Complete Summary

GUIDELINE TITLE

Venous thromboembolism prophylaxis.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Venous thromboembolism prophylaxis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Jun. 52 p. [99 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Venous thromboembolism prophylaxis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jun. 51 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.
- August 16, 2007, Coumadin (Warfarin): Updates to the labeling for Coumadin to include pharmacogenomics information to explain that people's genetic makeup may influence how they respond to the drug.

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SCOPE

DISEASE/CONDITION(S)

Venous thromboembolism

GUIDELINE CATEGORY

Prevention
Risk Assessment

CLINICAL SPECIALTY

Anesthesiology
Emergency Medicine
Family Practice
Hematology
Internal Medicine
Orthopedic Surgery
Preventive Medicine
Pulmonary Medicine
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To increase the percentage of hospitalized adult patients (18 years and older) who are appropriately assessed for venous thromboembolism (VTE) risk within 24 hours of admission

- To increase the percentage of patients who are assessed for VTE risk upon change in level of care, change in providers, and/or upon discharge
- To increase the percentage of hospitalized adult patients (18 years and older) who are at risk of VTE who have received education for VTE that includes VTE risk signs and symptoms and treatment/prophylaxis methods available within 24 hours of admission
- To increase the percentage of hospitalized adult patients who begin early and frequent ambulation to reduce VTE risk
- To increase the percentage of hospitalized adult patients (18 years and older) receiving appropriate pharmacological and/or mechanical prophylaxis treatment within 24 hours of admission
- To reduce the risk of complications from pharmacologic prophylaxis
- To increase the percentage of patients who are discharged on warfarin who have an international normalized ratio (INR) within one week

TARGET POPULATION

Adult (18 years and older) hospitalized patients

INTERVENTIONS AND PRACTICES CONSIDERED

1. Assessment of venous thromboembolism (VTE) risk including procedure-related risk and patient-related risk
2. VTE prophylaxis for low-risk patients including patient education and early ambulation
3. VTE prophylaxis for moderate- and high-risk patients including patient education, early ambulation, elastic graded compression stockings, intermittent pneumatic compression (IPC) if immobilized, and anticoagulant prophylaxis (unfractionated heparin [UFH] or low molecular weight heparin [LMWH - enoxaparin and dalteparin]) unless contraindicated.

   Note: Aspirin is not recommended.

4. VTE prophylaxis for very high-risk patients including patient education, early ambulation, elastic graded compression stockings, IPC if immobilized, and anticoagulant prophylaxis (LMWH, fondaparinux, or adjusted dose warfarin unless contraindicated)

   Note: Aspirin and unfractionated heparin are not recommended.

5. Assessment of the need for post-discharge anticoagulation

MAJOR OUTCOMES CONSIDERED

- Incidence and prevalence of venous thromboembolism in hospitalized patients undergoing procedures or suffering significant trauma
- Rate of thromboembolic events including pulmonary embolism in patients on low molecular weight heparin (LMWH) versus unfractionated heparin (UFH)
- Rate of perioperative death in patients on LMWH versus UFH
- Rate of intraoperative and postoperative bleeding (major and minor) in patients on LMWH versus UFH

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature search of clinical trials, meta-analysis, and systematic reviews is performed.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results

from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

New Guideline Development Process

A new guideline, order set, and protocol is developed by a 6- to 12-member work group that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, along with an Institute for Clinical Systems Improvement (ICSI) staff facilitator. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 members may be recruited from medical groups or hospitals outside of ICSI.

The work group will meet for seven to eight three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and footnotes and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Critical Review Process

Every newly developed guideline or a guideline with significant change is sent to ICSI members for Critical Review. The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within the Institute for Clinical Systems Improvement (ICSI).

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

Approval

Each guideline, order set, and protocol is approved by the appropriate steering committee. There is one steering committee each for Respiratory, Cardiovascular, OB/GYN, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each guideline based on the following:

- Member comments have been addressed reasonably.
- There is consensus among all ICSI member organizations on the content of the document.
- Within the knowledge of the reviewer, the scientific recommendations within the document are current.
- Either a critical review has been carried out, or to the extent of the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of critical review is not needed.

