# Preventing Hospital-Acquired Venous Thromboembolism

## A Guide for Effective Quality Improvement


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## A Guide for Effective Quality Improvement

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# Contents

# Preface

Hospitals are complex systems. Over time, each hospital accumulates its own set of care processes — some coordinated, some autonomous — that directly affect inpatient outcomes. As systems, hospitals are perfectly designed to achieve exactly what they do; thus, improving the output of a hospital requires change.

Not all change results in improvement, however. Recently, several systematic reviews have attempted to gauge the efficacy and effect of quality improvement strategies, but research in hospital care delivery has yet to elucidate a transferable strategy to deliver optimal care on a consistent basis.[1, 2, 3] A review of quality improvement studies published in major journals in the United States found that three-quarters of them used simple before-and-after designs, often at single sites within single centers, making it challenging to attribute observed benefits to the studied intervention.[4] The state of the science suffers from more than a lack of rigor in study design. The choices of particular interventions fundamentally lack compelling theories that can predict success.[5] While a taxonomy for quality improvement strategies was recently derived from one of these systematic reviews, the literature still does not reflect adoption of standardized language to articulate the mechanisms underpinning performance improvement.[6]

Until research in hospital care delivery is able to elucidate transferable strategies to deliver optimal care on a consistent basis, quality improvement (QI) practitioners, such as physicians, pharmacists, nurses, and risk managers, must rely heavily on experience and ingenuity. The same skills critical for driving actual improvement in the hospital — designing, managing, and leading change successfully over time — are also commonly missing from clinician skill sets. This guide, derived primarily from principles of QI and personal experiences, is designed to help the QI practitioner lead an efficient, reliable effort to improve prevention of one of the most important problems facing hospitalized patients, hospital-acquired venous thromboembolism (VTE).

## A Preventable Problem

Pulmonary embolism resulting from deep vein thrombosis (DVT) — collectively referred to as VTE — is the most common preventable cause of hospital death.[7, 8, 9] Fortunately, pharmacologic methods to prevent VTE are safe, effective, cost-effective, and advocated by authoritative guidelines.[10] Yet, despite the reality that hospitalized medical and surgical patients routinely have multiple risk factors for VTE, making the risk for VTE nearly universal among inpatients, large prospective studies continue to demonstrate that these preventive methods are significantly underutilized.[11, 12, 13, 14, 15]

The Agency for Healthcare Research and Quality calls thromboprophylaxis against VTE the "number one patient safety practice."[16] 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."[17] While individual centers have published results of successful local initiatives for improving prevalence of VTE prophylaxis, no single strategy has proven yet to be effective, sustainable, and widely applicable to other centers. This is evolving rapidly, as experience with

local efforts and the Society of Hospital Medicine's Venous Thromboembolism Prevention collaborative are validating the risk assessment techniques and implementation techniques presented here. One thing is certain, however. To implement effective protocols minimizing incidence of hospital-acquired VTE, while at the same time minimizing adverse outcomes, redesign is needed in both care delivery and performance tracking.

Ideas for what to change, how, and how to manage change successfully over time should come from a local improvement team, ideally a selection of established or emerging leaders with experience as frontline caregivers or complementary insights. Members of this multidisciplinary team should have knowledge of the evidence base, local influence or insight into care delivery, or a framework for leading QI. In a growing number of hospital systems, hospitalists are prime candidates to lead such teams.

Essential elements to reach breakthrough levels of improvement in care include:

- Institutional support and prioritization for the initiative, expressed in terms of a meaningful investment in time, equipment, personnel, and informatics, and a sharing of institutional improvement experience and resources to support any project needs.
- A multidisciplinary team or steering committee focused on reaching VTE prophylaxis targets and reporting to key medical staff committees.
- Reliable data collection and performance tracking.
- Specific goals or aims that are ambitious, time-defined, and measurable.
- A proven QI framework to coordinate steps towards breakthrough improvement.
- Protocols that standardize VTE risk assessment and prophylaxis.
- Institutional infrastructure, policies, practices, or educational programs that promote use of the protocol. The protocol that standardizes VTE risk assessment is so fundamental that it must not merely exist. It must be embedded in patient care. High-reliability design should be used to enhance effective implementation.

## How to Use This Guide

QI projects should always develop from recognition of a gap between optimal care and care that is actually being delivered. In its progress, QI unfolds along several parallel fronts. Many steps in an initiative occur simultaneously and are often interdependent. This guide offers a framework to help the QI practitioner achieve important milestones along the path to breakthrough levels of performance. The guide presents chapters that match the logical steps of a QI project:

1. Take essential first steps.
2. Lay out the evidence and identify best practices.
3. Analyze care delivery.
4. Track performance with metrics.
5. Layer interventions.
6. Continue to improve.

# Chapter 1. Take Essential First Steps

Quality improvement (QI) teams must be set up for success and can only proceed with the support of the institution and an understanding of the local environment. Teams must anticipate milestones, set goals, and use a framework for improvement.

## Ensure Support From the Institution

The time, energy, and expertise of a physician leader are necessary to drive improvement. But alone they will not be enough. Sponsorship and support from the medical center, specifically from key leaders, are absolutely essential. Basics, such as revisions to order sets, data collection resources, or tweaks of a health information system, may require special permission, fast-track approval processes, or dedicated personnel. While most obstacles will merely require patience or ingenuity, some may be insurmountable without the influence of executive leadership.

Real support should confer to the improvement team the authority and resources needed to design and manage change. The QI practitioner, such as a doctor, nurse, or risk manager, should pause long enough to get a commitment from the institution to back the effort. The single most effective way to attract this support is by aligning the goals of the QI effort with the strategic goals of the organization.

The QI practitioner must make hospital leadership aware of how an effective venous thromboembolism (VTE) prevention program aligns with its goals for medical care, performance reporting, customer service, and cost containment. A number of forces may fuel administrative interest in the project, including public reporting of hospital performance (e.g., The Joint Commission and National Quality Forum measures), cost savings from more efficient care, risk aversion, favorable payments for better care (e.g., pay for performance), nursing and medical staff retention (e.g., Magnet Recognition Program®), related projects (Surgical Care Improvement Project), and even quality for quality's sake. Further, the Centers for Medicare & Medicaid Services is currently considering the inclusion of hospital-acquired deep vein thrombosis (DVT) and pulmonary embolism (PE) in its list of events for which hospitals will no longer be reimbursed. Appendix A contains talking points and facts to assist in garnering support from hospital leadership.

Simple calculations that use back-of-the-envelope math can assist a QI practitioner in making gross estimates of the impact of VTE. Over 1 year, a 300-bed hospital that lacks a systematic approach to VTE prevention can expect roughly 150 cases of hospital-acquired VTE. Approximately 50 to 75 of those cases will be potentially preventable because of missed opportunities to provide appropriate prophylaxis. Approximately five of those patients will die from potentially preventable PE. Each hospital-acquired DVT represents an incremental inpatient cost of $10,000, while each PE represents approximately $20,000 in additional cost.

Another quick method of estimating the impact of a VTE prevention program uses coding information. The QI practitioner can run a query using all codes for DVT and PE. These codes,

listed at Table 1, represent both hospital-acquired VTE and the cases admitted to the medical center with pre-existing DVT or PE. At least half will be hospital-acquired VTE, and if the VTE prophylaxis rate is 50 percent, half of those will be potentially preventable hospital-acquired VTE. Alternatively, a patient may be defined as having hospital-acquired VTE when the diagnosis code is a secondary, rather than a primary, diagnosis.

**Table 1. Discharge Codes for Deep Vein Thrombosis and Pulmonary Embolism (Updated March 2007)**

| Number | Code |
|---|---|
| 453.40 | DVT lower extremity not otherwise specified |
| 453.41 | DVT proximal lower extremity |
| 453.42 | DVT distal lower extremity |
| 453.8 | DVT not elsewhere classified |
| 415.11 | Iatrogenic PE |
| 415.19 | Other PE |

Complementary codes of 997.2 and 999.2 qualify the above codes and may also be helpful.

Both methods can generate a rough estimate of the impact of a VTE prevention program. A more robust and accurate approach is outlined in Chapter 4 and addresses performance tracking. A rough estimate, however, can paint a useful picture to demonstrate the need of a VTE prevention program to members of care teams and administrators.

## Survey Previous or Ongoing Efforts and Resources

In many ways, a multidisciplinary QI team is building, flying, and navigating an aircraft that is already airborne. It pays to know what resources or circumstances are already available. Experience, precedents, or skilled individuals can significantly assist an effort. Conversely, working at odds with an infrastructure or strategic goals can sabotage the project.

Many factors can affect the approach to, interventions of, and the performance tracking system for the improvement effort. The QI team should determine the answers to these questions:

- What is the existing QI infrastructure?
- What support or services are available for this project?
- Are there any ongoing QI initiatives to learn from or to leverage?
- Are there any initiatives that could influence support for a VTE prevention effort (e.g., pursuit of Magnet Recognition Program®, Ventilator Associated Pneumonia bundle, Surgical Care Improvement Project, or The Joint Commission or National Quality Forum proposed core measures)?
- What performance data on VTE prevention or VTE events already exist?
- Are there any major lessons from previous or ongoing interventions to prevent VTE?

- How successful were previous VTE risk assessments? Why? Were they integrated into order sets?
- Are there ongoing VTE educational or awareness activities for medical staff?
- Are hospital policies capable of enforcing provider performance (e.g., medication reconciliation, vaccinations, VTE prophylaxis, etc.)?
- How fragmented is care in the hospital? Are intensive care units (ICUs) open or closed? Are patients geographically cohorted by service or specialty?
- What are the existing practices for standardizing care transitions between settings (e.g., emergency room to floor, intensive care unit to floor, operating room to floor, direct admissions)?
- Can precedents be leveraged that have engaged patients in promoting medical staff accountability for any specific care goals?
- In what areas of the hospital are nurses engaged in promoting medical staff accountability for any specific care goals (e.g., daily goals worksheet or participation in multidisciplinary rounds)?
- In what precedent-setting ways do clinical pharmacists participate in care delivery (e.g., participation in multidisciplinary rounds, pharmacokinetics consults, pages to providers to adjust medication dosages for estimated glomerulo filtration rate, etc.)?
- Could the electronic health information or paging system relay clinical information to members of the care team (e.g., alerts by e-mail, text page, fax, or computerized physician order entry [CPOE])?
- Is there a precedent anywhere in the institution for feeding back individual or service line performance to providers?
- Does the medical center have an electronic medical record, CPOE, or digital radiology?

## Clarify Key Stakeholders, Reporting Hierarchy, and Approval Process

Every medical center has stakeholders who should be made aware of efforts. Often, these stakeholders are individuals, but they can also be committees, services, training programs, hospital initiatives, or departments. Typically, these groups will include the:

- Pharmacy and therapeutics committee.
- Nursing groups.
- Orthopedics, surgery, or trauma leaders.
- Patient safety committee.
- Operating room or peri-operative committees.
- Chief residents and residency program directors.
- Departmental committees.

Providing awareness of the effort to stakeholders and gaining their buy-in will be important to boost early adoption of interventions. They may also advance educational efforts and offer legal protection for information that is uncovered. Early use of the proper reporting structure and approval processes is wise.

## Assemble an Effective Team

QI efforts often originate from just a few thought leaders who see a gap between best practices and current practices. The VTE prevention team should include the members listed below.

**Team Leader.** The team leader should be a physician the medical staff respects and, ideally, have some topic expertise on VTE prophylaxis and anticoagulation. This physician is responsible for setting the agenda, the frequency and the collaborative tone of team meetings, and for communicating directly with administrative and medical staff committees.

A physician hospitalist leader, pulmonologist, hematologist, critical care physician, surgeon, or other physician leader is the best choice to hold this position of influence. Though the team leader does not personally take minutes, the team leader should edit and "own" the minutes for presentation to senior leadership.

The team leader needs commitment and contributions from other team members to move the initiative forward. The team leader and the team may need to recruit local champions based on service or hospital geography. For example, a pulmonary or critical care physician may lead efforts on VTE prophylaxis in the ICUs, but a hospitalist may lead efforts on the floors or wards. Alternatively, a hospitalist or other individual may lead the entire effort. Whatever the format, a coordinated effort is required across the entire spectrum of care.

**Team QI Facilitator.** The QI facilitator, who may or may not be a physician, should be someone with QI experience. The QI facilitator plays the pivotal role of ensuring the team functions constructively and the project stays on track. This role requires project management skills and, at times, may call for the ability to balance team dynamics or introduce appropriate QI tools. The QI facilitator need not have mastery of QI tools at the onset of the project but should have a readiness to acquire new tools and a talent for moving projects forward. Mastery of the VTE literature is not important for this position. For smaller-scale projects, the QI facilitator can be the same person as the team leader. For more ambitious projects or for projects involving buy-in from disparate physician and nursing groups, having a separate facilitator is strongly recommended.

**Process Owners.** Frontline personnel involved in the process of providing VTE prophylaxis in the hospital are essential for an effective team wishing to optimize VTE prevention. Process owners should come from each service (pharmacy, nursing, etc.) and geography (medical, surgical, ICU, etc.).

