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Developing Venous Thromboembolism Prevention Program: A Comprehensive Systematic Approach

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Abstract:

Introduction: Venous thromboembolism (VTE) prevention is considered one of the patient safety priorities that need measuring and reporting considered.

Aim of the Study: This research serves as a guide for providing principles for effective designing, implementing, and monitoring of VTE prevention programs for inpatients in secondary-level care hospitals.

Subjects and Methods: A quantitative and qualitative study was used to design and develop a quality improvement framework that develops a rubric VTE prevention program.

Results: The initial baseline assessment revealed suboptimal practice of VTE prevention. It was followed by developing documentation of a standardized VTE risk assessment upon admission, a Local unified protocol and process map for assessing inpatients and prescription of optimal VTE prophylaxis, and a set of metrics developed for monitoring purposes. It included the categories of measures that needed to be collected with their specific collection time.

Conclusion: Collaborative team efforts and supportive leadership were the cornerstone of the development of successful standardized guidance for VTE risk assessment and prevention.

Keywords: Quality Improvement; Safety; Design.

1. Introduction

Venous thromboembolism (VTE) is recognized as one of the most common preventable complications of hospitalization and a preventable cause of hospital deaths [1]. Approximately 60% of all VTE cases originate from the hospitals, either during hospitalization or in the six weeks post-discharge.

VTE is associated with substantial morbidity and mortality and also it implies a burden on the healthcare system [2]. The appropriate use of prophylaxis is considered one of the most inclined safety practices, which is ultimately based on the impact and effectiveness [3]. Furthermore, numerous guidelines have been recommending thromboprophylaxis for decades. Despite the strong supporting evidence, there is suboptimal compliance with VTE risk assessment and prophylaxis for hospitalized patients [1, 4].

Almost every hospitalized patient is at risk for VTE and most have multiple risk factors [5]. In the absence of prophylaxis, the Deep venous thrombosis (DVT) (including asymptomatic DVT) incidence of various hospitalized patient groups ranges from 10% to 80% [4]. VTE is associated with increased patient mortality. The 30-day case fatality rate for DVT and PE is 2-5% and 33%, respectively [6].

Massive PE is the cause of death in approximately 10 per cent of all hospital deaths [3]. Its prevention is the number-one strategy to improve patient safety within hospitals [2, 7].

In addition to acute consequences of hospital-associated VTE, patients are still at risk for other complications. Patients who develop VTE experience a clinically important bleeding episode while on therapeutic anticoagulation (up to five per cent) per year [1]. 30-50% of DVT patients will develop post-thrombotic syndrome, and approximately 4% of PE patients will develop chronic thromboembolic pulmonary hypertension [8].

Thromboprophylaxis for high-risk inpatients has been associated with improved outcomes. It can reduce VTE by up to 65% and has a low incidence of major bleeding complications [2, 7].

Regulatory and quality initiatives have been instituted to improve VTE prevention [1, 4]. In 2008, the United States Surgeon General produced a call to action for VTE prevention and Many organizations

in the U.S. have made VTE prophylaxis a patient safety priority [9, 10].

In May 2020, the American Heart Association published a policy statement which serves as a call to action to reduce incidents of VTE. The policy statement provides policy guidance aimed at better implementation, tracking and prevention of VTE events [10].

Responding to international demands and enhancing patient safety to ultimately decrease these resulting preventable morbidity and mortality [1, 4, 11]. Our journey of implementing the VTE prevention program started in 2015 when the importance of having a comprehensive approach to the VTE prevention program was identified to fill the gap between evidence-based best practice and actual practice. This research will provide principles for effective designing, implementing, and monitoring of VTE prevention programs for inpatients in secondary-level care hospitals.

2. Subjects & Methods

2.1. Study design

A design and development study took place in one of the biggest governmental organizations in Kuwait. It delivers preventive, diagnostic, and curative services for about one-third of Kuwait residents. The hospital bed capacity is 867 beds. The clinical services delivered by the hospital are internal medicine and most of its divergent specialties, different surgical specialties as general, urology, vascular, orthopedic and ophthalmology and ICU specialties.

