Example of a Health Care Failure Mode and Effects Analysis for Anticoagulants

Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number	Actions to Reduce Failure Mode
Formulating a plan of care (Process steps 1-2)								
1) Assess patient	a) Diagnosis incorrect	• Diagnostic tests are not performed • Wrong diagnostic tests are performed • Diagnostic tests are analyzed incorrectly or misinterpreted • Diagnostic tests from the wrong patient are used during assessment • Diagnostic tests not available in timely manner	Patient receives anticoagulant when not indicated B, ADR	5				**1.a1** Testing protocol for patients who present with signs of thrombosis **1.a2** Interdisciplinary treatment guidelines for the use of anticoagulant therapy, which includes prescribing guidelines (e.g., indications, contraindications, dosing for treatment and prophylaxis), drug dispensing guidelines, drug administration guidelines, and monitoring requirements **1.a3** Pharmacy monitoring service in which the physician is notified when patients with a diagnosis that often requires anticoagulation (e.g., cardiac, vascular, orthopedic) do not have an appropriate anticoagulant prescribed upon admission **1.a4** Peer-review process for reviewing/rereading diagnostic tests based on severity of outcome of a misdiagnosis **1.a5** Use of two patient identifiers when communicating and posting diagnostic test results **1.a6** Require persons receiving verbal reports of test results to record and read-back the result **1.a7** Improve the timeliness of reporting critical test results **1.a8** Have all coagulation test results available on the patient record within 2 hours from the time of sample collection, or use point-of-care testing equipment at the patient's bedside for immediate results **1.a9** Use more than one test to diagnose when possible
			Patient does not receive anti-coagulant when indicated T, D	10				
	b) Anticoagulant contraindicated	• Diagnosis inconclusive • Didn't know about current/prior treatment • Didn't know about disease interactions, drug	Patient receives anticoagulant when contra-indicated B, ADR, D	10				**1.b1** Repeat inconclusive tests **1.b2** Medication reconciliation process **1.b3** Alerts during order entry for significant drug interactions/incompatibilities (and disease interactions, if possible)

B=Bleeding T=Thrombosis D=Death ADR=Other Adverse Drug Reaction

Scale 1-10: Severity: 10=most severe effect Probability: 10=very likely to occur Detection: 10=very unlikely to detect RPN=product of three scores

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		interactions, other contraindications and incompatibilities • Unreliable patient history						**1.b4** Communicate the patient's acute and chronic conditions (and other important data such as allergies, height, weight) to the pharmacy for consideration during order screening
	c) Unnecessary use of anticoagulants, particularly heparin (including heparin flush/heparinized solutions)	• Knowledge deficit • Outdated policies/ procedures	Unnecessary risk of error B, ADR	5				See **1.a2** (interdisciplinary treatment guidelines) **1.c1** Educate healthcare practitioners **1.c2** Establish and follow evidence-based practices regarding the use of heparin flushes/heparinized solutions **1.c3** Use saline, not heparin, flushes for peripheral lines **1.c3** Consider anticoagulants other than heparin when appropriate (heparin allows more opportunity for errors because of its availability in various concentrations, various modes of preparation, and several routes of administration) **1.c4** Consider using low-molecular weight heparin for prophylaxis and treatment of venous thrombosis (no need for dose adjustments, pump programming, analysis of aPTT, and patients may go home on this drug while being converted to warfarin) **1.c5** Consider using normal saline solution bags instead of heparin solutions for arterial lines (saline is equally good for flushing blood and medications through arterial lines)
2) Choose the anticoagulant	a) Wrong anticoagulant selected for specific patient	• Clinical diagnosis not known/considered • Patient-specific parameters not known/considered (e.g., renal and hepatic function, allergies, platelet count) • Knowledge deficit about drug indication • Drug specific contra-indications not known	Allergic response Patient receives the wrong anticoagulant B, T, ADR, D	10				See **1.a2** (interdisciplinary treatment guidelines) See **1.a3** (pharmacy monitoring service) **See 1.b2** (medication reconciliation) See **1.b4** (communicate patient information to the pharmacy) **2.a1** Computerized prescriber order entry (CPOE) with decision support (clinical alerts, etc.) **2.a2** Clinical pharmacy program to dose and monitor anticoagulant therapy **2.a3** Provide point-of-use access to drug information

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		• Mental slip • Standard protocols/ prescribing guidelines not followed or do not exist • Didn't know about prior treatment with anticoagulants						**2.a4** Lab/pharmacy computer system interface to alert practitioners to contraindications **2.a5** Anticoagulant team to manage patients with complicated thrombotic episodes
Prescribing (Process step 3)								
3) Prescribe the anticoagulant	a) Failure to initiate standard order set/preprinted orders	• Don't exist • Don't know they exist • Not followed/don't agree with protocols • Outdated/inaccurate • Numerous individual modifications	Therapy may not meet standard of care B, T, ADR, D	10				See **1.a2** (interdisciplinary treatment guidelines) **See 2.a2** (clinical pharmacy program) **3.a1** Gain consensus from the medical staff and establish standard order sets/preprinted orders or protocols for warfarin and heparin, including monitoring requirements (don't use *variable* sliding scales for warfarin or heparin dosing)
	b) Sections of pre-printed orders incomplete	• No standard process for making selections on forms/screens (e.g., cross outs, check marks, initials, fill in blanks) • Unfamiliarity with process • Human factors	Therapy may not meet standard of care Wrong drug/dose/ frequency B, T, ADR, D	10				**3.b1** Consistent process for making selections on preprinted orders or order sets **3.b2** Call for clarification if information is missing
	c) Wrong drug/form of drug/route of administration	• Knowledge deficit • Mental slip • Information about drug not readily available • Inadequate medication reconciliation process	B, T, ADR, D	10				See **1.a2** (interdisciplinary treatment guidelines) See **1.b2** (medication reconciliation) See **2.a3** (provide drug information) **3.c1** Check patient allergies before prescribing **3.c2** Match the patient's diagnosis to the indicated use of the drug before dispensing and/or administering the drug
	d) Wrong dose (e.g., daily dose, loading dose, maintenance infusion, titration)	• Clinical situation not known or considered (e.g., weight, age, renal function, platelet count) • Dose based on unverified weight • No distinction between treatment and prophylaxis • Knowledge deficit	B, T, ADR, D	10				See **1.a2** (interdisciplinary treatment guidelines) See **1.b2 (**medication reconciliation) See **1.b4** (communicate patient information to the pharmacy) See **1.a8** (test results available within 2 hours) See **2.a2** (clinical pharmacy program with dosing guidance) See **2.a3** (provide drug information) See **2.a4** (lab/pharmacy interface)