Once the guideline, order set, or protocol has been approved, it is posted on the ICSI Web site and released to members for use. Guidelines, order sets, and protocols are reviewed regularly and revised, if warranted.

Revision Process of Existing Guidelines

ICSI scientific documents are revised every 12 to 36 months as indicated by changes in clinical practice and literature. Every 6 months, ICSI checks with the work group to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Prior to the work group convening to revise the document, ICSI members are asked to review the document and submit comments. During revision, a literature search of clinical trials, meta-analysis, and systematic reviews is performed and reviewed by the work group. The work group will meet for 1-2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

If there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations, it is sent to members to review prior to going to the appropriate steering committee for approval.

Review and Comment Process

ICSI members are asked to review and submit comments for every guideline, order set, and protocol prior to the work group convening to revise the document.

The purpose of the Review and Comment process is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the order set and protocol. Review and Comment also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the guideline.

All member organizations are encouraged to provide feedback on order sets and protocol, however responding to Review and Comment is not a criterion for continued membership within ICSI.

After the Review and Comment period, the work group reconvenes to review the comments and make changes as appropriate. The work group prepares a written response to all comments.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): For a description of what has changed since the previous version of this guidance, refer to Summary of Changes Report – June 2007.

The recommendations for venous thromboembolism (VTE) prophylaxis are presented in the form of an algorithm with 9 components, accompanied by detailed annotations. An algorithm is provided for Venous Thromboembolism Prophylaxis; clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are provided at the end of the "Major Recommendations" field.

Clinical Highlights and Recommendations

- All patients should be evaluated for VTE risk upon hospital admission, change in level or care, change in providers, and prior to discharge. (*Annotations #1, 2*)
- All patients should receive proper education regarding VTE risk, signs and symptoms of VTE, and prophylaxis methods available. (*Annotations #4, 5, 6, 7, 8*)
- Early and frequent ambulation should be encouraged when possible in all patient groups. (*Annotations #4, 5, 6, 7, 8*)
- Risk of VTE development continues beyond hospitalization, and the need for post-discharge anticoagulation should be assessed. (*Annotations #7, 8*)
- All surgical/trauma patients who have moderate/high or very high risks for VTE should receive anticoagulation prophylaxis unless contraindicated. (*Annotations #7, 8*)
- All medical patients who have a high risk for VTE should receive anticoagulation prophylaxis unless contraindicated. (*Annotation #7, 8*)
- Aspirin is not recommended for routine VTE prophylaxis following hip/knee arthroplasty but may be considered in some circumstances. Further study is needed. (*Annotation #8*)
- Aspirin and antiplatelet drugs are not recommended for VTE prophylaxis in other surgical patients or medically ill patients. (*Annotations #7, 8*)
- For all patients receiving spinal or epidural anesthesia, precautions should be taken when using anticoagulant prophylaxis to reduce the risk of epidural hematoma. (*Annotation #9*)

Venous Thromboembolism Prophylaxis Algorithm Annotations

1. **Adult Admitted to an Acute Care Hospital**

   The American College of Chest Physicians (ACCP) consensus recommends that all institutions develop a formal strategy that addresses the prevention of thromboembolic complications. This guideline is intended for patients who may have patient-related and/or procedure-related risk factors that increase the risk for VTE.

   Appropriate prophylactic measures should be utilized whenever possible to minimize these risks and lower overall morbidity and mortality associated with this disease.

   Frequently encountered high-risk circumstances are best addressed with written protocols and order sets to standardize the care given to these types of patients.

2. **Assess VTE Risk**

Key Points:

- All patients should be assessed for VTE risk upon admission, change in level of care, change in providers, and/or upon discharge.
- Patients undergoing surgical procedures or suffering significant trauma are at risk for developing venous thromboembolism.
- Patients admitted for medical reasons should be evaluated for risk of VTE development.
- Appropriate prophylaxis measures should be initiated for patients based on risk for developing VTE.

