

PARTNERSHIP FOR PATIENT CARE

Proactive Risk Assessment

Research Summary

VENOUS THROMBOEMBOLISM PROPHYLAXIS



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Risk Data

The number of deaths from pulmonary emboli and deep vein thrombosis (DVT) that are preventable by appropriate prophylaxis has been estimated by several prominent organizations. The common approach is as follows:

- To stratify patients by level of risk
- To identify the appropriate methods of pharmacologic and mechanical prophylaxis for each patient risk category
- To estimate the reduction in mortality if these methods are optimally used

◆National Heart, Lung, and Blood Institute (NHLBI)◆

The National Heart, Lung, and Blood Institute (NHLBI) is one of the 27 Institutes and Centers that comprise the National Institutes of Health of the U.S. Department of Health and Human Services. Among responsibilities of the NHLBI is leadership for a national program in diseases of the heart, blood vessels, lung, and blood. The NHLBI provides and supports research and education about DVT and pulmonary embolism. Below is educational information about these topics from their Web site, <http://www.nhlbi.nih.gov>:

- In most cases, pulmonary embolism is a complication of a condition called DVT. In DVT, blood clots form in the deep veins of the body most often in the legs. These clots can break free, travel to the lung, and block an artery.
- Each year, more than 600,000 people in the United States have a pulmonary embolism, and more than 60,000 of them die. Most of those who die do so within 30 to 60 minutes after symptoms start.
- Pulmonary embolism is one of the most common causes of death in hospitalized people who must remain in bed for a long time.
- The risk for pulmonary embolism doubles every 10 years after age 60.
- More than half of people with pulmonary embolism do not have symptoms.
- When present, the most common symptoms of pulmonary embolism are:
- Unexplained shortness of breath
- Chest pain that gets worse with a deep breath, coughing, or chest movement
- Coughing up blood
- Preventing pulmonary embolism begins with preventing DVT.



◆Agency for Healthcare Research and Quality (AHRQ)◆

Technology Assessment: Prevention of Venous Thromboembolism

The Agency for Healthcare Research and Quality (AHRQ) is the lead federal agency for research on healthcare quality, costs, and outcomes and patient safety. AHRQ funds research that addresses concerns of very high public priority and then supports Evidence-based Practice Centers that review and synthesize scientific evidence for conditions or technologies that are costly, common, or important to the Medicare or Medicaid programs. (ECRI is one of 13 AHRQ-designated Evidence-based Practice Centers.)

AHRQ provides technology assessments for the Centers for Medicare and Medicaid Services to use in Medicare national coverage decisions and to inform Medicare carriers about new technology. Technology assessments may be done in-house by AHRQ staff, or they may be done in collaboration with an Evidence-based Practice Center. Technology assessments include a systematic review and analysis of the literature from multiple sources and an assessment of the clinical and financial value of medical interventions.

In July 2001, AHRQ published a technology assessment of patient safety practices that was prepared by the University of California San Francisco-Stanford University Evidence-based Practice Center. Chapter 31 of the report *Making Healthcare Safer: A Critical Analysis of Patient Safety Practices* is devoted to the prevention of venous thromboembolism. The researchers note that numerous randomized control trials and high-quality meta-analyses conducted over 30 years were included in their review. The AHRQ technology assessment clarifies the following about DVT and pulmonary embolism:³

- Venous thromboembolism (VTE) refers to occlusion within the venous system. It includes deep vein thrombosis (DVT), typically of the lower extremities, and embolism to the pulmonary vasculature.
- VTE is often clinically silent. As widespread screening is not recommended in general practice, the incidence of VTE in most studies appears higher than that encountered in clinical practice. The importance of clinically undetected VTE is not fully understood.

Below is a table from the AHRQ report that estimates the risk of DVT in high-risk patients who do not receive prophylaxis. For each high risk surgery or condition, the estimated reduction in risk by using methods of prophylaxis is estimated along with by the number of research studies included in the evidence base.



Estimated Risk of DVT Risk in Untreated Patients and Effectiveness of Prevention Methods by Risk Category

Surgery/ Condition	Risk of DVT in Untreated Patients	Type of Prophylaxis	Risk Reduction with Prophylaxis	Number of Studies Reviewed
General Surgery	25%	Graduated elastic stockings (ES)	44%	3
		Low-dose unfractionated heparin (LDUH)	68%	47
		Low molecular weight heparin (LMWH)	76%	21
		Intermittent pneumatic compression (IPC)	88%	2
Total Hip Replacement (THR)	54%	LMWH	70%	30
		Warfarin	79%	13
Total Knee Replacement (TKR)	64%	LMWH	52%	13
		IPC	73%	6
Neurosurgery	28%	LMWH	38%	3
		LDUH	72%	1
Trauma	30-60%	LMWH	30%	1
Acute Spinal Cord Injury (ACI)	80%	Not established		
Ischemic Stroke	55%	LDUH	56%	5
		LMWH	58%	3
		Danaparoid	82%	4
Medical Conditions	16%	LMWH	76%	2
			39%	2
		LDUH	61%	3

Detailed descriptions of the prophylaxis measures and AHRQ recommendations are found in the Evidence-based Practices section of this report.



◆American College of Chest Physicians (ACCP)◆

Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy: Prevention of VTE

The American College of Chest Physicians (ACCP) uses an evidence-based approach to making recommendations about VTE prophylaxis. The ACCP recommendations, included in the Standards and Guidelines section of this report, have been disseminated internationally and are in widespread use. The following description about the VTE risk is summarized from the background information that prefaces the guidelines.ⁱⁱ

VTE is an important healthcare problem resulting in significant mortality, morbidity, and resource expenditure. Approximately 10% of hospital deaths are attributed to pulmonary embolism (PE) caused by DVT.

Massive PE usually occurs without warning, and there is often no potential to resuscitate patients who experience this complication. In 70% to 80% of patients who die of PE while in the hospital, this diagnosis was not even considered prior to death.

Most thrombi are confined to the calf or are clinically silent and have no adverse consequences. However, research has shown that many symptomatic VTE develop from DVT that were initially silent. The risk for VTE continues after hospital discharge; the data suggests a symptomatic VTE case-fatality rate at 1 year as high as 34%.

The risk factors for VTE are generally cumulative. For example, patients with fractures of the hip are at high risk for VTE because they are older and immobile, they undergo a surgical procedure that lasts longer than 30 minutes, and the location of their injury near the femoral vein causes thrombi to form. Despite advances in medicine, the trend is for greater VTE risk because the average inpatient is older, has a higher incidence of cancer, undergoes more extensive surgical procedures, and stays longer in the ICU.

Diagnostic testing, usually by venous diagnostic ultrasound (DUS), is required to confirm a suspected VTE; treatment requires therapeutic anticoagulation therapy, with its potential for serious bleeding complications. DVT may result in postthrombotic syndrome, a painful and disfiguring condition characterized by chronic leg swelling, dermatitis, ulceration, and an increased risk of DVT.

Routine screening of asymptomatic patients for VTE is ineffective in preventing clinically important VTE; prophylaxis remains the only effective strategy. Following is the ACCP's list of VTE risk factors:



Risk Factors for VTE

- Surgery
- Trauma (major or lower extremity)
- Immobility, paresis
- Malignancy
- Cancer therapy (hormonal, chemotherapy, or radiation)
- Previous VTE
- Increasing age
- Pregnancy and postpartum period
- Estrogen-containing oral contraception or hormone replacement therapy
- Selective estrogen receptor modulators
- Acute medical illness
- Heart or respiratory failure
- Inflammatory bowel disease
- Nephrotic syndrome
- Myeloproliferative disorders
- Paroxysmal nocturnal hemoglobinuria
- Obesity
- Smoking
- Varicose veins
- Central venous catheterization
- Inherited or acquired thrombophilia (molecular hypercoagulability)

**DVT Risk for Hospitalized Patients
Not Receiving Thromboprophylaxis**

Patient Group	DVT%
Spinal cord injury	60-80
Major trauma	40-80
Hip or knee arthroplasty or hip fracture surgery	40-60
Stroke	20-50
Critical care patients	10-80
General surgery	15-40
Major gynecologic surgery	15-40
Major urologic surgery	15-40
Neurosurgery	15-40
Medical patients	10-20



Data Trends

State and federal agencies and healthcare organizations have been collecting data related to DVT and PE admissions and mortality in healthcare facilities. The data has historically been used for research and internal hospital quality improvement. The data collection methodology that has been used is discharge data abstract data mining. This section provides an overview of published data from these organizations and provides a description of each organization's data collection and analysis efforts.

◆Agency for Healthcare Research and Quality (AHRQ) and Centers for Medicare & Medicaid Services (CMS)◆

AHRQ National Healthcare Quality Report

AHRQ, a division of the U.S. Department of Health and Human Services, is charged with supporting the improvement of quality healthcare; reducing costs; improving patient safety and decreasing medical errors; and broadening access to healthcare services.

