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ORIGINAL RESEARCH

Challenges of Anticoagulation Management Service and Need of Establishing Pharmacist-Led Anticoagulation Clinic in Tertiary Care Teaching Hospital, Ethiopia: A Qualitative Study

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Pupose: To explore the challenges of anticoagulation management (AMS) and assess the need for establishing a pharmacist-led anticoagulation clinic (PLAC) at Tikur Anbessa Specialized Hospital (TASH) in Addis Ababa, Ethiopia.

Methods: We conducted a qualitative study at TASH. Using a semistructured interview guide, we interviewed 15 physicians from different specialties, heads of pharmacy and laboratory departments. We also included 20 patients to explore their general perceptions, and experiences with and challenges of AMS; and the need to implement PLAC in the hospital.

Results: Only three physicians responded that they had protocols for initiating and maintaining warfarin dosing. Having protocols for venous thromboembolism (VTE) risk assessment, VTE prophylaxis and treatment, bleeding risk assessment, and contraindication to anticoagulant therapy were reported by seven, six, four, and three participants, respectively. Lack of trained healthcare professionals and a separate AMS clinic, inconsistency in INR testing and anticoagulant availability, and longer appointment times were the biggest challenges of the existing AMS, according to 80% of respondents. Fourteen patient respondents indicated that their satisfaction with the AMS was affected by long wait times and inconsistent availability of anticoagulants and INR testing. The head of the laboratory stated that the facilities for INR testing are inadequate and affect the quality of AMS and customer satisfaction, and supplemented by the head of the pharmacy by adding irregularities of supplies and inadequate counseling on anticoagulants. Respondents suggested that there is a need to establish a PLAC with well-adopted standard operating procedures, qualified manpower, adequate training of assigned staff, and sustained supply of anticoagulants and INR testing.

Conclusion: The hospital's AMS is not optimal to provide adequate services during the study period. Based on these findings and recommendations, the supporting literature, and the experiences of other facilities, the PLAC was established in TASH.

Keywords: anticoagulation, need assessment, anticoagulation management service, pharmacist-led anticoagulation clinic, Ethiopia

Introduction

Thrombosis is pathological clot formation caused by inappropriately activated hemostasis without a bleeding event. The adequacy of primary prophylaxis for venous thromboembolism (VTE) in terms of type, dose, duration, and prevention of prolonged complications must be considered in the treatment of VTE.[1] Warfarin is the standard therapy for patients with VTE. Its efficacy in preventing and treating thromboembolism is well established. The percentage of time the international normalized ratio (INR) is within the therapeutic range is used to predict the efficacy and safety of warfarin therapy.[2,3] It is risky to use warfarin in clinical practice without considering factors such as the narrow therapeutic window, variability in dose-response, numerous drug and food interactions, miscommunication between patient and physician about dosing, and lack of patient compliance.[4–7]

The complexity of anticoagulation management has led to the development of different models of care in many countries, including patient self-management, anticoagulation clinics, and pharmacist-led services. Mechanisms such as consistent monitoring, warfarin dosage adjustment algorithms, early identification of patient risk factors, standardized and continuous patient education, and pharmacist-managed anticoagulation clinics (PMACs) achieve better patient outcomes than traditional models of care.[8–11] Young et al reported that patients in a pharmacist-led anticoagulation service spent significantly more TTR (73% vs 65%, p < 0.0001) than the usual medical care (UMC) group. Another study documented a significant increase in the percentage of INR within the target range in PMAC (65.1%, p < 0.005) compared to UMC (48.3%). In addition, the rate of hospitalizations was 6.5 and 28.2 events per 100 person-years in the PMAC and UMC groups, respectively.[12]

In a retrospective cohort study by Aidit et al, pharmacist involvement had a positive effect on PMAC, as reflected by pharmacist acceptance of recommendations (p = 0.01).[13] A recent systematic review and meta-analysis showed a lower risk of overall, minor bleeding, and thrombosis with pharmacist led anticoagulation management.[5]

