



National Patient Safety Goal 3E; Myths and Reality

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TOGETHER WE MAKE A GREAT TEAM



Presenter:



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Objectives

- Review the 2008 Joint Commission (TJC) NPSG (3E) requirements on anticoagulation therapy
- Describe the system requirements and implementation expectations for this standard
- Discuss implications for clinical practice, safety, and quality

History

- First time program specific goals were established for programs in 2005
- Same format for 2008
- 6th annual issuance of goals
- 2008 goals published in July edition of Perspectives
- Goals apply to 15,000 accredited facilities



WHY ANTICOAGULANTS ???

- Top 50 Reported Drug Errors

#5. heparin

#7. warfarin

#12. enoxaparin

- Top 10 Drug Errors Causing Harm

#3. heparin

#4. warfarin

- Medication Errors Occurring in Patients' Homes

#1. warfarin

#5. enoxaparin

#7. heparin

1. US Pharmacopeia. www.usp.org/patientSafety/resources/top50DrugErrors.html.

2. US Pharmacopeia. www.usp.org/products/medMarx.

3. US Pharmacopeia. www.usp.org/pdf/EN/patientSafety/posters/062004-03-29.pdf.

Recent Heparin Errors





Institute for Safe Medication Practices

A Nonprofit Organization Educating the Healthcare Community and Consumers About Safe Medication Practices

antithrombotic agents (anticoagulants), including warfarin, low-molecular-weight heparin, IV unfractionated heparin, Factor Xa inhibitors (fondaparinux), direct thrombin inhibitors (e.g., argatroban, lepirudin, bivalirudin), thrombolytics (e.g., alteplase, reteplase, tenecteplase), and glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)

ISMP's List of *High-Alert Medications*

<http://www.ismp.org/Tools/highalertmedications.pdf>



TJC NPSG - 3E Anticoagulant Therapy

- **Requirement:** Reduce the likelihood of patient harm associated with the use of anticoagulation therapy
- **Rationale:** Anticoagulation is a high risk treatment, commonly leads to ADRs
- Use of **standardized practices** can reduce ADRs
 - With anticoagulants: warfarin, LMWH, unfractionated heparin and other anticoagulants

Expectations/Timeline

- **April 1st, 2008**, the [organization]'s leadership has assigned responsibility for oversight and coordination of the development, testing, and implementation of NPSG Requirement 3E
- **July 1st, 2008**, an implementation work plan is in place that identifies adequate resources, assigned accountabilities, and a time line for full implementation of NPSG Requirement 3E by January 1st, 2009
- **October 1st, 2008**, pilot testing in at least one clinical unit is under way
- **January 1st, 2009**, the process is fully implemented across the organization

<http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/>



Implementation Expectations and Program Plan

1. The hospital implements a defined anticoagulant management program to individualize the care provided to each patient receiving anticoagulation therapy.
 - **UFH**: RN managed protocol
 - **LMWH / Fondaparinux**: dosing guidelines
 - **Warfarin (Inpatient)**: pharmacy managed dosing and monitoring program
 - **Warfarin (Outpatient)**: Centralized Pharmacy Managed Anticoagulation Program
 - **Referral Process**: standardized
 - **DTI**: dosing and monitoring guidelines

Implementation Expectations and Program Plan

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.
 - **Have oral unit dose policy in place**
 - **Revise policy to include pre-filled syringes, or pre-mixed infusion bags**

Implementation Expectations and Program Plan

3. The hospital uses approved protocols for the initiation and maintenance of anticoagulation therapy appropriate to the medication used, to the condition being treated, and to the potential for medication interactions.
 - Drug specific protocols
 - UFH
 - LMWH/Fondaparinux
 - Warfarin
 - DTI (HIT)
 - Disease specific protocols
 - VTE Treatment
 - Stroke
 - ACS (STEMI/NSTEMI)
 - HIT

Implementation Expectations and Program Plan

4. For patients starting on warfarin, a baseline International Normalized Ratio (INR) is available, and for all patients receiving warfarin therapy, a current INR is available and is used to monitor and adjust therapy.
 - The taskforce will develop a policy defining baseline and current INR and monitoring procedures
 - Rule/s to be constructed and built in EMR
 - Pharmacy (inpatient/outpatient) will enforce this prior to dispensing warfarin