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		• Mental slip • Variable dosing among low-molecular weight heparin products • Non-formulary drug • Wrong selection from list • Calculation error • Lab error (e.g., equipment calibration, overfilling blood collection tubes) • Inadequate medication reconciliation process						See **2.a5** (anticoagulant team for complicated thrombotic episodes) **3.d1** Stretchers with built-in bed scales in the ED **3.d2** Weigh all ambulatory patients **3.d3** Establish a consistent location to document the most current measured weight **3.d4** Choose one low-molecular weight heparin for the formulary **3.d5** Follow a standard weight-based heparin protocol **3.d6** Check and calibrate lab equipment **3.d7** Train lab staff about proper collection techniques
	e) Wrong frequency	• Knowledge deficit • Information about drug not readily available • Inadequate medication reconciliation process	Overdose B Subtherapeutic dose T	8				See **1.a2** (interdisciplinary treatment guidelines) See **1.b2** (medication reconciliation) See **2.a3** (provide drug information)
	f) Unsafe concomitant therapy with other anticoagulants Failure to adjust the dose when receiving concomitant therapy	• Prior anticoagulant therapy not known/documented • Prior anticoagulants not considered/not discontinued • Knowledge deficit about safe timing of first dose of new anticoagulant after prior anticoagulant discontinued • Human factors (e.g., forget) • Inadequate medication reconciliation process	Overdose B, D	10				See **1.a2** (interdisciplinary treatment guidelines) See **1.b2** (medication reconciliation) See **2.a2** (clinical pharmacy program) See **2.a5** (anticoagulant team for complicated thrombotic episodes) **3.f1** Prominent reminders on treatment guidelines and order forms to discontinue low-molecular weight heparin before starting a heparin infusion **3.f2** In treatment guidelines and order forms, include how long to wait before initiating heparin therapy if a patient has received a prior dose of low-molecular weight heparin **3.f3** Dispense heparin products (except flushing solutions) from the pharmacy as needed **3.f4** Review the patient's current and recent drug therapy before administering any heparin product **3.f5** Alerts on order entry and automated dispensing cabinet screens to warn about concomitant use/duplicate therapy **3.f6** Notify pharmacy to all heparin doses given to

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								ED patients who are admitted to the hospital **3.f7** Administer heparin only after a pharmacist has reviewed the order and another practitioner has independently checked the order and patient's drug profile (all MARs, documentation of drug administration) **3.f8** Mention all doses of heparin given to ED patients during handoff reporting to the admitting nurse on an inpatient unit **3.f9** Document all heparin (or other anticoagulants) administered in a consistent location (not imbedded in notes) **3.f10** Place an alert on the chart of patients who have received anticoagulants or are changing from one anticoagulant to another **3.f11** Prompts on preprinted forms, order sets, and CPOE systems to adjust doses accordingly when prescribing concomitant therapy
	g) Prescribed on wrong patient	• Similar patient names • Patient identifier not checked/not clear • Name does not appear on the order form or immediate screen when prescribing • Mistakenly pick up/select the wrong chart/file • Environmental factors (e.g., distractions, poor lighting)	Patient receives anticoagulant when not indicated B, ADR, D Patient does not receive anticoagulant when indicated T, D	5 10				**See 3.c2** (match indication to diagnosis) **3.g1** Display alerts for look-alike patient names **3.g2** Patient's name and other demographic information clearly visible on order forms and on the actual computer screens viewed while prescribing or dispensing medications **3.g3** Verify two patient identifiers on the patient's record before prescribing medications **3.g4** Quiet, well lit space for writing orders
	h) Orders for patient monitoring omitted, incomplete, or inaccurate (e.g., wrong lab test, frequency too often or not frequently enough)	• Knowledge deficit • Human factors • Environmental factors (e.g., distractions) • No standard protocol for monitoring	Failure to adjust the dose properly Failure to detect problems early to minimize harm B, T, ADR, D	10				See **1.a2** (interdisciplinary treatment guidelines) See **2.a2** (clinical pharmacy program) See **2.a5** (anticoagulant team for complicated thrombotic episodes) See **3.a1** (standard orders) **3.h1** Include standard monitoring process in order sets and preprinted orders
	i) Accidental discontinuation of	• Forget to restart after holding	Omitted therapy	8				See **1.a2** (interdisciplinary treatment guidelines)

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	anticoagulant	orders temporarily • Automatic stop orders (especially for patients taking an anticoagulant for an alternative purpose such as atrial fibrillation)	T					See **1.b2** (medication reconciliation) **3.i1** Add strategy for handling "hold" orders in the treatment guidelines. Include the following: **3.i2** For *daily* warfarin doses based on *daily* lab results, list the order in the pharmacy profile and MAR as an active order with a note that a daily dose should be prescribed. If a dose must be held, an order for "no warfarin today" should be received and documented on the pharmacy profile and MAR **3.i3** If the anticoagulant dose is not guided by daily lab values, hold orders should include instructions on when to resume the medication **3.i4** Reorder and reconcile post-procedure anticoagulants **3.i5** Prompts to reorder anticoagulants in post-procedure standardized order sets when applicable **3.i6** Tracking medications placed on hold, and contact patients regarding instructions for resuming the medication **3.i7** Tell patients when to expect a call, and if not received, to contact the physician **3.i8** Specific approval of the prescriber before discontinuing orders for antithrombotics that are governed by a "stop order" policy
Dispensing (Process steps 4-9)								
4) Send order to pharmacy	a) Order not received/ processed in pharmacy	• Unaware of order on nursing unit • Medication used from floor stock, so order not sent • Verbal order not documented	Omitted therapy Necessary dose changes not implemented B, T, ADR, D	10				See **2.a1** (CPOE) **4.a1** Flagging system for new orders **4.a2** Physician review of new orders with unit staff **4.a3** Shift chart checks **4.a4** Standard verbal order receipt/documentation process **4.a5** Policy to send all orders to pharmacy **4.a6** Require pharmacy review of orders for anticoagulants before administration (no overrides for anticoagulants except standard adult heparin flush solution)
	b) Delay in receiving/process-	• Order not flagged	Use of floor stock before	10				See **4.a1** (flag new orders) See **4.a6** (pharmacy order review before

