

MEDICAL CENTER ADMINISTRATIVE POLICY AND PROCEDURES

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| | | Revision Dates: | 6/01/06 12/20/07 02/11/08 02/25/09 04/22/09 10/16/09 03-24-10 |
| Accountable Department/Committee: Regional Medication Safety Committee | | | |
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I. Purpose

To establish safe medication practices for High Alert medications to maximize the safety of the medication processes associated with these medications.

II. Policy

1. High alert medications are those drugs which are involved in a higher percentage of medication incidences and/or sentinel and significant events, or that carry an increased risk for error, abuse, injury or other adverse outcomes. These medications are identified from KFH hospital-specific data, literature sources or are recognized as such by patient-safety organizations. Hazardous and cytotoxic medications are those in which studies in animals or humans indicate that exposures to them have a potential for carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity or genotoxicity. The special processes and interventions on the Northern California Regional High Alert medication list are adopted, and are implemented on all the patient care areas/units of KFH hospitals and medical offices. Medications used during medical emergencies are exempt from the medication management procedures in this policy. These special safeguards may relate to any step in the medication use process, including but not limited to: prescribing, prescription order communications, product labeling, packaging and nomenclature, storage, compounding, dispensing, distribution, administration, education, monitoring and use. A current admission weight should be obtained for all patients and fluctuations in body weight assessed when needed to ensure accurate weight-based dosing calculation. "Smart pump" technology with patient safety software activated will be used to administer IV infusions of high alert medications.

The Northern California Regional Medication Safety Committee is responsible for the creation and maintenance of the Regional High Alert medication list. The High Alert Medication List established by this policy is the sole list and is standardized throughout the Northern California Region of Kaiser Permanente. Requests for changes to the Regional High Alert medication list shall be forwarded for consideration to the Regional Medication Safety Committee.

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III. Procedures

A. Vinca Alkaloids: VinCRISTine (Oncovin[®]), VinBLASStine (Velban[®]), Vinorelbine (Navelbine[®])

Special processes to maximize safety

1. All doses of vinCRISTine and vinBLASStine shall be prepared and dispensed in 25mL minibags of 0.9% Sodium Chloride for Injection. Vinorelbine shall be prepared and dispensed in a maximum of 50 mL minibags of 0.9% Sodium Chloride for Injection.
2. The minibag label shall contain the warning, ***“Fatal if given intrathecally. For IV use only. Do not remove covering until moment of injection.”***
3. The minibag shall be affixed with a High Alert Drug label
4. Each minibag shall be placed in an over wrap (e.g., chemo bag) with the same warning listed above in (2).
5. As part of a pause for verification, an independent double check shall be conducted in the pharmacy by two health care professionals including an independent double check as stated in section III E, 5 below.
6. The Universal Protocol for “time out” shall be conducted at the bedside immediately prior to the administration of all doses by two qualified health care professionals (chemotherapy-proficient registered nurse and second chemotherapy-proficient registered nurse or pharmacist or physician) including the independent double check verifying the correct patient, drug, dose, dose calculations route of administration, label, infusion pump settings, IV tubing connection and site of line insertion and scheduled date and time of administration upon initiation, bag change, change in dosage and at handoff.
7. This double check shall be documented in the medical record by both parties. Order changes involving infusion rates and/or pump settings should be documented via current practices (i.e., flow sheet).
8. In very few specific cases where the health and safety of a young child, without central line access, could be compromised, the vinca alkaloid will be diluted in 10mL of 0.9% Sodium Chloride for Injection and dispensed in a 20 mL syringe and packaged and labeled as in number 2, 3 and 4 above. Pediatric Oncology Chiefs will establish criteria for determining which patients may fall under this exception.
9. Vinca alkaloids that are delivered via 20 mL syringe for specific pediatric patients (young children) must be delivered directly from the pharmacist who prepared/checked the product

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to the qualified health care professional who will administer the dose. This process may occur at the nursing unit or pharmacy location.

10. For specific drug handling, intravenous line management and patient monitoring procedures see Vinca Alkaloid Preparation and Administration Policy. Exceptions may be granted on a case by case basis.

