

# Preventing Hospital-Associated Venous Thromboembolism

## A Guide for Effective Quality Improvement



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**AHRQ Publication No. 16-0001-EF**  
**Replaces AHRQ Publication No. 08-0075**  
**Updated August 2016**



The author discloses that he has acted as an expert in cases involving venous thromboembolism (VTE). Dr. Maynard also sits on an expert review panel for a phase 3 study on rivaroxaban for VTE prophylaxis in medical patients (Mariner study, Janssen Pharmaceuticals). He has no other affiliations or financial involvement (e.g., employment, consultancies, honoraria, stock options, grants, patents received or pending, or royalties) that conflict with material presented in this guide.

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### **Suggested Citation**

Maynard G. Preventing hospital-associated venous thromboembolism: a guide for effective quality improvement, 2<sup>nd</sup> ed. Rockville, MD: Agency for Healthcare Research and Quality; August 2016. AHRQ Publication No. 16-0001-EF.

## Acknowledgments

The author would like to acknowledge those who contributed to the first version of the guide, most notably Dr. Jason Stein of Emory University. Dr. Maynard has also been inspired by all those who have engaged in collaborative improvement efforts using the previous version of this guide; these have greatly informed this updated and revised version.

In addition, many individuals contributed a great deal of their time and expertise to the development of the revised guide. For their expert input, the author gratefully acknowledges the following individuals from the Centers for Disease Control and Prevention (CDC):

- Michele G. Beckman, M.P.H., Epidemiologist, National Center on Birth Defects and Developmental Disabilities;
- Scott Grosse, Ph.D., Research Economist, National Center on Birth Defects and Developmental Disabilities; and
- Lisa C. Richardson, M.D., M.P.H., Director of Division of Cancer Prevention and Control

From the Center for Quality Improvement and Patient Safety at AHRQ:

- Barbara Bartman, M.D., M.P.H., Medical Officer and AHRQ VTE clinical expert advisor;
- Jeff Brady, M.D., M.P.H., Rear Admiral, U.S. Public Health Service and Director, CQuIPS;
- Eileen M. Hogan, M.P.A., Public Health Analyst.

Finally, AHRQ and the author acknowledge the patients and families who have shared their personal stories about the impact VTE had on their lives and their insights into the importance of prevention efforts.

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## Preface

### Hospital-Associated Venous Thromboembolism as a Public Health Problem

Pulmonary embolism (PE) and deep vein thrombosis (DVT), collectively known as venous thromboembolism (VTE), represent a major public health problem that affects 350,000 to 600,000 Americans annually.<sup>1</sup> Estimates vary widely, but the overall annual prevalence may be increasing.<sup>2</sup> VTE is primarily a problem of sick or injured patients who are hospitalized or were recently hospitalized,<sup>3,4</sup> and it is frequently estimated to be among the most common preventable causes of hospital death.<sup>5-7</sup>

Symptomatic DVT and PE are associated with extended duration of inpatient stays and high (10-15 percent) fatality rates. VTE generally requires therapeutic anticoagulation for a minimum of 3 months.<sup>8,9</sup> This therapeutic anticoagulation is associated with 1 to 2 percent major bleeding per patient year, resulting in fatal bleeding at least 0.1 to 0.3 percent per patient year in clinical trials. In real-world practices, the rates are much higher.<sup>10-12</sup>

When patients survive the VTE event and acute course of anticoagulant therapy—and all the inconvenience, anxiety, and cost that represents—they are still at risk for other complications. More than 20 percent of patients with proximal DVT/PE will suffer a recurrent event once anticoagulation has been discontinued, along with all the readmissions, mortality, and morbidity risk that entails.<sup>13</sup> Furthermore, 30 to 50 percent of DVT patients will develop postthrombotic syndrome,<sup>14</sup> and an estimated 4 percent of PE patients will develop chronic thromboembolic pulmonary hypertension.<sup>15</sup> Patients and their families relay powerful personal stories related to loss of function, difficulty with anticoagulant therapy, fiscal burden, and fear of recurrence.

Thromboprophylaxis for at-risk inpatients can reduce VTE by 30 to 65 percent, has a low incidence of major bleeding complications, and has well-documented cost-effectiveness.<sup>16,17</sup> Numerous guidelines from authoritative bodies outlining appropriate use of thromboprophylaxis are available,<sup>16,18-24</sup> yet study after study reflects unacceptably low rates of thromboprophylaxis in patients at risk.<sup>25-30</sup> For example, a recent cross-sectional international study of almost 70,000 patients in 358 hospitals found that appropriate prophylaxis was administered in only 58.5 percent of surgical and 39.5 percent of medical inpatients at risk for VTE<sup>27</sup>; another U.S. registry found only 42 percent of patients with hospital-associated DVT received prophylaxis within 30 days prior to diagnosis.<sup>30</sup> This constellation of facts presents a powerful imperative for improvement.

This “implementation gap” in VTE prophylaxis between evidence-based best practice and actual practice in the real world has not gone unnoticed as a major opportunity for improvement. In 2008, the U.S. Surgeon General produced a call-to-action document for VTE prevention.<sup>1</sup> In addition, key goals for VTE prevention are in place from the National Quality Forum and the Joint Commission,<sup>31,32</sup> mirrored by criteria for meaningful use criteria for electronic health records. The Surgical Care Improvement Project has widely used measures for VTE prevention,<sup>33</sup> and VTE Prevention is one of the focus areas of the Partnership for Patients, a major effort from the Centers for Medicare & Medicaid Services (CMS) to foster accelerated improvement.<sup>34</sup>

Reports commissioned by the Agency for Healthcare Research and Quality (AHRQ) called thromboprophylaxis the “number one” patient safety practice,<sup>17</sup> and a 2013 update continues to list improved prophylaxis for VTE as a top 10 patient safety strategy to act on now.<sup>35</sup> 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.”<sup>36</sup>

## Purpose of This Guide

In 2008, AHRQ published *Preventing Hospital-Acquired Venous Thromboembolism: A Guide for Effective Quality Improvement*.<sup>37</sup> That guide was based on success in VTE prevention<sup>38-41</sup> and quality improvement principles at the University of California, San Diego. The purpose of that publication and this update is to assist hospital improvement teams to close the implementation gap as effectively and efficiently as possible.

While guidelines often focus on defining best practice, this work focuses on the specifics of how to ensure those best practices are reliably delivered in your local inpatient environment. Multiple barriers and “failure modes” must be overcome to reliably provide prophylaxis to those at risk while avoiding over-prophylaxis of those who are not.

It turns out that VTE prophylaxis is a somewhat complex process in the very complex hospital environment. As systems, hospitals are perfectly designed to achieve the results they attain; improving care generally involves changing the basic design of elements of that system and carefully monitoring to adjust the interventions and ensure that the change leads to the desired improvement. The basic principles and essential elements to reach breakthrough levels of improvement in care have not changed since they were listed in the first edition:

- 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 quality improvement (QI) framework to coordinate steps toward breakthrough improvement.
- Evidence-based protocols that standardize VTE risk assessment and prophylaxis.
- Institutional infrastructure, policies, practices, and educational programs that promote use of the protocol.

The protocol that standardizes VTE risk assessment is so fundamental that it should not merely exist but also be embedded in patient care. High-reliability design may then be used to enhance effective implementation.

## What's New in This Guide

This revision reflects important changes in the environment, new guidelines, and lessons learned. More specifically, this version presents:

1. **Lessons from collaboratives and success stories:** The first edition of this guide was used as the centerpiece of a number of multisite collaborative improvement efforts funded by AHRQ. This experience in a wide variety of hospitals has provided insight into what works and, perhaps just as important, what does not work in real-world settings.<sup>42,43</sup> Many others have also published or shared outlines of what works and what did not work in their settings, and this guide has attempted to collate some of the strategies that may have portability across a variety of settings.<sup>44-64</sup>
2. **Context of new evidence and new guidelines** from the American College of Physicians, the 9<sup>th</sup> edition of the American College of Chest Physicians on Antithrombotic Therapy and Prevention of Thrombosis (AT9), and the American Academy of Orthopedic Surgeons (AAOS): The ACP Guideline (ACP1)<sup>18</sup> and supporting review<sup>65</sup> address VTE prophylaxis in nonsurgical patients, while the AT9 guidelines<sup>8</sup> also cover a wide variety of patient populations in separate guidelines for medical inpatients,<sup>19</sup> orthopedic patients,<sup>21</sup> and nonorthopedic surgical patients.<sup>20</sup> The complexity of the new guidelines, lack of consensus about VTE risk assessment, varied estimates of risk and benefit, and significant changes from AT8 have contributed to uncertainty about best practices in VTE prevention and design for VTE prevention protocols.
3. **Increased use of electronic health records (EHRs), computerized physician order entry (CPOE), and advanced information technology:** This revision features more examples of tools in this new environment and explores the “good, the bad, and the ugly” aspects of implementing protocols in the emerging computerized medical environment. We present tools to illustrate clinical decision support in CPOE and EHR formats, which go above and beyond the Department of Health and Human Services’ meaningful use criteria for VTE prophylaxis.
4. **New measures:** New and improved metrics for tracking the adequacy of VTE prophylaxis, including information on using measurement with concurrent intervention (aka measure-vention) are reviewed. Similar strategies to improve ambulation and address over-prophylaxis have been incorporated, as has a discussion of new ICD-9<sup>i</sup> codes for hospital-associated VTE (HA-VTE) that have been released since the last version of this guide was published. Guidance that outlines optimal use of administrative data to track HA-VTE is also updated to include the present on admission indicator and to capture patients readmitted with new VTE within 30 days of a prior hospital stay.
5. **New methods to improve on reliable delivery and enhanced adherence to VTE prophylaxis orders** (as opposed to focusing solely on getting the order correct): This is important in view of commonly reported deficiencies in adhering to mechanical VTE prophylaxis (50-60 percent) and pharmacologic prophylaxis (10-20 percent of doses commonly not delivered).

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<sup>i</sup> ICD-9 is the International Classification of Diseases, 9<sup>th</sup> Edition.

6. **New information focusing on the importance of patient engagement and education:** This includes transitions of care, indications for extended-duration prophylaxis, and prophylaxis in special populations (e.g., obese patients, patients with renal failure, and patients going to skilled nursing or rehab facilities).
7. **Frequently asked questions** for VTE prevention and a concise executive summary.

## **How To Use the Guide and Related Tools and Resources**

QI projects can help health care facilities close the gap between optimal care and the care that is actually delivered. The chapters in this guide follow the logical steps of a QI project. QI, however, often unfolds along several parallel fronts. Many steps in an initiative occur simultaneously and are often interdependent, so readers should feel comfortable skipping to the chapters that are most pertinent to them while keeping the larger framework in mind.

## Executive Summary

Hospital-associated venous thromboembolism (HA-VTE) is a common source of morbidity and mortality. While VTE sometimes occurs despite the best available prophylaxis, there are many lost opportunities to optimize prophylaxis and reduce VTE risk factors in virtually every hospital. This guide targets these failure modes in the process of preventing VTE in the inpatient setting and provides improvement teams with field-tested strategies and tools to enhance their chances of success.

Several essential elements are needed to achieve meaningful improvement in VTE prevention. These include an empowered, interdisciplinary team, supported by the institution, to standardize processes, monitor and measure VTE processes and outcomes, implement institutional policies, and educate providers and patients.

Guidelines for VTE prevention are numerous and do not always agree, and the complexity of the inpatient setting and the variability of patients make implementation of evidence-based guidelines challenging. This implementation guide reviews several guidelines, with a particular focus on the implications for implementation; it then breaks down the steps to translate these guidelines into practice in the form of a VTE prevention protocol.

A VTE prevention protocol includes a VTE risk assessment, a bleeding risk assessment, and clinical decision support (CDS) on prophylactic choices based on the combination of VTE and bleeding risk factors. The VTE protocol CDS must be available at crucial junctures of care, such as at admission to the hospital, at transfer to different levels of care, and postoperatively. This VTE protocol guidance is most often embedded in order sets that are commonly used (or mandated for use) in these settings, essentially hard wiring the VTE risk assessment into the process.

Risk assessment is essential, as there are harms, costs, and discomfort associated with prophylactic methods; for some inpatients, the risk of anticoagulant prophylaxis may outweigh the risk of HA-VTE. There is no perfect VTE risk assessment tool. This guide outlines strengths and limitations of the different models and discusses the inherent tension between the desire to provide comprehensive, detailed guidance and the need to keep the process simple to understand and measure.

This guide also discusses principles for effective implementation of reliable interventions, including simple to advanced models. Order sets with CDS are of no use if they are not used correctly and reliably, so monitoring this process is crucial. No matter which VTE risk assessment model is used, it is usually more effectively implemented if every effort is made to enhance ease of use for the ordering provider. This may include “carving out” special populations for modified VTE risk assessment and order sets, which allows streamlining and simplification of the VTE prevention order sets for the general medical and surgical population.

Successful integration of a VTE prevention protocol into heavily used admission and transfer order sets serves as a foundational beginning point for VTE prevention efforts. Throughout this guide, multiple failure modes are described, as are strategies to address potential lapses in care.

Publicly reported measures and CMS Core Measures set a relatively low bar for performance and are inadequate to drive breakthrough levels of improvement. Teams may wish to assess the adequacy of VTE prophylaxis not only on admission or transfer to the ICU, but also across the hospital stay. Month-to-month reporting is important to follow overall progress. But the team can also identify at least some *measures* that can drive concurrent *intervention* to address deficits in prophylaxis in real time. This method of active surveillance (aka *measure-vention*) is described in this guide along with other suggested methods for measuring HA-VTE outcomes, VTE prophylaxis rates, and other parameters (e.g., adherence to prescribed prophylaxis).

This guide outlines a comprehensive, interdisciplinary approach to optimizing inpatient VTE prevention, and the techniques described are designed to be portable to a wide variety of inpatient settings. We emphasize optimizing the EHR for standardization of order sets and integration of measurement systems in documentation and orders, which is a key strategy for dissemination within hospital systems.

# Chapter 1. The Framework for Improvement

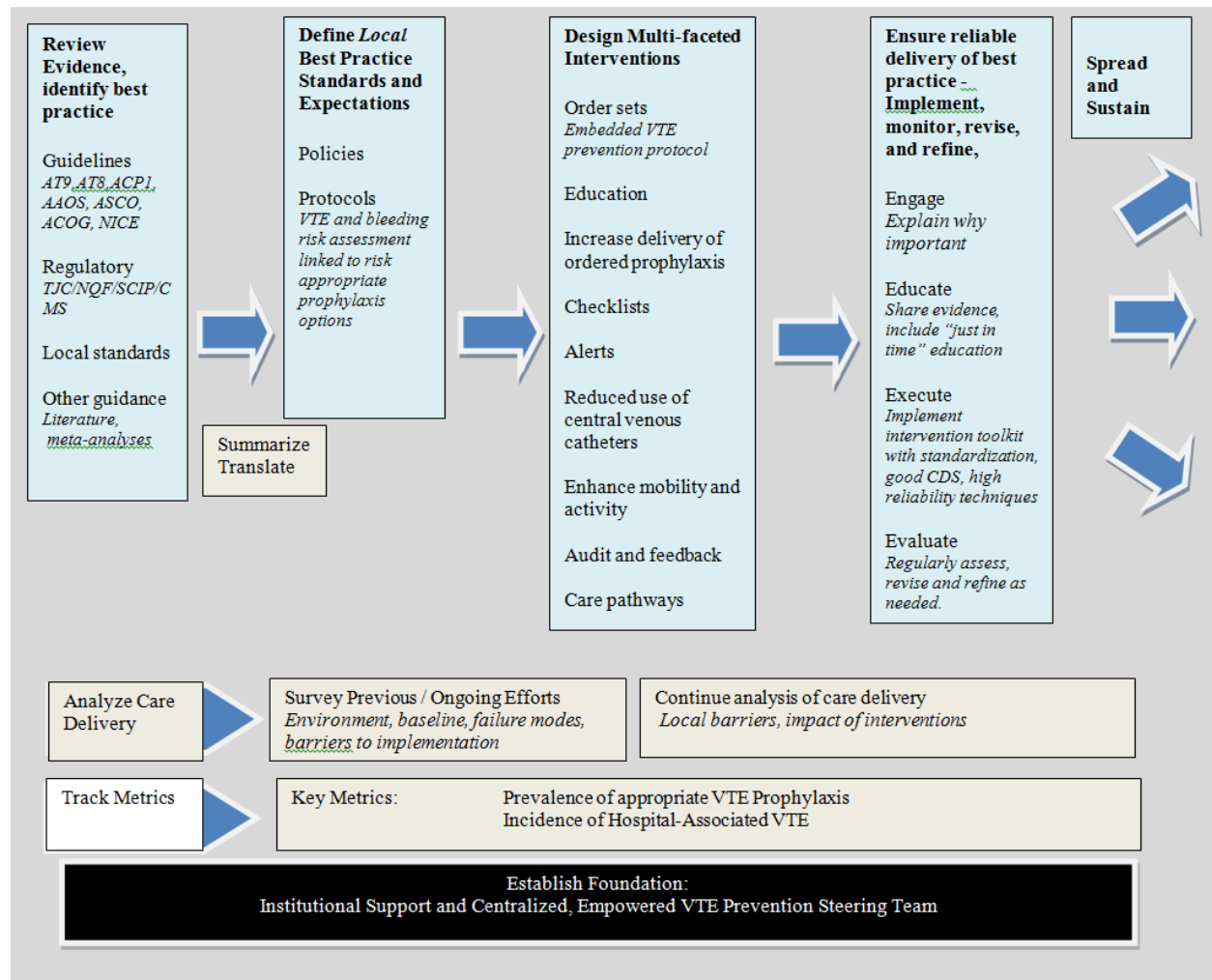
This chapter provides a roadmap and tools to start the team off on the right foot. As the team makes progress on each step, the next steps will tend to unfold in a logical progression.

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

This guide provides QI teams with information they need to progress through the framework for improvement identified in Figure 1.1. This framework serves as an outline for the guide. Users of this guide will have the best chance of success if they follow the Essential First Steps (below) before embarking on the framework.

**Figure 1.1** depicts a framework for formulating a protocol and deploying multiple interventions designed to reinforce the guidance from the venous thromboembolism (VTE) prevention protocol.

**Figure 1.1: Framework for Improving VTE Prevention**



## Essential First Steps

### ***Step 1: Ensure Support From the Institution***

The time, energy, and expertise of a clinician leader are necessary to drive improvement. Alone, however, they will not be enough. Sponsorship and support from the medical institution, and specifically from key leaders, are essential. True institutional support will be reflected in prioritization of the effort, including providing resources for good measurement of progress and by the institutional will to standardize the process even in the face of physician resistance.

Real support confers on the improvement team the authority and resources needed to design and manage change. The single most effective way to attract this support is by aligning the goals of the quality improvement effort with the strategic goals of the organization, and by understanding how VTE prevention efforts fit into the larger QI ecosystem.

VTE prevention is just one priority among many for busy clinicians and QI leaders, so it is helpful to make hospital leadership aware of how an effective VTE prevention program aligns with its many other goals for medical care, performance reporting, customer service, patient safety, and cost containment.

A number of forces may fuel leadership interest in the project, including public reporting of hospital performance (e.g., The Joint Commission [TJC] and National Quality Forum [NQF] measures), Partnership for Patients initiatives, 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<sup>®</sup>), related projects (e.g., Surgical Care Improvement Project), and even quality for quality's sake. Furthermore, the Centers for Medicare & Medicaid Services no longer reimburses for the incremental costs of DVT and pulmonary embolism (PE) related to some surgeries (including total knee replacement and total hip replacement), and is considering expanding that list. VTE prevention efforts can also be synergistic with efforts to increase patient activity, reduce central venous catheter complications, and meet meaningful use criteria for electronic health records.

A venous thromboembolism prevention protocol incorporates VTE and bleeding risk assessment tools and risk-appropriate prophylactic options. Relying on order sets alone will not reach desired levels of appropriate VTE prophylaxis. Analyzing care delivery, assessing and addressing barriers, and ongoing measurement and monitoring are also essential.

The QI framework presented in this chapter is a generic and relatively jargon-free model. It is derived from common elements of PDSA,<sup>1-3</sup> Lean,<sup>4,5</sup> Six Sigma,<sup>4,6,7</sup> TeamSTEPPS,<sup>8</sup> and the Johns Hopkins Quality and Safety Research Group,<sup>9</sup> and further refined in a large number of successful projects<sup>10-15</sup> and collaborative QI programs from the Society of Hospital Medicine.<sup>16-19</sup> Whichever QI model an institution is vested in can be used to implement this framework, provided that all the elements listed here are addressed.

This QI framework is also consistent with the findings from reviews and collaborative improvement experiences that outline the characteristics of interventions that are most likely to result in improved deep vein thrombosis (DVT) prophylaxis. Interventions that are active, rather than passive, appear to be the most effective, and multifaceted interventions that include an active surveillance and alert component, education, point-of-care clinical decision support, and education are more effective than single interventions used in isolation.<sup>20-25</sup>



An argument to leadership can also be made in terms of VTE incidence and costs. Queries from the University of California system and the University Healthcare Consortium provide estimates that are consistently 1 percent or more of admissions resulting in an HA-VTE. This means that a medical center with 10,000 adult discharges per year could expect to have 100 events of HA-VTE, many of them potentially preventable. The rate of hospital-associated VTE likely remains grossly underestimated, however, as reporting does not include patients readmitted to other hospitals, undiagnosed but clinically important VTE, and VTE that is treated in skilled nursing facilities and outpatient environments.

Each hospital-associated DVT event represents an incremental cost of \$7,700 to \$10,800, while each hospital-associated PE event represents \$9,500 to \$16,600 in additional costs. Acute HA-VTE in cancer patients bears an even higher cost, estimated at more than \$20,000 per episode.<sup>26</sup> As high as this cost is, it does not reflect the longer term costs to society and the patient of recurrent VTE, post-thrombotic syndrome, and pulmonary hypertension.

## ***Step 2: 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 are already available. Experience, precedents, and skilled individuals can significantly assist an effort. Conversely, working at odds with existing infrastructure and strategic goals can sabotage a project. Answering key questions about the landscape, available data, lessons learned, and barriers and opportunities will help the QI team identify the best approach for its improvement effort.

### **Review the QI Landscape**

The team should make sure the elements of success are addressed and stressed in the context of the locally preferred QI framework. By surveying all the efforts already underway in VTE prevention, redundancy can be avoided and coordination ensured.

- What is the existing QI infrastructure and preferred QI framework?
- What support or services are available for this project?
- Are there any ongoing QI initiatives to learn from or leverage?
- Are there any initiatives that could bolster support for a VTE prevention effort (e.g., pursuit of Magnet Recognition Program, ventilator-associated pneumonia bundle, Surgical Care Improvement Project, TJC or NQF measures, and Partnership for Patients)?

### **Understand the Data**

Publicly reported measures on VTE prevention and outcomes have some flaws. Despite this, alignment with these measures is desirable even as the improvement team seeks to track improved measures.

- What performance data on VTE prevention or VTE events already exist?

