

APRIL

2005

DROPERIDOL USE POLICY

The Pharmacy and Therapeutics Committee approved the new droperidol use policy, a formalization of the previously approved appropriate use guidelines.

Droperidol is currently the first-line agent for treatment of post-operative nausea and vomiting (PONV) on the current PONV/POV protocol. Droperidol will not be stocked in the automated dispensing machines outside the OR; dispensing outside the OR must come from the pharmacy.

Dispensing and handling droperidol must follow the policy guidelines. For all doses of droperidol, patients must have a 12-lead ECG prior to administration if they meet at least one of the following criteria: 1) past medical history significant for cardiac disease (CAD, MI, cardiomyopathy); 2) multi-organ dysfunction (diabetes, COPD, renal insufficiency); 3) concomitant medications that are known to cause QT prolongation.

In patients with a QTc > 450 msec, droperidol is not recommended. If administered, the patient must have continuous ECG monitoring for a minimum of 2 hours after the last dose to monitor for arrhythmias.

Droperidol is contraindicated and will not be dispensed for patients with known or suspected QT prolongation, including congenital long QT syndrome

For doses of droperidol outside the OR/PACU and greater than 1.25mg, pharmacists will contact ordering physician to inform them of droperidol's Black Box warning and suggest alternative formulary agents. If no alternative is acceptable, droperidol will be dispensed only after the patient receives a 12-lead ECG prior to drug administration to determine if a prolonged QT interval exists. In addition, the patient will undergo continuous ECG monitoring for a minimum of 2 hours after the last dose to monitor for arrhythmias.

OR/PACU patients dispensed droperidol for PONV can only receive single doses \leq 1.25 mg. Cumulative doses are not to exceed 2.5mg. In this case, 12-lead ECG monitoring is not required.

FACTOR VIIA USAGE GUIDELINES

Background

Factor VII is a recombinant DNA preparation of activated blood coagulation factor VII (rFVIIa). At the recommended dosage of 90 mcg/kg of body weight every 2 to 3 hours, the cost may exceed \$50,000 per day. The cost of Factor VII used for off-label indications (dosages between 20 mcg/kg and 120 mcg/kg) can range from \$10,000 to \$200,000. The potentially high cost of Factor VII led to the need for evidence-based usage requirements, a summary of which follows.

Indications:

Factor VII is indicated for the following:

- 1) treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX;
- 2) reversal of an anticoagulant with no known reversal mechanism (e.g., fondaparinux, low molecular weight heparins, lepirudin, argatroban) in cases of serious bleeding complications or need for acute surgery;
- 3) to correct or normalize laboratory and clinical hemostatic parameters in patients with liver disease prior to laparoscopic liver biopsy or other invasive procedure after attempted significant clotting factor replacement (20 mL/kg or 6 units of fresh frozen plasma, or 6 units of platelets x 2 if thrombocytopenic or 10 bags of cryoprecipitate x 2 if hypofibrinogenemic);
- 4) treatment of patients in a life-threatening coagulopathic state with acute bleeding (must have one of the following laboratory abnormalities: platelets < 50,000/mcL; INR \geq 1.5; PTT > 50 sec; fibrinogen < 100 mg/dL) who are unresponsive to conventional therapy or who require rapid treatment.

A hematology consult will be required for all other indications.

Coagulopathy without acute bleeding is an unapproved indication.

Contraindications, Warnings and Precautions

Contraindications include hypersensitivity to mouse, bovine, or hamster proteins and hypersensitivity to recombinant factor VIIa or other product components. Warnings/Precautions include increased risk of thrombotic events (risk factors include advanced atherosclerotic disease, crush injury, disseminated intravascular coagulation (DIC), septicemia, and signs or symptoms of coagulation system activation or thrombosis

Simultaneous use of activated prothrombin complex concentrates or prothrombin complex concentrates should be avoided.

Monitoring

Platelets, fibrinogen, prothrombin time (PT) and activated partial thromboplastin time (aPTT) should be monitored. Monitor for clinical signs of bleeding such as pain, swelling, joint circumference for hemarthrosis

Dosage and Administration

Recombinant Factor VIIa may only be prescribed by an attending physician. Drug should be administered as an IV bolus dose. No minimal effective dose has been established for off-label indications and lowest possible dose should be used. Doses should be rounded down to the nearest 1200 mcg vial size. Doses should be determined based on hemostasis and clinical symptoms. Coagulation parameters do not necessarily correlate with or predict effectiveness.