B. Continuous intravenous infusions of heparin, lepirudin and argatroban

Special processes to maximize safety

1. The abbreviation “u” shall not be accepted in the medication order
2. A standard concentration of 100 units/mL shall be used for all continuous heparin infusions.
3. Whenever feasible, preprinted orders shall be used for prescribing continuous infusions of heparin, lepirudin and argatroban.
4. All infusion bags shall be affixed with a High Alert Drug label.
5. If heparin, lepirudin and argatroban infusions are stored in Pyxis, a Clinical Data Category warning shall display upon drug removal, “High Alert Drug.”
6. The “profile” feature in the Baxter Colleague CXE infusion pumps or “Smart” pumps with patient safety software shall be used to infuse continuous infusions of heparin, lepirudin and argatroban
7. Two qualified pharmacy staff, one of whom must be a pharmacist, shall independently double check the accuracy of the product in the pharmacy department, using the method as specified in Section IV, B of this document, at the point of completion of compounding sterile dosage forms of heparin, lepirudin and argatroban. If two qualified healthcare professionals are not available in the pharmacy, the checks may be accomplished with a pharmacist and a registered nurse or physician at the location of administration using the documentation of the compounding activities. This check shall be documented in the pharmacy records (e.g., IV compounding profile, record or IV room log book) by both parties.
8. Two qualified healthcare professionals shall independently double check the correct patient, drug, dose, dose calculations, infusion pump settings, label, IV tubing connection and site of line insertion at the bedside whenever a continuous infusion bag of heparin, lepirudin and argatroban is initiated, upon any change in dosage, at bag change and at handoff.

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9. Double checks shall be documented on the electronic or paper Medication Administration Record (MAR) in the medical record by both parties. Order changes involving infusion rates and/or pump settings and double checks involving bag change or at hand-off may be documented via current practices (i.e., flow sheet).
10. All therapeutic continuous heparin, lepirudin and argatroban infusion bags shall be supplied by pharmacy to patient care areas of the facility with a patient specific label except as defined in policy for urgent case use below.
11. Therapeutic heparin, lepirudin and argatroban infusion bags may be stored as stock in critical care areas (e.g., Emergency Department, Intensive Care Unit, and Interventional Radiology) where it is not feasible for direct pharmacy supply for urgent cases. These pre-mixed heparin, lepirudin and argatroban bags supplied by the pharmacy as stock must be supplied through an automated dispensing system (e.g., Pyxis[®], AutoMed[®], Omnicell[®]) for patient safety and medication accountability and shall not be available for dispensing on “override,” i.e., prior to review of the order by a pharmacist.

C. Insulin Injection or Infusion

Special processes to maximize safety

1. Continuous Intravenous Infusions of Insulin

- a. The abbreviation “u” shall not be accepted in the medication order
- b. A standard insulin concentration of 1unit/mL shall be used for all continuous insulin infusions, except in neonates
- c. Whenever feasible, preprinted orders shall be used for prescribing continuous infusions of insulin.
- d. All continuous insulin infusions shall be affixed with a High Alert Drug label.
- e. The “profile” feature in the Baxter Colleague CXE infusion pumps or “Smart” pumps shall be used to infuse continuous infusions of insulin.
- f. Two qualified pharmacy staff, one of whom must be a pharmacist, shall independently double check the accuracy of the product in the pharmacy department using the method as specified in Section IV, B of this document, at the point of completion of compounding sterile dosage forms of insulin. If two qualified healthcare professionals are not available in the pharmacy, the checks may be accomplished with a pharmacist and a registered nurse or physician at the location of administration using the documentation of the compounding activities. This

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check shall be documented in the pharmacy records (e.g., IV compounding profile, record or IV room log book) by both parties.

- g. Two qualified healthcare professionals shall independently double check the correct patient, drug, dose, dose calculations, route of administration, label, infusion pump settings, IV tubing connection and site of line insertion at the bedside whenever a continuous infusion bag of insulin is initiated, upon any change in dosage, at bag change and at handoff.
 - h. Independent double checks shall be documented on the electronic or paper Medication Administration Record (MAR) in the medical record by both parties. Order changes involving infusion rates and/or pump settings and the double checks involving bag changes and at hand-off may be documented via current practices (i.e., flow sheet. Anesthesia practitioners will follow the High Alert Medication List Policy and Procedure for Anesthesia.
2. U-500 Insulin Injection for Inpatient and Emergency Department Use
- a. Inpatient orders for U-500 insulin shall be restricted and require endocrinology approval. U-500 insulin will not appear in the inpatient provider preference list in KP HealthConnect
 - b. The abbreviation “u” (indicating units) will not be accepted in the medication order
 - c. U-500 insulin vials shall not be stocked in patient care areas and shall only be stored in the pharmacy department in a location separated from other insulin preparations. Warnings, signs, labels or other methods shall be used to differentiate the U-500 concentration from other insulin products
 - d. A soft stop “Best Practice Alert” will appear in KP HealthConnect requiring the prescriber and pharmacist to confirm the need for the U-500 insulin concentration
 - e. Total doses of U-500 insulin ordered shall be expressed in terms of both units and volume (e.g., Admin. Amount: 0.22 mL = 110 units of 500 units/mL)
 - f. The pharmacy department shall prepare all doses of U-500 insulin in 1 mL tuberculin syringes with patient-specific labeling and including a “High Alert Medication” warning. U-100 insulin syringes shall not be used for administration of U-500 insulin
 - g. The term “Conc” (Concentrated) will appear immediately following the drug name and preceding U-500 in the product name description on the drug label and Medication Administration Record (MAR)