A combined quantitative and qualitative quality initiative approach was adopted to plan and accomplish the study. It included a quality improvement (QI) framework including four stages and had been preceded by two fundamental steps before the start. Some QI stages adopted quantitative, others adopted qualitative and some include both.

The first fundamental step was the revision of the published evidence, and international guidelines and identified best practices for preventing hospital-associated

VTE. The second one was obtaining the support and commitment of the leadership (the hospital administration and the quality department).

The framework aimed to outline and coordinate the steps toward breakthrough improvement starting from planning, designing, implementing and monitoring the program with identified responsibilities and a predetermined timeline. It had been derived from common elements of Plan, Do, Study, Act (PDSA), Lean, and Six Sigma [12-14]. **Table 1** and **Figure 1** illustrate the QI framework stages and steps.

Table 1: QI Framework stage and steps

Stages and steps of the QI framework	Responsibilities	Duration
1. ***Review the actual practice of VTE prophylaxis and design the plan.***		
1.1. Conduction of baseline audit to obtain the actual VTE prevention rates in hospitalized patients and their outcomes.	Head of the Clinical hematology unit.	4 months
1.2. Analysis of results, identifying the scope of the program, assimilating the definitions for best practice, and predicting the constraints and needed resources along with starting the QI framework. 1.3. Dissemination of findings to hospital Administration and other stakeholders for gaining the leadership commitment along with embedding the initiative as a strategic goal of the organization.	Head of Clinical hematology Unit and Quality department.	2 months
2. ***Introducing multifaceted interventions.***		
2.1. Formulation of a multidisciplinary team focused on reaching VTE prophylaxis targets as addressed in the strategic plan and reporting to key medical staff committees.	Hospital administration and Quality department.	1 month
2.2. Distillation of the most important best practices from the guidelines and other sources then translate that information into local VTE prevention protocols and policies (Annex 1) along with designing manual VTE risk assessment forms and pre-printed admission orders.	The multidisciplinary team.	4 months

2.3. A pilot study was done to assess the usability of manual VTE risk assessment forms and pre-printed admission orders for all admitted patients.	Clinical hematology unit.	1 month
2.4. Developing the slogan of (DVT-Safe Zone) and the formal start of implementation and monitoring.	Hospital administration and the multidisciplinary team	1 month
2.5. Finalizing approval and dissemination of unified standardized protocol and the process map of VTE prophylaxis.	The multidisciplinary team	3 months
2.6. Inclusion of information technology (IT) representatives to the team for the sake of designing the electronic VTE risk assessment and Physicians' admission orders.	The multidisciplinary team and IT	4 months
2.7. Robust inclusion of training for the target group of physicians to the whole staff in the form of (lectures, videos, focus group discussions, and hospital-wide awareness days). 2.8. Once the target group is covered, the training is repeated at regular intervals (annually) using the different methods mentioned.	The multidisciplinary team	3 months
3. ***Monitoring and refining the process and implementation.***		
3.1. Developing a set of metrics including the structure, process and outcome measures.	The multidisciplinary team and quality department facilitators	3 months
3.2. Initial monitoring for the compliance to create improvement adjuvant interventions to computerized physician order entry and to reinforce and integrate the protocol into practice in the form of: • Mandating the use of the VTE risk assessment forms and their related physicians' orders, along with. • Activating DHIS alert. • Continuous meetings of the multidisciplinary team. • Front liners champions as leverage advocates for the program in their departments.	The multidisciplinary team and hospital administration	6 months
4. ***Sustain, refine, and spread.***		

4.1. Continue monitoring using the prepared set of metrics with continuous reporting.	*Continuous*
4.2. Planning future steps as: • Alliance the diagnoses in DHIS with ICD 11 for effective surveillance and maximizing the effectiveness of the intervention. • Publication and conference talks.	