**Information Technology and Health Information System Experts.** From performance tracking to actual QI interventions, the contributions of information technology or health information system experts is pivotal. Enlist those who can report ICD-9 code frequencies at discharge, perform data entry, set up reports from the electronic clinical data warehouse and radiology, and serve as liaisons to the medical records office.

**Team Members.** While meetings with the whole team are invaluable, they can occasionally become impractical or impossible to schedule. Team huddles, where a fragment of the team meets briefly to advance action items, can be very effective for overall progress. How team members interact with one another is also important. The key dynamic for an effective team is the removal of authority gradients. Because the perspective of every team member is potentially critical, every perspective must be heard. Each team member must be comfortable expressing his or her viewpoint. Try to pick people who have reputations as collaborators. It is up to the leader and facilitator to enforce constructive team dynamics.

Listing the names and contact information for the VTE prevention team members and keeping the list updated, especially electronically or online, is very useful.

## Set General Goals and a Timeline

Setting a goal is a great way to help the team stay focused and communicate with stakeholders. For clarity of purpose and to overcome initial inertia in the early stages, the team needs only to agree on general goals (e.g., reduce cases of hospital-acquired VTE). The general goal also should be a "stretch," one that is aggressive enough to mandate a change in design from the current process to achieve it (e.g., eliminate preventable cases of hospital-acquired VTE).

In addition to setting a stretch goal, at this early stage it helps also to be clear about the initial and eventual scope of the effort (e.g., will the focus be on medical patients, surgical patients, or both?). Initially it is reasonable and even advisable to "take small bites" by piloting interventions on a small scale (e.g., eliminate preventable cases of hospital-acquired VTE from a specific medical floor).

Try to be as inclusive as possible about the eventual scope. Serial testing and learning on a small scale can make even very large projects more manageable. Improvement strategies can be spread to other areas (e.g., eliminate preventable cases of hospital-acquired VTE from all medical and surgical floors and all ICUs).

Lastly, the team needs a deadline to which it will hold itself accountable. The timeline should be ambitious but realistic. For piloting a single improvement intervention on a single medical floor, a timeline of 12 weeks is reasonable. For spreading a series of improvement changes across an entire system, 12 to 18 months may be more appropriate.

## Use a Structured Framework for Improvement to Plan and Guide Progress

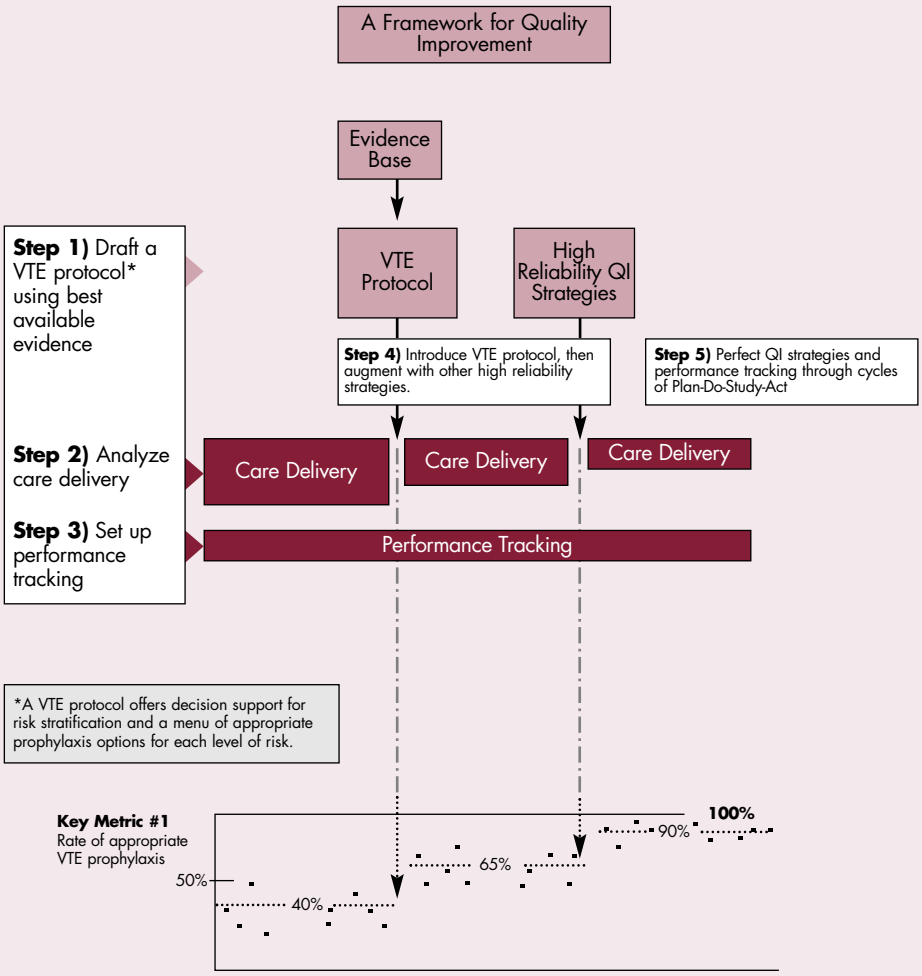
For team members (and as a communication aide for stakeholders), there is great value in knowing how each of the team's activities contributes to the overall progress of the improvement effort. A coherent framework is as important to quality improvement as an understanding of aeronautics is for building aircraft.

The team will advance the quality improvement project along several fronts simultaneously. A logical flow for a QI project is summarized below.

1. Lay out the evidence and identify best practices. Determine what needs to be done for whom and then draft a VTE protocol to standardize it.
2. Analyze care delivery. Highlight the steps in the clinical workflow where interventions will have the highest yield.
3. Track performance with metrics. Set up regular data collection and charting that is reliable, inexpensive, and directly relevant to the aim.
4. Integrate the VTE protocol into the clinical workflow and layer other QI strategies that use high-reliability mechanisms.
5. Perform cycles of Plan-Do-Study-Act to perfect 3 and 4, above.

Figure 1 presents the five steps and depicts inter-relationships.

**Figure 1. Sequence and Relationship of Steps in a Quality Improvement Project Aimed at Reducing the Incidence of Hospital-Acquired Venous Thromboembolism**



# Chapter 2. Lay Out the Evidence and Identify Best Practices

## Know What the Literature Says

The team will need to rely on at least one content expert who is fluent with the evidence base and best practices for preventing hospital-acquired venous thromboembolism (VTE). Especially relevant and authoritative are the published performance measures from The Joint Commission and guidelines from the American College of Chest Physicians (ACCP) Conference on Antithrombotic and Thrombolytic Therapy.[10] These should be supplemented, as needed, with the reading list in the "Literature Review" section of the Society of Hospital Medicine's VTE Quality Improvement Resource Room, which is available at www.hospitalmedicine.org/ResourceRoomRedesign/RR_VTE/html_VTE/03BestPrac/02_Literature.cfm.

At least three central realities emerge from the current VTE prevention literature, each with important implications for the team.

**Reality 1.** While the number and type of VTE risk factors appear to influence a patient's overall VTE risk, there is no validated method to predict accurately or efficiently an individual patient's risk for VTE.

Meanwhile, in the absence of prophylaxis, the risk of VTE across almost all populations of hospitalized patients is significant, as shown in Table 2.

**Table 2. Risk of Deep Vein Thrombosis in Hospitalized Patients**
No prophylaxis + routine objective screening for DVT

| Patient Group | DVT Incidence (%) |
|---|---|
| Medical patients | 10–26 |
| Major gynecological, urological, or general surgery | 15–40 |
| Neurosurgery | 15–40 |
| Stroke | 11–75 |
| Hip or knee surgery | 40–60 |
| Major trauma | 40–80 |
| Spinal cord injury | 60–80 |
| Critical care patients | 15–80 |

The 2004 ACCP conference statement supports a group-specific approach to prophylaxis. Its reasons for this approach are:

- The inability to confidently identify patients who do not require prophylaxis.
- The inability to predict how risk factors combine to position an individual patient along the spectrum of thromboembolic risk.
- The fact that individualizing prophylaxis is logistically complex and likely associated with suboptimal compliance.

Constructing simple risk assessment models that stratify all patients into three to four easy-to-understand groups, as opposed to complicated point-scoring systems, is preferable. The concept of the VTE protocol and suggestions for keeping it simple and effective are discussed below and in Chapter 5.

**Reality 2.** Instances of clear superiority or inferiority do exist among prophylaxis options but for just a few patient groups.

One of the team's fundamental duties is to come up with a way to recommend — as well as judge — the appropriateness of one prophylaxis option over another. For this reason, the second thing to know about the VTE literature is where clear evidence exists to recommend a particular method of prophylaxis over others. The team should know that the most appropriate choice of VTE prophylaxis depends on the patient group and circumstances of the hospital stay.

- In medical patients, fondaparinux and the low-molecular-weight heparins (LMWHs) enoxaparin and dalteparin have efficacy comparable to heparin given three times a day subcutaneously but offer lower complication rates and other advantages potentially important to patients and nursing staff.[18-21]
- In certain higher-risk patient groups (e.g., hip and knee replacement, trauma, and spinal cord injury) LMWH has demonstrated superiority over subcutaneous heparin.[10, 22-25]
- In certain patient groups (e.g., hip replacement, surgery for cancer, and possibly medical patients with reduced mobility), extending prophylaxis with LMWH to approximately 5 weeks is more effective than providing it for 1 week.[10, 26]
- In certain patient groups, such as medical inpatients, the adequacy of heparin given twice a day subcutaneously has not been proven. High quality randomized trials showing relative equivalence of LMWH to unfractionated heparin (UFH) all used a 5,000-unit, three times a day dosing of UFH.
- In very high-risk patient groups, the addition of mechanical prophylaxis to a pharmacologic regimen may offer an added benefit.
- Certain patient groups should not receive certain pharmacologic agents or doses or should receive smaller doses of LMWH (e.g., creatinine clearance less than 30 cc per minute).
- Certain patient groups should receive pharmacologic doses in close coordination with other events (e.g., surgery or neuroaxial blockade) or with special knowledge by involved physicians (e.g., spine surgeons).

**Reality 3.** In the quality improvement (QI) literature, no strategy has yet been described for getting the right prophylaxis to the right patient at sustainable and acceptable rates in a way that can be readily replicated by other institutions.

The typical successful strategy described in the literature profiles excellent use of special local resources but with limited transferability. Electronic alerts have raised the prevalence of VTE prophylaxis but in an academic setting with computerized physician order entry (CPOE), electronic decision support, and a high baseline prevalence of VTE prophylaxis.[27] In another academic setting, a monthly division-director-led audit and feedback of physician performance was combined successfully with monthly educational offerings for patients the medicine house staff cared for.[28] Replicating such strategies in nonteaching or non-CPOE settings would not be possible. More generally, because QI study designs tend not to confirm sustainability or reproducibility, the ability to articulate or judge discrete underlying mechanisms is limited.

At this stage, familiarity with the evidence base positions the team to draft a "VTE protocol," the document that becomes the foundation for the rest of the effort to prevent hospital-acquired VTE, from interventions through performance tracking.

The key concept with a protocol is routine. Doing a complex activity the same way each time is the best way to make sure that nothing is left out. In the hospital, protocols serve that purpose. They standardize and structure the care a group of providers deliver. Routine is important because across a population of patients, provider inconsistency is one of the most common sources of suboptimal care. For a variety of reasons, providers inevitably vary care, whether compared to each other or compared to themselves. In fact, a graph that depicts improved system performance over time almost always shows a progressive narrowing of the range of performance. In a powerful way, protocols have the capacity to improve care by reducing unnecessary variation in performance from medical decisionmaking to ordering.

The best protocols preserve the ability to customize care for special patient situations or circumstances. In contrast to variation arising from provider behavior, variation from the protocol that arises due to special patient situations is always acceptable. The protocol should make that clear.

## Construct the Venous Thromboembolism Protocol

The VTE protocol accomplishes several purposes at once. First, if it is well integrated into all admission, transfer, or post-operative orders, it prompts providers to do the right thing at the right time. Second, it gives providers the option of using, or not using, the decision-support elements. Third, the VTE protocol is a definition of what the team will consider "appropriate prophylaxis" for the patients within the scope of the improvement effort. This definition will be critical when it comes time to measure baseline and new prevalence of appropriate VTE prophylaxis.

The team must focus time and attention on drafting and field-testing the VTE protocol, which is useful as an educational tool and helps set expectations for care. QI intervention principles the team should consider when constructing and evaluating the VTE protocol are discussed in Chapter 5.

The ideal VTE protocol:

- Is applicable across all patients in the scope. The optimal approach is to have the team create a single VTE protocol for all patient groups targeted by the improvement effort. For example, if the scope includes all medical and surgical patients, the team should avoid customizing separate VTE protocols for general surgery, gynecology, oncology, orthopedic surgery, and medical patients. It should instead try to construct a single VTE protocol that can be applied to all patients. The advantage of this approach comes from the power of standardization.

  A universal VTE protocol:
  - Can be more readily approved and initiated.
  - Is more likely to be recognized as definitive in its authority.
  - Is easier to modify based on feedback.