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	ing order	• Inefficient process for sending orders to pharmacy • Order not seen/misplaced after reaching pharmacy • Pharmacy workflow bottlenecks • Inadequate staffing patterns • Environmental factors (e.g., interruptions)	pharmacy screening: possible error Delay of drug therapy T, D					administration) **4.b1** Standard, efficient process for sending orders to the pharmacy **4.b2** Timely review and triaging of orders received in pharmacy **4.b3** Handle anticoagulant orders on a priority basis **4.b4** Manage flow of work to pharmacy order entry staff to reduce the risk of interruptions and facilitate prioritization during order entry
5) Enter order into computer	a) Order misunderstood	• Illegible order • Use of abbreviations (e.g., U) Use of trailing zeroes • Misread decimal doses (e.g., 1.5 misread as 15) • Drugs with look-alike names (e.g., Avandia/Coumadin) • Order copy and/or faxed order unclear	Delay in therapy Subtherapeutic dose T, D Allergic response Overdose B, D	10				See **2.a1** (CPOE) See **3.a1** (preprinted order sets) See **3.c2** (match indication and diagnosis) **5.a1** Prohibit the use of error-prone abbreviations, dose expressions **5.a2** Use the original order if faxing an order to the pharmacy **5.a3** Seek clarification directly with prescriber if orders are illegible or order copies are unclear
	b) Order entered incorrectly	• Error-prone software design • Error-prone computer mnemonics • Absent or ineffective computer alerts • Drugs with look-alike names • Environmental factors (e.g., interruptions, noise, poor lighting, cluttered space) • Failure/absence of double check when appropriate	Wrong therapy B, T, ADR, D	10				See **4.b4** (reduce interruptions, prioritize order entry) See **4.a3** (shift chart checks) **5.b1** User-friendly order entry process **5.b2** Look-alike drug name alerts **5.b3** Enter test orders for anticoagulants periodically, and when adding a new product to the formulary, to ensure that the order entry system displays the necessary alerts **5.b4** Adequate lighting and space in order entry areas **5.b5** Copyholders for bringing orders to eye level when entering orders **5.b6** Double check process for order entry in the pharmacy and on the nursing unit (order matches drug dispensed) **5.b7** Post a daily list of current and recently discontinued drug therapy (created from the pharmacy computer) for physician review to verify correct order entry of prescribed medications **5.b7** Daily MAR checks

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	c) Wrong administration times selected	• Administration times not standardized • Administration times not coordinated with lab tests • Miscommunication between nursing and pharmacy about time of administration/start of infusion	Delayed therapy (medication not on unit) Floor stock drug given: possible error Omission Unnecessary patient-specific doses on unit B, T	10				See **4.a3** (shift chart checks) See **4.a6** (pharmacy order review before administration) **5.c1** Use standard administration times for anticoagulants that allow sufficient time to obtain changes is dose based on review of daily lab values **5.c2** Communication to pharmacy about timing of first dose/start of infusion
	d) Order entered into wrong patient profile or wrong patient encounter	• Poor presentation of patient demographics (fax interference, light imprint, order copy unclear) • Look-alike patient names • Dangerous ability to enter new inpatient orders into a record from a prior encounter (inpatient or outpatient) • Environmental factors (e.g., interruptions, noise, poor lighting, cluttered space)	Patient receives anticoagulant when not indicated B, T, ADR	5				See **2.a1** (CPOE) See **4.a3** (shift chart checks) See **4.b4** (reduce interruptions and prioritize order entry) See **5.b7** (daily MAR checks) **5.d1** Display vivid demographics on order forms/screens **5.d2** High quality fax machines with routine maintenance **5.d3** High quality imprint machines for patient addressograph, or use preprinted stickers **5.d4** *"View only"* access to prior patient encounters **5.d5** Computer alerts for look-alike names **5.d6** Access the patient's pharmacy profile by entering the medical record number, not name **5.d7** Independent double check before anticoagulants are dispensed from the pharmacy
			Patient does not receive anticoagulant when indicated T, D	10				
6) Evaluate safety/appro-priateness of order	a) Order not evaluated by a pharmacist/not	• Time constraints • Environmental factors (e.g., interruptions)	Floor stock drug adminis-tered: possible	10	Day			See **4.a5** (send all orders to pharmacy) See **4.a6** (pharmacy order review before administration)

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(pharmacy screening)	evaluated in a timely manner	• Didn't receive the order • Didn't know there was an order	error Delayed therapy B, T, ADR, D		Night			See **4.b2** (timely review of orders) See **4.b3** (anticoagulant orders a priority) See **4.b4** (reduce interruptions and prioritize order entry) **6.a1** Adequate staffing patterns to accommodate timely order entry
	b) Indication/ appropriateness not	• Did not know information about the patient (e.g.,	Unsafe/inappro-priate medica-	5				See **1.a2** (interdisciplinary treatment guidelines) See **1.b2** (medication reconciliation)

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	verified	weight, age, renal function, lab monitoring values, diagnosis) • Inadequate medication reconciliation process	tions/doses reach the patient B, T, ADR					See **1.b4 (**communicate patient information to the pharmacy) See **1.a8** (test results available within 2 hours) See **2.a2** (clinical pharmacy program)
	c) Contraindications, interactions, unsafe doses and routes of administration not detected	• Knowledge deficit • Use of nonformulary drug • Inadequate or absent computer alerts • Computer not available for screening • Computer alerts not available • Alerts not read • Alerts bypassed (interpretation biases) • Database not current • Inadequate medication reconciliation process (patient taking unknown medications) • Patient diagnoses unknown	Unsafe/inappropriate medications/doses reach the patient B, T, ADR, D	10				See **1.b2** (medication reconciliation) See **1.b4** (communicate patient information to the pharmacy) See **2.94** (lab/pharmacy interface) See **2.a2** (clinical pharmacy program) See **4.a5** (send all orders to pharmacy) See **4.a6** (pharmacy order review before administration) **6.c1** Test the order entry system to ensure that clinically significant alerts appear during order entry of an anticoagulant, and that clinically insignificant alerts are suppressed **6.c2** Ensure/add appropriate alerts to the order entry system for new products added to the formulary **6.c3** Update the drug information database monthly **6.c4** Periodically review report of bypassed alerts to monitor appropriateness **6.c5** Require pharmacists to document a reason for bypassing a clinically significant alert
7) Prepare medication	a) Wrong product or dose/concentration	• Look-alike products stored near each other (e.g., different strengths of heparin vials and solutions; look-alike IV bags of heparin, dopamine, lidocaine, Hespan; prefilled syringes of heparin flush, saline, immunizations) • Look-alike products mistakenly sent by wholesaler and/or misplaced in pharmacy stock • Failure to use a standard	Allergic reaction Overdose B, ADR, D Subtherapeutic dose T, D	10				See **1.a2** (interdisciplinary treatment guidelines) See **5.d7** (independent double check before dispensing anticoagulants) **7.a1** Separate look-alike products **7.a2** Warning messages in computer system for serious product labeling issues or look-alike packaging **7.a3** Checking process to verify stock upon arrival from wholesaler **7.a4** Standard concentration for heparin flushes and infusions **7.a5** Use standard, premixed solutions and prefilled syringes whenever available commercially **7.a6** Computer-generated work label with directions

