

JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



War Wounds: Debridement and Irrigation (CPG ID:31)

This CPG reviews indications for and the procedures associated with battle related wound debridement and irrigation, and associated initial wound management strategies for penetrating war wounds.

** Interim and Preliminary Update **

Final version is pending. For questions about this CPG, contact dha.jbsa.j-3.list.jts-pips@mail.mil

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SUMMARY OF CHANGES

- Inclusion of tetanus and antibiotic prophylaxis.
- Early identification and treatment of wounds at high risk for invasive fungal infection.
- Inclusion of antibiotic powder as an option for wound prophylaxis and contrasting effect of negative pressure wound therapy on local antibiotic delivery in wounds using polymethyl methacrylate (PMMA) antibiotic beads and antibiotic powder.
- Revision of section on a retained foreign object (RFO).

BACKGROUND

Wound debridement and irrigation (D&I) is the most frequently performed surgical procedure in the combat theater.¹ Given the power of war munitions, prompt removal of nonviable tissue, debris, blood and bacteria is imperative to prevent local and systemic complications associated with such a wound.² [Appendix A](#) outlines the injury patterns and resulting physiology from weapons of war. Care must be given to ensure all nonviable tissue is removed, while at the same time preserving as much soft tissue as possible for reconstructive surgery at higher echelons of care.³ Balancing these two competing factors often necessitates serial D&I. While there are a variety of different therapeutic options of varying efficacy, no one approach is perfect for all situations.

NOTE: Related CPGs: *Invasive Fungal Infection in War Wounds, Acute Traumatic Wound Management in the Prolonged Field Care Setting, Infection Prevention in Combat-Related Injuries*. CPGs can be viewed/downloaded from https://jts.amedd.army.mil/index.cfm/PI_CPGs/cpgs.

EVALUATION AND TREATMENT

IMMEDIATE PROPHYLACTIC MEASURES

U.S. Service Members should routinely receive tetanus toxoid and single-dose IV antibiotic (typically Ancef) for war wounds. Host nation patients or those with unclear vaccination histories should receive toxoid, Ancef and tetanus immune globulin. (Refer to [Infection Prevention in Combat-Related Injuries CPG](#)).

DEBRIDEMENT

Thorough inspection of the wounds with liberal use of surgical enlargement (i.e. wide surgical exposure) is necessary to inspect all levels of tissue, including examination of fascial planes and the integrity of neurovascular structures. This may require extension to outside the zone of trauma. When extending the wound into healthy tissue, consideration should be given to how this could potentially affect future reconstructive or closure options.⁴ In general, extremity wounds should be extended in a longitudinal manner (parallel with the bone) and truncal wounds should be extended along Langer's lines (see figure below). Wound configuration and need for additional vascular exposure must be considered and this may at times violate all of the above precepts.

Figure 1. Langer Lines

Source: *Integrated Activities in Primary Care – Minor Surgery in Family Medicine*. IntechOpen. 11 May 2016

It is critical that the wartime surgeon has an appreciation for the phenomenon of wound evolution and weapon ballistics. Military assault rifles and proximity blasts cause large areas of cavitation because the kinetic energy transfer exceeds the area of tissue destruction by the projectile.⁵ Such wounds are known to appear viable or questionably viable but progress to necrosis over the subsequent 24-72 hours from microvascular thrombosis and ischemia. Blast wounds are heavily contaminated with environmental debris and, sometimes, foreign tissue from other blast victims. Furthermore, regional vascular injury, tourniquet use, hemorrhagic shock, and persistent critical illness also diminish the capacity for wound healing and lead to disappointing evolution of the war wound. Therefore, avoid closure of wounds after the first washout or within the first 48 hours. Premature wound closure causes severe morbidity from necrotizing infection, often invisible on external exam until late in the process. [Appendix A](#) outlines the injury patterns and resulting physiology from weapons of war.

