*** Drug Safety Alert ***

Xarelto (Rivaroxaban) Tablets

**FDA MedWatch - August 2013 Safety Labeling Changes with revisions to Prescribing Information**

[Posted 09/13/2013]

The MedWatch August 2013 Safety Labeling Changes posting includes products with safety labeling changes to the following sections: BOXED WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS and PATIENT PACKAGE INSERT. The "Summary Page" provides a listing of product names and safety labeling sections revised:

Pradaxa (dabigatran etexilate mesylate): Drug Safety Communication - Should Not Be Used in Patients with Mechanical Prosthetic Heart Valves

The U.S. Food and Drug Administration (FDA) is informing health care professionals and the public that the blood thinner (anticoagulant) Pradaxa (dabigatran etexilate mesylate) should not be used to prevent stroke or blood clots (major thromboembolic events) in patients with mechanical heart valves, also known as mechanical prosthetic heart valves. A clinical trial in Europe (the RE-ALIGN trial) 1 was recently stopped because Pradaxa users were more likely to experience strokes, heart attacks, and blood clots forming on the mechanical heart valves than were users of the anticoagulant warfarin. There was also more bleeding after valve surgery in the Pradaxa users than in the warfarin users.

Pradaxa is not approved for patients with atrial fibrillation caused by heart valve problems. FDA is requiring a contraindication (a warning against use) of Pradaxa in patients with mechanical heart valves.

RECOMMENDATION: Health care professionals should promptly transition any patient with a mechanical heart valve who is taking Pradaxa to another medication. The use of Pradaxa in patients with another type of valve replacement made of natural biological tissue, known as a bioprosthetic valves, has not been evaluated and cannot be recommended. Patients with all types of prosthetic heart valve replacements taking Pradaxa should talk to their health care professional as soon as possible to determine the most appropriate anticoagulation treatment. Patients should not stop taking anticoagulant medications without guidance from their health care professional; stopping Pradaxa or other anticoagulants suddenly can increase the risk of blood clots and stroke.

Health Care Guideline
Venous Thromboembolism Prophylaxis

How to cite this document:

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Evidence Grading

Literature Search

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. Literature search terms for the current revision of this document include venous thromboembolism prevention and control, aspirin, hip arthroplasty, knee arthroplasty, low-molecular-weight heparin, risk stratification/factors, graduated compression stockings, pneumatic compression, systematic reviews, burns, thoracic surgery, trauma, neurosurgery outpatient, regional anesthesia. Formal searches spanned the time frame 18 months prior to the start of the revision. Additionally, ICSI Venous Thromboembolism Prophylaxis work group members brought forth a wide variety of articles to include. Publication dates went back two years from this publication date. Excluded were non-English, non-human and age less than 18. Databases included PubMed and Cochrane reviews.

Following a review of several evidence rating and recommendation writing systems, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

GRADE Methodology

Following a review of several evidence rating and recommendation writing systems, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

GRADE has advantages over other systems including the current system used by ICSI. Advantages include:

- developed by a widely representative group of international guideline developers;
- explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings;
- clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations;
- clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy-makers;
- explicit acknowledgement of values and preferences; and
- explicit evaluation of the importance of outcomes of alternative management strategies.

This document is in transition to the GRADE methodology

Transition steps incorporating GRADE methodology for this document include the following:

- Priority placed upon available Systematic Reviews in literature searches.
- All existing Class A (RCTs) studies have been considered as high quality evidence unless specified differently by a work group member.
- All existing Class B, C and D studies have been considered as low quality evidence unless specified differently by a work group member.
- All existing Class M and R studies are identified by study design versus assigning a quality of evidence. Refer to Crosswalk between ICSI Evidence Grading System and GRADE.
- All new literature considered by the work group for this revision has been assessed using GRADE methodology.
## Crosswalk between ICSI Evidence Grading System and GRADE

<table>
<thead>
<tr>
<th>ICSI GRADE System</th>
<th>Previous ICSI System</th>
</tr>
</thead>
<tbody>
<tr>
<td>High, if no limitation</td>
<td>Class A: Randomized, controlled trial</td>
</tr>
<tr>
<td>Low</td>
<td>Class B: [observational]</td>
</tr>
<tr>
<td></td>
<td>Cohort study</td>
</tr>
<tr>
<td>Low</td>
<td>Class C: [observational]</td>
</tr>
<tr>
<td></td>
<td>Non-randomized trial with concurrent or historical controls</td>
</tr>
<tr>
<td></td>
<td>Case-control study</td>
</tr>
<tr>
<td></td>
<td>Population-based descriptive study</td>
</tr>
<tr>
<td>*Low</td>
<td>Study of sensitivity and specificity of a diagnostic test</td>
</tr>
</tbody>
</table>

* Following individual study review, may be elevated to Moderate or High depending upon study design

<table>
<thead>
<tr>
<th>Class D: [observational]</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cross-sectional study</td>
<td>Case series</td>
</tr>
<tr>
<td>Case report</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Meta-analysis</th>
<th>Class M: Meta-analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systematic Review</td>
<td>Systematic review</td>
</tr>
<tr>
<td>Decision Analysis</td>
<td>Decision analysis</td>
</tr>
<tr>
<td>Cost-Effectiveness Analysis</td>
<td>Cost-effectiveness analysis</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Class R: Consensus statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
</tr>
<tr>
<td>Consensus report</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Class R: Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
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</table>

<table>
<thead>
<tr>
<th>Class X: Medical opinion</th>
</tr>
</thead>
</table>

### Evidence Definitions:

**High Quality Evidence** = Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate Quality Evidence** = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low Quality Evidence** = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain.

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature will be used to inform the reader of other topics of interest. This literature is not given an evidence grade and is instead identified as a Reference throughout the document.

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Foreword

Introduction

The purpose of this document is to provide clinicians with strategies to reduce morbidity and mortality related to venous thromboembolism events in hospitalized adult patients.

The primary change found in the 2012 edition of the ICSI Venous Thromboembolism Prophylaxis guideline compared to the 2011 edition is risk stratification and the removal of dosing information. Risk stratification promotes individualization of care by assessing unique patient factors in combination with factors related to their hospitalization to best estimate their risk of developing venous thromboembolism. Synthesis of current evidence should help provide clinicians with thematic guidance related to risk stratification and help counsel the patient regarding his or her risks as well as tailor a prophylaxis regimen.

The ICSI work group hopes this guideline will also help clinicians address the Triple Aim: optimization of population health, patient experience and total cost of care. Providing guidance considering individual patient risks and reducing variation in practice should help to decrease the incidence of venous thromboembolic events.

Goals of Venous Thromboembolism Prophylaxis

The goals of venous thromboembolism prophylaxis are to reduce all-cause mortality and/or morbidity associated with surgical procedures and/or hospitalization.

Evidence "Gaps"/Research Opportunities

The ICSI work group finds that evidence pertaining to aspirin's potential effectiveness in preventing VTE in the medical patient is generally lacking and would suggest studies of this clinical question be done.

Because surgical and hospital procedures are constantly changing, the impact of venous thromboembolism prophylaxis on mortality and morbidity may also be constantly changing. Therefore, all methods of venous thromboembolism prophylaxis require periodic reassessment by randomized controlled trials. There are several areas that are in urgent need of randomized controlled trials:

1. Patients who require orthopedic procedures – a comparison of aspirin with each of the other pharmacologic thromboprophylactic agents (low-molecular-weight heparins, fondaparinux, warfarin).

2. Patients who require aspirin and clopidogrel due to vascular stents – a comparison of aspirin + clopidogrel (alone) with aspirin + clopidogrel + each additional pharmacologic thromboprophylactic agent (unfractionated heparin, low-molecular-weight heparins, fondaparinux, warfarin).

3. Research has shown that clinicians may underestimate the risk of venous thromboembolic events and overestimate the risks of bleeding complications related to prophylaxis. Clinicians have also been hesitant to generalize best available evidence to their patient populations, avoiding prophylaxis because no evidence specific to their specialty exists. Additional studies in specific patient subgroups are warranted to address the extent to which recommendations may be generalized. Education may be needed to ensure that clinicians are aware of current best evidence.

4. Patients hospitalized for medical reasons – comparison of ASA with placebo or other pharmacologic thromboprophylaxis agent.

5. Mechanical thromboprophylaxis needs further research.

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Scope and Target Population

This guideline addresses risk assessment for venous thromboembolism, risk assessment for bleeding, and mechanical and pharmacologic therapies to reduce the occurrence of venous thromboembolism in adult hospitalized patients.