AHRQ acknowledges in the patient safety chapter of its 2005 National Healthcare Quality Report that “much progress has been made in recent years in raising awareness, developing event reporting systems, and developing national standards for data collection.” AHRQ selects a group of measures to trend hospital adverse events and postoperative complications. Among these indicators is postoperative venous thromboembolic events, chosen because “after surgery, patients are at higher risk for developing blood clots in their legs. This risk can be reduced by getting patients to walk as soon as possible after surgery and by giving patients medications and treatments that prevent blood clots.”ⁱⁱⁱ

The 2005 National Healthcare Quality Report showed that the rate of VTE as a surgical complication did not change significantly between 2002 (0.80%) and 2003 (0.78%). The data is from the Medicare Patient Safety Monitoring System (MPSMS), a sampling of records of discharged Medicare beneficiaries (see below paragraph). Readmissions for VTE were not captured; data was limited to events that occurred during the index surgical hospitalization.

The Medicare Patient Safety Monitoring System (MPSMS)

The MPSMS collects a national random sample of medical record discharge abstracts from the Medicare Hospital Payment Monitoring Program to identify rates of adverse events in the Medicare population. Postoperative Venous Thromboembolic Events is one of 15 hospital quality measures collected about adverse events. Beginning in 2002, over 30,000 medical records have been abstracted at the Medicare Clinical Data Abstraction Center using clinical algorithms to determine if an adverse event occurred. The sponsor of this project, the Centers for Medicare and Medicaid (CMS), collaborates with AHRQ to interpret this data and to make it public. More information is available on the Web site of the project administrator Qualidigm, Connecticut's Quality Improvement Organization, <http://www.qualidigm.org>.



◆Agency for Healthcare Research and Quality (AHRQ)◆

AHRQ Patient Safety Indicators

Postoperative pulmonary embolism or DVT is among 20 hospital-level patient safety indicators (PSIs) developed by AHRQ and released in 2003. This is one of the measures that AHRQ will use to assess the level of patient safety in the United States. The PSIs screen for patient safety problems using readily available and relatively inexpensive hospital administrative data. PSIs are potentially avoidable post operative complications and adverse events experienced by inpatients. Many of these events can be prevented by changes at the healthcare system or provider level. Information about the PSIs can be found at AHRQ's website, <http://www.qualityindicators.ahrq.gov>.

The 2002 research study that was used to validate PSIs prior to submitting them for panel review showed a rate of 6.95 cases of postoperative thrombus or pulmonary embolisms per 1000 population at risk (surgeries, excluding obstetrics). Expert reviewers noted because of the difference in the underlying risk, this indicator should be adjusted or stratified according to surgical procedure types. Reporting of DVT may be variable because some hospitals do not routinely screen for DVT, and of those that do, some require ultrasound while others require clinical symptoms^{iv}

HCUP: State Inpatient Databases

AHRQ sponsors the Healthcare Cost and Utilization Project (HCUP), which is comprised of several databases, one of which is the State Inpatient Databases. In 2003, twenty-six states contributed data to these databases (excluding Pennsylvania). The HCUP all-payer database contains inpatient discharge abstracts translated into a uniform format to allow nationwide comparisons. The HCUP Nationwide Inpatient Sample, which in 2003 was 38 million hospital discharges, is used to determine the rate for each of the PCIs

For the provider-level indicators, data is analyzed by hospital. PSI 12, the postoperative rate of pulmonary embolism or DVT per 1,000 discharges, was retrospectively calculated for the available six years of data. The below information is available at AHRQ's HCUPnet website: <http://hcup.ahrq.gov>:

Postoperative PE or DVT per 1000 discharges (PSI 12)

2003	2002	2001	2000	1997	1994
9.1	8.4	7.8	7.5	6.5	5.9

The above provider-level data shows an increasing trend between 1994 and 2003. The detailed data for the above years consistently shows that rates are higher with increased age, Medicaid payment source, in teaching hospitals, and in hospitals with over 500 beds. Rates are also consistently higher in females.



The measure PSI 12 is derived by screening all surgical discharges for DVT or pulmonary embolism in any secondary diagnosis field. Surgical discharges are defined by specific DRGs (diagnosis-related groups) and an ICD-9-CM (International Classification of Diseases, Ninth Revision, Clinical Modifications) code for an operating room procedure. It is important to note that obstetric patients are excluded as well as children under the age of 18 and patients admitted for treatment of VTE. The measure does not capture readmissions for VTE, which would have a primary diagnosis DVT or PE. Rates are adjusted based upon the 2000 U.S. population distribution of age and gender to increase the validity of multiyear trends. AHRQ makes available a free PSI software module that hospitals can apply to their administrative database. The software, which can be downloaded from AHRQ's Web Site, is intended to assist hospitals in identifying potential adverse events from their own data.

◆New York SPARCS Database◆

It has been noted above that AHRQ and CMS data only report DVTs or PEs that occur during the index surgical hospitalization. A study has shown that this method underreports VTE events because they also occur after discharge.^v The researchers analyzed data from the New York SPARCS (Statewide Planning and Research Cooperative System) database, which has the capability to track patients across multiple admissions. Of the 526,187 surgical patients in the 2001 SPARCS database, 4,908 met the AHRQ definition for PSI 12, a rate of 9.3 VTEs per 1,000 surgical discharges. When the researchers added the 1,059 cases of VTE readmitted within 30 days post surgery, New York's 2001 VTE rate increased to 11.3 per 1,000 discharges.

The researchers recommend that AHRQ require that all State Inpatient Databases (SIDs) have the capability to track patients over multiple admissions, and that PSI 12 be revised to include short-term readmissions; those within 30 days. They also recommended that prophylaxis, monitoring, and patient education be required after hospital discharge to reduce VTE risk.

◆Pennsylvania Healthcare Cost Containment Council (PHC4)◆

The Pennsylvania Healthcare Cost Containment Council (PHC4) collects quarterly inpatient hospital discharge abstracts from Pennsylvania hospitals. This data includes treatment, charge, and other financial data. The state agency analyzes the information and makes reports about the cost and quality of healthcare in Pennsylvania available to the public. 2005 statewide data shows that patients with a principle diagnosis of PE have a mortality rate 5 times higher than those with DVT.^{vi}

- Blood clot in extremities as principle diagnosis
 - Mortality rate: 0.5% of 7,645 admissions
 - Total statewide deaths as principle diagnosis: 40
- Blood clot in lungs as principle diagnosis
 - Mortality rate: 2.8% of 5861 admissions
 - Total statewide deaths as principle diagnosis: 163



The state also produced a report that focused on hip and knee replacements. The report which includes one year of data, from July 1, 2001, through June 30, 2002, found that readmissions for blood clot (lung/leg) generated \$2.4 million in charges and 889 hospital days. The reported statewide complication rate for joint replacement surgeries due to a blood clot (lung/leg) was 1.3% of surgeries.^{vii}

The state also tracked readmission rates for other conditions. Below are the 2005 reported conditions with the highest readmission rates due to venous thrombosis or pulmonary embolism:^{viii}

Pennsylvania 2005 VTE/PE Readmissions for Selected Conditions

Condition	2005 Index Hospitalizations	Venous Thrombosis/PE Readmissions	Venous Thrombosis/PE Readmission Rate (% of cases)
Stroke-hemorrhagic	2,106	29	1.38
Hip fracture surgical repair	12,183	68	0.56
Surgery for infectious or parasitic disease	4,549	24	0.53
Infection after surgery or trauma	3,765	18	0.48
Respiratory failure with mechanical ventilation	3,480	16	0.46
Kidney failure	14,915	62	0.42
Diabetes with amputation	1,967	8	0.41
Infectious pneumonia	44,645	169	0.38

2005 statewide data shows that hemorrhagic stroke and hip fracture surgical repair have the highest readmission risk for venous thrombosis/PE among conditions for which data is analyzed. Infectious pneumonia had the greatest number of DVT/PE readmissions; however, the readmit rate was lower due to the high number of statewide index hospitalizations for this diagnosis. The statewide reports are available at PHC4's Web site <http://www.phc4.org>.



2007 DATA COLLECTION

Public reporting of hospital patient safety indicators related to VTE begins with 2007 discharges. The data collection methodologies that will be used are discharge data abstract mining with added quality codes and patient satisfaction surveys. This section provides an overview of the new indicators for each organization.

◆Centers for Medicare & Medicaid Services (CMS) and Agency for Healthcare Research and Quality (AHRQ)◆

HCAHPS Survey

The CMS partnered with the AHRQ to develop the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS). Both agencies are part of the U.S. Department of Health and Human Services. CMS is primarily responsible for providing healthcare services to Medicare beneficiaries, while AHRQ is responsible for the cost and quality of healthcare services.