In a study conducted in Mekelle in the Tigray region of Ethiopia, almost all patients were taking medications that interact with warfarin. At least one abnormal drug interaction was present in 50% of the study participants. Twenty-two (16.5%) patients developed bleeding complications.[14] Several studies conducted at TASH pointed to the poor quality of AMS, as evidenced by low TTR (29%),[15] inadequate knowledge of patients and medical staff about warfarin therapy,[16,17] and poor practice in VTE risk assessment and inadequate use of thromboprophylaxis.[18,19] In Ethiopia, oral anticoagulants with more predictable pharmacological properties than warfarin are occasionally available. Therefore, warfarin is still the main treatment and prophylactic option for thrombosis and related events because of the high cost of these drugs. In Ethiopia, patients taking warfarin are managed by physicians in UMC, as is the case for general patients. Therefore, the aim of this qualitative study was to identify the challenges of AMS and the gaps that exist in the current AMS; and to assess the need for establishing a PLAC in Tikur Anbessa Specialized Hospital (TASH) in Addis Ababa, Ethiopia.

Methods
Study Area
The study setting was Tikur Anbessa Specialized Hospital (TASH). TASH is the largest tertiary teaching hospital in Ethiopia and has more than 700 beds. In TASH, ten thousand patients require anticoagulants and antithrombotics for VTE management.

Study Design and Period
The design was a qualitative study. We interviewed physicians (various specialties), heads of pharmacy and laboratory departments, and patients using a semi-structured questions guide. The interview explored perceptions and experiences towards the AMS at TASH and PLAC establishment needs in TASH.

Eligibility Criteria and Sampling Technique
Study participants' (key informants) selection was by using a purposive sampling technique based on their rich experience in the area of AMS. Accordingly, 15 physicians from different specialties, heads of pharmacy, and laboratory departments were included in this study. We also included 20 patients from those who had follow-up at the cardiac clinic of TASH, and taking warfarin using a simple random sampling technique. Seriously ill patients and physicians with minimal role and experience in AMS did not partake in the current study.

Data Collection and Management
The collection of data was by using thematic content analysis. A semi-structured interview guide was used by interviewing 15 physicians from different specialties, heads of pharmacy, and laboratory departments. We also included 20 patients to explore their overall ideas, perception, experience about AMS and the challenges of AMS, and the need to establish PLAC in the hospital. The prepared questionnaire for interview purposes includes questions that explore the knowledge of participants on the anticoagulant regimen they were taking, the sufficiency of counseling service, the availability of anticoagulants, and INR test, participants' suggestions on the UMC AMS, and their overall satisfaction with TASH AMS. Moreover, the questionnaire included questions that addressed possible ways to improve the AMS of

TASH. Then, observation was made to have a clear picture of the current workflow of AMS and its structure. The interview guide questions were developed from different works of literature.

Data Quality Assurance

Two experienced clinical pharmacists validated the instrument for clarity, simplicity, and comprehensibility and modified it before the interview began. The English version of the interview guide for interviewing patients was translated into Amharic and then translated back into English to maintain consistency or to compare the translations with the original text for quality and accuracy and to assess equivalence of meaning between the source and target texts. In case of discrepancies during transcription, translation, back-translation, and coding, consensus was reached through discussions with the investigator. The Amharic and English versions were used to interview patients and medical staff, respectively, in the study. An interview lasted an average of 15 to 40 minutes. An audio recording was made for those who were willing, and a note was made for those who refused to record their voice.

Data Collectors

Two postgraduate students in Pharmacy Practice from the Department of Pharmacology and Clinical Pharmacy, School of Pharmacy, Addis Ababa University were engaged in collecting data from health professionals and another post-graduate student from the same program collected data from patients. Data collection was supervised by the principal investigator of this study to ensure consistency and quality of data. The data collectors received one day of training on how to approach study participants and conduct the survey.