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- h. The “Admin Instructions” section of the MAR for U-500 insulin shall include a caution regarding syringe measurements, dosage expressed in both volume and units, use of a tuberculin syringe for administration of U-500 insulin and a “High Alert Medication” warning
- i. Two qualified pharmacy staff, one of whom must be a pharmacist, shall independently double check the accuracy of the product in the pharmacy department using the method as specified in Section IV.B. of this document, prior to dispensing. If two qualified healthcare professionals are not available in the pharmacy, the checks may be accomplished with a pharmacist and a registered nurse or physician at the location of administration and documented in the pharmacy records (e.g., IV compounding profile, record or IV room log book or other standard location) by both parties
- j. Two qualified healthcare professionals shall independently double check the correct patient, drug, dose, dose calculations, route of administration, and label at the bedside using the method described in Section IV.B. of this document, prior to administration. As appropriate, the patient will be consulted to confirm prior use of U-500 insulin prior to admission
- k. Independent double checks shall be documented on the electronic or paper Medication Administration Record (MAR) in the medical record by both parties.

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D. Neuromuscular Blocking Agents

Special processes to maximize safety

1. Neuromuscular blockers shall only be stored in specific areas within the hospital, e.g. OR, ICU, ED, after approval from the Pharmacy and Therapeutics Committee, for use by intubated patients.
2. Distinctive labeling and/or storage shall be used to distinguish neuromuscular blockers from other medications outside the O.R., e.g., segregation, colored labels, etc.
3. If neuromuscular blockers are stored in Pyxis, a “Clinical Data Category” warning shall display upon drug removal, **“WARNING: Paralyzing Agent – Causes Respiratory Arrest.”**
4. All infusions of neuromuscular blockers shall be affixed with a High Alert Drug label.
5. Two qualified pharmacy staff, one of whom must be a pharmacist, shall independently double check the accuracy of the product in the pharmacy department using the method as specified in Section IV, B of this document, at the point of completion of compounding sterile dosage forms of neuromuscular blocking agents. If two qualified healthcare professionals are not available in the pharmacy, the checks may be accomplished with a pharmacist and a registered nurse or physician at the location of administration using the documentation of the compounding activities. This check shall be documented in the pharmacy records (e.g., IV compounding profile, record or IV room log book) by both parties.
6. Two qualified health care professionals (two registered nurses or a registered nurse and physician) shall independently double check the correct patient, drug, route of administration, dose, dose calculations, label, infusion pump settings, IV tubing connection, site of line insertion and ventilator status at the bedside for all infusions of neuromuscular blockers at initiation, dosage change, at bag change and at handoff. Double checks shall be documented on the electronic or paper Medication Administration Record (MAR) in the medical record by both parties. Order changes involving infusion rates and/or pump settings and double checks involving bag changes and at handoffs may be documented via current practices (i.e., flow sheet).
7. Anesthesia practitioners will follow the High Alert Medication List Policy and Procedure for Anesthesia.

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E. Intravenous, Intraperitoneal and Intrathecal Cytotoxic Chemotherapy Agents

Special processes to maximize safety

1. Verbal/telephone orders shall not be accepted when prescribing intravenous, intraperitoneal or intrathecal cytotoxic chemotherapy agents with the exception of date or time changes and clarifications.
2. Whenever feasible, preprinted orders shall be used for prescribing intravenous, intraperitoneal or intrathecal cytotoxic chemotherapy agents.
3. When prescribing intravenous, intraperitoneal or intrathecal cytotoxic chemotherapy agents, orders shall be written for individual doses, not the total amount of drug for the entire course of therapy.
4. Complete orders for intravenous, intraperitoneal or intrathecal cytotoxic chemotherapy agents should include:
 - a. Patient name and medical record number, date and time the order is written
 - b. Statement whether this is a new order or a change to an existing order
 - c. All elements used to calculate the dose of a chemotherapy agent should be included on the order or prescription (e.g., height, weight, and/or BSA if applicable)
 - d. Indication that written informed consent was obtained for investigational drugs used in clinical trials or for non-FDA-approved drugs obtained for compassionate use, if applicable
 - e. Allergies (except for outpatient prescriptions)
 - f. Chemotherapy agent name, dose, route, and date of administration for each drug
 - g. Cycle number and/or week number as appropriate to the regimen, if applicable
5. All doses of intravenous, intraperitoneal or intrathecal cytotoxic chemotherapy agents shall be independently double checked by two qualified health care professionals (e.g., two pharmacists or one pharmacist and one qualified technician) in the Pharmacy before dispensing. When only one pharmacist is present this procedure may include qualified medical or chemo proficient nursing personnel. This check shall include a verification of the correct patient, drug, dose, route of administration, frequency of administration, scheduled date and time of administration and label. This check shall be documented in the IV compounding profile/record.
6. Specialized computer software (e.g. COPS, CAMMALOT, BEACON) shall be used by the pharmacy to assist with the monitoring of all intravenous, intraperitoneal or intrathecal cytotoxic chemotherapy agents.