Three broad goals have shaped development of the HCAHPS survey:

- To produce comparable data on care that allows objective and meaningful comparisons between hospitals on issues that are important to consumers;
- To create incentives for hospitals to improve their quality of care through public reporting; and
- To enhance accountability for the public investment in healthcare through public reporting of quality of care.

The National Quality Forum (NQF) endorsed HCAHPS survey is 27 questions in length and encompasses 7 key topics:

- Communication with doctors
- Communication with nurses
- Responsiveness of hospital staff
- Cleanliness and quietness of hospital environment
- Pain management
- Communication about medicines
- Discharge information

The following questions are patient-centered measures that NQF has identified as useful for monitoring VTE prophylaxis practices:



HCHPS Survey

Question Number	Question Description
15	During this hospital stay, were you given any medicine that you had not taken before?
16	Before giving you any new medicine, how often did hospital staff tell you what the medicine was for?
17	Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand?

The national implementation of HCAHPS began on October 1, 2006, with 2,800 hospital eligible to participate. Participation is voluntary; however, beginning with fiscal year 2008, hospitals that are subject to the Medicare Inpatient Prospective Payment System payment provisions must participate in HCAHPS or their Annual Payment Update (APU) will be reduced by 2%.^{ix}

The above information is available at <http://www.hcahpsonline.org>, the HCAHPS Web Site. Beginning in late 2007, HCAHPS hospital data will be publicly reported on the Hospital Compare Web Site, <http://www.hospitalcompare.hhs.gov>. At a later date, the HCAPS data may also be reported by the Joint Commission on their Quality Check Web Site, <http://www.qualitycheck.org>.

◆Centers for Medicare & Medicaid Services (CMS) and The Joint Commission◆

Surgical Care Improvement Project (SCIP)

The CMS and The Joint Commission have worked together to align their core hospital quality measures. Since July 2006, their perioperative measures have been integrated into the Surgical Care Improvement Project (SCIP). SCIP is a national quality partnership of organizations committed to improving the safety of surgical care through the reduction of postoperative complications. The goal is for all public and private purchasers, oversight and accrediting entities, payers and providers of hospital care to use these same measures in their national public reporting activities. The ultimate goal of the partnership is to save lives by reducing the incidence of surgical complications by 25% by the year 2010.

The SCIP National Quality Measures include the VTE Measure Set that was recently updated to incorporate the 2004 American College of Chest Physicians (ACCP) Guidelines (see Standards and Guidelines). The rationale for the VTE measures includes the following: “Despite the evidence that VTE is one of the most common postoperative complications and prophylaxis is the most effective strategy to reduce morbidity and mortality, it is often underused.”^x Timing of prophylaxis is based on the type of procedure, prophylaxis selection, and clinical judgment regarding the impact of patient risk factors. The optimal start of pharmacologic prophylaxis in surgical patients varies; the efficacy must be balanced with the



bleeding potential. The SCIP Technical Expert Panel recommended a medication administration timeframe that would encompass most procedures.

The SCIP VTE measures are NQF-endorsed national consensus standards for hospital care. For this process measure set, an improvement in the rate of VTE ordering or VTE provision is evidence of increased quality. In analyzing their data, hospitals should drill down by types of surgery to identify patients who did not have the recommended prophylaxis. The SCIP VTE measures are scheduled to begin with January 1, 2007 discharges. For The Joint Commission, collection of the following two measures satisfies one of the three core measures generally required to be reported by accredited hospitals:

SCIP-VTE-1: Surgery patients with recommended venous thromboembolism prophylaxis ordered

SCIP-VTE-2: Surgery patients who received appropriate venous thromboembolism prophylaxis within 24 hours prior to surgery to 24 hours after surgery

All surgery discharges are included in the above measures except the following

- Patients under age 18
- Laparoscopic procedures
- Surgery time of ≤ 30 minutes
- Postoperative length of stay ≤ 24 hours
- Burn patients
- Patients on warfarin
- Patients with contraindications to all recommended VTE prophylaxis



SCIP VTE Measures: Surgical Prophylaxis Selection

Surgery Type	Recommended Prophylaxis Any of the Following ¹ :
Intracranial neurosurgery	IPC with or without GCS LDUH LMWH (Recommended postoperative) LDUH or LMWH combined with IPC or GCS
Elective spinal surgery	LDUH LMWH IPC GCS IPC combined with GCS LDUH or LMWH combined with IPC or GCS
General surgery	LDUH LMWH LDUH or LMWH combined with IPC or GCS
General surgery with high risk for bleeding	GCS IPC
Gynecologic surgery	LDUH LMWH IPC LDUH or LMWH combined with IPC or GCS
Urologic surgery	LDUH LMWH IPC GCS LDUH or LMWH combined with IPC or GCS
Elective total hip replacement (THR)	Any of the following started within 24 hours of surgery: <ul style="list-style-type: none"> • LMWH • Factor Xa inhibitor • Warfarin

Beginning with fiscal year 2008, hospitals that are subject to the Medicare Inpatient Prospective Payment System payment provisions must submit data for the SCIP VTE Measure Set or their APU will be reduced by 2%.^{xi}

◆Centers for Medicare and Medicaid Services (CMS)◆

Physician Quality Reporting Initiative (PQRI)

The enabling legislation for the Physician Quality Reporting Initiative (PQRI) is the Tax Relief and Health Care Act of 2006. The PQRI establishes a financial incentive for physicians and other specified practitioners to submit quality measures to CMS. Reporting begins for dates of services on or after July 1, 2007. The 1.5% bonus, which applies to all fee-for-service claims submitted under a single taxpayer identification number, is payable if

¹ IPC=Intermittent pneumatic compression; LDUH= Low-dose unfractionated heparin; LMWH= Low-molecular-weight heparin; GCS=graduated compression stockings



at least three PQRI quality measures are reported for at least 80% of applicable cases. The PQRI program adopted measures developed for the Physician Voluntary Reporting Program (PVRP), which it replaces. For PQRI program updates refer to the CMS Web site: <http://www.cms.hhs.gov/PQRI>. The PQRI measures are described as follows:

Perioperative Care: VTE Prophylaxis (when indicated in all patients)

Percentage of patient age 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order one of the following methods of VTE prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time:

- Low Molecular Weight Heparin (LMWH)
- Low-dose unfractionated heparin (LDUH)
- Adjusted-dose warfarin
- Fondaparinux
- Mechanical prophylaxis

This is a surgical procedure specific measure. Included are the following procedures:

- Major, open urologic procedures
- Elective hip and knee arthroplasty
- Hip fracture surgery
- Major neurosurgery
- Major gynecologic surgery
- General surgery (certain procedures)

This measure has been approved by the American College of Surgeons and endorsed by the National Quality Forum.

Stroke and Stroke Rehabilitation Measure: DVT prophylaxis for ischemic stroke or intracranial hemorrhage

Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage who received DVT prophylaxis by end of hospital day two. The rationale for this measure is that patients on bed rest are at high risk for DVT; these patients have decreased mobility. This is a visit-specific measure that includes patients who are nonambulatory by the end of the second day. VTE prophylaxis may include any of the following:

- LMWH
- LDUH
- Intravenous heparin
- Low-dose subcutaneous heparin (may be initiated on the second day after the onset of the intracranial hemorrhage)
- Intermittent pneumatic compression devices (initially, for patients with intracranial hemorrhage)

The stroke and stroke rehabilitation measures have been approved by the American College of Neurology and endorsed by the National Quality Forum (NQF).



Evidence-based Practices

◆Agency for Healthcare Research and Quality (AHRQ)◆

Technology Assessment: Prevention of Venous Thromboembolism

The 2001 AHRQ report Making Healthcare Safer: A Critical Analysis of Patient Safety Practices systematically compared all of the patient safety interventions reviewed, ranking them in priority for widespread implementation. AHRQ ranked VTE prophylaxis as its highest priority among the 79 patient safety interventions it had assessed. This recommendation was based on evidence that thromboprophylaxis is effective in preventing adverse patient outcomes while decreasing overall costs, and is underused. The AHRQ report concluded that PE is the most common preventable cause of hospital death, and that appropriate use of thromboprophylaxis is the number one strategy to improve patient safety in hospitals. In the chapter about the prevention of venous thromboembolism, AHRQ described the below VTE prophylaxis measures currently in use and then specified recommended practices:^{xiii}

VTE Prophylaxis Measures (2001)

