JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)

Burn Wound Management in Prolonged Field Care (CPG ID: 57)
This Role 1 prolonged field care (PFC) guideline is intended to be used after Tactical Combat Casualty Care (TCCC) Guidelines, when evacuation to higher level of care is not immediately possible.

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INTRODUCTION

This Role 1, prolonged field care (PFC) guideline is intended to be used after Tactical Combat Casualty Care (TCCC) Guidelines, when evacuation to higher level of care is not immediately possible. A provider of PFC must first and foremost be an expert in TCCC. This Clinical Practice Guideline (CPG) is meant to provide medical professionals who encounter burns in austere environments with evidence-based guidance. Recommendations follow a “best,” “better,” “minimum” format that provides alternate or improvised methods when optimal hospital options are unavailable. A more comprehensive guideline for burn care is available in the Joint Trauma System Clinical Practice Guideline (JTS CPG) for Burn Care at https://jts.amedd.army.mil/index.cfm/PI_CPGs/cpgs

URGENT BURN CARE

Burns covering >20% of the total body surface area (TBSA), or those with smoke inhalation injury (and airway or breathing problems), are life threatening. Burns that affect vision, decrease hand function, or cause severe pain can take the warfighter out of action.

Hypothermia risk is high in burn patients. Anticipate that all burn casualties will become hypothermic and take immediate measures to prevent it by covering patient. Aggressively rewarm if temperature falls below 36°C (96.8°F).

Telemedicine: Management of burns is complex. Also, burns are highly visual and a lot can be communicated via pictures or video. Establish telemedicine consult as soon as possible.

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AIRWAY MANAGEMENT

Goal: Avoid airway obstruction due to inhalation injury or burn-induced swelling.

- Patients with smoke inhalation injury may present with a range of symptoms in terms of severity.
- Patients with severely symptomatic smoke inhalation injury (e.g., respiratory distress, stridor) require immediate definitive airway (cuffed tube in trachea) because they are at risk of immediate airway loss. Oxygenate and ventilate.
- All patients with burns covering >40% TBSA should be intubated because total-body swelling will tend to obstruct the airway. Patients with facial burns around the mouth may require intubation (Figure 1).
Figure 1. Severe facial burns with airway secured.

- **Best:** Rapid-sequence intubation by skilled provider, followed by continuous sedation and airway maintenance, supplemental oxygen, portable ventilator.
- **Better:** Cricothyroidotomy followed by continuous sedation and airway maintenance, supplemental oxygen via an oxygen concentrator, portable ventilator.
- **Minimum:** Cricothyroidotomy, ketamine, ambu bag with positive end-expiratory pressure (PEEP) valve.

**NOTES:**

- Patients with mild symptoms of smoke inhalation injury (e.g., some cough, no respiratory distress) can be observed.
- Burns or explosions in a closed space are associated with higher risk of inhalation injury than burns occurring in open areas.
- Supraglottic airway (e.g., laryngeal mask airway [LMA], King LT [Ambu, http://www.ambuusa.com/], or Combitube [Medtronic Minimally Invasive Therapies, http://www.medtronic.com/covidien]) is not appropriate because edema will continue to increase over 48 hours and these tubes do not overcome vocal-cord edema.
- Endotracheal tube must be secured circumferentially around the neck using cotton ties or similar. Tape does not stick to the face well enough in burn patients.
- Place nasogastric (or orogastric) tube to decompress stomach in intubated patients.
- Perform frequent endotracheal suction of intubated patients to ensure tube patency and remove mucus/debris (approximately once an hour or more frequently if oxygen saturation [SpO2] drops).
- If there is evidence of inhalation injury, use 3–5mL of endotracheal saline to facilitate suctioning and prevent tube insipation and obstruction.
- Monitoring end-tidal CO2 is an important capability for all intubated patients. A rising end-tidal CO2 could indicate clogging of endotracheal tube or poor ventilation from another cause (e.g., bronchospasm, tight eschar across chest).
- Use PEEP on all intubated patients.
- Perform a surgical escharotomy of the chest for tight, circumferential, full-thickness burns that impair breathing. Incision goes through the full thickness of the burn and into the fat (Appendix A). Expect some pain and bleeding.
- Use bronchodilators (e.g., albuterol inhaler) for intubated patients with inhalation injury, if available.

