

Implementation of the first pharmacist-managed ambulatory care anticoagulation clinic in South Korea

HAE MI CHOE, JUNGSUN KIM, KYUNG EOB CHOI,
AND BRUCE A. MUELLER

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Pharmacist-managed anticoagulation clinics have existed in the United States for many years. Improved efficacy of therapy and reduced hospitalizations have been documented and have made these clinics popular in health care systems.¹⁻⁸ To pharmacists in parts of the world where pharmacy practice is less advanced, pharmacist-managed anticoagulation clinics can seem remote and unattainable. This report describes the implementation of the first pharmacist-run anticoagulation clinic in South Korea based on the U.S. model.

Background. In Korea, ambulatory care clinics in major medical centers are structured to allow only physicians to make clinical decisions. Pharmacists are not integral members of the medical team in these clinics. The primary role of pharmacists is to dispense medications; patient counseling is not emphasized.

Patients receiving long-term warfarin therapy must be seen by a physician every month to obtain a one-

month supply of medications. Because of a heavy patient load, physicians spend 10 minutes or less with most patients. During an office visit, the physician often spends most of the time dealing with the patient's illness and has little time for anticoagulation therapy management or patient education. However, because of the risk of significant drug-drug, drug-disease, and drug-food interactions, as well as the potential for bleeding, comprehensive patient assessment and education are crucial. Patients taking warfarin may need to visit a health care provider more often than once a month to maintain effective and safe therapy.

Routine monitoring of warfarin therapy is often an inconvenience for patients. Usually, patients at the medical center are required to come to the hospital's laboratory one hour before their physician appointment to have their International Normalized Ratio (INR) checked. If no reminder calls are made to patients who have failed to have their INR checked, the warfarin dosage may remain unchanged when in fact it should be adjusted. Such follow-up is a service generally absent in Korea.

The typical drug distribution system in Korea also makes it difficult to adjust warfarin dosages. After a clinic visit, the physician sends an electronic prescription to the affiliated hospital outpatient pharmacy. Medications to be taken at the same time of the day are dispensed in one packet without a label indicating drug names. This system precludes dosage adjustment during the month or the use of different daily doses unless patients are able (and willing) to visually distinguish warfarin from the rest of their medications. Alternatively, the physician must take the extra steps of ordering warfarin separately and scheduling additional visits for dosage adjustments. This typically is not done.

Overcoming barriers. The first author was hired in 1995 by the pharmacy department at Samsung Medical

HAE MI CHOE, PHARM.D., is Clinical Pharmacist/Clinical Instructor, Clinical Science Department, College of Pharmacy, University of Michigan (UM), Ann Arbor. JUNGSUN KIM, B.S., is Pharmacist and KYUNG EOB CHOI, PHARM.D., is Director, Department of Pharmaceutical Services, Samsung Medical Center, Korea. BRUCE A. MUELLER, PHARM.D., FCCP, BCPS, is Chair and Professor, Clinical Science Department, College of Pharmacy, UM.

Address correspondence to Dr. Choe at 4260 Plymouth Road, Ann Arbor, MI 48109-2700 (haemi@umich.edu).

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Center in Seoul to implement innovative clinical services and introduce the concept of ambulatory care clinical pharmacy services. Since the Korean health care system is run primarily by middle-aged male physicians, it was very difficult for a young female pharmacist to even bring up the topic of clinical pharmacy services. Korean society is extremely hierarchical; seniority and male gender have dominance. Also, the author had been raised and educated in the United States since elementary school. This created another hurdle, because her understanding of the culture and ability to communicate with and persuade other health care professionals were limited.

Along with the idea of placing a pharmacist in the ambulatory care clinic, terms such as "pharmacist managed" and "medication management" elicited great concern and resistance among the physicians. When the concept of a pharmacist-managed anticoagulation clinic was presented to the medical center's cardiology department, only 1 of the 15 cardiologists agreed to refer patients to the service. The other physicians expressed doubt that a pharmacist could correctly adjust warfarin dosages. They believed that pharmacists are inadequately trained to make such clinical decisions and that physicians need no assistance managing anticoagulation therapy.

The physicians also questioned the suggestion of giving pharmacists limited prescribing authority. Most Korean pharmacists have a four-year bachelor's degree, and the curriculum places little emphasis on clinical pharmacy skills. However, if the physician had to be notified for each dosage adjustment, this would defeat the purpose of a pharmacist-managed anticoagulation clinic. After several months of debate, the hospital's administrators granted limited prescribing privileges to the anticoagulation clinic pharmacist.

The Korean government does not recognize anticoagulation manage-

ment by pharmacists, so the pharmacist's work was not reimbursed. Without such reimbursement, it was difficult to financially justify any pharmacist positions for the clinic. Shifting of responsibilities among pharmacists at the medical center made staffing possible.

