VTE Guide for Executive Leadership

Implementing a VTE Prophylaxis Process for Hospitalized Patients

A Supplement to the HSAG VTE Resource Kit

Project supported by sanofi-aventis, U.S.
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This document, the HSAG VTE Resource Kit, and other resources related to VTE prevention are available at [http://www.hsag.com/services/special/vte.aspx](http://www.hsag.com/services/special/vte.aspx).
The Case for Implementing a VTE Prophylaxis Process for Hospitalized Patients Now

**It’s the Right Thing to Do**

- More than 2 million Americans suffer from venous thromboembolism (VTE—which includes deep vein thrombosis [DVT] and pulmonary embolism [PE]) each year, with over half of these individuals developing their VTE in the hospital or in the 30 days post-hospitalization.
- One in ten of those who develop a VTE go on to die from PE. These 200,000 patient deaths represent more annual deaths than those from breast cancer, AIDS, and traffic accidents combined.
- VTE is the #1 cause of preventable death among hospitalized patients: an estimated 10 percent of inpatient deaths are secondary to PE. Patients who survive the initial diagnosis of PE face a mortality rate of 17.5 percent at 90 days.
- Over one year, a 300-bed hospital that lacks a systematic approach to VTE prevention can expect roughly 150 cases of hospital-acquired VTE. Approximately 50 to 75 of those cases will be potentially preventable because of missed opportunities to provide appropriate prophylaxis. Approximately 5 of those patients will die from potentially preventable PE.
- Not only do patients with VTE suffer a 30 percent cumulative risk for recurrence, they are also at risk for the potentially disabling post-thrombotic syndrome.
- Most hospitalized patients have at least one risk factor for VTE.
- Medical patients probably account for more than half of all hospital-acquired VTE events. In a typical hospital, it is estimated that fewer than 5 percent of medical patients could be considered at low risk for VTE.
- VTE prophylaxis is rated by Agency for Healthcare Research and Quality (AHRQ) as #1 out of 73 Patient Safety Practices, based on their impact and effectiveness.

**We Can’t Afford Not To**

- Cost-effectiveness of VTE prophylaxis has been repeatedly demonstrated. Pharmacologic prophylaxis reduces the incidence of VTE by 50 percent to 65 percent.
- The incremental length of stay and costs of treating a preventable VTE event are substantial. The Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project’s estimates of incremental cost are $10,000 per DVT and $20,000 per PE.
- The Centers for Medicare & Medicaid Services (CMS) has included VTE related to total knee replacement and hip replacement (when not present on admission) among the hospital-acquired conditions for which it will no longer pay, effective October 1, 2008.

**Our Future Performance Will Be Publicly Compared to Other Hospitals’ Performance**

- Two VTE measures have already been included for public reporting as part of the CMS Surgical Care Improvement Project (SCIP) quality measures set.
- Six VTE measures (related to both medical and surgical patients) endorsed by the National Quality Forum (NQF) have been approved as part of a core measure set for use in The Joint Commission’s ORYX program and may be included for public reporting on the Hospital Compare Web site and as components of the CMS Reporting of Hospital Quality Data for Annual Payment Update (RHQDAPU) program in 2012.

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“The Institute of Medicine has classified the failure to provide appropriate screening and preventive treatment [for DVT and PE] to hospitalized, at-risk patients as a medical error, and the Agency for Healthcare Research and Quality has ranked the provision of such preventive treatment as one of the most important things that can be done to improve patient safety. Proven, effective measures are available to prevent and treat DVT and PE in high-risk individuals. Yet today the majority of individuals who could benefit from such proven services do not receive them.”

— Michael O. Leavitt
Secretary of Health & Human Services,
United States Public Health Office
in The Surgeon’s Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism, 2008

Definitions of Deep Vein Thrombosis, Pulmonary Embolism, and Venous Thromboembolism

“Deep vein thrombosis (DVT) refers to the formation of one or more blood clots (a blood clot is also known as a ‘thrombus,’ while multiple clots are called ‘thrombi’) in one of the body’s large veins, most commonly in the lower limbs (e.g., lower leg or calf). The clot(s) can cause partial or complete blocking of circulation in the vein, which in some patients leads to pain, swelling, tenderness, discoloration, or redness of the affected area, and skin that is warm to the touch. However, approximately half of all DVT episodes produce few, if any symptoms. For some patients, DVT is an ‘acute’ episode (that is, the symptoms go away once the disease is successfully treated), but roughly 30 percent of patients suffer additional symptoms . . . The most serious complication that can arise from DVT is a pulmonary embolism (PE), which occurs in over one-third of DVT patients. A PE occurs when a portion of the blood clot breaks loose and travels in the bloodstream, first to the heart and then to the lungs, where it can partially or completely block a pulmonary artery or one of its branches . . . Pulmonary embolism frequently causes sudden death, particularly when one or more of the vessels that supply the lungs with blood are completely blocked by the clot. . . . DVT and PE are commonly grouped together and sometimes referred to as ‘venous thromboembolism’ (VTE).”

Introduction

VTE has been described as the most preventable cause of hospitalized patient death. More than 2 million Americans suffer from VTE each year, with over half of these individuals developing their VTE in the hospital or in the 30 days post-hospitalization.

Despite the availability of effective prophylaxis for at-risk patients and publication of evidence-based guidelines, inadequate and omitted prophylaxis in hospitalized patients with medical illness is widespread in U.S. hospitals. While routine thromboprophylaxis in surgical patients has been well documented and supported by national projects, non-surgical hospital patients remain seriously underdiagnosed and undertreated.

There are many reasons for the missing sense of urgency regarding this problem, not the least of which is that VTEs are often asymptomatic and their effects and diagnosis often do not occur until after the patient has left the hospital. At this point in time, however, a confluence of pressures is developing that make it essential that hospital executive leadership place a priority on addressing VTE prevention (see “The Case for Implementing a VTE Prophylaxis Process for Hospitalized Patients Now” on page 1).

In this *VTE Guide for Executive Leadership*, we provide many tools to help make the case to hospital executive leadership that urgent action is needed to develop VTE prevention processes. This case can be summarized as follows:

- We need to stop blood clots from forming in patients during hospitalization.
- Blood clots are the #1 cause of potentially preventable deaths in hospitalized patients.
- Blood-clot prevention is rated as the #1 most effective patient safety practice for hospitals.
- Treating blood clots is exponentially more costly than preventing them.
- Implementing a blood-clot prevention process is something we can start today to protect the hospital from the vulnerability of a public exposure that could have dire consequences.

This document also provides many resources that hospital executive leadership can use to help “drive” a VTE prophylaxis implementation process for its medical patients.

**Project Background**

In August 2007, Health Services Advisory Group, Inc., (HSAG) received funding from sanofi-aventis, U.S., to conduct a one-year project aimed at developing resources that would assist hospitals in developing effective VTE risk-assessment processes. HSAG approached this task by working with a pilot hospital that did not have a risk-assessment process in place for medical patients, and identifying and providing needed resources at each stage of process development. The resulting *VTE Resource Kit* was published in August 2008 (http://www.hsag.com/services/special/vte.aspx).

One of the very essential “lessons learned” that came out of that initial project was the importance of executive leadership support and involvement. Our pilot hospital staff stated that more active executive support could have improved project results. This is in concert with numerous studies that have found that the role of senior leadership and organizational culture is correlated with clinical quality initiative success; without strong leadership support, even the most essential changes are difficult to accomplish and sustain. Further, achieving high-level leadership commitment and support has been shown to be related to the perceived urgency and feasibility of any proposed changes.

Developing resources and strategies to assist hospital executive leadership in taking on the “driving” role for implementing a VTE prophylaxis process for hospitalized patients became the focus of a follow-up project (with additional funding from sanofi-aventis, U.S.), and this *VTE Guide for Executive Leadership* is the result.
Using This Guide

In the appendices to this document are an integrated set of tools to help hospital executive leadership take a driving role in implementing a VTE prophylaxis process for hospitalized patients. A short description of each tool and its use is provided. Native format (MS Word, MS PowerPoint) files for many of the tools are embedded in the document so that hospital staff can modify the tool to fit the hospital’s needs.

Appendix A: Business Case for VTE Prophylaxis
This document serves as the cornerstone for gaining commitment from administrative leadership. It presents the strategic imperative for establishing VTE prophylaxis for medical patients as one of the highest priorities of the administrative staff and board of directors (BOD) for improving patient safety. It can also be used as a secondary resource for obtaining clinical staff commitment.

Appendix B: Clinical Case for VTE Prophylaxis
This document serves as the cornerstone for gaining commitment from clinical leadership. It presents the medical imperative for establishing VTE prophylaxis for hospitalized patients as one of the highest priorities of the medical staff and BOD for improving patient safety. It can also be used as a secondary resource for obtaining administrative commitment.

Appendix C: Preliminary Leadership Tasks
This checklist provides a practical tool that will enable the chief executive officer (CEO) to drive development of a hospital infrastructure that can successfully balance leadership effort and commitment to preventing blood clots in hospitalized patients based on hospital goals, priorities, and resources. The checklist cross references other resource documents to be used in conjunction with each step in the checklist.

Appendix D: Sample Hospital VTE Prophylaxis Policy
This sample policy provides a concrete vision for the quality improvement team to pursue. It can be used by the CEO, chief medical officer (CMO), and the BOD in conjunction with the Business Case and Clinical Case to facilitate discussions and to set a mutual context for the initiative. It is provided in a native file format (MS Word) so that the hospital personnel can customize it and use it as a template for developing the hospital’s official policy.

Appendix E: Sample Leadership Roles and Responsibilities
This is a multifunctional document that leaders can use to negotiate and coordinate their individual responsibilities and make sure that all of the essential activities are covered. It can be used by the BOD, CEO, CMO, chief quality officer (CQO), C-Suite champion (CSC), and physician champion (PC) as a starting point for discussion. It is provided in a native file format (MS Word) so that it can also serve as a template for the final, approved version of leadership accountabilities.

Appendix F: Assessing C-Suite Champion Potential
This assessment tool may be used by the CEO to identify the C-Suite executive who has the greatest potential for leading a quality improvement project to achieve and sustain success. On
one sheet of paper it provides a snapshot of some key roles, responsibilities, and tasks that are often lacking in support of hospital quality improvement efforts. It provides a checklist of personal and interpersonal characteristics that have been demonstrated to result in more effective interactions to keep the project moving forward.

Appendix G: Assessing Physician Champion Potential
This assessment tool may be used by the CEO and CMO to identify the physician who has the greatest potential for leading a quality improvement project to achieve and sustain success. On one sheet of paper it provides a snapshot of some key roles, responsibilities, and tasks that are often lacking in support of hospital quality improvement efforts. It provides a checklist of personal and interpersonal characteristics that have been demonstrated to result in more effective interactions to keep the project moving forward.

Appendix H: Communication Plan
This tool is to be used in conjunction with the Hospital Leadership Responsibilities Checklist and the Leadership Roles and Responsibilities document. Together, these three items form the foundation for developing the administrative infrastructure necessary to support the hospital-wide activities for preventing blood clots in hospitalized patients.

Appendix I: Sample Aim Statement and Team Charter
These tools can be used by leadership to charter a VTE Prevention Project Team or to provide direction to an existing team. They can guide the team in organizing a QI project and developing a written, measurable, and time-sensitive description of the accomplishments the Team expects to make from its improvement efforts. The Aim Statement answers the question: “What are we trying to accomplish?”

Appendix J: Key Stakeholder Contact List
An important first step in any health care system quality improvement project is to clearly delineate roles and responsibilities of internal stakeholders, particularly those of senior leadership. This form (also provided as a native-format MS Word file) provides a place where senior leadership members of a hospital’s VTE Prevention Team can be identified and their primary project responsibilities (based on suggestions found throughout this Guide) can be documented. This, along with the Aim Statement, will help team members to develop a shared vision and understanding of how the hospital’s VTE Prevention Project will be implemented.

Appendix K: Sample Business Case PowerPoint
This presentation is to be used in conjunction with the Business Case document. The presentation provides a tool that can be used when addressing a non-clinical decision making group rather than an individual. It lends itself to engaging the audience in lively discussion to facilitate the group in making an official decision as to whether or not a VTE Prevention Project for hospitalized patients will be approved as a formal quality-improvement initiative/project.

Appendix L: Sample Clinical Case PowerPoint
This presentation is to be used in conjunction with the Clinical Case document. The presentation provides a tool that can be used when addressing a clinical decision making group rather than an individual. It lends itself to engaging the audience in lively discussion to facilitate the group in
making an official decision as to whether or not a VTE Prevention Project for hospitalized patients will be approved as a formal quality-improvement initiative/project.

Appendix M: Surgeon General’s Call to Action and AHRQ’s VTE Prevention Guidelines

When the original HSAG VTE Resource Kit was developed and published, the Surgeon General’s Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism and the Agency for Healthcare Research and Quality’s (AHRQ’s) Preventing Hospital-Acquired Venous Thromboembolism: A Guide for Effective Quality Improvement had not yet been released. The first publication—issued by Acting Surgeon General Steven Galson, MD, MPH—provides an excellent overview of the public health issues related to VTE, while the second publication—prepared for AHRQ through the Society of Hospital Medicine (SHM) by Greg Maynard, MD, MSc, and Jason Stein, MD—draws on the unique experience of the SHM Venous Thromboembolism Resource Room team and should be required reading for anyone planning to implement a VTE prevention program in a hospital.

Appendix N: Sample “Rule Out” VTE Prophylaxis Order Set

When HSAG was developing and field testing its VTE Resource Kit at a pilot hospital, a rather substantial stumbling block encountered was the fact that there was no validated “gold standard” VTE risk-assessment tool available. Members of the medical staff at that hospital spent many weeks debating and developing a unique tool for their hospital to use. Until a validated risk-assessment tool is available, another approach to take toward VTE prophylaxis is the “rule out” method.

It can be generally agreed that the great majority of hospitalized medical patients have at least one risk factor for developing a VTE. The “rule out” method basically proposes that a hospital adopt a policy that every medical patient receive VTE prophylaxis unless contraindications are documented, ruling out the need for VTE prophylaxis rather than ruling in the need based on a particular risk score. A case has been made for this approach—along with a very good overview of VTE risk factors and VTE prophylaxis in general—in a WebEx presented under the auspices of the CMS National Patient Safety QIOSC (Quality Improvement Organization Support Center) on September 16, 2009, by Michael J. Cox, MD, FACP, FCCP, Assistant Clinical Professor at Saint Louis University School of Medicine. The WebEx was recorded and can be viewed at https://ifmcevents.webex.com/ec0600l/eventcenter/recording/recordAction.do?siteurl=ifmcevent&theAction=poprecord&recordID=1582597. We’ve included a sample VTE “rule-out” form and a copy of Dr. Cox’s WebEx slides in this appendix.
Appendix A: 

Business Case for VTE Prophylaxis
large veins, most commonly in the lower limbs (e.g., lower leg or calf). The most serious complication De
Post-thrombotic syndrome, a complication that occurs in 40%–80% of patients who develop blood clots, may result in permanent disability.

* Definitions of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Venous Thromboembolism (VTE): DVT refers to the formation of one or more blood clots in one of the body’s large veins, most commonly in the lower limbs (e.g., lower leg or calf). The most serious complication that can arise from DVT is a PE, which occurs when a portion of the blood clot breaks loose and travels in the bloodstream—first to the heart and then to the lungs, where it can partially or completely block a pulmonary artery or one of its branches. DVT and PE are collectively referred to as VTE.

References

Bibliography

Resources
• American College of Chest Physicians: www.chestnet.org
• American Medical Directors Association—DVT Clinical Corners: www.amda.com/tools/clinical/dvt.cfm
• American Venous Forum: www.venous-info.com
• Case Management Adherence Guidelines for VTE: www.cmsa.org/portals/0/pdf/CMAG_DVT.pdf
• Coalition to Prevent DVT: www.preventDVT.org
• Consumers Advancing Patient Safety: www.patientsafety.org
• Society of Hospital Medicine—VTE Prevention Collaborative: www.hospitalmedicine.org
• Translating VTE Guidelines Into Practice: www.hsag.org/services/special/vte.aspx
• Vascular Disease Foundation: www.vdf.org
• Venous Resource Center: www.venousdisease.com
The Business Case for VTE Prophylaxis
Preventing Blood Clots in Hospitalized Patients

**Strategic Imperative**
VTE prophylaxis is recognized by AHRQ as #1 out of 73 recommended Patient Safety Practices based on their impact and effectiveness. In today's environment, leaders must increasingly cope with outside social and economic pressures, including:
- Public reporting on Hospital Compare.
- Accountability and responsibility to keep patients safe (IOM report).
- Increasing visibility of safety concerns in the media.
- Public expectation that will keep them safe, and growing perception that hospitals are unsafe.

**Value Proposition**
A hospital can't afford to not implement a VTE prophylaxis protocol for its patients.
- Prophylaxis reduces the incidence of VTE by 50%–65%. 1
- Estimates of incremental cost related to increased length of stay and treatment of preventable VTE are $10,000 per deep vein thrombosis (DVT) and $20,000 per pulmonary embolism (PE). 1
  - For a 300-bed hospital with a 40% prophylaxis rate, this translates to $1.17 million per year in additional costs.
- As of 2008, there are two VTE-related “Never Events” (hospital-acquired conditions for which Medicare will not pay the additional costs of treatment) in place: DVT or PE related to total hip or knee replacement.
- Having a VTE prophylaxis protocol in place:
  - Reduces hospital and governing board liability exposure.
  - Aligns with Centers for Medicare & Medicaid Services (CMS), National Quality Forum (NQF), Agency for Healthcare Research and Quality (AHRQ), and The Joint Commission priorities.
  - Protects patients, reduces costs, and improves outcomes on public performance measures.

**Legal Considerations**
Why doesn’t the hospital have a VTE prophylaxis protocol in place for its patients?
- Who is ultimately accountable for whether the hospital has a VTE prophylaxis protocol in place for its patients?
- What is the hospital’s liability exposure if a patient acquires a VTE during hospitalization:
  - If there is no prophylaxis protocol in place?
  - If there is a prophylaxis protocol in place and it was followed?
  - If there is a prophylaxis protocol in place and it was not followed?

**Likelihood**
A large proportion of hospitalized patients are at risk for VTE, but there is a low rate of prophylaxis. 4

VTE is the #1 cause of preventable death among hospitalized patients. A 300-bed hospital with a 40% VTE prophylaxis rate would have 5 potentially preventable 90-day pulmonary embolism (PE) mortalities.
- The DVT Free registry 4 found one VTE per hospital bed per annum; about half of those were hospital-acquired.
- 70% of VTEs are deep vein thrombosis (DVT) and 30% are pulmonary emboli (PE).
- Approximately 75% of fatal PEs that are diagnosed at autopsy are in medical patients.

**Prophylaxis**
With VTE prevention, there is a disconnect between evidence and execution. One large epidemiological study found that 71% of patients diagnosed with VTE had received no prophylaxis within the past 30 days. 5

Every patient admitted to the hospital should be considered to be at risk for VTE, and preventive measures should be considered the standard of care.

**CMS VTE Measures**
VTE reduction is a priority of the Centers for Medicare & Medicaid Services (CMS) and The Joint Commission (TJC).
There are currently two publicly reported Surgical Care Improvement Project (SCIP) measures included in the CMS Reporting of Hospital Quality Data for Annual Payment Update (RHQDAPU) program:
- SCIP-VTE-1 Surgery patients recommended venous thromboembolism (VTE) prophylaxis ordered anytime from hospital arrival to 24 hours after Anesthesia End Time.
- SCIP-VTE-2 Surgery patients who received appropriate venous thromboembolism (VTE) prophylaxis within 24 hours prior to Anesthesia Start Time to 24 hours after Anesthesia End Time.

**TJC VTE Measures**
The following NQF-endorsed TJC VTE measures have been approved as part of a core measure set for use in TJC’s ORYX program and may be included as components of the CMS RHQDAPU program in 2012:
- VTE-1 Proportion of patients who received VTE prophylaxis or have documentation why no prophylaxis was given within the first 24 hours of hospitalization hospital days (Med/Surg patients who have a 48h stay)
- VTE-2 Proportion of patients who received VTE prophylaxis or have documentation why no prophylaxis was given within the first two hospital days (ICU patients)
- VTE-3 Patients treated with parenteral anticoagulant and warfarin who have at least 5 days of overlap therapy with an INR > 2.0 prior to discontinuation of parenteral treatment (or who are discharged before 5 days on overlap therapy)
- VTE-4 Proportion of patients treated with UFH who have dose managed by nomogram/protocol that includes explicit platelet count monitoring protocols (baseline, day after initiation, and at least three times per week for up to 14 days)
- VTE-5 Proportion of patients discharged from the hospital on warfarin with documentation of discharge instructions addressing compliance, dietary restrictions, follow-up monitoring, and adverse drug reactions/interactions
- VTE-6 Proportion of patients with hospital-acquired VTE who received no prophylaxis prior to the event

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1. VTE reduction is a priority of the Centers for Medicare & Medicaid Services (CMS) and The Joint Commission (TJC).
2. There are currently two publicly reported Surgical Care Improvement Project (SCIP) measures included in the CMS Reporting of Hospital Quality Data for Annual Payment Update (RHQDAPU) program.
3. VTE prophylaxis is recognized by AHRQ as #1 out of 73 recommended Patient Safety Practices based on their impact and effectiveness.
4. The DVT Free registry found one VTE per hospital bed per annum; about half of those were hospital-acquired.
5. With VTE prevention, there is a disconnect between evidence and execution. One large epidemiological study found that 71% of patients diagnosed with VTE had received no prophylaxis within the past 30 days.
## Hospital Beds

300

Enter data about your hospital here

## Current VTE Prophylaxis Rate

40%

Typical rates are 30-50%; use the upper or lower end of this range if you are unsure of your hospital's current rate.

<table>
<thead>
<tr>
<th># Patients with Hospital-Acquired VTE (annually)</th>
<th>150</th>
<th>The DVT Free registry found one VTE per hospital bed per annum; about half of those were hospital-acquired.</th>
</tr>
</thead>
<tbody>
<tr>
<td># Prevented Hospital-Acquired VTE</td>
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<td>This is the number of VTE you are preventing with your current prophylaxis rate [occurrence estimate x prophylaxis rate]</td>
</tr>
<tr>
<td># Potentially Preventable Hospital-Acquired VTE</td>
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<td>This is your improvement opportunity - the number of preventable VTE that are not being caught with your current prophylaxis rate.</td>
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<tr>
<td># Potentially Preventable DVT (about 70% of Hospital-Acquired VTE)</td>
<td>63</td>
<td></td>
</tr>
<tr>
<td># Potentially Preventable PE (about 30% of Hospital-Acquired VTE)</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td># Potentially Preventable 90-Day PE Mortalities</td>
<td>5</td>
<td>The 90-day mortality rate for patients with PE is 18%</td>
</tr>
</tbody>
</table>

Appendix B:
Clinical Case for VTE Prophylaxis
Every hospitalized patient is considered at risk for developing blood clots, which are the most common preventable cause of death among hospitalized patients.

Photo © 2009 Michael J. Cox, MD, FACP, FCCP. Used with permission.

Post-thrombotic syndrome, a complication that occurs in 40%–80% of patients who develop blood clots, may result in permanent disability.

*Definitions of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Venous Thromboembolism (VTE): DVT refers to the formation of one or more blood clots in one of the body’s large veins, most commonly in the lower limbs (e.g., lower leg or calf). The most serious complication that can arise from DVT is a PE, which occurs when a portion of the blood clot breaks loose and travels in the bloodstream—first to the heart and then to the lungs, where it can partially or completely block a pulmonary artery or one of its branches. DVT and PE are collectively referred to as VTE.
Translating VTE Guidelines Into Practice

Background
- Up to 2 million Americans a year suffer from venous thromboembolism (VTE), which includes deep-vein thrombosis (DVT) and pulmonary embolism (PE).
- Almost 300,000 die from PE, most resulting from DVT,
- 93% of VTE-related deaths are due to sudden, fatal PE (34%) or follow undetected PE (59%).
- Complications from VTE kill more Americans than AIDS and breast cancer combined.
- DVT-related PE is the most common cause of preventable hospital death.
- 50% of all VTE occurring in the community is related to a previous hospitalization.
- Without prophylaxis, hospital-acquired VTE occurs in approximately 10% to 40% of at-risk patients.
- In one study, 75% of patients admitted to a hospital’s medical services were characterized as increased risk for VTE.
- Appropriate VTE prophylaxis in patients at risk is No. 1 in AHRQ’s Top 11 Safety Practices, according to strength of evidence.

Disease
According to the National Heart, Lung, and Blood Institute, venous thromboembolism (VTE, which includes deep-vein thrombosis (DVT)) is a blood clot that forms in a vein deep in the body. Blood clots occur when blood thickens and clumps together.
- A blood clot in a deep vein can break off and travel through the bloodstream. The loose clot that forms in a vein deep in the body is routinely employed.
- Blood clots in the thigh are more likely to break off and cause PE than blood clots in the lower leg or other parts of the body.
- DVTs are often asymptomatic. Symptoms that may present include leg pain, “Charlie Horse,” unilateral leg swelling, and/or prominence of veins in the affected leg.

Complications
DVT recours in ~30% of patients within 8 years following the discontinuation of anticoagulant therapy. Post-thrombotic syndrome (PTS) occurs in 40%-80% of patients with DVT. PTS refers to a constellation of symptoms that may include swelling, skin discoloration, ulceration, varicoses, veins, and pain. PTS may result in a permanent disability.
- Up to 15 million Americans are afflicted.
- 4% of the U.S. population has or will develop a venous leg ulcer.
- PTS patients may be at increased risk for recurrent VTE.
- PTS is preventable if thrombosis prophylaxis is routinely employed.
- Other complications of DVT include chronic pulmonary hypertension (2%) and pulmonary embolism (symptomatic = 25%, asymptomatic up to 70%, death from PE = 5%-10%).

