JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



Prevention of Venous Thromboembolism

To establish guidance for anti-thrombotic therapy for the prevention of deep venous thrombosis and pulmonary embolism and the management of inferior vena cava filters placed in theater for primary or secondary prophylaxis of pulmonary embolism.

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TABLE OF CONTENTS

BACKGROUND	4
RECOMMENDATIONS FOR VTE PROPHYLAXIS	4
SPECIAL POPULATIONS	5
Pending Surgery	5
Traumatic Brain Injury	6
Spine Trauma	6
Solid Organ Injury	7
Patients with Indwelling Epidural and/or Paravertebral Catheters	7
Pregnant Patients	8
Pediatric Patients ¹⁷	8
USE OF INFERIOR VENA CAVA FILTERS	8
RETRIEVABLE INFERIOR VENA CAVA FILTERS (RIVCF)	9
AEROMEDICAL EVACUATION CONSIDERATIONS	
PERFORMANCE IMPROVEMENT (PI) MONITORING	10
REFERENCES	
ADDITIONAL REFERENCES	14
APPENDIX A: VENOUS THROMBOEMBOLISM PREVENTION GUIDELINES	16
APPENDIX B: IVCF RECOMMENDATIONS	18
APPENDIX C: CLASS VIII MEDICAL MATERIEL	19
APPENDIX D: TELEMEDICINE / TELECONSULTATION	21
APPENDIX E: INFORMATION REGARDING OFF-LABEL USES IN CPGS	22

Rapid Update Summary

1. Guidance on timing of venous thromboembolism chemoprophylaxis and epidural catheters in line with the most recent American Society of Regional Anesthesia and Pain Medicine

SUMMARY OF CHANGES

- 1. The role of screening duplex ultrasounds for DVT in asymptomatic patients was changed from "not recommended" to "considered for patients with significant gaps in chemical VTE prophylaxis and periods of prolonged immobility."
- 2. Additional recommendations were included for special populations.

PREVENTION OF VENOUS THROMBOEMBOLISM

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Venous Thrombosis (VTE)

- > Trauma patients have a 58% incidence rate
- > Trauma patients with burns have a 65% incidence rate
- Missing 2 doses of VTE prophylaxis increases risk by 8.5x
- Do not hold chemical VTE prophylaxis for surgical procedures except brain, spine and eye

Begin VTE prophylaxis in all trauma patients within 24 hours of injury in patients without coagulopathy or increased risk of bleeding. Every missed dose increases VTE risk.

Risk Factors

- Hypercoagulable state of trauma
- ➤ Early transfusion (<24 hrs post injury)
- Transfusion of old blood (>28 days)
- ➤ Multiple amputation/AKAs
- Immobility/prolonged transport time
- Traumatic Brain Injury
- Use of fresh frozen plasma with <4 units packed red blood cells</p>

RECOMMENDATIONS

- Universal sequential compression device
- No direct oral anticoagulants or aspirin

IVC Filters – Retrievable are preferred. Limit duplex U/S to symptomatic patients only or a gap in pharmacologic prophylaxis for asymptomatic patients

- > Chemoprophylaxis Agent:
- CrCl >30mg/dL Enoxaparin 30 mg SC BID OR weight-based Enoxaparin (Anti-Xa monitoring available)
- CrCl <30 mg/dL Heparin 5000U SC TID
- Age >60: Enoxaparin 30 mg SC BID or Heparin 5000U SC TID

SPECIAL POPULATIONS

Traumatic Brain Injury

- Stable 24-hour head CT prior to prophylaxis
- Consult neurosurgery
- Hold prophylaxis if IC hemorrhage or IC monitor
- Interrupted prophylaxis increases VTE risk 6-fold

Spine Trauma Injury

- > Consult spine surgeon
- ➤ Initiate VTE prophylaxis 48–72hour post-op or post injury
- Hold VTE prophylaxis for suspected spinal injury or focal neurologic deficits until imaging/consultation

