Sentinel Event Alert

Preventing errors relating to commonly used anticoagulants

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Reports of accidental deaths and overdosing due to the improper use of anticoagulant drugs have received significant public attention. Anticoagulants have been identified as one of the top five drug types associated with patient safety incidents in the United States.(1) In the United Kingdom, anticoagulants are one of the classes of drugs commonly associated with fatal medication errors. (2)

The Joint Commission’s Sentinel Event Database includes 446 medication-related sentinel events (9.3 percent of all events) reported from January 1997 through December 2007, with 7.2 percent (32) of these involving anticoagulants; of those, two-thirds (21) involve heparin* (see sidebar for more data). According to the United States Pharmacopeia MEDMARX database, a total of 59,316 medication errors related to anticoagulants were reported to the MEDMARX program from 2001 to 2006 (these data do not include errors involving heparin lock flush). Nearly 60 percent of these errors reached the patient and nearly 3 percent resulted in harm or death. Performance error (e.g., administration) is the most common cause of adverse events relating to anticoagulant medications.

The anticoagulants cited most frequently in medication error reports are unfractionated heparin, warfarin and enoxaparin (classified as low molecular weight heparin, LMWH)*, according to MEDMARX and a hospital study. (3) These are also the most commonly used anticoagulants and the focus of this Alert. According to MEDMARX, in 2005, enoxaparin errors were associated with four patient deaths and two cases of permanent harm. Other anticoagulant errors have been associated with the concurrent use of heparin and enoxaparin and with argatroban and lepirudin.

Contributing factors

Patients under consideration for receiving anticoagulant drugs must be carefully screened for contraindications and drug interactions. While receiving anticoagulants, patients must be monitored closely to ensure effectiveness and to prevent side effects or overdosing. Heparin and warfarin in particular have narrow therapeutic ranges and a high potential for complications (4), so there is a greater risk of patient harm. (5) The following factors contribute to medication errors involving anticoagulants:

- Lack of standardization for the naming, labeling and packaging of anticoagulants creates confusion. For example, heparin flush syringes have been confused with LMW heparin syringes. In addition, other, lesser-known anticoagulant drug names exist (e.g., enoxaparin, dalteparin, tinzaparin) and are used less commonly, which can result in duplicate medication orders and erroneous dosing.
- Keeping current with different dosing regimens for various patient populations, newer assay methods, the expanding lists of drug interactions, and the potential reversal strategies can be a challenge for providers—especially those who infrequently prescribe or administer anticoagulants. (6)
- The specific and individualized instructions and monitoring information (for example, dose adjustments, lab values, changing patient condition) that accompany the prescribing and administration of anticoagulants may fail to get documented or communicated during transfers and hand-offs. (7)
- Neonates and other pediatric patients are problematic to treat, specifically because the medications are formulated and packaged primarily for adults. (8)

<table>
<thead>
<tr>
<th>Number of Reported Sentinel Events Related to Anticoagulants (1997-2007)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Involved</td>
</tr>
<tr>
<td>Heparin</td>
</tr>
<tr>
<td>Warfarin</td>
</tr>
<tr>
<td>Enoxaparin</td>
</tr>
<tr>
<td>Unknown*</td>
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<tr>
<td>Outcome (# of patients 34*)</td>
</tr>
<tr>
<td>Death</td>
</tr>
<tr>
<td>Loss of function</td>
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<tr>
<td>Settings</td>
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<td>Hospital</td>
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<td>Emergency</td>
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<tr>
<td>Department</td>
</tr>
<tr>
<td>Long Term Care</td>
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<tr>
<td>Cause of Event</td>
</tr>
<tr>
<td>Wrong drug</td>
</tr>
<tr>
<td>Wrong dose</td>
</tr>
<tr>
<td>Improper monitoring</td>
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<tr>
<td>Pump</td>
</tr>
</tbody>
</table>
Risk reduction strategies

