JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)

Acute Traumatic Wound Management in the Prolonged Field Care Setting (CPG ID: 62)

The intent of this guideline is to provide evidence- and experience-based solutions to those who manage both simple and complex wounds in an austere environment.

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INTRODUCTION

This Role 1, prolonged field care (PFC) guideline is intended for use after Tactical Combat Casualty Care (TCCC) guidelines when evacuation to higher level of care is not immediately possible. A provider must first be an expert in TCCC. The intent of this guideline is to provide evidence- and experience-based solutions to those who manage both simple and complex wounds in an austere environment. Emphasis is placed on the basics of wound care, using the tools most familiar to a Role 1 provider. Ideal hospital techniques are adapted to meet the PFC environment while still maintaining the highest standards of care possible.

SPECIAL CONSIDERATIONS IN AUSTERE ENVIRONMENT

Specific considerations for wound care in the PFC context: although all 10 of the PFC core capabilities should be implemented,[1] the following have areas of emphasis specific to longer-term wound care and management.

- **Physical examination:** Techniques specific to prolonged wound management include inspection of the wound and surrounding skin for evidence of necrosis or infection, passive and active range of motion to assess level of disability, ultrasound to assist in evaluating critical anatomy and/or guide regional anesthesia, distal pulse trending to assess for vascular compromise, and laboratory studies as an adjunct to determine the amount of blood loss or look for evidence of a developing infection.
- **Nursing:** Scheduled dressing changes are necessary to ensure proper wound healing and infection management. The bandage plan should include scheduled changes, materials to be used, as well as analgesia.
- **Surgical intervention:** Efforts are most likely geared toward irrigation and debridement. They should be scheduled and planned with evacuation timeline or inability to evacuate taken into consideration.
- **Telemedicine:** Should be initiated as early as possible so the consultant can properly guide the patient's management and monitor the patient's status. Photographs play a vital role in a consultant's ability to advise the Role 1 provider on wound care, especially in the assessment of viable tissue.

TYPES OF WOUNDS

- **Abrasion**: A wound created by scraping or wearing away of the skin. These are partial-thickness wounds.
- **Burn**: A wound created by thermal or chemical destruction of the skin and underlying tissues. These can be partial- or full-thickness wounds. Management of burn wounds is addressed in a separate guideline.
- **Puncture**: A wound caused by a narrow object and results in a relatively small skin opening relative to the depth.
- **Laceration**: A deep cut or tear in the skin.
- **Gunshot**: A wound caused by a bullet; involves a high transfer of energy and extensive damage to tissues.
- **Blast**: A complex wound that may involve penetrating fragments, extensive tissue damage or loss, and massive contamination with dirt and debris.
- **Crush injury**: A wound caused by blunt trauma and may include injury to skin, muscle, or bone.

The overall principles of wound management are the same for each type of wound. The size of the wound and the evacuation timeline, as well as resources available and level of training of the medical provider, will influence the wound management plan. In most cases, open wounds with contamination, devitalization, loss of tissue (skin, muscle, or bone), or infection will require a more complex treatment strategy because of the invasive nature of the wound, especially in the context of war wounds. Large abrasions still require careful cleansing and dressing with a high index of suspicion for skin infection. Careful evaluation of the wound should lead to development of a problem list in the event PFC will be required. The care provider should focus on anesthesia, debridement and irrigation, wound dressing, antimicrobial therapy, scheduled dressing changes, and pain control. In select cases, delayed primary closure (DPC) may be considered.

ANALGESIA

Goal: Irrigating, debriding, repairing, and bandaging wounds can be painful for the patient. Analgesia is often necessary to facilitate wound care and sedation may be required for more severe wounds.

- **Best**: Regional nerve block (for extremity wounds, ONLY if fully trained and equipped); and/or ketamine drip augmented with versed IV push as needed.
- **Better**: Local anesthetic and/or ketamine drip augmented with versed IV push as needed.
- **Minimum**: Local anesthetic and/or any pain medication.
    1. 1% or 2% lidocaine (with or without epinephrine)
    2. Oral (i.e., by mouth [PO]) acetaminophen and meloxicam
    3. PO acetaminophen/oxycodone (e.g., Percocet; Endo Pharmaceuticals, http://www.endo.com)
    4. Oral transmucosal fentanyl
    5. IV/IM ketamine
    6. IV morphine, hydromorphone, or fentanyl

Local anesthetic notes:

- For smaller wounds that require painful interventions, direct injection of local anesthetic into the wound margins with 1% or 2% lidocaine can provide enough analgesic effect for the patient's comfort.
- The maximum dose of lidocaine WITHOUT epinephrine is 3mg/kg (1% lidocaine has 10mg/mL and 2% lidocaine has 20mg/mL).
- The maximum dose of lidocaine WITH epinephrine is 7mg/kg (1% lidocaine has 10mg/mL and 2% lidocaine has 20mg/mL).
- Epinephrine injected with lidocaine has several properties that are advantageous: reduces bleeding, increases the duration of the local anesthetic effect by at least 50% depending on the site, and raises the maximum dose.
- Injection of epinephrine-containing anesthetics should be used with caution in the tip of the nose, ear, penis, fingers and toes, because of possible risk of ischemia.

- Buffering lidocaine with sodium bicarbonate using a 9:1 ratio (9mL lidocaine with 1mL bicarbonate), keeping the lidocaine at room temperature, and using smaller gauge needles can lessen the burning sensation associated with injection.
- Sodium bicarbonate buffers the acidity of local anesthetics, allowing for a more rapid analgesic onset.
- If properly trained and equipped with an ultrasound machine, the provider can perform ultrasound-guided regional blocks for those wounds in which local anesthesia will not manage the pain effectively during wound care. See PFC Analgesia and Sedation CPG.
- For wounds that require the patient to be on a surgical plane, see PFC Analgesia and Sedation CPG.

See the PFC Analgesia and Sedation CPG for a more comprehensive summary.

IRRIGATION

Goal: Because war wounds are most often grossly contaminated, proper irrigation techniques should be implemented as early as possible after wounding to reduce the possibility of infection. Pressure, fluid choice, and fluid amount are the tenants of irrigation: the solution to pollution is dilution.

- **Best**: Irrigate wounds with Dakin's solution or sterile isotonic solution.
- **Better**: Irrigate wounds with clean, potable tap water.
- **Minimum**: Irrigate wounds with the cleanest water available (nonpotable water should be boiled for a minimum of 3 minutes and then cooled to body temperature).

Irrigation notes:

- Cleansing the entire patient (shower or cloth bath) will reduce the risk of infection.
- Bacterial loads drop significantly with increases in wound irrigation fluid volumes.[2]
- Evaluate the wound size and contamination level to determine the optimal amount of irrigation: 1–3L for small or clean wounds, 4–8L for intermediate or dirty wounds, and ≥9L for large or very dirty wounds.
- Dakin's solution (0.025%) may be used for irrigation of large, very dirty, or infected wounds to help treat wound infection and prevent fungal infection. A diluted concentration of one-tenth the strength of "half-strength" Dakin's solution has been shown to be toxic to microorganisms without damaging tissues. The recipe is given below.[3–5]

  Half-strength Dakin's Solution

  1. 1L water, sterile or boiled
  2. 5mL household bleach (5.25% hypochlorite solution, unscented)
  3. Sodium bicarbonate: 1.5mL (1/2 tsp) of baking soda or 4 ampules (200mL) of 8.5% sodium bicarbonate injection (preferred, but can leave out if not available)
  4. Once mixed, Dakin's solution can be stored. The half-strength solution should be diluted 1:10 with water for wound irrigation solution.

