# JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE



# **Amputation: Evaluation and Treatment**

This CPG provides standardization of optimal care of wound management and life-saving amputations to ensure preservation of maximum limb length, promote healing of viable tissues, and facilitate optimal rehabilitative function.

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#### **SUMMARY OF CHANGES**

- 1. New references have been added based on clinical data from the Fluid Lavage of Open Wounds Study and improved outcomes seen with newer techniques in peripheral nerve management.
- 2. Although recent clinical data is inconclusive as to which irrigation method is superior, additives such as iodine or castile soap should not be added to the irrigation solution when irrigating open wounds.
- 3. Recommendations are made to avoid traction neurectomies acutely, when possible, to allow for targeted muscle reinnervation if deemed appropriate at the time of definitive wound closure.
- 4. Recommendation to NOT amputate through the most proximal fracture if stabilization of the fracture can result in an improved functional outcome and the associated wounds make salvage at the more distal level possible.
- 5. Recommendations made that if using negative pressure wound therapy (NPWT) during transport, consideration should be made to use antibiotic beads (if available) under the NPWT dressing if vacuum dressing fails.

# Combat Casualty Care

# **Evaluation & Treatment**

# EVALUATE

- Inspect thoroughly
- Extend wounds longitudinally as needed to examine all tissue levels
- Use Doppler/arteriography to evaluate perfusion of injured extremity.

# TREAT

- Control bleeding & gross contamination
- Debride non-viable tissue
- Irrigate with normal saline
- Double ligate vascular structures- separate from nerves
- Ensure hemostasis
- Avoid traction neurectomies -Possible targeted muscle reinnervation

# DECISION TO AMPUTATE

- Life over limb
- Amputation can potentially be deferred if:
  - There is adequate limb perfusion
  - Perfusion can be restored quickly with primary repair or shunt
  - Amputation can be deferred for volumetric loss, nerve injury, w/intact limb perfusion



# GOALS

- Preserve limb length
- Preserve perfusion
- Facilitate wound closure
- Eventual wound closure or coverage

#### **MECHANISM OF INJURY**

Blast • GSW • Crush

# COMORBIDITIES

Blood loss Massive resuscitation Burns

- Compartment syndrome
  - **Contamination** load

# AMPUTATE

- Most distal level possible
- Accept atypical skin flaps if viable
- No primary closure
  - Serial I & D (24-48 hours)
- No guillotine amputations
- Stabilize proximal fractures

# POST OP CARE

- Soft dry dressing
- Splint/bivalve cast
- Skin traction for short skin flap
- Avoid pillows under knee
- Negative-pressure wound therapy
  - Clean/healthy/hemostatic wounds
  - Neurovascular structures
    covered
  - Antibiotic beads

# EVACUATE

- Stabilize ortho injuries
- DVT prophylaxis
- Supplemental O2
- Prevent hypothermia
- Pain management
- NPWT remain covered
- Coordinate dressing/ debridement with schedule

This information is pulled from the evidence-based Joint Trauma System (JTS) Amputation: Evaluation & Treatment Clinical Practice Guideline (CPG). JTS CPGs can be found at the <u>JTS CPG website</u> or the <u>JTS Deployed Medicine site</u>.

Guideline Only/Not a Substitute for Clinical Judgment

Amputation wound not closed primarily

Repeat debridement/dressing change

within: 24hrs (extensive wound), 48hrs

Avoid guillotine amputations

(non-extensive wound)

#### BACKGROUND

Most combat casualties sustain musculoskeletal injuries with varying degrees of severity. Their prevalence and complexity present a challenge in which the management of the patient's overall pathophysiology must be balanced with efforts for limb preservation. Data from the Department of Defense Trauma Registry (DoDTR) demonstrates that 5,579 amputations have been performed from 2002-2024, with 32% of those performed on U.S. Service Members. Out of all traumatic injuries documented, the percentage of amputations range from 0.5%-8.0% per year, with the higher percentage registered during the height of the war in Afghanistan and Iraq (2002-2013). While it fluctuates in frequency of occurrence over the years, injury patterns that increase likelihood of amputations will continue to exist and may likely increase in future combat scenarios. Therefore, it is imperative that medical providers are familiar with the management of patients at high risk for amputations.