Surgeons should anticipate the need to frequently re-inspect and perform serial D&I on extensive soft tissue wounds.³ While there is not a strict guideline defining the time sequence of repeat D&I, a general rule is frequent inspections in the operating room (every 24 hours) until all non-viable tissue has been debrided while all other tissues are confidently viable. This prevents overly aggressive removal of questionably viable tissue at the early debridements while still aggressively addressing progression of necrosis. Once such wounds have stabilized with absence of nonviable tissue, inspections can be separated in time by 2 days or more until a final wound closure strategy is identified. Strategies include healing by secondary intent, delayed primary closure, split thickness skin graft, or tissue transfer. Patient movement decisions should be adapted to the requirements of surgical management – not the converse. When possible, ensure that a planned D&I is done within 24 hours prior to patient movement

to ensure the receiving team has adequate time to assess and schedule follow-on wound care. In general, leave the wound open until arrival at the definitive care facility.

It is recognized that unstable blast injury patients with multiple fragmentation injuries over much of their bodies may not be able to undergo thorough debridement of all wounds at initial operation; this can be due to instability, lack of resources, lack of personnel, or urgency of transfer. It is therefore important that extent and adequacy of what debridement has been done is documented to guide further treatment at receiving facilities.

Sharp surgical debridement is the mainstay of care for war wounds; irrigation is an adjunct, but in no way replaces debridement for removal of non-viable tissue in wounds. Meticulous sharp debridement using a scalpel and/or scissors should be a starting point for most wartime wounds. Assurance of hemostasis and removal of all nonviable skin, fat, fascia, muscle, and bone are essential to reduce the load of contamination and necrotic tissue prior to dressing application.⁴

The need for repeat serial inspection and wound debridement cannot be over-emphasized. Unstable blast injury patients with multiple fragmentation injuries may not receive thorough debridement of all wounds at initial operation due to resuscitation needs, lack of resources, lack of personnel, or urgency of transfer. Always document the extent and adequacy of debridement performed as well as debridements still required. When receiving a patient from a forward role of care within the first 24 hours of injury, urgent operative re-exploration of all wounds is a best practice. Pre-operative CT scan is an important adjunct to identify areas of radiopaque debris or soft tissue air. These serve as a signal for areas of occult injury, residual contamination or necrosis that guides the next debridement.

IRRIGATION

There are several acceptable devices available for wound irrigation. Simple bulb syringe irrigation and gravity irrigation are the preferred methods. Large bore gravity-fed tubing is favored for irrigations requiring large fluid volumes, such as those associated with contaminated open fractures. Cystoscopy tubing connected to a 3 liter saline bag is ideal for gravity irrigation of large or multiple wounds. Pulsatile jet lavage irrigation using a battery powered system is not associated with improved outcomes but increases expense, weight, and space.^{6,7} All methods of wound irrigation are adjuncts and not substitutes to sharp surgical debridement.

The current recommendations for volume of irrigation are as follows:

- 1-3 liters for small volume wounds.
- 4-8 liters for moderate wounds.
- 9 or more liters for large wounds or wounds with evidence of heavy contamination.

This takes into account that bacterial loads drop logarithmically with increasing volumes of irrigation. Depending on the environment and medical logistics support, the volume of sterile fluids may not be available. Normal saline, sterile water and potable tap water all have comparable efficacy and safety as irrigation solutions.^{8,9} The inclusion of irrigation fluid additives such as iodine, bacitracin or antibiotics is without proven benefit.⁷

WOUND DRESSINGS

While wet-to-dry dressings are a mainstay for the management of open traumatic wounds, negative pressure wound therapy (NPWT) has become the more common and frequently preferred method for large soft tissue wounds. The principals of wound care are cleanliness and micro debridement. Wet-to-dry dressings, when done properly, achieve both; dressings keep the wound moist and provide mechanical debridement when removed. If the wound is too wet, it will not debride. If the wound is too dry, then it will impede healing. Optimal wound care management with wet to dry dressing requires the dressing to be changed every 12-24 hours; more frequent dressings may be needed, depending on the wound's size, exudate burden, contamination, and vascularity. The use of either normal saline, sterile water, or potable water for the dressing are equally efficacious. This strategy for wet-to-dry dressings may need be adapted to a dry-to-wet dressing in a highly exudative/weeping wound. For highly contaminated wounds, the use of Dakin's solution has been suggested to decrease the rates of invasive fungal infections (IFI); however, the sodium hypochlorite may be toxic to macrophages, fibroblasts and neutrophils.^{10,11}

