The Comprehensive Management of Anticoagulation: Ochsner Coumadin Clinic

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Clinical privileging of pharmacists and the effective use of support staff and information technology have helped create an efficient pharmacist-operated anticoagulation clinic at Ochsner Clinic Foundation that will support future growth efforts for improved patient care. Developed by Ochsner's Department of Cardiology, the pharmacist-operated anticoagulation clinic cares for 2000 patients with a clinical pharmacist, staff pharmacist, registered nurse, and medical assistants. Patients are managed by face-to-face and telephone encounters. The pharmacists are privileged by medical staff to write prescriptions for warfarin, adjust warfarin doses, and conduct appropriate laboratory monitoring. Patients attend a mandatory initial visit where they are given medication instructions and educational materials. The pharmacist determines the treatment dose and schedules follow-up appointments. A software system developed by Ochsner's Information Services Department imports patient data from the institution's central computer system, allowing for a limited electronic patient record. Once fully implemented, this program will allow for more specific patient tracking and assist with quality improvement efforts. At present, approximately 68% of our patient population is within therapeutic range.

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Numerous descriptions of anticoagulation clinics are available in the literature. Most of these describe clinics with moderate patient enrollment (50-250 patients) in which various methods of management are used. There are essentially two categories that comprise most clinical management strategies. The first is made up of point of care services where laboratory tests are performed and patients are seen in person at each visit for consultation. The other is to manage laboratory values and consultations via telephone.

Clinical pharmacist- or nurse-managed clinics have been proven to be cost-effective and comparable to usual care by physicians (1-3). The Ochsner Clinic Foundation Anticoagulation Clinic is a pharmacist-operated, high-volume anticoagulation clinic (>1000 patients) that has integrated both methods of management and the development of a software system designed to streamline and optimize workload. This system has resulted in increased efficiency over standard anticoagulation management.

Clinic Staffing

Ochsner Clinic Foundation operates several pharmacist-managed clinics, one of which is the anticoagulation clinic located on the Ochsner main campus in New Orleans (expansion to satellite clinics in the greater metropolitan area is expected in the near future). Prior to the development of the clinic in 1997, anticoagulation patients were followed by their prescribing physician; only a small percentage of internal medicine patients were followed by a staff registered nurse. The anticoagulation clinic was developed to service cardiology patients but soon expanded to provide service to internal medicine patients whose primary care physicians were located on the Ochsner main campus. The clinic was originally staffed with a clinical pharmacist, a licensed practical nurse, and one medical assistant and provided care for approximately 700 patients. After 3 years of operation, the clinic's current enrollment exceeds 2000 patients. A clinical pharmacist serves as the director of the clinic, and

staffing includes a full-time staff pharmacist, a registered nurse, five medical assistants, and a data entry clerk. Pharmacy residents and students also provide staffing assistance on a rotational basis. One pharmacist and the registered nurse carry a pager in order to make a clinician available to patients and staff throughout the clinic's hours of operation.

The medical assistants help manage the patients who obtain their laboratory values from Ochsner's satellite clinics. These patients are managed using telephone care only, as they seldom visit our main campus to receive face-to-face consultations. Approximately two-thirds of our patient population is handled by this method with each medical assistant having a distinct patient population that they speak with on a consistent basis. The other third of our population uses our main campus to obtain laboratory values and are then seen by a pharmacist or nurse for consultation.

Pharmacists practicing in the anticoagulation clinic are privileged by the medical staff and the institution to write prescriptions for anticoagulation therapy (warfarin, low molecular weight heparin [LMWH]), adjust medication dosages, and order appropriate laboratory tests. Dosage adjustments and follow-up visits are scheduled at the discretion of the pharmacist. A cardiologist serves as the administrator for the clinic and reviews all decisions made by the pharmacist by receiving an electronic progress note for each patient at the end of the day. Each internal medicine physician whose patient is followed in the anticoagulation clinic is available at any time for discussion concerning his or her patient's care. Pharmacy residents, students, and new staff members train with the existing staff and cosignature of an experienced pharmacist is required for all clinical decision making and documentation until competency is demonstrated to the director of the anticoagulation clinic.

