“Preventing Adverse Drug Events and Harm”

Frank Federico, RPh, IHI Executive Director
Steve Meisel, PharmD, IHI Faculty

February 28, 2012
12:00 - 1:00pm ET
Beth O’Donnell, MPH, Institute for Healthcare Improvement (IHI), is responsible for managing and coordinating strategic partnerships. Ms. O’Donnell received her undergraduate degree at St. Lawrence University and her graduate degree from The Dartmouth Institute for Health Policy and Clinical Practice. She joined IHI in August.
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What is an Expedition?

ex·pe·di·tion (noun)
1. an excursion, journey, or voyage made for some specific purpose
2. the group of persons engaged in such an activity
3. promptness or speed in accomplishing something
Overall Objectives

Participants will be able to:

• Identify opportunities to decrease Adverse Drug Events (ADEs)
• Describe three process changes needed to reduce ADEs
• Discuss what measures are needed to determine the impact of interventions
Frank Federico, RPh

Frank Federico, RPh, Executive Director, Strategic Partners, Institute for Healthcare Improvement (IHI), works in the areas of patient safety, application of reliability principles in health care, preventing surgical complications, and improving perinatal care. He is faculty for the IHI Patient Safety Executive Training Program and co-chaired a number of Patient Safety Collaboratives. Prior to joining IHI, Mr. Federico was the Program Director of the Office Practice Evaluation Program and a Loss Prevention/Patient Safety Specialist at Risk Management Foundation of the Harvard Affiliated Institutions, and Director of Pharmacy at Children’s Hospital, Boston. He has authored numerous patient safety articles, co-authored a book chapter in Achieving Safe and Reliable Healthcare: Strategies and Solutions, and is an Executive Producer of "First, Do No Harm, Part 2: Taking the Lead." Mr. Federico serves as Vice Chair of the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP). He coaches teams and lectures extensively, nationally and internationally, on patient safety.
Steven Meisel, Pharm.D., Director of Patient Safety for Fairview Health Services, an integrated health system based in Minneapolis, Minnesota. In this role he is responsible for all aspects of patient safety improvement, as well as related measurement, reporting, educational and cultural initiatives. Dr. Meisel has served as faculty for the Institute for Healthcare Improvement safety since 1997. Dr. Meisel is the recipient of numerous awards, including the 2005 University Health-System Consortium Excellence in Quality and Safety Award. He is the author of several publications.
Session Agenda

• Homework – What did you learn?
• Anticoagulation
  - Harm
  - Measurement
  - Prescribing & Dispensing
  - Pharmacist’s Role
  - Patient & Staff Education
• Q&A
• Homework
Review of Homework

• Review your system for ensuring safety with insulin
• How are you identifying opportunities for improvement with this group of high-alert medications?
• What outcome and process measures are you using, or will use?
Lynn Eschenbacher, Pharm.D., MBA has a strong interest in process improvement and medication safety. After obtaining a BS in biology from Indiana University in Bloomington, IN she attended the University of Texas at Austin to obtain her PharmD. She then completed a pharmacy practice residency at Parkland Health & Hospitals in Dallas, Texas. Lynn worked at Duke University Hospital as a clinical pharmacist, clinical coordinator and medication safety officer. Additionally, she completed her MBA at the Fuqua School of Business at Duke University. She is currently the Assistant Director of Clinical Services at WakeMed Health & Hospitals in Raleigh, North Carolina and the PGY-1 Residency Director. Lynn was just selected for the Circle of Excellence award at WakeMed for Market Development and Quality Outcomes. She is also the ASHP Delegate for the Acute Care Forum in North Carolina, the immediate past-Chair of the ASHP Section Advisory Group for Medication Safety, a member of the Clinical Leadership ASHP Section Advisory Group an the chair-elect for the ASHP Section of Inpatient Care Practitioners.
Anticoagulation

Lynn Eschenbacher PharmD, MBA
Assistant Director Clinical Services

Jenna Huggins, PharmD, BCPS
Cardiology Clinical Coordinator
Objectives

1. Describe contributing factors to Anticoagulant-related harm

2. List two process changes to reduce anticoagulation-related harm

3. Describe how to measure anticoagulant-related harm
Contributing Factors to Anticoagulation Harm—TJC Sentinel Event Alert
Issue 41, September 24, 2008

• Lack of standardization for the naming, labeling and packaging of anticoagulants
  — Heparin flush syringes have been confused with LMW heparin syringes.
  — Lesser-known anticoagulant drug names exist (e.g., enoxaparin, dalteparin, tinzaparin) and are used less commonly, which can result in duplicate medication orders and erroneous dosing.

• Keeping current with different dosing regimens for various patient populations, newer assay methods, the expanding lists of drug interactions, and the potential reversal strategies.

• The specific and individualized instructions and monitoring information (for example, dose adjustments, lab values, changing patient condition) that accompany the prescribing and administration of anticoagulants may fail to get documented or communicated during transfers and hand-offs.

