Strategies for anticoagulation safety: National patient safety goals and beyond

Thursday December 11, 2008

ASHP Midyear Clinical Meeting

Lori L Schirmer, PharmD, BCPS

Objectives

- Describe methods to help enhance patient safety with anticoagulant medications
- Formulate teamwork skills among providers to enhance communication and create a safer patient environment
- Describe how one institution planned and developed an anticoagulation drug therapy management program and reflect on the incorporation of student pharmacists as monitors for anticoagulation therapy

NPSG.03.05.01

- "Reduce the likelihood of harm associated with the use of anticoagulant therapy."
  - "Anticoagulation therapy poses risks to patients and often leads to adverse drug events due to complex dosing, requisite follow-up monitoring, and inconsistent [patient] compliance."
  - "The use of standardized practices for anticoagulation therapy that include [patient] involvement can reduce the risk of adverse drug events associated with the use of heparin (unfractionated), low molecular weight heparin, and warfarin."

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Applicability

- "This requirement applies only to [organization]s that provide anticoagulant therapy and/or long-term anticoagulation prophylaxis where the clinical expectation is that the [patient]'s laboratory values for coagulation will remain outside normal values."
- "This requirement does NOT apply to routine situations in which short-term prophylactic anticoagulation is used for venous thrombo-embolism prevention and the clinical expectation is that the [patient]'s laboratory values for coagulation will remain within, or close to, normal values."

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Phase-In Deadlines

- April 1, 2008 - Responsibility assigned
- July 1, 2008 - Work plan in place
- October 1, 2008 - Pilot testing started
- January 1, 2009 - Process is fully implemented across the organization

Responsibility Assigned

- Executive Sponsors
  - Sharon Meyer, PharmD, MS, Ex Director Pharmacy
  - Kathie Nessa, Director Clinical Quality
- Team Leader
  - Angela Boord, PharmD, CDE
- Improvement Advisor
  - Linda Smith, PT, CIA

Team Members

- Nutrition
  - Heidi Mergen, RD
- Pharmacy
  - Gary Clark, PharmD
  - Lori Schirmer, PharmD, BCPS
- Clinical Lab
  - Jackie Ferguson
- Education
  - Mary Wood, RN
- Nursing
  - Erin Gittins, RN
  - Kristi Braafhart, RN
  - Roxanne Ackerson, RN
- Physician Staff
  - Rebecca Lachenmaier, MD
  - Michael Luepke, MD
  - David Vittetoe, MD

Performance Element 1

- "The hospital implements a defined anticoagulation management program to individualize the care provided to each patient receiving anticoagulant therapy."

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Performance Element 1 IHS DSM

- Organization's leadership realizes the importance and supports all expectations with sufficient resources
- Organization's medical staff acknowledges their role in meeting implementation expectations
- The organization has a written plan that addresses all implementation expectations for NPSG 3E
- Performance indicators have been developed and baseline is measured

Performance Element 2

- "To reduce compounding and labeling errors, the hospital uses only oral unit dose products, pre-filled syringes, or pre-mixed infusion bags when these types of products are available. Note: For pediatric patients, pre-loaded syringe products should only be used if specifically designed for children."

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Performance Element 2 IHS DSM

- Only unit dose oral anticoagulants including ½ tabs are available for use in the organization
  - Pharmacy will unit dose package 0.5mg tablets, all others commercially available in unit dose package
  - Heparin infusions will be administered with premixed solutions

Performance Element 3

- "The hospital uses approved protocols for the initiation and maintenance of anticoagulant therapy appropriate to the medication used, to the condition being treated, and to the potential for medication interactions."

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Performance Element 3 IHS DSM

- There is a written, medical staff approved anticoagulant therapy protocol for each anticoagulant specific to the age of the patient and the condition being treated including potential drug interactions. Protocols address ordering, dosing, administration and monitoring.

Performance Element 3 IHS DSM

- Currently approved protocols for warfarin and heparin:
  - Warfarin (also includes order sets that include warfarin)
  - Vitamin K
  - Heparin for ACS
  - Heparin for Stroke or High Risk (no bolus)
  - Heparin (with bolus)

Performance Element 3 IHS DSM

- Written policy concerning all other therapeutic anticoagulants includes:
  - Approved order sets must be used for the following anticoagulants:
    - Eptifibatide
    - Bivalrudin
    - Argatroban
    - Abciximab
  - The prescriber shall be contacted if an order for one of the above anticoagulants does not utilize one of the approved order sets

Performance Element 3

- Measure of success with this element is required

Performance Element 4

- "For patients starting on warfarin, a baseline INR is available, and for all patients receiving warfarin therapy, a current INR is available and is used to monitor and adjust this therapy."

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Performance Element 4 IHS DSM

- Written policy concerning warfarin includes:
  - Indication for warfarin and goal INR shall be documented in the medical record
  - Required monitoring for all warfarin therapy in acute care areas shall be baseline and daily INR, baseline and every three days Hgb
  - All warfarin orders in acute care areas shall be one time only orders
  - INR results shall be taken into account with doses of warfarin adjusted accordingly

Performance Element 4 IHS DSM

- The above may be achieved by:
  - Completion of the warfarin order set by a prescriber
  - Prescriber order for Pharmacy to manage warfarin
  - Prescriber orders for all of the required elements
- The prescriber shall be contacted if an order does not include all the required elements

Performance Element 5

- "When dietary services are provided by the hospital, the service is notified of all patients receiving warfarin and responds to its established food/medication interaction program"

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Performance Element 5 IHS DSM

- Dietary is provided with a list of patients receiving warfarin each day
- Pharmacy is consulted to provide education for new warfarin starts
- Dietary provides education and monitoring of food and nutritional supplements
- Dietary services are documented in the patient's medical record

Performance Element 5

- Measure of success with this element is required

Performance Element 6

- "When heparin is administered intravenously and continuously, the hospital uses programmable infusion pumps in order to provide consistent and accurate dosing."

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Performance Element 6 IHS DSM

- Written policy requires programmable infusion pumps for all heparin infusions
- Smart pumps will be available in 2009

Performance Element 7

- "The hospital has a written policy that addresses baseline and ongoing laboratory tests that are required for heparin and low molecular weight heparin therapies."

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Performance Element 7 IHS DSM

- Written policy concerning heparin includes:
  - Prescribers shall use one of the approved order sets for all heparin infusions
  - The prescriber shall be contacted if a heparin infusion order does not utilize one of the approved order sets

Performance Element 7 IHS DSM

- Written policy concerning LMWH includes:
  - LMWH orders shall include baseline and weekly SCr, baseline and every three days Hgb and plt
  - The prescriber shall be contacted if an order does not include all the required elements

Performance Element 8

- "The hospital provides education regarding anticoagulant therapy to prescribers, staff, patients and families."
  - Patient and family education includes
    - Importance of follow-up monitoring
    - Compliance issues
    - Dietary restrictions
    - Potential for adverse drug reactions and interactions

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Performance Element 8 IHS DSM

- Training is provided to prescribers, staff, patients and families
- Training and competence is documented

Performance Element 8

- Measure of success with this element is required

Performance Element 9

- "The hospital evaluates its anticoagulation safety practices, takes appropriate action to improve its practices and measures the effectiveness of those actions on a regular basis."

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Performance Element 9 IHS DSM

- Performance indicators are measured and compared to baseline
- Improvements to the program are made based on program evaluation
- Improvements are evaluated for effectiveness

Scorecard for IHS DSM

- 1 partially met, ongoing measurements
- 2 met
- 3 partially met, ongoing measurements
- 4 ongoing measurements on pilot units
- 5 partially met, ongoing measurements
- 6 met
- 7 partially met, ongoing measurements
- 8 education tool standardization and development ongoing
- 9 ongoing measurements

Measurements to date

- ILH ~450 doses warfarin/month
- IMMC ~1000 doses warfarin/month
- Pilot floors collecting data now
  - % compliance with lab monitoring
  - % compliance with warfarin one-time orders
  - % compliance with documentation

What do we need done?

- Monitoring
  - Lab values
  - Communication of abnormal values
- Education
  - Interview patients
  - Provide patient and staff education
- Quality
  - Collect data on performance measures

Skills/Knowledge required

- Pharmacology anticoagulants
- Communication skills
- Medical record
- Electronic chart
- Laboratory values
- Patient interview skills

Student schedule

- 0800 to 1000 MWF
- 1200 to 1400 TR
- 2 P2 students + 1 P4 student IMMC
- 2 P2 students + 1 P4 student ILH

Pre Rotation Preparation

- Syllabus
  - Competencies
- Lecture
- Test

Objectives

- Demonstrate skills in Drug Therapy Problem-Solving, Communication, and Professionalism.
- Monitor anticoagulation of patients under guidance of P4 students and preceptor at each site.
- Work with the pharmacist or P4 student in order to understand the process of making changes to anticoagulation therapy.
- Utilize charts and/or electronic records to collect subjective and objective information for one patient to enter into PEMS.
- P2 student should understand the process used for the pharmacist to document interventions and the method that the pharmacist uses to request changes in drug therapy.

Student Competencies

- Drug Therapy Problem Solving
  - 1.1-2 compiles patient-specific information
- Communication
  - 2.2-2 asks pertinent and relevant questions for obtaining unknown information from colleagues, health professionals, and patients
  - 2.2-3 uses appropriate formal writing techniques when preparing reports or documents
  - 2.2-4 demonstrates appropriate professional communication when interacting with patients, pharmacists, staff, and other health professionals
  - 2.3-1 uses appropriate literature to acquire new knowledge
  - 2.3-2 organizes material and is understood by target audience

Student Competencies

- Product and Service Management
  - 3.3-1 retrieve patient information from the computer system to appropriately interpret and analyze medication orders/prescriptions
  - 3.3-4 obtains prescriber information as required
- Professionalism
  - 4.1-1 comprehends and uses appropriate methods for discovering new knowledge
  - 4.1-2 uses initiative in achieving learning goals as identified in the rotation experience
  - 4.2-1 incorporates a holistic view of the **patient care**
  - 4.2-2 accepts personal responsibility for patient care
  - 4.2-3 makes decisions consistent with current ethical and legal standards of the profession
  - 4.2-4 work habits demonstrate punctuality, the ability to prioritize work and manage time efficiently

Student Activities

- Identify current patients from Pyxis report
- Fill out initial history form
- Fill out monitoring form
- Communicate abnormal values
- Chart review

Monitoring Forms

PHARMACY REVIEW (Pg. 1)

Today's Date:_____
Reviewer Initials: _____

Admission Date: _____
Discharge Date: _____(fill out when discharged)

Patient Name: _____
Room Number: _____ **Gender:** _____
Account Number: _____ **Age:** _____
MRN: _____ **DOB:** _____

Indication for Coumadin/Lovenox (why are they on these drugs?):
_____

Baseline lab values (labs drawn before first dose of warfarin or LMWH)
(Check Y or N)
Hemoglobin: ☐ Y ☐ N
Hematocrit: ☐ Y ☐ N
Platelets: ☐ Y ☐ N
Serum Creatinine: ☐ Y ☐ N
INR: ☐ Y ☐ N

