

# Reducing the Risk of Patient Harm with Anticoagulation Therapy

## Reducing the Risk of Patient Harm with Anticoagulation Therapy

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Products Most Frequently Involved in Medication Errors (categories e-l), cy 2006			Products Most Frequently Involved in Harmful Medication Errors (categories e-l), cy 2006		
Generic Name	n	%	Generic Name	n	%
Insulin*	2,482	3.7	Insulin*	438	18.2
Potassium Chloride*	4,481	2.3	Morphine*	123	4.6
Morphine*	4,269	2.2	Heparin*	83	3.1
Vancomycin	3,308	1.7	Hydromorphone*	71	2.7
Heparin*	3,246	1.7	Warfarin	61	2.3
Albuterol	3,217	1.6	Fentanyl*	59	2.2
Cefazolin	2,927	1.5	Potassium Chloride*	52	2.0
Warfarin	2,628	1.4	Vancomycin	45	1.7
Enalapril*	2,611	1.4	Flonase*	44	1.7
Furosemide	2,563	1.4	Clozapine	37	1.4
Acetaminophen	2,423	1.3	Furazemide	31	1.2
Hydrocodone and Acetaminophen	2,326	1.3	Total Parenteral Nutrition	28	1.1
Levofloxacin	2,146	1.1	Promethazine	25	0.9
Oxycodone and Acetaminophen	1,927	1.0	Levofloxacin	23	0.9
Meprobamate	1,895	1.0	Dicyclanole	22	0.8
Lorazepam	1,875	1.0	Ceftriaxone	21	0.8
Aspirin	1,788	0.9	Midazolam	21	0.8
Hydromorphone*	1,739	0.9	Phenytoin	21	0.8
Lidocaine	1,642	0.9	Clonidine	20	0.8
Levofloxacin	1,621	0.8	Hydrocodone and Acetaminophen	20	0.8
Piperacillin and Tazobactam	1,553	0.8	Sodium Chloride	20	0.8
Ibuprofen	1,546	0.8	Lorazepam	19	0.7
Ceftriaxone	1,536	0.8	Heparin*	19	0.7
Sildenafil	1,458	0.7	Metoprolol Tartrate	19	0.7
Fentanyl*	1,429	0.7	Cefazolin	18	0.7

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## Pa-PSRS Program

- 25% of all medications errors reported involve high alert medications
  - 44% involved pain management
  - 16.3% involved insulin products
  - **14.2% involved heparin**
  - **9.4% involved warfarin (Coumadin®)**

Pa-PSRS = Pennsylvania- Patient Safety Reporting System

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## Systems of Medication Use

- Patient Information
- Drug Information
- Communication
- Labeling, Packaging and Nomenclature
- Patient Education
- Environmental Factors
- Drug Storage, Stock, and Distribution
- Device Acquisition, Use and Monitoring
- Staff Competency and Education
- Quality Culture

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## Safeguarding high-alert medications

- Failure mode and effects analysis (FMEA)
- Constraints that limit access or use
- Forcing functions
- Standardize
- Simplify
- Externalize or centralize error-prone processes

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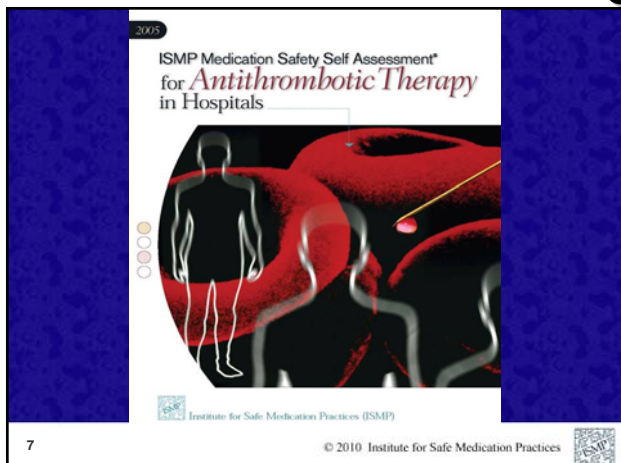
## Safeguarding high-alert medications

- Differentiate items
- Redundancy
- Reminders
- Improve access to information
- Patient monitoring

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# Reducing the Risk of Patient Harm with Anticoagulation Therapy



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## Patient Information

- **Lack of critical patient information**
  - laboratory values, height, weight, diagnoses, allergies, other drug therapy, etc.
  - lack of drug information systems that merge with patient information
  - patient misidentification

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## Patient Information Problems

- **Renal impairment**
  - Failure to reduce dose in patients with decreased renal function
- **Duplicate or concurrent therapy**
  - LMWH given in ED and heparin infusion started too soon on inpatient care unit
  - Concomitant use of warfarin and other antithrombotics

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## ISMP Antithrombotic Assessment

72) Upon inpatient admission, all medications administered in the ED or other outpatient setting (cath lab, etc) are immediately communicated to pharmacy and entered in the pharmacy computer system in a manner that facilitates an automated alert for duplicate therapy, contraindications, etc.

