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Special Points of Interest:

- P&T Update-Formulary Addition/Deletion
- Policy and Procedures/Floorstock Update
- Black Box Warnings
- New Guidelines Released by Joint National Committee (JNC) 8 for High Blood Pressure Management in Adults

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P&T Update

Formulary Addition/Deletion

1. Argatroban - Argatroban is a selective and short-acting direct thrombin inhibitor FDA approved for the prophylaxis or treatment of thrombosis or venous thromboembolism in patients with heparin-induced thrombocytopenia (HIT), and of coronary artery thrombosis during percutaneous coronary intervention in patients at risk of HIT. The formulary addition request was submitted by the Pharmacy Department with endorsement from Cardiology and Hematology representatives.
Formulary addition – approved
2. Argatroban dosing nomogram – **approved**
3. Dinoprostone 0.5mg gel (Prepidil®) – The Obstetrics, Gynecology, and Women’s Health Department no longer use dinoprostone gel for cervical ripening. The request to remove dinoprostone from the formulary was approved.
Formulary deletion – approved.
4. Hydroxocobalamin (Cyanokit®) - Hydroxocobalamin is indicated for treating cyanide toxicity. The UH ED department recommended adding hydroxocobalamin to the formulary in place of Cyanide antidote kit. The committee voted to approve the formulary addition of hydroxocobalamin. A mini-FMEA on hydroxocobalamin was also submitted. **Formulary addition – approved**
5. Cyanide antidote kit (Sodium Nitrate + Amyl Nitrate + Sodium Thiosulfate) - Cyanide antidote kit has been manufacturer discontinued. The committee voted to delete this product from the formulary. **Formulary deletion – approved**
6. Pertuzumab (Perjeta®) – Pertuzumab is a monoclonal antibody approved by the FDA to use in combination with trastuzumab and docetaxel as first-line therapy for HER2-positive metastatic breast cancer. **Formulary addition – approved**

Policies and Procedures/Floorstock Update

707-400-107 Security of Medication Storage Areas – Policy Revision

The existing policy is revised to authorize incidental access of the unlicensed healthcare staff such as environmental services personnel or senior material handlers to the medication storage areas to fulfill their duties. – Approved

707-100-340/707-600-174 Radiopharmaceutical Delivery and Management – Policy Revision

This is a combined policy by Radiology –Nuclear Medicine and Pharmacy. It is revised to outline the process of radiopharmaceutical delivery to UH. – Approved

707-800-103 Multi-dose Vial Policy – Policy Update

A list of immediate patient care areas and clinics at UH where Multidose Vials (MDV) will be discarded after single use is provided in this policy. Also the policy defines single dose vials, and the requirement that any injectable product should not be drawn up in syringes or spiked for more than an hour in advance in a non-sterile field before use. – Approved

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Policies and Procedures/Floorstock Update

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707-600-172 Radiology IV Contrast Policy – Policy Revision

The existing policy has been updated to accurately reflect the inventory of contrast media at different Radiology locations. Also the policy enforces discarding of single-dose contrast vials after single use, and that only the labeled pharmacy bulk packages (PBPs) may be used multiple times via an auto-injector, but not beyond the manufacturer's expiration timing after opening the PBPs. – Approved

707-600-162 Disposal of Chemotherapy within the Pharmacy – Policy Revision

The policy is updated to outline the process of disposing of chemotherapy within the Pharmacy, to include disposal of trace chemotherapy in the hood, outside of the hood and disposal of bulk chemotherapy. – Approved

707-600-167/704-400-200.2 Provision of Emergency Medications for Contrast Media Reactions – Policy Revision

The Emergency Radiology Kits are updated to include new tubing, Epinephrine 1:1000 ampules and filter straws. Also the pharmacy inventory of the Radiology kits is increased to 2. – Approved

707-600-155 Gloved Finger Tip Sampling for the Glove Boxes and the Pharmacy Staff – New Policy

This is a new policy ensuring that pharmacy personnel are properly trained in using the glove box, garbing, and aseptic technique. The pharmacy personnel will be tested initially (3 times) and then annually to assess compliance with gloved fingertip sampling procedure. – Approved