Risk Factors
A large proportion of hospitalized patients are at risk for VTE, and there is a low rate of appropriate prophylaxis.
- Previous venous thromboembolism
- Patients with prior DVT are five times more likely to develop a subsequent DVT.
- Increased age
- The rate of DVT and PE may be twice as common in patients between the ages of 50 and 81.
- Surgery, Leg Fractures
- Certain conditions are found in 60% of all patients with leg fractures.
- Immobilization—bedrest, stroke, paralysis
- Without prophylaxis, one-half of all patients develop acute DVT within 5 days following a stroke.
- Malignancy and its Rx (CTx, RTx, hormonal)
- In 25% of cancer patients and DVT, the DVTs is detected first.
- Heart or respiratory failure
- Extremity use, pregnancy, postpartum
- Pregnant women are five times more likely to develop DVT.
- Central venous lines
- Thrombophlebitic abnormalities/predispositions

Risk Assessment
DVT and PE are often undetected until it is too late. Approximately 80% of DVT cases are clinically silent.
- DVT-free: The largest epidemiological study of DVT (proven by ultrasound, Oct. 2001 to March 2002), 5,451 patients with a confirmed DVT at 183 study sites in the USA.
- Less than 30% of patients received prophylaxis within 30 days prior to a diagnosis of DVT.
- Of 2,727 patients who were hospitalized when DVT was diagnosed, 42% failed to receive prophylaxis within 30 days of diagnosis.
- 71% (~3,894) of all patients, including 2,295 non-surgical patients, received no prophylaxis within 30 days prior to diagnosis of DVT.
- Nonsurgical patients are less likely to receive prophylaxis than surgical patients.
- Approximately 75% of fatal PE’s are diagnosed at autopsy in medical patients.

Process

Prophylaxis
There is a disconnect between evidence and execution as it relates to VTE prevention.
- Every patient admitted to the hospital should be considered to be at risk for VTE, and preventive measures should be considered the standard of care.
- Rationale for thromboprophylaxis:
  - High prevalence of VTE
  - Most hospitalized patients have risk factors for VTE.
  - VTE is common in many hospitalized patient groups.
  - Hospital-acquired VTEs are usually clinically silent.
  - It is difficult to predict which at-risk patients will develop symptomatic thromboembolic complications.
  - Adverse consequences of unpreventable VTE
  - Symptomatic DVT and PE; Fatal PE
  - Costs of investigating symptomatic patients
  - Risks and costs of treating untreated VTE, especially bleeding.
  - Increased future risk of recurrent VTE
  - Chronic post-thrombotic syndrome
  - Effectiveness of thromboprophylaxis
  - Thromboprophylaxis is highly efficacious at preventing DVT, proximal DVT, symptomatic VTE, and fatal PE.

Discharge
When discharging and transitioning care, consider the following:
- If the patient is going home with a VTE prophylaxis program, it is important that a doctor-to-doctor conversation take place so that the physician or home health service will follow the patient in the community is aware of the diagnosis and the plan.
- Telephone conversations should be followed up by sending the discharge information to the physician’s office. This should include evidence-based guidelines or institutional protocols to ensure that best practices are being followed.
- The discharge plan should include—and the patient should be informed of—specifics about whether blood work should be done, where the lab is and whether results should be faxed or called in.
- Prior to discharge, patients should be educated and provided with written information regarding medications and red-flag events—including those side effects and symptoms for which patients should call their physician.

Resources
- Translating VTE Guidelines Into Practice: www.hsag.com/vte
- American College of Chest Physicians: www.chestnet.org
- American Medical Directors Association—DVT Clinical Corridors: www.amda.com/tools/clinical/dvt.cfm
- American Venous Forum: www.venous.info
- Case Management Adherence Guidelines for VTE: www.cmsa.org/portals/0/pdf/CMAG_DVT.pdf
- Coalition to Prevent DVT: www.preventDVT.org
- Society of Hospital Medicine—VTE Prevention Collaborative: www.hospitalmedicine.org
- Vascular Disease Foundation: www.vdf.org
- Venous Resource Center: www.venousdisease.com

References
7. Geerts WH, Jr.
13. Less than 30% of patients received prophylaxis within 30 days prior to a diagnosis of DVT.
14. Of 2,727 patients who were hospitalized when DVT was diagnosed, 42% failed to receive prophylaxis within 30 days of diagnosis.
15. 25% of non-surgical patients, received no prophylaxis within 30 days prior to diagnosis of DVT.
16. Nonsurgical patients are less likely to receive prophylaxis than surgical patients.
17. Approximately 75% of fatal PE’s are diagnosed at autopsy in medical patients.
Appendix C:

Preliminary Leadership Tasks
Preliminary Leadership Tasks
—Initiating VTE Prevention for Hospitalized Patients—

This checklist provides a practical tool that will enable the chief executive officer (CEO) to drive development of a hospital infrastructure successfully balance leadership effort and commitment to preventing blood clots in hospitalized patients based on hospital goals, priorities, and resources. The checklist cross references other resource documents to be used in conjunction with each step in the checklist.

### Sample Tasks to Be Accomplished

<table>
<thead>
<tr>
<th>Task Description</th>
<th>Suggested Leader(s) Responsible*</th>
<th>Resource (Appendix)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obtain Board approval for a VTE prevention initiative as high priority for</td>
<td>CEO</td>
<td>A, K</td>
</tr>
<tr>
<td>hospitalized patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approve roles and responsibilities of the Chief Quality Officer (CQO) for VTE</td>
<td>CEO</td>
<td>E</td>
</tr>
<tr>
<td>prevention in hospitalized patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Select and announce (to medical and hospital staffs) a C-Suite Champion (CSC)</td>
<td>CEO</td>
<td>F</td>
</tr>
<tr>
<td>for VTE prevention in hospitalized patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approve roles and responsibilities of the CSC for VTE prevention in</td>
<td>CEO</td>
<td>E</td>
</tr>
<tr>
<td>hospitalized patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approve roles and responsibilities of the Physician Champion (PC) for VTE</td>
<td>CEO, CMO</td>
<td>E</td>
</tr>
<tr>
<td>prevention in hospitalized patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assess potential candidates, recruit and announce (to medical and hospital</td>
<td>CEO, CMO</td>
<td>G</td>
</tr>
<tr>
<td>staffs) a Physician Champion for VTE prevention in hospitalized patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approve roles and responsibilities and select a Day-to-Day Team Leader (DDL)</td>
<td>CEO, CMO, CNO</td>
<td>E</td>
</tr>
<tr>
<td>and Administrative Support staff for VTE Prevention Team</td>
<td></td>
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</tr>
<tr>
<td>Announce (to medical and hospital staffs) and empower a Day-to-Day Leader</td>
<td>CSC, PC</td>
<td>E</td>
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<tr>
<td>for a VTE Prevention Team</td>
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<td></td>
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<tr>
<td>Approve VTE Prevention Team’s charter, including Aim Statement</td>
<td>CEO, CMO, CNO</td>
<td>D, I</td>
</tr>
<tr>
<td>Approve key stakeholder list for VTE prevention in hospitalized patients</td>
<td>CEO, CMO, CNO</td>
<td>J</td>
</tr>
<tr>
<td>Sample Tasks to Be Accomplished</td>
<td>Suggested Leader(s) Responsible*</td>
<td>Resource (Appendix)</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------------------------</td>
<td>---------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>☐ Approve time and resources necessary to develop, test, and implement desired changes for VTE prevention in hospitalized patients</td>
<td>CEO, CNO</td>
<td></td>
</tr>
<tr>
<td>☐ Appoint the VTE Prevention Team members</td>
<td>CSC, PC</td>
<td></td>
</tr>
<tr>
<td>☐ Approve multidisciplinary membership of VTE Prevention Team</td>
<td>CEO, CMO, CNO</td>
<td></td>
</tr>
<tr>
<td>☐ Approve VTE Prevention Team decision-making process</td>
<td>CQO</td>
<td></td>
</tr>
<tr>
<td>☐ Announce and empower the VTE Prevention Team</td>
<td>CEO, CMO</td>
<td>H</td>
</tr>
<tr>
<td>☐ Establish meeting schedule for the VTE Prevention Team</td>
<td>PC, DDL</td>
<td></td>
</tr>
<tr>
<td>☐ Approve channels and mechanisms for communicating direction, progress of the QI team, barriers, requests for resources, and QI measure results</td>
<td>CQO</td>
<td>H</td>
</tr>
<tr>
<td>☐ Approve channels and mechanisms for approving materials (e.g., policies, protocols, standing/pre-printed order sets) developed by the VTE Prevention Team</td>
<td>BOD</td>
<td>H</td>
</tr>
<tr>
<td>☐ Convene the first VTE Prevention Team meeting</td>
<td>PC, DDL</td>
<td></td>
</tr>
</tbody>
</table>

*Key: CEO = Chief Executive Officer, CMO = Chief Officer, CSC = C-Suite Champion, PC = Physician Champion, BOD = Board of Directors, CQO = Chief Quality Officer, DDL = Day-to-Day Leader, CNO = Chief Nursing Officer

Bibliography
Appendix D:
Sample Hospital VTE Prophylaxis Policy
Sample Hospital Policy for VTE Prophylaxis

This sample policy provides a concrete vision for the quality improvement team to pursue. It can be used by the chief executive officer (CEO), chief medical officer (CMO), and the BOD in conjunction with the Business Case and Clinical Case to facilitate a set a mutual context for the initiative. It is provided in a native file format (MS Word) so that the hospital personnel can customize it and use it as a template for developing the hospital’s official policy.

Guiding Principle:

“Quality improvement has always been the right thing to do. The driver for it has been moral and professional — if patients are suffering unnecessarily, or not getting all the evidence-based care that could help them, then we have a professional obligation to improve our care.”

James Reinertsen, MD
Senior Fellow, Institute for Healthcare Improvement
President, The Reinertsen Group
Alta, Wyoming, USA

Purpose of policy:
- To facilitate physician decision making related to VTE prophylaxis based on the combination of individual patients’ risks and contraindications.

Statement of Leadership Commitment:
- Our organization will develop and implement policies that reduce the risk of our hospitalized patients developing VTE. We will do this by assessing patient VTE risks or contraindications for VTE prophylaxis as defined by hospital policy, using a hospital-approved VTE prophylaxis assessment tool and providing standardized prophylaxis based upon the patient’s assessed status.

Policy requirements:
- Within 24 hours of inpatient admission (or within 48 hours of ICU admission) and at predetermined times thereafter, all hospitalized patients must be assessed for level of VTE risk or contraindications for VTE prophylaxis using a hospital-approved VTE prophylaxis assessment tool.
- All patients must receive VTE prophylaxis according to hospital-approved treatment standards based upon the patient’s assessed status.
- It is the responsibility of _________________ to conduct a VTE prophylaxis assessment of each hospitalized patient.
- It is the responsibility of _________________ to notify (and document notification) ________________ with the results of the patient’s VTE prophylaxis assessment status.
- It is the responsibility of _________________ to order VTE prophylaxis within _____ hours of receiving notification of the patient’s VTE prophylaxis assessment status.
- If the hospital’s approved standard prophylaxis treatment is not ordered by ________________, the rationale must be documented in the medical record.
- Failure of ______________ to order VTE prophylaxis or document a rationale for deviating from the hospital’s approved standard VTE prophylaxis protocol will constitute failure to follow established standards of practice.

________________________________________       ______________________
Approval signature                                  Approval date

________________________________________________________
Printed name and title
Appendix E:
Sample Leadership Roles and Responsibilities
Sample Leadership Roles and Responsibilities
for Quality Improvement: VTE Prevention

This is a multifunctional document that leaders can use to negotiate and coordinate their individual responsibilities to make sure that all of the essential activities are covered. It can be used by the BOD, CEO, CMO, chief quality officer (CQO), C-Suite champion (CSC), and physician champion (PC) as a starting point for discussion. It is provided in a native file format (MS Word) so that it can also serve as a template for the final, approved version of leadership accountabilities.

**Board of Directors (BOD, or Board)—can include whole Board or just its Quality Committee**
- Approves a blood-clot prevention initiative as a high priority
- Sets performance standards and benchmarks for blood-clot prevention
- Approves the format, frequency, and level of detail expected for the quality reports the Board receives
- Appropriates specific funds for clinical quality improvement activities
- Formally reviews and discusses venous thromboembolism (VTE, or blood clots) performance data and seeks explanations for rates that fail to meet standards and benchmarks
- Establishes and revises priorities for improving patient safety and clinical quality of care
- Assures structure is clearly delineated for: a) obtaining stakeholder input; and b) approving materials for improving clinical quality and patient safety (e.g., policies, protocols, standing/pre-printed order sets, patient education/staff education)
- Spends time on the nursing units talking to patients, families, and staff to understand problems related to preventing blood clots in hospitalized patients

Approved by _____________________________  Date of approval _____________________________
Chief Executive Officer (CEO)

- Obtains commitment from BOD (or its Quality Committee) for a VTE prophylaxis initiative as a high priority
- Assures that the roles and responsibilities for the BOD and CEO are clearly delineated for quality improvement and patient safety
- Works with the Chief Quality officer (CQO) to delineate CQO roles, responsibilities, and authority for patient safety and clinical quality improvement activities
- Approves roles, responsibilities, and authorities of the CQO for patient safety and clinical quality improvement activities
- Works with the Chief Medical Officer (CMO) or chair of the medical staff quality committee to delineate Physician Champion (PC) roles, responsibilities, and authorities for quality improvement activities related to preventing blood clots
- Co-approves roles, responsibilities and authorities of the PC for blood-clot prevention
- Works with the CMO or chair of the medical staff quality committee to delineate CQO roles, responsibilities, and authority for quality improvement activities related to preventing blood clots
- Assesses candidates and designates C-Suite Champion (CSC) for blood-clot prevention initiative
- Works with the CSC to delineate CSC roles, responsibilities, and authorities for quality improvement activities related to preventing blood clots
- Approves roles, responsibilities, and authorities of the CSC for quality improvement activities related to preventing blood clots
- Co-approves list of key stakeholders for blood-clot prevention (i.e., individuals or groups that can facilitate or obstruct quality improvement activities or be affected by the resulting actions, objectives, and policies)
- Approves time and resources necessary to develop, test, and implement evidence-based practices for blood-clot prevention
- Co-approves multidisciplinary membership of medical VTE Prevention Team
- Announces and empowers the VTE Prevention Team
- Presents VTE performance data to the Board and provides explanations regarding barriers and proposed solutions
- Communicates to both employees and medical staff the clinical value and relevance of VTE prophylaxis. (Practicing physicians can be skeptical about newly discovered evidence for a practice change. They tend to embrace the principle more readily when they hear administrators emphasizing clinical outcomes over regulatory requirements or financial benefits.)
- Talks with physicians individually to learn firsthand of their issues and concerns related to establishing and implementing a VTE prophylaxis policy
- Rounds on the nursing units talking to patients, families, and staff to understand problems related to preventing blood clots in hospitalized patients
- Celebrates successes with staff and identifies opportunities for improvement

Approved by __________________________ Date of approval __________________________
Chief Medical Officer (CMO)

- Assures that the roles, responsibilities, and authorities for CMO are clearly delineated for quality improvement and patient safety
- Works with the CEO to delineate Physician Champion (PC) roles, responsibilities, and authorities for quality improvement activities related to preventing blood clots
- Co-approves roles, responsibilities, and authorities of the PC for blood-clot prevention
- Works with the CEO to assess PC candidates’ strengths and weaknesses for leading the VTE prophylaxis initiative
- Works with the CEO to recruit and empower PC for leading the VTE prophylaxis initiative
- Co-approves list of key stakeholders for blood-clot prevention (i.e., individuals or groups that can facilitate or obstruct quality improvement activities or be affected by the resulting actions, objectives, and policies)
- Appoints the medical staff membership of the VTE Prevention Team
- Talks with physicians to understand and recognize their reluctance to embrace a change related to VTE prophylaxis and addresses these concerns in a manner that is forthright and informed
- Provides CSC with information from physicians regarding their reluctance to embrace a change related to VTE prophylaxis
- Communicates to both employees and medical staff the clinical value and relevance of VTE prophylaxis
- Holds medical staff accountable for compliance
- Celebrates successes with staff and identifies opportunities for improvement

Approved by _____________________________ Date of approval _____________________________
**Chief Nursing Officer (CNO)**

- Communicates to employees and medical staff the clinical value and relevance of VTE prophylaxis
- Assures nursing resources available as needed for compliance
- Is prepared with data from professional journals, national groups, and leaders in the field that demonstrate the need for the change and support the evidence (along with PC and CSC)
- Holds nursing staff accountable for compliance with policy and procedures
- Rounds on the nursing units talking to patients, families, and staff to understand problems related to preventing blood clots in medical patients
- Reviews written reports regarding team plans, progress, and barriers to progress
- Works with organizational leadership in all areas to remove barriers related to preventing blood clots in hospitalized patients
- Celebrates successes with staff and identifies opportunities for improvement

________________________________________                  ___________________________

Approved by                                                                             Date of approval
Chief Quality Officer (CQO)

- Educates and guides efforts of CEO, CMO and medical VTE Prevention Team to establish the culture, frameworks, resources, and mechanisms for:
  - Empowering individuals and teams (with clear responsibility, authority, education, resources, feedback, and recognition) to develop, test, and implement desired changes
  - Channeling communications to the Board, medical staff, and hospital staff regarding the priorities, activities, and results of the desired changes
  - Demonstrating evidence-based, fair, data-driven, and practicable approaches to change
  - Facilitating and coordinating efforts to manage the patients’ clinical conditions effectively and efficiently
  - Monitoring and analyzing the ongoing performance rates of targeted QI measures and indicators
  - Aligning QI priorities and goals of the Board, C-suite, medical staff, hospital staff, and patients/families
  - Proposing solutions to address barriers in the hospital’s culture and infrastructure that are impeding quality improvement (QI) efforts and activities

- Identifies barriers in the hospital’s culture and infrastructure that are impeding quality improvement efforts and activities related to VTE prevention
- Provides the team with QI tools for process design/redesign and analysis of cases that do not meet the standard
- Approves VTE Prevention Team decision-making process
- Proposes approaches to VTE Prevention Team to address barriers in the hospital’s culture and infrastructure that are impeding quality-improvement efforts and activities
- Works with the CSC to research both the implications of the proposed changes for various parts of the system and the more remote consequences such a change might trigger
- Leads VTE Prevention Team in developing an Aim Statement that includes goals and objectives
- Provides guidance on developing key stakeholder list, communication plan, team decision-making process, and organization-level approval process
- Works with the CSC and PC on determining membership of multidisciplinary team for medical VTE prophylaxis quality improvement
- Works with the PC and DDL on determining time and resources necessary for the VTE Prevention Team to develop, test, and implement desired changes
- Determines the functional level of the VTE Prevention Team and provides for individual and team training and skills development—both clinical and quality management (e.g., root cause analysis, process mapping/flow diagrams, failure modes and effects analysis, recognizing human factors issues, optimizing teamwork
- Leads the ongoing monitoring and reporting of process/outcome rates related to VTE prevention interventions
- Works with the PC and DDL to implement proposed solutions to barriers
- Celebrates successes with staff and identifies opportunities for improvement

________________________________________                  _____________________________
Approved by                                                                             Date of approval
Designated C-Suite Champion (CSC)

- Works with CEO to delineate CSC roles, responsibilities, and authorities for quality improvement in VTE prophylaxis
- Works with the PC to delineate and co-approve roles and responsibilities of the Day-to-Day Team Leader (DDL) for preventing blood clots
- Approves VTE Prevention Team decision-making process
- Designates and empowers (e.g., supports requests for resources) DDL for the VTE Prevention Team
- Researches both the implications of proposed changes for various parts of the system and the more remote consequences such a change might trigger
- Allocates the time and resources the VTE Prevention Team needs to achieve its aim
- Provides the CEO with information regarding barriers and proposed solutions related to preventing blood clots
- Rounds on the nursing units talking to patients, families, and staff to understand obstacles related to preventing blood clots
- Arranges for the necessary support to help schedule VTE Prevention Team meetings and get out the agenda, minutes, materials, and other communications
- Provides open access for Physician Champion and Day-to-Day Leader to approach the leadership/administration with ideas and roadblocks to changes
- Attends VTE Prevention Team meetings
- Reviews written reports regarding team plans, progress, barriers to progress and successes
- Works with organizational leadership in all areas to remove barriers and celebrate successes related to preventing blood clots in medical patients
- Is prepared to answer the following questions:
  - What is the evidence to support the change?
  - Why is the change necessary?
  - Are there others who have already adopted the change?
  - Is there value to the change, or is this change only for the sake of change?
  - Why should I want to change (what’s in it for me)?
- Is prepared with data from professional journals, national groups, and leaders in the field that demonstrate the need for the change and support the evidence (along with PC and CNO)
- Uses multiple forums—such as hospital staff meetings, impromptu discussions in the hallway, the employee cafeteria, etc.—to disseminate information and share knowledge regarding VTE prevention in medical patient
- Communicates to both employees and medical staff the clinical value and relevance of VTE prophylaxis. (Practicing physicians can be skeptical about newly discovered evidence for a practice change. They tend to embrace the principle more readily when they hear administrators emphasizing clinical outcomes over regulatory requirements or financial benefits.)
- Celebrates successes with staff and identifies opportunities for improvement

Approved by ____________________________ Date of approval ____________________________
Designated Physician Champion (PC)

- Works with the CSC and CQO to delineate and co-approve roles and responsibilities of the DDL for preventing blood clots
- Co-approves medical VTE Prevention Team decision-making process
- Works with DDL to establish a meeting schedule for the medical VTE Prevention Team
- Convenes the first VTE Prevention Team meeting
- Attends and leads VTE Prevention Team meetings
- Engages physicians in multiple forums (e.g., medical staff meetings, hallway discussions, medical staff lounge) to disseminate information and share knowledge gained through implementation experience in VTE
- Talks with physicians to understand and recognize their reluctance to embrace a change related to VTE prophylaxis and addresses these concerns in a manner that is forthright and informed
- Researches and offers responses to the following questions:
  - What is the evidence to support the change?
  - Why is the change necessary?
  - Are there others who have already adopted the change?
  - Is there value to the change, or is this change only for the sake of change?
  - Why should I want to change (what’s in it for me)?
- Is responsible for securing data from professional journals, national societies, and leaders in the field that:
  - Demonstrate the need for the change
  - Support the evidence
  - Demonstrate potential gaps between the evidence and practice
  - Compare an individual to others
- Investigates and informs the medical VTE Prevention Team regarding what does and doesn’t work, the typical problems people run into, and how these problems can be avoided or overcome
- Shares successes of others
- Leads formal peer discussions to build consensus for the proposed changes
- Works with the DDL to determine resources necessary to develop, test, implement, monitor, and report efficiency and effectiveness of VTE prophylaxis program
- Works with the DDL to set agendas for VTE Prevention Team meetings
- Edits the minutes of the VTE Prevention Team meetings for presentation to the CSC
- Rounds on the nursing units talking to patients, families, and staff to understand problems related to preventing blood clots in hospitalized patients
- Provides the CSC with explanations of perceived barriers to achieving the aims of the VTE Prevention Team and shares successes
- Works with the DDL, CSC, and VTE Prevention Team members to design ways to overcome barriers for preventing blood
- Celebrates successes with staff and identifies opportunities for improvement

Approved by ______________________________________ Date of approval _____________________________
**Designated Day-to-Day Leader (DDL)/QI Team Facilitator**

- Rounds on the nursing units talking to patients, families, and staff to understand problems related to preventing blood clots in hospitalized patients
- Works with the PC to determine resources necessary to develop, test, implement, monitor, and report efficiency and effectiveness of the VTE prophylaxis program
- Works with the PC to set agendas for VTE Prevention Team meeting
- Serves as facilitator at VTE Prevention Team meetings to ensure that the team functions constructively and stays on track
- Provides the team with QI tools for process design/redesign and analysis of cases that do not meet the standard
- Between VTE Prevention Team meetings, monitors progress of the team members in accomplishing their follow-up activities and reports barriers to the CSC and PC
- Works with the PC and CSC to design ways to overcome barriers and share successes
- Reviews cases that fall out (of numerator) and reports to team
- Assists with workflow development for compliance with policy and procedure
- Celebrates successes with staff and identifies opportunities for improvement

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Approved by ________________ Date of approval ________________

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**Administrative Support Staff**

- Documents (takes minutes) key discussion points, activities, decisions, and follow-up assignments from each VTE Prevention Team meeting
- Submits minutes to PC for editing and approval
- Disseminates minutes to team members from VTE Prevention Team meetings

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Approved by ________________ Date of approval ________________
Bibliography

Appendix F:
Assessing C-Suite Champion Potential
Assessing C-Suite Champion Potential for Success

This assessment tool may be used by the CEO to identify the C-Suite executive who has the greatest potential for leading a quality improvement project to achieve and sustain success. On one sheet of paper it provides a snapshot of some key roles, responsibilities, and tasks that are often lacking in support of hospital quality improvement efforts. It provides a checklist of personal and interpersonal characteristics that have been demonstrated to result in more effective leadership of the project moving forward.

<table>
<thead>
<tr>
<th>Examples: Roles and Responsibilities of the C-Suite Champion</th>
<th>Examples: Characteristics for Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Serves as an administrative leader who provides staff time and organizational resources for implementing evidence-based practices aimed at developing safe, effective, patient-centered, timely, efficient, and equitable patient care</td>
<td>Primary Characteristics</td>
</tr>
<tr>
<td>• Serves as the critical communication link between the hospital staff and the C-Suite and between the C-Suite and the medical staff</td>
<td>□ Authorized to commit resources for development, testing, implementation, ongoing monitoring, and reporting of improvement interventions and results</td>
</tr>
<tr>
<td>• Works with CEO to delineate C-Suite Champion roles and responsibilities for quality improvement in VTE prophylaxis</td>
<td>□ Spoken of in a positive and respectful manner by the medical staff and hospital staff</td>
</tr>
<tr>
<td>• Verbalizes the importance of ongoing monitoring and reporting of process/outcome rates related to improvement interventions</td>
<td>□ Stays connected to developments in patient safety, quality improvement, and risk-management practices through a variety of sources</td>
</tr>
<tr>
<td>• Works with the Physician Champion and Chief Quality Officer (CQO) to delineate Day-to-Day Leader roles and responsibilities for quality improvement in VTE prophylaxis</td>
<td>□ Is flexible and controlled when under stress</td>
</tr>
<tr>
<td>• Rounds on the nursing units talking to patients, families, and staff to understand quality problems related to preventing blood clots in medical patients</td>
<td>□ Is not afraid to speak his/her mind or of trying to influence others, but does so in a way that respects the personal boundaries of others</td>
</tr>
<tr>
<td>• Uses multiple forums—such as hospital staff meetings, impromptu discussions in the hallway, the employee cafeteria, etc.—to disseminate information and share knowledge regarding VTE prevention in medical patients</td>
<td>□ Able to discern mutual goals beyond apparent differences in order to build consensus</td>
</tr>
<tr>
<td>• Communicates to both employees and medical staff the clinical value and relevance of VTE prophylaxis. (Practicing physicians can be skeptical about newly discovered evidence for a practice change. They tend to embrace the principle more readily when they hear administrators emphasizing clinical outcomes over regulatory requirements or financial benefits.)</td>
<td>□ Communicates truthfully and does not withhold relevant information</td>
</tr>
<tr>
<td>• Questions the Champion should be prepared to answer can include:</td>
<td>□ Addresses others’ concerns in a manner that is forthright and informed</td>
</tr>
<tr>
<td>– What is the evidence to support the change?</td>
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</tr>
<tr>
<td>– Why is the change necessary?</td>
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</tr>
</tbody>
</table>
Assessing C-Suite Champion Potential for Success

The checklist in the right-hand column provides some concrete examples to look for when considering an executive for C-Suite Champion.

