



AMERICAN UNIVERSITY OF BEIRUT

PROPOSAL FOR ESTABLISHING A NURSE-LED  
INTERNATIONAL NORMALIZED RATIO OUTPATIENT CLINIC  
AT THE AMERICAN UNIVERSITY OF BEIRUT MEDICAL  
CENTER

by  
AHMAD GHADDAR

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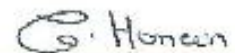
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# AN ABSTRACT OF THE PROJECT OF

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Title: Proposal for Establishing a Nurse-Led International Normalized Ratio Outpatient Clinic at The American University of Beirut Medical Center

Anticoagulant's use is common for treating and preventing cerebrovascular accident, cardiac disease, and thromboembolism in the outpatient setting. The use or misuse of these anticoagulants by patients, can lead to a significant harm despite its significant benefits. The risk of thromboembolic or bleeding complications will be increased with sub therapeutic or serotherapeutic levels relatively, as well as the healthcare cost. The direct and indirect cost of pulmonary embolism associated with atrial fibrillation for 177 patients over 2 years is equal to 13.6 million dollars (Hannon et al. 2014). Laboratory monitoring such as the International Normalized Ratio (INR) is the main constituent for a safe management of anticoagulant therapy.

Not all out-patients at the American University of Beirut Medical Center who are maintained on anticoagulant therapy are being managed and closely followed-up from a centralized operation. Establishing an out-patient nurse-led international normalized ratio clinic is believed to be necessary to achieve optimal patients' outcomes. According to the literature, INR clinics managed by nurses can reduce patients' hospitalizations, complications and emergency room visits and hence reduce overall costs. To obtain a systemic process in the clinic, nurses should be well trained, follow a pre-printed protocol for managing anticoagulant dosing, adhere to a follow-up system and patient education.

It has been proven that patients spend more time within their therapeutic target range when followed by an INR nurse-led clinic than a hematologist, in addition nurses are superior in managing patients newly maintained on anticoagulants. Furthermore, patients spend more time with the nurse discussing several aspects for their treatment which will lead to better patient education and knowledge.

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# CHAPTER I

## INTRODUCTION

Many diseases including congestive heart failure, atrial fibrillation, and valvular heart diseases require anticoagulation treatment to prevent venous thromboembolism (VTE), commonly known as blood clotting. VTE are two types: pulmonary embolism and deep venous thrombosis. Deep vein thrombosis occurs when a blood clot is formed in one of the deep veins of the body, mainly in the legs (Mayo Foundation for Medical Education and Research [MFMER], 2016). Pulmonary Embolism is a life-threatening event which happens when one of the pulmonary arteries in the lungs are blocked by blood clots coming from the legs or other parts of the body (MFMER, 2016).

In Europe, the overall annual incidence of VTE is between 100 – 200 per 100,000 and it is considered the third most prevalent cardiovascular disease (Konstantinides et al. 2014). In the United States, nearly one million cases are diagnosed with VTE each year many of which are recurrent (Anderson et al. 1991). Lee, Stephen, Agarwal, and Premkumar (2009) found that in 2009, the incidence of venous thromboembolism in India was 17.6 per 10,000 of hospital admissions. In Brazil, it is estimated that the annual incidence is 1 to 2 cases per 1000 inhabitants (Ferriera et al. 2013).

Predisposing risk factors for VTE include fracture (hip or leg) with a VTE incidence rate of 45%, hip or knee replacement (50%), major trauma (56%) and spinal cord injury (38%), and finally major general surgery of which its incidence rate depends on the type of surgery, age of

patient, the required general anesthesia time and amount of bedbound time after the surgery  
Frederick et al. 2003.

One of the most serious clinical presentations of venous thromboembolism is pulmonary embolism (PE). Pulmonary embolism symptoms are typically nonspecific and include sudden occurrence of shortness of breath, sudden sharp chest pain that worsens with breathing, tachycardia, tachypnea, sweating, palpitations, hemoptysis or fainting. PE is considered the major cause of hospitalization, morbidity among VTE patients. In a retrospective cohort study done in the US between 1999 and 2010 on adults aged 65 and above, showed that PE hospitalization rate has increased from 129/100,000 person-years in 1999 to 302/100,000 person-years in 2010; which is equal to an increase of 134% (Mengis et al. 2015). The study also stated that the mortality rate as a consequence of PE decreased but remained high (Mengis et al. 2015). This increase in hospitalization rates and continued high mortality rate confirm the substantial burden of PE on older adults. Similarly, Konstantinides et al. 2014 showed that 317,000 deaths were related to PE in 2004 in Europe.

The impact of PE on patient outcome is associated with an increase in cost of health services. Hannon et al. 2014 calculated the direct and indirect cost of PE associated with atrial fibrillation in 177 patients over 2 years to be equal to 13.6 million dollars. It is estimated that the lifetime cost of PE in Australia's Northern Territory in 2012-2013 was 207,218 USD per patient (Zhao, Condon, Lawton, He, & Cadilhac, 2016). Patients' readmission, emergency department visits, private physicians' clinic visits and even deaths are the indirect effect of suboptimal anticoagulation management, which have significant financial burden on third party payers.

Prevention of PE is possible. Warfarin, an anticoagulant medication, is often used for the prevention or treatment of PE, venous thrombosis, and thromboembolic complications related to

atrial fibrillation and cardiac valve replacement. Moreover, it is used to reduce the risk of death after an event of recurrent myocardial infarction. It is a prescribed treatment for many patients whether they are in hospitals, long-term care and outpatient setting. Many patients after initial treatment are maintained on warfarin long term therapy (Du Breuil & Umland, 2007).

Further, a blood clotting test, called the international normalised ratio (INR), is required to gauge the dose of Warfarin. A target INR is assigned for each patient based on his/her medical condition and maintained within an acceptable range of +/- 0.5 units. Exceeding those limits may lead to a thromboembolic event such as stroke (if under anti-coagulated) or the risk of bleeding (if over anti-coagulated). Surgeries, medical procedures, antibiotics, changes in diet, and transitions in care can complicate warfarin treatment efforts and entail a continuous monitoring and dosage changes. As a result, care coordination through unified delivery system is vital to the management of these patients.

Evidence-based guidelines recommend using the proportion of time in the therapeutic range (TTR) to control coagulation while the patient is on warfarin. One approach to calculate the TTR is the Rosendaal's method, where it takes into account the number of days between the INR tests. Hence, a line is drawn from the previous test result to the current test result and the number of days in which that line falls within the range is counted (Cannegieter et al. 1995). Based on the international guidelines and recommendations, TTR should be maintained of at least 60% in order to limit the warfarin's risk of adverse effect and maximize its benefits (Shaw, Harrison & Harrison, 2011).

Warfarin therapy is widely used worldwide. For example, in British Columbia, Canada, one percent of the general population require anticoagulation treatment using warfarin (Saokaew, Permsuwan, Chaiyakunapruk, Nathisuwan, & Sukonthasarn, 2010). Though warfarin therapy is

able to decrease the rate of thromboembolic events, not every patient obtains the full benefits of this therapy because of inadequate communication, ineffective management or poor patient adherence (Schillinger, Wang, Rodriguez, Bindman, & Machtinger, 2006).

Lindh, Holm, Dahl, Alfredsson, and Rane, (2008) showed that 2.3 percent of patients on warfarin experienced severe bleeding. It was revealed from the US death certificates in 2003 and 2004 that anticoagulants ranked first in the total number of deaths caused by drugs' adverse effects. (Wysowski, Nourjah, & Swartz, 2007). Deaths due to anticoagulant complication ranked first as a leading cause of death in United States (Wysowski et al. 2007). Furthermore, around 29,000 patients on warfarin visited the emergency room due to bleeding complications between 1999 and 2003 (Wysowski et al. 2007).

Askey and Cherry indicated that the successful use of anticoagulation depends on three factors: an attentive physician, a cooperative patient, and a reliable available laboratory. The physician should be fully focused on his patient and listen to every concern and every single detail the patient might be saying, like symptoms of bleeding, so that not to miss important information. At the same time, the patient on anticoagulation therapy should show responsibility which is characterized by taking his anticoagulation therapy as per prescription, and doing his INR tests on the specified dates. Finally, continuous quality checks should be done on the laboratory to ensure accurate results and proper handling of patients' blood samples.

More recently, different novel services for managing patients on anticoagulation therapy are being developed. Traditionally, primary physicians were responsible for ordering the blood test, following-up on the result, adjusting the dose and finally contacting the patient to inform them about the adjustment. Novel approaches propose either pharmacy-led INR clinic or nurse-led INR clinic. In a pharmacy-led INR clinic, pharmacists are delegated by the primary physician

and authorized via an authority agreement to perform INR testing, review results and conduct dose adjustments; however, the primary physician can still retain responsibility for the overall management and has the right to intervene any time. Patients who are enrolled in this clinic should be referred by their physician and should sign a consent form. Whereas, in a nurse-led INR clinic the nurse takes responsibility for INR interpretation and dose adjustment following a pre-set algorithm. Atypical cases are referred to a consultant cardiologist for advice and management.

Wilson et al. 2003, conducted a retrospective randomized controlled multicentre trial in Canada between January 1998 and September 2000 to compare the management of oral anticoagulation therapy between anticoagulation clinics managed either by pharmacist or physicians. Two hundred twenty-one patients were enrolled and randomly assigned: 112 to anticoagulation clinics managed by pharmacists and 109 to family physicians. The results showed that INR values for patients managed by anticoagulation clinics were within the therapeutic range 82% of the time against 76% for those managed by family physicians with a P value equals to 0.034. Moreover, it was observed that high-risk INR values ( $< 1.5$  or  $> 5$ ) occurred in 40% of patients managed by family physicians versus 30% among patients managed by the anticoagulation clinics with a P value equal to 0.005. In addition, patients followed by family physicians had more INR measurements than those followed by the anticoagulation clinic (13 v. 11,  $p = 0.001$ ). Finally, the patients reported in their satisfaction questionnaire that they were more satisfied when followed by the anticoagulation clinic than by their family physician with a P value equal to 0.001.