Data Analysis

A thematic analysis approach was used to analyze the data. Data analysis was based on the identification of key themes by two authors (TAT and AAA). Both the unrecorded (noted) and recorded interviews were transcribed verbatim, and the raw data were assigned to different themes. Participating patients were assigned code numbers from P1 to P20, and physicians were coded MD1 to MD15 at MD. We used these codes to describe each participant's individual outcomes when necessary.

Ethical Considerations

Ethical approval was obtained from the Ethics Review Committee of the School of Pharmacy, College of Health Sciences Addis Ababa University (ERB/SOP/27/10/2018). All participants were provided informed consent before participating in the study. Study participants were informed that the information they provided was kept strictly confidential. Personal identifiers were not used in the analysis and data were analyzed in aggregates.

Results

Socio-Demographic Characteristics of Healthcare Professionals

A total of 17 health professionals were interviewed. Fifteen of them were physicians, 1 pharmacist (head of the pharmacy), and 1 medical laboratory technician (MLT) (head of the laboratory). With the exception of 1 participant, they were all male and aged between 30 and 59 years (Table 1).

Experiences and Opinions of Health Professionals on AMS

For the analysis and interpretation of the results, a thematic content analysis was conducted in six core thematic categories. The adequacy of the current institution to provide adequate AMS, availability of resources (functional protocols, coagulation tests, and anticoagulants), challenges of AMS and proposed solutions, quality of AMS, benefits of establishing PLAC, and the role of clinical pharmacists in PLAC were the main themes identified.

Suitability of Current Setup to Provide Adequate AMS

The majority of study participants (13, 86.67%) indicated that the facility was not suitable for providing optimal AMS in the hospital. The lack of a dedicated clinic was repeatedly cited by 60% of respondents as the main reason for the

Table 1 Socio-Demographic Characteristics of Healthcare Professionals (N=17)

Variables		N	(%)
Sex	Male	16	94.12
	Female	1	5.88
Age (in years)	30–39	7	41.18
	40–49	6	35.29
	50–59	4	23.53
Maximum qualification	Cardiologist (Adult and Pediatric)	6	35.30
	Surgeon (Cardiothoracic and Orthopedic)	3	17.65
	Hematologist/Oncologist	3	17.65
	Pharmacist and MLT (Pharmacy and Lab Heads)	2	11.76
	Gynecologist and Obstetrician	1	5.88
	Emergency Medicine Specialist	1	5.88
	Internist	1	5.88
Year of experience in managing anticoagulation (in years)	2–5	7	41.18
	6–10	4	23.53
	>10	6	35.29

inconvenience of setting up AMS. In addition, four respondents stated that the workload and overcrowding of the facility result in patients who need AMS receiving less attention because they are treated the same as others. This was reinforced by a statement from two respondents.

> [… …] The delay in getting coagulation test (MD1) and the lack of a separate determination corner in the hospital make the facility poor for providing necessary AMS to patients. (MD12)

In contrast to this statement, two other respondents indicated that the facility is adequate for providing AMS.

> The setup is good for providing appropriate AMS because there are multiple specialties (MD 4) and well-trained staff (MD5) in the hospital.

Availability of Resources
Respondents indicated that lack of resources to provide anticoagulation services was one of the barriers to clinic operations. In terms of resources, functional protocols, coagulation tests, and anticoagulants were most commonly mentioned.

Functional Protocols
Regarding the availability of functional protocols/manuals, respondents indicated that there is no single department/clinic that has all the necessary protocols/manuals that assist delivering optimized AMS. However, the most responses were to the questions about risk stratification for VTE development assessment, and VTE prophylaxis and treatment protocols, which were answered by 7 (46.67%) and 6 (40%) respondents, respectively. It was mentioned that most clinical units did not have the other protocols/manuals, as their existence was reported only by 6.67% to 20% of the study participants (Table 2). The lack of an organized team to develop the protocols/manuals was cited by 5 respondents as the main reason for not having the protocols. Two physicians suggested that the development of these protocols/manuals was the

Table 2 Physicians' Response to the Availability of Functional Protocols for Providing AMS (N=15)