• Neonates and other pediatric patients are problematic to treat, specifically because the medications are formulated and packaged primarily for adults.¹
Contributing Factors to Anticoagulation Harm

- Lack of dosing guidelines and appropriate monitoring can lead to serious harm associated with this class of medications.²

- Warfarin is commonly involved in ADEs for a number of reasons.
  - Complexity of dosing and monitoring
  - Patient compliance
  - Numerous drug interactions
  - Dietary interactions that can affect drug activity³

- There is considerable variation in ordering, dosing, and monitoring of patients on unfractionated heparin. Often, there is confusion as to providing ongoing therapy while patients are receiving warfarin⁴
Notable events and lessons learned

• Automated dispensing cabinets
  — Original fill
  — Restocking
• Floor stock
• Human factors
  — 10 units/ml vs. 10,000 units/ml
• Multiple products and multiple concentrations
Heparin strategies

- Implement weight-based heparin protocol; limit these to no more than one or two protocols.
- Use preprinted order forms or ordering protocols.
- Ensure that heparin dosing protocols account for the use of thrombolytics and IIb/IIIa inhibitors.
- Ensure that heparin cannot be administered within 6-12 hours of a dose of LMWH.
- Use standard concentrations in OR, ER, and the ICUs.
- Separate like products when using or storing.
- Dispense the anticoagulant medication from pharmacy only.
- Use smallest size package, concentration, and dose for floor stock.
- Remove high-concentration products from floor stock.
- Make hep-flush available only in syringes.
- Ensure that appropriate monitoring parameters are implemented and used reliably.
- Establish guidelines to hold heparin and provide reversal therapy for heparin over-anticoagulation.
- Simplify by minimizing available concentrations.\(^4\)
Warfarin strategies

- Engage patients by ensuring that they understand how to take the medication, other medications that should be avoided, and identification of symptoms that indicate harm is critical.
- Simplify by minimizing available strengths of oral formulations
- Include a nutrition consult for patients on warfarin to avoid drug/food interactions and educate the patient about them.
- Develop a robust communication plan to share information with the next provider of care when a patient is discharged from the hospital.
- Standardize protocols and dosing.
  - Standardized protocols for the initiation and maintenance of warfarin therapy including Vitamin K dosing guidelines.
  - Develop a protocol, based on evidence, to discontinue and restart warfarin perioperatively.
- Make information available; for example, improve access to lab results and/or use of point-of-care testing in order to determine doses.
- Ensure appropriate monitoring and dose management through a centralized anticoagulation service.\(^4\)
### ISMP Antithrombotic Self Assessment

#### Self-Assessment Items

<table>
<thead>
<tr>
<th>Core Characteristic</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
</tr>
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<tbody>
<tr>
<td>Essential patient information is obtained and readily available in a useful form when prescribing, dispensing, and administering antithrombotic therapy.</td>
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</table>

1. A baseline hemoglobin, hematocrit, serum creatinine, and platelet count are obtained prior to initiating antithrombotic therapy (inpatient or outpatient) with unfractionated heparin or LMW heparin.  

2. During antithrombotic therapy (inpatient and outpatient) of more than 3 to 5 days with unfractionated heparin or LMW heparin, a platelet count is repeated every 3 days during the first 2 weeks of therapy.  

3. After initiating a heparin infusion, an aPTT test is obtained *no sooner* than 6 to 8 hours after the start of the infusion (unless bleeding occurs).  

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http://www.ismp.org/selfassessments/asa2006/Intro.asp
WakeMed Health & Hospitals Process Changes to Reduce Anticoagulation-related Harm

- Anticoagulation Adverse Event Review Team
- Prescribing
  - New medications and confusion
  - CPOE programming- INR reversal
  - Bivalirudin for HIT rather than Argatroban
- Prescribing and Dispensing
  - “New” heparin study
  - Heparin protocol redone
  - Bivalirudin aliquots- cost saving- ACS
- Pharmacist role
  - LMWH pharmacist P&T protocol
  - Xa levels
    - Pharmacist adjustment based on levels
    - Created new nomogram for dosing outside of currently published
  - Inpatient warfarin, direct thrombin inhibitor, and factor xa inhibitor monitoring
- Patient and Staff education
Measure Anticoagulation Harm

• % Warfarin Patients with Baseline INR
• % Patients with Pharmacist Documented Anticoagulation Education (warfarin, rivaroxaban, dabigatran)
• Others
Anticoagulation Adverse Event Review Team

• Use Data for Improvement
  – Individual feedback
  – Monitoring process changes to demonstrate improvement

• Master Spreadsheet for Analysis- Log of all events
  – Mini RCA for each
  – Identified 10mg issue
    ➢ MUE
    ➢ P&T
    ➢ Medical executive team follow up
      – Literature review, MUE results
  – One-on-one education

• Orientation
  – Module- check list
  – One-on-one mentoring
  – Educational needs assessment
  – Case based questioning
Pharmacy Orientation Checklist

Anticoagulation Monitoring

Purpose:
1. To familiarize the pharmacist with anticoagulation monitoring process at WakeMed
2. To ensure and develop competency in monitoring of selected anticoagulant medications and patient populations

Responsibilities:
1. Review self-study material:
   a. ACCP Guideline Executive Summary (2008)
   b. Anticoag pearls - Inservice
   c. WakeMed Anticoagulation Monitoring Policy (Policy no 1604)
   d. WakeMed Anticoagulation Monitoring Guideline
   e. Warfarin presentation by Catherine Lewis
   f. Heparin presentation by Catherine Lewis
   g. Warfarin bridging presentation by Janie Huggins
   h. Anticoagulation Pre/Post-Assessment
   i. Coumadin DVD
   j. WakeMed Warfarin (Coumadin) Education Booklet
   k. WakeMed Heparin Teaching Guide
   l. WakeMed Enoxaparin in Teaching Guide
   m. Lovenox Teaching Kit
2. Complete training with preceptor and achieve outcomes outlined below

Pre-requisite training:
- Sorian, EDM, Siemens Pharmacy, iPharmacy, SmartWeb
- Anticoagulation Competency Test 1/2/2009

Assessments:

Employee:

Preceptor(s):

Date:

