Original Article

Implementation of Pharmacist-Managed Anticoagulation Clinic in a Saudi Arabian Health Center

Jean G. Dib, PharmD^{*}; Khurram Mohammed, PharmD[†];
Hisham I. Momattin, MHSA, PharmD[‡]; and Ali M. Alshehri, MD, FRCP[§]

Abstract

Background: During the past 2 decades, a paradigm shift in the management of oral anticoagulation therapy has occurred. A multidisciplinary approach has been used and has proved beneficial from both a cost and quality perspective. However, this approach to anticoagulation therapy is not well established in Saudi Arabia and the Middle East, and the traditional way of managing anticoagulation patients is still the mainstay of care. The Pharmacy Services Division (PSD) in collaboration with physician, nursing, and medical support enterprises at the Dhahran Health Center established the pharmacy-managed anticoagulation clinic (ACC).

Objective: To describe the implementation process of the first pharmacist-managed anticoagulation clinic in the eastern province of Saudi Arabia and its impact on patient care.

Methods: The PSD in collaboration with medical staff successfully created a care delivery model utilizing clinical pharmacists' expertise to provide comprehensive anticoagulation management services at Saudi Aramco Medical Services Organization (SAMSO). Planning included analyzing existing practices, reviewing the relevant literature, obtaining physician input, formulating a business proposal, and developing clinical protocols and guidelines. Collaborative relationships were established with the center laboratory, scheduling services, and nursing and medical departments. Clinic services include patient assessment, anticoagulation monitoring, warfarin dosage adjustment, medication dispensing at the clinic, patient education, and feedback to referring physicians. Data (2 years before and after clinic inception) for all patients enrolled at the anticoagulation clinic were reviewed to evaluate the impact of the clinic on anticoagulation management, adverse events, and patient satisfaction.

Results: A total of 578 patients were enrolled in the ACC. The total percentage of international normalized ratio (INR) within the target range was 59% versus 48% when compared to the previous traditional practice. The number of INR tests per patient dropped by 19%. Minor and major adverse events occurred in 10% and 1.5% of patients, respectively. Overall, the patients were very satisfied with the new clinic compared to the previous practice.

Conclusion: Implementation of the pharmacist-managed ACC in the eastern province of Saudi Arabia had a positive impact on patient care based on the improvements in the number of patients whose INR was within therapeutic range and patient satisfaction scores.

Key Words—ambulatory care, anticoagulation, INR, pharmacist-managed clinic, warfarin

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^{*}Senior Pharmacy Supervisor, [†]Chief Pharmacist, [‡]Clinical Pharmacy Supervisor, [§]Interventional Cardiologist, Pharmacy Services Division, Johns Hopkins Aramco Healthcare (previously known as Saudi Aramco Medical Services Organization), Dhahran, Saudi Arabia. Corresponding author: Jean G. Dib, PharmD, Pharmacy Services Division, Johns Hopkins Aramco Healthcare, PO Box 76, Building 61, Room 10, Dhahran 31311, Saudi Arabia; phone: 966-38776860; e-mail: drjdib@yahoo.com

Warfarin (ie, coumarin, phenprocoumon, acenocoumarol) has been the mainstay of oral anticoagulant therapy for more than 60 years and is used worldwide for the prophylaxis of arterial and venous thromboembolism in primary and secondary prevention measures.^{1,2} In 1940, the first patients were treated as part of a trial with dicumarol (coumarin compound) as a prophylaxis against thromboembolic diseases. By the early 1950s, sodium warfarin was introduced into the market as an oral anticoagulant under the trade name *Coumadin Sodium*.³ Currently, warfarin is considered one of the 15 highest selling prescription medications in the United States, with over 2 million people taking it.^{4,5}