Implementation Expectations and Program Plan

5. When dietary services are provided by the hospital, the service is notified of all patients receiving warfarin and responds according to its established food/medication interaction program
 - A rule for a warfarin diet will be built into the EMR to allow a warfarin diet to be ordered automatically when a patient is prescribed warfarin
 - A warfarin diet has been developed by Food and Nutrition Services
 - Dietary will develop an internal process for ordering a warfarin diet

Implementation Expectations and Program Plan

6. When heparin is administered intravenously and continuously, the hospital uses **programmable infusion pumps** in order to provide consistent and accurate dosing
 - UIMCC currently has a contract with **Alaris**; the institution uses one type of programmable pump.
 - Will develop written statement on this as part of final program

Implementation Expectations and Program Plan

7. The hospital has a **policy** that addresses baseline and ongoing **laboratory tests** that are required for heparin and low molecular weight heparin therapies.
 - Develop **policy** for UFH and LMWH monitoring (aPTT for UFH, Platelet count for UFH and LMWH, and renal function for LMWH)
 - Build rules in EMR

Implementation Expectations and Program Plan

8. The hospital provides education regarding anticoagulation therapy to prescribers, staff, patients, and families.

- Comprehensive education program that must be tracked and documented.
- 1. **Patient Education** packet/materials will be developed
 - - Nursing suggested to take lead
 - - implement nursing order in the EMR
- 2. **Provider and Staff Education:**
 - - a combination of live hospital wide educational seminars/grand rounds and net learning (computer based) modules.

Implementation Expectations and Program Plan

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

- **Proposed QI Measures**
- **Outpatient:**
- **ATC INR - Time in Therapeutic Range**
- **INR > 5**
- **Clinic compliance with UIMCC guidelines when opting out of centralized pharmacy service**
- **Inpatient:**
- **Compliance with RN managed UFH protocol**
- **INRs > 5**
- **Therapeutic aPTTs within 1st 24 hours of therapy**

FMEA on Anticoagulants

- Consider doing a failure mode and effect analysis on anticoagulants
- Can help identify potential errors before they occur
- 28 page one available off ISMP website
- <http://www.ismp.org/Tools/FMEAofAnticoagulants.pdf>

The Joint Commission/NQF VTE Performance Measures

Risk Assessment and Prophylaxis

- | | |
|----|---|
| 1. | Prophylaxis ordered and given within 24 hours of hospital admission |
| 2. | Prophylaxis ordered and given within 24 hrs of transfer to ICU |

Treatment

- | | |
|----|---|
| 3. | Documentation of inferior vena cava filter indication |
| 4. | VTE patients with overlap of parenteral and warfarin anticoagulation therapy |
| 5. | VTE patients receiving UFH management by nomogram/protocol; VTE patients receiving UFH with platelet monitoring |
| 6. | VTE discharge instructions |

