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New Jersey Prescription Monitoring Program (NJMPMP)

By Jeff Nemeth, Pharm.D., MPA

In 2011, the Obama administration released the Prescription Drug Abuse Prevention Plan. Using the DEA, FDA and CMS, it focuses on education for prescribers, patients and parents, prescription drug-monitoring programs, proper medication disposal and effective enforcement, to retard the prescription drug abuse epidemic in the U.S.

Implemented in 2012 and administered by the Division of Consumer Affairs, the NJPMP is part of the national initiative to monitor, prevent and detect the abuse and diversion of Controlled Dangerous Substances (CDS) and identity patents for possible treatment. NJ licensed pharmacies are required to submit data electronically on all outpatient transactions for dispensed schedule II – V CDS and Human Growth Hormone that are dispensed in, or into the State of NJ.

With emergency departments wary of drug-seeking patients who describe pain complaints in hopes of being pre-

scribed pain medication, New York City's 11 public hospitals will no longer dispense Oxycodone (OxyContin) or fentanyl in the ED. Most recently, New York's Internet System for Tracking Over-Prescribing Act or I-STOP law requires physicians to check their patient's drug history in the state database before ordering CDS.

While the FDA has encouraged drug companies to develop abuse-deterrent formulations of opioids as well as altering labeling, the abuse of legal painkilling medication has already triggered a resurgence in the abuse of heroin by young people—which costs less and is more readily available than ever in suburban and rural areas (State of NJ Commission of Investigation "Scenes From an Epidemic" A report on prescription Pill and Heroin Abuse, July 2013). In New Jersey, medical practitioners who prescribe do not have to register with NJPMP but can access data.

Anticoagulation Safety Initiatives **By Radwa El-Srougy, Pharm.D.**

The Institute for Safe Medication Practices (ISMP) has recently published a Medication Safety Alert regarding anticoagulants. The report identifies two anticoagulants, warfarin (Coumadin®) and dabigatran (Pradaxa®), to be the most frequently suspected drugs leading to serious or fatal adverse events in 2012. Rivaroxaban (Xarelto®), a new oral anticoagulant, ranked tenth on the list. Anticoagulants have also been reported by the U.S. Department of Health and Human Services to have caused an estimated 10.2% of all drug related adverse events in the inpatient setting. The implementation of a multidisciplinary and systematic process will facilitate reductions in anticoagulation adverse events and will ensure patient safety among hospitalized patients.

There are several anticoagulation safety initiatives that have been implemented here at EHMC that act as preventative methods for medication errors and decrease the rate of adverse events. Medication management policy #700.50 (Anticoagulation Management) delineates the specific parameters for ordering, dispensing, monitoring and administration of these high risk agents. Warfarin, for example, should be ordered as a one-time dose by a physician after evaluation of the INR. A baseline INR must be documented in the medical record prior to initiation of warfarin therapy. A pharmacist can order a baseline INR, if not available. Continuation of warfarin therapy will require an INR be performed at least within the last 48 hours except for 4E where the presence of an INR within 7 days is sufficient to administer warfarin. Unfractionated heparin (UFH), low-molecular weight heparins (LMWHs) [e.g., enoxaparin], thrombin inhibitors (e.g., argatroban, dabigatran), and factor Xa inhibitors (e.g., apixaban, fondaparinux, rivaroxaban) are also included in the policy. A multidisciplinary approach to patient education is key in reducing adverse events.

Here at EHMC, all patients on warfarin are educated either by a pharmacist, nurse or dietitian upon discharge and during their hospital stay.

Anticoagulation continued on page 2

NJPMP Registration Instructions:

- **Physicians will need to go to www.njrxreport.com**
- **Click on "Not a member-Register"**
- **Welcome to the PMP registration process -page appears**
- **Choose the job type that best describes your profession - MD**
- **Enter the form of identification requested-N.J.State License, DEA#**
- **Click the next button. Complete the online form with the required information. Be sure all info is accurate.**
- **Click the register button and follow on the on-screen instructions.**

*You may print the PMP registration form from the website. A copy will be sent to your email.
The notarized form is required for approval of your registration*

CURRENT DRUG SHORTAGES

- Nitroglycerin vials
- Papaverine vials
- Regranex ointment
- Calcium Chloride vials
- Calcium Gluconate vials
- MVI injection
- Droperidol injection
- Sincalide injection

Prothrombin Complex Concentrate (PCC) can be used in warfarin reversal and management of other anticoagulation associated severe or life-threatening bleeding (See Medication Management Policy #700.51). Kcentra™, a 4 factor PCC, has been identified by the institution as an option in the reversal of anticoagulant agents such as warfarin when the use of PCC is recommended. PCC can also be considered in the management of severe or life-threatening bleeding caused by either dabigatran (Pradaxa®), apixaban (Eliquis®), or rivaroxaban (Xarelto®). Kcentra™ is contraindicated in patients with disseminated intravascular coagulation (DIC) and in patients with known heparin-induced thrombocytopenia (HIT) due to the presence of heparin in the product. In patients with such contraindications, Factor IX Complex (3-factor PCC) can be used as an alternative. A pharmacy protocol for Factor IX Complex use has been developed and can be found in the Eportal under the pharmacy division section. The use of both Kcentra™ and Factor IX Complex (Profilnine®) is restricted to anesthesiologists, critical care physicians, emergency room physicians, cardiologists and hematologists/oncologists.