The extent of the "zone of injury" is dependent upon the mechanism of injury (i.e. blast, gunshot and crush injuries), as well as the co-morbidities and physiologic status of the casualty. Factors such as severe blood loss with massive resuscitation, burns, compartment syndrome, tourniquet use, and contamination load often extend the actual amount of tissue damage beyond that which is apparent on initial visual inspection. Amputation terminology includes traumatic amputations which are immediate extremity amputations caused by the wounding mechanism itself. Primary amputations are those performed by a surgical team after evaluation of the mangled extremity, with the decision not to pursue limb salvage. Data from DoDTR show that 19.7% of total amputations were performed in Role 2 facilities, with only 4.4% performed on U.S. Service Members. In comparison, 73% were performed in Role 3 facilities, with 20% performed on U.S. Service Members. These data suggest that there is an attempt to pursue limb salvage of U.S. Service Members on initial and subsequent evaluation during the early phases of their trauma care. Secondary amputations can occur early (within 90 days) or late (after 90 days), with the latter referring to those amputations occurring after an initial attempt at limb salvage has been undertaken. Most commonly, primary, and early secondary amputations are performed for vascular injuries not amenable to repair or resulting in prolonged limb ischemia, nerve injuries not compatible with a functional extremity, or extensive nonviable tissue with potential for uncontrolled sepsis. Of the amputations performed, DoDTR data reveal that only 13% of the amputations had arterial injuries of which 70% had an arterial procedure performed to attempt limb salvage. Other factors other than perfusion, such as nerve injuries or nonviable tissue likely contributed to decision to amputate.

Late secondary amputations are generally performed due to patient preference or major complications (e.g., flap failure, recurrent osteomyelitis, persistent poor function or pain) of attempted limb salvage. Current consensus regarding extremity amputation following battle-injury is to preserve limb length and vascularity, facilitate adequate wound drainage, and achieve eventual coverage and closure of the amputation wound.<sup>1,2</sup>

# DECISION TO AMPUTATE

Although a number of scoring systems to predict the need for amputation exist, none is widely accepted or validated in the combat trauma population.<sup>3</sup> It is imperative that the combat-injured patient be adequately resuscitated and that the surgical team practices damage control surgery when required. Given the time that can be required to restore perfusion, especially in complex combat-related injuries, amputation may be a necessary damage control procedure in a massively injured patient – life over limb. Following resuscitation, adequacy of limb perfusion is the next major determinant. If the limb is adequately perfused, or perfusion can be restored expediently by shunt or repair, any decision regarding amputation due to the likelihood of having a poor functional recovery as a result of other soft tissue (i.e. nerve injury or volumetric muscle loss) or bony injury can potentially be deferred until later. The limb should be stabilized for transport by splinting or external fixation, as indicated.

# EVALUATION AND TREATMENT

- Thorough inspection of the wounds with liberal use of surgical wound extension is necessary to inspect all levels of tissue including examination of fascial planes. Wounds should be extended longitudinally rather than transversely around a limb when possible. If available, continuous wave Doppler examination and diagnostic arteriography can be used as adjuncts in cases where distal perfusion is a concern.<sup>4</sup>
- 2. Early control of active hemorrhage, gross decontamination, followed by a meticulous sharp debridement with a scalpel and/or scissors should be the starting point for wartime penetrating wounds.
- 3. Removal of all nonviable tissue, including skin, fat, fascia, muscle, and bone, is essential to reduce the load of contamination and necrotic tissue in the wound and is the hallmark of an adequate debridement.
- 4. Irrigation or lavage with normal saline is also important to decrease bacterial count and soiling. Irrigation or lavage of open wounds can be accomplished using various devices such as pulse lavage using a battery powered system or gravity irrigation using genitourinary tubing or bulb/syringe. Published clinical data is inconclusive as to which irrigation method is superior, however, additives, such as iodine or castile soap, should not be added to the irrigation solution (see <u>JTS War Wounds: Debridement and Irrigation CPG</u> for additional information).<sup>5</sup>
- 5. Confirmation of hemostasis is critical prior to evaluation for dressing or closure.
- 6. In the setting of an extremity amputation, appropriate vascular structures should be double-ligated (stick tie distal to a free tie) proximal to the bone resection but as distal as possible to ensure adequate tissue perfusion. Vascular structures should be separated from nerves prior to ligation. Avoid traction neurectomies when possible in patients who will have access to targeted muscle reinnervation treatment at the time of wound definitive closure.<sup>6</sup>
- 7. The amputation should be performed at the most distal level which provides viable bone and soft tissues for later closure. In select instances close to the proximal joint (e.g., knee, elbow), preservation of viable bone length in the absence of adequate viable soft tissue coverage is advocated in order to preserve options for either late free tissue transfer coverage and amputation level salvage or disarticulation. Ipsilateral fractures proximal to the level of viable tissue should be initially stabilized and should not be a determining factor for amputation level. These fractures can be stabilized with external fixation or splinting to facilitate evacuation.<sup>7</sup>
- 8. Be prepared to accept atypical skin and tissue flaps so long as the tissue is viable.
- 9. Do not perform primary closure of traumatic amputations. All wounds must be left open and re-evaluated with serial irrigation and debridements as the zone of injury declares itself.
- 10. Avoid open circular or guillotine amputations. These techniques are antiquated, sacrifice viable soft tissue, and relegate the casualty to more proximal revision, and are not that much faster than the open, length-preserving length of initial amputation advocated. All amputations should be performed at the most distal level possible with re-evaluation of the open amputation site within the first 24 hours.
- 11. Do not amputate through the most proximal fracture if stabilization of the fracture would result in an improved functional outcome and the associated wounds make salvage at the more distal level possible. For example, stabilizing a subtrochanteric femur fracture to allow for a more traditional above knee amputation or stabilizing a tibial plateau fracture to salvage a below knee amputation in what would otherwise be a knee disarticulation or above knee amputation can be performed when the injury pattern permits. Be aware, that these fractures can be associated with a high rate of infection and heterotopic ossification but can often be successfully treated to fracture union.<sup>7</sup>

