

Anticoagulation

Delivery of Optimized Inpatient Anticoagulation Therapy: Consensus Statement from the Anticoagulation Forum

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An estimated 4 million patients in the AUS and almost 7 million worldwide are receiving long-term therapy with oral anticoagulants, primarily warfarin or other coumarin derivatives, for prevention and treatment of venous and arterial thromboembolism.^{1,2} Hospitalized patients may be treated with anticoagulants for traditional ambulatory indications such as stroke prevention in those with atrial fibrillation, as well as for conditions encountered primarily in the inpatient setting, including venous thromboembolism (VTE) prophylaxis and treatment and acute coronary syndrome. Inpatients are exposed to a wide variety of anticoagulants, including unfractionated heparin, low-molecular-weight heparins, factor-Xa inhibitors, and direct thrombin inhibitors. Anticoagulants are high-risk medications associated with a significant rate of medication errors^{3,4} and adverse effects associated with this drug class are the leading cause of hospitalization among older adults.⁵ Among hospitalized patients, anticoagulants are associated with approximately 7% of all medication errors,^{6,7} resulting in a 20% increased risk of death.⁷ Similarly, the Joint Commission's Sentinel Event Database showed that 7.2% of all adverse medication events from January 1997 to December 2007 were related to anticoagulants.⁸

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OBJECTIVE: To provide recommendations for optimized anticoagulant therapy in the inpatient setting and outline broad elements that need to be in place for effective management of anticoagulant therapy in hospitalized patients; the guidelines are designed to promote optimization of patient clinical outcomes while minimizing the risks for potential anticoagulation-related errors and adverse events.

DATA SOURCES: The medical literature was reviewed using MEDLINE (1946-January 2013), EMBASE (1980-January 2013), and PubMed (1947-January 2013) for topics and key words including, but not limited to, standards of practice, national guidelines, patient safety initiatives, and regulatory requirements pertaining to anticoagulant use in the inpatient setting. Non-English-language publications were excluded. Specific MeSH terms used include algorithms, anticoagulants/administration and dosage/adverse effects/therapeutic use, clinical protocols/standards, decision support systems, drug monitoring/methods, humans, inpatients, efficiency/organizational, outcome and process assessment (health care), patient care team/organization and administration, program development/standards, quality improvement/organization and administration, thrombosis/drug therapy, thrombosis/prevention and control, risk assessment/standards, patient safety/standards, and risk management/methods.

STUDY SELECTION AND DATA EXTRACTION: Because of this document's scope, the medical literature was searched using a variety of strategies. When possible, recommendations are supported by available evidence; however, because this paper deals with processes and systems of care, high-quality evidence (eg, controlled trials) is unavailable. In these cases, recommendations represent the consensus opinion of all authors and are endorsed by the Board of Directors of the Anticoagulation Forum, an organization dedicated to optimizing anticoagulation care. The board is composed of physicians, pharmacists, and nurses with demonstrated expertise and experience in the management of patients receiving anticoagulation therapy.

DATA SYNTHESIS: Recommendations for delivering optimized inpatient anticoagulation therapy were developed collaboratively by the authors and are summarized in 8 key areas: (1) process, (2) accountability, (3) integration, (4) standards of practice, (5) provider education and competency, (6) patient education, (7) care transitions, and (8) outcomes. Recommendations are intended to inform the development of coordinated care systems containing elements with demonstrated benefit in improvement of anticoagulation therapy outcomes. Recommendations for delivering optimized inpatient anticoagulation therapy are intended to apply to all clinicians involved in the care of hospitalized patients receiving anticoagulation therapy.

CONCLUSIONS: Anticoagulants are high-risk medications associated with a significant rate of medication errors among hospitalized patients. Several national organizations have introduced initiatives to reduce the likelihood of patient harm associated with the use of anticoagulants. Health care organizations are under increasing pressure to develop systems to ensure the safe and effective use of anticoagulants in the inpatient setting. This document provides consensus guidelines for anticoagulant therapy in the inpatient setting and serves as a companion document to prior guidelines relevant for outpatients.

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In 2008, the Joint Commission introduced National Patient Safety Goal 03.05.01 (formerly 3E) with the intent of “reducing the likelihood of patient harm associated with the use of anticoagulant therapy.”⁹ Hospitals were required to “develop and implement standardized anticoagulation practices” to reduce adverse drug events and improve patient outcomes. Other entities, such as the Institute for Safe Medication Practices¹⁰ and the Centers for Medicare and Medicaid Services,¹¹ have also introduced initiatives with similar overarching goals of reducing anticoagulant-related errors and improving patient outcomes. With health care regulators increasingly focused on anticoagulants, hospitals are under increasing pressure to develop systems that optimize the safety and efficacy of anticoagulants in the inpatient setting.

This document provides consensus guidelines for optimized anticoagulant therapy in the inpatient setting. It is a companion document to our prior guidelines, “Delivery of Optimized Anticoagulant Therapy: Consensus Statement from the Anticoagulation Forum.”¹² Although the prior document suggested that its recommendations should “apply to all clinicians involved in the care of patients receiving anticoagulation, regardless of the structure and setting in which that care is delivered,” there are some anticoagulation-related challenges that are unique to the inpatient arena. The present guidelines discuss broad elements that need to be in place for effective management of anticoagulant therapy in hospitalized patients. They are designed to promote optimization of patient clinical outcomes while minimizing the risks for potential anticoagulation-related errors and adverse events. Recommendations in this document are, whenever possible, based on best available evidence. However, for some issues, published evidence is inconclusive or unavailable. In all instances, recommendations set forth represent the consensus opinion(s) of all authors and are endorsed by the Anticoagulation Forum’s Board of Directors. The Anticoagulation Forum is an organization dedicated to optimizing anticoagulation care for all patients (www.acforum.org). The Board of Directors is composed of physicians, pharmacists, and nurses with demonstrated expertise and experience in the management of hospitalized patients receiving anticoagulant therapy. The medical literature was reviewed for topics and key words including, but not limited to, standards of practice, national guidelines, patient safety initiatives, and regulatory requirements pertaining to anticoagulant use in the inpatient setting. Non-English-language publications were excluded. Specific MeSH terms used include algorithms, anticoagulants/administration and dosage/adverse effects/therapeutic use, clinical protocols/standards, decision support systems, drug monitoring/methods, humans, inpatients, efficiency/organizational, outcome and process assessment (health care), patient care team/organization and

administration, program development/standards, quality improvement/organization and administration, thrombosis/drug therapy, thrombosis/prevention and control, risk assessment/standards, patient safety/standards, and risk management/methods.