- Additives such as iodine, bacitracin, or alcohol are not associated with reduced infection.[6]
- Very high-pressure (>15 psi) irrigation is not associated with reduced infection and has been associated with tissue damage and injection of bacteria deeper into the tissues.[7] For smaller wounds, a large-bore catheter on the end of a syringe will provide high-pressure (6–15 psi) flow and is the ideal pressure for maintaining tissue viability and irrigation in a contaminated wound.[8] A 19-gauge catheter with a 35mL syringe will deliver approximately 8 psi. For moderate sized wounds, a bulb syringe or bottle with puncture holes in the top can be used for low pressure (<6 psi) irrigation. For large wounds, bags of IV fluids can be connected to IV tubing to facilitate large-volume irrigation or any large container may be used to pour water onto the wound while gently scrubbing the wound.[9]
- Debris made of wood, vegetative material, clothing, and any debris in the foot should be excised and/or removed if possible; however, foreign bodies penetrating into vital structures, including the eye, should be left in place until the patient can reach a surgical capability. Most retained metal fragments do not need to be removed, particularly if doing so creates additional tissue damage.

DEBRIDEMENT

Goal: Removal of devitalized tissue and debris reduces both infection and morbidity. Devitalized tissue acts as a medium for bacterial growth and inhibits leukocyte function. The goal is to remove this tissue while preserving as much perfused tissue as possible. A basic knowledge of debriding skills—cutting, clamping, grasping, ligation, and tying—allows the provider to effectively manage the balance between salvageable and unsalvageable tissue.

Identification of viable tissue may be challenging. Tissue that is clearly dead should be removed, whereas tissue of uncertain viability should be preserved and re-examined in 24–48 hours. Use the four Cs, along with clinical judgment, when excising muscle tissue: color, contraction, consistency, and circulation.

***Caution**: Debridement of large wounds or wounds associated with other injuries will result in significant blood loss. Be prepared to give blood transfusion.*

- **Best**: Use an assistant; remove nonviable tissue using sharp dissection (sterile scalpel or scissors) and control bleeding using tourniquet, topical hemostatic dressings, direct pressure, clamping, suture ligation, and/or electrocautery. Questionably viable tissue may be retained with repeat debridement once every 24–48 hours until arrival at surgical facility.[10]
- **Better**: Remove nonviable tissue using sharp dissection (sterile scalpel or scissors) and control bleeding using tourniquet, topical hemostatic dressings, direct pressure, clamping, and/or suture ligation. Repeat debridement or delayed primary closure in 3–5 days.
- **Minimum**: When unable to evacuate and resources for serial debridements are not available, remove all nonviable and questionably viable tissue, using sharp dissection (clean blade or scissors) and control bleeding with tourniquet and/or direct pressure. Leave clean dressing in place, then perform delayed primary closure in 4–7 days if no sign of infection.[11,12] See Appendix A for further details on the International Committee of the Red Cross (ICRC) method of wound care.

DEBRIDEMENT NOTES

Exposure

- Deeper wounds should be exposed through generous skin incisions in the long axis of the extremity.
- Avoid exposing major blood vessels, tendons, and nerves, unless they are injured.

Anatomic Considerations

- Review the anatomy of the injured body part before debridement. Extremity wounds are by far the most common and the need for reference anatomic diagrams should be anticipated.
- If a major blood vessel is injured, it will require ligation, repair, or shunting. In the extremity, ligation may result in amputation; however, vascular repair or shunting are advanced surgical skills.
- Damaged parts of tendons do not need much debridement and should be preserved when possible. Tendons may be repaired later as a delayed procedure.
- Damaged nerves should not be debrided. Some nerves may be repaired as a delayed procedure.
- Loose, unattached fragments of bone should be removed; however, any bone fragments still attached to muscle should be left in the wound. After debridement and dressing placement, a fractured extremity should be immobilized with a splint.
- After debridement, attempt to ensure that vital structures (i.e. blood vessels, nerves, tendons, bone) are covered with soft tissue. This may require partial wound closure or mobilization of soft tissue to cover the structure.
- Mangled extremities may require amputation. Amputation is best left to a surgical facility and the wound kept as clean as possible while awaiting evacuation. If evacuation is not possible, amputation may be necessary.
- An injured extremity may require fasciotomy. Be vigilant for signs of compartment syndrome.
- Wounds penetrating the chest cavity should not be probed and should be minimally debrided to avoid creating a pneumothorax. If a pneumothorax is present, a chest tube should be placed through a separate, clean skin incision.
- Wounds penetrating the abdominal cavity require abdominal exploration (i.e. laparotomy) if associated with hemodynamic instability or peritonitis. Otherwise, these wounds may be debrided and dressed as any other wound.
- Small wounds or puncture wounds can be managed using local anesthesia, washing (scrubbing) the wound with soap and water or disinfectant soap, irrigating, dressing, and then allowing the wound to close by secondary intent. Some minor excision of the wound edges may be indicated.
- Large wounds require careful attention to hemostasis, wound care, and consideration for repeat debridements or delayed closure.

 Complex wounds are best managed with a telemedicine consultation. Photos or video of the wound should be transmitted.

Assessment of Tissue Viability

- Color is the least reliable trait for measuring tissue viability. Evaluate the tissue's color relative to similar tissue deemed viable. Nonviable tissue appears pale, bluish, gray, or black. Bruised tissue that is viable may also have a dark coloration.
- Contractility refers to the retraction of muscle tissue when tension is placed on it by grasping. Nonviable muscle tissue does not contract.
- Consistency evaluation involves comparing potentially dead tissue with live tissue in terms of texture, density, and rigidity. Viable tissue has elasticity and firmness, whereas nonviable tissue is friable and/or is in a state of liquefaction.
- Circulation may be the best indicator of salvageable tissue because any tissue that bleeds when very minor trauma is applied can almost always be judged as perfused and, therefore, viable.

Debridement Techniques

- **Cutting**: Meticulous sharp surgical technique using scalpel and scissors should be the starting point for almost all war wounds that involve penetrating foreign bodies. Typically, #10 or #15 scalpel blades (or #11, as an alternative) are used for the removal of skin tissue, and sharp scissors (e.g., Metzenbaum, Mayo) are used for the removal of deeper tissues below the dermis.
- **Grasping**: Forceps, such as the Adson, Rat Tooth, and DeBakey, are used for grasping and tissue manipulation to fully explore a wound.
- Ideally, equipment used for debridement should be sterile. However, if this is not available, disinfected or clean instruments will suffice (see Appendix B for nonstandard tool sterilization/disinfection).

Hemorrhage Control Techniques

Consideration for hemorrhage control should be given before starting debridement. For larger areas of debridement to an extremity, place a tourniquet before debridement. Elevate the extremity before tourniquet placement to facilitate venous return and reduce bleeding. Monitor the tourniquet times closely and attempt to keep the total tourniquet time <90 minutes.