Ventilator management of burn patients can be complicated and evolve as pulmonary conditions change due to volume overload/edema and acute respiratory distress syndrome (ARDS). Telemedicine consultation with skilled providers is recommended.

**ASSESS BURN SIZE**

**Goal:** Accurately identify burn wound size to identify appropriate fluid resuscitation needs.

- Estimating burn wound size may be difficult. Engage remote specialty consultants early. If possible, send pictures of wounds that have been cleaned and debrided.
- **Best:** When wounds are cleaned/debrided, recalculate TBSA using the Lund-Browder chart (Appendix B).
- **Better:** Same as minimum.
- **Minimum:** For small wounds, calculate the size of the wound by using the patient’s hand size (including fingers) to represent a 1% TBSA. For larger wounds, calculate the patient’s initial burn size using the Rule of Nines (Appendix C).

**NOTE:** Significant over- or underestimation of burn wound size (by more than 10%) may lead to significant morbidity. Underestimation may lead to under-resuscitation and organ failure (i.e., renal failure, shock); overestimation may lead to resuscitation morbidity (i.e., respiratory failure, compartment syndromes).

1st degree (superficial) burns look like a mild-moderate sunburn. They appear red, blanch readily, do not blister, and hurt when touched. Do NOT include these wounds in the estimation of TBSA used for fluid resuscitation (Figure 2).

2nd degree (partial thickness) burns are moist, blister, blanch, and hurt. Include these wounds in the TBSA estimation (Figure 3).

3rd degree (full thickness) burns appear leathery, dry, nonblanching, do not hurt, and often contain thrombosed vessels that are visible. Include these wounds in the TBSA estimation (Figure 4).
Figure 2. First degree burns. (Do not include these wounds in the TBSA estimate!)

A. Sunburn
B. Mostly first degree burns with small area of superficial second degree.

Figure 3. Second-degree burns

A. Second-degree burn with intact blisters.
B. Deep (D), intermediate (I) & superficial (S) second degree burns.

Figure 4. Third-degree burns

A. Third-degree burn before cleaning and debridement of loose, dead skin.
B. Third-degree burn with eschar.
**FLUID RESUSCITATION**

**Goal:** Over the first 24–48 hours post burn, plasma is lost into the burned and unburned tissues, causing hypovolemic shock (when burn size is >20%). The goal of burn-shock resuscitation is to replace these ongoing losses while avoiding over-resuscitation.

**Best:** Isotonic crystalloids (e.g., lactated Ringer’s, Plasma-Lyte IV [Baxter, http://www.baxter.com/]);

- Start intravenous (IV) or intraosseous (IO) administration IMMEDIATELY.
- IV/IO can be placed through burned skin if necessary.
- NO bolus (unless hypotensive, in which case, bolus only until palpable pulses are restored).
- Initial IV rate 500mL/h; start while completing initial assessment.
- Adults: Measure burn size (TBSA) and multiply by 10. This is now your IV fluid rate. For example, if the burn size is 30%: 30 × 10 = 300. Starting rate is 300mL/h.
  - For patients with weight >80kg, add an extra 100mL/h for each 10kg. For example, for a 100kg patient with 30% burns, the starting rate is 300mL/h + 200mL/h = 500mL/h.
  - If resuscitation is delayed, DO NOT try to “catch up” by giving extra fluids.
- For children, 3 × TBSA × body weight in kg gives the volume for the first 24 hours. One half is given during the first 8 hours.
Better: Enteral (oral or gastric) intake of electrolyte solution

- Sufficient volume replacement will require “coached” drinking on a schedule using approximately the same amount of fluids that would be given IV/IO (see above).
- Oral resuscitation of patients with burns up to about 30% TBSA is possible (see Hydration side bar below).
- If a nasogastric tube (NGT) is available, it is preferable to resuscitate with infusion of electrolyte solution via NGT (e.g., 300–500mL/h. But watch for nausea/vomiting.

Minimum: Rectal infusion of electrolyte solution. Rectal infusion of up to 500mL/h can be supplemented with oral hydration (see Hydration side bar.)

### Hydration

Plain water is ineffective for shock resuscitation and can cause hyponatremia. If using oral or rectal fluids, they must be in the form of a premixed or improvised electrolyte solution to reduce this risk.

