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### Cover Page Footnote

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# Position Statement on In-hospital/Clinic Point-of-care Coagulation Testing for Anticoagulation Monitoring in Saudi Arabia

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## Abstract

**Objectives:** Hospital overload is a persistent occurrence in daily practice. Interventions such as point-of-care testing (POCT) are needed to alleviate the pressure faced by healthcare providers and administrators.

**Methods:** An invited panel of experts from Saudi Arabia was formed under the auspices of the Saudi Heart Association in order to discuss local treatment gaps in the management of patients receiving anticoagulation therapy. This was done in a series of meetings, which resulted in the development of official recommendations for the implementation of POCT for anticoagulation monitoring in the country. Recommendations were based on a comprehensive literature review and international guidelines taking into consideration local clinical practice, clinical gaps, and treatment/testing availabilities.

**Results:** Vitamin K antagonist (VKA)-based anticoagulation therapy requires routine monitoring. POCT is a promising model of care for the monitoring of International Normalized Ratio (INR) in patients receiving oral anticoagulation in terms efficacy, safety and convenience. The availability of POC INR testing should not replace the use of standard laboratory anticoagulation monitoring. However, there are several indications for implementing POCT INR monitoring that was agreed upon by the expert panel. POCT for anticoagulation monitoring should primarily be used in the warfarin (or other VKA) monitoring clinic in order to ensure treatment efficiency, cost-effectiveness of care, patient satisfaction, and quality of life improvement. The expert panel detailed the requirements for the establishment of a warfarin (or other VKA) monitoring clinic in terms of organization, safety, quality control, and other logistic and technical considerations. The limitations of POCT should be recognized and recommendations on best practices should be strictly followed. Core laboratory confirmation should be sought for patients with higher INR results (>4.7) on POCT. Proper training, quality control, and regulatory oversight are also critical for preserving the accuracy and reliability of POCT results.

**Conclusions:** POCT enables more rapid clinical decision-making in the process of diagnosis (rule-in or rule-out), treatment choice and monitoring, and prognosis, as well as operational decision-making and resource utilization. POCT thus can fulfill an important role in clinical practice, particularly for patients receiving VKAs.

**Keywords:** Anticoagulation therapy, Point-of-care, Warfarin, Anticoagulation monitoring, Saudi Arabia

## 1. Introduction

Anticoagulation therapy is needed for individuals suffering from conditions with a high risk of venous thromboembolism (VTE) (i.e.

atrial fibrillation (AF)), in order to reduce their risk of mortality [1,2]. Suboptimal use of guideline-recommended anticoagulation therapy remains a global concern, with significant geographical variability in the use and initiation of oral

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anticoagulants [1,3]. Consistently, both anticoagulation control and patient adherence are poor in clinical practice [1,4]. This should be addressed seeing as prophylactic anticoagulation therapy is needed for millions of individuals with elevated risk of VTE [5]. The Middle East/North Africa region has one of the highest prevalence of stroke survivors and most years lost to disability due to ischemic heart disease [5]. However, data on anticoagulation therapy remains limited from the Middle East Region, including Saudi Arabia. Available evidence reported poor quality of anticoagulation therapy in Saudi Arabia as patients spend at least 40 % of the time outside the therapeutic range [6,7]. Patient-centered initiatives are therefore needed in order to improve patient knowledge and satisfaction with treatment, and by extension, increase treatment adherence and quality of anticoagulation [8–10].

While the introduction of direct oral anticoagulants (DOACs) have affected trends in oral anticoagulation use [11–13], the Vitamin K antagonist (VKA) warfarin is still widely used for several indications. However, the use of warfarin entails regular monitoring of clotting time through International Normalized Ratio (INR) to ensure that the drug is both safe and effective. However, anticoagulation monitoring gaps persist in clinical practice with detrimental effects on the quality of anticoagulation [14]. Although conventional laboratory testing have a higher precision and reliability for INR (particularly higher ranges) [15,16], in-hospital/clinic point-of-care (POC) anticoagulation monitoring can still play an important role in patient management. POC testing (POCT) coagulometers are used in different settings for anticoagulation monitoring, such as patient self-monitoring, anticoagulation clinic POC INR as well as the rapid determination of activated clotting time in the operating room and cardiac catheterization suite [17].