1. Process

Every inpatient health care organization should use a system-based process for inpatient anticoagulation management to assure safe and effective use of these medications.

In 1999, the Institute of Medicine published its report *To Err is Human: Building a Safer Health System*,¹³ which estimated that as many as 1 of every 25 hospitalized patients is injured due to medical error. Systems failures, rather than human error, are the cause of 75% of these errors.¹⁴ In response, in 2002 the Institute for Safe Medication Practices introduced *Pathways for Medication Safety*,¹⁵ a comprehensive set of tools intended to help hospitals adopt a “process-driven, system-based approach” to reduce medication errors and improve patient care. This launched an era in which hundreds of safe medication practices were implemented. However, the effectiveness of these practices was reduced by a lack of standardization at both the health system level and across organizations. The need for a well-defined, formally endorsed set of safe medication practices became evident. In 2003, the National Quality Forum, in conjunction with the Agency for Healthcare Research and Quality, introduced *Safe Practices for Better Healthcare: A Consensus Report*¹⁶ in an effort to standardize medication safety processes. While not all-encompassing, this National Quality Forum report details 34 evidence-based practices that are generalizable to a wide variety of patient populations and care settings and, when properly implemented, are likely to have a significant impact on patient safety and outcomes. Some of these proven practices relate directly to anticoagulation management and have been adopted by the Joint Commission and other entities (Table 1).

For example, the use of standardized anticoagulation dosing protocols reduces errors and improves patient outcomes by providing evidence-based decision support, decreasing divergence in therapies, and facilitating timely monitoring of relevant laboratory parameters.¹⁷⁻²² Clinicians should be encouraged to use these dosing protocols and order sets. They should be available on every floor and/or from the hospital’s electronic medical record or intranet site. Implementation of technology, such as computerized physician order entry, bar code scanning, programmable infusion pumps, and dose range checking, is also associated with a decrease in medication errors.^{23,24} Human or computer-based alert systems result in higher rates of appropriate VTE prophylaxis and reduction in

thrombotic events.²⁵⁻²⁸ While not all hospitals are able to implement technology-based systems, there are several systematic approaches to anticoagulation management that most hospitals should be able to use. One example is a multidisciplinary approach to anticoagulation management, such as having a pharmacist on rounds, which has been shown to reduce medication errors by up to 78%.²⁹ Pharmacy-driven inpatient anticoagulation management services have a positive impact on patient care and are another systems-based approach used to ensure safe and effective use of anticoagulants.³⁰⁻³⁷ Regardless of the processes or systems used, the health care organization should create a culture of safety that encourages reporting and discussion of anticoagulation medication errors in a non-punitive manner to promote identification of systems-based solutions.

2. Accountability

The inpatient anticoagulation management system should have a clearly defined structure with respect to leadership, accountability, and responsibility, and it should promote multidisciplinary involvement.

Systematic improvements within hospitals should have multidisciplinary involvement, as all disciplines are likely to be affected and teamwork is integral for success. The anticoagulation multidisciplinary group or task force should be composed of frontline medical staff such as physicians, nurses, and pharmacists, along with clinicians from supportive disciplines such as quality and safety, laboratory, dietary, and information technology. Leadership within this group should be clearly delineated, with a dedicated champion (eg, physician leader) to communicate the vision of the group and drive initiatives. Regardless of

which discipline (eg, pharmacy, nursing, physician) is the primary driver of the inpatient anticoagulation management system, accountability and responsibility for day-to-day operation of the anticoagulation management system needs to be clearly outlined in hospital policy, procedure, or collaborative practice agreement for operational, clinical, and medical-legal reasons. Frontline staff members providing anticoagulation management need to be aware of resources to draw upon should they encounter clinical situations beyond their level of knowledge, experience, or scope of practice. A hierarchy should be in place that facilitates the delegation of increasingly complex therapeutic situations upward to more knowledgeable, experienced, and/or specialized practitioners. That hierarchy also should delineate a reporting structure and the relationship between the anticoagulation management system and executive level staff. Figure 1 provides one example of how such a hierarchy might be structured. However, no single model will fit all hospitals, as each has unique characteristics, infrastructure, resources, patient demographics, and regulations they must abide by.

3. Integration

The inpatient anticoagulation management system should be reliable, sustainable, and seamlessly integrated with all patient-care resources of the health care organization.