General dosing guidelines for anticoagulant reversal:

- non-emergent bleeding – 20-40 mcg/kg
- emergent and life-threatening bleeding – 41-90 mcg/kg
- other off-label uses 41-90 mcg/kg.

Dosing guidelines for Hemophilia A or B patients with inhibitors:

- 90 mcg/kg IV bolus over 2-5 minutes every 2 hours until hemostasis is achieved or until treatment has been determined to be adequate;
- for severe bleeds, give repeat doses every 3-6 hours after hemostasis to maintain hemostatic plug.

To correct or normalize laboratory and clinical hemostatic parameters in patients with liver disease prior to laparoscopic liver biopsy or other invasive procedure after attempted significant clotting factor replacement

- use 80-120 mcg/kg IV bolus over 2-5 minutes as a single dose 10 minutes prior to start of the biopsy procedure;
- may repeat as a single 80 mcg/kg dose if patient does not achieve hemostasis within ten minutes post-biopsy.

For treatment of patients in a life-threatening coagulopathic state with acute bleeding and platelets < 50,000 per mL administer platelets;

- if unresponsive to platelets or patient's condition requires rapid treatment, give Factor VIIa 40-90 mcg/kg IV bolus over 2-5 minutes as a single dose;
- may repeat once if response is inadequate.

INR \geq 1.5 or PTT > 50 seconds, administer fresh frozen plasma (and vitamin K if indicated);

- if unresponsive to plasma or patient's condition requires rapid treatment, give Factor VIIa 40-90 mcg/kg IV bolus over 2-5 minutes as a single dose;
- may repeat once if response is inadequate.

Fibrinogen < 100 mg/dL, administer cryoprecipitate;

- if unresponsive to cryoprecipitate or patient's condition requires rapid treatment, give Factor VIIa 40-90 mcg/kg IV bolus over 2-5 minutes as a single dose;
- may repeat once if response is inadequate.

Final Comments

All use of recombinant Factor VIIa at the University of Kansas Hospital will undergo a retrospective review by representatives from the Departments of Hematology, Surgery, Critical Care and Pharmacy

UPDATE ON DO NOT USE ABBREVIATIONS

The Medication Safety Subcommittee has revised the hospital policy for abbreviations. The abbreviations R and L have been removed from the list of Do Not Use Abbreviations.

MEDICATION DOUBLE CHECK

As part of KU's effort to ensure the safety of patients, a medication double check policy has been implemented. This policy identifies medications that require verification or double check by a second healthcare provider prior to administration for the purposes of safety and accuracy.

A medication double check or second provider verification will be required prior to administration of selected high-risk medications. A provider licensed to order, dispense, or administer medications may conduct the second check. This includes, but is not limited to, nurses, pharmacists, physicians and licensed independent practitioners. Documentation of the double check will be on the Medication Administration Record (MAR).

The minimum requirement for the medication double check or second provider verification will be double checks occurring:

1. with each dose/injection
2. for titratable infusions:
 - a. at the time of initiation of therapy;
 - b. at the time of a concentration change;
 - c. as part of the Nursing Safety Check at the change of each shift ;
 - d. with any dose change for selected medications where noted in the list of "Medications Requiring Double Check".

Medications Requiring Double Check:

Chemotherapy
Heparin (all forms including flushes)
Insulin (all forms including sliding scale orders)
Narcotic Patient Controlled Analgesia (PCA) and Infusions
Epoprostenol (Flolan[®]) **Requires double check of ANY dose change**
Trepstinil (Remodulin[®]) **Requires double check of ANY dose change**
Abciximab (Reopro[®])
Eptifibatide (Integrilin[®])
Tirofiban (Aggrastat[®])

PHARMACIST MANAGED DRUG THERAPY BY PROTOCOL

To optimize aminoglycoside and vancomycin therapy, the approved policy will allow clinical pharmacists to order the drug dosage and laboratory values to monitor patient's therapy while being initiated with these medications.

