The AHA/HRET HEN would like to acknowledge our partner, Cynosure Health, for their work in developing the Venous Thromboembolism (VTE) Change Package.
WHAT'S NEW IN THIS VERSION?

- Updated references.
- Outcome measures focus on assessing:
  - Preventable VTE
  - Post-OP VTE
- A new measure was added which may be more appropriate for small-volume hospitals.
- New process measures
- Patient and family engagement considerations (see the updated driver diagram, ideas to test and narrative section)
- Discussion of controversies in prophylaxis for medical patients included.
- Expanded focus on prophylaxis in surgical patients.
- Discussion of new oral anticoagulants and their role in VTE prophylaxis.

OVERVIEW

Background

- Venous thromboembolisms (VTE) (including pulmonary emboli) are the most common causes of preventable hospital death.
- The risk for developing VTE ranges from 10 – 85% (and varies based on the reason for admission).
- The rate of fatal pulmonary emboli more than doubles between the ages of 50 and 80.
- A U.S. multicenter registry study showed that the majority of hospitalized patients with risk factors for venous thromboembolism (VTE) did not receive prophylaxis.

Suggested AIMs

- Reduce the incidence of hospital-acquired VTE by 40% by December 8, 2014.
- Increase the utilization of appropriate VTE prophylaxis in at-risk patients to 100% by December 8, 2014.

Outcome Measures

Indicator Name: Post-Op VTE (EOM 105)

Definition: Number of surgical patients that develop a post-operative PE or DVT

Numerator: Discharges with ICD-9-CM codes for deep vein thrombosis or pulmonary embolism in any secondary diagnosis.

Denominator: All surgical discharges age 18 and older defined by specific DRGs or MS-DRGs and an ICD-9-CM code for an operating room procedure.

Source: AHRQ PSI-12

Indicator Name: Potentially Preventable VTE (EOM 104)

Definition: The number of patients diagnosed with confirmed VTE during hospitalization who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date.

Numerator: Patients who received no VTE prophylaxis prior to the VTE diagnostic test order date.

Denominator: Patients who developed confirmed VTE during hospitalization.

Source: JC VTE-6

Indicator Name: Days since last VTE

(AHA/HRET HEN-Rural CAH Data Collection Tool)

Definition: Days since last VTE

Numerator: Days since last VTE

Denominator: N/A

Process Measures

- The percentage of all inpatients screened on admission using a VTE risk-assessment tool. (EOM-132)
- The percentage of all patients admitted for surgery who are screened on admission using a VTE risk-assessment tool. (EOM-133)
- Compliance with appropriate VTE prophylaxis (i.e. the percentage of patients who should have received prophylaxis, whether screened or not, that actually received appropriate prophylaxis). (EOM 106)

Note: “Hospital-acquired” includes the 30-day period post discharge
<table>
<thead>
<tr>
<th>PRIMARY DRIVERS</th>
<th>IDEAS TO TEST</th>
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| Patient and Family Engagement | • Alert patients and families to the early signs and symptoms of VTE.  
• Give clearly written and well-explained VTE discharge instructions to patients and families.  
• Use the ‘teach back’ method to demonstrate that patients and families have a thorough understanding of prophylactic medication administration and dosing, as well as the necessary follow-up instructions regarding physician visits and/or laboratory testing. |
| Effective risk stratification | • Adopt an effective and reliable risk-assessment screening tool that is simple to use.  
• Screen patients upon admission, upon transfer to a new level of care, and when there is a change in their condition.  
• Simplify screening results by grouping patients in low, medium, and high risk categories that dictate specific treatment options. |
| Standardize care processes    | • Develop standard sets of written orders which link the results of risk-assessment to the choice of prophylactic treatments.  
• Identify contraindications to treatments and include them in order sets.  
• Allow for ‘opt-out’ as clinically indicated. |
| Decision support              | • Pilot pharmacist participation on rounds in the ICU or the post-op orthopedics unit.  
• Make pharmacists available to all clinical staff by telephone or EMR. |
| Prevention of Failure         | • If using paper records, have nursing staff fax all documented risk-assessments and medication contraindications along with the VTE prophylaxis orders to the pharmacy for review.  
• If using electronic records, allow pharmacists to access risk assessments and order sets.  
• Communicate each patient’s VTE risk and prescribed prophylaxis to the entire health care team, including consulting physicians and nurses.  
• If using electronic records, create hard stops that admitting and transferring physicians have to address VTE risks and prophylaxis. |
| Identification and Mitigation of Failure | • Via approved protocols, allow pharmacists to adjust unfractionated heparin and warfarin dosage based on acute lab values.  
• Via approved protocols, allow nursing to hold heparin or administer Vitamin K when appropriate based on the most recent lab results. |
| Smart Use of Technology       | • Capture accurate weights on all patients on prophylaxis.  
• Send the patient weight with the VTE prophylaxis orders to the pharmacy for review.  
• Use the proper level of alerts with stops and forcing functions. Provide drop-down, “opt-out” lists for drug interactions and allergies.  
• Use the EMR to monitor electronic alerts in real-time when dosing occurs outside a specified window. |

Key Resources

• Executive Summary: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines Chest February 2012; 141:2_suppl 7S-47S.
• Qaseem et al, Venous Thromboembolism Prophylaxis in Hospitalized Patients: A Clinical Practice Guideline From the American College of Physicians Annals Internal Medicine 1 November 2011 155 (9):625-633.
• Paje et al, New Oral Anticoagulants, Hospital Medicine Clinics. (2) e456-e471.
**AIM:** Reduce the Incidence of Hospital Acquired* Venous Thromboembolic Events by 30% by 12/8/14