Whenever possible, processes and tools utilized by the inpatient system of anticoagulation management should be hard-wired (electronically built and connected) into the health care organization and should not be person-dependent. The anticoagulation management system must incorporate a reliable means of identifying and tracking patients

Table 1. Systematic Approaches for Safe and Effective Inpatient Anticoagulation Management

System	Possible Action
Storage	Separation of anticoagulants in the pharmacy and in medication dispensing cabinets Distinct labeling to identify anticoagulants as high-risk medications
Ordering	Electronic alerts in pharmacy order entry system for required laboratory tests (eg, weight, SCr, INR) pertinent to anticoagulation therapy Use of approved, standardized preprinted or electronic order sets for all anticoagulants to promote uniformity and decrease errors related to illegible handwriting Use of computerized physician order entry
Preparation	Minimize number of stock concentrations of anticoagulants
Distribution	Dispense anticoagulants in oral unit dose, prefilled syringes, or premixed infusions when possible
Administration	Independent double check by nursing prior to administration Use of programmable infusion pumps Bedside barcode scanning
Therapeutic management	Utilization of dedicated anticoagulation programs and services that facilitate coordinated care management Involvement of pharmacists as drug experts in the care of patients on high-risk medications such as anticoagulants

INR = international normalized ratio; SCr = serum creatinine.

receiving anticoagulant therapy. If an outpatient anticoagulation management system is associated with the hospital and uses computer software for tracking patients, it may be beneficial to adopt the same or a similar software program tailored for inpatient use. Use of evidence-based, standardized, approved anticoagulation order sets is encouraged for initiation and maintenance of anticoagulation to promote consistent, sustainable practices. Hospital administration should provide adequate resources (eg, staffing, technology, and support for clinical initiatives) to ensure sustainability of the anticoagulation management system. Additionally, the inpatient anticoagulation management system must be seamlessly integrated with all patient-care resources in the health care system to facilitate accurate, efficient communication of pertinent patient information and delivery of optimized care. Table 2 provides recommendations for integration of the inpatient anticoagulation system.

4. Standards of Practice

4.1 The inpatient anticoagulation management system should use evidence-based standards of practice to ensure appropriate use of all related drug therapies in typical and special circumstances.

The clinical use of anticoagulants in the inpatient setting should be organized on a drug-specific basis using protocols, guidelines, policies, and procedures and/or other means to address the use of individual agents. All medical staff, house staff, pharmacists, mid-level providers, and nurses should be educated on the use of these protocols, guidelines, policies, and procedures. Examples of drug-specific standards of practice are noted in Table 3. It may be helpful to categorize these standards of practice as related to anticoagulant dosing, administration, and monitoring. They should be derived from evidence-based guidelines, with additional detail

according to the formulary status of specific agents, as well as further evidence from clinical trials, published experience in various clinical settings, and institutional experience with individual agents.

Anticoagulant use also may be organized from a disease management perspective, addressing the treatment and prevention of venous and arterial thromboembolism as well as the prevention and treatment of adverse effects associated with anticoagulant therapy. Examples of disease-specific standards of practice are noted in Table 4. These standards should be derived from evidence-based guidelines, with additional institution-specific detail as necessary. A multidisciplinary approach to the development and implementation of institutional standards of practice is recommended. The input of various disci-

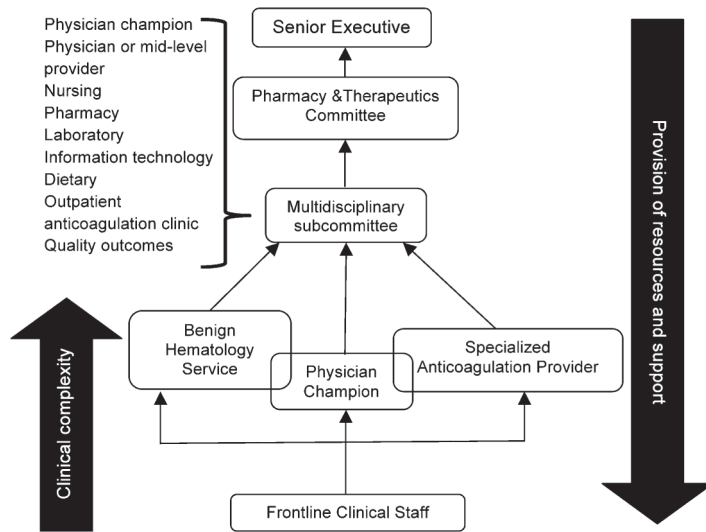


Figure 1. Example of hierarchy of inpatient anticoagulation management system.

Table 2. Integration of the Inpatient Anticoagulation System with the Health Care Organization

<p>Integration of pharmacy order entry system with laboratory reporting system to promote review of key laboratory values prior to processing of orders or dispensing of anticoagulants</p> <p>Process for quickly communicating and responding to critical anticoagulant laboratory values or adverse events</p> <p>Dietary department or another responsible entity should have a method to identify patients with potential for significant drug-food interactions, authority to address these, and a method to document recommendations or changes</p> <p>Provision of anticoagulation recommendations in a manner that is time sensitive and accessible to all practitioners</p> <p>Method of providing clear documentation of recommendations for dose adjustments of anticoagulants</p> <p>Anticoagulation education initiatives for both staff and patients aligned with initiatives, resources, and workflow of the health care system</p> <p>Case management consultations to triage insurance coverage of outpatient medications and arrangement of follow-up appointments</p> <p>Method to ensure continuity of anticoagulation management as care providers change (eg, change of shift) and as patients transition to different levels of care within the hospital</p> <p>Method of providing clear documentation of the inpatient anticoagulation dosing history, along with any patient education or other pertinent anticoagulation information to outpatient providers in a concise, user-friendly format</p>

plines and specialists in the diverse aspects of anticoagulant dosing, administration, and monitoring, as well as prevention, diagnosis, and treatment of relevant disease states, is critical to successful patient care. Leadership from hospital administration may be helpful to direct the overall process of development and implementation of clinical standards, and the guidance of a specialist “champion” is recommended.

4.2 These clinical standards should be reviewed and updated on a periodic basis to ensure that they reflect current evidence and are synchronized with other institutional processes, policies, and procedures.

A formalized method for review of institutional standards of practice is recommended. As new evidence becomes available or as new evidence-based guidelines are published, they should be incorporated into practice in a timely manner to ensure the effectiveness and safety of anticoagulant therapy. In addition, as hospital processes change (eg, the transition from pharmacist order entry to computerized physician order entry), clinical standards should be aligned accordingly.