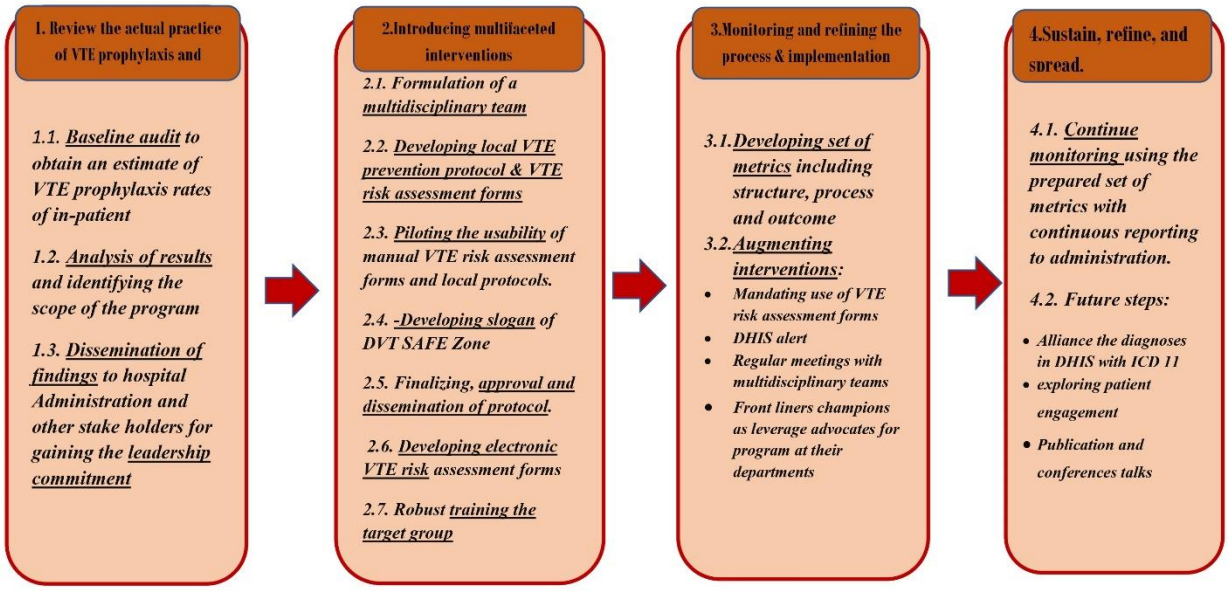


Figure 1: QI Framework stage and steps.

2.2. Subjects

No active inclusion of participants was done in this study. Only patient data from records were collected retrospectively from patient files and the Digital hospital information system (DHIS) using a unified data collection form.

Hospital managers were included from the start in the 2nd fundamental step before the start of the QI frame and throughout the QI stages as mentioned in Table 1: QI Framework stage and steps.

Inclusion criteria for baseline data were patients admitted in medical and surgical wards, who were aged 18 years and above.

2.3. Data collection and management

Baseline data about the current practice of VTE prophylaxis were. The data collection form included closed-ended questions related to VTE risk assessment upon admission, VTE assessment time, indications of prescribing prophylaxis, receiving the appropriate prophylaxis during hospital stay and upon discharge and any documented evidence of patient education.

Data was entered using Statistical Package for the Social Sciences (SPSS) version 25. Discrete data was generated. NO and percentages were used to identify baseline practice of VTE prophylaxis

No sampling technique was used because patient data of one month for all admitted patients were collected by qualified quality office members. The average monthly admission rate to different inpatient services is 99 patients while the total admission for the year 2016 reached 26138 inpatient admissions [15]. Data management was dealt with by SPSS version 25.

3. Results

Before the start of the planning phase, a Baseline Audit was conducted to obtain an estimate of VTE prophylaxis practice. It explored that none of the patients had a documented risk assessment in specific form. 90% of patients indicated thrombo-prophylaxis. Only 22% received appropriate thrombo-prophylaxis, and 77% were not prescribed anticoagulant or mechanical thromboprophylaxis. Twenty-three of the patients had a delay in starting thrombo-prophylaxis (more than 24 hours after admission). The wrong dose of anticoagulant thrombo-prophylaxis was observed in 4% of eligible patients for thromboprophylaxis, while 23% of patients had a contraindication to anticoagulant thromboprophylaxis but were not prescribed mechanical thromboprophylaxis.