To fulfill the role of POCT, it is critical to establish clear guidance and policies to ensure careful and adequate patient selection for POCT in addition to the organization of the complex logistics and management needed for the successful and safe use of POCT coagulometers. This Saudi Heart Association position statement, therefore, aims to provide guidance on POC coagulation testing in a hospital/clinic setting in Saudi Arabia, where the use of this platform remains limited. Recommendations on patient selection, POCT logistics, cost-effectiveness calculation, and future perspectives are offered in an effort to improve the quality of care of patients receiving anticoagulation therapy in Saudi Arabia.

#### Abbreviations

AF	atrial fibrillation
CAP	College of American Pathologists
CLIA	Clinical Laboratory Improvement Amendments
COVID-19	coronavirus disease 2019
DOACS	direct oral anticoagulants
FDA	Food and Drug administration
INR	International Normalized Ratio
LMWH	low-molecular weight heparin
POC	Point-of-care
POCT	Point-of-care testing
QC	Quality control
UFH	Unfractionated heparin
VKA	Vitamin K antagonist
VTE	Venous thromboembolism

## 2. Methodology

An invited panel of experts from Saudi Arabia was formed under the auspices of the Saudi Heart Association as part of ongoing efforts towards the Saudi vision 2030, which aims to improve community health and cardiovascular diseases. More specifically, the project was conceived to help develop and modernize the management of cardiovascular diseases and provide scientific and advisory services to all healthcare providers. The expert panel participated in several meetings to discuss local treatment gaps in the management of patients receiving anticoagulation therapy and develop official recommendations for the implementation of POC coagulation testing for anticoagulation monitoring in the country. A comprehensive literature review was conducted with no limits on date or language, using keywords such as “anticoagulation therapy”, “POC testing”, “anticoagulation monitoring”, “warfarin”, and “oral anticoagulants”. Additional references were identified by searching the reference lists of retrieved articles and from the authors’ knowledge of the field. Guidance on POC coagulation testing for anticoagulation monitors was then developed based on available literature and international guidelines taking into consideration local clinical practice, clinical, gaps, and treatment/testing availabilities.

## 3. Anticoagulation therapy: options and management

### 3.1. Anticoagulants

The main classes of anticoagulants currently used are heparins (unfractionated heparin (UFH) and low-molecular weight heparin (LMWH)), VKAs

(warfarin), and recently, direct oral DOACs. Both UFH and LMWH are recommended for the pharmacological VTE prophylaxis, with a preference for LMWH [18]. Anticoagulation response to heparins is more predictable and reliable compared to warfarin, with no requirement for frequent laboratory monitoring [19,20]. Since their approval, DOACs have quickly risen as leading alternatives to the long-standing standard of care in anticoagulation (VKAs and heparins). In a thromboembolic setting, DOACs are more effective, safe, and convenient treatment options compared to other anticoagulants [21]. Moreover, DOACs typically do not require laboratory monitoring.

By contrast, the use of warfarin entails close monitoring, the need for dose adjustments to prevent adverse drug reactions due to dietary/medication interference, as well as to account for genetic and nongenetic interindividual variability in response to warfarin. Despite this, warfarin continues to be the only approved drug for some primary and secondary prophylactic conditions. Warfarin carries a significantly higher risk of major bleeding, intracranial bleeding and gastrointestinal bleeding compared to other oral anticoagulants [2]. Typically, 1–3% of individuals treated with warfarin in a clinical trial setting will experience major bleeding [22,23], but rates could be significantly higher (up to 7%) in real-life practice [24,25]. That being said, bleeding rates with warfarin eventually decrease as they are highest in the first few months of treatment.

### 3.1.1. Local guidelines

VTE is treated in Saudi Arabia based on the Saudi Health Council's 2021 evidence-based clinical practice guideline on the screening, prophylaxis and management of VTE [26]. Pharmacological prophylaxis is preferred in the absence of a high bleeding risk, in which case mechanical prophylaxis could be considered. Treatment with a VKA or DOACs is recommended for recurrent VTE, with the need for periodic review of anticoagulant control, bleeding episodes and risk of bleeding. Monitoring the efficacy of anticoagulation is necessary; while routine laboratory monitoring of LMWH is not recommended, therapeutic dosing of UFH should be monitored. As for INR control in patients receiving VKA therapy, the Saudi guidelines recommend selecting the approach that provides the most precise INR control based on local conditions. Computer-assisted dosing algorithms are recommended, and patient self-testing and self-management may be considered for eligible patients and should be supported by a dedicated and well-trained anticoagulation team.

