# Anticoagulation Agent Adverse Drug Event Gap Analysis

## Component of Medication Management Assessment

| Specific Action(s) | Gap Analysis Questions | Yes | No | If answered question "No," identify the Specific Action plan(s) including persons responsible and timeline to complete.. |
|---|---|---|---|---|
| **All Antithrombotics** | | | | |
| 1) Antithrombotic management practices | 1a) The facility has assigned responsibility for coordinating anticoagulation monitoring functions. | ☐ | ☐ | |
| | **The facility has a process in place to ensure fields contained in standard protocols/order sets/flowsheets are consistently populated (manually or automatically) with key information, including at a minimum:** | | | |
| | 1b) The patient's diagnosis. | ☐ | ☐ | |
| | 1c) Allergies. | ☐ | ☐ | |
| | 1d) Most recent pertinent laboratory results. | ☐ | ☐ | |
| | **The facility has standard policies and practices in place for managing the initiation and maintenance of anticoagulation therapy which include:** | | | |
| | 1e) The specific medication used (e.g., low molecular weight heparin [LMWH], warfarin, unfractionated heparin [UFH], vitamin K reversal, direct thrombin inhibitors). | ☐ | ☐ | |
| | 1f) The condition being treated. | ☐ | ☐ | |
| | 1g) The potential for drug interactions. | ☐ | ☐ | |
| | 1h) The facility has a protocol in place to determine the need to reverse supra-therapeutic international normalized ratio (INR) values based on key criteria, (e.g., the INR value, the presence or absence of bleeding, individual patient situation such as imminent surgery). | ☐ | ☐ | |
| | 1i) The facility has a process in place to ensure that anti-platelet agents are used for the appropriate indication (e.g., patients with mechanical valves, acute coronary syndrome, recent stent, or bypass surgery). | ☐ | ☐ | |
| | **The facility's vitamin K practice specifies (in patients with no evidence of warfarin associated bleeding):** | | | |
| | 1j) No routine use of vitamin K for INR between 4.5–10. | ☐ | ☐ | |
| | 1k) The use of oral Vitamin K for INR >10. | ☐ | ☐ | |


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| | **In patients with warfarin associated major bleeding:** | | | |
| | 1l) Reversal may be accomplished with the addition of vitamin K 5–10 mg given slow IV infusion. | ☐ | ☐ | |
| | 1m) Reversal may also be accomplished with prothrombin complex concentrate and the addition of Vitamin K 5–10 mg given slow IV infusion. | ☐ | ☐ | |
| 2) Prevention and mitigation practices for all anti-thrombotics | 2a) Antithrombotics are included in the organization's defined list of high alert medications. | ☐ | ☐ | |
| | 2b) A system is in place to alert healthcare practitioners to significant drug interactions for patients on antithrombotic agents. | ☐ | ☐ | |
| | 2c) A system is in place to remind the prescriber to evaluate the need for antithrombotic therapy when antithrombotics are being held due to future surgical purposes. | ☐ | ☐ | |
| | 2d) A pharmacy-managed system is in place for antithrombotic drug shortage situations which outlines how standard medication safety processes will be followed. | ☐ | ☐ | |
| | 2e) The facility has a process in place to prevent IV antithrombotic orders from being entered into the pharmacy system without including patient weight. | ☐ | ☐ | |
| | **The facility uses smart infusion pumps for the IV administration of all antithrombotics (including platelet inhibitors), with functionality employed to:** | | | |
| | 2f) Intercept and prevent wrong dose errors. | ☐ | ☐ | |
| | 2g) Intercept and prevent wrong infusion rate errors. | ☐ | ☐ | |
| 3) Therapeutic practices for all anti-thrombotics | **The facility has a process in place, using a standardized tool, to address and document the following prior to initiating antithrombotic therapy:** | | | |
| | 3a) Nutritional status. | ☐ | ☐ | |
| | 3b) Recent trauma. | ☐ | ☐ | |
| | 3c) Surgery. | ☐ | ☐ | |
| | 3d) Bleeding problems experienced while receiving any previous antithrombotic therapy. | ☐ | ☐ | |
| | 3e) Clotting history. | ☐ | ☐ | |
| | 3f) Drug/drug Interactions. | ☐ | ☐ | |
| | 3g) The facility has a process in place for pharmacists to assist with identification of alternative antithrombotic agents when contraindications exist. | ☐ | ☐ | |