According to Saokaew et al. 2010 a pharmacist-led anticoagulation management service has resulted in reduced incidence of warfarin-related hospital admission, improved patient



compliance and satisfaction, enhanced anticoagulation control and decreased the frequency of drug interaction. Studies by Bond and Raehl in 2004 and Dager et al. 2000 showed that inpatient anticoagulation management services led by pharmacist resulted in decrease length of stay, lower rates of bleeding, lower Medicare charges and lower inpatient mortality rates. They also found that a pharmacist-managed warfarin dosing services have proved to out-perform physician-managed care and hence estimated to deliver significant savings in costs.

In most developed countries, such as the United States of America, Canada and the United Kingdom, hospital-based anticoagulation clinic led by nurses have better patient outcomes when compared to standard care management by general practitioners (Ansell et al. 2008; Baker, Cios, Sander, & Coleman, 2009; Connor, Wright, & Fegan, 2002).

A retrospective comparison study done by Obeid et al. 2016, which included 94 patients registered in the Nurse Led Prosthetic Valve Anticoagulation Clinic (PVATC) in King Abdul-Aziz Cardiac Center between April and June 2013. For a period of one year prior to their enrollment in PVATC, these patients received warfarin by general cardiology clinics. The proportion of time in therapeutic range (TTR) of the international normalized ratio (INR) was calculated and compared between pre-and post PVATC enrolment. The mean TTR was equal to 72% pre-enrollment in PVATC in comparison to 78.9% after with P value < 0.006. In addition, the median TTR was 75% pre-enrollment and 81.5% after attending the PVATC with a P value < 0.0001.

A quasi-experimental study was conducted by Amiri, Kargar, Borhanihaghighi, Soltani, and Zare, (2017) in the nurse-led warfarin clinics affiliated with Shiraz University of Medical Sciences on 80 ischemic stroke patients, where 40 patients were assigned to the control group and 40 in the experimental group. The mean standard deviation of the intervention was 144 +/-

84 days. The INR of 39 patients in the control group and 38 in the experimental group was between 2-3 which is considered within the therapeutic range. The control and the experimental group had a TTR of 44.58% +/- 25.12 and 64.08% +/- 18.7 respectively with a P value < 0.0001. While the percentage of total INRs within the therapeutic range was 40.6% in the control group and 52.5% in the experimental one with a P value equal to 0.001.

#### **A. Aims**

At the American University of Beirut Medical Center, INR test is a standard practice for patients on Warfarin. Patients present to the laboratory for blood collection, await their results in order to contact their physician for further instructions; some may require weekly testing. Barriers for compliance include wait time to obtain results, taking time off to visit the clinic and transportation challenges, particularly for patients with limited mobility. Consequently, the risk of complications increases resulting in an increase in financial cost incurred by the Ministry of Health and private insurance companies, Health Insurance Plan program at AUBMC and in some out-of-pocket payments.

We expect that the development of a nurse-led INR clinic at the American University of Beirut Medical Center (AUBMC) will assist in meeting a current care need and will expand access to care for AUBMC's patients. The INR clinic will potentially provide effective, safe, timely and patient centered care for patients using the service.

The aim of this project is to propose a protocol for establishing a nurse-led anticoagulation clinic that delivers high quality service for patients maintained on anticoagulants at AUBMC.

#### **B. The specific objectives are:**

1. To establish a one-stop shop for managing patients on anticoagulation therapy starting from patient's assessment and ending with adjusting the anticoagulation dose if necessary.
2. To ensure constant management and follow-up of care to patients receiving anticoagulation therapy.
3. To offer reliable education to the patients and/or family member regarding anticoagulation therapy.
4. To continuously identify non-adherent patients with their anticoagulation therapy's care plan and improve adherence by providing intensive information sessions, in order to decrease anticoagulation adverse effects.
5. To sustain a complete documentation for each patient on the care provided in the clinic.

## CHAPTER II

### LITERATURE REVIEW

A thorough literature review was conducted in order to discover best practice recommendations and available operational considerations for writing a protocol for a nurse-led anticoagulation clinic. The review addressed the following points, staffing considerations and necessary key players to ensure the clinic's success; organisational and operational input for providing high quality service; best practice standards and the identification of certain factors that contribute to health outcomes for patients maintained on anticoagulation therapy.

#### **A. Setting and multidisciplinary team**

Bungard, Grant, Ackman, and Tsuyuki (2008) performed a survey to describe the key operational characteristics of some anticoagulation management services in North America. 118 ambulatory clinics completed the survey which showed that 68% of the clinics had one full time equivalent (FTE) pharmacist and 38% had an FTE nurses, 19% had physicians working a median of 0.3 FTE and 3% had physicians' assistants working a median of 0.5 FTE. Clerical support was present in 26% of the clinics with 0.7 FTE as median.

In another anticoagulation, primary care setting in the United Kingdom which is managed by registered nurses, all elements of care were provided by the practice nurse with an available support from a general practitioner when needed (Parry, Fitzmaurice, & Raftery, 2000). In this ambulatory clinic, the operational nurse withdraws patients' blood, tests the sample using

Thrombotrak near-patient testing device and with the help of the computer decision support software Coventry the drug dosage is managed.

The anticoagulation clinic in Ochsner main campus is a pharmacist-led one, which is staffed with a full time clinical pharmacist that serves as a director for the clinic. In addition to a full-time pharmacist, a registered nurse, five medical assistants and a data entry clerk. The medical assistants' role is to manage the patients who receive their lab results from other clinics over the telephone. The pharmacist or the nurse consult and manage the patients who uses the clinic to obtain their blood result. A cardiologist also serves as the administrator of the clinic, who reviews the decisions of dosage adjustments made by the pharmacist and the nurse, after receiving an electronic note for each patient at the end of the day (Barrios, Ventura, & Milani, 2002).

## **B. Staff Training**

In an article by Brown et al. 1998, described the training process and the educational sessions for the two anticoagulant nurse specialists who were going to run the clinic, and who had 15 years of nursing experience each. The consultant hematologists assigned a three months training package including the following topics: the normal process of coagulation and the mode of action of warfarin and its indication; pharmacology, drug interaction, risks and side effects; general practitioner liaison; patient education; initiating anticoagulation treatment; practical demonstrations of blood testing in a laboratory setting; managing patients with assigned surgical or dental procedures; reversal of anticoagulation. These topics were delivered by the consultant hematologist, a pharmacist, and a laboratory staff each based on his specialty. An administrative staff had also introduced the hospital information system in a separate lecture. At the end of this

training period, both nurses underwent a formal assessment to evaluate their level of knowledge, understanding and competence to practice.

Francavilla (2008) stated that the registered nurses in the anticoagulation clinic were required to complete a certified program which was developed and administered in one of the academic institutions such as University of Southern Indiana, College of Nursing and Health Care Professions.

In order to optimize the anticoagulation therapy, healthcare professionals providing the service should be licensed in a patient-oriented field like nursing, having the core competency related to this therapy (Garcia et al. 2008). Additional training is recommended for these professionals, since anticoagulant therapy is complicated and may lead to substantial risks. The above-mentioned training should be given in the work environment through an experiential training program. The training covers topics regarding applied physiology and pathophysiology of thromboembolic agents, patient assessment and management, patient education, applied pharmacology and antithrombotic agents. An elaboration on the training topics are found in Table 2.1 below (Garcia et al. 2008).

Core training topics
<ul style="list-style-type: none"> <li>Applied physiology and pathophysiology of thromboembolic disorders: working knowledge regarding the normal physiologic processes of hemostasis and thrombosis and the etiology, risk factors and clinical manifestations of pathologic thrombus formation</li> </ul>
<ul style="list-style-type: none"> <li>Patient assessment and management: knowledge, skills, and competencies to manage and monitor patients on anticoagulant therapy including the ability to assess the efficacy and toxicity of the prescribed anticoagulant treatment, determine whether the therapeutic goals have been achieved, and identify patient related variables that affect therapy</li> </ul>
<ul style="list-style-type: none"> <li>Patient education: ability to provide patient education that is tailored to patients' specific needs to promote safety, enhance adherence, and possibly affect clinical</li> </ul>

outcomes, perform an educational assessment, develop an educational plan, and document the educational activities in the patient's medical record
<ul style="list-style-type: none"> <li>• Applied pharmacology of antibiotic agents: in-depth knowledge regarding the pharmacologic properties of all antithrombotic drugs</li> </ul>

### **C. Roles of the anticoagulant nurse specialist**

Mackie (1995) has mentioned in his article several roles to be played by the nurse running an anticoagulation clinic, like prescribing warfarin to the patients with the physician, communicating INR results to the patients and adjusting their doses if necessary, contacting the patients giving advice or information.

In another study by Brown et al. 1998, several responsibilities for the anticoagulation nurse specialist (ANS) were identified some of them were to: see and educate patients on anticoagulation treatment, adjust warfarin dose after INR result assessment, manage anticoagulation dose prior to surgical procedure, manage anticoagulation adverse effects, provide advise on diet, act as a liaison with the general practitioner and other healthcare professionals, follow up on patients who fail to return for INR check-ups and maintain patients records. However, prescribing warfarin was kept as the haematologists' responsibility.

Moreover, in an article entitled "Registered Nurse-Managed Anticoagulation Clinic: Improving Patient Outcomes", Francavilla (2008) listed the roles of nurses running the clinic which contained but not limited to the authority and autonomy to run the clinic. In addition to another critical component of these roles which is patient education.