  Adherence to a single VTE protocol can readily serve as a surrogate measure for performance tracking. The predictable disadvantages are those that come from any effort that tries to apply a common solution to different groups. The challenge is to strike a balance between limiting prophylaxis options too much and allowing for many options. There are several ways to overcome these disadvantages, but the simplest rule of thumb is always to allow providers the leeway of going "off protocol" when clinically appropriate.
- Is easy to access and easy to use. Simpler is better. Eventually the team may ask providers to refer to or recall elements of the VTE protocol several times during a patient's admission. One of the great determinants of the VTE protocol's success will be whether the team can make its use so easy and automatic that all patients coming into the hospital at any time from any place will be funneled through it.
- Links each level of risk to evidence-based choices for prevention.
- Lists contraindications to prophylaxis and encourages reasonable alternatives.

The VTE protocol consists of a standardized VTE risk assessment, a linked menu of appropriate prophylaxis options, and contraindications to pharmacologic or heparin prophylaxis. A sample VTE protocol is included at Appendix B.

**Standardized VTE Risk Assessment.** A standardized VTE risk assessment delivers decision support to the point of care. In other words, at the moment of medical decisionmaking, providers have what they need to stratify the patient to a specific VTE risk level. No single VTE risk assessment has been prospectively validated as superior to others. Many factors should be taken into account when adapting one. A list of published articles focusing on VTE risk factors and risk assessment appears in Appendix C.

**Linked Menu of Appropriate Prophylaxis Options.** This menu allows providers to choose the right VTE prophylaxis by "backing into" the choice from the VTE risk level that is derived from the standardized VTE risk assessment. The team must explore local factors that may play a role in selecting agents of choice for each level of VTE risk. The team must account for these local

## Case Study 1. Questions the University of California, San Diego Medical Center Encountered While Developing Its Venous Thromboembolism Protocol

### Should intermittent pneumatic compression (IPC) be a first-line, appropriate choice for patients at moderate risk of VTE?

At the University of California, San Diego (UCSD) Medical Center, a 300-bed referral center, the team originally wanted to keep IPC as an option for patients at moderate risk for VTE, despite the lack of solid evidence in the literature for medical patients. Team audits revealed about 55 percent compliance with IPC, however, and the UCSD team adapted the approach of the American College of Chest Physicians Conference on Antithrombotic and Thrombolytic Therapy, which relegates IPC to patients with contraindications for pharmacologic prophylaxis or as a secondary method to enhance the effectiveness of pharmacologic prophylaxis.

### Which patients need IPC in addition to pharmacologic prophylaxis?

At UCSD, the team decided the very high-risk patient must have it, while other patients could have it.

### Which patients should have 5,000 units of heparin every 12 hours as an option versus 5,000 units of heparin every 8 hours?

UCSD initially had four levels of VTE risk. They allowed 5,000 units of heparin every 12 hours as a choice for patients at moderate VTE risk (which described many medical ward patients), but advocated the higher-frequency 5,000 units of heparin every 8 hours for high-risk patients (which typified sicker medical and critical care patients).

Eventually UCSD collapsed its moderate and high-risk categories into a single category because:

- Poor compliance with IPC eliminated that as a viable first-line method.
- Many patients on 5,000 units of heparin every 12 hours were still developing VTE.
- It would greatly simplify the risk assessment tool and order sets if 5,000 units of heparin every 12 hours were eliminated as an option for all patients unless they weighed 50 kilograms (110 pounds) or less.

Other teams may make logical alternative choices based on local factors.

### Should 7,500 units of unfractionated heparin (UFH) every 12 hours be offered as an option?

At first glance, this is an attractive choice. It retains dosing at every 12 hours and pharmacodynamically should deliver the same protection as offered by the clinical-trial-proven regimen of 5,000 units of UFH every 8 hours. Unfortunately, UCSD found that its pharmacy or nurses had to draw up 7,500-unit doses on special order, while the 5,000-unit doses came prepackaged from the distributor. For UCSD, the 7,500-unit dose carried too many labor, cost, and potential safety issues.

### Should low molecular weight heparin (LMWH) or UFH be the recommended choice for VTE prophylaxis in moderate to high-risk patients?

This is a difficult decision for many institutions. The team should make a decision that is best for patients and nurses while still being fiscally responsible. To make an informed decision, consider:

- Pharmacy cost.
- Cost of administration (e.g., every 8 hours versus every day).
- Patient and nursing satisfaction.
- Lower incidence of heparin-induced thrombocytopenia with LMWH.
- The danger of using LMWH as default. For example, will staff forget to use UFH in patients with renal insufficiency, or will there be a reminder process in place for these situations?

*continued on page 12*

**Case Study 1. Questions the University of California, San Diego Medical Center Encountered While Developing Its Venous Thromboembolism Protocol *(continued)***

- Roughly equivalent performance. Some would argue a slight edge exists for LMWH, especially in critically ill patients.

At UCSD, they found the following:

| | Pharmacy cost | Admin time/cost | Total cost |
|---|---|---|---|
| LMWH every day | $16 | 10 mins/$5.33 | $21.33 |
| UFH every 8 hours | $1 | 30 mins/$16 | $17 |

The pharmacy costs above are based on actual pharmacy purchase costs at UCSD, not the retail cost to the customer. Admin time/cost is based on GRASP® Methodology estimates of nursing time to administer UFH every 8 hours versus LMWH every day, estimated as 10 minutes per injection, multiplied by the average registered nurse rate of $32 per hour. This does not mean that the institution actually reaps the savings of 20 minutes of nursing time per day, but rather that it represents an opportunity cost (i.e., the nurse is freed up for 20 minutes for other responsibilities).

While there was only a $4.33 difference in cost per patient day between these two options, and the every day dosing of LMWH is attractive to patients and nurses, UCSD decided to allow for either 5,000 units of UFH every 8 hours or 40 mg of enoxaparin every day as first options for patients at intermediate VTE risk. The UCSD team thought it was important to retain an UFH choice in patients with end-stage renal disease and had no valid reason to exclude it as an option in the intermediate-VTE-risk population. Other teams should make these decisions based on their local environment.

factors when drafting the VTE protocol. Case Studies 1 and 2 showcase how the University of California, San Diego Medical Center and Emory University Hospitals handled common VTE protocol questions.

The team must investigate not only which options are most appropriate for each level of risk but also which agents, given local factors, should be the preferred agents for each level of risk. Relative efficacy, dosing schedules, formulary costs, and side-effect profiles are all important considerations.

The steps to define appropriate prophylaxis are:

1. Create or adapt any VTE risk assessment to meet local needs.
2. Choose recommended options for each level of VTE risk.
3. Decide upon acceptable options for each level of VTE risk. The term "acceptable" is intentionally looser than "recommended" and will become significant when measuring whether prophylaxis is appropriate. For example, while intravenous heparin may not be recommended for VTE prophylaxis, it probably should be considered an acceptable alternative when it is being used for other indications.
4. Identify absolute and relative contraindications to pharmacologic prophylaxis and settle on acceptable alternatives for these patients.

**Case Study 2. Questions Emory University Hospitals* Encountered While Developing Their Venous Thromboembolism Protocol**

**Should low molecular weight heparin (LMWH) or unfractionated heparin (UFH) be the recommended choice for VTE prophylaxis in moderate- to high-risk patients?**

Because the literature demonstrates superiority of LMWH over UFH in a relatively small subset of patient populations (i.e., spinal cord injury, acute ischemic stroke, trauma, hip and knee arthroplasty, and bowel surgery for cancer patients), the Emory team decided to design a simple VTE protocol that could be applied to the majority of patients for whom efficacy is comparable. Emory found that this made it much easier to risk stratify and recommend prophylaxis options for these patients. Because only a small percentage of inpatients could be considered low risk, almost all inpatients without contraindications to pharmacologic prophylaxis would receive either UFH or LMWH.

For the several patient groups in which LMWH has demonstrated superiority, the Emory team decided it would not be difficult to customize VTE protocols. Similarly, the provider groups for patients for whom pharmacologic prophylaxis is contraindicated appreciated that the team could customize their VTE protocols to make it easy to order mechanical prophylaxis and difficult to order pharmacologic prophylaxis.

**Which patients need mechanical in addition to pharmacologic prophylaxis?**

The Emory team decided that mechanical prophylaxis should not be part of its recommendations for routine prophylaxis because of the very large intermediate- to high-risk group. The team did include mechanical prophylaxis as an additive option for patients with more risk factors and for patients with relative or absolute contraindications to pharmacologic prophylaxis. In the orthopedic VTE protocol, the team presented the combination of mechanical and pharmacologic prophylaxis as the recommended option.

**Which patients should have 5,000 units of heparin every 12 hours versus 5,000 units of heparin every 8 hours?**

The Emory team found that a portion of inappropriate prophylaxis derived from the choice of providing heparin twice a day (BID) in patients younger than 75, a group in which BID heparin is not convincingly better than placebo. So while the team wanted to reduce the frequency of BID heparin in those patients, it decided to preserve it as an option for patients older than 75. To discourage inappropriate use of BID heparin, the team indented it from the margin of the order sheet and added the qualifier "inadequate except for patients older than 75."

*Emory University Hospital is a 550-bed referral center and Emory Crawford Long Hospital is a 550-bed community teaching hospital.

**Contraindications to pharmacologic or heparin prophylaxis.** Like the VTE risk assessment, this feature of the VTE protocol delivers decision support to the point of care so that providers know when to choose alternative prophylaxis (i.e., if specific contraindications to anticoagulation or heparin products exist). The team should be wary of being too liberal in defining contraindications to pharmacologic prophylaxis. Many patients with relative contraindications develop VTE and end up on full dose anticoagulation. The team should be as specific as possible when using time parameters. For example, "recent gastrointestinal hemorrhage" is not as useful as "gastrointestinal hemorrhage within 1 month."

## Integrate the Venous Thromboembolism Protocol

The power of the VTE protocol will be unleashed only when it is well integrated into the clinical workflow. This integration will be the team's next objective. How the team accomplishes this will depend on institutional culture and infrastructure, such as whether the hospital uses CPOE or paper order sets.

A recommended approach is to ask a focus group of hospitalists, residents, or anyone who frequently writes admission orders to try out early drafts of the VTE protocol. It is never too early to start listening to the end user. Whatever is learned from focus groups should be incorporated immediately into a new version. Using qualitative feedback to make daily revisions for a week can bring the team very close to perfecting the usability of the VTE protocol. Chapter 4 provides more detail on how to get the most out of early pilot efforts.

Ultimately the team should strive for perfect integration of the VTE protocol into admission and transfer order writing; thus the importance of an easy-to-use model cannot be overstated. Even if the VTE protocol is supremely easy to use, it will be ineffective if patients bypass the protocol. A number of approaches to prevent this outcome, and other methods of enhancing the reliability of the VTE protocol are outlined in the coming chapters.

# Chapter 3. Analyze Care Delivery

To create its intervention, the team will need to diagram care delivery, which should be viewed as a series of intermediate steps that lead to a clinical endpoint. Diagramming helps members understand interrelated steps and identify where failures occur. By analyzing care delivery the team can identify "rate-limiting" steps and recognize which steps should serve as metrics for preventing hospital-acquired VTE.

## Diagram Care Delivery to Identify Failure Modes

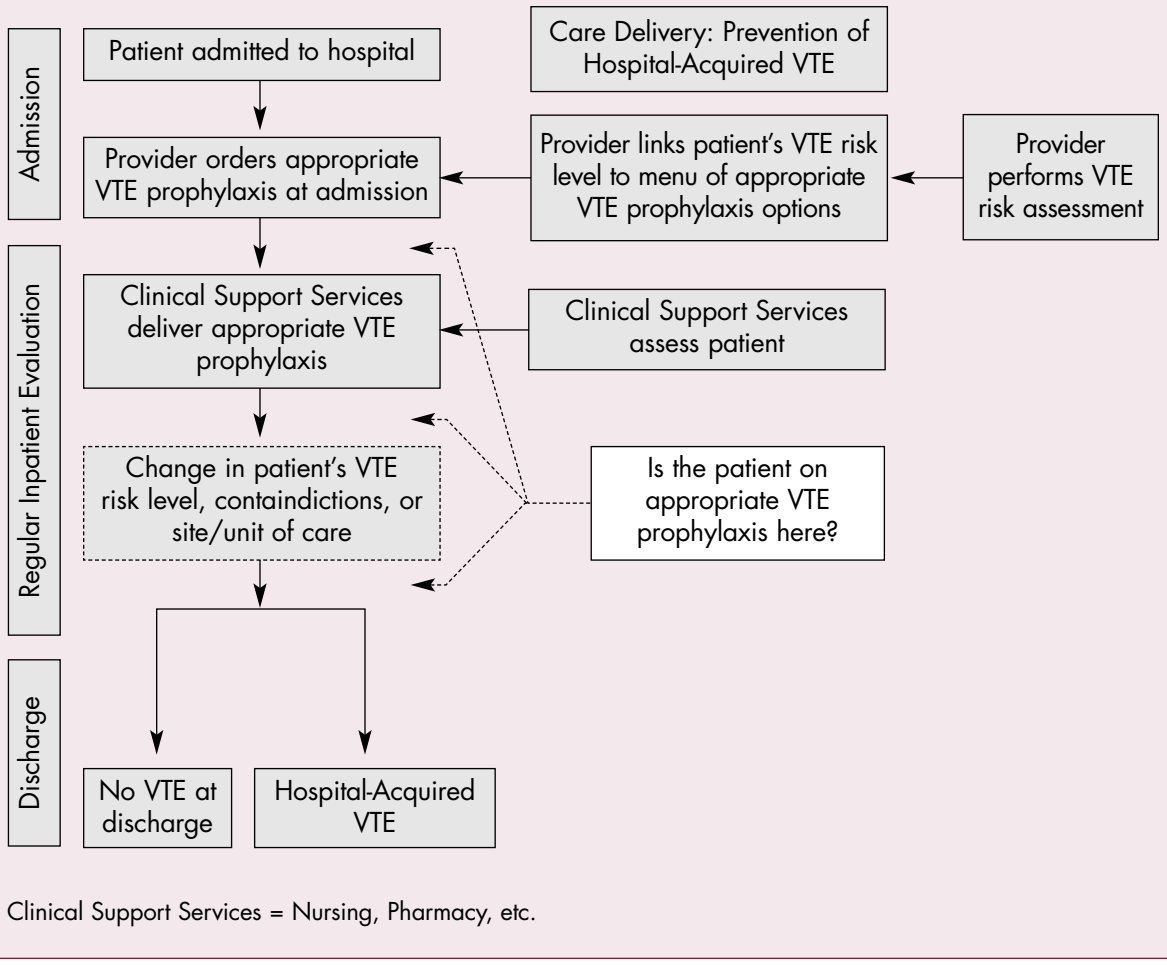
What the team learns from drawing and discussing a map of the current process can be surprising. The team may identify wasted or duplicated efforts, lack of consensus on the current process, hidden complexities, and opportunities to streamline or simplify.

