In November 2007, the Alaris® pumps (CareFusion Corporation) were implemented at MGH. These pumps are primarily available in patient care areas where intravenous infusions are provided including the hospital, hematology/oncology offices in Marquette/Escanaba/Sault Saint Marie/Iron Mountain, and U.P. Internal Medicine. The safety features of the Alaris® pumps includes the Guardrails Suite MX software which provides drug libraries containing drug selections for different patient care areas. Currently, the following Alaris® libraries have been built: Critical Care, FBC, General Medical, Oncology, and Peds. It should also be noted that the NICU is using a different smart pump (MedFusion® 3000 syringe pump by Smiths Medical). In addition to specific drug settings, these libraries consist of upper and lower limits and soft and hard stops for dose, duration, concentration, and infusion limits. Soft limits may be overridden whereas hard limits require pump reprogramming prior to proceeding with the infusion. As hard limits pertain to restricting prescribing, their implementation should be approved by the Pharmacy and Therapeutics Committee. Conversely, soft limits can be established by the Nurse Pharmacy Workgroup. The focus of this review is to briefly discuss ongoing performance improvement activities surrounding the use of the Alaris® pumps and to establish upper hard limits for selected high-alert medications (as defined in the Safe Medication Practices policy #100-170).

Each quarter, pump utilization data are made available by CareFusion which is reviewed by representatives from nursing, pharmacy, and information technology. Their review and subsequent recommendations are reported through the Nurse Pharmacy Workgroup. To date, the majority of activities have focused around the addition and/or modification of drug listings and settings based on available data and education to end-users to ensure safe and appropriate use.

Overall, total (Guardrail) suite usage has improved from less than 70% to over 80% in the past 12 months. However, as depicted in the CareFusion Executive Summary from October through December 2012, overrides remain above 70% with approximately 50% of overrides occurring within 2 seconds. The primary libraries with these overrides includes the Critical Care and Oncology libraries with midazolam, propofol, and insulin being the most frequently reported last quarter. Other high-alert medications with frequent overrides include phosphate salts (potassium and sodium), potassium chloride, and heparin.

Based on ongoing assessments and the necessity of establishing hard limits for high-alert medications, the P&T Committee approved the implementation of several upper hard limits as depicted in the following table.

### AUTOSTOP ORDERS
Currently, there are no stop times for most standard medication orders as they will continue for the duration of a patient’s stay unless written otherwise. Aside from selected restricted antimicrobials which require ID approval for initiation (exception includes 1-2 doses which can be dispensed until an ID consult can be obtained) or continuation.
Table: Upper Hard Limits for Alaris Pumps.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Current Upper Limits</th>
<th>Changes</th>
<th>Library</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium chloride</td>
<td>10 mEq/hr (soft)</td>
<td>10 mEq/hr (soft)</td>
<td>FBC, General Medical, Oncology, Peds</td>
</tr>
<tr>
<td></td>
<td>20 mEq/hr (soft)</td>
<td>20 mEq/hr (soft)</td>
<td>Critical Care</td>
</tr>
<tr>
<td></td>
<td></td>
<td>40 mEq/hr (hard)</td>
<td></td>
</tr>
<tr>
<td>Potassium phosphate</td>
<td>55 minutes to 4 hours (soft)</td>
<td>4 hours (soft)</td>
<td>Critical Care, FBC, General Medical, Oncology</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 hours (hard)</td>
<td></td>
</tr>
<tr>
<td>Sodium phosphate</td>
<td>4 hours (soft)</td>
<td>4 hours (soft)</td>
<td>Critical Care, FBC, General Medical, Oncology</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 hours (hard)</td>
<td></td>
</tr>
<tr>
<td>Insulin</td>
<td>10 units/hr (soft)</td>
<td>No changes</td>
<td>Critical Care, FBC, General Medical, Peds</td>
</tr>
<tr>
<td></td>
<td>30 units/hr (hard)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bivalirudin</td>
<td>1.9 mg/kg/hr (soft)</td>
<td>1.75 mg/kg/hr (soft)</td>
<td>Critical Care</td>
</tr>
<tr>
<td></td>
<td>2 mg/kg/hr (hard)</td>
<td>2 mg/kg/hr (hard)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.75 mg/kg/hr (soft)</td>
<td>1.75 mg/kg/hr (soft)</td>
<td>Oncology</td>
</tr>
<tr>
<td></td>
<td>2.5 mg/kg/hr (hard)</td>
<td>2 mg/kg/hr (hard)</td>
<td></td>
</tr>
<tr>
<td>Heparin drip (≥50 units/mL)</td>
<td>1600 units/hr (soft)</td>
<td>1600 units/hr (soft)</td>
<td>Critical Care, General Medical, Oncology</td>
</tr>
<tr>
<td></td>
<td></td>
<td>40 units/kg/hr (hard)</td>
<td></td>
</tr>
<tr>
<td>Propofol</td>
<td>80 mcg/kg/min (soft)</td>
<td>80 mcg/kg/min (soft)</td>
<td>Critical Care</td>
</tr>
<tr>
<td></td>
<td></td>
<td>150 mcg/kg/min (hard)</td>
<td></td>
</tr>
</tbody>
</table>