However, there remains a lack of local VTE guidelines regarding warfarin and POC INR monitoring. In Saudi Arabia, the accepted international guideline is the American College of Chest Physicians Evidence-Based Clinical Practice Guidelines on Antithrombotic Therapy and Prevention of Thrombosis [27,28].

### 3.2. POC monitoring as a promising model of care for oral anticoagulation in terms of efficacy and safety

Providing high-quality anticoagulation management services improves anticoagulation control, with settings such as clinical trials and anticoagulation clinics shown to have the best outcomes [29]. POCT refers to testing that is performed at the site of clinical care delivery by personnel that are not primarily trained in clinical laboratory science (including patients). By contrast, conventional laboratory monitoring is done through a structured approach designed to process many samples simultaneously using large instruments with different throughput operated by trained medical technologists.

POC INR testing is approved for VKA monitoring and can improve the time spent in the INR therapeutic range compared with the use of standard laboratory Prothrombin time/INR [30]. POCT for INR measurement can be as precise and accurate as laboratory testing [16,31–35], and can lead to comparable VKA-dosing decisions [33,35,36]. POC devices allow more convenient and frequent monitoring of anticoagulation therapy, inherently ensuring more patient education on anticoagulation management [37]. Consistently, improved anticoagulation therapy quality was reported in clinical trials with self-monitoring and self-management, in addition to a reduction in thromboembolic events and all-cause mortality (only in self-management) [38]. POC INR testing in the clinic has been shown to have better psychological impact on patients compared to traditional laboratory INR monitoring [38], leading to high patient satisfaction [40]. POCT also allows patients to access the necessary care in critical situations such as global pandemics, promoting adherence to routine monitoring and preserving or improving anticoagulation quality with high rates of patient satisfaction [41–44].

However, the majority of patients are not optimal candidates for POC anticoagulation monitoring [37]. Adequate education and training are essential prerequisites for the safe and effective use of this approach. Moreover, experience with POC INR testing remains rather limited in Saudi literature. One study compared the efficacy of POC INR

testing to standard laboratory measurement at a tertiary care hospital [45]. Results showed that POCT with validated results is comparable to conventional testing methods while simplifying clinic workflow, enhancing the patient experience and convenience (reduced waiting time, immediate result availability) and providing a less invasive alternative. That being said, the researchers cautioned against the reliance on higher INR results with POC devices, suggesting confirmation with core laboratory testing.

#### 4. Position statements –POC anticoagulation monitoring

##### 4.1. Clinical indications for POCT in anticoagulation monitoring

The availability of POC INR testing should not replace the use of standard laboratory anticoagulation monitoring. However, there are several indications for implementing POCT INR monitoring, namely:

- 1 Patients taking warfarin or other VKAs, for AF, VTE, mechanical heart valve or other indications where POC would be used.
- 2 For patients treated with VKAs who are motivated and can demonstrate competency in POC monitoring, including the usual outpatient and home INR monitoring (Patient Self-Management).
- 3 In the out-patient setting in case of busy anticoagulation clinic (i.e. limited time and staff, more than 24 h from blood sample collection till INR results); the use of POCT can reduce waiting time, improve the efficacy of clinical services and ensure patients receive the appropriate treatment for their condition in a timely manner [45–47].
- 4- In case of patients from remote areas with difficulty attending the anticoagulation clinic; the use of POCT is a convenient alternative for laboratory INR testing and provides patients in remote and rural areas access to rapid and effective care [48].
- 5- In the ER setting in case a patient presents with bleeding and requires immediate action; POCTs can be essential as part of goal-directed algorithms for coagulation therapy optimization during emergency situations and/or with massively blood loss [49,50].
- 6- In the Operating Room setting in case there is bleeding with a need to evaluate INR during surgeries; POCT provides rapid and reliable results for patient blood management during

surgery and can improve outcomes, and decrease the number of needed transfusions [51–55].

7- In situations when normal clinical services are inaccessible, such as lockdown during epidemics; POCT INR can be used in drive through locations to provide patients with the necessary anticoagulation monitoring. POCT anticoagulation monitoring can improve adherence to routine monitoring in addition to maintaining or in some cases improving anticoagulation quality all while ensuring patient satisfaction [41–44].