Anticoagulation therapy with warfarin reduces major thromboembolic complications in patients with many common medical conditions, including atrial fibrillation, history of deep vein thrombosis, pulmonary embolism, and mechanical heart valves.² However, warfarin has a narrow therapeutic index (NTI); its pharmacokinetic and pharmacodynamic profile is influenced by many factors such as disease state, other medications, food, and herbal products. In addition, it requires frequent and close laboratory monitoring to prevent patients from becoming excessively anticoagulated or under anticoagulated. Management of oral anticoagulation therapy traditionally has been considered to be a physician's function. The paradigm shift to manage patients utilizing a multidisciplinary approach has been beneficial from cost and quality perspectives. In addition, it has provided opportunities for other health care professionals such as clinical pharmacists to excel and be actively involved in direct patient care. This approach has pushed across final boundaries and allowed pharmacists and nurses to actively manage anticoagulation therapy under defined guidelines and protocols. By the early 1970s, the first anticoagulation clinics (ACCs) were established in the United States; today, there are over 1,500 ACCs worldwide. Improved patient outcome, safety, and hospitalization at pharmacist-managed ACCs have been well documented.⁶⁻¹⁸ Pharmacist-managed ACCs have not been well established in the Middle East, where the traditional way of managing anticoagulation patients is still the mainstay of care. At Dhahran Health Center (DHC), warfarin is classified as a high-alert medication with NTI and is commonly associated with adverse effects, primarily bleeding. The unstructured and nonsystematic approaches for delivering this therapy have led to a failure in providing adequate anticoagulation for a large portion of treated patients (>50%). To reduce

these events and improve anticoagulation management, use of special anticoagulation clinics for managing and monitoring patients receiving warfarin has been advocated by management. Furthermore, local and international regulatory agencies and standards are recognizing the need to establish a safe process for the management of anticoagulation therapy. This article will describe the implementation process and impact of the first pharmacist-managed ACC in the eastern province of Saudi Arabia.

ESTABLISHMENT OF PHARMACIST-MANAGED ANTICOAGULATION CLINIC

The Pharmacy Services Division (PSD) in collaboration with physician enterprise at the DHC in Saudi Arabia established a pharmacy-managed ACC. The ACC at DHC was developed as a component of the health care system at Saudi Aramco Medical Services Organization (SAMSO) to ensure the optimal use of oral anticoagulation in order to improve patients' health status and quality of life.

DHC is a 390-bed tertiary care facility, established in 1949, with 18 nursing units and 7 ambulatory care services. It is a facility of SAMSO, which is a part of the Saudi Arabian Oil Company (Saudi Aramco) that services over 350,000 employees and their dependents through aggressive wellness programs and state-of-the-art facilities. SAMSO is one of the few medical centers in the region that is accredited by the Joint Commission International (JCI). SAMSO initially earned accreditation by the Joint Commission on Accreditation of Hospitals and was cited for its high level of accomplishment and near-perfect level of excellence on April 17, 1956. In October 2011, JCI voted to continue SAMSO's accreditation through October 2014. It is expected that in 2014, one of the JCI medication use standards will require the close and structured monitoring of anticoagulation therapy. More than 110 pharmacists who hold bachelor of pharmacy, master of pharmaceutical sciences, or doctor of pharmacy degrees work at the PSD in the outpatient, inpatient, and ambulatory settings.

Period Prior to Pharmacist-Managed ACC

The primary model at DHC for oral anticoagulant care was either management by the patient's treating physician (traditional) or by an assigned cardiologist who cared for referred patients in the cardiology clinic (introduced in 2004). In all cases, patients were required to visit the lab and have blood drawn by venipuncture for an international normalized ratio (INR) test. The patients would return to

the cardiology clinic or their treating physician's office and wait approximately 1 to 2 hours for the test results; they were then seen by the physician. The physician would retrieve the INR results from the computerized laboratory system, assess the results for their patients, inform the patients of the results, and change the warfarin dose if required. A clinic nurse would perform patients' physical screening and assessment prior to their meeting with the physician. None to minimal patient education and counseling was performed by the treating physician. When the treating physician was unavailable, a covering physician would review, access, and manage these cases.

At the cardiology clinic, there was no scheduling system for appointments to see the physician. All patients were scheduled for follow-up on a specific day with no specific time (first-come, first-served basis). An assigned physician was available for only a few hours in the morning (until 11 a.m.) and then was on-call. Consequently, all patients came to the clinic in the morning, starting at 7 a.m. This long waiting time resulted in patients' frustration and low satisfaction, which was reflected by many complaints to customer services. After the patients were seen and assessed by the clinic physician, they went to the pharmacy and obtained their warfarin prescription and then returned to the clinic nurse educator for basic education. Some patients did not return to the clinic for convenience reasons. The process was disorganized, unstructured, and unsystematic. Education occurred only with new and/or changed warfarin prescriptions. No specific dosing nomogram was followed; individual physician knowledge and experience with the management of warfarin was utilized. Changes to warfarin dosing and the schedule for the next INR were recorded in the patients' chart.