### **Identify Lessons Learned**

Many VTE prevention efforts fail because of a lack of standardized guidance integrated at the point of care or due to flawed risk assessment models that either offer no guidance or are so

complicated that providers bypass them. Identifying why past efforts failed to produce desired results will help guide current efforts and avoid repeating the same mistakes.

- 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?

### **Identify Barriers and Opportunities**

It is important for teams to analyze the local QI ecosystem, address the barriers pertinent to VTE prevention, and use tools that have proven effective in the past. The most effective improvement strategies focus on improving ordered prophylaxis, monitoring for care deficiencies, and intervening where deficiencies are found. Understanding the tools available for these functions can assist in devising a maximally effective new system.

- 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)?
- How fragmented is care in the hospital? Are intensive care units (ICUs) open or closed? Are patients geographically grouped by service or specialty?
- What are the existing practices for standardizing care transitions between settings (e.g., emergency room to floor, ICU to floor, operating room to floor, direct admissions)?
- Can precedents that have engaged patients in promoting medical staff accountability be leveraged for specific care goals?
- In what areas of the hospital are nurses engaged in promoting medical staff accountability for specific care goals (e.g., daily goals worksheet or participation in multidisciplinary rounds)?
- In what ways do clinical pharmacists participate in care delivery (e.g., participation in multidisciplinary rounds, pharmacokinetics consults, pages to providers to adjust medication dosages)?
- Could the electronic health information or paging system relay clinical information to members of the care team (e.g., alerts by email, 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 health record, CPOE, or digital radiology?

### **Step 3: Clarify Key Stakeholders and the Reporting Hierarchy**

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:

- Pharmacy and therapeutics committees.
- Nursing groups.
- Hospitalists, hematologists, and oncologists.
- Orthopedics, surgery, and trauma leaders.

- Patient safety committee.
- Operating room and perioperative committees.
- Chief residents and residency program directors.
- Departmental committees.

Informing stakeholders of the effort and gaining their buy-in is important to boost early adoption of interventions. These stakeholders may also advance educational efforts and offer legal protection for information that is uncovered. In addition, early use of the proper reporting structures and approval processes is wise.

#### ***Step 4: Assemble an Effective Team***

QI efforts often originate from a few thought leaders who see a gap between current practice and best practice. The VTE prevention team may at a minimum want to include a team leader, a team QI facilitator, process owners, information technology and health information system experts, and patient representatives.

**The team leader** should be a clinician the medical staff respects with some topic expertise on VTE prophylaxis and anticoagulation. While the clinician leader does not need to be a physician, having strong physician partners can bolster both the acceptance and visibility of the effort. This person is responsible for setting the agenda, a collaborative tone, and the frequency of team meetings and with communicating with administrative and medical staff committees. In addition, the team leader and the QI facilitator need to enforce constructive team dynamics.

The team leader needs commitment and contributions from other team members and a coordinated effort across the spectrum of care 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 ICU, but a hospitalist may lead efforts on the floors or wards.

**The QI facilitator**, who should be someone with QI experience, plays the pivotal role of ensuring the team functions constructively and the project stays on track. This role requires project management and people management skills as well as the ability to 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 projects, the QI facilitator can also be the team leader. For more ambitious projects or for projects involving buy-in from disparate clinician groups, having a separate facilitator is strongly recommended.

**Process owners** are frontline personnel involved in providing VTE prophylaxis in the hospital and are essential for an effective team wishing to optimize VTE prevention. Ideally they represent each discipline (pharmacy, nursing, and so forth) and unit (medical, surgical, ICU, and so forth).

**Information technology and health information system experts** provide pivotal contributions, from performance tracking to actual QI interventions. Enlist those who can report ICD code frequencies at discharge, perform data entry, set up reports from the electronic clinical data warehouse and radiology, and serve as liaisons to health informatics. In addition, individuals

skilled in run charts, statistical process control charts, and statistics are highly desirable as ad hoc members of the team.

**Patient representatives** provide the patient's point of view in all aspects of the improvement effort. They can be particularly valuable when assessing adherence to mechanical prophylaxis and developing educational materials around the subset of patients who may require extended duration prophylaxis.

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 and each team member must be comfortable expressing his or her viewpoint. Try to pick people who have reputations as collaborators.

### ***Step 5: Define the Scope of VTE Prevention Efforts***

A wide variety of patient populations are at risk for VTE. Improvement teams need to decide whether to tackle VTE prevention across the spectrum of patients at risk or limit their efforts to some special cases. For example, an improvement team could focus efforts on just critical care patients and surgical patients and let others address VTE prevention for orthopedic, general medical, oncology, and obstetrics and gynecology patients.

Focusing on a specific population has some practical advantages. The scope of the effort is more manageable, and there are fewer clinicians, order sets, and points of view to consider. In addition, teamwork may be better if efforts are limited to a certain group.

Despite these considerations, there are cases where a systemwide approach to VTE prevention may be preferred. First, patients frequently move from one setting to another or belong to more than one area of focus, leading to inconsistency and confusion. Second, focusing on only certain groups leaves large populations vulnerable. For example, if adult VTE prevention efforts focused only on surgical patients, the medical population (in whom around half of HA-VTE occurs) would not be addressed. Third, having a common institutional standard may actually make some aspects of education and implementation easier.

### ***Step 6: Set General Goals and a Timeline***

Setting a goal helps the VTE prevention team stay focused and communicate effectively with stakeholders. For clarity of purpose and to overcome initial inertia in the early stages, the team needs only to agree on general goals. Making the general goals a stretch can ensure the effort is ambitious enough to change the current process but still achievable (e.g., eliminate preventable cases of hospital-associated VTE). After seeing initial success, the team can develop a more specific and measurable aim statement for VTE prophylaxis.

The team also needs a deadline to hold itself accountable, and 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 24 months may be more appropriate.

## **Step 7: Use Tools and Resources To Organize Team Efforts**

Appendix A contains an institutional self-assessment for VTE prevention. This tool was designed to communicate information to a consulting physician mentor in advance of a site visit, but can also be used to help improvement teams organize their efforts and their exploration of prior efforts. Appendix B also contains a sample aim statement and a variety of tools developed as part of AHRQ-funded projects to implement VTE prophylaxis.

## **Step 8: Use a Structured Framework for Improvement To Plan and Guide Progress**

A coherent framework is as important to QI as an understanding of aeronautics is for building an airplane. There is also great value in knowing how each of the team's activities contributes to the overall progress of the improvement effort. The framework is outlined in Figure 1.1.

1. *Analyze care delivery* (Chapters 1 and 2). Assess past efforts and barriers to implementation. Highlight the steps in the clinical workflow where interventions will have the highest impact. Identify key barriers and failure modes and prioritize which ones to tackle as a priority. Reassess and analyze with input from local stakeholders.
2. *Review the evidence and assimilate general definitions for best practice* from guidelines, regulatory agencies, and other sources (Chapter 3). These sources provide general standards for VTE prophylaxis in several different groups and in special populations.
3. *Distill the most important best practices from the guidelines and other sources and translate that information into local VTE prevention protocols and policies* (Chapters 4 and 5). Protocols provide specific guidance for managing groups of patients, in an algorithmic structure that facilitates clinical decisionmaking, tailored to the local environment.<sup>21</sup> A VTE protocol, reduced to its essence, is a standardized VTE risk assessment, linked to a menu of appropriate VTE prophylaxis options for each level of risk. Such a protocol also provides guidance for management of patients with contraindications to pharmacologic prophylaxis. This filtering or distillation of the guidelines is essential. From thousands of pages derived from a score of sources, teams must identify the most essential and important ones to reinforce in protocols.

Protocols embody the local definition of acceptable practice, and the operational definitions and details of the protocol will drive the design of order sets, measurement tools, and educational efforts. Protocol-driven order sets are ideally easy to use, provide the necessary guidance, and are positioned in such a way that the embedded guidance affects virtually all patients at key junctures (e.g., on admission, postoperatively, and on transfer from one level of care to another).<sup>20</sup>

Medical center policies add another layer of definition and reinforcement to local standards. Such policies, which will ideally state acceptable standards in more general terms, often require votes by medical center committees and medical staff to alter—and have a longer review and revision cycle. Protocols (which can take effect immediately), meanwhile, are typically more specific and easier to revise.

4. *Design multifaceted interventions to reinforce and integrate the protocol into practice, addressing weak links and failures in the process* (Chapter 4). Robust evidence from randomized trials on interventions that improve prophylaxis and outcomes is often limited, but there is some guidance available in the literature and from previous collaborative efforts.<sup>21-25</sup> Integrating VTE risk assessment into admission and transfer order sets is a key intervention, but this alone will not achieve the high degree of performance required to optimize prophylaxis and reduce HA-VTE. Additional interventions reinforcing the protocol, layered on top of the essential VTE prevention order sets, are the key to success. As noted above, multiple active interventions inclusive of real-time electronic or human alerts have been most successful.<sup>21-25</sup> One example combining real-time measurement with concurrent intervention (aka measure-vention),<sup>20</sup> is emphasized as a reliable additional intervention to drive improved prophylaxis.
5. *Implement the protocol and ensure reliable delivery of best practices* (Chapters 5 and 7). Implementation is where the rubber meets the road. Engaging stakeholders across the hospital, developing education plans, and using good clinical decision support, standardization, and other techniques increases the chances of optimizing prophylaxis. Ongoing evaluation, feedback, and revision and refinement are also needed.
6. *Track performance with metrics* (Chapter 6). Set up regular data collection and charting that is reliable, inexpensive, and directly relevant to the aim. Key metrics include the prevalence of appropriate VTE prophylaxis and the incidence of HA-VTE. Measurement helps assess baseline performance, but should also inform improvement efforts longitudinally.
7. *Hold the gains and spread the initiative to other units, hospitals, and/or settings* (Chapter 8). Holding the gains on VTE prevention and disseminating your successes is much more likely if the initial effort is done right. This includes building the right tools and infrastructure for order sets and measurement and achieving results via redesign of systems rather than by relying exclusively on interventions such as education.

## Stages of the Quality Improvement Effort

Early on in the effort to improve VTE prophylaxis, the team may focus entirely on launching a well-integrated, protocol-driven VTE prevention order set. This is indeed the key foundational intervention. There are many ways to get this wrong, and only two or three ways that seem to work reliably across a variety of settings, so this guide covers how to do this in great detail.

Even the best order set, however, will fail to achieve near-perfect appropriate prophylaxis. It is important for the improvement team to recognize this in advance and get a sense of where they will be going in the future. In that spirit, this guide introduces the concept of layering multiple interventions to achieve optimal VTE prophylaxis.

The hierarchy of reliability (Table 1.1) is a construct that depicts different stages of the QI effort and the results the team can expect to have at each stage.<sup>20,27,28</sup> While the estimates of predicted performance may vary, this hierarchy has also proven useful in glycemic control and anticoagulation improvement efforts.<sup>10,14,19</sup>

**Table 1.1: Hierarchy of Reliability**

Level		Predicted Performance
1	<b>No protocol</b> (“State of Nature”)	40%
2	<b>Pseudo-protocol:</b> decision support exists but not linked to order writing, or prompts within orders but no decision support	50%
3	<b>Protocol*:</b> well integrated into orders at point of care	65-85%
4	<b>Enhanced protocol:</b> complementary strategies increase use of protocol	90%
5	<b>Measure-vention:</b> oversights identified and addressed in real time	90+%

\* Protocol = standardized decision support, embedded within an order set.

The level achieved on the hierarchy of reliability is generally predictive of performance regarding the level of appropriate VTE prophylaxis. A protocol available at the point of care (Level 3), essential to embedding best practice in the clinical workflow, establishes a foundation for other interventions (Level 4) and measure-vention (Level 5).

Within the hierarchy, teams move beyond Level 1 by developing consensus on the definition of best care, embedding that definition as a protocol for standard work, and then monitoring and learning from variation from that protocol. Level 2 is achieved when protocol guidance exists but is not present at the right time or place to influence VTE prevention orders, or when there is a simple listing of options for prophylaxis in order sets with guidance about preferred options.

The first big bang for the buck in the hierarchy comes at Level 3. At this point, a best practice protocol is standardized by integrating it into the clinical workflow—most commonly by embedding it within a preprinted or electronic order set. This integration with clinical workflow gives clinicians the information they need, when and where they need it, to make an appropriate choice. The order set must earn high use by being easy to use, concise, and clear. Level 4 in the hierarchy is achieved when Level 3 is augmented by additional strategies (e.g., traditional delayed audit and feedback to care teams about protocol use) and by addressing factors that contribute to VTE (e.g., impaired mobility).

At Level 5, an improvement team uses measure-vention, a profound leap in reliability. Measure-vention represents a way to create improvement interventions directly from performance measurement. In other words, measure-vention introduces the variable of time to measurement systems: real-time measurement can highlight today’s potential missed opportunities, creating an opportunity to address them immediately.<sup>20,27,28</sup> As opposed to retrospective data collection commonly used to populate static dashboards, measure-vention techniques call for regular measurement of performance on every pertinent patient at daily or more frequent intervals. Measure-vention lends itself to automated data capture and display in run charts, especially when outliers are identified electronically.

## Chapter 2. Analyze Care Delivery

This chapter helps venous thromboembolism teams better understand their current environment and process for providing VTE prevention. The focus here is on identifying barriers to improvement and failures in the current process in order to address them.

Every improvement effort faces obstacles—both barriers and failure modes. In this guide the term “barrier” is used to describe more general problems that pose challenges; the term “failure mode” is used to describe more specific steps that need to be addressed in the local process.

It is useful to acknowledge as many obstacles as possible from the start and be prepared to face them, rather than to feel ambushed and disillusioned by their negative influence on the improvement effort as it unfolds.

### Identify Common Barriers to Improvement

Some barriers are generic. Every medical center faces competing priorities and, increasingly, improvement fatigue. Negative inertia and resistance to change often slow things down. And while medical staff in many hospitals embrace a culture of teamwork and standardization, this is by no means uniform. Appendix A includes talking points to help improvement teams overcome some of the general malaise and garner the crucial leadership support needed to move forward.

Translating complicated guidelines into everyday practice is difficult. It is often just as important to figure out what parts of the guidelines *not* to address as it is to identify the most important aspects to reinforce so as not to risk overwhelming staff with information and decision support they cannot use. Conflicting guidelines from medical specialty groups can make standardization difficult. Meanwhile, the evidence for or against prophylaxis in certain subpopulations shifts occasionally, and the role of new anticoagulants in prophylaxis continues to evolve.

The evidence is imperfect and not all venous thromboembolism (VTE) prophylaxis issues are black and white. Yet the improvement team must make some decisions about its institutional approach to VTE prevention to allow standardization and measurement against a common definition of best practice. The team will be faced with defining the term “appropriate prophylaxis” for almost every kind of patient imaginable, taking into account clot risk, bleeding risk, and leeway times around surgeries when cessation of prophylaxis is acceptable and often desirable. The team will also need to settle on a VTE risk assessment model even though no definitive evidence exists for superiority of one model over others.

Existing measures and standards can also slow progress as they compete for leadership attention, staff time, and resources. While the National Quality Forum, The Joint Commission, Surgical Care Improvement Project, and meaningful use criteria for electronic health records (EHRs) are all in place, these measures do not necessarily drive rapid improvement—and administrative leaders may focus on these measures to the extent that they steal attention and resources away from more meaningful and useful measures.



The EHR and computerized physician order entry environment, while holding great promise, does not necessarily always provide a safer or more efficient environment for order sets or informatics. In fact, improvement efforts often grind to a halt for several months around the “go live” date for these systems.

## Identify Common Failure Modes

In addition to more general barriers, there are a number of weaknesses in the processes specific to VTE prevention (see Figure 2.1).

One common failure mode is the lack of standardized protocols or order sets for VTE prevention. This equates to Level 1 on the Hierarchy of Reliability. This failure mode can be broken down further into (1) VTE risk assessment is not routine or standard; (2) bleeding risk assessment is not routine or standard; and/or (3) there are widely different impressions of when it is safe to start anticoagulation peri-procedure and post-trauma—and no agreement on appropriate leeway times.

Too many order sets is a variant of this failure mode worth special mention. While some customization of order sets is desirable to serve the needs of populations with particularly high bleeding risks or deep vein thrombosis (DVT) issues that do not fit the more general population, it is easy to allow so many order sets that standardization within and across services becomes unwieldy, unreliable, and difficult to maintain. While some service-specific order sets are desirable, having too many does not reflect a standardized approach and can compromise institutional performance.

Conducting a survey of all order sets in common use can be difficult. It is important to do so, however, on any journey toward better institutional quality—and the lessons learned can be applied to a host of other conditions.

Another common failure mode is when order sets and prompts that reference VTE prevention are in place but provide inadequate guidance. For example, simply listing options for prophylaxis does not provide adequate guidance. Similarly, order sets that provide detailed guidance that is bypassed (or not used) are of no use to providers. Mandatory hard stops to complete DVT risk assessment are often required to secure optimal prophylaxis rates; many hospitals, however, do not have these in place.<sup>1-3</sup> Order sets with guidance in place and used—but used incorrectly—is yet another failure mode. This is a common scenario when the order set is too time consuming or difficult to use.

These failure modes encompass the top two sources of breakdown in the process in Figure 2.1. Overcoming these failures will land the team at Level 3 on the Hierarchy of Reliability, with a projected 75 percent rate of appropriate VTE prophylaxis.

Additional common failure modes can include:

- Patient gets placed on the right prophylaxis, but VTE/bleeding risk changes and an adjustment is not made.
- Prophylaxis gets missed or changed on transfer to a perioperative setting.
- Correct prophylaxis is ordered but not administered (or the patient refuses treatment).
- Patient is not mobilized optimally.
- Preventable risk factors (e.g., central line) are not optimally managed.
- Prophylaxis is stopped at discharge even though the patient has indications for extended duration prophylaxis.

This list is not all inclusive, and an implementation team may well find more problems with the process of providing effective DVT prophylaxis to the inpatient population. This list does, however, cover the most pervasive problems; addressing them effectively should lead to very high rates of appropriate DVT prophylaxis.

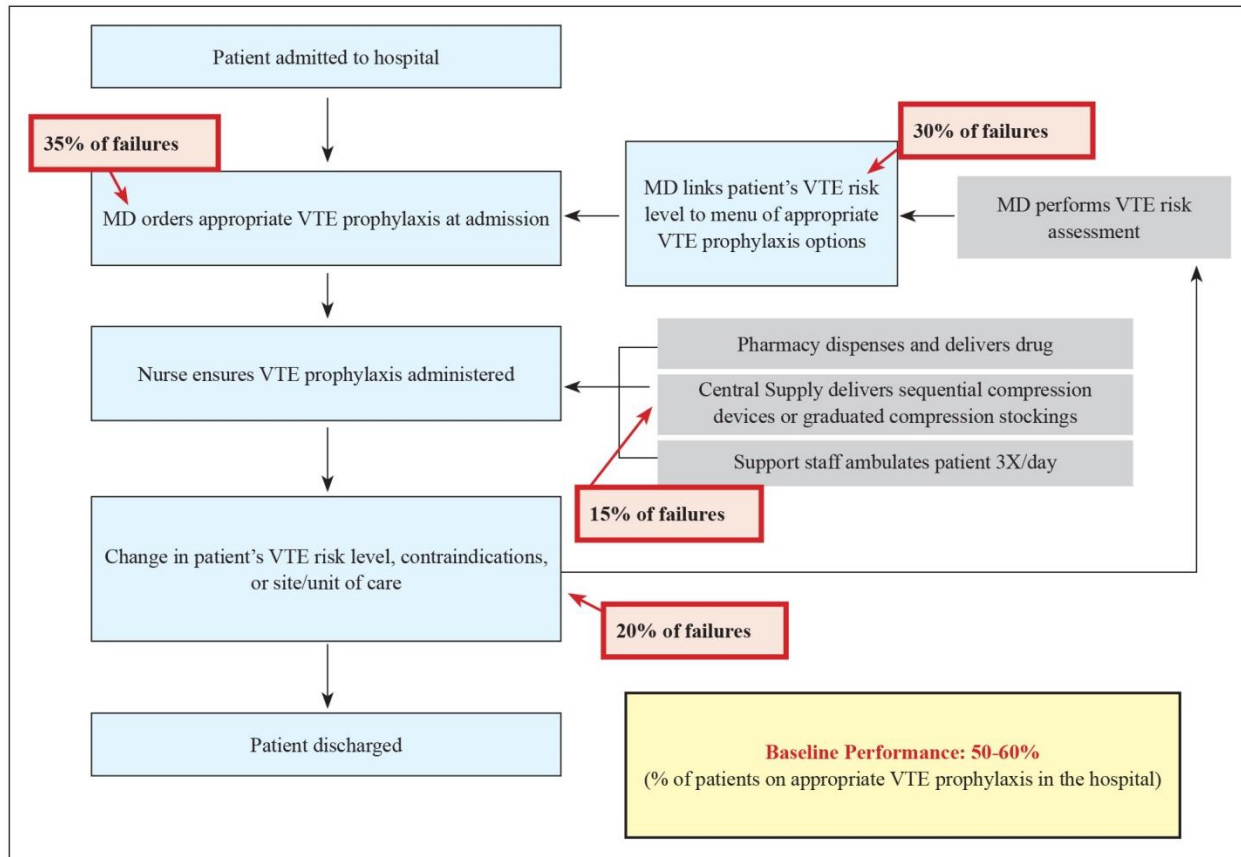
### **Diagram Care Delivery To Identify Failure Modes**

To create its interventions, the team will need to diagram care delivery. This may be viewed as a series of intermediate steps that lead to a clinical endpoint. Diagramming helps members to understand these interrelated steps and to identify where failures—or missed chances to prevent hospital-associated VTE (HA-VTE)—occur. These opportunities exist from the moment the patient is admitted and recur daily.

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 chances to prevent HA-VTE. By doing this type of analysis, the team can identify rate-limiting steps and recognize which steps can serve as metrics for preventing HA-VTE.

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 the process.

Figure 2.1 is an example of a diagram of steps in care delivery for preventing HA-VTE, along with the most common areas of process failure.

**Figure 2.1: Process Map of VTE Prophylaxis With Common Areas of Failure**

As a starting point in its analysis, the team should estimate how reliably each step occurs at its institution. For those steps that occur less than 100 percent of the time, the team will want to identify things that go wrong. This can reveal steps in the current process that are so obviously unreliable that they become the natural focus of interventions. Interventions can then be designed to address these failure modes and their underlying causes. The team should make an attempt at this point to prioritize these failure modes and to put some effort into delving into the root causes of why they occur.

The bulk of this guide addresses these barriers and is designed to help improvement teams navigate them and put in place effective protocols and processes to prevent VTE events.

## Chapter 3. Outline the Evidence and Identify Best Practices

This chapter outlines the evidence and best practices applied for many common conditions encountered in hospitals. This information is likely most useful to the team’s physician lead and/or the facility’s clinical leadership.

### Know What the Literature Says About the Risk of Venous Thromboembolisms and Measures for Prevention

Before initiating an intervention, it is important to determine the venous thromboembolism (VTE) prophylaxis protocol that the facility will follow. The VTE steering team will want to review the evidence base to identify best practices for preventing hospital-associated VTE (HA-VTE), and then refine the evidence to emphasize the most crucial points in protocols, education, and clinical decision support tools that are applicable for your institution. The majority of the guidance given by professional societies is consistent, but there are areas of difference and controversy to identify and manage.