707-600-166 Labeling Medications, Medication Container and Other Solutions for Use in the Procedural Settings – Policy Revision

The policy is updated to indicate that any injectable product should not be drawn up in syringes or spiked for more than an hour in advance in a non-sterile field before use i.e. any pre-drawn syringes or spiked IV medication bags should not have been prepared more than one hour before use in any non-ISO 5 environment. – Approved

707-700-101 Administering and Charting Medications to Patients – Policy Revision

The medication administration area of this combined

Pharmacy and PCS policy has been revised to indicate that medications shall only be accessed one patient at a time and administered to that patient, prior to accessing/administering medications to any subsequent patient. – Approved

707-600-175 Polypharmacy – Management of Psychopharmacological Medications in Patients Under Psychiatric Service – New Policy

This policy outlines the process of managing poly-pharmacy and the use of high doses of psychopharmacological agents to minimize any adverse effects/interactions while ensuring therapeutic efficacy. The original policy has been approved by the Psychiatry Subcommittee. – Approved

Titratable medication ERx revision proposal - TJC standards require that medication orders have specific criteria for adjusting the doses of titratable medications. – Approved





Black Box Warnings

The U.S. Food and Drug Administration (FDA) has several different roles with one primary purpose, to protect the health of consumers.¹ The FDA is responsible for reviewing the drug information within each package insert, or prescribing information, for all approved medications. Despite FDA approval, there is still a potential for harm if medications are used inappropriately.² Included in the package insert are three main sections regarding patient safety. These three sections include the warnings and precautions section, the contraindications section and when applicable, the boxed warning.³

Boxed Warnings, also known as black box warnings, are the most serious and are meant to draw one's attention to information that tells prescribers and consumers of all dangerous situations that may be associated with a specific drug. A boxed warning may warn about an adverse reaction associated with this medication that can be severely debilitating, life-threatening or fatal. In this situation the risks may outweigh the benefits. The FDA states that a boxed warning may also be used if, "There is a serious adverse reaction that can be prevented or reduced in frequency or severity by appropriate use of the drug (e.g., patient selection, careful monitoring, avoiding certain concomitant therapy, addition of another drug or managing patients in a specific manner, avoiding use in a specific clinical situation)". For example, the black box warning for warfarin (Coumadin®) states that there should be regular monitoring of a patient's INR with use of the medication due to the increased risk of bleeding.⁴ Black box warnings can be used even if the adverse reaction is not observed but can be anticipated.³ The drug lisinopril (Prinivil®) has a black box warning for

fetal toxicity because it acts directly on the renin-angiotensin system. Therefore, this medication is contraindicated in pregnant women.⁵ Some black box warnings may even apply to an entire class of medications rather than one specific drug. The purpose of every black box warning is to inform prescribers of safety concerns before prescribing a medication. The prescriber must then consider the information in black box warnings and evaluate the risks involved before making a clinical decision. As per UH black box warning policy (707-1400-102), an alert is displayed in the eMAR, when a medication with a black box warning is ordered on a patient.

References:

1. "What We Do." U. S. Food and Drug Administration, 19 Sept. 2013. Web. 13 Jan. 2014. <<http://www.fda.gov/AboutFDA/WhatWeDo/default.htm>>.
2. O'Connor, Nina. "FDA Boxed Warnings: How to Prescribe Drugs Safely" American Family Physician. 2010 Feb 1;81(3):298-303. Web. 13 Jan. 2014. <<http://www.aafp.org/afp/2010/0201/p298.html>>
3. "Guidance for Industry. Warnings and Precautions, Contraindications and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products- Content and Format". U. S. Food and Drug Administration, Oct. 2011. Web. 13 Jan. 2014. <<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075096.pdf>>
4. Prescriber Information for Coumadin. Bristol – Myers Squibb. Princeton, NJ. October 2011.
5. Prescriber Information for Prinivil. Merck & Co., Inc. Whitehouse Station, NJ. December 2012.