Pharmacists may assist in ordering drug dosage, drug-levels and serum creatinine (SCr) based on established criteria. This protocol is not a substitution for continued monitoring by physicians. The policy provides patient inclusion and exclusion criteria for use of protocol. Physicians may choose to opt out of pharmacy services.

The policy will not change any monitoring pharmacists are currently doing, it would allow pharmacists to write orders for levels or dose changes without the approval of the physician if the box on the order form is checked.

Formulary Additions and Deletions (January 1, 2004 - Present)					
Generic Name	Trade Name	Therapeutic Class	Action	Date	Comments
Abarelix	Plenaxis	Palliative Agent	Added	9/28/04	
Acetylcysteine	Acetadote	Antidote	Added	10/25/04	
Atomoxetine	Strattera	Non-stimulant ADHD medication	Added	9/28/04	
BCNU Wafers	Gliadel	Chemotherapeutic	Added	2/26/04	
Brompheniramine	N/A	Antihistamine	Deleted	3/19/04	
Brompheniramine/ Phenylpropanolamine	N/A	Antihistamine/ Decongestant	Deleted	3/19/04	
Daptomycin	Cubicin	Antibiotic	Added	1/25/05	See Feb Pharmacy Key
Darbepoetin Alfa	Aranesp	Hematopoietic Agent	Deleted	06/24/04	
DTaP, Hep B (Recombinant), and IPV Combined	Pediarix	Vaccine	Added	5/27/04	
Doxorubicin HCl Liposomal	Doxil	Chemotherapeutic	Added	5/27/04	
Guaifenesin/ Codeine	N/A	Expectorant	Added	1/22/04	
Halothane	N/A	Inhalational Anesthetic	Deleted	3/25/04	
Insulin	Humalog 75/25	Antidiabetic	Deleted	9/28/04	Autosubstitution to Novolog 70/30
Insulin	Humulin	Antidiabetic	Deleted	7/27/04	See Sept Pharmacy Key
Insulin	Lente	Antidiabetic	Deleted	9/28/04	Autosubstitution to Lantus
Insulin	Novolin	Antidiabetic	Added	7/27/04	See Sept Pharmacy Key
Insulin	Novolin 70/30	Antidiabetic	Added	9/28/04	Autosubstitution for Humalog75/25
Insulin	Ultralente	Antidiabetic	Deleted	9/28/04	Autosubstitution to Lantus
Lansoprazole IV	Prevacid	Proton Pump Inhibitor	Added	7/27/04	See guidelines for use
Lidocaine 5%	Lidoderm	Local Anesthetic	Added	8/28/03	
Mepivacaine	Carbocaine	Peripheral Nerve Blocker	Added	10/26/04	See Nov Pharmacy Key
Mivacurium	Mivacron	Neuromuscular Blocker	Added	2/26/04	
Morphine Extended Release	Avinza	Narcotic Analgesic	Added	4/29/04	See guidelines for use
Moxifloxacin	Avelox	Antibiotic	Deleted	6/24/04	
Nateglinide	Starlix	Antidiabetic	Added	4/29/04	
Olanzapine for Injection	Zyprexa IntraMuscular	Antipsychotic	Added	6/24/04	See guidelines for use
Oseltamivir	Tamiflu	Antiviral	Added	3/25/04	
Pantoprazole IV	Protonix	Proton Pump Inhibitor	Deleted	07/27/04	See guidelines for use
Pravastatin	Pravahol	HMG-CoA Reductase Inhibitor	Added	07/27/04	See Sept Pharmacy Key
Risperidone Long-Acting	Risperdal Consta	Antipsychotic	Added	2/26/04	See guidelines for use
Rofecoxib	Vioxx	COX-2 Inhibitor	Deleted	9/30/04	Taken off the market
Tiotropium	Spiriva	Anticholinergic	Added	07/27/04	
Tirofiban	Aggrastat	Glycoprotein IIb/IIIa Inhibitor	Deleted	01/25/05	
Valsartan	Diovan	Angiotensin Receptor Blocker	Added	09/28/04	
Zonisamide	Zonegran	Antiepileptic	Added	2/26/04	