Figure 2 diagrams the steps in care delivery for preventing hospital-acquired VTE. As a starting point, the team should estimate how often each step occurs. For those steps that occur less than 100 percent of the time, the team should list those things that go wrong in the current system. This simple qualitative analysis may reveal steps in the current process that are so obviously unreliable that they become the natural focus of interventions. The team can make an attempt at this point to prioritize these failure modes. Case Study 3 lists examples of actual failure modes identified at the University of California, San Diego Medical Center and Emory University Hospitals that may be helpful during reviews or discussions.

**Case Study 3. Actual Failure Modes from the University of California, San Diego Medical Center and Emory University Hospitals**

- VTE risk assessment is not routine or standard.
- Bleeding risk assessment is not routine or standard.
- Most appropriate prophylaxis option for each level of risk is not conveniently available for provider.
- Differing opinions or lack of awareness exist for how at-risk some medical or surgical patients were.
- Differing opinions exist on what is appropriate, even among experts.
- Protocols differ among orthopedics, surgery, and medicine.
- Noncompliance with mechanical prophylaxis exists. For example, mechanical prophylaxis is on the floor, on the window sill, not in the room, or not delivered to the room when the patient is admitted at night or over a weekend.
- Unnecessary immobility occurs because of excessive sedation, unnecessary restraints, central lines, catheters, intravenous fluids, or oxygen therapy.
- VTE and bleeding risks change, but there is no routine or standard reassessment.
- Platelet monitoring is haphazard when heparin is ordered.
- Nonretrievable inferior vena cava filters are overused.
- Transfers out of intensive care units may cause VTE prophylaxis to be dropped.
- Prophylaxis is stopped at discharge even when risk continues in some patients.
- Widely different impressions are held for when it is safe to start anticoagulation peri-procedure and post-trauma.

**Figure 2. Care Delivery for Preventing Hospital-Acquired Venous Thromboembolism**




Conceptual Flow Diagram of Care Delivery for Providing VTE Prophylaxis: A number of interrelated steps combine to determine whether a patient, at any given moment, is receiving appropriate VTE prophylaxis.

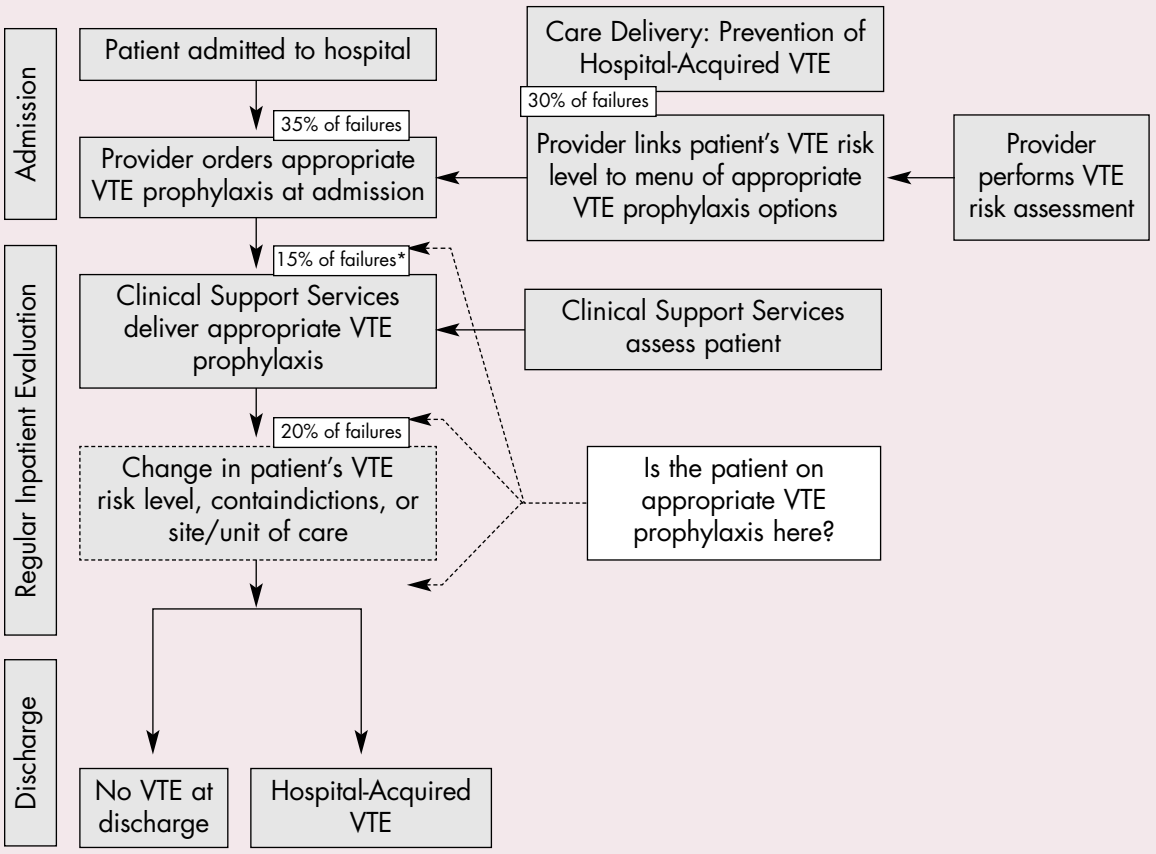
## Analyze Care Delivery to Identify "Rate-Limiting Steps"

Ultimately patients and providers care most about final clinical outcomes, like whether or not a patient has developed a hospital-acquired deep vein thrombosis (DVT) or pulmonary embolism (PE). The opportunity to reduce the likelihood of hospital-acquired VTE begins the moment the patient is admitted and actually recurs every day. To help the team focus its time on the most high-yield interventions, it is extremely helpful to identify the most frequent sources of missed opportunities to prevent hospital-acquired VTE. To a perfectionist, these missed opportunities can be thought of as "rate-limiting steps." To an optimist, they may be thought of as "high leverage points" for improvement.

Empirical analysis of each step below is useful. The following brief audit exercise is useful and recommended. The team should randomly choose 20 to 30 charts on the pilot unit. Team members should then tally the prevalence of appropriate prophylaxis as judged by the team's new gold standard, the VTE protocol. Next, they should look at the charts of the patients who were not on appropriate prophylaxis. If mechanical prophylaxis alone has been ordered, they should look at the patient to determine if mechanical prophylaxis is being worn. This should take no more than 2 to 3 hours using the chart audit form at Appendix D. Once the chart audit is complete, the team can make a simple tally sheet of the type and number of failures or annotate the diagram at Figure 3.

With quantitative information, the improvement team can make rational choices when deciding which steps in care delivery to redesign and which steps to measure. For VTE prevention in the hospital at Figure 3, a key moment occurs when physicians write admission orders. At that moment at least two different types of failure modes appear to contribute significantly to a poor overall baseline prevalence of appropriate VTE prophylaxis.

**Figure 3. Care Delivery for Preventing Hospital-Acquired Venous Thromboembolism**




* Mechanical prophylaxis not delivered to room or not on patient

A sample of 25 charts at this hospital showed that two-thirds of failures to order appropriate venous thromboembolism (VTE) prophylaxis occurred at the time of admission and are attributable either to the provider ordering or medical decisionmaking (i.e., 35 percent ordered nothing for VTE prophylaxis, another 30 percent ordered something that the VTE team considered inappropriate). One in five failures was due to failure to re-assess VTE risk later in the hospital stay. One in eight failures was due to a problem with delivering or wearing sequential compression devices.

# Chapter 4. Track Performance With Metrics

The team must employ metrics to fully appreciate the scope of hospital-acquired venous thromboembolism (VTE) and to determine how well its approach to reducing VTE is working. An aim statement can serve as a benchmark for the intervention's success, and run charts provide a visual representation of progress.

## Key Metric 1: Prevalence of Appropriate Venous Thromboembolism Prophylaxis

Though Figure 3 was used earlier to understand care delivery, it can now be used to measure care delivery, as shown in Figure 4. Specifically, this diagram will assist in selecting metrics — meaningful and measurable steps the team can use to track performance over time. In most instances the most telling metric is the prevalence of appropriate prophylaxis. Not only does it have the most important causal relationship to the main clinical endpoint, hospital-acquired VTE, but it is also a sensitive indicator of how well the various care delivery steps come together.

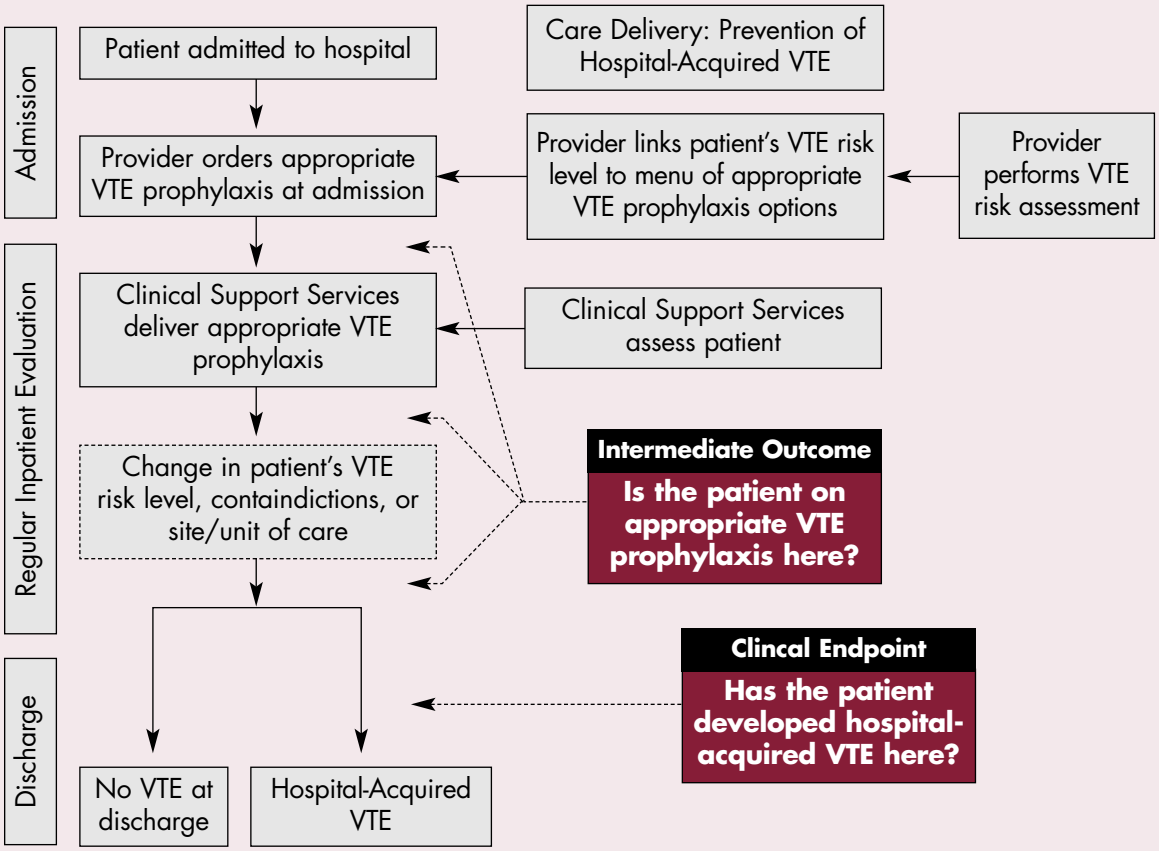
Using the prevalence of appropriate VTE prophylaxis as one of the team's two key metrics also offers something that can be measured regularly and reliably. Set up daily, weekly, or monthly data collection for this metric (see Key Metric 3, below). This data flow offers a reliable way to track performance of the changed care delivery system. What makes the clinical endpoint of hospital-acquired VTE unsuitable as a lone metric for performance tracking is that events are too infrequent and are often subclinical or too delayed in onset for timely, useful feedback.

