

## Director's Forum

# Advanced Practice Programs in Hospital Pharmacy: Anticoagulation Management

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The *Director's Forum* series is written and edited by Michael Sanborn and Robert Weber and is designed to guide pharmacy leaders in establishing patient-centered services in hospitals and health systems. Another specific goal of this column is to address many of the key challenges that pharmacy directors face today, while providing information to foster growth in pharmacy leadership and patient safety. This month's Forum focuses on specific ways to improve anticoagulation management in your hospital pharmacy department. This area presents an important opportunity for pharmacists to participate actively in improving patient safety.

The goal of *Director's Forum* is to provide guidance to pharmacy leaders on developing patient-centered services. As previously stated in this column, the role of pharmacists in this patient-centered approach (eg, pharmacist as part of a patient care team) improves the quality of care.<sup>1</sup> Medication patient-safety programs serve as valuable patient-centered services; recent information recommends the pharmacy director serve a leadership role in developing an institution's strategy and implementation plan for improving patient safety.<sup>2</sup> Steps in developing this plan include analyzing essential department and hospital data along with national information on medication errors. From these data, a patient safety strategic plan can be developed that focuses appropriate resources

on high-risk patient care situations.

A significant area of patient risk and concern is anticoagulation (AC) therapy. Warfarin sodium, unfractionated heparin, and low-molecular weight heparin (LMWH) are commonly prescribed for a wide variety of thrombotic disorders.<sup>3</sup> The clinical challenge in using these medications is the close monitoring required to balance the risk of bleeding against the recurrence of thrombosis. Medication errors and resulting adverse drug events are reported; these are preventable and pose a major opportunity for pharmacists. According to the United States Pharmacopeia's National Reporting System (*MEDMARX*), unfractionated heparin and warfarin sodium are among the top 10 drugs associated with serious out-

comes.<sup>4</sup> In most institutions, unfractionated heparin and warfarin sodium are often associated with severe bleeding events, some even fatal. Based on the types and causes of AC errors, pharmacists have the opportunity to be involved in systematically managing this therapy. Implementing an AC service has the potential to improve the understanding of AC management for staff and patients, maintaining updated procedures and protocol, and providing proper dosing and patient monitoring.

Improving the safety of AC dosing has also become a part of the national patient safety agenda. The Joint Commission's (TJC) National Patient Safety Goals (NPSG) promote specific improvements in patient safety. The Sentinel Event Advisory Group, working with TJC, annually takes a systematic review of the literature and available databases to identify potential new goals and requirements. By making AC therapy a goal for 2008, TJC acknowledges the patient safety problem in hospitals and all health care facilities. The goals are published mid-year and approved by TJC Board of Commissioners in June. For accreditation purposes, these goals need to be met or a plan implemented. The expectation to meet the requirements for AC services is to be implemented by January 2009.<sup>2</sup>

The 2008 NPSG outline 11 steps to meet the goal of reducing

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patient harm associated with AC therapy.<sup>2</sup>

Meeting NPSG for AC will aid in the continuity of patient care. Pharmacists can provide an important service in educating and monitoring the patient during the hospital stay as well as after discharge. Studies have shown that pharmacist-monitored AC therapy improves international normalized ratio (INR) values and produces excellent outcomes.<sup>4</sup> The NPSG and welfare of our patients require pharmacy leaders to develop strategies to involve pharmacists in AC management. This poses the following leadership challenges: (1) How is a systematic and sustainable AC management program established within a hospital or health care organization? (2) What steps are necessary to justify funding for the service?

The goal of this article is to provide hospital pharmacy directors guidance in establishing warfarin and LMWH-AC services in both the in- and outpatient setting. The specific aims of the article are to: (1) Describe the role of pharmacy in AC management; (2) Review the recommendations for AC management as established by TJC; (3) List some strategies for implementing AC management services; and (4) Describe barriers and challenges in implementing these services.