The Process Map of VTE Prophylaxis displayed in Figure 2 provides specific guidance for identifying and managing groups of patients in an algorithmic structure that facilitates clinical decision-making, tailored to the local environment.

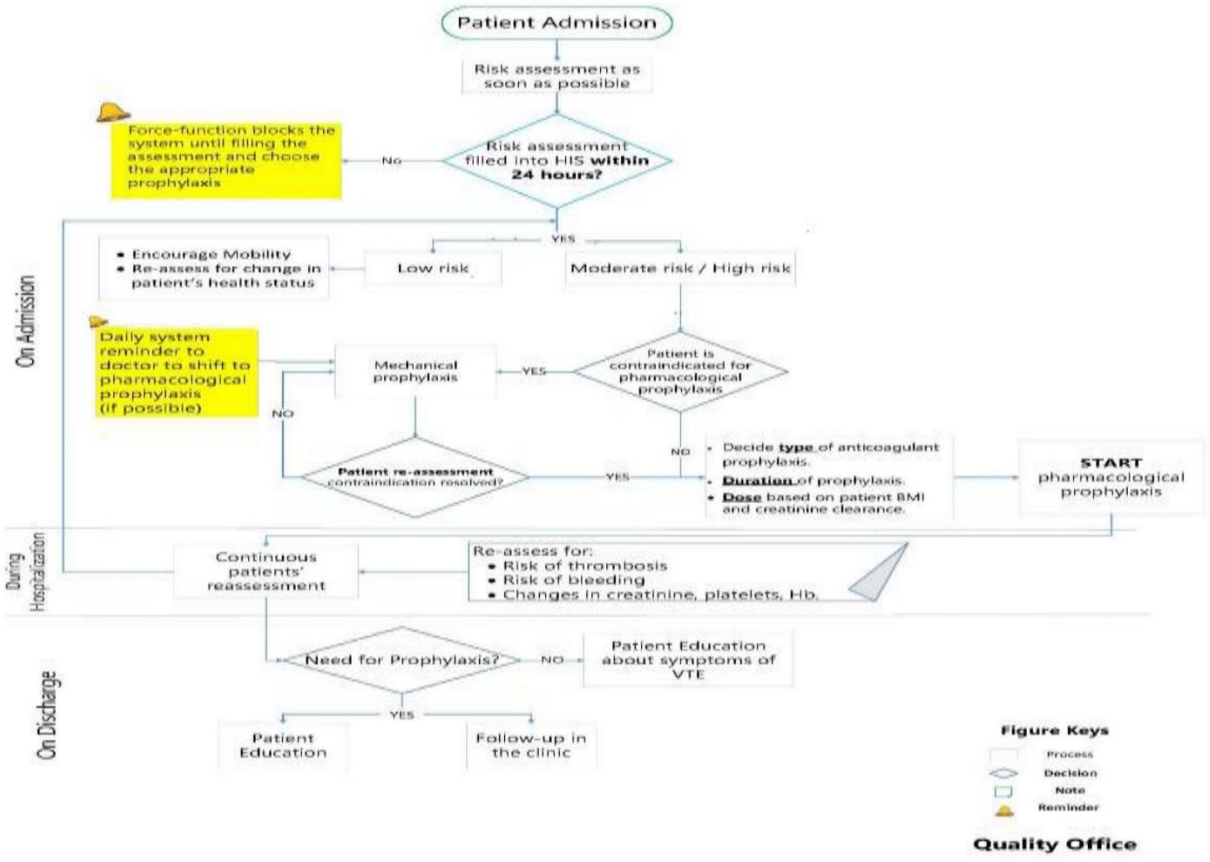


Figure 2: Process Map of VTE Prophylaxis starting from patient admission tell discharge.

The multidisciplinary VTE prevention team addressed in **Table 2** at a minimum included a team leader, QI facilitator, process owners and information technology expert. Each team member has specified responsibilities to be accomplished through the journey of implementing VTE prophylaxis. A team leader is preferred to be a clinician who has an experienced background in VTE prophylaxis and anticoagulation.

Table 2: The multidisciplinary VTE team members and their assigned descriptions and responsibilities.