- **Direct pressure** to a wound, preferably in combination with a hemostatic dressing, will stop most minor bleeding encountered during wound care.
- **Hemostatic dressings** should be applied along with direct pressure for a minimum of 3 minutes. At times, up to 10 minutes of direct pressure may be required.
    - **Basic hemostatic dressings** include Combat Gauze (Z-Medica; www.z-medica.com/healthcare), Celox gauze (Med-trade Products; http://www.celoxmedical.com), ChitoGauze (HemCon Medical Technologies, http://www.hemcon.com), and Surgicel (Johnson & Johnson, https://www.jnj.com).
    - **Advanced hemostatic agents** include FloSeal (Baxter Healthcare, http://www.floseal.com) and Evarrest (Johnson & Johnson, http://www.ethicon.com), among many others.
- **Clamping bleeding vessels** provides a temporary hemostatic maneuver. When applying a clamp, try to avoid crushing the surrounding tissues. The bleeding vessel can then be ligated and tied off. Clamps can be left on for an extended time, if necessary.

- **Ligatures/sutures** provide a definitive treatment. Use of a silk suture is generally sufficient, although other materials can be used as well (Appendix C). For smaller structures, either 3-0 or 4-0 suture is sufficient, whereas larger structures may require 0 or 2-0 suture.

- **Electrocautery** stops bleeding by burning the tissue. It is available as either a battery-powered, hand-held device or a larger portable device. This can be used to cauterize bleeding vessels up to 3mm in diameter. The bleeding site should be identified, the ends coapted between a pair of forceps or clamps, and electricity then applied. If the cautery device is used to "paint" the surface, this results in damage to surrounding tissues.

> ***Caution**: Aggressive debridement may cause uncontrollable bleeding. Do not debride an area larger than can be controlled with direct pressure or a tourniquet. Observe closely for bleeding for at least 1 hour after debridement.*

- **Debridement** is not a singular event.[10] War wounds often require multiple debridement procedures as the body physiologically responds and the wound evolves. When adequate resources are available, a patient's wound should be evaluated every 24 hours, or as often as the clinician deems necessary. When resources are very limited, the ICRC approach has been successfully used to limit interventions to an initial D&I with application of a bulky absorbent dressing.

DRESSINGS

Goal: Quality dressing application focuses on keeping wounds clean, absorbing drainage, debriding fibrinous exudate from the wound surface, and increasing the speed of healing.

Shallow Wounds or Abrasions

- **Best**: dressing tailored to the specific type of wound Abrasions: Apply antibiotic ointment (e.g., Bacitracin or Silvadene) to the skin, place a non-adherent dressing over the area (e.g., Adaptic [KCI, http://www.acelity.com] or Telfa [Medtronic, http://www.medtronic.com]), and cover with an absorbent gauze dressing (e.g., Kerlix [Medtronic]). This should be repeated daily.

  - Alternative: Silverlon (Argentum Medical, http://www.silverlon.com) can be applied directly to a clean wound and covered with a gauze dressing. Moisten outer gauze dressing with water or normal saline daily. Replace Silverlon every 3–5 days (can remove and clean with water and reuse for up to 5 days). The outer gauze can be changed as needed if it becomes saturated with exudate or otherwise dirty. If the patient develops any evidence of infection, the Silverlon must be removed and the wound inspected sooner than 3–5 days.

  - Puncture wounds or small open wounds: Apply an absorbent gauze dressing over the area and change as needed when it becomes saturated with exudate or otherwise dirty, or at least once every 24 hours.

  - Small, clean lacerations: may be sutured, or Dermabond (Johnson & Johnson, http://www.ethicon.com) can be applied to the skin to adhere the wound edges together. Ensure that the Dermabond is applied to the skin, not to the deeper tissues. If Dermabond is used to close the wound, this will also suffice as a dressing.

- **Better**: Apply any available sterile gauze dressing.

- **Minimum**: Apply any available clean dressing.

Deep or Large Open Wounds

- **Best**: Negative pressure wound therapy (NPWT)
  - Commercially available kits such as the KCI Wound vacuum-assisted closure (V.A.C. Therapy, KCI, http://www.kci-medical.com) device can be used to both cover the wound and promote wound healing.[13] For exposed soft tissue, the pressure is usually set at 75–125mmHg of continuous suction.
  - Field-expedient wound VAC devices can be improvised from gauze, Tegaderm or Ioban, and suction tubing hooked up to a suction device (Appendix D).
  - NPWT dressings are generally changed every 2–3 days. Although they can be left in place for a longer time, the degree of granulation that can occur after 3 days generally leads to some bleeding with their removal.
  - NPWT dressings placed over infected wounds should be changed daily, along with wound debridement and irrigation, until the infection is controlled.
- **Better**: Wet-to-dry dressing
  - Wet-to-dry dressings can be created using either a sterile isotonic fluid or clean water, if there is no sterile fluid available. A gauze dressing should be moistened (not soaked) and applied to all open, exposed tissues and loosely packed into the wound cavities. An absorbent gauze dressing or Army Battle Dressing pad is placed over top to absorb any extra fluids or exudate. This may be secured with tape or wrapped with a gauze bandage roll or elastic bandage.
  - Removal of dressings from a wound provides its own form of mechanical debridement; exudate adheres to the bandages and is then pulled from the wound during changing. Inspect old bandages during a dressing change for signs of infection by observing the color and odor of the exudate; the color should be off-white or slightly yellow, and the bandage should not smell sweet or foul. Do not moisten the gauze being removed to make the dressing change easier, otherwise the debridement effect will be lost.
  - Ideally, the dressing should be changed one or two times per day, unless the situation dictates a less frequent approach.
  - For wounds that are already draining heavily, a dry-to-wet dressing may be used instead.
- **Minimum**: Place a bulky dressing with dry gauze, absorbent padding, and elastic bandage; leave in place 4–7 days if wound is clean and without sign of infection. See Appendix A for further details on the ICRC method of wound care.

CLOSURE

Goal: In most cases, war wounds should be closed by a surgical facility, where infection can be more effectively mitigated and the wound can be explored more effectively. However, when appropriate, wound closure simplifies the overall management of the wound.

- Puncture wounds, in general, should not be primarily closed. Small wounds should be allowed to freely drain as needed and close by secondary intent. Larger puncture wounds may require debridement and irrigation, as described above.

- Lacerations with minimal tissue loss/destruction and minimal need for debridement can generally be primarily closed provided that the wound is clean, there is not significant tension with the closure, and there has been <12 hours from injury to closure (this can be extended to 24 hours for lacerations to the face or scalp).
- Lacerations that do not meet the above criteria can be considered for a DPC. These patients are provided 3–7 days of wound care to assure the wound is clean and without complications, and then is closed with either widely spaced sutures or staples.
- Undermine wound margins if needed to reverse the retracted and inverted edges, and relieve any tension to allow skin closure.
- Wounds with tissue loss or damage are generally not closed primarily. Instead, these wounds are treated with dressing changes and allowed to heal by secondary intent. However, there is occasionally a role for DPC in select wounds.
- When in doubt, it is better to leave a wound open and plan for healing by secondary intent.
- If a wound becomes infected after closure, it should be reopened and debrided to drain pus and remove infected, dead tissue.

> ***Caution:*** *Wound closure may speed healing; however, closure will also greatly increase the risk of infection. Only wounds that are very clean and have been well-debrided should be closed.*

INFECTION PREVENTION

Goal: Antimicrobial drug therapy is a critical complement to debridement and irrigation in the fight against infection. This includes prophylaxis against Clostridium tetani (the causal agent of tetanus), as appropriate.