*Includes events occurring within 30 days of discharge*

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| Effective Risk Stratification | • Adopt a risk assessment screening system.  
• Risk screen all patients admitted.  
• Repeat risk screening for patients who have a change of condition. | • Simplify screening results by grouping patients in low, medium, and high-risk categories that dictate specific treatment options. |
| | | • Screen patients upon admission, upon transfer to a new level of care, and when there is a change in their condition. |
| Standardized Care Process | • Create a system for incorporating regular updates from the medical literature.  
• Develop standard VTE order sets and protocols.  
• Allow “opt-out” functions where clinically appropriate.  
• Develop and implement ambulation protocols. | • Use key resources as a starting point. |
| | | • Develop and implement standardized order sets which link level of risk to appropriate prophylaxis. |
| | | • Analyze the use of order sets and exceptions to learn from the data and revise the process. |
| | | • Create a nurse/physical therapy-directed progressive mobility protocol. |
| Decision Support | • Use flow-sheets that accompany the patient along transitions of care.  
• Have a pharmacist available as part of the care team.  
• Use pharmacists to assist with identification of alternatives when contraindications exist. | • Understand the organization’s current practice status: use sampling strategies to perform real-time audits in various units from paper or EM records. |
<p>| | | • Use validated tools to assess current clinical staff knowledge about the risks of anticoagulants. |
| | | • Pilot pharmacist participation on rounds in the ICU or the post-op orthopedics unit. |
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<td>Smart Use of Technology</td>
<td>• Link order sets to risk stratification tool. • Link order sets to recent lab values. • Use alerts, but understand “alert fatigue” and the roles of soft and hard stops. • Use alerts for weight-based dosing for heparin. • Monitor medication administration and mitigate failures in real time. • Use “smart pumps” to minimize dosing errors.</td>
<td>• Capture accurate weights on all patients on prophylaxis. • Send the patient weight with the VTE prophylaxis orders to the pharmacy for review. • Use the proper level of alerts with stops and forcing functions. Provide drop-down, “opt-out” lists for drug interactions and allergies. • Use the EMR to monitor electronic alerts in real-time when dosing occurs outside a specified window.</td>
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PREVENTION OF VENOUS THROMBOEMBOLISM (VTE)

Venous thromboses are clots that develop in deep and superficial veins, frequently in the lower extremities, in individuals whose mobility is limited due to illness, trauma, or surgery. Patients with venous thromboses can experience blockage of the affected blood vessel and local circulation, along with symptoms such as pain and swelling of the surrounding tissue or limb. An embolus occurs if part of or all of the clot breaks away from a deep vein and travels through the venous system to the heart and lungs, leading to acute morbidity or mortality. A VTE, which can include a pulmonary embolus (PE) secondary to a deep vein thrombosis (DVT), is one of the most common preventable causes of hospital death.1,2,3

The risk for VTE is nearly universal among inpatients. Fortunately, pharmacologic and mechanical methods to prevent VTE are safe, cost-effective, and supported by evidence-based research. Yet, despite the reality that hospitalized medical and surgical patients routinely have multiple risk factors for VTE, large prospective studies continue to demonstrate that these preventive methods are significantly underutilized.4,5,6,7,8,9,10

The Agency for Healthcare Research and Quality calls thromboprophylaxis against VTE (i.e. the prevention of clots and emboli) the “number one” patient safety practice. The American Public Health Association has stated that the “disconnect between evidence and execution as it relates to DVT prevention amounts to a public health crisis.”11

This critical problem has engendered a large amount of literature researching the best approaches for VTE prevention. Several national professional societies, including the American College of Chest Physicians (ACCP), the American Association of Orthopedic Surgeons (AAOS), the American College of Physicians (ACP), and the Society of Hospital Medicine (SHM), have published best practice guidelines for the prevention of VTE. Many of the societies’ guidelines differ significantly from one another, but there are also areas in which the organizations consistently agree.

Consensus from the literature includes:

• VTE is common among hospitalized patients in both medical and surgical units.10
• 50% or more of VTEs may be preventable.10
• 10% of VTE events are associated with fatal pulmonary emboli, among the most common preventable causes of hospital death.10

• Complex assessment models for VTE risk are logistically difficult to incorporate into work-flows. The result, the assessment models are not implemented and utilization of prophylaxis for potential high-risk patients is suboptimal.4,10,12
• Additionally, complex assessment models cannot confidently identify patients who do not require prophylaxis or predict how risk factors may combine to position an individual patient along the spectrum of VTE risk.4,10,12

Concordant best practices include:

• All patients should be assessed upon hospital admission for risk of VTE and potential prophylaxis.
• VTE risk-assessment should be linked to and drive prophylaxis orders.
• Simple risk-assessment models that stratify patients into several major risk groups are favored over complicated point-scoring systems that focus on a single individual.10
• All surgical patients should receive VTE prophylaxis.

Controversies remain, however, regarding the risk of VTE among medical inpatients. The 8th edition of ACCP’s guidelines recommended a more aggressive approach to VTE prophylaxis for medical patients. In the most recent edition (9th), however, stricter criteria for study inclusion led to the exclusion of many studies which had supported prophylaxis in medical patients. As a result, the current ACCP guidelines recommend less aggressive VTE prophylaxis.12

The stance of the ACP13 is similar to that of the ACCP. On the other hand, SHM and the HRET-HEN Subject Matter Experts, Drs. Maynard and Jenkins of the University of California, San Diego, continue to support more aggressive prophylaxis in medical patients.11 Their reasoning is as follows: “Both guidelines discount asymptomatic VTE outcomes and caution against over-prophylaxis, but have different methodologies and estimates of risk/benefit.

