

## Evidence-based Practices for Thromboembolism Prevention: A Report from the ASPS Venous Thromboembolism Task Force Approved by ASPS Executive Committee: July 2011

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According to the 2008 report, *The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE)*, best estimates indicate that 350,000 to 600,000 Americans each year suffer from DVT and PE, and that at least 100,000 deaths may be directly or indirectly related to these diseases<sup>1</sup>. While the exact incident of Venous Thromboembolism (VTE) in the plastic surgery population is unknown, VTE prophylaxis has been a topic of interest for some time. In response, the focus of the 2009 ASPS Partners in Quality Leadership Summit was on VTE in plastic surgery. The primary action item to emerge from the Summit was the appointment of a VTE Task Force charged with:

- Evaluating the literature as it relates to VTE risk assessment in plastic surgery cases;
- Developing a modified Caprini Risk Assessment Module (RAM) and recommendations specific to plastic surgery cases; and
- Developing tools and aids to assist plastic surgeons across the health system to implement best practices for DVT/PE prevention and treatment.

This report will provide an overview of the VTE Task Force activities and work product.

## **Disclaimer**

This task force report provides strategies for patient management and was developed to assist physicians in clinical decision making. This task force report, based on a thorough evaluation of the present scientific literature and relevant clinical experience, describes a range of generally acceptable approaches to diagnose, manage, or prevent specific diseases or conditions. This report attempts to define principles of practice that should generally meet the needs of most patients in most circumstances.

This report, however, should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. It is anticipated that it will be necessary to approach some patients' needs in different ways. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of all the circumstances presented by the patient, the diagnostic and treatment options available, and available resources.

This task force report is not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all the facts or circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance, and as practice patterns evolve. This task force report reflects the state of knowledge current at the conclusion of the task force's activities (July 2011). Given the inevitable changes in the state of scientific information and technology, periodic review and revision will be necessary.

## I. Systematic Literature Search

The Task Force focused its literature search on VTE risk stratification methods and VTE prophylaxis regimes including chemo prophylaxis type, dosage, length, and cost. A thorough literature search of Pub Med, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and the Cochrane Library was performed to obtain the best available evidence on VTE risk stratification and chemo-prophylaxis use in plastic surgery. The plastic surgery specific literature search time frame was January 1, 2000 to May 1, 2011 and resulted in very limited evidence on VTE prophylaxis. The literature search was expanded to include orthopedic and general surgery because from a VTE risk perspective, they are similar in patient population, anatomical location, and degree of invasiveness. This search time frame was January 1, 2005 to May 1, 2011. See Appendix A for a detailed description of the clinical questions and literature search strategy.

## Critical Appraisal of the Literature

The ASPS evidence-based review procedure includes a rigorous critical appraisal process. Each article is appraised by at least two reviewers. If a discrepancy exists between the reviewers, the article is appraised by a third reviewer, and the level of evidence is determined by consensus. Articles are appraised with checklists appropriate for the clinical question (therapy, prognosis/risk, or diagnosis) and study design (RCT, cohort/comparative, case-control, etc). ASPS checklists are based on commonly used appraisal tools, e.g., Critical Appraisal Skills Programme (CASP) and the Centre for Evidence Based Medicine (CEBM). Studies were assigned levels of evidence according to the ASPS Evidence Rating Scales for Therapy, Risk, and Diagnosis, which can be found in Appendix B. Evidence ratings were not assigned to studies with inadequately described methods and/or worrisome biases.

## **II. Literature Findings**

## Selection of the 2005 Caprini Risk Assessment Model (RAM) (See Figure 1)

There are several VTE risk assessment tools available including the 2005 Caprini RAM, 2010 Caprini RAM, Davison-Caprini scale and numerous proprietary tools adopted by individual hospitals. In order to ensure that the Task Force recommendations can be consistently associated with a set of risk factors, one risk assessment tool was needed as a reference point or benchmark for comparison. The 2005 Caprini scale was selected as this reference point because it was formally validated to stratify plastic surgery patients based on their individual risk factors. The 2010 Caprini RAM was not selected because the additional points allotted for longer surgery times, common in many plastic surgery procedures, and higher BMI's, could result in an over scoring phenomenon artificially placing patients in a higher than necessary risk category.

#### Figure 1



## Applying the 2005 Caprini RAM Reference Point

Many of the therapeutic studies identified in the literature search addressing prophylaxis regimes did not include the study population's VTE risk levels. To ensure that like groups were evaluated, the Task Force analyzed the patient characteristics and risks in these studies and estimated a VTE risk score using the 2005 Caprini RAM. Table I includes the literature findings with corresponding levels of evidence.