5. Provider Education and Competency

The anticoagulation management system should provide an appropriate level of staff training, ongoing educational development, and documented competency assessment for all multidisciplinary personnel involved in anticoagulation management.

The multidisciplinary health care practitioners involved in the management of anticoagulation therapy should be educated and licensed in a patient-oriented clinical discipline (ie medicine, nursing, pharmacy) and trained in the assessment and care of the patient receiving anticoagulation therapy. Inadequate knowledge about the patient’s medication or condition is one of the most frequently cited causes of medication prescribing errors.³⁸ Recognizing this risk, the Joint Commission National Patient Safety Goal 03.05.01 on anticoagulation therapy calls for the provision of focused anticoagulation education and training for prescribers and staff on a regular basis. Systems providing anticoagulation management should devise in-house staff educational programs and corresponding competency assessments. In addition to internal institutional-based training, formal external certification, didactic, experiential, and self-study programs can be pursued. Examples of formal anticoagulant therapy management training programs are listed in Table 5. A multidiscipline national certification credential in anticoagulation is administered by the National Certification Board of Anticoagulation Providers (www.ncbap.org/). The credential CACP (Certified Anticoagulation Care Provider) is inclusive of inpatient and outpatient management needs. The core domains of competency for anticoagulation providers are outlined in Table 6.³⁹ Formal anticoagulant therapy management training programs should include the core domains of competency for anticoagulation providers required by the National Certification Board of Anticoagulation Providers.

Table 3. Drug-Specific Standards of Practice

<p>Anticoagulant dosing</p> <p>Novel oral anticoagulant (DTIs, factor-Xa inhibitors) dosing guidelines</p> <p>Warfarin initiation dosing guidelines/nomograms</p> <p>Warfarin maintenance dosing guidelines</p> <p>Heparin dosing protocol(s)</p> <p>Intravenous DTI dosing protocols</p> <p>LMWH and fondaparinux dosing guidelines for various indications</p> <p>Use of LMWHs, factor-Xa inhibitors, and DTIs in obesity</p> <p>Use of LMWHs, factor-Xa inhibitors, and DTIs in renal failure and hemodialysis</p> <p>Use of warfarin, UFH, LMWHs, factor-Xa inhibitors, and DTIs in pregnancy</p> <p>Use of warfarin, UFH, LMWHs, factor-Xa inhibitors, and DTIs in pediatric patients</p> <p>Drug interaction recognition and management</p> <p>Use of anticoagulants around neuraxial procedures</p> <p>Thrombolytic dosing and monitoring guidelines</p> <p>Selection and dosing of reversal therapies (eg, Vitamin K, protamine, prothrombin complex concentrate, recombinant factor VII)</p> <p>Anticoagulant dosing and monitoring in the critically ill patient</p> <p>Anticoagulant administration</p> <p>Infusion pump policies and procedures</p> <p>Acceptable subcutaneous injection sites for anticoagulants</p> <p>Timing of initiation of VTE prophylaxis for surgical and high-risk medical patients</p> <p>Timing of resumption of full-intensity anticoagulation in postoperative patients</p> <p>Time of administration of anticoagulants</p> <p>Accurate patient weight in kilograms</p> <p>Anticoagulant monitoring</p> <p>Target INR and INR goal range for various indications</p> <p>Frequency of INR monitoring</p> <p>Target aPTT and aPTT goal range for various indications</p> <p>Frequency of aPTT monitoring</p> <p>Alternative monitoring parameters for special circumstances</p> <p>Required baseline and ongoing laboratory values for various anticoagulants (eg, CBC with differential, basic metabolic panel,^a ACT, ECT, TT, anti-Factor Xa assay)</p> <p>Patient monitoring for signs and symptoms of bleeding and thrombosis</p>
<p>ACT = activated clotting time; aPTT = activated partial thromboplastin time; CBC = complete blood count; DTI = direct thrombin inhibitor; ECT = ecarin clotting time; LMWH = low-molecular-weight heparin; TT = thrombin time; UFH = unfractionated heparin; VTE = venous thromboembolism.</p> <p>^aBasic metabolic panel = glucose, calcium, sodium, potassium, CO₂, chloride, blood urea nitrogen, serum creatinine.</p>

6. Patient Education

The anticoagulation management system should be structured to routinely provide an adequate level of patient education regarding anticoagulant therapy prior to discharge to ensure safe and effective use of these medications in the care-transition and postdischarge periods.

Many patients have inadequate knowledge regarding their medication therapy. To achieve better patient outcomes, patient education is a vital component of an anticoagulation therapy program. Improved outcomes have been reported when patients take responsibility for, understand, and adhere to an anticoagulation plan of care.¹ The Joint Commission National Patient Safety Goals mandate that patient and family education be provided for hospitalized

patients receiving therapeutic anticoagulation therapy.⁹ The elements of patient education required by the Joint Commission include the importance of follow-up monitoring, adherence, drug-food interactions, and the potential for adverse drug reactions and interactions (Table 7). Effective methods of anticoagulation patient education include face-to-face interaction with a trained professional, group training sessions lasting 15-45 minutes, or the use of written materials and other audiovisual resources to review, teach-back, and reinforce the educational process. Structured programs based on established models of education may be more likely to improve a patient's knowledge level compared to improvised programs. Knowledge assessment tools, such as validated anticoagulation knowledge tests, can help the clinician assess and ensure that a patient's ed-

