

## Anticoagulation National Patient Safety Monitoring Program at TGH

Lindsay Bock, PharmD, BCPS



Since 2003, The Joint Commission has defined National Patient Safety Goals (NPSG) with the purpose of promoting improvements in patient safety. The Anticoagulation National Patient Safety Goal was released by the Joint Commission in July 2007 with

the requirement that it be fully implemented by January 1, 2009. Anticoagulants have been identified as one of the top five drug types associated with patient safety incidents. Adverse drug events related to anticoagulation therapy revolve around their complex dosing, narrow therapeutic window, and required monitoring.

The newest requirement focuses on reducing the likelihood of patient harm associated with the use of anticoagulation therapy.

The Anticoagulation NPSG is further defined by The Joint Commission to apply only to patients who are receiving therapeutic doses of anticoagulants (not prophylactic doses) or if the clinical expectation is that coagulation lab values will remain outside the normal range.

A one-year phase-in period was designed to help health care facilities implement processes to meet this requirement. Practitioners at TGH have been working diligently to ensure these milestones are met. The defined milestones to accomplish implementation by January 1, 2009 are as follows:

- April 1, 2008 - Identify and assign individual(s) responsible for oversight and coordination of the development, testing, and implementation
- July 1, 2008 - Create a formal plan for organization-wide implementation identifying resources, assigning accountabilities, and establishing a time line
- October 1, 2008 - Pilot testing underway in at least one clinical unit
- January 1, 2009 - Full implementation of plan throughout the organization

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### March is National DVT Awareness Month!

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## Elements of Performance

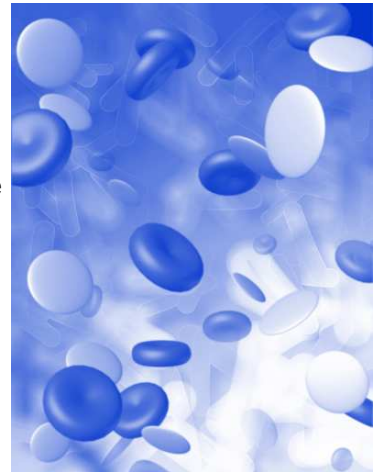
The Joint Commission (TJC) has further defined the requirement using nine elements of performance by which health care facilities must comply. These requirements include the development of a defined anticoagulation management program that individualizes care for each patient receiving therapeutic doses of warfarin, heparin (UFH), or low molecular weight heparin (LMWH). In addition, TJC addresses reduction of compounding and labeling errors, measuring baseline INRs and current labs for each anticoagulant, dietary adjustments for warfarin, the use of programmable pumps for heparin therapy, and education for patients and staff.



Over the past several months, pharmacists, physicians, nurses and other clinicians at TGH have worked to revise our processes to comply with this new requirement. The result is a new Anticoagulation Monitoring Program effective January 1, 2009. This new program is designed to improve the safety of anticoagulant use and involves an interdisciplinary approach to monitoring patients receiving warfarin, LMWH or UFH.

### Process Change: Warfarin

When warfarin is initiated at TGH, either a new order or continuation from home, a baseline INR must be drawn before the first dose is administered. Subsequently, a daily INR must be ordered until the patient's INR is therapeutic and stable. If a baseline or daily INR has not been ordered, a pharmacist may place the order. A baseline INR has been defined as an INR drawn no sooner than 72 hours prior to warfarin initiation and does not include labs drawn at an outside facility. If a pharmacist orders the baseline INR and the lab result will delay initiation of therapy (standard warfarin administration time is 1700) the pharmacist will contact the prescribing physician to notify them of the delay. The pharmacist is responsible for follow-up of baseline INR and dispensing warfarin if appropriate. If the baseline INR is greater than 1.4 for warfarin naïve patients or 3.6 for patients on previous warfarin therapy, the pharmacist will contact the prescribing physician and discuss the clinical situation prior to dispensing warfarin. The pharmacist will document the communication with the physician in the form of a progress note. Patients on long-term warfarin therapy whose INR values are stable, do not require daily INRs but should have INRs checked at a minimum on the 1<sup>st</sup> and 15<sup>th</sup> day of the month. As part of their clinical responsibilities, unit-based pharmacists will follow patients receiving warfarin therapy daily. Their focus will be to ensure that patients are receiving appropriate warfarin doses in order to avoid subtherapeutic and supratherapeutic INRs, as well as, ensure patients are progressing appropriately to the goal INR.