Guideline complexity and lack of consensus on VTE risk-assessment contribute to an implementation gap.”14 A thorough discussion of these controversies can be found in the October issue of the Journal of Hospital Medicine.14

Another controversy exists regarding thromboprophylaxis for patients having hip and knee replacements. The ACCP prefers low-molecular-weight heparin12 (LMWH), whereas the AAOS states that there is not enough evidence to recommend one form of pharmacologic prophylaxis over another.16
Additional points from the literature are summarized below:

• In medical patients, low-molecular-weight heparins (LMWH) enoxaparin and dalteparin have efficacy comparable to subcutaneous heparin (SQ heparin) when administered three times daily, but offer lower complication rates and other potential advantages for patients.16,17,18,19

• For certain higher-risk patient groups (e.g. patients who have had hip and knee replacement, trauma, or spinal cord injury), low-molecular-weight heparins have demonstrated superiority in some studies over subcutaneous heparin and the anticoagulant fondaparinux.4,12,20,21,22,23

• For certain patients (e.g. patients who have had hip replacements or surgery for cancer, as well as selected non-surgical patients who have reduced mobility), extending LMWH prophylaxis for approximately 4-5 weeks may be more effective than providing only one week of treatment. However, the AAOS states that there is not enough evidence to recommend such an extension routinely, and that such extensions should be individualized.4,16,24,25,26

• In certain patient categories, the adequacy of twice daily subcutaneous heparin in preventing VTE has not been proven.4

• For patients at very high risk, the addition of mechanical prophylaxis to a pharmacologic regimen may offer added benefits. The AAOS recommends this combination therapy in hip or knee replacement patients who have a history of prior VTE.4,12

• Certain patient groups, such as the elderly or patients with impaired liver or kidney function (i.e., elevated LFTs and/or creatinine clearance < 30 cc/minute), should not receive certain pharmacologic agents such or should receive lower doses of LMWH4. It is recommended that pharmacist consultation be sought in these circumstances.

• Coordinating the timing of pharmacologic doses is important for patients undergoing surgery or experiencing critical events.

A new oral anticoagulant, rivaroxaban, has been approved for VTE prophylaxis by the FDA for patients undergoing hip or knee replacement. In these patients, rivaroxaban appears to be equal to warfarin in VTE prophylaxis-effectiveness and carries a similar bleeding risk. As of the date of this publication, no new oral agent has been approved for VTE prophylaxis in non-orthopedic surgical patients or in medical patients.

Though the newer oral agents provoke fewer dietary interactions and do not require frequent dosage adjustments or regular blood tests, they do have the potential for side effects. Because they are primarily excreted via the kidneys, they must be used with caution and in reduced dosage in patients with renal failure and/or in the elderly. In addition, their half-life is very short, so strict adherence to dosing schedules is critical for successful prophylaxis. Finally, the lack of effective antidotes can be challenging in the event that bleeding complications occur.

SUGGESTED AIMS

• Reduce the incidence of hospital-acquired VTE by 30% by 12/8/2014.

• Increase the utilization of appropriate VTE prophylaxis in at-risk patients to 100% by 12/8/2014.

PATIENT AND FAMILY ENGAGEMENT

VTE prophylaxis is complex and there are many ways in which patients and families can be engaged as partners to reduce potential harm. Education of patients and families regarding the risk of VTE, anticoagulant-induced bleeding, and other complications, can both prevent and mitigate failures when they occur. The patient or family member may be the first to become aware of the signs of a complication of anticoagulation, side effects of mechanical prophylaxis, or signs and symptoms of VTE, and can share these observations with the healthcare team in a timely manner. Creating an environment in which the patient or family feels comfortable asking questions and raising issues to clinicians promotes good communication and patient safety.

Secondary Driver: Educate patients and families regarding the risks and symptoms of VTE, and the risks and symptoms of bleeding and other complications of prophylaxis.

It is important that patients and families understand the risks associated with prophylaxis as well as the risks of forgoing prophylaxis. Furthermore, patients and families who are engaged in this part of their care may be more compliant with the therapy, and may recognize complications sooner.

Change Ideas

• Alert patients and families to the early signs and symptoms of VTE.

• Give clearly written and well-explained VTE discharge instructions to patients and families.
• Use the ‘teach back’ method to demonstrate that patients and families have a thorough understanding of prophylactic medication administration and dosing, as well as the necessary follow-up instructions regarding physician visits and/or laboratory testing.
• Involve patients and families in the design of patient education materials that enhance communication with clinical staff and promote patient safety.

**Suggested Process Measure**
• The percentage of patients receiving any form of prophylaxis who have a “teach back” assessment of their understanding of the prophylaxis.
• The percentage of patients receiving the “teach back” who successfully demonstrate adequate understanding of the prophylaxis.
• The number of patients who are able to verbalize the warning signs of treatment complications and the next steps for clinical staff notification.

**“Hardwiring” Patient and Family Engagement in Improvement Plans**
To avoid overestimating the patient and family’s knowledge, consider requiring every patient undergoing any form of prophylaxis to receive “teach back” education. Don’t apply this to chemoprophylaxis only: mechanical devices are often refused by patients, and many do not fully understand what is expected when they are told to ambulate.

