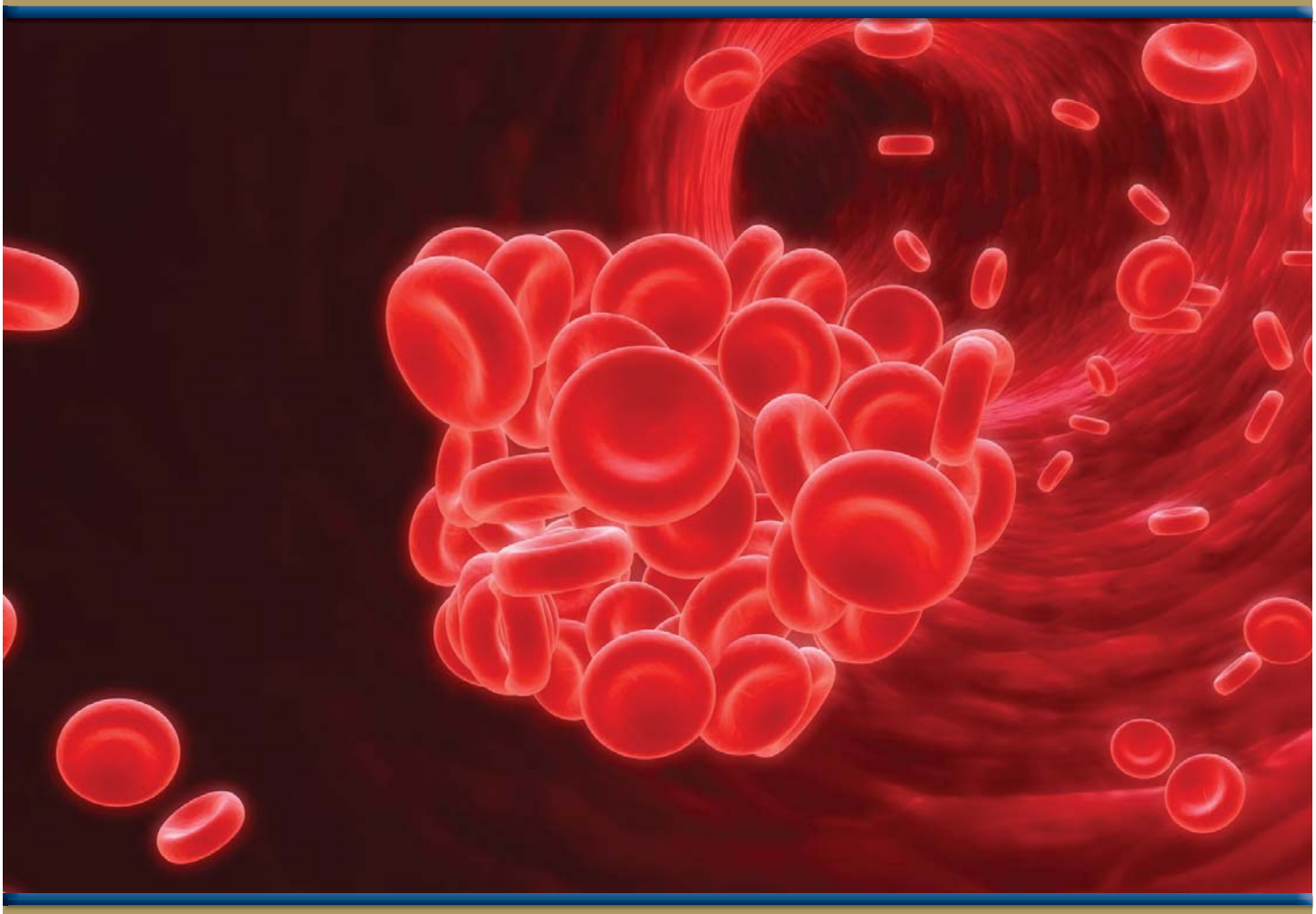
SCIP Surgical Care Improvement Project
A National Quality Partnership

Venous Thromboembolism & Prophylaxis In the Surgical Patient

A SCIP Quality Measure Self-Learning Module for Hospital Staff



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Sections & Topics Covered

(Main sections & topics are hyperlinks)

Module Abbreviations

As you go through the following educational module, feel free to refer to the list of important clinical and quality improvement abbreviations found in Table 1.

Table 1: Module Abbreviations

Module Abbreviations			
AAOS	American Academy of Orthopaedic Surgeons	**LMWH**	low molecular weight heparin
ABC	Achievable Benchmarks of Care	**NPSG**	National Patient Safety Goals
ACCP	American College of Chest Physicians	**NQF**	National Quality Forum
AHA	American Heart Association	**PE**	pulmonary embolism
CMS	Centers for Medicare & Medicaid Services	**SCIP**	Surgical Care Improvement Project
DVT	deep vein thrombosis	**THA**	total hip arthroplasty
ESRD	end stage renal disease	**THR**	total hip replacement
GCS	graduated compression stockings	**TKA**	total knee arthroplasty
HAC	hospital-acquired condition(s)	**TKR**	total knee replacement
HAM	high-alert medication	**UFH**	unfractionated heparin
HIT	heparin induced thrombocytopenia	**VFP**	venous foot pump
IPC	intermittent pneumatic compression	**VTE**	venous thromboembolism
LDUH	low-dose unfractionated heparin		

Learner Objectives

Upon completion of the module the learner will be able to:

1. List and explain the Centers for Medicare & Medicaid Services' Surgical Care Improvement Project venous thromboembolism measures.
2. Describe the pathophysiology of thrombogenesis and Virchow's triad.
3. Identify the top risk factors for venous thromboembolism.
4. Explain the symptoms of deep vein thrombosis and pulmonary embolism.
5. Describe two noninvasive and two invasive tests used to diagnose deep vein thrombosis and pulmonary embolism.
6. Identify the three types of most commonly used anticoagulant drugs in venous thromboembolism prophylaxis.
7. List three mechanical methods used to prevent venous thromboembolism.
8. Describe heparin-induced thrombocytopenia.
9. Describe the financial and quality-of-life impact of venous thromboembolism.
10. Discuss some of the frequent objections to the use of anticoagulants and evidence-based responses and successful strategies.

Scenario #1: *Ms. A is a 60-year-old woman who is three days post-operative following a right total hip replacement. Her height is 5 feet 5 inches and her weight is 187 pounds. She has not been willing to ambulate in the hall but insists on staying in bed. While in bed she has refused to wear the compression devices ordered. Her home medications include estrogen for hormone replacement. Upon examination Ms. A has swelling in her right calf and increased warmth in her leg, along with tenderness and redness.*

Consider:

- What do you think could be causing the right calf swelling, warmth, tenderness, and redness?
- What are some of the risk factors for her possible diagnosis?

Introduction

Venous thromboembolism (VTE) is a medical condition that includes deep vein thrombosis (DVT) and pulmonary embolism (PE). In VTE a clot forms (thrombus) in a vein (venous) and then breaks free and travels (embolism) through the venous system. DVT is the formation of one or more clots in one of the large deep veins, usually in the lower extremities and sometimes in the pelvis. One of the potential complications of DVT is a PE in which part of the clot breaks loose and travels in the venous system through the heart and into the lungs. Both DVT and PE require additional medical interventions, increased lengths of hospital stays, and potentially decreased quality of life, all of which lead to increased costs.

With the release of the Fiscal Year 2009 Medicare Final Rule (release date: July 31, 2008),[1] VTE following total knee replacement (TKR) and total hip replacement (THR) was added to the list of hospital-acquired conditions (HACs). Starting October 1, 2008, as a result of the HAC category, hospitals can face non-payment of costs associated with the treatment of a hospital-acquired DVT or PE following knee or hip surgery. The development of an HAC condition also has potential legal ramifications, such as malpractice lawsuits. Additionally, HACs have public reporting implications based on the availability to the public of measure data, such as on the Medicare Hospital Quality Compare Web site (www.hospitalcompare.hhs.gov).[2]

Despite the increased attention by the Centers for Medicare & Medicaid Services (CMS) and other organizations, including the American College of Chest Physicians (ACCP), along with studies supporting its efficacy, VTE prophylaxis continues to be under-ordered and under-administered. Medical, nursing, and pharmacy staffs, with the support of senior management, need to become more aware of VTE pathogenesis, risk factors, symptoms, diagnosis, and prophylaxis. Initiation of an effective VTE prophylaxis protocol will encounter resistance and varying levels of compliance; however, many facilities have responded to these barriers with successful strategies. These strategies have enabled committed facilities to meet and exceed national goals in the pursuit of patient safety, thereby showing that these goals are attainable.

Terms you will encounter as you read:

Thrombus (plural: thrombi) = a blood clot that forms within a vessel and remains in its original location

Thrombosis (plural: thromboses) = the formation or presence of a blood clot (thrombus) or blood clots (thrombi) inside a blood vessel or cavity of the heart

Embolus (plural: emboli) = a blood clot that forms and moves through the bloodstream to another location in the body

Embolism (plural: embolisms) = the movement of a blood clot or blood clots through the bloodstream to another location in the body

Surgical Care Improvement Project

In the fall of 2003, CMS and The Joint Commission began the Surgical Improvement Project (SIP) to align surgery-related quality improvement measures common to both organizations in order to lessen the data collection activities by hospitals. Subsequently on July 1, 2006, the SIP initiative transitioned to the Surgical Care Improvement Project (SCIP). As of August 1, 2008, CMS, as part of the SCIP initiative, identified nine quality improvement measures.[3] These nine measures represent three areas of preventable surgical complications.