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7. Distinctive labeling/packaging shall be used to distinguish intravenous, intraperitoneal or intrathecal cytotoxic chemotherapy agents from other medications.
8. All doses of intravenous, intraperitoneal or intrathecal cytotoxic chemotherapy agents shall be affixed with a High Alert Drug label
9. Missing dose requests for intravenous, intraperitoneal or intrathecal cytotoxic chemotherapy agents shall be investigated immediately by a pharmacist and a replacement dose shall not be dispensed until the disposition of the first dose is verified.
10. Only nurses with documented competency in chemotherapy administration may administer cytotoxic chemotherapy agents.
11. Two qualified health care professionals (one chemotherapy proficient registered nurse plus another chemotherapy proficient registered nurse or pharmacist or physician) shall independently double check all doses of intravenous, intraperitoneal or intrathecal cytotoxic chemotherapy agents at the bedside before administration or at initiation and upon any change in dosage, at bag change and at handoff. Double checks shall verify the correct patient, drug, dose, dose calculations, route of administration, frequency of administration, scheduled date and time of administration, label, infusion pump settings, IV tubing connection and site of line insertion. This check shall be documented in the medical record by both parties. Order changes involving infusion rates and/or pump settings may be documented via current practices (i.e., flow sheet).

F. Concentrated Electrolytes >0.9% Sodium Chloride Injection, and ≥ 0.4 mEq/mL Potassium Injection (chloride, acetate, and phosphate)

Special processes to maximize safety

1. Concentrated electrolyte injections shall be stored only in the pharmacy.
2. When infusions of concentrated sodium chloride injection are required for patient use, only commercially prepared products (when possible), with patient-specific labeling, shall be dispensed. All concentrated sodium chloride infusions shall be affixed a High Alert Drug label.
3. Two qualified pharmacy staff, one of whom must be a pharmacist, shall independently double check the accuracy of the product in the pharmacy department using the method as specified in Section IV, B of this document, at the point of completion of compounding sterile dosage forms of concentrated electrolytes. If two qualified healthcare professionals are not available in the pharmacy, the checks may be accomplished with a pharmacist and a registered nurse or physician at the location of

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administration using the documentation of the compounding activities. This check shall be documented in the pharmacy records (e.g., IV compounding profile, record or IV room log book) by both parties.

4. Two qualified healthcare professionals shall independently double check the correct patient, dose, dose calculations, route of administration, label, infusion pump settings, IV tubing connection and site of line insertion at the bedside whenever a continuous infusion of concentrated sodium or potassium injection is initiated, at dosage changes, at bag changes and at handoff. Double checks shall be documented on the electronic or paper Medication Administration Record (MAR) of the medical record by both parties. Order changes involving infusion rates and/or pump settings and the double checks involving bag change or at handoff may be documented via current practices (i.e. flow sheet).

G. Magnesium Sulfate Infusions (40mg/mL) With Total IV Bag Volume Size Larger Than 100mL.

Special processes to maximize safety

1. A standard concentration of 40mg/mL shall be used for all continuous infusions of magnesium sulfate.
2. If magnesium sulfate infusions are stored in Pyxis, a Clinical Data Category warning shall display upon drug removal, "High Alert Drug."
3. All magnesium sulfate infusions in these patient care areas shall be affixed with a High Alert drug label.
4. Two qualified pharmacy staff, one of whom must be a pharmacist, shall independently double check the accuracy of the product in the pharmacy department using the method as specified in Section IV, B of this document, at the point of completion of compounding sterile dosage forms of magnesium sulfate. If two qualified healthcare professionals are not available in the pharmacy, the checks may be accomplished with a pharmacist and a registered nurse or physician at the location of administration using the documentation of the compounding activities. This check shall be documented in the pharmacy records (e.g., IV compounding profile, record or IV room log book) by both parties.
5. Two qualified healthcare professionals shall independently double check the correct patient, dose, dose calculations, route of administration, label, infusion pump settings, IV tubing connection and site of line insertion at the bedside whenever a continuous

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infusion of magnesium sulfate with a total I.V. bag size is larger than 100ml is initiated, and upon any change in dosage at bag change and at handoff. Double checks shall be documented on the electronic or paper Medication Administration Record (MAR) in the medical record by both parties. Order changes involving infusion rates and/or pump settings and the double checks involving bag change or at handoff may be documented via current practices (i.e., flow sheet).