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		concentration (also patient population specific, including neonatal flush solutions) • Label ambiguity • Calculation error (e.g., volume of heparin to be added to TPN/electrolyte solutions) • Unsafe admixture technique (e.g., unnecessary vials of medications under the hood) • Admixing when premixed solutions are available • Knowledge deficit						for volume of heparin to be added to infusions **7.a7** Independent double check of admixture process when adding heparin to infusions **7.a8** Safe admixing protocols
	b) Wrong form of drug (e.g., not using preserva-tive-free IV heparin for neonates)	• Knowledge deficit • Poorly visible label information • Unclear labeling on vials	Toxicity (e.g., benzyl alcohol toxicity)	8				See **5.d7** (independent double check before dispensing anticoagulants) **7.b1** Add computer alert about using preservative-free heparin for neonates **7.b2** Affix auxiliary labels on vials
	c) Incompatibility not detected (e.g., retaplace and heparin)	• Knowledge deficit • Computer alerts not available • Alerts not read • Alerts bypassed (interpretation biases) • Adequate references not available	ADR	5				See **2.a2** (clinical pharmacy program) See **6.c5** (document reason for bypassing alert) See **6.c6** (review reports of bypassed alerts) **7.c1** Test the pharmacy system to ensure that clinically significant incompatibilities appear during order entry **7.c2** Make references available for incompatibilities **7.c3** Include significant incompatibilities on pharmacy-generated MARs
	d) Wrong preparation, packaging (e.g., wrong bar code applied or correct bar code not applied, if applicable)	• Unsafe technique when preparing medications • Admixing when premixed solutions are available • Knowledge deficit	B, T, ADR	5				See **5.d7** (independent double check before dispensing anticoagulants) See **7.a5** (use premixed solutions)

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	e) Variable bioavailability of warfarin	• Use of different manufacturers of warfarin	B, T	5				**7.a1** All strengths of warfarin tablets purchased from a single manufacturer to promote consistent bioavailability
8) Check medication before distribution	a) Check not completed	• Inadequate staffing patterns • Time constraints • Unaware that check was required • Inefficient workflow • Check perceived to be of low value • No checks in place (e.g., for stock replenishment)	Potential error not detected B, T, ADR, D	10	Pharmacist-prepared			See **5.d7** (pharmacy check before dispensing) **8.a1** Pharmacist verification of anticoagulants (including flush solutions) intended for floor stock and/or automated dispensing cabinets **8.a2** Adequate staffing patterns and workflow to allow verification process **8.a3** Demonstrate value of check to staff **8.a4** Engage staff in culture of safety **8.a5** Understand causes for prior violations (check not completed) and take action to eliminate barriers to consistent checks
					Technician-prepared			
	b) Check failed to detect an error	• Human factors • Environmental factors (e.g., distractions, space, lighting, noise) • Inefficient workflow • Check does not include comparison to original order	Potential error not detected B, T, ADR, D	10				**8.b1** Quiet, well lit space for checking orders **8.b2** Mental warm-ups before checking to increase task focus **8.b3** Use of verbal checks between practitioners **8.b4** Use original order (copy) to check anticoagulants before they are dispensed from the pharmacy
9) Deliver medication to patient care unit	a) Delay in distribution of medications	• Inefficient drug delivery system • Inadequate staffing patterns/equipment (e.g., tubes) used for delivery of drugs • Delivery equipment mechanical failure	Delayed therapy Omitted therapy Use of floor stock: possible error B, T, ADR	Routine medication 5				See **4.a6** (pharmacy order review before administration) **9.a1** Establish dedicated delivery system under direct control of the pharmacy **9.a2** Employ dedicated staff/equipment for medication delivery **9.a3** Establish delivery priorities and a reliable mechanism to deliver urgent/stat anticoagulants **9.a4** Routine maintenance and update of delivery equipment
			Delayed therapy Omitted therapy Use of floor stock: possible error B, T, ADR, D	Urgent/stat medication 10				

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	b) Delivered to wrong unit, or "lost" in system	• Inadequate, untimely communication or interface with admission/transfer information • Human factors • Drug mislabeled as to location of patient	Delayed therapy Omitted therapy T Use of floor stock: possible error B, T, ADR, D Unneeded drugs on wrong unit (possible administration to the wrong patient) B	8				See **4.a6** (pharmacy order review before administration) **9.b1** Timely and seamless communication of admissions/transfers to pharmacy **9.b2** Nursing staff alerted to medication delivery so they can confirm correct drug/dose immediately upon receipt
	c) Placed wrong drug/concentration in usual anticoagulant storage area/unit Placed anticoagulant in wrong storage area/unit	• Look-alike packaging • Look-alike drug names • Label ambiguity • Human factors • No verification of stocking process	Wrong drug/dose B, T, ADR, D Delay in therapy T, D					See **7.a1** (separate look-alike products) See **7.a4** (standard concentration for heparin flushes and infusions, to minimize risk of mix-ups) **9.c1** Manual or bar-coded verification process for anticoagulants placed into stock in automated dispensing cabinets or floor stock shelves/bins **9.c2** Add warning messages to automated dispensing cabinets to verify the dose/concentration of the anticoagulant removed
Administration (Process steps 10-19)								
10) Receive order/transcribe onto MAR	a) Order not processed	• Order not flagged • Order written in wrong place on order form • Electronic order entry system not functioning	Omitted therapy T, D	10				See **4.a3** (shift chart checks) See **4.a1** (flagging new orders) See **5.b7** (daily MAR checks) **10.a1** Create margins on order forms beyond which orders should not be written **10.a2** Backup for failure of CPOE system
	b) Written/ electronic (typed) order misunderstood	• Illegible order • Use of abbreviations (e.g., U) • Use of trailing zeroes • Misread decimal doses	Delay in therapy Subtherapeutic dose	10				See **2.a1** (CPOE) See **3.a1** (preprinted order sets) See **3.c2** (match indication and diagnosis) See **5.a1** (prohibit dangerous abbreviations, dose

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Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number	Actions to Reduce Failure Mode
		• Drugs with look-alike names (e.g., Avandia and Coumadin) • Knowledge deficit	T, D Allergic response Overdose B, D					expressions) **5.a2** (compare original order and product label) **5.a3** (clarify with prescriber) See **5.b7** (daily MAR checks)
	c) Verbal order misheard	• Drugs with sound-alike names • Unnecessary verbal orders • Failure to read back verbal orders after transcribing	Wrong drug therapy B, T, D	10				**10.c1** Limit non-urgent verbal orders **10.c2** Record and read back the order, stating doses using single digit number (e.g., say "one five" not "15)
	d) Order not reconciled	• Unverified patient history • Time constraints • Inadequate medication reconciliation process	Wrong drug therapy B, T, D	10				**See 1.b2** (medication reconciliation)
	e) Order transcribed onto MAR incorrectly	• Knowledge deficit • Too many sections/pages of MAR • Lack of support staff training • Environmental factors (e.g., distractions, noise, poor lighting) • Human factors • Failure/absence of double check	Delay in therapy Subtherapeutic dose T, D Overdose B, D	10				See **4.a3** (shift chart checks) See **5.b7** (daily MAR checks) See **10.c1** (limit non-urgent verbal orders) **10.e1** Use a pharmacy computer-generated MAR **10.e2** Staff training for transcription **10.e3** Quiet, well lit environment free of distractions during transcriptions **10.e3** Consistent double-check process for order transcription **10.e5** Reduce the variety/number of drugs in standard order sets to minimize the number of MAR pages
	f) Order not transcribed onto MAR	• MAR not used • MAR not available • Forgot to transcribe • Failed check system for initial transcription • Failed check system for recopying MARs	Delay/interruption in therapy T, D	10				See **4.a3** (shift chart checks) See **5.b7** (daily MAR checks) **10.f1** Require documentation of drug administration on a single, standard MAR whenever possible **10.f1** Written back-up for electronic MAR system failure