NPWT with Reticulated Open Cell Foam (NPWT/ROCF), commonly referred to as the VAC (vacuum assisted closure therapy system) dressing, is a commonly used alternative to wet-to-dry dressings. NPWT dressing can be left in place up to 72 hours depending on the extent and acuity of the wound. Utilization of NPWT requires a hemostatic wound bed and absence of purulence. The VAC Therapy System comes with a default negative pressure setting of 125mmHg. For large wound volumes, the pressure setting can be increased and/or an additional suction pad may be placed and connected with a "Y" connector. NPWT may aggravate bleeding in wounds with challenging hemostasis or venous hypertension. Clotted blood visible through the plastic covering or high amounts of dark sanguineous output indicate a need to return to the OR for hemostasis. Foam should not come into physical contact with exposed vessels. Use of VAC therapy has been proven safe and stable for long range air evacuation transports.¹²

The use of NPWT offers several advantages over wet-to-dry dressings. NPWT allows for accurate measurement of fluid loss from the wounds, prevents fluid soilage on linens and gurneys, obviates the need for painful bedside dressing changes, and promotes granulation tissue. However, there are many pitfalls that must be avoided with the placement of NPWT. It is imperative in large or deep wounds that all the ROCF is in contact with the suction source. If a piece of sponge in the wound is isolated from suction, bacteria will grow from fluid stasis. This especially applies to amputations from blasts where cavities track between muscle groups. In the unanticipated event of prolonged care at a Role 2 location, NPWT can be improvised without needing to stock commercial VAC supplies. NPWT can be devised using any suction source, Kerlex roll gauze, a conduit like a nasogastric tube (with the blue sump port tied in a knot), and an occlusive dressing like Ioban. The improvised VAC technique is further described in the [JTS Acute Traumatic Wound Management in the Prolonged Field Care Setting CPG](#).⁹

IFI CONSIDERATIONS

IFIs are opportunist infections which tend to occur at the far end on the spectrum of war wound severity. IFIs are so devastatingly morbid and lethal they have their own CPG ([Invasive Fungal Infections in War Wounds](#)). However, because there are clinical factors that can predict wounds at greatest risk for IFI and because the irrigation and dressings for these wounds should be managed differently from what has been mentioned above (using Dakin's solution), these differences will be highlighted here.

During the first debridement, assess patients for IFI risk factors:

- Dismounted blast injury
- Above knee immediate amputation
- Extensive perineal/genitourinary/rectal injury
- Massive transfusion of >20 units in the first 24 hours (or anticipation of 20 units)

If three of the above factors are present, switch irrigation to high-volume Dakin's solution and dressings should be wet-to-dry using Dakin's solution. Furthermore, because IFI also occurs with wounds not initially meeting the criteria listed above, additional criteria seen after subsequent debridement should also prompt the same change to Dakin's irrigation and dressings.

Look out for these additional IFI risk factors on subsequent inspections of wounds not previously considered at risk of IFI:

- Progression from below-knee to through-knee to above-knee amputation
- Recurrent necrosis following at least two consecutive debridements

(Refer to the [Invasive Fungal Infection in War Wounds CPG](#) for more discussion of steps taken at Roles 3, 4 and 5 for suspected IFI.)

EVACUATION CONSIDERATIONS

It is critical that the down-range surgeon be mindful of timing of D&I with casualty evacuation. To avoid extended periods without wound inspection due to fixed wing flight, a best practice is to anticipate movement and plan debridement within 24 hours of movement. Generally, large acute wounds will need inspection and D&I every 24 hours during the first few days after injury. Ideally, serial D&I should be completed by the same provider, and photo documentation of wounds obtained (in compliance with theater policy); however, the nature of patient evacuation may result in rapid transport from the point of injury to the Role 1, 2 and 3 in a compressed timeline. Most wounds should not be closed prior to arrival at a definitive care location. Providers receiving a patient with a closed wound should have a relatively low threshold to reopen a wound if there are any concerns for contamination or non-viable tissue having been left behind. This compulsive approach to combat soft tissue injuries will decrease the likelihood that a wound will worsen and result in adverse patient outcomes.