### **ROLE OF PHARMACISTS IN AC MANAGEMENT**

Pharmacists' roles in AC management have historically been focused on warfarin sodium dispensing. The complexity of warfarin dosing combined with its narrow therapeutic index requires close monitoring; pharmacists have provided expertise in appropriate management of

warfarin demonstrating excellent outcomes. Witt and colleagues (2005) studied patients receiving AC care via centralized telephonic interactions with the Pharmacy-AC Service compared with the usual physician AC care. The results of the 6-month study showed patients were less likely (39%) to have an AC-therapy-related adverse event when seen by the pharmacy-AC service. In addition, patients had better control of their target range INR with 64% compared with 55%.<sup>3</sup>

Dager and Gulseth (2007) demonstrated successful collaboration with a hospital medical staff in implementing AC services. The University of California at Davis and St. Mary's Medical Center of Duluth, Minnesota both performed a review on prescribing misadventures related to AC therapy. The results, which demonstrated problems with prescribing ACs, prompted development of a protocol approved by the hospitals' Pharmacy & Therapeutics Committee. The success of this service justified other services such as monitoring programs for heparin-induced thrombocytopenia, LMWH management, factor concentrate dosing (eg, Recombinant factor VIIa), and phytonadione (vitamin K) antidote protocols.<sup>5</sup>

Additionally, the Health Alliance of Greater Cincinnati pharmacy program's goal was to provide a seamless transition of care for a variety of diseases and treatments, including AC. Using a medication-therapy management approach for their beneficiaries, Health Alliance was able to fund and provide continuity of care services in AC. An AC program coordinated by the Alliance maintained continuity of care for 300 patients receiving AC services.<sup>6</sup>

### **TJC'S NATIONAL PATIENT SAFETY GOALS AND AC**

In June 2007, Board of Commissioners of TJC on Accreditation of Health Care Organizations approved the 2008 NPSG. In those goals, TJC addressed the safety needs associated with AC therapy. NPSG #3E states that for anyone given AC therapy, health care providers are to reduce the likelihood of patient harm associated with the use of AC therapy. The purpose of the NPSG is to promote standard prescribing practices to reduce the risk of adverse drug events from AC drugs such as heparin, LMWH, and warfarin.<sup>2</sup> The NPSG does not suggest specific guidelines for AC management except a conceptual framework for developing a systematic and sustainable approach to AC management. These strategy steps and TJC's framework are included in Table 1. Currently the Center of Medicare and Medicaid Services does not have a structured focused approach to AC therapy; however, the Medicare Prescription Improvement and Modernization Act of 2003 suggests that beneficiaries who are at high risk for adverse events be provided medication therapy management.<sup>7</sup> In addition, the NPSG reinforce ASHP's 2015 Health System Initiatives, suggesting increased pharmacist involvement in high-risk medications.<sup>7,8</sup>

### **IMPLEMENTING PHARMACY-AC SERVICES**

This section describes the steps in justifying and implementing pharmacy-AC services. In some hospitals, pharmacists are currently providing AC monitoring through routine medication order review and follow-up. However, implementing AC services requires 4 steps: (1) understanding hospital

**Table 1. The Joint Commission's Framework for Meeting the Anticoagulation NPSG<sup>2</sup>**

1. The health care organization implements a defined AC-management program to individualize the care provided to each patient.
2. When available, only oral unit-dose products and premixed infusions should be used in order to reduce compounding and labeling errors.
3. Warfarin should be dispensed in accordance with established monitoring procedures for each patient.
4. The health care organization should use approved protocols for the initiation and maintenance of AC therapy that is appropriate to medication, medical condition, and drug interactions.
5. Establish baseline INR for all patients started on warfarin and for all patients currently receiving warfarin therapy; current INR should be available and used to monitor and adjust therapy.
6. Dietary services should be modified, if provided, for all patients receiving warfarin and adjusted if necessary according to an established food/drug interaction program.
7. The organization should use programmable infusion pumps when heparin is administered intravenously and continuously.
8. The organization should establish a policy to address the baseline and ongoing laboratory tests that are required for heparin and low-molecular-weight heparin therapies.
9. The organization should provide education regarding AC therapy to prescribers, staff, patients, and families.
10. Patient/family education should include the importance of follow-up monitoring, compliance issues, dietary restrictions, and potential for adverse drug reactions and interactions.
11. The organization should evaluate AC-safety practices.

AC = anticoagulation; INR = international normalized ratio; NPSG: National Patient Safety Goals.

data on AC use; (2) designing an effective workflow for patient monitoring; (3) appropriate training for pharmacists providing AC services; and (4) tracking quality indicators for AC.

**Review Hospital-Specific Information on AC**

A justification of AC services requires that the hospital pharmacy director understand the patient outcomes related to AC as well as patient volumes. For example, the pharmacy director should know the number of medication errors and adverse events along with their type, cause, and severity. This provides a justification of the service as well as a baseline for measuring improvement in clinical indicators of AC once the program is initiated. Finally, it is strongly suggested that this information be reported through the medical staff executive committee to gain physician support for developing AC services.

