JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)

Infection Prevention in Combat-Related Injuries (CPG ID: 24)
Provides rationale and guidance for the prevention of infection after combat-related injuries.

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BACKGROUND

Infection has been a complication of war wounds throughout history. Infection prevention and control techniques in combat injuries, first widely practiced by Florence Nightingale in the Crimean War, have advanced significantly. The battlefield poses unique challenges in care for combat-related injuries. These include multiple patient transfers between hospitals and teams, the austere environment of theater medical care, and the difficulties arising during long distance aeromedical evacuation.[1-3] Infections caused by Multi-Drug Resistant Organisms (MDRO) have been reported in theater of host nation patients. In one study 22% of patients developed new colonization with MDRO after admission to one of the U.S. Role 5 facilities.[4] Infection prevention and control practices must be able to effectively adapt to these challenges and support the prevention and spread of infection by implementation of early and repetitive surgical wound care.

***NOTE**: Related CPGs: Ventilator-Associated Pneumonia, Initial Management of War Wounds.*

STANDARD PRECAUTIONS

This applies to all patients, regardless of suspected or confirmed infectious status. The application of Standard Precautions during patient care is determined by the nature of the health care worker-patient interaction and the extent of anticipated blood, body fluid, or pathogen exposure.[5] This includes the following but not limited to:

- **Hand washing:** The World Health Organizations "five moments of hand hygiene" include use of soap and water or alcohol-based sanitizer before patient contact, before aseptic task, after body fluid exposure risk, after patient contact and after contact with patient surroundings, even if gloves were worn.[6] The gold standard to ensure adherence is direct observation which allows for immediate corrective feedback.[7]
- **Gloves:** Use to prevent contamination of hands when anticipating direct contact with non-intact skin, mucous membranes and blood or body fluids (e.g., dressing changes, starting IVs).
- **Gowns:** Isolation gowns are specified by Standard and Transmission-Based Precautions to protect the health care worker's arms and exposed body areas and prevent contamination of clothing with blood, body fluids, and other potentially infectious material (e.g., changing dressings or open wounds). Gowns are always used in conjunction with gloves.
- **Masks:** Masks protect from contact with infectious material from patients and are also used to protect the patient when performing sterile technique to protect patients from exposure to infectious agents carried in a healthcare workers mouth or nose.
- **Goggles or Face Shields:** Use based on anticipated exposure Personal eyeglasses and contact lenses are not considered adequate eye protection.

TRANSMISSION-BASED PRECAUTIONS

This includes droplets, airborne and contact precautions. For this Clinical Practice Guideline (CPG) we will only describe the use of contact precautions for epidemiologically important organisms to include C. difficile.

- **Contact Precautions:** Gloves and gowns should be worn with all patients suspected or known to have MDRO colonization and/or infection with C-difficile- infection (CDI) Refer to CDC Appendix A of the 2007 Isolation Guidelines for a list of all diseases requiring contact precautions.[5]

***NOTE**: US personnel with skin and soft tissue infections presenting with abscess or furuncles should be assumed to have community-associated Methicillin-Resistant Staphylococcus Aureus (MRSA).*

- **Cohorting:** Cluster "long-term (host nation patient) (>72 hours)" and "short term (U.S Personnel) (<72 hour stay)" patients and separate when possible to reduce the risk of cross-contamination with MDROs. Furthermore, patients suspected of having infections such as CDI should be immediately placed into contact precautions.[8]

Emphasize basic infection prevention control efforts (e.g., cohorting, hand hygiene, transmission based isolation) to prevent spread from other hospitalized patients and to decrease antibiotic pressure selecting for resistant organisms.[9]

- **Skin care:** ICU patients should undergo daily Chlorhexidine Gluconate (CHG) "bath". CHG has broad activity against gram-positive and gram-negative bacteria, facultative anaerobes and aerobes. Daily bathing of ICU patients has shown a reduction of Vancomycin Resistant Enterococci (VRE) and MRSA. CHG reduces both skin flora and transient bacteria such as Gram-negative bacteria.[10] It was described that daily bathing with CHG washcloths significantly reduced the risk of acquisition of MDROs.[10,11] See Appendix D: Antiseptic Body Cleaning and implement a "Antibiotic Stewardship" program.[12]
- **Antibiotic control:**
  - Avoid unnecessary empiric use of broad spectrum antibiotics.[12]
  - When available, use local antibiogram to guide empiric therapy.
  - Limit duration of antibiotic therapy. Several well-controlled studies have shown benefit to shorter courses of antibiotic therapy for common infectious problems (e.g. pneumonia.) There is no evidence that prophylactic antibiotic therapy continued longer than 24 hours results in decreased infection.

SPECIAL SITUATION: CARE OF COMBAT INJURED SECONDARY TO SUICIDE BOMBER/BLAST INJURY

Blast Injuries, especially those related to a suicide bomber attacks, present a unique bloodborne pathogen risk if an impaled body part is introduced into the trauma patient. There have been reported cases of hepatitis B virus (HBV) impaled bone fragments recovered from suicide bomber victims in Israel.13,14 This prompted the Israeli Ministry to provide post-exposure HBV vaccination as a practice. Since the initiation of the vaccine, other HBV impaled fragments have been reported but no disease transmission.[15]

Prior to deployment, U.S. forces are required to receive a three shot vaccine series, but 5-14% of vaccinated patients fail to achieve immunity (anti HBs <10 mIU/ml) which places them at a seven times risk of transmission.[16,17] Thus we recommend attempting to verify anti-HBV status and provide HBV immunoglobulin (HBIG) and HBV vaccine for those incompletely vaccinated with unknown titers or anti-HBs<10 mIU/ml.