H. Alteplase (t-PA, Activase®) Intravenous Infusions

Special processes to maximize safety

1. All infusions of alteplase (t-PA) for use in all departments including, but not limited to, the hospital and emergency departments shall be prepared by a pharmacist. Administration of Alteplase via IV, intra-arterial push or instillation for resolving clots in tubing is excluded.
2. For emergency use, when the pharmacist is verified as not available to prepare the medication, one package dose of alteplase will be securely stored in the Emergency Department. When this dose must be used appropriate documentation containing patient identification and reason for use must be transmitted to pharmacy before a new emergency dose is issued. Use of these emergency doses will be audited for policy compliance.
3. All infusions of alteplase shall be affixed with a High Alert drug label.
4. Alteplase will be supplied from the pharmacy as two patient specific doses as determined by patient weight.
 - h. The bolus dose shall be supplied in a syringe with the patient specific dose to be administered (e.g., 10% of total patient specific dose)
 - i. The continuous infusion of alteplase shall be supplied as the patient specific dose for completion of the therapy. There shall be no over-fill. (e.g., 90% of total patient-specific dose)
5. The label for each alteplase dose shall include at a minimum; the patient name and Medical Record Number, the patient location, the generic and brand name of the drug, the concentration of the drug supplied in mg/ml, the total drug quantity/total volume of solution that is contained in the package, the expiration date and the rate of infusion/administration. Each label (the bolus syringe and the infusion container) shall be patient specific for that dose to be administered.

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6. The compounding of the medications should be accomplished without interruption and in an area that is sequestered from other activities of disruption.
7. Two qualified pharmacy staff, one of whom must be a pharmacist, shall independently double check the accuracy of the product in the pharmacy department using the method as specified in Section IV, B of this document, at the point of completion of compounding the sterile dosage forms of alteplase. If two qualified healthcare professionals are not available in the Pharmacy, the checks may be accomplished with a pharmacist and a registered nurse or physician at the location of administration using the documentation of the compounding activities. This check shall be documented in the pharmacy records (e.g., IV compounding profile, record or IV room log book) by both parties.
8. Two health care professionals (e.g., two registered nurses, or one registered nurse and one physician or pharmacist) shall independently double check the correct patient, dose, dose calculations, route of administration, label, infusion pump settings, IV tubing connection and site of line insertion at the bedside whenever an infusion of alteplase is initiated and at handoff. This check shall be documented in the medical record by both parties. Order changes involving infusion rates and/or pump settings shall be documented via current practices (i.e., flow sheet).
9. Whenever alteplase (t-PA) is stored in an automated dispensing cabinet (e.g., PYXIS[®], SureMed[®], Omnicell[®], etc.), a “Clinical Data Category” warning shall be used to differentiate the product from tenecteplase (TNKase) and minimize the possibility of a substitution error.

I. Tenecteplase (TNKase[®]) Intravenous Injections

Special Processes to maximize safety

1. Two health care professionals (e.g., two registered nurses, or one registered nurse and one physician or pharmacist) shall independently double check the correct medication, patient, dose, dose calculations and route of administration and label at the patient’s bedside whenever an injection of tenecteplase (TNKase[®]) is initiated.
2. Whenever tenecteplase (TNKase) is stored in an automated dispensing cabinet (e.g., PYXIS[®], SureMed[®], Omnicell[®], etc.), a “Clinical Data Category” warning shall be used to differentiate the product from alteplase (t-PA) and minimize the possibility of a substitution error.

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J. Epinephrine, Norepinephrine, Phenylephrine and Isoproterenol infusions Special processes to maximize safety

1. A standard concentration shall be used for all continuous infusions
 - a. Epinephrine 8 micrograms/mL
 - b. Norepinephrine 16 micrograms/mL
 - c. Phenylephrine 160 micrograms/mL
 - d. Isoproterenol 4 micrograms/mL