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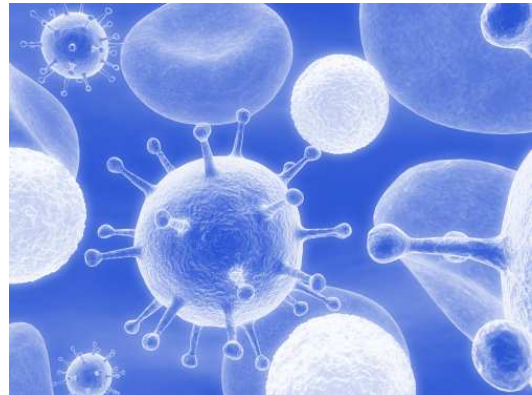
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**Process Change: LMWH (enoxaparin)**

When enoxaparin is initiated, the patient must have a baseline (within 24 hours) serum creatinine (SCr) and CBC drawn prior to the dose being given. If the baseline SCr and CBC are not available, the pharmacist will order a BMP and CBC. Because of the critical nature of LMWH therapy, the pharmacist is authorized to dispense a one-time dose so that therapy will not be delayed. As soon as the laboratory values are available, the pharmacist will review the information and make any necessary dose adjustments based on the renal dosing protocol for LMW heparin. Patients must have a weekly BMP and CBC while receiving LMWH therapy. The assigned unit based pharmacist will follow patients receiving LMWH by monitoring renal function, hemoglobin, hematocrit and platelet count. If abnormal lab results arise, the physician will be contacted to discuss any issues or concerns not previously addressed in the medical record. The intent of this procedure is to assist in monitoring lab values and avoid any potential adverse events related to anticoagulation therapy.

**Process Change: UFH**

The Weight Based Heparin Protocol order form should be used when initiating a heparin infusion. Patients on heparin infusion must have orders for daily CBC, aPTT at 6 and 12 hours after the start of the infusion, followed by daily aPTT with daily labs. If the order set is not used and the labs have not been ordered by the physician, the clinical pharmacists will place the orders for these labs. The pharmacist will assist by monitoring the daily CBC for clinically significant decreases in hemoglobin, hematocrit, and platelet count. If abnormal lab results arise, the physician will be contacted to discuss any issues or concerns that have not been previously addressed in the medical record.



The formation of the TGH Anticoagulation Monitoring Program is designed to be a collaborative practice model integrating all disciplines to proactively improve the safety of anticoagulation use at TGH in accordance with the anticoagulation NPSG. The implementation of this program will be an adjustment for all disciplines and everyone's cooperation during this time is greatly appreciated. In order to ensure quality improvement, the processes and results will be regularly reviewed for any necessary changes. It is our hope and expectation that implementation of this new program will improve safety for our patients requiring anticoagulation therapy.



## TGH Doctor's Day

March 30th, 2009

Let us show our appreciation at a special breakfast and lunch  
(Register for Raffle Prizes Too)



## TGH Employee Portal / Policies Online

Susan H. Eminizer, Policy Systems Coordinator

On April 28, 2008, without much fanfare, all hospital-wide policies from the TGH Policy Manual went live on the TGH Employee Portal. The addition of unit-specific policies was accomplished December 5, 2008. Personally, I think there should have been a parade, complete with marching bands and baton twirlers; because after many years of requests from hospital staff to have policies available online, the Information Systems Development Group made it happen!

It took two years to prepare policies for the portal and another six months protecting each document as it was put onto the portal. The Policy Systems Coordinator currently maintains both the paper policy system for all TGH Policy Manuals plus the duplicate electronic policy system on the portal. This is a duplication of effort; however, we plan to do a survey of all portal users to see how many of the 157 paper manuals can be eliminated. We want to keep a few paper manuals as backup, in case the portal is temporarily out of service. However, I foresee being able to discontinue at least half of the manuals.

The capability to do electronic “searches” for policies and forms is the most popular function of the portal among TGH staff. And it is “warp speed” fast!

The Information Systems Development Group isn’t finished yet. They plan to build out a routing/approval mechanism for both policies and forms.

### **Tips on using the online policy system:**

Policies in revision or in the sign-off process are not housed on the portal until they are finalized and issued to the paper manuals.

The portal is updated the same day that policies are distributed to the paper manuals.

All policies and forms on the portal are protected and cannot be changed.

If you are searching for a policy by Manual Code or Index Code, be sure to include the “dash” between the Section letters and the number: Example: TX-55.

Not all attachments/forms are available on the portal, as most attachments are sent to me in hard copy form, however, they will be added to the portal in the future. In the meantime, if you do a word search, all available forms will come up with a list of related policies.

Do not print out policies/forms and keep them for future use or make a folder/manual with documents that you have printed off the portal. You will have no way of keeping these current.