Team member	Description	Responsibilities
Team leader	A clinician from the medical staff (head of hematology unit) with fair expertise in VTE prophylaxis and anticoagulation.	• Setting the agenda, a collaborative tone, and the frequency of team meetings. • Communicating with administrative and medical staff committees. • Master the practice and guide the management of patients. • Preparing the broad lines protocols. • Enforce constructive team dynamics.
QI facilitator	Healthcare quality professional with quality improvement and management skills.	• Ensuring the team functions constructively, the project moving projects forward. • Preparing the QI framework, ensuring the achievement of each step. • Provides project management and people management skills. • The ability to introduce appropriate QI tools at a suitable time.
Process owners	Front liners (Clinical department representatives) personnel involved in providing VTE prophylaxis in the hospital	• Sharing in preparing and adjusting the in-house protocols. • Involved in providing VTE prophylaxis. • Sharing the training process and developing educational materials. • Involved in the monitoring process and feedback.
Information technology expert		• Design the framework of electronic forms with patient orders. • Retrieve the needed data for the monitoring process.

The bunch of metrics shown in **Table 3**, included the categories of measures needed to be collected. Each measure has a specific collection time with its needed sampling technique if required. Structural measures are advised to be collected at the

baseline and after the start of the implementation phase rather than being collected regularly. Process measures are the most important and reflect the checking of the VTE practice at different stages– within 24 hours of admission, during hospitalization and before discharge. The process measures shall be collected regularly by a systematic random technique from the whole number of admitted patients monthly. Only one outcome-effective measure is recommended; however, its collection is related to the event occurrence rather than the sampling technique.

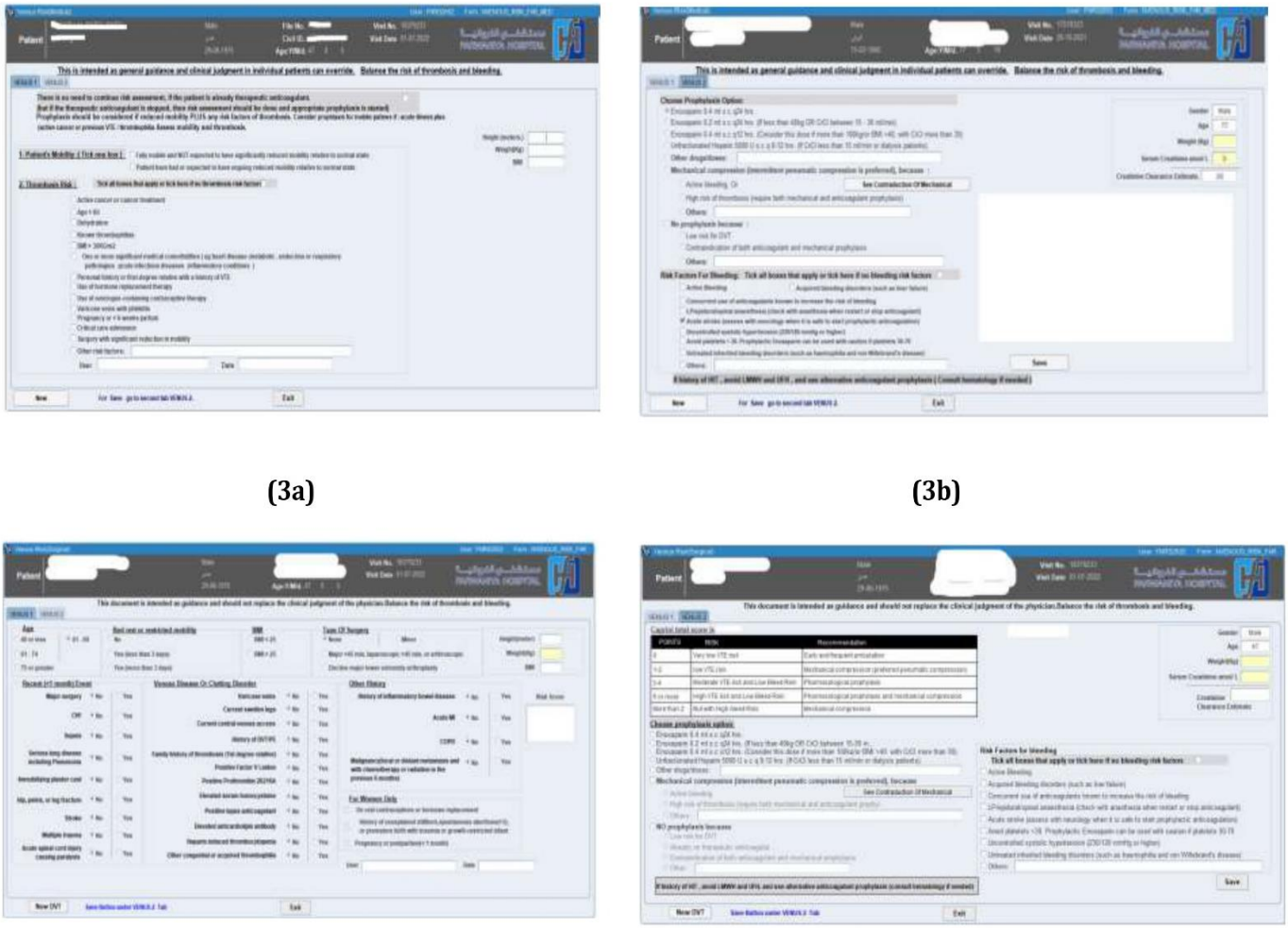
Table 3: Set of metrics for monitoring the VTE prevention program.