CLOSURE

War wounds are contaminated and frequently result from high velocity injuries. Unless they occur from mechanisms other than battle injury, war wounds should not be treated with primary wound closure in the deployed setting. Though no hard rules exist for the closure of battle injuries, wartime experience demonstrates four broad categories of wound outcome:

1. Healing by secondary intention
2. Delayed primary closure with or without drain placement
3. Split thickness skin graft over local soft tissue
4. Tissue transfer with subsequent split thickness skin graft

Which of these four closure strategies is best suited for any given wartime soft tissue injury is left to the discretion of the surgical team.

ANTIBIOTIC BEADS

Placement of antibiotic impregnated PMMA can be used as an adjunct to D&I to deliver increased local antibiotic concentrations while minimizing the associated side effects of high systemic loads of these antibiotics. Indications include contamination with open fractures and traumatic amputations, treatment of established osteomyelitis, and dead space management with associated soft tissue defect. Animal models demonstrate a PMMA bead pouch is more effective without NPWT because the antibiotic remains in the wound without collecting in the vacuum canister.¹³ The PMMA beads are usually prepared on a suture or wire and laid within the wound and covered with a semipermeable membrane, forming a bead pouch. Typically reserved for Role 3 and 4 use, a PMMA bead pouch may be used in conjunction with NPWT. It may be helpful to place the antibiotic beads in the deep portion of the wound and not in direct contact with the reticulated open cell foam to allow stasis of antibiotics concentrations in the wound. The choice of antibiotic should be directed by the local antibiogram. Common antibiotics include heat stable powder formulations of tobramycin, vancomycin, imipenem, and colistin. Recent evidence also supports prefabricating and sterile packaging PMMA beads for subsequent use, allowing for bead use in a multi-casualty/time constrained setting. The efficacy of this adjunct is supported by several small studies and case series which, in aggregate, suggest this can lead to a 10% or greater absolute decrease in wound infections.¹⁴ Further research is needed on its use in combat trauma patients. Recent epidemiologic studies by the Trauma Infectious Disease Outcomes Study Group showed an increased rate of osteomyelitis when PMMA antibiotic beads were used.¹⁵⁻¹⁷ These results should be viewed cautiously as they did not control for confounding factors (such as selection bias that the beads were used or patients at a higher baseline risk of developing osteomyelitis).

ANTIBIOTIC POWDER

There is a groundswell of interest in use of topical antibiotic powders (TAP) for prophylaxis in wounds with contaminated fractures. Recent large animal studies comparing TAP and antibiotic PMMA beads in wounds treated with NPWT show that TAP achieves higher sustained wound concentrations and is more effective at curbing bacterial growth.¹⁸ Analysis of the collected NPWT drainage indicates about half of the antibiotic is removed with suction, indicating that the amount of powder can be increased when used in conjunction with NPWT. A recent prospective randomized multicenter trial of 980 patients with tibial plateau or pilon fractures at high risk of infection showed a 33% relative risk reduction in deep surgical site infection (SSI) using 1gm of topical vancomycin powder immediately before wound closure. Analysis of the infecting organisms showed that the difference in overall infection rate was directly attributable to gram positive sensitivity to vancomycin, with a 50% relative risk reduction in gram positive deep SSI and no effect on gram negative deep SSI. Fractures without soft tissue coverage or with combined vascular injuries were excluded from enrollment.¹⁹ There is insufficient data at this time to advocate widespread antibiotic powder use during serial debridement of war wounds with concomitant fracture.

