The Pharmacy and Therapeutics Committee met ten times during calendar year 2013. This report summarizes the major topics considered and actions taken as a result of these meetings.

**Formulary Maintenance**

The Pharmacy and Therapeutics Committee reviewed 16 drug literature evaluations involving 21 different agents. Committee actions subsequent to these reviews resulted in the addition of 14 agents to the MGHS Formulary. These reviews were initiated through formulary addition requests and are depicted in Table 1.

Through routine review of medication usage patterns and nonstock drug requests, the Committee continued its efforts to reduce access to agents with limited or no advantages relative to formulary products and to make agents available for which there is no reasonable formulary alternative. This included the removal of 40 products from inventory and placed in nonstock status, including:

- Acetic acid, glacial (safety)
- Acyclovir ointment (low use, high expense, limited need in the acute care setting)
- Becaplermin gel (no use, high cost)
- Crotalidae polyvalent immune Fab (no use, high cost)
- Imatinib (high cost)
- Phenol (safety)
- Trichloroacetic acid (safety)
- Crotalidae polyvalent immune Fab (no use, high cost)
- Imatinib (high cost)
- Phenol (safety)
- Trichloroacetic acid (safety)

It also resulted in the addition of 2 agents to the formulary (i.e., hydromorphone 0.5 mg injection, hepatitis B immune globulin for adult use).

Based on recommendations from the Antimicrobial Stewardship Committee, MGH removed its conventional amphotericin B product from the Formulary.

The Committee continued to review products procured through the nonstock appeal process. Specifically, 26 nonstock requests were reviewed. One of the more frequent requests was for lurasidone which was ultimately added to the MGHS Formulary following a review by the Committee.

The MGHS Formulary is available on the MGH website (Online Formulary available at the following URL: [http://www.mgh.org/Physicians/SitePages/Formulary.aspx](http://www.mgh.org/Physicians/SitePages/Formulary.aspx)). Reference tables and drug monographs are updated monthly in this electronic version of the formulary. Under Committee direction, the website continues to improve to include links from drug monographs to guidelines for use, product shortages, P&T Committee Newsletters, medication safety alerts, links to additional medication information sources, and specific therapeutic reference tables. Monthly updates of P&T Committee decisions are also noted on this website as well as in the P&T Committee Newsletter.
P&T Committee Newsletter

In an effort to increase communication regarding specific P&T Committee actions, the Committee approved several articles for use in the P&T Committee Newsletter. The Newsletter articles are emailed monthly to the Committee membership, medical administration leaders, physicians, pharmacy staff, and the Health Sciences Library. Copies are available from July 2011 to present via the online formulary on the MGH website.

Overall, 12 issues were placed on the MGH website. Significant communications from the FDA, Joint Commission, and Institute for Safe Medication Practices were included to inform practitioners of regulatory and safety issues concerning drug use, as were significant changes in national guidelines (i.e., JNC 8 guideline updates) and ongoing national drug shortages. Selected topics are covered each year due to the seasonal nature of drug use (i.e., influenza immunization), or to provide prescribers with timely information about institution-specific issues (i.e., recent formulary decisions).

Medication Use/Performance Improvement Activities

The Committee continued its efforts towards overseeing medication management at MGH to promote rational utilization of medications. Selected key issues are presented below.

Medication Usage Evaluations (MUEs) conducted during 2013:

- Dabigatran (Pradaxa®) and rivaroxaban (Xarelto®)
- Dexametomidine (Precedex®)
- Vasopressin infusions
- Enoxaparin (Lovenox®) bridging
- Hydromorphone (Dilaudid®)
- Levalbuterol (Xopenex®)

MUE topics selected for 2014:

- Platelet aggregation inhibitors (clopidogrel, prasugrel, ticagrelor)
- Promethazine injection
- Meperidine injection
- Acetaminophen injection use in the OR
- Bivalirudin (Angiomax®)

Suspected Adverse Drug Reactions (SADRs)

The Committee reviewed the summary report of significant SADRs on a quarterly basis. One hundred two reports (reactions classified as 8 major, 58 moderate, and 36 mild) were reviewed by the Committee and none of the SADRs were submitted to the FDA. As four of the eight major reactions involved opiates, opiate safety will be a focus of the Committee in 2014.

Medication Errors

The Committee reviewed data from the Medication Error Program on a monthly basis noting the ongoing quality improvement initiatives by the pharmacy and nursing departments towards improved medication safety.

Quarterly Drug Expenditure Report

The Committee reviewed the report of Top Drug Expenditures on a quarterly basis.

Biannual Antimicrobial Stewardship Committee Report

The Committee reviewed the report of the Antimicrobial Stewardship activities on a biannual basis.

