



Coumadin/Warfarin Sodium: Safety-based rationales and guidelines



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MAG Mutual Insurance Company has seen an increase in claims caused by errors in the medically indicated use of warfarin sodium (Coumadin).

Tragically, some of these claims

were the result of patient deaths. These events can be directly linked to out-of-range PT/INR levels. They occurred most commonly because of communication failures and insufficient education of staff and/or patients. As a result of analysis of claims and direct research, MAG Mutual advocates the use of patient-safety training and literature, direct one-on-one patient education and the establishment of an office protocol to safely direct physicians, staff and patients in the proper use of this medication.

FDA and manufacturer's guidelines should be referenced to provide clinical and dosing criteria.

MAG Mutual has paid out more than \$5 million for claims in which Coumadin use was at issue. The breakdown of these claims by physician specialty shows that Internal Medicine, Family Practice and General Practice physicians were named most often (about 75 percent combined), while cardiologists and cardiovascular surgeons together were named less frequently (about 20 percent combined). Other specialties such as OB/GYN and plastic surgery were noted infrequently (about 5 percent). The use of Coumadin was appropriate to the patient's condition where noted, and as expected, the most common cause of injury was bleeding. Other claims could be linked to under use of

anticoagulant medication which resulted in CVAs and MIs. Descriptions for most claims indicate that PT/INRs were not followed closely in most of these individuals. Various reasons were noted, but more importantly, the question of how these patients' therapeutic levels were managed comes into play from a liability standpoint. Without well thought out protocols as well as thorough patient and staff education, there is little hope of mounting a good defense against allegations of negligence and more importantly, preventing errors when using anticoagulants.

Coumadin Clinics

The advent of Coumadin clinics has aided physicians and patients in safe and effective use of this medication. However, whether or not your patients are supervised in a Coumadin clinic, similar protocols may be utilized.

Warfarin (Coumadin) is reportedly the most frequently prescribed oral anticoagulant and the fourth most prescribed cardiovascular agent in the United States. It was initially discovered at the University of Wisconsin as a rat poison, but later research led to the agent's use as an anticoagulant. The benefit of this medication outweighs the risks when taken

appropriately. Yet in 1995, the Agency for Healthcare Policy and Research (AHCPR) reported that the agent might be underutilized in stroke prevention because of physicians' reluctance to prescribe warfarin due to safety concerns.

The most important aspect of the safe use of any agent or procedure is a thorough understanding of what is expected from all members of the team. The outpatient care team consists of the patient, physician, pharmacist and medical office staff.

Patient Education

Upon initiation of anticoagulant therapy, the patient and appropriate family member should be given written material, shown a video if available, given the opportunity to discuss any concerns and most importantly given face-to-face counseling in regards to the safe use of Coumadin (warfarin sodium). Educational materials should include written and visual

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representations of what the medications look like. **The importance of checking PT/INR levels must be stressed, and the patient should be informed that refills will not be given until the lab results are available.**

Patients must be educated to recognize symptoms of complications, adverse reactions and deviances from therapeutic levels.

Patient education is key in preventing adverse events or unanticipated outcomes for those taking anticoagulant agents. Additionally, patient education materials are available without charge online or upon request from DuPont Pharma (1-800-COUMADIN) and Barr Laboratories, Inc. (1-888-WARFARIN).

Staff Education

Your support and clinical staff must be trained to follow protocol for every patient receiving anticoagulant therapy. **The protocol for monitoring PT/INR levels and prescription refills should be followed carefully.** Protocols and a list of medications that require verification of criteria prior to refill should be posted by phones where staff members call in refills.

No refills should be given until the PT/INR results are known. If the results are delayed, the physician must decide whether or not to give the patient any additional medication and the PT/INR should be obtained as soon as possible.