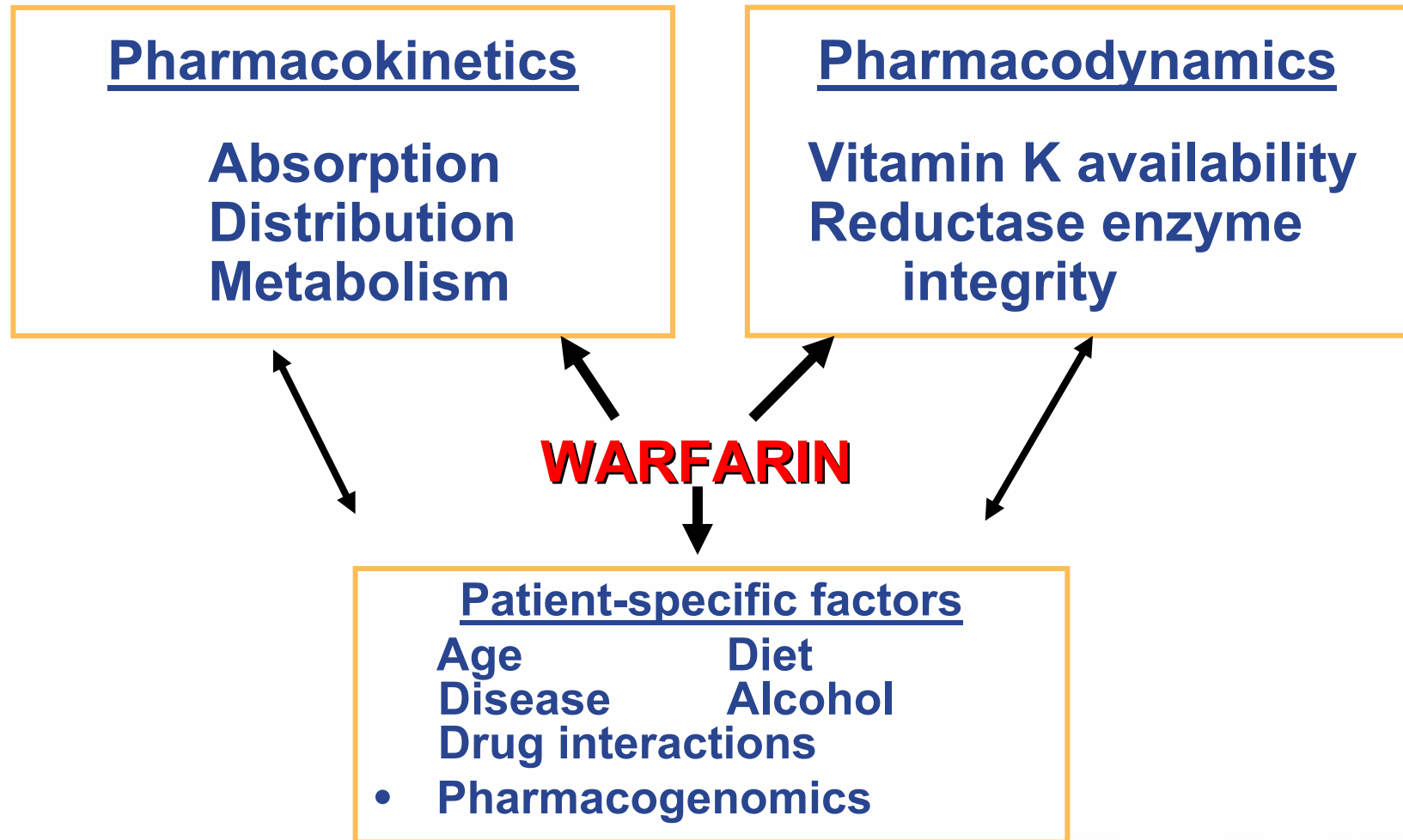
Outcomes

- | | |
|----|--|
| 7. | Incidence of potentially preventable hospital-acquired VTE |
|----|--|

Anticoagulant Therapy SCIP and VTE Measures

- Increase in anticoagulant use with new VTE initiatives
 - DVT occurs in 25% and pulmonary embolism in 7% of all major surgical procedures. (Source MedQic at <http://ww.medqic.org>)
- MedQic has sample standing orders, protocols and risk factor assessment forms, DVT order set, and DVT physician order sheets
- These can assist hospitals with complying with these standards

Warfarin: Dose / Response Relationships



Factors that influence sensitivity to warfarin

- Age > 75
- Clinical congestive heart failure
- Diarrhea
- Drug interactions (e.g. concurrent drugs that inhibit warfarin metabolism)
- Elevated baseline INR
- Fever
- Hyperthyroidism
- Malignancy
- Malnutrition or NPO > 3 days
- Two genes

Average Daily Dosing Method; for initiation of Warfarin especially for Ambulatory patient with goal of INR 2.0 to 3.0

	Non-Sensitive Patients	Sensitive Patients*
Initial Dose	5mg qd	2.5mg qd
First INR	3 days	3 days
< 1.5	7.5mg qd	5mg qd
1.5 - 1.9	5mg qd	2.5mg qd
2-3	2.5mg qd	1.25mg qd
3.1-4	1.25mg qd	0.5mg qd
>4	hold	hold
Next INR	2 to 3 days	2 to 3 days

* See factors that influence sensitivity to warfarin (below)