Table 3.1 depicts pertinent guidelines on VTE prevention, presented in reverse chronological order beginning with the latest recommendations.<sup>1-13</sup>

**Table 3.1: Major Guidelines Addressing VTE Prophylaxis**

Guideline	Acronym and Date	Description
American Society of Clinical Oncology guideline update: Venous Thromboembolism Prophylaxis and Treatment in Patients with Cancer. <sup>9</sup>	ASCO 2013	Update from 2007 guideline. More explicit guidance than 2007 on patients that do not warrant prophylaxis as well as those that do.
Antithrombotic Therapy and Prevention of Thrombosis, 9th ed.: American College of Chest Physicians (ACCP) Evidence-Based Clinical Practice Guidelines. <sup>1</sup>	AT9 2012	Guidelines for VTE prevention presented as four separate articles by the patient’s reason for hospitalization, including: <ul style="list-style-type: none"> <li>• Nonsurgical<sup>2</sup></li> <li>• Nonorthopedic surgical<sup>3</sup></li> <li>• Orthopedic<sup>4</sup></li> <li>• Pregnancy (online at <a href="http://www.chestnet.org/sitecore%20modules/web/~/media/chesnetorg/Foundation/Documents/Antithrombotic%20Therapy%20and%20Pregnancy.ashx">http://www.chestnet.org/sitecore%20modules/web/~/media/chesnetorg/Foundation/Documents/Antithrombotic%20Therapy%20and%20Pregnancy.ashx</a>)<sup>5</sup></li> </ul> <p>More information on AT9 is available online at <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278060/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278060/</a>.</p>
Venous Thromboembolism Prophylaxis in Hospitalized Patients: A Clinical Practice Guideline From the American College of Physicians (ACP). <sup>7</sup>	ACP1 2011	Guideline focused on nonsurgical patients. <sup>7</sup> Medical and stroke. Published with separate supporting literature review. <sup>8</sup>

Guideline	Acronym and Date	Description
American College of Obstetricians and Gynecologists Practice Bulletin No.123. Thromboembolism in Pregnancy (available online at <a href="http://www.acog.org/Resources_And_Publications/Practice_Bulletins/Committee_on_Practice_Bulletins/Obstetrics/Thromboembolism_in_Pregnancy">http://www.acog.org/Resources_And_Publications/Practice_Bulletins/Committee_on_Practice_Bulletins/Obstetrics/Thromboembolism_in_Pregnancy</a> ). <sup>12</sup>	ACOG 2011	Update expands and updates VTE prevention in pregnancy and cesarean deliveries.
Preventing Venous Thromboembolic Disease in Patients Undergoing Elective Hip and Knee Arthroplasty. Evidence-Based Guideline and Evidence Report From the American Academy of Orthopaedic Surgeons. Second Edition. <sup>10</sup>	AAOS2 2011	Second edition and AT9 now aligned on most issues. Many areas with limited guidance.
Reducing the Risk of Venous Thromboembolism (Deep Vein Thrombosis and Pulmonary Embolism) in Patients Admitted to Hospital. NICE clinical guideline 92. <sup>13</sup>	NICE 2010	National Institute for Health and Clinical Excellence, Great Britain, offers more aggressive stance than AT9, with a host of implementation tools. <sup>14</sup>
Antithrombotic Therapy and Prevention of Thrombosis, 8th ed: American College of Chest Physicians (ACCP) Evidence-Based Clinical Practice Guidelines.	AT8 2008	Guidelines for VTE prevention presented as one article. <sup>6</sup>
American College of Obstetricians and Gynecologists Practice Bulletin No.84. Prevention of Deep Vein Thrombosis and Pulmonary Embolism. <sup>11</sup>	ACOG 2007	Covers obstetrics and gynecology surgery issues.

Many of the recommendations described below, including the ACCP *Antithrombotic Therapy and Prevention of Thrombosis, 9<sup>th</sup> edition* (AT9), are those of the organizations referenced at the beginning of the chapter. More detailed information about the guidelines reviewed in Table 3.1 can be found at the National Guideline Clearinghouse (<http://www.guideline.gov/>).<sup>15</sup> In a systematic approach, inpatients are screened on admission for VTE risk based on institutional policies, protocols, education plans, and clinical decision support systems. Bleeding risk and patient preferences are also considered in the decisionmaking process.

### ***Patients With Medical Conditions (Nonsurgical)***

Acutely ill hospitalized patients at risk for thrombosis are likely candidates for anticoagulant prophylaxis in the form of low-molecular-weight heparin (LMWH), low-dose unfractionated heparin (UFH) (5,000 units subcutaneous BID or TID), or fondaparinux 2.5 mg/day. Mechanical prophylaxis is usually not offered as a first choice for prophylaxis in medical patients in the absence of bleeding risk factors, but is more likely to be used in patients with both bleeding and clot risk. Intermittent pneumatic compression devices (IPCDs) are favored for patients in this situation over graduated compression stockings (GCS) by some guidelines (e.g., ACP1), extrapolating from clinical trials in immobilized stroke patients that found that thigh-high GCS increased the risk of skin breakdown without reducing VTE.<sup>7,8</sup>

Patients who are at low risk for thrombosis very likely do not need either mechanical or pharmaco-prophylaxis.<sup>2,7</sup> There is no consensus on defining this low-risk medical group, but it may be a substantial proportion of medical inpatients in non-intensive care settings. Examples of low-risk medical inpatients include chronically immobilized patients without acute illness, short-stay observation patients, patients awaiting disposition who were never or are no longer acutely ill, and fully ambulatory patients not at risk for VTE or without multiple VTE risk factors.

The ACCP VTE prevention guidelines were published in 2012 as four distinct articles<sup>2-5</sup> as part of the larger ACCP *Antithrombotic Therapy and Prevention of Thrombosis, 9<sup>th</sup> edition*, commonly referred to as AT9.<sup>1</sup> This review reflects the broad scope and general prominence of AT9 but should not be construed as an endorsement of this guideline over others.

The AT9 guidelines reflected a different approach to analyzing prior studies than did the 2008 ACCP guidelines<sup>6</sup> (AT8) in terms of philosophy, methodology, and exclusion of asymptomatic VTE outcomes, resulting in new or altered recommendations. The approach by AT9 carefully grades the levels of evidence based on the strength of the recommendations and the quality of the evidence and places a focus on patient-centered outcomes.<sup>16</sup>

However, the approach taken by AT9 may pose unique challenges for clinicians attempting to translate the new recommendations into practice. Guidance from AT8 and other guidelines has generally been summarized in a manner and format that is more actionable. This tradeoff is reflected in this chapter. Most of the guidance on major topics, however, is consistent across guidelines.

### ***Patients Undergoing Surgical Procedures (Nonorthopedic)***

The risk of VTE in patients having nonorthopedic surgery depends on both patient-specific and procedure-specific factors.<sup>3</sup> Very low to low-risk procedures include most same-day surgical procedures and surgeries that do not involve longer open procedures on body cavities. Examples of these low-risk procedures include laparoscopic procedures of less than 30 minutes in duration, appendectomy, transurethral prostatectomy, inguinal hernia repair, mastectomy, and spinal surgery for nonmalignant disease. No VTE prophylaxis is typically recommended for patients undergoing these procedures unless the patient is hospitalized for more than a day and/or has other VTE risk factors.

Patients undergoing uncomplicated, scheduled cardiac procedures have only a slightly higher risk of VTE providing they can be mobilized within a day. Patients undergoing posterior approach spinal surgery for nonmalignant disease can be provided with mechanical prophylaxis, preferably with IPCD, as a sole option. Regular reassessments of VTE risk are generally done to ensure a transition to a more aggressive prophylaxis regimen if needed (i.e., the patient experiences delays in mobility or complications occur).

Procedures associated with a very high risk of VTE include abdominal or pelvic surgery for cancer, multiple major trauma, craniotomy/spinal surgery for malignant disease, and spinal surgery with an anterior approach. Patients undergoing thoracic surgeries, including pneumonectomy, extended pulmonary resection, esophagectomy, and extrapleural pneumonectomy of mesothelioma, are also at very high risk.<sup>3</sup> A combination of mechanical prophylaxis (preferably with IPCD) and anticoagulant prophylaxis is suggested for these high-risk patients.

For procedures with particularly high (~2%) risk of perioperative bleeding, in which local bleeding can have more severe consequences, IPCD alone can be used initially, until the risk of bleeding has subsided, at which time pharmacologic prophylaxis can be added. Examples include craniotomy, traumatic brain injury, spinal cord injury repair, major trauma, plastic surgery with a free flap, and pneumonectomy or extended pulmonary resection.

Patients undergoing most other surgical procedures requiring hospitalization fall into the moderate-risk category, including those having general surgical procedures, gastrointestinal surgery not related to malignancy, open urological procedures, gynecologic surgery, vascular surgery, and reconstructive surgery. In AT8 and other guidelines, anticoagulant prophylaxis is preferred over mechanical prophylaxis.<sup>6,13</sup> In AT9, pharmacologic prophylaxis with UFH or LMWH *or* mechanical prophylaxis are deemed acceptable choices, even though AT9 notes that better evidence exists for pharmacologic prophylaxis.

### ***Patients Undergoing Orthopedic Surgery***

A patient's risk for VTE after major orthopedic surgery is among the highest of all risks for VTE. Dual prophylaxis with an antithrombotic agent and an IPCD during the hospital stay is commonly recommended for patients undergoing major orthopedic surgical procedures.

#### **Duration of Prophylaxis**

Major orthopedic surgery patients are likely to require prophylaxis for a minimum of 10 to 14 days. Extending prophylaxis further up to 35 days results in additional reductions in DVT with a comparable safety profile and is also recommended.<sup>4</sup>

#### **Choice of Antithrombotic Agent in Major Orthopedic Surgery**

For total hip arthroplasty and total knee arthroplasty, LMWH is favored by AT9.<sup>4</sup> For hip fracture surgery, the anticoagulant choices are the same.

If LMWH is used for thromboprophylaxis, avoiding dosing in a 12-hour window preoperatively and postoperatively is recommended to reduce bleeding risk. Comorbidities or complicating factors may delay hip fracture repair, and starting LMWH between admission and surgery is desirable, providing this 12-hour window is maintained.

#### **Aspirin in Major Orthopedic Surgery Patients**

AT9<sup>4</sup> allows for the use of aspirin (acetylsalicylic acid, or ASA) in major orthopedic procedures, citing the 2000 Pulmonary Embolism Prevention Trial.<sup>17</sup> This trial was designed to investigate the effect of ASA on vascular death (pulmonary embolism, myocardial infarction, cerebrovascular accident). A positive impact on reducing VTE was only apparent in a post hoc analysis. The study findings were discounted in AT8 but accepted in AT9. Thus, in AT9, ASA is listed as an option for major orthopedic surgery patients even while AT9 labels LMWH as the preferred choice for this indication and stipulates that LMWH likely has greater efficacy. Although ASA use remains controversial (even among the AT9 panel), relatively low rates of VTE have been reported using ASA with progressive orthopedic techniques, early mobilization regimens, and concomitant use of IPCD.

## **Intermittent Pneumatic Compression Devices in Major Orthopedic Surgery Patients**

IPCD devices are generally recommended as part of a dual prophylaxis regimen, but for patients at risk of bleeding or those who place a high value on avoiding bleeding complications, IPCD is recommended over no prophylaxis. Only portable, battery-powered IPCDs capable of recording and reporting wear time on a daily basis are recommended for inpatient and extended duration outpatient use, ideally used for 18 hours or more.<sup>4</sup>

## **Prophylaxis for Knee Arthroscopy and Isolated Lower Leg Injuries Distal to the Knee**

Absent a prior history of VTE or multiple strong VTE risk factors, AT9 recommends no prophylaxis rather than pharmacologic prophylaxis for patients undergoing knee arthroscopy. The same recommendation applies to patients with isolated lower leg injuries distal to the knee that require leg immobilization.

## **Implementation Challenges**

The multitude of “acceptable” choices for major orthopedic surgery and the requirement for extended duration prophylaxis can pose problems for standardization and reliable delivery of appropriate prophylaxis. Insurance issues and limited availability of some options may exist. As always, patient preference may play a role in prophylaxis choice, particularly for those patients who require prophylaxis extended beyond the hospital stay.

## ***Oncology Inpatients***

The 2013 American Society of Clinical Oncology (ASCO) guidelines for prophylaxis and treatment of VTE in patients with cancer provide indepth guidance for this important population.<sup>9</sup> VTE is a leading cause of mortality in patients with malignancy. VTE risk is especially high for inpatients and those receiving active therapy, and the frequency of VTE appears to be increasing among cancer patients. VTE risk is highest in the first 3 to 6 months after diagnosis and is higher with advanced stage and histologic aggressiveness.

Chemotherapy, anti-angiogenesis therapy, hormonal therapy, radiation therapy, transfusion, and indwelling venous access are all risk factors, in addition to surgery and the cancer itself. Age, obesity, and comorbidities such as infection and pulmonary disease are additive risk factors, just as they are in patients without malignancy, and there is also an association of VTE with functional status. Biomarkers, such as an elevated platelet count or leukocyte count or hemoglobin <10 g/dL, are also cited as VTE risk factors.

ASCO recommends that hospitalized inpatients with acute medical illness or reduced mobility receive pharmacologic VTE prophylaxis, in the absence of any contraindications. In view of underlying high risk, even patients who have an active malignancy without additional risk factors may be considered for prophylaxis; however, the ASCO guidelines stipulate that data are inadequate to support routine thromboprophylaxis in patients admitted for minor procedures or short chemotherapy infusion. More research is also needed regarding appropriate options for stem cell/bone marrow transplantation.



Either UFH or LMWH are recommended for patients with malignancy undergoing major surgical intervention, unless contraindications are present, with prophylaxis commenced preoperatively. Combination prophylaxis is ideal for those at especially high risk. Mechanical prophylaxis as a sole agent in the absence of bleeding risk is not suggested. Extended duration prophylaxis for at least 7 to 10 days and up to 4 weeks postoperatively is considered for patients undergoing major abdominal or pelvic surgery for cancer who have high-risk features. Education and engagement of the patient regarding VTE risk factors, signs, and symptoms is strongly encouraged.

Prophylaxis for outpatients is generally beyond the scope of this implementation guide but is mentioned here for cancer patients in the context of making decisions about prophylaxis for patients leaving the hospital. While routine thromboprophylaxis is not recommended in cancer outpatients, patients with multiple myeloma receiving thalidomide or lenalidomide-based regimens with chemotherapy or dexamethasone are candidates for thromboprophylaxis with either LMWH or ASA for lower risk patients, or with LMWH for higher risk patients. Other highly selected patients with solid tumors receiving chemotherapy may be considered for thromboprophylaxis on a case-by-case basis.

While there are some subtle differences, the AT9 guidelines are largely consistent with ASCO guidelines. Institutions with large oncology services may want to consider separate “carve out” order sets and protocols tailored to that population.

## **Putting It All Together—Next Steps**

VTE prophylaxis can be a complex issue when one considers all the variations in prophylaxis to accommodate the risk for clots or bleeding, as well as patient preferences in diverse inpatient populations. In addition, multiple agents available for prophylaxis, and the nuances of dosing, timing, and duration of anticoagulants in different situations, further complicate the issues.

While this chapter condenses information from multiple guidelines and other sources to some degree, the VTE prevention team will want to simplify this conglomeration of best practices further in order to provide good clinical decision support at the point of care, build protocol-driven educational resources, and construct measurement tools. The following suggestions may help compartmentalize these tasks and make it easier.

### ***Provide Guidance Tailored to Services at Your Hospital***

Much of this chapter reviews recommendations for different types of patients. The prevention team may consider breaking down this information into more digestible formats tailored for different services (e.g., medical, surgical). This will simplify directions in order sets on options for prophylaxis and when to start/stop them and help to create succinct targeted educational tools.

### ***Reduce the Options to Preferred Options***

The improvement team may be able to simplify the information presented in this chapter by selecting a few preferred options for prophylaxis in situations, such as major orthopedic surgery, in which several options are available.

### ***Divide Up the Work***

There is a lot of information to absorb and integrate into policies, protocols, education programs, and clinical decision support. Dividing up the information and tasking different stakeholders makes this more manageable. For example, physicians on the team might focus on summarizing and reinforcing best practices for prescribing appropriate prophylaxis, while nursing staff could focus on best practices regarding adherence to mechanical prophylaxis, improving patient mobility, and helping to reassess the patient at various intervals. By the same token, pharmacists could take ownership of helping to narrow down pharmacologic choices, assisting with neuraxial blockade protocols, and integrating guidance about dosing and timing of prophylaxis into order sets, medication administration records, and care pathways.

### ***Prioritize***

Improvement teams may wish to consider focusing on the information that applies to 80 percent of the inpatient population at first—instead of the exceptions to the rule. This chapter and the references can be accessed when questions arise regarding the less common scenarios. Many practical tips for summarizing the most important best practices into a protocol, reinforcing protocol guidance with multiple layered interventions, and strategies to monitor performance are offered in subsequent chapters.

## Chapter 4. Choose the Model To Assess VTE and Bleeding Risk

This chapter provides an overview of the major categories and characteristics of VTE risk assessment models. Once barriers are identified and the team has analyzed its facility's care delivery process related to VTE prevention, a risk assessment model can be adopted.

A venous thromboembolism (VTE) prevention protocol is a standardized VTE risk assessment, linked to a menu of appropriate VTE prophylaxis options for each level of risk, which provides guidance for management of patients with contraindications to pharmacologic prophylaxis. Bleeding risk tools and guidance for the timing of administering anticoagulant prophylaxis around surgical procedures or other high bleeding risk intervals should also be part of a protocol. Protocols define best practice at the local level based on the best evidence available, with operational definitions that drive order set design, measurement tools, and other aspects of the quality improvement process.

The ideal VTE prevention protocol would have these characteristics:

- Accurately detect all patients at risk of developing deep vein thrombosis (DVT).
- Reliably exclude patients who would be unlikely to develop DVT, minimizing inappropriate over-prophylaxis in those of lower risk.
- Provide actionable recommendations for permutations of VTE and bleeding risk.
- Be simple to use in routine clinical practice, with minimal need for laboratory investigations or complex calculations.
- Have predictors of VTE risk available to ordering provider at the point of care.
- Provide decision support regarding those who would benefit from combination mechanical and anticoagulant prophylaxis.
- Integrate into clinical practice results in a way that decreases hospital-associated VTE without any increase in bleeding.
- Lend itself to automation, and even to dynamic ongoing reevaluations.

Unfortunately, there is no consensus regarding the preferred VTE risk assessment tool. VTE risk assessment is essentially a tool. Patients are targeted for interventions to prevent VTE (anticoagulant or mechanical prophylaxis and efforts to improve mobility) based on the assessment of risk of a VTE event. The positive potential to reduce VTE must be balanced with the discomfort, bleeding, expense, and other adverse effects that could result from the prophylactic measures. There is no consensus on the answer to the fundamental question, “How can hospitals assess VTE risk, then ensure adequate prophylaxis for patients who need it, while minimizing excess prophylaxis, in a practical, efficient way?”<sup>1</sup>

Several reviews of risk assessment models are available in the literature.<sup>2-4</sup> These reviews tend to focus on the rigor of model derivation and predictive value. This guide focuses on the practical issues of implementation and utility in clinical practice. Risk assessment models that are in wide use, that are featured in guidelines, or that have demonstrated efficacy in actual practice or clinical trials will be reviewed. While this chapter will not provide definitive guidance on the

fundamental question posed above, it will give VTE improvement teams the context under which to make a reasonable and thoughtful decision about what will work best in their setting.

## Overview—Major Categories and Characteristics of VTE Risk Assessment Models

### Prompts

In the absence of consensus on the best risk assessment model, one approach is to avoid this issue altogether and simply present a prompt to consider prophylaxis. A list of options for prophylaxis is presented in the following example (Figure 4.1), but no clinical decision support (CDS) is offered to sway the judgment of the individual provider.

**Figure 4.1: DVT Prophylaxis Orders**

<input type="checkbox"/> Anti-Thromboembolism Stockings
<input type="checkbox"/> Sequential Compression Devices
<input type="checkbox"/> UFH 5,000 units SubQ q 12 hours
<input type="checkbox"/> UFH 5,000 units SubQ q 8 hours
<input type="checkbox"/> LMWH (Enoxaparin) 40 mg SubQ q day
<input type="checkbox"/> LMWH (Enoxaparin) 30 mg SubQ q 12 hours
<input type="checkbox"/> No Prophylaxis, Ambulate
<input type="checkbox"/> Other

**Key:** UFH = unfractionated heparin; SubQ = subcutaneous; LMWH = low-molecular-weight heparin.

The Hierarchy of Reliability (Table 1.1) and published experience suggests this approach produces only very modest improvement insufficient to make a meaningful reduction in hospital-associated VTE (HA-VTE) rates.<sup>5,6</sup> Widespread, well documented under-prophylaxis<sup>7-10</sup> is largely the result of relying on physician judgment, imperfect human memory, and relatively passive interventions such as educational sessions and pocket cards.<sup>11</sup> Basic tenets of quality improvement also caution against this approach as it offers no opportunity for measurement, standardization, or even definition of best practice, and this approach would generally not meet meaningful use criteria or help institutions meet The Joint Commission’s standards for VTE prevention.<sup>1</sup>

### “Opt Out”

A second approach is the “opt out” approach (see Appendix B.2 at <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/appendixb.html>). This approach has an automatic default of anticoagulant prophylaxis and assumes the great majority of inpatients are candidates for it.

Ordering providers can “opt out” if they specify the patient is at low risk, on therapeutic anticoagulation, or has contraindications to prophylaxis. While this approach is appealing for the simplicity and effectiveness in inducing high rates of anticoagulant prophylaxis, it can easily result in over-prophylaxis, which is a particular concern in medical populations.<sup>12</sup>

Both ACP and AT9 guidelines<sup>13,14</sup> discourage the universal prophylaxis approach for this population. On the other hand, opt-out mechanisms can be appropriate for some services with uniformly high VTE risk. For example, an orthopedic surgery service focused on total hip replacement might have default orders for their preferred anticoagulant and mechanical prophylaxis in place, or colorectal surgeons with high volumes of cancer surgery might have combination prophylaxis as a default.

### ***Qualitative Models Versus Quantitative Risk Models***

Qualitative models ascribe groups of patients to broad risk categories or “buckets” of risk that are linked to appropriate prophylaxis options for each group, without going through individualized point scoring. These models tend to be relatively easy to use and have demonstrated success in the literature and unpublished experience in reducing HA-VTE. They have sometimes been criticized for being too simplistic and for setting too low a threshold for initiating prophylaxis. This threshold varies among the different models, however, and can be adjusted to be more discriminating.