2. In clinical situations where more concentrated infusions are required, the syringes/bags shall be affixed with a "Non-Standard Concentration" label.
3. Whenever feasible, all infusion bags of these medications shall be prepared by the pharmacy.
4. All infusions of these medications shall be affixed with a High Alert drug label.
5. Except for use on emergency trays or kits (e.g., Crash Carts), 30 mL vials of epinephrine 1:1000 (1 mg/mL) vials will not be stored outside the Pharmacy Department.
6. Two qualified pharmacy staff, one of whom must be a pharmacist, shall independently double check the accuracy of the product in the pharmacy department using the method as specified in Section IV, B of this document, at the point of completion of compounding sterile dosage forms of epinephrine, norepinephrine phenylephrine or isoproterenol. If two qualified healthcare professionals are not available in the pharmacy, the checks may be accomplished with a pharmacist and a registered nurse or physician at the location of administration using the documentation of the compounding activities. This check shall be documented in the pharmacy records (e.g., IV compounding profile, record or IV room log book) by both parties.
7. Two qualified healthcare professionals shall independently double check the correct patient, drug, dose, dose calculations, route of administration, label, infusion pump settings, IV tubing connection and site of line insertion at the bedside whenever a continuous infusion of one of these medications is initiated, at bag change and at handoff. Double checks shall be documented on the electronic or paper Medication Administration Record (MAR) in the medical record by both parties. Infusion rate changes do not require a double check. Order changes involving infusion rates and/or pump settings and the double checks involving bag change, and at hand off may be

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documented via current practices (i.e. flow sheet). Anesthesia practitioners will follow the High Alert Medication List Policy and Procedure for Anesthesia.

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K. Opiate/Narcotic infusions, including PCA therapy

Special processes to maximize safety

1. Whenever feasible, preprinted orders shall be used for prescribing opiate/narcotic infusions and PCA therapy
2. The following standard concentrations shall be used for PCA therapy: morphine 1mg/mL, meperidine 10mg/mL, hydromorphone 0.2mg/mL.
3. In clinical situations where more concentrated infusions are required, the syringes/bags/reservoirs shall be affixed with a “Non-Standard Concentration” label.
4. If opiate/narcotic PCA syringes/bags/reservoirs are stored in Pyxis, a Clinical Data Category warning shall display upon drug removal, “High Alert Drug.”
5. All opiate/narcotic infusion syringes/bags shall be affixed with a High Alert drug label. High Alert labels should be affixed to the exterior over packaging on commercially supplied syringes/bags to maintain tamper evidence.
6. Two qualified pharmacy staff, one of whom must be a pharmacist, shall independently double check the accuracy of the product in the pharmacy department using the method as specified in Section IV, B of this document, at the point of completion of compounding sterile dosage forms of opiate/narcotic infusions, including PCA. If two qualified healthcare professionals are not available in the pharmacy, the checks may be accomplished with a pharmacist and a registered nurse or physician at the location of administration using the documentation of the compounding activities. This check shall be documented in the pharmacy records (e.g., IV compounding profile, record or IV room log book) by both parties.
7. Two nurses shall independently double check the correct patient, dose, dose calculations, route of administration, label, PCA pump settings, IV tubing connection and site of line insertion at the bedside whenever an opiate/narcotic infusion bag is initiated, upon any change in dosage or infusion rate, at bag change and at handoff. Double checks shall be documented on the PCA Flow Sheet or the electronic or paper Medication Administration Record (MAR) in the medical record by both parties. Order changes involving infusion rates and/or pump settings and double checks involving bag change and at hand-off may be documented via current practices (i.e., flow sheet). Anesthesia practitioners will follow the High Alert Medication List Policy and Procedure for Anesthesia.

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L. Medications Administered via the Intrathecal Route

Special processes to maximize safety

1. When compounding medications for intrathecal use, compounding personnel shall pause for verification and perform an independent double check in the Pharmacy by two health care professionals (e.g. two pharmacists, one pharmacist and one technician, one pharmacist and one nurse) after the preparation of the Intrathecal dose to assure it is prepared and labeled correctly. This check shall include a verification of the correct patient, drug, dose, dose calculations, and route of administration. This check shall be documented in the IV compounding records.
2. The Universal Protocol for “time out”, including an independent double check, shall be conducted at the bedside immediately prior to the administration of all doses of Intrathecal medications by two qualified health care professionals (e.g., physician and registered nurse or pharmacist or two registered nurses). This check shall verify the correct patient, drug, dose, dose calculations, route of administration and label. Double checks shall be documented in the medical record by both parties. Order changes involving infusion rates and/or pump settings should be documented via current practices (i.e., flow sheet). Anesthesia practitioners will follow the High Alert Medication List Policy and Procedure for Anesthesia.