SN	Functional Protocols	No. of Response	
		Yes	No
1	Warfarin initiation dosing protocol	3	12
2	Warfarin maintenance dosing protocol	3	12
3	Indication, target INR and duration of anticoagulation	3	12
4	Frequency of INR monitoring	1	14
5	Risk stratification for VTE development assessment	7	8
6	Protocol on VTE prophylaxis and treatment	6	7
7	Risk stratification for bleeding assessment	4	11
8	Contraindication to warfarin and other anticoagulant therapy	4	11
9	List of drugs that interact with warfarin and their management	1	14
10	Warfarin reversal protocol with elevated INR	1	14
11	Patient education on anticoagulation protocol	1	14
12	Anticoagulation management during pre and post-operative	2	13

responsibility of other clinical departments, such as cardiology and hematology, which have the greatest burden of patients requiring anticoagulation therapy.

Availability of Coagulation Tests and Anticoagulant Drugs

Regular availability of coagulation tests (prothrombin time (PT), activated thromboplastin time (aPTT), INR) was reported as poor by 5 (33.34%) of the participants. A similar number of respondents answered that the availability of these important tests is rare/not constant. However, one physician responded that they are quite readily available in the hospital. Regarding the availability of anticoagulants (oral and parenteral), 40% of respondents indicated that they are "fairly well" or "well" available. Conversely, the same number of physicians stated that the availability of these vital anticoagulants was "not consistent or not constant or not regular or not sustained." In contrast, the remaining 20% of study participants said the availability of these agents was poor at the hospital.

Regarding the waiting time for INR test values from the laboratory, study participants had different experiences/ views. Thus, long waiting time (>3 days), 2–3 days and 1 day were described by 40, 33.34 and and 5.34% of the respondents respectively. However, two study participants stated that they had no information about the waiting time for INR value. The reliability of INR values was described as good, moderate and less reliable/bad/doubtful by 5.34, 33.34% and 20% of the study participants respectively. The remaining (40%) participants were unaware of the reliability of the INR values they received from the laboratories.

Challenges of Anticoagulation Management Service

Irregular availability of coagulation profile tests and anticoagulants was cited as the main challenge to providing the required AMS in the hospital studied, and a supply problem was quoted as the reason for the irregularity. In addition, most study participants explained the consequences of the unavailability of the tests and medications.

> This exposes patients to high costs for INR determination and obtaining medications drug outside the hospital from private pharmacies. (MD6)

One respondent explained his organization's challenges as follows:

> [....] we have limited knowledge about the interaction of anticoagulants with other drugs and the duration of anticoagulation, which affects the quality of anticoagulation therapy. (MD 1)

Another study participant explained the AMS challenge in the hospital as;

There are problems with compliance in continuing thromboprophylaxis in many patients for the specified period after surgery once they are discharged from the hospital, resulting in our patients being readmitted to the hospital for recurrent thromboembolic events (TEs). (MD4)

Inadequate patient education strategies, difficulty with timely consultations, a lack of beds to admit patients who developed TE, a longer wait time for patients requiring frequent follow-up and monitoring, unreliable INR results, and the lack of hospital/national INR target ranges (rather than relying solely on international recommendations) were cited mentioned by one participant as the greatest challenges of AMS in the hospital studied. In addition, 4 (26.67%) respondents indicated that the lack of clear standard operating procedures (SOPs) is one of the key challenges of the current AMS. The same number of study participants cited workload at the current facility as another key challenge, as patients seeking AMS do not receive the attention they need in such a busy clinical environment. Another key challenge cited by almost all respondents was the lack of a separately responsible clinic staffed with qualified professionals to manage AMS-related activities.

Proposed Solutions to Address Anticoagulation Management Service Challenges

Respondents to the study proposed various solutions to overcome the existing AMS problems. Nime (60%) and 8 (53.34%) study participants suggested the provision of coagulation profile testing (aPTT, PT, INR) and anticoagulant as a key way to improve AMS, respectively. Two-thirds of respondents indicated that anticoagulation should be managed centrally, ie, in one unit by creating a responsible multidisciplinary team (MDT) to address current gaps in AMS in the hospital. In addition, two physicians reminded that qualified healthcare professionals (HCPs) with adequate training are essential for providing optimal AMS.