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	g) Order transcribed onto wrong patient's MAR	• Unclear presentation of patient demographics on MAR (e.g., light imprint) • Look-alike patient names • Environmental factors (e.g., interruption during transcription, noise, poor lighting, cluttered space) • Order transcribed before patient identifier added to form	Patient receives anticoagulant when not indicated B	5				See **5.d3** (high quality imprint machines, stickers) **10.g1** Look-alike name alerts on chart/MAR **10.g2** Vivid patient demographics on MAR forms **10.g3** Add patient identifier to documentation form/screen before entering orders/notes
			Patient does not receive anticoagulant when indicated T, D	10				
11) Nurse receives signal to administer medication	a) Signal not received (nurse does not know to administer the medication at a particular time)	• Too many MAR pages • Nonstandard time for administration • Transcription error • Missing MAR • Thought someone else was administering the drug • Did not hear verbal order • Failure to communicate that dose is due during change in shift or level of care	Dose omitted/delay in therapy T, D	10				See **1.b2** (medication reconciliation) See **4.a3** (shift chart checks) See **5.c1** (standard administration times) See **5.c2** (communicate timing of therapy) See **10.e5** (minimize the number of MAR pages) See **10.c1** (limit non-urgent verbal orders) **11.a1** Design user-friendly MARs **11.a2** Implement a standardized approach to "hand off" communications about medications
12) Evaluate appropriateness of the anticoagulant	a) Current lab values not checked	• Lab values not available • Low perceived value • Time constraints • Wrong lab values checked (e.g., wrong patient, wrong day/time)	Dose not adjusted appropriately B, T, ADR	8				See **1.a2** (interdisciplinary treatment guidelines) See **1.a8** (coagulation test results available within 2 hours) See **1.a5** (two patient identifiers when communicating test results) See **1.a6** (record and read-back test results) See **2.a2** (clinical pharmacy program) See **2.a5** (anticoagulant team for complicated thrombotic episodes) See **3.h1 (**standard monitoring process in order sets and preprinted orders) **12.a1** Demonstrate value of monitoring lab values to staff **12.a2** Use an anticoagulant form/file that lists indications, drugs, doses, and documentation of

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								current lab values (e.g., SPC chart, flowsheet, checklist)
	b) Diagnosis does not support administration of anticoagulant	• Diagnosis not available • Evaluating wrong patient • Knowledge deficit about indication for drug therapy	Patient receives anticoagulant when not indicated B, ADR	5				See **2.a2** (clinical pharmacy program) See **2.a3** (provide drug information) See **3.c2** (match diagnosis and indication) See **12.a2** (anticoagulant form/file/flowsheet/SPC chart/checklist)
13) Obtain medication	a) Cannot find medication/not available on unit	• Pharmacy delivery problem • The medication was not yet dispensed due to a safety problem (e.g., allergy, unsafe dose, interaction) • Different pharmacy and nursing dosing schedules • Medication time/frequency was scheduled incorrectly • Order was not sent to pharmacy • No communication to nurse that medication was delivered • Par levels of floor stock inadequate • Nonformulary drug • Medication was given but not documented • Medication was given, but documentation of administration not seen • Medication was prescribed using a brand name and dispensed as a generic • Drug was discontinued but remains on the MAR • Automated dispensing cabinet not functioning	Delay in therapy T, D Use of floor stock/borrowed medication without pharmacy review B, ADR, D	10				See **4.a5** (send all orders to pharmacy) See **4.a6** (pharmacy order review before administration) See **9.a3** (pharmacy delivery priorities/ reliable delivery) See **10.f1 (r**equire documentation of all drug administration on a standard MAR) **13.a1** Include brand and generic names on product labels when appropriate **13.a2** Notify nursing staff upon delivery of medications to the unit **13.a3** Establish safe, adequate daily par levels for appropriate floor stock of heparin and warfarin **13.a4** Notify pharmacy, update current dosing schedule, resend order if requested for missing medication **13.a5** Pharmacist and nurse should both determine that missing medication is still an active order with no pending safety concerns

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	b) Select the wrong drug/concentration/ dose or the wrong product for indication and route of admin-istration	• Drug available as floor stock and obtained without pharmacy review • Obtained drug via override from automated dispensing cabinet • Look-alike products stored near each other in automated dispensing cabinets, floor stock, refrigerator • Drug strength not clear on vial • Wrong drug stored in usual area/bin/shelf • Unnecessary multiple concentrations available • Knowledge deficit • Calculation error (e.g., with loading dose, infusion rate)	Overdose B, D Allergic reaction ADR Subtherapeutic dose Omitted drug Wrong drug T	10				See **1.a2** (interdisciplinary treatment guidelines) See **2.a2** (clinical pharmacy program) See **2.a3** (drug information) See **3.d5** (standard weight-based heparin protocol) See **3.f7** (administer heparin after pharmacy review and an independent review of the patient's drug profile to prevent duplicate doses) See **4.a6** (pharmacy order review before administration, no overrides except for adult heparin flushes) See **7.a1** (separate look-alike products) See **7.a4** (standard concentration for heparin flushes and infusions) See **7.a5** (standard, premixed solutions and prefilled syringes) See **9.c1** (manual or bar-coded verification of stocking process) See **9.c2** (warning messages on automated dispensing cabinet screens to verify dose/concentration) **13.b1** Warning messages on automated dispensing cabinet screens for serious product labeling issues or look-alike packaging **13.b2** Auxiliary labels to note the strength or to distinguish the anticoagulant from other products with look-alike packaging **13.b3** Independent double check of calculations and anticoagulants (except adult heparin flushes) before administration **13.b4** Use standard dosing charts for heparin infusions **13.b5** Limit availability of heparin in various concentrations in floor stock/automated dispensing cabinets; eliminate storage if feasible
14) Prepare drug	a) Wrong drug,	• Unlabeled syringe/IV bag	Overdose	10	Day			See **1.a2** (interdisciplinary treatment guidelines)

