Anticoagulation   Failure Mode and Effects Analysis
Adverse Drug Effects User Group--Grid for individual organization analysis

Steps	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1-10)	Likelihood of Detection (1-10)	Severity (1-10)	Risk Priority Number (RPN)	Actions to Reduce Occurrence of Failure
1	Is Anticoagulant Indicated?							
1A	Is diagnosis correct?	Diagnostic tests not performed	Anticoagulant administered when not indicated				0	All caregivers double check diagnosis
			No treatment given when indicated				0	
			Failure of test to diagnosis.				0	Use 2 tests to diagnosis when possible. Repeat inconclusive tests.
		Doesn't meet standards of practice Clinicians unaware of standards	Inappropriate prescribing of anticoagulants				0	Pharmacists check indication Educate prescribers Establish treatment guidelines.
1B	Are there contraindications or disease interactions?	No or incomplete patient information Not evaluated Diagnosis inconclusive Didn't know patient had a given contraindication (ie epidural) Interpretation biases	Bleeding Death Thrombosis				0	Pharmacists double check Establish treatment guidelines that include information on contraindications.
1C	Are there drug or food interactions? Can they be managed?	Incomplete medication history No computer alerts Skipped alert Incomplete alert Herbal/supplement interactions not considered Didn't check	Bleeding Death Thrombosis				0	Use pharmacy computer system that screens for drug interactions Take a complete medication history including herbal/ supplement information.
			(Severity can range from 1-10)				0	

Likelihood of occurrence: 1-10, 10= Very likely to occur. Likelihood of detection: 1-10, 10=very unlikely to detect. Severity: 1-10, 10 = most severe effect. RPN= product of 3 scores. Page 1

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2	Initiate Therapy; Write Order						0	
2A	Initiate policy, pre-printed orders or protocol if exists	Don't exist Not followed Outdated, inaccurate Providers use differently Unclear when to use Preprinted order wrong Haven't standardized	Wrong drug Wrong dose				0	Establish guidelines. Use inpatient warfarin protocols. Do not use sliding scale warfarin schemes
			Cause bleed				0	Use protocols
2B	Select drug	Not formulary Not available Wrong drug for this patient Drug specific contraindications exist	Increase bleeding risk				0	Check for allergies Diagnosis heparin induced thrombocytopenia appropriately Use guidelines Appropriate diagnosis
2C	Select dose	Wrong dose Wrong route Age, size, renal function not considered Mixed up drug or strength Order of magnitude error in writing dose.	Increase bleeding risk				0	Pick one drug for formulary for LMWH. Pharmacist picks dose
			Dose too high: develop bleed				0	
			Dose too low: develop thrombosis				0	
2D	Write order	Illegible Inappropriate abbreviations Order unclear Key elements of order omitted Left out sections of preprinted orders Transcription errors No read back on verbal orders.	Wrong dose or drug administered. Bleeding				0	Avoid verbal orders. If do need to use, use read back procedure. Follow do not use abbreviations. Use preprinted order forms

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2E	Write orders for monitoring	Omitted or incomplete monitoring orders Over or under monitoring frequency Wrong time for lab test Wrong lab test ordered	Dose not adjusted appropriately.				0	Use preprinted orders Implement standard monitoring process Pharmacist check monitoring plan.

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3	Process Order						0	
3A	Pharmacy receives order	Order not received Not received in a timely manner	Delays in therapy Delays in changing dose when necessary				0	Use CPOE systems. Handle orders on a priority basis
3B	Indication check	Not done or incomplete Don't distinguish between treatment and prophylaxis	Potential error in giving anticoagulants when not indicated				0	Use consistent process for checking for all orders.
			Day shift				0	
			Evening and night shift				0	
3C	Contraindication check	Not done Information not readily available (eg is patient on epidural?)	Bleeding Death Thrombosis				0	Use consistent process for checking for all orders. Pharmacist needs access to patient information.
3D	Dose check and dose interval check						0	Use consistent process for checking for all orders.
3E	Dosage form selection	Wrong one selected.					0	Check order entry layout
3F	Enter in computer system	Wrong patient Computer entry error Wrong admission Entered on wrong profile (inpatient vs outpatient)	Wrong patient gets drug. Medication error occurs				0	Nurse double checks medication entry.
3G	Drug interaction check	Don't read Bypass alert Database not current Computer not available to check.	Bleeding Death Thrombosis				0	

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3H	Time dose	Wrong administration times Administration times not standard Time not coordinated with lab draws and other procedures. Miscommunication with team on appropriate time.					0	Use standardized dosing times.