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| | 3h) The indication and therapeutic goal for antithrombotic therapy is documented in the patient's medical record and communicated to pharmacy for monitoring and managing patient therapy. | ☐ | ☐ | |
| | **The facility has processes in place for timely access to routine test results which include:** | | | |
| | 3i) INR, partial thromboplastin time (PTT), and anti-Xa level available within 2 hours. | ☐ | ☐ | |
| | 3j) Healthcare providers can readily access inpatient and outpatient laboratory results to guide antithrombotic therapy. | ☐ | ☐ | |
| | 3k) When an antithrombotic agent is administered in the emergency department or other outpatient settings (e.g., cardiac cath lab, radiology), the inpatient medication record and chart is updated to communicate this information to other practitioners. | ☐ | ☐ | |
| | **For critical test results reporting, the facility has defined acceptable lengths of time between:** | | | |
| | 3l) Ordering critical hematologic tests (e.g., INR, PPT) and reporting of the test results. | ☐ | ☐ | |
| | 3m) The availability of the results and confirmation of receipt by a healthcare provider. | ☐ | ☐ | |
| | 3n) The receipt of results by a healthcare provider and clinically appropriate antithrombotic dose changes. | ☐ | ☐ | |
| **Warfarin** | | | | |
| 4) Warfarin management practices | **The facility has standard processes in place for initiation of warfarin therapy and daily dosing, which include:** | | | |
| | 4a) Collection of baseline lab values prior to prescribing anticoagulant (e.g., warfarin näive patient [30 days prior], warfarin maintenance patient [24 hrs. prior]). | ☐ | ☐ | |
| | 4b) Using the INR as the primary laboratory test to monitor and adjust warfarin therapy. | ☐ | ☐ | |
| | 4c) Nutritional assessment. | ☐ | ☐ | |
| | 4d) Drug/drug interactions. | ☐ | ☐ | |
| | 4e) Lab values. | ☐ | ☐ | |
| | 4f) History of thrombosis or bleeding event. | ☐ | ☐ | |
| | 4g) Recent trauma or surgery. | ☐ | ☐ | |
| | 4h) The ability to adjust INR target range for clinical indication is allowed. | ☐ | ☐ | |


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| | 4i) Screening for interactions between enteral nutrition products and antithrombotic therapy (e.g., drug/tube feed interactions). | ☐ | ☐ | |
| | 4j) Obtaining blood draws for INR at the same time each day. | ☐ | ☐ | |
| | 4k) Administering warfarin at the same time each day after INR results are available (e.g., afternoon / evening) | ☐ | ☐ | |
| | 4l) Warfarin is started on day 1 or 2 of LMWH or UFH therapy initiation. | ☐ | ☐ | |
| | 4m) Pharmacists can automatically modify warfarin therapy doses or directly contact the prescriber when laboratory values are below or above approved target ranges. | ☐ | ☐ | |
| | 4n) When warfarin therapy is initiated for a patient with active thrombosis, heparin or LMWH is continued until warfarin has been administered for a minimum of 5 (five) days and the INR reaches a therapeutic level for 2 (two) consecutive days. | ☐ | ☐ | |
| | 4o) The facility has a process in place for detection of contraindication of warfarin in pregnancy. | ☐ | ☐ | |
| 5) Prevention and mitigation practices for warfarin | **The facility's warfarin management practices include:** | | | |
| | 5a) Notification of dietary services when a patient is receiving warfarin therapy. | ☐ | ☐ | |
| | 5b) Automatic nutrition consults when patients are first placed on warfarin to avoid drug-food interactions. | ☐ | ☐ | |
| | 5c) Warfarin is dispensed in unit dose only (e.g., warfarin tablets are not split). | ☐ | ☐ | |
| | 5d) Warfarin is not available as floor stock unless stored in an automated dispensing cabinet that is interfaced with pharmacy. | ☐ | ☐ | |
| | 5e) All strengths of warfarin tablets dispensed within the facility are purchased from a single manufacturer. | ☐ | ☐ | |
| | **The facility's practice for hand-off communication to the next provider of care includes:** | | | |
| | 5f) Inpatient warfarin dosing history. | ☐ | ☐ | |
| | 5g) Inpatient INR value history. | ☐ | ☐ | |
| | 5h) Date the next INR is due. | ☐ | ☐ | |
| | 5i) Daily warfarin dosing schedule to be followed until date of next INR. | ☐ | ☐ | |
| | 5j) A confirmed appointment scheduled for laboratory, physician, and/or antithrombotic clinic. | ☐ | ☐ | |


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| | **The facility's practice for patients who are being discharged on warfarin therapy and have a sub-therapeutic INR includes a transition plan for:** | | | |
| | 5k) Consistent evaluation regarding the need for LMWH until a therapeutic INR is reached. | ☐ | ☐ | |
| | 5l) Maintaining patient on LMWH until a therapeutic INR is reached (when appropriate). | ☐ | ☐ | |
| **Parenteral Antithrombotics** | | | | |
| 6) Parenteral anticoagulants management practices | **The facility has processes in place for:** | | | |
| | 6a) Safely managing the care and removal of epidural catheters placed during regional anesthesia when LMWH has been administered for surgical prophylaxis. | ☐ | ☐ | |
| | 6b) Monitoring and/or discontinuing antithrombotic therapy prior to invasive procedures (e.g., INR within specific range or target). | ☐ | ☐ | |
| | 6c) The facility directs prescribers to employ a continuous infusion when IV heparin is prescribed (not intermittent IV administration) to achieve a therapeutic PTT or heparin level. | ☐ | ☐ | |
| | 6d) When LMWH or UFH therapy is greater than 3 days, a process is in place that ensures that a platelet count and serum creatinine are repeated every 3 days. | ☐ | ☐ | |
| | 6e) Standard guidelines are used for laboratory monitoring of LMWH in special populations (e.g. renal dosing, pregnancy, and morbid obesity). | ☐ | ☐ | |
| | **When laboratory reagents that are used to measure the PTT or other hematological tests are changed:** | | | |
| | 6f) There is a process in place to inform prescribers, pharmacists, and nurses about the change. | ☐ | ☐ | |
| | 6g) There is a process in place to update affected dosing protocols and order sets. | ☐ | ☐ | |
| 7) Management of parenteral anticoagulants: prevention and mitigation strategies | **The facility has processes in place to eliminate errors in preparation, storage, and dispensing which includes:** | | | |
| | 7a) Utilizing unit dose LMWH (round to the nearest dose if using a pen). | ☐ | ☐ | |
| | 7b) Limiting concentrations of heparin stored in automated dispensing machines and as floor stock (e.g., do not store 10,000 units/mL 1mL vials in automated dispensing cabinets or as floor stock). | ☐ | ☐ | |