Out of scope of this guideline:

- Burns
- Multiple trauma
- Neurosurgery
- Pregnancy
- Spine surgery

Aims

1. Increase the percentage of hospitalized patients 18 years of age and older who are assessed for venous thromboembolism risk within 24 hours of admission. (Recommendation Summary A; Annotation #1)

2. Increase the percentage of hospitalized patients 18 years of age and older who are evaluated for venous thromboembolism prophylaxis upon change in level of care, clinicians and/or upon discharge. (Recommendation Summary A; Annotation #1)

3. Increase the percentage of hospitalized patients 18 years of age and older at risk for venous thromboembolism who have received education within 24 hours of admission into inpatient care setting for venous thromboembolism that includes venous thromboembolism risk, signs and symptoms, early and frequent mobilization and clinically appropriate treatment/prophylaxis methods. (Recommendation Summary A; Annotation #1)

4. Improve the safety of using medications by reducing the likelihood of patient harm associated with the use of anticoagulation therapy in inpatient care setting for patients 18 years of age and older. (Recommendation Summaries B and C; Annotations #3, 5)

5. Increase the percentage of at-risk hospitalized patients 18 years of age and older receiving appropriate prophylaxis treatment within 24 hours of admission. (Recommendation Summaries B and C; Annotations #3, 5)

6. Reduce the risk of complications from pharmacologic thromboprophylaxis for hospitalized and discharged patients 18 years of age and older. (Recommendation Summaries B and C; Annotations #3, 5)

7. Increase the percentage of surgery patients 18 years of age and older who receive appropriate venous thromboembolism prophylaxis within 24 hours prior to anesthesia start-time to 24 hours after anesthesia end-time. (Recommendation Summaries B and C; Annotations #3, 5)
Clinical Highlights

- All patients should be evaluated for venous thromboembolism risk upon hospital admission, change in level of care, clinicians and prior to discharge. *(Recommendation Summary A; Annotation #1)*

- All patients should receive proper education regarding venous thromboembolism risk, signs and symptoms, early and frequent mobilization, and clinically appropriate treatment/prophylaxis methods. *(Recommendation Summary A; Annotation #1)*

- All hospitalized patients who are high risk for venous thromboembolism should receive pharmacologic thromboprophylaxis unless contraindicated. *(Recommendation Summaries B and C)*

- For all patients receiving spinal or epidural anesthesia, precautions should be taken when using VTE prophylaxis to reduce the risk of epidural perispinal hematoma. *(Recommendation Summary F; Annotation #9)*

Implementation Recommendation Highlights

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

- Implement a defined anticoagulation management program to individualize the care provided to each patient receiving anticoagulation therapy.

- (Clinics and Hospitals): Develop systems for monitoring the effects of anticoagulation therapy (heparin, low-molecular-weight heparin, warfarin and other anticoagulants) to include monitoring of outpatient therapy:
  - Use of standardized practices/protocols that include patient involvement.

- When heparin is administered intravenously and continuously, the organization should use programmable infusion pumps.

- Develop systems for providing patient/family education that includes the importance of follow-up monitoring, compliance issues, dietary restrictions, and potential adverse drug reactions and interactions.
  - Patient education to include documentation of the patient's own awareness of his/her risk for venous thromboembolism, signs and symptoms of venous thromboembolism, activity level when/how to seek treatment, and demonstrated understanding of the prescribed anticoagulation regimen.
  - The ICSI work group gleaned the following perspectives and insights from ICSI's Patient Advisory Council in June 2012:
    - Patients stated the following attributes would be important for effective delivery of information about VTE prophylaxis to the hospitalized medical patient:
      - Patients prefer that a clinician, preferably a physician, deliver prophylaxis information, in a compassionate and clear manner that can be understood by a layperson. Accompanying this with supporting material such as a visual aid in video format would be ideal. Written material might be saved for later but is not preferred at initial contact.
      - The medically ill patient may not be able to comprehend or retain information given his or her condition so it is important to involve an advocate such as a family member.
• Since the prophylaxis is not related to the primary treatment plan or reason for admission, patients would prefer that the clinician guide the decision by indicating whether he or she strongly recommends it or not. It is better received if the positive benefits of the treatment are stressed along with the fact it is a routine practice or standard of care.

• If a cost will be incurred by the patient, he or she appreciates knowing that to assist decision-making.

As to elective surgical procedures, patients indicated that they preferred to get the information from the surgeon during the preoperative evaluation process.

• Develop a policy for providing organizational education regarding anticoagulation therapy to prescriber(s), staff, patients and families.

• Develop protocols for the initiation and maintenance of anticoagulation therapy appropriate to the medication used, to the condition being treated, and to the potential for drug interactions.

See Appendix A, "Improvement Strategies," for additional information on implementation.

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Related ICSI Scientific Documents

Guidelines

• Antithrombotic Therapy Supplement
• Heart Failure in Adults
• Diagnosis and Treatment of Chest Pain and Acute Coronary Syndrome (ACS)
• Diagnosis and Initial Treatment of Ischemic Stroke
• Venous Thromboembolism Diagnosis and Treatment

Order Set

• Admission for Ischemic Stroke for Patients Not Receiving tPA

Protocol

• Prevention of Ventilator-Associated Pneumonia

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Definition

Clinician – All health care professionals whose practice is based on interaction with and/or treatment of a patient.

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Thromboembolic Prophylaxis for Adult Hospitalized Patients Recommendation Summary

A. General Recommendations (1)

• All patients should have venous thromboembolism risk assessed and addressed upon hospital admission, change in level of care and discharge.

• All patients should have proper education regarding venous thromboembolism risk, signs and symptoms and treatment/prophylaxis methods available.

• All patients should be encouraged to ambulate as early as possible, and as frequently as possible.

• All patients with moderate to high risk of venous thromboembolism should have pharmacologic prophylaxis based on the recommendations in this guideline – unless contraindicated. If pharmacologic therapy is contraindicated, then mechanical prophylaxis with intermittent pneumatic compression (IPC) is recommended.

B. Hospitalized Medical (Non-Surgical) Patients Recommended Assessment and Prophylaxis (3)

Assessment

Padua VTE Risk Assessment

Hospitalized medical patients who are not critically ill, hence not at high VTE risk, should be assessed for VTE risk in order to guide choices for prophylaxis (Kahn, 2012 [Guideline]).

There are several models available for estimating VTE risk (Prandoni, 2008 [Low Quality Evidence]). While none has been extensively validated, the Padua Prediction Score was validated in a prospective cohort study (Barbar, 2010 [Moderate Quality Evidence]) and is easy to use.

<table>
<thead>
<tr>
<th>Points</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>CA, past VTE, not mobile, thrombophilic condition</td>
</tr>
<tr>
<td>2</td>
<td>Trauma or surgery in past month</td>
</tr>
<tr>
<td>1</td>
<td>70 years or older, CHF, AMI, ischemic CVA, BMI greater than or equal to 30, hormones, other*</td>
</tr>
</tbody>
</table>

* Acute infections or rheumatologic disorder

Prophylaxis

<table>
<thead>
<tr>
<th>Low Bleed Risk</th>
<th>High Bleed Risk</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk</td>
<td>Prophylaxis not required</td>
<td>Prophylaxis not required</td>
</tr>
<tr>
<td>High Risk</td>
<td>Pharmacoprophylaxis</td>
<td>Intermittent pneumatic compression</td>
</tr>
</tbody>
</table>

May use aspirin for other indications, but not sufficient alone for VTE prophylaxis.

If on warfarin for other indications, probably sufficient VTE prophylaxis.

Key

VTE = Venous thromboembolism  Mobility = Reduced mobility  LMWH = Low-molecular-weight heparin
RAM = Risk assessment model  CA = Active cancer  LDUH = Low dose unfractionated heparin
C. Hospitalized Surgical Patients Recommended Assessment and Prophylaxis (5)

Assessment

Caprini VTE Risk Assessment for Use in Hospitalized Surgical Patients

Surgical patients should be assessed for VTE risk. Several risk assessment models exist, although none has been prospectively validated (Gould, 2012 [Guideline]). The ICSI work group suggests using the Caprini Risk Assessment Model as a guide for decision-making (Caprini, 2010 [Low Quality Evidence]). It is relatively easy to use, and it has been retrospectively validated in general, vascular and urological surgery patients (Bahl, 2010 [Moderate Quality Evidence]), and in plastic and reconstructive surgery patients (Panucci, 2011 [Moderate Quality Evidence]).

Thrombosis Risk Factor Assessment

Patient’s Name: ___________________ Age: ___ Sex: ___ Wgt: ___ lbs

Choose All That Apply

Each Risk Factor Represents 1 Point
- Age 41-60 years
- Minor surgery planned
- History of prior major surgery (< 1 month)
- Varicose veins
- History of inflammatory bowel disease
- Swollen legs (current)
- Obesity (BMI > 25)
- Acute myocardial infarction
- Congestive heart failure (< 1 month)
- Sepsis (< 1 month)
- Serious lung disease incl. pneumonia (< 1 month)
- Abnormal pulmonary function (COPD)
- Medical patient currently at bed rest
- Other risk factors

Each Risk Factor Represents 2 Points
- Age 60-74 years
- Arthroscopic surgery
- Malignancy (present or previous)
- Major surgery (> 45 minutes)
- Laparoscopic surgery (> 45 minutes)
- Patient confined to bed (> 72 hours)
- Immobilizing plaster cast (< 1 month)
- Central venous access

Each Risk Factor Represents 3 Points
- Elective major lower extremity arthroplasty
- Hip, pelvis or leg fracture (< 1 month)
- Stroke (< 1 month)
- Multiple trauma (< 1 month)
- Acute spinal cord injury (paralysis) (< 1 month)

For Women Only (Each Represents 1 Point)
- Oral contraceptives or hormone replacement therapy
- Pregnancy or postpartum (< 1 month)
- History of unexplained stillborn infant, recurrent spontaneous abortion (> 3), premature birth with toxemia or growth-restricted infant

Total Risk Factor Score

*If contraindications exist for both LMWH and LDUH, and there is high risk for VTE but not high risk for major bleeding, use fondaparinux or low-dose aspirin, or intermittent pneumatic compression.

VTE risk category is based on the Caprini Risk Assessment Model. Inferior Vena Cava Filter (IVCF) is not recommended for any of the risk categories. Periodic SurveillanceVenous Compression Ultrasoundography is not recommended for any of the risk categories.