Some of the anticoagulant nurses' roles practiced in the clinic were, maintaining patients' records such as listing their current drugs, educating patients especially on the effect of other medications on the anticoagulation process and health shop remedies (Taylor et al. 1997).

#### **D. Patient Selection**

Based on the Geerts et al. 2008, several indications for increased clot risk were published, in addition to the target INR for each indication. Patients are enrolled in the clinic for an INR target between 2 and 3 if they experience pulmonary hypertension, having a mechanical aortic valve, having antiphospholipid antibody syndrome, for secondary prevention of systemic arterial embolism, or had experienced recurrent DVT/PE especially postoperatively. Moreover, patients can be also enrolled and having an INR target range between 2.5 and 3.5 if they experienced recurrent thromboembolism while maintained therapeutically on warfarin, or if having a mechanical prosthetic valve in the mitral position or ball and cage valves in any position.

#### **E. Patient Assessment**

The initial assessment must include a complete medical history, family history of clotting disorders or bleeding, employment profile, lifestyle, medications, level of understanding, health beliefs, and healthcare resources. Caregivers and their patients should discuss the risks and benefits accompanied with anticoagulation therapy and agree on the initiation or continuation of therapy (Garcia et al. 2008).

#### **F. Documentation**

Accurate and accessible documentation systems must be available in order to retrieve any information related to anticoagulation therapy in a timely manner (Garcia et al. 2008). Paper forms can also be used to meet anticoagulation monitoring needs, which include information such as the demographics of the patient, in addition to several information regarding the treatment, etc. (Garcia et al. 2008). Moreover, the documentation system must facilitate the access to quality assessment information, such as rates of thromboembolic events, major



bleeding, percent time-in therapeutic range and total deaths (Garcia et al. 2008). Trends in the number of patients attending the clinic should also be documented, to assess staff and resources needs (Garcia et al. 2008).

### **G. Care Management and Coordination**

Written policies and procedures for managing anticoagulation therapy must be established by the healthcare professional who will be responsible for providing the anticoagulant care (Garcia et al. 2008). These policies and procedures will reduce variability in the care being delivered. They need to be reviewed, updated whenever evidence becomes available, and approved by appropriate committees regularly, then disseminated throughout the medical center (Garcia et al. 2008). The information addressed by the policies and procedures should include but are not limited to: patient's understanding, risks and benefits of therapy, target INR values, indications, planned duration and managing of therapy, documentation of adverse events, timely reporting of lab results, protocol for follow-up of missed appointments, managing transitions in care.

### **H. Initiation of therapy**

Another prominent step in managing anticoagulant service is establishing system-wide evidence-based protocols which clearly define the steps to be taken when therapy needs to be initiated, or when any changes to this therapy is to be done. The initiation of an anticoagulation therapy should guarantee that therapeutic doses of anticoagulants are attained in a timely manner and the supra-therapeutic risk of INR values is minimized (Garcia et al. 2008). Several clinical guidelines are in use after being established, reviewed and published. These guidelines and protocols ensure the coordination between providers within the system, which help them to use

the same tool. The practice guidelines published by the American College of Chest Physicians in 2012 aim to manage vitamin K antagonist and the prevention of thrombosis, which both outline the clinical practice recommendation for managing anticoagulated patients (Holbrook, 2012).

In 2008, the manager of the John Hopkins Anticoagulation Clinic has created practice limits for the nurses in the presence of a limited dosing algorithm and physician referral order. A new concept was added to the algorithms to include what was named “removable causes”. These causes include an increase/decrease in vitamin K consumption, alcohol use, missed/extra doses and other causes. These removable causes were added to the algorithms to aid nurses in decision making. The purpose of this innovation is to standardize the decision made by any healthcare provider using the same guide. When dosing requirement do not fall within the algorithm recommendation the nurse practitioner or the physician is consulted to assist the nurse with the plan of care (Hefter & Stack, 2011).

Patients were referred to the INR outpatient clinic by junior hospital doctors after filling a special form containing clinical information such as diagnosis, coexisting medical conditions, investigations, medications and warfarin dose (Brown et al. 1998). The author also reported in their article that clear guidelines, protocols and limitation to practice were developed by the haematologists and ANS’s, in order to ensure effective process implementation and safe practice.

Furthermore, protocols for the nurses’ use while managing the therapy were written in collaboration with the medical director of the clinic, based on evidence-based guidelines from the American Colleges of Chest Physicians, (Francavilla, 2008). These protocols were structured in a way that fostered autonomous decision making by the nurses.

## **I. Maintenance of therapy**

Follow up evaluation of an anticoagulation therapy should mention changes in lifestyle like diet, medication, adherence and health status (Garcia et al. 2008). Some rare cases, need to increase their target INR by 0.5 – 1 especially those who develop a clot while on therapeutic warfarin. For patients who are at fall risk, their target INR may be reduced to 1.5 since they have a high risk for bleeding. When there is a high risk of developing a TE, patients are advised to have a life-long anticoagulation therapy. Patients with massive pulmonary embolism are recommended to have a long-term therapy. When the clot risk is transitory or a result of a provoking event; such as DVT after hip replacement surgery; the patient is usually recommended for a short-term therapy (3 – 6 months). As a conclusion, if the clot is believed to be provoked or unprovoked strongly influence the duration for the therapy. It is very important that the clinician keeps in mind that the risk of complications whether its thrombosis or bleeding for a patient might change over time, hence the indications for target INR and treatment duration must be re-evaluated.

## **J. Patient Education**

Patient education is the cornerstone of safe and adequate anticoagulation management; where accurate knowledge of nutrition, drug interaction and co-infection diseases should be covered (Gurwitz et al. 2007). Patient's safety is increased when patients involved are educated, understand, and are responsible for their self-care (Garcia et al. 2008). The education can be done through a face to face interaction, the use of written materials or reinforced with audio-visual resources.

According to the Clinical Guidelines for Advanced Practice Nursing, the most frequent cause of INR change would be the oral vitamin K intake which can be found in dark green leafy vegetables such as spinach. At every visit to the anticoagulation clinic, the patient should be

reminded with the role of vitamin K in warfarin management and his oral vitamin K intake should be assessed and reinforced about some common vitamin K rich food. Moreover, patients should be educated about the unpredictable effect on the INR, since chronic alcohol use tends to lower the INR whereas acute consumption tends to increase it. Furthermore, the patient should be educated on the effect of comorbidities on warfarin. For example, changes in the liver, cardiac or thyroid functions may alter the individual's warfarin dose required. Moreover, educating the patients regarding the possibility of a drug interaction with warfarin is important. Patients are educated to report any acute illness, change in medicines, or new medicines. In addition, special accurate and enforced education should be given to patients regarding pain medications and especially NSAIDs, since they tend to increase the gastrointestinal bleed (Collins-Bride, Saxe, Duderstadt, & Kaplan, 2016).

Amiri et al. (2017) conducted a study tackling the effect of a nurse-led anticoagulation clinic on time spent of patient's INR in the therapeutic range. Patients received a special training covering the following topics, drug-drug interaction, diet tailored to anticoagulation therapy, anticoagulants' use in special situations such as pregnancy, lactation, or menstruation in women. In addition, they were informed about the risk of performing a surgical procedure while maintained on warfarin.

In another study entitled Evaluation of a Nurse Specialist Anticoagulation Clinic by Taylor, Gaminara, Cohen, Ramsay and Miller (1997), patients were tested for several anticoagulant knowledges at different occasions during the study. Some of the questions tackled the topic of changing the dose of a medication other than warfarin and its effect on anticoagulation or the impact of health shop remedies on homeostasis function. Furthermore, Brown et al. 1998, noted in their article "Setting up a nurse-led anticoagulation clinic" that an

educative leaflet for patients was developed including information about warfarin side-effects. In addition, an education checklist was formed and kept in the patient records to mark the educational topics covered.

Varney (2014) has developed an implementation plan for an anticoagulation management service and has used a knowledge tool which contain several questions that target the patient knowledge of anticoagulation therapy.

### **K. Patient role**

Two important patient's roles in INR management were identified: patient's adherence to medication regime, and compliance in INR monitoring.

Warfarin sodium is a commonly used drug with a narrow therapeutic index which is expected to be problematic if inadequate patient adherence was present (Hing, Cherry, & Woodwell, 2006). A study conducted by Kimmel et al. 2007, targeting patients' adherence to warfarin therapy showed that under adherence was significantly associated with under anticoagulation, but not over anticoagulation; where under coagulation is referred to INR values below the target range. The associations between under adherence and under coagulation was statistically significant in which for each 10% relative increase in missed doses there was a 14% increase in the odds of under anticoagulation with a P value < 0.001 (Kimmel et al. 2007). In addition, over adherence was associated with over anticoagulation where participants who had extra doses in more that 10% of the days had a significant increase in elevated INR levels (Kimmel et al. 2007).

Kauffman, Schroeder, and Witt (2015) conducted a qualitative study to figure out the specific reasons underlying patients' non-adherence to their INR monitoring. This qualitative

study suggested certain strategies to improve adherence to INR testing which are, assign the same anticoagulation providers to work with the patients, provide INR reminders, avoid lecturing patients following missed tests, reinforce patients after INR monitoring, make INR testing accessible.

## **L. Quality indicators**

It is necessary to set quality indicators, in order to evaluate the process, structure and outcomes of the clinic (Hefter & Stack, 2011). These indicators are important to minimize potential harm and maximize effectiveness (Rose, Berlowitz, Frayne & Hylek, 2009).

Effectiveness, efficiency and classification of outcomes are attributes of quality care.

