

# Implementing an Anticoagulation Management Program

Scott S. Malinowski, Pharm.D.  
Clinical Pharmacy Specialist  
Clinical Assistant Professor of Pharmacy Practice  
University of Mississippi Medical Center  
Jackson, Mississippi

July 2009



---

---

---

---

---

---

---

---

## Overview

- Benefits/risks of anticoagulation therapy
- Finding a balance
- Define Anticoagulation Management Program
- TJC standards and expectations (NPSG 3.05)
- NPSG 3.05 Elements of Performance
- Share ideas, examples, challenges



2

---

---

---

---

---

---

---

---

## Risks of Anticoagulation Therapy

- 5% of all ADE visits to EDs
  - 48.9% of patients >65 yrs will be hospitalized
- 7.2 - 7.44% of hospital ADEs
  - Fanikos, *Am J Cardiol* 2004
  - Bond, *Pharmacotherapy* 2006
- 7.1% of post-discharge ADEs
  - Forster, *J Gen Intern Med* 2005
- 10-16% frequency of major bleeding (warfarin)
  - Levine, *CHEST* 2001



3

---

---

---

---

---

---

---

---

## Risks of Anticoagulation Therapy

- From US death certificates, anticoagulants ranked first in 2003 and 2004 in the number of total mentions of deaths from drugs causing adverse effects during therapeutic use

- Wysowski, *Arch Int Med* 2007



4

---

---

---

---

---

---

---

---

## Balancing Safety and Efficacy



5

---

---

---

---

---

---

---

---

## Balancing Safety and Efficacy

- Protocols
- Pre-printed order forms
- CQI projects
- Multidisciplinary teams
- Physician champion
- Pharmacist involvement
- Patient/family involvement and education



6

---

---

---

---

---

---

---

---

## Balancing Safety and Efficacy

- Staff education
- Specialist consults
- Specialist clinics
- Policies and procedures

---

---

---

---

---

---

---

---

## Balancing Safety and Efficacy

- National Patient Safety Goal 3: Improve the safety of using medications.
  - NPSG.03.05.01: Reduce the likelihood of harm associated with anticoagulant therapy.

### Anticoagulation Management Program

- Goals
- Strategies
- Evaluation

---

---

---

---

---

---

---

---

## Rationale for NPSG 3.05

- Anticoagulants are high risk for ADEs and med errors:
  - Complex dosing
  - Narrow therapeutic index
  - Intense follow-up monitoring
  - Poor patient compliance
- Standardized practices can reduce risk of ADEs associated with heparin, LMWH, and warfarin

---

---

---

---

---

---

---

---

## Applicability of NPSG 3.05

- Institutions that provide anticoag therapy, and/or long-term prophylaxis, in which the coag labs are prolonged
  - Provide anticoag therapy means ordering, dispensing, or administering anticoagulants
- NOT outpatient pharmacies
- NOT short-term therapies for VTE prophylaxis (e.g. SQ heparin)



10

---

---

---

---

---

---

---

---

## Which Anticoagulants Does NPSG 3.05 Apply To?

- Warfarin
- Heparin (unfractionated)
- LMWHs
  
- Others may be added in the future
- TJC encourages including others in your AMP
  
- Flushes DO NOT APPLY



11

---

---

---

---

---

---

---

---

## NPSG 3.05

- Elements of Performance (EP)
- Some require documentation, and/or measurements of success



12

---

---

---

---

---

---

---

---

## NPSG 3.05 Elements of Performance

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

13



---

---

---

---

---

---

---

---

## EP #1

The term "defined anticoagulant management program" means a program, specified in writing, for individualizing anticoagulation therapy for each patient that involves the use of standardized practices and patient involvement, and which is specifically designed to reduce the risk of adverse drug events associated with the use of heparin (unfractionated), LMWH, warfarin, and other anticoagulants.

- From 2009 NPSG FAQ

14



---

---

---

---

---

---

---

---

## EP #1

- Suggestions:
  - Assignment of responsibility
  - Medical director
  - Formal policies and procedures
  - Purpose/mission statement
  - ???

15



---

---

---

---

---

---

---

---

**NPSG 3.05  
Elements of Performance**

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.



---

---

---

---

---

---

---

---

**EP #2**

- Suggestions:
  - Unit dose
  - Pre-filled syringe policy/procedure
  - Standardized pre-mix concentration
  - ???



---

---

---

---

---

---

---

---

**NPSG 3.05  
Elements of Performance**

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.