Solid Organ Injury

- ➤ AAST grade 1-3 liver, spleen, kidney → prophylaxis start 12-24 hours provided:
- No hemodynamic instability
- Serial hemoglobin stable
- No ongoing blood transfusion

Epidural/Paravertebral Catheters

- ➤ Enoxaparin: hold 12 hr pre-procedure and resume 12-hour post-procedure
- Unfractionated heparin: hold 4-6-hour pre-procedure and may resume immediately post procedure
- Avoid missing unnecessary doses of prophylaxis for epidural placement/removal

Pregnant Patients

- Enoxaparin & heparin –
 Considered SAFE for use
- Enoxaparin 30mg SC BID
- Enoxaparin 40mg SC BID (>90kg)

Pediatric Patients

Pre-puberty prophylaxis not recommended

VTE Metrics

- ✓ SCDs within 24 hours of injury
- ✓ Chemical VTE prophylaxis within 24 hours of injury or document contraindication
- ✓ Zero missed VTE prophylaxis doses



IVC Filter Metrics

- ✓ Retrievable IVCs removed within 6 months
- ✓ Document:
 - · Indication/Exact location
 - Retrievable vs Permanent
 - Manufacture/Brand/Serial #/Lot #

BACKGROUND

Trauma patients are at high risk for Venous Thromboembolism (VTE) including Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE). Trauma patients can have up to 58% incidence of DVT.¹ Sevitt and Gallagher reported an even higher incidence (65%) in injured and burned patients and reported a 16.5% incidence of PE found at autopsy in this cohort of patients.^{2,3}

In addition to the hypercoagulable state induced by severe injury in trauma, combat casualties have additional risk factors for DVT, including: 1,4-8

- Early transfusion of blood products (≤24 hours)
- Transfusion of old blood (≥28 days)
- Multiple and/or above the knee amputations
- Immobility/prolonged air transport time
- Traumatic brain injury (TBI)

The use of Fresh Frozen Plasma (FFP) outside of large volume blood product transfusion (less than 4 U PRBC's) incurs an increased risk of VTE.⁹ Early prophylaxis in this patient population is recommended provided hemostasis has been achieved.

Our deployed medical teams need to be prepared to care for injured children in the combat environment. While the incidence of DVT in pediatric trauma is much lower (6.2%) than that of adults in the civilian literature, ¹⁰ multiple risk factors including immobility and presence of central venous lines were associated with the development of DVT in pediatric trauma patients.

Prolonged airplane travel may also increase the occurrence of DVT, with one study noting a 10% prevalence of asymptomatic DVT in individuals undergoing flights of eight hours or more. ¹¹ Combat casualties will often undergo prolonged evacuation, with long flights and immobility further increasing their risk of VTE. Thus, it is important to start VTE prophylaxis as soon as clinically possible. ¹²

Different medical societies and working groups have published varying recommendations for chemical VTE prophylaxis. ¹³⁻¹⁷ The recommended clinical guidelines are based on supporting scientific evidence and expert consensus input. It is recommended to begin chemical VTE prophylaxis therapy as soon as coagulopathy is corrected in patients without an increased risk of bleeding.

RECOMMENDATIONS FOR VTE PROPHYLAXIS

Unless contraindicated, all admitted trauma patients should receive Sequential Compression Device (SCD) therapy as primary VTE prophylaxis. Chemical VTE prophylaxis should be initiated for all trauma patients 24 hours after injury unless contraindicated due to high risk of bleeding or in certain high risk special populations (see below). There are two options for chemical VTE prophylaxis:

- Low Molecular Weight Heparin (LMWH).
 - a. **Subcutaneous (SC) Enoxaparin 30 mg twice daily** should be considered for most trauma patients with normal creatinine clearance (>30 mg/dL). Most patients in the austere deployed setting should continue with 30 mg twice daily, which has been shown to be superior to 5000 U of unfractionated heparin three times daily for the prevention of VTE in patients with normal creatinine clearance (CrCl). ^{16,18}