- Guidance on specific antibacterial regimens can be found in the Joint Trauma System CPG Infection Control.
- In general, cefazolin 2g in 250 mL NS IV over 5 min every 8 hours for 24 hours is adequate for most dirty wounds of the head and neck, torso, and extremities.
- Oral antibiotics may be used: moxifloxacin 400mg PO once or clindamycin 300mg PO every 8 hours for 24 hours.
- Note: Moxifloxacin may be replaced with levofloxacin 750 mg PO daily to provide better coverage of bacteria found in wet terrain/ jungle environment.
- Ertapenem is commonly carried by Role 1 providers and gives broad-spectrum gram-positive, gram-negative, and anaerobic coverage. It is an acceptable choice when more-specific antibiotics are not available. Give 1g in 250 mL NS IV over 5 min (provides 24 hours of coverage).

If following the ICRC wound care method (Appendix A), continue antibiotics for 5 days or until DPC.

Prophylaxis against tetanus should be initiated, as appropriate, based upon the condition of the wound and the individual's immunization history.[14] (Appendix E).

INFECTION TREATMENT

Goal: If a wound develops signs of infection (e.g., increasing pain, erythema, purulent drainage) or the patient becomes systemically ill (e.g., fever, tachycardia, hypotension, lethargy, decreased mental status), wound infection must be identified and treated. Treat infected wounds with a combination of local wound care and systemic antibiotics.

- Remove all dressings and inspect wound.
- Wounds that have been closed must be reopened.
- Repeat wound debridement to drain pus and remove all dead, infected tissue. If necessary, extend the wound with an incision in the long axis of the extremity.
- Worst-case scenario may require amputation of an extremity to control life-threatening infection.
- Increase the frequency of dressing changes to once or twice daily.
- Continue antibiotics for 7–10 days, moxifloxacin 400mg PO daily, levofloxacin 750mg PO daily, or ertapenam 1g IV daily, or alternative broad-spectrum antibiotic as available (if possible, change antibiotic from prevention regimen).
- Wounds with known or suspected infections can be treated using Dakin's solution (dilute bleach) for irrigation and wet-to-dry dressing. This can be an effective adjunct, particularly for suspected fungal and Pseudomonal infections.[3,15]

Daily sugar or honey dressings for infected wounds may successfully treat infection in very austere settings.[12] This involves irrigating the wound with saline or the cleanest water available and then filling it with sugar or honey, which is left in place under a dry dressing, repeating every 24 hours.

Severe wound infection *is life threatening and may require aggressive debridement, up to and including amputation. Evacuate patient. If evacuation is not possible, obtain telemedicine consultation and initiate infection treatments above.*

SPECIAL CONSIDERATIONS

FACE AND SCALP

- These wounds rarely become infected because of the high blood flow of the face and scalp.
- Most face and scalp wounds can be closed after irrigation. Debridement should be minimized to reduce cosmetic deformity. If the patient will arrive at a surgical facility within 24 hours, it is better to defer wound closure.
- The clinician should take into consideration the low probability of infection when planning closure of a facial wound because of the poor cosmetic outcomes associated with delayed primary closure.
- When primary closure is acceptable, sutures should only remain in place for 4–5 days for the face and 7 days for the scalp.

OPEN GLOBE INJURY

- Apply an eye shield to prevent further damage.
- Do not place any type of dressing in contact with the globe or underneath the eye shield.
- Moxifloxacin 400mg PO daily to prevent endophthalmitis
- Ondansetron 4mg PO/IV every 4 hours as needed for associated nausea
- Pain control as needed (narcotics as well as ketamine are approved for use)
- Position the patient with the head elevated, if possible.
- Ultrasound evaluation is contraindicated when open globe injury is suspected.
- The best results are achieved if surgery occurs within 24 hours of injury.

ANIMAL BITES

- All animal bite treatments should begin with immediate, thorough cleaning of all wounds with soap and water.
- Most animal bites should be allowed to heal by secondary intent (especially puncture wounds).[16]
- Moxifloxacin 400mg PO daily OR Augmentin (amoxicillin/clavulanic acid; GlaxoSmithKline, http://us.gsk.com/) 875/125mg PO every 12 hours for 7 days are the best choices for most animal bites. Doxycycline (100mg PO twice a day) or clindamycin (300mg PO 3 times a day) with levofloxacin (750mg PO daily) are acceptable alternatives.
- Consider the need for rabies vaccination (Appendix E).

AQUATIC EXPOSURE

- Management of wounds exposed to fresh or salt water is unchanged; however, additional agents are occasionally required for adequate antimicrobial coverage.[17]
- Levofloxacin 750mg PO daily (second-line doxycycline 100mg PO twice daily) to cover for Aeromonas species and Vibrio species.


Given the risk of atypical infections, telemedicine consultation should be sought if the wound worsens.

CHRONIC NONHEALING WOUNDS

If a wound has not healed by 2 weeks, it is likely the result of underlying infection (consider osteomyelitis as a potential cause), inadequate tissue perfusion, or inadequate nutrition.[18] Often it is multifactorial and so more than one source needs to be addressed.


Consider telemedicine consultation if the wound is not healing.

- Packing and Planning Considerations. See Appendix F.
- Wound Management Summary Table. See Appendix G.

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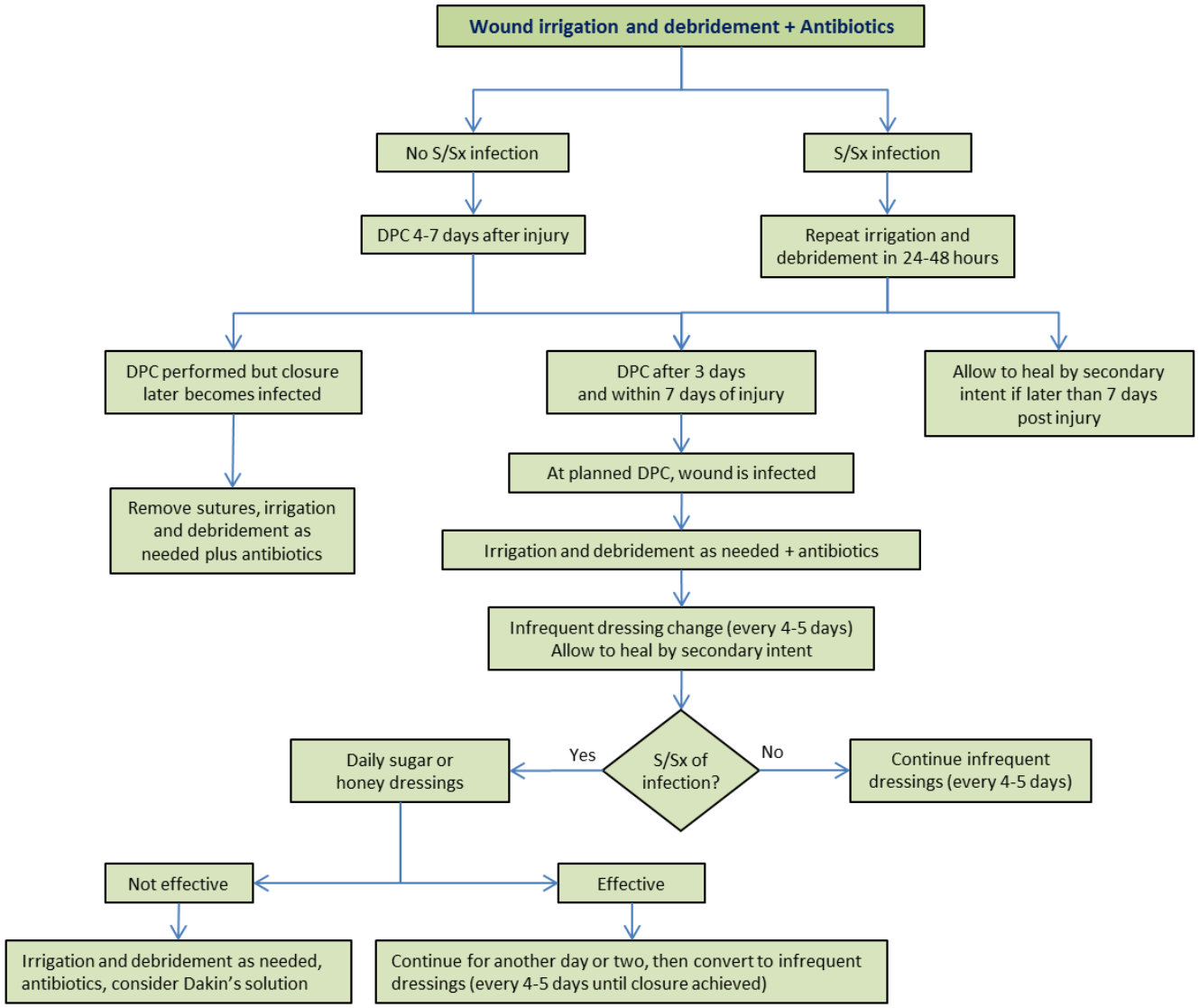
APPENDIX A : INTERNATIONAL COMMITTEE OF THE RED CROSS SURGICAL WOUND MANAGEMENT FLOW CHART