Table 1: Literature Search: Evidence Summaries		* Plastic Surgery Stud	
	Findings in the Orthopedic, General Surgery and Plastic Surgery Literature	Supporting Literature and Level of Evidence	
1.	Risk Stratification: The 2005 Caprini RAM is a valid scoring method that effectively stratifies patients into a VTE risk category based on their individual risk factors.	Risk Studies: • Bahl, 2010: Level II <sup>2</sup> • Hatef,* 2008: Level II <sup>3</sup>	
2.	Plastic Surgery Risk Stratification The 2005 Caprini RAM effectively risk-stratifies plastic and reconstructive surgery patients for increased 60 day VTE risk. Among patients with 2005 Caprini score > 8, 11.3% had a postoperative VTE when chemoprophylaxis was not provided. Patients with a Caprini score > 8 were significantly more likely to develop VTE when compared to patients with Caprini score of 3 to 4, 5 to 6, or 7 to 8. There was no evidence that VTE risk was limited to the immediate postoperative period in patients with Caprini score 7 to 8 or > 8.	Identified in May 2011 Search: Risk Study Pannucci*, 2011: Level II <sup>4</sup>	
3.	In patients with <i>estimated</i> 2005 Caprini RAM scores >3, the use of postoperative chemoprophylaxis, including Low Molecular Weight Heparin (LMWH), Unfractionated Heparin (UH), and Fondaparinux, for 1 week was effective in preventing VTE without significantly increasing bleeding risks.	Therapeutic Studies: • Turpie, 2007: Level I <sup>5</sup> • Kim*, 2009: Level III <sup>6</sup> • Edwards, 2008: Level II <sup>7</sup> • Senaran, 2006: Level II <sup>8</sup> • Chin, 2009: Level II <sup>9</sup> • Colwell, 2006: Level II <sup>10</sup>	
4.	In patients with <i>estimated</i> 2005 Caprini RAM scores >7, extended LMWH prophylaxis for up to 4 weeks is more effective at reducing the risk of VTE compared to 1 week LMWH, without significantly increasing the risk of hematoma or bleeding complications.	Therapeutic Studies: • Barrellier, 2010: Level I <sup>11</sup> • Bottaro, 2008: Level II <sup>12</sup> • Rasmussen 2006: Level II <sup>13</sup> • Rasmussen 2009: Level II <sup>14</sup>	
5.	<ul> <li>In-patient plastic surgery patients who received general anesthesia and received prophylactic-dose Enoxaparin during the duration of their hospitalization (starting 6 to 8 hours after surgery):</li> <li>Enoxaparin was effective in reducing VTE rates (compared to no VTE prophylaxis) <ul> <li>Minimal risk reduction was seen in 2005 Caprini RAM 3-6.</li> <li>Notable risk reduction was present in 2005 Caprini scores ≥ 7</li> </ul> </li> <li>Enoxaparin was not associated with increased rates of re-operative hematoma in the overall patient population or the high-risk breast surgery subgroups.</li> <li>Length of stay &gt; 4 days and 2005 Caprini score &gt; 8 were independent predictors of VTE.</li> <li>When controlling for length of stay and 2005 Caprini RAM score, postoperative Enoxaparin was protective against 60 day VTE.</li> </ul>	Therapeutic Study: Level III Pannucci* 2011: Level III <sup>15</sup>	
6.	Evidence suggests that combined UH or LMWH plus mechanical prophylaxis throughout the duration of chemical prophylaxis is more effective in preventing VTE in patients than either alone.	Therapeutic Studies: • Kakkos, 2008: Level II <sup>16</sup> • Seruya*, 2008: Level III <sup>17</sup> • Liao*, 2008: Level III <sup>18</sup>	

## **III. Prophylaxis**

## Prophylaxis Medication, Dosage and Timing:

The available evidence on chemo-prophylaxis medication choice, post-op timing and dosage varied among the studies. Administration of the first chemo-prophylaxis dosage ranged from preoperative administration to 1 to 12 hours postoperatively. Several different LMWH medications were utilized in the studies including Enoxaparin, Dalteparin, Tinzaparin, and Fondaparinux. Enaoxaparin was the most common LMWH prescribed; the dosage ranged from 30 to 60 total mgs per day. Task Force members agreed that there was not enough evidence to make all-inclusive recommendations for plastic surgery prophylaxis medication, dosage, or length of prophylaxis. Study protocols are listed below for reference.