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New Recommendations to Decrease Risk of Hepatitis B Reactivation with use of Arzerra® (ofatumumab) and Rituxan® (rituximab)

Medications today are more effective at treating diseases and symptoms than ever before. With the introduction of new medications and better treatments, medical professionals are now able to treat patients that once suffered from complicated diseases. However, the medical communities are dealing with increasing problems such as drug-resistant strains of bacteria and increasing adverse drug reactions.

On September 25, 2013, the US Food and Drug Administration (FDA) approved the changes to the prescribing information of Arzerra® (ofatumumab) and Rituxan® (rituximab), two immune suppressing and anti-cancer drugs, to address the potential risk of Hepatitis B (HBV) reactivation when taking the medication(s). HBV reactivation

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New Recommendations to Decrease Risk of Hepatitis B Reactivation

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vation is defined as “an abrupt increase in HBV replication manifesting as a rapid increase in serum HBV DNA level or detection of HBsAG in person who was previously HBsAG negative and anti-HBc positive.”¹ Hepatitis B is a viral disease that affects the liver, which eventually leads to liver cancer or liver failure. Management of HBV includes vaccination and the use of immune system modulators. While cases of HBV infections can be resolved with treatment, health professionals would have to be cautious and monitor for reactivation when using immune-suppressing medication. The dangers of reactivation of HBV are complications to ongoing chemotherapy and acute liver harm to the patient. Events of reactivation increase the chance of death and prolong recovery time for the patient.

The FDA reviewed its Adverse Event Reporting System (AERS) database for reports submitted between the drug market approval dates of November 1997 and October 2009 for Rituxan® and Arzerra®, respectively, to August 2012. The result was a report of 109 cases regarding liver damage from Hepatitis B reactivation. 32 of the cases met the HBV reactivation criteria with proper documentation and data. Of the 77 cases remaining, there was a lack of data, and from partial to no documentation of screening.¹ A new *Black Box Warning* has been added to the Arzerra® prescribing information, and a HBV reactivation precaution has been added to the existing Rituxan® *Black Box Warning*. The *Warnings and Precautions* section will include recommendations of screening, monitoring, and managing patients to decrease the risk for both medications.

These drugs are monoclonal antibodies for the CD20 proteins, found on the surface of B cells. B cells are white blood cells that help make up the immune system which is activated when fighting off a foreign substance. While both drugs are similar, their effect on the B cells differ; Arzerra® inhibits the activation of B cells, while Rituxan® destroys the existing B cells. Both drugs are used to treat lymphocytic leukemia. Rituxan® is also approved to treat other medical conditions, such as rheumatoid arthritis (RA). While these drugs inactivate/kill malignant white blood cells, they also affect healthy ones. With the B cells weakened, the patient will have a suppressed immune system, which leaves them vulnerable to viral, bacterial, and fungal infections.

The FDA recommends these courses of action for health professionals when dealing with medications that can potentially reactivate HBV:

- Screen all patients for HBV infection before starting treatment with Arzerra® or Rituxan® by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc).
- Consult with hepatitis experts regarding monitoring and use of HBV antiviral therapy when screening identifies patients at risk of HBV reactivation due to evidence of prior HBV infection.
- Monitor patients with evidence of prior HBV infection for clinical and laboratory signs of hepatitis B or HBV reactivation during Arzerra® or Rituxan® therapy and for several months thereafter, since reactivations have occurred several months following completion of therapy with these drugs.

In patients who develop reactivation of HBV while on Arzerra® or Rituxan®, immediately discontinue the drug and start appropriate treatment for HBV. Also discontinue any chemotherapy the patient is receiving until the HBV infection is controlled or resolved. Because of insufficient data, no recommendation can be made regarding the resumption of Arzerra® or Rituxan® in patients who develop HBV reactivation hepatitis.¹

These recommendations made by the FDA will help avoid and respond to the reactivation of HBV due to the use of anti-cancer immune suppressing medications. While more drugs are approved by the FDA and used in hospitals, health professionals should be aware of the risks, such as reactivation of diseases. Ultimately as healthcare professionals, we are responsible for thoroughly screening and monitoring patients for any abnormalities in order to prevent additional disease and preserve the health of our patients.