Guidelines for Use

The Committee continued the practice of formally approving guidelines for use on agents reviewed for addition to the MGHS Formulary. Additionally, several guidelines were developed based on the available published literature. Overall, 17 guidelines for use on agents were approved or revised and included (collaborating groups noted):

- Prochlorperazine injection (Cancer and Emergency Medicine Service Lines)
- Methylprednisolone injection (Digestive Health Service Line)
- Propofol injection (ICU Service Line)
- Intrathecal chemotherapy (Cancer Service Line)
- Platelet aggregation inhibitors (Cardiovascular Service Line)
- Parenteral iron formulations (Renal Service Line)

Table 1: Literature Evaluations Performed by the P&T Committee for Formulary Consideration.

<table>
<thead>
<tr>
<th>Request</th>
<th>Requesting Service Line</th>
<th>Action Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Febuxostat (Uloric®)</td>
<td>Renal</td>
<td>Added to Formulary</td>
</tr>
<tr>
<td>Intravenous Immune Globulin (Octagam®)</td>
<td>LifePoint Therapeutic Initiative</td>
<td>Added to Formulary with Restrictions</td>
</tr>
<tr>
<td>Dexamethasone (Focalin®)</td>
<td>Behavioral Health</td>
<td>Added to Formulary</td>
</tr>
<tr>
<td>Sterile Talc Powder</td>
<td>ICU</td>
<td>Added to Formulary</td>
</tr>
<tr>
<td>Natalaxone injection (Vivitrol ER®)</td>
<td>Behavioral Health</td>
<td>Added to Formulary with Restrictions</td>
</tr>
<tr>
<td>Ticagrelor (Brilinta®)</td>
<td>Cardiovascular</td>
<td>Added to Formulary</td>
</tr>
<tr>
<td>Ketotifen (Zaditor®)</td>
<td>Pharmacy</td>
<td>Added to Formulary</td>
</tr>
<tr>
<td>Parenteral Iron Products (Feraheme®)</td>
<td>LifePoint Therapeutic Initiative</td>
<td>Added to Formulary with Restrictions</td>
</tr>
<tr>
<td>Insulin Detemir (Levemir®)</td>
<td>LifePoint Therapeutic Initiative</td>
<td>Added to Formulary</td>
</tr>
<tr>
<td>Nasal anesthestic solution</td>
<td>OR (ENT)</td>
<td>Added to Formulary</td>
</tr>
<tr>
<td>Phenylephrine 1.5% ophthalmic</td>
<td>Ophthalmology</td>
<td>Added to Formulary</td>
</tr>
<tr>
<td>Colistimethate sodium (Coly-Mycin® M)</td>
<td>Infectious Diseases</td>
<td>Added to Formulary with Restrictions</td>
</tr>
<tr>
<td>Apixaban (Eliquis®)</td>
<td>Cardiovascular</td>
<td>Denied Addition to Formulary</td>
</tr>
<tr>
<td>4-factor prothrombin complex concentrate</td>
<td>Emergency Medicine</td>
<td>Added to Formulary with Restrictions</td>
</tr>
<tr>
<td>(Kcentra®)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TBO-filgrastim (Granix®)</td>
<td>LifePoint Therapeutic Initiative</td>
<td>Added to Formulary</td>
</tr>
<tr>
<td>Dinoprostrol (Prepil®)</td>
<td>Women’s Health</td>
<td>Denied Addition to Formulary</td>
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</tbody>
</table>

Colistimethate injection (Infectious Diseases service)
Prothrombin complex concentrate (Emergency Medicine Service Line)
Revisions to the anticoagulant guidelines
Intranasal medication delivery (Emergency Medicine Service Line)
Acetaminophen injection
Bivalirudin
Levalbuterol
Antimicrobial recommendations by infection type (Infectious Diseases service), to be included with annual antibiogram also reviewed by the Committee

Therapeutic Interchanges
The Committee reviewed and approved 3 therapeutic interchanges including: fluoroquinolones, inhaled corticosteroids, and phosphate binders.

Medication Reconciliation in Heart Failure Patients
The Committee reviewed the report by the Pharmacy Department summarizing their participation in the medication reconciliation process between August and November 2013. The Committee agreed to support the planned expansion to the stroke patient population.

Automatic Stop Orders
The Committee reviewed and approved the implementation of automatic stop times for the following medications:
- Injectable narcotics (retain current 14 day soft-stop)
- Injectable antibiotics (initiate 14 day soft-stop)
- Ketorolac, oral and intravenous (initiate 5 day hard stop)

Upper Hard Limits for Alaris Pumps
The Committee reviewed and approved the implementation of upper hard limits (UHL) for selected high-alert medications including:
- Potassium chloride
- Potassium phosphate
- Sodium phosphate
- Insulin infusion
- Bivalirudin
- Heparin infusion
- Propofol infusion

Protocol/Order Form Review
The Committee reviewed and approved the following order forms:
- Orthopedic Surgery: Standard Pain Cocktail
- Infusion Services: Status Migrainosus
- Infusion Services: Tocilizumab (Actemra®)

Renal Dosing Protocol
The Committee reviewed and approved the proposed protocol for renal dosing amongst several medications often requiring dosage adjustments in patients with renal insufficiency. It was noted this was intended to provide a consistent approach for the Pharmacy Department when requested to adjust doses for renal insufficiency as well as the basis for an order set in CPOE.