Physicians

Physicians should follow therapeutic recommendations in accordance with FDA and manufacturers' guidelines. The guidelines are available online or through major manufacturers. The physician must direct staff to educate and monitor the patient, communicate with pharmacies, give out educational materials and review the log sheets with the patient on every visit. It would serve well to include a duplicate flow sheet for this purpose in the patient's chart. The patient should maintain a copy at home and write in newly telephoned instructions for dosing, etc. The office and home

Closed Claim Abstract

CASE #1

Failure to monitor INR when refilling medication

A patient called his primary care physician's office to ask for a refill of his medications. The staff member took the refill and pharmacy information and cross-checked this with the patient's record for accuracy. She wrote out the requests and placed them on the physician's desk for approval. This staff member was not aware that the patient had not had his INR or any other routine bloodwork checked for several months. Because checking those results was expected of staff members when refilling anticoagulant medications, the physician did not directly question the employee and did not pursue this information. The prescriptions were approved and called in by the staff member on behalf of the physician. When the pharmacist asked if the INR was appropriate, the staff member reported yes. She mistakenly assumed the doctor had checked this. The patient presented to a local Emergency Department over the weekend with rectal bleeding. He was admitted but died three days later due to complications. The physician was the sole defendant and was held responsible for his staff member's error in following office protocol.

CASE #2

Failure to resume Coumadin past hospital discharge

A woman with a history of DVT was hospitalized for orthopedic surgery. The surgeon stopped her maintenance warfarin prior to the procedure and initiated heparin therapy. The surgery went well, the patient progressed as expected and was ready for discharge. The primary surgeon was out of town, but her partner evaluated the patient and wrote discharge orders. She did not reorder the Coumadin. The patient presented to her primary care physician with swelling and pain in her left calf several weeks past discharge. She was hospitalized again and started on IV heparin. Unfortunately, she experienced a massive pulmonary embolus and expired before resolution of the DVT. This case illustrates the tragedy that can occur when no one knows who's in charge. The orthopedists assumed that the PCP would restart the warfarin and the PCP assumed her routine medications would be resumed upon discharge from the hospital. The patient was not given instructions to follow up with her PCP and thought all was well. The PCP and both orthopedic surgeons were named in this case. The patient unfortunately was lost.