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Prophylaxis

Non-orthopedic General, and Abdominal Pelvic Surgery Including GI, GU, Bariatric, Vascular, Reconstructive, Cardiothoracic and GYN Surgery Hospitalized Surgical Patients

<table>
<thead>
<tr>
<th>VTE Risk Category</th>
<th>Low Bleeding Risk</th>
<th>High Risk for Major Bleeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Low Risk (Caprini score 0)</td>
<td>Early ambulation</td>
<td>Early ambulation</td>
</tr>
<tr>
<td>Low Risk (Caprini score 1-2)</td>
<td>Intermittent pneumatic compression (IPC)</td>
<td>Intermittent pneumatic compression</td>
</tr>
<tr>
<td>Moderate Risk (Caprini score 3-4)</td>
<td>LMWH or LDUH or intermittent pneumatic compression</td>
<td>Intermittent pneumatic compression</td>
</tr>
<tr>
<td>High Risk (Caprini Score ≥ 5)</td>
<td>LMWH or LDUH and intermittent pneumatic compression</td>
<td>Intermittent pneumatic compression until risk of bleeding diminishes and pharmacologic thromboprophylaxis can be initiated</td>
</tr>
<tr>
<td>Cancer Surgery (visceral cancer)</td>
<td>LMWH Extended duration (four weeks) if no risk for major bleeding</td>
<td></td>
</tr>
</tbody>
</table>

**Hip/Knee Arthroplasty, Hip Fracture (6)**

<table>
<thead>
<tr>
<th>Standard VTE Risk</th>
<th>Standard Bleeding Risk</th>
<th>Elevated Bleeding Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pharmacoprophylaxis and intermittent pneumatic compression prophylaxis</td>
<td>Intermittent pneumatic compression prophyaxis</td>
</tr>
<tr>
<td>Elevated VTE Risk</td>
<td>Pharmacoprophylaxis and intermittent pneumatic compression prophylaxis</td>
<td>Intermittent pneumatic compression, consider pharmacoprophylaxis in select patients</td>
</tr>
</tbody>
</table>

For pharmacoprophylaxis recommend minimum duration 10-14 days, consider extension to 35 days.

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D. Risk Factors for Major Bleeding Complications (7)

**General Risk Factors**
- Active bleeding
- Previous major bleeding
- Known untreated bleeding disorder
- Severe renal or hepatic disorder
- Thrombocytopenia
- Acute stroke
- Uncontrolled systemic hypertension
- Lumbar puncture, epidural or spinal anesthesia within previous 4 hours or next 12 hours
- Concomitant use of anticoagulants, antiplatelet therapy or thrombolytic agents

**Procedure Specific Risk Factors**
- Abdominal Surgery
  - Male sex
  - Preoperative Hgb < 13 g/dL
  - Malignancy and complex surgery defined as two or more procedures, difficult dissection or more than one anastomosis
- Pancreatoduodenectomy
  - Sepsis
  - Pancreatic leak
  - Sentinel bleed
- Hepatic resection
  - Number of segments
  - Concomitant extra hepatic organ resection
  - Primary liver malignancy
  - Lower preoperative Hgb level and platelet counts

**Procedures with High Risk**
- Craniotomy
- Spinal surgery
- Spinal trauma
- Reconstructive surgery involving free flap

---

E. Heparin-Induced Thrombocytopenia (HIT) (8)

**History of HIT, Thrombocytopenia, Coagulopathy**
- Use mechanical prophylaxis and consult an anticoagulation expert to discuss options for pharmacoprophylaxis.

**Monitoring for HIT**
- Medical patient with HIT risk 0.1-1% receiving prophylactic-dose UFH or receiving LMWH after first receiving UFH and postoperative patients with HIT risk > 1% receiving prophylactic-dose UFH or with HIT risk > 0.1-1% receiving LMWH or UFH intravascular catheter flushes.

**Protocol**
- Obtain baseline platelet count; then monitor platelets every two days from day 4 through 14, or until the UFH is stopped, whichever occurs first.
- Patients who have received UFH within the past 100 days or those patients in whom exposure is uncertain – start monitoring platelets within 24 hours of starting UFH or LMWH.

**Patients who received UFH/LMWH within 100 days or patients with uncertain exposure:**

**Protocol**
- Obtain baseline platelet count; then monitor platelets within 24 hours of starting UFH or LMWH. Continue monitoring every 2 days until day 14 or until UFH/LMWH has been stopped, whichever occurs first.
- Platelet monitoring not required for medical patient with HIT risk < 0.1% receiving only LMWH or UFH intravascular catheter flushes or patient receiving fondaparinux.

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### F. Neuraxial Blockade in Patients Receiving Prophylactic Antithrombotic Therapy (9)

<table>
<thead>
<tr>
<th></th>
<th>Rivaroxaban</th>
<th>Dalteparin or Enoxaparin</th>
<th>Fondaparinux</th>
<th>Unfractionated Heparin</th>
<th>Warfarin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion</td>
<td>At least 18 hours after the last dose</td>
<td>Prophylactic dose, single-daily dosing:</td>
<td>Insertion – fondaparinux not recommended prior to insertion</td>
<td>Insertion – at least 4 hours after the last dose of unfractionated heparin</td>
<td>Insertion – no consensus regarding highest acceptable INR</td>
</tr>
<tr>
<td>Removal</td>
<td>At least 18 hours after last dose</td>
<td>Insertion – at least 12 hours after the last dose. Subsequent dose at least 4 hours after catheter insertion</td>
<td>Removal – at least 36 hours after the last dose of fondaparinux</td>
<td>Removal – at least 4 hours after the last dose of unfractionated heparin</td>
<td>Removal – within 48 hours of initiation of warfarin and INR &lt; 1.5</td>
</tr>
<tr>
<td>Subsequent dose</td>
<td>At least 6 hours after catheter insertion or removal</td>
<td>Removal – at least 12 hours after the last dose. Subsequent dose at least 4 hours after catheter removal</td>
<td>Subsequent dose at least 12 hours after catheter removal</td>
<td>Dose subsequent at least 1 hour after catheter removal</td>
<td></td>
</tr>
<tr>
<td>If traumatic</td>
<td>Puncture occurs, delay administration for 24 hours</td>
<td>Prophylactic dose, twice-daily dosing:</td>
<td>Insertion – epidural catheter not recommended</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Insertion – epidural catheter not recommended</td>
<td>Removal – may initiate twice-daily dosing at least 4 hours after catheter removal</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<td>• Removal – no consensus regarding highest acceptable INR</td>
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Annotations

1. General Recommendations

   Ambulation

   Specific studies have yet to document the value of early ambulation to reduce venous thromboembolism risk, yet the ICSI work group recommends it for all patients, including those at high risk.

   Patient Education

   The impact of providing patient education about compliance with venous thromboembolism prevention through pharmacologic thromboprophylaxis has been studied (Piazza, 2012 [Low Quality Evidence]). Improved patient compliance was demonstrated with pharmacist-led education. Additional information regarding patient education is contained in the Implementation Recommendations section of this guideline.

   Recommendations for Mechanical Prophylaxis

   Mechanical thromboprophylaxis devices include graduated compression stockings and intermittent pneumatic compression devices. Graduated compression stockings (GCS) are specialized hosiery that provide graduated pressure on the lower legs and feet to help prevent thrombosis. Graduated compression stockings use stronger elastics to create significant pressure on the legs, ankles and feet. Graduated compression stockings should be tightest at the ankles and gradually become less constrictive toward the knees and thighs. Though routinely used, there is little evidence supporting the efficacy of GCS in the prevention of venous thromboembolism (VTE).

   Although mechanical prophylaxis devices have been evaluated extensively in clinical studies, their efficacy in venous thromboembolism prevention remains unclear. These studies have often failed to define exactly what device was used. Frequently the devices were used in combination with other prophylaxis methods, making it difficult to demonstrate their efficacy.

   Mechanical prophylaxis devices can have harmful consequences, most commonly related to skin irritation and breakdown.

3. Hospitalized Non-Surgical (Medical) Patients

   Early ambulation by medical patients, and the use of mechanical devices may be useful.

   For hospitalized acutely ill medical patients the 2012 American College of Chest Physicians Clinical Practice Guideline recommends the following (Kahn, 2012 [Guideline]):

   • That for acutely ill hospitalized medical patients at low risk of thrombosis, we recommend against the use of pharmacologic thromboprophylaxis or mechanical thromboprophylaxis.

   • For acutely ill hospitalized medical patients who are bleeding or at high risk for bleeding, we recommend against pharmacologic thromboprophylaxis.

   • For acutely ill hospitalized medical patients at increased risk of thrombosis who are bleeding or at high risk for major bleeding, we suggest the optimal use of mechanical thromboprophylaxis with graduated compression stocking (GCS) or intermittent pneumatic compression (IPC), rather than no mechanical thromboprophylaxis. When the bleeding risk decreases, and if VTE risk persists, we suggest that pharmacologic thromboprophylaxis be substituted for mechanical thromboprophylaxis. Patients are likely to decline mechanical prophylaxis if they are particularly susceptible to the potential for skin complications, averse to cost and have a need for clinical monitoring of GCS and IPC.
In critically ill patients who are bleeding or are at high risk for major bleeding, we suggest mechanical thromboprophylaxis with IPC until the bleeding risk decreases, rather than no mechanical thromboprophylaxis. When bleeding risk decreases, we suggest that pharmacologic thromboprophylaxis be substituted for mechanical thromboprophylaxis.