VTE Prophylaxis Practice	Type	Description	Comment
Graduated elastic stockings (ES)	Mechanical	Fitted hose that extend above the knee	Fitted hose are more efficacious than non-fitted
Intermittent pneumatic compression (IPC)	Mechanical	Devices fitted over lower extremities that sequentially inflate and deflate	
Aspirin	Pharmacologic	Usually 325 mg/d	
Warfarin	Pharmacologic	5-10 mg started the day of or after surgery; adjust to achieve an INR (international normalized ratio) of 2-3	Monitoring of INR needed
Low-dose unfractionated heparin (LDUH)	Pharmacologic	Generally 5000 units subcutaneous 2-3 times per day, though some studies have adjusted dose to maintain PTT (partial thromboplastin time) at high end of normal	Contraindicated if active bleeding or history of thrombocytopenia; no need to follow coagulation studies (unless adjusted dose is used)
Low Molecular Weight Heparin (LMWH)	Pharmacologic	Dose depends on type of surgery and VTE risk	No need to monitor coagulation studies



AHRQ Recommended VTE Prophylaxis (2001)

Surgery/Condition	Recommended Prophylaxis	Comments
General Surgery—low-risk: minor procedures, <40 years old, no additional risks	None	Early ambulation
General Surgery—moderate risk: minor procedure but with risk factor, nonmajor surgery age 40-60 with no risks, or major surgery <40 years with no risks	LDUH, LMWH, ES, or IPC	
General Surgery—high risk: nonmajor surgery over age 60 or over age 40 with risks.	LDUH, LMWH	
General Surgery—very high risk: major surgery over age 40 plus prior VTE, cancer or hypercoagulable state	LDUH or LMWH combined with ES or IPC	May consider postdischarge LMWH or perioperative warfarin
Elective Hip Replacement	LMWH or warfarin	May combine with ES or IPC; start LMWH 12 hours before surgery, 12-24 hours after surgery, or 4-6 hours after surgery at half the dose for initial dose. Start warfarin preoperatively or immediately after surgery, target INR 2-3.
Elective Knee Replacement	LMWH or warfarin	
Hip Fracture Surgery	LMWH or warfarin	
Neurosurgery	IPC, LDUH or LMWH	Start LMWH postsurgery
Trauma	LMWH with ES or IPC	If high risk of bleeding, may use ES and/or IPC alone.
Acute Spinal Cord Injury	LMWH	Continue LMWH during rehabilitation or convert to warfarin (target INR 2.5)
Ischemic Stroke	LDUH, LMWH	If contraindication to anticoagulant, use ES or IPC.
Medical Conditions	LDUH or LWMH	

The AHRQ practice recommendations incorporate 2001 American College of Chest Physicians (ACCP) guidelines from the Sixth Conference on Antithrombotic and Thrombolytic Therapy; since they were updated in 2004, some of the above recommendations may be superseded (refer to Standards and Guidelines).



Case Studies

The recently published case studies include comparison of FDA-approved anticoagulant medications, a long term multicenter study of VTE prophylaxis, and VTE performance improvement initiatives.

◆ South Texas Veterans Healthcare System◆

Economic Comparison of two VTE Prophylaxis Medications

The purpose of this analysis, conducted by South Texas Veterans Healthcare System and sponsored by the Department of Veterans' Affairs, was to independently determine which medication, enoxaparin (a LMWH) or unfractionated heparin (UFH), is more cost-effective for VTE prophylaxis in a medicine inpatient population.^{xiii} The analysis considered the following factors in constructing their economic model:

- Cost to the hospital for each medication
 - Acquisition costs
 - Other direct hospital costs (e.g., laboratory, nursing)
- Medicare reimbursement (payment by diagnosis-related group)
- Complication rates for each medication and their impact
 - Additional Medicare reimbursement for complications
 - Opportunity cost for a filled bed (additional length of stay of complications)
 - Reduction in patient quality of life
 - Possible litigation for substandard treatment

After reviewing the literature and performing the analysis, the researchers recommended use of LMWH as the preferred drug for VTE prophylaxis, primarily because of the costs associated with the major complication of UFH. This complication-heparin-induced thrombocytopenia with or without thrombosis (HITT/HIT)-increases the patient's length of stay and reduces their quality of life.

The cost to the payer, Medicare, is always less with LMWH because additional hospital reimbursement for complications is reduced. The direct cost to the hospital is higher with LMWH due to its higher acquisition cost; the decision to use this drug can be made more attractive with competitive pricing agreements. However, the increased drug cost of LMWH is offset by the opportunity to fill the bed with a new admission and risk reduction by using a treatment with a lower rate of serious side effects, which can cause economic as well as reputation loss.



◆University of Maryland School, University of Rochester, and Pennsylvania State University Schools of Medicine◆

Prevention of Readmission for VTE After Knee Replacement Surgery

This study, conducted by the Departments of Orthopedics at three schools of medicine—the University of Maryland, the University of Rochester, and the Pennsylvania State University—sought to find the optimal practices to prevent readmissions for VTE after knee replacement surgery.^{xiv} During the 20 years of the study, began in 1984, the perioperative management of joint replacement surgery has substantially changed at the hospitals affiliated with the medical schools, reducing the risk of DVT and PE. Current clinical practices, including surgical techniques that reduce operating time, use of regional anesthesia and pre-donated autologous blood, and early mobilization, when used with perioperative DVT prophylaxis, have shown such a significant reduction in the VTE risk for knee surgery that some surgeons have considered discharging patients without extended anticoagulant therapy.

The study showed that, although the incidence of a fatal PE is low and major bleeding complications from use of thrombotic agents do occur, a six week post-discharge course of warfarin is the preferred practice. The study demonstrated that treatment is needed to prevent emboli that can form up to 180 days after discharge and that a negative pre-discharge DVT screening test is not sufficient to omit treatment. The study, which enrolled 1,321 patients, initially provided post-discharge anticoagulation only to patients with a positive contrast venogram. However, a few incidents of PE among the three facilities, both fatal and non-fatal, convinced the researchers to abandon pre-discharge screening and to standardize their practice. Since 2003, orthopedic surgeons at the three institutions order six weeks of warfarin treatment for all knee replacement surgery patients, with twice weekly laboratory monitoring. The researchers emphasized that without the large database of patients from the three collaborating medical schools and long-term patient tracking, the low incidence event of post-discharge PE mortality may not have been recognized.

◆State University of New York (SUNY) Downstate Medical Center◆

In October 2002, the State University of New York (SUNY) Downstate Medical Center, a 400-bed urban teaching hospital located in Brooklyn, began a performance improvement initiative after an informal audit revealed a VTE prophylaxis rate of 50%.^{xv} For the formal baseline audit, all medical inpatients on two medical floors on a single day were included. The following data was collected from medical records and the pharmacy system:

- VTE risk factors
- Contraindications to anticoagulant prophylaxis
- Type of VTE received
- Appropriateness of prophylaxis (2001 ACCP guidelines adapted to a medical unit)

The Division Chief of General Internal Medicine interviewed the house staff and hospitalists to clarify:



- Reason for admission
- VTE risk factors present on admission
- Use of mechanical prophylaxis
- Ambulation status. Nurses were also asked if the patient had been observed walking

Each patient was evaluated as either:

- Appropriate prophylaxis (including no prophylaxis, if contraindicated or low risk)
- Questionable prophylaxis
- Inappropriate prophylaxis (including incorrect dosing)

The data, that was checked by the Department of Medicine's Performance Improvement Committee, confirmed that about half of the medical patients were receiving appropriate prophylaxis (43% appropriate, 14% questionable, and 43% inappropriate). The average patient had three risk factors, most commonly age >40, nonambulatory, and having cancer. The most frequent treatment contraindication was active gastrointestinal bleeding.

The hospital then selected three interventions from among those that appeared most promising in the literature, to improve the appropriateness of VTE prophylaxis:

Provider education about VTE risk factors and VTE prophylaxis:

- Monthly incoming house staff orientation
- Nursing education
- Posters at nursing stations and in physician charting rooms

Decision support tool in the form of a medication pocket card for physicians

Post-implementation audit and feedback, at 12 to 14 months and 19 to 21 months:

- Chart reviews on one randomly-selected day during the last 2 week of the monthly house staff rotation, including 40 to 50 randomly selected medical patients for each of the 6 audited months;
- Division Chief interview of house staff and attending (as described above); and
- Division Chief feedback to clinicians immediately following interviews

By the final 3 months of the audit, April-June 2004, SUNY Downstate Medical Center had increased the appropriateness of VTE prophylaxis to 85% in its two medical units. *The researchers received drug company support for the preparation of the manuscript and for the pocket cards (available at <http://www.lovenox.com>).*

◆Baystate Medical Center◆

In 2003, Baystate Medical Center, a 600-bed tertiary care teaching hospital located in Springfield, Massachusetts, began a performance improvement initiative as part of their participation in IHI's process-improvement training.^{xvi} Their goal was to reduce by 50% their quarterly rates of postoperative VTE and myocardial infarction (MI). It took Bayside 7



quarters to achieve this, reducing their postoperative VTE rate from 1.09% to 0.47% and their MI rate from 0.5 to 0.35. Below are Baystate's interventions related to postoperative VTE prophylaxis:

- Developed standardized guidelines and treatment recommendations for VTE prophylaxis
- Developed preprinted orders based on the ACCP's VTE guidelines
- Performed Computerized Physician Order Entry (CPOE) screening
- Screened orders for appropriateness of therapy (pre-op, immediate pre-op, post-op with RN prompting physicians, and implementing standing protocols)
- Implemented daily rounds to review VTE therapy
- Reviewed in real-time all postoperative VTE events
- Educated all clinicians providing care to at-risk population
- Anesthesiologist evaluated patients for VTE risk factors during preoperative screening
- Reported monthly measure data to the appropriate PI teams
- Adopted VTE rate as surgical services quarterly quality program monitor
- Reviewed cases for potential preventability with one-on-one communication with clinicians for any overuse, underuse or misuse
- Reviewed secondary coding to prompt physicians to determine "actual post-operative events" instead of "on admissions" events



Patient Safety Initiatives

The Institute of Medicine (IOMs) reports, beginning with the 1999 monograph *To Err is Human*, have brought concerns about patient safety to the forefront, prompting various initiatives aimed at improving healthcare systems. These initiatives have the following factors in common:

- Promoting public awareness
- Funding research and systems that collect and report data
- Setting time-limited measurable objectives for change
- Encouraging the implementation of evidence-based practices

◆National Quality Forum (NQF) and The Joint Commission◆

National Consensus Standards for the Prevention and Care of VTE

A joint Technical Advisory Panel of the National Quality Forum and The Joint Commission are working to develop National Consensus Standards for the Prevention and Care of VTE. For 6 months beginning January 1, 2007, a nationwide sample of 55 hospitals will be pilot testing the following measures:^{xvii}

Risk Assessment/Prophylaxis

- VTE risk assessment/prophylaxis within 24 hours of hospital admission
- VTE risk assessment/prophylaxis within 24 hours of transfer to ICU

Treatment

- Documentation of inferior vena cava filter indication
- VTE patients with overlap therapy
- VTE patients receiving unfractionated heparin with platelet count monitoring
- VTE patients receiving unfractionated heparin management by nomogram/protocol
- VTE discharge instructions

Outcome

- Incidence of potentially preventable hospital-acquired VTE

As pilot testing proceeds, the above measures may be modified. For information about the Consensus Standards, and project updates refer to the Joint Commission Web Site: <http://www.jointcommission.org>.

◆National Quality Forum (NQF)◆

Safe Practices for Better Healthcare

The NQF is a voluntary national consensus standards-setting organization that began in 2000 as a public-private collaborate. In 2006, this diverse group of healthcare stakeholders endorsed an updated list of Safe Practices, keeping VTE prophylaxis among its top priorities. The NQF rationale for this endorsement is as follows:



Pulmonary thromboembolism is the third most common cause of hospital-related deaths in the United States and the most common preventable cause of hospital death. Several clinical interventions are known to effectively prevent venous thromboembolism (VTE). The most appropriate specific intervention will depend on the thrombotic risk, the clinical setting, and other factors.^{xviii}

The NQF has endorsed the following recommended safe practice and safety objective:

NQF Safe Practice 17 Evaluate each patient upon admission, and regularly thereafter, for the risk of developing DVT/VTE. Utilize clinically appropriate methods to prevent DVT/VTE.

- Document the VTE risk assessment and prevention plan in the patient's record.
- Explicit organizational policies and procedures should be in place for the prevention of VTE.

NQF Safety Objective 17 Reduce the occurrence of venous thromboembolism.

The NQF supports rapid implementation and widespread dissemination of information about its endorsed Safe Practices. The Leapfrog Group, a stakeholder coalition of 150 public and private purchasers, began surveying hospitals in 2004 about NQF safe practices, and sharing this information with purchasers and groups that compare hospitals. In the 2006 Leapfrog Group Hospital Quality and Safety Survey, hospitals are asked if they have taken the following implementation steps related to VTE prevention:^{xix}

Leapfrog Survey

- Awareness
 - Literature review for readily available best practices
 - Evaluation of the frequency and severity of cases of VTE in hospital's patient population
 - Identify improvement opportunities in a report to administration
 - Implemented risk assessment protocols:
 - Clinicians
 - Staff education
- Accountability
 - Patient safety office or administrator reports VTE performance metrics to Board and CEO
 - Metrics include percent of inpatients with VTE risk assessment
 - Departmental and/or clinical service line managers held accountable for VTE risk assessments
 - Performance reviews or incentive compensation plans



- Ability
 - Dedicated resources to address VTE prevention
 - Staff education is conducted that includes knowledge transfer and skill development
 - VTE project status reports are presented to quality committees.

The NQF suggest the following indicators be collected to measure performance improvement related to its Safe Practice of VTE prophylaxis:

Outcome measure

- Intra or postoperative PE diagnosed during index hospitalization and within 30 days of surgery
- Intra or postoperative DVE diagnosed during index hospitalization and within 30 days of surgery

Process measures

- SCIP-VTE-1: Surgery patients with recommended VTE prophylaxis ordered
- SCIP-VTE-2: Surgery patients with appropriate VTE prophylaxis given with timeframe

Structure measures

- Identification, stratification and trending of specific risk factors of patients who have developed VTE/DVT or PE to determine success of mitigation strategies
- Documentation of risk assessment during admission evaluation

Patient centered measures

- NQF-endorsed HCAHPS patient satisfaction survey (see 2007 Data Collection)

The ACCP, author of the guidelines on which the NQF recommendations are based, appealed the NQF about Safe Practice 17. The ACCP proposes that physicians be required to deliver VTE prophylaxis to all inpatients or document why it is not prescribed. The ACCP believes that VTE risk assessment tools have not been adequately validated for use in clinical practice^{xx}

National Action Plan for DVT Prevention, Treatment, and Research

NQF convened an invitational summit on convened March 24, 2006, to identify a patient-centered national action plan for VTE prevention, treatment, and research. More than 100 research, clinician and consumer leaders participated. As an outcome of that meeting, NQF joined the Coalition to Prevent Deep-Vein Thrombosis (see Resources), and will participate in DVT Awareness Month in March 2007.

Descriptions of VTE Safe Practices and a National Action Plan are available at NQF's Web Site: <http://www.qualityforum.org>.



◆Institute for Healthcare Improvement (IHI)◆

5 Million Lives Campaign

In December 2006, the Institute for Healthcare Improvement (IHI) launched its campaign aimed at protecting patients from 5 million incidents of medical harm over 2 years. Over 4,000 hospitals will be enlisted to introduce evidence-based best practices on up to 12 interventions, with a goal of reducing patient injuries and saving lives. One of the interventions in IHI's 5 Million Lives Campaign is the prevention of VTE in surgical and ventilated patients by implementing clinically appropriate methods.

VTE prophylaxis is part of IHI's ventilator bundle, a group of interventions related to ventilator care, that when implemented together will reduce mortality due to ventilator-associated pneumonia. The following are components of the IHI ventilator bundle:

- Elevation of the head of the bed
- Daily "sedation vacations" and assessment of readiness to extubate
- Peptic ulcer disease prophylaxis
- DVT prophylaxis

VTE prophylaxis is also part of IHI's Reducing Surgical Complications Learning and Innovation Community that began in February 2007. Participating hospitals will significantly reduce adverse surgical events by employing the following methods:

- Standardizing and simplifying core processes
- Redesigning delivery systems using proven human factors principles
- Partnering with patients
- Creating safety cultures that minimize blame and maximize teamwork and communication
- Using technologies appropriately

The key areas of focus are:

- Cardiac events
- Emboli
- Post-operative bleeding
- High-risk events such as operative fires and wrong site surgery
- Simulation
- Teamwork

A goal of the Community is to achieve at least 95% compliance with DVT prophylaxis for high-risk patients by April 2008. More information about the 5 Million Lives Campaign, including the ventilator bundle and the Reducing Surgical Complications Learning and Innovation Community may be found on IHI's Web Site, <http://www.ihl.org>.



◆Institute for Safe Medication Practices (ISMP)◆

The Institute for Safe Medication Practices (ISMP) is a nonprofit organization devoted to medication error prevention and safe medication use. The ISMP receives medication error reports, both from the MERP, the U.S. Pharmacopeia nationwide voluntary program, and from PA-PSRS, the Pennsylvania state-mandated error-reporting program. ISMP analyzes the reports and publishes findings about the causes of errors and safe practice recommendations.

Heparin may be administered in the emergency department to prevent or treat DVT. The administration of this high alert medication (or any thrombolytic) must be communicated to the next providers of care to prevent duplication of therapy. In 2001, ISMP published a hazard alert following review of three voluntary reports of patient deaths from internal bleeding caused by the unintended concomitant use of two heparin products.^{xxi} ISMP safe practice recommendations concerning heparin include the following:

- Communicate all orders for heparin products to the pharmacy, including those prescribed in the emergency department for admitted patients.
- Screen all medication orders for unsafe duplication; with attention to alerts.
- Restrict access to heparin products when feasible.
- When automated dispensing cabinets are used, display alerts, and prohibit overrides before pharmacy review.
- Require an independent double check by two individuals before administering heparin products. Consider including an independent review of the patient's entire drug therapy profile and recent laboratory results in the check.