- Surgical infection prevention
- Cardiovascular complication prevention
- Venous thromboembolism prevention

Between August 1, 2008, and July 31, 2011, acute care hospitals are submitting data to CMS on these nine measures. Additionally, select groups of recruited hospitals in each state have implemented quality improvement initiatives, with the assistance of their state's Quality Improvement Organization (QIO), focused on these nine measures.[4] QIOs, under contract with CMS, work with healthcare providers to improve the quality of health for Medicare beneficiaries. The overall national goal for SCIP is to reduce preventable surgical morbidity and mortality by 25 percent by 2010.[5]

The SCIP initiative receives recommendations and support from a Steering Committee of 10 national organizations.[6] The following organizations belong to the Steering Committee:

- Agency for Healthcare Research and Quality
- American College of Surgeons
- American Hospital Association
- American Society of Anesthesiologists
- Association of periOperative Registered Nurses
- Centers for Disease Control and Prevention
- Centers for Medicare & Medicaid Services
- Institute for Healthcare Improvement
- The Joint Commission
- Veterans Health Administration

A technical expert panel—consisting of all the major surgical, medical, and nursing societies—provides additional input including resources utilizing evidence-based research. The recommendations of the SIP/SCIP Steering Committee and technical expert panel take into account the input of the participating organizations and also information included in peer review journals, results of clinical trials, and the availability of drugs.

Surgical Care Improvement Project Venous Thromboembolism Measures

As part of the CMS SCIP initiative, hospitals are tracking two VTE measures aimed at VTE prophylaxis, as indicated in Table 2:

Table 2: CMS VTE Measures

Measure Name/ID #	Measure Short Name/Description
SCIP-VTE-1	Surgery Patients with Recommended VTE Prophylaxis Ordered
SCIP-VTE-2	Surgery Patients Who Received Appropriate VTE Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery

Detailed information regarding these two VTE measures is available in the *Specifications Manual for National Hospital Inpatient Quality Measures*.[7] The *Specifications Manual* provides additional detail in the description section for each measure:

- **SCIP-VTE-1** – Surgery patients with 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.

CMS and The Joint Commission collaborate to produce the versions of the *Specifications Manual* with the goal of establishing a uniform set of national hospital quality measures for use by hospitals and their vendors. Note that the *Specifications Manual* is currently updated every 6 months with new versions published to cover discharge time frames starting every April 1st and October 1st. Current and previous versions of the *Specifications Manual* are available at the QualityNet Web site http://www.qualitynet.org/, under the Hospitals – Inpatient tab. Throughout this module all references to the *Specifications Manual* are taken from the *Specifications Manual* (Version 3.1a) for discharges April 1, 2010 (2Q10) through September 30, 2010 (3Q10) available at http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228749003528.[8]

For the SCIP-VTE measures, the *Specifications Manual* provides the criteria for including which surgical patients into the denominator for the two measures.[9] The criteria include those surgical patients who undergo surgery lasting more than 60 minutes and whose hospital length of stay is more than 3 days. Therefore, excluded from the SCIP-VTE measures are patients whose total surgery time is equal to or less than 60 minutes and whose hospital length of stay is equal to or less than 3 calendar days. To calculate the surgical time, the anesthesia start date and time are compared to the anesthesia end date and time. A three-day length of stay is defined as at least two nights in the hospital using the admission date and discharge date for the calculation. Therefore, the SCIP-VTE measures do not necessarily cover all patients that could benefit from VTE prophylaxis.

Patient populations excluded from the VTE measure include pediatric patients (less than 18 years of age), fully ambulatory behavioral health patients, and obstetric patients. Also, the SCIP-VTE measures exclude patients who have a hospital length of stay more than 120 days, burn patients, patients with procedures performed entirely by laparoscope, and patients who are on warfarin prior to admission.

This does not mean that these patients are free from VTE risks, and as a result, they too could benefit from VTE prophylaxis. The SCIP Technical Expert Panel's recommendations were based on consensus covering most surgical procedures. The type of surgery performed, the type of prophylaxis selected, and the patient risk factors identified influence the individual clinical decisions. Although a patient may not meet the criteria for SCIP-VTE prophylaxis, the clinician can still make the decision to order VTE prophylaxis with clarification of need documented in the medical record. Patients who have reasons for not receiving either mechanical or pharmacological prophylaxis are also excluded; however, there must be clear physician documentation of the reason in the medical record.

The *Specifications Manual* includes the following rationale in support of the appropriate ordering and administering of VTE prophylaxis as part of the CMS SCIP quality improvement project[10]:

- Over 30 million surgeries are performed in the United Status annually.
- Evidence shows that VTE is one of the most common postoperative complications.
- Prophylaxis is the most effective strategy to reduce morbidity and mortality.
- Frequency of VTE is related to the type and duration of surgery, patient risk factors, and duration and extent of postoperative immobilization.

The National Quality Forum (NQF), a national non-profit organization bringing together private and public sector stakeholders, has endorsed the two SCIP-VTE measures since May 2006 (NQF-Endorsed Standards # 0217 and #0218).[11]

For 1st Quarter 2009 (January-March 2009), the Achievable Benchmarks of Care (ABC)[12] that define the best-in-care performance received by the top 10 percent of patients in the United States for SCIP-VTE-1 and SCIP-VTE-2 are listed in Table 3.[13]

Table 3: 2009 First Quarter Benchmarks for Hospital-Abstracted SCIP Data

Performance Measure	Benchmark (%)
SCIP-VTE1: Recommended VTE Prophylaxis Ordered During the Admission	99.7%
SCIP-VTE2: Received VTE Prophylaxis within 24 Hrs Prior to or After Surgery	99.4%

The ABC benchmarks represent actual, achieved results rather than theoretical goals. The U.S. hospitals providing this level of best-in-care by meeting or exceeding these benchmarks serve as proof that this quality of care is possible.

The Joint Commission Venous Thromboembolism Measures

The CMS SCIP initiative is not alone in focusing on VTE prophylaxis. The Joint Commission has developed additional VTE measures in response to the National Consensus Standards for the Prevention and Care of Deep Vein Thrombosis Project.[14] The project began in January 2005 as a joint effort with NQF. Following testing and review, NQF endorsed the six VTE measures in May 2008. The six measures are aligned with the CMS measures and are available in the *Specifications Manual* in Section 2.7 with a link to The Joint Commission Web site.[15] Note that at this time, these six measures, as listed in Table 4, are reported to The Joint Commission; however, they are only for CMS informational purposes.

Table 4: The Joint Commission VTE Measures

Measure Name/ID #	Measure Short Name
VTE-1	Venous Thromboembolism Prophylaxis
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis
VTE-3	Venous Thromboembolism Patients with Anticoagulation Overlap Therapy
VTE-4	Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol
VTE-5	Venous Thromboembolism Discharge Instructions
VTE-6	Incidence of Potentially-Preventable Venous Thromboembolism

Hospitals that have earned The Joint Commission accreditation report data to The Joint Commission on all six of these VTE measures, in addition to reporting on the two CMS-selected SCIP-VTE measures. As mentioned before, CMS and The Joint Commission collaborate in regard to identifying quality improvement measures with the goal of establishing a uniform set of measures for use by hospitals and their vendors. Additionally, The Joint Commission includes anticoagulation therapy among its Patient Safety Goals – NPSG.03.05.01: "reduce harm associated with anticoagulation therapy." This patient safety goal for anticoagulation therapy does not apply to short-term use associated with surgical prophylaxis; however, the goal provides additional focus on the importance of patient safety initiatives.[16]

Other national organizations, such as the American Heart Association (AHA), are also focusing attention on the prevention of VTE. This organization's *Statistical Fact Sheet 2008 Update*[17] provides detailed statistics including the incidence of VTE, DVT, and PE, frequency in different population groups, risk factors, and mortality rates.

Pathogenesis of Venous Thromboembolism

VTE is a medical condition in which a clot forms (thrombus) in a vein (venous) and then breaks free and travels (embolism) through the venous system. VTE includes two conditions, DVT and PE. DVT is the formation of one or more clots in one of the large deep veins, usually in the lower extremities and sometimes in the pelvis, resulting in partial or complete blockage of blood flow. One of the potential complications of DVT is a PE in which part of the clot breaks loose and travels in the venous system through the heart and into the lungs blocking the blood supply within the lungs. PE is a potentially life-threatening condition. DVTs usually form in the proximal veins of the leg. In some cases, a PE may actually originate within the lungs. Postoperatively, thromboses are common but usually break up without intervention. Both DVT and PE require additional medical interventions, increased lengths of hospital stays, and potentially decreased quality of life, all of which lead to increased costs.

Virchow's Triad

Blood is a fluid while it passes through arteries and veins. Anything that alters the speed and force of the blood flow can result in blood becoming a solid (a blood clot). An analogy is to think of a blood vessel as a water hose.[18] Water normally flows through the hose smoothly without any difficulty. However, kink the hose or get dirt inside the hose and the water flow slows down and may become blocked.

Virchow's triad presents the three main causes for blood to clot while still in a blood vessel.[19,20] The triad is named for Rudolf Virchow, a German physician/pathologist (1821-1902), who proposed the origins for thrombus formation found in Table 5.

Table 5: Virchow's Triad

Virchow's Triad: Causes of Thrombosis
1. Changes in the vessel wall can develop as a result of endothelial damage or injury from surgery, prior VTE, central line use, or injection of irritating substances such as chemotherapy.
2. Changes in the blood flow can develop due to immobility, obesity, varicose veins, stroke, and anesthesia.
3. Changes in the blood composition (i.e., hypercoagulability) can result from medications such as estrogens and medical conditions such as cancer, nephrotic syndrome, sepsis, thrombophilia, pregnancy, smoking, obesity.