Effectiveness can be determined by comparing the attained improvements to best practices, like comparing the achieved percentages to benchmark statistics. Efficiency can be defined as lowering the cost of service without affecting its' quality. It is suggested that efficiency can be improved by raising the provider's skills, knowledge and judgement. Finally, the classification of outcomes does not only include the abnormalities of diagnostic testing (INR) but also the patient satisfaction, and coping skills of the patient and nurse (Block, 2006).

Moreover, Tylor et al. (1997) discussed the efficacy of a nurse specialist anticoagulation service which is aided by the Hillingdon computer dosing system, where the patient used to take instructions either by post or by telephone. It is worth mentioning here that the system has an over-ride dosing option which is used only when patients require specific dosing instructions prior to a surgical procedure or a dental appointment.

The most widely recognized quality metric to evaluate patients on anticoagulation management is the time in therapeutic range (TTR). Remarkable research has been done on the strong correlation between TTR and patient outcome and mortality rate. More time spent out of

therapeutic range was associated with an increase in hemorrhagic and thrombotic incidences (Phillips & Ansell, 2008; Witt, Sadler, Shanahan, Mazzoli, & Tillman, 2005). It is recommended that the frequency of INR testing is four weeks when stable and a minimum of every two weeks when unstable (Phillips & Ansell, 2008). Once dosing has been developed and the INR has been within the target range for more than three months, INR testing can be performed every eight to twelve weeks (Holbrook et al. 2012). Another accepted and reported quality metric is the adverse events incidence rate, which include hemorrhage and thromboembolism. It is suggested that the overall rates of hemorrhagic and thromboembolic events should not exceed 1 or 2% per patient year (Phillips & Ansell, 2008).

#### **M. Measures of cost-effectiveness or cost-opportunity**

Aziz, Corder, Wolffe, and Comerota, (2011) performed a study to compare the costs anticoagulation monitoring for patients receiving routine physician care (group I) versus anticoagulation service (group II). The cost of hospitalization and ED visits were documented for each patient and the average cost for each patient was documented during a six months' study. Results showed that 10.9% of patients in group I sought the ED; the average cost of ED visits was 288\$ and 31\$ is the average cost per patient treatment. On the other hand, the percent of patients requiring ED visits was 1.5; the average cost of ED visits was 139\$ and the average cost per patient treated was 2\$. Hence, the anticoagulation management service resulted in a 58\$ of annualized savings per patient or 5,800\$ per 100 patients.

In the same study, the researchers have compared the hospitalization costs between the two groups which showed that 12.8% of group I were admitted with an average cost equal to 15,125\$ and 1,929\$ for each patient. The results of group II showed only 2.3% were admitted with an average cost of 17,794\$ and 401\$ for each patient. As a result, the annual reduction in

hospitalization expenses for patients managed by the anticoagulation service was 3,056\$ or 305,600 per 100 patients.

Furthermore, the annual expense of staff required to treat 100 patients was 70,000\$ not taking into account the physician's time (Aziz et al. 2011). Finally, the annual net savings for 100 patients was equal to 241,000\$, after subtracting the cost of personnel from the ED costs and hospitalization costs savings.

Lynas (2013) has analysed the costs among patients maintained on warfarin while being treated either via standard care or in pharmacy-led anticoagulation clinic setting using a point of care testing (POCT). It appeared that the cost for anticoagulation monitoring per patient over five years receiving standard care is 24,000\$ comparing to 19,000\$ for those receiving POCT, a 5,000 \$ of cost avoidance over a five-years period for patients receiving POCT managed by healthcare staff.

Sullivan, Arant, Ellis, and Ulrich (2006) have compared in their study the lifetime societal costs for patients receiving anticoagulation management via usual care versus anticoagulation services, where dedicated specialized professionals like physicians and pharmacist monitor and oversee the patients. It was concluded that the anticoagulation services have reduced the costs by a mean of 2,100\$ per patient compared with usual care.

In 1998, Chiquette, Amato, and Bussey (1998) has performed a similar study to compare the cost of an anticoagulation clinic(AC) supervised by a clinical pharmacist with usual care. The cost of hospitalization and ED visits were reduced in the group of patients being managed by the AC by 73%. This hospitalization reduction with the patients attending the AC yielded an annual saving of 128,937\$ per 100 patients. Moreover, the annual savings due to ED visits for the same



group were equal to 3,149\$ per 100 patients. Therefore, the annual cost savings for the AC group was 132,086\$ per 100 patients.

In addition to the savings related to anticoagulation, there was also savings which are unrelated to anticoagulation. The study revealed that emergency department visits regarding prescription refills and other unrelated causes for the AC group patients were reduced, which yielded for an annual saving of 29,972\$ per 100 patients. As a result, the total annual savings were equal to 162,058\$.

## CHAPTER III

### STUDY MOTIVATION

At the American University of Beirut Medical Center (AUBMC) there is an oral anticoagulation management clinic under direct supervision of one of the cardiologists. This clinic operates from the outpatient private clinic, where each nurse works with a group of physicians and is responsible of managing the INR and adjusting the dose of the oral anticoagulation drug accordingly. All patients are referred to this clinic by either their cardiologist or a physician from the pulmonary team. Once the patient is referred to the anticoagulation clinic, the physician will advice him to follow up with his assigned nurse. In case the patient performs his INR test in a laboratory outside the premises of AUBMC, the patient is held responsible to communicate his/her test result with the designated nurse who will adjust the medication according to a preprinted protocol. In another scenario where the patient performs INR in one of AUBMC laboratories, the nurse will follow up on the result and contact the patient for dose adjustments if necessary and inform him/her with the upcoming test date. All the results and dosing adjustments are documented in an e-sheet message and placed in the patient's file after the primary physician signs it.

## CHAPTER IV

### PROPOSAL

This proposal requests the approval of establishing a nurse-led anticoagulation clinic in the outpatient services at the American University of Beirut Medical Center. An advanced practice nurse who is trained on all aspects of anticoagulation therapy will be managing the clinic. This clinic will serve patients maintained on long term anticoagulation therapy, especially patients with artificial heart valves, or had experienced a heart attack or stroke, in addition to patients suffering from atrial fibrillation. The anticoagulation therapy of these patients will be monitored and adjusted regularly when necessary by the advanced practice nurse based on a specific protocol. Moreover, patients will be educated on several topics related to his therapy like drug-food interaction, drug-drug interaction, etc.

#### **A. Staff training**

An effective anticoagulation service needs a coordinated and systematic patient care management by well-trained professionals. An extensive online module composed of two sections; a medical and an administrative one, must be provided to the Advanced Practice Nurse (APN). The module's period is 40 hours; where the medical section constitutes of 30 hours and the administrative one is 10 hours. The medical section will cover the following topics.

- 1.* Patient assessment
- 2.* The population requiring chronic use of anticoagulation therapy.
- 3.* Pathophysiology and physiology of thromboembolic agents.

4. The process of coagulation.
5. Interpreting patients' INR and adjusting the anticoagulant dose accordingly.
6. Drug-drug interaction and side-effects.
7. When and why an anticoagulant is prescribed, and initiated.
8. How to handle patients with dental or surgical procedure.
9. Diagnostic tests.
10. Providing patients' education.

The administrative part will be also taken by the clinic assistant and covering the following topics.

1. Managing patients' appointments.
2. Acquiring the liaison with the general practitioner.
3. Ordering the clinic's store items.
4. Training on specific software like SPSS, Wintime and Store.

At the end of the module an assessment will be filled to determine the staff's level of knowledge and competence of practice.

## **B. Coaching**

During the first six months of establishing the clinic, the service should be overlooked by a cardiologist. His role will be limited to providing advise when needed and ensuring proper management of the clinic, in terms of following the anticoagulation protocol by the APN properly. This coaching period will ensure smooth transition from the current practice (Physician-led care) into the proposed one (Nurse-led care).

## **C. Staffing**

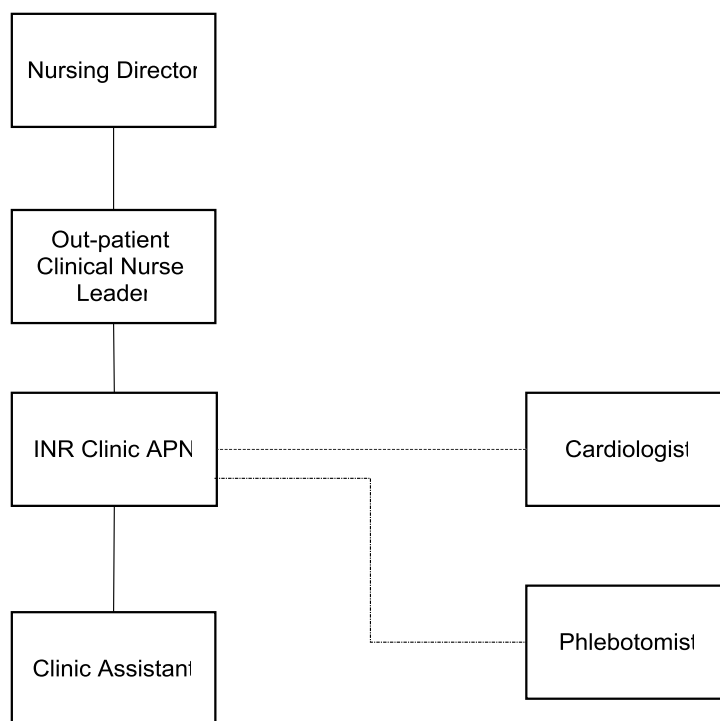
A well-established anticoagulation outpatient service needs to be reasonably staffed with competent members. As a start, the service will be staffed with an advanced practice nurse, 1 clinic assistant and a phlebotomist. All three will be working on part time basis three days a week, Monday, Wednesday and Friday. I have chosen an advanced practice nurse and not a registered nurse to run the service, because she is supposed to be better prepared to manage a service due to her graduate studies. In addition, an advanced practice nurse will have a better perception from the patients, physicians and the community when managing such a clinic. Finally, she will be perceived as someone who is competent, knowledgeable, experienced and trusted.