New Patient Enrollment

Any staff cardiologist or internal medicine physician whose practice is housed on the Ochsner main campus can enroll patients into the anticoagulation clinic. The new patients are called to inform or remind them of their initial appointment date and time. The laboratory appointment is scheduled before the pharmacist consultation appointment so the International Normalized Ratios (INRs) are available when the patient sees the pharmacist. Each new patient is given extensive education material, which begins with a 10-minute video presentation about warfarin or LMWH. Patients are encouraged to bring spouses or family members to this appointment where the video is used to help stimulate questions from the patient concerning their new drug therapy. The educational content of the visit includes the rationale of drug therapy; the mechanism of action of warfarin; monitoring of warfarin therapy (including an explanation of the INR); what to do in the event of missed doses; the influence of diet, illness, and changes in concomitant medications (including nonprescription items, vitamins and herbals); a description of the signs and symptoms of bleeding and clotting and appropriate actions to take if symptoms occur; the necessity of drug monitoring; and a description of clinic procedures. This appointment typically lasts 30-45 minutes (depending on the prior knowledge of the patient) and is documented in the chart that the patient received education and instructions.

Once the information is presented to the patient, the pharmacist addresses all questions and concerns. A brief medical history is obtained including a list of all concurrent medications, diet, and history of complications that may be aggravated by anticoagulation therapy. The clinical pharmacist determines the therapeutic range and duration of therapy on the basis of established guidelines (4) if they are not specified in the chart. The patient is given the INR results from that day and instructed on an appropriate dose of warfarin and a follow-up visit scheduled. Logistic issues are addressed for patients who live long distances from the Ochsner main campus. These patients often have blood drawn for INRs at either the satellite clinics or at other local hospitals and outlying laboratories. These patients are given a standing laboratory order that contains instructions for faxing or telephoning INRs to the clinic.

Patient Population

All anticoagulation patients are treated with warfarin (Coumadin®, DuPont Pharma, Willmington, DE); some patients enrolled in the outpatient deep vein thrombosis protocol are given LMWH. The average age of the patients is 67.4 years (range, 14-100 years). Sixty-six percent (66%) have their blood drawn at an outside laboratory. Indications for anticoagulation are atrial fibrillation (58%), heart valve replacements (15%), thromboembolism (9%), cerebral vascular accident or transient ischemic attack (8%), congestive heart failure (5%), coronary artery disease or myocardial infarction (2%) among others (2%).

Anticoagulation Clinic Operations

Ochsner Clinic Foundation has developed a computer program called Coumasoft that imports laboratory data from the hospital mainframe system and links the information to the appropriate patient. Each patient enrolled in the anticoagulation clinic has an electronic file. The medical assistants input all information such as patient demographics, enrolling diagnosis, therapeutic endpoints, and concurrent medications. The data entry clerk, in addition to her daily computer duties,

answers the telephone, takes messages, and forwards calls to the appropriate medical assistant.

Coumasoft looks for lab results based on the patient's appointment date, and each patient's electronic file is automatically sent to the appropriate medical assistant or pharmacist. If the PT/INR falls within therapeutic range, the electronic chart is automatically sent to the pharmacist for dosage instructions. If the PT/INR is outside of the therapeutic range, the electronic chart automatically appears on the computer of the corresponding medical assistant who will then call the patient to inquire of any changes. Once the patient whose PT/INR is out of range is questioned and adequate information is obtained, the chart (which includes all information obtained by the medical assistant) is then sent to the pharmacist for dosage instructions. Figure 1 shows the questionnaire that all medical assistants use as a guide to troubleshoot for patient changes. Once the pharmacist reviews the chart and documents their recommendations, the patients are then called and given the pharmacist's instructions.