##### 4.2. Frequency of INR monitoring

The frequency of INR monitoring depends on the risk of VTE in each individual patient as well as the treatment phase (initiation or maintenance phase); the initiation phase of warfarin requires more frequent monitoring, with slight variation between the hospital (daily) and outpatient (weekly) settings. More frequent monitoring is needed for patients with high thrombotic risk (e.g. deep vein thrombosis and renal failure), patients with suprathreshold or subtherapeutic INR, patients initiating/discontinuing/changing medication with known interactions with warfarin.

Overall, once INR anticoagulation dose and INR are stable and patients enter the maintenance phase of therapy, INR can be safely monitored every 4–6 weeks. For patients taking VKA therapy with consistently stable INRs, the American College of Chest Physicians guidelines suggest an INR testing frequency of up to 12 weeks rather than every 4 weeks [28]. Moreover, the guidelines suggest that in case of a single out-of-range INR of 0.5 below or above therapeutic in patients taking VKAs, current anticoagulation dose can be continued and INR be retested within 1–2 weeks [28].

INR testing requires many hospital and laboratory visits which increase the cost of management and affect the quality of life of patients and can result in more absence from work and schools. Despite this, there are currently no formal guidelines on the optimal frequency of INR testing with POC monitoring devices in the context of patient self-testing and patient-self management.

##### 4.3. Warfarin monitoring clinic

###### 4.3.1. Goals

Achieving optimal efficacy and safety are the two main goals of the warfarin monitoring clinic. As for optimal safety, it is reliant on continuously educating patients and providers alike, adopting a multidisciplinary approach for patient care

management and reducing adverse events, ER visits and hospitalizations.

The secondary goal consists of, cost-effectiveness of care, patient satisfaction and quality of life improvement.

#### 4.3.2. Purpose and standard precautions/safety

POCT is intended as a useful tool for healthcare practitioners who need to make immediate and informed decisions about patient care and management. All patient and laboratory specimens should be treated and handled as such according to standard precautions. Vaccination of POCT users is recommended in compliance with organizational requirements. Disinfection of POCT devices should be undertaken according to manufacturer recommendation.

#### 4.3.3. Organization

There is an organizational structure that should identify qualified personnel who will be responsible in pre-analytical, analytical and post-analytical aspects and phases of POCT (patient or client preparation, test performance, reporting of results and critical results) as well as the POCT management in particular.

It is important to consider that POCT may vary depending on the healthcare system in Saudi Arabia. Regulatory requirements should be considered early before creating a POCT program.

**4.3.3.1. POCT program director.** The POCT program director is the overseeing authority for the overall operation and administration of POCT. The responsibility of the director includes the involvement of the selection of instruments and tests, in charge of training and evaluation of personnel competence in performing POCT tests, recording and reporting of results in a timely manner, accurately, completely, quality management of operational process, and safety.

The director serves as the liaison between the laboratory and the patients. The director needs to develop and carry out the program as well as the test needed. It is the POCT director's responsibility to ensure that all POCT processes are implemented in accordance with applicable regulatory, accreditation local, national, and organizational requirements.

The director of POCT is ultimately responsible for all oversight of a POC program. The Clinical Laboratory Improvement Amendments (CLIA) requirements for Technical and/or Clinical Consultant must be met in the director of POCT. In general, credentials held by directors of POCT include

doctorate (PhD) in the biological or physical sciences or a medical doctor/doctor of osteopathic medicine (MD/DO). Additionally, directors of POCT hold certification by an appropriate board (clinical chemistry or pathology) for the conduction of these tasks. The responsibilities of the director of POCT consist of quality management (establishing and monitoring quality metrics), compliance with regulatory and accreditation standards, technical troubleshooting, evaluation of analytical method, training operators and assessing their competency, evaluation of new POCT requests, review and approval of policies and procedures related to POCT.

**4.3.3.2. POCT coordinator.** A successful POCT program greatly depends on the availability of qualified laboratory staff. The POCT coordinator should be an experienced medical technologist licensed by the Saudi Commission for Health Specialties, with adequate training in the use of POCT devices. The POCT coordinator will perform duties related to quality, training, assessment, review of reports etc. associated with the POCT program. Responsibilities generally include:

- Management and supervision of the POCT program
- Fulfillment with regulatory and accreditation standards
- Guaranteeing fulfillment with the policies and procedures
- Operator training and competency assessment
- Quality management establishment
- Registration and participation in approved proficiency testing

**4.3.3.3. POC site manager.** The site manager oversees day to day operation of POCT program. The site manager ensures that all POCT instruments are functioning and POCT is performed by certified users according to POCT policy.