Platelet activation occurs in response to damage to the blood vessel wall such as mechanical damage associated with surgery, especially orthopedic or abdominal surgery. The platelets adhere to each other and form a thrombus (clot). The thrombus either dissolves over time or grows and becomes large enough to block a vessel. Pieces of the thrombus can break off and

move, becoming an embolus. Once the thrombus and/or embolus forms and causes a blockage, the blood behind the blockage slows, resulting in pooling of the blood and the formation of additional clots.

Venous Thromboembolism Incidence: A Leading Source of Morbidity & Mortality

Statistics vary greatly regarding the level of morbidity and mortality associated with VTE; however, the available statistics highlight the severity of VTE and VTE-associated complications in the U.S. For example, in 2008 the U.S. Department of Health and Human Services issued "The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism." This document included the following statistics[21]:

- **Out of a U.S. population of about 300 million, at least 350,000 and as many as 600,000 cases of DVT/PE occur annually.**
- In 1991, about 270,000 Americans were hospitalized with DVT/PE—about 170,000 new cases and 99,000 recurrent cases.
- More than half of the DVT/PE cases that occur are never diagnosed.
- In a study of nursing home patients, PE was correctly diagnosed in only 39 to 50 percent of patients before death and subsequently was confirmed by autopsy.
- As the average age of the U.S. population increases, without better prevention, the increase in DVT/PE cases will grow faster than the increase in population.
- Together DVT and PE may cause more than 100,000 deaths per year.
- Approximately 20 percent of PE patients die almost immediately and 40 percent die within 3 months.
- For both DVT and PE, approximately 30 percent of patients die within 3 months of onset.
- Approximately 30 percent of DVT patients will have a recurrence within the next 10 years with the highest risk of recurrence in the first two years.
- Patients with symptomatic PE tend to have a higher risk of VTE recurrence than patients with DVT symptoms alone.

VTE is closely associated with current and recent hospitalizations. A retrospective review of the medical records of 911 residents of Olmsted County, Minnesota, who had had a case of DVT or PE between 1980 and 1990, identified that, for hospitalized patients, the incidence of VTE was 100 times greater than that of non-hospitalized, community residents.[22] Patients undergoing major surgery such as hip or knee joint replacement surgery or laparoscopic surgery, with resulting immobility, are at an increased risk of developing VTE unless prophylaxis is provided, as illustrated in Table 6.[23] The data, which show "rates based on objective diagnostic screening for asymptomatic DVT" in patients not receiving thromboprophylaxis, highlight the risk for surgical patients.

Table 6: Risk of DVT in Hospitalized Surgical Patients With No Prophylaxis*

Patient Group	DVT Incidence
Major gynecological/urological/general surgery	15% - 40%
Neurosurgery	15% - 40%
Hip/knee surgery	40% - 60%
Major trauma	40% - 80%
Spinal Cord Injury	60% - 80%

* Rates based on objective diagnostic screening for asymptomatic DVT

Venous Thromboembolism Risk Factors

A wide variety of demographics, pre-existing conditions and concurrent factors are associated with increased risks for the development of VTE in surgical patients. One of the greatest risks is the surgical procedure itself. Many patients undergoing surgery are already unhealthy. Surgeries, such as hip and knee replacement, can result in vascular damage. The use of anesthesia can activate the coagulation factors in blood. Longer surgeries, more than 30 to 45 minutes, increase the risks. Post-surgical traction, casts, immobility, and periods of bed rest further increase the VTE risks. The majority of surgical patients have at least one risk factor in addition to the surgery itself and the risk factors are cumulative.

Pre-existing Risk Factors for Venous Thromboembolism

The following list of risk factors, discussed by a number of sources, represents the main risk factors.[24,25,26,27,28] However, the list is not all inclusive. There are additional risk factors that are not listed.

Demographic

- Increasing age - risk rises steadily from age 40

Pre-existing Clinical/Physical/Medical Conditions

- Prolonged immobility or restricted mobility (acute illness, bed rest, paralysis of legs, plaster casts)

Chronic or Acute Illnesses

- Cancer and cancer therapy
- Cardiac problems, such as heart failure
- Systemic lupus erythematous
- Infection
- Microalbuminuria associated with end stage renal disease (ESRD)
- Stroke
- Nephrotic syndrome
- Trauma
- Inflammatory bowel syndrome
- Atherosclerosis

Prior Medical History

- History of DVT or PE
- Inherited or acquired predisposition to clotting
- Obesity
- Pregnancy and postpartum period
- Oral contraceptive or hormone replacement with estrogen
- Varicose veins

Surgery as a Risk Factor for Venous Thromboembolism

As previously indicated, among the greatest risks for VTE is the trauma associated with surgery, especially orthopedic surgery involving the hips and knees, major surgery lasting longer than 30 to 45 minutes, and surgery associated with extensive dissection and manipulation. Hospitalization, even without surgery, is a risk factor. Even the fully ambulatory hospitalized patient experiences a decrease in activity, compared to normal daily levels, due to increased periods of lying in bed or sitting in a chair.

Much of the literature regarding VTE prophylaxis and risk factors uses the surgical time frame of 30 to 45 minutes as a risk factor for VTE. As discussed in a previous section regarding the SCIP –VTE measures, for these measures, the criteria for including surgical patients in the denominator for the measures are those surgical patients who undergo surgery lasting more than 60 minutes and whose hospital length of stay is more than 3 days. Therefore, excluded from the SCIP-VTE measures are patients whose total surgery times are equal to or less than 60 minutes and whose hospital lengths of stay are equal to or less than 3 days. To calculate the surgical time, the anesthesia start date and time are compared to the anesthesia end date and time. A three-day length of stay is defined as at least two nights in the hospital using the admission date and discharge date for the calculation. Note that the SCIP-VTE measures do not necessarily cover all procedures that could benefit from VTE prophylaxis. The SCIP Technical Expert Panel's recommendations were based on consensus that would cover most surgical procedures. The type of surgery performed, the type of prophylaxis selected, and the patient risk factors identified influence the clinical decisions. Although a patient may not meet the SCIP criteria for VTE prophylaxis, the clinician can still make the decision to order a selected prophylaxis option.[9]

As illustrated in Table 7, most hospitalized patients have at least one risk factor for VTE and risk factors are **cumulative**.[29]

Table 7: Cumulative Effect of VTE Risk Factors

Number of Risks Factors	Proportion of Patients With DVT (%)
1	11%
2	24%
3	36%
4	50%
5	100%

Taking into consideration that there are numerous risk factors for VTE, that surgery itself presents a risk, and that risk factors are cumulative, many hospitals have implemented the use of VTE risk assessments. Table 8 shows an example of a risk-level assessment system.[18]

Table 8: Surgical Patients at Risk for VTE

Risk Level	Patient Population
Highest	• Patients undergoing hip or knee surgery • Patients with multiple risk factors • Patients with major trauma
High	• Patients older than 60 years • Patients ages 40-60 years with additional risk factors
Moderate	• Patients with additional risk factors undergoing minor surgery • Patients ages 40-60 years with no additional risk factors
Low	• Patients less than age 40 years with no additional risk factors undergoing minor surgery

It is important to note that the use of VTE risk assessments has not been validated in clinical trials, and there is no standard agreement regarding what to do with the results or number of points produced, in regard to the degree of risk represented and the associated choice of VTE prophylaxis. Additionally, there is lack of consensus regarding which staff member—physician or nurse—should be responsible for performing the risk assessment. Subsequently, there is the challenge of getting the physician to comply with the results of the risk assessment if it has been performed by the nurse. As a result, many VTE experts do not support the use of VTE risk assessments.

Symptoms of Venous Thromboembolism: Deep Vein Thrombosis & Pulmonary Embolism

Scenario #2: *Ms. A is a 60- year-old woman who is three days post-operative following a right total hip replacement. Her height is 5 feet 5 inches and her weight is 187 pounds. She has a 20-year history of smoking one pack a day. She has not been willing to ambulate in the hall but insists on staying in bed. Ms. A has developed shortness of breath and is agitated. The clinicians believe these symptoms are related to her smoking history. Later in the day, blood gas analysis shows that her oxygen saturation (SaO_2) has dropped significantly. She codes during shift change. The autopsy shows a massive PE.*

Consider:

- What other symptoms should you have looked for as part of your assessment?
- Before the code and autopsy, what additional causes of her symptoms should have been considered?

Often the individual with VTE will exhibit no symptoms.[30] In over half of DVT cases, there are no symptoms. For PEs, it is estimated that 80 percent occur without signs or symptoms, yet 1 in 100 hospitalized patients will die following a PE and two-thirds of deaths occur within 30 minutes. Signs and symptoms appear when there is an obstruction to the venous blood flow due to the blood clot becoming a DVT or the blood clot moving into the pulmonary circulation, becoming a PE. Since patients with VTE are frequently asymptomatic while they are in the hospital, the very first symptom may be a death that occurs after the patient has gone home. As a result, the hospital staff does not see the development of VTE as an issue for which they are responsible. This situation leads to the objection "my patients never develop VTEs" voiced by many physicians. Table 9 summarizes the signs and symptoms of VTE, classified as DVT and PE.[31]

Table 9: Signs and Symptoms of VTE

DVT	PE
Swelling of the calf, ankle, foot or thigh with increased extremity circumference	Sharp chest pain, worse during deep breathing
Tenderness or pain in the calf or thigh	Shortness of breath (dyspnea) and/or rapid breathing (tachypnea)
Purple or blue discoloration of the skin on the leg	Coughing up of blood (hemoptysis)
Increased warmth of the leg	Rapid heart rate (tachycardia)
Redness of the skin (erythema)	Feeling faint/anxious
	Sweating (diaphoresis) [added to table]