The same procedure is followed for patients who receive face-to-face consultation, except the pharmacist or nurse completes all steps in the software program. Review of the laboratory results and dosage adjustments are made at the time the patient is seen in clinic. The number of patients who have laboratory tests completed for warfarin monitoring can range from 170-200 per day. By using this program, the clinic has the opportunity to simplify and track patients more effectively for quality initiatives and improvements.

The frequency at which patients are followed varies from twice a week to once every 8 weeks depending on the clinical judgment of the pharmacist. Patients are encouraged to report any changes in their medications or medical care (e.g. procedures, hospital admissions, etc.) at any time between appointments. Patients with acute problems are referred to the emergency department or their primary care provider.

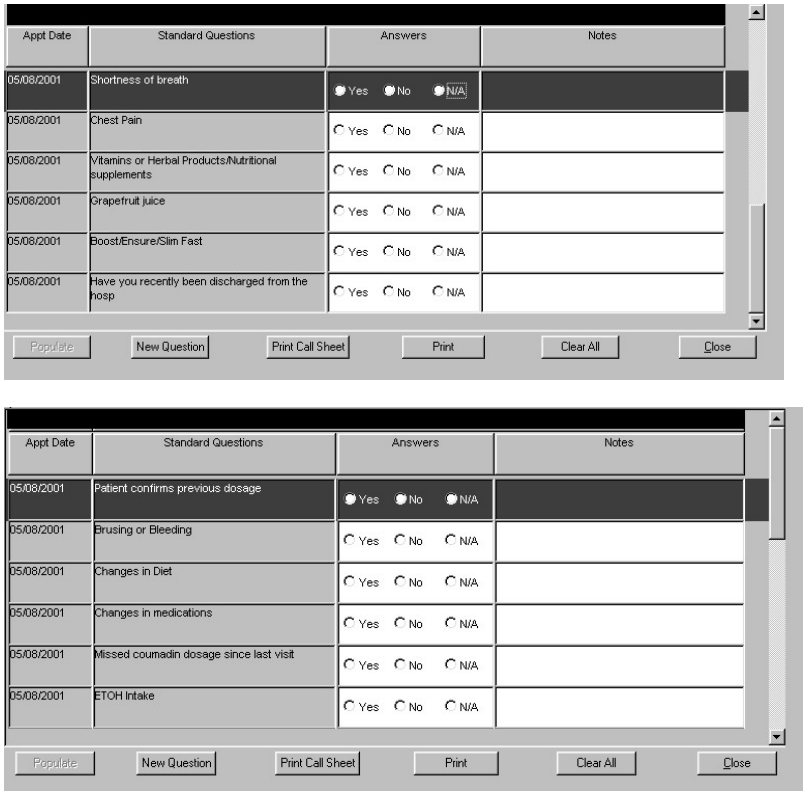
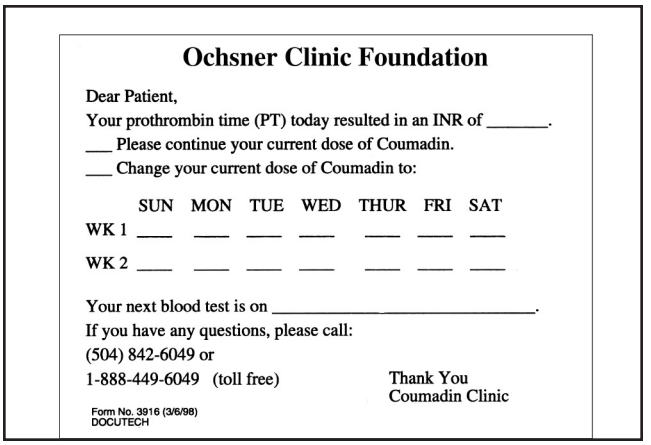


Figure 1. Electronic patient questionnaire used by medical assistants to troubleshoot individual patient warfarin dosage requirements.