	Venous Thromboembolism Prevention Study (VTEPS) Pannucci, et al. <sup>15</sup>	UT Southwestern Hatef, et al. <sup>3</sup>	Georgetown University Hospital Seruya M, et al. <sup>17</sup>	Asan Medical Center, Korea Kim E, et al.º
Patients	Various surgeries, general anesthesia, at least 1 overnight stay	Excisional body contouring patients	Various; head and neck reconstruction; breast reconstruction; abdominal wall reconstruction	TRAM flap immediate breast reconstruction patients
Risk Assessment Scale	2005 Caprini Risk Assessment Model	Caprini-Davison Risk Assessment Model	Caprini-Davison Risk Assessment Model	None
Protocol	Risk Score: 2005 Caprini RAM Score ≥3 Drug: Enoxaparin Dose: Sliding Scale: • BMI <40: 40 mg SQ QD • BMI >40: 30 mg SQ BID Timing: First dose 6-8 hrs postop, then daily until patient released: Length of prophylaxis: varied	<ul> <li>Risk Score: Moderate, High and Highest risk groups</li> <li>Drug: Enoxaparin</li> <li>Dose: 30 mg SQ</li> <li>Timing: <ul> <li>49 patients received first dose preop</li> <li>88 patients received first dose intraop or immediately postop.</li> <li>every 12 hours after initial dose</li> </ul> </li> <li>Length of prophylaxis: varied</li> </ul>	<b>Risk Scores:</b> 2005 Caprini RAM Score >4 <b>Drug:</b> Enoxaparin <b>Dose:</b> 40 mg SQ <b>Timing:</b> starting 12 hrs postop, then daily until ambulatory. Additional prophylaxis measures: IPC with elastic compression stockings (on at all times when not ambulating) <b>Length of prophylaxis:</b> varied, averaged 7.4 days	Risk Scores: N/A Drug: Enoxaparin Dose: 40 or 60 mg SQ (dependent on weight) Timing: 1 hour preop, then daily Length of prophylaxis: 7 days
Results	When controlling for independent risk factors, postop enoxaparin was protective against VTE without increased rates of re-operative hematoma	Enoxaparin significantly decreased DVT risk in patients undergoing circumfrential abdominoplasty. Enoxaparin administration was associated with increased hematoma and postop bleeding requiring transfusion.	Mechanical prophylaxis supplemented with low- molecular-weight heparin was effective in preventing VTE without significant increase in bleeding or hematoma rates.	Enoxaparin was effective in preventing VTE without significantly increasing bleeding related complications such as transfusions or hematoma.

## Cost/Medication:

Retail medication costs vary greatly depending upon the pharmacy and its location. Therefore, the Medicare Average Sale Price (ASP) was used to calculate the cost of the chemo prophylaxis regimes.

Drug	Administration	Dosage	Cost
Drug Classification: Low Molecular Weight Heparin			
Enoxaparin (Generic available July 2010)	Subcutaneous	40 mg x 8 (one post op dose + 7 daily doses)	\$223.68
(denenc available July 2010)		40 mg x 28 days	\$ 782.88
Dalteparin	Subcutaneous	5,000 IE x 8 (one post op dose + 7 daily doses)	\$189.12
		5,0000 IE x 28 days	\$661.92
Tinzaparin		3,500 IE x 8 (one post op dose + 7 daily doses)	\$77.54
	Subcutaneous	3,500 IE x 28 days	\$274.40
	Drug Classification: F	actor Xa Inhibitors	
Fondaparinux	Subcutaneous	2.5 mg x 8 (one post op dose + 7 daily doses)	\$238.80
		2.5 mg x 28 days	\$825.80
Rivaroxaban FDA approved July 1, 2011 for prevention of DVT and PE in patients undergoing total hip or total knee replacement surgery.	Oral	10 mg PO BID	TBD
Unfractionated Heparin			
Unfractionated Heparin	Subcutaneous	5,000 U BID x 8 doses	\$40.80
onnactionated nepann		5,000 U BID x 28 days	\$142.80
Direct Thrombin Inhibitor			
Dabigatran Etexilate FDA approved October 19, 2010, for prevention stroke and systemic embolism in patients with non-valvular atrial fibrillation.	Oral	75mg or 150 mg PO BID	TBD

If <u>intermittent pneumatic compression</u> device for home use after discharge is indicated, the cost to rent the device is approximately \$112.50 per week or \$450 for one month.

## **IV. Recommendations**

## Rationale for Task Force Recommendations:

Based upon the types of cases included in the literature review, Task Force members agreed that there was not enough evidence to make allinclusive recommendations for plastic surgery prophylaxis medication, dosage, or length of prophylaxis. However, the task force agreed that some plastic surgery procedures warranted additional prophylaxis considerations; and accepted the premise that the surgical cases included in the orthopedic and general surgery literature search were similar enough in their anatomical location, degree of invasiveness and patient population to make them comparable (from a VTE risk perspective) to the following plastic surgery cases: major body contouring; abdominoplasty; major breast reconstruction; major lower extremity procedures; and major head/neck cancer procedures. This belief was reinforced by the August 2010 publication by Murphy et al which documented the reality of VTE events in abdominoplasty and panniculectomy cases despite compliance with nationally recognized VTE prophylaxis measures.<sup>19</sup> Therefore, recommendations 3 to 5 were developed to address this subset of plastic surgery procedures.