References:

"FDA Drug Safety Communication: Boxed Warning and new recommendations to decrease risk of hepatitis B reactivation with the immune-suppressing and anti-cancer drugs Arzerra (ofatumumab) and Rituxan (rituximab)." Drugs. U.S. Food and Drug Administration, 02 Oct 2013. Web. 13 Jan 2014. <<http://www.fda.gov/Drugs/DrugSafety/ucm366406.htm>>.

"Hepatitis B Vaccine." VACCINE INFORMATION STATEMENT. Centers for Disease Control and Prevention, 02 Feb 2012. Web. 13 Jan 2014. <<http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hepb.pdf>>.

"HIGHLIGHTS OF PRESCRIBING INFORMATION: ARZERRA." GlaxoSmithKline, September 2013. Web. 13 Jan 2014. <http://us.gsk.com/products/assets/us_arzerra.pdf>.

"Rituxan." Genentech, 2013. Web. 13 Jan 2014. <<http://www.rituxan.com/index.html>>.

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Hydroxocobalamin for Acute Cyanide Poisoning

Cyanide causes intracellular hypoxia by binding to mitochondrial cytochromes, leading to cessation of aerobic cell metabolism. Early symptoms of acute cyanide poisoning, which can occur as soon as a minute after inhalation or ingestion, include anxiety, headache, mydriasis, and inability to focus the eyes. As cyanide levels increase, hypoxia progresses and often leads to loss of consciousness, seizures, coma and eventually death. Treatment of acute cyanide poisoning requires supportive care and immediate administration of antidotes. There are two major antidotes: the Cyanide Antidote Kit and hydroxocobalamin. The Cyanide Antidote Kit consists of amyl nitrite, sodium nitrite, and sodium thiosulfate. Amyl nitrate is administered via inhalation over 15 to 30 minutes while preparing for intravenous administration of sodium nitrite. Then sodium thiosulfate is administered intravenously over 30 minutes. The cyanide antidote kit has been discontinued by manufacturer. The alternative, hydroxocobalamin, is shown to be safer, better tolerated and as effective as the Cyanide Antidote Kit for acute cyanide poisoning.¹

Hydroxocobalamin (Cyanokit®) is a natural form of vitamin B12, and it binds to cyanide to form cyanocobalamin which is then renally excreted. Cyanide has a higher affinity for hydroxocobalamin than the cytochrome oxidases within the mitochondria, making hydroxocobalamin an effective antidote. There have been numerous studies in the recent years demonstrating its efficacy in cyanide poisoning via ingestion and inhalation. Borron S et. al. examined hydroxocobalamin for acute cyanide poisoning in smoke inhalation and another study examined hydroxocobalamin for both inhalation and ingestion. There was an average of a 70% survival rate in patients who received hydroxocobalamin as an antidote. A retrospective study of 8 years, following the use of hydroxocobalamin for smoke inhalation-associated poisoning in the Paris Fire Brigade, demonstrated a 42% survival rate and 21 out of 38 patients had a spontaneous return of circulation during pre-hospital care. According to this study, hydroxocobalamin has a risk benefit ratio suitable for pre-hospital use in the management of acute poisoning via smoke inhalation.^{2, 3, 4}

When comparing the safety profile of hydroxocobalamin to the Cyanide Antidote Kit, hydroxocobalamin is safer. Both amyl nitrite and sodium nitrite generate methemoglobin which can decrease the

oxygen carrying capacity in patients who have concurrent carbon monoxide toxicity from smoke inhalation. The nitrites may also lead to vasodilation and hypotension which is not desired in patients experiencing shock. The most common adverse effects of hydroxocobalamin include hypersensitivity reactions, transient hypertension lasting up to four hours and a self-limiting reddening of the skin and urine. This is due to the red color of hydroxocobalamin. Other minor adverse effects include rash, headache, erythema at the injection site, and photosensitivity. Hydroxocobalamin demonstrates a good safety profile in doses as high as 10 g and can be used in pregnant and pediatric patients.^{1, 5}