- b. Weight-based enoxaparin dosing is an acceptable alternative for trauma patients with a normal creatine clearance. Options include twice daily doses of 0.5-0.6 mg/kg,¹⁹⁻²¹ or 30 mg for 50 to 60 kg patients, 40 mg for 61 to 99 kg patients, and 50 mg for patients greater than 100 kg.²² Anti-Xa levels should be monitored when weight-based enoxaparin is administered because trauma patients experience fluctuations in creatinine clearance that might require dose adjustment. ²³
- c. Lower doses of enoxaparin can be considered in patients who weigh less than 50 kg. . For these patients, enoxaparin weight-based dosing (0.5-0.6 mg/kg) BID can be considered.
- d. Enoxaparin is renally excreted and should be avoided in patient with renal failure since it may lead to increased bleeding complications. ²⁴ In this population heparin SQ 5000 U TID is recommended for CrCl <30 mg/dL.
- e. The rate of Heparin Induced Thrombocytopenia (HIT) after prophylactic enoxaparin is 0% compared to 2.7% with prophylactic unfractionated heparin. Therefore, routine platelet monitoring is not required for trauma patients who are exposed only to enoxaparin.
- 2. Low dose Unfractionated Heparin (UFH)¹³⁻¹⁵
 - a. While enoxaparin is the preferred agent for chemical VTE prophylaxis in trauma patients with normal creatinine clearance, subcutaneous unfractionated heparin at 5000 U every 8 hours is preferred for patients with end-stage renal disease or a creatinine clearance of <30 mg/dL. ²⁴
 - b. In patients receiving UFH, platelet monitoring is recommended to monitor for HIT approximately every 3 days from day 4 to day 14 or until pharmacologic prophylaxis is stopped.²⁵ If HIT is diagnosed, heparin anticoagulants must be replaced with nonheparin anticoagulants (such as the direct thrombin inhibitor argatroban). These agents can be challenging to obtain and monitor in the deployed environment because these agents are irreversible and appropriate therapeutic levels are difficult to maintain. ^{25,27,28}

Pharmacologic prophylaxis with direct oral anticoagulants (DOACs) or aspirin should not be a primary choice for pharmacologic prophylaxis for most trauma patients because of the lack of related clinical trials.

Post discharge prophylaxis should be considered for patients with TBI, orthopedic or spine injuries and for those who underwent major surgery. Godat et al. reported that trauma patients who are at the highest risk to develop VTE (especially spinal cord injury with/without pelvic fracture) are at the greatest risk during the first three months after injury and that this risk decreases at six months post injury.^{3.23}

SPECIAL POPULATIONS

Pending Surgery

Except for brain or spine surgery, holding chemical VTE prophylaxis prior to surgery is not indicated.

- 1. Routinely holding pharmacological prophylaxis prior to surgery may increase VTE risk without an accompanying decrease in the risk of bleeding. Many specialties with high DVT rates are now administering chemoprophylaxis at the start of surgery. ²⁹⁻³²
- 2. A pending invasive procedure is the most common reason for a patient missing a dose of chemoprophylaxis. **Every missed dose increases VTE risk.** Patients that miss two to four doses are at 8.5 times higher DVT risk compared with those with no missed doses.³³