**AUTOSTOP ORDERS CONTINUED**
beyond 48 hours, the only two exceptions include injectable controlled substances (14 days) and antibiotics (30 days). In general, these are set up as soft-stops in that a report identifies the order set to expire 2 days in advance. A note is then left on the patient’s chart advising the prescriber that the drug needs to be re-ordered or it will be discontinued. If no order is received, a pharmacist writes an order to discontinue the medication. If a new order is received, the same expiration date will then be re-applied.

Based on recommendations from the Pharmacy Department, the P&T Committee approved to continue current processes with minor change of a 14 day soft-stop for **all injectable antibiotics**. Furthermore, a hard-stop for ketorolac (injection and oral) of 5 days per package labeling will be implemented.

**MEDICATION MANAGEMENT**
This section of the *P&T Committee Newsletter* focuses on medication management issues as highlighted primarily by The Joint Commission (TJC) and the Institute for Safe Medication Practices (ISMP).

**Question:** When a compounding pharmacy “registers” with FDA, what does it mean?

**Answer:** Presently, there is no requirement for compounding pharmacies to register with the US Food and Drug Administration (FDA), and there are no FDA-specified procedures that must be followed by compounding pharmacies to ensure safety. Some compounding pharmacies do register with FDA, but this does not mean that it is routinely inspected by FDA nor does “FDA-registered” mean that FDA has reviewed or approved any compounded preparations produced by the pharmacy.

**RECENT FDA ALERTS/WARNINGS**
The following links provide additional information on Drug Safety Communications that have been recently issued from the U.S. Food and Drug Administration.

- [FDA limits duration and usage of Samsca (tolvaptan) due to possible liver injury leading to organ transplant or death][1] 4/30/2013
- [Anti-seizure drug Potiga (ezogabine) linked to retinal abnormalities and blue skin discoloration][2] 4/26/2013

**DRUG SHORTAGES**
As of April 30, 2013, there remain over 200 drug shortages listed on [ASHP’s Drug Shortage website][3] and many continue to impact MGH which are listed on the [MGHS Online Formulary]. Those currently in critical supply necessitating selected restrictions and/or other actions at MGH include:
DRUG SHORTAGES CONTINUED

- Acetylcysteine inhalation
- Aminocaproic acid injection
- Caffeine and sodium benzoate injection
- Dextrose 25% and 50% injection
- Ketorolac injection
- Magnesium sulfate injection
- Multivitamins for injection
- Potassium acetate injection
- Selenium injection
- Sodium phosphate injection
- Trace elements injection
- Tromethamine (THAM) injection
- Zinc injection

Additional information is also available at the Food and Drug Administration Drug Shortage website. For additional information regarding ongoing drug shortages, please visit the MGHS Online Formulary or contact the Pharmacy Department at 225-3495.

