# CHA Medication Safety Committee
# High Alert Medication Guidelines for Select Anticoagulants

Anticoagulation is a high risk therapy involving complex dosing, monitoring, and ensuring patient adherence with outpatient therapy. Reports of adverse events related to the improper use of anticoagulant drugs have received significant public attention[1-9]. The following guidelines focus on safety strategies for the anticoagulants that are currently most commonly used - **unfractionated heparin, warfarin and enoxaparin**. Several oral anticoagulants have recently gained FDA approval and may be added later as we get more experience with these newer agents.

A number of tools are listed in the 'Resource Tools' section to assist with an organizational self assessment of best practices relating to anticoagulant use.

| Step | Actions to Consider to Increase Medication Safety | | |
|---|---|---|---|
| | **Heparin** | **Warfarin** | **Low Molecular Weight Heparin** |
| **Pharmacy Purchasing, Storage and Product Labeling** | • Purchase only commercially available, standard concentrations of IV heparin infusions for use throughout the facility.<br>• Restrict purchases and storage of premixed IV solutions to the pharmacy if feasible<br>• Limit the variety of concentrations and sizes purchased both for large volume parenterals and vials of heparin. Consider eliminating 10,000 units/ml vials<br>• Store away from other drugs in the pharmacy with look alike names or packaging. Use TALLman lettering on labels and bins to differentiate between HeSpan and hEParin<br>• Clearly differentiate heparin products used for treatment from low concentration products such as flushes.<br>• Purchase patient population specific strengths of prefilled heparin flush syringes ( e.g. Peds)<br>• Use Tallman lettering on labels, order screens, MARs and other documents when feasible | • Purchase all strengths from a single manufacturer to promote consistent bioavailability for this narrow therapeutic index drug | • Purchase commercially available doses in prefilled syringes |

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| **Patient Care Unit Storage** | **Common considerations:**<br>• Do not provide as unit stock unless in automated dispensing cabinets (ADCs)<br>• Only stock in automated dispensing cabinets that are interfaced with the pharmacy system to enable pharmacy review prior to removal (not available via override feature).<br>• Employ additional verification measures in procedure areas if ADCs are not interfaced with the pharmacy system<br>• Segregate vials of different concentrations in single access pockets ('cubies') in automated dispensing cabinets | | |
| **Prescribing** | **Heparin** | **Warfarin** | **Low Molecular Weight Heparin** |
| | • Ensure all patients are screened for known history of HIT and/or allergy to heparin prior to initiation of therapy. Positive responses are entered in the perpetual medical record<br>• Approved order sets are readily available and used for prescribing<br>• Error prone abbreviations are not permitted.<br>• Baseline labs are ordered for monitoring therapy - aPTT or factor Xa if available.<br>• Institute a protocol for rounding of doses (e.g. to closest 500 units) for weight based dosing. Consider maximum dosing for obese patients<br>• Do not permit custom concentrations of heparin or alterations in base solution. | • Require a baseline INR result be available prior to initiation of warfarin therapy and baseline liver function tests and albumin are ordered<br>• Consider adoption of protocols to allow pharmacists to monitor and order labs and adjust therapy<br>• Ensure that therapy is initiated at doses of 2.5 to 5 mg for patients 65 years and older, or younger patients with co morbid conditions which may affect their response to warfarin ( e.g. thyroid disease) | • Ensure all patients are screened for known history of HIT and/or allergy to heparin prior to initiation of therapy. Positive responses are entered in the perpetual record<br>• Institute a protocol for rounding of doses for weight based dosing |
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**Prescribing**

**Common considerations**

- Ensure a baseline serum creatinine and a complete blood count that includes hemoglobin, hematocrit and platelet count, are available prior to initiating therapy.
- Determine ongoing lab monitoring requirements and include them on the preformatted order or in policy/protocol
- Ensure only metric units are used for weight based dosing and orders/guidelines specify use of ideal or actual body weight
- Ensure medical staff approved protocols exist to treat patients with known or suspected HIT with direct thrombin inhibitors if antithrombotic therapy is required
- Include reminders on protocols, order forms and CPOE system to avoid concomitant use of heparin products or to discontinue other anticoagulants as appropriate
- Do not permit error prone abbreviations, dose expressions and symbols (e.g. u instead of units, trailing zeros or not using leading zeros, < or >) in orders, protocols or nomograms. Commas should be used when expressing large doses ( e.g. 10,000 units)
- Establish a procedure for 'hold' orders
- Reconcile all anticoagulants upon admission, transfer and discharge
- Update all guidelines/order sets to reflect current evidence based practice e.g. CHEST, ACC, AHA, etc.