- Are there others who have already adopted the change?
- Is there value to the change, or is this change only for the sake of change?
- Why should I want to change (what’s it for me)?
- Is prepared with data from professional journals, national groups, and leaders in the field that:
  - Demonstrate the need for the change.
  - Support the evidence.
  - Demonstrate potential gaps between the evidence and practice.
- Provides mechanism for open access for Physician Champion and Day-to-Day Leader to approach the leadership/administration with ideas and roadblocks to changes
- Provides the QI team with necessary time and resources
- Arranges for the necessary support to help schedule QI team meetings and get out the agenda, minutes, materials, and other communications
- Advocates for the ongoing monitoring and reporting of process/outcome rates related to improvement interventions
- Receives and reviews verbal and written reports regarding team plans, progress, and barriers to progress
- Works with organizational leadership to remove barriers
- Is responsible for proposing solutions to address barriers in the hospital’s culture and infrastructure that are impeding quality improvement (QI) efforts and activities

### Secondary Characteristics

- Seen as wanting something for patients and families rather than for administration
- Easy to talk to or deal with, welcomes contact by others, makes time to attend to their issues and shows interest in their views
- Able to defend self against aggressive incursions and foster self-control and respect in others
- Recognizes, perceives, and directly relates to the emotions of others
- Shows appreciation for the efforts and contributions of others
- Able to wait patiently and recognizes the importance of “timing” when initiating change

### Bibliography

Appendix G:
Assessing Physician Champion Potential
Assessing Physician Champion Potential for Success

This assessment tool may be used by the CEO and CMO to identify the physician who has the greatest potential for leading a quality improvement project to achieve and sustain success. On one sheet of paper it provides a snapshot of some key roles, responsibilities, and tasks that are often lacking in support of hospital quality improvement efforts. It provides a checklist of personal and interpersonal characteristics that have been demonstrated to result in more effective interactions to keep the project moving forward.

<table>
<thead>
<tr>
<th>Examples: Roles and Responsibilities of Physician Champions</th>
<th>Examples: Characteristics for Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attends and leads VTE Prevention Team meetings.</td>
<td><strong>Primary Characteristics</strong></td>
</tr>
<tr>
<td>Often described as a voluntary leadership role for a limited period of time. The literature equates the term with an opinion leader, a change agent, a physician who influences colleagues and friends.</td>
<td>□ Has a wide peer and social network and an extensive knowledge of how his/her colleagues interact with each other</td>
</tr>
<tr>
<td>An expert who provides education, champions a cause or product, or gives support to staff around the diffusion and implementation of clinical practice guidelines, protocols, or research evidence</td>
<td>□ Perceived as credible and is respected by peers</td>
</tr>
<tr>
<td>Able to influence other physicians to adopt or implement a new or revised process or guideline for the improvement of care quality or to become physician champions themselves within their own practice groups</td>
<td>□ Highly knowledgeable and stays connected to his/her area of expertise through a variety of sources</td>
</tr>
<tr>
<td>Promotes autonomy by modeling behaviors, serving as an example to others, and providing information and guidance to other physicians. He or she works with the health care organization to provide feedback to other physicians about their performance</td>
<td>□ Willing to share knowledge with others</td>
</tr>
<tr>
<td>Provides a vital link: A process change that is seen as advantageous by administrators may not be viewed as such from a practicing physician’s perspective. The Physician Champion’s role is positioned to serve as a liaison—updating administrators and physicians on project status, creating a mutual understanding of the needs of all parties, and facilitating a win-win solution to issues affecting processes and outcomes.</td>
<td>□ Willing to support and advocate for process changes</td>
</tr>
<tr>
<td>Uses his/her sphere of influence to promote changes within a specialty area and the professional setting</td>
<td>□ Willing to implement new guidelines and serve as a resource for others</td>
</tr>
<tr>
<td>Overcomes skepticism of practicing physicians about newly discovered evidence for a practice change by verbally supporting and physically implementing the change</td>
<td>□ Easy to talk to or deal with, welcomes contact by others, makes time to attend to their issues and shows an interest in their views</td>
</tr>
<tr>
<td>Shares the knowledge gained through implementation experience to ease the transition and narrow the gap between evidence and practice</td>
<td>□ Is flexible and controlled in the face of stress, leading others by example</td>
</tr>
<tr>
<td>Overcomes skepticism of practicing physicians about newly discovered evidence for a practice change by verbally supporting and physically implementing the change</td>
<td>□ Is not afraid to speak his/her mind or of trying to influence others, but does so in a way that respects the personal boundaries of others</td>
</tr>
<tr>
<td>Shares the knowledge gained through implementation experience to ease the transition and narrow the gap between evidence and practice</td>
<td>□ Able to defend self against aggressive incursions and foster self-control and respect in others</td>
</tr>
</tbody>
</table>

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Health Services Advisory Group, Inc.

Translating VTE Guidelines Into Practice

Project supported by sanofi-aventis, U.S.
Assessing Physician Champion Potential for Success

The checklist in the right-hand column provides some examples of what to look for when considering a physician for Physician Champion.

- Uses multiple forums to share information and knowledge, including:
  - Presenting the process change at medical staff meetings
  - Holding impromptu discussions in the hallway
  - Sharing new evidence in a medical staff lounge

- Understands and recognizes the reluctance and hesitation by others to embrace a change, and addresses these concerns in a manner that is forthright and informed

- Is prepared to answer questions that can include:
  - What is the evidence to support the change?
  - Why is the change necessary?
  - Are there others who have already adopted the change?
  - Is there value to the change, or is this change only for the sake of change?
  - Why should I want to change (what’s in it for me)?

- Is prepared with data from professional journals, national societies, and leaders in the field that:
  - Demonstrate the need for the change.
  - Support the evidence.
  - Demonstrate potential gaps between the evidence and practice.
  - Compare an individual to others.

- Leads peer discussions to build consensus for the change

- Able to discern mutual goals beyond apparent differences in order to build consensus among opposing parties

- Holds that all people should be treated as equals

- Recognizes, perceives, and directly relates to the emotions of others

- Communicates truthfully and does not withhold relevant information

- Shows appreciation for the efforts and contributions of others

- Follows through with duties and takes the time necessary to get the job done correctly

- Able to wait patiently and recognizes the importance of “timing” when initiating change

Bibliography

Appendix H:
Communication Plan
# Sample Communication Plan
## Quality Improvement: VTE Prophylaxis

This tool is to be used in conjunction with the Hospital Leadership Responsibilities Checklist and the Leadership Roles and Responsibilities document; these three items form the foundation for developing the administrative infrastructure necessary to support the hospital-wide activities for preventing blood clots in hospitalized patients.

<table>
<thead>
<tr>
<th>Who</th>
<th>Communicates What?</th>
<th>Communication Mechanisms, i.e.</th>
<th>To Whom?</th>
<th>Purpose of Communication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chief Executive Officer (CEO), Chief Medical Officer (CMO)</td>
<td>Roles and responsibilities (for VTE prophylaxis quality improvement) of the CEO, Board of Directors, CMO, C-Suite Champion, Chief Quality Officer (CQO), and Physician Champion</td>
<td>Official memo, newsletter, face-to-face meeting(s)</td>
<td>Board of Directors, C-Suite, Medical staff</td>
<td>For their information</td>
</tr>
<tr>
<td>C-Suite Champion / Physician Champion</td>
<td>Membership and charter of the VTE prophylaxis quality improvement team</td>
<td>Face-to-face meeting</td>
<td>CEO, CMO</td>
<td>To present to BOD (or their Quality Committee)</td>
</tr>
<tr>
<td>CEO</td>
<td>Membership and charter of the VTE prophylaxis quality improvement team</td>
<td>Official memo, newsletter, face-to-face meeting(s)</td>
<td>Board of Directors, CMO, C-Suite, hospital staff</td>
<td>For approval of charter (Aim Statement, including goals and objectives)</td>
</tr>
<tr>
<td>CMO</td>
<td>Membership and charter of the VTE prophylaxis quality improvement team</td>
<td>Official memo, newsletter, face-to-face meeting(s)</td>
<td>Medical staff</td>
<td>For their information and to empower the Physician Champion and the C-Suite Champion</td>
</tr>
<tr>
<td>CEO</td>
<td>Membership and charter of the VTE prophylaxis quality improvement team</td>
<td>Official memo, newsletter, face-to-face meeting(s)</td>
<td>Hospital staff</td>
<td>For their information and to empower the Physician Champion and the C-Suite Champion</td>
</tr>
</tbody>
</table>
## Sample Communication Plan
Quality Improvement: VTE Prophylaxis

<table>
<thead>
<tr>
<th>Who</th>
<th>Communicates What?</th>
<th>Communication Mechanisms, i.e.</th>
<th>To Whom?</th>
<th>Purpose of Communication</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-Suite Champion</td>
<td>Results of VTE prophylaxis performance measures</td>
<td>Face-to-face meeting</td>
<td>C-Suite</td>
<td>To discuss barriers and causes and identify departments that may be involved in changes</td>
</tr>
<tr>
<td>CQO (or designee)</td>
<td>Results of VTE prophylaxis performance measures</td>
<td>Written report, post on hospital intranet or Web page, presentations at staff meetings</td>
<td>Hospital staff</td>
<td>For their information</td>
</tr>
<tr>
<td>CEO</td>
<td>Results of VTE prophylaxis performance measures and explanations of barriers and causes and possible changes being considered</td>
<td>Face-to-face meeting, slide presentation, written report</td>
<td>Board of Directors</td>
<td>For their information; to have them set priorities when resources are insufficient to address everything (at the same time)</td>
</tr>
<tr>
<td>Physician Champion</td>
<td>Results of VTE prophylaxis performance measures (comparison [de-identified] by individual physician, department, nursing unit)</td>
<td>Face-to-face meetings, newsletter, written report</td>
<td>Medical staff</td>
<td>For discussion of issues and barriers, to solicit input on changes</td>
</tr>
</tbody>
</table>
Appendix I:
Sample Aim Statement and Team Charter Template
Sample Aim Statement for VTE Prophylaxis

These tools (Sample Aim Statement and Team Charter Template) can be used by leadership to charter a VTE Prevention Project Team or to provide direction to an existing team. They can guide the team in organizing a QI project and developing a written, measurable, and time-sensitive description of the accomplishments the Team and hospital expects to make from its improvement efforts. The Aim Statement answers the question: “What are we trying to accomplish?”

By ____(Date)____, ____% of hospitalized patients will receive VTE prophylaxis as defined by hospital-approved protocols and according to a patient’s assessed status of VTE risk or prophylaxis contraindications based on a hospital-approved VTE prophylaxis assessment tool. Contraindications will be clearly documented in the medical record for 100% of the cases in which VTE prophylaxis is not ordered.

Definition of an Aim Statement:
An Aim Statement is a written, measurable, and time-sensitive description of the accomplishments the hospital’s VTE Team expects to make from its improvement efforts. The Aim Statement answers the question: “What are we trying to accomplish?”

Critical Consideration:
The Aim Statement should be developed with input from senior leadership to ensure support for the VTE Team and alignment with the strategic goals of the organization. An organization will not improve without a clear and firm intention to do so. The performance goals should represent a challenge for the organization.

Developing an Aim Statement:
There is no one correct way to write an Aim Statement, but most effective Aim Statements have the following attributes:

- Communicate the expectations
- Are time-specific
- Are measurable
- Define the specific population or populations affected
- Are clear and unambiguous
- Are brief and concise
- They aim BIG
# Clinical Quality Improvement Team Charter

<table>
<thead>
<tr>
<th>Clinical Discipline/Service Team Name:</th>
</tr>
</thead>
</table>

**Executive Sponsor:** Please insert the name of the assigned Associate Administrator, Chief Nursing Officer, or Clinical Delivery Leader.

**Team Chair:** Please insert the name of the Team Chair.

**Team Vice-Chair:** Please insert the name of the Team Vice-Chair.

**Team Membership:** Please include name, credentials, and title.

<table>
<thead>
<tr>
<th>Name</th>
<th>Credentials</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

How are decisions made in the team?

To whom and how often does the team report its activities, barriers, and results?

**Frequency of meetings:**

**Purpose of Team or description of process(es) for improvement (attach process map)**

Process name(s):

**AIM Statement**

**Key measures** (indicate process or outcome)

<table>
<thead>
<tr>
<th>Key Goals &amp; Deliverables</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
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</table>
An important first step in any health care system quality improvement project is to clearly delineate roles and responsibilities of internal stakeholders, particularly those of senior leadership. This form (also provided as a native format MS Word file) provides a place where senior leadership members of a hospital’s VTE Prevention team can be identified and their primary project responsibilities (based on suggestions found throughout this Guide) documented. This, along with the Aim Statement, will help team members to develop a shared vision and understanding of how the hospital’s VTE Prevention Project will be implemented.

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Phone</th>
<th>E-mail</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chief Executive Officer</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Primary Project Responsibilities:</td>
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<td></td>
</tr>
<tr>
<td><strong>Designated Board of Directors Project Representative</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Primary Project Responsibilities:</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Designated C-Suite Champion</strong></td>
<td></td>
<td></td>
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<tr>
<td>Primary Project Responsibilities:</td>
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<tr>
<td><strong>Chief Medical Officer</strong></td>
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<tr>
<td>Primary Project Responsibilities:</td>
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<td></td>
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<tr>
<td><strong>Designated Project Physician Champion</strong></td>
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<tr>
<td>Primary Project Responsibilities:</td>
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<tr>
<td><strong>Chief Nursing Officer</strong></td>
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<tr>
<td>Primary Project Responsibilities:</td>
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<tr>
<td><strong>Chief Quality Officer</strong></td>
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<tr>
<td>Primary Project Responsibilities:</td>
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<tr>
<td><strong>Chief Pharmacy Officer</strong></td>
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<tr>
<td>Primary Project Responsibilities:</td>
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<tr>
<td><strong>Chief Information Officer</strong></td>
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<tr>
<td>Primary Project Responsibilities:</td>
<td></td>
<td></td>
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<tr>
<td><strong>Designated Project Day-to-Day Leader/QI Team Facilitator</strong></td>
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<tr>
<td>Primary Project Responsibilities:</td>
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<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Project Responsibilities:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix K:
Sample Business Case PowerPoint
The Business Case for Implementing a VTE Prophylaxis Process for Hospitalized Patients

Translating VTE Guidelines into Practice

The Business Case: Implementing a VTE Prophylaxis Process for Hospitalized Patients

Every hospitalized patient is considered at risk for developing blood clots (see photo), which are the most preventable cause of death among hospitalized patients.

Post-thrombotic syndrome, a complication that occurs in 40%-80% of patients who develop blood clots, may result in permanent disability.

Urgent action is needed by hospitals to develop VTE* (venous thromboembolism, or blood clot) prevention processes for hospitalized patients.

*VTE comprises deep-vein thrombosis (DVT) and pulmonary embolism (PE).

Treating VTE is exponentially more costly than preventing it.

- Estimated additional costs for treating each case of hospital-acquired DVT are $10,000—and $20,000 for each case of hospital-acquired PE.

Implementing a VTE prevention process is something we can start today to protect the hospital from the vulnerability of increased costs, legal liability, and public exposure that could have dire consequences.

Preventing Blood Clots in Hospitalized Patients

Preventing Blood Clots in Hospitalized Patients (Cont’d)

- VTE reduction is a priority of The Joint Commission (TJC) and the Centers for Medicare & Medicaid Services (CMS).
- VTE is the #1 cause of potentially preventable deaths in hospitalized patients.1
- VTE prophylaxis is rated by AHRQ as the #1 most effective patient safety practice for hospitals.2
- VTE prophylaxis rates are publicly reported on the Hospital Compare Web site.
- CMS no longer pays hospitals for the additional costs incurred for treatment of hospital-acquired VTE in selected patients.

Preventing Blood Clots in Hospitalized Patients (Cont’d)

- Treating VTE is exponentially more costly than preventing it.
- Estimated additional costs for treating each case of hospital-acquired DVT are $10,000—and $20,000 for each case of hospital-acquired PE.

Implementing a VTE prevention process is something we can start today to protect the hospital from the vulnerability of increased costs, legal liability, and public exposure that could have dire consequences.
The Business Case for Implementing a VTE Prophylaxis Process for Hospitalized Patients

Strategic Imperative

VTE prophylaxis is recognized by AHRQ as #1 out of 73 recommended Patient Safety Practices, based on their impact and effectiveness.²

Strategic Imperative (Cont’d)

In today’s environment, leaders must increasingly cope with outside social and economic pressures, including:

- Public reporting on Hospital Compare.
- Accountability and responsibility to keep patients safe (IOM report³).
- Increasing visibility of safety concerns in the media.
- Public expectation that hospitals will keep them safe and growing perception that hospitals are unsafe.

Value Proposition

A hospital can’t afford to not implement a VTE prophylaxis protocol for its patients.

Value Proposition (Cont’d)

- Prophylaxis reduces the incidence of VTE by 50% to 65%.¹
- Estimates of incremental cost related to increased length of stay and treatment of preventable VTE are $10,000 per DVT and $20,000 per PE.¹
  - For a 300-bed hospital with a 40 percent prophylaxis rate, the translates to a $1.7 million per year in additional costs.

Value Proposition (Cont’d)

- As of 2008, there are two VTE-related “Never Events” (hospital-acquired conditions for which Medicare will not pay the additional costs of treatment) in place: DVT or PE related to total knee or hip replacement.
- Having a VTE prophylaxis protocol in place:
  - Reduces hospital and governing board liability exposure
  - Aligns with Centers for Medicare & Medicaid Services (CMS), National Quality Forum (NQF), Agency for Healthcare Research and Quality (AHRQ), and The Joint Commission priorities
  - Protects patients, reduces costs, and improves outcomes on public performance measures.

Legal Considerations

Why doesn’t the hospital have a VTE prophylaxis protocol in place for its patients?
Legal Considerations (Cont’d)

- Who is ultimately accountable for whether the hospital has a VTE prophylaxis protocol in place for its patients?
- What is the hospital’s liability exposure if a patient acquires a VTE during hospitalization:
  - If there is no prophylaxis protocol in place?
  - If there is a prophylaxis protocol in place and it was followed?
  - If there is a prophylaxis protocol in place and it was not followed?

Likelihood (Cont’d)

- The DVT Free registry* found one VTE per hospital bed per annum; about half of those were hospital-acquired.
- 70% of VTEs are deep vein thrombosis (DVT) and 30% are pulmonary emboli (PE).
- Approximately 75% of fatal PEs that are diagnosed at autopsy are in medical patients.

Likelihood

A large proportion of hospitalized patients are at risk for VTE, but there is a low rate of prophylaxis.¹

VTE is the #1 cause of preventable death among hospitalized patients. A 300-bed hospital with a 40% VTE prophylaxis rate would have 5 potentially preventable 90-day pulmonary emboli (PE) mortalities.²

CMS/TJC VTE Measures

VTE reduction is a priority of the Centers for Medicare & Medicaid Services (CMS) and The Joint Commission (TJC).

CMS VTE Measures

Currently, the two publicly reported VTE measures included in the CMS Reporting of Hospital Quality Data for Annual Payment Update (RHQDAPU) program are:

- SCIP*-VTE-1: Surgery patients with recommended VTE prophylaxis ordered anytime from hospital arrival to 24 hours after Anesthesia End Time.
- SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours prior to Anesthesia Start Time to 24 hours after Anesthesia End Time.

*SCIP = Surgical Care Improvement Program

The Joint Commission (TJC) VTE Measures

The following NQF-endorsed VTE measures have been approved as part of a core measure set for use in TJC’s ORYX program and may be included as components of the CMS Reporting Hospital Quality Data for Annual payment Update (RHQDAPU) program in 2012.

- VTE1—Proportion of patients who received VTE prophylaxis or have documentation why no prophylaxis was given within the first 24 hours of hospitalization hospital days (Med/Surg patients who have a 48h stay).
The Business Case for Implementing a VTE Prophylaxis Process for Hospitalized Patients

The Joint Commission (TJC) 
VTE Measures (Cont’d)

- **VTE1**—Proportion of patients who received VTE prophylaxis or have documentation why no prophylaxis was given within the first two hospital days (ICU patients).
- **VTE2**—Proportion of patients treated with UFH who have dose managed by nomogram/protocol that includes explicit count monitoring protocols (baseline, day after initiation, and at least three times per week for up to 14 days).
- **VTE3**—Patients treated with parenteral anticoagulant and warfarin who have at least 5 days of overlap therapy with an INR > 2.0 prior to discontinuation of parenteral treatment (or who are discharged before 5 days on overlap therapy).

**Prophylaxis**

- There is a disconnect between evidence and execution as it relates to VTE prevention. One large epidemiological study found that 71% of patients diagnosed with VTE had received no prophylaxis within the past 30 days.
- Every patient admitted to the hospital should be considered to be at risk for VTE, and preventive measures should be considered the standard of care.

**References**


**Bibliography**

The Business Case for Implementing a VTE Prophylaxis Process for Hospitalized Patients

Resources

- American College of Chest Physicians: www.chestnet.org
- American Medical Directors Association—DVT Clinical Corners: www.amda.com/tools/clinical/dvt.cfm
- American Venous Forum: www.venous-info.com
- Case Management Adherence Guidelines for VTE: www.cmsa.org/portals/0/pdf/CMAG_DVT.pdf
- Coalition to Prevent DVT: www.preventDVT.org
- Consumers Advancing Patient Safety: www.patientsafety.org
- Society of Hospital Medicine—VTE Prevention Collaborative: www.hospitalmedicine.org
- Vascular Disease Foundation: www.vdf.org
- Venous Resource Center: www.venousdisease.com
Appendix L:
Sample Clinical Case PowerPoint
Translating VTE Guidelines Into Practice

Background
- Up to 2 million Americans a year suffer from venous thromboembolism (VTE, which includes deep-vein thrombosis [DVT] and pulmonary embolism [PE]).
- DVT-related PE is the most common cause of preventable hospital death.
- Complications from VTE kill more Americans than AIDS and breast cancer combined.
- Appropriate VTE prophylaxis in patients at risk is No. 1 in AHRQ’s Top 11 Safety Practices, according to strength of evidence.

Disease
According to the National Heart, Lung, and Blood Institute:
- Deep vein thrombosis (DVT) is a blood clot that forms in a vein deep in the body. Blood clots occur when blood thickens and clumps together.
- A blood clot in a deep vein can break off and travel through the bloodstream. The loose clot is called an embolus. When the clot travels to the lungs and blocks blood flow, the condition is called pulmonary embolism (PE), which can damage the lungs and other organs in the body and cause death.
- Blood clots in the thigh are more likely to break off and cause PE than blood clots in the lower leg or other parts of the body.
- DVTs are often asymptomatic. Symptoms that may present include leg pain, “Charlie Horse,” unilateral leg swelling, and/or prominence of veins in the affected leg.

Complications
- DVT reoccurs in ~30% of patients within 8 years following the discontinuation of anticoagulant therapy.
- Other complications of DVT include chronic pulmonary hypertension (2%) and pulmonary embolism (symptomatic = 25%, asymptomatic up to 70%, death from PE = 5%–10%). Post-thrombotic syndrome (PTS) occurs in 40%–80% of patients with DVT.
- PTS is preventable if thrombosis prophylaxis is routinely employed.

Risk Factors
- A large proportion of hospitalized patients are at risk for VTE, but there is a low rate of appropriate prophylaxis.
- Risk factors include:
  - Prior DVT (5 times more likely)
  - Increased age (twice as likely in patients between the ages of 50 and 81)
  - Malignancy (in 38% of concomitant cancer and DVT, the DVT is detected first)
  - Surgery, leg fractures (clot fragments are found in 60% of all patients with leg fractures)
  - Immobilization—bedrest, stroke, paralysis (without prophylaxis, 20% of all patients develop acute DVT within 5 days following a stroke)
  - Presence of central venous lines

Risk Assessment
- DVT and PE are often undetected until it is too late. Approximately 70% of DVT cases are clinically silent.
- Less than 30% of patients received prophylaxis within 30 days prior to a diagnosis of DVT.
- Approximately 75% of fatal PEs that are diagnosed at autopsy are in medical patients.
Our Process for Risk Assessment

- [Describe your process here]

Prophylaxis

- There is a disconnect between evidence and execution as it relates to VTE prevention.
- **Every patient admitted to the hospital should be considered to be at risk for VTE**, and preventive measures (including formal risk assessment of patients within 24 hours of admission and appropriate prophylaxis of high-risk patients) should be considered the standard of care.

Discharge

- Prior to discharge, patients should be educated and provided with written information regarding medications and red-flag events—including those side effects and symptoms for which patients should call their physician.

Resources

- Translating VTE Guidelines Into Practice: [www.hsag.com/vte](http://www.hsag.com/vte)
- American College of Chest Physicians: [www.chestnet.org](http://www.chestnet.org)
- American Medical Directors Association—DVT Clinical Corners: [www.amda.com/tools/clinical/dvt.cfm](http://www.amda.com/tools/clinical/dvt.cfm)
- American Venous Forum: [www.venous-info.com](http://www.venous-info.com)
- Coalition to Prevent DVT: [www.preventDVT.org](http://www.preventDVT.org)
- Society of Hospital Medicine—VTE Prevention Collaborative: [www.hospitalmedicine.org](http://www.hospitalmedicine.org)
Appendix M:
The Surgeon General’s Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism
and
AHRQ: Preventing Hospital-Acquired Venous Thromboembolism—A Guide for Effective Quality Improvement
The Surgeon General’s Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism

2008

U.S. Department of Health and Human Services
The Surgeon General’s Call to Action
to Prevent Deep Vein Thrombosis
and Pulmonary Embolism

2008
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Message from the Secretary
U.S. Department of Health and Human Services

Over the last several decades we have seen dramatic drops in the mortality rates from cardiovascular disease, the leading cause of death in this country. Yet challenges remain, and certain areas of medicine have not seen improvements. One of the biggest challenges relates to blood clots in the legs (a disease known as deep vein thrombosis or DVT), which can not only cause pain, swelling, and other discomfort, but also frequently travel to the lungs, causing a potentially fatal pulmonary embolism (PE).