AT8<sup>15</sup> and most major international guidelines incorporate qualitative models, whereas AT9 now implicitly endorses the individualized, quantitative approach, which requires summing a cumulative point score over multiple risk factors.<sup>16</sup> The risk factors are often weighted to reflect the variable impact of each risk factor. These quantitative, or point-based, scoring systems may be devised by expert opinion and review of the literature; they can also be derived empirically. External validation in other populations, while desirable, has only been performed on a few models.

Ideally, empirically derived models are scientifically sound and preferable to expert models, but the expert-derived models (Caprini and Padua, for example) are in more common use, and at least some of them have anecdotal evidence of effectiveness in clinical practice. The complexity of the scoring systems varies, but in general, these models have often been criticized for being difficult to implement and use—and, to date, effectiveness in reducing HA-VTE has not been demonstrated. Some of these models incorporate risk factors (e.g., length of stay, intensive care unit [ICU] days) that are not available to the provider on initial assessment and are better suited for reassessments during the stay or for raising the issue of extended duration prophylaxis. Others use only risk factors available at the time of admission to the hospital.

The next section looks at selected qualitative and quantitative models.

### **Qualitative/Grouping Models**

The most widely used qualitative model in the United States is the “**3 bucket**” or **University of California (UC) San Diego model**, which is derived directly from tables in the AT8 guideline.<sup>15</sup> It was disseminated widely in the earlier version of this AHRQ VTE prevention guide.<sup>17,18</sup>

In the classic “3 bucket” model (Figure 4.2), observation patients, patients with an expected hospital stay of 2 days or less, most same-day surgery patients, and patients with no acute HA-VTE risk factors are designated low risk, with a recommendation for ambulation and education. On the other end of the spectrum, patients with major, high-risk surgeries qualify for combination anticoagulant and mechanical prophylaxis. Most medical and surgical patients fall into the middle category, qualifying for anticoagulant thromboprophylaxis, unless they have bleeding risk factors.

In the original demonstration project at UC San Diego, this model was chosen after considering and rejecting more complicated individualized point-scoring systems that proved unpopular and had poor inter-observer agreement in pilot testing. In contrast, this risk assessment model was considered intuitive and easy to use. Direct observations revealed that it could be filled out in a few seconds, and there were high levels of inter-observer agreement. Integration into order sets, coupled with multifaceted interventions, resulted in marked improvements in protocol-defined adequate prophylaxis (from 58 percent to 98 percent) and reduced HA-VTE by 40 percent in medical and surgical populations without any increase in detectable bleeding or heparin-induced thrombocytopenia.<sup>19,20</sup>

**Figure 4.2: Classic “3 Bucket” Model Derived From AT8**

<b>Low Risk:</b> Minor surgery in mobile patients. Medical patients who are fully mobile. Observation patients with expected hospital stay <48 hours.	No prophylaxis; reassess periodically, ambulate.
<b>Moderate Risk:</b> Most general, thoracic, open gynecologic, or urologic surgery patients. Medical patients, impaired mobility from baseline or acutely ill.	UFH or LMWH prophylaxis*
<b>High Risk:</b> Hip or knee arthroplasty, hip fracture surgery, multiple major trauma, spinal cord injury or major spinal surgery, abdominal-pelvic surgery for cancer.	IPCD <b>AND</b> LMWH or other anticoagulant*

\* For those at moderate or high risk and contraindications to anticoagulation, use intermittent pneumatic compression device (IPCD).

A wide variety of other hospitals have enjoyed improved prophylaxis and reduced HA-VTE with a multifaceted approach that included variants of this VTE risk assessment model. This includes published results<sup>19,21</sup> and many unpublished results. Some of these site success stories are available online (<http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/vtguide5.html>). Large-scale VTE prevention collaborative efforts from SHM, AHRQ/QI organization partnerships, and many others have reported similar positive results, but these efforts did not have a standardized method to monitor outcomes.<sup>22,23</sup>

This model was updated (Figure 4.3) to be more discriminating in terms of a higher threshold for who receives thromboprophylaxis, in a manner more consistent with AT9 guidance to avoid prophylaxis in those at low risk. Note that medical patients without active cancer or past history of VTE must have reduced mobility and an acute illness to qualify for prophylaxis. This version offers more granular guidance at the expense of being slightly more complex.

**Figure 4.3: Updated “3 Bucket” Model In Use at UC San Diego**

<b>Low Risk:</b> Observation status, expected LOS <48 hours. Minor ambulatory surgery unless multiple strong risk factors. Medical patients ambulatory in hall and not moderate or high risk. Ambulatory cancer patients admitted for short chemotherapy infusion.	No prophylaxis; reassess periodically, ambulate.
<b>Moderate Risk (most general medical/surgical patients):</b> Most general, thoracic, open gynecologic, or urologic surgery patients. Active cancer or past VTE/known thrombophilia in medical patient with LOS >48 hours. Medical patients with decrease in usual ambulation <b>AND</b> VTE risk factors (myocardial infarction, stroke, congestive heart failure, pneumonia, active inflammation/infection, dehydration, age >65).	UFH or LMWH prophylaxis*
<b>High Risk:</b> Hip or knee arthroplasty, hip fracture surgery, multiple major trauma, spinal cord injury or major neurosurgery, abdominal-pelvic surgery for cancer.	IPCD <b>AND</b> LMWH or other anticoagulant*

\* For those at moderate or high VTE risk and contraindications to anticoagulation, use IPCD alone until bleeding risk subsides.

A model at the University of California, Davis (available online at <http://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/ucdavismodel.pdf>), deserves mention as an innovative approach that has lent itself to ongoing, dynamic risk assessment and active surveillance and has been associated with a significant decrease in HA-VTE (unpublished data as of yet).

Note the approach to ambulation taken in these models. Ambulation is not judged to be so protective as to eliminate the need for inpatient prophylaxis in patients with strong risk factors, such as active cancer, history of VTE/thrombophilia, and moderate to major surgery in the prior 7 days. On the other hand, most other medical conditions require reduced mobility *and* an acute illness to qualify for prophylaxis.

For all of these grouping variants, the following points should be kept in mind for implementation:

- Many include critically ill ICU patients in high-risk groups (this is reasonable but not directly supported by clinical trials).
- Patients on therapeutic anticoagulation can either be categorized as a low-risk population or be included in the contraindications to prophylaxis.
- Note that selected populations, such as elective cardiac surgery and some OB-GYN surgery, that may have IPCDs as a preferred first choice for prophylaxis would have their own order sets and be “carved out.” Alternatively, a fourth bucket for those who can have IPCD as a first choice could be added.
- Specific options for anticoagulant choices, dosing, and timing are presented in the actual order sets. They can be presented to the provider more simply if separate order sets are provided to selected services. For example, major orthopedic surgery patients have agents no one else uses in some hospitals, and the start time for anticoagulant prophylaxis will be different in medical and surgical patients. Having different versions for these patient populations can simplify the order sets and increase acceptance.

Many other variants of grouping VTE risk assessment models are in use across the globe,<sup>24-35</sup> including models from Australia and New Zealand,<sup>24-26</sup> Italy,<sup>27</sup> United States (Johns Hopkins),<sup>28-30</sup> and Great Britain (the NHS 2010 National Institute for Health and Clinical Excellence, or NICE, guideline).<sup>31-35</sup> Many of these models have shown clinical utility. Most are available for review in Appendix B online (<http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/appendixb.html>).

### **Expert-Derived Quantitative (Point-Scoring) Models**

**Caprini** pioneered individualized quantitative risk assessment models for both medical and surgical patients in the 1980s and 1990s, reasoning that a detailed and individualized risk assessment would be more accurate than those that describe broad categories of risk.<sup>36,37</sup> The model has been revised multiple times over the years, with the most recent version depicted in Figure 4.4, and with a computerized physician order entry (CPOE) implementation example.<sup>38-41</sup> Each individual weighted risk factor is designed to be checked off by the provider, with the cumulative score being used to place each patient into one of four risk categories, with different recommendations for each level.

The Caprini model is embedded in AT9 recommendations for VTE prophylaxis in the nonorthopedic surgical population.<sup>42</sup> It is not mentioned in the AT9 guideline for VTE prophylaxis in medical inpatients, but it is a commonly used point-based model for medical inpatients.

The model includes a scoring system with several sets of risk factors. One set is scored as 1 point for each risk factor, the second as 2 points, the third as 3 points, and the fourth as 5 points. Each set is scored to produce a subtotal, and the four subtotals are summed to yield the total risk factor score. The Caprini model is shown in Appendix B.10 (available online at <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/appendixb2.html>).

Until recently, the Caprini model was the only quantitative point-based model that had been externally validated as being predictive of VTE risk in general surgery, plastic surgery, and—in a modified form—in a sample of Jordanian oncology patients.<sup>40,43,44</sup> Recently, the Caprini model was found to be more sensitive to VTE risk in a retrospective cohort of Chinese patients with HA-VTE than the Padua or Kucher models.<sup>45</sup>

The Caprini model also has one published report of success in clinical practice, resulting in a reduction in HA-VTE. A layered combination of provider education, provider reminders with decision support, audit and feedback, and deployment of the Caprini tool resulted in an increase in appropriate prophylaxis from 63 percent to 96 percent, with an associated reduction in HA-VTE rate in a medicine department at a tertiary care hospital center.<sup>46</sup> In addition, the University of Michigan and University of Wisconsin both have unpublished records of success (the University of Michigan case study is presented in Chapter 5).

In spite of these impressive credentials, there are several caveats to those considering the use of individualized point-based models such as the Caprini model (see box below).



### Caveats Regarding Use of Caprini Model

In spite of these impressive credentials, there are several caveats to those considering the use of individualized point-based models such as the Caprini model. First and foremost is the relative complexity of the tool and the difficulty many sites have integrating the risk assessment into order sets. Experience from collaborative improvement efforts suggests that, for many hospitals, the model is too complex to be used reliably.<sup>22,23</sup> Clinicians often simply bypass the CDS offered in the tool rather than checking off all risk factors, adding up the point total, and identifying the appropriate prophylaxis choices based on the point total.<sup>22</sup>

A Michigan Hospital Medicine Safety Consortium funded by Blue Cross Blue Shield of Michigan and the Blue Care Network enrolled 43 hospitals in an effort to reduce HA-VTE in medical inpatients. The great majority of hospitals used the Caprini risk assessment model (RAM). The effort failed to reduce HA-VTE in a large cohort of noncritically ill patients, even in centers with relatively high adherence. It is unclear if this lack of progress is attributable to most hospitals using the Caprini model. In fact, hospitals with high rates of prophylaxis in this cohort did not have significantly lower rates of HA-VTE.<sup>47</sup>

This disconnect between higher rates of prophylaxis and VTE rates could stem from several factors. The population in this study represented a relatively low-risk patient group. Patients with any ICU days, VTE in 6 months prior to admission, and admissions that represented readmissions from the registry were excluded, and the definition of “at risk for VTE” required a score of  $\geq 2$  points, a relatively low threshold for inclusion. Median length of stay was just 4 days; although most VTE events were diagnosed postdischarge, the surveillance bias reported in surgical populations might also play a role.<sup>48</sup>

Complex point-based RAMs can suffer from poor inter-observer agreement when users attempt to apply them toward patient case scenarios in the literature; this proved the case in the pilot testing at UC San Diego.<sup>19,49</sup> There may also be a limited discriminatory ability for low-risk patients. In an external validation study performed in surgical patients, only 0.9 percent of patients were defined as low risk not requiring prophylaxis; 10.4 percent were classified as moderate risk, in whom anticoagulation was optional.<sup>40</sup>

A closer look at sites that have documented success also raises some important caveats. There is only one published report of clinical success with reduced HA-VTE, even though the tool has been widely available for more than 30 years. The successful published site used a multifaceted approach and limited its efforts to general medicine residency teaching teams. This effort enjoyed the support and “authority gradient” from faculty attending physicians, who cosigned the VTE risk assessments.<sup>46</sup>

In the unpublished experience at the University of Michigan, success with the Caprini RAM hinged on skillful deployment of a number of CPOE techniques outlined in more detail in Chapter 5. Although electronic health records and CPOE are becoming more and more common, this level of CDS capability remains the exception rather than the rule. At the University of Wisconsin, a safety net of pharmacy providers specifically tasked with double checking the accuracy of admission VTE risk assessment ensured otherwise poor compliance with the tool. Dr. Caprini has also suggested that it is possible to capture the VTE risk information from history and physical forms, especially for elective surgical procedures.<sup>41</sup>

In summary, the Caprini VTE RAM was the first quantitative model to enjoy wide use, and until recently was the only model to be externally validated for prediction of VTE risk. The relative complexity of the model has been overcome with closely supervised environments that enjoy an authority gradient, intelligent use of sophisticated CDS, or a safety net of nonphysician providers who redundantly check accuracy of scoring. These strategies can augment the success of any VTE RAM, but they may be more of a necessity for this model. Sites considering the Caprini VTE RAM may want to carefully consider the relative strengths and limitations and consider whether they have the environment and tools demonstrated to minimize the model’s limitations.

**The Brigham and Women's Hospital Model (aka the Kucher model;** see Appendix B11 online at <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/appendixb2.html>) is a weighted scoring system with eight risk factors. Patients with a cumulative score of  $\geq 4$  points are considered to be at high risk. This model was not designed as a screening tool to be embedded in admission order sets. Rather, it was designed to define a known high-risk population to target with computerized alerts. It is not a sensitive instrument to capture all patients at risk. In a randomized trial, an increase in prophylaxis and a decrease in VTE by 41 percent resulted when computerized alerts were sent to providers of patients with scores  $\geq 4$  but not on prophylaxis.<sup>50</sup> Physicians had to acknowledge the computer alert but could hold prophylaxis at their discretion. Similar results were obtained in an environment without the capacity for a computerized alert (in which a human alert was used instead).<sup>51</sup> The Kucher model has not been tested as a VTE RAM embedded in order sets.

The **Padua VTE RAM** (see Appendix B 12 online at <https://admin.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/appendixb2.html>) is derived from the Kucher model, and it is designed to address medical inpatients.<sup>52</sup> Like the Kucher model, active cancer, previous VTE, and known thrombophilia patients receive a weighted score of 3 points, but patients with bathroom privilege level of ambulation or less are also given 3 points, along with a few other modifications of Kucher. A score of  $\geq 4$  was associated with an HA-VTE risk of more than 11 percent in patients without prophylaxis in this Italian cohort study, while those with a score of  $< 4$  (approximately 60 percent of the Italian cohort) had a VTE risk of only 0.3 percent. The high predictive value of the model in the Padua population led the AT9 guidelines to prominently highlight the Padua VTE RAM, which many have taken as an implicit endorsement of the model.<sup>14</sup>

There are several limitations and caveats to consider. The Padua results have not been externally validated. The high predictive value of this model seen in this small Italian cohort seems almost too good to be true and is not consistent with the results of much larger observational studies described later in this chapter. More than 1 percent of patients with a Padua score of 3 suffered from pulmonary embolism, raising questions about the adequacy of sensitivity in the model.<sup>1</sup> A recent study found the Padua model inferior in predictive ability compared with the Caprini model.<sup>46</sup>

The Padua RAM has never been tested or shown to be effective as a VTE RAM in order sets. Since it is designed specifically for medical inpatients, medical centers wishing to use the Padua model require an entirely different VTE RAM for surgical populations.

### **Empirically Derived Quantitative (Point-Scoring) Models**

Typically, in empirically derived qualitative models, a VTE risk stratification tool is developed by applying multiple logistic regression modeling to a large inpatient population. Ideally, in the next step, the model is applied to a validation sample, and the predicted VTE incidence from the model is compared with the actually observed VTE incidence. The predictive accuracy of the model is summarized in a c-statistic, the area under the receiver operating curve (ROC curve), with the best scores approaching 1.0 and the worst being 0.5.

In an ideal world, the model would go through external validation in different patient populations to assess the generalizability of the model, and then an assessment of the clinical utility of the VTE RAM would be carried out.<sup>2-4,53</sup> To date, external validation has only been performed on one of these models (modified IMPROVE model with seven factors) and the clinical utility step has not been accomplished with any of them.

The **Rogers risk assessment model** was derived from more than 183,000 surgical patients.<sup>54</sup> This complex model with 15 weighted risk factors has never been used in clinical practice and is mentioned only because the AT9 guideline recommendations for nonorthopedic surgery patients mention the Rogers model within its recommendations, along with the Caprini model.<sup>55</sup>

The **Intermountain** model found prior VTE, known thrombophilia, bed rest orders, and placement of a peripherally inserted venous catheter (PICC) to be the most powerful predictors of VTE in medical inpatients.<sup>56</sup> Other risk factors, such as cancer, obesity, age >70, and other commonly reported risk factors, did not add significantly to the c-statistic score of 0.74 (originally published as 0.84, corrected in later erratum). The authors did not specifically report on how often the model would have missed VTE cases, and there is no experience reported using the model clinically.

The **IMPROVE** investigators leveraged a VTE registry to derive two kinds of VTE RAMs (see Appendix B14 online at <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/appendixb2.html>) in medical patients.<sup>57</sup> One model identified four factors available at admission that were most predictive of VTE during and up to 3 months after hospitalization. Patients with a score of 2 or 3 had a VTE risk of 1.9 percent, while those with a score of  $\geq 4$  had a risk of 5.0 percent. The authors proposed that patients with scores  $\geq 2$  (just 11 percent of the cohort) could benefit from prophylaxis with data available on admission, while the majority of patients with lower scores might not.

The predictive value of this model was relatively low with a c-statistic of 0.65. Also, setting the threshold for prophylaxis this high would essentially be giving up on preventing two-thirds of VTE in medical inpatients. A large proportion (56 percent) of the population with an IMPROVE score of 1 had a VTE risk of 1 percent, generating half of the VTE in the cohort, and this moderate threshold for prophylaxis may be appropriate for patients without significant bleeding risks. Patients with a score of zero, representing one-third of the cohort, had an observed VTE risk of 0.5 percent and suffered 17 percent of the VTE in the cohort. This study and the other large studies used to empirically derive RAMs likely portray a more realistic distribution of VTE risk than the smaller Padua study.

A second model that included three more factors that evolved over the course of hospitalization (lower limb paralysis, immobilization  $\geq 7$  days, admission to ICU or CCU during the hospital stay) was marginally better, with a c-statistic of 0.69. Patients with a score of 0 or 1 (69 percent of the medical cohort) had a 3-month VTE rate of <1/person, while those with higher scores had rates of 1.5 percent and up.

Recently, there have been two external validation studies of the 7-factor IMPROVE VTE RAM to predict VTE risk at 90 days posthospitalization. The first reported an improved c-statistic of 0.773.<sup>58</sup> In the validation cohort, the incidence of VTE was 0.20 percent, 1.04 percent, and 4.15 percent in the low- (score 0-1), moderate- (score 2-3), and high-risk (score  $\geq 3$ ) groups, respectively. In the second external validation study, 68 percent of the cohort with a score of 0 to 2 had a VTE event rate of 0.42, while patients with a score  $\geq 3$  had a VTE event rate of 1.29.<sup>59</sup> The vast majority of the VTE events occurred in the 90 days postdischarge rather than during the index admission. A length of hospital stay  $\geq 7$  days served as a proxy for prolonged immobility. The c-statistic was 0.702.

Modified versions of this second model are being deployed in clinical trials to identify potential high-risk medical patients for extended duration prophylaxis. While this approach to stratify patients for extended duration prophylaxis with the 7-factor variant is promising, it has not yet been shown to improve clinical care. Because the 7-factor VTE risk model includes some things (such as prolonged immobilization and critical care days) that are not always apparent on admission, utility as an admission VTE RAM may be limited. The IMPROVE model also provides a bleeding risk calculation juxtaposed with VTE risk (see **Assessing Bleeding Risk**, below).

The **Premier VTE Risk Model** was derived through analysis of a very large database representing all regions of the United States.<sup>60</sup> Age, sex, and 10 additional risk factors were associated with VTE during and up to 30 days after the hospital stay. They included risk factors that developed during the hospital stay as well as factors present on admission. The strongest risk factors identified were known thrombophilia, hospital stay  $\geq 6$  days, inflammatory bowel disease, central venous catheter placement, and cancer (among adults  $< 65$  years). The c-statistic for the validation set was 0.75. Their captured rate of VTE was lower than similar studies. The authors did not provide a practical weighted scoring system and, like the preceding models, this model has not been applied in clinical practice.

**Table 4.1: Characteristics of Four Empirically Derived Models for VTE Risk**

	Rogers <sup>53</sup>	Intermountain <sup>55</sup>	IMPROVE <sup>56</sup>	Premier <sup>58</sup>
Hospitals	142	22	52	374
Country	U.S.	U.S.	12 countries	U.S.
Design	Prospective	Retrospective	Prospective	Retrospective
Participants	Surgical	Medical	Medical	Medical
Derivation n	91,535	143,975	15,156	194,198
Validation n	91,534	46,856		48,540
% with VTE				
Derivation	0.6%	3.6%	1.2%	0.4%
Validation	0.6%	4.5%		0.5%
% with cancer	<3%	44%	22%	14%
Followup (days)	30	90	92	30
Prophylaxis	NS	NS	44%	30%
UE DVT	NS	Yes	No	No
Predictors	15	4	4	17
c-statistic	0.73	0.74	0.65	0.75

Table 4.1 summarizes the characteristics of these models and helps to illustrate the continuing reasons for controversy and lack of agreement among the models. There is a tenfold variation in the incidence of HA-VTE. There is variability in the proportion of patients on prophylaxis, and how this potential confounder is controlled for—or, in some cases, the proportion of patients on prophylaxis is not specified (NS). Methods to identify cases and the duration of followup after discharge varies. The cohorts used for validation vary for the distribution of important risk factors such as cancer and age. Upper extremity DVT and distal DVT are included in some models, but not others, and some include risk factors known only after a considerable length of time in the hospital.

Risk factors that are potent predictors in one model are seemingly inconsequential in the next. External validation and reports of the clinical utility of the models, with demonstrated reduction in HA-VTE, are not available for any of them. Some models, particularly the IMPROVE model, show some promise for beneficial clinical use in medical patients, especially for reevaluation of risk during hospitalization or to risk stratify for potential extended duration prophylaxis.

### **Assessing Bleeding Risk**

Bleeding risk is weighed along with a concurrent VTE risk assessment. Bleeding risk may be increased by surgery, medications, or factors inherent to the patient. A recent observational study by the IMPROVE investigators reported on factors found to be most predictive of in-hospital bleeding in medical patients.<sup>61</sup> Active gastroduodenal ulcer, active bleeding within 3 months prior to admission, and a platelet count  $<50,000$  were the strongest independent risk factors. Age  $\geq 85$  years, hepatic failure with an INR  $>1.5$ , GFR  $<30\text{mL}/\text{min}/\text{m}^2$ , ICU or CCU admission, central venous catheter, rheumatic disease, cancer, and male gender rounded out the list in order of descending importance.