This pathway should be used when conserving resources is a top priority and when evacuation is not possible. DPC, delayed primary closure; S, sign; Sx, symptom.

Notes on wound care according to the ICRC method: The ICRC wound care methods are most applicable for management of war wounds in austere conditions and with limited resources that prohibit serial (follow-on) debridements with associated postoperative care:

1. Dirty environment
2. Limited supplies
3. Limited manpower
4. Limited time (mission dictated)
5. Wounds older than 24 hours
6. Inability to evacuate (includes host-nation patient care where care provided in the austere environment is the definitive level of care available)

Serial debridement every 24–48 hours is not possible in this environment. Therefore, the initial debridement must remove all tissue that is nonviable or questionably viable to remove dead tissue that may act as a culture medium. The wound is then managed with a bulky absorbent dressing that can stay in place for 4–7 days with a low likelihood of infection. Continue antibiotics for 5 days or until delayed primary closure.

Wounds that become infected or have exposed vital structures, such as blood vessels, nerves, or bone, should be treated with more frequent debridement and dressing changes.

After 4–7 days, remove the dressing and evaluate both the dressing and the wound using adequate pain control and sedation, as needed. The bandage and dressing should be dry, stained (greenish-black), and have an ammonia-like odor (good-bad odor), and the dressing should be adherent to the wound. The wound base should bleed slightly and the muscle should contract. Any small area of collagen that was not removed with the dressing can be scraped off with an instrument. This reveals a clean wound that is ready for closure.

If the wound is infected, the dressing may slide easily off the wound without resistance because there is a layer of pus between the dressing and the wound surface. The wound may contain areas of necrotic tissue and the surface of the wound is dull or greyish-red, or may give off the "bad-bad smell" of wound sepsis. Such an infected wound requires further excision and DPC is delayed or the wound is allowed to close by secondary intent. Closure by secondary intent may take several weeks. ICRC recommends a change of dry bulky gauze dressing and gentle washing with normal saline every 4–5 days for closure by secondary intent.

The ICRC dressing change algorithm for closure by secondary intent is as follows:

Question 1: Is the wound clean? **Yes:** infrequent (every 4–5 days) dressing with dry bulky gauze. **No:** continue
Question 2: Is there erythema and tenderness around the wound? **Yes**: antibiotics and continue **No**: continue
Question 3: Is there a large volume of exudate? **Yes:** daily sugar or honey dressings; this involves rinsing the wound with saline and then filling it with sugar or honey, which is left in place under a dry dressing. This is repeated after 24 hours. **No:** infrequent dressing with dry bulky gauze
Question 4: Has there been a response to sugar/honey dressings? **Yes:** Continue sugar/honey dressings or convert to infrequent dry bulky gauze. **No:** Consider antiseptic solution or further surgical debridement
If the wound exudate continues, consider exploring the wound surgically.

APPENDIX B: INSTRUMENT STERILIZATION (STANDARD AND NONSTANDARD)

DEFINITIONS

Cleaning: Removes dirt, debris, and biological material from surgical instruments

Disinfect: Cleaning with a disinfectant to destroy bacteria

Sterilize: Making free from bacteria or other living organisms

NOTES

- Cleaning, disinfecting, and sterilizing are the three levels of instrument care.
- Critical tools are those that make contact with open wounds, open vasculature, and/or organs. Semicritical tools are those that contact the mucosa, and noncritical tools are those that contact intact skin.
- Sterilization is the goal for any tools that will be used for surgical intervention; however, if life depends on it and sterilization is not an option; disinfection can be achieved using one of the options listed below as the "Better" option.
- The goal of sterilization is to eliminate the presence of bacteria, viruses, parasites, and particulates; bacterial spores are the most difficult to destroy.
- For all nonstandard sterilization techniques, gross contamination should be removed from all instruments/equipment by scrubbing with soap and water first.
- Chemical sterilization elements should never be combined.
- Steam with distilled water is the preferred sterilization technique.

BEST: Remove gross contamination, using soap and water, then sterilize by steam or dry heat using one of these techniques:

- Steam sterilization using one of the following techniques and the following temperatures: 121°C (250°F) for 30 minutes or 132°C (270°F) for 4 minutes
- Autoclave (portable or standard size) and distilled water
- Steam sterilization using the SF medical Tac-Set portable sterilizer pot (NSN: 6530-00-926-2022), according to the manufacturer's operating instructions:
    1. Remove the cover by loosening the wing nuts in a counterclockwise motion. Always undo two opposite wing nuts at a time.
    2. Lubricate the metal-to-metal seal where side wall and bevel meet on the inside of the sterilizer. Use petroleum jelly or mineral oil.
    3. Remove the aluminum inner container. Pour clean (preferably distilled) water into sterilizer to a depth of not less than three-fourths of an inch, but no more than 1 inch.
    4. Place inner container rack into inner container with the lip or edge side downward. Place articles to be sterilized on container rack. Only steam should make contact with articles. Replace packed inner container into sterilizer, ensuring the air exhaust tube channel is in position on the right side of the container when it is placed into the unit.
    5. Place sterilizer cover on unit, making sure that the index alignment arrow on the cover aligns with index line/arrow on the side of the bottom. Ensure that the flexible tube is inserted into the guide channel on the inside wall of the aluminum container. Tighten the wing nuts evenly, always tightening down two opposite nuts simultaneously to assure a proper seal.
    6. Place unit onto a heat source. Open the control valve by placing valve lever in an upright position. It is important that steam be permitted to escape vigorously for at least 7 minutes or until the flow of steam is continuous. Afterwards, close the control valve. When pressure gauge reaches 17–19 psi, reduce heat as necessary to maintain a constant pressure of 17–19 psi within the unit.
    7. The sterilization period begins when the pressure steam gauge needle registers in the green sterilization band shown on the face of the gauge (i.e., 17–21 psi). This should be no less than 35 minutes. Note: At altitudes higher than sea level, settings need to be adequately adjusted to compensate for the effect of altitude on water's boiling point. The manufacturer suggests increasing pressure by 0.5 psi for every 1,000 feet of elevation above sea level.
    8. At the end of the sterilization period, remove unit from heat source and move the lever on the control valve to an upright position to allow the steam to escape. With caution, loosen wing nuts and remove the cover to retrieve sterilized items.