Studies comparing the two antidotes head-to-head are scarce. However, hydroxocobalamin has been used for years in places outside the United States, such as France, and has been proven to be effective. Certain guidelines are in place for use of the antidote, such as a requirement of a lactic acid level of greater than 10 mmol/L in smoke inhalation patients and greater than 8 mmol/L in patient suspected of cyanide ingestion. It is also important to administer as soon as poisoning is suspected as delay in treatment may lead to life-threatening consequences for the patient. Hydroxocobalamin, which is on the UH formulary, is an effective and safe alternative to the Cyanide Antidote Kit.⁶

References:

1. Hamel J. A review of acute cyanide poisoning with a treatment update. *Crit Care Nurse* 2011; 31(1): 72-81.
2. Borron SW, Baud FJ, Barriot P, et al. Prospective study of hydroxocobalamin for acute cyanide poisoning in smoke inhalation. *Ann Emerg Med* 2007; 49(6): 794-801.
3. Borron SW, Baud FJ, Megarbane B, et al. Hydroxocobalamin for severe acute cyanide poisoning by ingestion or inhalation. *Am J Emerg Med* 2007; 25: 551-558.
4. Fortin J, Giocanti J, Ruttimann M, et al. Prehospital administration of hydroxocobalamin for smoke inhalation-associated cyanide poisoning: 8 years of experience in the Paris Fire Brigade. *Clin Tox* 2006; 44: 37-44.
5. Uhl W, Golor G, Kovar A, et al. Safety of hydroxocobalamin in healthy volunteers in a randomized, placebo-controlled study. *Clin Tox* 2006; 44: 17-28.
6. Baud FJ, Borron SW, Megarbane B, et al. Value of

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New Guidelines Released by Joint National Committee (JNC) 8 for High Blood Pressure Management in Adults

In mid-December, the Eighth Joint National Committee (JNC 8) released a new, and more relaxed, set of guidelines for the management of hypertension. The evidence-based guidelines released by JNC 8 included nine new recommendations for the treatment of adult patients with high blood pressure. These guidelines affect treatment regimens in the elderly (≥ 60 years), general adult population (age 18-59), and patients 18 years and older diagnosed with Chronic Kidney Disease (CKD) and/or diabetes. The following are short summaries of the newly released guidelines.

When looking at treatment options in elderly patients, it is now recommended that physicians should start treatment in blood pressures exceeding 150 mm Hg systolic or 90 mm Hg diastolic, and continue to treat to below these thresholds.¹ Experts on the panel also mentioned that if pharmacologic treatment results in a lower achieved systolic blood pressure (SBP) (eg, < 140 mm Hg) and treatment is well tolerated, without any adverse effects on health or quality of life, treatment does not need to be adjusted.¹

Treatment options for general population have been adjusted slightly as well. The JNC 8 is recommending to initiate blood pressure treatment when diastolic blood pressure (DBP) ≥ 90 mm Hg and SBP is > 140 mm Hg.¹ The committee encourages treatment to a goal DBP of < 90 mm Hg and SBP of < 140 mm Hg.¹

Included in these nine new recommendations were more relaxed treatment-initiation thresholds in patients under the age of 60, diagnosed with diabetes and kidney disease. For treatment in these patients, JNC 8 has reported that treatment initiation should begin when SBP ≥ 140 mm Hg and DBP ≥ 90 mm Hg.² Therapy goals should result in a blood pressure $< 140/90$ mm Hg.²

Quite possibly the biggest change made to the guidelines revolves around which class is now labeled as "first-line" therapy. The previous guidelines, (JNC 7), stated that thiazide-type diuretics should be initial therapy in most patients.³ However, the new guidelines shy away from this recommendation, and instead suggest that an ACE inhibitor, angiotensin-receptor blocker (ARB), calcium-channel blocker (CCB), or thiazide-type diuretic are all reasonable first-line therapies.²