**Pharmacist Order Entry Process**

| Heparin | Warfarin | Low Molecular Weight Heparin |
|---|---|---|
| | • Implement a process to screen for drug/food/nutritional product interactions<br>• Consider standard administration time such as 17:00 or 18:00 | • Implement a process to screen for the presence of an epidural catheter |

**Common considerations:**

- Ensure height and weight in metric units is entered in pharmacy computer system before order entry
- Create pharmacy system alerts for duplicate orders from the same drug class. Provide dose range alerts for over/under dosing as applicable

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- Ensure one time doses administered in the ED or procedure settings are entered in the pharmacy system to prevent dose duplication
- Require pharmacist validation that all required baseline labs were reported

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<tr><td rowspan="2">Pharmacy Dispensing</td><td>Heparin</td><td>Warfarin</td><td>Low Molecular Weight Heparin</td></tr>
<tr><td>

- Require all heparin orders are verified by pharmacy prior to dispensing

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- All doses are provided in unit dose packaging.
- Consider elimination of pill splitting on nursing units

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<tr><td></td><td colspan="3">

Common considerations

- If available. ensure machine readable bar coding is used for verification prior to dispensing from the pharmacy for refill of automated dispensing cabinets or for single patient use

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<tr><td rowspan="2">Administration</td><td>Heparin</td><td>Warfarin</td><td>Low Molecular Weight Heparin</td></tr>
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- Conduct an independent verification of 5 “rights”, drug concentration, rate of infusion, pump channel selection, IV line labeling and attachment is conducted prior to administration and at change in therapy
- Use infusion pumps, preferably smart pumps with error reduction software, for IV infusions
- Use smart pumps to deliver bolus and continuous doses from the same container only when a bolus dose can be safely programmed (with hard limits on total dose and minimum infusion time), and the pump automatically converts to continuous infusion after bolus is delivered. Be mindful of the volume required for bolus doses delivered

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- Consider MAR documentation of pertinent lab values used to monitor therapy ( e.g. INR)
- Schedule warfarin administration for the same time each day after INR results are available ( afternoon or early evening)

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- Conduct an independent verification of 5 “Rights” and correct indication prior to administration
- Rotate and document injection sites
- Monitor injection sites for hematomas
- Use initial weight for weight based dosing. Do not adjust weight each day
- To avoid the loss of drug when using the 30 and 40 mg prefilled syringes, do not expel the air bubble from the syringe before the injection.

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| **Administration** | through the pump versus IV push dosing.<br>• Use initial weight for weight based dosing. Do not adjust weight each day unless there is a significant weight change as determined by organizational policy<br>• Require line labeling of IV heparin infusions to prevent line mix ups<br>• Trace back and reconcile IV lines upon initiation, change in orders and at shift handoff<br>• Do not administer IM | | |
| | **Common considerations**<br>• Make clearly labeled and approved protocols, pathways, nomograms, flow sheets and/or checklists readily accessible in print or electronic form<br>• Consider requiring MAR documentation of pertinent lab values used to monitor therapy ( e.g. aPTT,factor Xa levels, INR) when doses are administered<br>• Incorporate screening questions in automated dispensing cabinets to identify adverse drug reactions when reversal agents (e.g. protamine, Vitamin K) are dispensed<br>List specific interventions or treatments that are to be avoided (e.g. IM injections) on pharmacy and medication administration records | | |