**4.3.3.4. POCT users.** The POCT users are assigned to perform POCT. They are non-laboratory personnel that need to be trained in performing POCT testing. All staff using POCT equipment will receive initial training prior to use of the machine. After training, device operator/POCT user will have competency and must be assessed at periodic time intervals depending on the complexity of the test [56].

All POCT users must be suitably trained, maintain the knowledge and skills that enable them to perform POCT, and work within the scope of

practice and competencies. Testing personnel are also recommended to participate not only in training but also in education updates [57].

**Training and Competency for POCT Users:**

Training must be provided for all healthcare providers who use POCT devices. Ensuring that only trained and competent users access the POCT device. The training of POCT users should include all manufacturer and facility necessities, including the pre-analytical and post-analytical steps to ensure accuracy throughout the testing process. Training needs to include:

1. Quality control (QC) (e.g. frequency, documentation, troubleshooting of out-of-range controls)
2. Patient testing (e.g. type of specimen requires, specimen handling, result reporting and documentation)
3. Privacy of patient and client information
4. Preventive maintenance
5. Demonstration, practice, and troubleshooting of instrument operation.
6. Due to the importance of patient safety, the correct identification for POCT should be one of the main training objectives [56].

The competency of POCT practitioner performing waived or nonwaived should be assessed at a required frequency. Competency for nonwaived testing, such as INR, must be assessed, during the first year of an individual's duties at least semi-annually; after an individual has performed his/her duties for one year, competency must be assessed at least annually; retraining and reassessment must also occur when problems are identified with an individual's performance. All six elements listed below must be covered during each assessment. Training records must be retained for a minimum of two years. After the initial two-year period, records of successful ongoing competency assessments maybe used in lieu of training records (as per the POCT Checklist of the College of American Pathologists (CAP) Accreditation Program).

For waived test systems, it is not necessary to assess all six elements listed below at each assessment event. The POCT program may select which element to assess.

1. Direct observations of routine test performance, including as applicable, patient identification and preparation; and specimen collection, handling, processing, and testing.
2. Monitoring test result recording and reporting, including critical results if applicable.

3. Review of intermediate results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
4. Monitoring of instrument maintenance and function checks.
5. Assessment of test performance through testing previously analyzed specimen, internal blind testing samples, or external proficiency samples.
6. Evaluation of problem-solving skills.

#### 4.3.4. Benefits and advantages

POCT mainly provides accurate and timely test results that effectively contribute to make immediate informed decisions about individual care. POC coagulation testing allows rapid patient interventions; POC Prothrombin time/INR analyzers provide immediate, actionable results. This expedites patient management and reduces a warfarin anticoagulant therapy patient's visit from 3 hours or more to as few as 30 minutes. Moreover, POCT minimizes the visits to the Warfarin clinic and POCT can be used regardless of geographic differences [58]. A number of studies have shown that POCT does not have a different effect on the outcome by geographic location [58]. POCT ensures greater convenience and satisfaction for patients because of the speed of diagnosis and treatment decisions while also providing more opportunities for patients to engage with the practice team [57].

#### 4.3.5. Selecting equipment/INR POCT instrument

Selecting and purchasing the testing equipment should be determined in advance. Part of the POCT program is establishing a policy or procedure for purchasing POCT equipment that is fit for purpose in the clinical setting.

The first step in the implementation process is to contact the manufacturer or the suppliers of the measurement procedures and instruments to get information on the specification, costs, QC, and training needs. Upon review of the manufacturer's literature or manual, manufacturer's representative will be contacted to teach personnel with the devices. Evaluation of POCT INR/Coagulation machine will be suggested. Evaluation includes precision, accuracy, and heparin study (as needed for other coagulation tests like activated partial thromboplastin time, activated clotting time-low range, activated clotting time plus). The amount of consumables needed for the evaluation should be considered beforehand with the manufacturer.