M. Medications Administered via the Epidural Route

Special processes to maximize safety

1. Whenever feasible, preprinted orders shall be used for prescribing opiate/narcotic epidural infusions
2. If opiate/narcotic epidural infusions are stored in Pyxis, a Clinical Data Category warning shall display upon drug removal, “High-Alert Drug.”
3. When appropriate PCA pumps are available, all opiate/narcotic epidural infusions shall be administered using a PCA pump.
4. All opiate/narcotic epidural infusions shall be affixed with a High-alert drug label.
5. Whenever feasible, commercially prepared bags of opiates/narcotics shall be used for epidural infusion.
6. Where feasible, color-coded or labeled tubing without injection ports shall be used for administering opiate/narcotic epidural infusions.
7. Two qualified pharmacy staff, one of whom must be a pharmacist, shall independently double check the accuracy of the product in the pharmacy department using the method

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as specified in Section IV, B of this document at the point of completion of compounding sterile dosage forms of epidural medications. If two qualified healthcare professionals are not available in the pharmacy, the checks may be accomplished with a pharmacist and a registered nurse or physician at the location of administration using the documentation of the compounding activities. This check shall be documented in the pharmacy records (e.g., IV compounding profile, record or IV room log book) by both parties.

8. Two qualified health care professionals (e.g., two physicians or two registered nurses or one physician and one registered nurse) shall independently double check the correct patient, drug, dose, dose calculations, route of administration, label, infusion pump settings, tubing connection and site of line insertion at the bedside whenever an epidural medication is administered, at bag change and at handoff. This check is also required whenever an epidural opiate/narcotic infusion is initiated and upon any change in dosage. Double checks shall be documented on the electronic or paper Medication Administration Record (MAR) in the medical record by both parties. Order changes involving infusion rates and/or pump settings and double checks involving bag change and at hand-off may be documented via current practices (i.e., flow sheet).. Anesthesia practitioners will follow the High Alert Medication List Policy and Procedure for Anesthesia.
9. Invasive procedures such as epidural insertions require adherence to the Joint Commission's National Patient Safety Goals and use of the Universal Protocol for "time out." The above must be followed for the procedure but is not required for medication maintenance.

N. Medications Administered to Neonates in the Neonatal Intensive Care Unit (NICU) and Special Care Nursery (SCN)

Special processes to maximize safety

1. Two qualified pharmacy staff, one of whom must be a pharmacist, shall independently double check the accuracy of the product in the pharmacy department using the method as specified in Section IV, B of this document, at the point of completion of compounding sterile dosage forms of all medications for neonatal patients with the exception of intermittent infusions of short duration (e.g., IV antibiotics). If two qualified healthcare professionals are not available in the pharmacy, the checks may be accomplished with a pharmacist and a registered nurse or physician at the location of

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administration using the documentation of the compounding activities. This check shall be documented in the pharmacy records (e.g., IV compounding profile, record or IV room log book) by both parties.

2. For all doses of medications, two health care professionals (e.g., registered nurse, physician, pharmacist, or respiratory therapist) shall independently double check the correct patient, drug, dose, dose calculations, route of administration, label, IV tubing connection and site of line insertion and any infusion pump settings at the bedside before administration, at bag change and at handoff. Double checks shall be documented on the electronic or paper Medication Administration Record (MAR) in the medical record by both parties. Order changes involving infusion rates and/or pump settings and double checks involving, bag changes and at handoff may be documented via current practices (i.e., flow sheet).

O. Medications Administered to Pediatric patients (Age 0-13)

Special processes to maximize safety

1. Two health care professionals (e.g. two physicians or two registered nurses) shall independently double check the correct patient, drug, dose, dose calculations, route of administration, label, infusion pump setting, IV tubing connection and site of line insertion at the bedside before administration, with bag changes and at handoff for all medications listed below
 - a. Adult High Alert drug list and the additional medications listed below:
 - b. All doses of IV medications in critical care areas including ED
 - c. All medications used for procedural sedation except when administered by an anesthesia provider.
 - d. Digoxin (all routes)
 - e. Chloral hydrate (all routes)
2. Double checks shall be documented on the electronic or paper Medication Administration Record (MAR) in the medical record by both parties. Order changes involving infusion rates and/or pump settings and double checks involving bag changes and at handoff may be documented via current practices (i.e., flow sheet).
3. Two qualified pharmacy staff, one of whom must be a pharmacist, shall independently double check the accuracy of the product in the pharmacy department using the method as specified in Section IV, B of this document, at the point of completion of

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compounding sterile dosage forms of high alert medications for pediatric patients. If two qualified healthcare professionals are not available in the pharmacy, the checks may be accomplished with a pharmacist and a registered nurse or physician at the location of administration using the documentation of the compounding activities. This check shall be documented in the pharmacy records (e.g., IV compounding profile, record or IV room log book) by both parties.

