

## THE PREVENTION OF DEEP VENOUS THROMBOSIS – IVC Filter

Original Release/Approval	25 Dec 2004	Note: This CPG requires an annual review.	
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Supersedes:	The Prevention of Deep Vein Thrombosis, 21 Nov 2008		
<input type="checkbox"/> Minor Changes ( <i>or</i> )	<input type="checkbox"/> Changes are substantial and require a thorough reading of this CPG ( <i>or</i> )		
<input checked="" type="checkbox"/> Significant Changes	Additional information on IVCF; PI monitoring plan added		

1. **Goal.** To establish guidance for 1) anti-thrombotic therapy for the prevention of deep venous thrombosis (DVT) and pulmonary embolism (PE) and 2) the management of inferior vena caval filters placed in the combat theater for the purpose of either primary or secondary prophylaxis of pulmonary embolism
2. **Background.**
  - a. American College of Chest Physicians Conference recommended that, “every hospital should develop a written policy or other formal strategy for preventing thromboembolic complications, especially for high-risk patients.”
  - b. Proximal deep venous thrombosis (DVT) continues to be a frequent complication in hospitalized patients. Pulmonary embolism, a very serious potential outcome from DVT, has been seen in over 20% of patients hospitalized with DVTs in national reviews and is a major cause of morbidity and mortality in these patients.
  - c. There is an increasing recognition of DVT in individuals who complete an extended period of travel on an airplane. One study noted a 10% prevalence of asymptomatic DVT in individuals undergoing flights of 8 hours or more. Landstuhl Regional Medical Center is uniquely positioned to receive patients who have undergone extensive periods of travel prior to admission.
  - d. Different medical societies and working groups have published varying recommendations for DVT prophylaxis. Where these recommendations disagree, the clinical guidelines recommended here represent the guideline with either a higher level of scientific evidence supporting the recommendation, or the more conservative recommendation.
  - e. Due to the increasingly short aeromedical evacuation times achieved in our system today, it may be possible that certain patients will still be receiving blood product therapy to correct coagulopathy when they enter the chain. It is inherent on providers at each step in the aeromedical evacuation chain to evaluate patients for DVT prophylaxis and make adjustments in therapy as clinically appropriate. ***It is recommended to begin DVT prophylaxis therapy as soon as coagulopathy is corrected in patients not otherwise at increased risk of bleeding.***
  - f. Inferior vena cava filter (IVCF) placement in the combat theater is usually undertaken for primary prophylaxis (no evidence of venous thromboembolic (VTE) disease at the time of placement), and occasionally secondary prophylaxis (documented VTE), of pulmonary embolism (PE) in the polytrauma patient. Patients felt to be at particularly high risk for VTE development and who have a clinical contraindication to prophylactic anticoagulation are the most likely to have an IVCF placed. Indications for IVCF

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placement are addressed in the JTTS Guidelines for Deep Venous Thrombosis Prophylaxis. (attached)

- g. Most series examining the use of IVCF placement for primary prophylaxis of PE in the trauma patient support a low rate of subsequent PE (1-4%), although the studies are of variable design and a strong consensus supporting this clinical practice cannot be made based upon available data. There is no evidence that the prophylactic use of IVCF is associated with a decreased PE rate or fatal PE rate. It should be noted that when IVCF are placed they are done so to prevent FATAL Pulmonary Emboli as PE's still can occur. IVCF have no benefit in the prevention of DVTs and may be associated with development of IVC and deep venous thrombosis.
- h. The vast majority of IVCF devices placed in the combat theater are retrievable inferior vena cava filters (RIVCF). **Retrievable IVCF are preferred to avoid** some of the long term complications of filter placement and in recognition of the fact that many patients only need this form of VTE prophylaxis for a defined period of time early after injury.
- i. Rates of eventual removal of RIVCFs in large series of trauma patients in the United States have been low (20-30%). A recent experience published of Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) patients who had RIVCFs placed at a single medical treatment facility (MTF) in the United States noted a 21% eventual retrieval rate. It should be noted however, that in these studies there were significant numbers of patients who were lost to follow up or whose filters were not removed due to ongoing indications for use (65%-74%). Therefore, the overall retrieval technical success rate is much higher in the range of 78-87%.
- j. Most series support removal of the three most commonly used RIVCFs (Gunther Tulip/Cook, Recovery/Bard Peripheral Vascular and OptEase/Cordis Endovascular) as early as they are no longer necessary and no later than approximately three months. While it is possible to remove any of these three later than this time period, the technical success declines significantly as potential complications associated with the removal increase.
- k. Recent unpublished data from the JTTR suggest that patients who require a massive transfusion (MT) may be at higher risk for the development of DVT. Also, patients who present hypothermic to a Role III facility may be at higher risk for developing PE.