Challenges, advantages, and comments should be discussed and documented after evaluation of the machine or kit(s) and could include:



- Size of the machine
- Food and Drug administration (FDA) approval
- Maintenance requirements/planned preventative maintenance
- Easy to use and to operate
- Connectivity/WiFi/USB/Middleware
- Operator and QC lockout
- Calibration requirements
- Calibration Verification/Linearity Materials (nonwaived)
- Optimum capacity of battery when fully charged (if applicable)
- Cost analysis report to calculate the direct and indirect cost of the service (study of the total cost-effectiveness might help decision making/device selection (direct and indirect cost) [59])
- Sample requirement and amount of sample needed.
- Method of sample collection and processing (is it invasive or non-invasive method of collection? Can the sample be used directly from the collection container?)
- Frequency of QC
- Storage conditions, shelf-life and amount of consumables/reagents
- Other consumables (Syringe and single-use auto disabling finger prick)
- External quality assurance program
- Memory of the device for sample storage and number of users
- Accessories (printer, barcode scanner)
- Alpha-numeric keys response (Touch screen or buttons)
- Lancet and fingerpick specification

The selection of instrument is optimized when operators who are knowledgeable about laboratory testing and have tested the suggested instrumentation or kit(s) are part of the decision making process [56].

#### 4.3.6. Method validation

Validation is to confirm by examination and to obtain objective evidence that the particular requirements for a specific intended use are fulfilled. It is the responsibility of the manufacturer and laboratory to ensure that the testing devices and related equipment perform as expected for their intended use.

The analytical performance requirements of the lab must be defined prior to implementing a new POCT service or device. POCT through newly introduced FDA-approved, nonwaived tests/methods have go through thorough investigation prior to reporting of patient results.

As applicable, validation should include the study and acceptance of the following: 1) accuracy (verification of comparability of results), 2) analytic precision, 3) analytic sensitivity (detection limit); 4) analytic specificity/interference, 5) reportable range of patient test result/the analytical measurement range (AMR), and 6) reference interval validation (normal values-ranges).

Non-FDA cleared, modified, or Lab Developed Tests need to be assessed for all of the above-mentioned performance measures before patient test result reporting, as applicable. Interfering substances may be obtained from manufacturers or published literature (for more information, please refer to CAP All Common Checklist 2020).

To start with method validation, formulating a plan may be considered, including the following elements:

1. Name of Analyzer and analyzer type
2. Type of test/s (quantitative)
3. Measurement items/analyte (INR)
4. Sample type (fresh whole blood) and number of samples needed for validation
5. FDA approval
6. Consumables needed to be provided by company (QC materials and strips/cuvettes for precision, accuracy/comparison, linearity, normal values-ranges)
7. Date machine received or delivered in the area
8. Start date of validation
9. Target date of completion (validation)
10. Challenges and comments
11. Contact person from company and communication trail

Appropriate software (such as MS Excel, EP evaluator, Analyze-it, etc.) can be used to analyze and document validation study and to achieve standardization of key performance characteristics in the documentation of analytical assays. The validation spreadsheets should contain the following statement, "This validation study has been reviewed and the performance of the method/test is acceptable for patient testing", as per CAP requirement.

#### 4.3.7. Quality system

Responsibilities for the implementation of POCT for analytical and non-analytical assays must be defined in the quality system. The POCT supervisor/POCT Coordinator is the one assigned and has the authority to take responsibilities for 1) formulating policies and implementation, 2) establishing protocols to prevent the spread of infection, 3) staff education/training and POCT operational activities,

4) overall quality system of POCT performance and POCT devices, 5) monitoring internal quality control performance of POCT users, 6) keeping the in-house inventory of the required POCT consumables/reagents and 7) record keeping.

A periodic review of policies and procedures must be at least annually. Auditing of POCT services in clinical areas will be conducted by POCT coordinators to ensure compliance and corrective action will be discussed (if there is any). Enrolling and participating in a proficiency testing/external quality assessment (EQA) program such as that offered by the CAP is a requirement. However, if unable to participate in proficiency testing, an alternative assessment procedure for the affected analyte should be implemented (See All Common Checklist CAP Accreditation Program 2020).

12 quality essentials should be evident in the POCT program as described by the Clinical and Laboratory Standards Institute, as well as [ISO 15189](#). The 12 quality essentials are organization, personnel, equipment, purchasing and inventory, process control, information management, documents and records, occurrence management, assessment, process improvement, customer service, and facilities and safety.