Another respondent suggested as a solution to the AMS challenges:

> [...] the use of antithrombotics that do not require laboratory monitoring (INR) as a method to improve AMS, as we have not been able to optimize anticoagulation with a drug such as warfarin that requires frequent INR monitoring. (MD14)

Timely consultations, development of SOPs, and performing coagulation testing in dedicated hemostatic laboratories (each mentioned by one respondent) were also suggested solutions for addressing existing problems with AMS in their hospital.

Quality of Anticoagulation Management Service

Two-thirds of the participants described the quality of AMS in the hospital as poor, declaring it as"not adequate/not good/ below standard/suboptimal." On the other hand, 5 (33.34%) of the physicians described the quality as satisfactory, using words such as "average", "reasonably good," and "fairly to good."

Advantages of Establishing a PLAC

All respondents indicated that the establishment of a functional PLAC in the hospital has great benefits in improving the quality of care for patients requiring anticoagulation therapy.

> More focused and efficient patient care will be provided if PLAC is opened and functional in our hospital. (MD1)

However, a few respondents emphasized the importance of the assignment of HCPs to the service and the consistency of the service. This was reinforced by the following statements from respondents.

> Opening the clinic alone will not solve the problems associated with AMS if well-trained HCPs are not assigned and if the consistency/sustainability of the service is not ensured. (MD9, MD10, MD12)

> PLAC improves regular follow-up of patients and optimizes anticoagulation therapy. (MD 11, MD 13)

> [...] better patient follow-up and education and optimized anticoagulation management will be achieved if this new clinic is opened in the hospital. Finally, he stated that the establishment of a functional clinic is essential. (MD15)

Another participant adds a statement that supports this:

> […] a PLAC is very important in our hospital, but the issue of ownership and the specific training of the staff assigned to the clinic are very important issues to consider before setting up the clinic. (MD14)

Finally, 6 (40%) of the participating physicians emphasized the need to ensure the sustainability of the clinic without interruption.

When asked about the importance of working as MDT, ie, with the pharmacy team in PLAC, most respondents indicated that it was "very important", "very encouraging and necessary," and "highly recommended and very good" to work in a team.

The Role of Clinical Pharmacists in PLAC

Regarding respondents' perceptions of clinical pharmacists' involvement in PLAC, 5 (33.34%) indicated that they will contribute tremendously to improving patients' follow-up of their anticoagulation therapy. Two respondents described that clinical pharmacists will have a tremendous impact by providing a list of medications that interact with anticoagulants.

This was reinforced by one respondent as follows.

> Clinical pharmacists in the PLAC are helpful in addressing the problem of drug interactions/complications, and medication adherence. (MD8)

Laboratory and Pharmacy Heads Perspectives

When questioned by the laboratory head about issues related to INR testing in the hospital, the respondent stated that:

> […] there is no enough INR testing equipment and reagents needed for INR testing in the hospital.

In addition, the respondent recommended that a regular supply of these commodities is essential to ensure good quality of service and increase patient satisfaction with AMS.

> […] a separate INR machine is required in the proposed clinic and also the laboratory department will assign one or two laboratory staff to work in the clinic.

The head of the hospital's pharmacy department responded that

> […] there is an irregular supply of anticoagulants, especially warfarin, and inadequate education and counseling on the use of anticoagulants due to the workload and lack of a dedicated room.

In addition, this respondent said that

> […] there is no standard protocol for warfarin dosing and counseling. Also, nothing has been done with other departments regarding AMS and the establishment of PLAC.

However, an interviewee pointed out there is a need to establish a PLAC with a well-adopted SOP, qualified staff, sufficient training for assigned staff, and a sustainable supply of anticoagulation medications.

Patients' Experiences and Opinions on the Current AMS

An interview was conducted on 20 patients (P) (8 males and females). The median age was 51 years (range 19–72).