COMPOUNDING PHARMACY UPDATE

Since the October 2012 recalls submitted by the New England Compounding Center (NECC) and its affiliate, Ameridose, there have been several recalls issued from compounding pharmacies due to sterility concerns. More information can be obtained from the FDA’s Drug Recall website (click here). The following recalls have been issued since March 16, 2013:

- April 22, 2013 Nora Apothecary & Alternative Therapies Announces a Voluntary Multi-State Recall of All Sterile Compounded Products Due to a Lack of Sterility Assurance
- April 17, 2013 Balanced Solutions Compounding Pharmacy, LLC. Recalls All Sterile Compounded Products Due to a Lack of Sterility Assurance
- April 15, 2013 ApothéCure, Inc. Recalls All Lots of All Sterile Products Compounded, Repackaged, and Distributed by ApothéCure, Inc. Due to Sterility Assurance Concerns
- April 15, 2013 NuVision Pharmacy Recalls All Lots of All Lyophilized Products Compounded by NuVision Pharmacy Due to Sterility Assurance Concerns
- April 05, 2013 Green Valley Drugs Recalls All Lots of All Sterile Products Compounded, Repackaged, and Distributed by Green Valley Drugs Due to Quality Control Concerns
- March 26, 2013 Pallimed Solutions, Inc. Announces Voluntary Nationwide Recall of All Sterile Compounded Products Dispensed
- March 20, 2013 Medprep Consulting Inc. Announces Voluntary Nationwide Recall Of All Lots Of All Compounded Products Due To Potential Mold Contamination
- March 20, 2013 Clinical Specialties Compounding Pharmacy Recalls All lots of Sterile Products Repackaged and Distributed by Clinical Specialties Compounding Due to Lack of Sterility Assurance
- March 18, 2013 Clinical Specialties Issues Voluntary Nationwide Recall of Avastin Unit Dose Syringes due to Potential Serious Eye Infection
- March 17, 2013 Medprep Consulting Inc. Announces Voluntary Nationwide Recall Of All Lots Of All Compounded Products Due To Potential Mold Contamination
- March 16, 2013 Medprep Consulting Inc. Recalls All Lots Of Magnesium Sulfate 2gm In Dextrose 5 percent In Water, 50ml For Injection Due To Mold Contamination

Located on the FDA website is a section devoted to pharmacy compounding (click here) containing updated information on this ever-evolving topic. Included, is information on the FDA inspections of 31 different firms identified in producing high-risk sterile drug products.

Additionally, a draft proposal on pharmaceutical compounding from the US Senate Committee on Health Education Labor and Pensions is currently available for review and feedback (click here). This proposal is intended to provide more comprehensive regulation of pharmaceutical compounding.

FORMULARY UPDATES

The following provides a summary of P&T Committee activities for April 2013. A more complete summary of activities is available through the MGHS Online Formulary.

- Insulin detemir (Levemir®) was added to the Formulary as the preferred class-representative for the long-acting insulin analogs. Insulin glargine (Lantus®) will remain on the Formulary for inpatient use, primarily for continuation of outpatient therapy.
- Two compounded pharmaceutical formulations were added to the Formulary:
  - Nasal anesthetic solution (lidocaine 10%, tetracaine 4%, phenylephrine 1%) intended for the treatment of epistaxis.
  - Phenylephrine 1.5% in preservative-free balanced salt solution intended for intracameral injection for cataract surgery at the U.P. Surgery Center.
- The Committee reviewed and approved the following guidelines for use and protocols:
  1. Platelet aggregation inhibitors
  2. Parenteral iron formulations
  3. Orthopedic Surgery: Standard Pain Cocktail
  4. Infusion Services: Status Migrinosus
  5. Infusion Services: Tocilizumab (Actemra®)