Height: _____
Weight: _____
Calculated Ideal Body Weight:_____
Calculated Adjusted Body Weight: _____

Monitoring Forms

Home Warfarin (Y or N) _____
Home Dose Regimen: _____

Goal INR Range: _____ (Coumadin only)

Patient education provided on date:_____
Education provided by: ☐ Nurse ☐ Pharmacist ☐ PharmD Student ☐ Physician ☐ Other_____

Please check which drug(s) the patient is receiving
☐ Warfarin (Coumadin)
Policy requirements:
New written order for dose each day e.g. Coumadin 7mg PO today
Baseline, then daily INR
Baseline, then at least every three days Hgb

☐ Enoxaparin (Lovenox)
Policy requirements:
Baseline, then at least every seven days Scr
Baseline, then at least every three days Hgb and platelet count

Monitoring Forms

Patient Name_____
MR#_____ Acct #_____

PHARMACY REVIEW (Pg. 2)

Date	Physician Name	Coumadin dose (mg)	Daily order or once or today?	INR	Hgb	Hct	Plt count	Lovenox dose (mg)	Daily or q12?	Scr	CrCl	Interventions (describe) May attach additional sheet if needed – please date	initials

Student-Identified Interventions

- Drug interaction monitoring at ILH
  - 95 drug interactions were noted with 34 of these interactions classified as major (aspirin, simvastatin, acetaminophen, citalopram, escitalopram, clopidogrel, leflunomide, SMX/TMP)
- Dosage adjustments for CrCl at IMMC
  - 4 patients identified with CrCL <30mL/min

Database

- Access database
- Track performance elements
  - Education
  - Lab monitoring
  - Compliance by unit or prescriber

Reports

- Access database
- Reports
  - Education: who, when
  - Process measures
  - Prescriber education
  - Outcomes: INRs >5 (critical lab)

Questions?

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Anticoagulants

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Learning Objectives

- Identify relative risks associated with anticoagulant medications
- Describe strategies to evaluate the success or areas of improvement in an anticoagulant drug therapy management program

Risks Associated with Anticoagulant Medications

- ✓ National Patient Safety Goals (NPSG) of 2009 (from The Joint Commission) outlined changes to effect medication safety through the NPSG.03.05.01 which is to reduce the likelihood of patient harm associated with the use of anticoagulation therapy.
- ✓ Note: This requirement applies only to organizations that provide anticoagulant therapy and/or long-term anticoagulation prophylaxis (for example, atrial fibrillation) where the clinical expectation is that the patient's laboratory values for coagulation will remain outside normal values. This requirement does not apply to routine situations in which short-term prophylactic anticoagulation is used for venous thrombo-embolism prevention (for example, related to procedures or hospitalization) and the clinical expectation is that the patient's laboratory values for coagulation will remain within, or close to, normal values.

http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/09_hap_npsgs.htm

Rationale for NPSG.03.05.01

Anticoagulation therapy poses risks to patients and often leads to adverse drug events due to complex dosing, requisite follow-up monitoring, and inconsistent [patient] compliance. The use of standardized practices for anticoagulation therapy that include patient involvement can reduce the risk of adverse drug events associated with the use of heparin (unfractionated), low molecular weight heparin, and warfarin.

Accreditation Program: Hospital Chapter: National Patient Safety Goals. *The Joint Commission on Accreditation of Healthcare Organizations*, 2008. pages 10-11.

Experiences Specific to Iowa Health – Des Moines (IH-DM)

IH-DM is composed of three hospitals:

- ✓ Iowa Lutheran Hospital – a community hospital with 219 staffed beds
- ✓ Iowa Methodist Medical Center – a level three trauma center with 356 staffed beds
- ✓ Blank Children's Hospital – pediatric hospital with 88 staffed beds

The pharmacy department services all three hospitals with a staff of 50 pharmacists.

Role of Pharmacist at IH-DM

- ✓ Medications are dispensed through *Pyxis* system with decentralized pharmacists entering scanned orders on floors/units.
- ✓ All floor-based pharmacists are responsible for clinical activity including renal dose monitoring, parenteral nutrition management, IV to PO adjustments, pharmacokinetic dosing, and palliative care recommendations.
- ✓ Three pharmacists are Patient Education Pharmacists and provide diabetic education (all have CDE's) along with patient education for warfarin and low molecular weight heparin (LMWH) injection training.
- ✓ IMMC has two PGY-1 Pharmacy residents and the many of the pharmacists precept experiential students from Drake and Creighton.

Adverse Drug Reactions (ADR's) Involving Anticoagulants at IH-DM

Pharmacists documented ADR's over a 12 month period (Jul 07 – Jun 08) and found 113 anticoagulant associated reactions.

IH-DM categorizes ADR's into 6 levels with the following results:

- ✓ Level 1- ADR occured but required no change in treatment with suspected drug = 2 (all occurred within the hospital)
- ✓ Level 2 - Drug held, dc'd or changed but no additional treatment needed = 11 (5 occurred within the hospital)
- ✓ Level 3 - Drug held, dc'd or changed AND/OR antidote or other treatment required = 67 (27 occurred within the hospital)
- ✓ Level 4 - ADR required patient transfer to an intensive or emergent care setting = 28 (3 occurred within the hospital)
- ✓ Level 5 - ADR caused permanent harm to patient = 0
- ✓ Level 6 - either directly or indirectly lead to patient death = 5 (one occurred within the hospital)

Anticoagulant ADR's at IH-DM

ADR's during the 12 month period based on type of anticoagulant:

IH-DM Anticoagulation Adverse Drug Reactions
12 Months (July 07 to June 08)

Level of ADR	Warfarin	LMWH	Heparin	Clopidogrel	ASA	*Aggrenox*	Total*	Total ADR's
1	2	0	0	0	0	0	2	2
2	8	0	3	0	0	0	11	11
3	55	3	1	4	7	1	71	67
4	25	2	2	0	2	0	31	28
6	5	1	0	2	0	0	8	5
Total	95	6	6	6	9	1	123	113

* Note: some ADR's had more than one medication involved

Concerns with Antithrombotics

Medications that reduce or prevent thrombosis can cause significant bleeding. Those agents that are on the IH-DM formulary include:

- ✓ *anticoagulants* – warfarin, heparin, low-molecular-weight heparins (enoxaparin, dalteparin), and direct thrombin inhibitors (argatroban, bivalirudin)
- ✓ *antiplatelets* - thienopyridines (clopidogrel) and glycoprotein IIb/IIIa inhibitors (eptifibatide, abciximab)

Excluding warfarin (reversal agent is vitamin K) and heparin (reversal agent is protamine), there are not specific antidotes to reverse the other antithrombic agents.

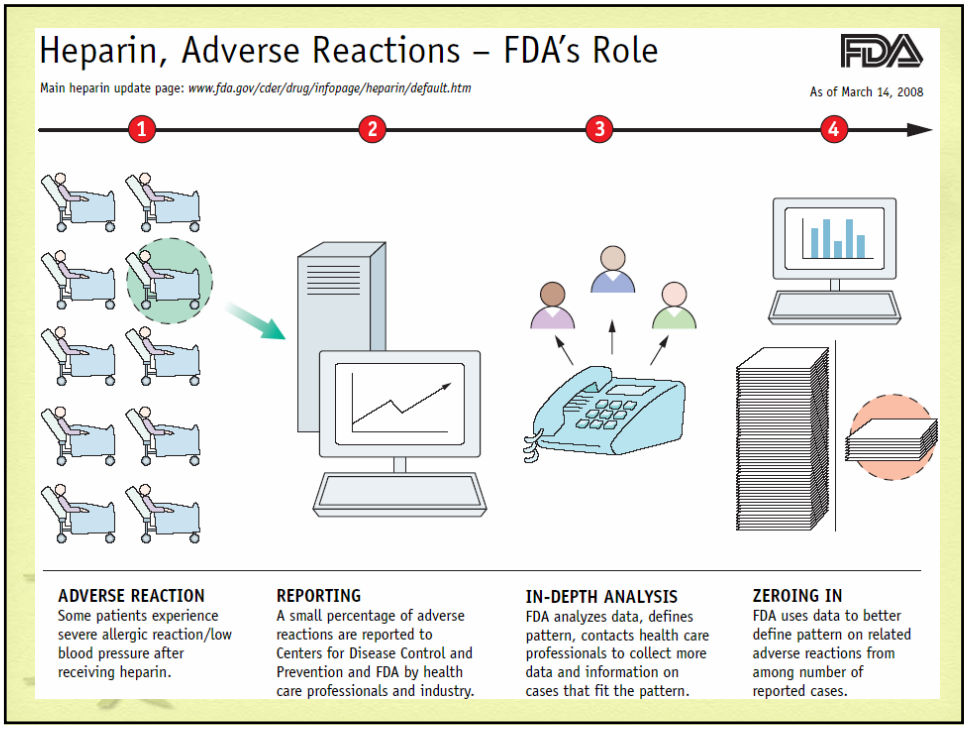
Concerns with Heparin

Number of Deaths of Patients Receiving Heparin Reported to FDA, January 1, 2006 through May 31, 2008

Quarter the Medical Event(s) Occurred	Number of Reported Deaths*	Reported Deaths with One or More Allergic/Hypotensive Symptom(s)
2006	55	3
1st Quarter 2007	13	6
2nd Quarter 2007	15	7
3rd Quarter 2007	13	9
4th Quarter 2007	56	39
1st Quarter 2008	113	71
Apr-08	7	4
May-08	5	3
Unknown Date	24	10
Total	**301**	**152**

*The reports in this table concern heparin produced by any manufacturer.

http://www.fda.gov/cder/drug/infopage/heparin/adverse_events.htm



Concerns with LMWH

- ✓Low Molecular Weight Heparin (LMWH) is an alternative to heparin but is not without risks.
- ✓The two used at IH-DM, enoxaparin (*Lovenox*) and dalteparin (*Fragmin*) can cause increased risk for bleeding events.
- ✓Enoxaparin needs to be adjusted for renal function to avoid the risk of significant bleeding and should be adjusted for lower weight or higher weight patients.

Concerns with Antiplatelets

- ✓ Injectable antiplatelets, such as the longer acting abcximiab (*Reopro*) and the shorter acting Eptifibatide (*Integrilin*), can cause significant bleeding problems.
- ✓ At IH-DM, initiation of these agents is limited to ED or Cath Lab and can only be ordered by a restricted order form.
- ✓ Due to potential for bleeding, especially with falls, ambulation of a patient is not allowed until at least 2 hours after an infusion has been discontinued

Concerns with Warfarin

Warfarin (*Coumadin, Jantoven*) accounts for the majority of anticoagulant associated adverse reactions at IH-DM.

The pharmacy department has evaluated the use of warfarin several times and has found concerns with the use of Vitamin K, and with the dosing and monitoring of warfarin.