RFO PREVENTION

An RFO event refers to an iatrogenic event in which a sponge or surgical instrument is deliberately or unintentionally left behind while the wound proceeds to definitive management. Both surgical and traumatic open wounds are at risk for RFOs. Several features unique to the deployed environment place patients at increased risk of this complication. Among these risk factors are multiple surgical teams performing procedures on multiple wounds simultaneously, multiple surgeons performing procedures at different times, instrument and sponge counts being omitted in hemodynamically unstable patients, patients undergoing care at multiple different treatment facilities, and minimal documentation on operative records. The most obvious example of this would be definitive closure of the abdomen with a retained lap sponge. A less obvious vignette would be deliberate temporary hemostatic closure of a thigh compartment over Combat Gauze unrecognized by subsequent surgical teams at higher roles of care. Even with a slower operational tempo, RFO events continue to happen as these are two examples of true events occurring in Iraq and Afghanistan within the last 5 years. The deployed environment is high risk for RFO events because of the frequency of severe injuries requiring staged operations with temporary packing for hemostasis, multiple locations with multiple surgical teams, limited OR support for sponge and instrument counts during exigent circumstances, and communication challenges during patient hand-offs between roles of care. Strategies must be undertaken to mitigate these risks.

Best practices include:

1. The medical record must reflect any material that has been purposefully left in the wound.
2. Physician-to-physician communication (preferably surgeon-to-surgeon) should occur if foreign bodies remain in the wound.
3. There should be a low threshold to obtain radiographs to confirm removal of all foreign bodies. This is particularly important for cases in which a sponge and instrument count were omitted due to hemodynamic instability, discrepancies during the closing or final sponge an instrument count, or when a wound is being closed by a different surgeon at a subsequent treatment facility. Ideally, the images should be reviewed by both the surgeon and radiologist before closing the wound and leaving the operating room. The use of radiofrequency-labeled sponges and detectors is an adjunct to improve detection of retained sponges, but does not remove the need to use x-rays to definitively clear a cavity of sponges. Not only is it possible that a forward role of care used non-RFID lap sponges, but combat gauze can be used to control challenging intracavitary bleeding and will only be detected on x-ray.

FACIAL WOUNDS

While traumatic facial wounds are treated in a similar fashion to wounds in other areas of the body, some aspects of facial wound management deserve special attention. Maxillofacial wounds sustained in combat typically involve both soft tissue and other structures including bone, teeth, cartilage, mucosa-lined structures (sinuses, mouth, etc.), eyes and the cranial vault. As such, maxillofacial wound management may be more complicated than soft tissue wounds in other parts of the body, and may warrant multidisciplinary care. Facial wounds and their management can significantly impact the patient's airway, vision, and ability to speak and eat. Severe injuries to the midface or mandible may necessitate immediate airway control.

The robust, redundant blood supply of the facial region promotes healing and reduces the incidence of wound infection compared to the trunk and extremities. As with other wounds, the first step in facial wound management involves excellent hemostasis, profuse irrigation, and meticulous debridement. All clearly non-viable tissue must be sharply excised. Threatened but potentially viable tissue should be maintained – especially around the eyes. Given the rich vascular supply of this region, it is better to conserve as much tissue as possible during the initial debridement as opposed to aggressive, wide debridement. Primary closure, while contraindicated in wounds in other areas of the body, is acceptable for many wounds of the face. Consider use of fast-absorbing sutures in any patient with unreliable follow up. Large areas of missing tissue may be covered temporarily with dressings, taking care to keep the tissues moist. Consider local or regional flaps in the acute phase when there is exposed bone or cartilage. In high velocity injuries, the surgeon should conserve as much tissue as possible during the first surgery and allow the wound to demarcate. After several days of wound care, the resulting defect can be repaired using a musculocutaneous flap.²⁰ Most importantly, the surgeon must cover all exposed bone and cartilage with vascularized tissue and an appropriate antibiotic ointment to prevent infections in these structures.

The use of NPWT/ROCF has not been well documented in the treatment of facial wounds but may be appropriate in some situations where there is extensive tissue loss. If a cerebrospinal fluid leak is suspected, this should be avoided. Foreign bodies, along with damaged bone and cartilage lacking periosteum and perichondrium, should be removed while carefully preserving the remaining viable tissues to the greatest extent possible. Antibiotics should be used for all facial wounds associated with sinus, nasopharyngeal or oropharyngeal injuries. Injuries to cartilaginous structures (i.e. ears, nose) are especially susceptible to *Pseudomonas aeruginosa* and *Staphylococcus aureus* infections. (Refer to the [Infection Prevention in Combat-Related Injuries CPG](#).)