<u>None</u>	<u>Partial</u>	<u>Full</u>
44%	35%	21%

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## Patient Information Problems

- **Lab Values**
  - Failure to verify lab values before administering
  - Too frequent dose adjustments without assessing upward or downward trend in INR values
- **Patient Weight**
  - Estimated or not verified
  - Mix-ups between pounds and kilograms

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## ISMP Antithrombotic Assessment

16) Antithrombotic drug orders cannot be entered into the pharmacy information system until the patient's height and weight are entered.

<u>None</u>	<u>Partial</u>	<u>Full</u>
85%		15%

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# Reducing the Risk of Patient Harm with Anticoagulation Therapy

## Key Improvements

### Standardize

- Record in a standardized location documentation of medications administered in the ED and cardiac catheterization lab
- Use only kilograms for patient weights
- Develop and follow a standardized:
  - Format for communicating to the pharmacy, all dose adjustments based on laboratory values
  - Process for obtaining aPTT values at required intervals and communicating results to prescribers

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## Key Improvements

### Reminders

- Assess all drug therapy to avoid concomitant use of heparin products
  - Protocols
  - Standard order forms
  - Guidelines

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## Key Improvements

### Improve access to information

- Provide key elements of patient information to the pharmacist upon admission
  - Age, gender, allergies, diagnosis, comorbidities, height, weight [actual] current drug therapy
  - Medications given in ED

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## Key Improvements

### Patient monitoring

- Obtain baseline hemoglobin, hematocrit, serum creatinine and platelet count prior to initiating anticoagulant therapy

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## Drug Information

- Lack of accessible or up-to-date references
- Computer systems that fail to detect unsafe orders
- Lack of a tightly controlled formulary
- Lack of clinical pharmacists in patient care areas
- Failure to use standardized drug protocols

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## ISMP Antithrombotic Assessment

39) Disease specific protocols are available and used to guide appropriate and safe warfarin therapy; and the different protocols are clearly labeled to ensure proper identification and use.

<u>None</u>	<u>Partial</u>	<u>Full</u>
54%	28%	18%

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# Reducing the Risk of Patient Harm with Anticoagulation Therapy

## ISMP Antithrombotic Assessment

- 56) A protocol exists to guide
- Reversal of supra-therapeutic INR values while taking into consideration the INR value,
  - Absence or presence of clinically significant bleeding, and
  - Other factors that gauge necessity and urgency of reversal.

<u>None</u>	<u>Partial</u>	<u>Full</u>
57%	21%	22%

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## Heparin Improvements

### Standardize

- Develop guidelines and protocols
- One weight based heparin protocol per disease state
  - ACS, DVT, Stroke
  - Differentiate the appearance of each
- Use weight-based infusion charts to determine bolus doses and infusion rates

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## Heparin Improvements

### Patient monitoring

- Establish and follow a protocol for
  - Detecting and treating heparin-induced thrombocytopenia (HIT),
  - Communicating this information to all practitioners caring for this patient

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## Warfarin – Key Improvements

### Patient Monitoring

- Implement pharmacy monitoring / dosing of warfarin therapy based on protocols
- Develop and follow protocols for the use of vitamin K for reversal of supratherapeutic INR's.
- Record the protocol being followed on the MAR and the pharmacy patient profile

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## Communication of Drug Information

### Barriers to ineffective communication

- Handwritten orders
- Dangerous abbreviations / dose designations
- Verbal orders
- Look alike names
- Ambiguous orders
- Fax-related problems
- Hold orders

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25 mc/hr

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## Warfarin - Problems

### Dosing Errors

- Directions are confusing (alternate day dosing)
- Changes in directions via telephone can cause confusion for some patients
- Failure to take recent prescribing of vitamin K into consideration when resuming therapy

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## Warfarin - Problems

### Accidental stoppage of therapy

- Automatic stop orders
- Failure to resume warfarin therapy after holding a dose(s),
  - Post-procedure or if the procedure is cancelled or delayed

### Look-alike names

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D Coumadin 5mg  
PO daily

Coumadin 5mg

Disp: #90

Sig:  $\dot{\bar{r}}$  PO daily

All previous Coumadin orders  
Coumadin 2mg p.o. b.i.d.  
Coumadin 4mg p.o. q.a.m.