One of the doctors on the committee, Dr. Paul A. James, had a message for prescribers: "We wanted to make the message very simple for physicians: treat to 150/90 mm Hg in patients over age 60 and 140/90 for everybody else. And we simplified the drug regimen as well, to say that any of these choices are good, just get people to goal. Monitor them, track them, remonitor them."²

References:

1. James PA, Oparil S, Carter BL, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). *JAMA*. 2013;():. doi:10.1001/jama.2013.284427
2. Wood, S. (2013, December 18). JNC 8 at Last! Guidelines Ease Up on BP Thresholds, Drug Choices. *Medscape Pharmacists*. Retrieved from <http://www.medscape.com/viewarticle/817991>
3. Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: The JNC 7 Report. *JAMA*. 2003;289(19):2560-2571. doi:10.1001/jama.289.19.2560.

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FDA Announces Safety Labeling Changes and Post-Market Study Requirements for Extended-Release and Long-Acting Opioid Analgesics

The U.S. Food and Drug Administration announced that there will be class-wide safety labeling changes made along with new post-market study requirements for all extended release and long acting (ER/LA) opioid analgesics intended for the treatment of pain. Oxycontin®, Opana ER®, Embeda®, Palladone™ and MS Contin® are examples of drugs that would fall into this class of medications. The new labeling change states that ER/LA opioids are indicated for “the management

patients and devastated too many families and communities,” said FDA Commissioner Margaret A. Hamburg, M.D.

Along with the new indication, the FDA is taking strides in the assessment of opioid analgesics and is implementing new post-market study requirements for the drug companies to take part in. As of now, more information is needed to successfully assess the risks associated with this class of drugs which include misuse, abuse, addiction, overdose, hyperalgesia (increased sensitivity to pain), and death. Therefore, more studies and clinical trials will be required now by the FDA to be conducted by the drug companies to effectively assess the aforementioned risks associated with ER/LA opioid analgesics.

A new black box warning will also be required for ER/LA opioid analgesics regarding neonatal opioid withdrawal syndrome, also known as NOWS. This is a condition that results from chronic maternal use of these products during pregnancy. The Center for Disease Control’s Vital Signs report revealed earlier in 2013 a startling fact that prescription painkiller overdoses killed nearly 48,000 women between 1999 and 2010. If exposed to the opioid drugs while in the mothers’ womb, the newborns may develop NOWS which causes symptoms of poor feeding, rapid breathing, trembling, excessive or high-pitched crying, and ultimately could be life-threatening. The new regulations aim to cut the number of deaths per year from opioid dependence. Management following protocols developed by neonatology experts will be required at an attempt to prevent NOWS from occurring in future cases.

References:

1. "FDA: New Indication, Boxed Warning for All ER/LA Opioids." *MPR*. N.p., 10 Sept. 2013. Web. 13 Jan. 2014.
2. "FDA Orders More Stringent Labeling For Opioid Drugs." *Counsel Heal Top News*. N.p., 11 Sept. 2013. Web. 13 Jan. 2014.
3. Kean, Nikki. "PROP versus PROMPT: FDA Speaks." *Practical Pain Management*. N.p., 31 Aug. 2013. Web. 13 Jan. 2014.
4. Liscinsky, Morgan. "U.S. Food and Drug Administration." *FDA Announces Safety Labeling Changes and Postmarket Study Requirements for Extended-release and Long-acting Opioid Analgesics*. FDA, 10 Sept. 2013. Web. 13 Jan. 2014.

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of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” These alternative treatments would include non-opioid analgesics or immediate-release opioids. As a result, the need for as-needed pain relief would be inadequate in making an ER/LA opioid analgesic recommendation. The updated indication serves the purpose of clarifying the fact that even at recommended dosages, high risks of addiction, abuse and misuse, overdose, and even death are prevalent.

“The FDA is invoking its authority to require safety labeling changes and post-market studies to combat the crisis of misuse, abuse, addiction, overdose, and death from these potent drugs that have harmed too many



2014-15 Targeted Medication Safety Best Practices for Hospitals

The Institute for Safe Medication Practices (ISMP) is a nonprofit organization dedicated to safe medication use and the prevention of medication errors. In December 2013, ISMP published a set of six practices that aims to address avoidable, fatal medication errors in hospitals. Strategies employed include modifying dispensing practices, exclusively utilizing metric units, or in the case of glacial acetic acid, eliminating it all together from the hospital.