<table>
<thead>
<tr>
<th>Training Topics</th>
<th>Training Outcomes</th>
<th>Date Reviewed/Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Initiation of Anticoagulation Monitoring Form</td>
<td>Identify patients who have been previously admitted to WakeMed and locate monitoring forms from previous admissions</td>
<td></td>
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<tr>
<td></td>
<td>Document monitoring status in Siemens Pharmacy Notes (coded text “AM” for monitoring and “PKS” for dosing consults)</td>
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<tr>
<td></td>
<td>Review available information and document indication and treatment history for anticoagulation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Review available information and document indication and treatment history for anticoagulation</td>
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</tr>
<tr>
<td>II. WakeMed Anticoagulation Monitoring Policy</td>
<td>Verify baseline INR is within acceptable time range: 7 days for new starts, 24 hrs for established patients (warfarin only)</td>
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<tr>
<td></td>
<td>Review INR daily until therapeutic for 3 days, then review at least every 3 days (warfarin only)</td>
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<tr>
<td></td>
<td>Review serum creatinine (SCr) and complete blood count (CBC, including platelets) every 3 days (enoxaparin only)</td>
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<tr>
<td>III. Daily Monitoring</td>
<td>Review appropriateness of therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Review laboratory data</td>
<td></td>
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<tr>
<td></td>
<td>Order laboratory tests as needed per WakeMed Anticoagulation Monitoring Policy</td>
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<tr>
<td></td>
<td>Review drug-drug interactions (Drug Interaction Report) (warfarin only)</td>
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<tr>
<td></td>
<td>Verify appropriate dose timing on Medication Administration Record (MAR/MAK)</td>
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<td></td>
<td>Document dose administered on previous day (Pylis or cart fill charges/MAK)</td>
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<tr>
<td></td>
<td>Document if dose ordered for today</td>
<td></td>
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<tr>
<td></td>
<td>Contact prescribers to communicate recommendations</td>
<td></td>
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<tr>
<td></td>
<td>Document recommendations and outcome (accepted or declined) on monitoring form</td>
<td></td>
</tr>
<tr>
<td>IV. Patient Education</td>
<td>Identify patients requiring warfarin counseling by pharmacists (new starts, unexplained non-therapeutic INRs)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Identify patients requiring enoxaparin counseling by</td>
<td></td>
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</table>
Prescribing: New Medications and Confusion

• Recommendation for holding prior to major procedure or surgery
• Recommendation for holding for spinal anesthesia/epidural
• Reversal
# New Anticoagulants

<table>
<thead>
<tr>
<th></th>
<th><strong>Dabigatran (Pradaxa)</strong></th>
<th><strong>Rivaroxaban (Xarelto)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Monitoring</strong></td>
<td>• Required for all doses of 150 mg or 75 mg BID</td>
<td>• Required for all atrial fibrillation treatment doses of 20 mg or 10 mg daily</td>
</tr>
<tr>
<td></td>
<td>• SCr, CBC every 3 days</td>
<td>• SCr, CBC every 3 days</td>
</tr>
<tr>
<td></td>
<td>• Drug interactions monitoring – i.e. dronedarone and dose reduction if CrCl &lt;50 ml/min</td>
<td>• Drug interactions monitoring – i.e. dronedarone and dose reduction if CrCl &lt;50 ml/min</td>
</tr>
<tr>
<td><strong>Prevention</strong></td>
<td>• Communication with physicians if dosing does not match renal function</td>
<td>• Communication with physicians if dosing does not match renal function</td>
</tr>
<tr>
<td></td>
<td>• Rules built in pharmacy system to fire if patient on concomitant enoxaparin, heparin,</td>
<td>• Education of staff (pharmacy, provider, nursing) through written and verbal education</td>
</tr>
<tr>
<td></td>
<td>warfarin due to risk of provider/pharmacist missing new anticoagulant on profile</td>
<td>• Comparison chart of all anticoagulants provided to providers in hospital</td>
</tr>
<tr>
<td></td>
<td>• Education of staff (pharmacy, provider, nursing) through written and verbal education</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Comparison chart of all anticoagulants provided to providers in hospital</td>
<td></td>
</tr>
</tbody>
</table>
## Prescribing: New Medications and Confusion

<table>
<thead>
<tr>
<th>Generic name (Brand name)</th>
<th>Medication Class</th>
<th>Usual dose and route of administration</th>
<th>Renal Dosing</th>
<th>Elimination half-life</th>
<th>Recommendations for holding prior to major procedures or surgery</th>
<th>Recommendations for holding for spinal anesthesia/epidurals</th>
<th>Reversal</th>
</tr>
</thead>
<tbody>
<tr>
<td>clopidogrel (Plavix)</td>
<td>antiplatelet</td>
<td>75 mg daily; PO</td>
<td>No adjustment necessary</td>
<td>~6 hours; platelet function restored in ~5 days</td>
<td>hold 5-10 days prior to procedure; may restart 24 hours after surgery if hemostasis achieved</td>
<td>hold 7 days prior to procedure; no recommendations with regard to administration while catheter in place or after catheter removal</td>
<td>no specific reversal agent; supportive care (platelet infusions)</td>
</tr>
<tr>
<td>dabigatran (Pradaxa)</td>
<td>anticoagulant; oral direct thrombin inhibitor</td>
<td>75 or 150 mg twice daily; PO</td>
<td>CrCl 15-30 ml/min: 75 mg PO BID; CrCl &lt; 15 ml/min: Use not recommended</td>
<td>12-17 hours (up to 34 hours in renally impaired)</td>
<td>hold 1 to 2 days (CrCl $\geq$ 50 mL/min) or 3 to 5 days (CrCl &lt; 50 mL/min) prior to procedure, potentially longer for spinal surgery/puncture or other major surgery; may restart when full anticoagulation deemed safe (therapeutic anticoagulation will occur 0-2 hours after administration)</td>
<td>hold a minimum of 5 days (longer if patient renally impaired) prior to spinal puncture or insertion of catheter; avoid use while catheter in place; may restart when full anticoagulation deemed safe, usually 8 hours after atraumatic puncture/removal or 24 hours after traumatic procedures (therapeutic anticoagulation will occur 0-2 hours after administration)</td>
<td>no specific reversal agent; consider hemodialysis if major hemorrhage or overdose; supportive care (anecdotal reports of Factor VIIa, PCC use)</td>
</tr>
</tbody>
</table>
Prescribing: CPOE programming - INR reversal