PERFORMANCE IMPROVEMENT (PI) MONITORING

POPULATION OF INTEREST

All patients with wounds requiring debridement and irrigation within 1 day of injury.

INTENT (EXPECTED OUTCOMES)

- Combat wounds are treated with sharp surgical debridement, augmented by irrigation, at the first surgical role of care, or reason for delay documented.
- Combat wounds remain open after initial operation (excluding face and scalp wounds).

PERFORMANCE/ADHERENCE MEASURES

- Number and percentage of patients in population of interest who received sharp debridement of combat wounds at the first surgical role of care.
- Number and percentage of patients in the population of interest who have wounds left open at the initial operation (excluding face and scalp wounds).

DATA SOURCES

- Patient Record
- Department of Defense Trauma Registry

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.

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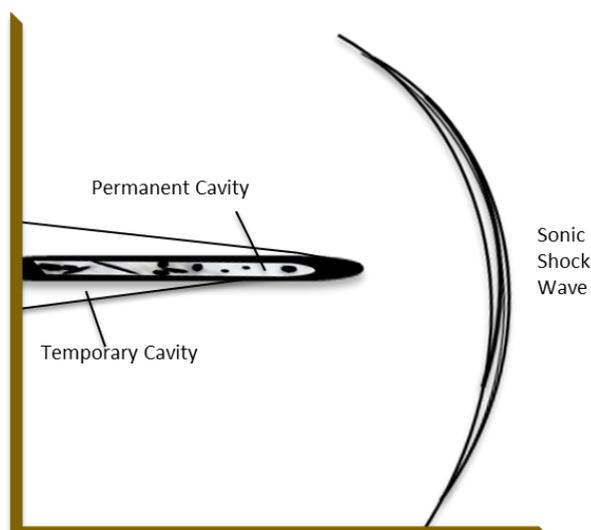
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APPENDIX A : WEAPON EFFECTS

Military munitions and firearms produce injuries not commonly seen in civilian trauma. Weapon types can be roughly divided into two major subtypes: small arms fire and explosive munitions. Small arms fire is typically from hand guns and assault rifles.¹

When a small arms projectile hits tissue, it produces two types of injuries: a permanent cavity and a temporary cavity. The permanent cavity is the tissue destroyed by the actual pathway of the projectile. Military rounds are designed to turn, or yaw, upon contacting tissue. As the bullet turns, the permanent cavity size increases. This is evidenced by small entry wounds and large exit wounds. A second, temporary cavity occurs from a pressure wave created by the high-velocity round. Elastic, and inelastic tissue, is put under stress which manifests as delayed necrosis and is one of the reasons we do not advocate for wound closure following the initial debridement. The degree of damage is proportional to a projectile's kinetic energy and more specifically its velocity (Kinetic Energy = $\frac{1}{2}$ (Mass) x Velocity). Particles distributed by blast explosions also create permanent and temporary cavities.