The best estimates indicate that 350,000 to 600,000 Americans each year suffer from DVT and PE, and that at least 100,000 deaths may be directly or indirectly related to these diseases. This is far too many, since many of these deaths can be avoided. Because the disease disproportionately affects older Americans, we can expect more suffering and more deaths in the future as our population ages—unless we do something about it.

Additionally, as in any area of medicine, gaps still remain in our knowledge about how best to care for certain patient subpopulations, and further research is needed.

This Surgeon General’s Call to Action represents an opportunity for multiple stakeholders to come together in a coordinated effort to reverse the projected trends and to dramatically reduce the pain and suffering caused by DVT and PE in this nation through specific steps in communication, action, research and evaluation. With the involvement of individuals, families, communities, all aspects of research and health care systems, organizations, governments, and the media, we can bring better health to this country. I urge everyone with an interest in improving health to work with the Surgeon General to achieve this Call to Action’s ambitious and essential vision.

Michael O. Leavitt
Secretary of Health & Human Services
United States Public Health Service
Foreword from the Acting Surgeon General
U.S. Department of Health and Human Services

As the acting Surgeon General, my primary role is to provide the American people with the information they need to improve their health and reduce the risk of injury and illness. This first “Call to Action to Prevent Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE),” provides vital information on critical health problems that cause enormous health consequences and numerous deaths in our country. Estimates suggest that at least 350,000, and as many as 600,000, Americans each year contract DVT/PE, and at least 100,000 deaths are thought to be related to these diseases each year. Many of those who survive have complications that have a serious and negative impact on the quality of their lives. Without the joint efforts of all stakeholders, including clinicians and families, the problem will only worsen as the population ages.

This Call to Action came out of a Surgeon General’s Workshop on DVT/PE held in May 2006. The message from that workshop was clear—there is great hope and optimism about prevention, diagnosis and treatment of these diseases. The presentations and discussion that took place during those two days demonstrated that we have made progress in our knowledge of how to prevent, diagnose and treat DVT/PE. It is also clear that we are not applying that knowledge on a systematic basis. The workshop highlighted the tremendous gap in understanding and knowledge that exists about these diseases. In order to address that gap, we must disseminate information more widely about the availability of effective interventions to prevent and treat DVT/PE. We must also continue to invest in basic scientific, clinical and epidemiological research related to DVT/PE. In addition, our investment in translational research is essential in order to ensure that the public and the medical community can put the latest evidence into practice quickly and easily. To make this vision a reality, the Surgeon General’s Call to Action is intended to serve as a stimulus for the development of a coordinated plan to reverse the current trend and dramatically reduce the morbidity and mortality caused by DVT/PE. The kinds of activities that are part of this plan are outlined in this document. The critical step for all stakeholders is to come together and address this important health problem. We seek to engage all levels of government as well as individuals and private sector institutions and organizations in a coordinated, multifaceted effort to prevent and reduce the incidence of deep vein thrombosis and pulmonary embolism.

I am encouraged by the participation of so many people and organizations in the May 2006 workshop and the development of this Call to Action. I would like to thank them for their willingness to assist us in gathering the best scientific evidence as a catalyst for improvement. Efforts to reduce the incidence of DVT/PE will demand the full attention and committed efforts of all stakeholders. I am confident that working together we can take real steps to reduce the burden of these diseases. The reward for this effort will be to prove the forecasters wrong. Instead of ever-increasing numbers of individuals developing and suffering from DVT/PE, we will see dramatic reductions in the incidence and prevalence of these conditions.

Steven K. Galson, M.D., M.P.H.
RADM, U.S. Public Health Service
Acting Surgeon General
Message from the Director of the National, Heart, Lung, and Blood Institute, National Institutes of Health

Thousands of Americans suffer from deep vein thrombosis (DVT) in the United States today, and many will die from its complication, pulmonary embolism (PE). The tragedy of these diseases is that their diagnosis is easy to overlook because the signs and symptoms are often diffuse and difficult to recognize. In many cases, there are no clinically apparent signs at all. Perhaps as many as 50 percent of the cases of DVT are “silent.” Very often the first symptom of DVT is a fatal PE.

There are few public health problems as serious as DVT/PE, yet these diseases receive so little attention. Some estimates suggest that these conditions cause more deaths each year than breast cancer, AIDS, or motor vehicle incidents—illnesses or injuries that are well understood by most Americans. Up until now, levels of public awareness and knowledge about the risks of these diseases have been extremely low. The “Surgeon General’s Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism” finds the status quo unacceptable.

The National Heart, Lung, and Blood Institute (NHLBI) is the primary agency within the National Institutes of Health that is responsible for promoting research leading to improved diagnosis and treatment of DVT/PE. The NHLBI has a long and distinguished record of supporting and guiding seminal advances in thrombosis research that have yielded unprecedented improvements in the nation’s health. It has supported basic research in venous biology for the development of improved treatment for venous diseases and their complications; indeed, much of the science contained in this Call to Action is a result of NHLBI-funded research. Despite these accomplishments, there are many factors that impede progress in research and treatment, including a limited understanding of venous biology and coagulation proteins, and the lack of a critical mass of investigators and providers devoted to this research. Without technological innovation, training opportunities, and committed investigators, progress will continue to be slow.

It is NHLBI’s hope that this Call to Action will stimulate innovative research by investigators who are committed to finding new ways to prevent and treat these conditions. As the Surgeon General stated at his workshop on DVT in May of 2006, there are many differences in how health professionals deal with the issue, and there is no consensus nationally by practitioners and hospitals on the best way to approach this problem. There is also an urgent need to develop a consensus on science-based standards of care, especially for high-risk groups. It is critical that we identify new areas of research related to venous biology, DVT/PE, their complications, and clinical interventions. This kind of basic and clinical science is needed to provide a foundation for the development of evidence-based guidelines.

This Call to Action concludes that in order to impact the incidence and burden of DVT/PE, stakeholders need to come together to increase public awareness, support the development of evidence-based practices, and carry out the scientific research that can address the gaps in knowledge. I urge all of us to work together to achieve this ambitious and essential vision. This is a vision that the NHLBI wholeheartedly supports.

Elizabeth G. Nabel, M.D.
Director, National Heart, Lung, and Blood Institute
National Institutes of Health
INTRODUCTION

Definitions of Deep Vein Thrombosis and Pulmonary Embolism

Deep vein thrombosis (DVT) refers to the formation of one or more blood clots (a blood clot is also known as a “thrombus,” while multiple clots are called “thrombi”) in one of the body’s large veins, most commonly in the lower limbs (e.g., lower leg or calf) 1. The clot(s) can cause partial or complete blocking of circulation in the vein, which in some patients leads to pain, swelling, tenderness, discoloration, or redness of the affected area, and skin that is warm to the touch. However, approximately half of all DVT episodes produce few, if any, symptoms 2. For some patients, DVT is an “acute” episode (that is, the symptoms go away once the disease is successfully treated), but roughly 30 percent of patients suffer additional symptoms, including leg pain and swelling, recurrent skin breakdown, and painful ulcers 3-5. In addition, individuals experiencing their first DVT remain at increased risk of subsequent episodes throughout the remainder of their lives 4, 6.

The most serious complication that can arise from DVT is a pulmonary embolism (PE) which occurs in over one-third of DVT patients 7. A PE occurs when a portion of the blood clot breaks loose and travels in the bloodstream, first to the heart and then to the lungs, where it can partially or completely block a pulmonary artery or one of its branches. A PE is a serious, life-threatening complication with signs and symptoms that include: shortness of breath, rapid heartbeat, sweating, and/or sharp chest pain (especially during deep breathing). Some patients may cough up blood, while others may develop dangerously low blood pressure and pass out. Pulmonary embolism frequently causes sudden death 6, particularly when one or more of the vessels that supply the lungs with blood are completely blocked by the clot. Those who survive generally do not have any lasting effects because the body’s natural mechanisms tend to resorb (or “lyse”) blood clots. However, in some instances, the blood clot in the lung fails to completely dissolve, leading to a chronic serious complication that can cause chronic shortness of breath and heart failure. DVT and PE are commonly grouped together and sometimes referred to as “venous thromboembolism” (VTE).
Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) represent a major public health problem, exacting a significant human and economic toll on the Nation. These common conditions affect hundreds of thousands of Americans each year. A 25-year population-based study published in 1998 found that the overall age- and sex-adjusted annual incidence of VTE was 1.17 per 1,000 (.48 per 1,000 for DVT and .69 per 1,000 for PE). Applying these figures to today’s population of approximately 300 million Americans suggests that more than 350,000 individuals are affected by DVT/PE each year. A 1991 study that extrapolated findings from 16 short-stay hospitals in Worcester, Massachusetts is fairly consistent with these estimates. This study found that approximately 270,000 individuals were hospitalized for DVT/PE in 1991, including 170,000 new cases and 99,000 recurrent ones.

But there is reason to believe that the true incidence rate (and total number of cases) could be significantly higher, as several studies suggest that these diseases are often undiagnosed. The Worcester study cited above also concluded that more than half of the cases that actually occur are never diagnosed, and therefore as many as 600,000 cases may occur each year. Another study found that the diagnosis of PE is often missed; this study of nursing home patients found that the condition was correctly diagnosed before death in only 39 to 50 percent of patients where it was confirmed in an autopsy. While the precise incidence and prevalence remain “elusive” and a matter of some debate, one thing is undeniably clear—DVT/PE are major national health problems that have a dramatic, negative impact on the lives of hundreds of thousands of Americans each year.

There is reason to believe that the magnitude of the problem will increase. Several studies have found that the incidence has remained relatively stable over time, although one study found an increased incidence of DVT in hospitalized patients between 1979 and 1999. Assuming that the overall incidence remains the same, one would expect the total number of DVT/PE cases to grow at the same rate as overall population growth. However, the incidence of DVT/PE increases markedly with age. Thus, as the United States population increases in average age, it is quite possible that, in the absence of other influences such as better prevention, the growth in the total number of DVT/PE cases will outpace population growth. Given that DVT/PE are already common and devastating conditions, it is imperative that all stakeholders come together to halt, and hopefully reverse, the growth in the number of cases.

What Are the Consequences of DVT and PE?

Mortality
DVT and PE together may be responsible for more than 100,000 deaths each year. DVT alone does not frequently result in death; the National Center for Health Statistics reports that it is an underlying or contributing cause of death in over 10,000 cases per year. PE is responsible for many more deaths, although estimates of the exact toll are also elusive and vary widely, ranging from just below 30,000 to over 80,000. The most conservative estimates come from studies that review death certificate data. A 20-year review of data from 1979-1998 found that the age-adjusted death rate for PE was 94 per 1,000,000 individuals. Extrapolating to today’s population suggests that an estimated 28,200 people die each year.
from this disease. But as noted previously, PE is often undiagnosed, and thus the true death rate is almost certainly substantially higher. In fact, community-based epidemiological studies suggest that roughly one in five individuals die almost immediately from PE, while 40 percent die within 3 months \(^{17, 18}\). Applying this 40 percent figure to the 207,000 recognized annual PE cases cited earlier suggests an annual death rate of 82,800.

Another way to estimate the death toll is to look at statistics related to both diseases. An estimated 30 percent of patients die within 3 months \(^6\). Applying this 30 percent figure to the previously cited estimates of between 350,000 and 600,000 cases each year suggests that at least 100,000, and perhaps as many as 180,000, individuals die directly or indirectly as a result of DVT/PE each year.

**Morbidity**

Many of those who survive will be affected for the rest of their lives. At a minimum, those who have had DVT or PE will remain at increased risk for another episode. (See figure 1). Roughly 30 percent of those who have a DVT in a given year will suffer from a recurrent episode sometime in the next 10 years, with the risk being greatest in the first two years \(^5, 6, 19, 20\). Recurrence is also more likely if the initial episode was “spontaneous”—that is, not provoked by transient (often one-time) events such as trauma, surgery, or hormonal changes due to pregnancy, oral contraceptives, or hormone replacement \(^4, 5\).

Patients with symptomatic PE tend to have a higher risk of recurrent VTE than those presenting with DVT symptoms alone. The recurrence in those who initially presented with PE is more likely to be another embolism (as opposed to DVT alone) \(^21\). For reasons that remain unclear, the risk of recurrent VTE is higher among men than women. (See figure 2). \(^22\).

To minimize the risk of recurrence, anyone who has had either disease must remain vigilant about avoiding and/or managing the potential impact of other risk factors such as prolonged air travel, surgery, or trauma.

Along with the potential for recurrence, individuals who suffer an initial episode may also experience chronic venous insufficiency (CVI), which is also referred to as postthrombotic syndrome or PTS, with 30 percent suffering from CVI either immediately or within 10-20 years of the initial episode \(^3, 19, 23\). In one cohort of VTE patients followed for 10 years, more than half showed signs of CVI, while six percent developed severe disease \(^20\). CVI occurs when the blood clot injures or destroys one or more of the venous valves that are located in the deep veins of the leg. When functioning properly, these valves work against gravity to help pump blood back to the heart when an individual is sitting or standing. When these valves are either damaged or destroyed, individuals may feel leg pain and experience swelling when standing. They may also develop other unpleasant symptoms, including mild or extensive varicose veins (which are cosmetically unappealing and can cause additional chronic pain and burning), skin breakdown, ulcers, and brownish skin pigmentation changes, which tend to be permanent and irreversible. The most severely affected patients may find that the skin inside their ankles becomes thickened, darkened, and prone to recurrent skin breakdown and painful ulcers (known as venous stasis ulcers) that often do not easily heal. CVI has been found to cause a significant reduction in the quality of life, similar to the impact caused by chronic heart, lung, or arthritic disease \(^24, 25\).
Figure 1:
The Cumulative Incidence of Recurrent Venous Thromboembolism in Patients with a First Episode of Symptomatic Deep Venous Thrombosis.

![Graph showing cumulative incidence of recurrent venous thromboembolism](image)


Figure 2:
Kaplan-Meier Estimates of the Likelihood of Recurrent Venous Thromboembolism According to Sex.

![Graph showing Kaplan-Meier estimates](image)

826 idiopathic VTE patients followed for 3 years

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No. at Risk
What Factors Raise the Risk for DVT and PE?

There are differential effects by gender, race, and age on individuals with DVT/PE. These diseases also disproportionately affect certain groups of individuals, such as those who:

- have experienced recent trauma
- have undergone major surgery
- are obese
- have cancer
- are pregnant
- use hormone therapy
- smoke

Age, Gender, and Race-Specific Incidence

Like many diseases, DVT/PE disproportionately affect the elderly. (See figure 3). The incidence among children (under the age of 14) is quite low, at less than 1 per 100,000 measured in person-years. Incidence rates rise relatively slowly until the age of 50, then accelerate dramatically, reaching 1,000 per 100,000 person-years by the age of 85.

Women have a higher incidence of DVT during their child-bearing years although this risk is still relatively low compared to risk levels for older men and women. However, after the age of 50, men are at greater risk than women.

Figure 3:
Annual Incidence of all Venous Thromboembolism, Deep Vein Thrombosis (DVT) Alone, and Pulmonary Embolism (PE) With or Without Deep Vein Thrombosis (PE+-DVT)
Among Residents of Olmstead County Minnesota from 1966 to 1990 by Age
For reasons that are not completely understood, African Americans and Caucasians tend to have a greater risk for these conditions than those whose ethnic background is either Asian or Native American. African Americans have a 30 percent higher risk than do Caucasians, while Asian and Native Americans have a 70 percent lower risk.\textsuperscript{26, 27}

Genetic Factors That Raise Risk

Thrombophilia is an inherited blood clotting disorder caused by one or more genetic risk factors or mutations that make a person susceptible to DVT/PE. These factors include deficiencies in the anticoagulation factors protein C, protein S, and antithrombin, and mutations in the factor V and prothrombin genes which result in Factor V Leiden and prothrombin G20210A\textsuperscript{28} respectively. Over one-third (35 percent) of DVT patients have at least one of these five factors.\textsuperscript{29, 30} An individual with such a genetic mutation will not necessarily develop these conditions, and fewer than 10 percent of those who carry the most common mutations will develop a detectable blood clot each year.\textsuperscript{31} But the risks are much greater for those individuals with thrombophilia compared to the population at large, particularly for those who also have another risk, such as surgery, hospitalization, or a prolonged bed stay.

In almost all cases, the presence of an inherited blood clotting disorder in an individual indicates that at least one of the parents also has the disorder, and there is a 50 percent chance that any sibling or child of that individual will have it as well. Other blood relatives, including aunts, uncles, and cousins, may also have the mutation.

Following is a brief description of the most common genetic mutations:

- **Factor V Leiden**: Factor V Leiden is a relatively common mutation in the gene for clotting factor V that leads to an increased risk of DVT/PE. An estimated 15 to 20 percent of DVT/PE patients have this abnormality.\textsuperscript{29, 30} This defect is most commonly found among Caucasians (with roughly five percent carrying it)\textsuperscript{32}, with Asians and Africans rarely carrying the mutation.

- **Prothrombin 20210**: Roughly two to three percent of Caucasians have a mutation in the gene that produces prothrombin, which is called clotting factor II\textsuperscript{33}. Approximately six percent of all DVT/PE patients have this mutation, which leads to a three-fold increase in the risk of thrombosis.\textsuperscript{34}

- **Antithrombin, Protein C, and Protein S Deficiency**: Mutations in the genes that produce protein C and its cofactor protein S are found in less than one percent of the population, while deficiencies in the gene that produces antithrombin are found in roughly 1 in 5,000 individuals.\textsuperscript{35, 36} Deficiencies in the natural anticoagulants protein C, protein S, and antithrombin lead to a tenfold increase in risk of thrombosis in an individual who inherits the gene mutation from one parent, with the highest risk in those with antithrombin deficiency.\textsuperscript{37}

Acquired Factors That Raise Risk

Exposure to steroid hormones—especially estrogen—can raise the risk of developing a blood clot. Thus, women using oral contraceptives in their child-bearing years and postmenopausal women who use hormone therapy (HT) are at increased risk. Oral contraceptives that contain both estrogen and progestin increase the risk of a blood clot by two- to eight-fold.\textsuperscript{38-43} (The risk may even be greater with patches that
contain transdermal contraceptives, since the amount of estrogen absorbed can be 60 percent higher\(^44\). An alternative to consider may be contraceptives that use only progestin as these do not appear to increase the risk of DVT or PE\(^45\)-\(^47\). However, it is important to keep in mind that the absolute risk for women of fertile age who use oral contraceptives is fairly low—2 to 8 per 10,000 person-years, which is still substantially less than the risk faced by older women and men\(^48\),\(^49\).

Pregnancy increases the risk of DVT fivefold compared to nonpregnancy, with the risk being even greater postpartum\(^50\). DVT can be life-threatening in pregnancy, as pulmonary embolism is the most common cause of maternal death in developed countries\(^51\). Comorbidities such as obesity and diabetes magnify the existing risk.

Post-menopausal women undergoing HT also have a higher risk of DVT/PE, with recent large studies suggesting a two- to four-fold increase in risk, with even larger increases in risk for those on high doses of estrogen (greater than 1.25 mg/day)\(^52\)-\(^55\). Women with thrombophilia who also are exposed to oral contraceptives, pregnancy, or HT will face a significantly greater risk than the above statistics suggest\(^28\).

Individuals who develop tumors have a greater tendency to develop blood clots, thus creating increased risk. About 10 percent of patients who present with DVT/PE will have an occult cancer diagnosed within two years of the thrombotic episode\(^56\).

Although all patients with active cancer have an increased risk of DVT/PE, the risk appears to be higher for those with pancreatic cancer, lymphoma, malignant brain tumors, cancer of the liver, leukemia, and colorectal and other digestive cancers. The risk is especially high for patients whose cancer has spread to other parts of the body\(^57\)-\(^60\). Cancer patients receiving chemotherapy are at even higher risk\(^57\),\(^61\)-\(^65\). Cancer patients with VTE face much worse outcomes than those with cancer alone. The probability of death within 183 days of initial hospital admission is over 94 percent for those with VTE and malignant disease, compared to

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**A Case Study**

This is the story of a college-age girl with a genetic susceptibility to blood clots who experienced an unusual manifestation of venous thrombosis that ultimately claimed her life. Like many young women, she was very self-conscious about her complexion. Her gynecologist explained that one of the beneficial side effects of hormone-based contraceptives is to help clear one’s complexion. So she began taking oral contraceptives and later switched to a patch. While the patch cleared her complexion, she and her parents did not know that she was one of 7,000,000 women in the U.S. with Factor V Leiden, a genetic abnormality that made her much more likely to develop DVT/PE\(^28\). The combination of a genetic predisposition and the use of oral contraceptives proved to be a deadly one, as she developed blood clots in the portal and hepatic veins of her abdomen. (The presence of clots in these locations is not technically classified as DVT, but it is considered a form of venous thrombosis, thus highlighting the fact that VTE can occur anywhere in the body.) After months of suffering from fatigue, nausea, and, ultimately, a markedly swollen abdomen, she died in May 2003 at the age of 21.
less than 40 percent for those with cancer alone. (See figure 4) \(^ {66}\).

The incidence of DVT/PE is substantially higher for cancer patients than for non-cancer patients across all types of major surgery, including neurosurgery, head and neck, vascular, urologic, gastrointestinal, and orthopedic surgeries \(^ {67}\). In the absence of preventive treatment, an estimated 40 to 80 percent of surgical cancer patients will develop DVT in the calf vein while 10 to 20 percent will develop DVT in a proximal vein. Between four and 10 percent of cancer patients undergoing major surgery will develop PE, and one to five percent are fatal \(^ {68}\). Once a cancer patient develops a first episode of VTE, he or she has three times the risk of developing a subsequent episode (compared to noncancer patients) \(^ {56}\).

For reasons that are not entirely clear, people who are obese are at greater risk of DVT/PE. Individuals with a body mass index (BMI)\(^ *\) greater than 30 have a two- to threefold increase in the risk of developing a blood clot, with the risk being even higher for those with a BMI above 40 \(^ {69-71}\). The combination of obesity and other risk factors increases the risk even further. For example, obese women on oral contraceptives face a tenfold increase in risk (compared to two- to threefold for nonobese women on oral contraceptives) \(^ {71}\).

The Role of Triggering Events

The majority of DVT/PE events are related to specific, identifiable triggering events such as hospitalization, major surgery, trauma, and prolonged periods of immobility (as can

\(^ *\) BMI is the statistical measure of the weight of a person scaled according to height. In the U.S., BMI is calculated as follows: \(703 \times \text{(an individual's body weight in pounds/the square of his or her height in inches)}\).
occur in a nursing home or during long flights). It is often the combination of an individual with genetic and/or acquired risk factors who also experience one of these triggering events that leads to the development of a DVT or PE.

*Hospitalization for Acute Medical Illness*

Hospitalization may be considered the single most important risk factor for developing a DVT/PE. Hospitalization has been shown to raise an individual’s risk of an event as compared to living in the community. Much of the increased risk is related to patients who must undergo major surgery (which is discussed separately in the next section). Those who are hospitalized for acute medical illness have more than a tenfold increased risk for VTE.

Most hospitalized patients have at least one risk factor, including immobility, cancer, infection, and/or surgery. In fact, in the absence of appropriate preventive treatment, 10 to 40 percent of medical and general surgery patients and 40 to 60 percent of patients requiring major orthopedic surgery develop thrombosis. Many of these events are not clinically apparent, but they can potentially lead to later problems, such as PE. In fact, roughly one out of 10 hospital deaths are related to PE, and many times this disease was not suspected before death.

Recent research suggests that certain identifiable subsets of acute medical inpatients are at especially high risk of DVT/PE, including those over the age of 75; those who are obese; and those with any of the following:

- prior history of these conditions
- active cancer
- acute infection
- neurological disease combined with lower extremity weakness

### A Case Study

July 17, 2005 started out as a normal Sunday for Heidi Blongastainer. She was 36 weeks pregnant and felt tired. She and her husband Brian were heading to her in-laws’ summer cottage in Cape Cod for a barbecue. On their way home, a car driven by a drunk driver who was drag racing crossed the median strip of the highway and hit their car head on while traveling 90 miles per hour. Heidi felt her water break upon impact. She was trapped in the car for approximately 45 minutes, with the dashboard on top of her legs. (Brian suffered only minor injuries and was able to get out of the car and call for help.) After being pried out of the car, Heidi was brought to a small hospital near Cape Cod where they confirmed that her daughter, just a few weeks from being born, did not have a heartbeat. She was then brought to Brigham and Women’s Hospital where she required emergency surgery and remained hospitalized for a week.

After returning home, Heidi had a walker and could walk only very short distances. Her feet and right hip were extremely swollen and bruised, making it difficult for her to move. During the next few days, her feet seemed to get worse, and she started to develop shooting pains in her back whenever she breathed. Thinking that the symptoms were due to cracked ribs, she downplayed them when talking to her doctors.

Her mother warned her about blood clots, but Heidi discounted her advice, not believing that an otherwise healthy 28-year-old woman could develop blood clots due to an automobile accident. Heidi
continued to downplay her symptoms at her followup visit with the surgeon. Later in the same week she started to experience shortness of breath and additional pain, soreness, redness, and swelling in her calf and feet. Sitting in bed, she could not catch her breath. That Saturday, 6 days after getting out of the hospital, she developed a fever. She paged her surgeon to tell him about her symptoms, focusing primarily on the pain and swelling in her feet. The surgeon told her to go to the Brigham and Women’s Hospital Department of Emergency Medicine, where she was diagnosed with cellulitis of the leg. But doctors also questioned her about her other symptoms. After hearing her answers, she was immediately taken for a CAT scan to check for blood clots. When the doctor came back, Heidi was informed that she had multiple, large blood clots in her lungs. She was immediately put on anticoagulation therapy, which continued for 6 months. She also participated in a PE support group that met every 3 weeks.

When Heidi presented her story at the Surgeon General’s Workshop—only 8 months after her accident—she still had pain in her calf and remained anxious about the possibility of developing a new clot (especially since discontinuing anticoagulation medication). But unlike before, she now knows what symptoms to look for and what to do if they develop.

- long-bone fracture
- chronic renal disease
- a prior superficial vein thrombosis
- prolonged immobilization

**Trauma and Major Surgery**

Any injury to body tissues, whether due to surgery or trauma, increases the risk of a blood clot, because the injury stimulates the body’s clotting processes. Blood clots due to trauma and surgery occur relatively quickly, with most developing within two weeks of the event, and some happening much more quickly (within a few hours or even during surgery). DVT/PE also can occur up to several months after surgery or major trauma.