Influenza Vaccine 2013-2014

By Alison Carulli, Pharm.D. and GaEun Joung, Pharm.D.

The influenza vaccine for the 2013-2014 flu season is now available from the pharmacy. Seasonal flu activity can begin as early as October and continue to occur as late as May, although it commonly peaks in January or February. The timing of the flu is very unpredictable and can vary from year to year so the CDC recommends vaccination as early as October. There are two types of flu vaccine: trivalent and quadrivalent. The trivalent vaccine protects against three strains of influenza and the quadrivalent vaccine protects against four. This year's standard dose trivalent vaccine contains an A/California/7/2009(H1N1)pdm09-like virus, an A(H3N2) virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011, and a B/Massachusetts/2/2012-like virus.

The trivalent flu vaccines (inactivated) available to inpatients at Englewood Hospital and Medical Center include Fluzone® and Fluzone® pediatric dose (for 6 to 35 months old), which are injected intramuscularly. Fluzone® intradermal (inactivated form) and Quadrivalent FluMist® (live attenuated) are available at Employee Health for employees of Englewood Hospital and Medical Center. It takes about two weeks for the body to develop antibodies against the most common predicted strains and is sustained for the entire flu season. Although the

vaccine is recommended for everyone who is greater than 6 months old, the CDC is particularly concerned about certain patient populations. These include children from 6 months old to 5 years old, anyone 50 years old or older, people with chronic conditions (asthma, heart disease/stroke, diabetes) immunocompromised (HIV/AIDS, cancer), pregnant, nursing home or long-term care residents, healthcare personnel, people in contact with children or the immunocompromised and patients who are morbidly obese. The inactivated influenza vaccine can be received at the same time as other inactivated vaccines or even live vaccines. However, after a patient receives a live vaccine, they should wait at least four weeks before they get another live vaccine. Children between 6 months to 8 years of age should receive two doses at least four weeks apart if this is their first time or have not received two or more doses of influenza vaccine since July 1, 2010.

Side effects to the inactivated influenza vaccine are uncommon, except for soreness at the injection site. In studies, common reactions to the intradermal flu shot included redness, swelling, toughness, pain, and itching at the injection site. With the exception of pain, these side effects were more common with the intradermal shot than they are with regular flu shots. Other side effects included headache, muscle ache,

and tiredness. These symptoms usually go away within three to seven days. Patients should speak with their physician before receiving the vaccine if they have an egg allergy, are pregnant, immunocompromised, or have a history of Guillain-Barré syndrome within six weeks of receiving a flu vaccine as they may not be eligible for certain types of the flu vaccine. The influenza vaccine has been associated with Guillain-Barré syndrome (GBS), a rare immune-mediated disease that can range from weakness of the extremities and the trunk to paralysis of respiratory muscles, requiring ventilator support. However, a thorough review of adverse effects of vaccines published by Institute of Medicine in 2012 concluded to reject an association between influenza vaccine and GBS. The effectiveness of the seasonal influenza vaccine in preventing influenza and related deaths outweighs the risks for the general population.

For more information, please visit: <http://www.cdc.gov/flu/index.htm>

REFERENCES:

2013-2014 Flu Season. Centers for Disease Control and Prevention. <http://www.cdc.gov/flu/about/season/index.htm>
Influenza Vaccine for 2013-2014. *The Medical Letter*. 2013 Sept 16;55(1425):73-75.
Walberg MP. The risk of Guillain-Barré syndrome after influenza vaccination. *Formulary*. 2013 Sept;48:303.

FORMULARY UPDATES

By Jacqueline Takere, PharmD., CCRP

Drugs added to the Formulary in September and October 2013:

Hoprost (Ventavis®)

Ceftaroline Fosamil (Teflaro®) - **Restricted to Infectious Disease Physicians Only**

Insulin detemir (Levemir®)

Additions of Dosage Forms of Formulary Drugs:

Lithium Carbonate ER 300mg and 450mg tablets

Ranolazine (Ranexa®) 500mg tablets

Deletions of Dosage Forms of Formulary Drugs:

Polysporin topical powder, USP

Drug Warnings :

Acetaminophen (Tylenol®) has been associated with a risk of rare but serious skin reactions. These skin reactions known as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute exanthematous pustulosis (AGEP) can be fatal. Other drugs used to treat fever and pain/body aches (e.g non-steroidal anti-inflammatory drugs such as ibuprofen and naproxen) also carry the same risk of serious skin reactions.

Ofatumumab (Arzerra®) and Rituximab (Rituxan®) have a new boxed warning on their prescribing information about the risk of reactivation of hepatitis B virus (HBV) infection. The FDA recommends screening, monitoring, and managing patients on these drugs to decrease risk.

Tigecycline (Tygacil®) has a new boxed warning describing an increase risk of death when used for both FDA-approved uses and non-approved uses. There was a higher risk of death among tigecycline patients compared to other antibacterial drugs.