Aspirin Use

Aspirin for DVT prophylaxis appears to be minimally effective. Effect of low-dose aspirin on the occurrence of VTE data suggests long-term, low-dose aspirin treatment has little effect on the prevention of VTE in initially healthy women (Glynn, 2007 [High Quality Evidence]). While this study was on an ambulatory population, it implies aspirin would not be effective.

The majority of studies have been done on surgical patients; there is no conclusive evidence for medical patients.

Heparin Duration

The optimal duration of heparin prophylaxis is uncertain. At least one study evaluated extended (post-hospitalization) heparin therapy for high-risk (immobile) patients, but the study had some methodologic limitations. More research on the balance of benefits and harms is needed to understand the effects of extended therapy beyond hospitalization (Hull, 2010 [Low Quality Evidence]).

5. Recommended Prophylaxis for Non-Orthopedic General and Abdominal Pelvic Surgery Including GI, Urological, Bariatric, Vascular, Plastic or Reconstructive, Cardiothoracic and Gynecologic Surgery

General and Abdominal Pelvic Gastrointestinal, Urologic, Gynecologic, Bariatric, Vascular, Plastic, Reconstructive Surgery

For patients undergoing general, GI, urological, gynecologic, bariatric, vascular, plastic or reconstructive surgery, the 2012 American College of Chest Physicians Clinical Practice guideline recommends the following (Gould, 2012 [Guideline]; Guyatt, 2012 [Guideline]):

- For patients at very low risk for VTE (Caprini score, 0), recommend no specific pharmacologic or mechanical thromboprophylaxis be used other than early ambulation.
- For patients at moderate risk for VTE (Caprini score, 3-4) who are at high risk for major bleeding complications are thought to be particularly severe, suggest mechanical thromboprophylaxis, preferably with IPC, over no prophylaxis.
- For patients at high risk for VTE (Caprini scale, > 5) who are not at high risk for major bleeding and for whom complications, recommend pharmacologic thromboprophylaxis with LMWH or LDUH over no prophylaxis. It is suggested that mechanical thromboprophylaxis with IPC should be added to pharmacologic thromboprophylaxis.
- For high-VTE-risk patients who are at high risk for major bleeding complications or those in whom the consequences of bleeding are thought to be particularly severe, suggest the use of mechanical thromboprophylaxis, preferably with IPC, over no prophylaxis until the risk of bleeding diminishes and pharmacologic thromboprophylaxis may be initiated.
- For patients at high risk for VTE (Caprini score, > 5) in whom both LMWH and UFH are contraindicated or unavailable and who are not at high risk for major bleeding complications, suggest low-dose aspirin, fondaparinux or mechanical prophylaxis, preferably with IPC over no prophylaxis.
Cardiac Surgery

For cardiac patients with an uncomplicated postoperative course, we suggest the use of mechanical thromboprophylaxis, preferably with optimally applied IPC, over either no thromboprophylaxis or pharmacologic thromboprophylaxis. For cardiac surgery patients whose hospital course is prolonged by one or more non-hemorrhagic surgical complication, it is suggested adding pharmacologic thromboprophylaxis with LDUH or LMWH to mechanical thromboprophylaxis (Gould, 2012 [Guideline]; Guyatt, 2012 [Guideline]).

Thoracic Surgery

For thoracic surgery patients at moderate risk for VTE who are not at high risk for perioperative bleeding, we suggest LDUH, LMWH or mechanical thromboprophylaxis with optimally applied IPC over no prophylaxis. For thoracic surgery patients at high risk for VTE who are not at high risk for perioperative bleeding, we suggest LDUH or LMWH over no prophylaxis. In addition, we suggest that mechanical thromboprophylaxis with IPC be added to pharmacologic thromboprophylaxis. For thoracic surgery patients who are at high risk for major bleeding, it is suggested that mechanical prophylaxis, preferably with optimally applied IPC, over no prophylaxis until the risk of bleeding diminishes and pharmacologic prophylaxis may be initiated (Gould, 2012 [Guideline]; Guyatt, 2012 [Guideline]).

Major Outpatient Procedures, Laparoscopic

The shift from inpatient to outpatient procedures has resulted in the need to assess VTE risk identification and treatment considerations in the outpatient setting. Although work is being done to identify outpatients at risk for VTE (e.g., patients with fractures and surgical patients with multiple comorbidities) and potential treatment methodologies, the body of work is insufficient to make recommendations at this time (Panucci, 2012 [Low Quality Evidence]).

6. Hip/Knee Arthroplasty, Hip Fracture

Since the last edition of the ICSI Venous Thromboembolism Prophylaxis guideline, both the American College of Chest Physicians (ACCP) and the American Academy of Orthopaedic Surgeons (AAOS) have published new guidelines for patients undergoing hip and knee arthroplasty procedures. The complete AAOS guideline can be found at http://www.aaos.org/research/guidelines/VTE/VTE_guideline.asp (Accessed July 5, 2012). The ACCP guidelines specifically address the hip fracture surgery patient population, as well. Although the AAOS guidelines do not specifically address the hip fracture surgery population, we feel it is reasonable to apply this guideline for hip and knee arthroplasty patients to those undergoing hip fracture surgery as well. Both of these guidelines differ substantially from previous editions. One of the most substantial differences is the change in the ACCP guideline to no longer recommend against the use of aspirin as pharmacologic thromboprophylaxis in these patient groups. The 2011 edition of this ICSI guideline was published when the previous ACCP guideline specifically recommending against the use of aspirin was in effect. The following, therefore, will discuss in broader terms the ACCP and AAOS recommendations contained in their most recent guidelines (Gould, 2012 [Guideline]; Jacobs, 2012 [Guideline]).

Risk Stratification

When evaluating patients undergoing hip/knee arthroplasty or hip fracture surgery, it is important to realize that these patients are, by definition, at high risk for VTE events. There is consensus on this. However, the concept that certain patients are at even higher risk is put forth in the AAOS guidelines. Despite conditions that have been regarded as VTE risk factors in the past, or in other patient populations, the AAOS recognizes only a history of prior VTE as a VTE risk factor. The ACCP does not comment on additional VTE risk factors, essentially treating all patients in these groups as having the same VTE risk (high).
Recommendations for prophylaxis may also vary based on a particular patient's perceived risk of bleeding. The AAOS recognizes patients with "a known bleeding disorder and/or active liver disease" as being at increased risk for bleeding. Again, despite conditions that may have been regarded as risk factors for bleeding in the past, or in different patient populations, only a known bleeding disorder and/or active liver disease are currently considered risk factors under the AAOS guideline. The ACCP guideline is even more vague. It does address the patient population with "increased risk of bleeding" but does not elaborate on what specific conditions constitute an "increased risk of bleeding."

**Recommendations**

Despite the paucity of specific identified VTE or bleeding risk factors in both documents, the ICSI work group believes it is useful to separate these patients into four different groups related to their risk of VTE and bleeding:

- Standard bleeding risk with standard VTE risk
- Standard bleeding risk with elevated VTE risk
- Elevated bleeding risk with standard VTE risk
- Elevated bleeding risk with elevated VTE risk

Prophylaxis recommendations are provided for each specific group. Neither the AAOS nor the ACCP Guidelines comment on patients with both an increased bleeding risk AND an increased VTE risk. The ICSI work group feels that these patients should all receive mechanical thromboprophylaxis. The decision regarding pharmacologic thromboprophylaxis should be addressed on a case-by-case basis with guidance from individuals with extensive knowledge of the specific VTE and bleeding risk factors for each individual patient.

As for selecting the type of pharmacologic thromboprophylaxis, the 2012 AAOS guideline states, "Current evidence is unclear about which prophylactic strategy (or strategies) is/are optimal." Therefore, we are unable to recommend for or against specific prophylactics in these patients. The ACCP recommends low-molecular-weight heparin (LMWH), fondaparinux, low-dose unfractionated heparin (LDUH), adjusted-dose vitamin K antagonists, or aspirin as options for hip fracture surgery patients. For hip/knee arthroplasty patients, all the above plus apixaban, dabigatran and rivaroxaban are given as options (Neumann, 2012 [High Quality Evidence]). The ACCP also suggests LMWH "in preference to the other agents" in both hip/knee arthroplasty patients and hip fracture surgery patients.

As for the duration of prophylaxis, ACCP recommends a minimum of 10-14 days and suggests extending prophylaxis for "up to 35 days." The AAOS simply recommends that "patients and physicians discuss the duration of prophylaxis."

Much work remains to be done in this area. Many of the recommendations made by both the ACCP and the AAOS have low levels of evidence to support them. The ICSI VTE Prophylaxis work group feels that the recommendations provided represent a reasonable approach to VTE prophylaxis in this patient population based on the best currently available research data and expert opinion.

**7. Risk Factors for Major Bleeding Complications**

**Recommendation:**

- Each patient and procedure should be evaluated for risk of bleeding.

**Bleeding Risk Table Annotation**

The Summary of Recommendations section of this guideline identifies risk factors for major bleeding complications. It includes general risk factors, procedure-specific risk factors, as well as procedures in
which bleeding complications may have especially severe consequences. Information presented in the Recommendations Summary D, can be used as a guide to help identify patients in whom the risk of bleeding is high or the consequences of bleeding are especially severe.

Certain situations and/or low-risk procedures lend themselves to bleeding and therefore may require only early ambulation or IPC devices for VTE prophylaxis (Forrest, 2009 [Guideline]).