Individuals undergoing certain types of surgery or who experience certain types of trauma are especially prone to blood clots, including those having

- pelvic (gynecological and urological) surgery
- orthopedic surgery (including hip replacement or fracture repair)
- spinal cord paralysis
- multiple limb fractures
- pelvis/hip socket injury.

**Nursing Home Residency**

Nursing home residents are an often overlooked risk group for DVT/PE, even though they are more than twice as likely as nonresidents of nursing homes to develop these conditions, and they account for over 13 percent of all such events that occur outside the hospital.75
Travel

Any sort of travel has the potential to increase the risk of DVT/PE. Prolonged air, car, and rail trips where the traveler is immobile for long periods of time appear to bring about the greatest risk. In fact, travel by air, car, train, or bus for four or more hours increases the risk about twofold for several weeks after the trip. The risk is even greater for travelers with other risk factors.

The Economic Costs of DVT/PE

There are very few data available on the economic costs of VTE, and more research is needed on both the direct and indirect costs to individuals and society at large. As noted earlier, conservative estimates suggest that over 350,000 people are affected by DVT/PE each year, and the vast majority of these individuals will require expensive inpatient treatment. Those who survive the disease may live with a long-term, chronic disorder that is often characterized by repeated episodes that result in additional hospitalizations and treatments. Many individuals with these disorders may also be unable to remain productive members of the workforce (i.e., they may not be able to work at all, may miss work periodically, or may be able to work but at diminished productivity levels), thus creating an economic hardship for their family and diminishing the overall productivity and economic output of the Nation.
Reducing the Risk for DVT/PE

Much is known today about how to prevent DVT/PE, and how to minimize the impact for those patients who suffer from these conditions. If this knowledge were applied consistently, the burden could be reduced substantially. Unlike other chronic diseases, there is at present little evidence on the impact of lifestyle changes on the risk for DVT/PE. While being overweight and smoking are known risk factors, it is not yet known whether smoking cessation, weight loss, increased physical activity, or other lifestyle changes significantly reduce risk. A recent study did find that a diet that includes more fruits, vegetables, and fish, and less red and processed meat is associated with a lower incidence of DVT/PE. But further studies on the impact of diet and other lifestyle changes are warranted.

As noted earlier, about half of those who develop DVT/PE have two things in common. First, they have one or more identifiable risk factors for the disease. Second, they experience some sort of triggering event, such as hospitalization, trauma, surgery, or a prolonged period of immobilization (e.g., due to nursing home confinement or a long trip by air, car, or train) that leads to the formation of one or more blood clots. The other half of those who get the disease have “unprovoked DVT/PE”—that is, the reasons for the events are unknown. There is much that can be done, however, to prevent high-risk individuals from developing these conditions. Providing preventive treatment (or primary prophylaxis) to these individuals can dramatically reduce the likelihood of a blood clot or PE.

Several drugs have been found to be effective in reducing the likelihood of a blood clot in high-risk individuals. These drugs are known as anticoagulants or blood thinners because they slow down the coagulation processes, and thus reduce the likelihood that a blood clot will form. Numerous studies over a long period of time confirm the benefits of using blood-thinning medications as a preventive measure in high-risk individuals.

Additionally, several mechanical devices exist to help prevent DVT and/or PE. These devices are often used for individuals who are at risk but are not able to tolerate anticoagulants. Mechanical devices deliver variable gradations of external pressure around the circumference of the leg to improve venous circulation.

Another preventive therapy option is the use of a permanent or retrievable implantable filter in the vena cava. These filters act like miniature umbrellas with holes that can trap blood clots—and thus prevent PE—without stopping the flow of blood. They have been used with success in a variety of patients, including those whose anticoagulation therapy must be stopped due to the need for urgent surgery, patients undergoing bariatric surgery, and patients who suffer multiple injuries from a motor vehicle accident. It is important to note, however, that these filters do not prevent DVT. Rather, they are designed to help prevent PE in those who are at high risk of DVT.

Existing Evidence-Based Guidelines, Standards, and Measures for DVT/PE

A search was conducted of the National Guidelines Clearinghouse™ (NGC), a comprehensive database of evidence-based clinical practice guidelines and related documents created by the Agency for Healthcare Research and Quality.
(AHRQ) in partnership with the American Medical Association and American Association of Health Plans. The search was conducted at [www.guideline.gov](http://www.guideline.gov) on June 27, 2006, and more than 100 guidelines related to PE and DVT were found. The initial search on the term “pulmonary embolism” produced 111 guidelines. While searching on the term “deep vein thrombosis” 88 guidelines were produced and the vast majority duplicated the initial search. These guidelines cover a wide variety of topics related to preventing, diagnosing, and treating DVT/PE in general and specific populations. Multiple guidelines exist related to certain common issues, such as when and how to provide preventive treatment or prophylaxis. While all guidelines included in the NGC are based on scientific evidence, the strength of the evidence behind these guidelines varies. The NGC includes a summary of the strength of the evidence that underlies each guideline that is included in the clearinghouse.

The clearest consensus in the guidelines exists on the need to screen hospitalized patients for risk of DVT/PE and to provide appropriate prophylaxis to those at risk. The Institute of Medicine 1999 landmark report on medical errors noted that failure to provide prophylactic therapy when indicated is a hospital error. AHRQ has evaluated and ranked the effectiveness of 79 safety practices based on strength of evidence, and found prevention to be the highest-ranked of all the practices evaluated. Based on this finding, the National Quality Forum (NQF) now recommends that all hospitalized patients be evaluated upon admission and regularly thereafter, and that those found to be at risk be given prophylaxis for VTE.

Guidelines from the American College of Chest Physicians provide recommendations on what prophylaxis regimen to give to hospitalized patients with varying levels of risk factors. Regimens may range from early, aggressive ambulation to a combination of anticoagulation therapy, intermittent pneumatic compression, and/or graduated compression stockings.

Consensus Standards for Prevention and Care of DVT/PE

In May 2006, the National Quality Forum NQF endorsed a set of 20 national voluntary consensus standards around model policies, practices, and performance measures related to the prevention and care of VTE. This set of 20 standards, which had been developed under the leadership of the Joint Commission (formerly known as the Joint Commission on the Accreditation of Healthcare Organizations), includes a policy statement recommending that every healthcare facility have a written, evidence-based policy to drive quality improvement related to risk assessment, prevention, diagnosis, and treatment. It also contains 17 key characteristics of preferred practices including general recommendations and practices related to risk assessment/stratification, prevention, diagnosis, and treatment/monitoring. In addition there are two performance measures that can be used for public reporting. The two measures relate to ordering and providing preventive treatment to hospitalized surgical patients. The specific measures are as follows:

- Surgery patients with recommended prophylaxis ordered
- Surgery patients who receive appropriate prophylaxis within 24 hours prior to surgery to 24 hours after surgery

The Joint Commission is still in the process of developing additional measures, and their work
is expected to be completed shortly. NQF will then consider endorsing these additional measures.

As noted, guidelines have been produced by a variety of organizations, often representing different medical specialties. Many researchers and clinicians who spoke at the Surgeon General’s Workshop on DVT noted that some of the guidelines may conflict with each other or are confusing. The result is that clinicians may find it difficult to use the guidelines in everyday practice. It is critical, therefore, that stakeholders involved in guideline development come together to produce—to the extent possible based on today’s best evidence—a more unified, synthesized, and clear set of guidelines related to the prevention, diagnosis, and treatment of DVT/PE in specific patient populations.
As discussed in the previous section, much is already known about how to prevent and treat DVT/PE. Yet the human and economic toll on both individuals and society as a whole remains high. Left unchecked, the aging of the population will increase this burden over time. Why do DVT and PE remain such serious problems, particularly given the availability of effective strategies for preventing and minimizing them? The answer lies primarily in the failure to consistently use evidence-based interventions in those high-risk individuals who need them. This failure may be due to clinicians’ lack of awareness, and consistent adherence to evidence-based practices. An additional factor is a health care system that may not consistently provide coverage for the provision of high-quality preventive and therapeutic treatment.

Application of Guidelines

A substantial body of evidence suggests that evidence-based DVT/PE guidelines are not being routinely followed. Most of this evidence relates to prophylaxis, although some data on treatment exist as well. High-risk patients and those with identifiable symptoms are not routinely receiving prophylaxis that could help to prevent the development of DVT and/or PE. A large epidemiological study of 5,451 patients with ultrasound-confirmed DVT (seen at 183 different clinical sites) found that the majority had been given no prophylaxis prior to their diagnosis despite being at high risk. Men were 21 percent more likely than women to have received prophylaxis. In other words, high-risk patients (especially women) are not being identified in a timely manner and provided with appropriate therapy designed to prevent the development of DVT/PE.

This finding is consistent across all age groups, in both academic and community hospitals, and throughout all regions of the United States. The gender difference persists even after adjusting for cancer, surgery, prior DVT, trauma, and age.

Other studies also confirm the failure to routinely provide preventive treatment to high-risk patients. A study of 2,017 patients in 16 short-stay Massachusetts hospitals found that only 32 percent of high-risk patients received appropriate prophylaxis, with rates across the hospitals ranging from 9 percent to 56 percent. A recent small study of 44 medical and surgical patients found that 38.6 percent of those who were classified as having potentially preventable VTE did not receive adequate prophylaxis.

The failure to provide preventive therapy is not limited to the United States. A study of 446 medical patients at two teaching hospitals in Hamilton, Ontario found very similar results, with only one-third of high-risk patients receiving some form of prophylaxis. While high-risk surgical patients appear to be more likely to receive prophylaxis than high-risk medical patients, preventive therapy remains underused in this population as well. A study of 1,907 high-risk surgical patients at 10 teaching and community-based hospitals found that 93.7 percent of high-risk orthopedic surgery patients and 75.2 percent of high-risk abdominal surgery patients received appropriate prophylaxis. Another study found that 14.4 percent of high-risk orthopedic surgery patients received inadequate preventive therapy or none at all. The same study found that orthopedic surgery patients who do get anticoagulation therapy typically receive it for only three to five days.
This is in stark contrast to current recommendations, which suggests a minimum of seven to 10 days and perhaps as long as 30 days for these patients. Lack of adherence to guidelines extends beyond preventive therapy to treatment of the disease as well. A 2005 study of 3,778 patients at 38 academic/teaching, community, and Veterans Administration hospitals concluded that in just under one-half of patients with DVT, PE, or both, anticoagulation therapy was discontinued too early. In addition, patients with DVT or PE were rarely discharged from the hospital with appropriate bridge therapy (an injectable anticoagulation agent plus warfarin). The reasons for poor adherence to established guidelines and standards are not entirely clear, although a variety of factors may be at play, including clinical concerns and other issues.

As noted earlier, one of the major themes of “The Surgeon General’s Workshop on DVT” was the issue surrounding potential inconsistencies, conflicts, and ambiguities within and across the many different guidelines that exist today. Some clinicians may not be aware of existing guidelines, or may not believe that the evidence supporting them is adequate. Some time-pressed clinicians may inadvertently overlook existing guidelines, while those in some specialties may feel uncomfortable using anticoagulant therapy due to the potential risk of bleeding.

Whatever the reasons for poor adherence, the good news is that effective strategies appear to be available to support clinicians in their efforts to practice evidence-based care. A recent meta-analysis of 30 U.S. and international studies evaluating various strategies for increasing the use of prophylaxis came to the following conclusions:

- Passive strategies (such as guideline dissemination by means of international or local publication) resulted in poor adherence to guidelines, with no more than half of patients receiving appropriate prophylaxis.
- More proactive strategies resulted in significantly higher adherence rates. These included computer-based clinical decision support systems, audit and feedback, documentation aids, and active monitoring of DVT/PE prophylaxis policies. Computer-based decision support resulted in nearly 100 percent compliance with guidelines, while the other strategies resulted in roughly 80 percent compliance. (See box below for a case example of a computerized reminder system that boosted use of prophylaxis and significantly reduced the incidence of both DVT and PE.)
- The use of multiple strategies consistently resulted in improved adherence to guidelines. Based on these findings, the authors of this study recommend a multipronged approach to increasing use of prophylaxis, including the following elements: continuing education to improve clinician knowledge of DVT/PE risk assessment and appropriate prophylaxis; documentation and/or computer-based systems to remind clinicians to assess risk and assist in prescribing appropriate prophylaxis; and ongoing assessment of the effectiveness of existing policies and interventions, with refinements as necessary.

Public Awareness about DVT

The American Public Health Association (APHA) commissioned a telephone survey of over 1,000 American adults to determine current levels of awareness of DVT among the public. The study found that DVT was the least known of the mentioned diseases and condi-
Computerized Reminders to Boost Adherence

While a variety of strategies are available to encourage physicians to adhere to evidence-based guidelines, one of the most effective appears to be electronic reminders that alert physicians to the potential need for a particular course of action based on the evidence. Brigham and Women’s Hospital (BWH) used this approach with physicians whose high-risk patients were not receiving DVT prophylaxis. BWH conducted a randomized controlled trial of 2,506 patients, with 1,255 in the intervention group (i.e., patients whose physicians received an alert) and 1,251 in the control group (i.e., patients whose physicians did not receive an alert) 22. The study found that 33.5 percent of high-risk patients in the intervention group received DVT prophylaxis, compared to 14.5 percent in the control group. While both figures are too low, the computerized system clearly helped improve adherence dramatically. More importantly, this improved adherence led to a 41 percent lower incidence of symptomatic disease among patients in the intervention group, as compared to those in the control group. Subsequent monitoring of the alert system has found that physicians are now ordering prophylaxis in response to the alert 40 percent of the time, suggesting that further improvement in physician adherence has occurred. Additional testing and analysis of strategies to further improve adherence rates are warranted.

It is important to note that the beneficial effect of the electronic alert system can potentially be replicated without computer support. A nurse, physician, or pharmacist could conduct patient rounds on all overnight admissions, review their charts, and determine whether specific patients are at high risk for developing DVT/PE during hospitalization. They could then review the written physician orders to determine whether prophylaxis had been instituted. For high-risk patients not receiving prophylaxis, the reviewer could page the responsible physician, point out the patient’s high risk, note the absence of prophylaxis orders, and suggest implementation of preventive measures.
tions, with less than a quarter of respondents having heard of the disease, compared to 93 percent who had heard of diabetes and allergies and 91 percent who had heard of stroke. Even colitis—at 42 percent awareness levels—was better known than DVT. Males, those under the age of 35, and those with lower levels of education were more likely to be unaware of DVT.

Among the one-quarter of the queried population with at least some awareness of the disease, less than half were familiar with any signs or symptoms of the disease (46 percent), had any knowledge of risk factors (43 percent), or knew that DVT could be prevented (25 percent).

In other words, only about 1 in 10 Americans know about DVT and are familiar with its symptoms and/or risk factors, and only about six percent of Americans know what it is and that it can be prevented.

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The Importance of Educating the Public: David Bloom’s Story

David Bloom died in April 2003 at the age of 39 while covering the war in Iraq as a reporter for NBC News. An avid tennis player who was in great health, he was subject to prolonged periods of immobility and dehydration in Iraq, often having to spend many hours inside a cramped tank. Unknown to David, he had an inherited blood coagulation disorder along with other acquired risk factors for DVT. Two nights before his death, David spoke with his wife, Melanie, on the telephone, telling her that his legs hurt because they had been cramped up inside the tank for too long. He told her that he was planning to sleep outside that night because he could not bear to be cooped up for another night. Having heard that he planned to sleep out in the open naturally made Melanie fear for his safety.

Two days later, as a result of DVT, a massive blood clot traveled from David’s leg to his lungs resulting in a PE that killed him almost instantly. He was a victim not of the war’s violence, but rather of a lack of awareness about DVT. Had he, his loved ones, or those around him been aware of the risk factors and warning signs, and had he known about his genetic predisposition to the disease, his life might have been saved. Melanie has now made it her mission to educate the public about DVT so that others will not die unnecessarily.
A Call to Action: A Public Health Response to Reducing DVT and PE

DVT and PE are major public health problems in the United States. Much is known about how to reduce their burden, yet this knowledge is not being applied systematically today. Without a concerted effort to stem this public health crisis, the incidence and burden of these diseases will only grow larger as the population ages.

In May 2006, the Surgeon General hosted a workshop on DVT. This meeting began a developmental process that led to this “Surgeon General’s Call to Action.” A menu of important actions has been assembled from the presentations, discussion, and comments that were made during that Surgeon General’s Workshop. This menu, which is presented in the following section, highlights areas that received significant attention during the workshop and in background papers prepared by scientists and clinicians who participated in the workshop. Although not meant to be prescriptive recommendations, the menu should establish useful starting points for consideration as individuals and groups focus their own skills, creativity, and inspiration on reducing the public health crisis of DVT and PE.

The discussions at the Surgeon General’s Workshop centered on research, activities, and interventions in three settings: communities, the health care system, and governments. The key actions discussed are presented for each of these settings, although many of these actions can be applied in all of the settings.

The key actions are organized by a framework called CARE: Communication, Action, Research, and Evaluation.

- Communication refers to the provision of information and tools to motivate and empower decisionmakers within the various settings to create change that will lead to more effective prevention, diagnosis, and treatment of first-time and recurrent DVT/PE.
- Action refers to interventions and activities that will assist various stakeholders in preventing, diagnosing, and treating the diseases more effectively.
- Research and evaluation refers to scientific investigations that will allow for a better understanding of issues that are currently not well understood related to the prevention, diagnosis, and treatment of these conditions.

Setting 1: Communities

Individuals, families, and their communities need to understand DVT and PE, the risk factors for these diseases, and how to reduce these risks. They also need to recognize the signs and symptoms and know about available treatments. Patients and family members should proactively discuss these conditions when interacting with their health care providers. The goal is to raise awareness among patients and family members and empower them to ask their physicians about preventive treatment during hospitalization, after a traumatic event, or in other high-risk situations.

A broad-based communications program can play a major role in raising awareness. From a public education and social marketing standpoint, communications programs can disseminate health messages aimed at educating individuals about DVT/PE and the fact that anyone can be at risk for them. These messages
can highlight the symptoms, warning signs, triggering events, and risk factors associated with these conditions.

One approach that an outreach effort can take is to work with various media, including the Internet, to help fill an important gap that exists today in the availability of appropriate educational materials.

A recent survey found that individuals and family members of those who have had a clot or who suffer from thrombophilia are interested in a variety of topics, most notably prevention, treatment, insurance issues; signs and symptoms of the disease; risk factors; genetics; general information on clots; and local, national, and regional resources to support those at risk or who have DVT/PE. An evaluation of available educational materials found that very few, if any, appropriate materials on these high-interest topics exist.

Community-based and national advocacy organizations can potentially play a critical role in helping individuals become more knowledgeable and empowered. Many of these organizations are already actively involved in this effort, and their work needs to be supported and expanded. Emphasis should be placed on family and community opportunities for communication and actions that will raise awareness of DVT/PE among the public at large and among specific, high-risk groups.

Initiating a Communications Campaign: A Case Example

The Coalition to Prevent DVT (The Coalition) established March 2004 as the first DVT Awareness Month. This month-long campaign included a celebrity spokesperson in conjunction with print media coverage, a satellite media tour, and a television public service announcement (PSA) that reached millions of Americans. The following year, the U.S. Senate passed Resolution 56, declaring March as DVT Awareness Month. In March 2005 representatives from The Coalition were seen on “Larry King Live,” the “Today Show,” and the “Jane Pauley Show.” A campaign PSA reached an additional 37 million people. Patient stories were the focus for DVT Awareness Month 2006, and the Coalition is currently preparing a book of patient stories for release by primary author Melanie Bloom, widow of NBC journalist David Bloom who died suddenly of a PE while covering the war in Iraq.

Communication

- Raise consumer awareness about DVT/PE and the magnitude of the burden caused by these conditions.
- Educate consumers about symptoms, risk factors, and triggering events, especially surgery, hospitalization, and trauma.
- Raise consumer awareness about genetic predispositions to DVT/PE.
- Promote the use of messages in news reports that educate the public by sharing informa-
tion on the magnitude of the problem, both in terms of incidence and mortality/morbidity.

- Disseminate to the public through news outlets and the Internet individual patient stories, as these stories can often have more impact than statistics alone.
- Emphasize the fact that there exists a large gap between what is known about how to prevent and treat DVT/PE and what is happening in practice today.
- Facilitate the development and dissemination of uniform messages about DVT/PE that are consistent with existing guidelines.

**Action**

- Form community coalitions to sponsor public awareness campaigns.
- Develop tools and materials that patients can use when talking with their physicians and other health professionals.
- Create local networks and peer support programs for patients and their family members.
- Work with volunteer groups, professional societies, and the media as part of a national awareness campaign intended to educate both the public and health professionals about the incidence of the disease, along with its symptoms and risk factors.
- Make available to the media accurate messages about DVT/PE for news stories and media programming, including television shows.
- Encourage community-based advertising campaigns.
- Consider using a celebrity spokesperson to deliver messages about these conditions, especially a celebrity who may have had a personal experience related to either DVT or PE.

**Research and Evaluation**

- Gain a better understanding of what the public already knows about DVT/PE, gaps in their understanding, and how best to address those gaps.
- Develop and test messages to determine which approaches work best to educate the public, inform them of when they are at risk, and empower them to raise issues proactively with their clinicians.
- Investigate, in a culturally and linguistically appropriate manner, why certain ethnic groups are more or less likely to develop these conditions.
- Investigate the causes of age- and gender-based variations in the incidence and recurrence of these diseases, including why men are more susceptible to a recurrence.
- Research the role that behavior modification (e.g., smoking cessation, increased physical activity, better diet, weight loss) plays, if any, in reducing risk.
- Conduct research to better understand why obesity increases risk.
- Investigate the role that prolonged immobility due to travel (air, car, rail), hospitalization, or nursing home confinement plays in increasing risk.
- Conduct an analysis of the economic toll of DVT/PE on individuals, families, communities, and the nation as a whole. This analysis should include not only the direct costs (i.e., healthcare expenditures), but also indirect costs such as lost productivity and wages due to time away from work.
- Evaluate the impact of communication and social marketing programs, including pre- and post-evaluation levels of consumer awareness and knowledge.
- Conduct formative research to ensure that media messages are positive, realistic, relevant, consistent, and effective.
Setting 2: The Health Care System

The health care system is uniquely positioned to implement interventions aimed at reducing the incidence and burden of DVT/PE. The majority of cases occur within the health care system, for example, during surgery, hospitalization, or treatment for trauma. Although much is known about effective prevention and treatment, this evidence is not being applied in a systematic way. Hospitals, health systems, medical schools and residency programs, researchers, universities, primary care and specialty group practices, physicians, nurses, and allied health professionals have a critical role to play in preventing and reducing the burden of DVT/PE. There is much work to be done—both to better apply evidence-based medicine in real-world settings today, and to investigate the many gaps in knowledge related to the basic and clinical science surrounding these diseases. Insurers, health plans, and other public and private purchasers also have a critical role to play in establishing payment policies that encourage the provision of high-quality, evidence-based care.

Communication

- Inform health care professionals and administrators about the problem of DVT/PE in terms of mortality, morbidity, and direct and indirect costs.
- Promote evidence-based practice by sharing existing guidelines with appropriate professionals on the prevention, diagnosis, and treatment in specific populations.
- Promote the findings and recommendations from groups such as the IOM, AHRQ, Joint Commission, and NQF related to the importance of screening all hospitalized patients for risk for these diseases, and providing appropriate preventive treatment based on those screenings.
- Raise awareness of current agency and organizational guidelines in relation to preferred practices and performance measures.
- Educate health professionals about the availability of genetic testing, when it may be appropriate to discuss with and test patients, and the importance of counseling for those who test positive.
- Educate primary care physicians and specialists about the true, relative risks of excessive bleeding from properly managed anticoagulation therapy versus the risks of not using such therapy.
- Inform health care providers about the availability and appropriate use of treatment options, including anticoagulation therapy and clot-dissolving/clot-removal therapies.

Action

- Convene cross-disciplinary forums to forge consensus on a single set of clear, standardized, evidence-based guidelines in those areas where multiple and/or conflicting guidelines currently exist.
- Institute formal systems related to risk assessment and the provision of preventive therapy (prophylaxis) to appropriate high-risk individuals in the hospital and community.
- Consistently track performance on current and future DVT measures that are endorsed by NQF, and develop quality improvement initiatives designed to improve performance on these measures over time.
- Develop and improve easy-to-use tools (e.g., reminder systems) that provide ready access to relevant data and information at the point of care. These tools help practitioners to follow existing evidence-based guidelines.
- Develop and/or refine tools and/or algorithms...
to determine who should undergo diagnostic imaging tests for DVT/PE. These tools could incorporate clinical manifestations, biomarkers and genetic profiles, patient and family history, the results of simple mechanical tests, and other information to determine who should be screened.

- Identify and support physician champions who can encourage their peers to provide evidence-based preventive, diagnostic, and therapeutic care.
- Encourage the development of new pharmaceutical agents that have fewer drawbacks than existing medications. The goal is to find agents with faster onset, a wider therapeutic range (thus reducing the need for frequent testing or monitoring of dosage), and fewer food and drug interactions.
- Encourage medical, nursing, and pharmacy schools, and residency programs to provide adequate classroom education and training to ensure that new physicians, nurses, and pharmacists are aware of the magnitude of the problem and how to prevent, diagnose, and treat DVT/PE in accordance with the latest scientific evidence.
- Encourage medical, nursing, and pharmacy schools, and other organizations to incorporate training into continuing medical education, certification, and recertification processes.
- Review payment policies to ensure that they provide appropriate reimbursement for high-quality, evidence-based care.
- Support the development of hospital- and community-based support programs for patients with DVT/PE and their family members.
- Analyze the merits of innovative approaches to anticoagulation therapy management, including, but not limited to, anticoagulation clinics and patient self-testing/management.
- Develop and/or encourage physicians, nurses, and other health professionals to attend education programs related to all aspects of DVT/PE.
- Support the training of investigators and providers by sponsoring fellowships and other training opportunities.