Operation of the clinic and collection of data. The pharmacist-managed anticoagulation clinic was established in May 1995, and clinical data were collected in a pilot study lasting one year from that date. All referred patients were enrolled in the clinic. A computerized prescription database was used to identify all other patients undergoing warfarin therapy managed by physicians. A laboratory database was used to retrieve INR values for all patients. Because of an inadequate outpatient charting system, indications for use and demographic information were not readily available to allow a comparison between the patients in the anticoagulation clinic and the patients with usual medical care.

Before the clinic opened, the first author trained two pharmacists at the medical center and a pharmacy student doing postgraduate work to help her run the clinic. The pharmacists learned to review anticoagulation therapy, interview and assess patients, document clinical interventions, and educate patients about their therapy.

During a patient's first clinic visit, a pharmacist provided the patient with comprehensive education. The pharmacist was also responsible for prescribing appropriate warfarin dosages and ordering INR tests. The initial visit took approximately 45 minutes. Subsequent follow-up visits were scheduled on the basis of INR test results, dosage-adjustment requirements, symptoms, and educational needs. Patients received a reminder call from the pharmacist if they failed to show up for a clinic appointment or laboratory tests. Face-to-face consultation was preferred over telephone management,

though, to ensure that patients understood complicated dosage regimens.

The clinic pharmacists did not follow a strict written protocol, since a pharmacy and therapeutics committee did not exist to oversee such protocols. The first author used her clinical judgment and experience to provide optimal patient care and warfarin dosage adjustments. She also served as a liaison between the patient and the physician to address other health care needs. She met with the physician monthly to discuss these issues, as well as the operation of the anticoagulation clinic. Each physician received a summary report of his patients' progress, current dosage regimen, and laboratory results before his monthly appointments with the patients. The summary report was designed to ensure communication and continuity of care between the physicians and the anticoagulation clinic pharmacists.

Experience with the clinic. By all measures, the pharmacist-managed anticoagulation clinic was a success. The percentage of INRs maintained within the therapeutic range in the clinic group ($n = 230$) was 82%, versus 66% in the usual-care group ($n = 450$) ($p < 0.01$, chi-square test). There were differences between the standard of therapy in the clinic and what is considered the usual standard of therapy, however. In the United States, the recommended INR range for warfarin therapy is 2.0–3.0, except for patients with mechanical heart valves or receiving therapy for prophylaxis of recurrent myocardial infarction, for whom the recommended range is 2.5–3.5.⁹ At the time of the pilot study, the physicians in Korea requested that INRs be maintained between 1.5 and 2.5 when warfarin is used for primary prevention in patients with a high risk of hemorrhage. Consequently, for the purpose of the study, an INR between 1.5 and 3.5 was considered to be therapeutic.

Current recommendations state that the INR should be assessed at least every four weeks in stable pa-

tients (those achieving targeted INRs).⁹ The frequency of INR testing was evaluated in the clinic and usual-care groups. All stable patients in the clinic group had their INR assessed at least every two months. In the usual-care group, the interval between INR tests exceeded two months in 58% of cases. The clinic group was monitored more frequently than the usual-care group.

Two patients in the clinic group were admitted to the hospital. One admission was due to intracranial hemorrhage and the other to pulmonary embolism. There were eight hospital admissions among patients in the usual-care group; reasons were cerebral infarction, GI bleeding, intracranial hemorrhage, and left atrial thrombosis. The difference in admission rates between the two groups was not significant. However, hospital admissions in the usual-care group could have been underreported if the patient was admitted to another hospital. The medical records from other hospitals were not accessible.

The clinic documented 16 warfarin-drug interactions during the pilot study. The use of antimicrobials and cimetidine increased the INR in eight patients, and discontinuation of lovastatin decreased the INR in two. There is substantial use of herbal products in Korea. Although patients were advised to avoid these products while taking warfarin, the INR either increased or decreased in six patients because of concurrent use of herbal products and warfarin. The clinic pharmacists

provided appropriate interventions and counseling to prevent adverse effects of warfarin.

Although the documented clinical outcomes of patients seen at the pharmacist-managed clinic were impressive, one should keep in mind that these patients were not randomly assigned and that their characteristics could not be compared because of insufficient information in their charts. All the patients were under the care of cardiologists. One should also note that patient care information for the usual-care group may not have been complete. Some patients may have had INR tests elsewhere or been admitted to another hospital.

The pilot study results were presented at a monthly meeting of the cardiologists. The number of referring physicians increased from 1 to 20 after the results were aired. The findings were also presented at the Korean Internal Medicine Conference. This was the first time a pharmacist had given a presentation at this conference.

The Korean Society of Hospital Pharmacists (KSHP) and Korean colleges of pharmacy took a special interest in the pharmacist-managed anticoagulation clinic. KSHP has formed the Anticoagulation Pharmacist Specialist Working Group to further the development of anticoagulation clinics in Korea. As ambulatory care pharmacy services come to life in Korea, pharmacists and pharmacy students are being encouraged to pursue this area of practice.

Since the inception of the clinic, over 1500 patients have been enrolled. Two other medical centers in Korea have now started pharmacist-managed anticoagulation services.

Conclusion. The first ambulatory care anticoagulation clinic managed by pharmacists was successfully implemented in South Korea.

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