The following statements about the quality of evidence refer to recommendations for patients undergoing general or abdominal-pelvic surgery. Because of indirectness, it is recommended the quality of evidence should be rated down in other surgical populations (Gould, 2012 [Guideline]).

Research attempting to identify risk factors for thromboprophylaxis-related bleeding in general or abdominal-pelvic surgery is lacking; however, there have been a few studies that have identified risk factors in patients undergoing cancer surgery, pancreaticoduodenectomy, partial hepatic resection and mixed abdominal surgery. Studies that specifically address the risk of bleeding complications following bariatric surgery have not been identified, although a list of potential risk factors is provided as a guide in the Summary of Recommendations section.

There are few studies that have examined the risk of bleeding in vascular surgery. Three randomized control trials of thromboprophylaxis reported that the pooled weighted risk of major bleeding in the control (no prophylaxis) was 0.3% (95% CI, 0.2-2.4%). On the other hand, an observational study among 973 patients undergoing complex major vascular procedures reported the incidence of life-threatening hemorrhage was 1.8%, with the majority of bleeding episodes occurring intraoperatively and only 0.4% of the patients experiencing severe bleeding postoperatively. Gould points out that since the baseline risk of bleeding is difficult to determine in vascular surgery, the baseline risk from studies of general abdominal-pelvic surgery (1.2%) was used to provide a list of risk factors as a guide (Gould, 2012 [Guideline]).

8. **Heparin-Induced Thrombocytopenia**

Heparin-induced thrombocytopenia (HIT) is a potential side effect of heparin and LMWH therapy. Postoperative patients and patients receiving unfractionated heparin (UFH) are at the highest risk of developing this complication. Refer to the Summary of Recommendations section for guidelines on monitoring for HIT (Warkentin, 2008 [Guideline]), as well as prophylaxis recommendations for those with HIT, thrombocytopenia coagulopathy.

9. **Neuraxial Blockade in Patients Receiving Prophylactic Antithrombotic Therapy**

**Recommendations:**

- Closely monitor all patients who receive neuraxial blockade for developing back pain or signs and symptoms of spinal cord compression (weakness, saddle numbness, numbness, incontinence) after injections, during infusions and after discontinuation of infusions.
- Both insertion and removal of neuraxial catheters are significant events. Carefully consider the timing of those events and the timing of any anticoagulation drugs. Take into account the pharmacokinetics and pharmacodynamics of the specific anticoagulant drugs.
- The emergence of new drugs and unexpected clinical scenarios can render any guideline obsolete. Consult an anesthesiologist who is experienced in regional anesthesia; it is essential for novel situations.
The American Society of Regional Anesthesia and Pain Medicine (ASRA) has developed extensive, peer-reviewed guidelines for the practice of regional anesthesia in the presence of anticoagulation, and they can be used for detailed management. Review these guidelines directly at http://www.asra.com/publications-anticoagulation-3rd-edition-2010.php (accessed July 5, 2012).

(Horlocker, 2010 [R])

Neuraxial blockade is not a contraindication for pharmacologic thromboprophylaxis. It is important to consider the use and timing of medications with neuraxial blockade. When an epidural is used for anesthesia, it is most appropriate to wait until the catheter is removed before starting pharmacologic thromboprophylaxis. Neuraxial blockade should generally be avoided in patients with a clinical bleeding disorder.

Neuraxial blockade (spinal or epidural anesthesia) is a valuable tool for both anesthesiologists and surgeons. The Cochrane Reviews and other sources have listed the usefulness of neuraxial blockade for both intraoperative anesthesia and postoperative analgesia. There are groups of patients that demonstrate improved morbidity and mortality with the use of regional rather than general anesthesia. Similarly, the usefulness of VTE prophylaxis in preventing morbidity and mortality in surgical patients has been well established. However, there is concern about an increased risk of perispinal hematoma in patients receiving antithrombotic medications for venous thromboembolism prophylaxis in the setting of neuraxial blockade. Perispinal hematoma is a rare but serious complication of neuraxial blockade. Thus, it is important to consider both the use and the timing of antithrombotic medications in these patients.

(Tyagi, 2002 [Low Quality Evidence]; Millar, 1996 [Low Quality Evidence])

**Pharmacologic Thromboprophylactic Agents and Neuraxial Blockade**

1. **Subcutaneous unfractionated heparin (5,000 units twice daily):**

   It is acceptable to place and maintain epidural catheters in patients on subcutaneous unfractionated heparin (UFH). Dosing should be such that the activity of the last dose is near its nadir. Epidural placement should be prior to starting the regimen or at least four hours after the last dose. When discontinuing the epidural catheter, an interval of at least four hours should have transpired since the last dose, and the next heparin dose should be given no sooner than one hour after pulling the catheter.

   Subcutaneous unfractionated heparin (UHF) (5,000 units three times daily):

   According to the ASRA guidelines, the safety of neuraxial blockade in patients receiving doses greater than 10,000 units of UFH daily or more than twice-daily dosing of UFH has not been established. Although the use of thrice-daily UFH may lead to an increased risk of surgical-related bleeding, it is unclear whether there is an increased risk of spinal hematoma. The ASRA guidelines suggest that the risk and benefits of thrice-daily UFH be assessed on an individual basis and that techniques to facilitate detection of new/progressive neurodeficits (e.g., enhanced neurologic monitoring occur and neuraxial solutions to minimize sensory and motor block) be applied (Horlocker, 2010 [Guideline]).

2. **Low-molecular-weight heparins (LMWH):**

   Patients on preoperative thromboprophylaxis can be assumed to have altered coagulation. Needle placement in these patients should occur at least 12 hours after the last dose of LMWH. In patients receiving higher (treatment) doses of LMWH such as enoxaparin 1 mg/kg every 12 hours or 1.5 mg/kg daily, dalteparin 120 u/kg every 12 hours, or dalteparin 200 u/kg daily, epidural needle placement is not recommended. For general surgery patients who have received a dose of LMWH four hours preoperatively, neuraxial techniques are not recommended because needle placement would occur during peak anticoagulation activity.

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3. Fondaparinux:

Inadequate data exist at this time regarding the maintenance of epidural catheters while employing this agent. Early data suggest that holding fondaparinux for 36 hours may allow safe epidural catheter removal. However, additional study is necessary before this can be endorsed. Currently, it is recommended that the epidural catheter be removed prior to initiating thromboprophylaxis with this drug.

4. Warfarin:

The American Society of Regional Anesthesiologists (ASRA) guideline recommends that caution be used when performing neuraxial techniques in patients recently discontinued from long-term warfarin therapy. Although no studies have directly examined the risk of procedure-related bleeding and the international normalized ratio (INR) in patients recently discontinued from warfarin, careful consideration should be given before performing neuraxial blocks in these patients. This recommendation is based on general agreement on efficacy from observational and epidemiological series (Horlocker, 2010 [Guideline]).

In the first one to three days after discontinuation of warfarin therapy, the coagulation status (reflected primarily by factor II and X levels) may not be adequate for hemostasis despite a decrease in the INR (indicating a return of factor VII activity). The ASRA guideline recommends that the anticoagulant therapy must be stopped (ideally four to five days before the planned procedure) and the INR must be normalized before initiation of neuraxial block. This recommendation is based on general agreement on efficacy from observational and epidemiological series (Horlocker, 2010 [Guideline]).

5. Postoperative warfarin:

As thromboprophylaxis with warfarin is initiated, the ASRA guideline suggests that neuraxial catheters should be removed when the INR is less than 1.5. This value was derived from studies correlating hemostasis with clotting factor activity levels greater than 40%. The ASRA (2010) guideline also suggests that neurologic assessment be continued for at least 24 hours after catheter removal for these patients. These comments represent mere suggestions, rather than recommendations, because suggestions are based on general consensus that there is conflicting evidence or opinion from case reports or expert opinion.

In patients with INR greater than 1.5 but less than 3, we recommend that removal of indwelling catheters should be done with caution and the medication record reviewed for other medications that may influence hemostasis that may not effect the INR (e.g., NSAIDs, aspirin, clopidogrel, ticlopidine, UFH, LMWH). This recommendation is derived from case reports or expert opinion with conflicting evidence or opinion on the usefulness of the information. ASRA recommends that neurologic status be assessed before catheter removal and continued until the INR has stabilized at the desired prophylaxis level. This recommendation is based on general agreement from information derived from case reports and expert opinion.

In patients with an INR greater than three, the ASRA recommends that the warfarin dose be held or reduced in patients with indwelling neuraxial catheters. This recommendation is based on general agreement in the efficacy of either randomized clinical trials or meta-analysis. Due to conflicting evidence or opinion on the usefulness of the information from case reports or expert opinion, ASRA made no definitive recommendation regarding management to facilitate removal of neuraxial catheters in patients with therapeutic levels of anticoagulation during neuraxial catheter infusion (Horlocker, 2010 [Guideline]).

6. Postoperative low-molecular-weight heparins (LMWHs):

Patients who will receive postoperative LMWH thromboprophylaxis may safely undergo single-injection and continuous catheter techniques. The management of these patients is based on total daily dose, dosing schedule and the timing of the first postoperative dose. The following recommendations are based on general agreement from case reports and/or expert opinion (Horlocker, 2010 [Guideline]).
Single-daily dosing

The first postoperative LMWH dose should be administered six (6) to eight (8) hours postoperatively. The second postoperative dose should occur no sooner than 24 hours after the first dose. Indwelling neuraxial catheters may be safely maintained. However, the catheter should be removed a minimum of 10 to 12 hours after the last dose of LMWH. Subsequent LMWH dosing should occur a minimum of four hours after catheter removal. No additional hemostasis-altering medications should be administered, due to the additive effects (Horlocker, 2010 [Guideline]).