Research and Evaluation

- Conduct further research into the benefits and risks associated with various strategies (pharmacological, mechanical, and surgical) for dissolving or removing clots, and to determine which patients, if any, would benefit from these approaches (as an alternative to anticoagulation therapy).
- Conduct further research into the pathophysiology of DVT/PE, including the roles of inflammation, obesity, stasis, and the basic endothelial cell biology and vessel response to stasis and thrombosis. This research can lead to the development of novel prevention and treatment strategies.
- Investigate whether biomarkers can be identified that will allow for the development of individualized risk profiles for primary and recurrent DVT/PE, and chronic venous insufficiency. These biomarkers can be used to help predict an individual’s response to therapy.
- Investigate the role of prolonged air, car, or rail trips (and other situations causing long periods of immobility) on raising risk, both for the general population and certain high-risk groups, such as women on oral contraceptives or individuals with a genetic predisposition to DVT/PE.
Surgeon General’s Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism

- Investigate the role of compression ultrasonography (CUS) in diagnosing isolated calf DVT, and study the benefits and costs associated with treatment.
- Study the effectiveness of the D-dimer test in diagnosing recurrence of the disease.
- Investigate the safety and effectiveness of various approaches to diagnosing DVT/PE in pregnant women.
- Conduct further research into the best drugs, dosing strategies, and treatment regimens for anticoagulation therapy for certain patient populations, including children (from infancy through adolescence), obese individuals, and those with renal insufficiency.
- Conduct further research on the benefits and risks of preventive and therapeutic anticoagulation therapy for certain patient populations, including children, pregnant women, individuals with a genetic predisposition to DVT/PE (with or without prior events), cancer patients, and the elderly. Such research should also address how to treat individuals with multiple risk factors, such as pregnant women or children with genetic predisposition.
- Conduct further research into the appropriate duration of anticoagulation therapy in specific patient populations, including whether some high-risk groups should remain on the therapy indefinitely.
- Investigate the role that pharmacogenetics can play in determining optimal warfarin dosing in individuals.
- Investigate the role of inferior vena caval (IVC) filters as a primary means of preventing PE, and research the risks and benefits related to permanent versus retrievable placement of IVC filters.
- Investigate and evaluate the various approaches (e.g., pharmacological, mechanical, and/or a combination) to reducing the risk and impact of chronic venous insufficiency.
- Investigate the risks and benefits of using clot-dissolving medications in patients with PE.
- Conduct research into when genetic testing is appropriate, including whether and when to test the asymptomatic family members of those with a genetic predisposition to DVT/PE.
- Conduct further research into the optimal therapy for those with genetic predisposition, and how that therapy might vary depending upon the number of genetic and other acquired risk factors or triggering events. Research should focus on the impact of specific thrombophilic disorders on anticoagulant therapy management and the identification of optimal prophylactic strategies for asymptomatic individuals during high-risk situations.
- Conduct research into how upper extremity DVT—a less common and less studied form than DVT in the legs—should best be evaluated, diagnosed, and managed.

**Setting 3: Policymakers and Governments**

Policymakers and various branches of local, tribal, state, and national governments also have a critical role to play in raising awareness and encouraging the development and use of evidence-based guidelines.

**Communication**

- Raise policymakers’ awareness of DVT/PE and the magnitude of the problems caused by the disease, as well as the need to support research, infrastructure, and payment policies that are consistent with the provision of evidence-based care.
- Support public awareness campaigns, including DVT Awareness Month activities.
- Support the education of health professionals,
including the dissemination of evidence-based guidelines.

**Action**

- Review reimbursement policies to ensure that they encourage the provision of evidence-based prevention, diagnosis, and treatment.
- Support the formation of community-based, regional, and national multistakeholder coalitions dedicated to raising awareness about these diseases.
- Form task forces, steering committees, or advisory committees dedicated to addressing the problems resulting from these conditions.
- Support actions that lead to enhanced public awareness about DVT/PE among health professionals and greater adherence to evidence-based practices.

**Research and Evaluation**

- Support basic, clinical, and epidemiological research that is intended to fill critical gaps in today’s knowledge about DVT/PE.
- Support translational research and the development of other tools that are intended to speed the adoption of new scientific knowledge into the everyday practice of medicine.
- Support the training of scientific investigators and providers who are interested in these diseases.
This “Surgeon General’s Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism” is intended to serve as a catalyst for the development of coordinated efforts to prevent and treat these diseases. Translating the ideas raised in this report will require a great national commitment. Collectively identifying current gaps in knowledge and action, and developing and initiating programs to fill those gaps are necessary. Public and private partnerships will be critical to this task. While the magnitude of the problem is great, the range of potential solutions is even greater. The design of successful interventions and actions for prevention and appropriate diagnosis and treatment of DVT/PE will require the careful attention of many individuals and organizations working together at multiple levels.

**The Power of Partnerships**

Partnerships and collaborations can be powerful vehicles for stimulating positive change. These collaborations can play a critical role in any or all of the following:

- educating the public, patients, and healthcare providers
- assessing the true educational needs and evaluating educational efforts through formal research
- creating and distributing educational messages and materials for the public and patients through seminars, printed material, Web sites, and the media
- encouraging the development of scientific studies for at-risk populations
- promoting the development of evidence-based standards related to prevention, diagnosis, and treatment
- making existing standards accessible and easy to use for all providers
- participating in the development of national treatment guidelines and endorsing them.

Fortunately, there are already successful partnerships on which to build. A number of them are included in the presentations given at the Surgeon General’s Workshop on Deep Vein Thrombosis (www.surgeongeneral.gov/topics/deepvein/). The following are three examples.

**Government-Provider Collaboration**

The Thrombosis and Hemostasis Centers Pilot Program was initiated in 2001 as a collaborative program between the Division of Blood Disorders of the Centers for Disease Control and Prevention and eight Thrombosis and Hemostasis Centers. The intended purpose of the program is to:

- determine the efficacy of integrated multidisciplinary care and prevention services for persons with hemostatic disorders to reduce morbidity and mortality associated with bleeding and clotting diseases
- assess unmet needs for service delivery and identify outreach strategies designed to improve access to care
- develop effective messages aimed at disease management and prevention; and
- foster the development of training programs to enhance provider skills for the delivery of hemostasis and thrombosis care.
During the first five years of this pilot program, the collaborative program has established a patient registry that includes over 3,300 patients (as of October 2006) and has published a manuscript on essential components for a multidisciplinary program in support of patients with thrombotic and hemorrhagic disorders. In July of 2007, the Thrombosis and Hemostasis Centers Research and Prevention Network was established to further epidemiologic and clinical research investigations in thrombosis and thrombophilia (and their associated complications). For more information, please see www.cdc.gov/ncbddd/hbd/clotting.htm.

**Government-Professional Society Collaboration**

In February 2003, the APHA and CDC convened 60 of the nation’s leading medical experts and patient advocates in Washington, DC for a Public Health Leadership Conference on DVT. The purpose of the conference was to highlight the urgency of increased diligence related to disease prevention on the part of the healthcare community, as well as the need to raise awareness of DVT/PE and its complications among the general public. The conference identified several areas in need of immediate attention for education about these conditions:

- Create a national coalition to advocate for greater awareness of DVT/PE among healthcare professionals and the general public.
- Enlist the support of medical, professional, and patient advocacy organizations to make awareness part of their agendas.
- Develop a public awareness campaign and communication tools to educate consumers about the risk factors, symptoms, and prevention measures.
- Encourage state medical licensing boards to include DVT/PE in their CME/CE licensing renewal requirements.
- Close the gap between clinical practice guidelines for prophylaxis and actual practice through the creation and implementation of institutional standards.
- Encourage academic centers to incorporate education into curricula for all medical professionals.
- Ask accreditation and “standardization” institutions to ensure that healthcare providers and institutions implement clinical practice guidelines for prevention.
- Encourage the Joint Commission to make adherence to prevention guidelines part of its accreditation process.
- Educate policymakers about the cost-effectiveness of prevention and treatment of these conditions.

**Public-Private Sector Collaboration**

The Centers for Medicare and Medicaid Services (CMS) and the Joint Commission have joined together to adopt standardized performance measures for hospitals to report. The DVT/PE quality measures initiative is expected to become a CMS required reportable item, thus allowing CMS to benchmark hospitals’ care of these diseases against best performance.

Other examples can be found in the proceedings of the Surgeon General’s Workshop on Deep Vein Thrombosis.
CONCLUSION

A Vision for the Future

As the previous section illustrates, there is no shortage of interest in grappling with the problem of DVT/PE. High-profile individuals and organizations with substantial resources are committed to the task. The key for these stakeholders is to come together to build a coordinated plan that can lead to a dramatic reduction in the incidence and burden of these diseases in this nation.

This Call to Action is for all who can have an impact on the incidence and burden of DVT and PE in the United States. It calls for these stakeholders to take effective action to create a future where:

- The public at large is knowledgeable about the risk factors, triggering events, and symptoms of these diseases, and individuals feel empowered to talk with their clinicians about them whenever appropriate.
- Evidence-based practices for the screening, prevention, diagnosis, and treatment of DVT/PE are clearly understood and routinely applied by all medical professionals in all settings.
- New scientific evidence is routinely being discovered to fill gaps in knowledge, and these findings are quickly and easily disseminated to the public and put into practice by health professionals.

The overall results of this action agenda will be to save tens of thousands of lives each year and to reduce the suffering for many more. Implementing this vision will not be an easy task, and progress will take time. Many barriers stand in the way, but solutions must be found and, more importantly, set into motion. We will need the energy and commitment of individuals, families, the health care system, private sector organizations, and government at all levels to work together to build solutions that will bring better health to Americans. With these dedicated efforts we can make this vision a reality.
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Preventing Hospital-Acquired Venous Thromboembolism

A Guide for Effective Quality Improvement
AHRQ Mission: To improve the quality, safety, efficiency, and effectiveness of health care for all Americans.
Preventing Hospital-Acquired Venous Thromboembolism

A Guide for Effective Quality Improvement

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Preface

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

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

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

A Preventable Problem

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

The Agency for Healthcare Research and Quality calls thromboprophylaxis against VTE the “number one patient safety practice.”16 The American Public Health Association has stated that the “disconnect between evidence and execution as it relates to DVT prevention amounts to a public health crisis.”17 While individual centers have published results of successful local initiatives for improving prevalence of VTE prophylaxis, no single strategy has proven yet to be effective, sustainable, and widely applicable to other centers. This is evolving rapidly, as experience with
local efforts and the Society of Hospital Medicine’s Venous Thromboembolism Prevention collaborative are validating the risk assessment techniques and implementation techniques presented here. One thing is certain, however. To implement effective protocols minimizing incidence of hospital-acquired VTE, while at the same time minimizing adverse outcomes, redesign is needed in both care delivery and performance tracking.

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

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

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

**How to Use This Guide**

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

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

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

Ensure Support From the Institution

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

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

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

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

Another quick method of estimating the impact of a VTE prevention program uses coding information. The QI practitioner can run a query using all codes for DVT and PE. These codes,
listed at Table 1, represent both hospital-acquired VTE and the cases admitted to the medical center with pre-existing DVT or PE. At least half will be hospital-acquired VTE, and if the VTE prophylaxis rate is 50 percent, half of those will be potentially preventable hospital-acquired VTE. Alternatively, a patient may be defined as having hospital-acquired VTE when the diagnosis code is a secondary, rather than a primary, diagnosis.

<table>
<thead>
<tr>
<th>Number</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>453.40</td>
<td>DVT lower extremity not otherwise specified</td>
</tr>
<tr>
<td>453.41</td>
<td>DVT proximal lower extremity</td>
</tr>
<tr>
<td>453.42</td>
<td>DVT distal lower extremity</td>
</tr>
<tr>
<td>453.8</td>
<td>DVT not elsewhere classified</td>
</tr>
<tr>
<td>415.11</td>
<td>Iatrogenic PE</td>
</tr>
<tr>
<td>415.19</td>
<td>Other PE</td>
</tr>
</tbody>
</table>

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

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

**Survey Previous or Ongoing Efforts and Resources**

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

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

- What is the existing QI infrastructure?
- What support or services are available for this project?
- Are there any ongoing QI initiatives to learn from or to leverage?
- Are there any initiatives that could influence support for a VTE prevention effort (e.g., pursuit of Magnet Recognition Program®, Ventilator Associated Pneumonia bundle, Surgical Care Improvement Project, or The Joint Commission or National Quality Forum proposed core measures)?
- What performance data on VTE prevention or VTE events already exist?
- Are there any major lessons from previous or ongoing interventions to prevent VTE?
• How successful were previous VTE risk assessments? Why? Were they integrated into order sets?
• Are there ongoing VTE educational or awareness activities for medical staff?
• Are hospital policies capable of enforcing provider performance (e.g., medication reconciliation, vaccinations, VTE prophylaxis, etc.)?
• How fragmented is care in the hospital? Are intensive care units (ICUs) open or closed? Are patients geographically cohorted by service or specialty?
• What are the existing practices for standardizing care transitions between settings (e.g., emergency room to floor, intensive care unit to floor, operating room to floor, direct admissions)?
• Can precedents be leveraged that have engaged patients in promoting medical staff accountability for any specific care goals?
• In what areas of the hospital are nurses engaged in promoting medical staff accountability for any specific care goals (e.g., daily goals worksheet or participation in multidisciplinary rounds)?
• In what precedent-setting ways do clinical pharmacists participate in care delivery (e.g., participation in multidisciplinary rounds, pharmacokinetics consults, pages to providers to adjust medication dosages for estimated glomerulo filtration rate, etc.)?
• Could the electronic health information or paging system relay clinical information to members of the care team (e.g., alerts by e-mail, text page, fax, or computerized physician order entry [CPOE])?
• Is there a precedent anywhere in the institution for feeding back individual or service line performance to providers?
• Does the medical center have an electronic medical record, CPOE, or digital radiology?

Clarify Key Stakeholders, Reporting Hierarchy, and Approval Process

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

• Pharmacy and therapeutics committee.
• Nursing groups.
• Orthopedics, surgery, or trauma leaders.
• Patient safety committee.
• Operating room or peri-operative committees.
• Chief residents and residency program directors.
• Departmental committees.
Providing awareness of the effort to stakeholders and gaining their buy-in will be important to boost early adoption of interventions. They may also advance educational efforts and offer legal protection for information that is uncovered. Early use of the proper reporting structure and approval processes is wise.

**Assemble an Effective Team**

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

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

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

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

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

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

**Information Technology and Health Information System Experts.** From performance tracking to actual QI interventions, the contributions of information technology or health information system experts is pivotal. Enlist those who can report ICD-9 code frequencies at discharge, perform data entry, set up reports from the electronic clinical data warehouse and radiology, and serve as liaisons to the medical records office.
**Team Members.** While meetings with the whole team are invaluable, they can occasionally become impractical or impossible to schedule. Team huddles, where a fragment of the team meets briefly to advance action items, can be very effective for overall progress. How team members interact with one another is also important. The key dynamic for an effective team is the removal of authority gradients. Because the perspective of every team member is potentially critical, every perspective must be heard. Each team member must be comfortable expressing his or her viewpoint. Try to pick people who have reputations as collaborators. It is up to the leader and facilitator to enforce constructive team dynamics.

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

**Set General Goals and a Timeline**

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

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

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

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

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

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

The team will advance the quality improvement project along several fronts simultaneously. A logical flow for a QI project is summarized below.
1. Lay out the evidence and identify best practices. Determine what needs to be done for whom and then draft a VTE protocol to standardize it.

2. Analyze care delivery. Highlight the steps in the clinical workflow where interventions will have the highest yield.

3. Track performance with metrics. Set up regular data collection and charting that is reliable, inexpensive, and directly relevant to the aim.

4. Integrate the VTE protocol into the clinical workflow and layer other QI strategies that use high-reliability mechanisms.

5. Perform cycles of Plan-Do-Study-Act to perfect 3 and 4, above.

Figure 1 presents the five steps and depicts inter-relationships.
Chapter 2. Lay Out the Evidence and Identify Best Practices

Know What the Literature Says

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

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

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

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

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>DVT Incidence (%)</th>
</tr>
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<tbody>
<tr>
<td>Medical patients</td>
<td>10–26</td>
</tr>
<tr>
<td>Major gynecological, urological, or general surgery</td>
<td>15–40</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>15–40</td>
</tr>
<tr>
<td>Stroke</td>
<td>11–75</td>
</tr>
<tr>
<td>Hip or knee surgery</td>
<td>40–60</td>
</tr>
<tr>
<td>Major trauma</td>
<td>40–80</td>
</tr>
<tr>
<td>Spinal cord injury</td>
<td>60–80</td>
</tr>
<tr>
<td>Critical care patients</td>
<td>15–80</td>
</tr>
</tbody>
</table>
The 2004 ACCP conference statement supports a group-specific approach to prophylaxis. Its reasons for this approach are:

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

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

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

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

- In medical patients, fondaparinux and the low-molecular-weight heparins (LMWHs) enoxaparin and dalteparin have efficacy comparable to heparin given three times a day subcutaneously but offer lower complication rates and other advantages potentially important to patients and nursing staff.\(^{18, 21}\)

- In certain higher-risk patient groups (e.g., hip and knee replacement, trauma, and spinal cord injury) LMWH has demonstrated superiority over subcutaneous heparin.\(^{10, 22-25}\)

- In certain patient groups (e.g., hip replacement, surgery for cancer, and possibly medical patients with reduced mobility), extending prophylaxis with LMWH to approximately 5 weeks is more effective than providing it for 1 week.\(^{10, 26}\)

- In certain patient groups, such as medical inpatients, the adequacy of heparin given twice a day subcutaneously has not been proven. High quality randomized trials showing relative equivalence of LMWH to unfractionated heparin (UFH) all used a 5,000-unit, three times a day dosing of UFH.

- In very high-risk patient groups, the addition of mechanical prophylaxis to a pharmacologic regimen may offer an added benefit.

- Certain patient groups should not receive certain pharmacologic agents or doses or should receive smaller doses of LMWH (e.g., creatinine clearance less than 30 cc per minute).

- Certain patient groups should receive pharmacologic doses in close coordination with other events (e.g., surgery or neuroaxial blockade) or with special knowledge by involved physicians (e.g., spine surgeons).
Reality 3. In the quality improvement (QI) literature, no strategy has yet been described for getting the right prophylaxis to the right patient at sustainable and acceptable rates in a way that can be readily replicated by other institutions.

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

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

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

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

Construct the Venous Thromboembolism Protocol

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

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

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

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

Adherence to a single VTE protocol can readily serve as a surrogate measure for performance tracking. The predictable disadvantages are those that come from any effort that tries to apply a common solution to different groups. The challenge is to strike a balance between limiting prophylaxis options too much and allowing for many options. There are several ways to overcome these disadvantages, but the simplest rule of thumb is always to allow providers the leeway of going “off protocol” when clinically appropriate.

- Is easy to access and easy to use. Simpler is better. Eventually the team may ask providers to refer to or recall elements of the VTE protocol several times during a patient’s admission. One of the great determinants of the VTE protocol’s success will be whether the team can make its use so easy and automatic that all patients coming into the hospital at any time from any place will be funneled through it.
- Links each level of risk to evidence-based choices for prevention.
- Lists contraindications to prophylaxis and encourages reasonable alternatives.

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

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

**Linked Menu of Appropriate Prophylaxis Options.** This menu allows providers to choose the right VTE prophylaxis by “backing into” the choice from the VTE risk level that is derived from the standardized VTE risk assessment. The team must explore local factors that may play a role in selecting agents of choice for each level of VTE risk. The team must account for these local...
Case Study 1. Questions the University of California, San Diego Medical Center Encountered While Developing Its Venous Thromboembolism Protocol

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

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

Which patients need IPC in addition to pharmacologic prophylaxis?

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

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

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

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

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

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

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

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

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

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

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

continued on page 12
Case Study 1. Questions the University of California, San Diego Medical Center Encountered While Developing Its Venous Thromboembolism Protocol (continued)

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

At UCSD, they found the following:

<table>
<thead>
<tr>
<th></th>
<th>Pharmacy cost</th>
<th>Admin time/cost</th>
<th>Total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>LMWH every day</td>
<td>$16</td>
<td>10 mins/$5.33</td>
<td>$21.33</td>
</tr>
<tr>
<td>UFH every 8 hours</td>
<td>$1</td>
<td>30 mins/$16</td>
<td>$17</td>
</tr>
</tbody>
</table>

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

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

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

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

The steps to define appropriate prophylaxis are:

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

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

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

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

Which patients need mechanical in addition to pharmacologic prophylaxis?

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

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

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

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

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

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

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

Ultimately the team should strive for perfect integration of the VTE protocol into admission and transfer order writing; thus the importance of an easy-to-use model cannot be overstated. Even if the VTE protocol is supremely easy to use, it will be ineffective if patients bypass the protocol. A number of approaches to prevent this outcome, and other methods of enhancing the reliability of the VTE protocol are outlined in the coming chapters.
Chapter 3. Analyze Care Delivery

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

Diagram Care Delivery to Identify Failure Modes

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

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

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

- VTE risk assessment is not routine or standard.
- Bleeding risk assessment is not routine or standard.
- Most appropriate prophylaxis option for each level of risk is not conveniently available for provider.
- Differing opinions or lack of awareness exist for how at-risk some medical or surgical patients were.
- Differing opinions exist on what is appropriate, even among experts.
- Protocols differ among orthopedics, surgery, and medicine.
- Noncompliance with mechanical prophylaxis exists. For example, mechanical prophylaxis is on the floor, on the window sill, not in the room, or not delivered to the room when the patient is admitted at night or over a weekend.
- Unnecessary immobility occurs because of excessive sedation, unnecessary restraints, central lines, catheters, intravenous fluids, or oxygen therapy.
- VTE and bleeding risks change, but there is no routine or standard reassessment.
- Platelet monitoring is haphazard when heparin is ordered.
- Nonretrievable inferior vena cava filters are overused.
- Transfers out of intensive care units may cause VTE prophylaxis to be dropped.
- Prophylaxis is stopped at discharge even when risk continues in some patients.
- Widely different impressions are held for when it is safe to start anticoagulation peri-procedure and post-trauma.
Figure 2. Care Delivery for Preventing Hospital-Acquired Venous Thromboembolism

Provider orders appropriate VTE prophylaxis at admission

Clinical Support Services deliver appropriate VTE prophylaxis

Change in patient’s VTE risk level, contraindications, or site/unit of care

Is the patient on appropriate VTE prophylaxis here?

No VTE at discharge

Hospital-Acquired VTE

Provider performs VTE risk assessment

Clinical Support Services assess patient

Provider links patient’s VTE risk level to menu of appropriate VTE prophylaxis options

Care Delivery: Prevention of Hospital-Acquired VTE

Patient admitted to hospital

Conceptual Flow Diagram of Care Delivery for Providing VTE Prophylaxis: A number of interrelated steps combine to determine whether a patient, at any given moment, is receiving appropriate VTE prophylaxis.
Analyze Care Delivery to Identify “Rate-Limiting Steps”

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

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

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

A sample of 25 charts at this hospital showed that two-thirds of failures to order appropriate venous thromboembolism (VTE) prophylaxis occurred at the time of admission and are attributable either to the provider ordering or medical decisionmaking (i.e., 35 percent ordered nothing for VTE prophylaxis, another 30 percent ordered something that the VTE team considered inappropriate). One in five failures was due to failure to re-assess VTE risk later in the hospital stay. One in eight failures was due to a problem with delivering or wearing sequential compression devices.
Chapter 4. Track Performance With Metrics

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

Key Metric 1: Prevalence of Appropriate Venous Thromboembolism Prophylaxis

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

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

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

Key Metric 2: Incidence of Hospital-Acquired Venous Thromboembolism

The team cares most about how well the steps of care delivery come together to prevent hospital-acquired VTE, the main clinical endpoint or outcome. Clearly, the incidence of hospital-acquired VTE must be one of the team’s key metrics. A common definition for “hospital-acquired deep vein thrombosis or pulmonary embolism” would be a clot first discovered during the course of hospitalization or discovered within 30 days of a prior hospitalization. Table 3 shows various methods for trying to capture this metric in a useful way. Each has its own advantages in terms of accuracy and efficiency.
Whether a patient develops a preventable hospital-acquired deep vein thrombosis (DVT) or pulmonary embolism (PE) depends heavily on recent, appropriate venous thromboembolism (VTE) prophylaxis. While one key metric to track is the intermediate outcome “appropriate VTE prophylaxis,” the more proximal steps in the care delivery pathway are where care redesign will likely occur (e.g., the VTE protocol). The other key metric to track is the prevalence of hospital-acquired DVT or PE.

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

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

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

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

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

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

Once the team has defined “hospital-acquired VTE” and figured out how to find the cases, it has another decision to make. Should it simply track the raw number of hospital-acquired VTE, or should it control for the number of patients or patient-days? Controlling for patient-days at risk for VTE adds a little more work, but it reduces some of the noise in the data by controlling for the probability that more hospital-acquired VTE events occur with higher hospital occupancy. At UCSD, for example, each month the team calculates the total number of patient-days for adult inpatients in the hospital for more than 48 hours and uses that as the denominator. The team uses the total number of hospital-acquired VTE events as the numerator. This helped UCSD generate a specific aim, a concept discussed later in this chapter.
Another option to consider, if the team has the capacity to look at all newly diagnosed events of DVT and PE in the hospital, is to track the number of days between hospital-acquired VTE events or potentially preventable hospital-acquired VTE events. This allows the team to chart days between events. Each event becomes a point on the x-axis while the number between events appears on the y-axis.

**Data Collection**

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

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

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

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

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

- How much time is acceptable in peri-operative or trauma settings for a patient not to be on pharmacologic prophylaxis? (The readings at Appendix C can suggest some parameters.)
- What are the acceptable versus preferred VTE prophylaxis options for each level of VTE risk? Realize that when auditing, there will be VTE prophylaxis options that make sense to consider as adequate, even though they are not listed as recommended in the VTE
protocol. For example, the auditor may accept 7,500 units of unfractionated heparin subcutaneously every 12 hours as acceptable prophylaxis for the patient who is at moderate risk for VTE, even if it is not listed as an option on the VTE protocol because of the lack of prepackaged syringes or the absence of clinical trials supporting that regimen.

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

Several common sampling strategies follow.