Type of measure	Measure/s name	Timing of collection	Sampling technique
Structure	• The institution has a VTE prevention policy in place.	• Baseline phase. • Pilot testing phase. • The start of the implementation phase.	NA.
	• A standardized order sets incorporating clinical decision support.		
	• A measurement system is in place.		
Process	• The VTE risk assessment sheet is filled within 24 hours of admission.	• Baseline phase. • Pilot testing phase. • Quarterly basis after the start of the implementation phase.	Systematic random sampling.
	• Medium and High-risk patients received prophylaxis within 24 hours of admission.		Convenience sample.
	• Prescribing pharmacological treatment for indicated cases.		Convenience sample.
	• During hospitalization, reassessment is done to resolve contradiction for pharmacological prophylaxis/continuing pharmacological prophylaxis.		Convenience sample.
	• Patient education about VTE symptoms upon discharge.		Systematic random sampling.
	• Patient discharge on VTE prophylaxis.		Convenience sample.
Outcome	• HA-VTE incidence (morbidity/mortality) during or after hospitalization.	• A after the start of the implementation phase.	No sampling.

As shown in **Figures 3a & 3b** is the medical department VTE risk assessment form and its recommended prophylaxis method. All the screens display the patient's basic and demographic data. Venus 1 shows the steps needed to be done by the physician once a risk assessment is started. The BMI calculator on the right side of the screen is the start point entering height in cm and weight in kg, and then automatically BMI will appear. After that, the physician shall assess and tick the item that indicates either the patient's mobility is full and not expected to significantly be reduced or the patient already had or expected reduction of his/her mobility. That is followed by ticking the factor/s that could serve as thrombosis risk from the drop list. After pressing the save button the screen will display Venus 2 (**Figure 3b**).

Venus 2 displays the options of prophylaxis either pharmacological choices or mechanical compression if the patient experiences a contraindication for pharmacological prophylaxis. Even if the patient does not indicate prophylaxis (justification cause is addressed as options). The lower half of Venus 2 includes the factors of risk of bleeding, that the physician shall tick if applicable to the patient's condition.