Table 4. Disease-Specific Standards of Practice

<p>Disease management</p> <p>DVT treatment</p> <p>PE treatment</p> <p>Stroke prevention in AF</p> <p>VTE prophylaxis for medical and surgical patients, including risk stratification</p> <p>Extended VTE prophylaxis</p> <p>Risk stratification for periprocedural anticoagulation bridging</p> <p>Bridging therapy guidelines</p> <p>Guidelines for anticoagulation management in cardioversion</p> <p>Treatment of cancer-associated thrombosis</p> <p>Guidelines for transitioning between various anticoagulants</p> <p>Guidelines for anticoagulation management in special circumstances such as patients with mechanical devices, bypass circuits, presence of a coagulopathy</p> <p>Adverse effects management</p> <p>Management of bleeding</p> <p>Treatment of heparin-induced thrombocytopenia</p> <p>Reversal of anticoagulation</p> <p>Correction of over-anticoagulation</p> <p>Methods to prevent and treat dental bleeding</p> <p>Bleeding risk assessment</p>
<p>AF = atrial fibrillation; DVT = deep venous thrombosis; PE = pulmonary embolism; VTE = venous thromboembolism.</p>

Table 5. Anticoagulation Therapy Certification and Training Programs for Multidisciplinary^a Care Providers Involved in the Management of Patients Receiving Anticoagulants

<p>Certified Anticoagulation Care Provider (CACP)</p> <p>Bestowed by the National Certification Board for Anticoagulation Providers to formally recognize anticoagulation providers meeting educational and patient-care experiential requirements</p> <p>American Society of Health-System Pharmacists Foundation Antithrombotic Pharmacotherapy Traineeship</p> <p>Curriculum consists of a self-study program and a 5-day experiential program</p> <p>University of Southern Indiana College of Nursing and Allied Health Professions Anticoagulant Therapy Management Certificate Program</p> <p>Interactive 6-week, 40-hour internet certificate program for nurses, pharmacists, and physicians</p> <p>University of Florida College of Pharmacy Anticoagulation Therapy Management Certificate Program</p> <p>A 12-week program containing 3 independent learning modules of independent study and assignments</p>
<p>^aMedicine, nursing, pharmacy.</p>

educational needs are met.¹² Teaching aids include written materials (booklets), visual supports (video), drawings to illustrate daily situations, and medication administration calendars. Written materials provided to patients should be developed at an appropriate reading level and, when possible, in the patient's native language. Local health literacy rates should also be considered when developing patient educational materials.

7. Care Transitions

The anticoagulation management system should be designed to ensure appropriate care transitions for patients receiving anticoagulant therapy.

The health care system in the US has a fragmented structure, and care transitions from one health care setting to another have been shown to be prone to error. Thirty-

Table 6. Competency Domains for Anticoagulation Providers^a

<p>Applied Physiology and Pathophysiology of Thromboembolic Disorders Working knowledge regarding the normal physiologic processes of hemostasis and thrombosis, and the etiology, risk factors, and clinical manifestations of pathologic thrombus formation</p> <p>Patient Assessment and Management Knowledge, skills, and competencies to manage and monitor patients receiving anticoagulant therapy including the ability to assess the efficacy and toxicity of the prescribed anticoagulant treatment, determine whether the therapeutic goals have been achieved, and identify patient-related variables that affect therapy</p> <p>Patient and Family Education Ability to provide patient education that is tailored to patients' specific needs to promote safety, enhance adherence, and positively affect clinical outcomes; perform an educational assessment; develop an educational plan; and document the educational activities in the patient's medical record</p> <p>Applied Pharmacology of Antithrombotic Agents In-depth knowledge regarding the pharmacologic properties of all antithrombotic drugs</p> <p>Operational (Administrative) Procedures Evaluate need for services, assess personnel and compensation requirements, develop effective communication strategies with patients and health care team, perform quality assurance and risk management activities, compliance with standards</p> <p>^aAdapted from www.ncbap.org.</p>

Table 7. Elements of Patient Education for Oral Anticoagulants¹²

Novel Anticoagulants Education Points	Anticoagulation basics	Indicate the reason for initiating anticoagulation Review the name of the anticoagulant drug (generic and trade), how it works Onset of action, duration, dosing, frequency, potential drug interactions, storage, reversibility, duration of therapy	Warfarin Educational Points
	Risk-benefit	Common signs and symptoms of bleeding and what to do when they occur Common signs and symptoms of thrombosis and what to do when they occur The need for birth control for women of child-bearing age Precautionary measures to reduce the risk of trauma or bleeding (eg, shaving, brushing teeth, acceptable physical activities) Common side effects or allergic-type reactions	
	Accessing health care	Which health care providers (eg, physicians, dentists) to notify of the use of anticoagulant therapy When to notify an anticoagulation provider (dental, surgical, or invasive procedures or hospitalizations are scheduled) Carrying identification (eg, identification card, medical bracelet or necklace) Using one pharmacy for all prescription drug needs	
	Adherence	Consequences of nonadherence or taking too much of the medication When to take an anticoagulant medication and what to do if a dose is missed	
	Laboratory monitoring	Periodic (6-12 months) monitoring of renal function for novel anticoagulants The meaning and significance of the INR for warfarin; the need for frequent INR testing and target INR values appropriate for treatment The narrow therapeutic index and the emphasis on regular monitoring as a way to minimize bleeding and thrombosis risk	
	Diet and lifestyle	The influence of dietary vitamin K use and the need to limit or avoid alcohol	
	INR = international normalized ratio.		

day hospital readmission rates among Medicare beneficiaries, a commonly used indicator of appropriateness of care transitions, are nearly 20% and associated annual costs exceed \$26 billion.⁴⁰ Patients with complex or chronic medical conditions, including those on high-risk anticoagulation therapy, are particularly prone to adverse outcomes from inadequate care transitions. Therefore, an inpatient anticoagulation management system should be designed to ensure appropriate care transitions from inpatient to outpatient or other settings for patients receiving anticoagulation therapies, thus avoiding unnecessary readmissions.

There are 3 fundamental elements of effective care transitions: education, follow-up care, and communication (Figure 2). Education on anticoagulant agents through written, oral, and electronic media should be provided to the patient and family as well as staff involved in the patient's care. The empowerment of patients and their families through heightened awareness of medical conditions and appropriate use of medications is strongly recommended, as they are the most constant element in the care transition process. In addition to education on anticoagulant therapies, it is recommended that health care professionals undergo transition-specific competency training, as most do not receive this during medical education.

