including concentration programmed into pump, if applicable
- Rate, if applicable
- Total volume, if applicable

5.3.4 The second RHCP independently verifies the medication preparation. The practitioner caring for the patient does not communicate what the second practitioner should see.

5.3.5 The patient’s identity is confirmed at the bedside using at least two patient-specific identifiers prior to drug administration.

5.3.6 If no discrepancy is identified during the independent double check, the RHCP caring for the patient administers the drug.

5.3.7 If a discrepancy is identified during the independent double check process both RHCPs resolve the discrepancy before the intervention is initiated. If necessary, a third RHCP performs an independent double check.
5.3.8 Both RHCPs initial the Medication Administration Record (MAR) or the patient care unit/clinic specific documentation record.

6. Monitoring
6.1 The KGH Parenteral Drug Therapy and the NICU Drug Manual guide the administration and monitoring of parenteral high-alert drugs.
6.2 Documentation of monitoring may include description of assessments, time and the patient’s response following administration of high-alert medications.

References

Related Documents:
Administrative Policy 06-170 Incident Reporting, Follow-up and Review
Administrative policy 11-046 Standardized Order Sets
Administrative policy 11-210 Smart Infusion Devices
Administrative policy 14-040 Medication Procurement, Preparation, Distribution and Storage

HDH site:
Administrative policy 2250 Patient Care Orders
Administrative policy 0465 Patient Identification

KGH site:
Administrative policy 11-040 Patient Care Orders
Administrative policy 13-010 Patient Identification

KGH site Nursing Policies:
- M-1710 Medication: Administration of Chemotherapy and Biotherapy Agents: Advanced Competency (AC) for Registered Nurses (only when administered for cancer treatment)
- M-1711 Medication: Intravenous Administration of Chemotherapy & Biotherapy Agents for Cancer Treatment: Advanced Competency (AC) for Registered Nurses
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Authorizing Signature:

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President and Chief Executive Officer