## Table 3 (See Appendix B for the ASPS Level of Evidence Rating Scales)

ASPS VTE Task Force Risk Assessment and Prevention Recommendations			
Step One: Risk Stratification			
Patient Population		Recommendation	
		Should complete a 2005 Caprini RAM risk factor assessment tool in order to stratify patients into a VTE risk category based on their individual risk factors. Grade B	
<b>In-patient</b> adult aesthetic and reconstructive plastic undergo general anesthesia	surgery who	Or	
		Should complete a VTE risk assessment tool <u>comparable to</u> the 2005 Caprini RAM in order to stratify patients into a VTE risk category based on their individual risk factors. Grade D	
		Should consider completing a 2005 Caprini RAM risk factor assessment tool in order to stratify patients into a VTE risk category based on their individual risk factors. Grade B	
Out- patient adult aesthetic and reconstructive plast undergo general anesthesia	ic surgery who	Or	
		<b>Should consider</b> completing a VTE risk assessment tool <u>comparable</u> <u>to</u> the 2005 Caprini RAM in order to stratify patients into a VTE risk category based on their individual risk factors. <b>Grade D</b>	
	Step Two: P	revention	
Patient Population	2005 Caprini RAM Score	<b>Recommendations</b> The scores associated with the recommendations apply to the <b>2005 Caprini RAM</b> and were not intended for use with alternative VTE risk assessment tools	
<b>Elective Surgery Patients</b> (when the procedure is scheduled in advance and is not performed to treat an emergency or urgent condition)	7 or more	Should consider utilizing risk reduction strategies such as limiting OR times, weight reduction, discontinuing hormone replacement therapy and early postoperative mobilization. Grade C	
Patients undergoing one of the following major procedures when performed under general anes-	3 to 6	Should consider the option to use postoperative LMWH or Unfractionated heparin. Grade B	
<ul><li>thesia lasting more than 60 minutes:</li><li>Body contouring,</li><li>Abdominoplasty,</li><li>Breast reconstruction,</li></ul>	3 or more	Should consider the option to utilize mechanical prophylaxis throughout the duration of chemical prophylaxis for non-ambulatory patients. Grade D	
<ul> <li>Lower extremity procedures,</li> <li>Head/neck cancer procedures</li> </ul>	7 or more	Should strongly consider the option to use extended LMWH postoperative prophylaxis Grade B	

## **V. Education Initiatives**

#### Evidence-based Performance Measures

The following VTE prophylaxis measures were developed by the Task Force to:

- · help surgeons incorporate best practices into their day to day office activities;
- provide a tool to meet the Joint Commission's Ongoing Professional Practice Evaluation (OPPE) requirements; or
- provide an opportunity to earn CME (see below)

#### Measure # 1: Modified Caprini RAM score documented preoperatively

- Numerator: Patients who have a 2005 Caprini RAM score (or comparable VTE risk assessment tool) documented prior to surgery.
- **Denominator:** All aesthetic and reconstructive preoperative patients aged 18 years and older - **Denominator Exclusions:** None
- Measure: Percentage of patients who had a modified Caprini RAM score documented prior to surgery

#### Measure #2: Patient evaluated for postoperative prophylactic LMWH or unfractionated heparin use.

- Numerator: Patients who were evaluated for postoperative prophylactic LMWH or unfractionated heparin use.
- **Denominator:** All patients age 18 and older undergoing major body contouring, abdominoplasty, major breast reconstruction, major lower extremity procedures, or major head/neck cancer procedures patients.
  - \*Major is defined as procedures performed under general anesthesia lasting more than 60 minutes.
  - Denominator Exclusions: Patients who declined prophylaxis.
- **Measure:** Percentage of patients age 18 and older undergoing major body contouring, abdominoplasty, major breast reconstruction, major lower extremity procedures, or major head/neck cancer procedures with documentation indicating that they were evaluated for postoperative prophylactic LMWH or unfractionated heparin use.

#### Measure #3: Receipt of post-operative VTE educational materials (see Appendix D)

- **Numerator:** Patients or their caregiver with documentation that they received post operative VTE educational materials. \*Definition of appropriate education = Signs and symptoms of VTE and actions to take if they occur.
- **Denominator:** All postoperative patients age 18 and older with a 2005 Caprini RAM score of 3 or more. – **Denominator Exclusions:** None
- Measure: Percentage of patients or their caregiver with documentation that they received post op VTE educational materials.

#### Performance Improvement CME

In 2005, the AMA approved the Performance Improvement CME (PI CME) activities described as a structured, long-term process by which a physician or group of physicians learns about specific performance measures, retrospectively assess their practice, apply these measures prospectively over a useful interval, and re-evaluate their performance. Starting in April 2012, ASPS will utilize the VTE performance measures in a PI CME activity where by surgeons can earn up to 20 category 1 CME credits if they complete each stage of the PI CME cycle.

#### Patient Education Tools

A patient handout with patient postoperative instructions including signs and symptoms of DVT/PE and actions to take if they should occur is available on the ASPS website (see Appendix C).