Establishing Pharmacist-Managed ACC

The PSD prepared a complete business proposal based on published literature for establishing a pharmacist-managed ACC. This proposal was presented and discussed with the cardiology service, surgical service, and other divisions such as quality improvement at DHC for their input and support. As a result, the senior management approved the proposed concept to establish a pharmacist-managed ACC. After this approval, a task force for the development of pharmacist-managed ACC policies and procedures was established. The task force constituted representatives from nursing, cardiology, scheduling, and laboratory and was chaired by pharmacy. After several meetings, the pharmacist-managed ACC policies,

procedures, and protocol were developed and submitted to the Pharmacy & Therapeutics Committee for review and approval, which was attained.

A specific area in the cardiology clinic is allocated for a clinical pharmacist and a nurse with complete support of the medical staff. Patients are enrolled through physician referral to the ACC. Under normal conditions, physicians will refer their patients to the clinic and an appointment will be scheduled by the nurse for outpatients and by the ward clerk for inpatients. The referral form includes all required information for managing the patient such as indication, INR goal, duration of treatment, and so on (Figure 1A and B). The clinic operates from 7 a.m. to 4 p.m., Saturday through Wednesday, as those are the regular working days in Saudi Arabia. A trained clinical pharmacist is responsible for the clinic's operation and is supported by a qualified, trained nurse. The clinical pharmacist had 1 year of training in the United States and was certified in anticoagulation management. The clinical pharmacist acts as an agent for the referring physician within the approved protocol. A trained certified clinical pharmacist initiates, refills, and adjusts the dose of oral anticoagulation based on the approved protocol. In addition, the clinical pharmacist reviews the patients' medical chart, electronic profile, and history and orders laboratory tests as deemed necessary to achieve therapeutic anticoagulation goals (eg, INR, hemoglobin/ hematocrit, hepatic function, and renal function). After the introduction of INR point of care (POC) test, all INR testing is performed at the clinic via POC unless INR results are significantly high (>5), then another INR is done by the laboratory for confirmation. The primary referring physician is contacted for any patient care issues or concerns. If the primary referring physician cannot be contacted, the attending on call for the specific service is contacted. Any suspected serious bleeding episode, thromboembolic complication, or other urgent medical conditions are referred to the emergency medical services.

All visits to the ACC are scheduled by appointment; there are a few drop-in cases for urgent reasons. The patient's first visit is approximately 20 to 30 minutes in length during which the clinical pharmacist develops a patient-customized pharmaceutical care plan. The pharmacist documents all actions and recommendations taken at the clinic in the patient's chart to be reviewed by the referring physician. During the visit, the clinical pharmacist assesses the patient for any adverse drug reactions, drug-drug or drug-food interactions, medication

A

Figure 1. Referral form: (A) front page; (B) reverse page. AF = atrial fibrillation; BUN = blood urea nitrogen; CAD = coronary artery disease; CBC = complete blood count; DOB = date of birth; DVT = deep vein thrombosis; INR = international normalized ratio; MVP = mitral valve prolapse; PE = pulmonary embolism; PT = prothrombin time; PTT = partial thromboplastin time; TIA = transient ischemic attack.