It should now be clear how the VTE protocol serves not just as the main ingredient for the improvement intervention but also for the measurement system that can track performance.

## Key Metric 2: Incidence of Hospital-Acquired Venous Thromboembolism

The team cares most about how well the steps of care delivery come together to prevent hospital-acquired VTE, the main clinical endpoint or outcome. Clearly, the incidence of hospital-acquired VTE must be one of the team's key metrics. A common definition for "hospital-acquired deep vein thrombosis or pulmonary embolism" would be a clot first discovered during the course of hospitalization or discovered within 30 days of a prior hospitalization. Table 3 shows various methods for trying to capture this metric in a useful way. Each has its own advantages in terms of accuracy and efficiency.

**Figure 4. Outcomes Chain for Hospital-Acquired Venous Thromboembolism**




Whether a patient develops a preventable hospital-acquired deep vein thrombosis (DVT) or pulmonary embolism (PE) depends heavily on recent, appropriate venous thromboembolism (VTE) prophylaxis. While one key metric to track is the intermediate outcome "appropriate VTE prophylaxis," the more proximal steps in the care delivery pathway are where care redesign will likely occur (e.g., the VTE protocol). The other key metric to track is the prevalence of hospital-acquired DVT or PE.

Method 1 is very simple and can be done with minimal effort. Method 3 introduces the concept that the team can actually get more from a chart review than just a classification of hospital-acquired versus community-acquired VTE. The VTE can now also be classified as "hospital-acquired while on appropriate prophylaxis" versus "hospital-acquired while not on appropriate prophylaxis."

By using Method 3, the team can plot the incidence of preventable hospital-acquired VTE. This subset of all hospital-acquired VTE events communicates the most about the entire VTE prevention effort. Method 3 also allows surveillance for other factors that lead to the formation of a hospital-acquired clot. For example, was the patient sedated or restrained? Did the patient

| Table 3. Methods for Defining Hospital-Acquired Venous Thromboembolism | |
|---|---|
| Method 1 (Minimum) | Track total number of deep vein thrombosis (DVT) and pulmonary embolism (PE) diagnosis codes in the medical center. (Table 1 in Chapter 1 provides codes for DVT and PE.) Divide that number by 2 to estimate the fraction for those that are hospital-acquired. The literature suggests that approximately half of all cases of DVT and PE diagnosed in the hospital are hospital acquired. Alternatively, use all venous thromboembolism (VTE) codes as a secondary diagnosis as a surrogate for hospital-acquired VTE. |
| Method 2 (Better) | Perform Method 1 and then pull charts post-discharge and retrospectively determine if DVT or PE was hospital or community acquired. |
| Method 3 (Better Yet) | Perform Method 2 and then retrospectively determine if hospital-acquired VTE patients were on appropriate prophylaxis when the VTE developed. |
| Method 4 (Best) | Prospectively capture new cases of DVT or PE as they occur by setting up a reporting system with radiology or vascular departments. |

have a central-line-associated clot, and if so, was the line really needed at the time the clot formed? Given the time and resources, the team could do a mini-root cause analysis to generate other potential strategies to prevent hospital-acquired VTE.

Method 4 offers all the benefits of the other methods with the additional advantage that chart review is much easier when the patient is still in the hospital. The chart review can also be more efficient if it has the capability to query a digital imaging system to screen all pertinent imaging studies regularly.

In the 350-bed facility at University of California, San Diego Medical Center (UCSD), a nurse or nurse practitioner screens all pertinent studies from the prior day, identifies all new hospital-acquired clots, and completes a thorough chart review on all new hospital-acquired VTE. The process takes less than an hour each weekday. It can be done efficiently by using automated search criteria if the radiology department uses a suitable digital imaging system. The team should try to create a flow of data that pulls up all pertinent diagnostic studies, complete with their reports, at the click of a button. Depending on the limitations of the radiology information system, the team may come up with another method that is more useful and expedient.

Once the team has defined "hospital-acquired VTE" and figured out how to find the cases, it has another decision to make. Should it simply track the raw number of hospital-acquired VTE, or should it control for the number of patients or patient-days? Controlling for patient-days at risk for VTE adds a little more work, but it reduces some of the noise in the data by controlling for the probability that more hospital-acquired VTE events occur with higher hospital occupancy. At UCSD, for example, each month the team calculates the total number of patient-days for adult inpatients in the hospital for more than 48 hours and uses that as the denominator. The team uses the total number of hospital-acquired VTE events as the numerator. This helped UCSD generate a specific aim, a concept discussed later in this chapter.

Another option to consider, if the team has the capacity to look at all newly diagnosed events of DVT and PE in the hospital, is to track the number of days between hospital-acquired VTE events or potentially preventable hospital-acquired VTE events. This allows the team to chart days between events. Each event becomes a point on the x-axis while the number between events appears on the y-axis.

## Data Collection

While data collection can be costly in terms of time and money, the focus should remain on improvement rather than measurement. To track performance regularly and to advance plan-do-study-act (PDSA) cycles, the team needs just enough data to know whether changes are leading to improvement. A sampling strategy that uses 20 randomly selected patient charts per month can be statistically appropriate as well as relatively quick and easy. To make the time commitment more manageable, five charts can be audited each week with the results rolled up into monthly reports. The team should designate an individual or two to collect, collate, plot, and manage the data. Many improvement projects falter or die simply because data collection is inadequate.

The team should also choose between sampling active inpatients or recent discharges. The former approach may offer several real-time advantages. Providers can be alerted to prophylaxis oversights, which might create moments to improve care as well as educate staff. In addition, by sampling active inpatients, insights into process barriers and valid reasons to amend the new process may emerge more readily. Self-coding and scannable forms can lessen the burden of data entry.

Available data collection resources in any given hospital may dictate methods and definitions. Whatever method is chosen, consistency and usefulness are critical. It is usually helpful to pilot the metric definitions and steps in data collection to learn about and solve stumbling blocks. In much the same way as the team performs cycles of PDSA for care delivery improvements, it should go through several cycles of PDSA to perfect the performance tracking system. For example, to refine the VTE protocol and develop it as a valid audit tool, the team can apply the VTE protocol to audit 10 to 20 patients, using three independent reviewers. Questions that should be answered include:

- Did the reviewers arrive at the same risk level?
- Did they agree on absence or presence of contraindications to pharmacologic prophylaxis?
- Did they share the same conclusion about whether the patient was receiving adequate prophylaxis?

There are several questions that sequential pilots of the audit tool should help answer.

- How much time is acceptable in peri-operative or trauma settings for a patient not to be on pharmacologic prophylaxis? (The readings at Appendix C can suggest some parameters.)
- What are the acceptable versus preferred VTE prophylaxis options for each level of VTE risk? Realize that when auditing, there will be VTE prophylaxis options that make sense to consider as adequate, even though they are not listed as recommended in the VTE

protocol. For example, the auditor may accept 7,500 units of unfractionated heparin subcutaneously every 12 hours as acceptable prophylaxis for the patient who is at moderate risk for VTE, even if it is not listed as an option on the VTE protocol because of the lack of prepackaged syringes or the absence of clinical trials supporting that regimen.

- What patients will be included in the sampling? Depending on the scope of the initiative, it may make sense to exclude:
  - Patients receiving obstetric care.
  - Patients being seen on the psychiatric or behavioral health unit.
  - Patients hospitalized less than 24 or 48 hours.
  - Young patients.
- Which data collection strategy should the team use for performance tracking? The team could look at a representative sample of patients at baseline and then repeat with a representative sample after introducing the VTE protocol. This before-after approach is simple, but the data can be misleading. Day-to-day variation in prevalence of VTE prophylaxis can be as wide as 35 percent. This variation indicates that multiple sampling events are necessary to ensure accurate conclusions. Rather than using several data points before an intervention, use at least 20 data points before an intervention and as many as necessary after the intervention to determine the new steady-state prevalence of prophylaxis. Results can be tracked and trended in run charts.

Several common sampling strategies follow.

**Convenience sampling.** Reviewers select patients because they are available on the ward, but otherwise there is no particular selection process. Convenience samples categorized by ward or service are a common model.

**Random sampling.** All patients in a representative population are subject to selection. The University of California, San Diego (UCSD) Medical Center uses this model. All patients over 18 and in house for more than 24 hours are assigned a number, and a random number generator (a free plug-in application for Microsoft® Excel®) produces a list of 10 patients to subject to review that day. The data collector selects the first random patient generated for the audit. This has the advantage of giving an accurate picture of the demographics and VTE risk in the institution. The main disadvantage is the possibility that some small but important patient group will be subject to only a few audits.

**Stratified random sampling.** Patients from several important patient groups are randomly sampled (e.g., medical versus surgical versus orthopedic, or critical care versus noncritical care). The advantage of this method is the ability to target patient groups at higher risk for VTE or with other criteria important to the VTE prevention effort.

Before piloting and finalizing an audit tool, it will be important to pilot and finalize the VTE protocol. Feedback from the VTE protocol pilot test may change the audit form.

## Data Reporting Using Run Charts

At every meeting, the team should review specific aims and present its progress towards the aims. The best way to do this is with a graph. When presenting performance within the institution's reporting structure, graphical formats, such as run charts or statistical process control (SPC) charts, will be more effective than denser tabular formats.

Run charts are easy to make and are usually adequate for graphing improvement data in order to follow performance over time. Compared to tables of data, run charts offer a quicker picture of how an intervention is working relative to a baseline. The table and run chart in Figure 5 represent data from UCSD. The run chart makes it easy to appreciate the dramatic trends in performance over time.

Run charts should be annotated along the x-axis where new interventions or events occur. This addition can make it easier to see the effects of different stages of an intervention or to subtract the effect of known secular trends. For run charts, ubiquitous software (Excel® or any several free online run chart applications) is available, and no statistical expertise is needed.

For quality improvement projects, monthly plots are usually adequate, although when testing new or revised improvement strategies via PDSA, weekly plots may be desirable to see effects quickly.

SPC charts are a special kind of run chart that are useful to help the team gauge whether fluctuations in run charts are due to noise in the data and variation within an unchanged system, versus real change indicating that the underlying process has changed. A full discussion of SPC charts is beyond the scope of this publication,. Improvement teams can learn more about the technique at http://reliability.sandia.gov/Manuf_Statistics/Statistical_Process_Control/statistical_process_control.html.

## Transform General Goals Into a Metric-Specific Aim Statement

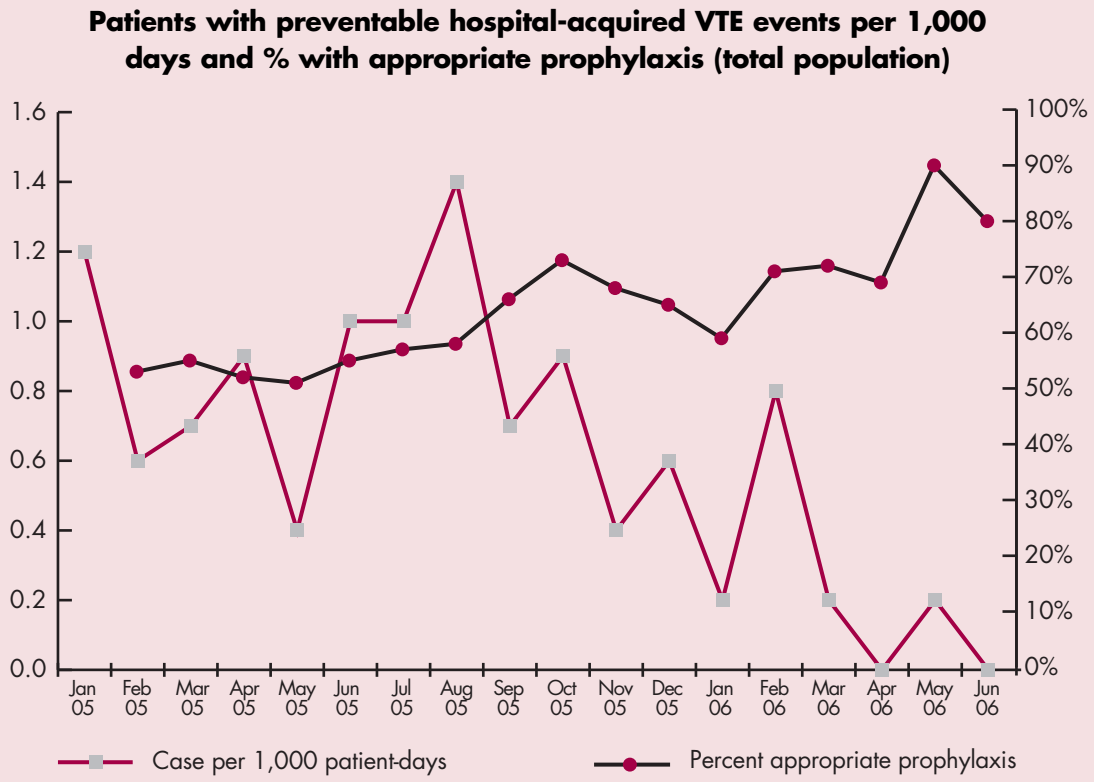
In Chapter 1, the team set a purposefully ambitious general goal to give a broad sense of the breakthrough success the team wanted to achieve. In the current chapter, the team defined key metrics. With these metrics, the team can commit to accomplishing something specific and formalize that commitment in an aim statement.