A point-scoring quantitative model was built to predict bleeding risk, analogous to the quantitative VTE risk models. One half of bleeding episodes occurred in the 10 percent of patients with a high ( $\geq 7$ ) score. This model has not been externally validated, and the scoring model is cumbersome to integrate into clinical practice. However, the AT9 panel considered bleeding risk to be excessive if patients had any one of the top three risk factors or multiple other risk factors.<sup>14</sup> Note that several of these risk factors are also frequently listed as risk factors for VTE. A patient age 86 and with cancer, for example, may still be considered for prophylaxis, even though both are considered risk factors for bleeding. Most hospitals avoid complicated scoring systems for bleeding risk and instead provide lists of bleeding risk factors to consider. Explicit definitions of “leeway” times for short-lived bleeding risk factors can also guide assessment of prophylaxis in audits, as well as guide therapy at the point of care. Table 4.2 depicts one example; several others are available in Appendix B.

**Table 4.2: Bleeding Risk Factors and Conditions To Consider With Pharmacologic VTE Prophylaxis**

Active bleeding (last 3 months unless low risk profile on endoscopy)	Intracranial bleeding within last year or until cleared by neurological services
Active gastroduodenal ulcer	Intraocular surgery within 2 weeks
Platelet count <50,000, or <100,000 and downtrending	Untreated inherited bleeding disorders
Therapeutic levels of anticoagulation	Hypertensive urgency/emergency
Advanced liver disease with INR >1.5	Postoperative bleeding concerns*
Heparin induced thrombocytopenia (no heparinoids; consider consultation)	Epidural/spinal anesthesia within previous 4 hours or expected within next 12 hours

\* Leeway times:

- 24 hours maximum for most general surgery, orthopedic surgery
- Status posttransplant or multiple major trauma to clear bleeding risk: 48 hours
- Status post spinal cord open surgery: 5 days leeway

## Chapter 5. Implement the VTE Prevention Protocol

This chapter provides guidance to bring the VTE prevention protocol effectively to bear at the point of care and to build out the infrastructure for monitoring and measuring this work.

### The Importance of Effective Implementation

After reviewing the evidence and selecting a venous thromboembolism (VTE) risk assessment model, the improvement team will begin gearing up for the all-important implementation phase. If performed skillfully, implementation of the VTE prevention protocol into orders at the point of care will lift adequate prophylaxis rates to 80 percent or more and set the stage for effective measurement, monitoring, and other interventions to eventually reach Level 5 on the Hierarchy of Reliability (see Table 1.1).

Skilled implementation can overcome the weakness of a suboptimal VTE prevention protocol; similarly, flawed implementation of an excellent VTE prevention protocol will result in mediocrity and failure to reach the goal of reducing hospital-associated VTE (HA-VTE). Effective implementation of the VTE prevention protocol addresses the first four failure modes discussed in Chapter 2:

- No standardized protocols or order sets for VTE prevention exist.
- Order sets and prompts that reference VTE prevention are in place, but they provide inadequate guidance.
- Order sets with guidance are in place, but the order set is bypassed or not used.
- Order sets with guidance are in place and used, but used incorrectly.

With implementation, the improvement team will want to add more granular detail to the general VTE risk assessment models depicted in Chapter 4. For example, dosing of unfractionated heparin and low-molecular-weight heparin (LMWH) needs to be spelled out, and the mechanisms and responsibility for dosing adjustments for renal failure, obesity, and other conditions have to be defined. In addition, the team will want to engage with different services to determine which ones will need a variation from the general VTE prevention protocol. The potential pitfalls in these steps are numerous, and adding more layers of guidance for special populations can lead to complexity and poor efficiency of ordering.

Well-developed and effective clinical decision support (CDS) involves getting the right information, to the right people, in the right intervention formats, through the right channels, at the right points in workflow.<sup>1</sup> A clinical decision template that outlines different desired functionality at each stage may help an implementation team think about building optimal CDS and measurement into different steps in the process of delivering optimal prophylaxis to the patient.

It is helpful at this point to identify the principles for effective implementation of VTE protocols in CDS. These principles bring the protocol guidance effectively to bear at the point of care and build the infrastructure for other interventions and monitoring. This can save effort and time down the road.

## Five Principles for Effective Implementation in Clinical Decision Support

### ***Principle 1: Keep It Simple for the End User***

Improvement teams must strike a fine balance between providing a good risk assessment for the majority of the inpatient population and keeping the process simple and efficient for the end user. Almost always, simpler is better and less is more. Usability is immensely important, and success or failure may hinge on it.<sup>2</sup>

It is far more effective to provide less guidance in the time and space where prophylaxis is ordered. For substantial minority populations with special needs (e.g., OB/GYN, spinal surgery, or cardiovascular surgery patients), a dedicated order set tailored to them is likely a better approach than inserting details about these populations into a general medicine or surgery VTE prevention order set.

It is important to involve frontline ordering providers to make sure the VTE protocol is easy to use. Without their input, implementation will not go smoothly.

It is also important to minimize the calculations and data entry end users have to make and to automate the process for them. Even ticking off multiple risk factors for VTE in a point-based model becomes a tiresome task many providers will skip, particularly if it is already evident to them what prophylaxis is needed. For some risk factors or contraindications, it may help to auto-populate data elements from elsewhere in the record. Age, body mass index, creatinine clearance, already prescribed antiplatelet or anticoagulant agents, and platelet counts are a few examples of discrete data elements that could be auto-populated.

There are at times several acceptable options for prophylaxis, and there are often multiple choices for a given LMWH or oral anticoagulant. Improvement teams can simplify the work for the end user and reinforce standardization by streamlining the choices. For example, while the 9<sup>th</sup> edition of the American College of Chest Physicians on Antithrombotic Therapy and Prevention of Thrombosis (AT9) allows a wide variety of prophylaxis options for major orthopedic surgery, the protocol might only list the preferred institutional choices.

### ***Principle 2: Do Not Interrupt Workflow***

In general, an intervention that interrupts workflow will be rejected. This has several implications for design and implementation of VTE prevention order sets.

VTE prevention order sets enjoy the highest utilization when they simply appear as a module that is fully integrated into admission and transfer order sets that are already in use, rather than as a standalone order set clinicians must go out of their way to identify and choose. For example, confusion and workflow interruption can occur if nurses and physicians on the floor are not in sync on how the risk assessment is managed.

The VTE risk assessment and bleeding risk assessment are ideally performed quickly and concurrently when the choices for that combination of risks are presented directly to the provider, without interruption by intervals in time or space. In some computerized physician



order entry (CPOE) systems, after a VTE risk level is determined, the appropriate prophylaxis options for the chosen level of VTE risk emerge from their nested position under the risk designation. In other CPOE systems, the risk assessment data entered on the first screen trigger the appearance of a second screen that contains only the choices appropriate for that level of risk in an algorithmic fashion. In these cases, the ordering provider is not asked to remember the risk designation from a previous screen, add up points, and so forth. These tasks are either done for the provider or are eliminated from the process to provide a smooth and uninterrupted workflow.

### ***Principle 3: Design Reliability Into the Process***

Part of the improvement team's job is to engineer higher reliability into the process of preventing HA-VTE. To achieve breakthrough improvement, the team must move beyond traditional methods (e.g., personal checklists, working harder next time, and education) to design order sets and reinforcing interventions that use at least one of the following high-reliability strategies:

- The desired action has a ***forcing function***. Completion of a VTE prevention order set can be made mandatory by a forcing function. An electronic or human forcing function ensures that every patient being admitted or transferred in the hospital undergoes a VTE risk assessment.
- The desired action is the ***default*** action (i.e., not doing the desired action requires opting out). Only the protocol-preferred choices can be presented to ordering providers for any given combination of VTE and bleeding risk they designate. Choices other than those on the preferred list can be made, but a clinician must first explicitly opt out. For example, a progressive ambulation/mobility protocol can be made the default mode for physical therapy and nursing to pursue unless the physician provides guidance and opts out of that pathway.
- The desired action is ***prompted*** by a reminder or a decision aid. A daily reminder to reassess and certify the need for a central venous catheter is an example that can reduce upper extremity deep vein thrombosis (DVT) and line-associated infections.
- 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). Standardized order sets with embedded risk assessment are an obvious example. Surveying existing order sets impacting VTE prophylaxis as part of the initial needs assessment, and replacing outdated VTE prevention order sets with new standardized ones, can help to discourage physicians from making up their own personal order sets and bypassing the standardized pathways.
- The desired action is ***scheduled*** to occur at known intervals (e.g., integrating DVT prophylaxis assessments into a larger quality and safety checklist to be reviewed daily).
- Responsibilities for a desired action are ***redundant***. If nurses were to focus on patients who were not already on prophylaxis, for example, and to use the same protocol that physicians were using, their redundant check of VTE prophylaxis could be efficient and useful. An electronic alert might provide some of the same functionality.

If designed well, the VTE protocol will be an intervention that invokes several of these high-reliability strategies.

### ***Principle 4: Pilot Interventions on a Small Scale***

Piloting on a small scale creates opportunities to iron out glitches before implementing more broadly. Small-scale pilots can be as simple as a 5-minute focus group where five physicians give feedback on several versions of the protocol. Taking an order set out for a “test drive” is far more effective, however, when the pilot risk assessment and order set are applied to patient case scenarios, as ease of use and issues of ambiguity become much more apparent. Piloting measurement and monitoring techniques with early assessment is also highly recommended.

### ***Principle 5: Monitor Use of the Protocol (and Plan for Measurement)***

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

A central challenge of standardization is constructing protocols that work for the great majority of patients while allowing for individualization of treatment. It is reasonable to anticipate variations from the protocol, but the team should capture these instances, learn from them, and take steps to reduce them. When providers bypass the protocol, their reasons might derive from logistics and deviations from normal workflow rather than resistance to the concept of standardization. Questions the team can ask include:

- 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 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 (if on paper) and in the workflow in all the key areas in the hospital?

The team will also want to plan for measurement. Automating measures is easier if planned into the process at inception. Meeting with the CPOE and/or the information technology team early and often about order set design and how to make measurement an integral part of the process can help. Some examples to consider:

- Storing information as discrete data elements as they can be recalled and organized into meaningful reports more easily than free text.
- Capturing all data element choices in the ordering process, including the declared DVT risk level and any contraindications to anticoagulant prophylaxis.
- Making graduated compression stockings or intermittent pneumatic compression devices (IPCDs) orders into discrete data elements, as well as the documentation for whether they are in place and turned on. A nurse could, for example, be asked to chart each shift whether IPCD was on or off and, if off, a pull-down menu could capture the reason.

- Capturing ambulation status as a discrete data element in monitoring adherence to protocols. Agree on an operational definition of full versus impaired mobility and structure documentation to routinely capture whether the patient is meeting that standard. Many centers have adapted definitions such as “ambulates independently outside of room twice daily” or “ambulates 50 feet or more independently.”

It may help to also think ahead about how to audit patients and determine whether they are on protocol-directed, adequate prophylaxis. In general, complexity of risk assessment in the ordering process will lead to similar complexity in monitoring whether patients are on appropriate prophylaxis. The importance of ease of use applies to both the ordering process and the measurement tools the team will need to deploy.

A properly designed order set, when well positioned and implemented, will prevent errors and get most patients on the correct prophylaxis. Monitoring order set use, and designing an ongoing process to identify patients who have fallen through the cracks, can spur mitigation of lapses in care concurrently. Finally, redesign of the process and order sets should continue to improve the system.<sup>3,4</sup>

### **Three Examples of Effective Implementation and Clinical Decision Support**

The following are examples of effective order set design and implementation. They illustrate the central importance of implementation and clinical decision support techniques across disparate hospital settings and VTE risk assessment models.

The **Johns Hopkins** collaborative team used the “translating research into practice” (TRIP) model to implement mandatory VTE risk assessment and risk-appropriate prophylaxis.<sup>5</sup> The TRIP model is consistent with the principles presented throughout this guide. Important steps included summarizing the evidence from a centralized steering group; identifying barriers through pilot testing, good measurement, and feedback; and reinforcing appropriate prophylaxis through staff engagement, education, regular evaluation, good clinical decision support in order sets, and layered interventions to reinforce the protocol.<sup>6</sup>

The Johns Hopkins team created VTE prevention decision algorithms for 16 distinct service groups (medicine, general surgery, trauma, and so forth) and integrated those algorithms into “smart” order sets. Order set implementation in medicine inpatient populations resulted in an increase in risk-appropriate prophylaxis and a large reduction in documented symptomatic VTE detected during or within 90 days after hospital discharge without any change in major bleeding or all-cause mortality.<sup>7</sup> Implementation on trauma and surgery services enjoyed similar results.<sup>7,8</sup>

The risk assessment models this team used had some drawbacks. They were complex to use and not well used in paper form, and the threshold for prophylaxis in some models was much lower than the threshold supported by the AT9 guidelines in many cases (e.g., medical patients qualify simply by having a “major” risk factor of age >60 years).

The Johns Hopkins model is presented here for its effective approach to implementation, rather than to highlight the risk assessment model itself. The keys to successful implementation included advanced CDS integrated into CPOE versions of the tool.

Johns Hopkins Internal Medicine used several of the key principles of CDS. A forcing function made risk assessment mandatory, and the order sets were embedded in medicine admission orders. The tool was made easier to use by displaying relevant clinical data for risk assessment, automatically pulling in some data elements from the EHR, and by displaying default choices for prophylaxis corresponding to the VTE and bleeding risk factors chosen by the provider. Completion of the VTE risk assessment, risk level, and alignment with protocol guidance was explicitly captured to raise situational awareness at the point of care and for monitoring and feedback. Careful order set design therefore reached Level 3 on the Hierarchy of Reliability and set the stage for further progress and interventions. A slide presentation on the model is available online at <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/vtguide5.html>, courtesy of Dr. Michael Strieff.

The **University of Michigan** overcame the inherent complexities of the Caprini VTE risk assessment model with skillfully deployed CDS in CPOE. The improvement team adjusted its approach out of necessity and added more of the key principles of CDS outlined in this chapter after earlier attempts failed to achieve the desired results. Key strategies for success, arrived at over time, included targeting all adult inpatients, adding forcing functions with hard stops to guarantee a risk assessment was done, using algorithmic logic, grouping risk factors for the convenience of providers, and auto-populating some risk factors.

Importantly, the addition of risk score points is performed behind the scenes, with options appropriate for the point total displayed as the default prophylaxis choice. Note also the capture of VTE risk level, the dosing guidance for renal insufficiency, and the mandatory documentation of anticoagulation contraindications in those who defer risk-appropriate anticoagulant prophylaxis. In addition, a full suite of educational and faculty engagement techniques were used. The end result of this implementation effort was significant reductions in surgical and medical VTE rates. A slide presentation on the model is available online at <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/vtguide5.html>, courtesy of Marc Moote, PA-C.

**Banner Good Samaritan Regional Medical Center** participated in a Society of Hospital Medicine-sponsored mentored implementation collaborative and enjoyed a 59 percent reduction in total HA-VTE events, a 65 percent reduction in pulmonary embolism, and a 57 percent reduction in DVT. The comprehensive implementation effort included deployment of the CDS principles in reinforcing the medical center's VTE prevention protocol.

Certain key elements, such as weight and creatinine clearance, were pulled into the order set and made available to the ordering provider at the point of care. Mandatory selection of high, moderate, or low risk was mandated on admission and transfer. Risk-appropriate prophylaxis options were presented on declaration of VTE risk level, with dosing guidance for different situations and indications. Opting out of anticoagulant prophylaxis for moderate- or high-risk patients led to capture of anticoagulant contraindications and default choices for mechanical prophylaxis. Standardized timing of perioperative prophylaxis doses were offered as a default by designating the patient's status as surgical pre-op or surgical post-op.

The VTE risk level, orders, contraindications, and other data elements were captured and presented on the medication administration record and in transfers, and were also used to assist in monitoring prophylaxis patterns. Banner Good Samaritan used measure-vention, multiple methods to engage nurses and physicians, and audits to monitor and improve adherence to IPCDs. A slide presentation on the model is available at <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/vtguide5.html>, courtesy of Dr. Lori Porter.

## Chapter 6. Track Performance With Metrics

This chapter addresses the importance of measurement in tracking and preventing hospital-associated venous thromboembolism and discusses key metrics and strategies for using them effectively.

### The Importance and Purpose of Measurement

A good system of measurement is crucial to achieving a goal of optimal venous thromboembolism (VTE) prevention. The previous chapter discussed how to plan for measurement; this chapter explains measurement more fully and how to use it to meet your goals.

The inability to secure a good system of metrics for VTE prevention is among the most common sources of improvement team failure. This inability may reflect lack of institutional support and prioritization, failure to create a protocol with measurable operational definitions, or failure to appreciate which particular metrics can drive improvement efforts and effect real change.

Measurement serves several purposes. It is required to assess baseline performance and understand the health care delivery process. Many measures also satisfy public reporting and the reporting requirements of regulatory bodies, many of which are increasingly tied to reimbursement.

Metrics are necessary to monitor progress and the impact of interventions. Good measurement also informs ongoing improvement efforts and illuminates pockets of strengths and weaknesses (opportunities for improvement) within the system, allowing for smarter deployment of precious time and resources and concurrent remediation of failures in the health care delivery process. In addition, local data can raise the health care team's awareness of the need for improvement and can engage members in improvement efforts. Ultimately, a meaningful measurement system drives improved care.

### Categories of Measurement

Measures are commonly categorized as assessing structure, process, or outcomes, complemented by balancing measures that monitor for unintended negative consequences.

**Structural measures** assess the availability of organizational tools to support VTE prevention efforts. For example, does the institution have a VTE prevention policy in place? Are there standardized order sets incorporating clinical decision support that reinforce appropriate VTE prophylaxis? Is a measurement system in place?

**Process measures** examine the reliability of crucial steps in health care delivery. Examples in VTE prevention might include the percentage of patients who have a documented VTE risk assessment within 24 hours of admission, the percentage of patients with mechanical prophylaxis ordered that actually have compression devices properly in place, and order set utilization.

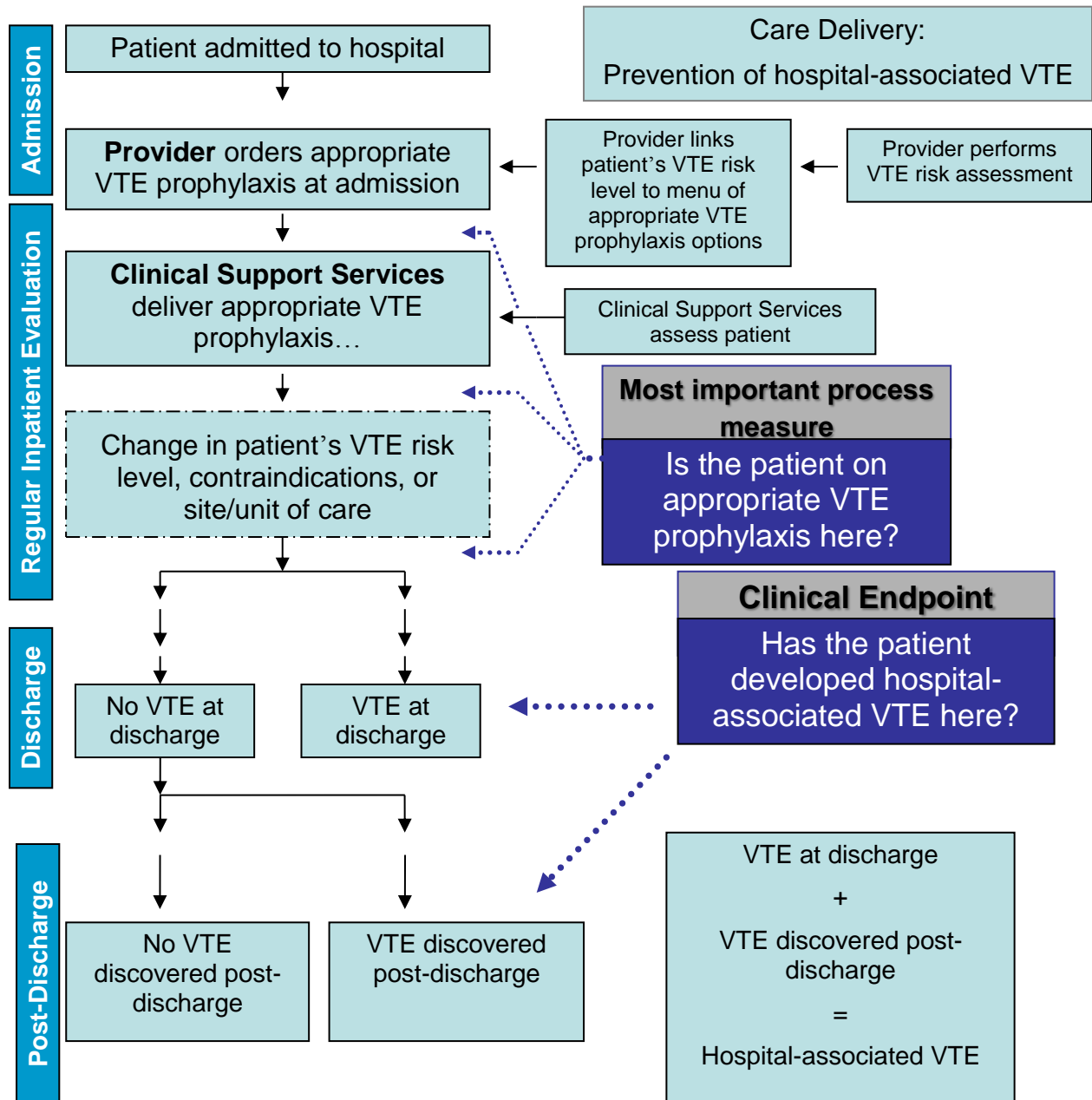
Good process measures are strongly linked to outcomes. The incidence of appropriate VTE prophylaxis has the potential to be just such a measure in populations with strong evidence of the efficacy of prophylaxis. Not only does it have the most causal relationship to the main clinical endpoint of hospital-associated VTE (HA-VTE), but it is also a sensitive indicator of how well the various care delivery steps come together. Defining “appropriate” implies that standardization and measurable operational definitions are in place, underscoring that the VTE protocol serves as the main ingredient not only for the improvement intervention but also for the measurement system that can track performance.

**Outcome measures** assess the impact of the effort on a clinical outcome. Specifically, in the context of this guide, an outcome measure is to safely reduce the incidence of HA-VTE and its associated morbidity, costs, emotional suffering, and mortality. This clinical endpoint is unsuitable as a lone metric for performance tracking, however, because the events are too infrequent, subclinical, or delayed in onset to provide timely and useful feedback to the team. Thus, it should be coupled with process and structural measures to accurately track performance.

**Balancing measures** monitor for potential unintended adverse consequences of interventions. This is a fourth category of measures that improvement teams may want to consider. For VTE prophylaxis, an important balancing measure would assess the incidence of bleeding complications attributable to anticoagulant prophylaxis.

Figure 6.1 illustrates care delivery at different stages and depicts an outcomes chain for HA-VTE. The outcome (whether a patient develops an HA-VTE) is linked to use of the order set, whether the patient was assessed and appropriately reassessed for VTE and bleeding risk throughout his or her stay, and whether ordered prophylaxis was reliably delivered. The most important summary process measure ascertains whether the patient is on appropriate VTE prophylaxis at different stages of hospitalization.