Thromboembolic Disorder	INR Range	Duration	Comments
Venous Thromboembolism (VTE): DVT or PE			
DVT/PE with reversible or time-limited risk factors	2-3	At least 3 months	Time-limited risk factors: surgery, immobilization, estrogen
First idiopathic PE or proximal DVT	2-3	At least 6 months	Treat recurrence or continuing risk factor (CA, anti-cardiolipin antibody syndrome (AAS)) for > 12 months; INR 2.5-3.5 if AAS
Isolated symptomatic calf DVT	2-3	At least 6-12 weeks	
Acute Myocardial Infarction			
After myocardial infarction in combination with aspirin and clopidogrel	2-2.5	3 months to long-term	
After acute anterior myocardial infarction or acute myocardial infarction with severe left ventricular dysfunction, chronic heart failure, previous emboli, or evidence of mural thrombosis or apical thrombus	2-3	3 months to long-term	
Atrial Fibrillation			
<65 years of age without risk factors*,***			Use aspirin 325 mg
1 moderate risk factors*	2-3	Long-term	Can use either Warfarin or ASA in patients with one 'moderate' risk factor
>1 moderate risk factors*	2-3	Long-term	If Warfarin contraindicated or declined by patient offer aspirin
>1 high risk factors**	2-3	Long-term	
Conversion of Atrial Fibrillation			
Elective DC cardioversion of atrial fibrillation	2-3	7 weeks	3 weeks prior to and 4 weeks after cardioversion
Valvular Heart Disease			
Rheumatic mitral valve disease with history of systemic embolism or AF	2-3	Long-term	If recurrent systemic embolism occurs despite warfarin should increase target INR to 2.5-3.5 or add ASA 81 mg/day
Rheumatic mitral valve disease in sinus rhythm, if left atrial diameter is >5.5 cm	2-3	Long-term	
MVP with documented systemic embolism or recurrent TIAs despite aspirin therapy	2-3	Long-term	
MAC (Mitral Annular Calcification with systemic embolism (not calcific embolism))	2-3	Long-term	
Mechanical and Bioprosthetic Heart Valves			
Bioprosthetic heart valve	2-3	3 months	Alternative for aortic valve: ASA: switch to aspirin 81 mg/day long-term following warfarin
Bioprosthetic heart valve with left atrial thrombus at surgery or systemic embolism	2-3	3-12 months	Duration is for embolism: uncertain duration for left atrial thrombus
Mechanical prosthetic heart valve: Aortic	2-3	Long-term	If nl size and in sinus rhythm: valves: St Jude bileaflet, Carbomedics bileaflet, Medtronic tilting disk: 2.5-3.5 if AF
Mechanical prosthetic heart valve: Mitral	2.5-3.5	Long-term	An alternate is 2-3 plus ASA 81 mg/day
<p>*Moderate risk factors: Age 65-75, diabetes, CAD with preserved left ventricular systolic function</p> <p>**High risk factors: Prior stroke/TIA or systemic embolus, hypertension, poor left ventricular function, age >75 years, rheumatic mitral valve disease or prosthetic heart valve</p> <p>ANTICOAGULATION CLINIC REFERRAL MED-5344 (01/11) - Reverse © Copyright 2011. Saudi Aramco. All rights reserved</p>			

Figure 1. (CONT.)

safety, medication knowledge, compliance, and effectiveness of therapy (ie, INR, complications, etc). Pertinent laboratory test values are examined before initiation and/or adjustment of anticoagulation therapy. The patient is instructed regarding the indications, adverse effects, and potential complications of anticoagulation therapy as part of patient education. In addition, during the educational session, patients are informed of their role in disease management, the need for compliance with therapy and blood testing, and the importance of contacting the anticoagulation clinic with any changes to their health condition and medications. Other factors that might affect anticoagulation therapy, such as diet and alcohol, are also explained. Follow-up visits are approximately 10 to 15 minutes long and are scheduled based on patient status and condition, ranging from 3 days for new patients or patients with dosage adjustment to 4 to 6 weeks for INR stable patients. Medications are stored at the clinic in a locked cabinet. Patients receive their medications, instructions, information package, and one-on-one education at the clinic. If the patient is elderly or has difficulty understanding instructions, a caregiver must be present during the visit. Patient medication compliance and adherence are assessed during the patient's clinic visit via patient self-reporting, pill counts, and number of visits to the clinic.

Health care professionals' (eg, physicians, nurses, and nutritionists) support for the clinic was fostered by the PSD. An educational campaign was initiated before and after the clinic was launched. This process educated other health care professionals about the important role of the pharmacist in enhancing patients' quality of life, preventing medication-related problems, and managing costs.

RESOURCES

The anticoagulation clinic is located in the heart of the cardiology clinic and is large enough to include an office and an area for the patient assessment, POC testing, and education. This proximity provides an opportunity for collaborative relationships to be established and communication with other health care professionals to be maintained. Furthermore, the clinic is well equipped with computerized medical references and databases that are updated monthly. Health care software that was developed in house allows the clinic staff to access and input information, including laboratory values and progress notes, for each patient. The clinic is run by an anticoagulation-certified clinical pharmacist and a registered nurse; they are required to keep their

knowledge up to date by participating in continuing education programs and attending anticoagulation care-related conferences and workshops.