The second critical element of care transitions is follow-up care. A follow-up appointment with the patient's primary care physician or subspecialist should be scheduled within a prespecified period of time after discharge to ensure patient safety. This time frame should be delineated in hospital policy. A follow-up patient phone call within 48-72 hours after discharge is beneficial to identify issues that may occur in the immediate postdischarge period. Similarly, the patient and/or

family should be provided with a "safety net" telephone number prior to discharge should they need to call for assistance with barriers to care in the postdischarge period. The final step in effective care transition is communication with the receiving health care provider through verbal and written communication. For anticoagulant therapy, this includes inpatient dosing history, patient discharge instructions, and a discharge summary. The inpatient anticoagulation management system should use a care transition checklist to ensure all essential elements have been addressed prior to discharge (Table 8). It is also essential to address care transitions when patients receiving anticoagulant therapy are admitted to the hospital.

8. Outcomes

The inpatient anticoagulation system should measure pertinent quality indicators to assess the effectiveness of the system, analyze the impact on patient outcomes, and identify opportunities for improvement.

With health care costs rising rapidly, along with an increasing array of patient safety initiatives, there is increased pressure on health care facilities to evaluate their practices, report their findings, and look for ways to improve their performance. At stake is financial or accreditation punishment for noncompliance. Continuous quality improvement is integral to the process of improving patient safety and optimizing outcomes while reducing costs. Within continuous quality improvement, there are 2 broad categories of quality indicators: process measures (how well the system works) and outcome measures (what impact the system ultimately has on the patient). The inpatient anticoagulation management system should be familiar with quality indicators pertinent to their organization, particularly those that are required by regulatory bodies such as Centers for Medicare and Medicaid Services and the Joint Commission. Table 9 provides some examples of quality indicators relevant to inpatient anticoagulation management. The institution's system should develop a method for tracking, reporting, and responding to these indicators. It is often challenging to identify resources, such as personnel or information technology, to accomplish this, and the multidisciplinary anticoagulation management team should anticipate these challenges and proactively plan for resource acquisition during the planning stages. It is recommended that findings be reported to key groups within the organization, such as an anticoagulation subcommittee, pharmacy and therapeutics committee, or hospital administration, on a regular basis to showcase progress of the inpatient anticoagulation system or highlight needs for additional resources or support.

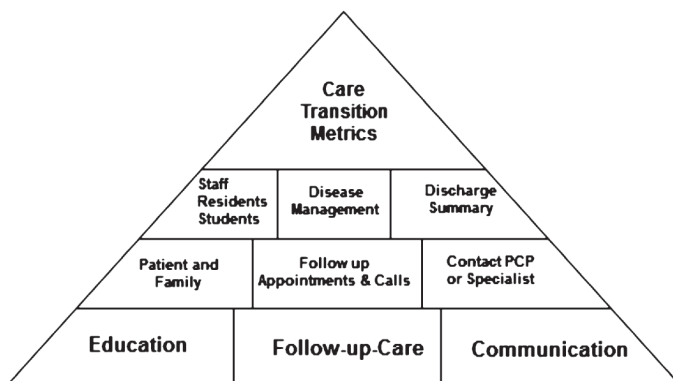


Figure 2. Basics of care transition programs. Care Transition Metrics = readmission, recurrent thromboembolic events, bleeding, follow-up visits, primary care provider (PCP) or specialist contacted, discharge summary of hospitalization in 24 hours; staff (nursing, pharmacy, physicians), residents, and medical students trained and involved in care transition processes; Disease Management = management of diseases requiring anticoagulation; Discharge Summary = dictated within 24 hours of discharge; Patient and Family = education program for patient and family; Follow up Appointments and Calls = Follow-up appointments with primary care physician, specialists, anticoagulation program; Contact PCP or Specialist = phone call placed at time of discharge to PCP and specialists.

Summary

Anticoagulants are high-risk medications associated with a significant rate of medication errors among hospitalized patients. Several national organizations have introduced initiatives to reduce the likelihood of patient harm associated with the use of anticoagulants. Health care organizations are under increasing pressure to develop systems to ensure the safe and effective use of anticoagulants in the inpatient setting. This document provides consensus guidelines for anticoagulant therapy in the inpatient setting and serves as a companion document to prior guidelines developed for outpatients.

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Table 8. Care Transitions Checklist

Element/s of Care

- Patient family education on disease state(s) and medication(s) and verbal expression of understanding
- Demonstration of ability and comfort to self-administer parenteral anticoagulant
- Assurance of affordability, insurance coverage, and retail availability of anticoagulant therapies
- Appropriate and accurate prescriptions given to patient prior to discharge
- “Safety net” phone number provided to patient prior to discharge
- Referral to outpatient anticoagulation clinic (if applicable) prior to discharge
- Follow-up appointment within prespecified timeframe scheduled with primary care physician or subspecialist prior to discharge
- Inpatient dosing history, discharge instructions, and discharge summary sent to receiving provider in time to allow for receiving provider to effectively care for the patient
- Verbal communication between inpatient and receiving providers regarding patient’s anticoagulation therapy in time to allow for receiving provider to effectively care for the patient
- Follow-up phone call to patient/family within 48-72 hours after discharge

Table 9. Anticoagulation Quality Indicators

Process measures

Inpatient	<ul style="list-style-type: none"> Rate of use of anticoagulation protocols Percentage of patients receiving anticoagulation education prior to discharge Percentage of patients with appropriate VTE prophylaxis Percentage of patients with appropriate duration of overlap anticoagulation therapy Percentage of patients with appropriate laboratory monitoring of anticoagulation parameters Percentage of patients with supratherapeutic INRs Number of days to therapeutic INR Percentage of patients with follow-up appointment scheduled prior to discharge
Transition	<ul style="list-style-type: none"> Percentage of patients with appropriate referral to outpatient anticoagulation clinic Percentage of patients receiving follow-up phone call within the specified time period Rate of documented communication between inpatient and outpatient providers Percentage of patients with discharge instructions and discharge summary sent to receiving provider Percentage of patients with documented follow-up within prespecified timeframe of discharge Percentage of patients with therapeutic INR at the first follow-up visit posthospitalization
Outcome measures	<ul style="list-style-type: none"> Incidence of thrombotic events Incidence of bleeding events Incidence of incidental adverse effects (eg, heparin-induced thrombocytopenia)

INR = international normalized ratio; VTE = venous thromboembolism.