As previously mentioned, studies report the reliability of POC INR readings in comparison to standard laboratory based method of INR [16,31–35]. In one study, the INR values by POCT method were significantly correlated to the standard laboratory method with correlation coefficient of 0.875 [60]. This strong correlation was more evident at lower INR readings (<2.5) with differences ranging between 0.1–0.3. However, the disagreement between the two methods was more often observed with higher INR values; the difference between POC and laboratory INR measurement can be up to 1.0 for INR values between 2.5 and 4.5 and can reach 2.0 for INR values higher than 4.5.

This was confirmed in a published local Saudi; results indicated that caution is needed with regard to higher INR results (>4.7), which call for core laboratory confirmation [61]. It is therefore essential to know the limitation of the POCT method in order to generate safe guidelines for clinical practice. Based on the published data about the accuracy of POCT, it is not clear which INR cut-off value should be used to consider a repeat of the test by conventional laboratory methods. While it is important to standardize the POCT procedure from sample collection to analysis and also ensure the adequate quality of the instrument, guidelines are needed on when to consider repeating INR POCT by laboratory methods in specific cases such as:

- high INR level >4.0,
- fluctuating results between visits,
- major change in the warfarin dose,
- a clinical episode of bleeding and thrombosis despite POCT INR values being within therapeutic range.

It is recommended to consider INR of 4.7 as the cut-off point that mandates a repeat INR test using conventional laboratory methods.

#### 4.3.8. Workplace/POCT site

A safe and secure area is essential to ensure effective POCT test performance. The POCT site must address to all aspects of POCT such as POCT test performance, POCT device location, Internet/Wifi for connectivity, phlebotomy chair (as applicable), equipment maintenance and equipment function checks including documentation, reagent storage and consumables, patient sample storage and records, pre-testing counselling, specimen testing, result reporting and critical results reporting, waste management as well as safety requirement.

All POCT equipment must be operated by a trained/certified POCT user only. In the event of machine failure, there must be a contingency plan to continue operation with validated backup devices provided by the POCT lab. A copy of the Operator's Manual should be readily available near the POCT device in addition to a list of certified competent POCT users.

#### 4.3.9. Connectivity

When electronic medical records are available in-patient care setting, suitable connectivity must be in place between the test system and the medical information system to ensure POCT results are incorporated into the medical record. This will guarantee the availability of test results anytime for health care providers. If connectivity is not available, the POCT user can record the results manually following the hospital policy of results documentation and reporting of critical results.

Using a middleware for POCT machine might help the POCT coordinators manage the device and POCT operators. The middleware receives data from the connected POCT devices and can send the patient results to the laboratory/hospital information system. POCT coordinators are able to manage and quickly resolve issues related to device performance. One can also adjust device settings using the middleware. The use of middleware plays an important role in managing QC violation and calibration issues. Corrective actions can be done

remotely. QC data, Levey Jennings chart, and calibration data, audit trail, and analyzer messages can be saved and can be extracted if needed for documentation and investigation purposes.

## 5. Conclusions

POCT enables more rapid clinical decision making in the process of diagnosis (rule-in or rule-out), treatment choice and monitoring, and prognosis, as well as operational decision making and resource utilization. POCT thus can fulfill an important role by helping address the pressures faced by healthcare providers and administrators, particularly in the emergency department. Hospital overload and delayed clinical action are faced on a daily basis in clinical practice. While this issue is multifactorial, one of its main drivers is the overflowing of emergency departments. By implementing POCT, better clinical follow up and earlier discharge can be ensured by improving the efficiency of hospital departments. This is achieved through the reduction of the number of people that need to be admitted, be it to the emergency department or any other department. That being said, the limitations of POCT should be recognized and recommendations on best practices should be strictly followed. Core laboratory confirmation should be sought for patients with higher INR results (>4.7) on POCT. Proper training, quality control and regulatory oversight are also critical for preserving the accuracy and reliability of POCT results.

## Author contribution

Conception and design of Study: FAA. Literature review: FAA, MAM, MHA, MAS, TO. Acquisition of data: FAA, MAM, MHA, MAS, TO. Drafting of manuscript: FAA, MAM, MHA, MAS, TO. Revising and editing the manuscript critically for important intellectual contents: FAA, MAM, MHA, MAS, TO. Supervision of the research: FAA. Research coordination and management: FAA. Funding for the research: FAA.

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## Conflict of interest

None declared.

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