DRY HEAT

- Dry heat may also be used to sterilize surgical instruments.
- Instruments can be wrapped in aluminum foil or placed in sterilization trays before putting them in the oven.
- Allow the instruments to cool to room temperature inside the oven before use or storage.
- Instruments can be heated to any of the following to be considered sterilized:
  - 180°C (356°F) for 30 minutes
  - 170°C (338°F) for 1 hour
  - 160°C (320°F) for 2 hours
  - 149°C (300°F) for 2.5 hours
  - 141°C (286°F) for 3 hours

BETTER: Remove gross contamination using soap and water, then sterilize with improvised autoclave or chemical disinfection.

- Improvised autoclave using a pressure cooker that can reach the steam sterilization temperatures listed above.
  - Place wire rack in the bottom to prevent the instruments from becoming submerged. Only steam should make contact with the instruments. Begin timing for sterilization once steam starts to vent from the pressure cooker.
  - Pressure cookers operate at various pressures and temperatures. Sterilization time of 60 minutes is recommended.
- Glutaraldehyde (Cidex©; Johnson & Johnson): Widely available and accepted as a high-quality disinfectant in healthcare facilities.
  - Can be used to sterilize aluminum, brass, copper, stainless steel, plastics, and elastomers.
  - Once the container is open, the chemical has a limited shelf life—a minimum of 14 days, usually 28–30 days; refer to the specific product's manual for the exact shelf life.
  - Test strips can indicate the efficacy of an opened container of glutaraldehyde.
  - Alkaline glutaraldehyde mixes are more effective than acidic glutaraldehyde mixes.
  - Items should be soaked for 60 minutes for maximum efficacy.
  - Long-term exposure can cause irritation to tissues; rinse tools before use.
- Formaldehyde: Prepare 5% formaldehyde solution.
  - Both metallic and plastic medical equipment can be sterilized using formaldehyde.
  - Wrap a 5mg tablet of formaldehyde in gauze and crush the tablet.
  - Place the gauze-wrapped tablet in 100mL of potable water (can be cold water).
  - This solution can be stored for up to 30 days without losing its potency.
  - Lower concentrations of formaldehyde can be used, but the amount of time the instruments are submerged in the solution needs to be increased to compensate for this change.
  - Clean the instruments with soap and water, and remove any blood and tissue.
  - Soak the instruments in the 5% formaldehyde solution for at least 1 hour but preferably for 12–24 hours.[19,20]
  - Duration should be closer to 24 hours if 1% formaldehyde solutions are used (i.e., 5mg tablet in 500mL of water).
  - The instruments and formaldehyde solution can be kept at room temperature.
  - Remove the instruments and rinse with water or saline before use.
- Alcohol: 60% to 90% minimum; tools need 3 hours of contact time. Consumable alcohol must be a minimum of 120 proof. This method is not sporicidal and, therefore, not recommended as a primary modality for surgical items.
- Sodium hypochlorite (household bleach)
  - This disinfectant is caustic to eyes, oropharynx, esophagus, and gastric tissue.
  - Undiluted (5.25%) sodium hypochlorite should be used to disinfect instruments categorized as critical.
  - Instruments should have a minimum contact time of 5 minutes.

MINIMUM: Remove gross contamination, using soap and water, then boil instruments in at least 100°C (212°F) water for at least 1 minute.

***NOTE*:** *This method does not sterilize instruments and should be used as a last resort for surgical instruments.*

APPENDIX C: SUTURE CHART

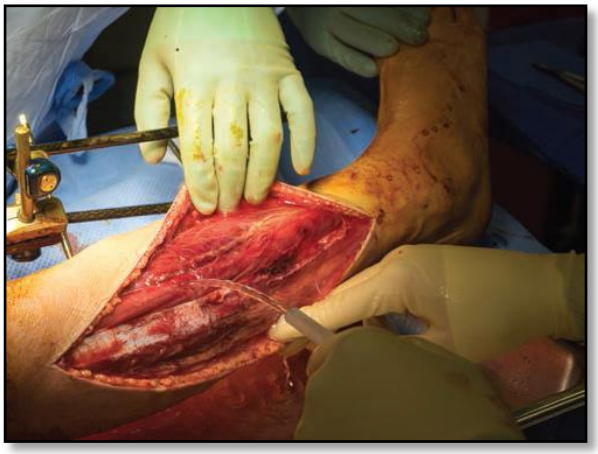
- When supplies are limited, any suture may be used for any purpose; however, as a general guideline, absorbable suture should be used to approximate tissues deep to the skin, silk may be used to ligate blood vessels, and a monofilament suture (nylon/Prolene; Johnson & Johnson) should be used for the skin.
- Most suturing/ligating can be accomplished with 2-0 sutures. Finer suture (3-0 or 4-0) may be used on the face for better cosmetic result. Heavier suture (0 or 1) may be used for DPC of larger wounds or for the scalp.
- Tapered needles are best for suturing soft-tissue layers; cutting needles are best for suturing skin; strait needles do not require a needle holder.
- Undesired tissue reactivity is greater with:
  - Multifilament (compared with monofilament)
  - Larger suture gauge
  - Natural material (compared with synthetic)
- Recommended multipurpose sutures: 2-0 Vicryl suture with CT-1 needle, 0 Prolene or Nylon with FSLX needle, 0 silk with strait needle.

Absorbable Sutures				
Suture	Effective wound support, days	Time to complete absorption, days	Comments	Usual indications
Surgical gut	8–9	30	Rarely used; high tissue reactivity	Approximate soft-tissue layers deep to the skin
Chromic gut	10–21	>90	Gut treated with chromium to decrease tissue reactivity and slow absorption	Approximate soft-tissue layers deep to the skin
Fast-absorbing gut	5–7	14–28	Gut treated with heat to speed absorption	Skin closure when suture removal will be difficult or impossible
Polyglactin (Vicryl)	21	90	Less reactive than gut; synthetic	Approximate soft-tissue layers deep to the skin
Vicryl Rapide (Johnson & Johnson)	10	42	Gamma-irradiated to speed absorption	Skin closure when suture removal will be difficult or impossible

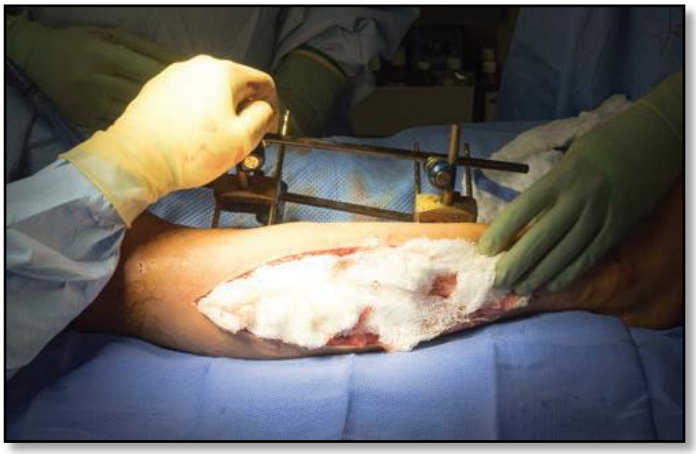
Non Absorbable Sutures				
Suture	Tensile Strength	Tissue Reactivity	Comments	Usual Indications
Silk	Low	High	Multifilament, pliable	Ligate blood vessels
Nylon (e.g., Ethelon; Johnson & Johnson)	High	Low	Monofilament, stiff	Skin closure
Polypropylene (e.g., Prolene)	Moderate	Very Low	Monofilament, less knot security (may need extra knot)	Skin closure, repair blood vessels