Examples:

- World Health Organization (WHO) Oral Rehydration Solution (per package instructions or 1L of potable water with 6 level teaspoons sugar, 0.5 level teaspoon salt)
- Mix 1L of D5W solution with 2L of Plasma-Lyte
- Per 1L water: add 8tsp sugar, 0.5tsp salt, 0.5tsp baking soda
- Per quart of Gatorade (Stokely-Van Camp Inc., http://www.gatorade.com/): add 0.25tsp salt, 0.25tsp baking soda (If no baking double the amount of salt in the recipe.)

The principles of hypotensive resuscitation according to TCCC DO NOT apply in the setting of burns (without severe bleeding).

**HOWEVER**

In the unusual setting of burns associated with noncompressible (e.g., thoracic, abdominal, pelvic) hemorrhage, aggressive fluid resuscitation may result in increased hemorrhage. Balancing the risk of uncontrolled hemorrhage against the risk of worsening burn shock from under-resuscitation should be guided by expert medical advice (in-person or telemedicine). Be prepared for blood transfusion.

### MONITORING

**Goal:** Maintain adequate oxygenation and ventilation, avoid hypotension, trend response to resuscitation. Document blood pressure (BP), heart rate (HR), urine output (UO), mental status, pain, pulse oximetry, and temperature, and record data on a flow sheet (*Appendix D*).

### VITAL SIGNS

- **Best:** Portable monitor providing continuous vital-signs display; capnography if intubated; document vital-signs trends frequently (every 15 minutes initially, then every 30–60 minutes once stable for more than 2 hours).
- **Better:** Capnometry in addition to minimum requirements (if intubated).
- **Minimum:** blood-pressure cuff, stethoscope, pulse oximetry, document vital-signs trends frequently.
URINE OUTPUT

Urine output (UO) is the main indicator of resuscitation adequacy in burn shock.

Goal: Adjust IV (or oral/rectal intake) rate to UO goal of 30–50mL/h. For children, titrate infusion rate for a goal UO 0.5–1 mL/kg/hr.

- **Best:** Place Foley catheter
  - If UO too low, increase IV rate by 25% every 1–2 hours (e.g., if UO = 20mL/h and IV rate =300mL/h, increase IV rate by 0.25 × 300 =75mL/h. New rate is 375mL/h.)
  - If UO too high, decrease IV rate by 25%.

- **Better:** Capture urine in premade or improvised graduated cylinder
  - Collect all spontaneously voided urine and carefully measure; >180mL every 6 hours is adequate for adults.
  - A Nalgene® (Thermo Fisher Scientific Inc., http://www.nalgene.com/) water bottle is an example of an improvised graduated cylinder

- **Minimum:** Use other measures
  - If unable to measure UO, adjust IV rate to maintain HR less than 140, palpable peripheral pulses, good capillary refill, intact mental status.
  - Measure the BP and consider treating hypotension, but remember: BP does not decrease until relatively late in burn shock, because of catecholamine release. On the other hand, BP may be inaccurate (artificially low) in burned extremities.

**NOTE: Electric injury**

- Patients with high-voltage electric injury causing muscle damage and gross pigment in the urine (and similar patients, such as rhabdomyolysis or crush injury) have a higher target UO of 70–100mL/h in adults. See PFC Crush CPG.
- If this does not cause gradual clearing of the pigment (urine turns lighter on three or four hourly checks), the patient likely needs urgent surgery for decompression/debridement.

EXTREMITY BURNS

Burned extremities are vulnerable to injury from post burn swelling.

Goal: Prevent and manage swelling (edema) of burned extremities to prevent long-term damage.

- **Best:** Elevate burned extremities above heart level. Encourage patient to exercise burned extremities to decrease edema. Monitor peripheral pulses on all burned extremities hourly, using a Doppler flowmeter if available. If the peripheral pulses are diminished or absent and evacuation will be delayed, perform escharotomies of circumferential burns to restore blood flow (Appendix A). Be prepared to stop bleeding with combat gauze, electrocautery, or tourniquet as needed. Anticipate blood loss and prepare for blood transfusion.

  Obtain teleconsultation.
Better: Consider doing escharotomies for circumferential full thickness (3rd degree) burns of an extremity if extremity is edematous, you are unable to palpate distal pulses, and evacuation will be delayed. Anticipate blood loss and prepare for blood transfusion.