**Developing the Pharmacy AC-Monitoring Process**

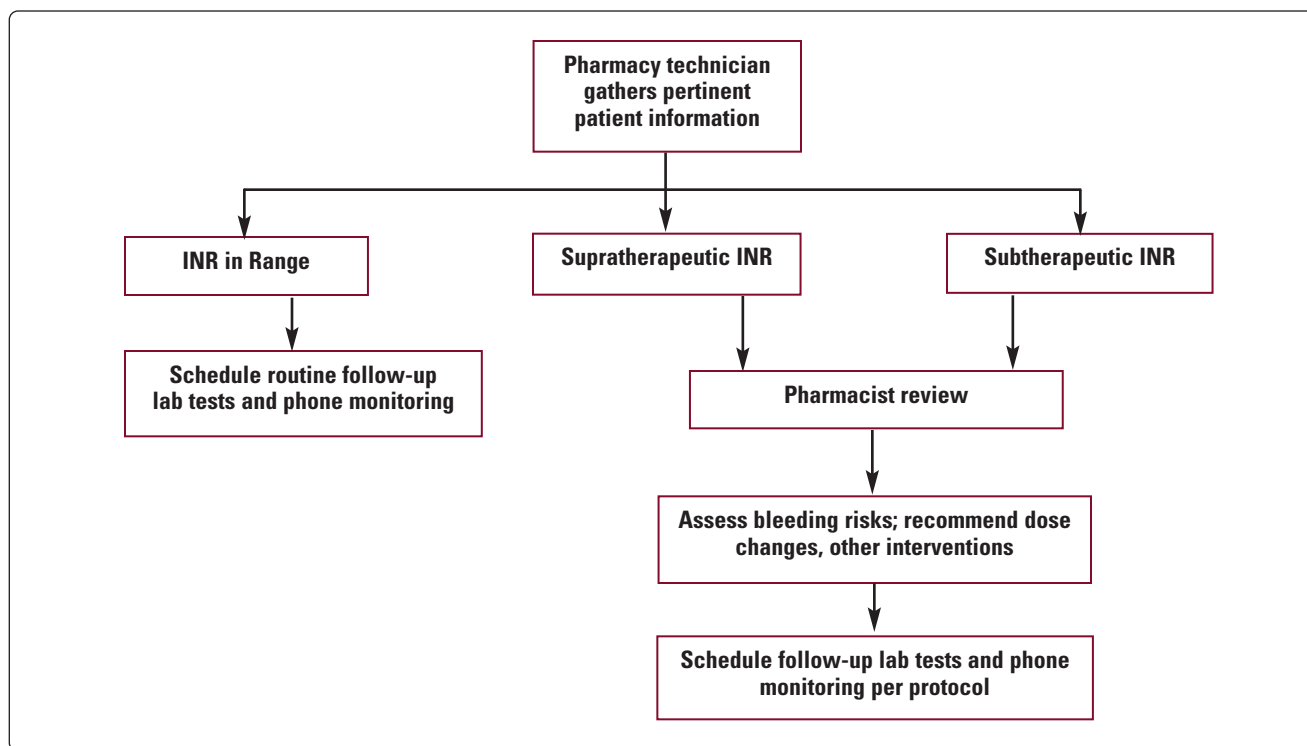
After essential hospital data on AC are reviewed, the pharmacy director should focus on developing a process for monitoring AC that does not interrupt the current pharmacy workflow. The University of Pittsburgh Medical Center (UPMC) operates an AC monitoring service for warfarin sodium and LMWH patients. The service, which is based on approved physician and pharmacist protocols, is a combination of patient visits (hospital discharge) and remote telephone management of INR values and warfarin dosing. The workflow employs both pharmacist and technician activities; an example of AC workflow is provided in Figure 1.

The pharmacists and technicians recruited to provide AC services must be specifically trained to deal with a variety of clinical situations, as they are often the first

called for a patient experiencing an adverse event to AC.<sup>9</sup> A listing of the possible job functions of both the pharmacist and technician performing AC services is provided in Tables 2 and 3. Certification for pharmacists in AC is available through various online courses. The University of Southern Indiana College of Nursing and Health Professionals provides a 6-week interactive online certification course on AC therapy (<http://health.usi.edu/certificate/anticoag/index.asp>). The National Certification Board for Anticoagulation Providers (<http://www.ncbap.org/index.aspx>) provides certification for pharmacists.