The surgical department VTE risk assessment form and its recommended prophylaxis method are displayed in **Figures 3c & 3d.** All the screens display the patient's basic and demographic data. Venus 1 included Cabrini risk assessment items which were obtained and redesigned to fit in the electronic screens. Venus 1 shows the steps needed to be done by the physician once a risk assessment is started. The surgeon shall choose from the options displayed in the first part of Venus 1 as age group options, patient's mobility status, BMI score and type of surgery. In medical form weight in kg and height in cm will be calculated to obtain BMI on the right side of the screen. As regards the patient's history, it is further divided into recent events (less than 1 month) that exposed the patient to be at high risk for VTE. Other and other history categories include the history of inflammatory bowel disease, acute MI, COPD and malignancies. A specific section is dedicated to female patients and includes closed-ended questions about obstetric history. Also, Venous disease /clotting disorders questions were displayed as yes/no questions which the surgeon will choose from. After pressing the save button the screen will display Venus 2 (**Figure 3d**).



(3a) **(3b)**

(3c) **(3d)**

Figure 3: Medical and surgical electronic risk assessment forms and their VTE prophylaxis methods.

In Venus 2, Cabrini's total score occupies the upper one-third of the screen and displays the result of Cabrini's score, with the level of risk and recommendations of actions.

The middle of the screen included the options of prophylaxis either pharmacological choices or mechanical compression if the patient experiences a contraindication for pharmacological prophylaxis or no prophylaxis with justification options. There is another section in the lower half of Venus 2 that includes the factors of risk of bleeding, that the physician shall tick if applicable to the patient's condition.

4. Discussion

Venous thromboembolism (VTE) comprising deep vein thrombosis (DVT) and pulmonary embolism (PE) are among the common causes of preventable morbidity and mortality for patients in hospitals [16, 17]. Consequently, VTE prophylaxis is a highly demanded process in a very complex hospital environment.

Tangible leadership support was clear and had been reflected in the corporation of the program within hospital strategic targets, developing the slogan (VTE safe zone) and by that support, the hospital standardized the process even in the face of physician resistance.

In the current study, from the start a quality improvement (QI) framework was adopted and was particularly helpful in introducing changes for obtaining desired outcomes and closing the gap between optimal care and actual delivered one [18]. The framework was a logical step and was put into use immediately by the multidisciplinary team and facilitated by our hospital quality department. The QI framework principles presented throughout this study came in consistent with the "Translating research into practice" (TRIP) model's steps to implement mandatory VTE risk assessment and risk-appropriate prophylaxis [16]. Also, it came following the framework used by Maryland (4) which depicted multiple interventions designed to reinforce the guidance implementation of the (VTE) prevention protocol.

The QI framework of the current study included four stages, which varied in their timeline. As observed, the first stage of reviewing the actual practice and designing the plan took six months while, the second stage completion time had exceeded one year, while the 3rd and 4th stages are still ongoing. The expected timeline specified to accomplish each step enriched the advice for any organization that would adopt a similar framework.

In the first stage, a baseline assessment of VTE practice was done in 2016. However, across the globe, there is greater variation in approach [19]. Our hospital baseline audit revealed suboptimal practice when compared to what was reported by Epidemiologic International Day for the Evaluation of Patients at Risk of Venous Thrombosis in the Acute Hospital Care Setting (ENDORSE) study, and Getting It Right First Time (GIRFT) Thrombosis Survey [20-23].

It came also less than what was stipulated at level 2 of the hierarchy predicted table addressed in the Agency for Healthcare Research and Quality (AHRQ) guidance. It started when protocol guidance exists but is not present at the right time or place to influence VTE prevention orders or without standardized protocol as addressed in the current study, the compliance is about 40% [4].

The recommendations resulted from the baseline audit aimed to answer the key questions that helped in scoping the program and outlining the target appropriate level of prophylaxis for the prevention of thromboembolism (the target is 100% of assessment and providing prophylaxis)

The second is considered the real start of our journey, where team Tools to Enhance Performance and Patient Safety (STEPPS) principles were followed to organize and manage the multidisciplinary (24). The team leader was the head of the clinical hematology unit who had a postgraduate degree in the field and had the curiosity for implementing the approach. Along with an expert QI facilitator and the process owners from different departments.

The team introduced tangible multifaceted improvement strategies which had a valuable effect and matched the five principles for effective implementation in clinical decision support previously addressed [4, 25].