IV. Definitions:

- A. Universal Protocol for Time Out:** Immediately before starting administration/procedure, Time Out must be conducted in the location where the procedure/medication will be done/administered. *It must involve the entire care/procedure team*, use active communication, be documented, using the KP Universal Protocol documentation forms, and must, at the least, include:
1. Correct patient identity (use 2 patient identifiers).
 2. Correct side and site (verify appropriateness of drug (right drug, dose, route, time, and if giving medication IV, verify patency of IV line).
 3. Agreement on the procedure and/or medication to be done/given with the patient (discuss with the patient the medication and administration procedure).
 4. Correct patient position.
 5. Availability of correct implants and any special equipment or special requirements (e.g., infusion devices).
 6. Follow the organization's processes reconciling differences in staff responses during the Universal Protocol for "time out."

B. Independent Double Check

A procedure in which two authorized, qualified practitioners will separately check each component of the work process. An example would be one person calculating a medication dose for a specific patient and a second individual independently performing the same calculation (not just verifying the calculation) and matching the results. The pharmacy will be consulted in the event that agreement cannot be reached.

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The two practitioners should check all factors applicable to the point of the patient bedside. For medications, the factors to be verified during the independent double check may include, but are not limited to:

1. Right patient identification using two identifiers per local policy
2. Right drug (e.g., check against MAR, physician order, Pyxis tape per local policy)
3. Right dose of drug including:
 - a. Mathematic calculations using appropriate factors and formula (e.g., mg/m², mg/kg, etc.)
 - b. Strength or concentration of drug
4. Right route of administration
5. Right date and time of administration
6. IV pump setting, if applicable
7. Rate of infusion, including calculations, if applicable
8. Labels
9. IV tubing connection and site of line insertion
10. Other factors to be included in the decision-making process, as appropriate:
 - a. Does the drugs indication match the patient's diagnosis or condition?
 - b. Is this the right formulation of the drug?
 - c. Is the prescribed dose appropriate for this patient?
 - d. Is the dosing frequency/timing appropriate for this patient?
 - e. Is the route of administration safe and proper for this patient?
 - f. Is the infusion line connected to the right port?
 - g. Have appropriate monitoring tests and guidelines been prescribed?

For IV infusions of high alert medications compounded in the pharmacy, the independent double check in the pharmacy department shall include:

1. Patient name and location
2. Date and time of scheduled administration
3. Drug name
4. Additive quantities and calculations
5. Concentration
6. Route of administration
7. Frequency and duration of administration
8. Infusion rate

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9. Required alerts, warnings and labels
10. Storage requirements (e.g., refrigeration required)
11. Expiration date
12. Stability, including clarity and color, of the final product

When preparing an IV infusion containing a high alert drug, the additive must be drawn up into a syringe and the drug name, quantity and original stock container checked by a pharmacist prior to addition to the base solution.

C. Hand-Off

An independent double check is required whenever there is a transfer of responsibility for the care of the patient. Transfer of responsibility occurs at change of shift, change of primary assignment, transfer of patient's between units or levels of care. It is not the intention of this policy to include independent double checks at break relief unless there is anticipated to be a bag change, change in drug dose, rate of infusion or pump settings while the nurse is on break

D. High Alert Drug Labels:



2" x 2"



3/4" x 3/4"

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Appendix 1:

Cytotoxic Chemotherapy Agents*

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| ALDESLEUKIN (IL-2) | FLUOROURACIL |
| ARSENIC TRIOXIDE | GEMCITABINE |
| ASPARAGINASE | GEMTUZUMAB OZOGAMICIN |
| AZACITIDINE | IDARUBICIN |
| BENDAMUSTINE | IFOSFAMIDE |
| BLEOMYCIN | IRINOTECAN |
| BORTEZOMIB | IXABEPILONE |
| BUSULFAN | MECHLORETHAMINE |
| CARBOPLATIN | MELPHALAN |
| CARMUSTINE | METHOTREXATE |
| CISPLATIN | MITOMYCIN |
| CLADRIBINE | MITOTANE |
| CLOFARABINE | MITOXANTRONE |
| CYCLOPHOSPHAMIDE | NELARABINE |
| CYTARABINE | OXALIPLATIN |
| DACARBAZINE | PACLITAXEL |
| DACTINOMYCIN | PEGASPARGASE |
| DAUNORUBICIN | PEMETREXED |
| DAUNORUBICIN LIPOSOMAL | PENTOSTATIN |
| DECITABINE | STREPTOZOCIN |
| DENILEUKIN DIFTITOX | TEMSIROLIMUS |
| DOCETAXEL | TENIPOSIDE |
| DOXORUBICIN | THIOTEPA |
| DOXORUBICIN LIPOSOMAL | TOPOTECAN |
| EPIRUBICIN | VINBLASTINE |
| ETOPOSIDE | VINCRISTINE |
| FLOXURIDINE | VINORELBINE |
| FLUDARABINE | |

* Drugs considered hazardous and requiring special precautions to prevent workplace exposure