Diagnosis of Venous Thromboembolism: Deep Vein Thrombosis & Pulmonary Embolism

The signs and symptoms of VTE are very similar to those associated with many other medical conditions. The clinical symptoms of lower extremity DVT, such as leg swelling and pain, can be confused with other conditions including cellulitis, musculoskeletal injury, and lymphedema.[32] As a result, making the diagnosis of VTE can be challenging. However, the accurate and timely diagnosis of VTE is crucial since, untreated, a VTE can lead to a DVT or PE, resulting in severe illness, post-event medical problems, permanent impairment, and death. As a consequence of undiagnosed DVTs, more than 60,000 Americans die annually from resulting PEs.[33]

An accurate diagnosis of DVT requires more than the patient history and physical examination. Prior to performing diagnostic testing, calculating the pre-test probability of DVT/PE is useful. One example of the probability calculation is performed based on scoring for the presence of the following [34]:

- Active cancer
- Paralysis/paresis/recent plaster immobilization of lower extremities
- Bed rest for more than 3 days or major surgery within 4 weeks
- Localized tenderness in the region of the deep venous system
- Swelling of the calf and thigh
- Calf swollen 3 cm more than asymptomatic side
- Pitting edema in the symptomatic leg
- Dilated superficial veins (non-varicose)
- Previously documented DVT

Each positive finding is scored as a "1" for a possible total of "9." Then, if an alternative diagnosis is as likely as or more likely than DVT, a "2" is subtracted from the total. If the score is 1 or less, the probability of DVT is low; if the score is 2 or more, the probability of DVT is high. The resulting score assists the physician in determining the next steps in regard to diagnostic tests and treatment approaches. While a pre-test is useful, it is limited by the level of subjectivity and experience of the examiner.

Diagnostic Tests
For Deep Vein Thrombosis & Pulmonary Embolism

The use of contrast venography for diagnosing a DVT and pulmonary angiography for diagnosing a PE are considered the "gold standard" for confirming the diagnosis.[35, 36] However, despite being the "gold standard," contrast venography and pulmonary angiography are rarely used today due to the invasive nature of these two tests and the associated disadvantages. Therefore, contrast venography and pulmonary angiography are usually not the first diagnostic tests when a DVT or PE is suspected. These two tests are primarily used when the diagnosis remains questionable following noninvasive tests.

Non-Invasive Diagnostic Tests

A number of non-invasive tests are currently available for diagnosing the presence of a DVT or PE. Some of these tests are specific to the diagnosis of either a DVT or a PE, while others can diagnose, or provide assistance, in the diagnosis of both a DVT and PE. Each test has advantages and disadvantages. Different diagnostic approaches are recommended, depending on the experience of the clinician, the perceived sensitivity and specificity of the tests, the suspected location of the DVT or PE, and the medical condition of the patient.[33, 36]

Compression Ultrasonography (used for DVT testing)

This non-invasive test combines real-time imaging of the deep veins of the upper and lower extremities with venous compression.[33] For the lower extremity, the patient is supine with the head elevated 10 to 20 degrees, the leg positioned with the knee slightly bent, and the hip slightly rotated externally.

Advantages -

- Is noninvasive
- Provides 89% to 100% sensitivity for symptomatic DVT

Disadvantages -

- Lacks standardized techniques
- Is potentially limited in use by morbid obesity, severe edema, casts, other immobilization devices
- Exhibits variation or limitations in sensitivity and specificity, depending on location of thrombosis such as iliac vein thrombi

Magnetic Resonance Imaging (used for DVT testing)

The test uses a powerful magnetic field to align the nuclear magnetization of hydrogen atoms in water in the body to construct an image of the different layers of soft tissue of the body.[33]

Advantages -

- Is effective in diagnosis of pelvic or inferior vena cava DVT
- Is as effective as venography in diagnosing DVT in the thigh
- Is noninvasive
- Enables simultaneous visualization of both legs

Disadvantages -

- Is expensive
- Is not always readily available
- Cannot be used if patient has implants (pacemaker, etc.)
- Has potential for claustrophobia when using closed MRI

Impedance Plethysmography (used for DVT testing)

The procedure[35,37,38] detects changes in blood volume in the leg as a change in electrical resistance or electrical impedance between two probes with use of a pressure cuff. The pressure cuff is first inflated, and then the cuff pressure is decreased or released. In a normal leg, rapid venous outflow occurs; in a leg with a venous thrombosis, the venous emptying is slow.

Advantages -

- Is non-invasive
- Can be used to detect blood clots in the deep veins of the leg (DVT) and the source of blood clots in the lungs (PE)

Disadvantages -

- Does not accurately indicate the presence or absence of partially obstructing thrombi in major vessels
- Has limitations in accuracy - can be affected by factors such as patient not breathing normally or not keeping leg muscles relaxed

Pulmonary Ventilation/Perfusion Scan (VQ Scan) (used for PE testing)[39,40]

This test consists of two scans using radioisotopes and measures air (ventilation) and blood (perfusion) flow throughout the lungs. If a chest radiography is normal, the VQ scan can be diagnostic by diagnosing or excluding PE.

Advantages -

- Is relatively painless and risk free
- Utilizes amount of radiation equal to about the same exposure amount naturally experienced in one year

Disadvantages -

- Has limits in findings - may be inconclusive in patients with lung disease, etc., may require additional tests
- May result in rare allergic reaction to the radioactive materials used
- May cause claustrophobia due to mask used for ventilation

D-Dimer Test (used for DVT and PE testing)

D-dimer is a protein fragment present in the blood after a blood clot has been broken down by fibrinolysis. The D-dimer test is a non-invasive procedure[32] that measures the presence of D-dimer in the blood associated with the formation and break-down of a clot. Small amounts of D-dimer are normally present in the blood of healthy individuals. However, when coagulation and fibinolysis are activated, such as with DVT, D-dimer concentration increases significantly.

Advantages -

- Is non-invasive test for suspected DVT or PE
- Is inexpensive and rapid, which makes it useful in ambulatory care and emergency patients
- Can eliminate the need for more expensive, time-consuming, and/or invasive imaging studies

Disadvantages -

- Provides availability of more than 30 different D-dimer assays utilizing different techniques
- Can vary greatly in resulting values depending on which assay is used and the associated calibration
- Lacks currently established reference method or standard universal calibrator, resulting in potential false-positives
- Can give positive results following surgery with or without presence of DVT or PE
- Requires confirmation of renal function

Duplex or Doppler Ultrasonography (used for DVT, presumptive PE testing)

In this test,[41,42,43] projected sound waves are bounced off leg structures to create images of abnormalities. With the addition of color, Doppler imaging accuracy improves.

Advantages -

- Is noninvasive and painless
- Requires no radiation; can be repeated regularly
- Is less costly than venography

Disadvantages -

- Requires skilled operator for accurate results
- Is less sensitive in detecting thrombi in calf and has limited ability to image pelvic deep veins

Computed Tomography Angiogram (CTA) (used for PE testing; can be extended to DVT testing)[44,45]

If the chest radiography is abnormal, CTA should be performed. This test requires the use of iodinated contrast agents.

Advantages -

- Can evaluate both mediastinal and parenchymal structures
- Shows emboli directly
- Is noninvasive, inexpensive, and widely available
- Provides significant additional information related to alternate diagnoses; can establish specific reason for symptoms and additional diagnoses
- Can be easily adapted for CT venography for DVT presence

Disadvantages -

- Requires contrast materials – use may not be possible in patients with impaired renal function or severe allergy to the contrast material
- May miss small, peripheral emboli
- Requires radiation exposure, with associated radiation risk, especially with repeated testing

Invasive Diagnostic Tests

As previously discussed, the contrast venography and pulmonary angiography are rarely used today due to the invasive nature of these two tests and the associated disadvantages. They are usually not the first diagnostic tests performed and are primarily used when the diagnosis remains questionable following noninvasive tests.

Contrast Venography (used for DVT testing)

The procedure utilizes the injection of contrast material through insertion of an IV into a vein in the top of the foot.[33]

Advantages -

- Provides image of deep veins in the calf up to the groin; blood clots not actually visualized but seen as "filling defects" in the dye-filled vessels

Disadvantages -

- Is invasive – causes patient pain, may cause injury to venous system
- May cause allergic reactions, urticaria, bronchospasm, cardiovascular collapse, or extravasation associated with intravenous contrast
- Represents risk for patients with poor renal function and risk of kidney injury
- Requires delivery of contrast into foot vein, resulting in potentially difficult access or lack of venous access
- Is expensive and time-consuming

Pulmonary Angiography (used for PE testing)

Similar to contrast venography,[46] this procedure uses contrast material and X-rays to see how blood flows through the lungs. The catheter is inserted through a small incision in a vein, usually in the arm or groin. The catheter is moved into and through the heart chambers into the pulmonary artery.

Advantages -

- Highlights blockages in blood flow

Disadvantages -

- Is invasive
- May cause abnormal cardiac rhythm, allergic reaction to contrast material, blood vessel damage, blood clots with resulting embolism, and excessive bleeding

Venous Thromboembolism Prophylaxis Options

The main goals of VTE prophylaxis are to stop a clot from forming or growing and to reduce the chance of another clot developing. VTE prophylaxis treatment focuses on the appropriate selection of pharmacological and non-pharmacological/mechanical approaches, based on the individual patient's risk factors and type of surgery.[21] One element of VTE prophylaxis is early ambulation following surgery. However, physician orders such as "bathroom privileges" or "ambulation as tolerated" generally do not result in sufficient activity and associated prophylaxis. Therefore, in addition to ambulation, VTE prophylaxis options, in most cases, need to include pharmacological and/or non-pharmacological/mechanical options. Table 10 summarizes the options for VTE prophylaxis,[47] using information from the *Specifications Manual* for hospital discharges April 1, 2010 through September 30, 2010.