Availability of Warfarin and INR Testing

Regarding the availability of INR tests and warfarin, almost all clients complained about the unavailability of INR tests and the drug warfarin. This was confirmed by the statement of one patient.

> Most of the time, I could not find the drug warfarin at the hospital. The same is true for the INR tests. (P2)

Another respondent confirmed this thought,

> The problem is not only getting the drug and the test in the hospital, but also finding them outside easily. We are looking for it all over Addis Ababa. (P4)

Considering the problem of unavailability, patients are forced to get them from outside the hospital, which involves additional costs.

This was further strengthened by a quote from a 48 years old male patient

> There is a big price difference between the hospital and other sources. It's expensive in the other sources and we can not afford it permanently if we keep getting it from an outside source. (P14)

Warfarin being the most used anticoagulant, INR testing is a must regularly for patients.

One respondent said:

> We really want the test to be done in the hospital. Without it, the drug warfarin is worthless to us. (P7)

Anticoagulation Management Service Challenges

Patients discussed several factors about AMS challenges in the hospital. Most patients agreed on the general problems, with slight differences in problem depth and perspective. The commonly mentioned challenges were inadequate patient waiting area, high patient load, unavailability of the card, and poor hospitality.

One 64-year-old patient described the situation as follows:

> There are not enough patient waiting areas for patients like us. Moreover, the space/waiting area is not comfortable for patients. (P12)

In addition, most patients also complained about the patient load.

One patient said:

The problem with patient card management is another limitation in the delivery of UMC services. Some of the patients reported how difficult it is for them to get their cards for treatment from the card room.

> Because of the large number of patients using the service, I did not have enough time to ask for a consultation and inform the doctor properly about my situation. (P11)

A 72-year-old patient said:

> For an old man like me, looking for a lost card is a burden. I look for it by myself from one building to another (P18)

Regarding card administration, more than 10 patients complained about the poor hospitality they receive from card administration staff and nurses.

One patient said:

> When I look for my card, the officers do not respect me. Even with my card, they insult me. (P12)

Another patient corroborated:

> The nurses are always angry with us. They are enraged, irritable, apoplectic, ignore and despise us for no reason. (P7)

In addition to the challenges, most patients also offered suggestions on how to solve the problems. The solutions can be summarized in three main points. A separate room should be available for service, additional health professionals should be hired, and INR testing should be available in the hospital.

In this context, one patient said:

> How can I ask for a consultation? How can I maintain my queue for service in such a crowd? If we do not have a separate room for service, we will not get good service. (P9)

750

Journal of Multidisciplinary Healthcare 2022:15

Patient load is mentioned as a major challenge. They suggested that more professionals are needed to reduce the workload.

When asked about patients' satisfaction with AMS, almost half of the patients were poorly satisfied with the services they received.

Discussion

In this qualitative study, we explored the challenges of AMS and assessed the need for establishing a PLAC at TASH from the perspective of healthcare professionals and patients receiving long-term oral anticoagulants (warfarin). Most study participants indicated that the current AMS is not adequate to provide appropriate services, citing lack of prerequisites (basic infrastructure) such as a separate clinic/room, hospital/country-specific INR target ranges and functional work protocols, longer office hours, unreliable coagulation testing, and high workload. In addition, poor availability of coagulation tests and anticoagulants, longer waiting times for INR testing and AMS service utilisation, and lack of trained professionals to provide AMS were among the most frequently cited drawbacks affecting AMS quality in the hospital studied.