Traumatic Brain Injury

- 1. Enoxaparin 30mg SQ twice daily remains the dosing of choice.
- 2. Prior to starting chemical VTE prophylaxis in TBI patients:
 - a. Consult a neurosurgeon.
 - b. Obtain CT scan of the head 24 hours post injury to assess for intracranial hemorrhage stability.
- 3. Prophylaxis should be withheld in the setting of progression of intracranial hemorrhage or presence of an intracranial monitor.
- 4. In patients with stable intracranial hemorrhage on repeat head CT, initiating chemical VTE prophylaxis 24-72 hours following traumatic brain injury does not increase the progression of intracranial hemorrhage.^{26,27}
- 5. Initiating VTE chemical prophylaxis **is recommended in TBI patients with a stable head CT 24 hours after injury**. Even in the setting of combat related penetrating TBI, for those patients with a stable repeat head CT, initiating pharmacologic prophylaxis 24 hours after injury was safe, with similar rates of progression.³⁴ Caution should be taken in starting chemical VTE prophylaxis 24 hours post injury and discussion with neurosurgeon is recommended for TBI patients with the following conditions:
 - a. Polytrauma with or at risk for coagulopathy
 - b. Have intracranial monitor/drain in place.
 - c. Have one or more of the following TBI features that are "high risk" for progression according to the Norwood-Berne criteria:
 - □ SDH > 8mm
 - Epidural hemorrhage > 8mm
 - Largest single contusion > 2cm
 - More than one contusion per lobe
 - Diffuse or scattered subarachnoid hemorrhage.
 - Diffuse or scattered intraventricular hemorrhage.

For these patients, chemical VTE prophylaxis is typically restarted 72 hours post-injury or from last stable CT head, or as neurosurgeon recommends. ^{35,36}

6. Avoid interruptions in dosing for TBI patients who are started on chemical VTE prophylaxis. Interrupted dosing in this patient population causes a 600% increase in the VTE rate.³⁷

Spine Trauma

- 1. Enoxaparin 30mg twice daily remains the recommended dosing.
- 2. Prior to starting chemical VTE prophylaxis, consult a spine surgeon.
- 3. Patients with traumatic spine injury or who undergo spine surgery should have VTE prophylaxis initiated within 48-72 hours after injury or after spine surgery.

- a. Chemical VTE prophylaxis initiated within 48 hours of operative fixation of traumatic spine fractures does not increase the risk of bleeding, progression of neurological injury, or postoperative complications including spinal hematoma. 38
- b. Delays longer than 72 hours lead to a substantial increase in VTE rate. ³⁹
- 4. Patients with suspected traumatic spinal injury and neurologic deficits should have chemical VTE prophylaxis held until imaging and spinal surgical consultation are obtained.

Solid Organ Injury

- 1. Chemical VTE prophylaxis should be initiated in patients with moderate (AAST grades 1-3- liver, spleen, kidney) solid organ injury in the absence of:
 - a. Hemodynamic instability
 - b. Hemoglobin drops greater than 2 g/dL in less than 12 hours
 - c. Ongoing blood transfusion after the initial resuscitation has been completed. ^{24,29,40,41}
- 2. Chemical VTE prophylaxis started within 12-24 hours of injury in this cohort decreased VTE rates without an increased risk of bleeding that required blood transfusion or intervention.⁴²
- 3. There is insufficient evidence on outcomes related to patients with grade 4 and 5 injuries because these patients often undergo operative management. All Grade 4 and 5 splenic injuries should undergo splenectomy. (See <u>JTS Blunt Abdominal Trauma, Splenectomy, and Post-Splenectomy Vaccination CPG</u>). Initiating chemical VTE prophylaxis post-operatively, in the absence of coagulopathy or other increased risk of bleeding, is considered safe.

Patients with Indwelling Epidural and/or Paravertebral Catheters

Patients who require an epidural catheter increasingly have interruptions in pharmacologic prophylaxis, such that epidural catheter placement is now associated with an increased VTE rate, whereas previously this was not the case. 45,46,47,48 Please refer to the <u>JTS Pain, Anxiety, and Delirium CPG</u> for further detail.