<table>
<thead>
<tr>
<th>Warfarin (Coumadin) Reversal Orders</th>
</tr>
</thead>
<tbody>
<tr>
<td>for all patients:</td>
</tr>
<tr>
<td>□ PT/INR AMDraw Once</td>
</tr>
<tr>
<td>□ Pharmacy Communication: Discontinue Warfarin Orders</td>
</tr>
<tr>
<td>□ Nurse Communication: check with physician during warfarin reversal prior to giving other blood-thinning medications (eg. ASA, Plavix, Ticlid, Effient, heparin, Lovenox, Arixtra, Fragmin, Pradaxa, etc.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>for life-threatening bleeding and INR &gt;1.5:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Phytonadione (Vit K) Adult 10mg/50mL NS x 1 dose STAT</td>
</tr>
<tr>
<td>□ Transfuse FFP, 2 Unit</td>
</tr>
<tr>
<td>□ PT/INR Timed Q12Hrs for 2 Times</td>
</tr>
<tr>
<td>□ Notify Physician: INR results</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>for serious bleeding and INR &gt;1.5:</th>
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<tbody>
<tr>
<td>□ Phytonadione (Vit K) Adult 10mg/50mL NS x 1 dose STAT</td>
</tr>
<tr>
<td>□ PT/INR Q12Hrs for 2 Times</td>
</tr>
<tr>
<td>□ Notify Physician: INR results</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>for urgent surgery and INR &gt;1.5:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Phytonadione (Vit K) 5 mg ORAL x 1 dose</td>
</tr>
<tr>
<td>□ Phytonadione (Vit K) Adult 5mg/50mL NS x 1 dose STAT</td>
</tr>
<tr>
<td>□ Notify Physician: INR results</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>for INR &gt;9 without bleeding:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Phytonadione (Vit K) 5 mg ORAL x1 dose</td>
</tr>
<tr>
<td>□ Phytonadione (Vit K) Adult 5mg/50mL NS x 1 dose STAT</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>for INR between 5 and 9 without bleeding:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Phytonadione (Vit K) 1 mg ORAL/TUBE x 1 dose STAT</td>
</tr>
<tr>
<td>□ Phytonadione (Vit K) 2.5 mg ORAL/TUBE x 1 dose STAT</td>
</tr>
</tbody>
</table>
Prescribing: Bivalirudin for HIT

• Bivalirudin (Angiomax®) for HIT rather than Argatroban
  ➢ INR goal of 4 created nursing/pharmacy confusion and often stopped too early
  ➢ Argatroban with hepatic metabolism, so changed to cleaner drug (enzymatic metabolism)

• Implementation
  ➢ Orderset
  ➢ Nursing Education
# SYSWD Heparin Induced Thrombocytopenia (Bivalirudin) Orders for Adults

**DATE:**

**TIME:**

### 4Ts Scoring System

<table>
<thead>
<tr>
<th></th>
<th>2</th>
<th>1</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thrombocytopenia</td>
<td>Nadir 20 AND &gt; 50% platelet fall AND no surgery within past 72 hours</td>
<td>Nadir 10-19 or 30-50% platelet fall; &gt; 50% platelet fall BUT surgery within past 72 hours</td>
<td>Nadir &lt;10 or &lt;30% platelet fall</td>
</tr>
<tr>
<td>Timing of onset of platelet fall</td>
<td>5-10 days after starting heparin or within 1 day if heparin given in previous 5-30 days</td>
<td>5-10 days after starting heparin but missing lab values or within 1 day if heparin given in previous 30-100 days or &gt; 10 days after starting heparin</td>
<td>0-4 days after starting heparin AND no heparin exposure in past 100 days</td>
</tr>
<tr>
<td>Thrombosis or other sequelae</td>
<td>Proven thrombosis, skin necrosis at injection site or acute reaction following administration</td>
<td>Progressive, recurrent, or silent thrombosis; erythematous skin lesions at injection site</td>
<td>Thrombosis not suspected</td>
</tr>
<tr>
<td>Other cause of platelet fall</td>
<td>None evident</td>
<td>Possible other causes (e.g. IABP, CRRT, sepsis)</td>
<td>Definite other causes (e.g. within 72hr of surgery, chemo, TTP, meds)</td>
</tr>
</tbody>
</table>

**Determine Score**

**SCORE =**

### Choose the Appropriate Anticoagulant

**HIT highly unlikely**

Start prophylaxis-dose fondaparinux (Arixtra):
- fondaparinux 2.5 mg SQ daily
- fondaparinux (Arixtra) contraindicated if CrCl <30 mL/min

**Low suspicion of HIT (Score 0-3 AND/OR NO Heparin Induced Platelet Antibody)**

Start therapeutic fondaparinux (Arixtra) based on patient weight:
- Wt < 50 kg: fondaparinux 5 mg SQ daily
- Wt 50-100 kg: fondaparinux 7.5 mg SQ daily
- Wt > 100 kg: fondaparinux 10 mg SQ daily
- fondaparinux (Arixtra) contraindicated if CrCl <30 mL/min

**High suspicion of HIT (Score ≥ 4 AND/OR Positive Heparin Induced Platelet Antibody)**

Initiate treatment with bivalirudin (Angiomax) 250mg/50mL (Certain rates may require micropump):
- CrCl > 30 mL/min: bivalirudin 0.15 mg/kg/hr IV
- CrCl < 30 mL/min or dialysis (HD/CRRT) patient: bivalirudin 0.06 mg/kg/hr IV
- Adjust bivalirudin infusion per Bivalirudin Dosing Nomogram on Flowsheet and document on bivalirudin monitoring flowsheet
Prescribing and Dispensing: Evaluation of “New” Heparin

- October 1, 2009 FDA notification:
  - New reference standard and test method used to determine the potency of heparin and able to detect impurities that may be present in heparin.