Assuming there are 500 patients that are eligible to attend the anticoagulant clinic at the American University of Beirut Medical Center. Based on the literature each patient should be seen by the advanced practice nurse for a time between 6 to 10 minutes. On average, each patient will be seen by the APN for 8 minutes, which means the APN can accommodate 45 patients a day from 7am till 1pm. This will be equal to 135 patients per week and 540 patients each month. It should be noted here that from the 1pm until 4pm no direct contact with patients will be done, like blood withdrawal, patient assessment or education; this time will be dedicated to administrative work only during which documentation will be completed, and contacting patients for dose adjustments.

See Appendix A, B and C for detailed job descriptions, required competencies and working schedules for the advanced practice nurse, clinical assistant and phlebotomist consecutively.

#### **D. Organizational Chart**

Figure 1 below is the organizational chart for the proposed INR clinic.



### E. Patients' inclusion criteria

Table 4.1 below represents the inclusion criteria for potential patients, in addition to the proposed INR range for every case, as well as the duration of the therapy.

Indication	INR range	Duration of Therapy
Treatment of DVT/PE - (Provoked by transient risk factor) - (Unprovoked) - Recurrent	2-3	3 – 6 months
		>6 months
		Long Term
Stroke/ TIA	2-3	Long Term
Systemic Arterial Embolism (secondary prevention)	2-3	Long Term
Prevention of Systemic Embolism - Acute Coronary Syndrome - Atrial Fibrillation - Valvular Heart Disease - Sever Left Ventricular Dysfunction (EF <30%) - Post-surgical DVT/PE prophylaxis	2-3	Varies with indication

Pulmonary Hypertension	2-3	Long Term
Aortic Mechanical Valve	2-3	Long Term
Antiphospholipid Antibody Syndrome	2-3	Long Term
Recurrent Thromboembolism while maintained on Warfarin	2.5-3.5	Long Term
Mitral Prosthetic Valve	2.5-3.5	Long Term
Any position Ball and Cage Valves	2.5-3.5	Long Term

## **F. Patient Education**

An optimized patient care in the clinic needs to address the educational needs of the patient. To increase patients' knowledge on his anticoagulation therapy, several methods will be used to deliver the information effectively, like face to face interaction, audiovisual material and written leaflets.

Generally, every patient will have a face to face education enforcement while being assessed by the advanced practice nurse during his clinic visit. This enforcement should not exceed 5 minutes where the APN will judge the patients' knowledge and identify potential learning needs by asking him the following questions.

1. Can you tell me why you are on an anticoagulation therapy?
2. How do you take your medication, in terms of dosage and timing?
3. What is your target INR?
4. Have you experienced any signs of bleeding?
5. Are you taking any new medication like antibiotics or pain killers?
6. Do you know what to do in case you have to undergo any surgery or dental procedure?
7. Did you change your eating habits?
8. Do you drink alcohol?

Based on the patient's response, the APN will indicate his knowledge regarding different aspects of the therapy. In case the patient had minimal knowledge or needed enforcement, he will be advised to attend the monthly educational sessions being held in the clinic and lasts for 30 minutes.

The educational sessions will tackle topics on the desired INR target range, diet restrictions, medication indication, etc. A note will be written in each patient's file indicating the completion of the educational session.

After completing the educational sessions, the patient should master the following learning outcomes.

1. The indication of initiating the therapy.
2. The working mechanism of the drug.
3. Duration of the therapy.
4. The need for frequent INR monitoring and the target range.
5. Common signs of bleeding and its implications.
6. Common signs of clotting and its implications.
7. The effect of diet and especially food rich with vitamin K on the therapy.
8. Potential drug-drug interaction.
9. The effect of alcohol on the therapy.
10. Importance of notifying the doctor in case of dental or surgical procedure will be done.
11. Drug use in special situations like pregnancy and lactation.
12. Necessary lifestyle changes like fall awareness and practicing contact sports.
13. What to do in case of a missed dose.



Educational leaflets will also be present on the clinic front desk that contains a general information on the anticoagulation therapy. These leaflets act as an enforcing agent for patient's knowledge. See Appendix D for the proposed leaflet.

## **G. Needs Analysis**

Normative needs: All patients that fits the inclusion criteria have the right to manage their anticoagulation therapy in a credible clinic. The service will be initiated to address all outpatients on oral anticoagulants, follow their lab results closely and educate them on all aspects of their therapy.

## **H. Patient-Centered Needs**

- 1. Perceived needs:* In order to establish the clinic and initiate the service, the patients' needs have to be assessed so that the implemented interventions would be addressed adequately. Accordingly, the patients' knowledge will be assessed by the APN to acquire the patients' knowledge regarding their condition, diet restrictions, and other aspects of the therapy.
- 2. Expressed educational needs:* The APN will be gathering information from the patients during their first assessment, in addition to information from the follow up appointments and accordingly their educational needs will be addressed during the teaching sessions.
- 3. Relative needs:* Patients attending AUBMC and those living in the greater Beirut area need an anticoagulation clinic that deals with their anticoagulation therapy from A to Z. The staff will be considering the cultural variation as well as the socioeconomic statue of these patients.

### ***I. Target population***

The target population that is needed to join the clinic are all patients attending the AUBMC outpatients' clinic in addition to patients referred by other clinics outside AUBMC who are maintained on oral anticoagulant and fit the following criteria.

1. Patients who are being treatment for DVT/PE whether it is provoked by transient risk factor, unprovoked, or recurrent.
2. Patients who suffered from Stroke/ TIA.
3. Patients who need secondary prevention of Systemic Arterial Embolism.
4. Patients who require prevention of Systemic Embolism, whether it is related to Acute Coronary Syndrome, Atrial Fibrillation, Valvular Heart Disease, Sever Left Ventricular Dysfunction (EF <30%) or Post-surgical DVT/PE prophylaxis.
5. Patients suffering from Pulmonary Hypertension, Aortic Mechanical Valve, Antiphospholipid Antibody Syndrome, Recurrent Thromboembolism while maintained on Warfarin.
6. Patients having Mitral Prosthetic Valve or any position Ball and Cage Valves.

Physicians working at one of the outpatient clinics at AUBMC need to fill the Anticoagulation Clinic Referral form (Appendix E), when referring a patient to the anticoagulation clinic.

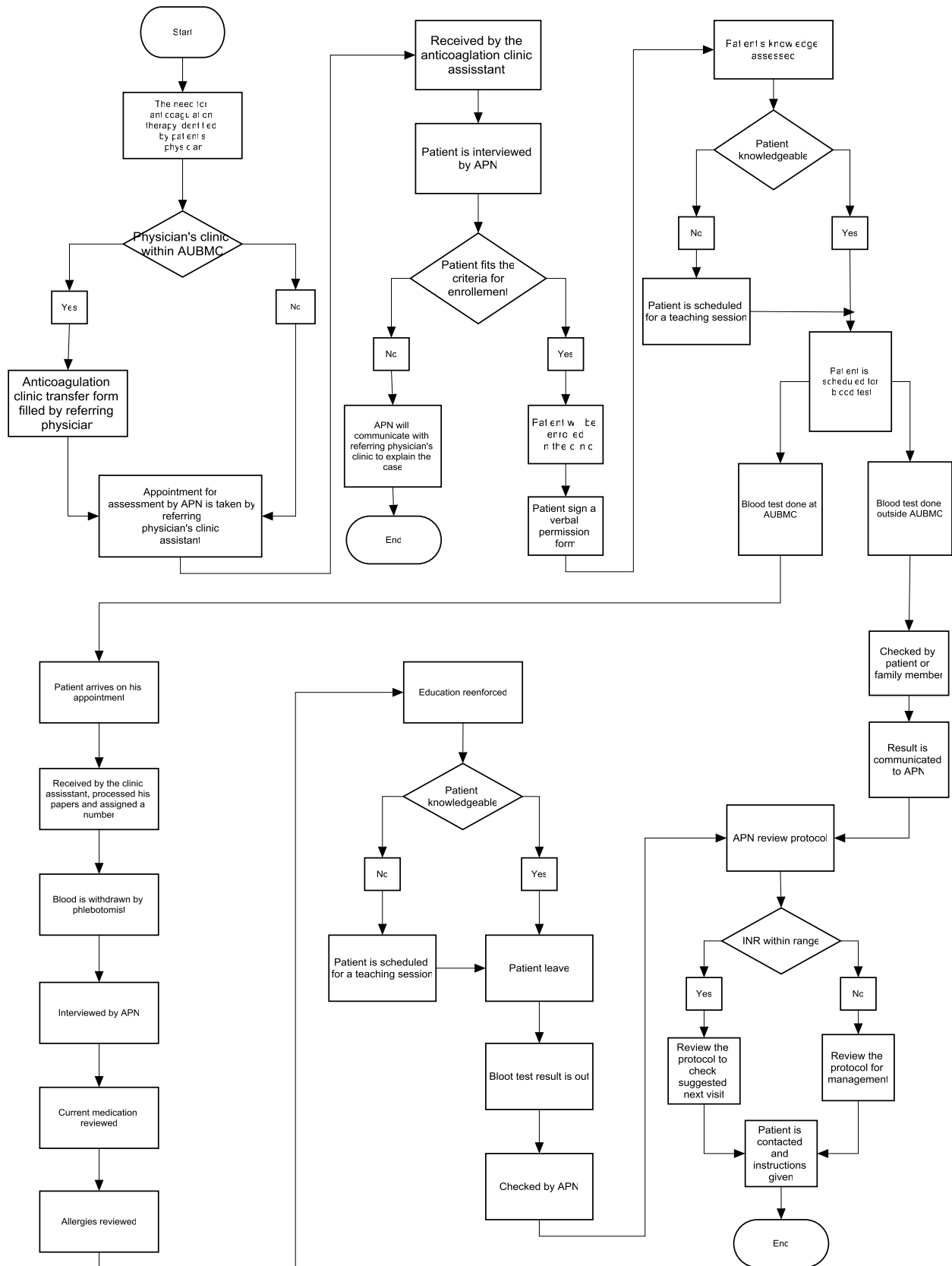
## **J. Services**

The anticoagulation clinic will have different sections for delivering the service which are listed below.