# **POST-OPERATIVE MANAGEMENT**

- 1. Soft/dry dressing should be applied around the amputation site and extremity. Circumferential wraps with gauze rolls and ace wraps must be applied in a figure eight fashion without excessive compression.
- 2. The limb may be placed in a splint or bivalved cast to prevent joint contractures and provide soft tissue support when necessary. There should be ample access for wound inspection.
- 3. In the event of the short skin flaps, skin traction to prevent soft tissue retraction is an option.
- 4. Avoid placement of pillows under the knee to prevent contractures when dealing with amputations below the knee.
- 5. Negative Pressure Wound Therapy (NPWT) device/ Vacuum Assisted Closure (VAC) dressing is recommended for management of appropriate amputation wounds, when available.<sup>8</sup> The VAC device has been the primary NPWT device used within the DoD. Clinical studies support the use of the VAC as a soft tissue wound management adjunct in appropriately prepared wounds as a bridge to delayed closure, flap coverage, or coverage with a split thickness skin graft. In appropriately debrided and prepared wounds the VAC has been shown to increase the rate of granulation and decrease bacterial colonization leading to effective amputation coverage and or closure.<sup>8</sup> Use of NPWT should be considered only after complete wound debridement and hemostasis have been achieved and only after the wound has had frequent debridements and demonstrated wound stability. More extensive and acute soft tissue wounds should have the VAC dressing removed with further irrigation and debridement on shorter intervals (every 24 hours) compared to less extensive wounds (greater than every 24 hours). Neurovascular structures should be covered with tissue or other barrier (white foam, Adaptic, or petroleum gauze) prior to applying the NPWT. The VAC sponge should cover the open wound bed and be set to 50-125 mm Hg continuous pressure. The use of NPWT dressings has been demonstrated to be safe in patients during strategic aeromedical evacuation. Consideration should be given to the placement of antibiotic beads, if available under the NPWT dressing to convert the wound to an antibiotic bead pouch in the event of vacuum dressing failure (seal leak or machine shutdown) during patient transport.<sup>8</sup>
- 6. Upon arrival to the next level of care, direct wound inspection needs to be completed by a surgeon.
- 7. Wounds in the early phase of management need frequent inspection to ensure infection control and no evolution of injury; however, NPWT/ reticulated open-cell foam dressings can be left in place for 48-72 hours if there are no concerns for infection or injury progression. Wounds with concern for ongoing infection and evolution of injury need daily inspection.
- 8. Coordinate dressing changes/repeat debridement with evacuation schedule to avoid extended periods without wound care or inspection. Given the extent of many soft tissue wounds, dressing changes and repeat debridements should be performed in the operating room affording the patient the comfort of conscious sedation or general anesthesia and the surgeon access to the full array of equipment necessary to perform adequate debridement. Also, reapplication of the VAC dressing may be more complete and effective if performed in the operating room with the support of operating room and anesthesia teams when possible.

# **AEROMEDICAL EVACUATION CONSIDERATIONS**

Due to the requirement to move the coalition patient with traumatic amputation to Role 4 facilities usually out of theater, early and safe transport of these patients should involve consideration of the following factors.

1. Concomitant injury management is crucial during flight. Additional orthopedic injuries should be stabilized and structurally sound for transport. Limbs should be splinted or ex-fixed and positioned to decrease the possibility of post traumatic contractures.