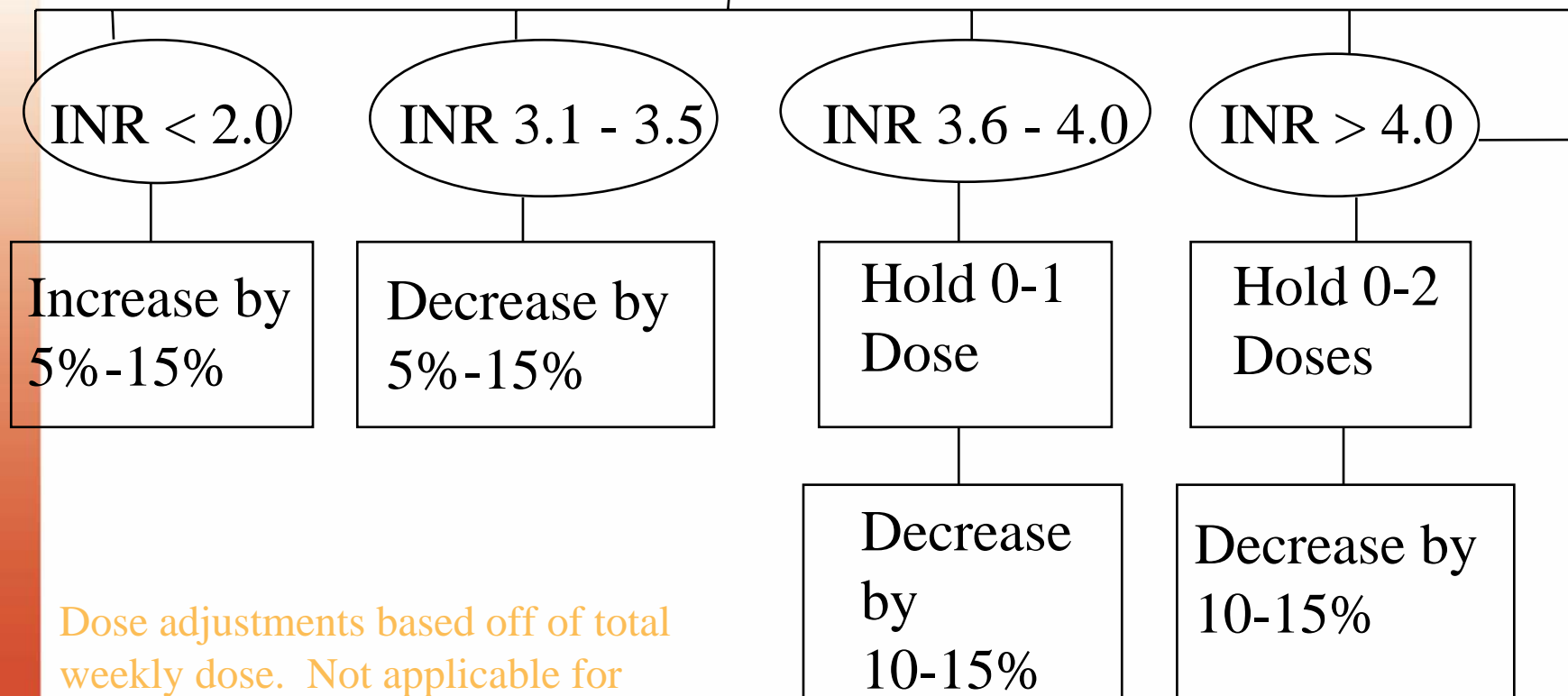


Frequency of Warfarin Monitoring

- flexible initiation
 - daily INR days 1-4; then within 3-5 days
- average daily dosing
 - first within 3-5 days; then within 1 week
- after hospital discharge
 - stabilized: within 3-5 days
 - not stabilized: within 1-3 days
- first month of therapy
 - weekly (or less if necessary)
- after first month of therapy
 - use maintenance guidelines

Warfarin: Maintenance Dose Adjustment

Dose alteration for Goal INR 2.0-3.0



Dose adjustments based off of total weekly dose. Not applicable for initiation phase.

Dosing Adjustment Nomogram for Maintenance Therapy

GOAL INR <u>2.0 - 3.0</u>		GOAL INR <u>2.5 - 3.5</u>
< 2.0	<ul style="list-style-type: none"> • reload x 0-1 • increase by 5-15% 	< 2.5
2.0 - 3.0	<ul style="list-style-type: none"> • no change 	2.5 - 3.5
3.1 - 3.5	<ul style="list-style-type: none"> • decrease by 0-15% 	3.6 - 4.0
3.6 - 4.0	<ul style="list-style-type: none"> • hold 0-1 dose • decrease by 5-15% 	4.1 - 4.5
> 4.0	<ul style="list-style-type: none"> • hold until therapeutic • +/- minidose vitamin K • decrease by 10-20% 	> 4.5