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

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

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

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

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

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

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

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

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

Transform General Goals Into a Metric-Specific Aim Statement

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

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

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

Referring to the preceding examples, the team should now be able to write an aim statement for its chosen metrics.
Figure 5. Comparison of Tabular Data and Run Chart From the University of California, San Diego Medical Center

Patients with preventable hospital-acquired VTE events per 1,000 days and % with appropriate prophylaxis (total population)

<table>
<thead>
<tr>
<th></th>
<th>Patients with Preventable VTE</th>
<th>Patient-Days</th>
<th>Case per 1,000 Patient-Days</th>
<th>% Appropriate Prophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2005</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jan</td>
<td>6</td>
<td>5198</td>
<td>1.2</td>
<td>53</td>
</tr>
<tr>
<td>Feb</td>
<td>3</td>
<td>4652</td>
<td>.6</td>
<td>55</td>
</tr>
<tr>
<td>Mar</td>
<td>4</td>
<td>5583</td>
<td>.7</td>
<td>55</td>
</tr>
<tr>
<td>Apr</td>
<td>5</td>
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<td>.9</td>
<td>52</td>
</tr>
<tr>
<td>May</td>
<td>2</td>
<td>4695</td>
<td>.4</td>
<td>51</td>
</tr>
<tr>
<td>Jun</td>
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<td>55</td>
</tr>
<tr>
<td>Jul</td>
<td>5</td>
<td>4850</td>
<td>1.0</td>
<td>57</td>
</tr>
<tr>
<td>Aug</td>
<td>6</td>
<td>4322</td>
<td>1.4</td>
<td>58</td>
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<td>Sep</td>
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<td>Nov</td>
<td>2</td>
<td>5709</td>
<td>.4</td>
<td>68</td>
</tr>
<tr>
<td>Dec</td>
<td>3</td>
<td>4928</td>
<td>.6</td>
<td>65</td>
</tr>
<tr>
<td><strong>2006</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jan</td>
<td>1</td>
<td>5894</td>
<td>.2</td>
<td>59</td>
</tr>
<tr>
<td>Feb</td>
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<td>.8</td>
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<td>Mar</td>
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<td>5501</td>
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<td>72</td>
</tr>
<tr>
<td>Apr</td>
<td>0</td>
<td>4614</td>
<td>.0</td>
<td>69</td>
</tr>
<tr>
<td>May</td>
<td>1</td>
<td>4741</td>
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<tr>
<td>Jun</td>
<td>0</td>
<td>5205</td>
<td>.0</td>
<td>80</td>
</tr>
</tbody>
</table>
Balancing Measures

Now that the team has an aim statement for its key performance metrics, it is ready to plan changes to the system. But what if the improvement changes lead to unintended consequences for patients or the hospital? How will the team know? The team should consider monitoring potential areas of concern to detect any detrimental effects of improvement changes. These additional metrics are called “balancing measures.” For example, the team may decide to track the incidence of heparin-induced thrombocytopenia, bleeding episodes, or the cost of using more pharmacologic prophylaxis as balancing measures.
Chapter 5. Layer Interventions

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

The Venous Thromboembolism Protocol

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

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

Key Principles for Effective Quality Improvement Interventions

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

Principle 1. Keep it simple for the end user.

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

Principle 2. Do not interrupt workflow.

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

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

If the team cannot incorporate a VTE risk assessment within admission, postoperative, or transfer order sets, a stand-alone VTE risk assessment sheet should be stapled to the order set. The order set must be easy to find and restocked regularly because end users are unlikely to go out of their way to download or locate a VTE risk assessment form.
Principle 3. Design reliability into the process.

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

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

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

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

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

Principle 5. Monitor use of the protocol.

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

When providers do not use the protocol or deviate from it, reasons might derive from logistics, patients, providers, and other variables. The team should anticipate variations from the protocol but should capture those instances, learn from them, and take steps to reduce them. The team should ask:
• Why is the order set not used in some areas?
• Can it be integrated into other heavily used order sets?
• Which types of admissions are inadvertently bypassing the protocol?
• Which patients just do not fit the protocol?
• Can the protocol be changed so it fits more patients and situations?
• Which providers would benefit from focused educational efforts?
• Is the protocol stocked and restocked in all the key areas in the hospital?

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

**Beyond the Venous Thromboembolism Protocol: Using a “Hierarchy of Reliability”**

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

<table>
<thead>
<tr>
<th>Level</th>
<th>Predicted Prophylaxis Rate %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No protocol (i.e., &quot;state of nature&quot;)</td>
</tr>
<tr>
<td>2</td>
<td>Decision support exists but not linked to order writing or prompts exist within orders but no decision support at hand</td>
</tr>
<tr>
<td>3</td>
<td>Protocol well-integrated into orders at point of care</td>
</tr>
<tr>
<td>4</td>
<td>Protocol enhanced by other QI and high-reliability strategies</td>
</tr>
<tr>
<td>5</td>
<td>Oversights identified and addressed in real time</td>
</tr>
</tbody>
</table>

**Level 1. State of Nature**

In the unimproved modern hospital, patients receive care that depends solely on their physicians’ knowledge, skills, and memory. There is no standardized assessment for VTE risk, and there are no reminders within the real-time flow of care delivery to prompt physicians to order VTE prophylaxis. In this “state of nature,” expect approximately 40 percent of patients to be on appropriate VTE prophylaxis at any given moment.
Level 2. Average
Many hospitals that have tried to improve VTE prophylaxis find themselves at Level 2, with only partially effective components of a VTE protocol:

- A standardized VTE risk assessment to guide the choice of a VTE prophylaxis exists, but it is not well integrated into admission and transfer order sets (e.g., the VTE protocol exists only as a stand-alone form or pocket card).

- A prompt to order VTE prophylaxis is nested within admission and transfer order sets, but no VTE risk assessment exists to guide the choice of a VTE prophylaxis.

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

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

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

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

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

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

Use Table 5 as a source for additional Level 4 ideas. Most of these other strategies leverage the existence of a VTE protocol that is well integrated into the workflow. Providers, nurses, pharmacists, and patients can refer back to the VTE protocol for clarity, confidence, or advocacy. Any additional, layered interventions should include at least one high-reliability mechanism in the
<table>
<thead>
<tr>
<th>Quality Improvement Strategy Category</th>
<th>Specific Ideas for VTE Prevention</th>
</tr>
</thead>
</table>
| Provider education                    | • Didactic sessions on VTE prevention (e.g., noon conference or grand rounds)  
• Distributed educational materials (e.g., pocket cards with VTE risk factors) |
| Provider reminder systems             | • Prompts nested within paper admission, transfer, or post-op order sets supported by VTE risk assessment as decision support (VTE protocol)  
• Prompts using computerized physician order entry with risk assessment as decision support (VTE protocol)  
• Stickers on charts or posters in order-writing areas |
| Facilitated relay of clinical data to providers | • Alerts to physicians by means other than medical records (e.g., page, electronic alert, phone call, or e-mail regarding VTE prophylaxis oversights) |
| Audit and feedback of performance to providers | • Feedback of VTE prophylaxis performance to individual providers or groups of providers with or without benchmarking to top performers |
| Patient education                     | • Discrete disclosure to patients of increased risk for VTE (e.g., pamphlets, physician or nurse teaching of patient or caregiver, closed-circuit television program in patient rooms) |
| Organizational or operational change  | • Administrative support personnel dedicated to ensure constant stocking of VTE protocol order set in needed areas  
• Clinical support personnel dedicated to ensure and document that mechanical prophylaxis is worn by patients  
• Hospital-wide or unit-specific teams or individuals with regular responsibility to ensure each patient is receiving appropriate VTE prophylaxis (e.g., physician, nurse, pharmacist) |
| Incentives, regulation, and policy    | Provider directed:  
• Recognition of highest performers each month or quarter  
• Financial incentives based on achievement of VTE prophylaxis performance goals  
• Punitive actions for failures to meet minimum performance (e.g., suspension of privileges)  
Health system directed:  
• Enforced policy mandating use of VTE protocol (e.g., “hard stops” in processing of admission, transfer, or post-operative orders that fail to prescribe VTE prophylaxis) |

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

**Level 5. Oversights Identified and Mitigated**

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

A mature Level 5 program will also judge the efficacy of mitigation, and its failures will be immediately remedied. Failure modes of mitigation are systematically cataloged, analyzed, and eliminated. Achieving this level of reliability across an entire hospital represents a pioneering effort in VTE prevention. Level 5 solutions transferable to other institutions represent something transformative for hospital care.
Chapter 6. Continue to Improve

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

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

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

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

<table>
<thead>
<tr>
<th>Table 6. Advantages of Plan-Do-Study-Act and Principles for Success</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advantages of PDSA</strong></td>
</tr>
<tr>
<td>• Allows for valuable modifications to improve effectiveness or preserve productivity</td>
</tr>
<tr>
<td>• Allows “failures” to come to light without undermining performance and momentum</td>
</tr>
<tr>
<td>• Identifies areas of resistance that might undermine spread to other units</td>
</tr>
<tr>
<td>• Allows costs and side effects of the change to be assessed</td>
</tr>
<tr>
<td>• Increases certainty that change will result in improvement</td>
</tr>
<tr>
<td>• Allows for detailed documentation of improvement</td>
</tr>
<tr>
<td><strong>Principles for Success</strong></td>
</tr>
<tr>
<td>• Start new changes on the smallest possible scale, e.g., one patient, one nurse, one doctor</td>
</tr>
<tr>
<td>• Run just as many PDSA cycles as necessary to gain confidence in a change, then spread the change incrementally</td>
</tr>
<tr>
<td>• Spread change incrementally to more patients, then more nurses, then doctors, and finally units</td>
</tr>
<tr>
<td>• Balance changes within the overall system to ensure that other processes are not adversely stressed</td>
</tr>
<tr>
<td>• Pay special attention to preserving productivity and workflow</td>
</tr>
</tbody>
</table>
Spreading Improvement to Other Units

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

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

Just as for the pilot, let the key principles for layering effective QI interventions discussed in Chapter 5 guide the team’s efforts to spread the improvement.
Appendix A: Talking Points to Attract Administration Support for Venous Thromboembolism Prevention Programs

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

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

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

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

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

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

- The high prevalence of hospital-acquired VTE is largely due to the underutilization of simple, cost-effective prophylactic measures. Of the 2,726 patients who had their DVT diagnosed while hospitalized in the DVT FREE Registry, only 1,147 (42 percent) received prophylaxis within the 30 days before diagnosis.
Several prominent organizations acknowledge the magnitude of this implementation gap. The AHRQ report, “Making Healthcare Safer,” cited the provision of appropriate VTE prophylaxis as the paramount effective strategy to improve patient safety.

- “Thromboprophylaxis is the number one patient safety practice to prioritize among the nearly 70 practices reviewed.” — AHRQ
- PE is “the most common preventable cause of hospital death in the United States.” — Leapfrog
- “Physicians and other healthcare providers must be aware of risk factors and risk stratification. Moreover, they must take more aggressive action in screening patients for risk factors and in prescribing preventive interventions.” — American Public Health Association

The current reality in American hospitals is arrestingly substandard, especially considering what could be accomplished with simple, safe, and effective prophylaxis for the at-risk inpatient.

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

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

Reliably preventing VTE in the hospital is inherently complex.

- More education alone won’t get the job done.
- VTE risk and bleeding risk vary within patient populations.
- The risk of VTE and the risk of bleeding may change for individual patients several times as they progress through their hospital stay.
- Medication changes, weight, age, renal function, and recent or impending invasive interventions may all influence decisions about the best VTE prevention options.
- Transitions across care providers and locations lead to multiple opportunities for breakdown in the delivery of optimal VTE prophylaxis.
- Thoughtful, evidence-based protocols; multidisciplinary system changes; and comprehensive educational efforts are required to achieve optimal VTE prophylaxis in the complex hospital setting.
• Essential elements are needed for effective and safe prevention of VTE in the hospital.
  – Educational and awareness efforts alone have proven inadequate in increasing appropriate use of VTE prophylaxis. Similarly, order sets and critical pathways not supported by a healthy quality improvement framework are unlikely to succeed.
  – Process redesign and continuous attention must include two essential elements:
    1) Performance of a VTE risk assessment for every patient on admission and regularly throughout hospitalization.
    2) Selection of appropriate prophylaxis by linking the VTE risk to a corresponding menu of proven options.

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

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

**A roadmap is in place.**

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

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

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

<table>
<thead>
<tr>
<th>Low Risk</th>
<th>Moderate Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambulatory patient without additional VTE risk factors or expected length of stay &lt;2 days</td>
<td>Patients who aren’t in either the low- or high-risk group (see VTE risk factor table on reverse)</td>
<td>Elective hip or knee arthroplasty</td>
</tr>
<tr>
<td>Minor surgery in patient without additional VTE risk factors (same day surgery or operating room time &lt;30 minutes)</td>
<td>Select one pharmacologic* option:</td>
<td>Acute spinal cord injury with paresis</td>
</tr>
<tr>
<td></td>
<td>Enoxaparin* 40 mg SQ q 24 hours</td>
<td>Multiple major trauma</td>
</tr>
<tr>
<td></td>
<td>UFH 5,000 units SQ q 8 hours</td>
<td>Abdominal or pelvic surgery for cancer</td>
</tr>
<tr>
<td></td>
<td>UFH 5,000 units SQ q 12 hours (use only if wt &lt;50kg or &gt;75 yrs)</td>
<td>Select one pharmacologic # option:</td>
</tr>
<tr>
<td></td>
<td>or</td>
<td>Enoxaparin* 40 mg SQ q 24 hours</td>
</tr>
<tr>
<td></td>
<td>No pharmacologic prophylaxis because of contraindication (see reverse)</td>
<td>Enoxaparin* 30 mg SQ q 12 hours (knee replacement)</td>
</tr>
<tr>
<td></td>
<td>No pharmacologic prophylaxis because it is optional in this special population (GYN surgery)</td>
<td>Warfarin mg PO daily, target INR 2-3; hold INR &gt;3</td>
</tr>
<tr>
<td></td>
<td>Sequential compression device aka SCDs (Optional for these patients if they are on pharmacologic prophylaxis, mandatory if not)</td>
<td>or</td>
</tr>
<tr>
<td></td>
<td>SCDs to</td>
<td>UFH 5,000 units SQ q 8 hours (only if creatinine clearance is &lt;30, Scr &gt;2, and warfarin is not an option)</td>
</tr>
<tr>
<td></td>
<td>Both lower extremities</td>
<td>No pharmacologic prophylaxis because of contraindication (see reverse)</td>
</tr>
<tr>
<td></td>
<td>Right leg only</td>
<td>and</td>
</tr>
<tr>
<td></td>
<td>Left leg only</td>
<td>SCDs to</td>
</tr>
<tr>
<td></td>
<td>Patient intolerant or has skin lesions on both legs, do not use SCDs</td>
<td>Both lower extremities</td>
</tr>
</tbody>
</table>

*Early ambulation

---

*See contraindications on reverse.

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

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

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

<table>
<thead>
<tr>
<th>Age &gt;50 years</th>
<th>Prior history of VTE</th>
<th>Acute or chronic lung disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myeloproliferative disorder</td>
<td>Impaired mobility</td>
<td>Obesity</td>
</tr>
<tr>
<td>Dehydration</td>
<td>Inflammatory bowel disease</td>
<td>Known thrombophilic state</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>Active rheumatic disease</td>
<td>Varicose veins/chronic stasis</td>
</tr>
<tr>
<td>Active malignancy</td>
<td>Sickle cell disease</td>
<td>Recent post-partum with immobility</td>
</tr>
<tr>
<td>Hormonal replacement</td>
<td>Estrogen-based contraceptives</td>
<td>Nephrotic syndrome</td>
</tr>
<tr>
<td>Moderate to major surgery</td>
<td>Central venous catheter</td>
<td>Myocardial infarction</td>
</tr>
</tbody>
</table>

### Contraindications or Other Conditions to Consider With Pharmacologic VTE Prophylaxis

<table>
<thead>
<tr>
<th><strong>Absolute</strong></th>
<th><strong>Relative</strong></th>
<th><strong>Other Conditions</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Active hemorrhage</td>
<td>• Intracranial hemorrhage within last year</td>
<td>• Immune mediated heparin-induced thrombocytopenia</td>
</tr>
<tr>
<td>• Severe trauma to head or spinal cord with hemorrhage in the last 4 weeks</td>
<td>• Craniotomy within 2 weeks</td>
<td>• Epidural analgesia with spinal catheter (current or planned)</td>
</tr>
<tr>
<td>• Other</td>
<td>• Intraocular surgery within 2 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Gastrointestinal, genitourinary hemorrhage within the last month</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Thrombocytopenia (&lt;50K) or coagulopathy (prothrombin time &gt;18 seconds)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• End stage liver disease</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Active intracranial lesions/neoplasms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hypertensive urgency/emergency</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Post-operative bleeding concerns*</td>
<td></td>
</tr>
</tbody>
</table>

*Scheduled return to OR within the next 24 hours: major ortho: 24 hours leeway; spinal cord or ortho spine: 7 days leeway; general surgery, status post transplant, status post trauma admission: 48 hours leeway.
Appendix C. Suggested Reading for Venous Thromboembolism Protocol Development

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


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


Appendix D. Chart Audit Form

Reviewer _____________________ MR# _________________ Name ___________________ Dx#1 _______
Date/Time ___________________ Date of Admission ______________________________ Dx#2 _______
Ht: ____________ Wt ____________ BMI ____________ Age ____________ Sex M F Dx#3 _______
Service ______________________ Ward/Location _______________________________________________

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

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

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

Adequate Prophylaxis Regimens for Each Level of VTE Risk

<table>
<thead>
<tr>
<th>Low risk</th>
<th>Moderate risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early ambulation</td>
<td>Heparin 5,000 units SC q 8 h or</td>
<td>Dalteparin 5,000 units SC daily or</td>
</tr>
<tr>
<td></td>
<td>Heparin 7,500 units SC q 12 h or</td>
<td>Enoxaparin 30 mg SC q 12 hours or</td>
</tr>
<tr>
<td></td>
<td>Dalteparin 5,000 units SC daily or</td>
<td>Enoxaparin 40 mg SC q day or</td>
</tr>
<tr>
<td></td>
<td>Enoxaparin 40 mg SC daily or</td>
<td>Fondaparinux 2.5 mg SC daily or</td>
</tr>
<tr>
<td></td>
<td>Heparin 5,000 units SC q 12 hours</td>
<td>Warfarin, INR 2.3.</td>
</tr>
<tr>
<td></td>
<td>(only for patients with weight &lt;50 kg or age &gt;75 years)</td>
<td>and SCDs (unless not feasible)</td>
</tr>
</tbody>
</table>

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


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

Pharmacologic
- Heparin 5,000 units subcutaneous q 12 hours
- Heparin 7,500 units subcutaneous q 12 hours
- Heparin 5,000 units subcutaneous q 8 hours
- Enoxaparin (Lovenox) 40 mg subcutaneous q day
- Enoxaparin (Lovenox) 30 mg subcutaneous q 12 hours
- Dalteparin (Fragmin) 2,500 units subcutaneous q day
- Dalteparin (Fragmin) 5,000 units subcutaneous daily
Fondaparinux (Arixtra) 2.5 mg subcutaneous daily ($28.63/day). Start 6 hours post-op.
Coumadin ______mg daily
Other ________________________________________________________________________________

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

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

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

8. If no, list reason given below.

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

<table>
<thead>
<tr>
<th><strong>Low Risk</strong></th>
<th><strong>Moderate Risk</strong></th>
<th><strong>High Risk</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambulatory patient without additional VTE risk factors or expected length of stay &lt;2 days</td>
<td>Patients who aren’t in either the low- or high-risk group (see VTE risk factor table below)</td>
<td>Elective hip or knee arthroplasty</td>
</tr>
<tr>
<td>Minor surgery in patient without additional VTE risk factors (same day surgery or operating room time &lt;30 minutes)</td>
<td></td>
<td>Acute spinal cord injury with paresis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Venous Thromboembolism Risk Factors</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt;50 years</td>
</tr>
<tr>
<td>Myeloproliferative disorder</td>
</tr>
<tr>
<td>Dehydration</td>
</tr>
<tr>
<td>Congestive heart failure</td>
</tr>
<tr>
<td>Active malignancy</td>
</tr>
<tr>
<td>Hormonal replacement</td>
</tr>
<tr>
<td>Moderate to major surgery</td>
</tr>
</tbody>
</table>
Contraindications or Other Conditions to Consider With Pharmacologic VTE Prophylaxis

<table>
<thead>
<tr>
<th>□ Absolute</th>
<th>□ Relative</th>
<th>□ Other Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Active hemorrhage</td>
<td>• Intracranial hemorrhage within last year</td>
<td>• Immune mediated heparin-induced thrombocytopenia</td>
</tr>
<tr>
<td>• Severe trauma to head or spinal cord with hemorrhage in the last 4 weeks</td>
<td>• Craniotomy within 2 weeks</td>
<td>• Epidural analgesia with spinal catheter (current or planned)</td>
</tr>
<tr>
<td>• Other______</td>
<td>• Intraocular surgery within 2 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Gastrointestinal, genitourinary hemorrhage within the last month</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Thrombocytopenia (&lt;50K) or coagulopathy (prothrombin time &gt;18 seconds)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• End stage liver disease</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Active intracranial lesions/neoplasms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hypertensive urgency/emergency</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Post-operative bleeding concerns*</td>
<td></td>
</tr>
</tbody>
</table>

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

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


Appendix N:
Sample “Rule Out” VTE Prophylaxis Order Set
VTE PROPHYLAXIS ORDER SET

DATE: __________  TIME: ________

### SECTION A: VTE PROPHYLAXIS ASSESSMENT

- [ ] Yes  [ ] No  Patient has orders on this admission to receive heparin, Enoxaparin (Lovenox), Fondaparinux (Arixtra), Warfarin (Coumadin), Argatroban, Lepirudin (Refudan), or pneumatic compression hose.

Note: This does not include Aspirin, Clopidogrel (Plavix) or Ticlopidine (Ticlid); check the "No" box

* If “Yes”, assessment is complete – RN Signature: ___________________________  Date: ________  Time: ________

* If “No”, answer all questions in Section B below.

### SECTION B: CONTRAINDICATION ASSESSMENT

- [ ] Yes  [ ] No  Known allergy or hypersensitivity to Heparin or Enoxaparin (Lovenox)

- [ ] Yes  [ ] No  Suspected intracranial or intraspinal bleed (i.e., subdural hematoma)

- [ ] Yes  [ ] No  Suspected bleeding conditions (i.e., GI bleed, nose bleed, bloody urine, vaginal bleeding)

- [ ] Yes  [ ] No  Congenital or acquired bleeding disorder (i.e., hemophilia, factor deficiency)

- [ ] Yes  [ ] No  Hemoglobin level less than 10 grams/deciliter - (if not done, contact House PA for CBC order)

- [ ] Yes  [ ] No  Platelet count less than 140,000/microliter - (if not done, contact House PA for CBC order)

- [ ] Yes  [ ] No  Patient could not reliably answer the above questions.

Explain: __________________________________________________________________________

NOTE:
- If all “No” answers in Section B, call the attending physician or the House PA for order to initiate one of the VTE prophylaxis options listed in Section C.
- If there are any “Yes” answers (contraindication) in Section B, select “Apply pneumatic compression hose”; then date, time and sign Section C of the form.

RN Signature: ___________________________  Date: ________  Time: ________

### SECTION C: SELECT THE APPROPRIATE ORDER BELOW

**Anticoagulation (select one):**

- [ ] Heparin 5,000 units subcutaneously every 8 hours
- [ ] Enoxaparin (Lovenox) 40mg subcutaneously daily (creatinine clearance greater than or equal to 30 ml/min)
- [ ] Enoxaparin (Lovenox) 30mg subcutaneously daily (creatinine clearance less than 30 ml/min)
- [ ] Fondaparinux (Arixtra) 2.5mg subcutaneously daily

If either Heparin or Lovenox is ordered above:

- [ ] Allergies: ___________________________  Height ________  Weight ________
- [ ] Order CBC every 3 days
- [ ] Place VTE Prophylaxis notification sticker in progress notes (unit secretary)

**Mechanical Device**

- [ ] Apply pneumatic compression hose
  - Place VTE Prophylaxis notification sticker in progress notes (unit secretary)
- [ ] Physician does not wish to order VTE Prophylaxis at this time
  Reason for not ordering: ________________________________________________________________________________________________

Physician Signature: ___________________________  Date: ________  Time: ________

NOTE: The VTE Prophylaxis Order Set is not appropriate for every patient and does not imply that every patient requires VTE Prophylaxis. A physician may choose to order VTE Prophylaxis despite the presence of a “Yes” answer above. Other prophylaxis measures may be appropriate but must be prescribed by a physician.
VTE Prophylaxis for the Hospitalized Patient

Michael J. Cox, MD, FACP, FCCP
Faculty Physician - Critical Care Medicine Training Program
St. John’s Mercy Medical Center
Assistant Clinical Professor
Saint Louis University School of Medicine
St. Louis, Missouri

Disclosure!

Speaker’s Bureau: Sanofi-Aventis (Enoxaparin)
GlaxoSmithKline (Fondaparinux)

Research Activity: Enoxaparin (Discharge Alert Study)
Dalteparin (PROTECT Trial)
Rivaroxaban (MAGELLAN Trial)
Annual Fatality Rates in US

- Pulmonary Embolism
- Highway Fatalities
- Breast Cancer
- AIDS

![Bar chart showing the annual fatality rates in US with Pulmonary Embolism having the highest rate.](image)
Table 4: Absolute Risk of DVT in Hospitalized Patients*

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>DVT Prevalence, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical patients</td>
<td>10-20</td>
</tr>
<tr>
<td>General surgery</td>
<td>15-40</td>
</tr>
<tr>
<td>Major gynecologic surgery</td>
<td>15-40</td>
</tr>
<tr>
<td>Major urologic surgery</td>
<td>15-40</td>
</tr>
<tr>
<td>Neuromuscular</td>
<td>15-40</td>
</tr>
<tr>
<td>Stroke</td>
<td>20-50</td>
</tr>
<tr>
<td>Hip or knee arthroplasty, hip fracture surgery</td>
<td>40-60</td>
</tr>
<tr>
<td>Major trauma</td>
<td>40-80</td>
</tr>
<tr>
<td>Spinal cord injury</td>
<td>60-80</td>
</tr>
<tr>
<td>Critical care patients</td>
<td>10-80</td>
</tr>
</tbody>
</table>

*Rates based on objective diagnostic testing for DVT in patients not receiving thromboprophylaxis.

The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy
Chest 2004; 126:338S-400S

AHRQ Top 10 Safety Practices

According to Strength of Evidence
- Appropriate VTE prophylaxis in patients at risk
- Perioperative β-blockade
- Maximum sterile barriers for CVC insertion
- Perioperative antibiotics to reduce postsurgical infections
- Patients relaying/recalling what they have been told when giving informed consent
- CASS to prevent ventilator-associated pneumonia
- Pressure-relieving bedding to prevent pressure ulcers
- Real-time ultrasonography to guide insertion of CVCs
- Self-management of warfarin
- Nutritional support postoperatively and in critically ill patients

CASS, continuous aspiration of subcutaneous, CVC, central venous catheter.
Rear Admiral Steven K. Galson, M.D., M.P.H., Acting U.S. Surgeon General, issued a Call to Action to drive awareness to reduce the number of cases of DVT and PE in the United States.