In 2006, three premature infants died after receiving an umbilical heparin flush that contained 10,000 units instead of 10 units of heparin per mL. Following this tragedy, ISMP issued the following additional recommended safe practices concerning heparin use:^{xxii}

- Use bar coding to stock automated medication cabinets. Double check cabinets before they leave the pharmacy.
- Avoid stocking items in cabinets that require additional preparation by nurses.
- Assess medications and strengths stocked in cabinets used for high-risk patients
- Examine which medications can be removed from a dispensing cabinet without a pharmacist's review
- Minimize look-alike packages and labels. Consider lowering the strength of heparin stocked anywhere in the facility.
- Consider using bar coding for bedside scanning to confirm accuracy of the patient, drug, and dose.



Standards and Guidelines

◆American College of Chest Physicians◆

Prevention of Venous Thromboembolism: The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy

The American College of Chest Physicians (ACCP) VTE prophylaxis guidelines, presented below, are the practices most frequently cited by evidence-based practice reviewers and quality measure developers. They are available from the National Guideline Clearinghouse at <http://www.guideline.gov>.

Below are extracted the Grade 1 recommendations that apply to hospitalized patients. For these recommendations the evidence clearly shows that the benefits outweigh risks, burden, and costs.^{xxiii}

General Recommendations

- The guideline developers recommend that mechanical methods of prophylaxis be used primarily in patients who are at high risk of bleeding. The guideline developers recommend that careful attention be directed toward ensuring the proper use of, and optimal compliance with, the mechanical device.
- The guideline developers recommend **against** the use of aspirin alone as prophylaxis against VTE for any patient group.
- For each of the antithrombotics agents, the guideline developers recommend that clinicians consider the manufacturer's suggested dosing guidelines.
- The guideline developers recommend consideration of renal impairment when deciding on doses of low-molecular-weight heparin (LMWH), fondaparinux, the direct thrombin inhibitors, and other antithrombotic drugs that are cleared by the kidneys, particularly in elderly patients and those who are at high risk for bleeding.
- In all patients undergoing neuraxial anesthesia or analgesia, the guideline developers recommend special caution when using anticoagulant prophylaxis.

General Surgery

- In low-risk general surgery patients who are undergoing a minor procedure, are <40 years of age, and have no additional risk factors, the guideline developers recommend **against** the use of specific prophylaxis other than early and persistent ambulation.
- Moderate-risk general surgery patients are those patients undergoing a nonmajor procedure and are between the ages of 40 and 60 years or have additional risk factors, or those patients who are undergoing major operations and are <40 years of age with no additional risk factors. The guideline developers recommend prophylaxis with low-dose unfractionated heparin (LDUH), 5,000 units twice a day, or LMWH, ≤3,400 units daily.



- Higher-risk general surgery patients are those undergoing nonmajor surgery and are >60 years of age or have additional risk factors, or patients undergoing major surgery who are >40 years of age or have additional risk factors. The guideline developers recommend thromboprophylaxis with LDUH, 5,000 units three times a day, or LMWH, >3,400 units daily.
- In high-risk general surgery patients with multiple risk factors, the guideline developers recommend that pharmacologic methods (i.e., LDUH, three times per day, or LMWH, >3,400 units daily) be combined with the use of graduated compression stockings (GCS) and/or intermittent pneumatic compression (IPC).
- In general surgery patients with a high risk of bleeding, the guideline developers recommend the use of mechanical prophylaxis with properly fitted GCS or IPC, at least initially until the bleeding risk decreases.
- In selected high-risk general surgery patients, including those who have undergone major cancer surgery, the guideline developers suggest post-hospital discharge prophylaxis with LMWH.

Vascular Surgery

- For patients undergoing major vascular surgical procedures who have additional thromboembolic risk factors, the guideline developers recommend prophylaxis with LDUH or LMWH.

Gynecologic Surgery

- For gynecologic surgery patients undergoing brief procedures of ≤ 30 minutes for benign disease, the guideline developers recommend **against** the use of specific prophylaxis other than early and persistent mobilization.
- For patients undergoing laparoscopic gynecologic procedures, in whom additional VTE risk factors are present, the guideline developers recommend the use of thromboprophylaxis with one or more of the following: LDUH, LMWH, IPC, or GCS.
- The guideline developers recommend that thromboprophylaxis be used in all major gynecologic surgery patients.
- For patients undergoing major gynecologic surgery for benign disease, without additional risk factors, the guideline developers recommend LDUH, 5,000 units twice per day. Alternatives include prophylaxis with LMWH, $\leq 3,400$ units daily, or IPC started just before surgery and used continuously while the patient is not ambulating.
- For patients undergoing extensive surgery for malignancy, and for patients with additional VTE risk factors, the guideline developers recommend routine prophylaxis with LDUH, 5,000 units three times per day, or higher doses of LMWH (i.e., >3,400 units daily). Alternative considerations include IPC alone continued until hospital discharge or a combination of LDUH or LMWH plus mechanical prophylaxis with GCS or IPC.
- For patients undergoing major gynecologic procedures, the guideline developers suggest that prophylaxis continue until discharge from the hospital. For patients who

are at particularly high risk, including those who have undergone cancer surgery and are >60 years of age or have previously experienced VTE, the guideline developers suggest continuing prophylaxis for 2 to 4 weeks after hospital discharge.

Urologic Surgery

- In patients undergoing transurethral or other low-risk urologic procedures, the guideline developers recommend **against** the use of specific prophylaxis other than early and persistent mobilization.
- For patients undergoing major, open urologic procedures, the guideline developers recommend routine prophylaxis with LDUH twice or three times daily. Acceptable alternatives include prophylaxis with IPC and/or GCS or LMWH.
- For urologic surgery patients who are actively bleeding or are at very high risk for bleeding, the guideline developers recommend the use of mechanical prophylaxis with GCS and/or IPC at least until the bleeding risk decreases.
- For patients with multiple risk factors, the guideline developers recommend combining GCS and/or IPC with LDUH or LMWH.

Laparoscopic Surgery

- The guideline developers recommend against routine thromboprophylaxis in these patients, other than aggressive mobilization.
- For patients undergoing laparoscopic procedures and who have additional thromboembolic risk factors, the guideline developers recommend the use of thromboprophylaxis with one or more of the following: LDUH, LMWH, IPC, or GCS.

Orthopedic Surgery

Elective Hip Arthroplasty

- For patients undergoing elective total hip replacement, the guideline developers recommend the routine use of one of the following three anticoagulants:
 - LMWH (at a usual high-risk dose, started 12 hours before surgery or 12 to 24 hours after surgery, or 4 to 6 hours after surgery at half the usual high-risk dose and then increasing to the usual high-risk dose the following day);
 - Fondaparinux (2.5 mg started 6 to 8 hours after surgery); or
 - Adjusted-dose vitamin K antagonist (VKA) started preoperatively or the evening after surgery (international normalized ratio [INR] target, 2.5; INR range, 2.0 to 3.0).
- Underlying values and preferences: The guideline developers have not recommended the use of fondaparinux over LMWH and VKA, or the use of LMWH over VKA, because they place a relatively low value on the prevention of venographic thrombosis and a relatively high value on minimizing bleeding complications.
- The guideline developers recommend **against** the use of aspirin, dextran, LDUH, GCS, IPC, or venous foot pump (VFP) as the only method of thromboprophylaxis in these patients.



Elective Knee Arthroplasty

- For patients undergoing elective total knee replacement arthroplasty (TKA), the guideline developers recommend routine thromboprophylaxis using LMWH (at the usual high-risk dose), fondaparinux, or adjusted-dose VKA (target INR, 2.5; INR range, 2.0 to 3.0).
- Underlying values and preferences: The guideline developers have not recommended fondaparinux over LMWH and VKA, or LMWH over VKA, because they place a relatively low value on the prevention of venographic thrombosis and a relatively high value on minimizing bleeding complications.
- The optimal use of IPC is an alternative option to anticoagulant prophylaxis.
- The guideline developers recommend **against** the use of any of the following as sole methods of thromboprophylaxis: aspirin; LDUH; or VFP.

Hip Fracture Surgery

- For patients undergoing hip fracture surgery (HFS), the guideline developers recommend the routine use of fondaparinux, LMWH at the usual high-risk dose, adjusted-dose VKA (target INR, 2.5; INR range, 2.0 to 3.0), or LDUH.
- The guideline developers recommend **against** the use of aspirin alone.
- If surgery will likely be delayed, the guideline developers recommend that prophylaxis with either LDUH or LMWH be initiated during the time between hospital admission and surgery.
- The guideline developers recommend mechanical prophylaxis if anticoagulant prophylaxis is contraindicated because of a high risk of bleeding.