Multiple studies have identified risk factors associated with VTE in hospitalized patients. Medical factors are considered to be contributory to surgical- and trauma-related factors, though the degree of increased risks to patients has not been well studied.

Procedure-Related Risk

Patients undergoing surgical procedures have VTE risks associated with the procedure such as:

- Site
- Surgical technique
- Duration
- Type of anesthesia
- Complications (infection, shock, etc.)
- Degree of immobilization

Procedures that are considered high-risk include:

- Major open abdominal or urologic surgery
- Cranial and spinal neurosurgical procedures
- Open gynecologic procedures

Lower extremity joint replacement and hip fracture repair are considered very high VTE risk in themselves.

Patients with trauma have VTE risks dependent on location and severity. Patients with multi-system, spinal cord, or lower extremity blunt trauma appear to be at very high-risk.

Refer to the original guideline document for patient-related VTE risk factors that play an additive role and for VTE risk for surgery without prophylaxis.

Evidence supporting this recommendation is of classes: A, M, R

3. **Contraindications to Pharmacologic prophylaxis?**

Pharmacologic prophylaxis is not without risk; however, for short-term prophylactic anticoagulation there are relatively few conditions with excessive bleeding risk or other considerations that would contraindicate anticoagulation. The patient's risk for thrombosis needs to be balanced with their risk of bleeding. There is no substitute for critical assessment and judgment on the part of the clinician when considering the relative benefits and risks of prophylactic anticoagulation.

Contraindications for pharmacologic prophylaxis include:

a. Active major, significant bleeding (e.g., cerebral hemorrhage)
b. Extreme thrombocytopenia (less than 50,000 mm^3)
c. History of heparin-induced thrombocytopenia (HIT), contraindicated for use of heparins
d. Uncontrolled hypertension (systolic greater than 200, diastolic greater than 120)
e. Bacterial endocarditis
f. Active hepatitis or hepatic insufficiency
g. Other conditions that could increase the risk of bleeding

Neuraxial blockade is not a contraindication for pharmacologic prophylaxis. 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 prophylaxis. See Annotation #9, "Neuraxial Blockade" for more information.

4. **VTE Prophylaxis Plan**

Patients with contraindications to pharmacologic prophylaxis should receive VTE prophylaxis to the extent possible in relation to procedure-related and patient-related risks.

Patients at high risk for thrombosis and contraindications for pharmacologic prophylaxis present special challenges, and consultation with an anticoagulation expert may be considered.

Patients at risk for developing a VTE should receive patient education, early ambulation, and elastic graded compression stockings. If confined to bed, intermittent pneumatic compression (IPC) should be considered. Although no specific studies exist to document the value of patient education and early ambulation to reduce VTE risk, the work group believes these measures are important for patients at risk for VTE, including those in the high-risk group.

Patient Education

All patients, irrespective of their risk for VTE, should receive patient education about VTE. Patient education should include VTE risk, signs and symptoms of VTE, and treatment/prophylactic measures available. Patient education should encourage early and frequent ambulation and flexion/extension exercises for the ankles.

Ambulation

Early mobilization is a therapy to enhance a patient's well-being. This therapy may result in shorter hospitalization due to a specific mobilization program utilized to help patients start regaining their strength. This practice may start mobilization earlier than normally practiced.

Physical therapy may need to be involved as soon as possible, and mobilization will start by sitting and progress to walking if applicable. This should be done every shift or more based on how the patient tolerates mobilization.

Elastic Graded Compression Stockings and Intermittent Pneumatic Compression Devices

In moderate-risk patients with contraindications to pharmacologic prophylaxis, elastic graded compression stockings and intermittent pneumatic compression may be considered an alternative to unfractionated heparin (UFH) and low-molecular-weight heparin (LMWH), bearing in mind that there is less data to support this strategy, that hemorrhagic complications are low with both strategies, and that compliance may be a significant problem when relying on intermittent pneumatic compression alone for VTE prophylaxis.