Twice-daily dosing

This dosage regimen is associated with an increased risk of spinal hematoma. The first dose of LMWH should be administered no earlier than 24 hours postoperatively, regardless of anesthetic technique, and only in the presence of adequate (surgical) hemostasis. Indwelling catheters should be removed before initiation of LMWH thromboprophylaxis. If a continuous technique is selected, the epidural catheter may be left indwelling overnight but must be removed before the first dose of LMWH. Administration of LMWH should be delayed for four hours after catheter removal (Horlocker, 2010 [Guideline]).
The Aims and Measures section is intended to provide guideline users with a menu of measures for multiple purposes, which may include the following:

- Population health improvement measures
- Quality improvement measures for delivery systems
- Measures from regulatory organizations such as The Joint Commission
- Measures that are currently required for public reporting
- Measures that are part of Center for Medicare Services Physician Quality Reporting initiative
- Other measures from local and national organizations aimed at measuring population health and improvement of care delivery

This section provides resources, strategies and measurement for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Aims and Measures
- Implementation Recommendations
- Implementation Tools and Resources
- Implementation Tools and Resources Table
Aims and Measures

1. Increase the percentage of hospitalized patients 18 years of age and older who are assessed for venous thromboembolism risk within 24 hours of admission. *(Recommendation Summary A; Annotation #1)*

Measure for accomplishing this aim:

a. Percentage of hospitalized patients who have a venous thromboembolism risk assessment within 24 hours of admission to the hospital.

2. Increase the percentage of hospitalized patients 18 years of age and older who are evaluated for venous thromboembolism prophylaxis upon change in level of care, clinicians and/or upon discharge. *(Recommendation Summary A; Annotation #1)*

Measure for accomplishing this aim:

a. Percentage of patients who are evaluated for venous thromboembolism prophylaxis upon referral or transfer to another setting, service, practitioner or level of care within or outside the organization.

3. Increase the percentage of hospitalized patients 18 years of age and older at risk for venous thromboembolism who have received education within 24 hours of admission into inpatient care setting for venous thromboembolism that includes venous thromboembolism risk, signs and symptoms, early and frequent mobilization and clinically appropriate treatment/prophylaxis methods. *(Recommendation Summary A; Annotation #1)*

Measure for accomplishing this aim:

a. Percentage of hospitalized patients at risk for venous thromboembolism who have documented venous thromboembolism education within 24 hours of admission that includes: *(composite measure)*

   - Venous thromboembolism risk
   - Signs and symptoms
   - Early and frequent mobilization
   - Clinically appropriate treatment/prophylaxis methods available within 24 hours of admission

4. Improve the safety of using medications by reducing the likelihood of patient harm associated with the use of anticoagulation therapy in inpatient care settings for patients 18 years of age and older. *(Recommendation Summaries B and C; Annotations #3, 5)*

Measures for accomplishing this aim:

a. Percentage of patients who have a baseline international normalized ratio (INR) drawn when initially prescribed warfarin.

b. Percentage of patients on warfarin with current international normalized ratio that is used to monitor and adjust therapy.

c. Percentage of patients on prescribed heparin and low-molecular-weight heparin who have appropriate baseline laboratory tests documented.

d. Percentage of patients on prescribed heparin or low-molecular-weight heparin who have appropriate ongoing laboratory tests that are used to adjust therapy.

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5. Increase the percentage of at-risk hospitalized patients 18 years of age and older receiving appropriate prophylaxis treatment within 24 hours of admission. *(Recommendation Summaries B and C; Annotations #3, 5)*

Measure for accomplishing this aim:

a. Percentage of patients undergoing procedures for which VTE prophylaxis is indicated in all patients who had an order for low-molecular-weight heparin (LMWH), low-dose unfractionated heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end-time. *(AMA-PCP/NCQA, CMS Physician Quality Reporting Initiative Measure Set 2012 – Measure #23)*

6. Reduce the risk of complications from pharmacologic thromboprophylaxis for hospitalized and discharged patients 18 years of age and older. *(Recommendation Summaries B and C; Annotations #3, 5)*

Measures for accomplishing this aim:

a. Percentage of hospitalized patients receiving heparin therapy for venous thromboembolism prophylaxis who have a baseline platelet count before starting heparin, and then a platelet count every other day.

b. Percentage of hospitalized adult patients 18 years and older with a creatinine clearance less than 30 mL/min in the medical record who receive a reduced dose of anticoagulation therapy.

c. Percentage of discharged patients who are readmitted to the hospital for conditions related to venous thromboembolism within 30 days of discharge.

7. Increase the percentage of surgery patients 18 years of age and older who receive appropriate venous thromboembolism prophylaxis within 24 hours prior to anesthesia to 24 hours after anesthesia. *(Recommendation Summaries B and C; Annotations #3, 5)*

Measures for accomplishing this aim:

a. Percentage of surgery patients with recommended venous thromboembolism prophylaxis ordered anytime from hospital arrival to 24 hours after anesthesia end-time. *(SCIP-VTE 1, NQF endorsed, required for CMS reporting)*

b. Percentage of surgery patients who received appropriate venous thromboembolism prophylaxis within 24 hours prior to anesthesia start-time to 24 hours after anesthesia end-time. *(SCIP-VTE-2, NQF endorsed, required for CMS reporting)*
Measurement Specifications

Measurement #1a

Percentage of hospitalized patients who have a venous thromboembolism risk assessment within 24 hours of admission.

Population Definition

Patients 18 years and older admitted to the hospital for a medical condition or surgery.

Data of Interest

\[
\frac{\text{# of patients who are assessed for venous thromboembolism risk within 24 hours of admission}}{\text{# of hospitalized patients}}
\]

Numerator/Denominator Definitions

Numerator: Number of adult patients hospitalized for a medical condition or surgery who are assessed for venous thromboembolism risk assessment within 24 hours of admission to the hospital.

Denominator: Number of adult patients who are hospitalized for a medical condition or surgery.

Method/Source of Data Collection

From discharge records, a list of all adult patients hospitalized during the target period. The medical records can be reviewed to determine the documentation of a completed venous thromboembolism risk assessment.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

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Measurement #2a

Percentage of hospitalized patients who are evaluated for venous thromboembolism prophylaxis upon referral or transfer to another setting, service, practitioner or level of care within or outside the organization.

Population Definition

Patients 18 years and older admitted to the hospital for a medical condition or surgery.

Data of Interest

| # of patients evaluated for venous thromboembolism prophylaxis upon referral or transfer to another setting, service, practitioner or level of care within or outside the organization | # of hospitalized patients |

Numerator/Denominator Definitions

Numerator: Number of adult patients hospitalized for a medical condition or surgery evaluated for venous thromboembolism prophylaxis upon referral or transfer to another setting, service, practitioner or level of care within or outside the organization.

Denominator: Number of adult patients who are hospitalized for a medical condition or surgery.

Method/Source of Data Collection

From discharge records, a list of all adult patients hospitalized during the target period. The medical records can be reviewed to determine whether patients were evaluated for venous prophylaxis before referral or transfer.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.
Measurement #3a

Percentage of hospitalized patients at risk for venous thromboembolism who have venous thromboembolism education within 24 hours of admission that includes 1) venous thromboembolism risk, 2) signs and symptoms, 3) early and frequent mobilization, and 4) clinically appropriate treatment/prophylaxis methods.

Population Definition

Patients 18 years of age and older admitted to the hospital for a medical condition or surgery.

Data of Interest

# of hospitalized patients at risk for venous thromboembolism who have venous thromboembolism education within 24 hours of admission that includes 1) venous thromboembolism risk, 2) signs and symptoms, 3) early and frequent mobilization, and 4) clinically appropriate treatment/prophylaxis methods

# of hospitalized patients at risk for venous thromboembolism

Numerator/Denominator Definitions

Numerator: Number of adult patients hospitalized for a medical condition or surgery at risk for venous thromboembolism who have venous thromboembolism education within 24 hours of admission that includes 1) venous thromboembolism risk, 2) signs and symptoms, 3) clinically appropriate treatment/prophylaxis methods, and 4) early and frequent mobilization.

Denominator: Number of adult patients who are hospitalized for a medical condition or surgery at-risk for venous thromboembolism.

Method/Source of Data Collection

From discharge records, a list of all adult patients hospitalized during the target period. The medical records can be reviewed to determine whether patients at risk for venous thromboembolism were provided education within 24 hours of admission to the hospital.

Time Frame Pertaining to Data Collection

Monthly.

Notes

Improvement is noted as an increase in the rate.

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Measurement #4a

Percentage of hospitalized patients who have a baseline international normalized ratio when initially prescribed warfarin.

Population Definition

Patients 18 years of age and older admitted to the hospital for a medical condition or surgery and prescribed warfarin.

Data of Interest

\[
\frac{\text{# of patients on warfarin who have a baseline international normalized ratio}}{\text{# of hospitalized patients prescribed warfarin}}
\]

Numerator/Denominator Definitions

Numerator: Number of adult patients hospitalized for a medical condition or surgery and on warfarin who have a baseline international normalized ratio.

Denominator: Number of adult patients who are hospitalized for a medical condition or surgery and prescribed warfarin.