Current practice at IH-DM

Heparin – due to the concern about different concentrations of heparin available and the potential for the use of wrong strength vials, IH-DM has limited the use of heparin by allowing only certain heparin concentrations to be used in different areas. IH-DM does not carry 10,000 unit/mL vials, nor 100 unit/mL flush vials (only the syringes for flushes are available), and the 1000 unit/mL 2mL vials were removed from NICU.

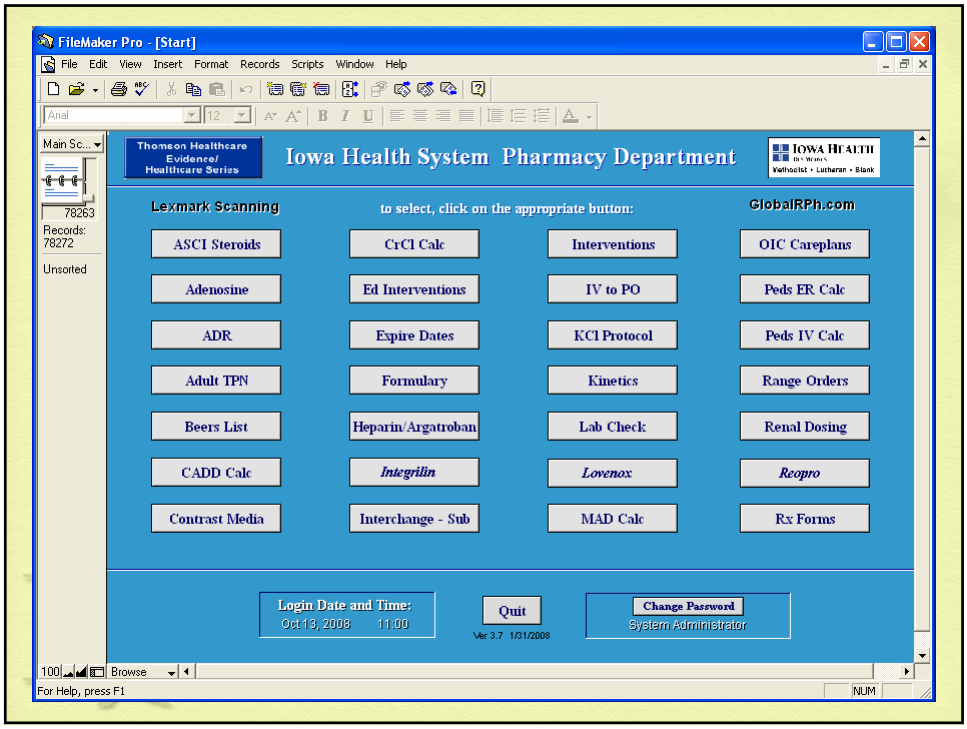
Warfarin – all potential doses of warfarin are available through the pharmacy and are stocked in the automated *Pyxis* machines.

Current practice at IH-DM

Rx Calc – is a home-grown database program that is used for the heparin orders, *Intergilin* and *Reopro* orders, and HIT plus *Argatroban* orders on all patients.

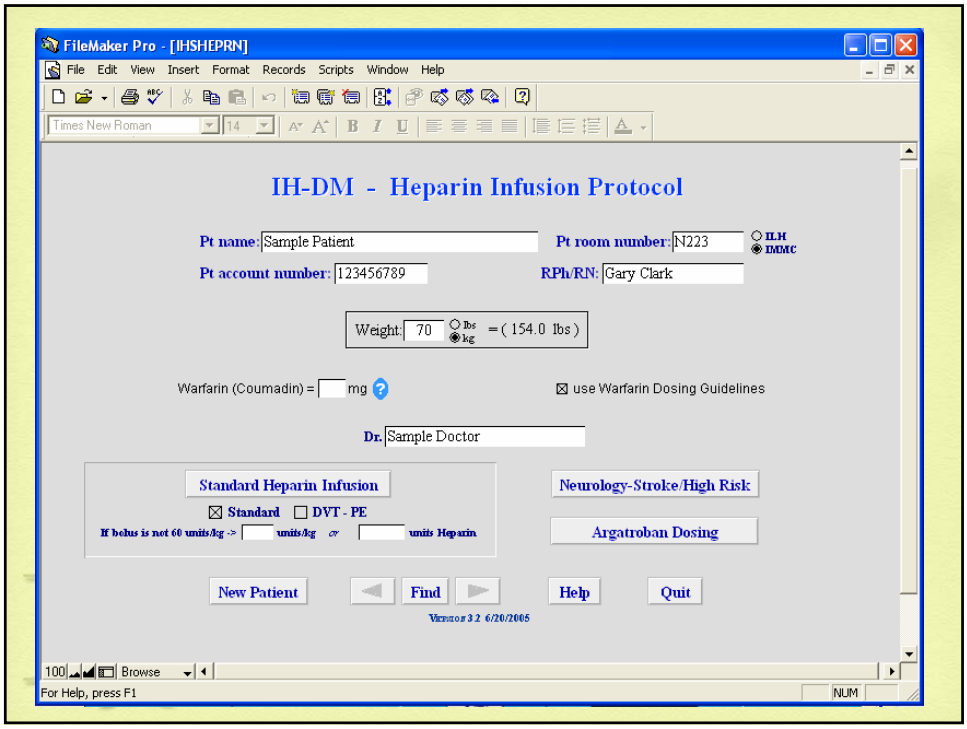
All calculations on infusion adjustments are done by the computer and the orders are clearly printed with all information clear.

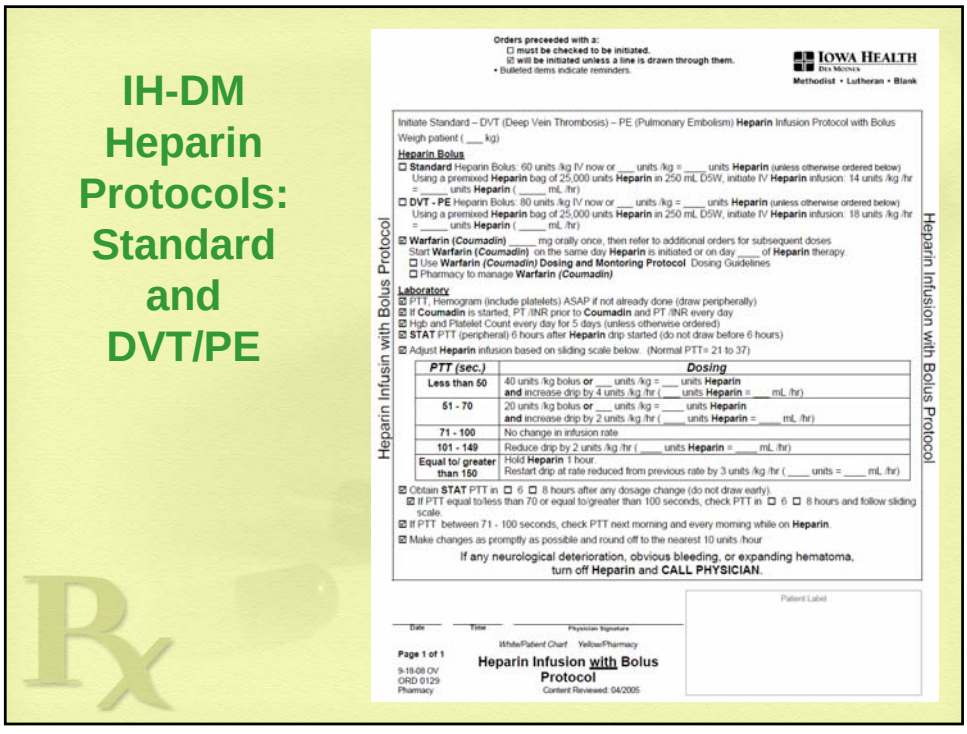
Also is used as database to track all variables associated with the orders.



Current practice at IH-DM

- ✓ Heparin protocol order sets that have been in use for several years and are generated through a program in the pharmacy department (Rx Calc) that calculates changes in drip rates based on aPTT's. There are currently 3 unique heparin orders:
  - *Heparin Infusion with Bolus* - for standard or DVT/PE treatment
  - *Neurology/Stroke/High Risk Heparin Infusion without Bolus Protocol*
  - *IV Heparin Protocol: Acute Coronary Syndrome (ACS)* – restricted to use in the cath lab and with the use of *Integrilin*


FileMaker Pro - [IHSHEPRN]
File Edit View Insert Format Records Scripts Window Help
IH-DM - Heparin Infusion Protocol
Pt name: Sample Patient
Pt room number: N223
ILH
IMMC
Pt account number: 123456789
RPh/RN: Gary Clark
Weight: 70 lbs kg = (154.0 lbs)
Warfarin (Coumadin) = mg
use Warfarin Dosing Guidelines
Dr. Sample Doctor
Standard Heparin Infusion
Standard DVT - PE
If bolus is not 60 units/kg -> units/kg or units Heparin
Neurology-Stroke/High Risk
Argatroban Dosing
New Patient
Find
Help
Quit
Version 3.2 6/20/2005
Browse
For Help, press F1
NUM