IMPACT OF THE PHARMACIST-MANAGED ACC

Pharmacist-managed ACC at SAMSO was established in 2010. Data (pre and post) for all patients enrolled at the anticoagulation clinic that are available through the computerized system at DHC were reviewed to evaluate the impact of the clinic on anticoagulation control, adverse events, and patient satisfaction. In June 2012, we reviewed the electronic patient profile and medical records for all currently active patients at the clinic. Patient demographics, indication for warfarin, INR target, comorbid conditions, concomitant medications, and inpatient admission were abstracted from the computerized system. Adverse events (eg, minor and major bleeding) were assessed during enrollment at the clinic, because data were not available before. To evaluate the patient satisfaction with the new service, a survey was conducted 6 months after inception.

A total of 578 patients were enrolled at the pharmacist-managed ACC. Patient demographic characteristics and other pertinent information are listed in **Table 1**. The mean age of the patients was 67 ± 16 years (range, 24 to 95 years), and 51% were females. The most common comorbid conditions were diabetes mellitus (48%), hypertension (38%), hyperlipidemia (20%), coronary artery disease (15%), and heart failure (8%). Atrial fibrillation was the most common indication for utilizing warfarin (74% of patients). Other indications included venous thromboembolism (deep vein thrombosis and pulmonary embolism), cerebrovascular accident, transient ischemic attack, peripheral vascular disease, and prosthetic valve. The most common INR target range was 2 to 3 in 88% of patients. Patients' concomitant medications and supplements are also listed in **Table 1**.

Anticoagulation control, defined as the percentage of all INRs that were measured that fell within the target range for each patient, was reviewed 2 years before and after the clinic was established. The total percentage of INRs that were within the target range was 59% versus 48% in the previous traditional practice. When a variance above and below the target range of ± 0.2 was assessed, the percent within the target range increased to 73%. The number of INR tests per patient dropped by 19% compared to the previous practice. This drop was reflected in a decrease in the annual cost of INR testing by \$10,000 annually. Data for adverse events were not available

Table 1. Demographic data of patients at the pharmacist-managed anticoagulation clinic (*N* = 578)

Demographic characteristics	No. of patients (%)
Gender	
Male	283 (49)
Female	295 (51)
Comorbid conditions	
Diabetes mellitus	277 (48)
Hypertension	220 (38)
Hyperlipidemia	116 (20)
Coronary artery disease	87 (15)
Heart failure	46 (8)
Indications	
Atrial fibrillation/flutter	428 (74)
Deep vein thrombosis or pulmonary embolism	69 (12)
Valvular disorder	17 (3)
Miscellaneous (ie, cerebrovascular accident or transient ischemic attack, peripheral vascular disease)	64 (11)
Medications	
Beta blockers	249 (43)
Diuretics	249 (43)
Calcium channel blockers	185 (32)
Angiotensin-converting enzyme inhibitors/ angiotensin II receptor blockers	197 (34)
Digoxin	110 (19)
Amiodarone	87 (15)
Supplements/vitamins	220 (38)
Target INR range	
2.0-3.0	508 (88)
2.5-3.5	70 (12)

Note: Mean (SD) age was 67 (16) years.

for the period preceding the clinic inception; therefore, the 2-year period after inception was reviewed. Major adverse events, defined as major hemorrhagic events that required treatment and/or admission to the hospital, occurred in 1.5% of patients. No fatal cases were reported secondary to anticoagulation treatment or its intent. Minor adverse events, defined as minor hemorrhagic events that did not require any treatment intervention, that were reported to the pharmacist/nurse involved around 10% of patients. Minor hemorrhagic events include gum bleeding, bruises, and epistaxis. All patients were asked during each visit to report any adverse event, and it was documented in their files. The introduction of the INR POC test at the clinic has saved the patients hours of waiting and improved their satisfaction.