Other Prophylaxis Issues in Major Orthopedic Surgery

- For major orthopedic surgical procedures, the guideline developers recommend that a decision about the timing of the initiation of pharmacologic prophylaxis be based on the efficacy-to-bleeding tradeoffs for that particular agent. For LMWH, there are only small differences between starting preoperatively or postoperatively, and both options are acceptable.
- The guideline developers recommend **against** the routine use of Doppler ultrasonography (DUS) screening at the time of hospital discharge in asymptomatic patients following major orthopedic surgery.
- The guideline developers recommend that patients undergoing THR, TKA, or HFS receive thromboprophylaxis with LMWH (using a high-risk dose), fondaparinux (2.5 mg daily), or a VKA (target INR, 2.5; INR range, 2.0 to 3.0) for at least 10 days.
- The guideline developers recommend that patients undergoing THR or HFS be given extended prophylaxis for up to 28 to 35 days after surgery. The recommended options for THR include LMWH, a VKA, or fondaparinux. The recommended options following HFS are fondaparinux, LMWH, or a VKA.

Elective Spine Surgery

- For spinal surgery patients with no additional risk factors, the guideline developers recommend against the routine use of any thromboprophylaxis modality, apart from early and persistent mobilization.



- The guideline developers recommend that some form of prophylaxis be used in patients undergoing spinal surgery who exhibit additional risk factors such as advanced age, known malignancy, presence of a neurologic deficit, previous VTE, or an anterior surgical approach.
- For patients with additional risk factors, the guideline developers recommend any of the following prophylaxis options: postoperative LDUH alone; postoperative LMWH alone; or perioperative IPC alone. In patients with multiple risk factors for VTE, the guideline developers recommend combining LDUH or LMWH with GCS and/or IPC.

Neurosurgery

- The guideline developers recommend that thromboprophylaxis be routinely used in patients undergoing major neurosurgery.
- The guideline developers recommend the use of IPC with or without GCS in patients undergoing intracranial neurosurgery.

Trauma, Spinal Cord Injury, Burns

Trauma

- The guideline developers recommend that all trauma patients with at least one risk factor for VTE receive thromboprophylaxis, if possible.
- In the absence of a major contraindication, the guideline developers recommend that clinicians use LMWH prophylaxis starting as soon as it is considered safe to do so.
- The guideline developers recommend that mechanical prophylaxis with IPC, or possibly with GCS alone, be used if LMWH prophylaxis is delayed or if it is currently contraindicated due to active bleeding or a high risk for hemorrhage.
- The guideline developers recommend DUS screening in patients who are at high risk for VTE (e.g., the presence of a spinal cord injury [SCI], lower extremity or pelvic fracture, major head injury, or an indwelling femoral venous line), and who have received suboptimal prophylaxis or no prophylaxis.
- The guideline developers recommend against the use of inferior vena cava filters (IVCFs) as primary prophylaxis in trauma patients.
- The guideline developers recommend the continuation of thromboprophylaxis until hospital discharge, including the period of inpatient rehabilitation.

Acute Spinal Cord Injury

- The guideline developers recommend that thromboprophylaxis be provided for all patients with acute SCIs.
- The guideline developers recommend **against** the use of LDUH, GCS, or IPC as single prophylaxis modalities.
- In patients with acute SCI, the guideline developers recommend prophylaxis with LMWH, to be commenced once primary hemostasis is evident. The guideline developers recommend the use of IPC and/or GCS when anticoagulant prophylaxis is contraindicated early after injury.



- The guideline developers recommend **against** the use of an IVCF as primary prophylaxis against pulmonary embolism (PE).
- During the rehabilitation phase following acute SCI, the guideline developers recommend the continuation of LMWH prophylaxis or conversion to an oral VKA (INR target, 2.5; INR range, 2.0 to 3.0).

Burns

- The guideline developers recommend that burn patients with additional risk factors for VTE, including one or more of the following: advanced age, morbid obesity, extensive or lower extremity burns, concomitant lower extremity trauma, use of a femoral venous catheter, and/or prolonged immobility, receive thromboprophylaxis, if possible.
- If there are no contraindications, the guideline developers recommend the use of either LDUH or LMWH, starting as soon as is considered safe to do so.

Medical Conditions

- In acutely ill medical patients who have been admitted to the hospital with congestive heart failure 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, the guideline developers recommend prophylaxis with LDUH or LMWH.
- In medical patients with risk factors for VTE, and in whom there is a contraindication to anticoagulant prophylaxis, the guideline developers recommend the use of mechanical prophylaxis with GCS or IPC.

Cancer Patients

- The guideline developers recommend that cancer patients undergoing surgical procedures receive prophylaxis that is appropriate for their current risk state. (Refer to the recommendations in the relevant surgical subsections.)
- The guideline developers recommend that hospitalized cancer patients who are bedridden with an acute medical illness receive prophylaxis that is appropriate for their current risk state. Refer to the recommendations in the section dealing with medical patients.
- The guideline developers recommend **against** the use of fixed-dose warfarin to try to prevent thrombosis related to long-term indwelling central venous catheters.

Critical Care

- The guideline developers recommend that, on admission to a critical care unit, all patients be assessed for their risk of VTE. Accordingly, most patients should receive thromboprophylaxis.
- For patients who are at high risk for bleeding, the guideline developers recommend mechanical prophylaxis with GCS and/or IPC until the bleeding risk decreases.



- For intensive care unit (ICU) patients who are at moderate risk for VTE (e.g., medically ill or postoperative patients), the guideline developers recommend using LDUH or LMWH prophylaxis.
- For patients who are at higher risk, such as that following major trauma or orthopedic surgery, the guideline developers recommend LMWH prophylaxis.

◆National Comprehensive Cancer Network (NCCN)◆

Clinical Practice Guidelines in Oncology: Venous Thromboembolic Disease

The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for venous thromboembolic disease, updated in 2006 by a panel of expert clinicians from National Cancer Institute (NCI) facilities, represent the consensus of clinicians treating cancer patients. These guidelines, summarized below, list VTE risk factors commonly found in cancer inpatients and describe decision-making considerations for clinicians prescribing VTE prophylaxis:^{xxiv}

VTE Risk Factor Assessment

- Age
- Prior VTE
- Familial thrombophilia
- Active cancer*
- Trauma
- Major surgical procedures
- Acute or chronic medical illness requiring hospitalization or prolonged bed rest*
- Central venous catheter/IV catheter*
- Congestive heart failure (CHF)
- Pregnancy
- Regional bulky lymphadenopathy with extrinsic vascular compression
- Modifiable risk factors
 - Lifestyle (diet, environment)
 - Smoking, tobacco
 - Obesity
 - Activity level/exercise
- Therapeutic agents associated with increased risk:
 - Chemotherapy*
 - Exogenous estrogen compounds
 - Hormone Replacement Therapy (HRT)
 - Oral contraceptives
 - Tamoxifen/Raloxifene
 - Diethylstilbestrol
 - Thalidomide/lenalidomide

*Risk factors common to cancer inpatients. (Cancer patients have multiple VTE risk factors.)



Relative contraindication to anticoagulation treatment

- Recent central nervous system (CNS) bleed, intracranial or spinal lesion at
- High risk for bleeding
- Active bleeding (major): more than 2 units transfused in 24 hours
- Chronic, clinically significant measurable bleeding >48 hours
- Thrombocytopenia (platelets <50,000/mcL)
- Severe platelet dysfunction (uremia, medications, dysplastic hematopoiesis)
- Recent major operation at high risk for bleeding
- Underlying coagulopathy
- Spinal anesthesia/lumbar puncture
- High risk for falls

Decision not to treat

- Patient refusal
- No therapeutic advantage
 - Limited survival
 - High risk
- No planned oncologic intervention
- *No palliative benefit* (e.g., alleviate dyspnea, prevent leg swelling)
- Unreasonable burden of anticoagulation treatment
 - Painful injections
 - Frequent monitoring with phlebotomy

VTE prophylaxis (no relative contraindications and decision to treat)

Anticoagulant treatment with or without Sequential Compression Device:

- LMWH: Use with caution in patients with renal insufficiency and failure. Dose adjustments may be required
 - Enoxaparin 40 mg subcutaneous daily
 - Tinzaparin 4,500 units (fixed dose) subcutaneous daily or 75 units/kg subcutaneous daily
 - Dalteparin 5,000 units subcutaneous daily
- Pentasaccharide:
 - Fondaparinux 2.5 mg subcutaneous daily
- Unfractionated Heparin: 5,000 units subcutaneous three times daily

Anticoagulant Agent Selection Criteria

- Renal failure
- FDA approval
- Cost
- Ease of administration
- Monitoring
- Ability to reverse anticoagulation



Mechanical prophylaxis (relative contraindications to anticoagulant and decision to treat)

- Graduated compress device
- Graduated compression stockings

◆Institute for Clinical Systems Improvement (ICSI)◆

VTE Prophylaxis

The Institute for Clinical System Improvement (ICSI) is a collaborative group of guideline developers comprised of healthcare providers located in Minnesota and South Dakota that is primarily supported by regional payers. In June 2006, ICSI published a guideline for VTE prophylaxis with a companion order set, which may be found at <http://www.isci.org>. The ICSI evidence-based guidelines for VTE prophylaxis are summarized below:^{xxv}

Risk Assessment

- Assess VTE risk
- Patient-related risk
- Procedure-related risk (surgery/trauma)
- Condition-related risk (medical)

Ambulation

- All patients should receive early ambulation, regardless of risk category.
- Involve physical therapy as soon as possible.
- Mobilization will start by sitting with flexion/extension exercises for the ankles and progress to walking.
- This should be done every shift or more based on patient tolerance.