IH-DM Heparin Protocols: Standard and DVT/PE
Orders preceeded with a:
must be checked to be initiated.
will be initiated unless a line is drawn through them.
• Bulleted items indicate reminders.
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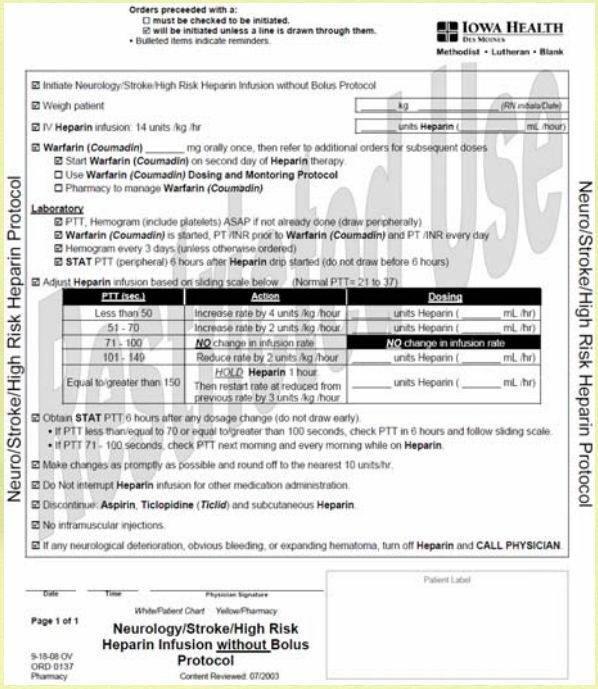
Initiate Standard – DVT (Deep Vein Thrombosis) – PE (Pulmonary Embolism) Heparin Infusion Protocol with Bolus
Weigh patient (___ kg)
Heparin Bolus
Standard Heparin Bolus: 60 units /kg IV now or ___ units /kg = ____ units Heparin (unless otherwise ordered below)
Using a premixed Heparin bag of 25,000 units Heparin in 250 mL D5W, initiate IV Heparin infusion: 14 units /kg /hr = ____ units Heparin (_____ mL /hr)
DVT - PE Heparin Bolus: 80 units /kg IV now or ___ units /kg = ____ units Heparin (unless otherwise ordered below)
Using a premixed Heparin bag of 25,000 units Heparin in 250 mL D5W, initiate IV Heparin infusion: 18 units /kg /hr = ____ units Heparin (_____ mL /hr)
Warfarin (Coumadin) _____ mg orally once, then refer to additional orders for subsequent doses
Start Warfarin (Coumadin) on the same day Heparin is initiated or on day ____ of Heparin therapy.
Use Warfarin (Coumadin) Dosing and Montoring Protocol Dosing Guidelines
Pharmacy to manage Warfarin (Coumadin)
Laboratory
PTT, Hemogram (include platelets) ASAP if not already done (draw peripherally)
If Coumadin is started, PT /INR prior to Coumadin and PT /INR every day
Hgb and Platelet Count every day for 5 days (unless otherwise ordered)
STAT PTT (peripheral) 6 hours after Heparin drip started (do not draw before 6 hours)
Adjust Heparin infusion based on sliding scale below. (Normal PTT= 21 to 37)
PTT (sec.) | Dosing
Less than 50 | 40 units /kg bolus or ___ units /kg = ___ units Heparin and increase drip by 4 units /kg /hr (___ units Heparin = ___ mL /hr)
51 - 70 | 20 units /kg bolus or ___ units /kg = ___ units Heparin and increase drip by 2 units /kg /hr (___ units Heparin = ___ mL /hr)
71 - 100 | No change in infusion rate
101 - 149 | Reduce drip by 2 units /kg /hr (___ units Heparin = ___ mL /hr)
Equal to/ greater than 150 | Hold Heparin 1 hour. Restart drip at rate reduced from previous rate by 3 units /kg /hr (___ units = ___ mL /hr)
Obtain STAT PTT in 6 8 hours after any dosage change (do not draw early).
If PTT equal to/less than 70 or equal to/greater than 100 seconds, check PTT in 6 8 hours and follow sliding scale.
If PTT between 71 - 100 seconds, check PTT next morning and every morning while on Heparin.
Make changes as promptly as possible and round off to the nearest 10 units /hour
If any neurological deterioration, obvious bleeding, or expanding hematoma, turn off Heparin and CALL PHYSICIAN.
Heparin Infusin with Bolus Protocol
Heparin Infusion with Bolus Protocol
Date
Time
Physician Signature
White/Patient Chart Yellow/Pharmacy
Patient Label
Page 1 of 1
9-18-08 OV
ORD 0129
Pharmacy
Heparin Infusion with Bolus Protocol
Content Reviewed: 04/2005

IH-DM Heparin Protocols: no Bolus



Orders preceded with a:
☐ must be checked to be initiated.
☑ will be initiated unless a line is drawn through them.
• Bulleted items indicate reminders.

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Neuro/Stroke/High Risk Heparin Protocol

☑ Initiate Neurology/Stroke/High Risk Heparin Infusion without Bolus Protocol
☑ Weigh patient _____ kg _____ (RN initials/Date)
☑ IV **Heparin** infusion: 14 units /kg /hr _____ units **Heparin** (_____ mL /hour)
☑ **Warfarin (*Coumadin*)** _____ mg orally once, then refer to additional orders for subsequent doses
☑ Start **Warfarin (*Coumadin*)** on second day of **Heparin** therapy.
☐ Use **Warfarin (*Coumadin*) Dosing and Monitoring Protocol**
☐ Pharmacy to manage **Warfarin (*Coumadin*)**

Laboratory
☑ PTT, Hemogram (include platelets) ASAP if not already done (draw peripherally)
☑ **Warfarin (*Coumadin*)** is started, PT /INR prior to **Warfarin (*Coumadin*)** and PT /INR every day
☑ Hemogram every 3 days (unless otherwise ordered)
☑ **STAT** PTT (peripheral) 6 hours after **Heparin** drip started (do not draw before 6 hours)

☑ Adjust **Heparin** infusion based on sliding scale below (Normal PTT= 21 to 37)

PTT (sec.)	Action	Dosing
Less than 50	Increase rate by 4 units /kg /hour	units Heparin (_____ mL /hr)
51 - 70	Increase rate by 2 units /kg /hour	units Heparin (_____ mL /hr)
71 - 100	***NO*** change in infusion rate	***NO*** change in infusion rate
101 - 149	Reduce rate by 2 units /kg /hour	_____ units Heparin (_____ mL /hr)
Equal to/greater than 150	*HOLD* **Heparin** 1 hour. Then restart rate at reduced from previous rate by 3 units /kg /hour	_____ units Heparin (_____ mL /hr)

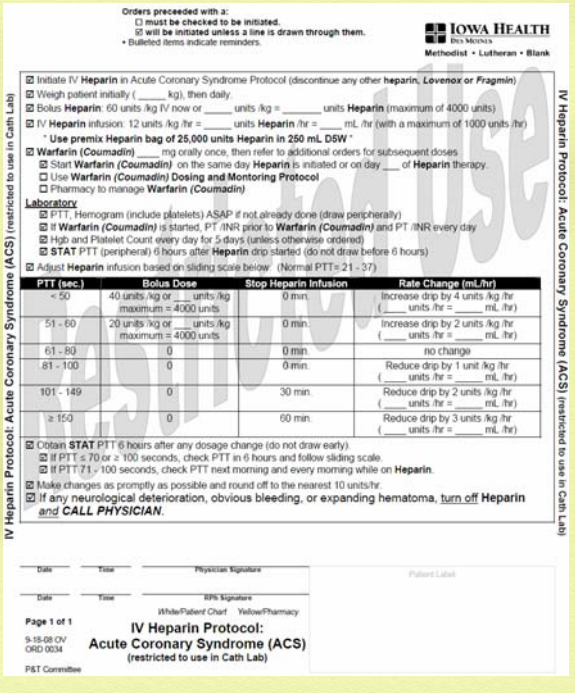
☑ Obtain **STAT** PTT 6 hours after any dosage change (do not draw early).
• If PTT less than/equal to 70 or equal to/greater than 100 seconds, check PTT in 6 hours and follow sliding scale.
• If PTT 71 - 100 seconds, check PTT next morning and every morning while on **Heparin**.
☑ Make changes as promptly as possible and round off to the nearest 10 units/hr.
☑ Do Not interrupt **Heparin** infusion for other medication administration.
☑ Discontinue: **Aspirin**, **Ticlopidine** (***Ticlid***) and subcutaneous **Heparin**.
☑ No intramuscular injections.
☑ If any neurological deterioration, obvious bleeding, or expanding hematoma, turn off **Heparin** and **CALL PHYSICIAN**.

Date Time Physician Signature
White/Patient Chart Yellow/Pharmacy
Page 1 of 1
Patient Label
9-18-08 OV
ORD 0137
Pharmacy

Neurology/Stroke/High Risk Heparin Infusion without Bolus Protocol
Content Reviewed: 07/2003

Restricted to use in Cath Lab

IH-DM Heparin Protocols: Acute Coronary Syndrome (ACS)



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IV Heparin Protocol: Acute Coronary Syndrome (ACS) (restricted to use in Cath Lab)

☑ Initiate IV **Heparin** in Acute Coronary Syndrome Protocol (discontinue any other **heparin, *Lovenox* or *Fragmin***)
☑ Weigh patient initially (_____ kg), then daily.
☑ Bolus **Heparin**: 60 units /kg IV now or _____ units /kg = _____ units **Heparin** (maximum of 4000 units)
☑ IV **Heparin** infusion: 12 units /kg /hr = _____ units **Heparin** /hr = _____ mL /hr (with a maximum of 1000 units /hr)
" **Use premix Heparin bag of 25,000 units Heparin in 250 mL D5W** "
☑ **Warfarin (*Coumadin*)** _____ mg orally once, then refer to additional orders for subsequent doses
☑ Start **Warfarin (*Coumadin*)** on the same day **Heparin** is initiated or on day ___ of **Heparin** therapy.
☐ Use **Warfarin (*Coumadin*) Dosing and Monitoring Protocol**
☐ Pharmacy to manage **Warfarin (*Coumadin*)**

Laboratory
☑ PTT, Hemogram (include platelets) ASAP if not already done (draw peripherally)
☑ If **Warfarin (*Coumadin*)** is started, PT /INR prior to **Warfarin (*Coumadin*)** and PT /INR every day
☑ Hgb and Platelet Count every day for 5 days (unless otherwise ordered)
☑ **STAT** PTT (peripheral) 6 hours after **Heparin** drip started (do not draw before 6 hours)

☑ Adjust **Heparin** infusion based on sliding scale below (Normal PTT= 21 - 37)

PTT (sec.)	Bolus Dose	Stop Heparin Infusion	Rate Change (mL/hr)
< 50	40 units /kg or ___ units /kg maximum = 4000 units	0 min.	Increase drip by 4 units /kg /hr (____ units /hr = ____ mL /hr)
51 - 60	20 units /kg or ___ units /kg maximum = 4000 units	0 min.	Increase drip by 2 units /kg /hr (____ units /hr = ____ mL /hr)
61 - 80	0	0 min.	no change
81 - 100	0	0 min.	Reduce drip by 1 unit /kg /hr (____ units /hr = ____ mL /hr)
101 - 149	0	30 min.	Reduce drip by 2 units /kg /hr (____ units /hr = ____ mL /hr)
≥ 150	0	60 min.	Reduce drip by 3 units /kg /hr (____ units /hr = ____ mL /hr)

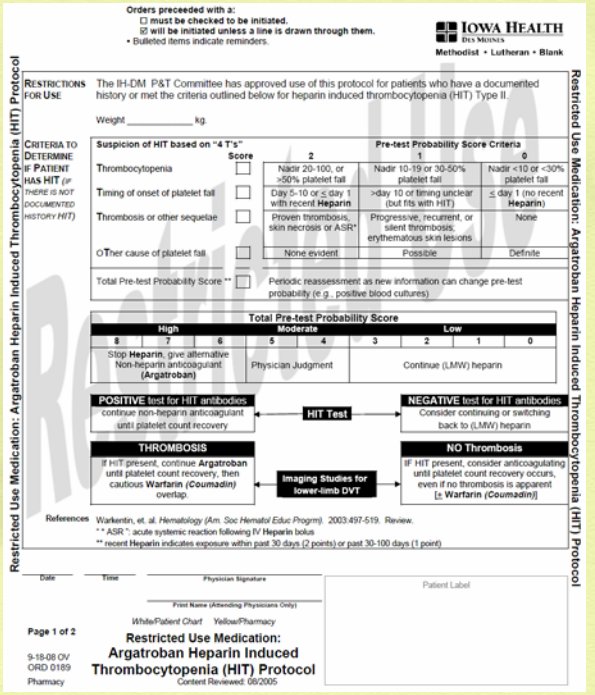
☑ Obtain **STAT** PTT 6 hours after any dosage change (do not draw early).
☑ If PTT ≤ 70 or ≥ 100 seconds, check PTT in 6 hours and follow sliding scale.
☑ If PTT 71 - 100 seconds, check PTT next morning and every morning while on **Heparin**.
☑ Make changes as promptly as possible and round off to the nearest 10 units/hr.
☑ If any neurological deterioration, obvious bleeding, or expanding hematoma, turn off **Heparin** ***and CALL PHYSICIAN***.