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## Standardize Order Communication

- Standardized order forms
  - List specific products
  - Prompts to fill
- Standardized protocols
- Establish and enforce safe ordering guidelines
  - List of dangerous abbreviations
  - Trailing zeros; leading zeros
  - Verbal orders
  - Eliminate use of non-standard symbols

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## Drug Labeling, Packaging, and Nomenclature

### Healthcare setting

- Unlabeled syringes prepared by staff
- Unclear computer-generated labels
- Unlabeled, open and undated insulin vials

### Manufacturer

- Ambiguous manufacturer labeling and packaging
- Similar drug names, packaging or labeling

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# Reducing the Risk of Patient Harm with Anticoagulation Therapy

## Heparin Problems

### Concentration errors

- Various concentrations mixed up due to look-alike vials and IV bags
- Mix-ups between 1,000 units/500 mL bags used for maintenance of arterial lines and 25,000 units /500 mL bags for IV use
- Standard concentration of commercially available product is *not used*

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## Heparin Problems

### Improper manufacturer labeling

- 10,000 units/mL 2 mL vial instead of 20,000 units/2mL

### Preservatives

- Heparin containing benzyl alcohol as a preservative have cause toxicity in newborns

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## Heparin Problems

### Similar packaging

- Heparin and Hespan
- Heparin 1 mL vials and other 1 mL vials
- Carpuject syringes
- Heparin and flushes

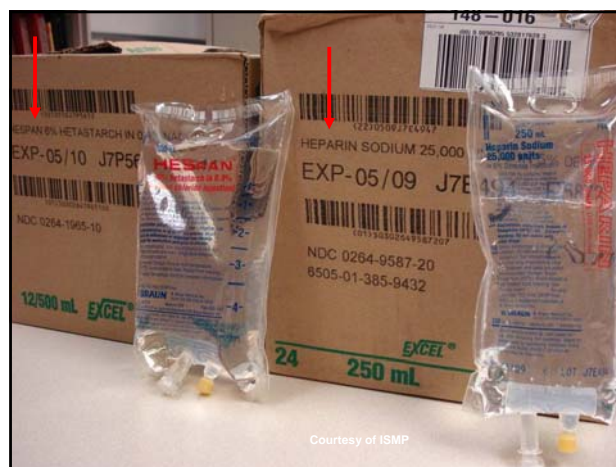
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# Reducing the Risk of Patient Harm with Anticoagulation Therapy



## Drug Storage, Stock, Standardization, and Distribution

- Poor control of floor stock & automated dispensing cabinets
- Unnecessary or unsecured medications available in patient care areas
- Uncontrolled access to hazardous substances
- Drug admixture on patient care units

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## Heparin Improvements

### Constraints

- Do not store heparin flush vials on top of medication carts, counters, or under laminar flow hoods in the pharmacy
- Purchase prefilled syringes for heparin flush
- Separate heparin and insulin

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# Reducing the Risk of Patient Harm with Anticoagulation Therapy

## Heparin Improvements

### Standardize

- Develop one standard concentration for infusions
- Purchase premixed products
- Limit the number of different heparin concentrations in the facility and on patient care units
- Use one concentration for bolus doses and use pre-filled syringes for flushes

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## LMWH – Key Improvements

### Limit access or use

- Limit floor stock of LMWH to ED
- Dispense all other doses from the pharmacy or make it available in ADC's only after pharmacy review of the order.