Figure 6.1: Outcomes Chain for HA-VTE



Whether or not a patient develops a preventable, hospital-associated deep vein thrombosis (DVT) or pulmonary embolism (PE) depends heavily on recent, appropriate VTE prophylaxis. While one key metric to track this is the process measure for the prevalence of “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 incidence of hospital-associated DVT or PE. HA-VTE includes VTE events detected during the index admission as well as those found in patients who were discharged without a diagnosis of VTE but present with VTE at some time interval after discharge (this guide uses 30 days; some go out to 90 days).

## Metric Selection

While an entire array of metrics may be useful, the two key metrics to focus on are the prevalence of appropriate VTE prophylaxis and the incidence of HA-VTE (with an important subset of potentially preventable HA-VTE). Publicly reported measures included in the National Hospital Inpatient Quality Measures for VTE prevention (Table 6.1) attempt to capture these two key metrics.

This section explains what the National Hospital Inpatient Quality Measures capture and how “appropriate prophylaxis” and HA-VTE rates can be measured more accurately and usefully in a project.

Table 6.1 depicts several National Hospital Inpatient Quality Measures for VTE. These VTE measures and others were developed as a set of aligned measures common to The Joint Commission and the Centers for Medicare & Medicaid Services (CMS).<sup>1-3</sup>

**Table 6.1: National Hospital Inpatient Quality Measures for VTE Prevention and Management**

Measure ID	Measure Abbreviated Name
VTE-1	VTE Prophylaxis
VTE-2	ICU VTE Prophylaxis
VTE-3	VTE Patients with Anticoagulation Overlap Therapy
VTE-4	VTE Patients Receiving UFH with dosages/platelet count monitoring by protocol or nomogram
VTE-5	VTE Warfarin Therapy Discharge Instructions
VTE-6	Hospital-Acquired Potentially-Preventable Venous Thromboembolism
STK-1	VTE Prophylaxis (in Stroke)
SCIP-VTE-2	Surgery Patients Who Received Appropriate VTE Prophylaxis Within 24 Hours After Surgery

**Note:** Many VTE measures are publicly reported and available on Hospital Compare (<https://www.medicare.gov/hospitalcompare/search.html>).

VTE-1, VTE-2, STK-1, and SCIP-VTE-2 pertain to the prevalence of appropriate VTE prophylaxis in different populations (see Key Metric 1, below), while VTE-6 focuses on tracking the incidence of potentially preventable HA-VTE. VTE-3, VTE-4, and VTE-5 are more relevant to the management of VTE.

Individual hospitals may already be collecting data on most if not all of these measures. In addition, the Health Information Technology for Economic and Clinical Health (HITECH) Act offers incentives for hospitals that meet specific meaningful use criteria for important health problems.<sup>4</sup> Meaningful use criteria to promote VTE prevention are aligned with VTE-1 and VTE-2 measures.

### **Key Metric 1: Prevalence of Appropriate VTE Prophylaxis**

Several measures focus on the proportion of eligible patients who receive prophylaxis. VTE-1 estimates the proportion of eligible patients who receive prophylaxis the day of or the day after hospital admission (or the day of or the day after surgery for surgeries that start the day of or the day after hospital admission) or have documentation of why no prophylaxis was given.

Exclusion criteria are patients <18 years of age, a length of stay <2 days or >120 days, patients with comfort measures only, and patients enrolled in clinical trials. VTE-2 is similar, but focuses on patients admitted or transferred to the intensive care unit (ICU); STK-1 focuses on stroke patients.



There are several limitations to this approach to measuring prophylaxis. First, the use of *any* prophylaxis equates with *appropriate* prophylaxis in these measures. Therefore, hospitals can appear to have very high performance on these measures even if the majority of patients do not receive adequate prophylaxis. For example, a critically ill cancer surgery patient with a host of VTE risk factors and no bleeding risk would pass the standard of care if he had only anti-thromboembolism stockings—even when guidelines would call for pharmacologic or combination prophylaxis. In addition, hospitals with radically different prophylaxis patterns and different levels of adequate prophylaxis might look exactly the same under this measurement approach.

Second, these measures reflect prophylaxis provided only during narrow time periods: on admission to the hospital, on admission or transfer to the ICU, or perioperatively. The ability to adjust prophylaxis after these time intervals pass is not assessed. Ideally, measures will capture prophylaxis across the patient stay, not during narrow 24-hour time periods.

Third, this approach uses retrospective data collection, leaving no opportunity to address deficits in care proactively.

SCIP-VTE-2 addresses one of these deficits in that it lists acceptable VTE prophylaxis options for each surgery addressed by the measure.<sup>2</sup> The choices are often (but not always) aligned with the ACCP guidelines (AT9), and improvement teams may want to review this measure for alignment with their VTE prevention protocol.

### **Strategies To Improve on the National Hospital Inpatient Quality Measures for VTE Prevention**

The limitations of the National Hospital Inpatient Quality Measures should not lead institutions to abandon them. Instead, improvement teams can deploy a number of strategies to leverage the data collection already being done, ensure very high performance on the measures, and address all of their limitations—thereby sparking accelerated improvement. The following strategies have been successfully used in a wide variety of hospitals in large-scale national collaborative efforts.<sup>5,6</sup> Improvement teams can review and prioritize which options are most feasible and impactful in their setting.

#### ***Change VTE-1, VTE-2, and STK-1 Into Measures of Appropriate Prophylaxis***

Data collection for these measures captures the type of VTE prophylaxis, if any, that the patient is receiving. Adding just a few more items to the team's audit tool can allow facilities to track the percentage of eligible patients receiving appropriate prophylaxis per the protocol. This additional information can also help the team understand where the process is failing so they can make appropriate adjustments.

Questions that could be added include:

- Was the standardized VTE order set used on admission or transfer to the unit?
- What was the risk level or score documented by the physician?
- What is the risk level or score from the reviewer evaluation?

- Does the VTE prophylaxis the patient is receiving match the choices listed in the VTE protocol?
  - If so, patient can be classified as having appropriate prophylaxis.
- If the risk level or score warrants anticoagulant prophylaxis but the patient is not on a protocol-accepted anticoagulant prophylactic agent:
  - Does the patient have a documented contraindication or condition that justifies using alternatives to anticoagulant prophylaxis?
- If the risk level or score warrants mechanical prophylaxis but the patient is not on a protocol-accepted mechanical agent:
  - Does the patient have a documented contraindication for mechanical prophylaxis?
- Final judgment: Is the current prophylaxis the patient is receiving appropriate, as defined by the VTE protocol?
  - Yes.
  - No, patient was under-prophylaxed, OR No, patient was over-prophylaxed.

### ***Proactively Review Patients in the First 24 Hours***

Proactively reviewing patients in the 24-hour window after admission or transfer can identify and address deficiencies in care very early in the hospitalization and improve performance on the National Hospital Inpatient Quality Measures for VTE. A review could quickly identify whether a patient is on an anticoagulant, mechanical prophylaxis, both, or neither. Many hospitals can pull those data elements into the report itself; others have a unit champion perform this review.

In its simplest version, the proactive review ends if either anticoagulant or mechanical prophylaxis is in place and the patient “passes”; those patients on no prophylaxis are reviewed more carefully to see if there is justification for the lack of prophylaxis (e.g., low risk, bleeding, mechanical prophylaxis contraindications). A more indepth review could also be performed for patients on mechanical prophylaxis alone to determine whether they meet the protocol definition of appropriate VTE prophylaxis. Scripted phone calls, pages, or notes can then be used, if appropriate, to contact the responsible prescribing provider to ask for clarification or a prophylaxis order.

### ***Perform a VTE Prevention Audit***

As noted earlier in this chapter, National Hospital Inpatient Quality Measures look at VTE prophylaxis at specific points in time during the patient’s hospitalization. However, VTE risk and bleeding risk can change during the course of a hospitalization. Therefore, measuring the prevalence of appropriate VTE prophylaxis across the length of the hospital stay is important.

One method for assessing VTE and bleeding risks throughout the hospital stay entails assessing appropriate VTE prophylaxis on a representative sample of patients. Assessing the adequacy of prophylaxis on active inpatients (rather than recent discharges) offers several real-time

advantages. It is faster and easier to do. In addition, providers can be alerted to prophylaxis oversights, which might create opportunities to improve care as well as to educate staff. Moreover, sampling active inpatients may allow insights into process barriers and valid reasons to amend the new processes to emerge more readily.

To track performance and advance Plan-Do-Study-Act (PDSA) cycles, the team will need just enough data to know whether changes are leading to improvement. A sampling strategy that uses 20 to 30 randomly selected patient charts per month can be statistically appropriate for most hospitals; it is also relatively quick and easy. To make the time commitment more manageable, charts can be audited each week with the results rolled up into monthly reports. A team member can be designated to collect, collate, plot, and manage the data.

Available data collection resources in any given hospital may dictate methods and definitions. Whatever method is chosen, consistency and usefulness are critical. It is often helpful to pilot the metric definitions and steps in data collection to identify and solve stumbling blocks. The team can also use PDSA cycles to perfect the performance tracking system. For example, to refine the VTE protocol and develop it as a valid audit tool, the team can use three independent reviewers to apply the protocol to audit 10 to 20 patients. (Appendix E contains case scenarios that can be useful to pilot protocols and measurement tools.) These principles apply to all the measurement strategies in this section, not just this strategy of auditing patients throughout their stay.

When you assess audit results, questions that should be answered include:

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

There are also questions that sequential pilots of the audit tool should help answer:

- How much time is acceptable in perioperative or trauma settings for a patient not to be on pharmacologic prophylaxis? What is the appropriate leeway time for these conditions?
- Which 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 48 hours.
  - Patients <18 years of age.
  - Comfort care patients.
  - Patients on therapeutic anticoagulation.
  - Patients enrolled in clinical trials.
- Which data collection strategy is best for performance tracking?

Note that improvement teams often use a simple before-and-after approach to see the effects of an intervention. Unfortunately, that approach can be misleading to accurately assess prevalence of VTE prophylaxis, which can vary by as much as 35 percent day to day. Rather, multiple sampling events are recommended to ensure accurate conclusions. Results can be tracked and trended in run charts.

## Sampling Techniques

There are three main sampling techniques that teams can use for a VTE prevention audit:

- **Convenience sampling:** Reviewers select patients because they are available on the ward (with no other 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. As an example, a roster of all adult inpatients hospitalized for more than 48 hours could be assigned a random number (a number of free random number generators are available on the Internet). 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 potential that some small but important patient group could be underrepresented.
- **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.

The need for unambiguous operational definitions of ambulation and mobility, bleeding risk factors, and a host of other terms will become apparent during the piloting process.

**Note:** Before piloting and finalizing an audit tool, the team should pilot and finalize the VTE protocol, as feedback from the VTE protocol pilot may change the audit form.

### ***Use Stoplight Audits To Identify and Mitigate Under-Prophylaxis***

Another way to audit appropriate VTE prophylaxis and improve upon the National Inpatient Hospital Quality Measures is a measurement method called the red/yellow/green or stoplight method.<sup>5,6</sup> The medication administration record or an automated report is generated identifying the VTE prophylaxis status of each patient on the ward as being “green” (receiving therapeutic or prophylactic anticoagulant), “yellow” (mechanical prophylaxis as a sole method of prophylaxis), or “red” (no prophylaxis ordered). This is essentially the same as the proactive review approach discussed earlier, except that this method is directed at all patients on a given unit rather than restricted to patients in the first 24 hours after hospitalization or transfer to the ICU. There are a number of variations, depending on local resources and the sophistication of the reporting tool.

Figure 6.2 depicts an automated report using the stoplight method. The report shows all active inpatients on a given unit. The service, VTE risk category chosen by the ordering provider, anticoagulant (if present), absence or presence of sequential compression devices (SCD), and several lab contraindications (low platelet count, low hemoglobin, or elevated INR) are all captured and available to the reviewer. Color coding is added to enhance ease of use.

In a stoplight report, Green represents the presence of an anticoagulant, yellow represents SCDs, and red represents patients with no VTE prophylaxis. The orange color represents patients with a lab contraindication within the last 2 days who are on mechanical prophylaxis only.

**Figure 6.2: Automated Version of a Stoplight Report**

BED_LABEL	Service	VTE Risk Category	Medication	Dose	SCD	Lab Contra	Orders state contra	Orders state LOW VTE Risk
2250A	Medicine Thornton	LOW	warfarin (COUMADIN) tablet 3 mg	3 mg EVERY EVENING Oral	Y	N	N	Y
2250B	Medicine Thornton	MODERATE	enoxaparin (LOVENOX) injection 30 mg	30 mg DAILY Subcutaneous	Y	N	N	N
2251	Medicine Thornton	MODERATE	heparin injection 5,000 Units	5000 Units EVERY 12 HOURS Su	Y	N	N	N
2252	Cardiothoracic Surgery	MODERATE/HIGH	No Anticoag Med	No Anticoag Dose	Y	Y	N	Y
2253	Medicine Thornton	MODERATE	enoxaparin (LOVENOX) injection 40 mg	40 mg DAILY Subcutaneous	Y	Y	N	N
2254	Medicine Thornton	MODERATE	heparin injection 5,000 Units	5000 Units EVERY 8 HOURS Sub	Y	N	N	N
2255	Medicine Thornton	MODERATE	heparin injection 5,000 Units	5000 Units EVERY 12 HOURS Su	Y	N	N	N
2256A	Medicine Thornton	MODERATE	enoxaparin (LOVENOX) injection 40 mg	40 mg DAILY Subcutaneous	Y	N	N	N
2256B	Pulmonary Vascular Medicine	MODERATE/HIGH	enoxaparin (LOVENOX) injection 50 mg	50 mg EVERY 12 HOURS Subcut	Y	Y	N	N
2257A	Medicine Thornton	MODERATE	enoxaparin (LOVENOX) injection 40 mg	40 mg DAILY Subcutaneous	Y	N	N	N
2257B	Gynecology	MODERATE/HIGH	No Anticoag Med	No Anticoag Dose	Y	Y	N	N
2258	Medicine Thornton	MODERATE	enoxaparin (LOVENOX) injection 30 mg	30 mg DAILY Subcutaneous	Y	N	N	Y
2259	Medicine Thornton	MODERATE	No Anticoag Med	No Anticoag Dose	Y	N	N	N
2260	Pulmonary/Critical Care	LOW	No Anticoag Med	No Anticoag Dose	N	N	N	Y
2261	Medicine Thornton	MODERATE/HIGH	No Anticoag Med	No Anticoag Dose	Y	Y	N	N
2262A	Medicine Thornton	LOW	enoxaparin (LOVENOX) injection 40 mg	40 mg DAILY Subcutaneous	Y	N	N	Y
2262B	Medicine Thornton	MODERATE	enoxaparin (LOVENOX) injection 40 mg	40 mg DAILY Subcutaneous	Y	N	N	N
2263	Medicine Thornton	MODERATE/HIGH	No Anticoag Med	No Anticoag Dose	Y	Y	N	N
2264	Pulmonary Vascular Medicine	MODERATE	warfarin (COUMADIN) tablet 5 mg	5 mg EVERY EVENING Oral	Y	Y	N	Y
2265	Pulmonary Vascular Medicine	LOW	heparin injection 5,000 Units	5000 Units EVERY 8 HOURS Sub	Y	N	N	Y
2265	Pulmonary Vascular Medicine	LOW	warfarin (COUMADIN) tablet 10 mg	10 mg EVERY EVENING Oral	Y	N	N	Y
2266	Medicine Thornton	MODERATE	heparin injection 5,000 Units	5000 Units EVERY 8 HOURS Sub	Y	N	N	N
2267	Pulmonary Vascular Medicine	HIGH	enoxaparin (LOVENOX) injection 100 mg	100 mg EVERY 12 HOURS Subcu	Y	Y	N	Y
2268	Cardiothoracic Surgery	LOW	enoxaparin (LOVENOX) injection 40 mg	40 mg DAILY Subcutaneous	Y	N	N	Y
2269	Cardiothoracic Surgery	No Risk Category	No Anticoag Med	No Anticoag Dose	N	N	N	N
2270	Cardiothoracic Surgery	No Risk Category	No Anticoag Med	No Anticoag Dose	N	N	N	N
2271	Medicine Thornton	MODERATE	heparin injection 5,000 Units	5000 Units EVERY 12 HOURS Su	Y	N	N	N
2272	Pulmonary Vascular Medicine	HIGH	fondaparinux (ARIXTRA) injection 7.5 mg	7.5 mg DAILY Subcutaneous	Y	Y	N	Y

Patient identifiers have been removed.

This kind of reporting has many strengths. The automation allows monitoring of virtually every inpatient on a daily basis as opposed to focusing only on the first hospital day or on a relatively small subset of patients captured by sampling techniques. Attention can quickly be focused on those who are at highest risk of under-prophylaxis—namely those in the red and the yellow. This method of audit or *measurement* can spur concurrent *intervention* (aka measure-vention), which will be discussed in more detail in the next chapter. This technique can very rapidly improve VTE prophylaxis rates.<sup>5,6</sup>

More detailed reviews can be performed on samples of patients to make sure that the prophylaxis being delivered is consistent with the institutional VTE prevention protocol. Patterns of prophylaxis by service and unit will very quickly become apparent, focusing the attention of the improvement team on underperforming units. Patients without a captured VTE risk level from the protocol (in the example, two cardiothoracic surgery patients coded red) identifies providers and services that somehow evaded the VTE prevention order set. Finally, measures around the pattern of prophylaxis can provide a constant frame of reference, even if the protocol and the definition of “appropriate” prophylaxis evolves.

### ***Use Audits To Target Over-Prophylaxis***

As previously stated, the risk of HA-VTE can change throughout a patient’s hospitalization. Thus, a few point-in-time assessments have the potential to lead to under-prophylaxis as well as over-prophylaxis. To address the latter, a similar stoplight (red/yellow/green) method can be used. Sampling some patients in the “green” category of the example stoplight report and determining whether they meet criteria for low risk can be done fairly efficiently.

Adding a data field to a report to capture whether the patient is ambulating can efficiently identify ambulatory patients on anticoagulation. For example, the Braden decubitus risk scale captures the degree of ambulation on a 4-point scale:

1. **Bedfast** – Confined to bed.
2. **Chairfast** – Ability to walk is severely limited or nonexistent. Cannot bear own weight and/or must be assisted into a chair or wheelchair.
3. **Walks occasionally** – Walks occasionally during the day, but only for very short distances, with or without assistance. Spends the majority of each shift in bed or in a chair.
4. **Walks frequently** – Walks outside of the room at least twice a day and inside the room at least once every 2 hours during waking hours.

This scale can also be used to identify patients who are walking frequently and on prophylaxis and targeted for further review, with the goal of removing prophylaxis from low-risk patients. The score need merely be added as a distinct data field (rather than as free text) to allow it to be incorporated into an automated report.

### ***Key Metric 2: Incidence of Hospital-Associated VTE***

The goal of the improvement team is to reduce the overall incidence of HA-VTE. Completely eliminating HA-VTE is unrealistic, as clinical trials typically achieve a 30 to 65 percent reduction in events with the best possible prophylaxis available—and many patients have contraindications for prophylactic agents.<sup>7</sup> Tracking potentially preventable HA-VTE is an attractive corollary measure, as these are the events most amenable to remediation. The VTE-6 measure is one method to track HA-VTE; however, like the other National Hospital Inpatient Quality Measures for VTE, this measure has some serious limitations.

The VTE-6 measure is restricted to patients with non-principal diagnosis of VTE not present on admission. Since October 2007, medical centers designate diagnoses as:

- Y = Yes (present at the time of inpatient admission, or POA)
- W = Provider is unable to clinically determine if condition was present on admission
- N = No (not present at the time of inpatient admission, or NPOA)
- U = Unknown (documentation is insufficient to determine if condition was present on admission)

One major limitation of the measure is that only VTE events with a POA indicator of N or U are included in the measure. This results in an underestimation of VTE associated with hospitalization (and potentially preventable HA-VTE) as it fails to recognize that VTE associated with hospitalization may not present until *after* the index hospitalization.

Capturing patients who are readmitted with newly diagnosed VTE is very important, as a very large proportion of VTE can present in the 30 days after hospital discharge. This is especially true for medical inpatients, and readmitted VTE patients may outnumber not-present-on-admission patients.

A second major limitation of this measure is the definition of “potentially preventable.” *Any* prophylaxis provided before the VTE diagnostic order date leads to the conclusion that the VTE was not preventable. For example, a VTE event that is discovered on the tenth day of hospitalization would be deemed not preventable if the patient had received mechanical prophylaxis on the ninth hospital day but inadequate or no prophylaxis throughout the remainder of his or her stay.

AHRQ’s Quality Indicators include a Patient Safety Indicator (AHRQ PSI #12) that does not use the POA indicator and is focused only on patients with surgical diagnoses or operating room procedure codes.<sup>8</sup> Using this indicator, some patients who are readmitted with VTE may be captured, but only if VTE is not the primary reason for admission.

Improvement teams need to understand the important limitations of ICD-9 coding and administrative data in tracking outcomes.

### **Compensate for the Limitations in Using Administrative Data**

Improvement teams need to understand the important limitations of ICD-9 coding and administrative data in tracking outcomes.

First, not all patients will be readmitted to the same hospital; others who are diagnosed with a VTE event may remain in the skilled nursing or rehabilitation facility that accepted the patient after hospitalization. In addition, not everyone with HA-VTE will be readmitted; newer oral anticoagulants and low-molecular-weight heparin can be used to treat some patients with VTE without hospitalization.

The predictive value of the present on admission designation is only 71 percent and 81 percent in studies of surgical and medical inpatients, respectively, with higher performance in those with total knee arthroplasty.<sup>9-12</sup> Both underestimates and overestimates of HA-VTE rates can occur.

Second, although major guidelines<sup>13,14</sup> recommend against routine screening for asymptomatic VTE in the hospital, the practice remains common for high-risk populations (e.g., trauma or cancer patients) in many hospitals. Hospitals performing more routine screening will therefore appear to have higher rates of symptomatic VTE than those that do not perform this screening.

Even in centers that do not practice routine screening for asymptomatic patients, medical centers with ongoing improvement and educational efforts may have a lower threshold for ordering tests. This surveillance bias can make it especially hard to compare performance across different medical centers and to identify top performers.<sup>15-18</sup> In fact, a recent study found that hospitals with higher quality scores for VTE often had worse risk-adjusted VTE rates, most likely due to surveillance bias.<sup>15</sup> Increasingly sensitive CT scans and variability in diagnosing small, subsegmental PE also pose challenges to tracking VTE over time and to comparing performance across different institutions.

Finally, the improvement team should revisit the accuracy of administrative coding for HA-VTE and attempt to reduce any inappropriate routine screening for deep vein thrombosis. Screening practices and coding accuracy can vary widely from hospital to hospital, and this may represent a valid opportunity to reduce the reported number of hospital-associated cases of VTE.

### **Strategies To Improve on the National Hospital Inpatient Quality Measures for VTE Prevention**

Several strategies are available to improve on the VTE-6 metric (and AHRQ PSI #12) and to track potentially preventable and nonpreventable HA-VTE.

#### ***Capture Patients Readmitted With Diagnostic Codes for VTE***

One strategy to better track the incidence of HA-VTE is to set up a data query to capture both patients who develop VTE during an admission *and* patients who are readmitted within 30 days with a newly diagnosed VTE. Another data point to consider tracking and reporting is the incidence of upper extremity DVT. This is an important but distinct diagnosis with different implications for prevention.