Date Time Physician Signature
Date Time RPh Signature
White/Patient Chart Yellow/Pharmacy
Page 1 of 1
Patient Label
9-18-08 OV
ORD 0034
P&T Committee

IV Heparin Protocol: Acute Coronary Syndrome (ACS)
(restricted to use in Cath Lab)

Restricted to use in Cath Lab

Restricted Meds: HIT with Argatroban (page 1)



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Restricted Use Medication: Argatroban Heparin Induced Thrombocytopenia (HIT) Protocol

RESTRICTIONS FOR USE
The IH-DM P&T Committee has approved use of this protocol for patients who have a documented history or met the criteria outlined below for heparin induced thrombocytopenia (HIT) Type II.

Weight _____ kg.

CRITERIA TO DETERMINE IF PATIENT HAS HIT (IF THERE IS NOT DOCUMENTED HISTORY HIT)

Suspicion of HIT based on "4 T's"	Score	Pre-test Probability Score Criteria 2	1	0
Thrombocytopenia	☐	Nadir 20-100, or >50% platelet fall	Nadir 10-19 or 30-50% platelet fall	Nadir <10 or <30% platelet fall
Timing of onset of platelet fall	☐	Day 5-10 or ≤ day 1 with recent **Heparin**	>day 10 or timing unclear (but fits with HIT)	≤ day 1 (no recent **Heparin**)
Thrombosis or other sequelae	☐	Proven thrombosis, skin necrosis or ASR*	Progressive, recurrent, or silent thrombosis, erythematous skin lesions	None
OTher cause of platelet fall	☐	None evident	Possible	Definite
Total Pre-test Probability Score **	☐	Periodic reassessment as new information can change pre-test probability (e.g., positive blood cultures)		

Total Pre-test Probability Score

High			Moderate			Low		
8	7	6	5	4	3	2	1	0
Stop **Heparin**, give alternative Non-heparin anticoagulant **(Argatroban)**			Physician Judgment			Continue (LMW) heparin		

POSITIVE test for HIT antibodies: continue non-heparin anticoagulant until platelet count recovery

HIT Test

NEGATIVE test for HIT antibodies: Consider continuing or switching back to (LMW) heparin

THROMBOSIS: If HIT present, continue **Argatroban** until platelet count recovery, then cautious **Warfarin (*Coumadin*)** overlap.

Imaging Studies for lower-limb DVT

NO Thrombosis: IF HIT present, consider anticoagulating until platelet count recovery occurs, even if no thrombosis is apparent [+ **Warfarin (*Coumadin*)**]

REFERENCES
Warkentin, et. al. *Hematology (Am. Soc Hematol Educ Progrm).* 2003:497-519. Review.
* ASR: acute systemic reaction following IV **Heparin** bolus
** recent **Heparin** indicates exposure within past 30 days (2 points) or past 30-100 days (1 point)

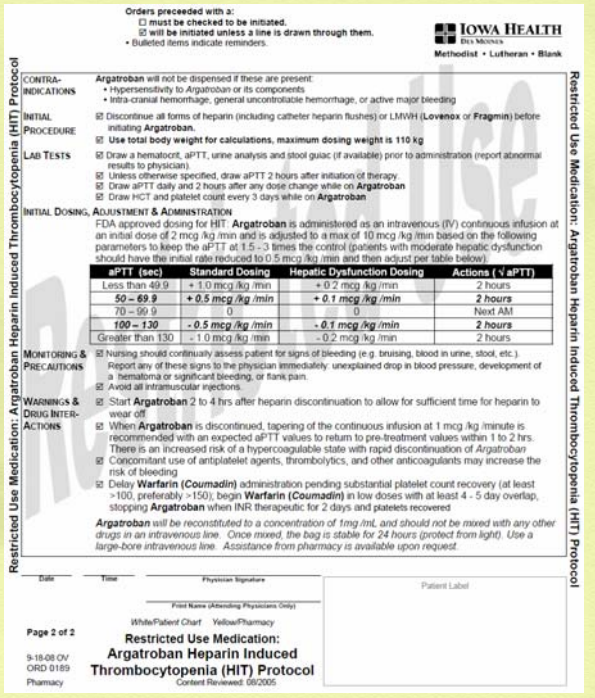
Date Time Physician Signature
Print Name (Attending Physicians Only)
Patient Label

White/Patient Chart Yellow/Pharmacy

Page 1 of 2
9-18-08 OV
ORD 0189
Pharmacy

Restricted Use Medication: Argatroban Heparin Induced Thrombocytopenia (HIT) Protocol
Content Reviewed: 08/2005

Restricted Meds: HIT with Argatroban (page 2)



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Restricted Use Medication: Argatroban Heparin Induced Thrombocytopenia (HIT) Protocol

CONTRA-INDICATIONS
Argatroban will not be dispensed if these are present:
• Hypersensitivity to *Argatroban* or its components
• Intra-cranial hemorrhage, general uncontrollable hemorrhage, or active major bleeding

INITIAL PROCEDURE
☑ Discontinue all forms of heparin (including catheter heparin flushes) or LMWH (**Lovenox** or **Fragmin**) before initiating **Argatroban**.
☑ **Use total body weight for calculations, maximum dosing weight is 110 kg**

LAB TESTS
☑ Draw a hematocrit, aPTT, urine analysis and stool guiac (if available) prior to administration (report abnormal results to physician).
☑ Unless otherwise specified, draw aPTT 2 hours after initiation of therapy.
☑ Draw aPTT daily and 2 hours after any dose change while on **Argatroban**
☑ Draw HCT and platelet count every 3 days while on **Argatroban**

INITIAL DOSING, ADJUSTMENT & ADMINISTRATION
FDA approved dosing for HIT: **Argatroban** is administered as an intravenous (IV) continuous infusion at an initial dose of 2 mcg /kg /min and is adjusted to a max of 10 mcg /kg /min based on the following parameters to keep the aPTT at 1.5 - 3 times the control (patients with moderate hepatic dysfunction should have the initial rate reduced to 0.5 mcg /kg /min and then adjust per table below):

aPTT (sec)	Standard Dosing	Hepatic Dysfunction Dosing	Actions (√ aPTT)
Less than 49.9	+ 1.0 mcg /kg /min	+ 0.2 mcg /kg /min	2 hours
50 – 69.9	***+ 0.5 mcg /kg /min***	***+ 0.1 mcg /kg /min***	***2 hours***
70 – 99.9	0	0	Next AM
100 – 130	***- 0.5 mcg /kg /min***	***- 0.1 mcg /kg /min***	***2 hours***
Greater than 130	- 1.0 mcg /kg /min	- 0.2 mcg /kg /min	2 hours

MONITORING & PRECAUTIONS
☑ Nursing should continually assess patient for signs of bleeding (e.g. bruising, blood in urine, stool, etc.). Report any of these signs to the physician immediately: unexplained drop in blood pressure, development of a hematoma or significant bleeding, or flank pain.
☑ Avoid all intramuscular injections.

WARNINGS & DRUG INTER-ACTIONS
☑ Start **Argatroban** 2 to 4 hrs after heparin discontinuation to allow for sufficient time for heparin to wear off.
☑ When **Argatroban** is discontinued, tapering of the continuous infusion at 1 mcg /kg /minute is recommended with an expected aPTT values to return to pre-treatment values within 1 to 2 hrs. There is an increased risk of a hypercoagulable state with rapid discontinuation of *Argatroban*
☑ Concomitant use of antiplatelet agents, thrombolytics, and other anticoagulants may increase the risk of bleeding
☑ Delay **Warfarin (*Coumadin*)** administration pending substantial platelet count recovery (at least >100, preferably >150); begin **Warfarin (*Coumadin*)** in low doses with at least 4 - 5 day overlap, stopping **Argatroban** when INR therapeutic for 2 days and platelets recovered

***Argatroban** will be reconstituted to a concentration of 1mg /mL and should not be mixed with any other drugs in an intravenous line. Once mixed, the bag is stable for 24 hours (protect from light). Use a large-bore intravenous line. Assistance from pharmacy is available upon request.*

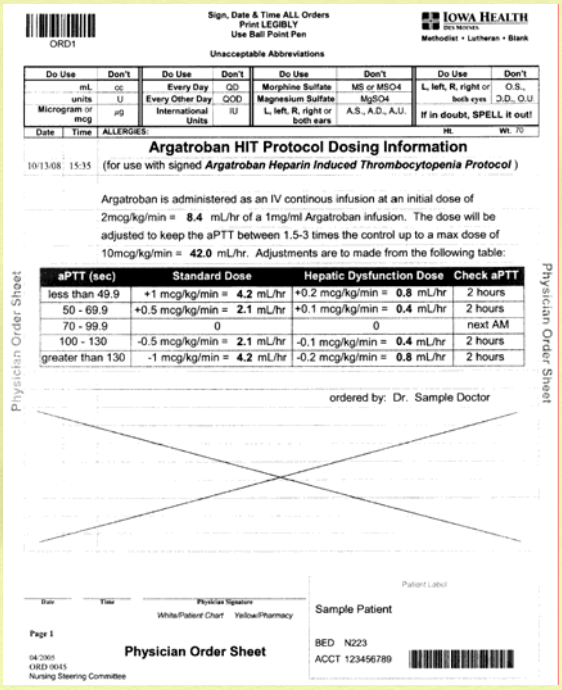
Date Time Physician Signature
Print Name (Attending Physicians Only)
Patient Label

White/Patient Chart Yellow/Pharmacy

Page 2 of 2
9-18-08 OV
ORD 0189
Pharmacy

Restricted Use Medication: Argatroban Heparin Induced Thrombocytopenia (HIT) Protocol
Content Reviewed: 08/2005

Restricted Meds: HIT with Argatroban Physicians Order with Dosing Adjustment Table



ORD1

Sign, Date & Time ALL Orders
Print LEGIBLY
Use Ball Point Pen

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Unacceptable Abbreviations

Do Use	Don't	Do Use	Don't	Do Use	Don't	Do Use	Don't
mL	cc	Every Day	QD	Morphine Sulfate	MS or MSO4	L, left, R, right or both eyes	O.S., O.D., O.U.
units	U	Every Other Day	QOD	Magnesium Sulfate	MgSO4		
Microgram or mcg	µg	International Units	IU	L, left, R, right or both ears	A.S., A.D., A.U.	If in doubt, SPELL it out!	