Refer to the original guideline document for additional information about above-the-knee versus bellow-the-knee stockings and ICP devices.

Evidence supporting this recommendation is of classes: A, C, D, M, R

5. **Initiate VTE Prophylaxis Based on Risk Level**

All patients irrespective of their risk for VTE should receive patient education about VTE. Patient education should include VTE risk, signs and symptoms of VTE, and available treatment/prophylactic measures available. Patient education should encourage early and frequent ambulation and flexion/extension exercises for the ankles.

Clinicians should reevaluate the patient and the continuing risk for VTE when there is a change in level of care, change in providers, and prior to discharge. Risk of developing VTE may extend beyond hospitalization. Consideration should be given to extending the period of anticoagulation prophylaxis beyond hospitalization, depending on the patient's risk of VTE and the clinician's judgment.

Evidence supporting this recommendation is of classes: A, B, R

6. **Low VTE Risk**

Low-risk patients include those under the age of 40 with no additional risk factors undergoing minor procedures. See Annotation #2, "Assess VTE Risk for Procedure-Related and/or Patient-Related Risk Factors" (for patient-related risk factors see the original guideline document).

In this group, the incidence of proximal deep vein thrombosis (DVT) is 0.4% and of fatal pulmonary embolism (PE) 0.002%.

VTE Prophylaxis Plan for Low Risk

No specific measures are required beyond patient education and early ambulation.

Evidence supporting this recommendation is of class: D, R

7. **Moderate/High VTE Risk**

Key Points:

- Pharmacologic prophylactic regimens are started one to two hours prior to surgery.
- Aspirin is not recommended as an anticoagulation regimen.
- For short-term prophylactic anticoagulation there are relatively few conditions with excessive bleeding risk or other considerations that would contraindicate anticoagulation.

Moderate-risk patients include:

- Major surgery in those less than 40 years of age
- Minor surgery in those age 40 to 60
- Minor surgery in those less than age 40 with additional risk factors (prior VTE, cancer, hypercoagulability)

Without prophylaxis, moderate-risk VTE patients have a 2 to 4% proximal DVT risk, 1 to 2% clinical PE risk, and a 0.1 to 0.4% risk of fatal PE.

High-risk patients include:

- Minor surgery in those over 60 years of age without additional risk factors
- Major surgery in those over 40 years of age without additional risk factors
- Minor surgery in those over 40 years of age with additional risk factors (prior VTE, cancer, hypercoagulability)

Without prophylaxis, high-risk VTE patients have a 4 to 8% proximal DVT risk, 2 to 4% clinical PE risk, and a 0.4 to 1.0% risk of fatal PE.

See Annotation #2, "Assess VTE Risk for Procedure-Related and/or Patient-Related Risk Factors" (for patient-related risk factors see the original guideline document).

Evidence supporting this recommendation is of classes: B, D, R

VTE Prophylaxis Plan for Moderate/High VTE Risk

In addition to patient education and early ambulation, all patients with moderate risk for VTE should receive elastic graded compression stockings, intermittent pneumatic compression if immobilized, and pharmaco-logic prophylaxis unless contraindicated. Pharmacologic regimens reduce compliance issues and have been shown to reduce the incidence of postoperative VTE.

- **Pharmacologic Prophylaxis**

  For short term prophylactic anticoagulation there are relatively few conditions with excessive bleeding risk or other considerations that would contraindicate anticoagulation. Acceptable pharmacologic regimens include UFH and LMWH. Aspirin is not recommended.

Selecting a Pharmacologic Agent

Three issues that need to be addressed are choice of agent, dosing, and duration of therapy. For moderate-risk patients who do not have a contraindication to pharmacologic prophylaxis, the current choice is between LMWH and UFH started 1 to 2 hours prior to surgery, subcutaneously every 8 to 12 hours. Aspirin has not been shown to be an effective agent in general surgical patients and is not recommended.

UFH is cost effective and effective in reducing the risk of postoperative VTE in moderate-risk patients. While LMWH has the convenience of single-day dosing, it is not superior to UFH and is significantly more expensive. Further, overall complication rates appear similar between UFH and LMWH.