ACCP Recommendations: IV Heparin Dosing

- * corresponds to anti-Xa level of 0.3 – 0.7 u/ml
- Table adapted from Raschke et al²
- Measure aPTT 6 hrs post bolus
- Adapt therapeutic range to aPTT reagent used

Weight Based aPTT	Nomogram Dose
Initial dose	80 u/kg bolus 18 u/kg/hr
< 35 sec	80u/kg bolus ↑ 4 u/kg/hr
35 – 45 sec	40 u/kg bolus ↑ 2 u/kg/hr
46 – 70 sec*	No change
71 – 90 sec	↓ 2 u/kg/hr
> 90 sec	Hold x 1 hr ↓ 3 u/kg/hr

Chest 2004; 126: 189s-203s

²*Arch Int Med* 1996; 156: 1645-49



Sample Heparin Order Sheet

aPTT* (seconds)	Bolus dose	Infusion hold time	Infusion rate change
Under 50	4000 units	none	Increase by 200 units/hr
50-59	2000 units	none	Increase by 100 units/hr
60-100	No bolus	none	No rate change

***Goal aPTT range is institution dependent**



Heparin Monitoring with Anti-Xa Levels

- Experience with heparin monitoring using anti-Xa
- 0.3 – 0.7 u/ml by anti-Xa therapeutic
- Dosing equation developed using estimated blood volume (requires height & weight) & age
- 62% therapeutic in 8 hrs
- No outcomes data

Anti-Xa Level	Adjustment Factor
0 – 0.15	1.4
0.16 – 0.25	1.25
0.26 – 0.35	1.2
0.36 – 0.4	1.175
0.41-0.6	1
0.61-0.7	0.8
0.71-0.8	0.75
0.81-0.9	0.7
0.91 – 1.0	0.625
1.01 – 1.11	0.6
> 1.1	.575

Pharmacotherapy 2004; 24(6): 713-719



Resources



- **FDA Medication Guide for Patients at**
<http://www.fda.gov/cder/Offices/ODS/MG/warfarinMG.pdf>
- **FMEA on Anticoagulants published by the Institute for Safe Medication Practices,**
<http://www.ismp.org/Tools/FMEAofAnticoagulants.pdf>
- **Institute for Clinical Systems Improvement at**
<http://www.icsi.org>

Summary

- Review the 2008 JC NPSG (3E) requirements on anticoagulation therapy
- Describe the system requirements and implementation expectations for this standard
- Discuss implications for clinical practice, safety, and quality

Presenter:



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Objectives

- Describe practical, real world ideas to comply with the national patient safety goal 3E
- Identify common myths about the national patient safety goals

Warfarin Support Items

- **Baseline INR policy**
 - Defined that a baseline/current INR is within the last 24 hours since warfarin prescribing at any facility
 - Sets expectation for provider to include the INR in all warfarin orders
 - If no INR is available, pharmacist will order INR
 - **If pharmacist had to order/obtain INR**
 - Order will be dispensed if $INR < 3$
 - If $INR > 3$, pharmacist will make a professional decision if order is appropriate or if provider needs to be contacted prior to dispensing
 - Pharmacist will write order stating “Okay to give warfarin ____ mg as ordered by PROVIDER X, INR is ____”

Warfarin Support Items

- **Daily dose policy**
 - Warfarin orders greater than 24 hours in duration are not accepted by pharmacy
 - Pharmacists order daily INRs for all warfarin patients if not ordered already
 - Pharmacists put a warfarin “place holder” on MAR
 - Pharmacist can honor first dose of an order greater than 24 hours if dose is clinically appropriate
 - Professional decision by the pharmacist

5-mg Warfarin Nomogram		
Day	INR	Dosage
1		5.0 mg
2	< 1.5 1.5 - 1.9 2.0 - 2.5 >2.5	5.0 mg 2.5 mg 1.0 - 2.5 mg 0.0
3	< 1.5 1.5 - 1.9 2.0 - 2.5 2.5 - 3.0 > 3.0	5.0 - 10.0 mg 2.5 - 5.0 mg 0.0 - 2.5 mg 0.0 - 2.5 mg 0.0
4	< 1.5 1.5 - 1.9 2.0 - 3.0 > 3.0	10.0 mg 5.0 - 7.5 mg 0.0 - 5.0 mg 0.0
5	< 1.5 1.5 - 1.9 2.0 - 3.0 > 3.0	10.0 mg 7.5 - 10.0 mg 0.0 - 5.0 mg 0.0
6	< 1.5 1.5 - 1.9 2.0 - 3.0 > 3.0	7.5 - 12.5 mg 5.0 - 10.0 mg 0.0 - 7.5 mg 0.0

Crowther MA, et. al. *Arch Intern Med.* 1999; 159: 46-48.