Local unified protocol included the local definition of acceptable practice and physicians' admission orders were developed according to the National Health Service (NHS) and Advanced Clinical Practice Definition (ACCP). Choosing these guidelines had an outstanding effect in succeeding the project because it worked for the great majority of patients as reported by [26].

Adopting NHS guidelines and Cabrini score as Risk assessment measures (RAMs) for medical and surgical patients respectively, has a great hand in executing structural assessment of VTE for patients upon admission. The Cabrini model is a quantitative point-based model and has been externally validated as being predictive of VTE risk in general surgical patients [27].

To empower the intervention, the team diagramed the VTE process, which was viewed as a series of intermediate steps that lead to a clinical endpoint and existed from the moment the patient is admitted and recur daily. Diagramming helps remember a sequence of events and recall interactions in

a complex process. It empowers also members to understand the interrelated steps and to identify where failures or missed chances to prevent hospital-associated VTE (HA-VTE) could occur [28].

In the third stage, the team and the QI facilitators had prepared comprehensive measures to track the effectiveness of the VTE process once the implementation started.

The metrics proposed to evaluate structural, process and outcomes aspects. Developed structural measures aimed at assessing the availability of organizational tools to support VTE prevention efforts. They are proposed to be collected from all inpatients' services (medical, surgical and ICU).

Process measures were prepared according to the process map's stages (admission, hospital stay and discharge) to examine the reliability of crucial steps in healthcare delivery. It matched what is prepared by different studies and occupied the most prepared measures [26], this referred to the fact that good process measures are strongly linked to outcomes.

Outcome measures were prepared to assess the impact of the intervention and the efficacy of the prophylaxis.

The researchers in the current study paid attention to the timing of collection as each metric and its recommended sampling technique were displayed to serve the aim of the study as a guide for any organization which may adopt the model's metrics.

The initial data obtained from monitoring empowered taking augmenting actions such as the conversion of the practice from manual forms into paperless practice using the Digital Hospital Information System (DHIS). It was highly demanded and came by what was reported previously [29], because digitalization helped to make the practice as efficient as possible, a better understanding of how to improve the practice, follow-up of the compliance and minimizing any chance of missing data that may occur.

On the contrary, some providers who had bypassed the protocol empowered the decision to mandate the usage of manual and electronic risk assessment models which was recommended later in 2021 by WHO in pointing to its importance [30].

In the fourth stage, overall agreement of spreading the implemented intervention to other local healthcare organizations had been obtained, which reflected the supportive role of leadership in taking a

successful implementation process from a pilot to a wide-scale implementation.

Also, future steps and challenges faced by the team throughout their journey were picturized. The main future steps are the alliance of the diagnoses in DHIS with the International Classification of Diseases (ICD) version 11 for effective surveillance of the effectiveness of the intervention, and requesting the national mandating of the VTE assessment and needed prevention for admitted patients highly favorable as it also recommended by WHO, NHS [30].

Where main challenge is the continuous demand to alleviate the tension between the desire to provide comprehensive, detailed guidance and the need to keep the process simple to understand and measure. Also, successful management of reported deficiencies in adhering to mechanical and pharmacologic prophylaxis VTE prophylaxis is just one priority among many for busy clinicians and QI leaders.

5. Conclusions

Hospital-associated VTE is a common and potentially devastating complication of hospitalization. Guidelines for VTE prevention are numerous and do not always agree, and the complexity of the inpatient setting and the variability of patients make implementation of evidence-based guidelines challenging. This research served as a foundational beginning point that outlined the crucial steps to start the implementation and embed VTE prevention practices before the start of admission services for different hospital departments.

Collaborative team efforts and supportive leadership were the cornerstone of the development of standardized guidance for VTE risk assessment and prevention. This research outlined a comprehensive, interdisciplinary approach to inpatient VTE prevention, and the techniques described are designed to be portable to a wide variety of inpatient settings. Also, this research opens the gate for future research about the impact of the program on outcome measures and the whole compliance to metrics will take place soon

The study was conducted in one health care facility. The baseline data was collected according to certain parameters not as the metrics that have been developed later.

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Availability of data and material: All data generated or analyzed during this study are included in this published article.

Competing Interest: All authors declare no conflict of interest

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