#### **Task Force Members:**

Robert X. Murphy Jr., MD	Task Force Chair	
Amy Alderman, MD	Quality Performance Measurement Committee Representative	
Karol Gutowski, MD	Patient Safety Committee Representative	
Carolyn Kerrigan, MD	Quality Performance Measurement Committee Representative	
Loren Schechter, MD	Patient Safety Committee Representative	
Edwin Wilkins, MD	Plastic Surgery Education Foundation Representative	

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## **Appendix A. Clinical Questions and Literature Search Strategies**

## **Literature Attrition Flow Chart**

**PROJECT:** VTE Task Force, Plastic Surgery specific articles

#### **CLINICAL QUESTIONS:**

- In patients undergoing plastic surgery, does the use of (insert drug) compared to (insert drug) decrease the risk of a VTE event?
- In patients undergoing plastic surgery, does the use of perioperative prophylaxis compared to posteroperative prophylaxis only reduce the occurrence of VTE? (What is the recommended timing and duration of prophylaxis?)
- What is the recommended dosage of prophylaxis in the low, moderate, high, and very high risk Groups?
- In patients undergoing plastic surgery, does the use of prophylaxis compared to no prophylaxis increase the risk of intraoperative and postoperative bleeding?

#### **SEARCH TERMS:**

Medline: ("Surgery, Plastic" [Mesh] OR "Reconstructive Surgical Procedures" [Mesh] OR "Cosmetic Surgery") AND ("Prophylaxis" OR "chemoprophylaxis" OR "Anticoagulants" [Mesh] OR "Heparin" OR "Enoxaparin" OR "Warfarin" OR "Dalteparin" OR "Fondaparinux" OR "Lovenox" NOT "Antibiotic Prophylaxis" [Mesh]) AND ("Dosage" OR "Timing"); ("Surgery, Plastic" [Mesh] OR "Reconstructive Surgical Procedures" [Mesh] OR "Cosmetic Surgery") AND ("Prophylaxis" OR "chemoprophylaxis" OR "Anticoagulants" [Mesh] OR "Heparin" OR "Enoxaparin" OR "Warfarin" OR "Dalteparin" OR "Fondaparinux" OR "Lovenox" NOT "Antibiotic Prophylaxis" [Mesh]) AND ("Venous Thromboembolism/prevention and control" [Mesh] OR "Venous Thrombosis/prevention and control" [Mesh] OR "Venous Thromboembolism" [Mesh] OR "Deep Vein Thrombosis" OR "Pulmonary Embolism/prevention and control" [Mesh]); ("Surgery, Plastic" [Mesh] OR "Reconstructive Surgical Procedures" [Mesh] OR "Cosmetic Surgery") AND ("Venous Thromboembolism/prevention and control" [Mesh] OR "Venous Thrombosis/prevention and control" [Mesh] OR "Venous Thromboembolism" [Mesh] OR "Deep Vein Thrombosis" OR "Pulmonary Embolism/prevention and control" [Mesh]); ("Surgery, Plastic" [Mesh] OR "Reconstructive Surgical Procedures" [Mesh] OR "Cosmetic Surgery") AND ("Venous Thromboembolism/prevention and control" [Mesh] OR "Venous Thrombosis/prevention and control" [Mesh] OR "Venous Thromboembolism" [Mesh] OR "Deep Vein Thrombosis" OR "Pulmonary Embolism/prevention and control" [Mesh]) AND "Caprini Risk Assessment"; (("Surgery, Plastic" [Mesh]) OR "Reconstructive Surgical Procedures" [Mesh] OR "Cosmetic Surgery") AND ("Prophylaxis" OR "chemoprophylaxis" OR "Anticoagulants" [Mesh] OR "Heparin" OR "Enoxaparin" OR "Warfarin" OR "Dalteparin" OR "Fondaparinux" OR "Lovenox" NOT "Antibiotic Prophylaxis" [Mesh]) AND ("Hematoma" [Mesh] OR "Postoperative Hemorrhage" [Mesh] OR Bleed\*)); (("Surgery, Plastic" [Mesh] OR "Reconstructive Surgical Procedures" [Mesh] OR "Cosmetic Surgery") AND ("Prophylaxis" OR "chemoprophylaxis" OR "Anticoagulants" [Mesh] OR "Heparin" OR "Enoxaparin" OR "Warfarin" OR "Dalteparin" OR "Fondaparinux" OR "Lovenox" NOT "Antibiotic Prophylaxis" [Mesh]) AND ("Venous Thromboembolism/prevention and control" [Mesh] OR "Venous Thrombosis/prevention and control" [Mesh] OR "Venous Thromboembolism" [Mesh] OR "Deep Vein Thrombosis" OR "Pulmonary Embolism/prevention and control" [Mesh]) AND ("Hematoma" [Mesh] OR "Postoperative Hemorrhage" [Mesh] OR Bleed\*))