- The change, which will also harmonize the USP unit dose with the WHO International Standard unit dose, will result in approximately a 10% reduction in the potency of the heparin marketed in the United States.5
Initial Plan

• Analysis of current stock allows for transition in December 2009
  — Plan to decrease existing “old” heparin and begin to purchasing “new” heparin
  — Daily monitoring of the current product availability

• Plan to convert all 4 campuses and all locations on the same date

• Letter from the P&T chairs and Medical Director of the Laboratory to educate medical staff of plan

• Medical Director for the Laboratory to attend Cary and Raleigh P&T to discuss plan

• Coordinate with Laboratory when complete change is completed to begin to gather patient samples for analysis
Analysis of Conversion

• 30 clean patients:
  ‒ No other anticoagulants, liver/renal disease, concomitant warfarin
  ‒ Heparin anti-Xa factor assay
• Brill-Edwards⁶ to determine a new UFH therapeutic range for the APTT reagent
• New heparin therapeutic range
  ‒ 55-90 seconds therapeutic
  ‒ ≥100 seconds critical value
Prescribing and Dispensing: Heparin Nomogram Revised

- Modified Nursing Protocol with new ranges
- Bolus caps added for ACS indication
SYSWD Heparin Weight-Based Protocol

DO NOT USE if patient is also receiving GPIIb/IIIa Platelet Inhibitors or Fibrinolytic

DATE: ____________  TIME: ____________

CAUTION: If dalteparin (Fragmin), enoxaparin (Lovenox), Argatroban, fondaparinux (Arixtra), Activase (t-PA), Retavase, or TNKase have been given in last 12 hours, contact MD before initiating these orders. CAUTION: DO NOT USE THESE ORDERS if patient also receiving GPIIb/IIIa Platelet Inhibitors [abciximab (Reopro), epifibatide (Integrilin), or tirofiban (Aggrastat)] follow dosage guidelines on the GPIIb/IIIa Platelet Inhibitor Order.

Initial Loading Dose and Initial Maintenance Dose

☒ ACUTE CORONARY SYNDROME (ACS).

without concomitant GP IIb/IIIa inhibitors or fibrinolytic

☐ Initial Loading Dose: 60 units/kg
   (not to exceed 4,000 units)
☐ Initial Maintenance Dose: 12 units/kg/hr
   (not to exceed 1,000 units/hr)
☐ Adjust Heparin maintenance infusion per Heparin Dosing Nomogram on flowsheet and document on Heparin Monitoring Flowsheet
   ☐ Other Initial Loading Dose: _______units/kg
   ☐ Other Initial Maintenance Dose: _______units/kg/hr
   ☐ No Initial Loading Dose: Give subsequent bolus doses as needed per nomogram on the flowsheet.
   ☐ No Initial Loading Dose: Do not give subsequent bolus doses per nomogram on the flowsheet. Only change the infusion rate per nomogram.

☐ OTHER INDICATIONS - deep vein thrombosis or pulmonary embolism, atrial fibrillation, mechanical valve patients

☐ Initial Loading Dose: 80 units/kg
   (not to exceed 6,000 units)
☐ Initial Maintenance Dose: 16 units/kg/hr
   (not to exceed 1,500 units/hr)
☐ Adjust Heparin maintenance infusion per Heparin Dosing Nomogram on flowsheet and document on Heparin Monitoring Flowsheet
   ☐ Other Initial Loading Dose: _______units/kg
   ☐ Other Initial Maintenance Dose: _______units/kg/hr
   ☐ No Initial Loading Dose: Give subsequent bolus doses as needed per nomogram on the flowsheet.
   ☐ No Initial Loading Dose: Do not give subsequent bolus doses per nomogram on the flowsheet. Only change the infusion rate per nomogram.

1. Patient total body weight: _______kg (use Admission weight or weight specified by provider/MD)
   Please contact physician if current weight is different from admission weight by greater than10kg.

2. Labs:
   ☑ STAT APTT, PT, INR, CBC with platelets (if not already done in the past 24 hours)
   ☑ Timed APTT 6 hours after initiating heparin or after a dose change
   ☑ CBC with platelets q Day x 3 days, then q 3 days while on heparin
   ☑ Timed APTT every 24 hours with AM labs

3. Nursing:
   ☑ Monitor Intake and Output
   ☑ Test stools daily for occult blood while on heparin

4. Notify MD for:
   ■ Signs of significant* bleeding (*blood oozing from IV site, new hematomas, hematuria, positive stool guaiac, hematemesis, hemoptysis)
   ■ APTT greater than 100 and then less than 40
   ■ Wide fluctuations in APTT in patients taking warfarin (Coumadin)
   ■ Two consecutive increases or two consecutive decreases in rate of 200 units/hr or greater
   ■ For confusion/mental status changes or back pain

Protocol initiated per prior order of: __________________________________________________________________________

Transcribed by: ____________________________________________  Checked by (Nurse): ____________________________________________

Date: ____________  Time: ____________  Date: ____________  Time: ____________

Physician: ____________________________  Date: ____________  Time: ____________

Date: ____________  Time: ____________
# SYSWD HEPARIN WEIGHT-BASED PTT/HEPARIN DRIp FLOWSheet

**Patient total body weight** kg (use Admission weight or weight specified by provider/Medical Director).

**Please contact physician if current weight is different from admission weight by greater than 10kg.**

**CAUTION:** If dafarin (Fragmin), enoxaparin (Lovenox), Argatroban, fondaparinux (Arixtra), Activase [tPA], Retevase, or TNKase have been given in last 12 hours, contact MD before initiating these orders.