Studies, primarily in patients over 40 years of age, have shown that UFH is as effective as LMWH as an anticoagulant prophylactic agent for moderate- and high-risk surgical patients. [*Conclusion Grade I: See Conclusion Grading Worksheet A - Annotation #7, 8 (Selecting Heparin) in the original guideline document*]

See Appendix C, "Pharmacologic Prophylaxis Table" for more information.

- **Mechanical Prophylaxis**

  Data suggest that below knee and above knee stockings are equally effective and the effectiveness of stockings is enhanced when combined with other measures. Side effects are rare, although a proper fit, particularly in the obese, may be difficult in 10-15% of patients. In general, the data would not support the use of elastic stockings as the sole measure in this group.

  The clinical implications of this are unknown although augmentation with foot pumps was less than with IPC devices. Foot pumps may be better tolerated and can be applied in cases in which the leg is not available for placement of an IPC device but the work group is not aware of any studies comparing IPC and foot pumps in general surgery or trauma patients.

See Annotation #4 for more information on elastic graded compression stockings and intermittent pneumatic compression devices.

Although the work group recommends all of the above non-pharmacologic methods for high-VTE-risk patients, the work group also strongly recommends pharmacologic prophylaxis in these patients unless specifically contraindicated. There is no substitute for critical assessment and judgment on the part of the clinician when considering the relative benefits and risks of prophylactic anticoagulation.

Evidence supporting this recommendation is of classes: A, C, M, R

Supportive Statements for Pharmacotherapy of High-VTE-Risk Patients:

1. For most general surgery patients, UFH remains the agent of choice. LMWH has been found to be as safe and effective yet remains significantly more expensive.
2. In general surgery, patients may receive preoperative heparin without increased risk of bleeding.
3. LMWHs cause less heparin-induced thrombocytopenia (HIT) than UFH. There is early evidence to support the use of fondaparinux in HIT although further confirmatory studies are needed.
4. LMWH should be adjusted at prophylactic doses for patients with a creatinine clearance less than 30 mL/minute. The manufacturer-recommended dose of enoxaparin is 30 mg daily in this population; the manufacturer of dalteparin does not list a similar dose recommendation.
5. Fixed-dose prophylaxis in the severely obese patient will likely result in underdosing. Current expert opinion suggests that LMWH be increased by 25% in the very obese patient (body mass index [BMI] 35 or more): for example, enoxaparin 40 mg every 12 hours.
6. In gynecologic surgery, evidence is strongest to support use of UFH. For patients with malignancy, a regimen of every-8-hour dosing should be maintained.

Additional patient related risk factors may place younger patients and/or those with more minor procedures into the high-risk category. (See Annotation #2 in the original guideline document for more information.)

8. **Very High VTE Risk**

Key Points:

- For short-term prophylactic anticoagulation there are relatively few conditions with excessive bleeding risk or other considerations that would contraindicate anticoagulation.
- Consideration should be given to extending the period of pharmacologic prophylaxis beyond hospitalization.
- Aspirin and antiplatelet drugs are not recommended for VTE prophylaxis in other surgical patients or medically ill patients.

Very high-risk patients include:

- Major surgery in patients over 40 years of age with a history of prior VTE or cancer
- All hip and knee arthroplasty patients
- All hip fracture patients
- All major trauma patients
- All spinal cord injury patients

Without prophylaxis, very-high-risk patients have VTE rates ranging from 40 to 80%. The risk of PE ranges from 4 to 10%, with 0.2 to 5% of patients having a fatal PE.

Evidence supporting this information is of classes: A, B, C, D, R

Prophylaxis Plan for Very High VTE Risk

All patients at very high risk for VTE should receive patient education, early ambulation, elastic graded compression stockings, intermittent pneumatic compression if immobilized, and pharmacologic prophylaxis unless contraindicated. For short-term prophylactic anticoagulation, there are relatively few conditions with excessive bleeding risk or other considerations that would contraindicate anticoagulation. Aspirin is not recommended for VTE prophylaxis in other surgical patients or medically ill patients.