- 1. Assessment:* The patients' physical assessment will be performed by the APN, in addition to their current knowledge regarding their anticoagulation therapy. After which the decision will be done to test whether they fit the inclusion criteria.

- 2. Data completion:** If the patients fit the criteria, information will be taken by the clinic assistant in order to create a clinic file for them. At this stage, a Verbal Communication form (Appendix F) will be signed by the patient and added to his medical file, for the purpose of communicating blood results later on.
- 3. Blood withdrawal:** Patients will present to the clinic for blood withdrawal by the phlebotomist.
- 4. Education:** Patients' education will be given by the APN during their appointment in the clinic in addition to the assigned sessions that will tackle different anticoagulation topics thoroughly.
- 5. Communicating test result to the patient:** On the same day of the blood test, the result will be checked by the APN, communicate the result and advise for anticoagulant dose adjustment if necessary with the patient, and finally complete the documentation on the patient's electronic chart.

Figure 2 below is a detailed process map for the operation of the anticoagulation clinic.



## K. Service delivery and clinic location

The clinic will be located at the AUBMC main building, phase 2 as part of the outpatient cardiology clinics. It will consist of 3 rooms, the first room will be a reception in addition to a waiting area, the second room will be for blood withdrawal, and the last one will be the assessment room.

1. The reception's area will be 28m<sup>2</sup> and will contain a front desk occupied by the clinic assistant and a five seat benches for the patients to sit on while waiting their turn for the service.
2. The blood withdrawal room will be 9m<sup>2</sup> and will contain a small desk and a chair for the phlebotomist, in addition to a recliner for patient's use while withdrawing blood.
3. The assessment room will be 12m<sup>2</sup> and will contain a desk and chairs for the APN to conduct the interviews, in addition to a stretcher to perform the assessment.

#### **L. Marketing and advertisement**

There are several ways to consider advertising for the program.

1. The first method will be by the AUBMC physicians themselves, where they will be referring their patients to the anticoagulation clinic.
2. The second method will be hanging posters in different areas of the hospital for it to be observed by AUBMC attendees.
3. The last method will be by placing pamphlets in all outpatient clinics that describe the services provided by the clinic.

#### **M. SWOT analysis**

##### ***1. Strengths***

- Registered nurses are highly skilled and are experts in educating patients on anticoagulation therapy, such as drug-drug and drug-food interaction.

- Registered nurses are able to assess the patients thoroughly.
- The APN is more accessible and approachable than the current nurses, since the operation will be separated from the outpatient cardiology clinic.
- Nurses and physicians at AUBMC practice good communication which will reflect on the service's outcomes.

## ***2. Weaknesses***

- Physicians does not trust the nurses' ability in managing the service.
- The nurses' does not have the authority to prescribe medication or lab tests.

## ***3. Opportunity***

- With the required additional training, nurses will be able to assess the patients' INR value and adjust anticoagulant dose accordingly.
- Nurses can provide positive outcomes with their individualized patient care in terms of patients' knowledge.
- The good rapport between physicians and nurses at AUBMC can enhance future programs.
- The aging population along with its sedentary lifestyle, will result in an increase in chronic diseases, including atrial fibrillation.

## ***4. Threats***

- Patients do not show-out to their lab test appointments.
- Physicians will not refer their patients to the clinic.
- Patients will refuse to be transferred to the anticoagulation clinic.
- The APN will not have access to lab tests done outside AUBMC for follow-up and management.

## **N. Quality Assurance**

Like any clinic, quality indicators need to be set in order to assess the clinical practice and hence achieve a high-quality anticoagulation management. These quality indicators will be measured quarterly and will determine the clinic's performance and the patient's outcome. They are crucial to maximize the effectiveness and minimize the potential harm that may be caused for a patient when being registered in the clinic.

Two indicators need to be measured to monitor the performance which are patients' satisfaction and the time spent by the patient in the clinic during each visit. Patient's satisfaction rate should be at least 85%, and it should be filled by each patient once every month. Regarding the time of each patient's visit, it must not exceed 30 minutes from check-in to check-out.

As for measuring patient's outcome, another three indicators will be monitored which are the proportions of patient's INR within the therapeutic range (TTR), hemorrhagic and thromboembolic rates. The TTR should be at least 60% in order to limit the anticoagulant side-effect and maximize its benefits. Furthermore, the hemorrhagic events should be minimal and does not exceed 6%. Finally, thromboembolic events must also be limited and does not exceed 3%.

## CHAPTER V

### DISCUSSION

Establishing a nurse-led anticoagulant clinic is a big task but also a rewarding one. Some difficulties need to be taken into consideration while developing such a service, like the legal aspect of anticoagulant dose management by the advanced practice nurse. The American University of Beirut Medical Center (AUBMC) is one of the leaders in the region for expanding the role of its nurses. The nurses' roles include being clinical experts, educators, change agents, consultants, researchers and advocates; hence managing an anticoagulation clinic is among those roles. In order to implement this proposal into practice we are suggesting a policy brief that will summarize this proposal (Appendix G).

Generally, when patients are managed by an anticoagulation service they less likely experience a thromboembolic event or hemorrhagic complication. This result is linked to the frequent INR checks, implementation of self-improvement program and the use of a standardized protocol in the anticoagulation clinic.

A nurse-led anticoagulation clinic will be organised under the lead of the advanced practice nurse, controlling over all the operational aspects of the service. The team will be working with a single set of protocols and one referral system. In addition, nurses dedicate more time to patients to discuss issues related to changes in behavior which may affect the anticoagulant metabolism. Not to forget that face to face communication positively reflects on communication and enhance teaching opportunities.



Nurse led clinics have proven that they can manage patients on long term anticoagulation treatment as good as physician lead clinics, however nurse-led clinics are superior in aspects of managing new patients. This finding can be based on the better documentation of clinical details and good control of drugs being taken by patients which might interact or inhibit haemostatic function. In addition, patient's treatment stop dates are recorded and followed carefully and investigating the out of target range INR values. These clinics have also proved that they can improve patients' education and knowledge, which will help in reducing medication errors.

Furthermore, patients followed by the nurse-led clinics spend a larger time within their therapeutic target range than those followed by a hematologist. This finding is correlated to the nurses' commitment to their new assigned roles and needed to gain trust, so they were highly motivated which lead them to record all related patient information like date of admission to hospital, alcohol consumption, diet, omitted or wrong dose. As a result of this INR stability, the intervals between patients' clinic appointments were wider, hence no need to review the patients frequently.

Regarding the educational requirement for the APN who will be managing the clinic, a masters degree in nursing administration or adult care is mandatory, since this expansion in the role of the registered nurses needs to be underpinned with professional education. Moreover, training on anticoagulant management is crucial in order for the advanced practice nurse to succeed in her/his new role. This training is mandatory because whatever the APN's previous experience is, she/he will not be well prepared or competent for this complex role. The accomplishment of this training will result in proper dosing of anticoagulants to avoid sub-therapeutic or supra-therapeutic anticoagulation. Since there is no recognized courses nation wise for anticoagulant management, it is essential to provide this training locally at AUBMC.

### **A. Implication for practice**

The advanced practice nurse will be uniquely qualified in the field of anticoagulants management in the medical center, which will enhance nurses' roles. The APN will be a reliable and resourceful healthcare professional that acts as a reference for other colleagues. Moreover, she will have the full autonomy in managing patients maintained on anticoagulants based on the institutional pre-printed protocols, as well as discussing with patients and family members the educational needs related to their treatment. In addition, for the responsibility of managing the anticoagulant clinic from A to Z, that will add credibility for nurses on managing outpatient services. Finally, the development of this service will not only contribute to nurse-led practice in anticoagulant care, but also the development of autonomous nurses in other areas.

### **B. Implication for research**

Establishing an anticoagulation clinic will have a direct inference on the available patient's data and hence its analysis, that will result in advanced and targeted statistics. Having all the patients who are maintained on anticoagulants attend and being followed by the anticoagulation clinic will ease the process of data collection regarding any possible future topic that needs to be tackled. This data will eventually be used for research purposes including evaluating the effect of this clinic on preventing adverse events.

### **C. Limitations**

It was challenging to gain access to data regarding both, number of patients who are maintained on anticoagulants and being followed up by their physicians at AUBMC, and the cost of the INR test. Furthermore, I did not have access to the number of adverse events for these patients whether it is a result of being over coagulated or under coagulated, in other words their outcomes. As a result, I could not prepare a forecast of expenditures and savings because no

information on the above-mentioned costs were available. However, and based on the literature, patients who were attending a nurse-led anticoagulant clinic has at least the same mean proportion of time spent in their therapeutic range as those attending a physician-led anticoagulant clinic. On the other hand, fewer patients attending the nurse-led INR clinics were taking other drugs that might interact and/or inhibit their haemostatic function. In terms of satisfaction, patients demonstrated high satisfaction rates with their nurse-led anticoagulant clinic. This leaves us with an understanding that a nurse-led anticoagulant clinic is at least as safe as a physician-led one, but is superior in terms of quality assurance aspects.