Table 10: VTE Prophylaxis Options

Pharmacological Options	Non pharmacological/Mechanical Options
Low-dose unfractionated heparin (LDUH)	Intermittent pneumatic compression (IPC)
Low molecular weight heparin (LMWH) or Factor Xa Antagonist	Graduated compression stockings (GCS)
Warfarin	Venous foot pump (VFP)
Oral Factor Xa Inhibitor (Rivaroxaban)	

Table 11, as found in the *Specifications Manual*, provides guidance in the appropriate selection of pharmacological and non-pharmacological/mechanical prophylaxis approaches for surgical patients.[7] As previously discussed, the SCIP initiative receives recommendations and support from a National Expert Panel/Steering Committee whose participants include CMS, The Joint Commission, and all the major surgical, medical, and nursing societies. Their recommendations take into account the practice guidelines of the major surgical specialties, including the ACCP. As a result, certain approaches, such as the inferior vena cava filter, are not included among the current options.

Table 11: VTE Prophylaxis Options for Surgery

Surgery Type	Recommended Prophylaxis Options
Intracranial neurosurgery	Any of the following: • Intermittent pneumatic compression devices (IPC) with or without graduated compression stockings (GCS) • Low-dose unfractionated heparin (LDUH) • Low molecular weight heparin (LMWH)* • LDUH or LMWH* combined with IPC or GCS
General surgery	Any of the following: • Low-dose unfractionated heparin (LDUH) • Low molecular weight heparin (LMWH) • Factor Xa Inhibitor (Fondaparinux) • LDUH or LMWH or Factor Xa Inhibitor (Fondaparinux) combined with IPC or GCS
General surgery with a reason for not administering pharmacological prophylaxis	Any of the following: • Graduated compression stockings (GCS) • Intermittent pneumatic devices (IPC)
Gynecologic surgery	Any of the following: • Low-dose unfractionated heparin (LDUH) • Low molecular weight heparin (LMWH) • Factor Xa Inhibitor (Fondaparinux) • Intermittent pneumatic compression devices (IPC) • LDUH or LMWH or Factor Xa Inhibitor (Fondaparinux) combined with IPC or GCS
Urologic surgery	Any of the following: • Low-dose unfractionated heparin (LDUH) • Low molecular weight heparin (LMWH) • Factor Xa Inhibitor (Fondaparinux) • Intermittent pneumatic compression devices (IPC) • Graduated compression stockings (GCS) • LDUH or LMWH or Factor Xa Inhibitor (Fondaparinux) combined with IPC or GCS
Elective total hip replacement	Any of the following started within 24 hours of surgery: • Low molecular weight heparin (LMWH) • Factor Xa Inhibitor (Fondaparinux) • Warfarin • Oral Factor Xa Inhibitor (Rivaroxaban)
Elective total knee replacement	Any of the following started within 24 hours of surgery: • Low molecular weight heparin (LMWH) • Factor Xa Inhibitor (Fondaparinux) • Warfarin • Intermittent pneumatic compression devices (IPC) • Venous foot pump (VFP) • Oral Factor Xa Inhibitor (Rivaroxaban)

Surgery Type	Recommended Prophylaxis Options
Hip fracture surgery	Any of the following: • Low-dose unfractionated heparin (LDUH) • Low molecular weight heparin (LMWH) • Factor Xa Inhibitor (Fondaparinux) • Warfarin • Oral Factor Xa Inhibitor (Rivaroxaban)
Elective total hip replacement with a reason for not administering pharmacological prophylaxis	Any of the following: • Intermittent pneumatic compression devices (IPC) • Venous foot pump (VFP)
Hip fracture surgery with a reason for not administering pharmacological prophylaxis	Any of the following: • Graduated compression stockings (GCS) • Intermittent pneumatic compression devices (IPC) • Venous foot pump (VFP)

*Current guidelines recommend postoperative LMWH for intracranial neurosurgery.

With the release of *Specifications Manual*, Version 3.1a, for inpatient hospital discharges April 1, 2010, through September 30, 2010, the oral Factor Xa inhibitor rivaroxaban is a new addition to the VTE prophylaxis options for elective total hip replacement (THR), elective total knee replacement (TKR), and hip fracture surgery. As discussed previously, the *Specifications Manual* is currently updated every 6 months with new versions published to cover hospital discharge timeframes starting every April 1st and October 1st. The addition of rivaroxaban illustrates the importance of confirming that the correct version of the *Specifications Manual* and any reference tools correspond to the discharge dates. Current and previous versions are available at the QualityNet Web site http://www.qualitynet.org/ under the Hospitals – Inpatient tab.

Stop To Consider:

How will you remember what surgery is associated with which recommended prophylaxis options?

- Would making copies of Table 11 above listing the prophylaxis options for the appropriate discharge period and posting the copies at the nurses' station and where the doctors write their orders help?
- Would implementation of a VTE prophylaxis protocol and pre-printed orders help?

What other strategies can you think of that would help your hospital improve VTE prophylaxis compliance?

Pharmacologic Prophylaxis with Anticoagulants

Pharmacologic prophylaxis consists of using anticoagulant drugs that bind to antithrombin and inhibit the clotting factors. The treatment approach can include low-dose unfractionated heparin (LDUH), low molecular weight heparin (LWMH), Factor Xa antagonists, or oral anticoagulants. LDUH and LMWH can reduce the development of VTE. LMWH is associated with a lower incidence of heparin-induced thrombocytopenia (HIT) (see section on Additional Consideration: Heparin-Induced Thrombocytopenia). An additional advantage of LMWH over LDUH is its once or twice daily administration compared with the up to three times a day administration of LDUH. Factor Xa antagonist (fondaparinux) only acts on Factor Xa and does not affect platelets; as a result fondaparinux does not cause HIT. As previously noted, rivaroxaban is a newly recommended VTE prophylaxis option for some surgical procedures.

The following bullets summarize some of the key points regarding each pharmacological option:

- LDUH inactivates clotting factors thrombin and Factor Xa. Administration is by intravenous infusion or subcutaneously (two to three times a day). The dosage depends on the patient's activated partial thromboplastin time and platelet count. For patients who have received spinal or epidural anesthesia there is a rare but increased risk of perispinal hematoma; as a result, LDUH should be used with caution. Anticoagulant prophylaxis should be delayed for 2 hours after removal of the spinal needle or catheter.[23, 47, 48]

- LMWH acts on thrombin and is given subcutaneously once or twice a day. The dosage is adjusted based on the patient's weight, the patient's renal functioning, the specific product, and the facility's protocol. LMWH requires daily or every other day monitoring of partial thromboplastin time. Current guidelines recommend postoperative low molecular weight heparin for intracranial neurosurgery. If the patient is going home on LMWH injections, patient education needs to include instruction on the proper technique for subcutaneous abdominal injections, site rotation, and bleeding risks.[23,47,48,49]

- Factor Xa antagonist, fondaparinux, is given subcutaneously at a fixed dose once a day. Patients being discharged on fondaparinux need education on proper injection technique and site rotation. Fondaparinux is excreted unchanged by the kidneys; therefore, it is used with caution in patients with renal insufficiency and is contraindicated in patients with renal failure.[23,47,48]

- Warfarin, an oral anticoagulant, inhibits Vitamin K, which is necessary for the formation of several clotting factors. Warfarin by itself requires 3 to 5 days to take full effect, so overlap therapy, such as with a LMWH, is recommended. At discharge, patient education is extremely important. Education topics include what nutritional supplements can cause increased anticoagulation, what foods can cause decreased anticoagulation, maintenance of a consistent diet, and the importance of regular blood tests to monitor prothrombin time and international normalized ratio (INR).[23]

- The oral direct Factor Xa inhibitor rivaroxaban, newly added to the SCIP prophylaxis options for certain surgeries, restricts thrombin generation. Its advantages include once-daily oral administration and rapid onset of action. A clinical trial has shown efficacy with 10 mg once daily started 6 to 8 hours after surgery. For VTE prophylaxis, continued administration for at least 10 to 14 days after TKR is recommended.[50,51]

Table 12 outlines pharmacological options.

Table 12: A Quick Look at Pharmacological Options

Name	Route	Frequency	Dose	Special Considerations
Low-dose unfractionated heparin (LDUH)	Intravenous or Subcutaneous	Two to three times a day	5,000 IU every 8-12 hours or 7,500 IU every 12 hours subcutaneously; depends on patient's activated partial thromboplastin time and platelet count	Spinal or epidural anesthesia—delay for 2 hours after removal of the spinal needle or catheter
Low molecular weight heparin (LMWH) (Ardeparin, Dalteparin, Danaparoid, Enoxaparin)	Subcutaneous	Once or twice a day	Adjusted based on patient's weight, specific product, facility's protocol, patient's platelet count	Avoid in patients with renal insufficiency; spinal or epidural anesthesia—delay 2 hours after removal of the spinal needle/catheter; instruct in proper technique for subcutaneous abdominal injections and site rotation
Factor Xa antagonist (Fondaparinux)	Subcutaneous	Once a day	Fixed dose – 2.5 mg	Caution in patients with renal insufficiency; contraindicated in patients with renal failure
Warfarin	Oral	Once daily	Dosage monitored by prothrombin time and the international normalized ratio (INR)	Requires 3-5 days to take full effect—overlap therapy with LMWH required to provide adequate prophylaxis
Rivaroxaban	Oral	Once daily	10 mg (found to be optimal dose)	Needs to be continued for 10-14 days post-operative

Post-operative and post-discharge prophylaxis is crucial in the prevention of VTE. According to one reference,[41] as many as 80 percent of patients will develop DVT, and 10 percent to 20 percent will develop PE, if no prophylaxis is provided following major orthopedic surgery. Additionally, this reference emphasized that even with VTE prophylaxis, VTE is the most common cause of hospital readmissions and death following joint replacement. Other sources[21,23] indicated that without appropriate VTE prophylaxis, 40 to 60 percent of patients undergoing major orthopedic surgery develop DVT. Therefore, depending on the type of surgery and the individual patient's risk factors, decisions regarding the type of inpatient prophylaxis used and length of prophylaxis need to be an important part of discharge planning and follow-up.