- **Pharmacologic Prophylaxis**

  Acceptable anticoagulation regimens include LMWH, fondaparinux, and adjusted dose warfarin to keep the international normalized ratio (INR) between 2.0 and 3.0. UFH is not recommended.

  Consideration should be given to extending the period of anticoagulation prophylaxis beyond hospitalization, depending on the length of hospital stay. If anticoagulation is contraindicated, placement of an inferior vena cava (IVC) filter should be considered in this patient group.

- **Ambulation and Mechanical Prophylaxis**

  Although no specific studies exist to document the value of patient education and early ambulation to reduce VTE risk, the work group believes these measures are important for all VTE risk patients, including those in the very-high-risk group. Several studies have documented the efficacy of elastic stockings in moderate- and high-VTE-risk patients (See Annotation #4, "VTE Prophylaxis Plan").

  Although not studied as a sole method of prophylaxis in very-high-VTE-risk patients, the work group recommends elastic stocking use in this group as an adjunct to other methods. Several studies support the use of pneumatic compression devices as effective in reducing the VTE rate in the very-high-VTE-risk.

Although the work group recommends all of the above non-pharmacologic methods for very-high-VTE-risk patients, the work group also strongly recommends prophylactic anticoagulation in these patients unless contraindicated.

Evidence supporting this recommendation is of classes: A, B, C, D, M, R

Supportive Comments for Pharmacotherapy of Patients at Very High VTE Risk:

1. Warfarin is contraindicated in the first trimester of pregnancy. Refer to the National Guideline Clearinghouse (NGC) summary of the Institute for Clinical systems Improvement (ICSI) Antithrombotic Therapy Supplement for further dosing information.
2. Warfarin (INR 2.0 to 3.0) alone without concomitant heparin has been shown effective in prevention of venous thromboembolism for patients requiring hip replacement surgery or elective knee arthroplasty.
3. Warfarin may be used when the patient has a history of heparin-induced thrombocytopenia (HIT)
4. LMWHs cause less HIT than UFH. There is early evidence to support the use of fondaparinux in HIT although further confirmatory studies are needed.
5. LMWH should be adjusted to prophylactic doses for patients with a creatinine clearance less than 30 mL/min. The manufacturer-recommended dose of enoxaparin is 30 mg daily in this population; the manufacturer of dalteparin does not list a similar dose recommendation.
6. Fixed-dose prophylaxis in the severely obese patient will likely result in underdosing. Current expert opinion suggests that LMWH be increased by 25% in the very obese patient (body mass index [BMI] 35 or more): for example, enoxaparin 40 mg every 12 hours.
7. In patients who have undergone total knee replacement (TKR), total hip replacement (THR), and hip fracture repair, a minimum of 10 days of anticoagulation prophylaxis is recommended. For patients undergoing total hip replacement or hip fracture repair, extending prophylaxis to 28 to 35 days of postoperative anticoagulation should be considered.
8. Dalteparin and enoxaparin are started 12 to 24 hours post-op depending on physician determination of adequate hemostasis.
9. Fondaparinux is the only anticoagulant with an FDA-approved indication for hip fracture.
10. UFH is not recommended for very high-risk patients.
11. For trauma patients, contraindications to early pharmacotherapy include intracranial bleeding, incomplete spinal cord injury, ongoing, uncontrolled bleeding, and uncorrected coagulopathy.

Use of Aspirin Following Hip/Knee Arthroplasty

Although it remains controversial, interest persists in the orthopedic community regarding the use of aspirin for VTE prophylaxis following elective hip and knee arthroplasty. The debate over the use of aspirin for VTE

prophylaxis is occurring in Minnesota and across the U.S. The work group has put in a Pro/Con forum in the original guideline document to illustrate this debate. The American College of Chest Physicians (ACCP) recommends against the use of aspirin. Aspirin is not recommended for routine VTE prophylaxis following hip/knee arthroplasty but may be considered in some circumstances. Further study is needed.