The amount of pharmacist and technician full-time equivalents necessary to provide AC services varies; generally, a pharmacist can manage between 200 and 325 patients at any given time.<sup>10,11</sup>

It is critical that quality outcome indicators be tracked for the



**Figure 1. Example of a process workflow for anticoagulation monitoring.**

INR = international normalized ratio.

**Table 2. Sample of a Job Description for an Anticoagulation (AC) Pharmacist**

1. Provide pharmaceutical care activities to AC patients that are consistent with regulatory, accreditation, and professional standards. Activities include medication order review for safe and effective indication, dose, route, and scheduled administration.
2. Perform therapeutic interventions consistent with the evidence-based guidelines of the department's Drug Use and Disease State Management program.
3. Where possible, manage drug therapy through a collaborative-care agreement with physicians that is approved by the Pharmacy & Therapeutics Committee.
4. Electronically document and track interventions and provide a summary report of activities with calculated impact on patient care.
5. Actively participate in medication safety programs. Active participation means identifying opportunities to improve safety (reporting errors and adverse drug events, and implementing system-based changes as a result of those opportunities).
6. Educate health care professionals on the most current evidence-guiding drug use in AC therapy.
7. Participate in preparing drug-use evaluations, therapeutic-drug reviews, and designing evidence-based clinical practice guidelines.
8. Mentor pharmacy students and residents to support ongoing teaching programs and the missions of the Department of Pharmacy & Therapeutics and the University of Pittsburgh School's of Pharmacy.
9. Contribute to the general knowledge of AC-therapy pharmacy practice by publishing the results of practice innovations or research in the peer-reviewed literature.

AC services. These indicators can be a focus on the operational, clinical, and financial aspects of the

**Table 3. Sample of a Job Description for an Anticoagulation (AC) Technician**

1. Assist the pharmacists by providing timely, regular reviews of patient medical information and pertinent laboratory results.
2. Assist the pharmacists in organizing patient medical information and proper storage.
3. Assist the pharmacists in scheduling patient appointments and phone interviews.
4. Assist the pharmacists in conducting patient bleeding risk assessment.
5. Update patient information in AC tracking database.
6. Assist in the preparation of drug-use evaluations and therapeutic-drug reviews.
7. Assist in the AC therapy education of health care personnel.

**Table 4. Example of Operation, Financial, and Clinical Quality Indicators for AC Services**

<i>Indicators</i>	<i>Type</i>	<i>Frequency</i>	<i>Data Source</i>
Number of patients/FTE	Operations	Semi-annually	Pharmacy workload report
LOS cost savings	Financial	Monthly	Hospital finance system
Major bleeding rate	Clinical	Monthly	Medical error reporting system
Minor bleeding rate	Clinical	Monthly	Medical error reporting system
INR within goal range	Clinical	Quarterly	AC data system

AC = anticoagulation; FTE = full-time equivalent; INR = international normalized ratio; LOS = length of stay.

service. Table 4 includes examples of quality indicators that would be tracked for an AC service. It is important to note that the definition of quality parameters may differ among institutions; it is recommended that a consensus on what defines success in AC be agreed upon prior to implementing a program.

AC services can have very positive outcomes. At the UPMC, a significant cost savings has been demonstrated through AC services provided therein. In 2006, the AC service was able to show a cost savings of nearly \$480,000 in LMWH based on inpatient days (590 days) saved in early discharge. From a clinical perspective, INR results (N = approximately 23,500) showed 64% of patients managed by the UPMC service were within the goal range for their indication on warfarin.

**IMPLEMENTATION CHALLENGES**

There are 4 challenges in implementation of AC services. The first is evaluating the organization's need to establish such a service. This would include the number of errors attributed to AC therapy or providing better patient-centered services for this high-risk population. Second is identifying the stakeholders; stakeholders need to see the justification for funding such a service. Moreover, funding can be limited based on whether or not the stakeholders agree on the purpose of the program. The third challenge is to recruit the right personnel to run the service. Last, leaders are faced with the challenge of continuously seeking new talent and service opportunities throughout the health care organization.

**SUMMARY AND CONCLUSION**

AC services can effectively sup-

port and establish a patient-centered focus for a hospital pharmacy department. The director of pharmacy must use a dynamic approach when developing AC services. The development and implementation involves using essential department data, collaborating with other health care professionals, and structuring a program evaluation based on the hospital's financial, operational, and quality missions.

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