SMMC Warfarin Dosing Method

- **Initiation**
 - **Give an appropriate initial dose**
 - Recommendations vary from 2.5-7.5 mg based on patient variables
 - **Give same dose on day two if less than 0.2 rise in INR, hold if greater than 0.4 rise**
 - **Day 3 and on, assess INR rise over two days**
 - If less than 0.3 rise, increase dose 25-50%
 - If 0.3-0.5 rise, keep same dose
 - If 0.5-1.5 rise, decrease dose 25-75%

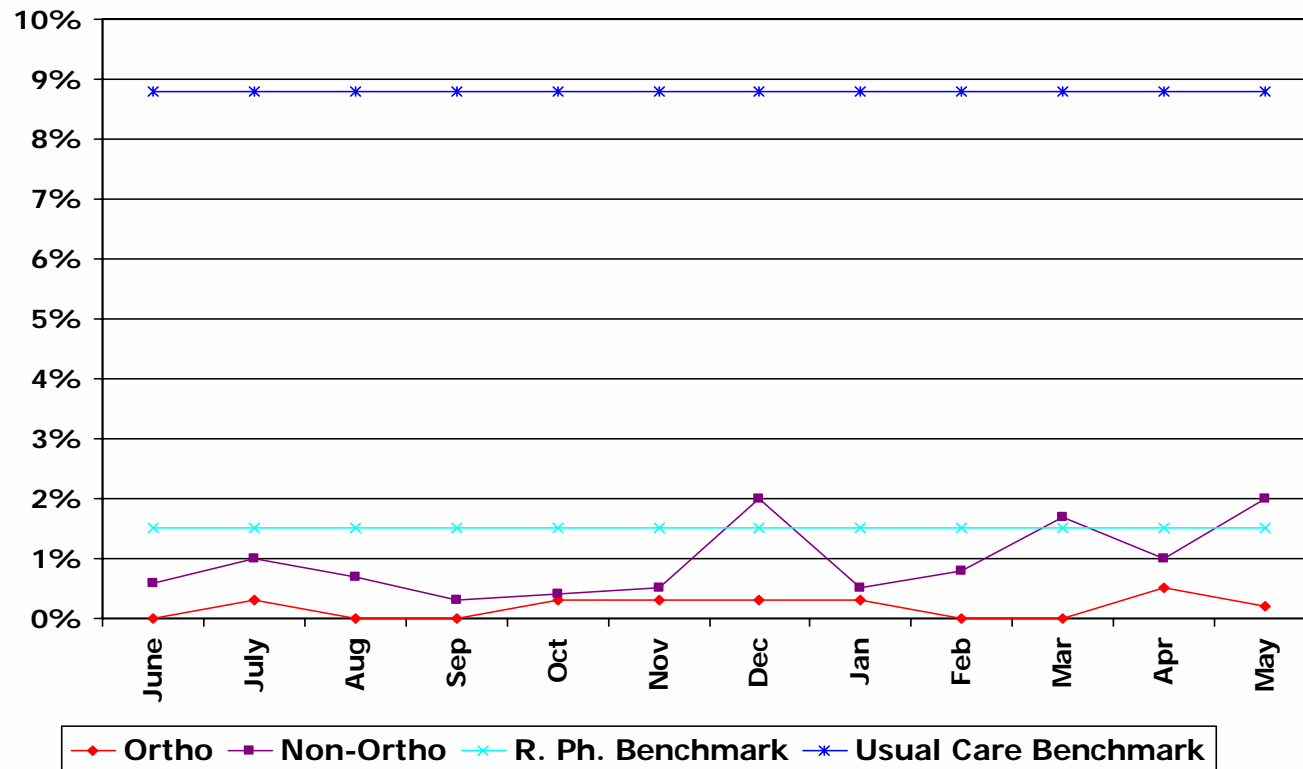
SMMC Warfarin Dosing Method

- **Maintenance dosing**
 - **In range:** Use home dose
 - **Low:** Consider 25-50% increase on first day
 - **High:** Consider 25-75% decrease on first day
 - Consider impact of current disease states and medication use
- **Dosing once in range**
 - What dose is currently having the largest effect on the INR?
 - How many mg's of warfarin did the patient require to get therapeutic?
 - How will the clinical conditions of the patient affect the INR?
- **When to hold:**
 - Generally, anytime when $INR > 4$
 - Any increase of 1.5 in INR in 24 hours

Warfarin Support Items

- **Discharge items:**
 - SMMC pharmacists use a check-off sheet to confirm all aspects of care are completed
 - SMMC pharmacist also fill out a pre-printed discharge anticoagulation order which specifies warfarin/LMWH dosing, discharge date INR and location, who is managing outpatient warfarin/LMWH dosing, and that the patient has received full education
 - SMMC developed their own warfarin education items, and the Sanofi-Aventis enoxaparin training

% INRs > 6 By Month



Dagger W. *The Annals of Pharmacotherapy*.2000;34:567-72

Vitamin K Tools

- **Vitamin K Policy**
 - **All subcutaneous and intramuscular vitamin K is automatically substituted to oral at the same dose if patient is taking oral**
 - Neonates excluded
 - Subcutaneous only used if strict NPO
 - **IV vitamin K piggybacked and give over 30 minutes**
 - Important to have this in writing and important training issue

Vitamin K Tools

- **Vitamin K Reversal Guideline**
 - Contains important pharmacology and kinetic information on vitamin K and FFP
 - Attempts to standardized dosing beyond classic CHEST recommendations
 - Covers correction for invasive procedures

Anticoagulation Bridging Guidelines

- **Attempt to standardize management of patient on chronic anticoagulation having a procedure**
 - Covers type and dose of parenteral anticoagulant therapy for both before and after a surgical procedure that should be considered based on warfarin indication