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| **Education** | • Instruct patients diagnosed with HIT to communicate this to all healthcare providers | • Give patients and caregivers verbal and written information at 8th grade reading level or below, preferably in their language:<br>○ on proper dietary methods and their effect on therapy goals<br>○ how their therapy is monitored with changes in dose based on lab results and adherence to prescribed treatment<br>○ instructions on how to manage dose changes safely at home when existing tablet strength differs from a new dose<br>○ signs and symptoms of bleeding (e.g. bleeding gums) or thromboembolic complications<br>○ drug and herbal interactions. Ensure patients/caregivers understand that warfarin and Coumadin are the same drug<br>○ Ensure the patient understands importance of adherence with anticoagulation dosing<br>• Prior to discharge, stress the importance of follow up appointments. Facilitate a confirmed appointment with the lab, physician or anticoagulation clinic | • Have patients/caregivers demonstrate proficiency if they are to self administer at home<br>• Use videos, pamphlets, and other facility approved tools to complement one on one education<br>• Instruct patients diagnosed with HIT to communicate this to all healthcare providers |
| | **Common considerations**<br>• Consider initial training and baseline competency evaluation for all practitioners who prescribe, dispense and/or monitor therapy (including physicians, nursing, pharmacy and dieticians)<br>• Include anticoagulants on list of High Alert meds and educate staff on risk reduction strategies that are employed to improve safety<br>• Share information about error-prone situations and errors within and outside the facility with practitioners on an ongoing basis<br>• For inpatients, provide education about antithrombotics at initiation of therapy; aim to provide most of the information about therapy after discharge at least 24 hours prior to discharge | | |

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| **Monitoring** | • Monitor complete blood counts at routine intervals<br>• Obtain an aPTT or factor Xa level between 6-8 hrs after initiation of heparin therapy ( unless bleeding)<br>• Modify dosing protocols and nomograms if lab changes are made that impact test values (e.g. reagents, testing methods).<br>• Check and recalibrate point of care and monitoring devices when new lots of reagent are received | • Draw blood specimens at the same time each morning so results are available before warfarin doses are prescribed<br>• If the patient is placed on NPO status, contact the prescriber for new anticoagulation orders as appropriate<br>• Ensure a protocol exists to guide the reversal of supra therapeutic INR when clinically indicated. **Oral** phytonadione is used unless rapid reduction is required.<br>• Ensure a process is in place to notify the food and nutrition department when patients are on warfarin therapy<br>• If IV Vitamin K is required, require dilution in at least 50 ml of solution, administered over 30-60 min. Avoid IM administration of Vitamin K | • Ensure baseline serum creatinine, hemoglobin, hematocrit and platelet count are available prior to initiating therapy<br>• Monitor platelet counts at routine intervals ( e.g. every 3 days) for the first 2 weeks of therapy<br>• Adjust dose for renal impairment and extremes of body weight as specified by medical staff approved protocols |
| | **Common Considerations**<br>• Implement a protocol or guideline for monitoring and/or discontinuing therapy prior to invasive procedures<br>• Include alerts on pharmacy order entry screens, automated dispensing cabinets, protocols/pathways to review medications the patient has received in the last 24hrs (including in ED) to ensure that an adequate time has lapsed between doses<br>• Ensure that all practitioners have easy access to inpatient (and preferably applicable outpatient) lab results to guide therapy<br>• Report critical values to the responsible caregiver within the facility identified time frame<br>• If platelet counts decline to less than 100,000/mm3 or less than 50% of baseline, ensure there is a mechanism in place for HIT evaluation, and | | |