Date | Time | ALLERGIES: | Ht. | Wt. 70

Argatroban HIT Protocol Dosing Information

10/13/08 15:35 (for use with signed ***Argatroban Heparin Induced Thrombocytopenia Protocol***)

Argatroban is administered as an IV continous infusion at an initial dose of 2mcg/kg/min = **8.4** mL/hr of a 1mg/ml Argatroban infusion. The dose will be adjusted to keep the aPTT between 1.5-3 times the control up to a max dose of 10mcg/kg/min = **42.0** mL/hr. Adjustments are to made from the following table:

aPTT (sec)	Standard Dose	Hepatic Dysfunction Dose	Check aPTT
less than 49.9	+1 mcg/kg/min = **4.2** mL/hr	+0.2 mcg/kg/min = **0.8** mL/hr	2 hours
50 - 69.9	+0.5 mcg/kg/min = **2.1** mL/hr	+0.1 mcg/kg/min = **0.4** mL/hr	2 hours
70 - 99.9	0	0	next AM
100 - 130	-0.5 mcg/kg/min = **2.1** mL/hr	-0.1 mcg/kg/min = **0.4** mL/hr	2 hours
greater than 130	-1 mcg/kg/min = **4.2** mL/hr	-0.2 mcg/kg/min = **0.8** mL/hr	2 hours

Physician Order Sheet

ordered by: Dr. Sample Doctor

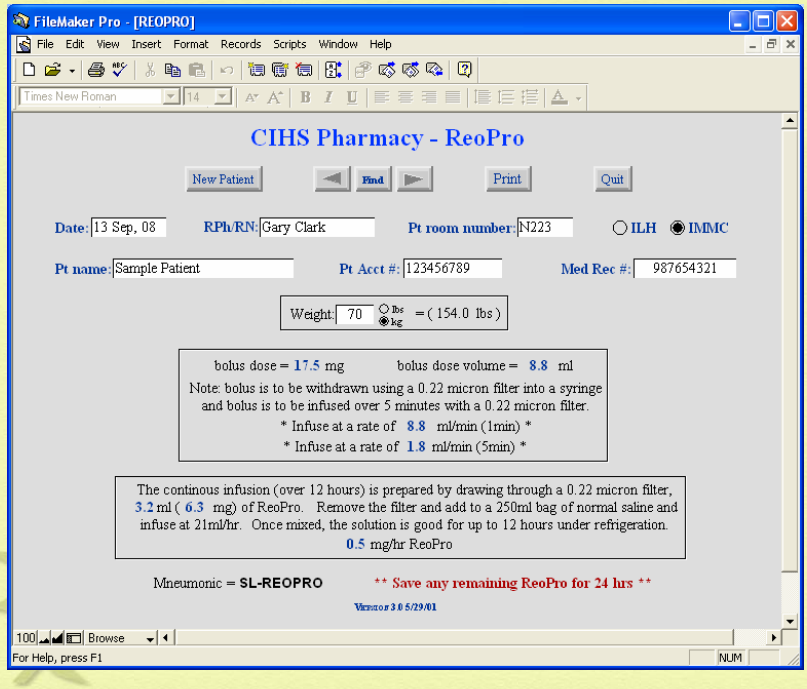
Date | Time | Physician Signature
White/Patient Chart Yellow/Pharmacy

Page 1

04/2005
ORD 0045
Nursing Steering Committee

Physician Order Sheet

Patient Label
Sample Patient
BED N223
ACCT 123456789



FileMaker Pro - [REOPRO]

File Edit View Insert Format Records Scripts Window Help

Times New Roman 14

CIHS Pharmacy - ReoPro

New Patient | Find | Print | Quit

Date: 13 Sep, 08 RPh/RN: Gary Clark Pt room number: N223 ○ ILH ◉ IMMC

Pt name: Sample Patient Pt Acct #: 123456789 Med Rec #: 987654321

Weight: 70 ○ lbs ◉ kg = (154.0 lbs)

bolus dose = 17.5 mg bolus dose volume = 8.8 ml
Note: bolus is to be withdrawn using a 0.22 micron filter into a syringe and bolus is to be infused over 5 minutes with a 0.22 micron filter.
* Infuse at a rate of 8.8 ml/min (1min) *
* Infuse at a rate of 1.8 ml/min (5min) *

The continous infusion (over 12 hours) is prepared by drawing through a 0.22 micron filter, 3.2 ml (6.3 mg) of ReoPro. Remove the filter and add to a 250ml bag of normal saline and infuse at 21ml/hr. Once mixed, the solution is good for up to 12 hours under refrigeration.
0.5 mg/hr ReoPro

Mneumonic = **SL-REOPRO** ** Save any remaining ReoPro for 24 hrs **

Version 3.0 5/29/01

100 Browse

For Help, press F1 NUM

Restricted Meds: Abciximab (*Reopro*)

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Restricted Use Medication: ABCIXIMAB (*ReoPro*) Infusion Protocol

☑ Initiate **ABCIXIMAB** (*ReoPro*) Infusion Protocol

Laboratory

☑ Platelet count within 14 days prior to bolus of **ABCIXIMAB** (*ReoPro*) *OR* _____
☑ Platelet count 2 to 4 hours following bolus dose of **ABCIXIMAB** (*ReoPro*)
☑ Platelet count 24 hours following bolus dose of **ABCIXIMAB** (*ReoPro*) or prior to discharge, whichever comes first.

☑ Call doctor if any platelet count is below 100,000 or there is a decrease greater than/equal to 25% of pre-treatment value.
☑ Weigh patient: _____ kg
☑ **Bolus ABCIXIMAB** (*ReoPro*): 0.25 mg /kg IV over 1 minutes, 10-60 minutes prior to procedure.
☑ **ABCIXIMAB** (*ReoPro*) Infusion:
☐ Weight less than 80 kg to receive 0.125 mcg /kg /minute
☐ Weight equal to / greater than 80 kg to receive 10 mcg /minute
(Standard Mix: 12 hour dose in 250 mL 0.9% Sodium Chloride to run at 21 mL /hr)
• Administer **ABCIXIMAB** (*ReoPro*) in a separate intravenous line. Do NOT mix with other drugs.
• Use a 0.2 or 0.22 micron low protein binding filter for continuous infusion.
☑ Stop **ABCIXIMAB** (*ReoPro*) infusion at _____(military time). Discard any unused portions.
☑ Discontinue Heparin in cath lab
☑ Pull sheath per Post Cardiac Cath Orders

Nursing Use:
Patient weight _____ kilograms
_____
RN Initial /Date

Pharmacy Use:
Bolus:
_____ mg **ABCIXIMAB** (*ReoPro*)
Infusion:
_____ mg /hr **ABCIXIMAB** (*ReoPro*)
_____ mL /hr **ABCIXIMAB** (*ReoPro*)

Restricted Use Medication: ABCIXIMAB (*ReoPro*) Infusion Protocol

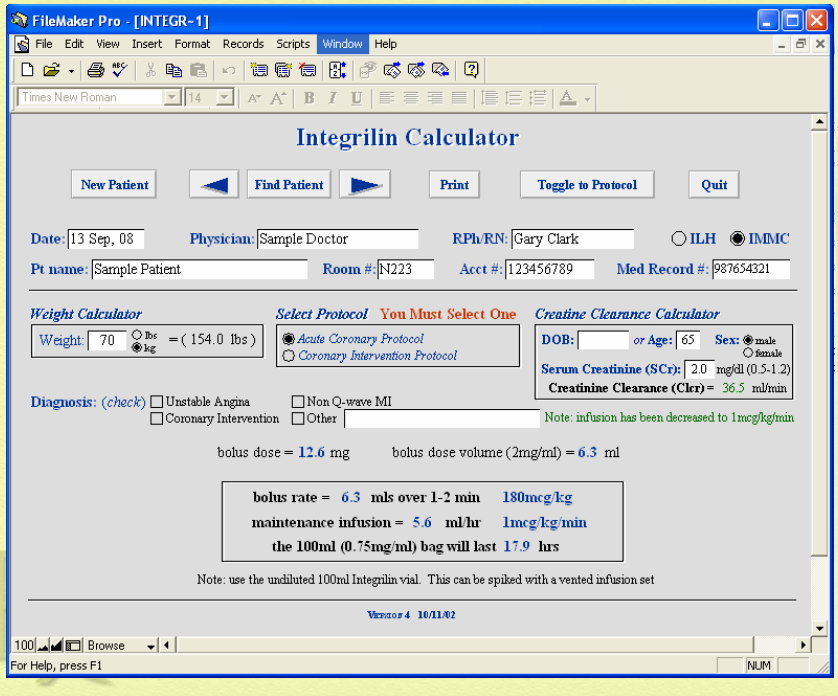
Date | Time | Physician Signature
White/Patient Chart Yellow/Pharmacy

Patient Label

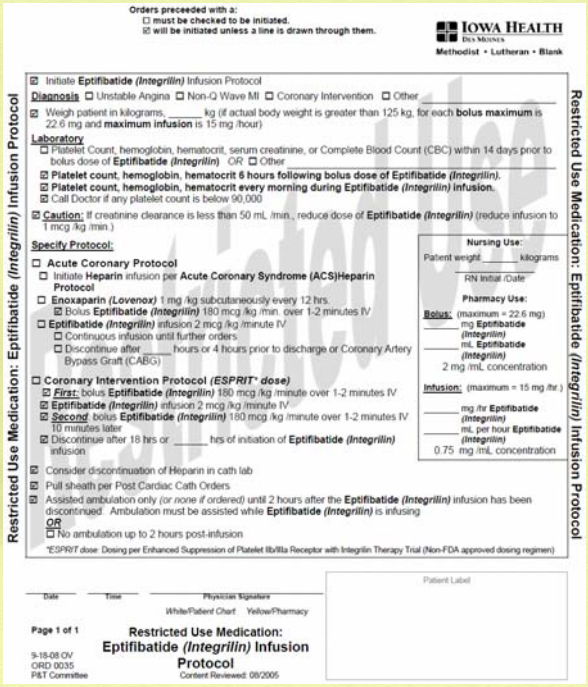
Page 1 of 1

9-18-08 OV
ORD 0055
P&T Committee

Restricted Use Medication:
ABCIXIMAB (*ReoPro*)
Infusion Protocol
Content Reviewed: 08/2005



Restricted Meds: Eptifibatide (*Integrilin*)



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Restricted Use Medication: Eptifibatide (*Integrilin*) Infusion Protocol

☑ Initiate **Eptifibatide *(Integrilin)*** Infusion Protocol

Diagnosis ☐ Unstable Angina ☐ Non-Q Wave MI ☐ Coronary Intervention ☐ Other _____

☑ Weigh patient in kilograms. _____ kg (if actual body weight is greater than 125 kg, for each **bolus maximum** is 22.6 mg and **maximum infusion** is 15 mg /hour)

Laboratory
☐ Platelet Count, hemoglobin, hematocrit, serum creatinine, or Complete Blood Count (CBC) within 14 days prior to bolus dose of **Eptifibatide *(Integrilin)***. *OR* ☐ Other _____
☑ **Platelet count, hemoglobin, hematocrit 6 hours following bolus dose of Eptifibatide *(Integrilin)*.**
☑ **Platelet count, hemoglobin, hematocrit every morning during Eptifibatide *(Integrilin)* infusion.**
☑ Call Doctor if any platelet count is below 90,000

☑ **Caution:** If creatinine clearance is less than 50 mL /min., reduce dose of **Eptifibatide *(Integrilin)*** (reduce infusion to 1 mcg /kg /min.)