The inadequate facilities identified in this study (lack of a dedicated anticoagulation clinic and a separate corner for coagulation testing), workload and overcrowding, long waiting and appointment times) may affect the quality of AMS. A study conducted by Anakwue showed that the structure of anticoagulation in Africa is poorly developed.[20]

Specialized anticoagulation clinics (AC) that use standardized procedures achieve better control of anticoagulation than UMC, where patients requiring anticoagulation are seen as part of the general patient population, which is not common in sub-Saharan Africa, including Ethiopia.[21] A study conducted at a Malaysian tertiary hospital by Thanimalai et al showed that patients in the warfarin medication therapy adherence clinic (WMTAC) had significantly higher actual TTR (65.1 vs 48.3%; $p < 0.05$), lower admission rate (6.5 vs 28.2 events per 100 person-years), and lower bleeding incidence compared with the UMC group.[13] Another systemic review and meta-analysis showed that the risk of hemorrhagic events and thrombotic events decreased significantly in pharmacist-led anticoagulation management groups compared with other management models.[5] Furthermore, a series of randomized clinical studies from elderly rural patients receiving warfarin in Croatia showed that pharmacist interventions improved median TTR significantly (93 vs 31.2% for intervention and control, respectively; $P < 0.001$),[22] report of lower cumulative incidence of adverse drug reactions in the intervention group (6-months rate 29% vs 85% for intervention and control, respectively;[23] and also improved health-related quality of life significantly in the intervention group by scoring lower to all domain of satisfaction questionnaire (median being 86.5 and 66.0 in the control and intervention groups, respectively; $p < 0.001$), indicating the higher health-related quality of life.[24]

Facility-specific protocols are critical to the delivery of optimal, high-quality AMS care by minimizing decision variability among working healthcare providers.[25,26] However, the current study found that essential work protocols for AMS care were rarely found in the hospital (Table 2). The lack of validated guidelines/protocols for the local population has been shown to lead to inconsistent practice among hospital prescribers, with a wide range of warfarin initiation doses being used and adjusted for non-therapeutic INRs.[27] This requires the collaborative work of experts from different disciplines who organize purposefully to develop and modify hospital guidelines and protocols.

Regarding the availability of INR testing in the study, issues were raised by physicians and patients. Both participants confirmed that the test is often unavailable on the hospital campus when they need it. Even when it is available, there is the problem of inconsistency and delayed reporting of INR results (long wait time), which discourages patients from taking the test and forces them to get tested from an outside source. When the test is from an external source, laboratories in Addis Ababa are not easily accessible due to lack of awareness, transportation, and other factors, INR testing is much more expensive in private laboratories than in government hospitals, and test results from external sources are not always reliable. Test calibration varies from laboratory to laboratory and standards of practice differ, so results may be biased.[28] These performance limitations impact prescribing physicians' timely and outcome-based anticoagulant dosing decisions.

To address the above service-related issues, INR testing should be performed from the point of care, a central laboratory should be established within the hospital, the waiting time for the INR test report should be shortened, and work should be done on the continuous provision of the testing service when available.[21] As commonly described by physicians and patients, the inadequate availability of anticoagulants such as warfarin in the study hospital forces patients

to obtain the drugs from private sources at high cost. Furthermore, this contributes to poor adherence and suboptimal anticoagulation outcomes, which may lead to thromboembolic events.[29]

Inadequate knowledge about anticoagulation, particularly about the interaction between warfarin and other drugs, was another challenge most frequently cited by physicians in providing the expected AMS. A study conducted by Dejene et al at the same hospital confirmed this finding, with only 9.8% of healthcare providers correctly answering the question about medications that may interact with warfarin.[17] Longer waiting times for patients requiring frequent follow-up and monitoring have been cited as a barrier to existing AMS services. However, many international guidelines and validated institutional manuals suggest a patient-specific INR monitoring frequency that takes into account factors such as duration since warfarin initiation, nontherapeutic INR levels, presence of medications that interact with warfarin, presence of disease, and comorbidities that affect INR levels.[6,13,26,30–36]

Provision of facilities for coagulation testing and anticoagulants, management of anticoagulation in a dedicated central facility, assignment of trained HCPs, SOPs, and timely counseling were the main solutions recommended by most HCPs involved in the study. Providing blood thinners and coagulation tests, increasing the number of trained healthcare professionals, and establishing dedicated (separate) rooms for AMS were also suggested as solutions by patients. This was reinforced by statements from the Anticoagulation Forum in its guidance on the core elements of anticoagulation stewardship programs.[37]