**EFFECTIVE RISK STRATIFICATION**
Effective risk stratification allows for the development of standardized processes that can drive more effective prophylaxis. Employing simple risk stratification makes this process easier to accomplish and more likely to be reliably applied in the busy hospital setting. Although easier to implement, this risk-grouping approach does not reduce the effectiveness of the selected therapeutic alternatives for individual patients

**Secondary Driver: Adopt a risk-assessment screening system.**
A screening tool should address the risks of VTE and the risk of bleeding for each patient.
Adopt a risk-assessment screening tool that is easy to complete and embed it into the work-flow. More complex tools demand extra work and create reliability and sustainability challenges, while offering limited advantages in determining a therapeutic approach.

**Secondary Driver: Risk screen all patients admitted.**
Develop a VTE risk-screening tool and determine when and by whom it will be completed. As VTE morbidity and mortality is high, all admitted patients should be screened.

**Secondary Driver: Repeat risk screening for patients with a change of condition.**
Reevaluating the risks of VTE and the appropriateness of therapy is critical as a patient’s condition changes. For example, patients may have had contraindications for anticoagulation because of planned surgery or certain types of injury. As they recover or move to a less intensive level of care, anticoagulant therapy may no longer be contraindicated and may even be beneficial. Conversely, patients whose status worsens might require a readjustment of their thromboprophylaxis orders. A post-operative case with complications may benefit from the addition of mechanical as well as pharmacological thromboprophylaxis to the treatment plan.

**Change Ideas**
• Screen upon admission, upon transfer to a different level of care, and with a change of condition.
• Link VTE risk-screening to another mandatory process such as medication reconciliation.
• Select a tool that segments patients into risk groups and recommends associated treatment options.

**Suggested Process Measure**
• The percentage of patients who receive screening upon admission
• The percentage of patients who receive screening upon transfer
• The percentage of patients who develop VTE and are not on prophylaxis

**“Hardwiring” Effective Risk Stratification in Improvement Plans**
To avoid underestimating the risk of VTE in hospitalized patients, screening should be tied to a mandatory trigger such as admission orders, transfer orders, or medication reconciliation. Examples include:
• Developing a policy to require screening at specified intervals for units using paper records
• Creating a “soft stop” in an electronic medical record. The literature reveals that VTE prophylaxis soft alerts can be effective, but that this effectiveness wanes over time (“alert fatigue”). While these alerts are an important adjunctive part of a VTE prophylaxis strategy, they cannot by themselves be expected to increase prophylaxis.27,28,29,30,31
Adding an independent reassessment by a hospital pharmacist of any patient screened as low risk or who does not receive VTE prophylaxis orders within a designated period of time. Determining who performs the risk-stratification (physician, nurse, or pharmacist), and how the results of risk-assessment are communicated to the healthcare team, can promote staff adherence to the policy.

**STANDARDIZED CARE PROCESSES**

Standardized tools and processes ensure that every patient is evaluated and treated appropriately. To ensure regular and routine use, these tools may be linked to triggers such as admission, transfer, or surgery.

**Secondary Drivers: Create a system to provide regular updates from the medical literature.**

As evidenced by changing recommendations from the ACCP, AAOS, ACP, and SHM, best practices are still evolving. It is very important that each healthcare institution stay current. Designate a subcommittee of the medical staff such as the Pharmacy & Therapeutics Committee to oversee periodic review of the medical literature regarding VTE prevention and treatment, including the identification and dissemination of updated protocols for thromboprophylaxis.

**Secondary Driver: Develop standard VTE order sets and protocols.**

“Standard work” assures that patients get the agreed upon standard of care by default, unless a patient is known to have a condition that would dictate alternate care. Order sets are one approach that can produce standard work and improve compliance by providing prompts for ordering providers. However, order sets offer a limited array of choices that may need to be adapted for patients in special circumstances.

**Secondary Driver: Allow “opt-out” methodology where clinically appropriate.**

Reliability theory has demonstrated that an “opt-out” approach, wherein a physician must act to remove a specific portion of an order set and justify those actions, can, in certain circumstances, lead to better outcomes. Analysis of “opt-out” orders and justified changes can:

- show where there may be a need to improve a standard process;
- lead to opportunities to educate clinicians as to best practices, and
- underscore that certain uncommon or complex conditions may require clinician interventions that go beyond “standard work.”

**Secondary Driver: Develop ambulation protocols.**

Reduced mobility is a risk factor for the development of VTE. Institute a process that assesses a patient’s mobility and generates recommendations for safe mobilization and interventions such as physical therapy, as appropriate. Nurse-driven mobility protocols have been shown to be effective in reducing immobility-related complications and hospital lengths-of-stay.

**Change Ideas:**

- Start with key literature references that summarize current best practices.
  - Keep in mind that evidence is evolving and that recommendations may change as new data are collected.
  - Recommendations from academic associations and specialty professional societies may also vary and evolve.
- Use the ISMP newsletters and other national references to stay abreast of the findings in the literature; assign specific staff the responsibility to monitor and update the care teams.
- Develop standardized order sets. See Appendix I for an example. Risks assessed should be linked with appropriate prophylaxis standards in the order sets.
- List the most common reasons for an ‘opt-out’ on the order sheet so that physicians can document justifications for subsequent analysis.
- Analyze opt-out justifications on a regular basis to help improve order sets, as well as to mentor users about the standard process.
- Create a progressive mobility protocol directed by nursing or physical therapy staff.

**Suggested Process Measures**

- The percentage of patients who are classified in moderate or high risk groups and have VTE prophylaxis ordered.
- The percentage of patients who receive the correct form of VTE prophylaxis.

