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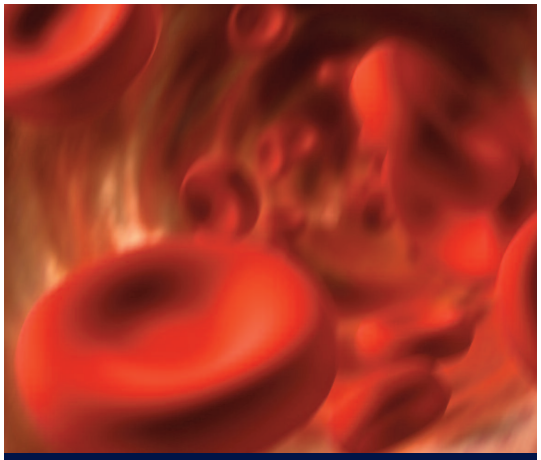
PATHWAYS TO PATIENT SAFETY: ANTICOAGULATION/ ANTITHROMBOTIC THERAPY

Many new pharmacologic agents (low molecular weight heparins, antiplatelet drugs, thrombolytics, direct thrombin inhibitors, etc.) can significantly affect morbidity and mortality, but in order for an anticoagulant to help, it must be used properly; complications from misuse can result in serious injury or death. These injuries are normally related to the complexity of dosing, monitoring and ensuring patient compliance. The prescriber has to weigh the risk of blood clots if the patient is not treated, against the risk of bleeding if the patient is given an anticoagulant.

ANTICOAGULANTS = HIGH RISK

Patient safety organizations, such as the Institute for Safe Medical Practices (ISMP), U.S. Pharmacopeia (USP), The Institute for Healthcare Improvement (IHI), and the Joint Commission consider anticoagulants high-risk medications. In 2002, the US Pharmacopeia MEDMARX program reported that heparin had the highest number of harmful improper medication dosing reports in seniors. USP data analysis determined that death rates were 11.4% higher with heparin and 6.2% higher with warfarin in hospitals without R.Ph. (Registered Pharmacist) managed anticoagulation therapy protocols. The lack of these R.Ph. managed programs is also costly, requiring 10.05% more patient days to care for heparin patients and 5.86% more days for those on warfarin.

To meet the challenges of managing these patients, many organizations have opened “anticoagulation clinics” for those taking warfarin (a.k.a. Coumadin)according to ECRI 1. Studies comparing use of a clinic setting compared to standard care have found that the



WHAT ARE THEY?

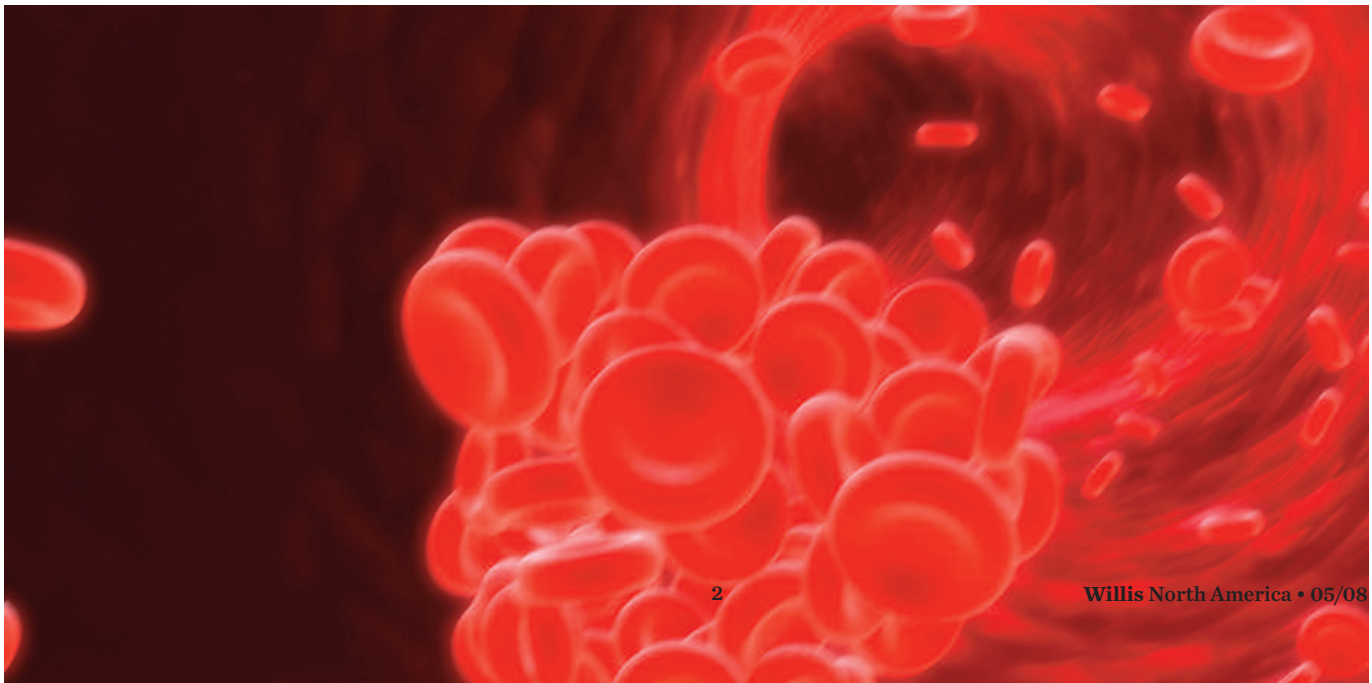
Antithrombotic (anticoagulant) drugs are used to decrease the risk of thrombosis by interfering with the homeostatic clotting mechanism. Anticoagulants decrease the clotting ability of the blood and this can help prevent harmful clots from forming in blood vessels (arteries and veins). The major side effect of these drugs is bleeding, either from supratherapeutic effect or by accentuating the blood loss of patients with an existing source of bleeding. Medicines such as heparin and warfarin are sometimes called blood thinners, although they do not actually thin the blood. Anticoagulants will not dissolve clots that already have formed, but they may prevent the clots from becoming larger and causing more serious problems. Anticoagulants are often used as treatment for certain blood vessel, heart and lung conditions such as deep vein thrombosis, atrial fibrillation, stroke and pulmonary emboli.