Method/Source of Data Collection

From discharge records, a list of all adult patients hospitalized during the target period. The medical records can be reviewed to determine whether patients who are initially prescribed warfarin have a baseline international normalized ratio.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.
Measurement #4b

Percentage of hospitalized patients on warfarin with current international normalized ratio that it is used to monitor and adjust therapy.

Population Definition

Patients 18 years of age and older admitted to the hospital for a medical condition or surgery and prescribed warfarin.

Data of Interest

# of patients on warfarin for whom current international normalized ratio is used to monitor and adjust therapy

# of hospitalized patients on warfarin who have current international normalized ratio

Numerator/Denominator Definitions

Numerator: Number of adult patients hospitalized for a medical condition or surgery and on warfarin for whom current international normalized ratio is used to monitor and adjust therapy.

Denominator: Number of adult patients hospitalized for a medical condition or surgery who are on warfarin and have current international normalized ratio.

Method/Source of Data Collection

From discharge records, a list of all adult patients hospitalized during the target period. The medical records can be reviewed to determine whether patients who are on ongoing warfarin and have current international normalized ratio, and whether it is used to monitor and adjust therapy.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

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Measurement #4c
Percentage of hospitalized patients on prescribed heparin or low-molecular-weight heparin who have appropriate baseline laboratory tests documented.

Population Definition
Patients 18 years of age and older admitted to the hospital for a medical condition or surgery and prescribed heparin and low-molecular-weight heparin.

Data of Interest
\[
\frac{\text{# of hospitalized patients who have appropriate baseline laboratory tests documented}}{\text{# of hospitalized patients prescribed heparin and low-molecular-weight heparin}}
\]

Numerator/Denominator Definitions
Numerator: Number of adult patients hospitalized for a medical condition or surgery and on heparin or low-molecular-weight heparin who have appropriate baseline laboratory tests documented.
Denominator: Number of adult patients who are hospitalized for a medical condition or surgery prescribed heparin or low-molecular-weight heparin.

Method/Source of Data Collection
From discharge records, a list of all adult patients hospitalized during the target period. The medical records can be reviewed to determine whether patients who are prescribed heparin or low-molecular-weight heparin have appropriate baseline laboratory tests.

Time Frame Pertaining to Data Collection
Monthly.

Notes
This is a process measure, and improvement is noted as an increase in the rate.

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Measurement #4d

Percentage of adult hospitalized patients on prescribed heparin or low-molecular-weight heparin who have appropriate ongoing laboratory tests drawn and used to adjust therapy.

Population Definition

Patients 18 years of age and older admitted to the hospital for a medical condition or surgery and prescribed heparin and low-molecular-weight heparin.

Data of Interest

\[ \frac{\text{# of hospitalized patients who have appropriate ongoing laboratory tests drawn and used to adjust therapy}}{\text{# of hospitalized patients prescribed heparin or low-molecular-weight heparin}} \]

Numerator/Denominator Definitions

**Numerator:** Number of adult patients hospitalized for a medical condition or surgery and on heparin or low-molecular-weight heparin who have appropriate ongoing laboratory tests drawn and used to adjust therapy.

**Denominator:** Number of adult patients who are hospitalized for a medical condition or surgery who are prescribed heparin or low-molecular-weight heparin.

Method/Source of Data Collection

From discharge records, a list of all adult patients hospitalized during the target period. The medical records can be reviewed to determine whether patients who are on heparin or low-molecular-weight heparin have appropriate ongoing laboratory tests available.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.
Measurement #5a

Percentage of patients undergoing procedures for which VTE prophylaxis is indicated in all patients who had an order for low-molecular-weight heparin (LMWH), low-dose unfractionated heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end-time.

Notes

This measure is from the Centers for Medicare and Medicaid Services (CMS), Physician Quality Reporting Initiative (PQRI) Measure Set 2011, Measure #23. Measures developers are American Medical Association-sponsored Physician Consortium on Performance Improvement (AMA-PCPI) and National Committee for Quality Assurance (NCQA).

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Measurement #6a

Percentage of adult hospitalized patients receiving heparin therapy for venous thromboembolism prophylaxis who have a baseline platelet count before starting heparin, and then a platelet count every other day over the course of 14 days.

Population Definition

Patients 18 years of age and older admitted to the hospital for a medical condition or surgery.

Data of Interest

\[
\frac{\# \text{ of hospitalized patients receiving heparin therapy who have a baseline platelet count before starting heparin, and then a platelet count every other day over the course of 14 days}}{\# \text{ of hospitalized patients receiving heparin therapy}}
\]

Numerator/Denominator Definitions

Numerator: Number of adult patients hospitalized for a medical condition or surgery and on heparin therapy for venous thromboembolism prophylaxis who have a baseline platelet count before starting heparin, and then a platelet count every other day over the course of 14 days.

Denominator: Number of adult patients who are hospitalized for a medical condition or surgery and receiving heparin therapy for venous thromboembolism prophylaxis.

Method/Source of Data Collection

From discharge records, a list of all adult patients hospitalized during the target period. The medical records can be reviewed to determine whether those patients who are on heparin therapy for venous thromboembolism prophylaxis had a baseline platelet count before starting heparin.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.
**Measurement #6b**

Percentage of adult hospitalized patients with creatinine clearance less than 30 mL/min in the medical record who receive a reduced dose of anticoagulation therapy.

**Population Definition**

Patients 18 years of age and older admitted to the hospital for a medical condition or surgery with creatinine clearance less than 30 mL/min.

**Data of Interest**

\[
\frac{\text{# of hospitalized patients with creatinine clearance less than 30 mL/min who receive a reduced dose of anticoagulation therapy}}{\text{# of hospitalized patients 18 years of age and older with creatinine clearance less than 30 mL/min}}
\]

**Numerator/Denominator Definitions**

**Numerator:** Number of adult patients hospitalized for a medical condition or surgery and with creatinine clearance less than 30 mL/min who receive a reduced dose of anticoagulation therapy.

**Denominator:** Number of adult patients who are hospitalized for a medical condition or surgery with creatinine clearance less than 30 mL/min.

**Method/Source of Data Collection**

From discharge records, a list of all adult patients hospitalized during the target period. The medical records can be reviewed to determine whether those patients with creatinine clearance less than 30 mL/min received a reduced dose of anticoagulation therapy.

**Time Frame Pertaining to Data Collection**

Monthly.

**Notes**

This is a process measure, and improvement is noted as an increase in the rate.

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**Measurement #6c**

Percentage of discharged patients who are readmitted with venous thromboembolism within 30 days of discharge.

**Population Definition**

Patients 18 years of age and older discharged after hospitalization for a medical condition or surgery.

**Data of Interest**

\[
\frac{\text{# of discharged patients who are readmitted with venous thromboembolism within 30 days of discharge}}{\text{# of discharged patients}}
\]

**Numerator/Denominator Definitions**

Numerator: Number of adult discharged patients who are readmitted to the hospital with venous thromboembolism within 30 days of discharge.

Denominator: Number of adult patients who are discharged after hospitalization for a medical condition or surgery.

**Method/Source of Data Collection**

A list of all discharged adult patients during the previous target period. The medical records can be reviewed to determine the documentation of readmission with venous thromboembolism.

**Time Frame Pertaining to Data Collection**

Monthly.

**Notes**

This is a process measure, and improvement is noted as a decrease in the rate.

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Measurement #7a

Percentage of surgery patients with recommended venous thromboembolism prophylaxis ordered anytime from hospital arrival to 24 hours after anesthesia end-time.

Notes

This is a SCIP-VTE-1 measure and is NQF-endorsed consensus standard for hospital care. This measure is required for reporting to the Centers for Medicare and Medicaid Services (CMS).

Full specifications for this measure can be found at The Joint Commission Web site at:

http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures/

Web site link is up-to-date as of March 2011.

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Measurement #7b

Percentage of surgery patients who received appropriate venous thromboembolism prophylaxis within 24 hours prior to anesthesia start-time to 24 hours after anesthesia end-time.

Notes

This is a SCIP-VTE-2 measure and is NQF-endorsed consensus standard for hospital care. This measure is required for reporting to the Centers for Medicare and Medicaid Services (CMS).

Full specifications for this measure can be found at the Joint Commission Web site at:

http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures/

Web site link is up-to-date as of March 2011.

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Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization.

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline:

- Implement a defined anticoagulation management program to individualize the care provided to each patient receiving anticoagulation therapy.

- (Clinics and Hospitals): Develop systems for monitoring the effects of anticoagulation therapy (heparin, low-molecular-weight heparin, warfarin and other anticoagulants) to include monitoring of outpatient therapy:
  - Use of standardized practices/protocols that include patient involvement.

- When heparin is administered intravenously and continuously, the organization should use programmable infusion pumps.

- Develop systems for providing patient/family education that includes the importance of follow-up monitoring, compliance issues, dietary restrictions, and potential adverse drug reactions and interactions.
  - Patient education to include documentation of the patient's own awareness of his/her risk for venous thromboembolism, signs and symptoms of venous thromboembolism, activity level when/how to seek treatment, and demonstrated understanding of the prescribed anticoagulation regimen.
  - The ICSI work group gleaned the following perspectives and insights from ICSI's Patient Advisory Council in June 2012:
    - Patients stated the following attributes would be important for effective delivery of information about VTE prophylaxis to the hospitalized medical patient:
      - Patients prefer that a clinician, preferably a physician, deliver prophylaxis information, in a compassionate and clear manner that can be understood by a layperson. Accompanying this with supporting material such as a visual aid in video format would be ideal. Written material might be saved for later but is not preferred at initial contact.
      - The medically ill patient may not be able to comprehend or retain information given his or her condition so it is important to involve an advocate such as a family member.
      - Since the prophylaxis is not related to the primary treatment plan or reason for admission, patients would prefer that the clinician guide the decision by indicating whether he or she strongly recommends it or not. It is better received if the positive benefits of the treatment are stressed along with the fact it is a routine practice or standard of care.
      - If a cost will be incurred by the patient, he or she appreciates knowing that to assist decision-making.