Patient Education

- All patients should receive education, regardless of risk category
- Patient education should include VTE risk, VTE signs and symptoms, and VTE prophylaxis methods available.

VTE Mechanical Prophylaxis

- Elastic graded compression stockings, if not low risk.
- Intermittent pneumatic compression is often not well tolerated by the patient; reserve for immobilized patients, at moderate to very high risk.

VTE Pharmacologic Prophylaxis

- Medical patients at high risk for VTE should receive anticoagulation prophylaxis at admission and continue while risk continues, unless contraindicated.
- Surgical/trauma patients at moderate to very high risk for VTE should receive anticoagulant prophylaxis unless contraindicated
 - Anticoagulation is started 1-2 hours prior to surgery
 - Aspirin is not recommended as an anticoagulation regimen



- Risk of VTE development continues beyond hospitalization, and the need for post-discharge anticoagulation should be assessed.
- Pharmacologic prophylaxis is not without risk. Patients should be evaluated for an increase risk of bleeding. The following are contraindications for pharmacologic prophylaxis:
 - Extreme thrombocytopenia
 - History of Heparin-Induced Thrombocytopenia (HIT) is contraindicated for use of heparins
 - Uncontrolled hypertension (blood pressure >200/120)
 - Bacterial endocarditis
 - Active hepatitis or hepatic insufficiency
 - Other conditions that could increase the risk of bleeding
- Precautions should be taken when using pharmacologic prophylaxis in the following:
 - Patients with renal insufficiency (CrCl less than 30 mL/min) should receive lower doses.
 - Patients receiving spinal or epidural anesthesia, who have a higher risk of epidural hematoma.
 - Patients with suspected Heparin-induced Thrombocytopenia (HIT) are at increased risk for thrombosis; treatment with heparin should be stopped, a direct thrombin inhibitor used, and the patient managed by an anticoagulation expert (i.e., hematologist).

ISCI's priority aims for VTE prophylaxis of hospitalized adult patients are as follows:

- Increase percent of patients who are appropriately assessed for VTE
- Increase percent of patients who are at risk for VTE who have received education for VTE (as described above)
- Increase percent of patients who begin early and frequent ambulation
- Increase percent of patients receiving appropriate pharmacological and/or mechanical prophylaxis treatment
- Reduce percent of complications from pharmacologic prophylaxis



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Glossary

ACI	Acute spinal cord injury
Direct thrombin inhibitors	Non-heparin anticoagulants that inhibit thrombin (e.g., argatroban). May be used to treat patients with HIT.
DVT	Deep vein thrombosis
DUS	Venous doppler ultrasound, used to diagnose DVT
ES/GCS	Graduated elastic stockings/Graduated compression stockings
Factor Xa Inhibitor	Non-heparin anticoagulants that inhibit factor Xa (e.g., fondaparinux).
HIT	Heparin-induced thrombocytopenia, an adverse effect of anticoagulants that occurs more commonly with LDUH than with LMWH.
HITT	Heparin-induced thrombocytopenia with thrombosis, an adverse effect of anticoagulants
IPC/SCD	Intermittent pneumatic compression devices/Sequential compression devices. An external air pump used to improve venous blood return.
INR	International normalized ratio; used to monitor anticoagulation
IVCF	Inferior vena cava filters; implanted device used to prevent pulmonary emboli.
LDUH	Low-dose unfractionated heparin, an anticoagulant
LMWH	Low molecular weight heparins (e.g., enoxaparin, tinzaparin), heparinoids, (e.g., danaparoid), and heparin derivatives (e.g., dalteparin). Anticoagulants that inhibit factor Xa and factor IIa (thrombin) that lead to clotting.
PE	Pulmonary embolism
THR/THA	Total hip replacement surgery/Total hip arthroplasty
TKR/TKA	Total knee replacement surgery/Total knee arthroplasty
VFP	Venous foot pump; an external pump used to improve venous blood return.
VKA	Adjusted-dose vitamin K antagonist; warfarin is an oral vitamin K antagonist.
VTE	Venous thromboembolism



Selected Resources

ECRI Institute, accessed at <http://www.ecri.org>, is a nonprofit health services research firm. ECRI Institute is the state's contractor for PA-PSRS, the Pennsylvania Patient Safety Reporting System, and an AHRQ Evidence-based Practice Center. ECRI Institute provides technical support for the Partnership for Patient Care.

American College of Chest Physicians (ACCP), accessed at <http://www.chestnet.org>, is a professional society of critical care and cardiopulmonary clinicians whose mission is to promote the prevention and treatment of diseases of the chest through leadership, education, research, and communication. ACCP publishes CHEST, which includes the proceedings from the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy.

American Vascular Foundation (AVF), accessed at <http://www.venous-info.com>, is a nonprofit organization that funds venous disease research projects. AVF has developed a DVT risk assessment software for PDAs that clinicians can use to determine a patient's DVT risk category and review treatment options. The AVF initiated the National Screening Program for Venous Disease; over 150 facilities in 46 states screened 4,000 patients during National Venous Screening Week, held in November 2006.

Coalition to Prevent DVT, accessed at <http://www.preventdvt.org>, is a coalition of about 35 organizations committed to educating the public and healthcare community about DVT. The Coalition sponsors DVT Awareness month, which is March. Available on their Web site is a DVT risk assessment tool for use by patients.

Institute for Clinical Systems Improvement, accessed at <http://www.icsc.org>, is a collaborative group of healthcare providers and payers, located in Minnesota and South Dakota, which develops clinical practice guidelines and conducts technology assessments.

Institute for Healthcare Improvement, accessed at <http://www.ihl.org>, is a nonprofit organization driving the improvement of health by advancing patient safety initiatives.

Institute for Safe Medication Practices, accessed at <http://www.ISMP.org>, is a nonprofit organization devoted to medication error prevention and safe medication use. ISMP publishes medication safety alerts.

The Joint Commission, accessed at <http://www.jointcommission.org>, is an independent, nonprofit organization that evaluates and accredits more than 15,000 healthcare organizations and programs in the United States.

National Heart, Lung, and Blood Institute (NHLBI), at <http://www.nhlbi.nih.gov>, conducts and supports research, clinical trials, and education projects related to the causes, prevention, diagnosis, and treatment of venous thromboembolism.



National Alliance for Thrombosis and Thrombophilia, at <http://www.nattinfo.org>, is a nonprofit organization dedicated to educating healthcare providers to recognize and treat thrombosis and thrombophilia.

National Quality Forum, accessed at: <http://www.qualityforum.org/>. is private, nonprofit membership organization created to develop and implement a national strategy for healthcare quality measurement and reporting.

National Patient Safety Foundation, accessed at <http://www.npsf.org/>, is non-profit organization dedicated to improving the safety of patients. A NPSF focus area is acute and surgical care and prevention of adverse events; their annual Patient Safety Congress will include speakers on this topic.

Pennsylvania Patient Safety Authority, accessed at <http://www.psa.state.pa.us>, is an independent Pennsylvania state agency charged with taking steps to reduce and eliminate medical errors. Pennsylvania's mandated error-reporting system is PA-PSRS, the Pennsylvania Patient Safety Reporting System.

U.S. Surgeon General, accessed at <http://www.surgeongeneral.gov>, is the chief spokesperson on matters of public health. In May 2006, the U.S. Surgeon General held a 2-day workshop on DVT and PE bringing together advocates and medical experts to address priorities to decrease death and disability.

Vascular Disease Foundation, accessed at <http://www.vdf.org>, is a public, nonprofit organization that provides public education and improves awareness of vascular disease. Its mission is to reduce death and disability from vascular diseases and improve vascular health. VDF provides free patient information about DVT written by clinical experts.



Endnotes

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