clinics significantly reduced the incidence of bleeding and other adverse events. Also, patients enrolled in clinics often maintained target INRs for longer periods of time than patients receiving standard treatment. Only about 40%-50% of patients fall within the target INR range with the traditional management efforts. Use of formal anticoagulation clinics or management programs can result in about 70% of patients falling within this range. These services can also free up hospital beds and reduce emergency room visits.
The success and safety of any anticoagulation service is only as good as the care providers involved. The team should be multidisciplinary, including medical providers,, nursing, pharmacy, and dietary). Practices to consider when evaluating an anticoagulation management program should include:

- A focus on planning a program in compliance with Joint Commission NPSG 3E
- Addressing patient assessment, the prescribing of anticoagulants and ongoing monitoring of therapy, including transition therapy from inpatient to outpatient
- A review of the literature and an evaluation of anticoagulation therapy best practices, such as independent double-checks and machine readable coding
- Providing education to staff, patients and care providers about anticoagulation therapies, importance of compliance, and the potential for adverse drug reactions and interactions associated with certain foods, dietary supplements and herbs
- Developing protocols to address lab testing for anticoagulant therapy, timing and reporting of results and specimen collection
- Standardizing use of programmable infusion pumps for IV anticoagulants; to include reducing and standardizing the size of infusion bags for IV mixtures and considering IV incompatibility issues and infusion-related interruption issues
- Employing established food-drug interaction programs developed with dietary services
- Using approved protocols for anticoagulation therapy initiation and maintenance
- Providing education on the proper use of reversal agents
- Implementing risk mitigation practices to reduce or eliminate errors due to look-alike and sound-alike medications, drug concentrations and storage issues (removing floor stock)
- Implementing risk mitigation techniques related to dosing errors for all populations including pediatrics
- Improving documentation, communication and information flow

By January 9, 2009 the Joint Commission expects accredited hospitals to be well on the way to reducing the likelihood of patient harm associated with anticoagulation therapy by implementing the National Patient Safety Goal (NPSG) 3E. The JC emphasizes the need for standardized protocols "resulting in the effective individualized treatment plans for each patient." There are 11 implementation steps. Unlike new goals in previous years, requirement 3E must be implemented within a specific timetable. The checkpoints included in the rationale for requirement 3E call for:

- Assignment of leadership responsibility by April 1, 2008
- Implementation work plan in place by July 1, 2008
- Pilot testing in at least one clinical unit by Oct. 1, 2008
- Full implementation by Jan. 1, 2009



Furthermore, as recently announced, the Centers for Medicare & Medicaid Services (CMS) proposes to expand the list of conditions considered reasonably preventable through proper care and for which they will no longer pay at a higher rate if the patient acquires them during a hospital stay. 2 Included on this list is "deep-vein thrombosis/pulmonary embolism (formation/movement of a blood clot)."

The second initiative CMS proposes is the expansion (six new venous thromboembolism (VTE) measures) of the hospital-quality measures reporting program, which reduces the amount a hospital is paid if it does not participate in the voluntary reporting of standardized quality measures.

The common goal of all these initiatives is to improve the safety and care of patients receiving the high-risk thromboembolitics/anticoagulants while controlling the costs of that treatment. Risk managers should be involved in their facilities' risk reduction programs as respects these initiatives and be prepared to address their own facilities' frequency and severity of adverse events and payments related to anticoagulants.

ADDITIONAL RESOURCES

- **Sample FMEA (Failure Mode and Effect Analysis)**
- **Self-Assessment Tool**
- **Guidelines**
- **JC rationale for requirement and implementations expectations NPSG 3E**

References

1. "Anticoagulation Clinics: Ensuring Safety for a High-Risk Medication," ECRI Risk Management Reporter October 2006
2. Press Release: Details for: CMS proposes to Expand Quality Program for Hospital Inpatient Services in FY 2009 www.cms.hhs.gov

HEPARIN PROTOCOL FAILURE

A patient underwent successful coronary artery bypass grafting at defendant hospital. Over a week later, he began to suffer from pain and swelling in his left calf. He went back to the hospital and was diagnosed with deep venous thrombosis (DVT), or clots in his leg. The patient was admitted and treated with anticoagulant therapy. The medical records indicated some confusion on the part of the medical staff regarding the proper anticoagulant protocol to administer. The morbidly obese patient was placed on a heparin regimen designed for someone about half his size. A few days into his hospital stay, the patient's clot broke and traveled to his lungs, causing a fatal pulmonary embolism. He was survived by his 3 adult children. The plaintiff's firm obtained a verdict in the amount of $875,000 plus interest. The parties later entered into a settlement for $960,000.

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