Non-pharmacologic/Mechanical Prophylaxis

The guidelines established by the CMS SCIP quality improvement project for VTE prophylaxis recommend the use of the following non-pharmacologic or mechanical prophylaxis devices:

- Intermittent pneumatic compression (IPC)
- Graduated compression stockings (GCS)
- Venous foot pumps

The purposes of these devices are to increase venous outflow and to reduce venous stasis. As indicated in the table of VTE prophylaxis options (Table 11), their use is recommended when there is a reason for not utilizing pharmacological prophylaxis due to contraindications or other factors preventing pharmacological options, as in the case of patients with a high risk of bleeding. They are less effective than pharmacologic prophylaxis in preventing VTE and, therefore, are usually used in conjunction with anticoagulants, especially for patients with no or reduced risk of bleeding and/or patients at high risk for VTE.

Intermittent Pneumatic Compression (IPC)[52,53,54]

This form of mechanical prophylaxis uses an air pump to create intermittent pulses of compressed air, inflating and deflating an airtight sleeve or series of chambers beginning at the ankle and moving up the leg. The result is a "milking" effect aiding in venous emptying. IPCs are available in knee and thigh lengths.

Graduated Compression Stockings (GCS)

The stockings, available in knee and thigh lengths, apply pressure on the leg, with the greatest amount of pressure at the ankle and then gradually decreasing pressure moving up the leg. Contraindications to the use of GCS include severe leg edema, skin graft, and leg dermatitis.

Venous Foot Pump[55]

This device stimulates the venous plantar plexus, a large vein located in the foot, to increase blood circulation by reproducing the movement of blood resulting from walking.

IPC and GCS are useful VTE prophylaxis options. However, they must be used consistently by the patient to be effective. Patient compliance is one of the challenges of mechanical prophylaxis. Wearing the devices only intermittently or only during part of the day is not effective. The devices need to be worn the majority of the time, approximately 22 out of 24 hours or 90 percent of the time, with only brief periods of removal per day. Patient education needs to include instruction on the importance of consistent use despite complaints of discomfort. One study[56] evaluated compliance with physician orders regarding compression

device prophylaxis, utilizing a series of six observations during a 24-hour period (two during morning shift, two during evening shift, two overnight) of non-ambulatory trauma patients in their post-admission period in a non-critical care setting. The study considered full compliance as the devices on and functioning during all six observations. Study findings included that the most common periods for non-compliance were midmorning and early afternoon, in almost half of the observations trauma patients at risk for DVT were not receiving mechanical prophylaxis according to physician orders, and fewer than 20 percent of the patients had the devices on and functioning during each of the six observations. The study highlighted the need for hospital staff education and the use of additional prophylaxis options.

IPCs require accurate settings for patient safety and comfort. GCSs require accurate measurements to provide proper fit and to be effective. Knee-high versus thigh-high IPCs are usually recommended because they are easier to put on, do not have the risk of popliteal compression, and are more comfortable.

Key elements in supporting compliance with the use of any of the devices include the following:

- The appropriate device must be available.
- The device must be in working order.
- The staff must know how to use the device.
- The patient must understand the need for the device.

Additional Consideration: Heparin-Induced Thrombocytopenia

Heparin has been in use as an anticoagulant since its introduction by a Canadian research team with the first human trials for surgical procedures conducted in May 1935.[57] Annually, approximately 12 million hospitalized Americans receive some form of heparin.[58] However, heparin is associated with risks and is a high-alert medication (HAM). One consequence of heparin use is paradoxical thrombosis: blood clot formation resulting from the use of heparin referred to as heparin-induced thrombocytopenia (HIT). In the presence of heparin, an immune reaction can lead to platelet activation and thrombocytopenia.

Pathophysiology

- In patients not previously exposed to heparin, HIT develops within 5 to 10 days following the initiation of heparin therapy. In the Complications After Thrombocytopenia Caused by Heparin (CATCH) registry, one-third (36.4 percent) of patients in the prolonged heparin group who received heparin for 96 hours developed thrombocytopenia.[58,59]
- In patients exposed to heparin within the previous 100 days, rapid onset of HIT within 0.5 to 2.8 days can develop due to heparin's interaction with already circulating antibodies.[58]

- The paradox of HIT is that the immune reaction to the administered heparin, in addition to causing thrombocytopenia, can also result in deep vein thrombosis and pulmonary embolism, the conditions the heparin was aimed at preventing.
- In HIT patients with thrombosis, approximately 10 percent require a limb amputation, and the mortality rate is estimated at 17 percent to 30 percent.[59]

Prevalence

- Up to 5 percent of patients receiving unfractionated heparin (UFH) may develop HIT, resulting in morbidity and mortality due to thrombotic complications.[58]
- All surgical procedures, if heparin has been used, are potentially associated with HIT.

Risk Factors

- The strongest risk factor is prior exposure to heparin.
- Additional risk factors include the duration of heparin therapy, especially for more than a week, and the type of heparin (UFH more than LMWH).[59]

Diagnosis

- Platelet count less than 150,000 per microliter of circulating blood or 50 percent or more fall in platelet count from baseline value prior to starting heparin or LMWH is indicative of HIT.
- Presence of HIT antibodies is key in confirming the diagnosis of HIT.[58,59]
- False positive or negative results can occur due to other medications.[59]

Treatment Measures

- In suspected HIT, immediate discontinuation of heparin, both UFH and LMWH is an important first step. The ACCP recommends the elimination of all potential sources of heparin exposure (heparinized catheters, heparin lock flushes, etc).[60]
- Recommendations include discontinuation of other thrombocytopenia causing medications.
- Replacement with a non-heparin anticoagulant such as a direct thrombin inhibitor (lepirudin, argatroban) is recommended for at least 7 days or until a normal platelet count is achieved.[59,60]
- Subsequently, low-dose warfarin therapy should be begun slowly with at least a five-day overlap period with the direct thrombin inhibitor.[59,60]

Costs of Venous Thromboembolism Events

More than one-half of DVTs result in chronic venous insufficiency. After anticoagulation has been discontinued, 30 percent of DVTs recur within 10 years. DVTs can lead to PEs and associated morbidity and mortality. In the case of PEs, 4 percent may evolve into chronic thromboembolic pulmonary hypertension.[61]

Estimates of additional costs to treat patients vary. One calculation[61] indicated the annual estimated cost to treat DVT and PE as the following:

- DVT – $10,800 per patient
- PE – $16,600 per patient
- Recurrence – 20 percent increased hospitalization costs due to increased length of stay
- Plus, time lost from work

Another study examined the discharge summaries and itemized bills from 220 U.S. acute care hospitals for patients undergoing surgery for total hip or knee replacement or hip-fracture repair between January 1998 and June 1999.[62] This study's findings included those listed in Table 13:

Table 13: DVT/PE – Length of Stay Days, ICU Days and Inpatient Care Cost

	Mean LOS Days	Mean ICU Time Days	Mean Inpatient Care Cost
Patient w/o VTE	5.4	0.2	$9,345
Patient w/ DVT	11.5	1.7	$17,114
Patient w/ PE	12.4	2.7	$18,521

MacDougall et al. looked at administrative claims data for patients with a diagnosis of DVT or PE and patients with possible evidence of post-thrombotic syndrome (PTS) between January 1, 1997 and March 31, 2004.[63] The calculations included the cost of resources utilized as well as direct medical costs of care and were compared to a matched control group for a total of 26,958 patients meeting the study inclusion criteria. The study identified the following annualized median costs for inpatient, outpatient, and pharmacy services:

- Patient without DVT or PE – $680
- Patient with DVT – $17,512
- Patient with PE – $18,901
- Patient with DVT and PE – $25,554
- Patient with PTS – $20,569

A study concentrating on PE and associated clinical outcomes and resource utilization looked at patients discharged between 1998 and 2005 with the primary or secondary discharge diagnosis of PE. The study findings concluded that improvements had been made during the eight-year period with a decrease in hospital fatality rates from 12.3 percent to 8.2 percent and decrease in length of hospital stay from 9.4 days to 8.6 days. However, at the same time, total hospital charges increased from $25,293 to $43,740.[64] An estimate of the economic burden placed the annual cost of care for VTE at $1.5 billion.[21]

In addition to the preceding examples of the costs associated with VTE events and the cost benefits derived from VTE prophylaxis, other references provide supporting evidence for the financial and business case for VTE prophylaxis.[65,66,67] Among the current resources for building a business case for VTE prophylaxis is the kit developed by Health Services Advisory Group (HSAG), "VTE Guide for Executive Leadership," available at http://www.hsag.com/services/special/vte.aspx. This resource kit includes strategies for building business and clinical cases for VTE prophylaxis, involving senior leadership, and developing a communication plan.[68]

As previously discussed, with the release of the Fiscal Year 2009 Medicare Final Rule (release date July 31, 2008), VTE following TKR and THR was added to the list of HACs. As a result of the HAC category that began on October 1, 2008, a hospital could find itself treating a hospital-acquired DVT or PE and bearing the entire cost of the treatment.[1]

Venous Thromboembolism Prophylaxis & Quality of Life

Scenario #3: *A gentleman of about 70 is walking in front of you into the grocery store. He walks very slowly and appears to be in pain. His lower right leg appears swollen, with dark reddish-brown areas of hardened, dry skin and sores.*

Consider:

- What do you think could be the problem?
- How do you think his physical condition has affected his quality of life?