**“Hardwiring” Standardized Care Processes in Improvement Plans**

If orders are provided on paper, create one form on a single page that serves as both a risk-assessment form and a prophylaxis order form. The risk-assessment should drive the prophylaxis orders. If orders are delivered electronically, design the system so that the risk-assessment must be completed first and can then drive appropriate prophylaxis. The order form should also list the most common alternate therapies and their justifications, allowing physicians to document the reasons for their decisions on the order form. These data can be collected and aggregated to promote individual and institutional learning.
**DECISION-SUPPORT**

Decision-support can be divided into passive versus active. “Passive” decision-support occurs when clinicians are offered resources they can query regarding a specific patient condition or medication. Passive support is voluntary and not forced, and has not been shown to effectively change clinician practices enough to improve overall patient safety.

“Active” decision-support occurs when a prompt is given to the caregiver suggesting a best practice based on both research evidence and system knowledge about the individual patient (including the risk-assessment). An electronic medical record (EMR) can use logic algorithms in real-time to analyze a patient’s clinical information, and notify clinicians of provider-approved recommended treatments. For paper records, a risk-stratification tool can be linked to a pre-approved order set on the same page. “Active” decision-support has been shown to improve clinical practices and patient care.

Note: such recommendations may not incorporate all of the significant patient factors, and should only serve as guides for physicians as they use their clinical judgment.

**Secondary Drivers: Use flow sheets that follow the patient through care transitions.**

Medication administration flow sheets for anticoagulants should follow the patient from unit to unit with each transfer. Lack of continuity of information during a hand-off can result in errors with transitions of care.

**Secondary Driver: Have a pharmacist available as part of the care team.**

When clinical pharmacists are available on units and able to round as part of the care team, the team is more likely to utilize the pharmacist’s knowledge and expertise, improving medication-related decision-making and reducing errors. To optimize clinical pharmacist resources, target areas in the hospital where medication orders are frequent and complex, and where errors are more common.

**Secondary Driver: Use pharmacists to identify alternatives when contraindications exist.**

When a patient has a contraindication to standard therapy, decision-making can become challenging. Consulting a clinical pharmacist can provide guidance regarding other prophylaxis formulations and regimens available.

**Change Ideas:**

- Assess the current status of VTE prophylaxis and events for hospital units: use sampling strategies to perform paper or EMR audits for all units.
- Use validated tools to assess the current knowledge of clinical staff regarding the risks of VTE and anticoagulant therapies.34,35
- Pilot pharmacist participation on rounds in the ICU or the post-op orthopedics unit.
- Have pharmacists available for consultation with all clinical staff via telephone or electronic device.

**Suggested Process Measures**

- The number of consultation requests that the clinical pharmacist receives.
- The number of prophylactic anticoagulant orders that were modified as a result of pharmacist consultation.

**“Hardwiring” Standardize Interventions for Patients at Risk for Falling in Improvement Plans**

Add the pharmacists’ phone or pager number to the “opt-out” section of the order set.

**PREVENTION OF FAILURE**

According to principles of reliability theory, processes to prevent failure, supported by processes to promptly identify and mitigate failure, provide the best mechanisms to provide reliable, effective and safe care. The following are some strategies and change ideas that have been successful in this regard.

**Secondary Driver: Independent double-checks of all VTE prophylaxis orders.**

Independent double-checks recognize “human factors”; i.e. that humans are not perfect and make mistakes. Assuming that clinicians never make mistakes leads to predictable error. Having one clinician double-check the work of another, (e.g. a pharmacist reviewing a physician’s VTE prophylaxis orders), helps to insure that order errors (e.g. drug, dose, frequency, and route) do not occur.
Change Ideas:
- If using paper records, have nursing staff fax the VTE prophylaxis orders along with all risk-assessments and documentation of medication contraindications to the pharmacy for review.
- If using electronic records, provide access to medication orders and risk-assessments to the pharmacists.
- Ask pharmacists to double check the appropriateness, correctness, and completeness of the VTE orders as guided by evidence-based medical staff policy.
- Communicate each patient’s VTE risk and prophylaxis recommendations and/or orders to the entire healthcare team including consulting physicians, nurses, and physical therapists (e.g. designate a location where all members of the healthcare team have access).
- Create process “stops” at admission and transfer that require the appropriate clinician to acknowledge and address VTE risk and prophylaxis.

Suggested Process Measures
- The percentage of “opt-out” orders that are sent to the pharmacist.
- The percentage of patients with VTE prophylaxis orders that are changed at transfer to a different unit or level of care.
- The percentage of moderate or high risk patients without VTE prophylaxis orders.

“Hardwiring” Prevention of Failure in Improvement Plans
Create process “stops” in workflows that:
- require pharmacy review of VTE prophylaxis orders, and
- require clinician review of risk and VTE prophylaxis orders when a patient is admitted or transferred to a different level of care.

IDENTIFICATION AND MITIGATION OF FAILURE
It is very difficult to design a system that prevents failure at all times. Early identification and mitigation of failure when it does occur is critical for the promotion of process reliability.

Secondary Driver: Develop systems to (1) identify at risk patients not receiving VTE prophylaxis, and (2) implement prophylaxis in these patients
Even the best system will fail to identify some patients who should receive prophylaxis. Mechanisms that promptly identify these treatment omissions, coupled with mechanisms which lead to prompt and appropriate prophylaxis, are excellent methods to promptly identify system failure and address it.

Secondary Driver: Utilize protocols for anti-coagulation.
One of the causes of delay in treating over- or under-anticoagulation is the necessity of locating and consulting with the ordering physician. Allowing nurses or pharmacists to respond to an emergency and stop anticoagulation per a pre-approved protocol can reduce delays and risks for patients. Pharmacy driven warfarin management using medical staff approved protocols have proven to be the only successful method of decreasing high INRs to date in the HRET-HEN.