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(if necessary)	dose, diluent, concentration Breach in sterility	• Failure to use premixed solutions • Unfamiliarity with IV admixture process • Pharmacy service not provided 24 hours/day, • 7 days/week • Absent or failed double check • Insufficient environment/ equipment to maintain sterile work environment for compounding • Re-entry into a multiple-dose vial with a contaminated needle	B, D Subtherapeutic dose, wrong drug T, D Allergic reaction, ADR Infection					See **7.a5** (use standard, premixed solutions and prefilled syringes [provides reliable labeling and reduces the risk of cross contamination from using a multiple-dose vial]) See **3.f7** (administer heparin after pharmacy review and an independent review of the patient's drug profile to prevent duplicate doses) See **4.a6** (pharmacy order review before administration, no overrides except for adult heparin flushes) See **13.b3** (independent double check before administration) See **13.b5** (limit availability of heparin in floor stock/automated dispensing cabinets) **14.a1** Eliminate admixture on patient units; all heparin doses and solutions prepared in the pharmacy **14.a2** Provide pharmacy services 24/7
					Night			
15) Obtain infusion pump (if necessary)	a) No pump available	• Inadequate pump supply • Hoarding of pumps • Bottlenecks with pump cleaning process • Can't leave unit to locate pump	Delay in therapy T, D Inaccurate administration without a pump B, T, D	10				**15.a1** Purchase an adequate supply of pumps **15.a2** Central distribution center for pumps in area open 24/7 **15.a3** Efficient cleaning process **15.14** Adequate staffing patterns to retrieve or deliver a pump, as needed
16) Program pump (if necessary)	a) Misprogram the pump: wrong flow rate (dose), concentration, loading dose	• Design flaw in pump which makes programming error-prone • Environmental factors (e.g., distraction, poor lighting) • Mental slip • Human factors • Pump use by untrained staff • Failure to use a standard concentration • Failure to limit the variety of anticoagulants used • Knowledge deficit about the	Overdose B, ADR, D Subtherapeutic dose T, D	10				See **1.a2** (interdisciplinary treatment guidelines) See **2.a3** (provide drug information) See **7.a5** (use standard, premixed solutions and prefilled syringes) See **3.i1-3.i7** (strategies for safely handling "hold" orders or stopped infusion) See **13.b3** (independent double check before administration [performed at the bedside so all pump settings, line attachment, and patient can be verified along with the drug/concentration/infusion rate]) **16.a1** Pumps that are easy to program **16.a2** Smart pumps with dose checking capability **16.a3** Use failure mode and effects analysis (FMEA) process to determine potential failure modes of

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		drug • Confusion between units/hour and mL/hour • Forgetting to reset the pump after a temporary increase to deliver a bolus dose • Forgetting to restart the pump after a heparin infusion has been placed on "hold" temporarily						pumps to guide use and purchasing decisions **16.a4** Regularly train staff to use pump and maintain annual competencies **16.a5** Limit the variety of pumps used **16.a6** Deliver bolus heparin doses from syringes (not the infusion bag) dispensed by pharmacy
17) Check drug/ pump settings before administration	a) Check not completed	• No double check required • Inadequate staffing patterns • Time constraints • Low perceived value of check • Check process not integrated into the way care is delivered	Potential error not detected B, T, ADR, D	10				See **8.a2** (adequate staffing/workflow) See **8.a3** (demonstrate value of check) See **8.a4** (engage staff in culture of safety) See **8.a5** (understand reasons check not completed) **17.a1** Build check processes into the care delivery model being used to promote completion as part of daily activities
	b) Check inadequate	• Environmental factors (e.g., distractions, space, lighting, noise) • Inefficient workflow • Human factors • Check not completed at bedside (to verify drug and pump settings, line attachments, etc.)	Potential error not detected B, T, ADR, D	10				See **8.b1** (quiet, well lit space for checking) See **8.b2** (mental warm-ups before checking) See **8.b3** (verbal checks between practitioners) See **13.b3** (independent double check performed at the bedside)
18) Administer anticoagulant	a) Wrong patient	• Look-alike names • Failure of double check at bedside using two identifiers • Anticoagulant ordered on wrong patient • Anticoagulant transcribed on wrong MAR • Failure to match drug with an	Patient receives anticoagulant when not indicated B, ADR	5				**See 3.c2** (match indication to diagnosis) **See 3.g1** (display alerts for look-alike patient names on automated dispensing cabinets, MARs, and charts) **18.a1** Patient's name and other demographic information clearly visible on MAR **18.a2** Bring MAR to the patient's bedside **18.a3** Verify two patient identifiers before administering medications **18.a4** Educate patients about anticoagulants before

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		indication for use	Patient does not receive anticoagulant when indicated T, D	10				administration so they can help detect an error
	b) Wrong drug, dose, or flow rate	• Failure to review/consider current lab values • Failure to review/consider prior doses • Unlabeled syringe or infusion bag • Start/restart the wrong solution if multiple infusions are running • Failed or absent double check • Pump malfunction • Loss of power to pump • Pump not protected from free flow • Inaccurate pump calibration	Overdose B, D Subtherapeutic dose T, D	10				See **1.a2** (interdisciplinary treatment guidelines) See **2.a2** (clinical pharmacy program) See **3.a1** (standard order sets/preprinted orders; do not use *variable* sliding scales for warfarin or heparin dosing) See **3.i2** (for daily doses based on labs, list the order in the pharmacy profile and MAR as an active order with a note that a daily dose should be prescribed) See **4.a6** (pharmacy review before administration) See **5.c1** (standard administration times to allow time to obtain changes is dose based on labs) See **7.a5** (premixed solutions and prefilled syringes) See **12.a2** (anticoagulant form/file/flowsheet/SPC chart/checklist) See **13.b3** (independent double check before administration) See **14.a1** (eliminate admixture on patient units) See **16.a3** (FMEA on pumps) **18.b1** Appropriately discard unlabeled syringes/ infusion bags **18.b2** Use of pumps with free-flow protection **18.b3** Back-up power source for pump **18.b4** Routine preventive maintenance on pumps **18.b5** Trace tubing from bag/bottle/syringe through pump to verify pumps settings when starting or restarting infusions, and when changing bags/bottles/syringes
	c) Wrong route	• Line attachment confusion • Failure or absence of double check at bedside • Knowledge deficit	Toxicity Hematoma B, D	10				See **13.b3** (independent double check before administration [performed at the bedside so all pump settings, line attachment, and patient can be verified along with the drug/concentration/infusion rate]) **18.c1** Label proximal ends of lines near insertion ports

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								18.c2 Trace tubing from bag/bottle/syringe through the pump and down to the access site to verify attachment/route of administration
	d) Duplicate dose/ dose administered too soon	• The medication was already given but not documented • The medication was already given but documentation of administration was not seen • Documentation of drug therapy on various forms (e.g., ED notes, OR record, PACU record, MAR) • Failed hand-off communication upon transfer of the patient • Transcription error • Failure to discontinue another form of anticoagulant • Knowledge deficit • Start time of new anticoagulant not clear (especially in relation to a previously discontinued anticoagulant)	Overdose B, D	10				See **1.a2** (interdisciplinary treatment guidelines) See **1.b2** (medication reconciliation) See **2.a2** (clinical pharmacy program) See **3.f1** (reminders on treatment guidelines and order forms to discontinue low-molecular weight heparin before starting a heparin infusion) See **3.f2** (in treatment guidelines and order forms, include how long to wait before initiating heparin therapy if a patient has received a prior dose of low-molecular weight heparin) See **3.f3** (dispense heparin products [except flushing solutions] from the pharmacy) See **3.f4** (review the patient's recent drug therapy before administering any heparin) See **3.f5** (alerts on automated dispensing cabinet screens to warn about concomitant use) See **3.f6** (alert pharmacy to all heparin doses given to ED patients who are admitted) See **3.f7** (administer heparin only after a pharmacist has reviewed the order and another practitioner has independently checked the order and patient's drug profile [all MARs, documentation of drug administration]) See **3.f8** (mention all doses of heparin given to ED patients during hand-off reporting to the admitting nurse) **See 3.f9** (document heparin doses administered in a consistent location) See **10.f1** (require documentation of drug administration on a single MAR whenever possible) See **12.a2** (anticoagulant form/file/flowsheet/SPC chart/checklist) **18d.1** Ensure pharmacy computer alerts for duplicate therapy are fully functional for heparin and warfarin
	e) Interruption of	• Stopping heparin infusion for	Subtherapeutic	10				See **3.i1-3.i7** (recommendations regarding "hold"