Good aim statements articulate a stretch goal that is specific, measurable, time limited, and applicable to a particular population of patients. Figure 4 shows an intermediate outcome (sometimes called a "process measure") and a clinical endpoint. For example:

- Intermediate Outcome: "95 percent of patients admitted to medical units 5G and 6G will be on appropriate VTE prophylaxis as defined by our protocol by October 31, 2009."
- Clinical Endpoint: "Reduce the rate of hospital-acquired VTE from the baseline of 1.2 events per 1,000 patient-days by half to 0.6 per 1,000 patient-days by October 31, 2009."

Referring to the preceding examples, the team should now be able to write an aim statement for its chosen metrics.

**Figure 5. Comparison of Tabular Data and Run Chart From the University of California, San Diego Medical Center**




| | Patients with Preventable VTE | Patient-Days | Case per 1,000 Patient-Days | % Appropriate Prophylaxis |
|---|---|---|---|---|
| **2005** | | | | |
| Jan | 6 | 5198 | 1.2 | |
| Feb | 3 | 4652 | .6 | 53 |
| Mar | 4 | 5583 | .7 | 55 |
| Apr | 5 | 5704 | .9 | 52 |
| May | 2 | 4695 | .4 | 51 |
| Jun | 5 | 4799 | 1.0 | 55 |
| Jul | 5 | 4850 | 1.0 | 57 |
| Aug | 6 | 4322 | 1.4 | 58 |
| Sep | 3 | 4476 | .7 | 66 |
| Oct | 4 | 4691 | .9 | 73 |
| Nov | 2 | 5709 | .4 | 68 |
| Dec | 3 | 4928 | .6 | 65 |
| **2006** | | | | |
| Jan | 1 | 5894 | .2 | 59 |
| Feb | 4 | 5028 | .8 | 71 |
| Mar | 1 | 5501 | .2 | 72 |
| Apr | 0 | 4614 | .0 | 69 |
| May | 1 | 4741 | .2 | 90 |
| Jun | 0 | 5205 | .0 | 80 |

## Balancing Measures

Now that the team has an aim statement for its key performance metrics, it is ready to plan changes to the system. But what if the improvement changes lead to unintended consequences for patients or the hospital? How will the team know? The team should consider monitoring potential areas of concern to detect any detrimental effects of improvement changes. These additional metrics are called "balancing measures." For example, the team may decide to track the incidence of heparin-induced thrombocytopenia, bleeding episodes, or the cost of using more pharmacologic prophylaxis as balancing measures.

# Chapter 5. Layer Interventions

A systematic effort to improve venous thromboembolism (VTE) prophylaxis prevalence starts with a single, specific intervention: the VTE protocol. The team should consider the VTE protocol the prerequisite, enabling layer for any subsequent interventions. An example of a VTE protocol appears at Appendix B. Once the VTE protocol is in place, the team can layer additional interventions (e.g., education and performance audits and feedback) to leverage it.

## The Venous Thromboembolism Protocol

The team may come up with a dozen interventions to optimize prevalence of appropriate VTE prophylaxis. One intervention every team should implement first is a very well-integrated VTE protocol. See Chapter 2 for an overview of the components of a VTE protocol.

For selected inpatients, such as those with major orthopedic procedures, there are high-level recommendations from the American College of Chest Physicians to extend VTE prophylaxis beyond the duration of the hospital stay. The evidence base may eventually identify other populations that may benefit from extended prophylaxis. The team should address this issue and incorporate guidance on extended duration of VTE prophylaxis into the discharge process.

## Key Principles for Effective Quality Improvement Interventions

A VTE protocol and any subsequent layers of quality improvement (QI) interventions will usually fail unless the team pays attention to details. Principles for effective interventions follow.

### Principle 1. Keep it simple for the end user.

Inevitably there will be tradeoffs between the depth of detail to give providers and the simplicity of the forms and processes they are asked to accept. Almost always, simpler is better. Minimize calculations the end user has to make or automate that process for them. For a VTE protocol, limit prophylaxis options to as few as possible for each VTE risk category.

### Principle 2. Do not interrupt workflow.

The caregiving team will have multiple demands competing for attention and time. In general, if an intervention interrupts workflow, it will be rejected. Involve frontline workers to make sure the VTE protocol is easy to use. Without their input, implementation will not go smoothly. Focus-group feedback is invaluable and easy to obtain.

Clinicians will want to use the order sets if they are designed properly. When designing the form, consider the fact that checkbox orders are easier to use than free text and can encourage acceptance of a new form.

If the team cannot incorporate a VTE risk assessment within admission, postoperative, or transfer order sets, a stand-alone VTE risk assessment sheet should be stapled to the order set. The order set must be easy to find and restocked regularly because end users are unlikely to go out of their way to download or locate a VTE risk assessment form.

### Principle 3. Design reliability into the process.

Do not expect humans to be perfect, especially in the complicated health care setting. Part of the team's job is to engineer higher reliability into the process of protecting patients from hospital-acquired VTE. If the VTE protocol relies solely on traditional methods — order sets, personal checklists, working harder next time, performance feedback, and awareness and training — the team will be disappointed with the results. These traditional methods are helpful, and some are even necessary, but they are not sufficient to achieve breakthrough improvement. The team must design interventions that use at least one of the following high-reliability strategies:

- The desired action is the default action (i.e., not doing the desired action requires opting out).
- The desired action is prompted by a reminder or a decision aide.
- The desired action is standardized into a process (i.e., it takes advantage of work habits or patterns of behavior so that deviation feels weird).
- The desired action is scheduled to occur at known intervals.
- Responsibilities for desired action are redundant.

If designed well, the VTE protocol will be an intervention that invokes several of these high-reliability strategies. If it is nested into existing order sets, it can serve as a reminder to prompt ordering of prophylaxis. If admission, postoperative, or transfer order sets are easy to use, always stocked, and easy to find where providers need them, the VTE protocol can be standardized into the process of writing most admission orders. If a clerk or pharmacist is empowered to halt the processing of an order set that has no prophylaxis selected, the responsibility for ensuring VTE prophylaxis can be made redundant. If a member of the care team performs regular reviews of patient medication administration records, responsibility for finding prophylaxis outliers can be scheduled and also made redundant. All these strategies would increase the reliability that patients receive VTE prophylaxis appropriately.

### Principle 4. Pilot interventions on a small scale before attempting wide implementation.

No plan survives its first contact with reality. Inevitably there will be glitches with a first pass at anything new. Pilot testing on a small scale creates opportunities to iron out glitches before implementing more broadly. Small-scale pilot tests can be as simple as a 5-minute focus group where five physicians give feedback on several versions of the protocol. The next pilot can consist of trying out the protocol on one patient with one physician and one nurse.

### Principle 5. Monitor use of the protocol.

Rolling out the protocol is only a beginning. The team must have a plan that ensures that the VTE protocol is part of the completed admission orders for every patient who enters the medical center.

When providers do not use the protocol or deviate from it, reasons might derive from logistics, patients, providers, and other variables. The team should anticipate variations from the protocol but should capture those instances, learn from them, and take steps to reduce them. The team should ask:

- Why is the order set not used in some areas?
- Can it be integrated into other heavily used order sets?
- Which types of admissions are inadvertently bypassing the protocol?
- Which patients just do not fit the protocol?
- Can the protocol be changed so it fits more patients and situations?
- Which providers would benefit from focused educational efforts?
- Is the protocol stocked and restocked in all the key areas in the hospital?

While no protocol will fit every patient, the goal is to squeeze needless variability out of medical decisionmaking and ordering. However, the provider must have the freedom to vary from the protocol due to medical necessity. There will always be a need for providers to tailor care to meet the needs of individual patients or to accommodate special circumstances.

## Beyond the Venous Thromboembolism Protocol: Using a "Hierarchy of Reliability"

Consider the "hierarchy of reliability" in Table 4 when planning and executing the VTE prevention initiative. By using this guide and a little ingenuity, a serious institutional effort should be able to achieve the impressive performance gains of level 4. Successful level 5 reliability, as demonstrated in pilots at University of California, San Diego Medical Center and Emory University Hospitals, is within reach of many institutions with electronic medication administration records.

**Table 4. Hierarchy of Reliability**

| Level | | Predicted Prophylaxis Rate % |
|---|---|---|
| 1 | No protocol (i.e., "state of nature") | 40 |
| 2 | Decision support exists but not linked to order writing or prompts exist within orders but no decision support at hand | 50 |
| 3 | Protocol well-integrated into orders at point of care | 65–85 |
| 4 | Protocol enhanced by other QI and high-reliability strategies | 80–90 |
| 5 | Oversights identified and addressed in real time | 95+ |

### Level 1. State of Nature

In the unimproved modern hospital, patients receive care that depends solely on their physicians' knowledge, skills, and memory. There is no standardized assessment for VTE risk, and there are no reminders within the real-time flow of care delivery to prompt physicians to order VTE prophylaxis. In this "state of nature," expect approximately 40 percent of patients to be on appropriate VTE prophylaxis at any given moment.

### Level 2. Average

Many hospitals that have tried to improve VTE prophylaxis find themselves at Level 2, with only partially effective components of a VTE protocol:

- A standardized VTE risk assessment to guide the choice of a VTE prophylaxis exists, but it is not well integrated into admission and transfer order sets (e.g., the VTE protocol exists only as a stand-alone form or pocket card).
- A prompt to order VTE prophylaxis is nested within admission and transfer order sets, but no VTE risk assessment exists to guide the choice of a VTE prophylaxis.

At Level 2, expect approximately 50 percent of patients to be on appropriate VTE prophylaxis at any given moment.

### Level 3: VTE Protocol

Level 3 is the entry point for most serious QI efforts: a complete VTE protocol is available. All three elements of a complete VTE protocol are combined within a paper order set or computerized physician order entry. The most effective VTE protocols also have a visual link from the level of VTE risk to the options for appropriate prophylaxis. This visual link enables providers to make a rapid, accurate decision and order appropriate prophylaxis.

At a Level 3 VTE prevention program, not only are providers prompted to order VTE prophylaxis when completing admission or transfer orders, but they also have a standardized VTE risk assessment immediately available to support medical decisionmaking. Level 3 makes it possible for providers to have what they need, when and where they need it, to make an appropriate prophylaxis choice. Expect 65 to 85 percent of patients to be on appropriate VTE prophylaxis at Level 3.

Providers should always retain the freedom to deviate from the protocol when meeting the needs of a given patient. The protocol, with successive refinements, eventually should drive management choices for the majority of patients.

### Level 4. Layers of QI Strategies that Leverage the VTE Protocol

For a Level 4 VTE prevention program, all of the conditions of Level 3 exist, but the use of the VTE protocol at admission and transfer is enhanced by additional QI strategies. Level 4 uses high-reliability mechanisms to make it a rare event for a patient to enter the hospital without going through a VTE protocol.

Also at Level 4, any variations from the protocol or adverse effects while on the protocol are studied in depth. The protocol and its integration are continually refined and its use is continually increased based on these events, using the collective intelligence, experience, and investigation of the institution.

Use Table 5 as a source for additional Level 4 ideas. Most of these other strategies leverage the existence of a VTE protocol that is well integrated into the workflow. Providers, nurses, pharmacists, and patients can refer back to the VTE protocol for clarity, confidence, or advocacy. Any additional, layered interventions should include at least one high-reliability mechanism in the

**Table 5. Armamentarium of Quality Improvement Strategies**

| Quality Improvement Strategy Category | Specific Ideas for VTE Prevention |
|---|---|
| Provider education | • Didactic sessions on VTE prevention (e.g., noon conference or grand rounds)<br>• Distributed educational materials (e.g., pocket cards with VTE risk factors) |
| Provider reminder systems | • Prompts nested within paper admission, transfer, or post-op order sets supported by VTE risk assessment as decision support (VTE protocol)<br>• Prompts using computerized physician order entry with risk assessment as decision support (VTE protocol)<br>• Stickers on charts or posters in order-writing areas |
| Facilitated relay of clinical data to providers | • Alerts to physicians by means other than medical records (e.g., page, electronic alert, phone call, or e-mail regarding VTE prophylaxis oversights) |
| Audit and feedback of performance to providers | • Feedback of VTE prophylaxis performance to individual providers or groups of providers with or without benchmarking to top performers |
| Patient education | • Discrete disclosure to patients of increased risk for VTE (e.g., pamphlets, physician or nurse teaching of patient or caregiver, closed-circuit television program in patient rooms) |
| Organizational or operational change | • Administrative support personnel dedicated to ensure constant stocking of VTE protocol order set in needed areas<br>• Clinical support personnel dedicated to ensure and document that mechanical prophylaxis is worn by patients<br>• Hospital-wide or unit-specific teams or individuals with regular responsibility to ensure each patient is receiving appropriate VTE prophylaxis (e.g., physician, nurse, pharmacist) |
| Incentives, regulation, and policy | Provider directed:<br>• Recognition of highest performers each month or quarter<br>• Financial incentives based on achievement of VTE prophylaxis performance goals<br>• Punitive actions for failures to meet minimum performance (e.g., suspension of privileges)<br>Health system directed:<br>• Enforced policy mandating use of VTE protocol (e.g., "hard stops" in processing of admission, transfer, or post-operative orders that fail to prescribe VTE prophylaxis) |

**Source:** Adapted from Stein J. The Language of Quality Improvement: Therapy Classes. *J Hosp Med.* 2006 Nov;1(6):327-30.

design. Expect 80 to 90 percent of patients to be on appropriate VTE prophylaxis at Level 4. This is an extremely impressive level of performance that places the medical center among high performers.