Obtain teleconsultation.

Minimum: Triage patient to more rapid evacuation if extremity is edematous and you are unable to palpate distal pulses. Elevate burned extremities above heart level and have patient exercise or provide passive range of motion (PROM) to burned extremities to mobilize edema. Provide pain control to enable PROM.

PAIN MANAGEMENT

Refer to Analgesia and Sedation Management CPG for Prolonged Field Care.

Burns can be painful and can cause hypovolemia. Thus, frequent, smaller doses of an IV opioid or ketamine are preferred.

- In hypovolemic burn patients, ketamine can be used for severe pain or for painful procedures, but less than the full anesthetic dose is safer (e.g., 0.1–0.2mg/kg IV push, assess response and redose ketamine as needed every 5–10 minutes).

- For prolonged care of burn patients, a ketamine infusion may provide more consistent analgesia and help conserve supplies of analgesic medications.

- Burn wound care is extremely painful. Ensure an adequate supply of analgesic agents is available before starting wound cleaning, debridement, escharotomy, or dressing change. Refer to Analgesia and Sedation CPG or obtain telemedicine advice for adequate dosing of procedural analgesia for burn care.

- Consider administering an oral or IV benzodiazepine for anxiety (common with repeated painful wound care).

INFECTION

Burn wounds are easily infected.

Goal: Prevent burn wound infection through wound care. If evacuation to higher level of care is anticipated within 24 hours, simply cover burns with clean, dry gauze and leave intact blisters in place. Always avoid wet dressings, because of the risk of hypothermia. If evacuation is not anticipated for more than 24 hours, and time, medication, and human resources permit, provide wound care as soon as possible after the injury (within the first 24 hours). If resources are not available initially, provide wound care as soon as possible.


  Silverlon can be left in place for 3–5 days as long as the wound is clean when the Silverlon is applied.
The outer gauze dressings (e.g., Kerlix [Covidien]) should be moistened (not soaked) at least daily. Use sterile (or at least clean, uncontaminated) water or normal saline.

- The outer gauze dressings should be changed, leaving the Silverlon in place, sooner than 3 days if they become 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.
- The Silverlon can be removed and cleaned in sterile, or at least clean uncontaminated, water and reused for up to 5 days.

**Better:** Clean wounds and debride loose dead skin by washing with any antibacterial soap in clean water, dress wounds with any available dressings; optimize wound and patient hygiene to the extent possible given environment.

**Minimum:** Cover with clean sheet or dry gauze. Leave blisters intact. Avoid wet dressings.

### ANTIBIOTICS

- IV or oral antibiotics are not normally used for prophylaxis in burn patients in the absence of other open wounds requiring them (e.g., open fractures.)

- After several days, if patient develops cellulitis (spreading erythema around edges of burn), treat for gram-positive organisms, (e.g., cefazolin or clindamycin).

- If patient develops invasive burn wound infection (signs: sepsis/septic shock, changes in color of wound, possible foul smell of wound), treat with broad-spectrum antibiotics to include gram-positive and gram-negative coverage that ideally includes coverage for *Pseudomonas aeruginosa* (e.g., ertapenem + ciprofloxacin).

Fluid and equipment planning considerations. See Appendix E.

Summary Table. See Appendix F.

### ABOUT THE AUTHORS

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APPENDIX A: ESCHAROTOMY INCISIONS

The incisions on the extremities are placed along the mid-medial and/or mid-lateral joint lines. The bold lines indicate the importance of always carrying the incisions across any involved joints. The incisions on the chest are intended to free up a mobile “plate” of tissue to restore adequate chest movement with breathing.

Source: Figure 26.1, p. 379, Chapter 26 (Burns). In: Anonymous, Emergency War Surgery, 4th United States Revision. Fort Sam Houston, TX: Office of the Surgeon General, Borden Institute, 2013.

Figure A1. Photograph of a patient undergoing escharotomy of the leg, using electrocautery. The goal is to go through the burned skin into viable tissue (i.e., subcutaneous fat).