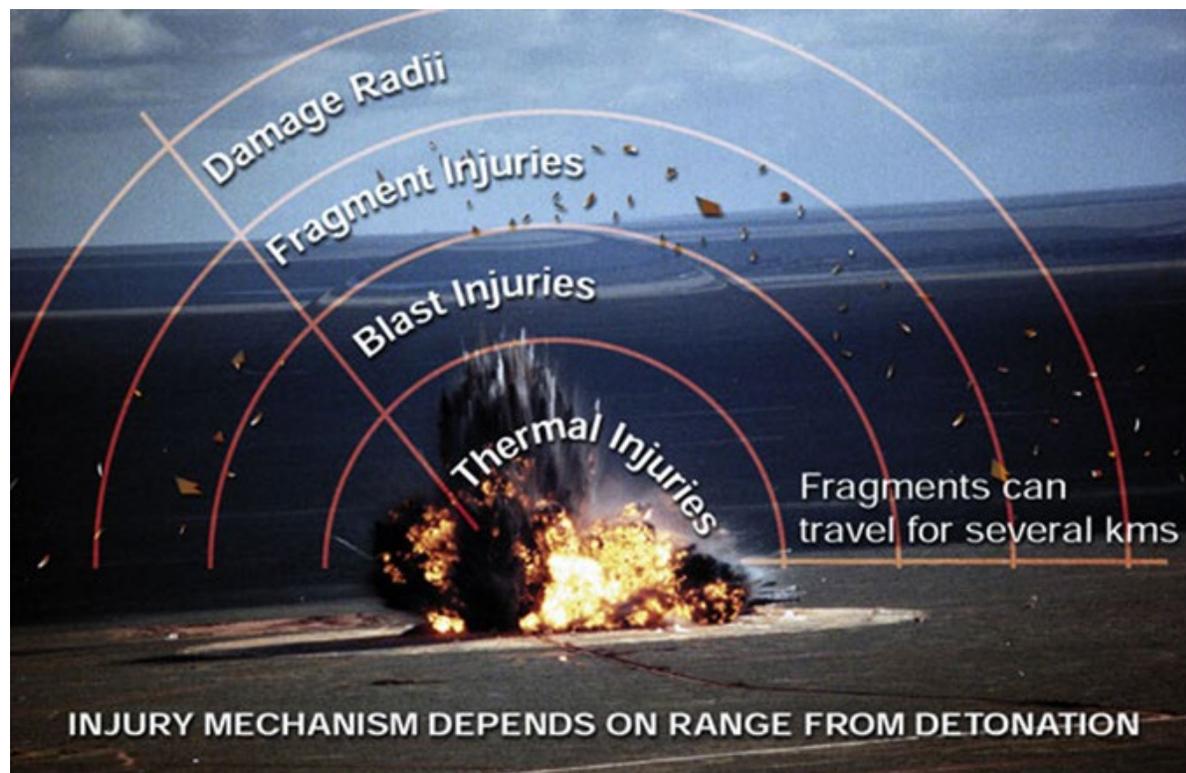
Figure A-1. Two areas of projectile-tissue interaction



Explosive munitions injure through four major mechanisms. The number of mechanisms a person is exposed to depends on their distance from the explosion, with persons closer to blasts being exposed to more mechanisms of injury. (See Figure 2 below.) Primary blast injuries occur from a pressure wave known as a blast wave. The blast wave can shear off tissue, damage solid organs, and damage hollow viscus injuries from pressure changes in the air contained within the organs. These injuries may manifest several days after the blast and are typically discovered on serial examinations of the injured patient. Secondary blast injuries are penetrating injuries which result from particles contained within the munition or from debris from the surrounding environment distributed by the blast. Tertiary blast injuries comprise two subtypes of injury. The first is a negative pressure wave called a blast wind which follows the positive pressure of a blast wave. Similar injuries are produced by both blast wind and blast waves. The second subtype of injury is blunt trauma resulting from large objects being projected into a body, or a person's body being projected into the surrounding environment, like a wall or the ground. When a blast hits a vehicle, occupants are susceptible to being injured by sequential pressure waves as they reflect around the inside of the vehicle. Quaternary blast injuries also comprise two major subtypes. The first subtype is burn injuries, which are treated as outlined in the [JTS Burn Care Clinical](#)

[Practice Guideline](#). The second are CBRNE injuries (Chemical, Biological, Radiological, Nuclear, and Environmental Injuries) and are managed as outlined in [CBRNE guidelines](#).

Figure A-2. Four mechanisms of blast injury



Virtually every organ is susceptible to injury from blast explosions and many of these injuries, particularly hollow viscus injuries and soft tissue necrosis, present in a delayed format, necessitating serial exams and clinical awareness.

Reference: Cubano, M.A., et. al. Chapter 1: Weapons Effects and War Wounds. Emergency War Surgery, 5th United States Revision. Fort Sam Houston, TX: Borden Institute, 2018.

APPENDIX B: 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.