Change Ideas:
- Allow nursing staff to hold heparin administration or to administer Vitamin K based on designated acute lab test result values via pre-approved protocols.
- Allow pharmacists to manage unfractionated heparin and warfarin dosage based on current lab values via pre-approved protocols.

Suggested Process Measures
- The number of out-of-range lab values in one week for patients receiving prophylactic anticoagulation.
- The percentage of patients on warfarin managed by a pharmacist driven protocol.

“Hardwiring” Identification and Mitigation of Failure in Improvement Plans
Create and approve medical staff policies that allow pharmacists and nurses, in pre-approved situations, to stop or adjust coagulation doses based on the most recent lab values without first contacting the treating physician. Develop a “closed-loop” system to address critical lab values that identifies all the steps necessary to rectify the concern and ensure it is managed appropriately. Periodically audit the process to ensure it is functioning as a closed-loop.

SMART USE OF TECHNOLOGY
Technology, used smartly, can drive improvement. Technology must be designed and implemented to be aligned with human approaches to thinking and workflow, and to eliminate or mitigate common causes of human error.

Secondary Driver: Link order set to risk stratification tool.
This is perfectly suitable for the smart use of technology. When the clinician completes risk-stratification, the technology automatically leads the clinician to the recommended choices of orders for that risk-stratification.
Secondary Driver: Link order sets to recent lab values.
As pre-approved in medical staff policies and procedures, laboratory test results can prompt clinicians to alter anticoagulation therapy. For example, a medical staff policy can be developed that allows a nurse or pharmacist to alter an anticoagulant dose if a specific lab test result is outside of accepted range.

Secondary Driver: Use alerts but understand alert fatigue, and the roles of soft and hard stops.
Alerts can be very useful, but if overused when not necessary, they are likely to be ignored, i.e. “alert fatigue.” “Soft stops” are alerts or pop-ups that encourage providers to consider recommendations, reminders, triggers, or information in their decision-making process, but do not require a specific action. “Hard stops” halt the process, and require a specific action to resume process function. Before implementing hard stops, assess the risk/benefit to the patient of a complete process stop, given the reality of your specific clinical situation.

Secondary Driver: Use alerts for weight based dosing for heparin.
Some protocols require the calculation of heparin dosing by weight. Weight-based dosing can be safer and more effective, particularly in populations with widely-varying BMIs. An electronic medical record can easily assist with calculating the recommended dose by using the entered patient weight. The pharmacist can also double-check the dose via an integrated EMR system.

Secondary Driver: Monitor medication administration and mitigate failures in real-time.
Electronic monitoring of medication administration allows charge nurses and pharmacists to run real-time reports regarding delayed administration of medications. Delayed administration or missed doses of an anticoagulant could have significant negative consequences for the patient. Catching and mitigating these delays in real-time can improve the efficacy of prophylaxis. In addition, analyzing the data may lead to insights that promote improvements in the systems of medication delivery that will decrease the incidence of delays.

Secondary Driver: Use “smart pumps” to minimize dosing errors.
Smart pumps can alert clinicians to potentially unsafe drug therapy prior to drug administration. The smart pump is designed to fuse traditional infusion-pump technology with pre-determined clinical guidelines and IV drug administration protocols. If program choices entered are outside a designated range, the pump sounds an alarm, indicating a “soft stop” or “hard stop” warning. A soft stop allows the infusion to continue without the need for dosing choices to be reentered. With a hard stop, the choices must be reprogrammed to comply with the pre-approved dosing guidelines.

Change Ideas:
• Capture accurate weights for all patients on prophylaxis for use by the ordering clinician.
• Provide the patient weight to the pharmacist along with the VTE prophylaxis orders.
• Use alerts with forcing functions and stops at the proper level and frequency.
• Provide an acknowledgement and drop-down opt-out list for drug interactions, contraindications, and allergies.
• Use EMR real-time reports to send electronic alerts when dosing occurs outside specified guidelines.

Suggested Process Measures
• The percentage of patients stratified to moderate or high-risk groups that receive appropriate prophylaxis orders by weight.

“Hardwiring” Smart Use of Technology in Improvement Plans
Hardwiring clinical processes into electronic systems promotes safety and reduces the ability of staff to ignore or work-around necessary measures. However, so as not to be brushed aside, implemented alerts should be designed to be relevant and helpful to the clinician. Overuse of alerts may fatigue clinicians and condition them to ignore warnings and other types of intelligent electronic support provided.
Potential Barriers

- Given the varying recommendations from among professional societies, failure to form a consensus at an institution on best practices may lead to provider resistance. For example, expecting VTE prophylaxis to be ordered for routine medical admissions early in the VTE prophylaxis implementation process may lead to push-back from internists. This push-back may delay or hamper the implementation of VTE prophylaxis in orthopedic and surgical patients. At a minimum, the recommendation should be to screen all patients for VTE risk, and to implement prophylaxis for all orthopedic, surgical, and high-risk medical patients. C-section patients who are at high risk of VTE should also be included.

- Recognize that the use of “smart” technology will be a change in practice for some physicians. Physicians may also resist pharmacist input regarding anticoagulation. Research has shown, however, that clinicians have traditionally underestimated VTE risk. Physicians may be unaware of the expertise and knowledge pharmacists have in the area of VTE prophylaxis that can aid in clinical decision-making. It may be necessary for individuals or groups from the medical staff to receive education and coaching which outlines the benefits of these new approaches for both providers and patients. Enlisting respected physician champions who have successfully used these new technologies and processes as mentors can help transition more hesitant clinicians towards acceptance.

- Some physicians may be uncomfortable with having pharmacists review orders. Physician and pharmacist education, supported by approved medical staff policies that outline the pharmacists’ scope of practice and their communications with ordering physicians, can help to overcome these barriers.