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	therapy	administration of another drug • Failure to restart the anticoagulant after placed on hold temporarily • Infiltration	dose T, D					orders) **18.e1** Do not stop a heparin infusion to administer another medication/solution
	f) Incompatibilities not detected (e.g., retaplace and heparin)	• Knowledge deficit • Adequate references not available • Use of anticoagulation infusion as the primary infusion into which other IV medications are administered	ADR Subtherapeutic dose T, D	5				**See 2.a3** (provide drug information, including incompatibilities) **18.f1** Check compatibility reference before administration if patient is receiving other IV medications **18.f2** Do not allow other solutions/medications to be administered through a heparin infusion line
	g) Infiltration/ hematoma at injection site Epidural or spinal hematoma	• Site not rotated • Drug administered incorrectly • Failure to immobilize limb/body part of the access site • Failure to properly anchor the catheter hub and tubing • Rubbing injection site • Concurrent use of heparin and spinal/epidural puncture/procedures	Hematoma Interruption of therapy T	5				See **1.a2** (interdisciplinary treatment guidelines) **18.g1** In treatment guidelines, include strategies for preventing and treating IV/arterial infiltration/ hematoma at injection site **18.g2** Restart IV as soon as possible if infiltration occurs **18.g3** Do not use site of hematoma **18.g4** Establish clinical guidelines to direct patient selection for epidural/spinal anesthesia when receiving/will receive anticoagulation, conditions for holding anticoagulation, timing of restarting the therapy, and conditions for removal of an epidural catheter
19) Document anticoagulant	a) Drug administration not documented/ misdocumented	• Human factors • Environmental factors (e.g., distractions) • Time constraints • Inefficient documentation process • Multiple MAR pages/screens • Documentation required in multiple locations • Documentation before actual administration	Duplicate therapy Overdose B, D Drug omission T	10				**See 3.f9** (document heparin doses administered in a consistent location) See **3.f9** (document administered anticoagulants in a consistent location) See **5.b7** (daily MAR checks) See **10.e5** (reduce variety/number of MAR pages) See **10.f1** (require documentation of drug administration on a single MAR whenever possible) See **11.a1** (design user-friendly MARs) See **18.a2** (bring MAR to the bedside) See **18.a3** Verify two patient identifiers before administering medications

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								19.a1 Review MAR documentation before the end of each shift to ensure completeness
Monitoring (Process steps 20-21)								
20) Monitor the effects of the anticoagulant	a) Lab tests not performed, incomplete, or inaccurate	• Failure to request prescribed lab tests • Blood collection on the wrong patient • Wrong test performed on blood specimen • Lab error (e.g., human error, using the wrong reagent with testing equipment, mechanical failure) • Variations in INR readings based on different equipment • Knowledge deficit • Environmental factors (e.g., distractions) • No standard protocol for monitoring, leading to variability • Ineffective communication between practitioners	Failure to detect and treat thrombocyto-penia B, T, ADR	8				**See 1.a2** (interdisciplinary treatment guidelines with monitoring requirements) **See 2.a2** (clinical pharmacy program) See 2.a5 (anticoagulant team to manage complicated thrombotic episodes) **See 3.a1** (standard orders) **See 3.h1** (include standard monitoring process in order sets and preprinted orders) **See 3.d6** (check and calibrate lab equipment) **See 3.d7** (train lab staff about collection techniques) **20.a1** Standardized INR testing equipment used throughout organization/health system **20.a2** Use of two patient identifiers when drawing lab specimens **20.a3** Label blood collection tubes while at the bedside **20.a4** Lab to investigate if INR values do not seem to correspond to clinical picture
	b) Lab tests ordered at the incorrect times and intervals	• Knowledge deficit • Failed or absent standard protocol for testing • Mental slip • Ineffective communication between practitioners	Failure to detect and treat thrombocyto-penia Infrequent or inaccurate dose adjustments B, T, ADR	8				See **1.a2** (interdisciplinary treatment guidelines with monitoring requirements) See **2.a2** (clinical pharmacy program) See **3.a1** (standard order sets/preprinted orders for warfarin and heparin, including monitoring requirements)
	c) Current lab values not checked	• Lab values not available • Low perceived value of tests • Assume someone else is checking lab tests • Time constraints • Wrong lab values checked	Failure to detect and treat thrombocyto-penia B, T, ADR	8				See **1.a2** (interdisciplinary treatment guidelines) See **1.a8** (coagulation test results available within 2 hours) See **1.a5** (two patient identifiers when communicating test results) See **1.a6** (record and read-back test results)

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		(e.g., wrong patient or wrong time/day)						See **2.a2** (clinical pharmacy program) See **2.a5** (anticoagulant team for complicated thrombotic episodes) See **12.a1** (demonstrate value of monitoring) See **12.a2** (anticoagulant flowsheet) **20.c1** Assign clear accountability for monitoring lab values
	d) Failure to monitor for signs of bleeding and/or thrombosis/ communicate changes to the physician/treat condition	• Lack of standard evaluation process • Knowledge deficit • Time constraints • Difficult to detect occult bleeding • Reluctance to call prescriber with assessment information (intimidation) • Patient not informed to alert practitioners to signs and symptoms	B, D, T, D	10				See **1.a2** (interdisciplinary treatment guidelines) See **1.a8** (coagulation test results available within 2 hours) See **2.a2** (clinical pharmacy program) See **12.a2** (anticoagulant flowsheet) **20.d1** Educate healthcare providers and patients about signs of bleeding **20.d2** Protocol to guide the treatment/reversal of supra-therapeutic INR or aPTT values **20.d3** Include guidelines for transition from heparin to warfarin in interdisciplinary treatment guidelines **20.d4** Tally the total amount of heparin the patient received each shift/day and document on anticoagulant flowsheet **20.d5** Address intimidation by prescribers
	e) Failure to diagnose/treat thrombocytopenia	• Knowledge deficit • Inadequate lab monitoring • Forget to discontinue all sources of heparin	Thrombocyto-penia T, D	10				See **1.a2** (interdisciplinary treatment guidelines with monitoring requirements) See **2.a2** (clinical pharmacy program) See 2.a5 (anticoagulant team to manage complicated thrombotic episodes) See **3.h1** (include standard monitoring process in order sets and preprinted orders) **20.e1** Protocol for evaluation and treatment of HIT, including diagnostic tests, ongoing monitoring, indications for direct thrombin inhibitors, communication of diagnoses to all healthcare providers, and discontinuation of all sources of heparin (e.g., arterial line infusions, flushes, heparin-coated catheters/instruments)