# Appendix A

## Advanced Practice Nurse Job Description

### Job Summary

Provide direct and indirect nursing care for assigned patients in the anticoagulation clinic within the framework of Patient Centered Care (PCC). Responsible for overseeing and managing the operations of the anticoagulation clinic. This includes coordination of care for patients, staffing and scheduling, ensuring adherence to standards of care and practice, patient and staff education and participation in continuing education programs and quality improvement activities. Primarily responsible for professional performance and safe patient care. The role encompasses nursing assessment, diagnosis, planning, intervention, evaluation, and coordination of care across the health care continuum involving families. Accountable for clinical, educational, quality, and fiscal patient care outcomes, using the PCC principles and in accordance with established institution's policies, procedures, guidelines, Professional Practice Model and standards of care and practice. Carries out planned activities to promote Magnet standards and participates in voluntary community activities. Promotes a work environment that supports and facilitates ethical practice, in accordance with the ANA Code of Ethics and the Lebanese Order of Nurses Code of Ethics. Practices within the ANA Bill of Rights. Utilizes knowledge of human development stages, and cultural diversity into the provision of patient care. Abides by the Joint Commission International Accreditation (JCIA) requirements, including but not limited to International Patient Safety Goals, national and international standards.

Support the mission and vision of the American University of Beirut Medical Center (AUBMC), the Nursing Services Department and Anticoagulation Clinic.

### Essential Functions / Task Groups

#### Patient Centered Care:

- Perform patient assessment using appropriate, problem focused, and age-specific assessment techniques.
- Analyze the assessment data, set priorities according to patient's needs, formulate a plan of care, implement and evaluate the outcome.
- Document all relevant data in the medical record according to hospital/departmental standards.
- Involve the patient, significant others, and health care providers in the plan of care when appropriate.
- Instruct and counsel patients by describing therapeutic regimens.
- Provide continuity of care by developing and implementing patient management plans.
- Adjust anticoagulant dose monitor desirable and undesirable effects and intervene accordingly.
- Provide assessment of the patient's health status as it relates to the relative risks of hemorrhagic or thrombolytic event.
- Provide basic life support when needed.

- Recognize subtle cues to anticipate potential problems.
- Implement and monitor infection control measures.
- Apply safety measures related to patient care.
- Operate all unit required equipment safely.
- Perform clerical duties when needed.
- Provide patient and family education.
- Assess patient and family readiness and identify learning needs relevant to anticoagulation therapy.
- Accountable for the organization, the profession, and self.
- Accountable for the use of patients' and hospital resources.
- Assume responsibility for meeting JCI required mandatory education, e.g., fire, safety, infection control and others.
- Participate in voluntary community health activities to promote, maintain and restore health and prevent diseases.

### **Administrative Duties:**

- Coordinate the daily patient care operations of the anticoagulation clinic.
- Coordinate services with other patient care areas as required such as outpatient clinics; maintain communication with allied services and maintain liaison as appropriate.
- Act as a liaison between the service and other medical center departments (billing, outpatient clinic, patient access, social service, etc.).
- Coordinate with hospital stakeholders to develop workflows like patient referrals
- Identify appropriate internal controls for the department; provide mechanisms to monitor and enforce compliance.
- Promote continuous improvement of workplace safety and environmental practices.
- Develop, coordinate and implement policies, systems and procedures and standards for the service/specialty.
- Work with physicians and the pharmacy department to set guidelines and protocols.
- Analyze workloads and skill requirements to meet patient care needs.
- Develop the weekly schedule of staff and ensure resource availability.
- Manage vacation scheduling.
- Coordinate staff meetings.
- Participate in the supervision of employees.
- Assist in monitoring and evaluating staff performance.
- Assess staff competencies as well as conduct on-going assessment of staff educational needs and establish in-service/development programs to meet these needs.
- Participate in the annual staffing plan to provide adequate resources.
- Ensure proper care in the use and maintenance of equipment and supplies.
- Plan, prepare, implement, evaluate and monitor resources (human and material) use for area of responsibility.
- Responsible for planning, preparing, utilizing, evaluating and monitoring of approved budget.
- Accountable for the use of patients' and hospital's resources as in monitoring overall use on a monthly basis and ensuring best practices are incorporated.
- Troubleshoot and appropriately attend to problematic issues.

- Collect, organize, and report information in a comprehensible form.
- Develop and use systems to organize and keep track of information.
- Responsible for on-going analysis, development and implementation of methods and automated softwares to improve the overall outcomes, efficiency and effectiveness of the unit's clinical functions.
- Prepare and update patient education material in coordination with the patient education coordinator.
- Conduct other projects as needed.
- Participate in quality initiatives and quality improvement activities for improving the unit standards of quality provided.
- Coordinate the department's research activities and the collection of relevant data.

### **Critical Competencies**

- Client Focus, Achievement Orientation, Organizational Awareness, Initiative, Communication Skills, Safety and Health Management, Ethical Practice, Developing Others, Resource Management, Problem Solving, Technical Expertise, Professional Development, Team Skills, Planning and Organizing, Human Resources Management, Information and Records Administration, Quality Management, Applied Technology, Professionalism, Computer Skills, English Comprehension, Stress management, Health education, prevention and promotion, Patient Assessment, Drug Administration.

### **Knowledge / Know-How**

- **Knowledge:**  
BLS Provider  
Knowledge of scope of the Staff Nurse  
Knowledge of and appropriate application of the nursing process  
Knowledge of professional theory, practices and procedures  
Working knowledge of different anticoagulation therapies and its management.  
Working knowledge and completion of JCIA and other regulatory requirements  
Knowledge of daily clinic operations and organization ranging from patient scheduling and reception to delivery of health care services and processing of paperwork  
Knowledge of care in Outpatient Department
- **Education:**  
Minimum Education: Master's of Nursing
- **Requirements:**  
Nursing Colloquium  
Nursing License from the Ministry of Public Health  
Registered in the Order of Nurses in Lebanon  
Preferred Requirement:  
ANCC Certification  
Membership in a professional organization
- **Experience:**  
Minimum Experience: At least 5 – 7 years of experience
- **Languages:**  
Minimum Languages: Arabic and English (IET  $\geq$  500)  
Preferred Languages: French is an asset

- **Computer Skills:**  
Proficient knowledge in Microsoft Office

### **Impact of Actions / Decisions**

- Performance of duties in a sound way ensures smooth clinic operations.

### **Job Structure**

- Work according to pre-established standards of care and practice.

### **Managerial / Supervisory Responsibility**

- Reporting Channel:  
1st level: Nurse Leader for Clinical Affairs  
2nd level: Director of Nursing
- Supervisory Channel:  
Supervise Ambulatory Staff and Administrative Staff

### **Job Characteristics**

- **Physical Effort:** Moderate Physical Effort
- **Work Schedule:** Three days a week from 7am till 4pm
- **Working Conditions:** Exposed to patient element

# Appendix B

## Clinic Assistant Job Description

### Job Summary

Carry out receptionist duties at assigned clinic. Schedule appointments, receive patients and ensure delivery of complete medical records to attending physicians. Handle high volume of patients.

Support the mission and vision of the American University of Beirut Medical Center (AUBMC) and that of the Department.

### Essential Functions / Task Groups

#### Clinic Support Duties:

- Consult appointments book (hardcopy or online) and previous day's schedule and retrieve medical file of patients.
- Coordinate the completion of required forms related to patient visit.
- Handle paperwork related to insurance or organizations contracted by the practice (embassies, travel agencies, etc).
- Ensure that results of blood tests requested by the physician are available in the patient's file.
- File reports and transcriptions when needed.
- Enter data into computer programs when needed.
- May handle clinic store by ordering and receiving from department store and verify quantities according to present standards and stock them in an organized manner.
- Complete other miscellaneous clerical duties as assigned.

#### Receptionist Duties:

- Carry out receptionist duties at the assigned clinic including but not limited to answering phone calls directed to the unit, pick-up messages and follow-up on them as well as opening the clinic in the morning.
- Receive patients, evaluate patients' need and direct them through the clinic according to the schedule.
- Handle walk-in patients.
- Maintain call back records to provide follow up for patients on instructions of tests and procedures as requested by the advanced practice nurse.

#### Critical Competencies

- Client Focus, Achievement Orientation, Initiative, Communication Skills, Safety and Health Management, Problem Solving, Team Skills, Planning and Organizing, Information and Records Administration, Professionalism, Applied Technology, Computer Skills, Organizational Awareness, English Comprehension.



### **Knowledge / Know-How**

- **Knowledge:**  
Basic knowledge of daily clinic operations and organization ranging from patient scheduling and reception to delivery of health care services and processing of paperwork.
- **Education:**  
Minimum Education: BACC II.  
Preferred Education: Bachelor of Arts or Sciences.
- **Experience:**  
Preferred Experience: Familiarity with a health care clinical setting.
- **Languages:**  
Minimum Languages: Arabic and English (IET score  $\geq$  450)  
Preferred Languages: French is a plus.
- **Computer skills:**  
Proficient in all common computer software such as Microsoft Office tools (Excel, PowerPoint, Word).

### **Impact of Actions / Decisions**

- Tardiness heavily affects quality of service provided as well as patients' satisfaction of the hospital services.

### **Job Structure**

- Perform coordination and support services under regular supervision and following established procedures and instructions.

### **Managerial / Supervisory Responsibility**

- Reporting Channel:  
1st Level: Unit Coordinator
- Supervisory Channel:  
None

### **Job Characteristics**

- **Physical Effort:** Little or no Physical Effort
- **Work Schedule:** Three days a week from 7am till 4pm
- **Working Conditions:** Exposed to patient element

# Appendix C

## Phlebotomist Job Description

### Job Summary

Draw blood specimens from people of all ages (adults, children and neonates) by venipuncture and skin puncture as needed for medical tests in a prompt, accurate and reliable manner according to established hospital and departmental policies and procedures. Adhere strictly to safety and infection control procedures while performing their technical duties. Support the mission and vision of the American University of Beirut Medical Center and that of the Department.