### Level 5. Oversights Identified and Mitigated

A Level 5 VTE prevention program represents a dramatic leap in quality. Here the team improves care by a whole order of magnitude, a rare achievement in health care. All the conditions of Level 4 exist, plus there is a strategy to identify and address prophylaxis oversights that inevitably occur. Back at Level 4, at least 1 in 10 patients still fail to receive appropriate prophylaxis. Will the team be satisfied with that considerable gain? It depends on whether the team is merely pursuing excellence relative to "industry standards" or actually pursuing perfection. Instances will always occur where VTE prophylaxis is not ordered on admission or transfer, not replaced with alternatives when contraindications arise, not resumed when suspected contraindications fail to materialize, or not administered properly when ordered (e.g., mechanical prophylaxis). Strategies that identify and mitigate[29] these oversights are critical for sustaining prophylaxis prevalence above 90 percent. Level 5 may be impractical or unsustainable without an electronic medication record and reporting mechanism.

A mature Level 5 program will also judge the efficacy of mitigation, and its failures will be immediately remedied. Failure modes of mitigation are systematically cataloged, analyzed, and eliminated. Achieving this level of reliability across an entire hospital represents a pioneering effort in VTE prevention. Level 5 solutions transferable to other institutions represent something transformative for hospital care.

# Chapter 6. Continue to Improve

Reality has a way of exposing the weaknesses of even the best plans. In a complex environment like a hospital, there will always be unforeseen glitches when trying something new.

## Learning in the Clinical Setting: Plan-Do-Study-Act

Teams should start small and scale quickly by using rapid cycles of action-oriented learning. A great way to do this is by using the Plan-Do-Study-Act (PDSA) model.

The team should start by planning (plan) the intervention and then test (do) it. In the next step, team members should observe (study) the test firsthand, paying close attention to competing demands and physical space. They should listen to individuals involved in the test to hear what worked and what did not. They should ask for alternative ideas and discuss them on the spot. The idea is to understand what could or should be done differently from how the team originally planned it. Whoever observes and studies the test should record lessons and suggested alternatives. These lessons and alternatives should be shared at the next multidisciplinary team meeting. The Institute of Healthcare Improvement has a PDSA Worksheet on its Web site that may be useful (http://www.ihi.org). In the last step, the team should revise the plan and try it again (act). Table 6 highlights the advantages of PDSA as well as principles for doing it well.

**Table 6. Advantages of Plan-Do-Study-Act and Principles for Success**

Advantages of PDSA

- Allows for valuable modifications to improve effectiveness or preserve productivity
- Allows "failures" to come to light without undermining performance and momentum
- Identifies areas of resistance that might undermine spread to other units
- Allows costs and side effects of the change to be assessed
- Increases certainty that change will result in improvement
- Allows for detailed documentation of improvement

Principles for Success

- Start new changes on the smallest possible scale, e.g., one patient, one nurse, one doctor
- Run just as many PDSA cycles as necessary to gain confidence in a change, then spread the change incrementally
- Spread change incrementally to more patients, then more nurses, then doctors, and finally units
- Balance changes within the overall system to ensure that other processes are not adversely stressed
- Pay special attention to preserving productivity and workflow

## Spreading Improvement to Other Units

Spreading successful improvements to other areas of the hospital requires the new process that was refined in the pilot test to be woven into the wider fabric of everyday clinical work. The IHI white paper, "A Framework for Spread,"[30] offers the following field-tested lessons for disseminating improvements:

- Committed organizational leadership is crucial.
- Begin planning for spread as early as possible.
- Be specific in the aims of spread (who, what, where, when).
- Leverage existing infrastructure and identify infrastructure gaps.
- Execute the spread plan but learn and revise as you go.

Just as for the pilot, let the key principles for layering effective QI interventions discussed in Chapter 5 guide the team's efforts to spread the improvement.

# Appendix A: Talking Points to Attract Administration Support for Venous Thromboembolism Prevention Programs

**Hospitalized patients are at high risk for venous thromboembolism (VTE).**

- More than 2 million Americans suffer from VTE each year, with over half of these individuals developing their VTE in the hospital or in the 30 days post hospitalization. In a large registry trial capturing more than 5,450 patients at 183 sites over a 6-month period, 50 percent (2,726) developed their VTE during hospitalization.
- Most hospitalized patients have at least one risk factor for VTE.
- Every year, 23 million people undergo surgery in the United States. A significant number of these people are considered at high or highest risk for developing VTE.
- Without the benefit of VTE prophylaxis, the incidence of proximal deep vein thrombosis (DVT) and clinical pulmonary embolism (PE) in the majority of surgical patients is unacceptably high. Up to 20 percent of surgical patients in the highest risk category (e.g., those undergoing hip or knee arthroplasty or hip fracture surgery) develop proximal DVT. Proximal DVT is the most dangerous and frequently leads to PE without anticoagulation prophylaxis.
- The medical patient is also at high risk. In a typical hospital, it is estimated that fewer than 5 percent of medical patients could be considered at low risk by most VTE risk stratification methods.
- Medical patients probably account for more than half of all hospital-acquired VTE events. In the DVT FREE Registry study, half the inpatients who suffered from VTE were nonsurgical and had had no surgical procedures in the preceding 3 months.
- Without prophylaxis, the range of DVT risk is from 10 to 26 percent in general medical patients, 17 to 34 percent in patients with myocardial infarction, 20 to 40 percent in patients with congestive heart failure, 11 to 75 percent in patients with stroke, and 25 to 42 percent in general medical intensive care patients.
- A 400-bed hospital with an average prevalence of VTE prophylaxis can expect that 200 patients will suffer from hospital-acquired VTE each year. Around half of these events are potentially preventable (estimates derived from DVT FREE Registry and as yet unpublished University of California, San Diego Medical Center experience).

### Venous thromboembolism leads to substantial inpatient costs, morbidity, and mortality.

- One in 10 of the more than 2 million Americans developing DVT goes on to die from PE. These 200,000 patient deaths represent more annual deaths than those from breast cancer, AIDS, and traffic accidents combined.
- Many of these VTE deaths contribute to hospital mortality. PE is the most common preventable cause of death in the hospital. An estimated 10 percent of inpatient deaths are secondary to PE. Patients who survive the initial diagnosis of PE face a mortality rate of 17.5 percent at 90 days.
- Not only do patients with VTE suffer a 30 percent cumulative risk for recurrence, they are also at risk for the potentially disabling post-thrombotic syndrome.
- While many VTEs are clinically silent, symptoms of hospital-acquired VTE often require ongoing therapy and represent a significant morbidity.
- The incremental length of stay and costs of treating a case of a preventable VTE event are substantial. The Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Projects' estimates of incremental inpatient cost are $10,000 per DVT and $20,000 per PE.
- The Centers for Medicare & Medicaid Services is currently considering the inclusion of hospital-acquired DVT and PE in its list of events for which hospitals will no longer be reimbursed.

### Effective, safe, and cost-effective measures to prevent hospital-acquired VTE exist.

- Pharmacologic prophylaxis reduces the incidence of asymptomatic and symptomatic DVT and PE by 50 to 65 percent.
- Prevention of DVT also prevents PE and fatalities from PE.
- Cost-effectiveness of VTE prophylaxis has been repeatedly demonstrated.
- The chief concern of prophylaxis is bleeding, but bleeding risk secondary to pharmacologic prophylaxis is a rare event, based on abundant data from meta-analyses and placebo-controlled randomized controlled trials.
- Overwhelming evidence reveals that pharmacologic VTE prophylaxis not only prevents adverse patient outcomes, it is also cost-effective.

### The gap between current practice and optimal practice is very large.

- The high prevalence of hospital-acquired VTE is largely due to the underutilization of simple, cost-effective prophylactic measures. Of the 2,726 patients who had their DVT diagnosed while hospitalized in the DVT FREE Registry, only 1,147 (42 percent) received prophylaxis within the 30 days before diagnosis.

- Several prominent organizations acknowledge the magnitude of this implementation gap. The AHRQ report, "Making Healthcare Safer," cited the provision of appropriate VTE prophylaxis as the paramount effective strategy to improve patient safety.
  - "Thromboprophylaxis is the number one patient safety practice to prioritize among the nearly 70 practices reviewed." — AHRQ
  - PE is "the most common preventable cause of hospital death in the United States." — Leapfrog
  - "Physicians and other healthcare providers must be aware of risk factors and risk stratification. Moreover, they must take more aggressive action in screening patients for risk factors and in prescribing preventive interventions."— American Public Health Association
- The current reality in American hospitals is arrestingly substandard, especially considering what could be accomplished with simple, safe, and effective prophylaxis for the at-risk inpatient.

**VTE Prevention is increasingly incorporated into public reporting, guidelines, regulatory agency priorities, and national quality initiative priorities.**

- Organizations include:
  - The Joint Commission. The Joint Commission is currently piloting measures of VTE prophylaxis, incidence of hospital-acquired VTE, and VTE diagnosis and treatment.
  - Surgical Care Improvement Project, or SCIP
  - Leapfrog
  - AHRQ
  - Centers for Medicare & Medicaid Services.

**Reliably preventing VTE in the hospital is inherently complex.**

- More education alone won't get the job done.
- VTE risk and bleeding risk vary within patient populations.
- The risk of VTE and the risk of bleeding may change for individual patients several times as they progress through their hospital stay.
- Medication changes, weight, age, renal function, and recent or impending invasive interventions may all influence decisions about the best VTE prevention options.
- Transitions across care providers and locations lead to multiple opportunities for breakdown in the delivery of optimal VTE prophylaxis.
- Thoughtful, evidence-based protocols; multidisciplinary system changes; and comprehensive educational efforts are required to achieve optimal VTE prophylaxis in the complex hospital setting.

- Essential elements are needed for effective and safe prevention of VTE in the hospital.
  - Educational and awareness efforts alone have proven inadequate in increasing appropriate use of VTE prophylaxis. Similarly, order sets and critical pathways not supported by a healthy quality improvement framework are unlikely to succeed.
  - Process redesign and continuous attention must include two essential elements:
    1) Performance of a VTE risk assessment for every patient on admission and regularly throughout hospitalization.
    2) Selection of appropriate prophylaxis by linking the VTE risk to a corresponding menu of proven options.

### VTE prevention programs can be cost-effective.

- Achieving optimal prevention of hospital-acquired VTE requires incremental monitoring, educational efforts, system change, and coordination of the services of many hospital divisions, all of which may incur incremental costs.
- This incremental expense can be cost-effective in a variety of settings.
- Costs of VTE prevention initiatives can demonstrate a good return on investment through:
  - Improved length of stay, readmission, morbidity, and mortality rates.
  - Improved documentation of patient acuity and related payment for acuity.
  - Income generated via incremental physician and allied health professional billing.

### A roadmap is in place.

- Extensive guidance is available from the literature and consensus conferences.
- The Society of Hospital Medicine has produced a comprehensive guide to effective implementation of VTE prevention programs, using a proven performance improvement framework, firsthand experience, and the collective wisdom of several institutions addressing VTE prevention. The guide includes practical information on:
  - Organizing and managing a multidisciplinary steering committee, reporting into the medical center administration.
  - Practical methods to assess institutional performance in VTE prophylaxis and the identification and tracking of patients with hospital-acquired VTE.
  - Constructing an institutional VTE risk assessment model, and integrating it into workflow and order sets.
  - Methods to bolster chances of success by integration of high-reliability design features and attention to effective implementation techniques

## Summary — Push for Support

- Hospital-acquired VTE is an important issue. Effective, safe, and evidence-based measures to prevent hospital-acquired VTE are currently underutilized at many medical centers, resulting in needless mortality and morbidity.
- Personnel who are ready to address this issue aggressively are needed to reduce the prevalence of hospital-acquired VTE. A number of guides are available to help them achieve their goals.
- Administrative support for an empowered multidisciplinary steering committee is needed.
- Institutional prioritization and the will to standardize and improve systems in the face of substantial cultural and complex barriers is an absolute necessity to achieve breakthrough levels of improvement.
- Improved data collection and reporting, incremental monitoring, creation of metrics, and improved documentation are necessary.
- Depending on how advanced or ambitious the effort, it may be important for the team to lay out a business plan, including specific aim, timeline, personnel, full-time equivalent support, and other required resources.