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Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number	Actions to Reduce Failure Mode
21) Adjust doses according to monitoring results	a) Failure to adjust the dose properly in a timely manner Failure to treat patient/treat patient incorrectly when therapeutic levels are dangerously elevated	• Lab studies not performed or communicated • Failure to monitor patient lab values frequently enough • Critical lab values not flagged for reporting • Critical lab values/ assessment findings not communicated in a timely manner • Unable to reach physician with critical lab results/assessment information • No protocols for dose adjustments • No protocols for treatment of dangerously elevated INR/aPTT • Forgot to restart medication after holding • Interpreter biases • Patient-specific parameters not known/considered (e.g., renal and hepatic function, allergies, platelet count) • Making dose changes more or less frequently than necessary for the desired clinical outcomes • Failing to consider the residual blocking effects of phytonadione if this drug has been administered before a procedure (to reverse the effects of an anticoagulant)	Labile anticoagulant levels B, T, D	10				See **1.a2** (interdisciplinary treatment guidelines with monitoring requirements) See **1.a8** (test results available within 2 hours) See **2.a2** (clinical pharmacy program) See 2.a5 (anticoagulant team to manage complicated thrombotic episodes) See **3.a1** (standard orders) See **3.h1** (include standard monitoring process in order sets and preprinted orders) See **12.a2** (anticoagulant flowsheet/SPC chart) See **20.d2** (protocol for treating supra-therapeutic INR or aPTT values) See **20.d3** Include guidelines for transition from heparin to warfarin in interdisciplinary treatment guidelines See **20.d4** Tally the total amount of heparin the patient received each shift/day and document on anticoagulant flowsheet **21.a1** For more timely adjustments, establish protocols that allow for titration of heparin by dose standard dose adjustment intervals (e.g., 1 unit/kg/hour for aPTT between 40 and 49, etc.) **21.a2** In treatment guidelines, include dose adjustment guidelines that will reduce large fluctuations in anticoagulation levels **21.a3** In treatment guidelines, include directions for resumption of anticoagulation after reversal of an anticoagulant effects for surgery

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Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number	Actions to Reduce Failure Mode
Patient Self-Administration (Process step 22)								
22) Patient complies with prescribed therapy after discharge	a) Patient is not educated about his/her illness, medication, and error/injury prevention	• Language barrier • Literacy barrier • Time constraints • Caregiver not available for education and/or translation • No written educational material available to give to patient (in the correct language/reading level) • Healthcare provider knowledge deficit • Accountability for educating patients is not clear	Possible readmission B, T, ADR, D	10				See **2.a2** (clinical pharmacy program, to help with patient education) See **18.a4** (educate patients so they can help detect an error) **22.a1** Outpatient warfarin dosing service or clinic **22.a2** Certified, specially trained staff to provide patient education (disease process, medications, monitoring requirements, signs of bleeding/ thrombosis/point-of-care testing) **22.a3** Written educational materials for patients about drug therapy and potential for errors (e.g., changing doses) in primary language and reading level **22.a4** Have patients maintain their own medication administration record in the hospital for educational purposes (and for verification of the drug therapy) **22.a5** Patient-directed warfarin administration while hospitalized to provide an opportunity for education **22.a6** Automatic consultation to the food and nutrition service for education **22.a7** Hospital interpreter/language line
	b) Patient does not fill his/her prescription after discharge	• Duration of therapy is not clear to patient • Financial/insurance reimbursement concerns • Local pharmacy does not carry the prescribed medication • Lack of transportation to pharmacy	Possible readmission T, D	10				**22.b1** Evaluate patient's ability to fill prescriptions before discharge **22.b2** Refer patient to social services **22.b3** Sample medications when necessary
	c) Patient does not take the medication as prescribed/ follow consistent dietary guidelines	• Understanding is not assessed before discharge • Failure to provide written materials in primary language and reading level • Changes in dose are not clearly provided to the	Possible readmission B, T, ADR, D	10				See **2.a2** (clinical pharmacy program, to help with patient education) See **3.i6** (contact patients about resuming medications previously on hold) See **3.i7** (patient to contact physician if orders to resume medication have not been received) See **22.a1** (outpatient warfarin dosing service or

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Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number	Actions to Reduce Failure Mode
		patient when dose adjustments are required • Verbal instructions are misheard on misunderstood when doses are changed • Actual dose may not match the directions on the current supply of medication • Confusion regarding brand and generic names (thus, may be taking duplicate therapy) • Confusion regarding doses to be taken on alternate days • Patient unaware of who to call for clarification of instructions after discharge • Instructions conflict with instructions from other healthcare providers • Financial incentives lead to taking less than the prescribed dose or taking the medication on alternate days						clinic) See **22.a2** (certified educators) See **22.a3** (written educational materials) See **22.a4** (patient-maintained MAR) See **22.a5** (patient-directed warfarin administration while hospitalized) **22.c1** Systematic process for educating patients on anticoagulants before discharge **22.c2** Written directions for drug therapy prescribed upon discharge **22.c3** Design anticoagulation flowsheets so patients can understand them and continue to use them at home **22.c4** Develop weekly dosing regimens to give to patients and begin documentation with the dose prescribed upon discharge; tally the total dose of warfarin taken each week for verification **22.c5** Follow-up phone calls **22.c6** Assess level of understanding before discharge, including patient's understanding of duration of therapy
	d) Patient does not have outpatient blood tests completed or attend the follow-up visit with the primary care physician or specialist	• Appointment not made for first outpatient lab test, if indicated, before discharge • Appointment not made for first outpatient visit with physician • Appointment dates and locations not communicated to the patient • Patient misunderstands directions for follow-up care • Patients are not called if they miss an appointment to find out why and to reschedule	Possible readmission B, T, ADR, D	10				See **22.a1** (outpatient warfarin dosing service or clinic) See **22.a2** (certified educators) See **22.a3** (written educational materials) See **22.b2** Refer patient to social services **22.d1** Set up appointments before discharge **22.d2** Provide written directions for follow-up care **22.d3** Follow-up to check if patient kept appointments **22.d4** Process to communicate finding from hospitalization to primary care physician (e.g., send History and Physical, Discharge Notes, Medication List [see **1.b2** medication reconciliation process])

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		the appointment • Patient may have no form of transportation after discharge • Primary care physician is unaware that he patient was hospitalized and the medications prescribed for the patient upon discharge						

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