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Pharmacy & Therapeutics Update: Drug Information for Health Care Professionals

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Pharmacy & Therapeutics

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October 2008

Preventing Patient Harm with National Patient Safety Goal 3E: Implementing an Anticoagulation Management Program By Ashley Tyler, PharmD

PGY1 Pharmacy Resident

Anticoagulants are often considered a double-edged sword. They can save patient lives by preventing clots from forming in arteries and veins; however, they have been identified by many patient safety organizations, including the Institute for Healthcare Improvement (IHI), the Institute for Safe Medical Practices (ISMP), US Pharmacopeia (USP), and the Joint Commission (JC) as high-risk medications because they can cause significant harm when given incorrectly or as a result of an error.¹ The USP MEDMARX program found that heparin had the greatest number of dosing errors resulting in harm to elderly patients.¹ Furthermore, warfarin was highlighted as one of the top 10 medications most frequently associated with medication errors in hospitals.²

As a result, several organizations have developed programs to manage patients taking anticoagulants. At first, most anticoagulation management programs were developed as pharmacistrun anticoagulant clinics for outpatients. Studies revealed significant benefits such as fewer bleeding reports and other adverse events, more patients with an INR (international normalized ratio) or PT (prothrombin time) within the therapeutic range, and a favorable cost:benefit ratio.^{1,3}

Because promising results were shown with anticoagulation clinics, organizations decided to extend anticoagulation programs to the inpatient setting. Reports have demonstrated that hospitals with pharmacist-run anticoagulation programs resulted in lower death rates than those without such programs.¹ An assessment of over 700,000 Medicare patients in approximately 1,000 hospitals without anticoagulation programs noted an increase in mortality rates, length of hospital stay, Medicare charges, bleeding rates, and the need for transfusions.³ An anticoagulant therapy service managed by pharmacists at St. Joseph HealthCare in Kentucky demonstrated a > 90% decrease in adverse events relating to anticoagulants.³ Similar advantages have also been found in other trials evaluating pharmacist-run programs in the inpatient setting.⁴⁻⁶

Table 1: Eleven Expectations for the Anticoagulation Program²

- 1. An anticoagulation program is created to individualize patient therapy.
- 2. Only oral unit-dose products and premixed infusions are dispensed when available.
- 3. Warfarin monitoring procedures are developed and followed when pharmacy services are provided.
- 4. Protocols are developed for each anticoagulant, indicating guidelines for appropriate initiation and maintenance of therapy based on the condition being treated and possible drug interactions that may occur.
- 5. A baseline INR is required for all patients starting warfarin therapy. Current INRs are required to monitor and adjust warfarin therapy in patients receiving this medication.
- 6. A food-drug interaction program established by dietary services is in place. The dietary service is notified of all patients taking warfarin in order to create an appropriate diet.
- 7. Programmable infusion pumps should be used to deliver intravenous, continuous infusions of heparin when appropriate.
- 8. Baseline lab tests for heparin and low molecular-weight heparins (LMWH) are required. The frequency of future lab tests for these anticoagulants needs to be determined.
- 9. Physicians, staff, patients, and family members need to be educated on anticoagulant therapy.
- 10. Patients and family members need to be educated on possible side effects or interactions with other medications, the importance of adhering to their anticoagulant therapy and specific diet, and scheduling follow-up appointments to monitor anticoagulant therapy.
- 11. The organization must assess the implemented anticoagulation safety practices.

There is clearly a need for strategies to decrease patient harm associated with errors relating to anticoagulant administration. The JC has responded to this need by creating a new patient safety goal, #3E, which focuses on developing and implementing a model plan for anticoagulation management. Unlike past new patient safety goals, JC provides a specific timeline (see below) that must be followed to ensure full implementation of goal 3E.²

- A leader is assigned, who is responsible for the development, testing, and implementation of the program, by April 1, 2008
- A work plan to execute the program is in place by July 1, 2008
- Pilot testing of the program in at least one clinical unit by October 1, 2008

Implementation of the program throughout the entire organization must be completed by January 1, 2009

JC has created 11 expectations for the anticoagulation program that will apply starting January 1, 2009 (Table 1).²

The Pharmacy Department is currently in the process of developing an anticoagulation program to meet this patient safety goal. A policy has been created specifying the goals for the program, as well as changes that need to be implemented based on the 2008 CHEST Guidelines update on antithrombotic and thrombolytic therapy. This policy is currently under review by a multidisciplinary anticoagulation oversight committee consisting of physicians, nurses, and pharmacists who will provide feedback. The entire policy will then be revised and presented for approval by the Pharmacy and Therapeutics Committee.

Based on the timeline provided by JC, pilot testing of the program at began October 1, 2008 on the 5 East unit of ART. A preprinted warfarin order form has been developed for use. Physicians will need to fill in the appropriate indications, dosing, and monitoring parameters when completing the order form. The preprinted form will be tested on other units with the overall goal being to implement the program throughout the entire hospital by January 1, 2009.

Practitioners should expect to encounter many changes as a result of the utilization of the anticoagulation program. At present, protocols for heparin and direct thrombin inhibitors (DTIs) exist; however, protocols will need to be developed for the other anticoagulants on the formulary. Specifically, order forms for enoxaparin

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and fondaparinux, including information relating to the indications for use, dosing, and monitoring, will need to be created and put into practice. Education sessions providing information on changes as a result of the program will need to be scheduled for pharmacists, nurses, and physicians.

Finally, dietary services will need to place a stronger emphasis on

education regarding food-drug interactions, especially with war-farin.