### ***Use Chart Review To Capture Potentially Preventable Versus Nonpreventable HA-VTE***

HA-VTE should be considered potentially preventable if there was a significant lapse in protocol-directed VTE prophylaxis (i.e., rather than the VTE-6 standard of a complete lack of any prophylaxis) prior to VTE diagnosis at any time prior to the diagnostic test for VTE. Diagnostic coding is not perfectly accurate, and chart review allows validation of whether the patient experienced an HA-VTE.

Chart review also allows the team to prioritize its educational efforts and understand where the process is most prone to failure. In addition, chart review can raise awareness of HA-VTE, and potentially preventable HA-VTE can be referred for peer review where the powerful human stories revealed by chart review can garner support for the VTE prevention program.

### ***Track the Incidence of HA-VTE and Concurrent Case Review***

The methods reviewed above rely on identification of VTE diagnostic codes. A better method, if feasible, is to identify and review all VTE cases as they are diagnosed by CT angiograms of the chest, Doppler-ultrasound tests of the extremities, ventilation perfusion scans, venograms, and autopsy findings.

One center, for example, designed a query in the digital radiology information system that could efficiently pull up a roster of all VTE diagnostic studies performed in the previous 1 to 3 days.<sup>19</sup> A nurse data reviewer screened the studies for a new VTE diagnosis, then determined through further chart review if the VTE was hospital associated or community acquired. If an HA-VTE was diagnosed, further review using a case review form determined whether the HA-VTE was potentially preventable. This strategy allows a more efficient, less labor-intensive, and more complete case review, often completed while the patient is still in the hospital.

### ***Track Bleeding Episodes Associated With Anticoagulant Prophylaxis***

Concern about bleeding complications limits how aggressively anticoagulant prophylaxis can be used. Bleeding complications, however, are notoriously difficult to track accurately, and determining the incremental rate of bleeding induced by anticoagulant prophylaxis can be even more difficult. Patients followed longitudinally over time, such as patients in registries and the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP<sup>®</sup>), may provide the most robust opportunity to track risk complications. Unfortunately, high-quality registries, if available in a hospital at all, typically cover a minority of patients.

Voluntarily reported cases can provide useful insights, but many cases are not detected in this manner as the approach lacks sensitivity. Electronic monitoring for patients requiring transfusion or having significant drops in hemoglobin while on anticoagulation can spur chart review to determine if an adverse drug event occurred, to assess the level of harm, and to examine the case for error.<sup>20</sup>

An approach popularized by the Institute for Healthcare Improvement does not require advanced clinical decision support. A small sample of charts is reviewed for a list of “triggers” for further review.<sup>21</sup> Triggers potentially related to anticoagulant adverse drug events (ADEs), such as an elevated INR, elevated PTT, use of anticoagulant reversal agents, change in level of care, or blood transfusions, lead to further analysis to determine if an ADE occurred. Each method has

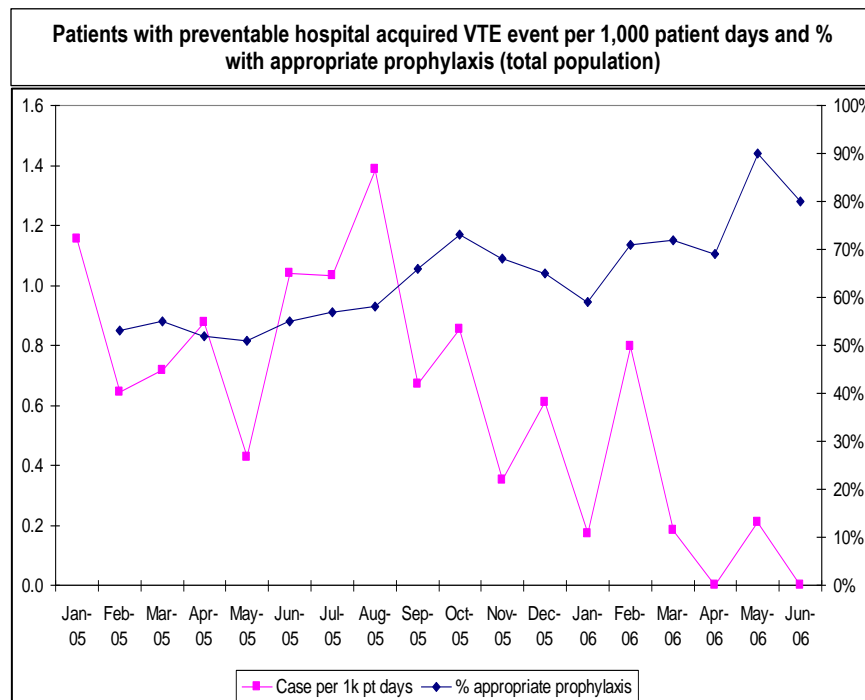
strengths and limitations, and it appears that using a combination of them is likely most sensitive. Of course, some of these methods are directed at capturing ADEs from therapeutic, rather than prophylactic, doses of anticoagulant, so refinement of reporting is needed to capture these nuances.

### Using Charts for Data Reporting

**Run charts** are easy to make and tend to be a useful way to graph the improvement data needed to follow performance over time. Compared with tables of data, run charts offer a quicker picture of how an intervention is working relative to the baseline. The table and run chart in Figure 6.3 represent data from the University of California, San Diego. As is visible, the run chart makes it easy to appreciate dramatic trends in performance over time.

**Figure 6.3: Comparison of Tabular Data and Run Chart on Appropriate Prophylaxis**

	Patients w/ Preventable VTE	Pt Days	Case per 1k pt days	% appropriate prophylaxis
Jan-05	6	5198	1.2	
Feb-05	3	4652	0.6	53%
Mar-05	4	5583	0.7	55%
Apr-05	5	5704	0.9	52%
May-05	2	4695	0.4	51%
Jun-05	5	4799	1.0	55%
Jul-05	5	4850	1.0	57%
Aug-05	6	4322	1.4	58%
Sep-05	3	4476	0.7	66%
Oct-05	4	4691	0.9	73%
Nov-05	2	5709	0.4	68%
Dec-05	3	4928	0.6	65%
Jan-06	1	5894	0.2	59%
Feb-06	4	5028	0.8	71%
Mar-06	1	5501	0.2	72%
Apr-06	0	4614	0.0	69%
May-06	1	4741	0.2	90%
Jun-06	0	5205	0.0	80%

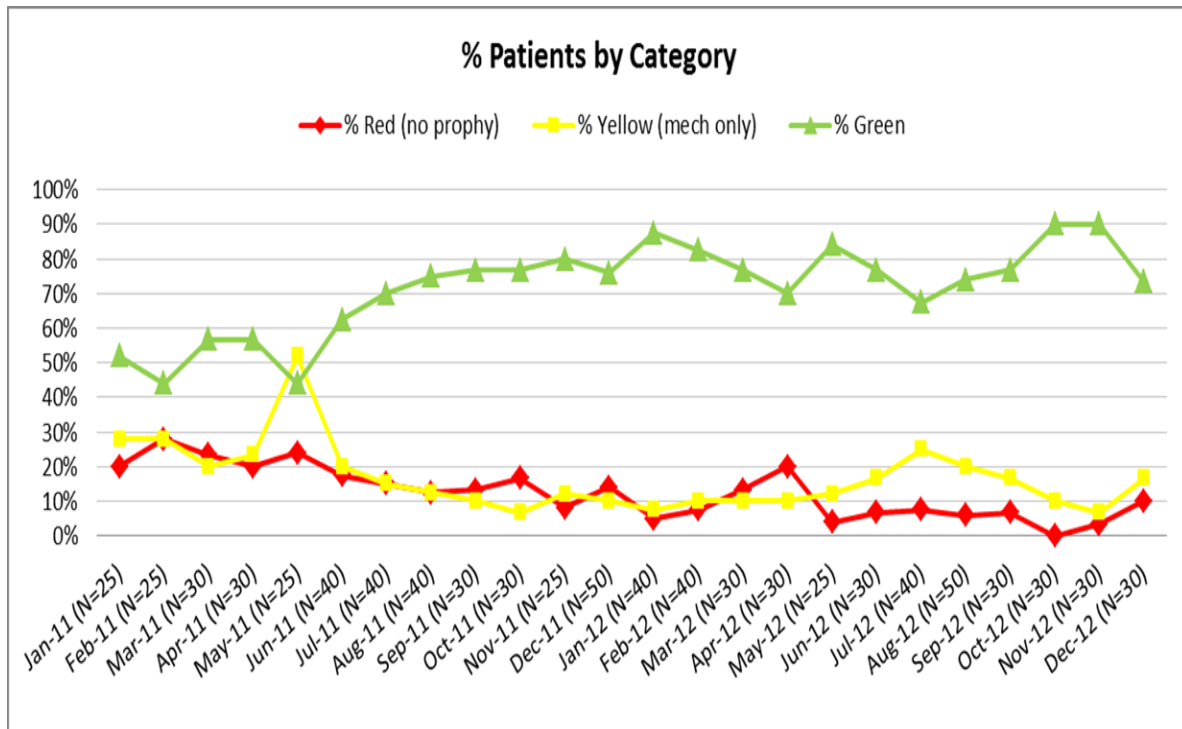


**Source:** University of California, San Diego.

**Note:** The run charts are more intuitive to use and often have more weight than the tabular presentation of data.

Run charts can 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 effects of known local trends. Ubiquitous software (Excel<sup>®</sup> or any of several free online run chart applications) can be used to create run charts without statistical expertise. For quality improvement projects, monthly plots are usually adequate; when testing incremental layered interventions and ongoing longitudinal monitoring, however, weekly plots will let the team see the results faster. Figure 6.4 depicts a run chart of prophylaxis patterns, with monthly plotting.

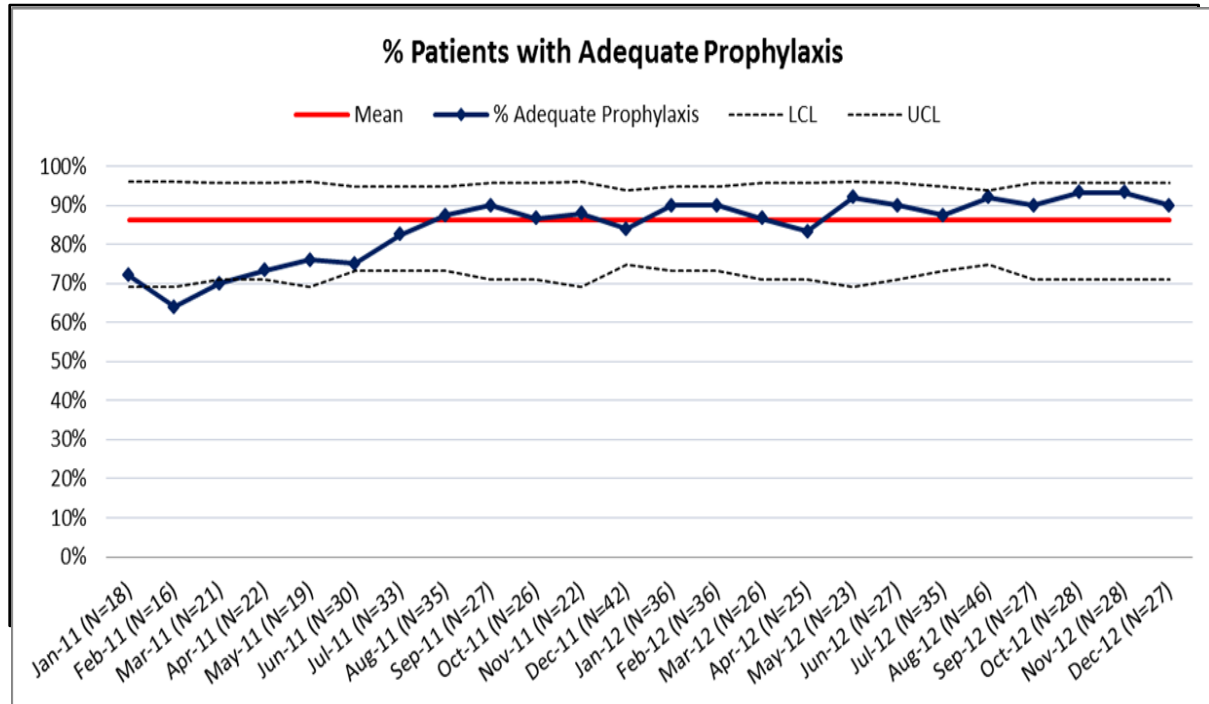
**Figure 6.4: Run Chart of Prophylaxis Patterns**



Generated from audit tool in Appendix C.3, available online at <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/appendixc.html>.

**Statistical process charts (SPCs)** are a special kind of run chart that are useful in gauging whether fluctuations in run charts are due to noise in the data (and variation within an unchanged system) or to real change (indicating that the underlying process has changed). Different types of SPC charts are required for different types of data.

Figure 6.5 depicts an SPC chart of trends in the percentage of patients receiving adequate prophylaxis.

**Figure 6.5: SPC Chart of the Percentage of Patients With Adequate Prophylaxis**

Generated from audit tool in Appendix C.3, available online at <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/appendixc.html>.

## Summary of the Approach to Measurement

Improvement teams need a meaningful measurement system to support improvement. The two key metrics of measurement include the prevalence of appropriate prophylaxis and the incidence of HA-VTE and potentially preventable HA-VTE. While publicly reported measures for these metrics exist, they have some shortcomings, and improvement teams will want to consider how to add more granularity to capture more meaningful data. Measurement of important metrics can often be made easier if documentation and order sets are designed proactively to capture them, rather than treating measurement as an afterthought.

## Chapter 7. Layering Interventions and Moving Toward Excellence

This chapter discusses how to layer interventions to take your team's project toward excellence. It will help your team address all the failure modes in the process of VTE prevention, and how persistence, consolidation of Level 3 performance, and a variety of active surveillance techniques are the keys to success.

The example outlines a common occurrence in implementation of hospital-associated venous thromboembolism (HA-VTE) prevention projects: although the medical center found some success from its implementation project, it hit a stumbling block. The following points demonstrate what can be done to address this kind of barrier by layering interventions and moving the effort toward excellence.

### Example

Superior Medical Center has been actively working on venous thromboembolism prevention (VTE) for 18 months. Nearly a year after launching new protocol-driven VTE prevention order sets along with educational efforts, Superior Medical Center's measures of adequate prophylaxis improved from 60 percent to 80 percent on audits, and SCIP VTE measures are routinely around 95 percent—yet the incidence of hospital-associated VTE has not really improved. How should the VTE prevention team respond to the situation?

### Reviewing the Basics—Order Set Design and Implementation

If this happens, a productive and appropriate response would be to reassess efforts and make sure the foundation for improvement is in place—and then to layer on interventions in order to gradually achieve near-perfect prophylaxis.

Whether orders are on paper or in computerized physician order entries (CPOEs), every attempt should be made to integrate the VTE prophylaxis protocol into the processes for admission and for transfer from one hospital unit to another. This will require that the VTE prevention orders be tightly linked to all appropriate admission, transfer, and perioperative order sets. Better yet, the VTE prevention orders can be integrated into these larger order sets as a standard component, with all nonstandardized reference to VTE prophylaxis removed. Audits of order set use, dialogue with physicians, and direct observation can be carried out and modifications made until the great majority of patients are reliably assessed for VTE risk and assigned risk-appropriate prophylaxis on admission and transfer.

### Beyond the Basics—Addressing Failure Modes and Layering Interventions

A variety of failure modes commonly occur in quality improvement interventions. Table 7.1 outlines the failure modes introduced in Chapter 2, along with strategies and solutions to address each. The first four failure modes are addressed by optimizing order set design and integration, reaching Level 3 on the Hierarchy of Reliability. Improvement teams can then start moving beyond the basics to address the other failure modes in the table.

**Table 7.1: Common Failure Modes in Providing Optimal VTE Prophylaxis and Strategies and Solutions To Address Them**

	<b>Failure Mode</b>	<b>Strategies and Solutions</b>
1	<i>No standardized protocols or order sets for VTE prevention exist.</i>	Standardize VTE prevention and codify in an institutional protocol. Embed VTE protocol guidance in admission, transfer, and perioperative order sets.
2	<i>Order sets/prompts that reference VTE prevention are in place but provide inadequate guidance.</i>	Provide guidance for VTE risk assessment, bleeding, and prophylaxis choices for each combination of VTE and bleeding risk factors. Provide explicit operational definitions (e.g., cutoff for low platelets, definition of “ambulatory”).
3	<i>Order sets with guidance are in place, but the order set is bypassed or not used.</i>	Hard stops to make completion of order sets mandatory. Algorithmic design that allows ordering of prophylaxis only after VTE risk and bleeding risk assessments are complete. Active surveillance to detect those bypassing order sets.
4	<i>Order sets with guidance are in place and used, but used incorrectly.</i>	Education. Refinement of order sets to make them less ambiguous. Active surveillance to detect improper use of the order set.
5	<i>Patient gets placed on right prophylaxis, but VTE/bleeding risk changes and adjustment is not made.</i>	Education. Integrate VTE prophylaxis assessment into checklists or care pathways, especially in critical care units and elective surgery patients. Audit and feedback. E-alerts or human alerts. Measure-vention.
6	<i>Prophylaxis gets missed/changed on transfer/perioperative setting.</i>	Hard stop for VTE and bleeding risk assessment and VTE prevention orders postoperatively and with every transfer to a different level of care.
7	<i>Correct prophylaxis is ordered but not administered, or patient refuses.</i>	Education programs for nurses and patients. Engage patients in the process. Audit and feedback. Measure-vention.
8	<i>Patient is not mobilized optimally.</i>	Progressive activity and mobility programs. Measure-vention that incorporates mobility. Flow sheets that juxtapose activity orders with actual performance. Education.
9	<i>Preventable risk factors (central line) are not optimally managed.</i>	Central line/peripherally inserted venous catheter programs to minimize excessive use of central lines and ensure proper insertion and maintenance. Use smallest caliber lines possible.
10	<i>Prophylaxis is stopped at discharge even though the patient has indications for extended duration prophylaxis.</i>	Define populations that require extended duration prophylaxis and embed in clinical pathways and discharge checklists. Case management or discharge pharmacy should ensure patient can obtain extended duration prophylactic agent prior to discharge.

Intervention strategies can be either passive or active. **Passive interventions**, such as educational sessions and posters, can be useful, but they are generally not as effective as **active interventions** that provide clinical decision support (CDS), reminders, and correction of lapses in care.<sup>1-7</sup> Active surveillance techniques find ways to detect potential failures in the process and intervene to correct the lapse in care on a regular basis. Active interventions are described in more detail below.

## ***Use Checklists, Prompts, and Care Pathways That Reinforce VTE Prevention Order Sets***

Reminders for VTE prophylaxis can be integrated into history and physical forms, critical care rounding tools, and a variety of other instruments. A simple checklist can spur meaningful improvement in a powerful way, and checklists that incorporate VTE prophylaxis can be particularly useful in perioperative and critical care settings.<sup>4,6,8</sup> These strategies are most effective when used as a redundant mechanism (rather than as primary strategies) to leverage the VTE prevention order set.

Many institutions integrate VTE prophylaxis into care pathways, particularly for major orthopedic surgery, neurosurgery, and other selected surgical procedures.<sup>5-7</sup> Populations that may benefit from extended duration prophylaxis (e.g., major orthopedic surgery patients, patients with abdominal/pelvic surgery with cancer) should have VTE prevention measures in their care pathway or discharge checklist. Aligning the checklist and care pathways with the VTE prevention protocol embedded in the order sets is crucial to avoid confusion and mixed messages.

## ***Consider Alerts To Improve Appropriate Orders for Prophylaxis***

The benefits of electronic alerts (e-alerts) to increase thromboprophylaxis and reduce VTE rates among hospitalized patients have been demonstrated in clinical trials.<sup>9,10</sup> Almost 2,500 high-risk patients identified by data available in the electronic health record who were *not* receiving prophylaxis were assigned to an intervention or control group. In the intervention group, the treating physician received an unsolicited e-alert, resulting in improved prophylaxis rates and fewer VTE events at 90 days.<sup>9</sup> A study using human alerts, rather than e-alerts, provided similar findings, demonstrating that electronic health records are not required to use this strategy.<sup>11</sup> These findings suggest that alerts are useful—but they should complement other strategies to be most effective.

Active surveillance alerts have up to three steps:

1. A screen or filter that identifies a current potential lapse in care.
2. A rapid triage step in which the potential lapse in care is confirmed or denied.
3. An intervention that entails some form of notification to the ordering provider.

There was no triage step in the studies discussed above, and the screening step triggered an alert without any further adjudication. When this strategy is used, having the screening step err on the side of being specific, rather than sensitive, for those at VTE risk can reduce false alerts and alert fatigue.

## ***Use Audit and Feedback To Assess Performance and Provide Targeted Education***

Traditional audit and feedback, accomplished by giving periodic reports to provider groups on their performance on VTE prophylaxis, has also demonstrated some success.<sup>1,2,12</sup> Posting results and making them public can be an effective method, but it needs to be approached with sensitivity to the political climate and, ideally, with the permission of the physicians involved. Audit and feedback can also help target groups that might benefit from educational detailing.

## ***Address Reliability of Prophylaxis Administration, Adherence, and Prescribing***

Clinical decision support, order sets, and the like are strategies to increase the rates of appropriate *prescribing*, but the reliability of *administering* the ordered prophylaxis is often suboptimal, particularly for mechanical prophylaxis.<sup>13-15</sup> One prospective study of postoperative patients with deep vein thrombosis (DVT) risk factors and mechanical prophylaxis orders found that patients on routine nursing units had properly functioning intermittent pneumatic compression (IPC) devices during 48 percent of the visits, while ICU patients had them 78 percent of the time.<sup>13</sup> Another observational study had similar findings, with errors in mechanical prophylaxis being present in 44 percent of the observations of patients with orders for IPC alone, and 56 percent with errors when combination mechanical and anticoagulation prophylaxis were ordered. Errors in misapplication of the IPC devices and errors of omission both played roles.<sup>15</sup> Sites enrolled in Society of Hospital Medicine collaborative VTE improvement programs frequently reported similar findings.<sup>16,17</sup>

The difficulty in attaining high rates of mechanical prophylaxis adherence has two major implications. First, even though current guidelines make this an acceptable choice for selected subsets of surgical patients, health care providers may want to reconsider mechanical prophylaxis as a primary means of VTE prevention in those without contraindications to anticoagulation. Second, improvement teams should find methods to monitor mechanical prophylaxis administration and improve the reliability of administration.

Targeted education of nurses can be modestly effective in improving mechanical prophylaxis adherence but should not be relied on as a sole strategy. Patient engagement and education programs can reduce patient refusal of prophylactic measures. Society of Hospital Medicine collaborative VTE improvement sites have had success when coupling education with monitoring and intervention programs.<sup>16,17</sup>

Active surveillance techniques can be used to monitor and improve on reliable administration of mechanical prophylaxis. One strategy is to create a report that lists each patient on a given unit, juxtaposing the order for mechanical prophylaxis with the nursing documentation that the mechanical prophylaxis is on and in place. Some sites generate a roster of patients with orders for mechanical prophylaxis and then directly observe whether the mechanical prophylaxis is being administered on a regular basis.