In response to cases of accidental intrathecal administration of vinCRISTine and other vinca alkaloids, ISMP recommends dispensing vinCRISTine in a minibag rather than a syringe. The volume of vinCRISTine dispensed in a minibag exceeds the volume used for intrathecal administration thus eliminating the possibility of accidental intrathecal administration. Oral liquids also present a similar problem when dispensed in parenteral syringes as they may be accidentally administered intravenously. ISMP recommends dispensing all oral liquids in oral syringes as they will not connect to the patient's vascular access lines.

Other recommendations focus on ensuring the right dose makes it to the right patient. ISMP recommends the exclusive use of metric units (grams and kilograms) when measuring and documenting patient weights. This should minimize dosing errors that occur from mistaking a patient's weight in pounds for their weight in kilograms. In addition, oral liquid dosing devices should only measure metric units (milliliters). Patients may confuse milliliters with ounces, drams, teaspoons, and tablespoons as they have a variety of oral dosing devices at home. ISMP recommends supplying patients with oral dosing devices upon discharge if necessary to ensure they are able to measure their medications accurately.

Pharmacists play an important role in promoting safe medication use. When verifying orders, pharmacists should use a weekly dosage default for methotrexate instead of daily. In order to override the weekly dosing default a hard stop verification should be required explaining an appropriate oncologic indication. Furthermore, pharmacists should educate patients on methotrexate about their dosing schedule and have the patient repeat the instructions to ensure the patient comprehends the regimen.

Glacial acetic acid is a caustic and noxious highly concentrated form of acetic acid; it is always diluted

before use. In one reported case a nurse called the pharmacy to request "acetic acid for irrigation". Glacial acetic acid was erroneously dispensed and administered to a patient for two days. The patient suffered severe burns at the sites of wound irrigation and ultimately the wounds never healed. Now ISMP recommends not carrying glacial acetic acid at all in order to prevent any further mistakes.

Incorporating these ISMP recommendations to everyday practice will optimize patient safety and minimize medication errors.

The 2014-15 Targeted Medication Safety Best practices for Hospitals are as follows:

1. Dispense vinCRISTine (and other vinca alkaloids) in a minibag of a compatible solution and not in a syringe.
2. Use a weekly dosage regimen default for oral methotrexate. If overridden to daily require a hard stop verification of an appropriate oncologic indication. Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.
3. Measure and express patient weights in metric units only. Ensure that scales used for weighing patients are set and measure only in metric units.
4. Ensure that all oral liquids that are not commercially available as unit dose product are dispensed by the pharmacy in an oral syringe.
5. Purchase oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale.
6. Eliminate glacial acetic acid from all areas of the hospital. Laboratory use is excluded if the lab purchases the product directly from an external source.

References:

1. ISMP. Targeted Medication Safety Best practices for Hospitals. <http://www.ismp.org/tools/bestpractices/TMSBP-for-Hospitals.pdf>. Accessed Feb 14,2014.
2. ISMP Canada. Preliminary results from the International Medication Safety Self Assessment for Oncology. ISMP Canada Safety Bulletin. 2013;13(6):1-5.
3. Institute for Safe Medication Practices. End the ice age – is glacial acetic acid really needed? ISMP Medication Safety Alert:2005 May 5;10(9):1-2.

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Diabetes Mellitus 2014 Updates

Diabetes mellitus is becoming an increasingly prevalent disease in the world and updates in research, guidelines, medications, etc. are necessary to keep up with such a growing issue. According to the Centers of Disease Control (CDC), one out of ten Americans above 20 years old have diabetes and by 2050, that number is projected to triple to one out of every three adults in America. In the past, diabetes treatment followed a one-size-fits-all approach in terms of glucose goals and hemoglobin A1C targets (HbA1C). Recently, diabetes treatment has evolved more to evidence-based medicine and a patient-centered focus. Now, treatment is tailored towards the individual's specific factors: age, hypoglycemic episodes, usual glucose readings, and life expectancy.