### 3. Education and Treatment.

- a. Refer to [Appendix A](#) for specific guidance on different subsets of patients after various surgical procedures.
- b. Refer to [Appendix B](#) for additional recommendations regarding IVC filters.

### 4. Performance Improvement (PI) Monitoring.

- a. Intent (Expected Outcomes).
  - 1) When Lovenox or Unfractionated Heparin is ordered, there is documentation in the record that the medication was administered to the patient in the correct dose.

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- 2) When an IVCF is inserted in a patient, there is documentation in the medical record and TMDS as to whether the IVCF is retrievable or not, manufacturer, brand, MRI compatibility, serial number, lot number and exact location.
- b. Performance/Adherence Measures.
  - 1) All patients for whom Lovenox or Unfractionated Heparin was ordered received the medication in the correct dose as documented in the patient's medical record.
  - 2) In every patient in whom an IVCF was inserted, the medical record and TMDS contained documentation as to whether it was retrievable or not, manufacturer, brand, MRI compatibility, serial number, lot number and exact location of placement.
- c. Data Source.
  - 1) Patient Record
  - 2) Joint Theater Trauma Registry (JTTR)
- d. System Reporting & Frequency.

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed.

The system review and data analysis will be performed by the Joint Theater Trauma System (JTTS) Director, JTTS Program Manager, and the Joint Trauma System (JTS) Performance Improvement Branch.

**5. Responsibilities.** It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.

- a. All Health Care Providers will:
  - 1) Become familiar with the guidelines for the prevention of DVT (see [Appendix A](#)).
  - 2) Appropriately manage patients who may be at risk of developing DVT.
  - 3) Provide feedback on these guidelines and suggestions for changes to the CPG to the JTTS Theater Trauma Director.
- b. The Senior surgeon and/or Intensivist at each Level III facility will:
  - 1) Review all thromboembolic events in the Level III facility to assess ways to reduce the risk to the patient.
  - 2) Coordinate with the Theatre Trauma Coordinator on the appropriateness of the guidelines being used and provide input for updates on an as needed basis.

**6. References.**

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Approved by CENTCOM JTTS Director,  
JTS Director and CENTCOM SG

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## APPENDIX A

GUIDELINES FOR PREVENTION OF DEEP VENOUS THROMBOSIS	
<u>Risk Group</u>	<u>Prophylactic Measures</u>
<b>TRAUMA SURGERY</b>	
Emergency trauma surgical procedures in patients with prohibitive risk of bleeding, or ongoing coagulopathy	SCD (sequential compression device) until able to be anticoagulated (ideally start Lovenox within 12 hours of cessation of coagulopathy); see IVC filter and Duplex screening sections below.
Emergency trauma surgical procedures in all patients, except patient with prohibitive risk of bleeding (once coagulopathy not present)	Lovenox 30 mg BID; <i>strongly</i> consider adding SCD
Isolated major orthopedic surgery of extremities, spine, and pelvis	SCD + Lovenox 30 mg BID; See IVC filter section below Continue tx for 7-10 days post-op
<b>IVC FILTER PLACEMENT*</b>	
<p>Patients with:</p> <ol style="list-style-type: none"> <li>1. Recurrent PE despite full anticoagulation</li> <li>2. Proximal DVT and contraindications for full anticoagulation</li> <li>3. Proximal DVT and major bleeding while on full anticoagulation</li> <li>4. Progression of iliofemoral clot despite anticoagulation</li> </ol>	<p>Level I evidence for placement of IVC filter</p> <p><b>*Removable filters <i>strongly</i> preferred; document if the IVCF is retrievable or not, manufacturer, brand, MRI compatibility, serial number, lot number and exact location in record and TMDS; PE may still occur despite IVC filter</b></p>
<p>Patients with established DVT or PE and:</p> <ol style="list-style-type: none"> <li>1. Large free-floating thrombus in the iliac vein or IVC</li> <li>2. Following massive PE in which recurrent emboli may prove fatal</li> <li>3. During/after surgical embolectomy</li> </ol>	<p>Level II evidence for “extended” indications for prophylactic IVC filter for patients with established DVT or PE</p>