Inclusion of Transfusion and Transplant Committee Activities
The Committee discussed the plan to include the Transfusion and Transplant Committee activities into the scheduled agenda beginning in 2014.

Product Shortages
The Committee reviewed reports of current and potential product shortages each month. Updates are posted on the Online Formulary continuously in an effort to improve communication on drug shortages impacting MGH. Noting one specific shortage, the Committee reviewed and approved the request to restrict the European-based products (sodium phosphate injection and pediatric trace elements) to the Neonatal Intensive Care Unit at this time. It was noted that these have been imported into the US due to ongoing severe shortages among related products and that there were differences between the US-based and European-based products.

Procurement, Prescribing, Dispensing, and Administration of Drugs
Ten hospital policies were reviewed and approved/revised by the Committee including:
- Independent Double Check for High Alert Medications
- Medication Administration by Healthcare Staff
- Vascular Access Devices
- Safe Medication Practices
- Standard Times of Medication Administration
- Surgical Prophylaxis: Antibiotic Recommendations for Adult Patients
- Malignant Hyperthermia
- Downtime Procedures for Automated Dispensing Machines
- Formulary System of Drug Use
- Patient Medications Brought from Home

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 approves label changes for antibacterial Doribax (doripenem) describing increased risk of death for ventilator patients with pneumonia 3/6/2014
- FDA Drug Safety Communication: FDA to review heart failure risk with diabetes drug saxagliptin (marketed as Onglyza and Kombiglyze XR) 2/11/2014
- FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products 1/31/2014

ISMP MEDICATION SAFETY ALERTS
The following links provide additional information on Medication Safety Alerts that have been recently issued from the Institute for Safe Medication Practices and are readily available on the MGHSNet.
- ISMP Canada identifies themes associated with fatal medication events in the home 2/27/2014
- Survey links PN component shortages to adverse outcomes 2/13/2014
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: Does the Joint Commission have recommendations regarding a hospital’s drug formulary?

Answer: Yes. Medication Management (MM) chapter 02.01.01 provides oversight towards the selection and procurement of medications. There are 15 elements of performance a hospital can be scored on including the following examples:

- Members of the medical staff, licensed independent practitioners, pharmacists, and staff involved in ordering, dispensing, administering, and/or monitoring the effects of medications develop written criteria for determining which medications are available for dispensing or administering to patients.
- The hospital develops and approves criteria for selecting medications.
- Before using a medication new to the hospital, the hospital determines a method to monitor the response of the patient.
- The hospital maintains a formulary, including medication strength and dosage.
- The hospital makes its formulary readily available to those involved in medication management.
- The hospital standardizes and limits the number of drug concentrations available to meet patient care needs.
- The hospital has a process to select, approve, and procure medications that are not on its formulary.
- Medications designated as available for dispensing or administration are reviewed at least annually based on emerging safety and efficacy information.

DRUG SHORTAGES
As of March 7, 2014, there remain over 200 drug shortages listed on ASHP’s Drug Shortage website and many continue to impact MGH which are listed on the MGHS Online Formulary. Those currently in critical supply necessitating selected restrictions at MGH include:

- Atropine injection
- Bupivacaine with Epinephrine injection
- Caffeine and sodium benzoate injection
- Calcium chloride injection
- Calcium Gluconate injection
- Dextrose 5% IV fluid
- Diphtheria, tetanus toxoid, and acellular pertussis vaccine
- Droperidol injection
- Epinephrine injection (Abbojects)
- Glycopyrrolate injection
- Lactated Ringers IV fluid
- Multivitamins for injection
- Nalbuphine injection
- Nicardipine injection
- Nitroglycerin injection
- Plasmalyte A IV fluid
- Potassium salts (acetate, phosphate) injection
- Prochlorperazine injection
- Sodium chloride injection (IV fluids and flushes)
- Sodium phosphate injection
- Trace elements 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.

FORMULARY UPDATES
The following provides a summary of P&T Committee activities for February 2014. A more complete summary of activities is available through the MGHS Online Formulary.

Guidelines for Use/Therapeutic Interchanges:
The Committee reviewed and approved the proposed protocol for surgical prophylaxis intended for pediatric cases.

Hydromorphone (Dilauidid®) Injection:
The Committee reviewed and approved the following actions pertaining to hydromorphone injection:
1. Limit initial doses listed in protocols; and
2. Develop a pain protocol to encourage appropriate dosages and frequencies.

Promethazine Usage Evaluation:
The Committee reviewed the medication usage evaluation on promethazine (Phenergan®) injection and approved the following actions:
1. Communicate the findings of this MUE;
2. Encourage education regarding the safe use of promethazine injection; and
3. Change the dispensing process so that IM doses are available from Acudose and IV doses will be prepared by Pharmacy.