Health care organizations that dispense or administer anticoagulant medications can prevent errors relating to anticoagulants by implementing specific risk reduction strategies. Since the management of anticoagulants is interdisciplinary, any risk strategies should be implemented by all staff who manage anticoagulants, which can include physicians, nurses, pharmacists, dieticians, and case managers. Specific guidelines regarding anticoagulant management have been developed by the United Kingdom's National Patient Safety Agency, the Institute for Safe Medication Practices, and the Institute for Healthcare Improvement. These guidelines stress improving staff communication and access to information; implementing close pharmacy oversight and involvement; and enhancing patient education. Research shows there is a significant reduction in the risk of thromboembolic events and death among patients who manage their anticoagulation therapy compared with those who rely solely on their doctor to monitor their treatment. In addition, organizations may consider:

- Implementing a pharmacist-managed anticoagulation service. In addition to helping discharged patients receiving warfarin therapy, this service can assist staff caring for patients on all types of anticoagulants.
- Implementing or using, when available, computerized provider order entry (CPOE) and/or bar coding technology. Pharmacy can use bar coding to replenish regular anticoagulant medication stock or automated dispensing cabinets.

Existing Joint Commission requirements

- Standard MM 7.10: The organization develops processes for managing high-risk or high-alert medications. Elements of performance include identifying these medications and developing and implementing processes for procuring, storing, ordering, transcribing, preparing, dispensing, administering, and monitoring them.
- National Patient Safety Goal 3E: Reduce the likelihood of patient harm associated with the use of anticoagulant therapy. Targeted for full implementation by January 1, 2009, the requirement has a one-year phase-in period during 2008 that includes defined milestones (see the EPs at: http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/).
- National Patient Safety Goal 8: Accurately and completely reconcile medications across the continuum of care. Related requirements were revised based on feedback obtained from a Medication Reconciliation Summit convened in late 2007 and are effective January 1, 2009. These requirements include the communication of the reconciled list during transfer or discharge, and modified medication reconciliation processes.

Other Joint Commission suggested actions

For all anticoagulants:

1. Perform an organizational-wide risk assessment for anticoagulant therapy.
2. Use best practices or evidence-based guidelines regarding the use of anticoagulants.
3. Establish organization-wide dose limits on anticoagulants and screen all orders for exceptions (i.e., require a confirmatory override by the physician).
4. Clearly label or otherwise differentiate syringes and other containers used for anticoagulant drugs.
5. Clarify all anticoagulant dosing for pediatric patients.
6. Promptly re-evaluate patients whose anticoagulant is being held for a procedure. The re-evaluation should include an assessment of the need to reorder anticoagulant therapy.
7. Hospitals and ambulatory facilities (both hospital-owned/managed and independent ambulatory care providers) should provide timely communication of all anticoagulant-associated lab values to the provider or the person managing the anticoagulation therapy.
8. Under the supervision of clinical staff, educate and assist inpatients who require anticoagulant drugs to practice administering their own medications. This will help reduce the risk of errors after discharge.
For heparin:

9. Consolidate and limit the number of institutional unfractionated heparin dosing nomograms. (18, 19) For all heparin medication orders (inpatient and outpatient), require prescribers to include the calculated dose and the dose per weight (e.g. milligrams per kilogram) or body surface area to facilitate an independent double-check of the calculation by a pharmacist, nurse or both. Note: For morbidly obese patients, the standard nomograms may not be accurate.

10. Before the start of a heparin infusion and with each change of the container or rate of infusion, require an independent double check of the drug, concentration, dose calculation, rate of infusion, pump settings, line attachment and patient identity.

11. Use heparin flush only for central lines and eliminate heparin flush of peripheral intravenous lines. (20) Stock and use only pre-filled syringes commercially prepared at set unit doses for flush solutions.

12. Identify patients with heparin-induced antibodies and heparin-induced thrombocytopenia (HIT) to avoid life-threatening events from heparin exposure. (21)

13. Dispense only preservative-free heparin to neonates and build an alert to pharmacists with this directive into order entry systems.

For warfarin:

14. Consider reports of INRs greater than three and episodes of vitamin K administration as possible indicators of warfarin-associated adverse drug events and take immediate steps to address these events. (7)

15. Do not automatically discontinue warfarin according to automatic stop policies without verifying the drug’s indication and contacting the prescriber.

* All the medications are named by their generic names; they may be better known by brand names.

References


(10) Institute for Healthcare Improvement: Reduce adverse drug events involving anticoagulants. 2006. Available online: (accessed 4/16/08)


Other resources