Recently, portable, battery-powered intermittent pneumatic compression devices (IPCDs) have been designed to increase compliance in the hospital by offering untethered use. This allows patients more mobility and the ability to maintain use while traveling to other areas of the hospital for testing. (A small meter embedded in the device monitors the time the device is on and in place.)

Pharmacologic prophylaxis represents another opportunity to address failures in the VTE prevention process.<sup>18-21</sup> Figure 7.1 shows the result of an electronic audit of pharmacologic prophylaxis delivery. In a 7-month period, 9.3 to 11.7 percent of ordered doses were not administered. More than 60 percent of the time, the reason given for not administering the dose was patient or family refusal.



**Figure 7.1: Percentage of Ordered Subcutaneous Pharmacologic Prophylaxis Doses That Were Not Administered to Adult Inpatients**

<b>UCSD Inpatient Discharges - 3/1/2011 - 8/31/2011</b>	
<b>Anticoagulation Medications Ordered but Not Given</b>	
<b>Month</b>	<b>NotGiven%</b>
March	11.70%
April	9.80%
May	11.20%
June	10.50%
July	9.30%
August	9.50%
<b>Breakdown of Anticoag Meds Not Given</b>	
<b>NotGivenReason</b>	<b>NotGiven%</b>
Continuous IV infusing	0.6%
Contraindicated	2.0%
Duplicate Order	2.5%
Given at alternate time	3.1%
Loss of IV access	0.1%
Med DC'd	6.0%
Medication not available	0.3%
Not in room	0.8%
Order parameters not met	0.6%
Other	20.0%
Patient not available	0.7%
Patient sleeping	0.3%
Patient/family refused	61.5%
Pt. NPO	0.4%
Transfer to a Procedural area	1.1%

**Note:** The chart shows both the doses not administered and the reason the dose was not given as recorded in the medication administration record.

Published studies have similar findings, with 10 to 15 percent of ordered doses not administered.<sup>18,21</sup> The studies found substantial heterogeneity in nonadministration among patients, floors, and floor types, and a relatively small proportion of patients who missed multiple doses represented the majority of administration failures.<sup>21</sup> This represents an opportunity to focus improvement efforts efficiently.

### ***Address Central Venous Catheter-Related VTE/Upper Extremity DVT***

Upper extremity DVT (UE DVT) events constitute 30 to 40 percent of hospital-associated DVT. Central venous catheters (CVCs) are the predominant cause of UE DVT, and the overall incidence of UE DVT has increased coincident with the increasing use of peripherally inserted central catheters (PICCs).<sup>22-25</sup> The incidence of symptomatic DVT following CVC placement is 2 to 6 percent, with an 11 to 19 percent risk of asymptomatic DVT.<sup>22</sup> Larger catheter size, infection, and improper placement are all strongly associated with DVT risk. Comorbidities such

as cancer, diabetes, and trauma increase DVT risk, as do infusions of chemotherapy, antibiotics, or TPN through the CVC.<sup>22,25</sup>

The cost and length of stay attributable to PICC-associated DVT has been estimated at \$15,973 and 4.6 days, respectively.<sup>23</sup> PE associated with UE DVT has been reported as high as 12.4 percent.<sup>22</sup> The annualized recurrence rates, while lower than lower extremity DVT, are still substantial at 2.3 to 4.7 percent.<sup>22</sup> Removal of the CVC and several months of therapeutic anticoagulation are generally recommended, with all the potential for bleeding risk that entails.<sup>18</sup>

Appropriate VTE prophylaxis for comorbidities may be modestly beneficial in preventing UE DVT, but American College of Chest Physicians (ACCP) guidelines recommend against routine use of anticoagulant prophylaxis solely on the basis of an indwelling CVC. Significant reductions in UE DVT rates are feasible, however, by other methods. One tertiary trauma center reported a reduction in PICC-associated DVT from 3.0 percent to 1.9 percent; interventions included interdisciplinary consensus on the need for each PICC, early PICC removal, assurance of proper placement, use of a PICC with the smallest number of lumens required, and a change to smaller diameter PICCs.<sup>23</sup> These changes are inexpensive, save money, and reduce morbidity. Improvement teams may wish to examine their practices around PICC and other CVC placements and make similar changes when needed.

### ***Improve Mobility/Activity***

Reduced mobility is common in the inpatient setting, and immobility is a well-established and powerful risk factor for HA-VTE. In fact, relative immobility in the hospital is a risk factor for delirium, decubiti, ileus, deconditioning, bone loss, and prolonged loss of cognitive and physical function.<sup>26-30</sup> Early ambulation programs have improved outcomes after surgeries, including major orthopedic surgery.<sup>31-33</sup> Early ambulation and progressive mobility protocols seem to hold great potential as a nonpharmacologic method to improve outcomes, including VTE, across a number of inpatient populations without the potential consequences of adverse drug effects.<sup>34-38</sup>

There are many barriers to mobility during hospitalization. Patient-related factors, such as severity of illness, dementia, pain, and weakness make mobility difficult. Concern about falling, inadequate staffing, and attitudes about the priority of mobility during hospitalization can also act as barriers.<sup>26</sup> Many barriers to mobility are modifiable, however, including unnecessary physician orders for bed rest, oversedation, and overuse of Foley catheters, central catheters, and restraints.

Many programs are beginning to overcome these barriers and are finding that progressive mobility programs are feasible even in mechanically ventilated and critically ill patients.<sup>34-38</sup>

Strategies to improve mobility include:

- Using mobility and activity order sets that make progressive mobility the default rather than “activity ad lib” or bed rest.
- Reducing sedatives, restraints, and inappropriate Foley catheters.
- Exploring the use of nonnarcotic measures for pain control.
- Using sequential compression devices only when appropriate to do so.

- Standardizing mobility/ambulation orders and aligning them with physical therapy and nursing terminology.
- Juxtaposing the expectations for mobility and activity with the mobility actually achieved in flow sheets.
- Implementing patient and nursing education and engagement programs.

VTE improvement teams might wish to survey their institution for services that already have aggressive mobility programs and attempt to spread them to a broader segment of patients.

## **Achieving Measure-vention: Reaching Level 5 on the Hierarchy of Reliability**

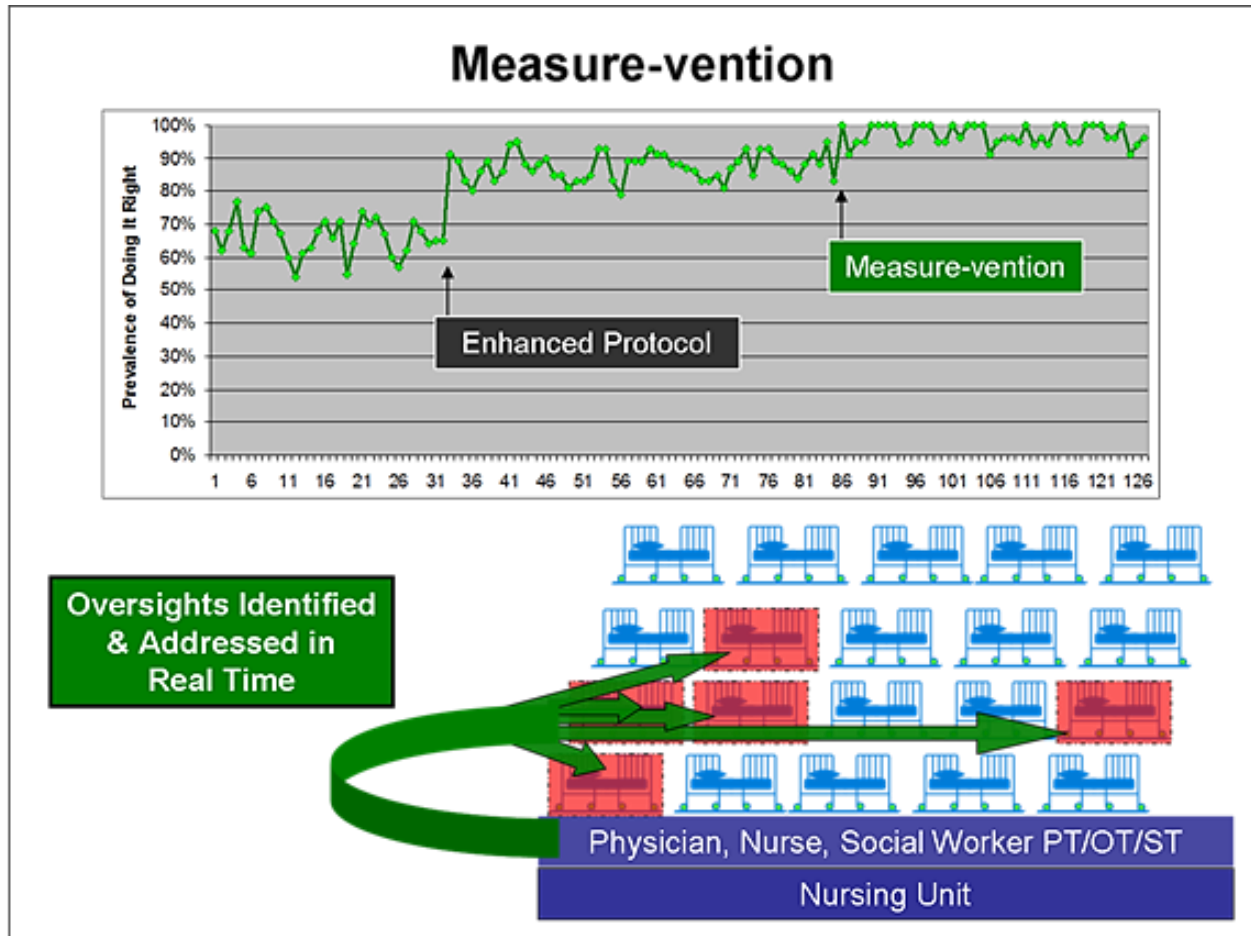
Under the stoplight method of measurement (see Chapter 6), the medication administration record or an automated alert identifies the active VTE prophylaxis orders for each patient on the ward as “green” (therapeutic or prophylactic anticoagulant ordered), “yellow” (mechanical prophylaxis is the sole method of prophylaxis ordered), or “red” (no prophylaxis ordered). Lab contraindications to anticoagulant, the declared VTE risk level from the ordering physician, activity status from the Braden scale, and documentation of sequential compression device (SCD) application can be pulled into the report, thereby capturing prophylaxis patterns and a number of other factors that influence prophylaxis choices.

Measure-vention occurs when this form of *measurement* is coupled with *intervention* to correct identified lapses in care on a daily basis. When measure-vention happens, very rapid improvements in VTE prophylaxis can result.<sup>16,39,40</sup>

Measure-vention is an active surveillance strategy that addresses multiple failure modes simultaneously. The measurement portion of measure-vention can start very early in the improvement process, while the intervention coupled with this measurement is best deployed after the protocol-driven order set is well integrated into the admission and transfer process. In other words, Level 3 on the Hierarchy of Reliability should be in place before embarking on measure-vention, which can elevate performance to Level 5. Figure 7.2 offers a graphic representation of the measure-vention process.

Measure-vention, the concurrent identification and relay of quality outliers to the frontline care team, simultaneously represents an intervention and a measurement system. In the Hierarchy of Reliability, measure-vention is a Level 5 quality improvement strategy.

Figure 7.2: The Measure-vention Process



**Figure 7.3** shows an excerpt from a measure-vention tool that illustrates the screening and triage process. A member of the health care team on the unit would receive this report on a daily basis or access it on demand. Generally, this daily screening is performed by a nurse, although in some institutions a pharmacist or other provider performs measure-vention.

**Figure 7.3: Excerpt From Automated Measure-vention Screening Tool (Enhanced Stoptight Method)**

BED_LABEL	VTE Risk Category	Medication	Dose	SCD order	SCD On	AC Contraindication	Braden Activity
601A	Low	No Anticoag Med	No Anticoag Dose	N	No SCD	N	Walks Frequently
601B	Moderate	No Anticoag Med	No Anticoag Dose	Y	On	Y	Chairfast
608B	Moderate	enoxaparin (LOVEN	40 mg DAILY Subcutaneous	N	No SCD	N	Walks Frequently
609A	Low	No Anticoag Med	No Anticoag Dose	N	No SCD	N	Walks Frequently
609B	Moderate	heparin injection 5,	5000 Units EVERY 12 HOURS	N	No SCD	N	Walks Occasionally
611A	High	enoxaparin (LOVEN	40 mg DAILY Subcutaneous	Y	Off	N	Chairfast
611B	Moderate	enoxaparin (LOVEN	40 mg DAILY Subcutaneous	N	Patient Refus	N	Walks Occasionally
612A	Moderate	No Anticoag Med	No Anticoag Dose	Y	Patient Refus	N	Bedfast
612B	Low - Anticoagulat	enoxaparin (LOVEN	1 mg/kg EVERY 12 HOURS Su	N	No SCD	N	Chairfast
615A	Moderate	No Anticoag Med	No Anticoag Dose	Y	On	N	Chairfast

Patient identifiers have been removed.

Potential under-prophylaxis is identified by patients on no prophylaxis (in the red). In this case, both “red” patients were declared low risk by their physician and have documentation of walking frequently; by protocol, no prophylaxis is required.

Patients on mechanical prophylaxis may also be subject to scrutiny. Mechanical prophylaxis is often not an acceptable form of prophylaxis in the absence of contraindications to anticoagulants at a prophylactic level. The patient in 601B has SCDs and a documented lab contraindication to anticoagulant. The color coding for this situation (orange) makes this acceptable combination known to the nurse at a glance.

The patients in 612A and 615A, meanwhile, both have mechanical prophylaxis, a declared moderate VTE risk level, impaired mobility, and no contraindication for anticoagulant captured in the laboratory. These cases may represent under-prophylaxis and an opportunity for intervention if the nurse does not pick up any other obvious contraindication to anticoagulant during triage (such as scheduled surgery that day, active bleeding, or epidural insertion or removal). In addition, patient refusal of SCDs will need to be confirmed after education is provided to the patient. Finally, potential over-prophylaxis is identified by “green” patients on anticoagulant who are ambulating actively outside their rooms.

This example demonstrates how automated reports can pull together much of the information required to screen for potential care deficiencies, and assist in rapid triage, to confirm or deny a potential lapse in care.

Piloting measure-vention on one or two units is a great way to reduce false alarms and work out any bugs in the process. When measure-vention is done well, the number of cases requiring intervention goes down very rapidly and rates of adequate prophylaxis improve in just a few days. Figure 7.4 shows the results reported at Emory’s hospitals, which have been replicated by others in collaborative QI efforts.<sup>16,39,40</sup>

In a performance improvement pilot in Emory's hospitals, measure-vention was initiated on three different nursing units over 100 days. All three units were at Level 3 on the Hierarchy of Reliability, with high-quality VTE order sets in place and adequate VTE prophylaxis rates hovering around 70 percent. In this staggered time series, measure-vention quickly resulted in a statistically significant increase in the prevalence of adequate VTE prophylaxis in all three units.

**Figure 7.4: Piloting Measure-vention at Emory's Hospitals**

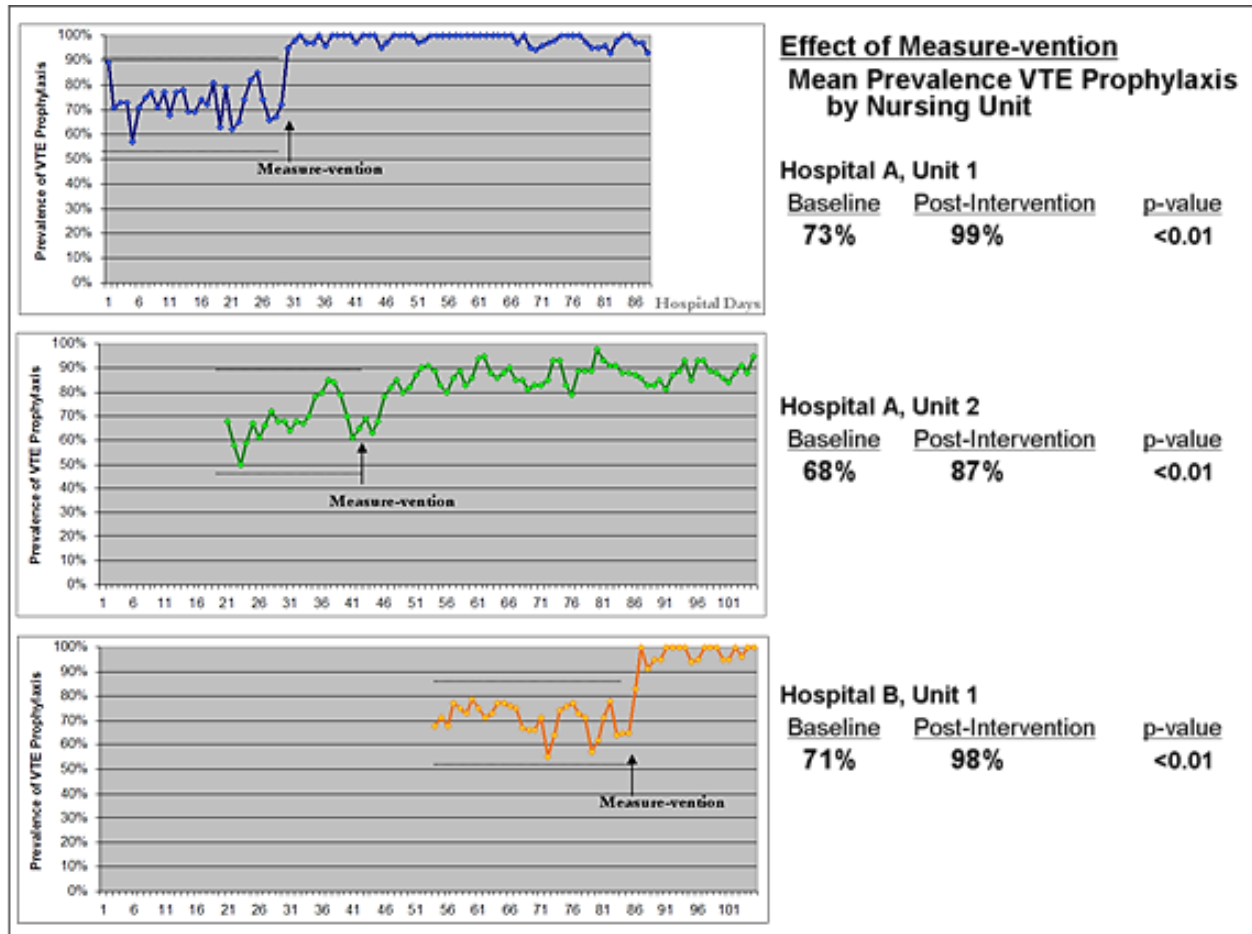


Figure courtesy of Dr. Jason Stein.

## Taking Measure-vention to the Next Level

In an ideal world, every patient would have bleeding and VTE risk factors reassessed each day. While this is too labor intensive and difficult to perform reliably in most hospitals, some are now starting to leverage the electronic health record to automatically pull important VTE risk factors (such as cancer diagnoses and mobility) and bleeding risk factors (such as high INR and low platelets) on at least a daily basis. This dynamic process is beyond the reach of most hospitals, but pioneers are beginning to show that this natural extension of measure-vention techniques may be feasible.

## Chapter 8. Continue To Improve, Hold the Gains, and Spread the Results

As discussed throughout this guide, teams might want to consider starting small and scaling up 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.

Under PDSA, team members start by planning (plan) the intervention and then testing (do) it. In the next step, team members observe the test firsthand (study), paying close attention to competing demands and physical space. They listen to individuals involved in the test to hear what worked and what did not. They 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 records the lessons learned and suggested alternatives. These lessons and alternatives are then shared at the next team meeting. In the last step, the team revises the plan and tries it again (act).

Table 8.1 highlights the advantages of PDSA as well as principles for doing it well.

**Table 8.1: Advantages of Plan-Do-Study-Act and Principles for Success**

<p><b>Advantages of PDSA</b></p> <ul style="list-style-type: none"><li>• Allows valuable modifications to improve effectiveness or preserve productivity.</li><li>• Allows “failures” to come to light without undermining performance and momentum.</li><li>• Identifies areas of resistance that might undermine dissemination to other units.</li><li>• Allows costs and side effects of the change to be assessed.</li><li>• Increases certainty that change will result in improvement.</li><li>• Allows detailed documentation of improvement.</li></ul> <p><b>Principles for Success</b></p> <ul style="list-style-type: none"><li>• Start new changes on the smallest possible scale (e.g., one patient, one nurse, one doctor).</li><li>• Run just as many PDSA cycles as necessary to gain confidence in a change.</li><li>• Spread each change incrementally to more patients, then more nurses, then doctors, and finally to units.</li><li>• Balance changes within the overall system to ensure other processes are not adversely stressed.</li><li>• Pay special attention to preserving productivity and workflow.</li></ul>
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## Maintain and Spread the Gains

After successfully addressing the failure modes and putting in place an effective VTE prevention protocol, it is important to avoid assuming that the new process is “fixed” in perpetuity. Instead, keep monitoring the process.

Although implementation teams may be able to reduce the intensity of the process monitoring over time, some ongoing assessment of how the process is functioning is necessary. In addition, new findings from research publications, new therapies, and new patient situations arise frequently and may require revisiting the process or intervention. It is helpful if the team remains responsible for monitoring these issues, updating tools and processes, and revising the intensity of scrutiny based on the stability of the metrics. Ongoing measurement and intermittent audit and feedback reinforce best practices and avoid lags in performance.

Creating breakthrough levels of improvement is hard work, but it can also be exciting and rewarding. Indeed, the improvement in the venous thromboembolism (VTE) prevention process a team engineers can serve as a model for other areas in the organization. Ideally, the implementation success will spread as others learn from the experience, customize it to their own environment, and implement that version at a rapid pace.

An implementation project is generally considered ready for spread when:

1. There is evidence of improvement.
2. There is a model for the improvement that others in the organization can use (e.g., implementing on other units or in other hospitals within the health system).
3. There is strong support from senior leadership to spread the intervention.

Once these three goals have been achieved, the VTE improvement team may want to consider setting forth a plan for spreading the results. The plan should consider the following:

- Which patient population to spread to next?
- Which specific improvements to spread (i.e., not all may be appropriate for all populations)?
- What modifications to interventions might be needed as the locations and population of patients change?
- What timeframe is most appropriate?
- What are the specific goals or targets for improvement?

Dissemination can be accelerated by adaption of clinical decision support and risk assessment tools in CPOE, by use of measurement reports, and by collaborative communities sharing examples of tools and resources. A spread plan should build on the organization’s existing approach to spread and rollout. It often helps for the team to work with a senior executive sponsor when developing the spread plan. Lastly, when executing the spread plan, be sure to measure performance and obtain feedback on the spread plan in order to improve upon the plan for the next idea.



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