Primary Search Limits: English Only; Humans; January 1, 2000 to May 1, 2010 Updated Search Limits: English Only; Humans; May 1, 2010 to May 1, 2011

**CINHAL:** ("Plastic Surgery" OR "Reconstructive Surgery" OR "Cosmetic Surgery") AND ("Venous Thromboembolism" OR "Venous Thrombosis" OR "Deep Vein Thrombosis" OR "Pulmonary Embolism"); ("Plastic Surgery" OR "Reconstructive Surgery" OR "Cosmetic Surgery") AND ("Prophylaxis" OR "chemoprophylaxis" OR "Anticoagulants" OR "Heparin" OR "Enoxaparin" OR "Warfarin" OR "Dalteparin" OR "Fondaparinux" OR "Levana" NOT "Antibiotic Prophylaxis")

Primary Search Limits: English Only; Research Article; 2000-2010; Updated Search Limits: English Only; Research Article; 2010-2011

**Cochrane:** ("Plastic Surgery" OR "Reconstructive Surgery" OR "Cosmetic Surgery") AND ("Venous Thromboembolism" OR "Venous Thrombosis" OR "Deep Vein Thrombosis"); ("Plastic Surgery" OR "Reconstructive Surgery" OR "Cosmetic Surgery") AND ("Prophylaxis" OR "Chemoprophylaxis" OR "Thromboprophylaxis")

Primary Search Limits: 2000-2010; Updated Search Limits: 2010-2011

#### **INCLUSION CRITERIA:**

• Relevance to topic, evaluates the efficacy of chemical prophylaxis, chemical prophylaxis drug approved by FDA





## **Literature Attrition Flow Chart**

PROJECT: VTE Task Force; Abdominal, orthopedic, trauma surgeries

#### **CLINICAL QUESTIONS:**

In patients undergoing plastic surgery, does the use of (insert drug) compared to (insert drug) decrease the risk of a VTE event? In patients undergoing plastic surgery, does the use of perioperative prophylaxis compared to posteroperative prophylaxis only reduce the occurrence of VTE? (What is the recommended timing and duration of prophylaxis?)

What is the recommended dosage of prophylaxis in the low, moderate, high, and very high risk Groups?

In patients undergoing plastic surgery, does the use of prophylaxis compared to no prophylaxis increase the risk of intraoperative and postoperative bleeding?

#### **SEARCH TERMS:**

PubMed: (("General Surgery" [Mesh] OR "Surgical Procedures, Operative" [Mesh]) AND ("Orthopedics" [Mesh] OR "Hip" OR "Knee" OR "Lower Extremity" [Mesh] OR "Abdomen" [Mesh] OR "Trauma" OR "Abdominal") AND "High Risk")) AND (("Prophylaxis" OR "chemoprophylaxis" OR "Anticoagulants" [Mesh] OR "Heparin" OR "Enoxaparin" OR "Warfarin" OR "Dalteparin" OR "Fondaparinux" OR "Lovenox" NOT "Antibiotic Prophylaxis" [Mesh]) AND ("Venous Thromboembolism/prevention and control" [Mesh] OR "Venous Thrombosis/prevention and control" [Mesh] OR "Venous Thromboembolism" [Mesh] OR "Deep Vein Thrombosis" OR "Pulmonary Embolism/prevention and control" [Mesh])); (("General Surgery" [Mesh] OR "Surgical Procedures, Operative" [Mesh]) AND ("Orthopedics" [Mesh] OR "Hip" OR "Knee" OR "Lower Extremity" [Mesh] OR "Abdomen" [Mesh] OR "Trauma")) AND (("Prophylaxis" OR "chemoprophylaxis" OR "Anticoagulants" [Mesh] OR "Heparin" OR "Enoxaparin" OR "Warfarin" OR "Dalteparin" OR "Fondaparinux" OR "Lovenox" NOT "Antibiotic Prophylaxis" [Mesh]) AND ("Dosage" OR "Timing")); (("General Surgery" [Mesh] OR "Surgical Procedures, Operative" [Mesh]) AND ("Orthopedics" [Mesh] OR "Hip" OR "Knee" OR "Lower Extremity" [Mesh] OR "Abdomen" [Mesh] OR "Trauma")) AND ("Venous Thromboembolism/prevention and control" [Mesh] OR "Venous Thrombosis/prevention and control" [Mesh] OR "Venous Thromboembolism" [Mesh] OR "Deep Vein Thrombosis" OR "Pulmonary Embolism/ prevention and control" [Mesh]); (("General Surgery" [Mesh] OR "Surgical Procedures, Operative" [Mesh]) AND ("Orthopedics" [Mesh] OR "Hip" OR "Knee" OR "Lower Extremity" [Mesh] OR "Abdomen" [Mesh] OR "Trauma")) AND (("Prophylaxis" OR "chemoprophylaxis" OR "Anticoagulants" [Mesh] OR "Heparin" OR "Enoxaparin" OR "Warfarin" OR "Dalteparin" OR "Fondaparinux" OR "Lovenox" NOT "Antibiotic Prophylaxis" [Mesh]) AND ("Hematoma" [Mesh] OR "Postoperative Hemorrhage" [Mesh] OR Bleed\*)); (("General Surgery" [Mesh] OR "Surgical Procedures, Operative" [Mesh]) AND ("Orthopedics" [Mesh] OR "Hip" OR "Knee" OR "Lower Extremity" [Mesh] OR "Abdomen" [Mesh] OR "Trauma")) AND (("Prophylaxis" OR "chemoprophylaxis" OR "Anticoagulants" [Mesh] OR "Heparin" OR "Enoxaparin" OR "Warfarin" OR "Dalteparin" OR "Fondaparinux" OR "Lovenox" NOT "Antibiotic Prophylaxis" [Mesh]) AND ("Venous Thromboembolism/prevention and control" [Mesh] OR "Venous Thrombosis/prevention and control" [Mesh] OR "Venous Thromboembolism" [Mesh] OR "Deep Vein Thrombosis" OR "Pulmonary Embolism/prevention and control" [Mesh]) AND ("Hematoma" [Mesh] OR "Postoperative Hemorrhage" [Mesh] OR Bleed\*) Primary Search Limits: Randomized Controlled Trial; Meta-analysis; Humans; English Only; January 1, 2005 to May 1, 2010 Primary Search Limits: Randomized Controlled Trial; Meta-analysis; Humans; English Only; May 1, 2010 to May 1, 2011