Post-thrombotic syndrome,[15,69,70,71] also referred to as post-phlebitic syndrome, is a form of chronic venous insufficiency. This condition is a consequence of DVT in response to the growth of a thrombus that has embedded itself into the vein wall, causing damage to the vein. The result of the damage involves destruction of the valves and enlargement of the vein leading to persistent swelling and pain. Post-thrombotic syndrome may affect 20 percent to 66 percent of patients with DVT, usually within 1 to 2 years following the acute DVT episode.[71]

Characteristics of post-thrombotic syndrome[70,71]:

- Varicose veins
- Pain
- Edema, swelling
- Dark brownish pigmentation around ankle
- Induration, skin hardening
- Skin ulceration, sores
- Pruritis

A patient's quality of life can be decreased due to reduction of physical activity, reduction of the ability to work, and reduction of other activities of daily living.

Venous Thromboembolism Prophylaxis: Level of Use

VTE prophylaxis is underused. The ENDORSE (Epidemiologic International Day for the Evaluation of Patients at Risk for Venous Thromboembolism in the Acute Hospital Care Setting)[72] study looked at surgical patients in 358 hospitals in 32 countries to assess the patients at risk for VTE, based on review of hospital charts. Then, utilizing the 2004 ACCP VTE guidelines, the study determined whether these patients received recommended VTE prophylaxis. Of the surgical patients, 64 percent were determined to be at risk for VTE. However, of the surgical patients considered to be at risk for VTE, only 59 percent received ACCP-recommended prophylaxis. (Note: The study also looked at medical patients. The use of recommended VTE prophylaxis was even lower for medical patients considered at risk for VTE). Another resource highlighted the low compliance with evidence-based VTE prophylaxis despite the large number of randomized trials demonstrating the benefits and the more than 20 practice guidelines, including the American Society of Colon and Rectal Surgeons,[73] recommending VTE prophylaxis since 1986.[23] Abundant evidence-based literature supports the use of VTE prophylaxis.[74] Despite the existence of medical specialty guidelines, increased attention by private agencies and governmental agencies (such as AHRQ),[75] and supporting clinical and investigative data, VTE prophylaxis continues to be underutilized.

The reasons for lack of VTE prophylaxis include the following[76,77]:

- **Physicians**
  - Low awareness of VTE risk factors and incidence
  - Belief that VTE is not a problem in their practice
  - Concern regarding bleeding complications
  - Insufficient knowledge about recommended standards for prevention/numerous guidelines – different specialty guidelines
- **Nurses**
  - Lack of awareness of VTE risk factors, incidence, signs and symptoms
  - Lack of knowledge regarding prevention measures (pharmacologic and mechanical)
  - Lack of confidence in conferring with physicians regarding need for prophylaxis
  - Response to patient/family request to remove mechanical devices (IPCs, etc.)
- **Patients/Family Members**
  - Unawareness of VTE or associated warning signs
  - Lack of knowledge regarding VTE risk factors, incidence, prevention measures
  - Non-compliance with pharmacological and mechanical prophylaxis – concerns regarding comfort and/or convenience

Venous Thromboembolism Prophylaxis: Perceived Barriers and Responses

VTE prophylaxis continues to be underutilized, although patients over age 40 who are given general anesthesia lasting more than 30 to 60 minutes and who have a length of stay greater than 2 to 3 days need some type of prophylaxis. The previous section listed some of the reasons physicians may not utilize the recommended VTE prophylaxis options for surgical patients. Based on FMQAI's experience through quality improvement work with hospitals, Table 14 lists some of the perceived barriers voiced by physicians and the evidence-based responses that the members of the SCIP team, quality improvement staff, or the nursing staff can use to promote VTE prophylaxis.

Table 14: VTE Prophylaxis – Perceived Barriers and Evidence-Based Responses

Perceived Barrier	Response
"I ambulate my patients quickly."	Having bathroom privileges is inadequate for VTE prophylaxis.
"My patients don't get DVT/PE."	Any surgical patient can get a DVT/PE.
"No literature to support VTE prophylaxis."	The literature is extensive and quite clear in supporting VTE prophylaxis.
"Aspirin is just fine for all my patients. It was good enough 30 years ago and is still good enough now."	Aspirin has limited, if any, value in VTE prophylaxis.
"Elastic stockings are all you need."	Elastic stockings (not to be confused with sequential compression devices) by themselves are inadequate for VTE prophylaxis.
"My patient had a bleeding ulcer 10 years ago; it's too risky to give anticoagulants."	History of GI bleeding is not a contraindication for pharmacological prophylaxis.
Conclusion: Patients over age 40, having general anesthesia for more than 30 to 60 minutes and a length of stay greater than 2 to 3 days, need some type of prophylaxis.	

Strategies from the Field

In meeting with and talking to hospital quality improvement teams the concepts and processes that have brought them the most success in improving VTE prophylaxis include the following:

- **Physician Champions**

  Many hospitals have recruited a member of the staff, usually the surgical staff, to act as a physician champion in regard to VTE prophylaxis. Successful physician champions are medical staff members who are well respected by their peers and have the ability to influence attitudes and behaviors in a positive and consistent manner. They are seen as leaders and role models. It is important that they support the goals of the VTE prophylaxis program, are willing to stand up for the ideas of the prophylaxis team, and play an active role in quality improvement initiatives.

- **Standardized Protocols and Pre-printed Orders**

  The use of pre-printed orders has become more frequent in hospitals. The selling point to the physicians is that they help protect the patient, physician, and hospital by supporting VTE prophylaxis. Measure compliance increases significantly when the use of protocols and pre-printed orders is made mandatory.

- **Concurrent Review/Audits/Feedback**

  Among hospitals participating in the current CMS SCIP initiative, the use of concurrent review, along with audits and feedback, has become one of the most effective processes for increasing the use of VTE prophylaxis. The concurrent reviewer can work on a daily basis with the medical and nursing staffs to review charts, identify potential lapses in prophylaxis ordering and administration, and provide support. A potential measure failure is caught before it is too late. Also, the concurrent reviewer can work with the staff to identify "bottlenecks" in the system.

- **Establishment of Physician, Nurse, and Pharmacist Roles and Responsibilities**

  A clear delineation of all staff member roles and responsibilities has helped hospitals in opening the lines of communication. The use of techniques such as huddles and rounding encourage the sharing of concerns and decrease tension. Pharmacy staffs have become increasingly active, providing their expertise in seeing that VTE prophylaxis is ordered appropriately and administered in a timely manner. Quality improvement strategies such as TeamSTEPPS™ (Strategies and Tools to Enhance Performance and Patient Safety)[78] support communication and teamwork among the different staff members involved in patient care.

- **Risk Assessments for "Rule In" versus "Rule Out"**

To identify high-risk patients, some facilities utilize a risk assessment that assigns points corresponding to each risk. One example of a "rule in" risk assessment scoring system is shown in Table 15.[79] Using this system, healthcare professionals add up the points for each risk factor the patient has. A score of more than 4 points indicates a high risk for VTE.

Table 15: VTE Risk Assessment

Risk Factor	Points
Cancer History	3
Prior VTE	3
Hypercoagulability	3
Major Surgery	2
Bed rest	1
Advanced Age (> 70 years)	1
Obesity	1
Hormone Replacement Therapy/Oral Contraceptives	1
Total Number of Points	_____

Not all clinicians support the use of the "rule in" approach due to the lack of a uniform definition of the term "high-risk." As mentioned previously, the use of VTE risk assessments has not been validated in clinical trials, and there is no standard agreement on what to do with the results or number of points produced in regard to the degree of risk represented and the associated choice of VTE prophylaxis. Additionally, there is lack of consensus regarding which staff member—physician or nurse—should be responsible for performing the risk assessment. Subsequently, there is the challenge of getting a physician to comply with the results of the risk assessment if it has been performed by a nurse. As a result, many VTE experts do not support the use of VTE risk assessments.

Another approach is a "rule out" assessment, such as the one available in the MedQIC section of the QualityNet Web site at http://www.qualitynet.org/. On this Web site, there

is a tab entitled MedQIC (Medicare Quality Improvement Community).[80] The MedQIC Web site is a source for free quality improvement tools and other resources. With the "rule out" assessment, the questions first determine if the patient already has orders for mechanical or pharmacological VTE prophylaxis, then the assessment looks at the presence of contraindications to pharmacologic prophylaxis. The contraindication section provides for documentation of known allergy or hypersensitivity to heparin or LMWH, suspicion of an intracranial or intraspinal bleed, suspicion of bleeding conditions, presence of congenital or acquired bleeding disorders, presence of low hemoglobin level or low platelet count, and reliability of patient answers. Depending on the patient's Yes/No answers, pharmacological and/or mechanical prophylaxis is ordered.

- **Physician Report Cards**

  Hospitals are using various approaches to physician report cards. In some cases, the results are provided directly to each physician; sometimes the results are posted in the physician lounge; and in still other cases, the results are displayed in more visible areas such as the inpatient units. Some hospitals display the results as "blinded" displays without identifying physicians, while in other hospitals the physicians are identified by name.

- **Staff Education**

  Hospitals are including education on VTE prophylaxis in their medical, pharmacy, and nursing staff orientation and re-orientation sessions. Sessions cover morbidity, costs, and benefits. Training includes the importance of teamwork and open communication, taking examples from the aviation industry.

- **Patient Education**

  One example of patient and family education is one hospital's use of "Joint Camp" in which prior to knee and hip surgeries, the patient and family are invited for an educational session that includes discussion of what to expect prior to and after surgery. One of the topics is the use of pharmacological and mechanical VTE prophylaxis.