Figure A2. Photograph of a patient undergoing escharotomy of the leg and foot, using a scalpel. When using a scalpel, there may be increased blood loss compared to electrocautery, as shown here.
**APPENDIX B: LUND & BROWDER BURN WOUND CALCULATION WORKSHEET**

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**BURN DIAGRAM**

Age __________________________

Sex __________________________

Date of Burn __________________

ISR Staff MD __________________

**COLOR CODE**

Blue = 2nd Degree
Red = 3rd Degree
APPENDIX C: RULE OF NINES BURN WOUND CALCULATION

Use this image to calculate the percent of total body surface area (%TBSA) involved by second and third degree burn wounds (do NOT include first degree wounds in this assessment). Example: Second and third degree wounds involving the entire anterior torso and right upper extremity, front and back, would be cover 27% TBSA. If this wound had scattered areas of unburned skin and/or first degree burns, adjust the %TBSA downward. %TBSA is an estimate. Both over- and underestimates have potential negative impacts on a patient’s resuscitation.
# APPENDIX D: JOINT TRAUMA SYSTEM (JTS) BURN RESUSCITATION FLOW SHEET

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<td>Calculate Rule of Tens (if &gt;40-80kg, %TBSA x 10 = starting rate for LR)</td>
<td>Calculate max 24hr volume (250ml x kg) Avoid over-resuscitation, use adjuncts if necessary</td>
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APPENDIX E: FLUID & EQUIPMENT PLANNING CONSIDERATIONS

**Assumptions:** One patient with a 50% total body surface area (TBSA) burn, weighing 80kg, and requiring 4mL/kg/%TBSA for resuscitation the first day (16L), half that the second day (8L), and half that the third day (4L).

**Note:** For planning purposes only, the Parkland formula of 4mL/kg/%TBSA provides an estimate for the first 24-hour fluid requirements; however, hourly fluid resuscitation should start with the rule of 10s.

**Best:**
- Fluids: IV fluid (lactated Ringer’s solution or Plasma-Lyte) to provide resuscitation for 72 hours (28L)
- Equipment: Portable monitor with capnography; lab capability for serum electrolytes, arterial blood gases, and lactate; Foley catheter with graduated collection system; portable ventilator; portable suction; electrocautery or scapel; oxygen or oxygen concentrator; airway management kit to include endotracheal suction catheter
- Medications: pain medications (refer to **Analgesia, Sedation CPG**)
- Burn-specific dressings: Hibiclens to clean wounds, Silvadene and/or Sulfamylon cream (two 400g jars per patient per day), or silver nylon (Silverlon) dressings
- Nonspecific dressings: roller gauze, torso dressings, tape or stapler
- Hypothermia prevention: sleeping bag or Hypothermia Prevention & Management Kit (HPMK)
- Monitoring: Portable monitor providing continuous vital-signs display; capnography, if intubated; document vital-signs trends, intake and output, GCS, and pain level on a regular basis; burn-resuscitation flow sheet
- Push-pack capability: prepackaged additional 24-hour supplies of fluids, dressings for scenarios >24 hours or >1 patient
- Communications: real-time video telemedicine consultation

**Better:**
- Fluids: IV fluid (lactated Ringer’s solution or Plasma-Lyte) to provide resuscitation for 24 hours (16L); oral electrolyte replacement
- Equipment: Blood pressure cuff, stethoscope, pulse oximeter, capnometry, portable ventilator, oxygen or oxygen concentrator, airway management kit to include endotracheal suction catheter
- Graduated container to monitor urine output
- Pain medications
- Nonspecific dressings: roller gauze, torso dressings, tape or stapler
- Hypothermia prevention: sleeping bag/HPMK/ Blizzard Blanket (Blizzard Protection Systems Ltd., http://www.blizzardsurvival.com/)
- Monitoring: Frequent vital signs, examination, fluid input, urine output, flowsheet document
- Communications: telephone; e-mail digital photos

**Minimum:**
- Fluids: Resuscitation with commercial or improvised electrolyte solution (oral, enteral, rectal)
- Equipment: Blood pressure cuff, stethoscope, pulse oximeter, bag-valve mask with positive end-expiratory pressure (PEEP) valve, airway management kit
- Graduated or improvised graduated container to monitor urine output
- Pain medications
- Clean sheet, any available trauma dressings
- Hypothermia prevention: sleeping bag/emergency blanket/blankets
- Monitoring: Frequent vital signs, examination, fluid input, urine output documented on preprinted or improvised flowsheet
- Communications: Telephone.
### Airway