**CINHAL:** ("General Surgery" OR "Abdominal Surgery" OR "Orthopedic Surgery" OR "Trauma Surgery") AND ("Venous Thromboembolism" OR "Venous Thrombosis" OR "Deep Vein Thrombosis" OR "Pulmonary Embolism"); ("General Surgery" OR "Abdominal Surgery" OR "Orthopedic Surgery" OR "Trauma Surgery") AND ("Prophylaxis" OR "chemoprophylaxis" OR "Anticoagulants" OR "Heparin" OR "Enoxaparin" OR "Warfarin" OR "Dalteparin" OR "Fondaparinux" OR "Levana" NOT "Antibiotic Prophylaxis"); ("General Surgery" OR "Abdominal Surgery" OR "Orthopedic Surgery" OR "Trauma Surgery") AND ("Prophylaxis" OR "chemoprophylaxis"); ("General Surgery" OR "Abdominal Surgery" OR "Orthopedic Surgery" OR "Trauma Surgery") AND ("Prophylaxis" OR "chemoprophylaxis" OR "Anticoagulants" OR "Heparin" OR "Enoxaparin" OR "Warfarin" OR "Dalteparin" OR "Fondaparinux" OR "Levana" NOT "Antibiotic Prophylaxis") AND ("Venous Thromboembolism" OR "Venous Thrombosis" OR "Deep Vein Thrombosis" OR "Pulmonary Embolism") AND ("Hematoma" OR "Bleeding") Primary Search Limits: English Only; Research Article; 2005-2010; Updated Search Limits: English Only; Research Article; 2010-2011

**Cochrane:** ("General Surgery" OR "Abdominal Surgery" OR "Orthopedic Surgery" OR "Trauma Surgery") AND ("Deep Vein Thrombosis" OR "Venous Thrombosis" OR "Pulmonary Embolism") Primary Search Limits: 2000-2011; Updated Search Limits: 2010-2011

#### **INCLUSION CRITERIA:**

Relevance to topic; evaluated the efficacy of chemo-prophyalxis; chemical prophylaxis drug approved by FDA; surgery similar to plastic surgery





## **Literature Attrition Flow Chart**

PROJECT: VTE Task Force, Plastic Surgery and Orthopedic/General Surgery articles

#### **CLINICAL QUESTION:**

In patients undergoing plastic, reconstructive, general or orthopedic surgery, is the Caprini Risk Assessment Module an effective tool in predicting VTE risk?