9. **Neuraxial Blockade**

Neuraxial blockade is not a contraindication for pharmacologic prophylaxis. 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 prophylaxis. Neuraxial blockade should generally be avoided in patients with a clinical bleeding disorder.

General Guidelines:

1. All patients who receive neuraxial blockade should be monitored closely 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.
2. Both insertion and removal of neuraxial catheters are significant events. The timing of those events and the timing of any anticoagulation drugs should be taken into consideration as well as the pharmacokinetics and pharmacodynamics of the specific anticoagulant drugs.
3. The emergence of new drugs and unexpected clinical scenarios can render any guideline obsolete. Consultation with an anesthesiologist experienced in regional anesthesia is essential for novel situations.
4. 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 can be used for detailed management. These guidelines are available at http://www.asra.com.

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 as well as 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 VTE 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.

Evidence supporting this recommendation is of classes: D, R

Heparin with Neuraxial Blockade

In general, the most critical time for risk of perispinal hematoma is with indwelling catheter insertion and removal.

- **Unfractionated Heparin**

  UFH for VTE prophylaxis in patients receiving neuraxial blockade does not appear to have significant risk. The ASRA guideline indicates no change in approach to patients receiving UFH. If the patient has received four or more days of UFH preoperatively, he or she should be assessed for HIT. Optimally, the insertion of an epidural catheter occurs after three to four half-lives of the drug have elapsed. Depending on the drug and the renal clearance of the patient, this can be 12 to 24 hours for UFH or LMWH. An epidural catheter should be removed when the anticoagulation effect is at its minimum; approximately two hours before the next scheduled injection. Anticoagulation therapy may be resumed two hours after the catheter has been removed.

- **Low-Molecular-Weight Heparin**

  LMWH for VTE prophylaxis in patients receiving neuraxial blockade has some potential issues. In 1997, the U.S. Food and Drug Administration (FDA) issued a physician advisory for LMWH and risk of spinal hematoma. They described 43 U.S. patients who developed perispinal hematoma after receiving the LMWH enoxaparin for VTE prophylaxis. Many of these patients developed permanent neurologic sequelae despite 65% receiving aggressive therapy and laminectomy. The median age of the patients was 78 years, and 78% of the patients were women. The potential risk factors were many, including presence of underlying hemostatic disorder, traumatic needle or catheter insertion, repeated needle insertion attempts or a bloody return in the catheter, catheter insertion or removal in the setting of significant anticoagulation, concurrent use of other antithrombotic agents, use of continuous epidural catheters, anticoagulant dosages and vertebral column abnormalities. There were not large enough patient numbers to develop prevalence data nor establish relative risk for any of the individual risk factors. Therefore, no specific conclusions could be made.

Evidence supporting this recommendation is of classes: B, R, Not Assignable

Warfarin with Neuraxial Blockade

There is no increased risk of perispinal hematoma in patients receiving warfarin postoperatively. However, the mean time to catheter removal was approximately 36 hours and the majority of patients did not have an international normalized ratio (INR) above 1.5 at the time of removal in the study by Horlocker detailed in the original guideline document.

The ASRA guideline (http://www.asra.com) indicates removal of catheter when INR is less than 1.5 with INR checks perioperatively and daily if the first dose of coumadin was given greater than 24 hours preoperatively.

Evidence supporting this recommendation is of classes: B, D

Newer Anticoagulant Drugs with Neuraxial Blockade

The use of the newer Factor Xa inhibitor, fondaparinux, or the thrombin inhibitors related to hirudin is a relative contraindication to all regional anesthesia. The emergence of other newer anticoagulant drugs requires that each be evaluated with regard to its safety in combination with regional anesthesia. In all such circumstances, consultation with an anesthesiologist experienced in regional anesthesia is recommended.