 - Covers when to stop/start warfarin, when to start/stop parenteral therapy, and when to get INRs

Staff/Provider Education Ideas

- **Has your hospital implemented an electronic education system?**
- **Can the education be tied to provider credentialing?**
- **Can provider newsletters be used for education?**
- **For the providers of your anticoagulation program, I strongly recommend verifying skills in practice**

Myth Busting Time

- **“Joint Commission requires pharmacists to be the ones dosing/managing all anticoagulants”**
 - Wrong-facilities need a defined anticoagulation management program
 - Up to the facility to determine what professionals are part of that program
- **“It is okay for nurses to “squirt” out enoxaparin” (example: 70 mg enoxaparin dose)**
 - Area of controversy
 - Early communication we received from Joint Commission indicated that pharmacy needs to provide all anticoagulants to nursing in a “unit of use”
 - Prefilled syringes must be used if available
 - Watch for further clarification

Myth Busting Time

- **“It is okay for nurses to split warfarin tablets when needed” (example: 0.5 mg of warfarin)**
 - Area of controversy
 - Early communication we received from Joint Commission indicated that pharmacy needs to provide all anticoagulants to nursing in a “unit of use”
 - Thought was that the exact dose would need to be in each package
 - Watch for further clarification
- **“It is okay for pharmacists to dispense warfarin without a baseline INR since the MD must have looked at it”**
 - Wrong-Joint Commission wants the pharmacist to review the INR prior to dispensing

Myth Busting Time

- **“The national patient safety goal applies to prophylactic treatment of heparin and LMWH”**
 - Wrong-The safety goals only apply to therapeutic treatment
 - If prophylactic therapy uses keeps patient in therapeutic ranges, the goals would apply
- **“The national patient safety goals cover fondaparinux”**
 - Wrong-fondaparinux is not a LMWH
 - Please treat it like a LMWH in your efforts

The “Unknown”

- The LMWH and warfarin issues already mentioned
- What about heparin in the cath lab? OR?
- What will come next year?

Conclusion

- **Hopefully, this has given you some “practical” ideas of tools needed to support a “defined anticoagulation management program”**
- **Keep an eye on the Joint Commission’s website for further clarifications**
- **We are all learning together, but remember why these requirements are happening**



QUESTIONS?