**Best**
- Rapid Sequence Intubation
- Continuous sedation + airway maintenance and suctioning
- \( \text{O}_2 \) and portable ventilator

**Better**
- Cricothyroidotomy
- Continuous sedation + airway suctioning
- \( \text{O}_2 \) concentrator and portable ventilator

**Minimum**
- Cricothyroidotomy
- Ketamine
- Bag-valve-mask with PEEP valve

### Assess Burn Size

**Best**
- For initial estimate: Rule of 9s
- After wounds are cleaned/debrided: re-calculate burn size using Lund-Browder chart

**Better**
- Same as minimum

**Minimum**
- For large burns: Rule of 9s
- For small burns: Use patient’s hand = 1% TBSA

### Fluid Resuscitation

**Best**
- Use isotonic crystalloid: Lactated Ringer’s (LR) or Plasma-Lyte
- Starting fluid rate is rule of 10s (TBSA x 10; +100 ml/hr for each 10 kg over 80 kg)

**Better**
- Oral resuscitation with electrolyte solution (avoid plain water)
- Possible for up to 30% TBSA burns
- “Coached” drinking on a schedule to meet target fluid rate

**Minimum**
- Rectal infusion of electrolyte solution
- Can infuse up to 500 ml/hr
- May use to supplement oral hydration

### Teleconsultation

- Establish contact early
- Ventilator management
- Measuring burn size
- Hemorragic shock + burns
- Burn > 20% TBSA
- Electrical burn
- Escharotomy needed
- Infection

### Monitoring

#### Vital Signs

**Best**
- Portable monitor
- Capnography
- Document vital signs (VS) and I/O on flow sheet

**Better**
- BP cuff, stethoscope
- Pulse oximetry, Capnography
- Document VS and I/O on flow sheet

**Minimum**
- Blood Pressure (BP) cuff, stethoscope
- Pulse oximetry
- Document VS on flow sheet

### Urine Output

**Best**
- Foley catheter, titrate fluids to keep urine output (UO) 30-50 ml/hr
- Increase or decrease fluid rate by 25% each hour if UO not at goal

**Better**
- Collect urine in graduated container
- >180 ml every 6 hours is adequate

**Minimum**
- If unable to measure UOP, adjust fluids to maintain HR <140, good capillary refill, intact mental status
- Treat hypotension if needed, but this is a late sign of hypovolemia
## Extremity Burns

**Best**
- Elevate, Exercise
- Monitor pulses hourly, Doppler flow meter
- Escharotomy if circumferential 3rd degree burn

**Better**
- Elevate, Exercise
- Monitor pulses hourly
- Escharotomy only if unable to palpate distal pulses and evacuation delayed

**Minimum**
- Elevate, Exercise
- Monitor pulses hourly

## Pain Management

**Best**
- Ketamine infusion
- Supplement with IV opioids and midazolam (e.g., Versed), frequent small doses

**Better**
- Ketamine IV
- Supplement with IV opioids and midazolam, frequent small doses

**Minimum**
- Fentanyl Lozenge
- Oral acetaminophen/oxycodone (e.g. Percocet, Endo Pharmaceuticals, http://www.endo.com/)

## Infection

### Prevent Infection

**Best**
- Clean wound and debride loose dead skin using gauze and Hibiclens in clean water
- Apply antimicrobial cream (Silvadene or Sulfamylon), cover with gauze.
- Alternative: Apply Silverlon dressings to clean wounds, cover with gauze

**Better**
- Clean wound and debride loose dead skin using any antibacterial soap in clean water
- Apply any available dressing
- Optimize wound care and hygiene to extent possible

**Minimum**
- Cover with clean sheet or dry gauze
- Leave blisters intact

### Treat Infection

**Best**
- If cellulitis (spreading erythema around edge of burn) treat with IV antibiotics (e.g., cefazolin or clindamycin)
- If invasive infection with sepsis, foul smell, or burn wound color change, cover gram-positive and gram-negative and Pseudomonas bacteria (e.g. ertapenem + ciprofloxacin)

**Better**
- Same as minimum

**Minimum**
- If cellulitis (spreading erythema around edge of burn) or invasive infection, treat with antibiotics.
- Any available antibiotic
APPENDIX G: 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.