- **Protocols with Process Ownership**

  Hospitals have developed clear protocols and identified which staff members "own" which steps in the VTE prophylaxis process regarding:

  - Patient assessment for VTE risk factors
  - Confirmation and follow-up for VTE prophylaxis orders
  - Administration of timely pharmacological VTE prophylaxis according to physician orders and guidelines

- Encouragement of patient mobility
- Assurance of proper fitting, application, and use of mechanical VTE options
- Education of patients and their families on the purpose and benefits of pharmacological and mechanical VTE prophylaxis
- Education of patients on post-discharge VTE prophylaxis, including the following: mechanical and pharmacological options at home, compliance with medications and associated lab tests, knowledge of preventive measures (mobility, diet, medication interactions, etc), signs and symptoms of VTE (DVT and PE), and contact names
- Post-discharge assessment/screening follow-up, via telephone call or postcard, with patient and/or family regarding potential development of VTE.

Conclusion

VTE represents a serious medical condition that can develop into a DVT and/or PE, resulting in significant morbidity associated with increased hospital lengths of stay, additional medical interventions, decreased quality of life, increased cost, and potential death. A large portion of patients seeking medical care and undergoing surgery have at least one of the risk factors (demographic, chronic illness, or prior medical history) associated with an increased potential for the development of VTE. Additionally, surgery itself represents a major risk factor.

CMS and other public and private organizations have recognized the associated benefits of VTE prophylaxis for the patient and healthcare provider as well as the potential of prophylaxis to decrease the incidence of VTE. In response, these entities have developed a number of initiatives, including the CMS Surgical Care Improvement Project, that aim to increase the ordering and administration of recommended VTE prophylaxis. A number of medical specialty organizations, such as the ACCP and the American Academy of Orthopaedic Surgeons (AAOS), have issued clinical guidelines regarding VTE prophylaxis for surgical patients.[81] However, despite these initiatives and guidelines, VTE prophylaxis remains underused, based on physician, nursing staff, and patient concerns, including the fear of bleeding, lack of knowledge, and lack of clear processes. Despite lingering resistance to VTE prophylaxis, some hospitals have developed strategies to overcome barriers to VTE prophylaxis that have resulted in increased staff compliance and increased patient safety.

The field of VTE prophylaxis is constantly evolving as new tests, treatment options, and guidelines are researched and developed.[82] The topic is not without disagreement and the status of a pharmacological agent that is currently recommended can change. For example, some clinicians question the use of warfarin alone (warfarin monotherapy) immediately following hip and knee surgeries due to the medication's delayed effectiveness.[83] Warfarin requires 3 to 5 days for full effect and many clinicians, as well as The Joint Commission, recommend the use of overlap therapy. New pharmacologic agents are being developed and released. For instance, rivaroxaban, an oral direct inhibitor of Factor Xa, is now available as an option for some surgical procedures, as noted in the *Specifications Manual*, Version 3.1a. Meanwhile, other oral anticoagulants, such as dabigatran, apixaban, and YM150, are in clinical trials.[84,85,86]

Every clinician—including physicians, nurses, and pharmacists—as well as hospital senior leadership, must take on the challenge of identifying current practices, improving the rate of compliance, and sustaining the momentum toward providing the best level of care in order to prevent the development of VTE. As discussed throughout this module, the prevention of VTE is a crucial element in quality care and patient safety.

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Post-Test

1. The CMS Surgical Care Improvement Project (SCIP) includes the following VTE measures:
    a. Surgery patients with recommended VTE prophylaxis ordered
    b. Surgery patients who received appropriate VTE prophylaxis within 24 hours prior to surgery to 24 hours after surgery
    c. Venous thromboembolism patients with anticoagulation overlap therapy
    d. Both a and b

2. Virchow's Triad indicates that the three main causes for blood to clot and form a thrombus in a blood vessel are the following:
    a. Changes in the vessel wall
    b. Changes in blood flow
    c. Changes in the blood composition
    d. All of the above

3. Which of the following is <u>not</u> a risk factor for VTE:
    a. History of DVT or PE
    b. Increasing age
    c. Normal weight
    d. Surgery

4. Additional risk factors include all of the following <u>except</u>:
    a. Prolonged immobility
    b. Marathon running
    c. Obesity
    d. Oral contraceptive or hormone replacement with estrogen

5. Surgery as a risk factor for VTE includes the following:
    a. Orthopedic surgery involving the hips and knees
    b. Major surgery lasting longer than 30 to 45 minutes (more than 60 minutes for SCIP measure inclusion)
    c. Both a and b
    d. Only a

6. VTE risk factors can be described as:
    a. Cumulative
    b. Independent of each other
    c. Unknown
    d. Difficult to determine

7. The presence of a PE is:
    a. Easily identified by the hospital staff
    b. Often identified upon autopsy
    c. Characterized by signs and symptoms very different from other medical conditions
    d. Usually identified while the patient is in the hospital

8. In an asymptomatic patient, signs of possible DVT include the following:
    a. Swelling of the calf, ankle, foot, or thigh with increased extremity circumference
    b. Increased warmth of the leg
    c. Purple or blue discoloration of the skin on the leg
    d. All of the above

9. The signs and symptoms of PE include all of the following except:
    a. Sudden, severe neck pain
    b. Sharp chest pain worsening during deep breathing
    c. Coughing up blood
    d. Feeling faint or anxious

10. Diagnostic tests for DVT and/or PE include all of the following <u>except</u>:
    a. Contrast venography
    b. Lumbar puncture
    c. Pulmonary angiography
    d. D-dimer test

11. Non-invasive diagnostic tests for DVT and/or PE include the following:
    a. Impedance plethysmography
    b. D-dimer test
    c. Pulmonary ventilation/perfusion scan
    d. All of the above

12. The *Specifications Manual Version 3.1a* lists the following nonpharmacologic/mechanical prophylaxis options except:
    a. Intermittent pneumatic compression
    b. Graduated compression stockings
    c. Inferior vena cava filter
    d. Venous foot pump

13. Key elements in supporting patient compliance with the use of mechanical VTE prophylaxis devices include:
    a. The patient understands the need for the device.
    b. Staff know how to use the device.
    c. Only a.
    d. Both a and b

14. Pharmacological VTE prophylaxis options included in the *Specifications Manual Version 3.1a* include:
    a. LDUH and LMWH
    b. Factor Xa antagonist
    c. Warfarin
    d. All of the above

15. LMWH has the following advantage over LDUH:
    a. Given once or twice a day
    b. No need to delay administration following removal of spinal needle or catheter
    c. Does not have any HIT risk
    d. Does not have any advantages over LDUH

16. If warfarin is used, the following must be taken into consideration:
    a. No patient education is needed
    b. Requires three to five days to take full effect and overlap therapy with LMWH is recommended to provide adequate prophylaxis
    c. No monitoring of INR required
    d. No changes required in the patient's diet and use of supplements

17. Characteristics of HIT include the following:
    a. Blood clot formation resulting in thrombocytopenia, and possibly DVTs/PEs, from the use of heparin
    b. Risk factors of prior heparin exposure and duration of heparin therapy
    c. Platelet count less than 150,000, or 50 percent or more fall in platelet count from baseline prior to initiation of heparin or LMWH
    d. All of the above

18. The potential additional costs associated with not providing VTE prophylaxis include the following:
    a. Increased length of hospital stays and need for additional treatment
    b. Increased frequency of VTE recurrence and hospital readmissions
    c. Both a and b
    d. None of the above

19. As a result of the 2009 Medicare Final Rule regarding hospital-acquired conditions (HACs), if a patient develops VTE following total knee replacement or total hip replacement and requires hospitalization, which of the following is true?
    a. The hospital risks providing needed treatment with no reimbursement by Medicare.
    b. Medicare will reimburse the hospital for only 50 percent of the treatment costs.
    c. The hospital will be fully reimbursed for the treatment.
    d. The HAC list does not address VTE development following total knee replacement or total hip replacement.

20. VTE prophylaxis can contribute to the patient's quality of life as a result of:
    a. Decreased time lost from work
    b. Decreased emotional suffering
    c. Decreased post-VTE complications
    d. All of the above

21. The characteristics of post-thrombotic syndrome include all of the following except:
    a. Edema, swelling
    b. Loss of skin pigmentation/skin lightening
    c. Dark brownish pigmentation around ankle
    d. Skin ulceration, sores

22. The following people involved in the patient's care can contribute to the underutilization of VTE prophylaxis:
    a. Physicians
    b. Nurses
    c. Patients
    d. All of the above

23. Frequent reasons physicians cite for not ordering VTE prophylaxis, resulting in barriers to compliance, include:
    a. "I get my patients up and ambulating quickly."
    b. "My patients don't get DVT/PE."
    c. "No literature to support VTE prophylaxis."
    d. All of the above

24. Strategies to support compliance with VTE prophylaxis include all except:
    a. Handwritten physician orders
    b. Physician champions
    c. Standardized and mandatory protocols and pre-printed orders
    d. Concurrent review, audits, and feedback

25. Education supporting compliance with VTE prophylaxis should include:
    a. Patient and family education
    b. Staff education in orientation and re-orientation sessions
    c. Both a and b
    d. No education is needed

Post-Test Answer Key

1. D. Both a and b
2. D. All of the above
3. C. Normal weight
4. B. Marathon running
5. C. Both a and b
6. A. Cumulative
7. B. Often identified at autopsy
8. D. All of the above
9. A. Sudden, severe neck pain
10. B. Lumbar puncture
11. D. All of the above
12. C. Inferior vena cava filter
13. D. Both a and b
14. D. All of the above
15. A. Given once or twice a day
16. B. Requires three to five days to take full effect and overlap therapy with LMWH is recommended to provide adequate prophylaxis
17. D. All of the above
18. C. Both a and b
19. A. The hospital risks providing needed treatment with no reimbursement by Medicare.
20. D. All of the above
21. B. Loss of skin pigmentation/skin lightening
22. D. All of the above
23. D. All of the above
24. A. Handwritten physician orders
25. C. Both a and b