Specify Protocol:

☐ **Acute Coronary Protocol**
☐ Initiate **Heparin** infusion per **Acute Coronary Syndrome (ACS)Heparin Protocol**
☐ **Enoxaparin *(Lovenox)*** 1 mg /kg subcutaneously every 12 hrs.
☑ Bolus **Eptifibatide *(Integrilin)*** 180 mcg /kg /min. over 1-2 minutes IV
☐ **Eptifibatide *(Integrilin)*** infusion 2 mcg /kg /minute IV
☐ Continuous infusion until further orders
☐ Discontinue after _____ hours or 4 hours prior to discharge or Coronary Artery Bypass Graft (CABG)

☐ **Coronary Intervention Protocol *(ESPRIT* dose)***
☑ ***First:*** bolus **Eptifibatide *(Integrilin)*** 180 mcg /kg /minute over 1-2 minutes IV
☑ **Eptifibatide *(Integrilin)*** infusion 2 mcg /kg /minute IV
☑ ***Second*** bolus **Eptifibatide *(Integrilin)*** 180 mcg /kg /minute over 1-2 minutes IV 10 minutes later
☑ Discontinue after 18 hrs or _____ hrs of initiation of **Eptifibatide *(Integrilin)*** infusion

Nursing Use:
Patient weight _____ kilograms
_____
RN Initial /Date

Pharmacy Use:
Bolus: (maximum = 22.6 mg)
_____ mg **Eptifibatide *(Integrilin)***
_____ mL **Eptifibatide *(Integrilin)***
2 mg /mL concentration

Infusion: (maximum = 15 mg /hr.)
_____ mg /hr **Eptifibatide *(Integrilin)***
_____ mL per hour **Eptifibatide *(Integrilin)***
0.75 mg /mL concentration

☑ Consider discontinuation of Heparin in cath lab
☑ Pull sheath per Post Cardiac Cath Orders
☑ Assisted ambulation only *(or none if ordered)* until 2 hours after the **Eptifibatide *(Integrilin)*** infusion has been discontinued. Ambulation must be assisted while **Eptifibatide *(Integrilin)*** is infusing
OR
☐ No ambulation up to 2 hours post-infusion

**ESPRIT dose*: Dosing per Enhanced Suppression of Platelet IIb/IIIa Receptor with Integrilin Therapy Trial (Non-FDA approved dosing regimen)

Date _____ Time _____ Physician Signature _____
White/Patient Chart Yellow/Pharmacy

Patient Label

Page 1 of 1

9-18-08 OV
ORD 0035
P&T Committee

Restricted Use Medication: Eptifibatide *(Integrilin)* Infusion Protocol
Content Reviewed: 08/2005

RPh Interventions for Warfarin

Data from documented pharmacist interventions involving warfarin (12 month period of Jul 07 to Jun 08):

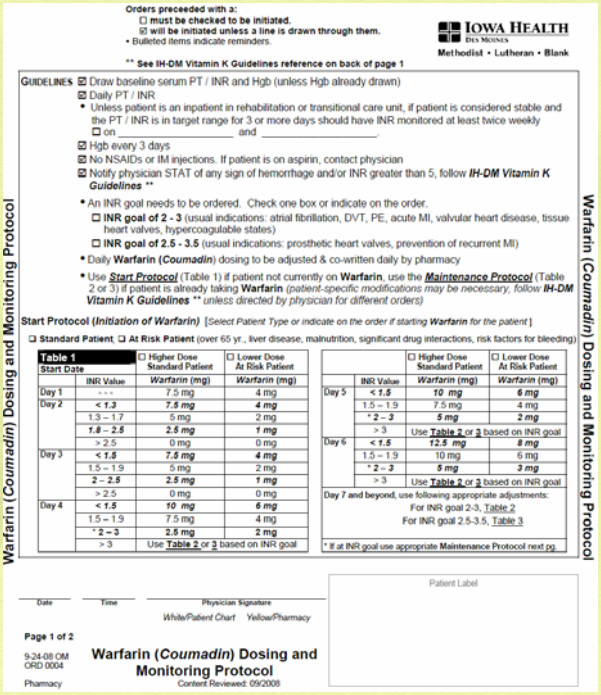
Pharmacist Interventions for Warfarin
12 Months (July 07 to June 08)

Results of Recommendation	
current order changed	62
daily pharmacy program	66
drug added	127
drug discontinued	12
information provided	30
lab ordered	4
order clarified	12
not completed	16
total	**329**

Intervention Identified	
chart review	1
lab monitoring	38
pharmacist referred	26
physician order	51
MD/DO/RN request	195
unkown	18
total	**329**

Campus	
ILH	216
IMMC	113
total	**329**

Warfarin Dosing and Monitoring Protocol (page 1)



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** See IH-DM Vitamin K Guidelines reference on back of page 1

GUIDELINES ☑ Draw baseline serum PT / INR and Hgb (unless Hgb already drawn)
☑ Daily PT / INR
• Unless patient is an inpatient in rehabilitation or transitional care unit, if patient is considered stable and the PT / INR is in target range for 3 or more days should have INR monitored at least twice weekly
☐ on _____ and _____.
☑ Hgb every 3 days
☑ No NSAIDs or IM injections. If patient is on aspirin, contact physician
☑ Notify physician STAT of any sign of hemorrhage and/or INR greater than 5, follow ***IH-DM Vitamin K Guidelines*** **

• An INR goal needs to be ordered. Check one box or indicate on the order.
☐ **INR goal of 2 - 3** (usual indications: atrial fibrillation, DVT, PE, acute MI, valvular heart disease, tissue heart valves, hypercoagulable states)
☐ **INR goal of 2.5 - 3.5** (usual indications: prosthetic heart valves, prevention of recurrent MI)
• Daily **Warfarin (*Coumadin*)** dosing to be adjusted & co-written daily by pharmacy
• Use ***Start Protocol*** (Table 1) if patient not currently on **Warfarin**, use the ***Maintenance Protocol*** (Table 2 or 3) if patient is already taking **Warfarin** *(patient-specific modifications may be necessary, follow **IH-DM Vitamin K Guidelines** ** unless directed by physician for different orders)*

Start Protocol (*Initiation of Warfarin*) *[Select Patient Type or indicate on the order if starting **Warfarin** for the patient]*
☐ **Standard Patient** ☐ **At Risk Patient** (over 65 yr., liver disease, malnutrition, significant drug interactions, risk factors for bleeding)

Table 1 Start Date	INR Value	☐ Higher Dose Standard Patient *Warfarin* (mg)	☐ Lower Dose At Risk Patient *Warfarin* (mg)
Day 1	- - -	7.5 mg	4 mg
Day 2	***< 1.3***	***7.5 mg***	***4 mg***
	1.3 – 1.7	5 mg	2 mg
	1.8 – 2.5	***2.5 mg***	***1 mg***
	> 2.5	0 mg	0 mg
Day 3	***< 1.5***	***7.5 mg***	***4 mg***
	1.5 – 1.9	5 mg	2 mg
	2 – 2.5	***2.5 mg***	***1 mg***
	> 2.5	0 mg	0 mg
Day 4	***< 1.5***	***10 mg***	***6 mg***
	1.5 – 1.9	7.5 mg	4 mg
	**** 2 – 3***	***2.5 mg***	***2 mg***
	> 3	Use Table 2 or 3 based on INR goal	

	INR Value	☐ Higher Dose Standard Patient *Warfarin* (mg)	☐ Lower Dose At Risk Patient *Warfarin* (mg)
Day 5	***< 1.5***	***10 mg***	***6 mg***
	1.5 – 1.9	7.5 mg	4 mg
	**** 2 – 3***	***5 mg***	***2 mg***
	> 3	Use Table 2 or 3 based on INR goal	
Day 6	***< 1.5***	***12.5 mg***	***8 mg***
	1.5 – 1.9	10 mg	6 mg
	**** 2 – 3***	***5 mg***	***3 mg***
	> 3	Use Table 2 or 3 based on INR goal	

Day 7 and beyond, use following appropriate adjustments:
For INR goal 2-3, Table 2
For INR goal 2.5-3.5, Table 3

* If at INR goal use appropriate Maintenance Protocol next pg.

Warfarin (*Coumadin*) Dosing and Monitoring Protocol

Warfarin (*Coumadin*) Dosing and Monitoring Protocol

Date _____ Time _____ Physician Signature _____
White/Patient Chart Yellow/Pharmacy

Patient Label

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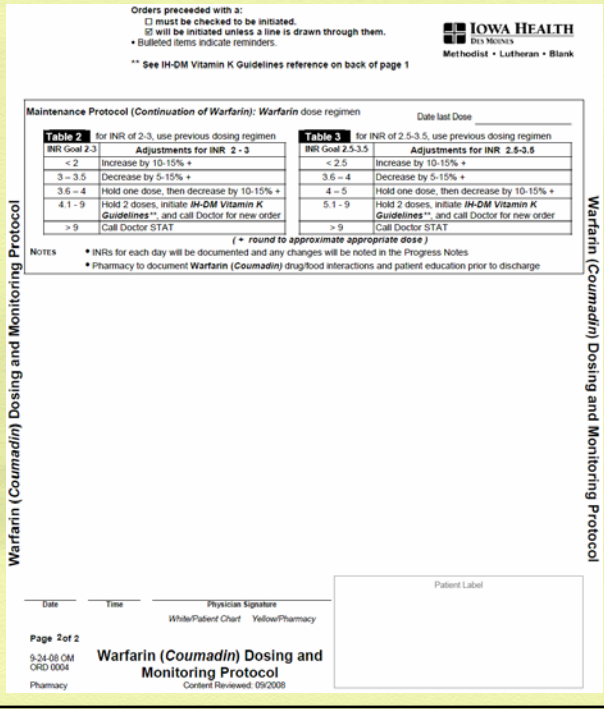
Warfarin (*Coumadin*) Dosing and Monitoring Protocol
Content Reviewed: 09/2008

Warfarin Dosing and Monitoring Protocol (page 2)



Orders preceeded with a:
☐ must be checked to be initiated.
☑ will be initiated unless a line is drawn through them.
• Bulleted items indicate reminders.