- 1. The timing of administration for chemical VTE prophylaxis may need to be modified to accommodate the placement and/or removal of an epidural.⁴³
 - a. Regional Anesthesia Guidelines recommend a 12-hour interval between enoxaparin dose and epidural placement. After placement, resumption of prophylactic enoxaparin should begin in 12 hours. Before removing the epidural catheter, hold LMWH 12 hours prior to removal. Resumption may start 4 hours after removal. 43,44
 - The maximum recommended prophylactic dose of enoxaparin is 40mg SQ daily.
 - For unfractionated heparin, a 4 to 6-hour interval is recommended before epidural placement. After placement, resumption of prophylactic heparin can begin immediately.
 Before removing the epidural catheter, hold heparin 4-6 hours prior to removal.
 Resumption may start immediately after removal.
 - The maximum recommended prophylactic dose of heparin is 5000U SQ TID.
- 2. Avoid missing doses of VTE prophylaxis for epidural placement, if possible.
- 3. In the combat casualty requiring an epidural pain catheter, modification of enoxaparin dosing to 40mg daily does not increase the incidence of venous thromboembolism.²⁸

Pregnant Patients

- 1. Both unfractionated heparin and enoxaparin are considered safe in pregnancy as neither crosses the placenta. 49-51
- 2. Pregnant trauma patients should receive an initial dose of 30 mg of enoxaparin twice daily titrated by anti-Xa levels, (if available) targeting a peak range of 0.2 to 0.4 IU/mL or a trough range of 0.1 to 0.2 IU/mL.
 - Pregnancy increases renal clearance, leads to changes in weight, and induces hormonal changes that result in hypercoagulability. All these factors influence drug dosing for chemoprophylaxis.
- 3. For pregnant trauma patients who weigh more than 90 kg, initiating 40 mg of enoxaparin twice daily is recommended with similar anti-Xa level titration.

Pediatric Patients 17

- 1. There is insufficient high-quality evidence to make strong recommendations regarding the institution of chemical VTE prophylaxis in children hospitalized after trauma.
- 2. Based on the current recommendations of the Eastern Association for the Surgery of Trauma and the Pediatric Trauma Society, it is recommended that chemical VTE prophylaxis be considered for children older than 15 years who are at low risk of bleeding and for children younger than 15 years old who are post pubertal if they have an ISS greater than 25.
- 3. For prepubertal children, even with ISS greater than 25, routine chemical VTE prophylaxis is NOT recommended.

Refer to <u>Appendix A: Prevention of Venous Thromboembolism Guidelines</u> for specific guidance on different subsets of patients after various surgical procedures.

USE OF INFERIOR VENA CAVA FILTERS

Inferior Vena Cava Filter (IVCF) placement in the combat theater may be used for:

- 1. Primary prophylaxis (no evidence of VTE disease at the time of placement).
- 2. Secondary prophylaxis (documented DVT) of 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.

Most series examining the use of IVCF placement for primary prophylaxis of PE in the trauma patient support a low rate of subsequent PE (1.6%), although the studies are of variable design and a strong consensus supporting this clinical practice cannot be made based upon available data.²⁹ There is no evidence that 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 DVT and PE still can occur.³⁰⁻³⁴

IVCF has no benefit in the prevention of DVTs and may be associated with the development of IVC and Deep Venous Thrombosis. 14,37

The role of duplex ultrasound in the diagnosis of DVT should be reserved for the symptomatic patient. Serial screening duplex ultrasound for the diagnosis of DVT is not recommended.¹⁴

For those asymptomatic trauma patients with significant injuries and gaps in pharmacologic prophylaxis, venous compression duplex may be considered.⁵² If a DVT or PE is identified, then therapeutic

anticoagulation is necessary per current guidelines, and if it is contraindicated, then an inferior vena cava (IVC) filter should be considered.

Refer to Appendix B for additional recommendations regarding IVC filters.

RETRIEVABLE INFERIOR VENA CAVA FILTERS (RIVCF)

The vast majority of IVCF devices placed in the combat theater are Retrievable Inferior Vena Cava Filters (RIVCF). RIVCF are preferred to avoid some of the long-term complications of filter placement. Additionally, many patients only need this form of VTE prophylaxis for a defined period of time early after injury.