**CAUTION:** DO NOT USE THESE ORDERS if patient also receiving Glycoprotein Platelet Inhibitors [Abciximab (ReoPro), eptifibatide (Integrilin), or Ilotibabin (Aggrastat)] follow dosage guidelines on the Glycoprotein Platelet Inhibitor Orders.

- [ ] Acute Coronary Syndrome (ACS)
- [ ] Other Indications

## Heparin Dosing Calculations
(Refer to calculations chart)

<table>
<thead>
<tr>
<th>IV Initial Loading Dose</th>
<th>IV Initial Maintenance Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>___ units/kg x ___ kg = ___ units (Round off to the nearest 100 units)</td>
<td>___ units/hr x ___ kg = ___ units/hr (Round off to nearest multiple of 40 units/hr)</td>
</tr>
</tbody>
</table>

- [ ] Other Initial Loading Dose: ___ units/kg
- [ ] Other Initial Maintenance Dose: ___ units/hr

No Initial Loading Dose: Give subsequent bolus doses as needed per nomogram below.

No Initial Loading Dose: Do not give subsequent bolus doses per nomogram below. Only change the infusion rate per nomogram.

Do not exceed maximum loading dose per indication: 4000 units for ACS (Acute Coronary Syndrome), 5000 units for Other Indications.

Concentration for Initial Loading Dose/Initial Bolus Dose: Heparin 1000 units/mL (vial)

Concentration for Maintenance Dose: Heparin 29,000 units/mL 500mL W5W

Initials of nurses verifying: ____________ ____________

Initials of nurses verifying: ____________ ____________

## Heparin Dosing Nomogram

<table>
<thead>
<tr>
<th>APTT (Seconds)</th>
<th>Subsequent Bolus Dose</th>
<th>Hold Heparin</th>
<th>Rate Change</th>
<th>Next APTT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than or equal to 40</td>
<td>60 units/kg (maximum dose = 4000 units for ACS and 6000 units for Other) 60 units/kg x ___ kg = ___ units</td>
<td>0 minutes</td>
<td>Increase rate by 4 units/kg/hr 4 units/kg/hr x ___ kg = ___ units/hr</td>
<td>STAT 6 hours</td>
</tr>
<tr>
<td>41 - 54</td>
<td>No Bolus</td>
<td>0 minutes</td>
<td>Increase rate by 2 units/kg/hr 2 units/kg/hr x ___ kg = ___ units/hr</td>
<td>STAT 6 hours</td>
</tr>
<tr>
<td>55 - 90</td>
<td>NO CHANGE</td>
<td></td>
<td>STAT APTT with AM labs 8h or 2 consecutive results in therapeutic range then</td>
<td></td>
</tr>
<tr>
<td>91 - 99</td>
<td>No Bolus</td>
<td>0 minutes</td>
<td>Decrease rate by 2 units/kg/hr 2 units/kg/hr x ___ kg = ___ units/hr</td>
<td>STAT 6 hours</td>
</tr>
<tr>
<td>Greater than or equal to 100</td>
<td>No Bolus</td>
<td>Hold 60 minutes</td>
<td>Decrease rate by 3 units/kg/hr 3 units/kg/hr x ___ kg = ___ units/hr</td>
<td>STAT 6 hours</td>
</tr>
</tbody>
</table>

Calculations performed by: ____________ Checked by: ____________

Notify MD for:
- Signs of significant bleeding (bleeding from IV site, new hematomas, hematuria, positive stool guaiac, hematemesis, hemoptysis)
- APTT greater than 100 and then less than 40
- Wide fluctuations in APTT in patients taking warfarin (Coumadin)
- Two consecutive increases or two consecutive decreases in rate of 200 units/hr or greater
- Confusion/mental status changes or back pain

**Labs while on Heparin Drip:**
- [ ] STAT APTT, PT/INR, CBC with platelets (if not already done in the past 24 hours)
- [ ] Timed APTT 6 hours after initiating heparin or after a dose change
- [ ] CBC with platelets q Day x 3 days, then q 3 days while on heparin
- [ ] Timed APTT every 4 hours with AM labs

**Patient Identification**

**WakeMed Health and Hospitals**

Systemwide Common Orders: Heparin
Prescribing and dispensing: Bivalirudin Aliquots

• Bivalirudin (Angiomax®) aliquots- cost saving for Acute Coronary Syndrome (ACS)
• Pharmacy prepared in clean room rather than in the catheterization lab
• Efficiency during cases
Pharmacist Role: LMWH P&T protocol