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| | **Dispensing commercially prepared, pre-mixed IV solutions of UFH:** | | | |
| | 7c) In limited concentrations. | ☐ | ☐ | |
| | 7d) In limited vial sizes. | ☐ | ☐ | |
| | 7e) In prefilled heparin flush syringes. | ☐ | ☐ | |
| | **The facility has a process in place to perform an independent double-check for UFH (e.g., with smart pump technology or nurse double-check) with:** | | | |
| | 7f) Each new bag hung. | ☐ | ☐ | |
| | 7g) Each rate change. | ☐ | ☐ | |
| 8) Management of parenteral anticoagulants: therapeutic strategies | **The facility has processes in place to initiate and monitor heparin via lab values including:** | | | |
| | 8a) A baseline hemoglobin, hematocrit, serum creatinine, and platelet count are obtained prior to initiating antithrombotic therapy with unfractionated heparin or LMW heparin. | ☐ | ☐ | |
| | 8b) PTTs are obtained no sooner than 6–8 hours after UFH initiation. | ☐ | ☐ | |
| | 8c) Laboratory tests have standard intervals for assessment (e.g., hemoglobin [hgb] every 3 days, platelets every 3 days). | ☐ | ☐ | |
| | 8d) Prior to ordering any heparin product, the facility requires prescribers to specifically ask patients if they have a known history of heparin induced thrombocytopenia (HIT) and/or an allergy to heparin; positive responses are documented in the medical record. | ☐ | ☐ | |
| | 8e) A venous thromboembolism (VTE) prophylaxis protocol is in place for acutely ill or critically ill medical patients that includes use of low dose UFH, LMWH, or fondaparinux. | ☐ | ☐ | |
| | 8f) The facility's renal anticoagulant dosing program allows a pharmacist or prescriber to routinely adjust the doses of LMWH, Factor Xa inhibitors, and direct thrombin inhibitors. | ☐ | ☐ | |
| | 8g) The facility's documentation process for LMWH injections includes date and time of dose, and site of injection. | ☐ | ☐ | |
| | **For patients on UFH:** | | | |
| | 8h) If platelet count decreases to less than 100,000/mm3 or less than 50% of the baseline that the patient is evaluated for HIT in real-time. | ☐ | ☐ | |
| | 8i) If the patient is diagnosed with HIT, all sources of heparin are discontinued including heparin flush. | ☐ | ☐ | |


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| **Critical Thinking and Knowledge Strategies** | | | | |
| 9) Implement appropriate critical thinking and knowledge strategies | **The facility provides interdisciplinary education on antithrombotic therapy, which includes:** | | | |
| | 9a) Initial training for new hires and existing staff members, including protocols and guidelines. | ☐ | ☐ | |
| | 9b) Post test incorporating a case-study approach to demonstrate proficiency. | ☐ | ☐ | |
| | 9c) Plan for targeting gaps in knowledge. | ☐ | ☐ | |
| | 9d) Ongoing antithrombotic education is provided to direct care staff members when new relevant information is available. | ☐ | ☐ | |
| **Patient Education** | | | | |
| 10) Provide patient and family education | 10a) When initiating antithrombotic therapy, patients/caregivers receive verbal and written information on purpose, action, side effects, and monitoring. | ☐ | ☐ | |
| | **The facility has a process in place to educate patients and families on anticoagulants, using teach-back method, to ensure safe therapy including:** | | | |
| | 10b) Indication | ☐ | ☐ | |
| | 10c) Symptoms for monitoring | ☐ | ☐ | |
| | 10d) Dietary issues | ☐ | ☐ | |
| | 10e) Drug interactions | ☐ | ☐ | |
| | 10f) Disease interactions | ☐ | ☐ | |
| | 10g) Monitoring requirements | ☐ | ☐ | |
| | 10h) Duration of therapy | ☐ | ☐ | |
| | 10i) Potential adverse effects | ☐ | ☐ | |
| | 10j) Pharmacists are available for consultations to assist with patient education when any healthcare practitioner identifies a patient who is at risk for non-adherence. | ☐ | ☐ | |

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