Combat injured patients from Operation Iraqi Freedom and Operation Enduring Freedom who had RIVCFs placed have an overall retrieval rate of 18%.⁵⁴ Despite successful removal of IVCF beyond 180 days and high success and low complication rate for attempted IVCF removal, rates of eventual removal of RIVCFs in multiple studies of trauma patients in the U.S. have been as low as 14% to 22%.^{36-39,53}

It should be noted that the majority of patients was lost to follow up or did not have filters removed due to ongoing indications for use (82%). Therefore, the overall retrieval technical success rate may be much higher. Most series support removal of the most commonly used RIVCFs as early as they are no longer necessary and no later than approximately three months.⁴² While it is possible to remove any of these later than this time period, the technical success declines significantly as potential complications associated with removal increase. Clear electronic documentation and a dedicated tracking system at the final continental U.S. (CONUS) medical treatment facility (MTF) must be in place to improve retrieval rates and minimize loss to follow up.⁴³

AEROMEDICAL EVACUATION CONSIDERATIONS

- 1. Aeromedical Evacuation (AE) from any area of responsibility to continental U.S. can require multiple flights over the course of days before the patient arrives at his or her final destination.
- 2. There is a clear association between long-distance travel and an increased risk of VTE, even in a "healthy traveler."
- 3. Stresses of flight such as prolonged immobility and decreased humidity may contribute to VTE formation, especially in groups who already carry a high risk (trauma patients, recent surgeries, long bone fractures, smokers, pregnancy or post-partum, recent Myocardial Infarction, active cancer, presence of splint or cast, etc.).
- 4. Prophylaxis is essential to reduce the risk of VTE associated morbidity and mortality in all AE patients.
 - a. AE crews will encourage patient ambulation every 2 hours for patients whose condition allows.
 - b. SCD use should be universal for inpatients unless contraindicated by injury pattern. The Kendal SCD Express compression system is approved for use on military aircraft.
 - c. Chemical VTE prophylaxis is also recommended as above for all trauma or medical inpatients unless specifically contraindicated by the medical condition such as ongoing bleeding or coagulopathy.

- 5. AE Patients with KNOWN acute VTE should be treated prior to flight unless there is a clear contraindication.
 - a. Treatment depends on the clinical situation, but may include low-molecular-weight Heparin, Fondaparinux, oral Xa inhibitors, or Unfractionated Heparin.
 - b. Oxygen and continuous pulse-oxygenation monitoring should be available during AE for patients with known VTE in case supportive measures are needed.
 - c. In the case of known or suspected Pulmonary Embolism, a Cabin Altitude Restriction should be considered to mitigate the effects of altitude on oxygenation and respiration.
 - d. Addition of a Critical Care Air Transport Team should also be considered in cases of PE with significant respiratory or hemodynamic compromise.

PERFORMANCE IMPROVEMENT (PI) MONITORING

POPULATION OF INTEREST

All trauma patients admitted to Role 2 or higher.

INTENT (EXPECTED OUTCOMES)

- 1. All patients in population of interest receive VTE prophylaxis with sequential compression device within 24 hours of injury.
- 2. All patients in population of interest start chemical VTE prophylaxis within 24 hours of injury or contraindication documented.
- All ordered doses of chemical VTE prophylaxis are administered (no missed doses) or contraindication documented.
- 4. When IVCF is inserted, there is documentation in the medical record regarding the indication for procedure, whether the IVCF is retrievable, manufacturer, brand, serial number, lot number, and exact location of placement.
- 5. Retrievable IVC filters are removed within 6 months.

PERFORMANCE / ADHERENCE METRICS

- 1. Number and percentage of patients in the population of interest who start VTE prophylaxis with sequential compression device within 24 hours of injury.
- 2. Number and percentage of patients in the population of interest who receive chemical VTE prophylaxis within 24 hours of injury or have contraindication documented.
- 3. Number and percentage of patients in the population of interest who receive all ordered doses of chemical VTE prophylaxis or have contraindication documented.
- 4. Number and percentage of patients who receive IVC filter placement who have complete documentation of indication for procedure, whether the IVCF is retrievable, manufacturer, brand, serial number, lot number, and exact location of placement.
- 5. Number and percentage of retrievable IVC filters placed that are removed within 6 months.