Regarding the overall assessment of the quality of AMS in the hospital, it was described as suboptimal by the majority of physicians. Similar quality concerns were frequently expressed by patients, citing poor anticoagulation counseling, prolonged unavailability of INR testing in the hospital, which affects anticoagulation monitoring and satisfaction with AMS, and poor control of anticoagulation, which puts patients at risk of developing warfarin-related complications such as thromboembolism and bleeding.[38]

The establishment of a PLAC in the hospital has been proposed by all HCPs to improve the quality of care for patients requiring anticoagulation therapy through targeted and efficient patient care, improved patient education and care, optimization of AMS, and incorporation of a multidisciplinary team approach. Studies from Saudi Arabia,[39] Malaysia,[13] Sudan,[40] China,[41] and Thailand[42] reported that the quality of AMS improved in patients in PLAC with a higher percentage of TTR compared with patients in UMC.

PLAC pharmacists provide patient education and pharmaceutical counseling to those who had been taking warfarin for a long period of time, but in whom the prothrombin time-i value was unstable and sometimes outside the target range. Accordingly, management, education, and counseling on anticoagulation therapy in ambulatory patients are critical for better treatment outcomes. A study conducted in Japan confirmed the pharmacist's pivotal role in providing information to facilitate patient education, positively influence appropriate anticoagulation therapy for AF, and improve patient satisfaction.[43] Improving AMS through the establishment and functioning of PLAC will be more effective if approached as a multidisciplinary team (consisting of pharmacists and physicians) working in the clinic and putting patients at the center of the process.[21] This has been supported by studies done elsewhere on anticoagulation management.[5,8]

Based on the findings from this study and recommendations from the literature on the importance of improving AMS, the PLAC was established in April 2018 at TASH. The Anticoagulation Protocol, which provides guidance on anticoagulation management, is used to support the work of the clinic. It is located in a multidisciplinary outpatient clinic of the hospital. Since then, she has been providing AMS two days a week (Tuesday morning and Friday afternoon) and counselling by phone to patients with non-therapeutic INRs who cannot wait for the next clinic day for warfarin dose adjustment. On average, 25 patients visit the PLAC daily, and each counselling session lasts about 10 minutes.

Strength and Limitation of the Study

Our study has some important strengths. It is the first study in Ethiopia to address the challenges of AMS and the need to establish PLAC, which can serve as a basis for establishing and expanding PLAC service to other hospitals in the country. This study identified gaps and opportunities for the establishment of PLAC in the hospital, which in turn helped us to start pharmacist-led anticoagulation patient care. In addition, the study attempted to include the views of HCPs and patients. On the other hand, the study also has some limitations. Although the researchers made every effort to interview key informants to obtain in-depth information about the topic under study, some of them were unwilling to participate (move or act with great haste) in the study.

Conclusions

This study identified the general challenges of AMS and the need to establish PLAC. In summary, the hospital's AMS is not optimal to provide adequate services during the study period. Based on the results of the current study and the experiences in other hospitals, the PLAC was established at TASH and provides anticoagulation care.

Abbreviations

AC, anticoagulation clinic; ACCP, American College of Chest Physicians; AVK, antivitamin K; DOAC, direct oral anticoagulant; INR, international normalization ratio; LMWH, low molecular weight heparin; NOAC, novel oral anticoagulants; PLAC, pharmacist-led anticoagulation clinic; PMAC, pharmacist-led anticoagulation clinic; TASH, Tikur Anbessa Specialized Hospital; TTR, total therapeutic range; UFH, unfractionated heparin; UMC, usual medical care; VTE, venous thromboembolism; WMTAC, warfarin medication therapy adherence clinic.

Ethical Approval

Ethical approval was obtained from the Ethics Review Committee of the School of Pharmacy, College of Health Sciences Addis Ababa University (approval number: ERB/SOP/27/10/2018). Informed consent was obtained from all participants prior to participation in the study. The participants informed consent included publication of anonymized responses.

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Disclosure

The authors report no potential conflicts of interest related to the research, authorship, and/or publication of this article.

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