Last year, the Joint National Committee (JNC) has raised the blood pressure target of diabetics from <math><130/80\text{mmHg}</math> to <math><140/90\text{mmHg}</math>. This was due to the fact that there was no significant additional benefit seen in patients who met the <math><130/80\text{mmHg}</math> blood pressure goal. The 2014 guidelines have been updated to include the following: pharmacological therapy for hyperglycemia in type 2 diabetes was changed from three–six months to three months for a trial with noninsulin monotherapy; retinopathy exams are now recommended every two years in patients with no retinopathy instead of every two–three years; and hospitals are discouraged against the sole use of sliding-scale insulin for management of inpatient diabetics.

Over the past year, a new class of medication has entered the market for the treatment of diabetes. The sodium-glucose linked transporters (SGLT2) located in the proximal tubule of the nephron are responsible for glucose reabsorption in the kidneys. Canagliflozin (Invokana®) and dapagliflozin (Farxiga®) are inhibitors of this system, which leads to decreased glucose reabsorption and increased glucose excretion. Both medications have shown a significant decrease in HbA1C when used in conjunction with metformin.

The newest major addition to the guidelines includes the recommendation of either the one-step or two-step method in the screening for gestational diabetes. Previously, the ADA solely recommended the one-step method which was due to the fact that it identified more gestational diabetes cases. The Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study showed an increased pregnancy adverse event profile in mild



hyperglycemia cases, therefore it would be important to identify all cases, even mild, of gestational diabetes. However this conclusion was inappropriate due to the study being an observational one which is not backed up by a randomized clinical trial. With that said, along with the recommendation for the two-step method by the National Institute of Health (NIH) and American Congress of Obstetricians and Gynecologists (ACOG), the ADA stated that there is not enough evidence to recommend one screening over the other.

These are the most recent and up-to-date changes in a disease that we are still working to completely understand. With the increasing prevalence of diabetes it is important to continue to research, create, understand, and update current standards in diabetic care.

References:

1. Number of Americans with Diabetes Projected to Double or Triple by 2050. Centers of Disease Control and Prevention. 2010. Available at: <http://www.cdc.gov/media/pressrel/2010/r101022.html>. Accessed February 14, 2014.
2. James PA, Oparil S, Carter BL, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). *JAMA*. 2014;311(5):507-520. doi:10.1001/jama.2013.284427.
3. Summary of revisions to the 2014 clinical practice recommendations. *Diabetes Care*. 2014;37 Suppl 1:S4.

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Rutgers University-New Jersey Medical School Pre-Medical Honors Program: High School Students' Experience at University Hospital Pharmacy



The Pre-Medical Honors Program at Rutgers University-New Jersey Medical School has been in existence for 13 years. It is an 8-week program in which highly qualified high school students are invited to participate. The students attend lectures and participate in didactic sessions conducted by the medical school professors and medical students once a week. It is sponsored by the Office of the Dean, the Office of Diversity and Community Engagement, as well as faculty, medical students, staff members of the George F. Smith Library, Academic Computing Services, and

University Hospital Education and Professional Development Services.

Part of the program involves visiting the Pharmacy Department to give the students a glimpse of the role the pharmacists play inside and outside of the hospital. Dr. Chu, Dr. Mina Malaak and three Pharm. D. students from Rutgers University, Ernest Mario School of Pharmacy (Marcus Lawson, Rosa Gonzalez, and Denise Olusala) welcomed the students and quickly engaged them by asking them what they think a pharmacist does. The students spoke about the admissions process, the competitive salary, the responsibilities of a pharmacist, and the numerous career paths available to pharmacists. They were given a tour of the pharmacy and a brief explanation of the general workflow. The students were very interested and asked many questions.

Overall, the students enjoyed their experience and left with a broader knowledge base and a better understanding of what the profession of pharmacy entails. This exposure will aid them in deciding their future career goals and what path they wish to pursue amongst the various healthcare occupations.

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