Table 2. Results of patient satisfaction survey (*N* = 80)

Questions	Mean satisfaction response ^a
I prefer having my warfarin medication given to me at the ACC.	4.9
The pharmacist explains my need for anticoagulation therapy.	4.8
The pharmacist answers my questions in a way that I can understand.	4.8
Overall, I am satisfied with the services provided by the ACC.	4.8
Pharmacist is courteous and professional.	4.7
The appointments with the pharmacist have been kept on time.	4.7
Seeing the pharmacist for my warfarin is better than previous process.	4.7
There is adequate time during my appointment to discuss my concerns with the pharmacist.	4.6
I feel I can ask the pharmacist for additional information about my other medications if needed.	4.5
The printed materials provided are helpful and easy to understand.	4.4
I am satisfied with the space and design of ACC.	3.8

Note: ACC = anticoagulation clinic.

^aBased on a 5-point Likert scale, where 1 = *strongly agree*, 2 = *agree*, 3 = *neutral*, 4 = *disagree*, 5 = *strongly disagree*.

Six months after implementation, a satisfaction survey was conducted of all patients visiting the clinic during that month. Eighty patients participated and completed the paper survey. The survey consisted of 11 questions in both English and Arabic. The intent and the purpose of the survey were explained to the patients prior to completing the survey. Overall, the patients were very satisfied with the new clinic compared to the previous practice. The clinic space was the major complaint expressed by the patients (Table 2).

DISCUSSION

The pharmacist-managed ACC at SAMSO demonstrated a substantive improvement in patients' anticoagulant care compared with traditional management. The expanded therapeutic INR range of this clinic (± 0.2) was achieved over 73% of the time. The frequency of INR testing over time was

lower when compared to the previous practice at SAMSO. This drop correlates with the increased number of patients within the target INR range. All INR readings for clinic patients were obtained from the patients' electronic profile without distinguishing between INR readings during the initiation of therapy or warfarin dosage adjustment phase (usually subtherapeutic). This had a direct effect on the target INR percentage. The adequacy of anticoagulant control within pharmacist-managed ACC population is consistent with other published literature, with up to 63% of patients' INRs within the targeted range.^{10,17-22} Rates of major adverse events reported at the clinic (1.5%) were comparable to other pharmacist-managed ACCs and were lower than some (1.8%-8%).^{10,17-22} Minor adverse events (10%) were lower than in reported literature (17%).¹⁷ This could be due to some patients not reporting minor events or clinic staff not documenting them in patients' medical records. The pharmacist-managed ACC model was more rigorous in providing follow-up care for patients and obtaining regular INR tests, which may also reduce the risk of adverse events. All patient records, outpatient and inpatient, were easily accessed, because both settings are under the DHC electronic system that is being utilized by the clinic. Patients' major events were obtained directly from their medical records and electronic profiles. The overall success of the pharmacist-managed ACC at SAMSO is due primarily to the great collaboration between health care professionals and the consistency in warfarin monitoring and dosage adjustment. In addition, well-organized patient education contributes to improved compliance and a greater understanding of anticoagulation therapy, which produces higher INR values within the target range. Patients' compliance and adherence rate to medication was around 84% based on correct pill count. However, the correlation between compliance and INR control was not measured. Ninety-six percent of the clinic patients were adherent to their scheduled visits. Patients self-reported perfect adherence 95% of the time. The difference between self-reported adherence and correct pill count adherence can be due to several factors such as medication wastage/loss, incorrect medication dispensing quantity, medication being stored in other location (eg, pill box), missing doses, adverse effects, and others.

The results of the patient survey suggest that this pharmacist-managed ACC is associated with high levels of patient satisfaction. Patients appear to be satisfied with the pharmacist's ability to provide

educational information regarding anticoagulation therapy. Patients also stated they preferred receiving a prescription for warfarin at the clinic rather than from the outpatient pharmacy. The clinic space and design was the only patient dissatisfaction. As with any study, this survey has limitations that should be kept in mind when interpreting the results. First, no attempt was made to determine the extent of nonresponse bias. Another limitation of this study was the small sample size, which was 80 patients.

Implementation of the pharmacist-managed ACC in the eastern province of Saudi Arabia had a positive impact on patient care based on the improvements in the number of patients whose INR was within therapeutic range and patient satisfaction scores. More physician time is now available for direct patient care. The benefits of pharmacist-managed ACC include reductions in cost of care, concurrent interacting drugs, and adverse medication-related events while still achieving treatment goals. In addition, the pharmacist-managed ACC has been well received by other health care professionals and patients. Implementation of the clinic has led to an expansion of pharmacy services and an increased opportunity to improve patient care.

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