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As to elective surgical procedures, patients indicated that they preferred to get the information from the surgeon during the preoperative evaluation process.

- Develop a policy for providing organizational education regarding anticoagulation therapy to prescriber(s), staff, patients and families.

- Develop protocols for the initiation and maintenance of anticoagulation therapy appropriate to the medication used, to the condition being treated, and to the potential for drug interactions.

See Appendix A, "Improvement Strategies," for additional information on implementation.

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Implementation Tools and Resources

Criteria for Selecting Resources

The following tools and resources specific to the topic of the guideline were selected by the work group. Each item was reviewed thoroughly by at least one work group member. It is expected that users of these tools will establish the proper copyright prior to their use. The types of criteria the work group used are:

- The content supports the clinical and the implementation recommendations.
- Where possible, the content is supported by evidence-based research.
- The author, source and revision dates for the content is included where possible.
- The content is clear about potential biases and when appropriate conflicts of interests and/or disclaimers are noted where appropriate.

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## Implementation Tools and Resources Table

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<tr>
<th>Author/Organization</th>
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<th>Audience</th>
<th>Web Sites/Order Information</th>
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</thead>
<tbody>
<tr>
<td>Anticoagulation Forum</td>
<td>The forum is a multidisciplinary non-profit organization of health care professionals across the country. The site is useful for finding clinics in other states and professional meetings relevant to anticoagulation.</td>
<td>Health Care Professionals</td>
<td><a href="http://www.acforum.org">http://www.acforum.org</a></td>
</tr>
<tr>
<td>Care Clinical Research</td>
<td>The Web site provides resource on cardiovascular and respiratory diseases, by a clinical research company engaged in drug and device research. All information is peer reviewed by a select panel of professionals and laypersons. It includes information specific to antithrombotic therapy.</td>
<td>Health Care Professionals; Patients and Families</td>
<td><a href="http://www.careinternet.net">http://www.careinternet.net</a></td>
</tr>
<tr>
<td>The Coalition to Prevent Deep Vein Thrombosis</td>
<td>This site is designed to provide information about DVT/PE, promote DVT awareness and DVT screening, and provide tools and resources that can help identify DVT risk. Sponsored in part by sanofi-aventis U.S. LLC.</td>
<td>Patients and Families</td>
<td><a href="http://www.preventdvt.org/">http://www.preventdvt.org/</a></td>
</tr>
<tr>
<td>Health Services Advisory Group</td>
<td>VTE Guide for Executives. Practical tools and materials that hospital executive leadership can use to take a driving role in implementing a VTE prophylaxis process for its patients.</td>
<td>Health Care Professionals</td>
<td><a href="http://www.hsag.com/services/special/VTE.aspx">http://www.hsag.com/services/special/VTE.aspx</a></td>
</tr>
<tr>
<td>National Blood Clot Alliance</td>
<td>Blood clot education for patients and professionals. Public (CDC), non-profit, and for-profit sponsors.</td>
<td>Patients and Families; Health Care Professionals</td>
<td><a href="http://www.stoptheclot.org/">http://www.stoptheclot.org/</a></td>
</tr>
</tbody>
</table>

*Return to Table of Contents*
<table>
<thead>
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<th>Author/Organization</th>
<th>Title/Description</th>
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</tr>
</thead>
</table>
| Society of Hospital Medicine | The Quality Improvement (QI) Resource Rooms present the information and tools needed to lead quality improvement projects.  

The following guide is available in the VTE resource room, which is sponsored in part by a non-educational sponsorship from Sanofi-Aventis U.S. LLC.                                                                                                                                                                                                 | Health Care Professionals; Quality Improvement Staff | Stein, J, Maynard G. Preventing Hospital-Acquired Venous-Thromboembolism, A Guide for Effective Quality Improvement, Version 3.3. Society of Hospital Medicine Web site, Venous Thromboembolism Quality Improvement Resource Room.  

http://www.hospitalmedicine.org/ResourceRoomRedesign/RR_VTE/html_VTE/00_ImplementationGuide.cfm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Vascular Disease Foundation | A four-minute video educates patients on how blood clots form. It is appropriate for both medical and surgical scenarios.  

The foundation does not have medical experts on staff. Its purpose is to provide public education about vascular diseases.                                                                                                                                                                                                                                                                                                                                                                                      | Patients and Families; Health Care Professionals | http://vasculardisease.org/education-prevention/knowledge-is-power/how-blood-clots-form/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
Supporting Evidence:
Venous Thromboembolism Prophylaxis

The subdivision of this section is:

- References
- Appendix
References

Links are provided for those new references added to this edition (author name is highlighted in blue).


Appendix A – Improvement Strategies

The following improvement strategies and elements are helpful to develop, implement, and improve quality and patient safety.

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

1. Institutional support and prioritization for the initiative, expressed in terms of a meaningful investment in time, equipment, personnel and informatics, and a sharing of institutional improvement experience and resources to support any project needs.

2. A multidisciplinary team or steering committee focused on reaching VTE prophylaxis targets and reporting to key medical staff committees.

3. Reliable data collection and performance tracking.

4. Specific goals, or aims, which are ambitious, time-defined and measurable.

5. A proven QI framework to coordinate steps towards breakthrough improvement.


7. Institutional infrastructure, policies, practices, or educational programs promoting the use of the protocol.

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

The information was gathered from http://www.hospitalmedicine.org/ResourceRoomRedesign/RR_VTE/PDFs/VTEPreventionGuidev3.3.pdf

The detailed guide found on the Web site may be useful to your organization to direct improvement and sustainment activities.

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ICSI has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report, Clinical Practice Guidelines We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at http://bit.ly/ICSICOI.

**Funding Source**

The Institute for Clinical Systems Improvement provided the funding for this guideline revision. ICSI is a not-for-profit, quality improvement organization based in Bloomington, Minnesota. ICSI's work is funded by the annual dues of the member medical groups and five sponsoring health plans in Minnesota and Wisconsin. Individuals on the work group are not paid by ICSI but are supported by their medical group for this work.

ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups and sponsoring health plans review and provide feedback but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

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Financial/Non-Financial Conflicts of Interest: Husband works for Abbott Labs, which does not make pharmaceuticals for VTE prophylaxis

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Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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All ICSI documents are available for review during the revision process by member medical groups and sponsors. In addition, all members commit to reviewing specific documents each year. This comprehensive review provides information to the work group for such issues as content update, improving clarity of recommendations, implementation suggestions and more. The specific reviewer comments and the work group responses are available to ICSI members at http://bit.ly/VTEProphy1112.

The ICSI Patient Advisory Council meets regularly to respond to any scientific document review requests put forth by ICSI facilitators and work groups. Patient advisors who serve on the council consistently share their experiences and perspectives in either a comprehensive or partial review of a document, and engaging in discussion and answering questions. In alignment with the Institute of Medicine’s triple aims, ICSI and its member groups are committed to improving the patient experience when developing health care recommendations.

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Acknowledgements

ICSI Patient Advisory Council

The work group would like to acknowledge the work done by the ICSI Patient Advisory Council in reviewing the Venous Thromboembolism Prophylaxis guideline and thank them for their suggestion to improve the Venous Thromboembolism Prophylaxis guideline and patient education about venous thromboembolism prevention.

Invited Reviewers

During this revision, the following groups reviewed this document. The work group would like to thank them for their comments and feedback.

CentraCare, St. Cloud, MN
Marshfield Clinic, Marshfield, WI
Mayo Clinic, Rochester, MN

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Document History and Development:
Venous Thromboembolism Prophylaxis

Document History

2011

- Implemented GRADE approach to classing the strength of articles
- Use of new Summary of Changes template
- Incorporated Order Set into the guideline

2012

- Removed Order Set from the guideline

Released in September 2012 for Ninth Edition.

The next scheduled revision will occur within 24 months.

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<td>HealthPartners Medical Group</td>
<td>Affiliated Community Medical Centers</td>
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Online at http://www.ICSI.org

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ICSI Document Development and Revision Process

Overview

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

Audience and Intended Use

The information contained in this ICSI Health Care Guideline is intended primarily for health professionals and other expert audiences.

This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in their individual case.

This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Document Development and Revision Process

The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The ICSI staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other guidelines, regulatory statements and other pertinent literature. This literature is evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the guideline. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each guideline as part of the revision process. They provide comment on the scientific content, recommendations, implementation strategies and barriers to implementation. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the guideline is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

Implementation Recommendations and Measures

These are provided to assist medical groups and others to implement the recommendations in the guidelines. Where possible, implementation strategies are included that have been formally evaluated and tested. Measures are included that may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included.

Document Revision Cycle

Scientific documents are revised every 12-24 months as indicated by changes in clinical practice and literature. ICSI staff monitors major peer-reviewed journals every month for the guidelines for which they are responsible. Work group members are also asked to provide any pertinent literature through check-ins with the work group midcycle and annually to determine if there have been changes in the evidence significant enough to warrant document revision earlier than scheduled. This process complements the exhaustive literature search that is done on the subject prior to development of the first version of a guideline.

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