A "contract for care" has been developed to help illustrate to the patients the necessity of anticoagulation monitoring and how imperative their involvement and cooperation is. The contract states that the patient will take responsibility for their care by assisting our communication either by phone or by being compliant with their regularly scheduled appointments. If patients become noncompliant with their appointment date, a letter, generated by Coumasoft, will be sent to the patient to remind them of the appointment. In the event that the patient still chooses to miss his or her appointment, another letter is generated explaining the necessity of proper monitoring. The last step with noncompliant patients takes them back to their enrolling physician who is then responsible for following the patient. Our current noncompliance rate is approximately 10%.

Due to the nature of the drug, most warfarin patients are taking a very precise dose that can vary from day to day. We attempt to keep patients on one strength of warfarin and instruct them to change their dose by taking fractions or multiples of the one tablet strength. Multiple tablet strengths could easily lead to confusion and, ultimately, poor patient outcomes. Due to the intricate dosing scheme most patients require, we have developed a dosing card (Figure 2) that illustrates the patient's dose on a daily schedule. The card has become a very handy tool for the patients to reference. We encourage them to keep it near their medications and to follow the directions on the card only



Ochsner Clinic Foundation

Dear Patient,
Your prothrombin time (PT) today resulted in an INR of _____.
___ Please continue your current dose of Coumadin.
___ Change your current dose of Coumadin to:

	SUN	MON	TUE	WED	THUR	FRI	SAT
WK 1	___	___	___	___	___	___	___
WK 2	___	___	___	___	___	___	___

Your next blood test is on _____.
If you have any questions, please call:
(504) 842-6049 or
1-888-449-6049 (toll free)

Thank You
Coumadin Clinic

Form No. 3916 (3/6/98)
DOCUTECH

Figure 2. Patient dosing card.

(and not their prescription bottle, which may be outdated). The dosing cards also have the phone number to the clinic to improve accessibility.

Coumasoft facilitates management of the clinic by compiling quality assurance (QA) reports. Patient data can be sorted by location of laboratory, diagnosis, medical assistant, and physician. Summaries of growth and target INR goal attainment are printed quarterly for review. A detailed patient report has been made available that compiles all data recorded that may have been related to out-of-range INRs. This report alone will help create quality improvement initiatives and avenues for future research.

Outcomes

Quarterly QA reports are compiled that detail the percentage of patients within therapeutic range as of their most recent INR. Approximately 68% of patients are within therapeutic range, including face-to-face visits and telephone-managed patients. As of the date of this writing, we have not comparatively studied the different patient groups for variances in outcomes; however, most literature suggests that in-person consultations produce the best outcomes. Further studies are currently underway including one investigation assessing the variances among patient outcomes between patients enrolled in the anticoagulation clinic compared with those that are not. The purpose of the study is to illustrate how pharmacist operated anticoagulation clinics are superior in improving patient outcomes by reducing hospital admissions, avoiding emergency room visits and preventing adverse drug reactions. This will be the first such study using an Ochsner Clinic Foundation patient population.

Historically, and regardless of the provider status (pharmacist vs. physician), telephone-managed patients have always resulted in a financial deficit. There is no process established to bill Medicaid or any other insurance plan for a telephone consult. In fact, the only patients the Ochsner Anticoagulation Clinic can receive payment for are those patients who have been counseled in person (one-third of the clinic's total patient population). In order to increase efficiency (income received can help with expansion, which will allow us to access the 5000 patients--or 60% of all warfarin patients--who are not yet enrolled), the institution is interested in placing a PharmD in each of Ochsner's satellite clinics in order to remove the telephone-managed component of the clinic. This process will allow for increased face-to-face patient consultations, more revenue, and perhaps increased compliance--all resulting in improved patient outcomes.

Conclusion

Several factors contribute to the quality of care, efficiency, and productivity of the Ochsner Anticoagulation Clinic. These include the effective use of clinical pharmacists and supporting staff, the development and implementation of a locally designed computer software program, use of patient contact by phone and in person, and quality assessment and improvement. All of these components help provide the type of comprehensive care that comprises the philosophy of the Ochsner Clinic Foundation.

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