**Pubmed:** ("Surgery, Plastic" [Mesh] OR "Reconstructive Surgical Procedures" [Mesh] OR "Cosmetic Surgery" OR "General Surgery" [Mesh] OR "Surgical Procedures, Operative" [Mesh] OR "Orthopedic Surgery" OR "Surgery") AND ("Venous Thromboembolism/prevention and control" [Mesh] OR "Venous Thromboembolism/prevention and control" [Mesh] OR "Venous Thromboembolism/prevention and control" [Mesh] OR "Pulmonary Embolism/prevention and control" [Mesh]) AND ("Caprini Risk Assessment" OR Risk Assessment/\*methods) Primary Search Limits: Humans; English Only; January 1, 2005 to May 1, 2010 Updated Search Limits: Humans; English Only; May 1, 2010 to May 1, 2011

**CINAHL:** ("Plastic Surgery" OR "Reconstructive Surgery" OR "General Surgery" OR "Orthopedic Surgery") AND ("Venous Thromboembolism" OR "Deep Vein Thrombosis") AND ("Caprini Risk Assessment" OR "Risk Assessment") Primary Search Limits: English Only; 2005-2010; Updated Search Limits: English Only; 2010-2011

**Cochrane:** "Surgery" AND ("Deep Vein Thrombosis" OR "Venous Thromboembolism") AND ("Risk Stratification" OR "Risk Assessment") Primary Search Limits: 2005-201; Updated Search Limits: 2010-2011

#### **INCLUSION CRITERIA:**

Relevance to topic; validated VTE risk assessment scale





# Appendix B. ASPS Level of Evidence Rating and Grades of Recommendation Scales

#### **Evidence Rating Scale for Therapeutic Studies**

Level of Evidence	Qualifying Studies
High-quality, multi-centered or single-centered, randomized controlled trial with adequate power; or system these studies	
II Lesser-quality, randomized controlled trial; prospective cohort or comparative study; or systematic review of these studies	
III	Retrospective cohort or comparative study; case-control study; or systematic review of these studies
IV	Case series with pre/post test; or only post test
V	Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research or "first principles"

#### **Evidence Rating Scale for Diagnostic Studies**

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, cohort study validating a diagnostic test (with "gold" standard as reference) in a series of consecutive patients; or a systematic review of these studies
II	Exploratory cohort study developing diagnostic criteria (with "gold" standard as reference) in a series of consecutive patient; or a systematic review of these studies
III	Diagnostic study in nonconsecutive patients (without consistently applied "gold" standard as reference); or a systematic review of these studies
IV	Case-control study; or any of the above diagnostic studies in the absence of a universally accepted "gold" standard
V	Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research or "first principles"

## Evidence Rating Scale for Prognostic/Risk Studies

Level of Evidence	Qualifying Studies
High-quality, multi-centered or single-centered, prospective cohort or comparative study with adequate power atic review of these studies	
II Lesser-quality prospective cohort or comparative study; retrospective cohort or comparative study; untreated co a randomized controlled trial; or a systematic review of these studies	
III	Case-control study; or systematic review of these studies
IV	Case series with pre/post test; or only post test
V	Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research or "first principles"

## Scale for Grading Recommendations

Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong Recommendation	Level I evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
В	Recommendation	Levels II, III, or IV evidence and find- ings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences.
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
D	Option	Level V: Little or no systematic empirical evidence	Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

# Appendix C



# What is Deep-Vein Thrombosis (DVT)?

DVT occurs when a blood clot forms in one of the large veins, usually in the lower limbs, leading to either partially or completely blocked circulation. The condition may result in health complications, such as a pulmonary embolism (PE) and even death if not diagnosed and treated effectively.

#### Most common risk factors for DVT:

- Major surgery
- Congestive heart failure or respiratory failure
- Restricted mobility
- Recent injury
- Cancer
- Obesity
- Age over 40 years
- Recent surgery
- Smoking
- Prior or family history of venous thromboembolism (VTE)

## Signs and Symptoms of DVT:

About half of people with DVT have no symptoms at all. For those who do have symptoms, the following are the most common and can occur in the affected part of the body, typically in the leg or calf region:

- Swelling unrelated to the surgical site,
- Pain or tenderness, unrelated to the surgical site and often worse when standing or walking,
- Redness of the skin,
- Warmth over the affected area.
- \* If you develop symptoms of a deep vein thrombosis, contact your health care provider for guidance.



# What is a Pulmonary Embolism (PE)?

A pulmonary embolism (PE) is a very serious condition that occurs when a blood clot blocks the artery that carries blood from the heart to the lungs (pulmonary artery). A clot that forms in one part of the body and travels in the bloodstream to another part of the body is called an embolus. PEs often come from the deep leg veins and travel to the lungs through blood circulation.

#### Signs and Symptoms of PE

- Difficulty breathing;
- Faster than normal heart beat;
- Chest pain or discomfort, which usually worsens with a deep breath or coughing;
- Coughing up blood; or
- Very low blood pressure, lightheadedness, or blacking out.

\*If you develop symptoms of a Pulmonary Embolism, seek emergency medical attention immediately.

Sources: http://www.cdc.gov/ncbddd/dvt/faq\_dvt.htm; http://www.mayocline.com/health/deep-vein-throm bosis/DS01005/DSECTION=symptoms; http://www. preventdvt.org/questions/dvt-questions.aspx

Geerts WH, Pineo GF, Heit JA et al. Prevention of venous thromboembolism: The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. Chest.2004; 126(suppl): 338S-400S.





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