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References

- Garcia DA, Schwartz MJ. Warfarin therapy: tips and tools for better control. *J Fam Pract* 2011;60:70-5.
- Wysowski DK, Nourjah P, Swartz L. Bleeding complications with warfarin use: a prevalent adverse effect resulting in regulatory action. *Arch Intern Med* 2007;167:1414-9.
- Budnitz DS, Pollock DA, Weidenbach KN, Mendelsohn AB, Schroeder TJ, Annest JL. National surveillance of emergency department visits for outpatient adverse drug events. *JAMA* 2006;296:1858-66.
- QuarterWatch. Monitoring FDA MedWatch Reports. Anticoagulants the leading reported drug risk in 2011. www.ismp.org/QuarterWatch/pdfs/2011Q4.pdf (accessed 2013 Jan 7).
- Budnitz DS, Lovegrove MC, Shehab N, Richards CL. Emergency hospitalizations for adverse drug events in older Americans. *N Engl J Med* 2011;365:2002-12. doi: 10.1056/NEJMs1103053
- Fanikos J, Stapinski C, Koo S, Kucher N, Tsilimingras K, Goldhaber SZ. Medication errors associated with anticoagulant therapy in the hospital. *Am J Cardiol* 2004;94:532-5.
- Bond CA, Raehl CL. Adverse drug reactions in United States hospitals. *Pharmacotherapy* 2006;26:601-8.
- The Joint Commission. Sentinel event alert. Preventing errors relating to commonly used anticoagulants. www.jointcommission.org/assets/1/18/SEA_41.PDF (accessed 2013 Jan 7).
- The Joint Commission. National patient safety goals NPSG 03.01.05. www.jointcommission.org/assets/1/18/NPSG_Chapter_Jan2013_AHC.pdf (accessed 2013 Jan 7).
- Institute for Safe Medication Practices. Improving medication safety with anticoagulant therapy. www.ismp.org/tools/anticoagulantTherapy.asp (accessed 2013 Jan 7).
- Centers for Medicare and Medicaid Services. Hospital-acquired conditions. www.cms.gov/HospitalAcqCond/06_Hospital-Acquired_Conditions.asp (accessed 2013 Jan 7).
- Garcia DA, Witt DM, Hylek E, et al. Delivery of optimized anticoagulant therapy: consensus statement from the Anticoagulation Forum. *Ann Pharmacother* 2008;42:979-88. doi: 10.1345/aph.1L098.
- Institute of Medicine. To err is human: building a safer health system. 1999. www.iom.edu/~media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20report%20brief.pdf (accessed 2013 Jan 7).
- Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. ADE prevention study group. *JAMA* 1995;274:35-43.
- Institute for Safe Medication Practices. Organizations release new tools for reducing medication errors. 2012. www.ismp.org/Tools/pathways.asp (accessed 2013 Apr 3).
- National Quality Forum. Safe practices for better healthcare. www.qualityforum.org/Publications/2009/03/Safe_Practices_for_Better_Healthcare%e2%80%93Update.aspx (accessed 2013 Jan 7).
- Raschke RA, Reilly BM, Guidry JR, Fontana JR, Srinivas S. The weight-based heparin dosing nomogram compared with a "standard care" nomogram. A randomized controlled trial. *Ann Intern Med* 1993;119:874-81.
- Elliott CG, Hiltunen SJ, Suchyta M, et al. Physician-guided treatment compared with a heparin protocol for deep vein thrombosis. *Arch Intern Med* 1994;154:999-1004.
- Cruikshank MK, Levine MN, Hirsh J, Roberts R, Siguenza M. A standard heparin nomogram for the management of heparin therapy. *Arch Intern Med* 1991;151:333-7.
- Hollingsworth JA, Rowe BH, Brisebois FJ, Thompson PR, Fabris LM. The successful application of a heparin nomogram in a community hospital. *Arch Intern Med*. 1995;155:2095-100.
- Phillips WS, Smith J, Greaves M, Preston FE, Channer KS. An evaluation and improvement program for inpatient anticoagulant control. *Thromb Haemost* 1997;77:283-8.
- Brown G, Dodek P. An evaluation of empiric vs nomogram-based dosing of heparin in an intensive care unit. *Crit Care Med* 1997;25:1534-8.
- Bates DW, Teich JM, Lee J, et al. The impact of computerized physician order entry on medication error prevention. *J Am Med Inform Assoc* 1999;6:313-21.
- Poon EG, Keohane CA, Yoon CS, et al. Effect of bar-code technology on the safety of medication administration. *N Engl J Med* 2010;362:1698-707. doi: 10.1056/NEJMs10907115
- Garcia DA, Highfill J, Finnerty K, et al. A prospective, controlled trial of a pharmacy-driven alert system to increase thromboprophylaxis rates in medical inpatients. *Blood Coagul Fibrinolysis* 2009;20:541-5. doi: 10.1097/MBC.0b013e32832d6cfc
- Kucher N, Koo S, Quiroz R, et al. Electronic alerts to prevent venous thromboembolism among hospitalized patients. *N Engl J Med* 2005;352:969-77.
- Piazza G, Rosenbaum EJ, Pendergast W, et al. Physician alerts to prevent symptomatic venous thromboembolism in hospitalized patients. *Circulation* 2009;119:2196-201. doi: 10.1161/CIRCULATIONAHA.108.841197
- Sobieraj DM. Development and implementation of a program to assess medical patients' need for venous thromboembolism prophylaxis. *Am J Health Syst Pharm* 2008;65:1755-60. doi: 10.2146/ajhp070598
- Kucukarslan SN, Peters M, Mlynarek M, Nafziger DA. Pharmacists on rounding teams reduce preventable adverse drug events in hospital general medicine units. *Arch Intern Med* 2003;163:2014-8.
- Dager WE, Gulseth MP. Implementing anticoagulation management by pharmacists in the inpatient setting. *Am J Health Syst Pharm* 2007;64:1071-9.
- Dager WE, Branch JM, King JH, et al. Optimization of inpatient warfarin therapy: impact of daily consultation by a pharmacist-managed anticoagulation service. *Ann Pharmacother* 2000;34:567-72. doi: 10.1345/aph.18192
- Bond CA, Raehl CL. Pharmacist-provided anticoagulation management in United States hospitals: death rates, length of stay, Medicare charges, bleeding complications, and transfusions. *Pharmacotherapy* 2004;24:953-63.
- Donovan JL, Drake JA, Whittaker P, Tran MT. Pharmacy-managed anticoagulation: assessment of in-hospital efficacy and evaluation of financial impact and community acceptance. *J Thromb Thrombolysis* 2006;22:23-30.
- Locke C, Ravnan SL, Patel R, Uchizono JA. Reduction in warfarin adverse events requiring patient hospitalization after implementation of a pharmacist-managed anticoagulation service. *Pharmacotherapy* 2005;25:685-9.
- Schillig J, Kaatz S, Hudson M, Krol GD, Szandzik EG, Kalus JS. Clinical and safety impact of an inpatient pharmacist-directed anticoagulation service. *J Hosp Med* 2011;6:322-8. doi: 10.1002/jhm.910
- Ellis RF, Stephens MA, Sharp GB. Evaluation of a pharmacy-managed warfarin-monitoring service to coordinate inpatient and outpatient therapy. *Am J Hosp Pharm* 1992;49:387-94.