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## Key Improvements

### Separate problem products

- Separate storage of drugs with look-alike packaging/names
  - Stock LMWH syringes away from look-alike heparin flush syringes
  - Stock heparin infusions away from Hesperin

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## Differentiate Items

- Purchase look-alike products from different vendors
- Use tall-man lettering on labels, order entry screens, e.g., HeSPAN - HEParin
- Use other means to “make things look different” or call attention to important information
  - Stickers, labels, enhancement with pen or marker

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## Drug Device Acquisition, Use, and Monitoring

- Failure to limit the variety of pumps used
- Use of pumps without free-flow protection
- Unlabeled lines
- Lack of an independent double check system for high alert medications

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## Heparin Problems

### Dosing errors

- Pump setting errors with
  - Concentration
  - Rate of infusion - Units vs. mLs
- Infusion pumps used to deliver bolus then not adjusted back to continuous infusion rate

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## Unfractionated Heparin Improvements

### Simplify

- Do NOT deliver a bolus dose by temporarily modifying the infusion rate of a maintenance infusion
- Administer the bolus directly from a syringe

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## Heparin Improvements

### Redundancies (on patient care unit)

- Require an independent double check:
  - Drug
  - Concentration
  - Dose calculations
  - Patient identity
  - Rate of infusion
  - Pump settings
  - Line attachment

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## Measuring Safety of Anticoagulation Therapy

- **Outcome Measures**
  - How is the system performing?
  - What is the result?
- **Process Measures**
  - Assess how well you are performing core processes
  - Are the parts/steps in the system performing as planned?

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## Process Measures - General

- 1)  $\frac{\# \text{ of Anticoagulant orders in the pharmacy computer without the patient's weight}}{\# \text{ of Anticoagulant orders}}$
- 2)  $\frac{\# \text{ of Coagulation test results (INR, aPTT, platelet count) that are available on the patient's chart within 2 hours after drawing the blood}}{\# \text{ of Coagulations test results}}$

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## Process Measures - Warfarin

- Number of patients that were discharged from the hospital without:
  - An appointment for the next INR measurement, or
  - Consultation with an appropriate healthcare professional for follow-up

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## Process Measures - Heparins

- Percent of patients on heparin with a baseline hemoglobin, hematocrit, serum creatinine, and platelet count prior to initiation
- Percent of patients on enoxaparin with renal impairment (specify test parameters) who do not have a dose reduction

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# Reducing the Risk of Patient Harm with Anticoagulation Therapy

## Outcome Measures – General

- Percent of patients who develop
  - Bleeding, or
  - Thrombosis while on anticoagulants

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## Outcome Measures - Warfarin

- Percent of patients on warfarin whose INR is above 6
- Percent of patients who receive Vitamin K for high INR and not actively bleeding

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## Outcome Measures - Heparin

- Percent of patients on unfractionated heparin with an aPTT:
  - Greater than 1.5 times the upper end of the therapeutic range, or
  - Less than the lower limit of the therapeutic range after 24 hours of therapy
- Percent of patients with platelet counts of
  - Less than 100,000/mm<sup>3</sup> or
  - Less than 50% of the baseline who undergo laboratory testing for the hit antibody

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## Methods of Collecting Data on Anticoagulant Safety

- Proactive Risk Assessment
  - Self Assessments
  - Failure Mode and Effects Analysis (FMEA)
  - External Sources of Data
- Concurrent Risk Assessment
  - Trigger and Markers
  - Pharmacy Interventions
- Retrospective Risk Assessment
  - Observational methodology
  - Data from Technology
  - Chart reviews
  - Internal, voluntary reporting

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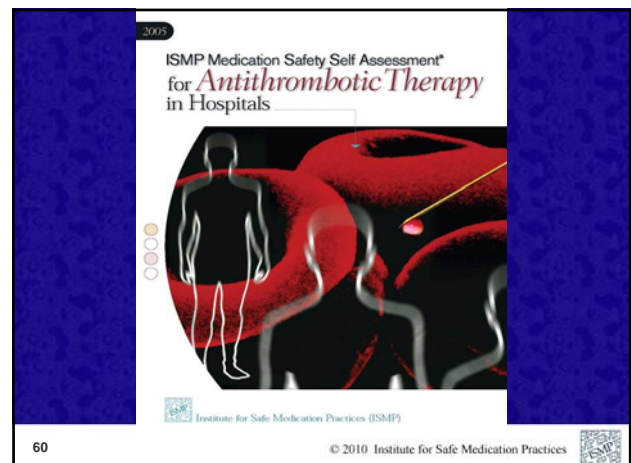


## Tools on ISMP Website

- [www.ismp.org/Tools/anticoagulantTherapy](http://www.ismp.org/Tools/anticoagulantTherapy)
  - Failure Mode and Effects Analysis for Anticoagulants
  - ISMP Medication Safety Self Assessment® for Antithrombotic Therapy in Hospitals

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# ***Reducing the Risk of Patient Harm with Anticoagulation Therapy***

**QUESTIONS?**

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