If you need to print out a policy or form, in the course of your work, please do this on a daily basis, as the documents may be revised and updated on the portal at any time.

If you pull up a policy that has red tracking on it, just go to the top tool bar and find the small window on the left that states “Final Showing Markup.” Click on the “down arrow” beside that window and then click on “Final.” That will temporarily remove the red tracking.

If you do not have an “Employee Portal” icon on your desktop, contact Technology Support Center at Ext.7490. They will assist you in creating an icon.

If you have additional questions regarding the online policy system, call Susan Eminizer at Ext.7440.

## Recombinant Factor VIIa (NovoSeven®) Guidelines for Use in the Non-Hemophiliac Patient

Maresa Glass, Pharm.D., BCPS—Critical Care Pharmacotherapy Specialist

Recombinant Factor VIIa promotes hemostasis by activating the extrinsic pathway of the coagulation cascade. It is indicated for the treatment or prevention of bleeding in patients with hemophilia and congenital factor VII deficiency.

There is literature supporting the use of Factor VIIa outside of these FDA approved uses. At TGH, Factor VIIa use is closely monitored because of the high cost and safety concerns associated with this drug. Data is collected on each dose of Factor VIIa administered to assure appropriateness as well as to collect information on patient response and outcomes.

The Pharmacy and Therapeutics Committee along with the Medical Staff Officers Committee recently approved a revision to the guidelines for the use of recombinant Factor VIIa for the prevention or control of bleeding in non-hemophiliac patients.

A summary of these guidelines, along with the approved restrictions on the use of Factor VIIa is provided in this article.

### **Formulary Restrictions**

Order must be written by attending level physician

### **The following criteria must be verified prior to Factor VIIa administration**

Known coagulopathy or active bleeding

Potential positive outcome if bleeding ceases

Minimal risk factors for thromboembolic event (no recent history of ischemic stroke, CVA, or TIA, venous (DVT, PE) or arterial (MI, CVA) thrombotic event)

Platelets above 50,000, Fibrinogen above 100, PT/aPTT less than or equal to 1.5 times normal value **OR** administration of appropriate blood products with intent to correct coagulopathy

Continued massive bleeding and inability to correct coagulopathy or platelet deficiency despite aggressive transfusion support

Arterial pH above 7

Core body temperature greater than or equal to 35° C

Attempt at surgically correcting bleeding, if appropriate

Any ordered blood products must finish infusing prior to administration of Factor VIIa

### **Clinical Pearls**

Patients should be monitored for signs of thrombosis. Thrombotic events may be increased in patients with DIC, sepsis, crush injury, or a recent history of thromboembolic event.

Adequate platelets are required for Factor VIIa to induce coagulation.

The pro-thrombotic effects of Factor VIIa are only maintained for 2-3 hours after administration. Therefore, it is important to coordinate administration of Factor VIIa appropriately with the planned procedure, etc.

Factor VIIa will be ordered x 1 dose only. Further doses to be ordered upon reevaluation of patient situation.

All doses will be rounded to the nearest vial size (1000 mcg and 5000 mcg vials) to minimize waste.

A complete copy of the guidelines can be found in the MicroMedex Formulary Advisor. To access Formulary Advisor from any TGH computer desktop or from the link in PreCise follow these steps:

Open MicroMedex (Healthcare Series)

Click on the "Formulary Advisor" blue tab on the right side

Click on the "Guidelines for Use" blue tab on the left side

Open up the document titled "Recombinant Factor VIIa (NovoSeven®) Guidelines for Use in the Non-Hemophiliac Patient"

*Tampa General Hospital  
Quality Improvement Department*

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## TGH Welcomes our new Physicians



The physicians below were added to TGH staff Jan 31 & Feb 28th

Amanda N. Alvelo-Malina, MD  
Jonathon P. Alvior MD  
Edson S. Franco. MD  
Jennifer L. Giglia, MD  
Virginia R. Goytia, MD  
Gregory A. Hale, MD  
Umesh S. Lingegowda, MD  
Kyle Maung, MD  
Jacinto B. Moya, MD  
Lori A. Spoor, DO  
Frank J. Vazzana, DO

Obstetrics and Gynecology  
Internal Medicine  
General Surgery  
Hematology-Oncology  
Radiation Oncology  
Pediatrics  
Internal Medicine  
Internal Medicine  
Anesthesiology  
Family Practice  
Family Practice

This newsletter is produced by Tampa General Hospital's Quality Improvement Department. All comments, responses or suggestions are welcome and should be directed to:

Sally H. Houston, M.D.  
Sr. V.P. &  
Chief Medical Officer  
Tampa General Hospital,  
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Tampa, Florida 33601

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