- Syringe size rounding
- Renal Impairment

<table>
<thead>
<tr>
<th>Enoxaparin Dose Range</th>
<th>Enoxaparin Rounded Dose</th>
<th>Syringe to Dispense/Select from Pyxis</th>
<th>Volume to Waste from Appropriate Syringe</th>
<th>Volume to Administer from Appropriate Syringe</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-34 mg</td>
<td>30 mg</td>
<td>30 mg</td>
<td>--</td>
<td>0.3 ml (full syringe)</td>
</tr>
<tr>
<td>35-44 mg</td>
<td>40 mg</td>
<td>40 mg</td>
<td>--</td>
<td>0.4 ml (full syringe)</td>
</tr>
<tr>
<td>45-54 mg</td>
<td>50 mg</td>
<td>60 mg</td>
<td>0.1 ml</td>
<td>0.5 ml</td>
</tr>
<tr>
<td>55-64 mg</td>
<td>60 mg</td>
<td>60 mg</td>
<td>0.1 ml</td>
<td>0.6 ml (full syringe)</td>
</tr>
<tr>
<td>65-74 mg</td>
<td>70 mg</td>
<td>80 mg</td>
<td>0.1 ml</td>
<td>0.7 ml</td>
</tr>
<tr>
<td>75-84 mg</td>
<td>80 mg</td>
<td>80 mg</td>
<td>--</td>
<td>0.8 ml (full syringe)</td>
</tr>
<tr>
<td>85-94 mg</td>
<td>90 mg</td>
<td>100 mg</td>
<td>0.1 ml</td>
<td>0.9 ml</td>
</tr>
<tr>
<td>95-104 mg</td>
<td>100 mg</td>
<td>100 mg</td>
<td>--</td>
<td>1 ml (full syringe)</td>
</tr>
<tr>
<td>105-124 mg</td>
<td>120 mg</td>
<td>120 mg</td>
<td>--</td>
<td>0.8 ml (full syringe)</td>
</tr>
<tr>
<td>125-140 mg</td>
<td>135 mg</td>
<td>150 mg</td>
<td>0.1 ml</td>
<td>0.9 ml</td>
</tr>
<tr>
<td>141-154 mg</td>
<td>150 mg</td>
<td>150 mg</td>
<td>--</td>
<td>1 ml (full syringe)</td>
</tr>
<tr>
<td>155-164 mg</td>
<td>160 mg</td>
<td>two 80 mg syringes</td>
<td>--</td>
<td>0.8 ml x 2 (2 full syringes)</td>
</tr>
<tr>
<td>165-174 mg</td>
<td>170 mg</td>
<td>100 mg + 80 mg syringe</td>
<td>0.1 ml from 80 mg syringe</td>
<td>1 ml + 0.7 ml from 80 mg</td>
</tr>
<tr>
<td>175-184 mg</td>
<td>180 mg</td>
<td>100 mg + 80 mg syringe</td>
<td>--</td>
<td>1 ml + 0.8 ml from 80 mg</td>
</tr>
<tr>
<td>185-215 mg</td>
<td>200 mg</td>
<td>two 100 mg syringes</td>
<td>--</td>
<td>1 ml x 2 (2 full syringes)</td>
</tr>
</tbody>
</table>
Pharmacist role- Adjustment of all Xa levels

• Developed a chart/nomogram on dosing
  — Linear kinetics
  — Peak levels
  — Only current published nomogram in pediatrics and not validated in adults

• Mandatory pharmacy to adjust
  — Nested CPOE order to consult pharmacy is anti-xa level ordered
Inpatient Warfarin, direct thrombin inhibitor, and factor Xa inhibitor monitoring

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Goal INR Range</th>
<th>Conditions that might increase risk of bleeding</th>
<th>Possible warfarin drug interactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVT Treatment</td>
<td>2 - 3</td>
<td>Anemia, A/H O bleeding</td>
<td>Amiodarone</td>
</tr>
<tr>
<td>PE Treatment</td>
<td>2.5 - 3.5</td>
<td>HTN, Renal insufficiency</td>
<td>Antibiotics</td>
</tr>
<tr>
<td>DVT prophylaxis</td>
<td></td>
<td>Hepatic disease</td>
<td>Antifungals</td>
</tr>
<tr>
<td>PE/DVT history</td>
<td></td>
<td></td>
<td>Betamethasone</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mitral mechanical valve</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aortic mechanical valve</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tissue/bioprosthetic valve</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CVA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent Warfarin ADR Bleed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Patient Education

<table>
<thead>
<tr>
<th>Education Needed</th>
<th>YES</th>
<th>NO</th>
<th>Data of Teaching</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated Discharge Date</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Education Methods

- Warfarin Booklet
- Warfarin Video
- Verbal Warfarin
- Enoxaparin Video and Kit
- Enoxaparin Teaching
- Given by RPh RN

**Other:** ____________

**Was NOT an warfarin non-admission?**
- NO
- YES, if yes, non-admission reason: ____________
Patient and Staff Education

• Educational documents
  - Nursing and pharmacy education guides
  - Patient education guides
    - Dabigatran (Pradaxa®)
    - Ticagrelor (Brilinta®)
  - Prescribers
    - Warfarin pocket guide

• Important to do education to medical staff, nursing and pharmacists prior to rolling out to prevent confusion and ensure safety and success
# STANDARDIZED ENOXAPARIN (LOVENOX) INPATIENT COUNSELING FORMAT

FOR NURSING AND PHARMACY USE ONLY- NOT TO BE GIVEN TO PATIENTS

## 1. INDICATION FOR LOVENOX

a. **DVT/PE Treatment:** You have been prescribed enoxaparin (Lovenox) to treat a blood clot in your leg/arm/lungs/etc. Lovenox is a blood thinner that will help prevent the clot from growing and prevent new clots from forming.

b. **DVT/PE Prophylaxis:** You have been prescribed enoxaparin (Lovenox) to prevent a blood clot from forming in your leg/arm/lungs/etc while you are in the hospital, recovering from surgery and/or not as mobile as before.

c. **If patient is also taking warfarin:** You have been prescribed enoxaparin (Lovenox) to prevent blood clots from forming until your warfarin begins to work. Once your physician determines your warfarin is working fully, you will not have to use the Lovenox.