37. Rivey MP, Peterson JP. Pharmacy-managed, weight-based heparin protocol. *Am J Hosp Pharm* 1993;50:279-84.
38. Tully MP, Ashcroft DM, Dornan T, Lewis PJ, Taylor D, Wass V. The causes of and factors associated with prescribing errors in hospital inpatients: a systematic review. *Drug Saf* 2009;32:819-836. doi: 10.2165/11316560-000000000-00000
39. National Certification Board for Anticoagulation Providers. <https://www.ncbap.org/aboutcacpexam.aspx> (accessed 2013 Apr 3).
40. Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. *N Engl J Med* 2009;360:1418-28. doi: 10.1056/NEJMs0803563

RÉSUMÉ

Optimisation de l'Anticoagulothérapie chez des Patients Dans un Contexte Hospitalier (Patients Hospitalisés ou Suivis en Clinique Externe): Déclaration Consensuelle du Forum sur l'Anticoagulothérapie

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OBJECTIF: Fournir des recommandations pour l'optimisation de l'anticoagulothérapie dans le contexte hospitalier et définir les éléments à mettre en place pour la gestion efficace de l'anticoagulothérapie chez des patients hospitalisés. Les lignes directrices sont conçues afin de promouvoir l'optimisation des résultats cliniques tout en minimisant les risques d'erreur et d'effets indésirables liés à l'anticoagulothérapie.

SELECTION DES DONNÉES ET DE L'INFORMATION: En rapport avec l'objet de ce document, la recherche dans la littérature médicale a été faite en utilisant diverses stratégies. Lorsque possible, les recommandations sont supportées par l'évidence scientifique disponible; cependant, parce que ce document s'intéresse aux processus et aux systèmes de soins, des données de grande qualité (issues d'essais contrôlés) ne sont pas disponibles. Les recommandations représentent donc une opinion consensuelle des auteurs et sont entérinées par le comité de direction du Forum sur l'anticoagulothérapie, une organisation dédiée à l'optimisation des soins aux personnes anticoagulées. Le comité est composé de médecins, pharmaciens, et infirmières possédant une expérience et une expertise particulières dans le suivi des patients recevant une anticoagulothérapie.

SYNTHÈSE DES DONNÉES ET DE L'INFORMATION: Les recommandations pour procurer un traitement optimal aux patients anticoagulés dans un contexte hospitalier ont été développées en collaboration par les auteurs et sont résumées en 8 sections: processus, responsabilité, intégration, normes de pratique, compétence et formation du professionnel, éducation du patient, transfert de responsabilité de soins et résultats. Les recommandations ont pour but de supporter le développement de systèmes de soins coordonnés, contenant les éléments essentiels ayant montré des bénéfices dans l'amélioration des mesures de résultats de l'anticoagulothérapie. Ces recommandations s'appliquent à tous les cliniciens impliqués dans les soins aux patients hospitalisés anticoagulés.

CONCLUSIONS: Les anticoagulants sont des médicaments à haut risque, pour lesquels on observe un taux élevé d'erreurs médicamenteuses chez les patients hospitalisés. Plusieurs organisations nationales ont pris des initiatives afin de minimiser les risques pour les patients, risques liés à l'utilisation des anticoagulants. Les organisations de soins de santé subissent des pressions croissantes pour développer des systèmes améliorant l'innocuité et l'utilisation efficace des anticoagulants dans le contexte hospitalier. Ce document renferme les lignes directrices consensuelles pour l'anticoagulothérapie dans un contexte hospitalier et se veut un document de consultation précédant des lignes directrices en milieu ambulatoire.

Traduit par Denyse Demers