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<tr><td></td><td>discontinuation of all sources of heparin including flushes and heparin coated instruments<br>• Enhance detection of potential adverse events by interfacing pharmacy and lab systems and incorporating alerts to the pharmacy system for selected values of lab tests (e.g. aPTT greater than 100 sec, platelet count less than 100,000/mm$^3$, facility defined value of elevated INR)<br>• Monitor patients for fall risk and notify physician immediately post fall</td></tr>
<tr><td rowspan="2">Other</td><td>Heparin</td><td>Warfarin</td><td>Low Molecular Weight Heparin</td></tr>
<tr><td>• Consider inpatient pharmacy managed anticoagulation services<br>• Use saline flushes (not heparin flushes) for peripheral venous access catheters<br>• Discontinue heparin 4 hours before surgery</td><td>• Consider inpatient and outpatient pharmacy managed anticoagulation services<br>• Discontinue 5 days prior to surgery or procedures. For patients at high risk for VTE, consider bridge therapy with LMWH or heparin.</td><td>• Consider inpatient pharmacy managed anticoagulation services<br>• Implement a protocol or guideline for safely managing the care and removal of epidural catheters placed during regional anesthesia when LMW heparin has been administered for surgical prophylaxis<br>• Administer last dose 24 hours prior to surgery. Give ½ total daily dose for last pre-operative dose.</td></tr>
<tr><td rowspan="2">Transitional Care: Discharge Planning</td><td>Heparin</td><td>Warfarin</td><td>Low Molecular Weight Heparin</td></tr>
<tr><td colspan="3">1. Provide education on the importance of vigilant adherence with anticoagulation therapy<br>2. Educate patients to be mindful of brand to brand variation resulting in differences in bioavailability when refilling prescriptions for warfarin<br>3. Facilitate a confirmed appointment with the lab, physician and/or anticoagulation clinic prior to discharge from the hospital. Stress the importance of making and keeping follow up appointments.<br>4. Prior to discharge, collaborate with case managers and social workers to identify and address barriers for adherence to medication therapy e.g. insurance coverage, prescription affordability, access and transportation for physician appointments, support in post discharge setting<br>5. Collaborate with long term care providers and community based organizations who can provide follow up visits or phone calls to encourage medication adherence<br>6. See Resource Tools section for WARFARIN DOSE REMINDER CHART</td></tr>
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| **References** | 1. The Joint Commission Accreditation Program: Hospital National Patient Safety Goals. http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals<br>2. Fanikos J, et. al. Medication errors associated with anticoagulant therapy in the hospital. *Am J Cardiol* Aug 15 2004;94(4):532-5.<br>3. Winterstein AG, et. al. Identifying clinically significant preventable adverse drug events through a hospital's database of adverse drug reaction reports. *Am J Health Syst Pharm* Sep 15 2002;59(18):1742-9.<br>4. Errors Involving Drug Products Used to Treat Cardiovascular Diseases: Part III. USP *CAPSLink Newsletter*. May 2005. http://www.usp.org/pdf/EN/patientSafety/capsLink2005-05-01.pdf.<br>5. Hicks RW, Becker SC, Cousins DD. MEDMARXR data report. A report on the relationship of drug names and medication errors in response to the Institute of Medicine's call for action. Rockville, MD: Center for the Advancement of Patient Safety, US Pharmacopeia;2008.<br>6. Hicks RW, Becker SC, Cousins DD. MEDMARXR data report: A Chartbook of Medication Error Findings from the Perioperative Settings from 1998-2005. Rockville, MD: Center for the Advancement of Patient Safety, US Pharmacopeia; 2006.<br>7. Santell JP, Hicks RW, Cousins DD. MEDMARXR data report: A Chartbook of 2000-2004 Findings from Intensive Care Units and Radiological Services.Rockville, MD: Center for the Advancement of Patient Safety, US Pharmacopeia; 2005.<br>8. Adverse events in Hospitals OIG report http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf |
| **Resource tools** | 1. **ISMP Medication Safety Self Assessment for Antithrombotic Therapy in** Hospitals http://www.ismp.org/selfassessments/asa2006/Intro.asp<br>2. **ISMP - Failure Mode and Effects Analysis for Anticoagulants** http://www.ismp.org/Tools/FMEAofAnticoagulants.pdf<br>3. **The Joint Commission Sentinel Event Alert**, **Issue 41: Preventing errors relating to commonly used anticoagulants** http://www.jointcommission.org/<br>4. **ASHP Anticoagulation Resource Center http://www.ashp.org/anticoagulation**<br>5. **Anticoagulant Toolkit Developed by Purdue University PharmaTAP in collaboration with the Indiana Patient Safety Center (IPSC), Indiana Hospital Association (IHA) and VHA Central, this toolkit aims to reduce adverse drug events associated with high-alert medications.**<br>6**. LA County - Best Practice Recommendations Guidelines for the Use of Concentrated Heparin**<br>7. **Warfarin Dose Reminder Chart** http://www.aafp.org/fpm/2005/0500/p77.html<br>8. **AHRQ Guide to Using Warfarin Safely**: http://www.ahrq.gov/consumer/btpills.htm#booklet |