## 2. MONITORING

a. We will monitor your blood while you are in the hospital, but minimal monitoring will be needed once you are discharged.

## 3. HOW TO USE THE MEDICATION

a. **If you feel comfortable injecting yourself,** you can give yourself your own doses. If you do not feel comfortable, have a family member/friend help give you the injection.

b. **Try to give Lovenox and the same time(s) every day.** If you forget a dose, take it as soon as you remember. If it is close to the next dose time, skip the dose. Do not double dose!

c. **To give Lovenox,** follow the steps below:

   1. Whoever administers the dose should wash and dry their hands thoroughly.
   2. Lovenox is available in a pre-filled syringe. Your dose will be determined by your physician. If your dose is less than the total amount in the syringe, you will need to waste the extra amount from the syringe into a sink or trash can **BEFORE** giving yourself the dose (nurses and pharmacists: please see the Lovenox Dose Rounding and Renal Dosing Protocol for the appropriate volume to waste from the syringe).
1. INDICATION FOR WARFARIN

**PE:** You have been prescribed warfarin to treat a blood clot in your leg/arm/lungs/etc. Warfarin is a blood thinner that will help prevent the clot from growing and prevent new clots from forming.

**Atrial fibrillation:** You have been prescribed warfarin to prevent strokes. You have a heart rhythm called atrial fibrillation. When your heart is in this rhythm, it doesn’t pump blood normally. Instead, the top part of the heart quivers. Since it is not pumping normally, blood tends to get stuck in parts of the heart. Whenever blood sits around, it tends to clot. If a clot formed, there is a chance that it could be pumped into the vessels in your brain, causing a stroke. Warfarin thins the blood, making it less likely to clot and thus reducing your risk of stroke.

**Prevention of DVT/PE:** You have been prescribed warfarin to prevent a blood clot from forming in your legs/arms/lungs/etc. Whenever you are inactive for long periods of time (like after surgery), blood doesn’t move as well throughout the body. Sometimes blood can pool in one spot. When blood sits around, it tends to clot. Warfarin thins the blood, making it less likely to clot.

**Secondary prevention of ischemic stroke:** You have been prescribed warfarin to prevent another stroke. Warfarin is a drug that thins the blood, making it less likely to clot. This reduces the likelihood that another clot will form in your brain, causing another stroke.

**Post-myocardial infarction:** You have been prescribed warfarin to prevent a blood clot from forming in your heart. Sometimes after a heart attack, the heart doesn’t work as well as normal. This may be permanent or it may only be temporary and will go away after the heart recovers. Until the heart pumps normally, blood can get stuck in the parts that aren’t working as well. When blood sits around, it tends to clot. If a clot formed, there is a chance that it could be pumped into the vessels in your brain, causing a stroke. Warfarin thins the blood, making it less likely to clot and thus reducing your risk of stroke.
**Why do I need Pradaxa?**

- You have a heart rhythm that has an irregular, rapid heartbeat called atrial fibrillation. When your heart is

- Do not break, chew, or open the capsule and empty the pellets from the capsule; always swallow whole.

- You can take it with or without food.
Guidelines for the Initiation and Monitoring of Warfarin (Coumadin®) in Adult Patients
Measure:

% Warfarin Patients with Baseline INR

[Graph showing the percentage of Warfarin patients with baseline INR, with data points for Oct-11, Nov-11, Dec-11, and Jan-12.]
Measure:

% Patients with Pharmacist Documented Anticoagulation Education
Measure Others:

- **Outcome:**
  - INRs $\geq 5$ and PTT $\geq 200$ (alternative: anti-Xa levels) with a denominator of the number of patients with an order for warfarin or heparin drips

- **Process:**
  - % of INR/PTT in the desired range, high, and low
  - % of discharged patients with a f/u appt within 3 days
  - Patient education
  - Adherence to protocols
  - Referrals to a warfarin clinic
Warfarin Transitions

- Bridge Therapy
- Medication Reconciliation
- Transition Clinics
Warfarin Transitions

• Bridge Therapy
  — Pharmacist to dose and monitor enoxaparin therapeutic bridging
  — Required pharmacist counseling of patients with enoxaparin kit sent home with concomitant enoxaparin/warfarin bridge
  — Pharmacy Technician
    ➢ Patient Assistance Program
      – Enrolls enoxaparin patients as needed
      – Enrolls in other programs such as fondaparinux
Warfarin Transitions

• Medication Reconciliation
  — Pharmacist monitoring includes finding out home dose of warfarin as initial monitoring step
  — Calls pharmacy, reviews home bottles, interviews patients/families
  — Medication History Technicians in emergency department
Warfarin Transitions

• Re-Admissions
  — Sheets kept for 1 year after patient discharge
  — Pharmacists instructed to retrieve old sheets to review trends with warfarin dosing if patients readmitted
References

1. http://www.jointcommission.org/assets/1/18/SEA_41.PDF
Homework for Next Call

- Review your system for ensuring safety with Anticoagulant
- Examine standardized processes around anticoagulation medication. If in place, are processes used as designed?
- Identify one change you will test to improve management of one of the anticoagulants.
- What outcome and process measures are you using, or will use?
Next Call

Session 5 - Medication Reconciliation and Health Literacy

Date: Tuesday, March 13th
12:00-1:00pm ET
Listserv

- ade_expedition@ls.ihi.org
- Send and receive questions and comments to/from faculty and participants
- To be added to the listserv please email bodonnell@ihi.org