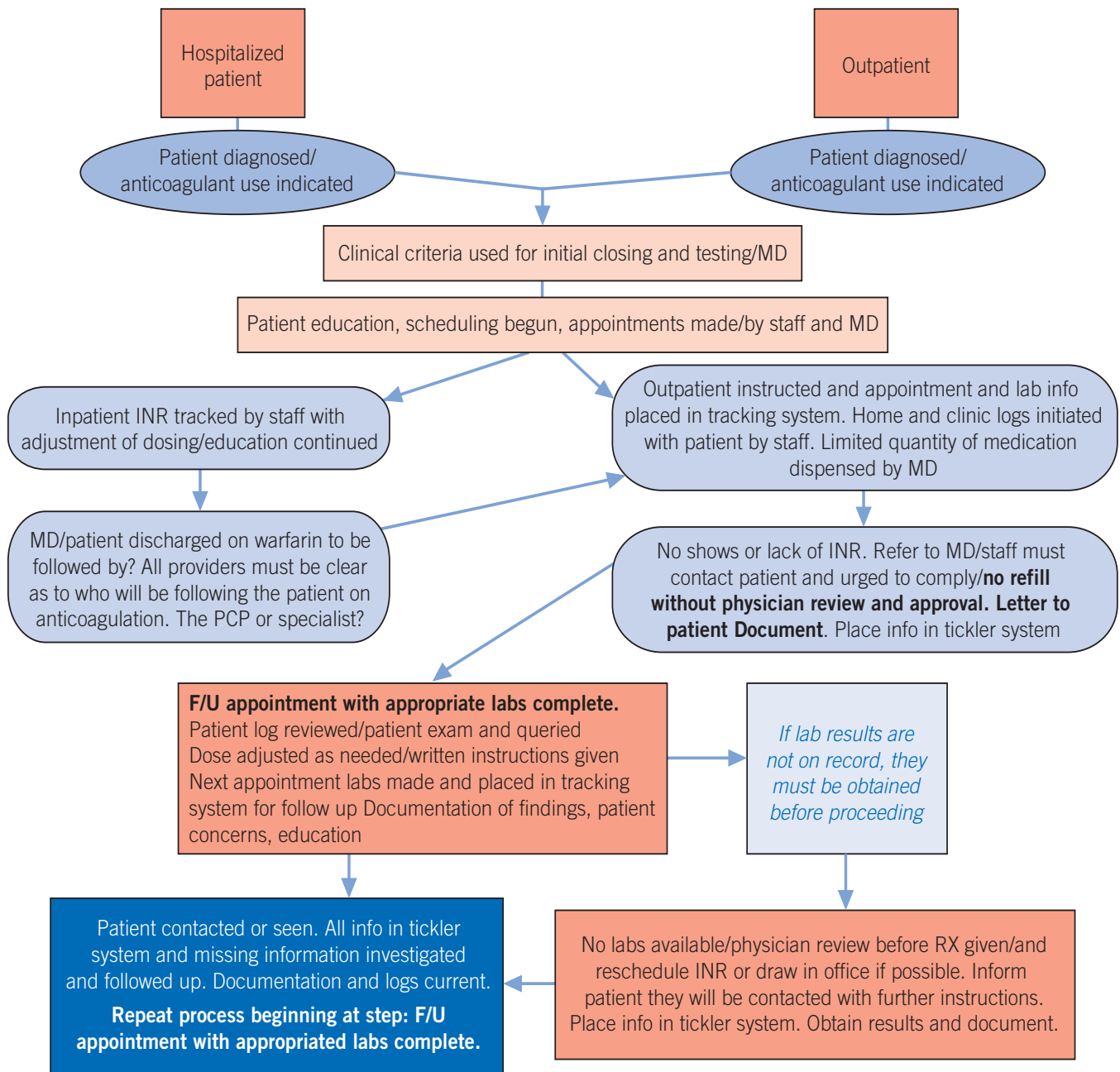
CASE #3

Failure to communicate dose to the patient

An elderly gentleman hand carried his new prescription for Coumadin to his local pharmacy. The prescription was illegible and was misinterpreted by the pharmacist. The patient did not question the dose and took it as directed. He had been given three times his prescribed dose and suffered a massive cerebral hemorrhage two weeks later. The error was discovered during a family conference with the family and physician. The patient, who had been active and alert, remained permanently impaired.

COUMADIN/WARFARIN

Patient Safety Protocol



flow sheets should be reconciled whenever the patient visits the practice. Additionally, patients must be queried of any changes in medication or diet.

*Note: Changes in diet and lifestyle will affect PT/INR levels. Additionally, some reports indicate that patients are more stable when maintained on a particular version of this medication, brand or specific generic as **some fluctuation of levels has been recorded when changing from a specific generic or brand to another.***

When patients have been hospitalized and another physician has provided care, be sure that you follow up with the patient and other provider to determine if anticoagulant therapy was initiated and who will be directing the protocols. If you as a physician write a prescription for Coumadin, you become responsible for monitoring the PT/INR even if you haven't before now. **This is very important. If you are not planning to follow the patient's coagulation, you should make the patient and other physician aware of their responsibility. When your patient is hospitalized, place your patient's name in the tickler file so that periodic updates can be made.** This step is crucial to ensure that your patient is safely followed.

Pharmacies

Close cooperation with local pharmacies is encouraged for all practitioners. Pharmacists serve as another safety net for all medication and prescriptions. Always write out the

name of the medication, the dose, indication and administration instructions clearly to prevent misunderstanding. Remember, it's not so much that the pharmacist can read the prescription, but more so that he or she cannot misunderstand the prescription.

The primary goal of any Coumadin protocol is to provide safe and efficacious follow-up and dose adjustment in order to maintain a PT/INR within designated therapeutic ranges specific to the needs of each patient. Finally, the patient must be able to identify his/her proper dose by sight and written description and recognize if he/she has been given the wrong dose. **The patient must be educated to ask questions when unsure of their dose.**

- i) National prescription audit: physician specialty report, dispensed data. Plymouth Meeting, Pa: IMS America, 1998. Accessed August 27, 2003
- ii) Agency for Health Care Policy and Research. Life-saving treatments to prevent stroke underused. Press release, September 1995. Accessed August 27, 2003
- iii) <http://internalmedicine.medscape.com/ASHP/AJHP/2000/> accessed August 27, 2003
- iv) http://www.mamc.amedd.army.mil/Referral/guidelines/cardio_coumadin.htm accessed August 28, 2003
- v) DuPont Pharma <http://www.coumadin.com/consumer/consumer.shtm> consumer information accessed August 28, 2003
- vi) <http://www.warfarininfo.com/home.html> Accessed August 30, 2003

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