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- If adequate tissue perfusion is a concern, supplemental oxygen should be given to increase oxygen tissue delivery. Assess amputation wound in flight. Liberal use of ABGs to look at pAO2. O2 saturations can be normal in flight, but O2 delivery may still be marginal. If substantial decrease in pAO2 at altitude, consider increasing supplemental oxygen.
- 3. Large wounds or wound vacuums can add an area of increased heat loss. Take preventive measures to reduce risk of hypothermia.
- 4. Flight stresses include movement and vibration which can increase pain during transport. It is likely pain medication requirements will increase during these times. Evaluate analgesia protocols as well as the patient's analgesia needs and response to pain medications.
- 5. Do not remove drains or NPWT dressings in the immediate period prior to aeromedical evacuation. Coordinate dressing change timing with the patient movement schedule. Consider placement of antibiotic beads in amputation wounds being managed with NPWT during transport to convert the dressing into an antibiotic bead pouch in the event of NPWT vacuum failure.<sup>8</sup> Refer to the <u>Negative Pressure Wound Therapy CCAT, 11 Feb 2020 CPG</u> on the JTS CPG website.
- 6. Patients with poly-trauma require deep vein thrombosis prophylaxis if anatomically feasible and not contraindicated. Refer to the *JTS Prevention of Venous Thromboembolism, 29 Mar 2024 CPG* for specific guidance.

# PERFORMANCE IMPROVEMENT (PI) MONITORING

#### **POPULATION OF INTEREST**

All patients with diagnosis of limb amputation or limb amputation procedure code.

#### INTENT (EXPECTED OUTCOMES)

- 1. Amputation wounds are not closed at the initial operation.
- 2. Circular/guillotine amputation is avoided (viable soft tissue is preserved).
- 3. Repeat debridement/dressing change within 24 hours of first debridement/amputation procedure.
- 4. Document if patient received antibiotic beads or topical antibiotic (this PI metric is for tracking purposes and does not imply it is a requirement).

#### PERFORMANCE/ADHERENCE METRICS

- 1. Number and percentage of patients in the population of interest who have amputation wounds left open at initial operation (closed flap amputation at first procedure = non-adherence).
- 2. Number and percentage of patients in the population of interest who underwent a non-guillotine or non-circular amputation.
- 3. Number and percentage of patients in the population of interest who have their dressing change/repeat debridement within 24 hours of initial amputation/procedure.
- 4. Number and percentage of patients that received antibiotic beads or topical antibiotic. (This PI metric is for tracking purposes and does not imply it is a requirement).

#### DATA SOURCE

- Patient Record
- 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.

#### REFERENCES

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- 7. Gordon WT, O'Brien FP, Strauss JE, Andersen RC, Potter BK. Outcomes associated with the internal fixation of long-bone fractures proximal to traumatic amputations. J Bone Jt Surg Am Vol. 2010;92(13):2312-2318.
- 8. Streubel PN, Stinner DJ, Obremskey WT. Use of negative-pressure wound therapy in orthopaedic trauma. J Am Acad Orthop Surg. 2012;20(9):564-574.

# APPENDIX A: CLASS VIII MEDICAL MATERIEL

# Coming Soon

# APPENDIX B: TELEMEDICINE / TELECONSULTATION

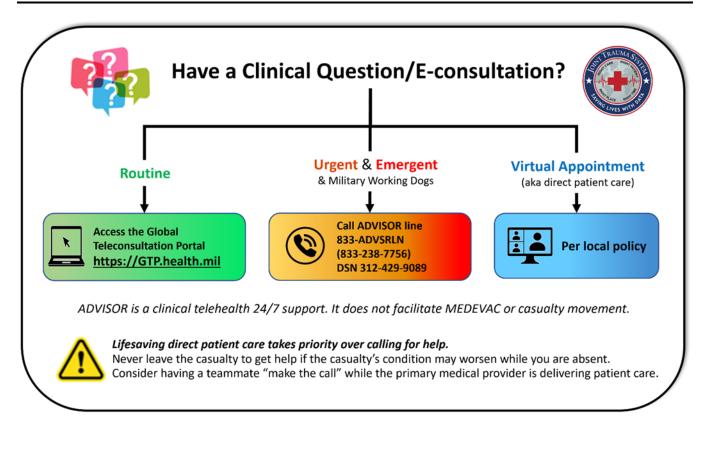


Illustration by Raymond Samonte

GTP: <u>https://GTP.health.mil</u>

#### APPENDIX C: INFORMATION REGARDING OFF-LABEL USES IN CPGS

#### PURPOSE

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of "offlabel" 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 offlabel 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.