- Emphasizes need for increased awareness and evidence-based practices for DVT and PE
- Urges a coordinated, multifaceted plan to reduce the number of cases of DVT and PE nationwide
- Calls for more research on the causes, prevention, and treatment of DVT

The Coalition to Prevent Deep-Vein Thrombosis

### Prevention of VTE

- **Mechanical Devices**
  - Intermittent Pneumatic Compression Hose
  - Venous Foot Pump
  - Graduated Compression Stockings

- **Medications**
  - Heparin (UFH)
  - Low-Molecular Weight Heparin (LMWH)
  - Fondaparinux
  - Warfarin
Pneumatic Compression Hose

“Ideal Use” vs. Real Life!

The Eighth ACCP Conference on Antithrombotic and Thrombolytic Therapy
Chest 2008; 133:381S-453S

Table 6—Advantages and Limitations of Mechanical Thromboprophylaxis Modalities (Section 1.A.3)

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not increase the risk of bleeding Can be used in patients at high bleeding risk</td>
<td>Not as rigorously studied as pharmacologic thromboprophylaxis (fewer studies and smaller)</td>
</tr>
<tr>
<td>Efficacy has been demonstrated in a number of patient groups</td>
<td>Efficacy has been demonstrated in a number of patient groups</td>
</tr>
<tr>
<td>May enhance the effectiveness of anticoagulant thromboprophylaxis</td>
<td>May reduce leg swelling</td>
</tr>
<tr>
<td>May reduce leg swelling</td>
<td>No established standards for size, pressure, or physiologic features</td>
</tr>
<tr>
<td>Many specific mechanical devices have never been assessed in any clinical trial</td>
<td>Almost all mechanical thromboprophylaxis trials were unblinded and therefore have a potential for bias</td>
</tr>
<tr>
<td>All high-risk groups are less effective than anticoagulant thromboprophylaxis</td>
<td>In high-risk groups are less effective than anticoagulant thromboprophylaxis</td>
</tr>
<tr>
<td>Greater effect in reducing calf DVT than proximal DVT</td>
<td>Greater effect in reducing calf DVT than proximal DVT</td>
</tr>
<tr>
<td>Effect on PE and death unknown</td>
<td>Effect on PE and death unknown</td>
</tr>
<tr>
<td>May reduce or delay the use of more effective anticoagulant thromboprophylaxis</td>
<td>May reduce or delay the use of more effective anticoagulant thromboprophylaxis</td>
</tr>
<tr>
<td>Compliance by patients and staff often poor</td>
<td>Compliance by patients and staff often poor</td>
</tr>
<tr>
<td>Trials may underestimate the protection compared with routine use</td>
<td>Trials may underestimate the protection compared with routine use</td>
</tr>
<tr>
<td>Cost: associated with purchase, storage, dispensing, and cleaning of the devices, as well as ensuring optimal compliance</td>
<td>Cost: associated with purchase, storage, dispensing, and cleaning of the devices, as well as ensuring optimal compliance</td>
</tr>
</tbody>
</table>
### General Surgery

**ACCP Guidelines on Antithrombotic and Thrombolytic Therapy Guidelines**

<table>
<thead>
<tr>
<th>2004 Guidelines</th>
<th>2008 Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.1.5.</strong> In general surgery patients with a high risk of bleeding, we recommend the use of mechanical prophylaxis with properly fitted GCS or IPC, at least initially until the bleeding risk decreases (Grade 1A).</td>
<td><strong>2.1.5.</strong> For general surgery patients with a high risk of bleeding, we recommend the optimal use of mechanical thromboprophylaxis with properly fitted GCS or IPC (Grade 1A). When the high bleeding risk decreases, we recommend that pharmacologic thromboprophylaxis be substituted for or added to the mechanical thromboprophylaxis (Grade 1C).</td>
</tr>
</tbody>
</table>

---

### UFH vs. LMWH and Fondaparinux

<table>
<thead>
<tr>
<th></th>
<th>UFH</th>
<th>LMWH</th>
<th>Fonda</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dosing frequency</strong></td>
<td>2-3X/day</td>
<td>1X/day</td>
<td>1X/day</td>
</tr>
<tr>
<td><strong>Monitoring (treat)</strong></td>
<td>required</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td><strong>Self administration (treat)</strong></td>
<td>no</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td><strong>Predictable response</strong></td>
<td>less</td>
<td>more</td>
<td>more</td>
</tr>
<tr>
<td><strong>HIT frequency</strong></td>
<td>low</td>
<td>very low</td>
<td>“zero”</td>
</tr>
<tr>
<td><strong>Efficacy</strong></td>
<td>good</td>
<td>better</td>
<td>better</td>
</tr>
<tr>
<td><strong>Bleeding Risk</strong></td>
<td>low</td>
<td>lower</td>
<td>lower</td>
</tr>
<tr>
<td><strong>Cost</strong></td>
<td>low</td>
<td>higher</td>
<td>higher</td>
</tr>
<tr>
<td><strong>Renal dosing</strong></td>
<td>no</td>
<td>yes</td>
<td>contraindicated</td>
</tr>
<tr>
<td><strong>Epidural concerns</strong></td>
<td>less</td>
<td>black box</td>
<td>contraindicated</td>
</tr>
<tr>
<td><strong>Low weight (&lt; 50 kg)</strong></td>
<td>less</td>
<td>less</td>
<td>contraindicated</td>
</tr>
<tr>
<td><strong>Reversibility</strong></td>
<td>yes</td>
<td>yes</td>
<td>no</td>
</tr>
</tbody>
</table>
VTE Prophylaxis – ACCP (2008)

- General Surgery
- Vascular Surgery
- Gynecologic Surgery
- Urologic Surgery
- Laparoscopic Surgery
- Bariatric Surgery
- Thoracic Surgery
- Coronary Artery Bypass Surgery
- Orthopedic Surgery
- Neurosurgery
- Trauma
- Spinal Cord Injury
- Burns
- Medical Conditions
- Cancer Patients
- Critical Care
- Long Distance Travel

UFH/LMWH/Fondaparinux vs. Placebo?
<table>
<thead>
<tr>
<th>Study/Year</th>
<th>Patients (Mean Age, yr)</th>
<th>Method of DVT Screening</th>
<th>Intervention</th>
<th>DVT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Control</td>
<td>Experimental</td>
</tr>
<tr>
<td>Galis et al.1997</td>
<td>CHF (N=114)</td>
<td>PUT x 11 d</td>
<td>No thromboprophylaxis</td>
<td>LDUH 86</td>
</tr>
<tr>
<td>Fiedler et al.1999</td>
<td>CROS (N=111)</td>
<td>PUT x 14 d</td>
<td>No thromboprophylaxis</td>
<td>LDUH 86</td>
</tr>
<tr>
<td>Catkini et al.1998</td>
<td>Medical patients plus second risk factor (N=111)</td>
<td>PUT x 11 d</td>
<td>Placebo</td>
<td>LDUH 86</td>
</tr>
<tr>
<td>Dukhan et al.1999</td>
<td>Age &gt; 65 yr (N=114)</td>
<td>PUT x 10 d</td>
<td>Placebo</td>
<td>Enoxaparin, 60 mg/d</td>
</tr>
<tr>
<td>Sakuwa et al.1999</td>
<td>Age &gt; 40 yr plus second risk factor (N=114)</td>
<td>Venography or DUS day 6-14</td>
<td>Placebo</td>
<td>Enoxaparin, 50 mg</td>
</tr>
<tr>
<td>Leizorovicz et al.2001</td>
<td>Age &gt; 40 yr plus acutely ill medical patients (N=111)</td>
<td>DUS day 1</td>
<td>Placebo</td>
<td>Dalteparin, 5,000 USP</td>
</tr>
<tr>
<td>Goloubev et al.2006</td>
<td>Acutely ill medical patients plus age &gt; 60 yr (N=111)</td>
<td>Venography day 6-15</td>
<td>Placebo</td>
<td>Fondaparinux, 5 mg</td>
</tr>
</tbody>
</table>

*Includes randomized clinical trials in which routine screening with an objective diagnostic test for DVT was used. CHF = congestive heart failure; see Table 11 for expansion of abbreviations.
[1] Clinically important VTE (recurrent of objectively verified symptomatic DVT or PE, sudden death, and symptomatic proximal DVT).
UFH BID vs. TID?

Table 3  Primary Outcome Events

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cade et al.16</td>
<td>BID</td>
<td>140</td>
<td>Fibrinogen once daily</td>
<td>14</td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td>Celerio et al.23</td>
<td>BID</td>
<td>877</td>
<td>Antegrade</td>
<td>82</td>
<td>42</td>
<td>124</td>
</tr>
<tr>
<td>Zavalka et al.40</td>
<td>BID</td>
<td>50</td>
<td>Fibrinogen once daily</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Borrgo and Nordman13</td>
<td>BID</td>
<td>223</td>
<td>Fibrinogen once daily</td>
<td>10</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Cade et al.16</td>
<td>TID</td>
<td>425</td>
<td>Fibrinogen once daily</td>
<td>9</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>Lottl et al.20</td>
<td>TID</td>
<td>482</td>
<td>Ultrasonoc on days 1, 7, 8-11, or when clinically unexpected</td>
<td>44</td>
<td>4</td>
<td>48</td>
</tr>
<tr>
<td>Frey et al.44</td>
<td>TID</td>
<td>74</td>
<td>Fibrinogen once daily</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Heenberq et al.40</td>
<td>TID</td>
<td>726</td>
<td>Ultrasonoc on days 1, 7, 8-11, or when clinically unexpected</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Bolin et al.28</td>
<td>TID</td>
<td>56</td>
<td>Fibrinogen once every other day</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Holm et al.29</td>
<td>TID</td>
<td>549</td>
<td>Ultrasonoc on days 9, 11, and at study end and venography</td>
<td>99</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Heenberq et al.40</td>
<td>TID</td>
<td>62</td>
<td>Ultrasonoc, impedance plethysmography on days 1, 3. LV1 confirmed by venography</td>
<td>4</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Cade et al.16</td>
<td>LID</td>
<td>35</td>
<td>Fibrinogen once daily</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>634</td>
<td></td>
<td>144</td>
<td>42</td>
<td>144</td>
</tr>
</tbody>
</table>

Table 3—Summary of Outcome Event Rates

<table>
<thead>
<tr>
<th>Outcome</th>
<th>UFH Group</th>
<th>THD Group</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VTE events</td>
<td>0.49 (0.45 - 0.53)</td>
<td>0.51 (0.49 - 0.53)</td>
<td>0.42</td>
</tr>
<tr>
<td>PE</td>
<td>1.20 (1.00 - 1.44)</td>
<td>0.73 (0.61 - 0.88)</td>
<td>0.001</td>
</tr>
<tr>
<td>Combined</td>
<td>5.41 (2.47 - 8.39)</td>
<td>5.40 (2.45 - 8.40)</td>
<td>0.95</td>
</tr>
<tr>
<td>Venous plus PE</td>
<td>2.31 (1.34 - 3.80)</td>
<td>0.80 (0.30 - 1.42)</td>
<td>0.085</td>
</tr>
<tr>
<td>Bleeding events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major</td>
<td>0.13 (0.06 - 0.25)</td>
<td>0.14 (0.06 - 0.25)</td>
<td>0.52</td>
</tr>
<tr>
<td>Major death</td>
<td>0.56 (0.38 - 0.86)</td>
<td>0.56 (0.38 - 0.86)</td>
<td>0.90</td>
</tr>
</tbody>
</table>

*Data are presented as rate per 1,000 patient days (95% CI).

UFH vs. LMWH vs. fondaparinux?
The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy
Chest 2004; 126:338S-400S

Table 13—Thromboplastin Trials of LDH vs LMWH in General Medical Patients

<table>
<thead>
<tr>
<th>Study/Year</th>
<th>Patients (mean age/yr cancer rate)</th>
<th>Method of DVT Screening</th>
<th>Enoxaparin, mg daily</th>
<th>LMWH, mg daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bergmann and Neukart (1996)</td>
<td>Bedridden, age 85 yr (83.7%)</td>
<td>PUT x 10 d</td>
<td>5,000 U bid</td>
<td>Enoxaparin, 20 mg daily</td>
</tr>
<tr>
<td>Hansen et al. (1996)</td>
<td>Bedridden, age 90 yr + 2nd risk factor (26.8%)</td>
<td>Proximal DUS day 8-11</td>
<td>5,000 U tid</td>
<td>Unfractionated heparin, 5,000 U daily</td>
</tr>
<tr>
<td>Lofkin et al. (1996)</td>
<td>Bedridden, age 87 yr + 2nd risk factor (74.14%)</td>
<td>DUS day 7</td>
<td>5,000 U tid</td>
<td>Enoxaparin, 40 mg daily</td>
</tr>
<tr>
<td>Marenghi et al. (1999)</td>
<td>Severe respiratory disease, CIHF, or stroke (NR, NR)</td>
<td>Venography</td>
<td>5,000 U bid</td>
<td>Enoxaparin, 40 mg daily</td>
</tr>
<tr>
<td>Klapper et al. (2003)</td>
<td>Severe respiratory disease or CIHF (70.6%)</td>
<td>Venography or D-dimer or fibrin monomer positive days 9-14</td>
<td>5,000 U bid</td>
<td>Enoxaparin, 40 mg daily</td>
</tr>
</tbody>
</table>

*Includes randomized clinical trials in which LDH and LMWH were compared and enoxaparin with an objective diagnostic test for DVT was used. CIHF = anti-factor Xa CIHF = congestive heart failure. NR = not reported.

Values given as No. of patients with DVT/Total No. of patients (%).


Data are mean values. *Values in parentheses indicate that the difference was not statistically significant. **Values in parentheses indicate that the difference was statistically significant.

Total No. of patients: 108 (53% enoxaparin, 55% unfractionated heparin; 52% LMWH, 48% unfractionated heparin). Patients also received aspirin and/or DVT prophylaxis. Data excludes 1 patient who did not receive LMWH or unfractionated heparin.

Table 2: Incidence of venous thromboembolic events up to day 14 in the efficacy group
Medical Conditions – ACCP (2008)

- For acutely ill medical patients admitted to hospital with CHF or severe respiratory disease, or who are confined to bed and have one or more additional risk factors, including active cancer, previous VTE, sepsis, acute neurologic disease, or inflammatory bowel disease, we recommend thromboprophylaxis with LMWH (Grade 1A), LDUH (Grade 1A), or fondaparinux (Grade 1A).

- For medical patients with risk factors for VTE, and for whom there is a contraindication for anticoagulant thromboprophylaxis, we recommend the optimal use of mechanical thromboprophylaxis with GCS or IPC (Grade 1A).

(No RCT data exists using mechanical devices in any medical group)
Duration of prophylaxis?

Inpatient vs. Outpatient VTE

- New VTE: 74% outpatient and 26% inpatient
- Outpatient VTE: 23% were post-op and 37% were hospitalized in last 90 days
- Outpatient VTE with recent medical encounter: 67% developed VTE within 30 days of surgery/hospitalization (see Figure)
- Outpatient VTE with recent hospitalization: < 50% received anticoagulant prophylaxis

Hospital Stays Are Often Shorter Than Recommended Prophylaxis Duration

Average Hospital LOS vs Recommended Duration of Prophylaxis

<table>
<thead>
<tr>
<th>Thrombosis prophylaxis indications</th>
<th>Average hospital length of stay (LOS)</th>
<th>Approved length of DVT prophylaxis with enoxaparin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical illness (acute)</td>
<td>5-6 days(^{12})</td>
<td>6-11 days</td>
</tr>
<tr>
<td>Abdominal surgery</td>
<td>4-12 days(^{13})</td>
<td>7-10 days</td>
</tr>
<tr>
<td>Total hip replacement surgery</td>
<td>6-7 days(^{2})</td>
<td>7-10 days or 3 weeks (extended therapy)</td>
</tr>
<tr>
<td>Total knee replacement surgery</td>
<td>6-7 days(^{2})</td>
<td>7-10 days</td>
</tr>
</tbody>
</table>

\(^{1}\) for chronic obstructive lung disease or congestive heart failure, estimated from >200 New York State hospitals during 1999-2001.
\(^{2}\) for colonic resection.
\(^{3}\) for major joint procedures, including hip and knee replacement, estimated from >200 New York State hospitals during 1999-2001.

2. de Jong JD et al. Health Serv Res. 2006;41:374-394.

Extended Prophylaxis

- **Surgical**
  - Cancer
  - Hip arthroplasty
  - Knee arthroplasty
  - Hip fracture repair
- **Trauma**
  - Impaired mobility
- **Spinal cord injury**
- **Medical**
Study Design

Treatment period
- Enoxaparin 40 mg SC daily
- Placebo SC daily

Follow-up
- Enoxaparin 40 mg SC daily
- Follow-up up to day 180±10

-2 days Screening
10±4 days Initial open-label treatment
28±4 days Double-blind treatment
Day 0 Enrollment
Day 10 ± 4 Randomization
Day 38 ± 4 End Treatment


Results: Primary Efficacy Endpoint

VTE Rate at the End of the Double-Blind Treatment Period

RRR 44%
P = 0.0011

Placebo (n=1681)
Enoxaparin (n=1666)

Extended DVT/PE Prophylaxis

EXCLAIM: Safety Endpoints @ End of Double Blind Treatment Period

![Bar chart showing incidence of total bleeding, major bleeding, and minor bleeding for placebo and enoxaparin groups.]


How to improve compliance?
Reporting Hospitals (Voluntary)  
Surgical Care Improvement Project

- Proposed IPPS rule suggested that hospitals needed to start reporting SIP measures in January to avoid losing 2% of their Medicare annual payment update. Final rule did not require reporting until July 2006.

Changes in National Performance  
Baseline to Q1, 2008

Recommended VTE prophylaxis  
VTE prophylaxis received

CMS Proposes to Expand Quality Program for Hospital Inpatient Services in FY 2009

- CMS is proposing to expand the list of conditions that need to be reported if present when a patient is first admitted
  - Deep vein thrombosis/Pulmonary Embolism (formation/movement of a blood clot)
- The second initiative CMS is proposing is the expansion of the hospital quality measure reporting program, which reduces the amount a hospital is paid (by 2%) if it does not participate in the voluntary reporting of standardized quality measures.
  - Surgical Care Improvement Project (SCIP) – 1 new measure
  - Venous thromboembolism measures (VTEs) - 6
  - Stroke measures (STK) - 5

### NQF-endorsed VTE Measures

<table>
<thead>
<tr>
<th>VTE-1</th>
<th>Proportion of patients who received VTE prophylaxis or have documentation why no prophylaxis was given within the first twenty-four hours of hospitalization hospital days (Med/Surg patients--who have a 48h stay)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VTE-2</td>
<td>Proportion of patients who received VTE prophylaxis or have documentation why no prophylaxis was given within the first two hospital days (ICU patients)</td>
</tr>
<tr>
<td>VTE-3</td>
<td>Patients treated with parenteral anticoagulant and warfarin who have at least 5 days of overlap therapy with an INR &gt; 2.0 prior to discontinuation of parenteral treatment (or who are discharged before 5 days on overlap therapy)</td>
</tr>
</tbody>
</table>

### NQF-endorsed VTE Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>VTE-4</td>
<td>Proportion of patients treated with UFH who have dose managed by nomogram/protocol that includes explicit platelet count monitoring protocols (baseline, day after initiation, and at least three times per week for up to 14 days)</td>
</tr>
<tr>
<td>VTE-5</td>
<td>Proportion of patients discharged from the hospital on warfarin with documentation of discharge instructions addressing compliance, dietary restrictions, follow-up monitoring, and adverse drug reactions/interactions</td>
</tr>
<tr>
<td>VTE-6</td>
<td>Proportion of patients with hospital-acquired VTE who received no prophylaxis prior to the event</td>
</tr>
</tbody>
</table>

2. JCAHO. Available at: [http://www.jointcommission.org/PerformanceMeasure/PerformanceMeasurement/NationalConsensusStandards/13919/PreventionofVenousThrombembolism/](http://www.jointcommission.org/PerformanceMeasure/PerformanceMeasurement/NationalConsensusStandards/13919/PreventionofVenousThrombembolism/).

### 2008 – General Recommendations

**Hospital Thromboprophylaxis Policy**

- “For every general hospital, we recommend that a formal, active strategy that addresses the prevention of VTE be developed.” (Grade 1A)
- “…in the form of a written, institution-wide thromboprophylaxis policy (Grade 1C)
- “…using strategies known to increase thromboprophylaxis, adherence, including
  - Computer decision support systems (1A)
  - Preprinted orders (1B)
  - Periodic audit and feedback (1C)


Table 1: Thromboprophylaxis and venous thromboembolic outcomes

<table>
<thead>
<tr>
<th></th>
<th>Phase 1 (85 Patients, 467 Days)</th>
<th>Phase 2 (252 Patients, 2819 Days)</th>
<th>Phase 3 (85 Patients, 1125 Days)</th>
<th>p  Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recipient prophylaxis (primary outcome)</td>
<td>66 (8, 369)</td>
<td>90 (50, 369)</td>
<td>100 (43, 100)</td>
<td>.01</td>
</tr>
<tr>
<td>Prophylactic or therapeutic anticoagulation, median (IQR)</td>
<td>66.4 (45.7, 100)</td>
<td>93.9 (87.2, 100)</td>
<td>100 (98.1, 100)</td>
<td>.001</td>
</tr>
<tr>
<td>Mechanical prophylaxis, median (IQR)</td>
<td>0 (0, 25.0)</td>
<td>0 (0, 85.5)</td>
<td>0 (0, 0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Any anticoagulant or mechanical prophylaxis, median (IQR)</td>
<td>73.8 (0, 100)</td>
<td>100 (93.3, 100)</td>
<td>100 (76.5, 100)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Any anticoagulant or mechanical prophylaxis in the absence of contraindication to heparin*</td>
<td>88.0 (0, 100)</td>
<td>100 (93.3, 100)</td>
<td>100 (100, 100)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Error of omission, no heparin prophylaxis secondary outcome YTE before ICU admission</td>
<td>29 (0, 53.8)</td>
<td>0 (0, 63.3)</td>
<td>0 (0, 0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>3 DVT and 1 PE concurrent</td>
<td>0 (0, 3)</td>
<td>9 (7 DVT and 2 PE)</td>
<td>6 (4 DVT and 2 PE)</td>
<td>NS</td>
</tr>
<tr>
<td>Clinically suspected and diagnostically confirmed YTE in ICU</td>
<td>0</td>
<td>6 patients (3 DVT and 3 PE)</td>
<td>6</td>
<td>NS</td>
</tr>
<tr>
<td>IUI diagnosed or confirmed by ultrasound screening in ICU</td>
<td>NA</td>
<td>22</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

ICU, intensive care unit; IQR, interquartile range; YTE, venous thromboembolic; DVT, deep venous thrombosis; PE, pulmonary embolism; NS, not significant; NA, not applicable. We present this type of thromboprophylaxis or anticoagulation used in phases 1, 2, and 3, along with YTE outcomes. Mechanical prophylaxis refers to either antigravity maneuvers or pneumatic compression devices.

*Denominator excludes days on which patient required therapeutic anticoagulation. *Contraindication to heparin: current or potential bleeding, coagulopathy (international normalized ratio >2.0), partial thromboplastin time >40 sec, thrombocytopenia (platelets <50 x 10^9/L), known or suspected heparin-induced thrombocytopenia, disseminated intravascular coagulation.
Table 2. Prophylactic Measures against Venous Thromboembolism.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Intervention Group (N=1255)</th>
<th>Control Group (N=1251)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>no. of patients (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical</td>
<td>125 (10.0)</td>
<td>19 (1.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Compression stockings</td>
<td>52 (4.1)</td>
<td>7 (0.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pneumatic boots</td>
<td>73 (5.8)</td>
<td>12 (1.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pharmacologic</td>
<td>296 (23.6)</td>
<td>163 (13.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Unfractionated heparin</td>
<td>213 (17.0)</td>
<td>81 (6.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Warfarin</td>
<td>28 (2.2)</td>
<td>41 (3.3)</td>
<td>0.11</td>
</tr>
<tr>
<td>Enoxaparin</td>
<td>55 (4.4)</td>
<td>41 (3.3)</td>
<td>0.18</td>
</tr>
</tbody>
</table>

Kucher, N et al. Electronic Alerts to Prevent Venous Thromboembolism among Hospitalized Patients.
NEJM 2005; 352:969-977

Table 3. Study End Points.

<table>
<thead>
<tr>
<th>End Point</th>
<th>Intervention Group (N=1255)</th>
<th>Control Group (N=1251)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>no. of patients (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venous Thromboembolism</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All 50 days</td>
<td>11 (0.9)</td>
<td>5 (0.4)</td>
<td>0.08</td>
</tr>
<tr>
<td>30 days</td>
<td>8 (0.7)</td>
<td>5 (0.4)</td>
<td>0.58</td>
</tr>
<tr>
<td>90 days</td>
<td>9 (0.7)</td>
<td>4 (0.3)</td>
<td>0.04</td>
</tr>
<tr>
<td>Enoxaparin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All 50 days</td>
<td>19 (1.5)</td>
<td>15 (1.2)</td>
<td>0.57</td>
</tr>
<tr>
<td>30 days</td>
<td>15 (1.2)</td>
<td>12 (1.0)</td>
<td>0.28</td>
</tr>
<tr>
<td>90 days</td>
<td>15 (1.2)</td>
<td>11 (0.9)</td>
<td>0.65</td>
</tr>
<tr>
<td>Unfractionated heparin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All 50 days</td>
<td>19 (1.5)</td>
<td>15 (1.2)</td>
<td>0.57</td>
</tr>
<tr>
<td>30 days</td>
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</tr>
</tbody>
</table>

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Hospital VTE Prophylaxis Compliance
VTE Prophylaxis Retrospective Chart Review Comparisons

<table>
<thead>
<tr>
<th>Timeline (12 months)</th>
<th>Charts Reviewed</th>
<th>Charts Excluded</th>
<th>Patients that Developed VTE</th>
<th>Eligible Patients with VTE Prophylaxis Ordered</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 1 - December 31, 2001</td>
<td>97</td>
<td>62</td>
<td>15</td>
<td>6 (40%)</td>
<td>2 (13%)</td>
</tr>
<tr>
<td>July 1, 2003 - June 30, 2004</td>
<td>205</td>
<td>155</td>
<td>49</td>
<td>34 (76%)</td>
<td>4 (8%)</td>
</tr>
</tbody>
</table>

Note: 14 of the 49 patients that developed VTE were orthopedic patients (29%)

Questions?

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