# Appendix B: Sample Venous Thromboembolism Protocol/ Order Set

**University of California, San Diego Medical Center**
**VTE Risk Assessment and Prophylaxis Orders**
**(paper version of computerized order set)**

### ☐ Low Risk

Ambulatory patient without additional VTE risk factors or expected length of stay <2 days

Minor surgery in patient without additional VTE risk factors (same day surgery or operating room time <30 minutes)

* Early ambulation

### ☐ Moderate Risk

Patients who aren't in either the low- or high-risk group (see VTE risk factor table on reverse)

**Select one pharmacologic* option:**

☐ Enoxaparin# 40 mg SQ q 24 hours

☐ UFH 5,000 units SQ q 8 hours

☐ UFH 5,000 units SQ q 12 hours (use only if wt <50kg or >75 yrs)

***or***

☐ No pharmacologic prophylaxis because of contraindication

_____

*(see reverse)*

☐ No pharmacologic prophylaxis because it is optional in this special population (GYN surgery)

*Sequential compression device aka SCDs (Optional for these patients if they are on pharmacologic prophylaxis, mandatory if not)*

SCDs to

☐ Both lower extremities

☐ Right leg only

☐ Left leg only

☐ Patient intolerant or has skin lesions on both legs, do not use SCDs

### ☐ High Risk

Elective hip or knee arthroplasty

Acute spinal cord injury with paresis

Multiple major trauma

Abdominal or pelvic surgery for cancer

**Select one pharmacologic # option:**

☐ Enoxaparin* 40 mg SQ q 24 hours

☐ Enoxaparin* 30 mg SQ q 12 hours (knee replacement)

☐ Warfarin _____mg PO daily, target INR 2-3; hold INR >3

***or***

☐ UFH 5,000 units SQ q 8 hours *(only if creatinine clearance is < 30, SCr >2, and warfarin is not an option)*

☐ No pharmacologic prophylaxis because of contraindication

_____

*(see reverse)*

***and***

SCDs to

☐ Both lower extremities

☐ Right leg only

☐ Left leg only

☐ Patient intolerant or has skin lesions on both legs, do not use SCDs

*See contraindications on reverse.

#Enoxaparin should only be used in patients with CrCl>30 and SCr<2; do not use if epidural/spinal catheter is in place.

SCDs should be used in all patients for whom pharmacologic prophylaxis is contraindicated and in all high-risk patients unless patient is intolerant or with contraindications to SCDs.

Note: Enoxaparin is the USCD Medical Center formulary low molecular weight heparin (LMWH); other LMWHs are considered equivalent.

| Venous Thromboembolism Risk Factors | | |
|---|---|---|
| Age >50 years | Prior history of VTE | Acute or chronic lung disease |
| Myeloproliferative disorder | Impaired mobility | Obesity |
| Dehydration | Inflammatory bowel disease | Known thrombophilic state |
| Congestive heart failure | Active rheumatic disease | Varicose veins/chronic stasis |
| Active malignancy | Sickle cell disease | Recent post-partum with immobility |
| Hormonal replacement | Estrogen-based contraceptives | Nephrotic syndrome |
| Moderate to major surgery | Central venous catheter | Myocardial infarction |

| Contraindications or Other Conditions to Consider With Pharmacologic VTE Prophylaxis | | |
|---|---|---|
| ☐ **Absolute** | ☐ **Relative** | ☐ **Other Conditions** |
| • Active hemorrhage | • Intracranial hemorrhage within last year | • Immune mediated heparin-induced thrombocytopenia |
| • Severe trauma to head or spinal cord with hemorrhage in the last 4 weeks | • Craniotomy within 2 weeks | • Epidural analgesia with spinal catheter (current or planned) |
| • Other_____ | • Intraocular surgery within 2 weeks | |
| | • Gastrointestinal, genitourinary hemorrhage within the last month | |
| | • Thrombocytopenia (<50K) or coagulopathy (prothrombin time >18 seconds) | |
| | • End stage liver disease | |
| | • Active intracranial lesions/neoplasms | |
| | • Hypertensive urgency/ emergency | |
| | • Post-operative bleeding concerns* | |

*Scheduled return to OR within the next 24 hours: major ortho: 24 hours leeway; spinal cord or ortho spine: 7 days leeway; general surgery, status post transplant, status post trauma admission: 48 hours leeway.

# Appendix C. Suggested Reading for Venous Thromboembolism Protocol Development

No single venous thromboembolism (VTE) risk assessment has been prospectively validated as superior to others. Many factors should be taken into account when adopting one. These articles focus on VTE risk factors or VTE risk assessment.


Anderson F, Spencer F. Risk Factors for Venous Thromboembolism. *Circulation* 2003;107:I-9-I-16.

Caprini J, Arcelus J, Reyna J. Effective Risk Stratification of Surgical and Nonsurgical Patients for Venous Thromboembolic Disease. *Seminars in Hematology* 2001;38(2)Suppl 5:12-19.

Gensini G, Prisco D, Falcini M, Comeglio M, Colella A. Identification of Candidates for Prevention of Venous Thromboembolism. *Seminars in Thromboembolism and Hemostasis* 1997;23(1);55-67.

Goldhaber, S (Chair). National Experts' Consensus Panel for Clinical Excellence in Thrombosis Management. Venous thromboembolism (VTE) prophylaxis in the hospitalized medical patient. 2003 DVT Prophylaxis Consensus Panel Guidelines and Recommendation. *Hospital Medicine Reports:* 1-20.

Haas S. Venous Thromboembolic Risk and Its Prevention in Hospitalized Medical Patients. *Seminars in Thromboembolism and Hemostasis* 2002;28(6);577-583.

Labaräre J, Bosson J-L, Bergmann J-F, Thilly N. Agreement of Four Competing Guidelines on Prevention of Venous Thromboembolism and Comparison with Observed Physician Practices. *Journal of General Internal Medicine* 2004);9(8):849-855.

Labarere J, Bosson J-L, Brion J-P, Fabre M, Imbert B, Carpentier P, Pernod G. Validation of a clinical guideline on prevention of venous thromboembolism in medical inpatients: A before-and-after study with systematic ultrasound examination. *Journal of Internal Medicine* 2004;256(4);338-348.

Motykie G, Zebala L, Caprini J, Lee C, Arcelus J, Reyna J, Cohen E, Courtney T, Sullivan L. A Guide to Venous Thromboembolism Risk Factor Assessment. *Journal of Thrombosis and Thrombolysis* 2000;9:253-262.

Samama MM, Dahl OE, Mismetti P, Quinlan DJ, Rosencher N, Cornelis M, de Vries H, van Beusekom I, Kahan JP. An electronic tool for venous thromboembolism prevention in medical and surgical patients. *Haematologica*. 2006 Jan;91(1):64-70.

# Appendix D. Chart Audit Form

**Appendix D. Chart Audit Form**

Reviewer _____ MR# _____ Name _____ Dx#1 _____

Date/Time _____ Date of Admission _____ Dx#2_____

Ht: _____ Wt _____ BMI _____ Age _____ Sex M F Dx#3_____

Service _____ Ward/Location _____

1. Is patient eligible for survey? (i.e., not currently on full anticoagulation)
   Yes No If No, stop here.

2. Assign venous thromboembolism risk (See next page and circle category).
   Low Moderate High

3. Does patient have **relative** or **absolute** contraindications to pharmacologic prophylaxis or **condition of concern**? (circle appropriate category, if present)
   Yes No

**Adequate Prophylaxis Regimens for Each Level of VTE Risk**

| Low risk | Moderate risk | High risk |
|---|---|---|
| Early ambulation | Heparin 5,000 units SC q 8 h ***or***<br>Heparin 7,500 units SC q 12 h ***or***<br>Dalteparin 5,000 units SC daily ***or***<br>Enoxaparin 40 mg SC daily *or*<br>Heparin 5,000 units SC q 12 hours (only for patients with weight <50 kg or age >75 years)<br>***and*** Suggest adding SCDs | Dalteparin 5,000 units SC daily ***or***<br>Enoxaparin 30 mg SC q 12 hours ***or***<br>Enoxaparin 40 mg SC q day ***or***<br>Fondaparinux 2.5 mg SC daily ***or***<br>Warfarin, INR 2-3.<br>**and** SCDs (unless not feasible) |

This table is to be used only in audit tools; it is not for use in order sets. Sequential compression devices (SCDs) are appropriate if anticoagulant use is contraindicated.

4. Document current prophylaxis ordered.

**Non Pharmacologic**

- ☐ Sequential compression device Are these in place and on?_____
- ☐ Elastic stockings

**Pharmacologic**

- ☐ Heparin 5,000 units subcutaneous q 12 hours
- ☐ Heparin 7,500 units subcutaneous q 12 hours
- ☐ Heparin 5,000 units subcutaneous q 8 hours
- ☐ Enoxaparin (Lovenox) 40 mg subcutaneous q day
- ☐ Enoxaparin (Lovenox) 30 mg subcutaneous q 12 hours
- ☐ Dalteparin (Fragmin) 2,500 units subcutaneous q day
- ☐ Dalteparin (Fragmin) 5,000 units subcutaneous daily

## Appendix D. Chart Audit Form *(continued)*

☐ Fondaparinux (Arixtra) 2.5 mg subcutaneous daily ($28.63/day). Start 6 hours post-op.
☐ Coumadin _____mg daily
☐ Other _____

5. Do the prophylactic measures match the measures in the above table? (Remember that SCDs alone may be appropriate in patients who have contraindications to pharmacologic prophylaxis.)
Yes No

6. If mismatch, notify physician within 24 hours.
Physician notified _____ Date/Time _____

7. Did physician change order to a matched prophylaxis as a result of the intervention?
Yes No

8. If no, list reason given below.

9. Final judgment: Was the prophylaxis ordered for the patient at the time of the survey adequate?
Yes No Not Sure

---

| ☐ **Low Risk** | ☐ **Moderate Risk** | ☐ **High Risk** |
|---|---|---|
| Ambulatory patient without additional VTE risk factors or expected length of stay <2 days<br><br>Minor surgery in patient without additional VTE risk factors (same day surgery or operating room time <30 minutes) | Patients who aren't in either the low- or high-risk group (see VTE risk factor table below) | Elective hip or knee arthroplasty<br><br>Acute spinal cord injury with paresis<br><br>Multiple major trauma<br><br>Abdominal or pelvic surgery for cancer |

| **Venous Thromboembolism Risk Factors** | | |
|---|---|---|
| Age >50 years | Prior history of VTE | Acute or chronic lung disease |
| Myeloproliferative disorder | Impaired mobility | Obesity |
| Dehydration | Inflammatory bowel disease | Known thrombophilic state |
| Congestive heart failure | Active rheumatic disease | Varicose veins/chronic stasis |
| Active malignancy | Sickle cell disease | Recent post-partum with immobility |
| Hormonal replacement | Estrogen-based contraceptives | Nephrotic syndrome |
| Moderate to major surgery | Central venous catheter | Myocardial infarction |

## Appendix D. Chart Audit Form *(continued)*

| Contraindications or Other Conditions to Consider With Pharmacologic VTE Prophylaxis | | |
|---|---|---|
| ☐ **Absolute**<br>• Active hemorrhage<br>• Severe trauma to head or spinal cord with hemorrhage in the last 4 weeks<br>• Other_____ | ☐ **Relative**<br>• Intracranial hemorrhage within last year<br>• Craniotomy within 2 weeks<br>• Intraocular surgery within 2 weeks<br>• Gastrointestinal, genitourinary hemorrhage within the last month<br>• Thrombocytopenia (<50K) or coagulopathy (prothrombin time >18 seconds)<br>• End stage liver disease<br>• Active intracranial lesions/neoplasms<br>• Hypertensive urgency/ emergency<br>• Post-operative bleeding concerns* | ☐ **Other Condition**<br>• Immune mediated heparin-induced thrombocytopenia<br>• Epidural analgesia with spinal catheter (current or planned) |

*Scheduled return to OR within the next 24 hours: major ortho: 24 hours leeway; spinal cord or ortho spine: 7 days leeway; general surgery, status post transplant, status post trauma admission: 48 hours leeway.

# Glossary

| | |
|---|---|
| ACCP | American College of Chest Physicians |
| AHRQ | Agency for Healthcare Research and Quality |
| BID, b.i.d. | twice a day |
| CPOE | computerized physician order entry |
| DVT | deep vein thrombosis |
| HIT | heparin-induced thrombocytopenia |
| ICU | intensive care unit |
| IHI | Institute for Healthcare Improvement |
| IPC | intermittent pneumatic compression |
| LMWH | low-molecular-weight heparin |
| PDSA | Plan-Do-Study-Act |
| PE | pulmonary embolism |
| q | each, every |
| QI | quality improvement |
| SCD | sequential compression device |
| SCIP | Surgical Care Improvement Project |
| SQ | subcutaneously |
| UCSD | University of California, San Diego |
| UFH | unfractionated heparin |
| VTE | venous thromboembolism |

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