MUSC is working diligently to make sure the 11 expectations for the program are met by the proposed deadline. Staff can expect to see many changes in the next few months. Updates will be provided as they come available to inform staff of the progress of the anticoagulation program.

This necessary program will achieve the goal to improve overall patient care by helping to eliminate potential anticoagulation dosing errors and improve monitoring in those patients receiving anticoagulation.

References available upon request

Did You Know...

Primary Changes and Updates in the 2008 Advisory Committee on Immunization Practices (ACIP) Recommendations

The 2008 recommendations include 5 principal changes or updates:

- Beginning with the 2008-09 influenza season, annual vaccination of all children aged 5 to 18 years is recommended.
 - Annual vaccination of all children aged 5 to 18 years should begin in September or as soon as vaccine is available for the 2008-09 influenza season, if feasible. Annual vaccination of all children aged 5 to 18 years should begin no later than during the 2009-10 influenza season.
- Annual vaccination of all children aged 6 months to 4 years (59 months) and older children with conditions that place them at increased risk for complications from influenza should continue.
 - Children and adolescents at high risk for influenza complications should continue to be a focus of vaccination efforts as providers and programs transition to routinely vaccinating all children.
- Either trivalent inactivated (killed) vaccines (TIV; Fluzone[®], Fluviron[®]) or live, attenuated influenza vaccines (LAIV; FluMist[®]) can be used when vaccinating healthy persons aged 2 to 49 years.
 - Children aged 6 months to 8 years should receive 2 doses of vaccine if they have not been vaccinated previously at any time with either LAIV or TIV (doses separated by 4 or more weeks); 2 doses are required for protection in these children.
 - Children aged 6 months to 8 years who received only 1 dose in their first year of vaccination should receive 2 doses the following year.
 - LAIV should not be administered to children <5 years with possible reactive airways disease, such as those who have had
 recurrent wheezing or a recent wheezing episode.
 - Children with possible reactive airways disease, persons at higher risk for influenza complications because of underlying medical conditions, children aged 6 to 23 months, and persons aged >49 years should receive TIV.
- The 2008-09 trivalent vaccine virus strains are A/Brisbane/59/2007 (H1N1)-like, A/Brisbane/10/2007 (H3N2)-like, and B/Florida/4/2006-like antigens.

Oseltamivir-resistant influenza A (H1N1) strains have been identified in the United States and other countries. However, oseltamivir or zanamivir continue to be the recommended antivirals for treatment of influenza because other influenza virus strains remain sensitive to oseltamivir, and resistance levels to other antiviral medications remain high.

MUSC is currently offering the flu vaccine to its employees. There are many campus-wide satellites hosted by Employee Health Services and Infection Control where vaccinations are available. For more information, please visit <u>http://mcintranet.musc.edu/ehs/flu_2008.htm</u>

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FORMULARY UPDATE FOR SEPTEMBER 2008

The Pharmacy and Therapeutics Committee recently approved the actions listed below. The formulary effective was October 13, 2008.

Added: Perflutren protein-type A microspheres (OptisonTM)

OptisonTM is a second-generation contrast agent used in echocardiography studies to improve imaging. It is indicated to opacify the left ventricle (LV) and to enhance LV endocardial border delineation in patients with suboptimal echocardiograms. In February 2005, the P&T Committee approved the addition of OptisonTM to the formulary with the deletion of Definity[®] based on lower cost, reduced preparation time, physician preference, and convenience of use. In April 2006, Optison[™] became unavailable from the manufacturer; at that time, Definity[®] was re-added to the formulary as a temporary product replacement. Optison[™], now being available again, is also being used in a registry trial in the adult echocardiogram lab. It has been requested that both agents, Optison[™] and Definity[®], be available for the trial. After the trial is over, the agents may be re-evaluated to determine the preferred contrast agent of choice.

3-mL vials

Change in Restriction: Regadenoson (Lexiscan[®])

Regadenoson is indicated as a pharmacologic stress agent for radionuclide myocardial perfusion imaging (MPI). It was originally restricted to patients who failed imaging with adenosine. However, based on additional information from the Division of Nuclear Medicine, the restriction was changed to patients unable to undergo adequate exercise stress (ie, Bruce treadmill protocol exercise).

Automatic Therapeutic Substitution (ATS):

Bupropion (Wellbutrin XL[®])

An ATS protocol has been developed to decrease confusion regarding orders for bupropion (Wellbutrin[®]) immediate-release (IR), sustained-release (SR), and extended-release (XL) formulations. Orders written for bupropion XL will be changed to the appropriate bupropion SR dose. Physicians not wanting to use the ATS protocol for bupropion must write *DAW* (*dispense as written*) on the order with a clinical justification.

Warfarin Preprinted Order Form

A preprinted warfarin order form for the anticoagulation program was piloted on 5 East (ART) on October 1st. Physicians will need to complete the form for orders pertaining to warfarin by filling in the appropriate indications, dosing, and monitoring parameters. This warfarin order form addresses the JC 2008 National Patient Safety Goals for all health care systems to have an existing inpatient anticoagulation monitoring program.

Line Extension:

 Nicardipine (Cardene[®]) 20mg/200-mL premix infusion

October is American Pharmacists Month



October is American Pharmacists Month. The Department of Pharmacy will be recognizing its employees during Pharmacy Week (Oct. 19th - 25th) with various activities. Also, the American Pharmacists Association Academy of Student Pharmacist (APhA-ASP) will be sponsoring events throughout the campus in recognition of American Pharmacists Month. Past activities have included bake sales, "brown bag" medication reviews

for patients, and special CE programs for pharmacists and technicians. More information regarding specific planned activities and dates will be forthcoming.

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