Definitions:

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided for Venous Thromboembolism Prophylaxis

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate risk assessment for venous thromboembolism (VTE); risk assessment for bleeding; and mechanical and pharmacologic therapies to reduce the occurrence of VTE in adult hospitalized patients

POTENTIAL HARMS

Side Effects of Anticoagulant Medications (Unfractionated Heparin [UFH] and Low Molecular Weight Heparin [LMWH])

- Bleeding (major and minor)
- Heparin-induced thrombocytopenia (LMWH causes less heparin-induced thrombocytopenia than UFH)

Side Effects of Mechanical Methods of Venous Thromboembolic Prophylaxis

- Side effects of elastic graded compression stockings are rare, although a proper fit, particularly in the obese, may be difficult in 10 to 15% of patients.
- Complications with intermittent pneumatic compression devices include perineal neuropathy and compartment syndrome with lithotomy position and weight loss as risk factors. Compliance may also be significantly more difficult than with heparin regimens.

CONTRAINDICATIONS

CONTRAINDICATIONS

- For trauma patients, contraindications to *early pharmacotherapy* include intracranial bleeding; incomplete spinal cord injury; ongoing, uncontrolled bleeding; and uncorrected coagulopathy.
- Contraindications to *warfarin* include the first trimester of pregnancy.
- The use of the newer Factor Xa inhibitor, fondaparinux, or the thrombin inhibitors related to hirudin is a relative contraindication to all regional anesthesia.
- Contraindications to *pharmacologic prophylaxis*:
    - Active, major significant bleeding (e.g., cerebral hemorrhage)
    - Extreme thrombocytopenia (less than 50,000 mm^3)
    - History of heparin-induced thrombocytopenia (HIT), contraindicated for use of heparin

- Uncontrolled hypertension (systolic greater than 200, diastolic greater than 120)
- Bacterial endocarditis
- Active hepatitis or hepatic insufficiency
- Other conditions that could increase the risk of bleeding

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for release, a member group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Key Implementation Recommendations

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.

1. Medical groups and hospitals are encouraged to develop a formal strategy that addresses the prevention of thromboembolic complications.
    - Develop organization-specific protocols.
    - Develop documents outlining the operational steps taken when formalizing strategies around prevention of thromboembolic complications.

2. Medical groups and hospitals are encouraged to develop systems that support:
    - Early identification of patients at risk for VTE development (possibly through use of order sets or similar tools)
    - Appropriate prophylaxis initiation (possibly through order sets and/or anticoagulation protocols)
    - Patient education to include documentation of the patient's own awareness of their risk for VTE, signs and symptoms of VTE and when/how to seek treatment, and demonstrated understanding of the prescribed anticoagulation regimen

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Clinical Algorithm
Pocket Guide/Reference Cards
Quality Measures

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- Venous thromboembolism (VTE) prophylaxis: percentage of adult hospitalized patients who are assessed for VTE risk within 24 hours of admission.
- Venous thromboembolism (VTE) prophylaxis: percentage of adult hospitalized patients who are assessed to be at risk for VTE who receive pharmacologic prophylaxis, unless contraindicated.
- Venous thromboembolism (VTE) prophylaxis: percentage of hospitalized adult patients who require hospital readmission within 30 days of discharge for conditions related to VTE.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Venous thromboembolism prophylaxis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Jun. 52 p. [99 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Oct (revised 2007 Jun)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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GUIDELINE COMMITTEE

Cardiovascular Steering Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform users. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Venous thromboembolism prophylaxis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jun. 51 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Venous thromboembolism prophylaxis. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2007 Jun. 1 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
- Order sets. Venous thromboembolism prophylaxis for the medically ill patient. Bloomington (MN): Institute for Clinical Systems Improvement, 2007. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
- ICSI pocket guidelines. April 2006 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2006. 298 p.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 29, 2004. It was updated by ECRI on September 16, 2005, and September 18, 2006. This summary was updated by ECRI on March 6, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Coumadin (warfarin sodium). This summary was updated by ECRI Institute on June 22, 2007 following the U.S. Food and Drug Administration (FDA) advisory on heparin sodium injection. This NGC summary was updated by ECRI Institute most recently on September 11, 2007. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection.

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