### Essential Functions / Task Groups

#### Administrative Duties/Related Technical Duties:

- Assist in sorting and recording specimens received in the laboratory.
- Participate in in-house training, phlebotomy workshops and education programs (i.e., new specimen collection techniques, equipment, safety and other educational programs).
- Respond to opportunities to help others.
- Demonstrate willingness to participate in inter and intra departmental committees.
- Demonstrate willingness to participate and share ideas for performance improvement projects.
- Demonstrate willingness to participate in statistical data gathering and testing/validating new collection procedures.

#### Specimen Collection and Handling:

- Match physicians' requests with the amount of blood to be drawn and the types of samples for every test.
- Demonstrate human relation skills when working with patients and others; recognizing the different patients' medical conditions and severity; understanding of patient rights and promoting the comfort and well being of the patient/donor while performing blood and other laboratory related body fluid collection duties.
- Demonstrate proficiency in performing simple to moderately complex blood collection techniques such as venipuncture, heel stick and finger stick.
- Identify appropriate sites for heel stick, finger stick and venipuncture.
- Identify the various types of anticoagulants, preservatives and gels used in blood collection and the vacuum tube color code for the additives. Identify the type of preservatives used in 24 hours urine collection gallons.
- Adhere and comply to safe and efficient work practices in collection and processing of specimens.
- Maintain the integrity of the specimen in relation to the test to be performed.

- Demonstrate a practical knowledge in identifying the most common complications associated with heel stick, finger stick and venipuncture; their causes, prevention and treatment within expected capabilities.
- Collect timed specimens and timely delivery/distribution of specimens to laboratory sections.
- Demonstrate ability to use basic problem-solving skills to troubleshoot simple routine procedures that do not fall within standards, take corrective actions or inform an appropriate supervisor.
- Report to Advanced Practice Nurse in case of complex operational and administrative problem.
- Perform competency assessment questionnaire.
- Follow prudent practices of safety, infection control, and fire safety planning.
- Clean up and decontaminate the phlebotomy stations at the beginning and end of the shift.

### **Equipment & Collection Supplies:**

- Prepare collection trays for specimen procurement; ensure usage of appropriate type of blood collection equipment and supplies according to age specific patient categories.
- Responsible for the efficient and cost-effective use of supplies, reagents and equipment.

### **Critical Competencies**

- Client Focus, Achievement Orientation, Initiative, Communication Skills, Safety and Health Management, Technical Expertise, Team Skills, Planning and Organizing, Professionalism, Quality Management, Organizational Awareness, Problem Solving, Resource Management, Computer Skills, English Comprehension, Information and Records Administration.

### **Knowledge / Know-How**

- **Knowledge:**  
Basic knowledge and understanding of human anatomy and physiology, the overall organization and operations of the laboratory as well as in depth knowledge of the specimen collection tools, techniques and related quality control measures.  
Basic knowledge in communicable diseases and infection control procedures according to hospital and department safety regulations and policies.  
Basic knowledge in medical terminology and laboratory tests with ability to interpret physicians' orders.
- **Education:**  
Minimum Education: BACC II degree or equivalent.  
Preferred Education: Phlebotomy certification.
- **Experience:**  
Minimum Experience: One-year experience in basic laboratory operations, nursing or related science preferably in the blood collection specialty.
- **Languages:**  
Minimum Languages: Arabic and English (IET score  $\geq$  450)  
Preferred Languages: French is an asset.

- **Computer Skills:**  
Basic knowledge and ability to interact with laboratory information system (LIS) and/or hospital information system (HIS) computer functions as it relates to phlebotomy duties.

### **Impact of Actions / Decisions**

- Error in sample identification, labeling and collection of specimens would probably be caught by review within the laboratory or by review of test results and reports. However, not all work is technically checked so unreliable results may cause material or financial loss and may affect the diagnosis of the patient and consequently on the treatment and quality of patient care reflecting adversely the laboratory.  
Inappropriate adherence to safety precautions may facilitate the transmission of infectious diseases especially blood transmitted diseases among fellow staff and patients.  
Providing timely phlebotomy services facilitates the work of others within the immediate organizational unit and patient floors.

### **Job Structure**

- Perform specific technical duties according to pre-established hospital and departmental policies and regulations.

### **Managerial / Supervisory Responsibility**

- Reporting Channel:  
1st Level: Advanced Practice Nurse
- Supervisory Channel:  
None

### **Job Characteristics**

- **Physical Effort:** Moderate Physical Effort
- **Work Schedule:** Three days a week from 7am till 11am
- **Working Conditions:** Hazardous working conditions

# Appendix D

## Educational Leaflet

The mission of the AUBMC Anticoagulation clinic is to provide safe and effective management of anticoagulation therapy

**Contact Us**  
American University of Beirut Medical Center  
Riad Solh Street, Beirut, Lebanon  
+961-1-350000 ext:xxxx  
[inrclinic@aub.edu.lb](mailto:inrclinic@aub.edu.lb)

**AUBMC**  
**Anticoagulation clinic**  
Warfarin/Coumadin Therapy



### Using other medications

Some medications may alter your INR level, few of them are listed below.

- Acetaminophens (Tylenol)
- Ibuprofen (Advil)
- Antibiotics (Flagyl)
- Anticonvulsants (Phenytoin)
- Herbal products (Fish oil)

Always inform the anticoagulation clinic about the supplements or medicines you are taking.

### Diet and Warfarin

Eat consistent amount of food rich in vitamin K, since it may alter your INR level.

- Vegetables (Cabbage, Spinach, Lettuce, and Broccoli)
- Avoid goose liver as it contains high amount of vitamin K.



### How to take Warfarin?

- Take Warfarin every day at the same time as instructed by the anticoagulation clinic.
- Never skip a dose or take a double dose.
- If you forget to take your dose, take it as soon as you remember, as long as on the same day.
- Warfarin can be taken with other medication as well as with food

### Warfarin's side effect

Minor bleeding (like gum bleeding) is a common side effect and is not dangerous.

Major bleeding (red urine color) or if you are seriously injured is not common. Seek medical care immediately.

### What is Warfarin?

Warfarin is an anticoagulant, which is used to prevent or treat clot formation in the veins, arteries, heart or lungs by slowing down the clotting process.

### Why Warfarin is prescribed for you?

You may have one of the following health condition.

- Atrial fibrillation
- Artificial heart valve
- Certain genetic disorder

Or may have a history of one of the following.

- Stroke (CVA)
- Deep vein thrombosis (DVT)
- Pulmonary embolism (PE)
- Heart attack (MI)

### Blood Test

Your INR needs to be checked regularly or as directed by the anticoagulation clinic.



I acknowledge that I am referring this patient for anticoagulation management by warfarin therapy. I understand that the patient will be referred back to me if he falls outside the criteria indicated by the anticoagulation clinic.



# Appendix F

## Verbal Permission Form

_____	_____
(name of patient)	(date of birth)
_____	_____
(street address)	(city)
_____	
(phone number)	

I permit the Anticoagulation Clinic (AC) personnel (Health Care Providers) to leave information regarding ongoing anticoagulation therapy on my voice mail or answering machine.

In addition, this authorization allows the AC personnel to discuss health information, in person or by telephone with the following family members involved in my medical care: (List family members and state the person's relationship to the patient).

Patient's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

If this Release is signed by a representative on behalf of the patient, complete the following:

Representative's Name: \_\_\_\_\_

Relationship to Patient: \_\_\_\_\_

**If, at any time in the future, I would like to change any of the above information or do not want this information to be left on my answering machine, I must notify the Anticoagulation clinic:**

- **by telephone, or**
- **in person at the Anticoagulation Clinic at the American University of Beirut Medical Center**

# Appendix G

## Policy Brief

Registered Nurses are allowed to manage and modify drug therapy based on a written protocol between the anticoagulant nurse and a specific physician who is responsible for the patient care and is authorized to prescribe drugs.

By signing this document, the names physicians will agree that the named advanced practice nurse will work collaboratively with them in managing their patients who are receiving oral anticoagulation therapy.

Advanced Practice Nurse Name: \_\_\_\_\_

Physician's Name: \_\_\_\_\_

Physician's Name: \_\_\_\_\_

Physician's Name: \_\_\_\_\_

Physician's Name: \_\_\_\_\_

Date of implementation:

Date of annual review completed:

Purpose:

A formal anticoagulation protocol at the American University of Beirut Medical Center to manage the patients is deemed necessary. When patients managed by several physicians are ordered to undergo an INR testing, it is nearly impossible to follow up on all those patients and manage their therapy using a unified tool by specialized personnel in a designated unit. Not all out-patients are being managed at AUBMC. Only those who seek help from their physicians are being contacted by a nurse working in the private clinics to manage their therapy, without sharing information regarding the patient's diet, drugs ... etc.

A nurse-led anticoagulation clinic; managed by an advanced practice nurse; is felt to be necessary for managing all out-patients maintained on oral anticoagulants. This will provide the opportunity to develop a protocol to be used by the advanced practice nurse to manage those patients. Which will enable more consistent care for the patients, and permits the needed time for an exchange of various clinical information. Data from literature is available that a nurse-led anticoagulation service can improve care, reduce hospitalizations, reduce complications, and emergency room visits. The American College of Chest Providers (ACCP) consensus conference regarding antithrombotic therapy has recommend that clinicians must have a systematic process for managing oral anticoagulation dosing which includes a knowledgeable provider, organized follow-up system, and patient communication and education.

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