Suture Removal Time Frames	
Body Part	Number of Days After Suturing
Face	4-5
Scalp	7
Chest, extremities	10-14
High tension areas, joint, back	14-21

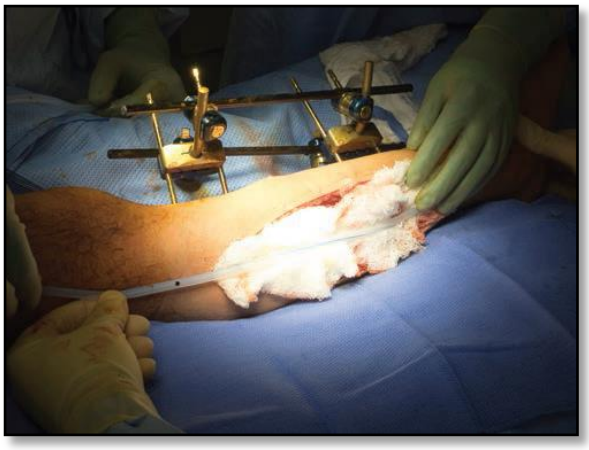
APPENDIX D: FIELD-EXPEDIENT WOUND VACUUM-ASSISTED CLOSURE



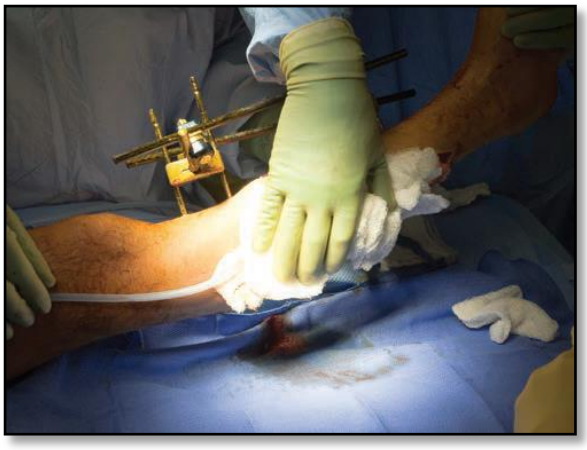
1. Copious irrigation with debridement of necrotic tissue and removal of foreign debris.



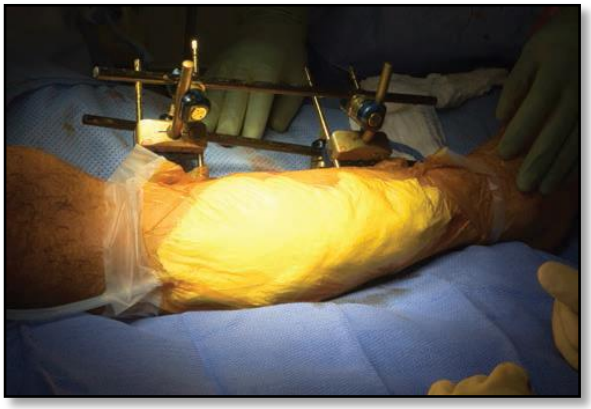
2. Placement of gauze or reticulated sponge at base of wound.



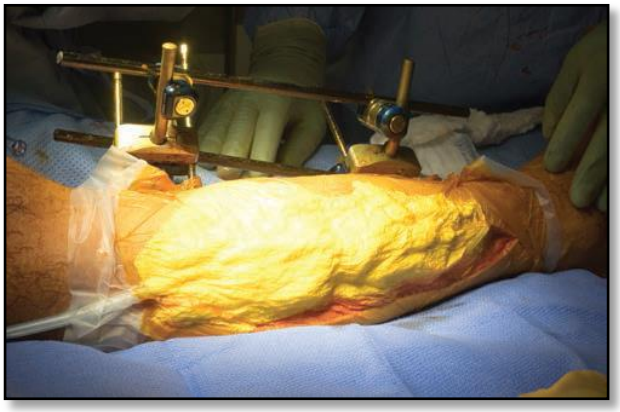
3. Placement of suction tubing (e.g., Blake, Jackson-Pratt, nasogastric, red rubber with holes) that can be attached to a suction source.



4. Placement of additional layer of reticulated sponge or gauze over suction tubing to separate suction from occlusive layer.



5. Placement of occlusive impermeable dressing, such as Ioban or Tegaderm, over the gauze/sponge and suction tubing



6. Connect to suction source.

APPENDIX E: TETANUS IMMUNIZATION CHART

(Special Operations Forces Medical Handbook; US Department of Defense; Washington, DC: Government Printing Office)

Tetanus Immunization Status	Minor Clean Wound	Major Clean Wound	Contaminated Wound (War Wounds)
Fully immunized recent Td booster	N/A	N/A	N/A
Fully immunized Td booster 5–10 years ago	N/A	Tdap	Tdap
Fully immunized, no booster for >10 years	Tdap	Tdap	Tdap
Unknown, none, or incomplete immunization	Tdap	Tdap and TIG (250U)	Tdap and TIG (500U)

N/A, not applicable; Td, tetanus and diphtheria; Tdap, tetanus-diphtheria-acellular pertussis; TIG, tetanus immune globulin.

***Note**: Tetanus vaccination of mother gives her protection and protects the newborn in the first few weeks of life.*

Rabies Postexposure Immunization[21]		
Animal Type	**Evaluation & Disposition of Animal**	**Recommendations for Prophylaxis**
Dogs, cats, ferrets	Healthy and available for 10-day observation	Do not start unless animal develops symptoms, then immediately begin HRIG + vaccine
	Rabid or suspected rabid	Immediate HRIG + vaccine
	Unknown (escaped)	Consult public health officials
Skunks, raccoons, bats, foxes, coyotes, most carnivores	Regard as rabid	Immediate vaccination
Livestock, horses, rodents, rabbits; includes hares, squirrels, hamsters, guinea pigs, gerbils, chipmunks, rats, mice, woodchucks	Consider case-by-case	Consult public health officials. Bites of squirrels, hamsters, guinea pigs, gerbils, chipmunks, rats, mice, other small rodents, rabbits, and hares almost never require postexposure immunization.
If Not Previously Vaccinated		
Treatment	Regimen	
Local wound cleaning	All post-exposure treatment should begin with immediate, thorough	
Human rabies immune globulin (HRIG)	20 units per kg body weight given once on day 0. If anatomically feasible, the full dose should be infiltrated around the wound(s), or the rest should be administered IM in the gluteal area. If the calculated dose of HIRG is insufficient to inject all the wounds, it should be diluted with normal saline to allow infiltration around additional wound areas. HRIG should not be administered in the same syringe or into the same anatomical site as vaccine, or more than 7 days after the initiation of vaccine. Because HRIG may partially suppress active production of antibody, no more than the recommended dose should be given.	
Vaccine	Human diploid cell vaccine (HDCV), rabies vaccine adsorbed (RVA), or purified chick embryo cell vaccine (PCECV) 1 mL IM (deltoid area), one each days 0, 3, 7, 14.	
If Previously Vaccinated		
HRIG	Do not give	
Vaccine	HDCV or PCECV 1mL IM (deltoid area), one each on days 0 and 3.	