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### GUIDELINES FOR PREVENTION OF DEEP VEIN THROMBOSIS

<u>Risk Group</u>	<u>Prophylactic Measures</u>
Very High Risk Patients: those who cannot receive anticoagulation because of increased bleeding risk and :  1. Severe closed head injury (GCS<8)  2. Incomplete spinal cord injury with paraplegia or quadriplegia  3. Complex pelvic fractures with associated long-bone fractures  4. Multiple long-bone fractures	Level III evidence for consideration of placement of prophylactic placement of IVC filter. Impact of retrievable filters is unclear in this patient population
<b>ROLE OF DUPLEX SCREENING</b>	
Asymptomatic patients	Serial duplex ultrasound imaging of high-risk patients may be cost-effective and decrease the incidence of PE (Level III)
Symptomatic patients	Duplex ultrasound may be used without confirmatory venography (Level I)
<b>GENERAL SURGERY</b>	
<u>Low Risk:</u>	
– Minor procedure in patients < 40 years, no risk factors	Early mobilization
<u>Moderate Risk:</u>	
– Minor procedure with additional risk factors for thrombosis;	Unfractionated Heparin 5000 units BID <b><u>or</u></b> Lovenox 40 mg QD
– Non major surgery in patients 40-60 years, with no additional risk factors;	
– Major surgery in patients < 40 years with no additional risk factors)	
<u>Higher Risk:</u>	
– Non major surgery in patients > 60 years or have additional risk factors;	Unfractionated Heparin 5000 units TID <b><u>or</u></b> Lovenox 30 mg BID
– Major surgery in patients > 40 years or have additional risk factors	

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<u>Risk Group</u>	<u>Prophylactic Measures</u>
<u>High Risk:</u>	
– Patients with multiple risk factors	Unfractionated Heparin 5000 units TID <u>or</u> Lovenox 30 mg BID <b>plus</b> GCS (graduated compression stocking) <u>or</u> SCD
<u>Moderate Risk or Higher Patients with high risk of bleeding</u>	GCS or SCD
<b>VASCULAR SURGERY</b>	
Patients without additional thromboembolic risk factors	No need for thromboprophylaxis
Patients with additional thromboembolic risk factors	Unfractionated Heparin 5000 units BID <u>or</u> Lovenox 40 mg QD
<b>UROLOGIC SURGERY</b>	
Low Risk urologic procedures	Early ambulation
Major, open urologic procedures	Unfractionated Heparin 5000 units BID or TID
Patients actively bleeding or at risk for bleeding	GCS or SCD
Patients with multiple risk factors	GCS or SCD <b>and</b> Unfractionated Heparin 5000 units BID or TID or Lovenox 40 mg QD
<b>NEUROSURGERY</b>	
Intracranial neurosurgical procedures	SCD with or without GCS
High Risk neurosurgery patients	SCD and/or GCS OK to use Lovenox following stable CT scan in consultation with neurosurgeon

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## APPENDIX B IVCF RECOMMENDATIONS

1. All IVCFs placed in the combat theater should be **retrievable**.
2. Documentation detailing the IVCF brand, model, MRI compatibility, and exact location of placement should be documented in ALTHA T or TC2.
3. All RIVCFs placed in the combat theater should be removed as soon as contraindications to chemical prophylaxis of VTE disease no longer exist or there is no longer a need for VTE prophylaxis. Exceptions include those that were placed for secondary prophylaxis in a patient who demonstrated new VTE disease while on therapeutic anticoagulation or in patients who are still deemed to be high risk.
4. All RIVCFs should be removed within three months unless a long term indication for their continued use is present.
5. The decision to remove an RIVCF placed in the combat theater (versus leaving it in place permanently) should be made at the first CONUS Level V MTF the patient transitions through while returning from deployment. When possible, the removal should take place at this same facility prior to transition to the next level of care. This approach decreases the chance that a decision will be deferred until removal becomes technically prohibitive.
6. **The presence of a RIVCF in a patient receiving care at the Level IV MTF should be made known to the receiving Level V MTF. Typically, retrieval of the RIVCF will be accomplished at the Level V MTF.**
7. Any patient with a known DVT and without a current contraindication to therapeutic anticoagulation who has an IVCF in place should receive full dose anticoagulation. This is preferably accomplished with Coumadin to target an INR of 2.0-3.0. If further surgical procedures are planned, consideration may also be given to the use of low molecular weight heparin dosed at 1 mg/kg bid or an unfractionated heparin drip until such time as the use of Coumadin is felt to be appropriate.
8. The presence of an IVCF, brand, model, MRI compatibility, whether or not it is retrievable, its exact location and the date of insertion should be clearly annotated in TMDS and again in AHLTA when the patient has returned to the United States.
9. Efforts should be made in the future to standardize the type of RIVCF used at all combat theater locations.

## APPENDIX C

### ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

1. **Purpose.** The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of “off-label” uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.
2. **Background.** Unapproved (i.e., “off-label”) uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing “investigational new drugs.” These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.
3. **Additional Information Regarding Off-Label Uses in CPGs.** The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the “standard of care.” Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.
4. **Additional Procedures.**
  - a. **Balanced Discussion.** Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.
  - b. **Quality Assurance Monitoring.** With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.
  - c. **Information to Patients.** Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.