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** See IH-DM Vitamin K Guidelines reference on back of page 1

Maintenance Protocol (*Continuation of Warfarin*): *Warfarin* dose regimen Date last Dose _____

Table 2 for INR of 2-3, use previous dosing regimen	
INR Goal 2-3	**Adjustments for INR 2 - 3**
< 2	Increase by 10-15% +
3 – 3.5	Decrease by 5-15% +
3.6 – 4	Hold one dose, then decrease by 10-15% +
4.1 - 9	Hold 2 doses, initiate ***IH-DM Vitamin K Guidelines*****, and call Doctor for new order
> 9	Call Doctor STAT

Table 3 for INR of 2.5-3.5, use previous dosing regimen	
INR Goal 2.5-3.5	**Adjustments for INR 2.5-3.5**
< 2.5	Increase by 10-15% +
3.6 – 4	Decrease by 5-15% +
4 – 5	Hold one dose, then decrease by 10-15% +
5.1 - 9	Hold 2 doses, initiate ***IH-DM Vitamin K Guidelines*****, and call Doctor for new order
> 9	Call Doctor STAT

(+ round to approximate appropriate dose)

NOTES
• INRs for each day will be documented and any changes will be noted in the Progress Notes
• Pharmacy to document **Warfarin (*Coumadin*)** drug/food interactions and patient education prior to discharge

Warfarin (*Coumadin*) Dosing and Monitoring Protocol

Warfarin (*Coumadin*) Dosing and Monitoring Protocol

Date _____ Time _____ Physician Signature _____
White/Patient Chart Yellow/Pharmacy

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Warfarin (*Coumadin*) Dosing and Monitoring Protocol
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Collaborative Practice Agreement for Warfarin Dosing & Monitoring

- The hospital practice protocol was developed to assist pharmacist in providing warfarin dosing and management and is clear to physicians how C*oumadin* is being dosed and monitored.
- Provides rationale, procedures (including ordering drug, specifics of progress notes, ordering labs, assessing other findings, and continuity of care process), quality assurance, and development and training of authorized pharmacists.
- Includes guidelines for warfarin management and use of vitamin K, and examples of significant drug interactions.

Patient Education RPh Role

- ✓ IH-DM has three pharmacists that provide patient education at ILH and IMMC.
- ✓ Work 7 days a week during the day shift.
- ✓ Provide patient education for inpatient diabetics (all 3 have their CDE's), injection training for *Lovenox* and *Fragmin*, and warfarin patient education.
- ✓ Have a P4 experiential rotation that provides anticoagulation education experience where the students monitor anticoagulation therapy for patients admitted to the hospital and provide discharge instruction on the proper use of these medications.

Patient Education for Warfarin

Data from documented patient education interventions with warfarin (12 month period of Jul 07 to Jun 08):

Patient Education Interventions for Warfarin

12 Months (July 07 to June 08)

Education Opportunity Identified	
chart review	11
pharmacist request	1
physician request	452
nurse request	5
rounds	10
unkown	21
total	**500**

Campus	
ILH	168
IMMC	332
total	**500**

# with warfarin teach time	424
# with no time documented	76
average time/interention	27.7 min

Warfarin Drug Use Evaluation

Over an 18 day period in September, 2001 a total of 99 patients received warfarin at IMMC. Results of the DUE include:

- ✓ initial dose = 3.9mg average (1-15mg)
- ✓ diagnosis: A. Fib = 17, AMI = 6, DVT treatment = 8, PE treatment = 1, DVT prophylaxis = 27, other = 36, unknown = 5
- ✓ admitted on warfarin = 34, initiated on warfarin at IMMC = 46, unknown = 19
- ✓ INR draws = 3.88 per patient on average (0 tp 20 per patient)
- ✓ Vitamin K use = 4 (10mg sq for INR of 2.7, 5mg SQ for INR of 1.79, 5mg PO for IMR of 4.9, and 5mg IV for INR of 8.8)

Warfarin Protocol DUE

For a three month period in early 2007, a drug use evaluation (DUE) to compare the safety and efficacy of initiating warfarin therapy via the pharmacy-managed warfarin protocol versus physician-managed warfarin was conducted.

A retrospective chart review of patients receiving warfarin at IMMC was done. There were 15 pharmacy managed and 60 physician managed warfarin. Data was collected from warfarin initiation through discontinuation/discharge or a maximum of 10 days of therapy per patient.

Warfarin Protocol DUE

Results of the evaluation included:

- ✓ Pharmacy-managed warfarin initiation is at least as safe and effective as physician-managed warfarin at initiating patients to a goal INR range.
- ✓ There was not a difference in time to therapeutic INR between low-risk pharmacy-managed and physician-managed patients.
- ✓ High-risk (low-dose) pharmacy-managed patients tended to take ~1.3 days longer to reach therapeutic INR than standard-risk or physician-managed patients but are maintained at goal at least as well as the other groups.
- ✓ Upon review of pharmacy-managed patients who deviated from the protocol, in 100% (4/4) of cases the pharmacist had used appropriate clinical judgment for the deviation. The deviations appeared to be related to analysis of the rate of change of INR rather than just on the INR value alone or drug interactions with the warfarin.

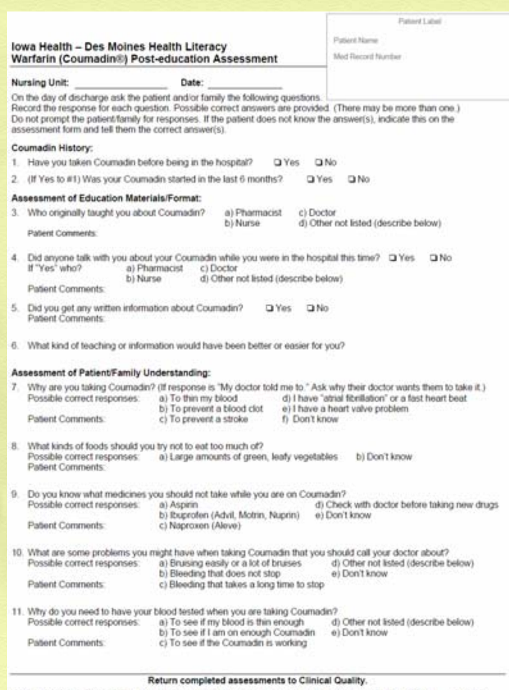
Healthcare Literacy Project

In 2005, the IH-DM Pharmacy department and Clinical Quality department developed a Warfarin education program with the goal of measuring the effectiveness of healthcare literacy.

Phone call follow-up surveys were made on 69 of the 103 patients educated by pharmacy in the hospital that agreed to be surveyed.

The average age was 69.3 (ranged from 26 to 92 years old). The average time from education to follow phone call was 3.3 weeks (ranged from 1 to 8 weeks).

Healthcare Literacy Porject on Warfarin Education for Inpatients: Follow-up Survey Questions



Patient Label
Patient Name
Med Record Number

Iowa Health – Des Moines Health Literacy
Warfarin (Coumadin®) Post-education Assessment

Nursing Unit: ____________ **Date:** ____________

On the day of discharge ask the patient and/or family the following questions.
Record the response for each question. Possible correct answers are provided. (There may be more than one.)
Do not prompt the patient/family for responses. If the patient does not know the answer(s), indicate this on the assessment form and tell them the correct answer(s).

Coumadin History:

1. Have you taken Coumadin before being in the hospital? ❑ Yes ❑ No
2. (If Yes to #1) Was your Coumadin started in the last 6 months? ❑ Yes ❑ No

Assessment of Education Materials/Format:

3. Who originally taught you about Coumadin? a) Pharmacist c) Doctor b) Nurse d) Other not listed (describe below)
   Patient Comments:
4. Did anyone talk with you about your Coumadin while you were in the hospital this time? ❑ Yes ❑ No
   If "Yes" who? a) Pharmacist c) Doctor b) Nurse d) Other not listed (describe below)
   Patient Comments:
5. Did you get any written information about Coumadin? ❑ Yes ❑ No
   Patient Comments:
6. What kind of teaching or information would have been better or easier for you?

Assessment of Patient/Family Understanding:

7. Why are you taking Coumadin? (If response is "My doctor told me to." Ask why their doctor wants them to take it.)
   Possible correct responses: a) To thin my blood b) To prevent a blood clot c) To prevent a stroke d) I have "atrial fibrillation" or a fast heart beat e) I have a heart valve problem f) Don't know
   Patient Comments:
8. What kinds of foods should you try not to eat too much of?
   Possible correct responses: a) Large amounts of green, leafy vegetables b) Don't know
   Patient Comments:
9. Do you know what medicines you should not take while you are on Coumadin?
   Possible correct responses: a) Aspirin b) Ibuprofen (Advil, Motrin, Nuprin) c) Naproxen (Aleve) d) Check with doctor before taking new drugs e) Don't know
   Patient Comments:
10. What are some problems you might have when taking Coumadin that you should call your doctor about?
    Possible correct responses: a) Bruising easily or a lot of bruises b) Bleeding that does not stop c) Bleeding that takes a long time to stop d) Other not listed (describe below) e) Don't know
    Patient Comments:
11. Why do you need to have your blood tested when you are taking Coumadin?
    Possible correct responses: a) To see if my blood is thin enough b) To see if I am on enough Coumadin c) To see if the Coumadin is working d) Other not listed (describe below) e) Don't know
    Patient Comments:

Return completed assessments to Clinical Quality.

Healthcare Literacy Project

The results of the survey questions included:

6 *Coumadin* Knowledge Related Questions:

Knew About *Coumadin*

- 92.8% (64) gave correct responses to at least 1 question.
- 34.8% (24) gave correct responses to all 6 questions.

Did Not Know About *Coumadin*

- 7.2% (5) did not give correct responses to 3 or more of the questions.

Did Not Respond

- 5.8% (4) did not respond to all 6 of the questions.

Most Frequently Answered as Didn't Know:

Q10: Why do you need to take your *Coumadin* the same time each day?
20 (29.0%) didn't know

Q8: What medicines should you NOT take while you are on *Coumadin*?
17 (24.6%) didn't know

Q9: What are some problems you might have when taking *Coumadin* that you should call your doctor about?
12 (17.4%) didn't know

Healthcare Literacy Project

Discussion:

Older patients and those where there was a longer time between the education and survey tended to have a higher number of questions they did not know a correct response to. There did not appear to be a significant difference in the percent of patients who did not know an answer to a question based on the pharmacist who provided the education.

Recommendations:

- ✓ Review written materials for content covering 3 most frequently missed questions.
- ✓ Review health literacy aspects of written materials
- ✓ Review how pharmacists are covering this information during education session.
- ✓ Revise written materials as indicated for content and health literacy.
- ✓ Incorporate Ask-Me-3 strategies into written materials and education.
- ✓ Continue follow-up phone call surveys through Call Center after materials and education methods are reviewed and revised as indicated.

Conclusions

The use of anticoagulants has inherent risk associated with them. Information from published reports, FDA safety alerts and documented adverse drug reactions specific to anticoagulants use at IH-DM led the Pharmacy & Therapeutics Committee to develop tools to decrease those risks.

IH-DM has had in place the following tools to assist in the dosing, monitoring and education of anticoagulants:

- ✓ specific order sets for heparin, parenteral antiplatelets, argatroban and warfarin
- ✓ database program that calculates and prints anticoagulant orders
- ✓ several forms of heparin were removed to eliminate confusion, and all strengths of warfarin were made available to prevent nursing from cutting warfarin tablets
- ✓ a collaborative practice agreement for dosing and monitoring warfarin
- ✓ patient education for warfarin and LMWH's (*Lovenox* and *Fragmin*) that includes active learning with the patient and family and with healthcare literacy in mind
- ✓ evaluation of warfarin use (including education) and tracking of adverse drug reactions for all anticoagulants is ongoing