APPENDIX F: PACKING AND PLANNING CONSIDERATIONS

- This list is not all encompassing.
- Quantities of items listed are highly mission variable and up to provider discretion.
- All efforts were made to list items in common use.

Instruments	Hemorrhage control
· Metzenbaum scissors · Mayo scissors · Rat Tooth/Adson/DeBakey forceps · Kelly, Mosquito, Hemostat forceps · Allis forceps · Needle drivers · #10/#11/#15 scalpels · Volkmann or Weitlaner retractors · Bovie pen	· Combat Gauze/ChitoGauze · C-A-T[b] tourniquet/SOF Tactical tourniquet, wide[c]/Esmarch bandage/ sphygmomanometer with Esmarch bandage
Meds	**General supplies**
· Bacitracin/Silvadene · 2% Lidocaine with/without epinephrine · 8.4% sodium bicarbonate · 0.5% tetracaine hydrochloride (eye drops) · IV ertapenem · IV cefazolin · Oral moxifloxacin 400mg or oral levofloxacin 750mg · (Note: levofloxacin is preferred in wet/jungle environment) · Oral clindamycin 300mg · Pain and sedation medications · NaCl (for irrigation)/potable water source · Sterile water	· Alcohol pads · Betadine swabs · 1mL, 5mL, 10mL, 35mL, 60mL syringes · 19g Catheter · 18g IV 1.5", 25g 1.5" hard needle · Irrigation bulb · Basin · Chux pads · Gloves of various sizes (small, medium, large) · IV tubing · Large-bore catheter · Constricting band · Saline lock · Suture/ligature (see Appendix A) · Skin stapler · Cotton tip applicators · Morgan lens · Sterile drapes or draping material that can be sterilized · Surgical masks · Surgical gowns · Sterile gloves · Ioban 2–23" × 23" · Tegaderm · Suction tubing · Suction device (SSCOR Quickdraw suction; TAC-SET)
Dressings	
· Kerlix · 6", 4" Ace wrap · Coban[a] · 3", 2", 1" medical tape · Telfa/Adaptic · Silverlon · Dermabond/superglue · Steristrips	

[a]3M, http://www.3m.com;

[b]Combat Application Tourniquet, Composite Resources, http://combattourniquet.com/;

[c]Tactical Medical Solutions, https://www.tacmedsolutions.com.

APPENDIX G: WOUND MANAGEMENT SUMMARY TABLE

Goals of Wound Care	
• Hemorrhage control • Minimize risk of infection • Promote optimal healing • Reduce discomfort • Minimize disability/loss of function associated with treatment • Implement definitive care when possible	
Types of Wounds	
• Abrasion • Burn • Puncture • Laceration	• Gunshot • Blast • Crush injury
◑ Telemedicine	
• Large or complex wounds • Associated injury to bone, blood vessel, tendon, nerve • Penetrating chest or abdominal wound • Infected wounds • Chronic, nonhealing wounds	
Irrigation	
Best	Irrigate wounds with dilute Dakin's solution or sterile isotonic solution.
Better	Irrigate wounds with clean potable tap water.
Minimum	Irrigate wounds with the cleanest water available (nonpotable water should be boiled for a minimum of 3 minutes and then cooled to body temperature).
Debridement	
Best	Use an assistant, remove nonviable tissue using sharp dissection (sterile scalpel or scissors) and control bleeding using tourniquet, topical hemostatic dressings, direct pressure, clamping, suture ligation, and/or electrocautery. Questionably viable tissue may be retained with repeat debridement once every 24–48 hours until arrival at surgical facility.
Better	Remove nonviable tissue using sharp dissection, control bleeding using tourniquet, topical hemostatic dressings, direct pressure, clamping, and/or suture ligation. Repeat debridement or delayed primary closure in 3–5 days.
Minimum	When unable to evacuate and resources for serial debridement every 24–48 hours are not available, remove all nonviable and questionably viable tissue using sharp dissection (clean blade or scissors) and control bleeding with tourniquet and/or direct pressure. Leave clean dressing in place then delayed primary closure in 4–7 days if no sign of infection (ICRC wound care method).
Dressings – Shallow wounds or abrasions	
Best	• Abrasions: Apply antibiotic ointment (e.g., Bacitracin or Silvadene) to skin, place nonadherent dressing over the area (e.g., Adaptic or Telfa), cover with absorbent gauze dressing, repeat daily. Alternative: Apply Silverlon dressing to a clean wound, cover with gauze, moisten gauze daily. Replace Silverlon every 3–5 days. • Puncture wounds or small open wounds: Apply absorbent gauze dressing, change when saturated with exudate or otherwise dirty, or at least once every 24 hours. • Small, clean lacerations: suture or Dermabond
Better	Apply any available sterile gauze dressing.
Minimum	Apply any available clean dressing.

Dressings – Deep or large open wounds	
Best	NPWT ・Commercial available kits such as the KCI Wound VAC device can be used to both cover the wound and promote wound healing. ・Field expedient wound VAC devices can be improvised from absorbent gauze, Tegaderm or Ioban, and suction tubing hooked up to a suction device. ・Change NPWT dressings every 2–3 days. ・Change NPWT dressings placed over infected wounds, along with wound debridement and irrigation, daily.
Better	Wet-to-dry dressing ・Wet-to-dry dressings using sterile isotonic fluid or clean water. ・Change the dressing 1–2 times per day unless the situation dictates a less frequent approach. ・For wounds that are draining heavily, a dry-to-wet dressing may be used instead.
Minimum	Place a bulky dressing with dry gauze, absorbent padding, and elastic bandage; leave in place 4–7 days if wound is clean without sign of infection.
Infection prevention	
・Tetanus prophylaxis if immunization status unknown ・In addition to wound care, treat open wounds with antibiotics as soon as possible after injury and continue for 24 hours with one of the following antibiotics: ・Moxifloxacin 400mg PO × 1 dose or levofloxacin 750mg PO × 1 dose ***Note:*** levofloxacin is preferred in wet/jungle environment ・Clindamycin 300mg PO every 8 hours ・Cefazolin 2g IV every 8 hours ・Ertapenem 1g IV 1 dose ・If following the ICRC wound care method, continue antibiotics for 5 days or until delayed primary closure.	
Infection treatment	
・Remove all dressings and inspect wound. ・Wounds that have been closed must be reopened. ・Repeat wound debridement to drain pus and remove all dead, infected tissue. If necessary, extend the wound with an incision in the long axis of the extremity. ・Worst-case scenario may require amputation of an extremity to control life-threatening infection. ・Increase the frequency of dressing changes to once or twice daily. ・Continue antibiotics for 7–10 days, moxifloxacin 400 mg PO daily or levofloxacin 750mg PO daily or ertapenam 1g IV daily, or alternative broad-spectrum antibiotic as available. ・Use Dakin's solution for the wet-to-dry dressing, particularly for suspected fungal and pseudomonal infections. ・Daily sugar or honey dressings for infected wounds may successfully treat infection in very austere settings	

NPWT, negative pressure wound therapy; VAC, vacuum-assisted closure.

APPENDIX H: ADDITIONAL 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 "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.