- Clinicians may resist a process stop that requires reassessment of VTE risk when a patient is transferred to a different level of care. Reporting of data and experiences in which stops resulted in treatment changes that reduced VTE risk and improved patient outcomes can be helpful.

- Use “smart” technology intelligently. Some clinicians may resist adoption of technology because the process is too complicated and burdensome — make their work easier, not harder. For example, outline the common contraindications (as supported by current evidence) for a specific VTE protocol/order set and provide this information clearly on the ordering page to assist the clinician in decision-making.

- These improvements will be new territory not only for physicians, but also for many nurses and pharmacists. Nurses and pharmacists may be concerned about making a mistake or about not having adequate training to implement the new policies. They may also fear that the medical staff will not be receptive or cooperative. Education of all parties about the risks of delayed intervention vs. the efficacy of immediate intervention will help mitigate these concerns. Highlighting the fact that nurses and pharmacists are often the “first-line responders” with VTE and PE could underscore the value of including them in the development and implementation of VTE prevention processes.

Use administrative leadership and sponsorship to help remove or mitigate barriers:

- Implementing changes in practices to reduce VTEs will demand advocacy from all the units involved via effective physician, pharmacy, and nursing leaders and champions. Their efforts can overcome perceptions that such changes are burdensome, punitive, or dangerous.

- An executive sponsor from senior management, who recognizes the value of preventing VTE and its complications to patients for the organization, can help brainstorm and implement solutions to promote stakeholder acceptance. The sponsor can remove barriers, as well as provide resources and education across the organization that underscore the benefits of these new processes.

Change not just the practice, but the culture

- Changing the culture will likely be necessary, especially for physicians, who will be asked to trade their traditional individualized approach to risk-assessment and prophylaxis for a team-based standardized approach. They may be loath to relinquish control and worried about negative consequences for their practice and their patients. Providing education about the proven benefits of standard processes can reassure hesitant physicians that these changes will benefit their patients.

- Order sets may make some physicians uncomfortable. Most physicians learn best from peers and will often value their peers’ recommendations over “expert advice.” Physician champions and early adopters can provide a positive peer influence that can inspire other physicians to embrace new procedures.

- Some physicians are not used to consulting with pharmacists regarding patient treatment decisions, and may not be aware of the breadth and depth of their training and expertise. Beginning the change process with a receptive local unit for a small test of change can demonstrate the value of pharmacy consultations. Successful trials can then be disseminated to other units across the organization.
TIPS ON USING THE MODEL FOR IMPROVEMENT

• Tips for identifying barriers to timely anti-coagulant administration:
  — Design and conduct a very quick assessment of the last 20 doses of anticoagulants on VTE patients.

• Tips on mitigation of error:
  — Examine data or reports about the length of time it takes to contact a treating physician to get orders changed if lab results are out of range, and identify the consequences of these delays for patient safety.

• Tips for developing and implementing risk stratification and VTE prophylaxis order sets:
  — Ask one or two of the physicians on the improvement committee to trial these processes during their next three admissions.
  — Begin the trials in one unit.
  — Reconvene and debrief after the small trials and identify modifications needed in the process. Repeat the trial if needed.

• Order sets: Design a small pilot on a unit where the lead physicians and nurses are open to testing this innovation.
  — Try the new procedures with a few patients.
  — Reconvene and debrief after the small trials and identify modifications needed in the process. Repeat the trial if needed.

• Consider implementing nursing or pharmacy intervention at first only with critical values well beyond the expected lab result range. For example, allow nurses or pharmacists to stop warfarin when the INR >6.0.
  — Once the team achieves success and confidence in implementing these procedures, the INR at which nurses and pharmacists would be authorized to act can be lowered.
APPENDIX I: UC SAN DIEGO’S “3 BUCKET MODEL” FOR VTE PROPHYLAXIS

3 BUCKET MODEL

<table>
<thead>
<tr>
<th>Low Risk</th>
<th>Moderate Risk</th>
<th>Highest Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation patients, expected LOS &lt;48 hrs; Minor Ambulatory surgery or Age &lt; 50 and NO other risk factors, or Already on therapeutic anticoagulation</td>
<td>Most medical/surgical patients CHF, pneumonia, active inflammation, advanced age, dehydration, urine output &lt;200mL, less than fully and independently ambulatory, many other factors. All patients not in the Low or Highest Risk Categories (see reverse for more risk factors)</td>
<td>Effective hip or knee arthroplasty Acute spinal cord injury with paralysis Multiple major trauma Abdominal or pelvic surgery for cancer</td>
</tr>
</tbody>
</table>

**DVT/PE RISK LEVEL & PROPHYLAXIS ORDERS**

- Early ambulation, education
- Education
- **CHOOSE ONE PHARMACOLOGIC option**
- Enoxaparin 40 mg SC q 24 hrs
- Enoxaparin 30 mg SC q 24 hrs (renal insufficiency dosing)
- Heparin 5000 units SC q 8 hrs
- Heparin 5000 units SC every 12hrs (if weight <50kg or age > 75) 
  - Also (OPTIONAL)
  - Sequential compression device
- **CHOOSE ONE PHARMACOLOGIC option**
- Enoxaparin 40 mg SC q day
- Enoxaparin 30 mg SC q 24 hrs (for renal insufficiency)
- Heparin 5000 units SC q 8 hrs (End stage renal disease only)
- Enoxaparin 30 mg SC q 12 hrs (knee replacement)
- Fondaparinux 2.5 mg SC q day
- AND
  - Sequential compression device
- **OR**