DATA SOURCE

- Patient Record
- Department of Defense Trauma Registry (DoDTR)

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 JTS Chief and the JTS PI Branch.

RESPONSIBILITIES

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

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 JTS Chief.

The senior surgeon and/or Intensivist at each Role 3 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 JTS Performance Improvement Chief on the appropriateness of the guidelines being used and provide input for updates on an as needed basis.

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APPENDIX A: VENOUS THROMBOEMBOLISM PREVENTION GUIDELINES

RISK GROUP	PROPHYLACTIC MEASURES	
TRAUMA PATIENTS		
 Emergency trauma surgical procedures in patients with prohibitive risk of bleeding, or ongoing coagulopathy Emergency trauma surgical procedures in all patients, except patient with prohibitive risk of bleeding (once coagulopathy not present) Isolated major orthopedic surgery of extremities, spine, and pelvis 	 SCD (sequential compression device) until able to be anticoagulated (ideally start Enoxaparin within 12 hours of cessation of coagulopathy); see IVC filter and Duplex screening sections below. SCD (unless contraindicated by injury) + Enoxaparin 30 mg SC BID. If poor creatinine clearance, then Heparin 5000 U SC q 8 hours. SCD (unless contraindicated by injury) + Enoxaparin 30 mg SC BID and no evidence of TBI/SCI and normal creatinine clearance. 	
IVC FILTER PLACEMENT		
 Patients with: Recurrent PE despite full anticoagulation Proximal DVT and contraindications for full anticoagulation Proximal DVT and major bleeding while on full anticoagulation Progression of iliofemoral clot despite anticoagulation Patients with established DVT or PE and: Large free-floating thrombus in the iliac vein or IVC Following massive PE in which recurrent emboli may prove fatal During/after surgical embolectomy Very High-Risk Patients: those who cannot receive anticoagulation because of increased bleeding risk and:	1. Placement of retrievable IVC filter (RIVCF) 2. Document if the IVCF is retrievable or not, manufacturer, brand, magnetic resonance imaging (MRI) compatibility, serial number, lot number and exact location in record and TMDS; PE may still occur despite IVC filter 3. "Extended" indications for placement of IVC filter for patients with established DVT or PE 4. Consideration of placement of prophylactic placement of IVC filter.	
ROLE OF DUPLEX SCREENING		
Asymptomatic patients	 Serial duplex ultrasound imaging considered for patients with gaps in VTE prophylaxis and periods of prolonged 	

immobility.

RISK GROUP	PROPHYLACTIC MEASURES	
Symptomatic patients	 Duplex ultrasound may be used without confirmatory venography. 	
GENERAL, VASCULAR, UROLOGIC SURGERY		
LOW RISK:		
Minor procedure in patients < 40 years, no risk factors	Early mobilization	
MODERATE RISK:		
 Minor procedure with additional risk factors for thrombosis 	■ SCD + Unfractionated Heparin 5000 units SC q 8 hours or Enoxaparin 30 mg SC BID	
 Non major surgery in patients 40-60 years, with no additional risk factors 	 Chemical VTE prophylaxis is withheld in patients with high risk of bleeding. 	
 Major surgery in patients < 40 years with no additional risk factors) 		
HIGH RISK:		
 Non major surgery in patients > 60 years or have additional risk factors 	■ SCD + Unfractionated Heparin 5000 units SC q 8 hours or Enoxaparin 30 mg SC BID	
 Major surgery in patients > 40 years or have additional risk factors 	Chemical VTE prophylaxis is withheld in patients with high risk of bleeding.	
NEUROSURGERY		
■ Intracranial neurosurgical procedures	■ SCD	
■ High Risk neurosurgery patients	 Chemical VTE prophylaxis following stable CT scan in consultation with neurosurgeon 	