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4	Drug Preparation and Delivery						0	
4A	Select product and preparation method	Wrong drug, dose Select wrong product Select wrong product for route Wrong storage	Bleeding Death Thrombosis				0	Standard Concentrations Don't stock heparin Minimize use of heparin
4B	Prepare drug in pharmacy	Wrong packaging Wrong syringe needle Wrong equipment Poor technique Incompatibilities Draw up wrong dose or concentration	Increase bleeding risk				0	Use prefilled syringes Use premixed preparations
4C	Pharmacist check product	Check omitted Failed to detect an error	Increase bleeding risk				0	Standard, rigorous procedures Define role of checking culture of patient safety
4D	Deliver product to unit	Delivered to wrong unit Lost in system Delays in delivery	Delay in therapy				0	Heightened sense of delay
4E	Drug available from floor stock	Wrong product selected Incompatibility issues Not double checked	Increase bleeding risk				0	Do not stock anticoagulants as floor stock. No double check Evaluate "special areas" and what real needs are. Limit choices available.
4F	Drug available from automated dispensing unit	Wrong drug stocked Not in dispensing unit System is down	Increase bleeding risk				0	Double check.
4G	Nurse can over-ride	No double check Pharmacist doesn't profile	Increase bleeding risk				0	Do not allow override for anticoagulants

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4H	Drug approved for dispensing (profiling)	Not profiled Failed to detect an error	Delay in therapy				0	
4I	Ready to select from automated dispensing unit	Wrong product stocked Cabinet not set up to prevent an error Wrong bar code (if applicable)	Increase bleeding risk				0	Check dispensing unit set up. Check bar code set up.

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5	Drug Administration						0	
5A	Nurse checks labs if needed	Labs not available on time Labs not checked Wrong lab checked (time mix up)	Dose not appropriately adjusted				0	Establish protocols Use PTT stat Double checks in system
5B	Nurse gets dose	Dose not available Gets wrong dose or drug	Disease progresses Adverse effect of medication				0	Check methods of storage Bar coding
5C	Nurse prepares if needed	Error in preparation	Disease progresses Adverse effect of medication				0	Nurse does not prepare medication
5D	Check timing	Incorrect time Failure to communicate dose due	Therapy delayed				0	Detected but after the fact
5E	Select pump	Programmed wrong Incorrect use Wrong tubing (heparin) Free flow pumps used	Bleeding Death Thrombosis				0	Do not use free flow pumps
			Alaris pumps or other "smart pumps"				0	
			Traditional pumps				0	Consider upgrading pumps Don't use heparin RN double checks
5F	Check compatibility	Didn't check References not available or poor information	Thrombosis				0	Check compatibility references
5G	Verify patient	Wrong patient	Thrombosis to patient not receiving dose.				0	Bar coding Double checking

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5H	Check injection site and administer drug	Site not rotated Site not documented IV not patent Poor technique Lack of documentation Administered incorrectly	Hematomas Fatal bleeding				0	Protocols for administration Education to those administering Don't rub injection site
5I	Administer	Wrong route	Hematomas Fatal bleeding				0	

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6	Monitoring						0	
6A	Appropriate labs ordered and run	Ordered at wrong time Not ordered Ordered but not drawn Drawn wrong Ran wrong test Wrong test ordered Lab error	Dose not adjusted appropriately.				0	Use protocols
6B	Check labs	Not available in a timely fashion No one checks No action taken to critical lab Misread Not flagged as critical value Misinterpreted	Dose not adjusted appropriately. Bleeding				0	Protocols Use alerts (computerized)
6C	Check patient status: signs of bleeding and disease progression	Patient not evaluated Occult bleeding not detected No standard evaluation Not reported to caregiver Patient not informed Accountability for monitoring unclear	Bleeding				0	Protocols Use alerts (computerized) Involve patient in care--have them alert care giver immediately if any symptoms
6D	Adjust dose or drug as needed	Adjusted incorrectly Failure to adjust Ongoing dose adjustments not done Orders not processed Not adjusted appropriate for changes in renal, hepatic, platelet or allergy status	Dose not appropriately adjusted				0	Use protocols Identify heparin induced thrombocytopenia (HIT) appropriately. Use alerts Notify patient if allergic

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7	Patient Education						0	
7A	Educate patient and caregiver	Materials vary Misunderstanding Language and literacy barriers not provided incomplete variations in practice Accountability unclear Caregiver not available Injury prevention not included	Bleeding Death Thrombosis				0	Systematic process for educating patients on anticoagulants.
			Failure to educate patient on disease and efficacy				0	
			Failure to educate patient on ADRs including HIT				0	
			No education received by patient				0	
7B	Assess understanding	Lack of formal assessment of understanding Active assessment mechanisms not used	Use drug inappropriately Increase risk of bleeding				0	Formalize options when patient and or caregiver do not understand education

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8	**Discharge**						**0**	
8A	Duration of therapy established	Not established Variation in standards and guidelines Physician variation Not communicated to patient	Exposed to drug longer than needed Progression of disease				0	Use protocols Document clearly disease being treated and duration of therapy Communicate information to outside caregivers
8B	Follow-up appointment set if indicated	No follow-up appt set Appt or place not communicated to patient Pt or family does not understand	Patient has complications and unclear where to go Develops drug or disease interactions				0	Use protocols Discharge documentation process established Communicate with outside caregivers Follow-up that patient went to follow-up appt.
8C	Follow-up with primary care provider	Communication doesn't happen Communication not received	Patient has complications and unclear where to go Develops drug or disease interactions				0	Establish process to communicate with outside caregivers
8D	Get prescription filled	Payment or reimbursement issues not addressed Pharmacy doesn't carry Don't get script filled Variations in counseling. Conflicts with other information received	Patient has complications and unclear where to go Develops drug or disease interactions				0	Establish process to work with patient/caregiver to address these issues prior to leaving the hospital and as part of the follow-up.
			depending on system, can vary in frequency from 3-7				0	
							0	
8E	Patient attends follow-up appointment	Transportation problems Patient reschedules No follow-up on missed appointments	Bleeding Death Thrombosis				0	Use follow-up protocol.