The risk of adverse effects of pharmacologic prophylaxis outweighs the risk of DVT/PE

Contraindication to pharmacologic prophylaxis (see reverse):

- Mechanical prophylaxis with sequential compression device OR
- Contraindicated (peripheral vascular disease or wounds)
APPENDIX II: SIMPLIFIED VTE PROPHYLAXIS 2013 10,16,21,27, 28

**Principles:**
- Sensible prophylaxis is effective in moderate-risk and high-risk patients.
- Bleeding concerns tend to be overestimated.
- Every hospital should develop a formal strategy that addresses the prevention of VTEs.
- VTE prophylaxis protocols must become a routine part of the patient care culture.
- ‘Simple’ is effective:
  - If an intervention isn’t simple, opportunities will be missed, and errors will be more likely to occur.
  - When prophylactic methods are equivalent, choose the method that simplifies the overall approach.
  - Remember that clinically acceptable alternatives exist.

The following is an example of a Simplified Evidence Based Recommendation: (normal bleeding risk)

<table>
<thead>
<tr>
<th>VTE Risk: Low</th>
<th>• Medical: fully mobile, brief admission</th>
<th>• No specific pharmacoprophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Surgical: procedure &lt;45 minutes, mobile</td>
<td>• Early mobilization</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>VTE Risk: Moderate</th>
<th>• Medical: bed rest, sick</th>
<th>• LMWH (Grade 1A)\textsuperscript{i}</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>• Surgical: major general, urologic or gynecologic procedures</td>
<td>• Start post-op</td>
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<tr>
<td></td>
<td></td>
<td>• Continue until discharge</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>VTE Risk: High\textsuperscript{ii}</th>
<th>• Major orthopedics \textsuperscript{iii}</th>
<th>• LMWH\textsuperscript{iv}</th>
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<tbody>
<tr>
<td></td>
<td>• Major trauma</td>
<td>• Continue for up to 35 days (Grade 2B)</td>
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<tr>
<td></td>
<td></td>
<td>• THR, TKR: Start 12 hours pre-op (Grade 1B)</td>
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<tr>
<td></td>
<td></td>
<td>• HFS: Start &gt;4 hours pre-op if surgery delayed</td>
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</tbody>
</table>

\textsuperscript{i} LDUH is also Grade 1A\textsuperscript{16}

\textsuperscript{ii} Addition of mechanical prophylaxis to LMWH in patients at high risk for VTE may be beneficial (Grade 2C)\textsuperscript{16}

\textsuperscript{iii} The AAOS states there is not enough evidence to distinguish among pharmacologic prophylaxis options.\textsuperscript{21}

\textsuperscript{iv} The ACCP states that fondaparinux and LDUH are now Grade 2B.\textsuperscript{16} The AAOS states there is not enough evidence to distinguish between pharmacologic prophylaxis options.\textsuperscript{21}

**Recommendations: high bleeding risk:**
- Active bleeding
- Known major bleeding disorder
- Platelet count <50,000
- Intracranial bleeding in prior five days
- All neurological and spinal surgeries
- Heparin induced thrombocytopenia
- Use mechanical prophylaxis, preferably IPC (Grade 2C)
- Re-evaluate and add LMWH when bleeding risk subsides. (Grade 2C)

**Notes:**
- Inferior vena cava filters are not indicated for VTE prophylaxis and will increase DVT risk.
- Routine calf ultrasound surveillance for DVT not indicated.
- IPCs are generally preferred to GCSs but may be tolerated less well, be more costly, and result in lower adherence by patients and staff. Calf length is preferred and results in better compliance and fewer infections.

**Abbreviations used:**
- GCS Graduated compression stockings
- HFS Hip fracture surgery
- IPC Intermittent pneumatic compression
- LDUH Low density unfractionated heparin
- LMWH Low molecular weight heparin
- THR Total hip replacement
- TKR Total knee replacement
- VTE Venous thromboembolic events
### Venous Thromboembolism (VTE) Top Ten Checklist

#### TOP TEN EVIDENCE BASED INTERVENTIONS

<table>
<thead>
<tr>
<th>PROCESS CHANGE</th>
<th>IN PLACE</th>
<th>NOT DONE</th>
<th>WILL ADOPT</th>
<th>NOTES (RESPONSIBLE AND BY WHEN?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adopt a VTE risk assessment screening tool</td>
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<tr>
<td>Instead of selecting patients arriving at the hospital with specific diagnoses or who are presenting for specific procedures, assess <em>every</em> patient upon admission for his/her risk for VTE using the VTE risk assessment screening tool.</td>
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<td>Adopt a standardized risk-linked menu of choices for VTE prophylaxis.</td>
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<td>Develop standard written order sets which link risk assessment results to a specific prophylaxis option.</td>
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<td>Use protocols for dosing and monitoring <em>all</em> chemoprophylaxis agents.</td>
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<td>Use pharmacists to provide key real-time ‘decision support’ for prophylaxis option selection, discussion of contraindications, and protocol development.</td>
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<td>Make prophylaxis ordering an “opt-out” process instead of an “opt-in” process.</td>
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<td>Use success stories of patients whose positive screenings allowed life-saving early intervention to underscore the benefits of screening and prophylaxis for VTE/PE.</td>
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<td>Give nurses the same tools you give physicians – physicians get a hard stop CPOE process for ordering, coordinate with the IT department to utilize the EMR to identify the VTE at-risk patient for risk assessment.</td>
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<td>If assessments are not being performed reliably, try shifting staff roles – e.g. physicians can do the assessments instead of nurses or pharmacists may use trigger tools to enhance assessments.</td>
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REFERENCES