APPENDIX B: IVCF RECOMMENDATIONS

- 1. All IVCFs placed in the combat theater should be retrievable.
- 2. Documentation detailing the ICVF brand, model, MRI compatibility, and exact location of placement should be documented in Armed Forces Health Longitudinal Technology Application T or TC2 (Theater Medical Information Program -Joint Composite Health Care System Cache)
- 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 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 should be made known to the receiving CONUS MTF. Typically, retrieval of the RIVCF will be accomplished at the CONUS 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 international normalize ratio (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 the medical record 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: CLASS VIII MEDICAL MATERIEL

To prepare for the prevention of venous thrombosis in trauma patients, especially in austere or combat settings, the following itemized list includes the necessary medical materials and equipment:

Mechanical Prophylaxis

- 1. Sequential Compression Devices (SCDs)
- 2. SCD machine/controller
- 3. SCD cuffs (various sizes)
- 4. Replacement SCD tubing
- 5. Graduated compression stockings (various sizes)
- 6. Thigh-high or knee-high options depending on the patient's condition

Chemical Prophylaxis

- 1. Enoxaparin syringes (30 mg prefilled syringes)
- 2. Weight-based dosing syringes for enoxaparin (30 mg, 40 mg, 50 mg, or specific mg/kg dosing)
- 3. Storage and transport containers for LMWH syringes
- 4. Unfractionated Heparin (UFH)
- 5. Heparin vials (5000 units)
- 6. Heparin syringes (for subcutaneous administration)
- 7. Dosing charts and calculation aids for weight-based dosing

Monitoring Supplies

- 1. Anti-Xa Level Testing Kits
- 2. Blood sampling kits for anti-Xa monitoring
- 3. Anti-Xa assay kits

Creatinine Clearance Monitoring

- 1. Blood sampling kits for creatinine level measurement
- 2. Portable point-of-care testing devices for creatinine and kidney function

Additional Supplies

- 1. Inferior Vena Cava Filters
- 2. Retrievable Inferior Vena Cava Filters (recommended)
- 3. Renal Function Monitoring
- 4. Creatinine clearance calculators
- 5. Dosing Guides and Protocols
- 6. Laminated dosing charts for quick reference
- 7. Portable electronic devices or apps with dosing calculators
- 8. Education and Training Materials

- 9. Training manuals on VTE prophylaxis
- 10. Patient education brochures on the importance of prophylaxis
- 11. Leg and arm immobilizers to reduce patient movement

Prophylaxis for Pediatric Trauma

- 1. Pediatric SCD cuffs and compression stockings
- 2. Pediatric dosing charts and syringes for heparin

Transport Logistics

- 1. Supplies for managing prolonged patient transport and immobility
- 2. Aeromedical evacuation specific prophylaxis kits

For additional information including National Stock Number (NSN) refer to <u>Logistics Plans & Readiness</u> (<u>sharepoint-mil.us</u>)

APPENDIX D: TELEMEDICINE / TELECONSULTATION

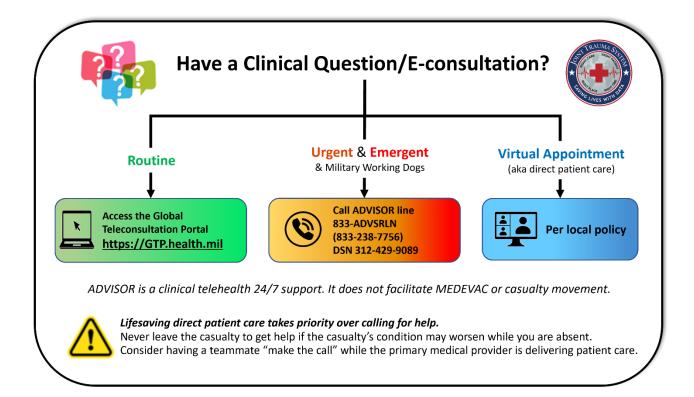


Illustration by Raymond Samonte

GTP: https://GTP.health.mil

APPENDIX E: INFORMATION REGARDING OFF-LABEL USES IN CPGS

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.

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.

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.

ADDITIONAL PROCEDURES

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.

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.

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.