- \* Measure of success needed
- \* Documentation required



---

---

---

---

---

---

---

---

## EP #3

- Suggestions:
  - Policy/protocol
  - Approved by P&T, Med Exec, etc
  - Pre-printed order forms
    - Heparin
    - AMI
    - DVT/PE

19



---

---

---

---

---

---

---

---

## EP #3 - Suggestions (continued)

- DOCUMENTATION
  - Policies (AMP, RPh screening)
  - Pre-printed order forms
- MEASUREMENT OF SUCCESS
  - Audits (assessing compliance with policy)
  - Clinical interventions
  - Other???

20



---

---

---

---

---

---

---

---

## NPSG 3.05 Elements of Performance

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 this therapy.

21



---

---

---

---

---

---

---

---

## EP #4 - Baseline INR

- “The pharmacy should not dispense anticoagulants without the results of lab INR. Dispensing the drug when the test has been ordered, but without results, is not acceptable.”

- *TJC Surveyor Training Module*  
*Darryl Rich, PharmD*



22

---

---

---

---

---

---

---

---

## EP #4

- Suggestions:
  - Policy
  - Pre-printed order form
  - Pharmacy computer prompt
  - Audits (baseline, follow-up, dosage adjustments)



23

---

---

---

---

---

---

---

---

## NPSG 3.05 Elements of Performance

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.

\* Measure of success needed



24

---

---

---

---

---

---

---

---

## EP #5

- Suggestions:
  - Formal policy
  - Communicate with Dietary
  - Pharmacy report
  - Action depends on your policy
  - Audit (measurement of success required)
  - Other???

25



---

---

---

---

---

---

---

---

## NPSG 3.05 Elements of Performance

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

26



---

---

---

---

---

---

---

---

## NPSG 3.05 Elements of Performance

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.

\* Documentation required

27



---

---

---

---

---

---

---

---

## EP #7

- Suggestions:
  - Formal policy
  - Staff education
  - Built into pre-printed order form
  - Labs:
    - baseline aPTT and CBC
    - aPTT q6h until 2 consecutive aPTTs w/i therapeutic range, then once daily. Repeat if dose changed or restarted.
    - CBC every 3 days

28



---

---

---

---

---

---

---

---

## NPSG 3.05 Elements of Performance

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

**Note:** Patient/family education includes the importance of follow-up monitoring, compliance issues, dietary restrictions, and potential for adverse drug reactions and interactions.

\* Measure of success needed

29



---

---

---

---

---

---

---

---

## EP #8

- Suggestions:
  - Utilize your physician champion
  - Annual competency
  - Inservices
  - Newsletters
  - Patient education sheets (warfarin)
  - Patient education documented in chart
  - HOW TO MEASURE SUCCESS?

30



---

---

---

---

---

---

---

---

## NPSG 3.05 Elements of Performance

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.

31



---

---

---

---

---

---

---

---

## EP #9 - Suggestions:

- Anticoagulation Safety Team
  - AMP medical director (Chair)
  - P&T Chair
  - Pharmacy
  - Nursing
  - PI
  - Patient Safety Officer
  - Dietary

32



---

---

---

---

---

---

---

---

## EP #9 - Suggestions (continued)

- Anticoagulation Safety Plan
  - Purpose
    - ongoing system based process to evaluate and improve the safe use of anticoagulants
  - Process
    - core safety practices monitored quarterly
    - annual report to P&T Committee
    - list of items/outcomes routinely monitored

33



---

---

---

---

---

---

---

---

## EP #9 - Suggestions (continued)

- Anticoagulation Safety Plan items/outcomes monitored:
  - Annual review of AMP, protocols
  - ADR reports related to anticoagulants
  - Warfarin measures of quality and safety:
    - % patients with baseline INR
    - % patients with follow-up INRs
    - % INRs above therapeutic range (or > 6)
    - Vitamin K for reversal (usage statistics, dosing)
    - % patients with documented education
    - Time to achieve therapeutic INR

34



---

---

---

---

---

---

---

---

## EP #9 - Suggestions (continued)

- Anticoagulation Safety Plan items/outcomes monitored:
  - Eval of warfarin food-drug interaction procedure
  - Q.I. projects in outpatient Anticoagulation Clinics
  - Compliance with policies/protocols (heparin, etc)
  - Eval of overrides to ADMs, smart pumps
  - Appropriate use of pre-printed order forms
  - Eval of heparin infusion admixtures (type, conc.)
  - Analysis of pharmacist interventions (anticoags)

35



---

---

---

---

---

---

---

---

## Want a copy of our packet?

If you would like a copy of the 77 page packet that we prepared for the TJC survey regarding NPSG 3.05 and our Anticoagulation Management Program (in PDF file format), e-mail me at:

[SMalinowski@pharmacy.umsmc.edu](mailto:SMalinowski@pharmacy.umsmc.edu)

36



---

---

---

---

---

---

---

---