The risk of transmission for Human Immunodeficiency Virus (HIV) is considered very low and generally warrants no action.18 However, in the case of penetrating blast injury in a highly endemic region; expert teleconsultation should be obtained to discuss case specifics. Specific recommendations can be obtained via teleconsultation (infect.cntrl.consult@us.army.mil). Hepatitis C (HCV) has no available prophylaxis but testing can be considered in penetrating blast injury at the time of injury and at two, four, and six months.[18,19]

- **Healthcare Blood borne Pathogen Exposure:** Staff caring for patients with combat wounds are at risk for blood borne pathogens (HBV, HIV and HCV). At risk activities include security personnel searching patients (e.g. patting down patients who are IV drug users), needle sticks, break in surgical technique and blood splatters to non-intact skin, eyes or mucosa.

- **Source testing should be obtained for HBV, HIV and HCV.** Testing for HBV and HIV should be obtained at time of exposure and up to six months post-exposure.[18,20,21] There is no post-exposure treatment for HCV.
    - For HBV, treatment is based on the source's HBV surface antigen (HBVsAg) and the exposed patient's vaccine completion and post-vaccine titer (anti-HBs >10 mlU/ml. Refer to the 2013 CDC Guidance for evaluating Health Care Personnel for Hepatitis B. [20]
    - **For high risk HIV exposure,** 28 days of post-exposure prophylaxis should be administered within 1-2 hours but no later than 72 hours post-exposure. Refer to Updated U.S. Public Health Service Guidelines for the management of occupational exposures to HIV and recommendations for post-exposure prophylaxis.[21]

CARE OF COMBAT-INJURED PERSONNEL BASED ON ROLE OF CARE

- See Appendix A: Recommendations to Prevent Infections Associated with Combat-related Injuries based on role of care.
- Infection Control questions can be fielded by the U.S. Army teleconsultation program (IC.consult.army@mail.mil and id.consult.army@mail.mil).
- Ideally, Role 2 and 3 facilities should have a designated Infection Control Officer (ICO) as an additional duty or a full-time position if supported by manning levels. The U.S. Army holds an "Infection Control in the Deployed Setting" course. The U.S. Army requires deployed Combat Support Hospitals (CSH) to identify and ensure adequate training of an ICO for each deployed location of the CSH.

PERFORMANCE IMPROVEMENT (PI) MONITORING

INTENT (EXPECTED OUTCOMES)

1. All patients with skin, soft tissue, open fractures, exposed bone or open joint injuries, Cefazolin 2 gm IV every 6-8 hours or Clindamycin 600 mg IV every 8 hours will be initiated at the first role of surgical care.
2. All patients with penetrating brain injury, Cefazolin 2 gm IV q6-8 hours with consideration of adding Metronidazole 500mg IV every 8-12 hours will be initiated at the first role of surgical care.
3. All patients admitted to the ICU will have Sage antiseptic body cleaning daily.

PERFORMANCE/ADHERENCE MEASURES

1. Cefazolin 2 gm IV or Clindamycin 600 mg IV was initiated at the first role of surgical care, within 3 hours of admission, on patients with skin, soft tissue, open fractures, exposed bone or open joint injuries.
2. Cefazolin 2 gm IV PLUS Metronidazole 500mg was initiated at the first role of surgical care on patients with penetrating abdominal injury and suspected/known hollow viscus injury, soilage and rectal/perineal injuries.
3. Cefazolin 2 gm IV PLUS Metronidazole 500mg IV was initiated at the first role of surgical care on patients with penetrating brain injury.
4. Sage antiseptic body cleaning was performed on ICU patient daily.

DATA SOURCE

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

SYSTEM REPORTING & FREQUENCY

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed.

The system review and data analysis will be performed by the JTS Director and the JTS Performance Improvement Branch.

RESPONSIBILITIES

The trauma team leader, along with his or her infection control team, will ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.

All Health Care Providers will:

1. Become familiar with the national guidelines for infection prevention and control such as the Society of Hospital Epidemiologist of America (SHEA) 2014 Compendiums for the prevention of HAI.
2. Use recommended standard precautions as described in the 2006 CDC Guidelines for Isolation.
3. Provide feedback on these guidelines and suggestions for changes to the CPG to the JTS email group usarmy.jbsa.medcom-aisr.mbx.webmaster@mail.mil.

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APPENDIX A: RECOMMENDATIONS TO PREVENT INFECTIONS ASSOCIATED WITH COMBAT-RELATED INJURIES BASED ON ROLE OF CARE

LEVEL OF CARE*	CARE CATEGORY	RECOMMENDATIONS
Role 1 (Prehospital)	Initial care in the field	• Bandage wounds with sterile dressings (avoid pressure over eye wounds) • Stabilize fractures • Transfer to surgical support as soon as feasible
	Post-injury antimicrobials	• Provide single dose point of injury antimicrobials (Appendix B) if evacuation is delayed or expected to be delayed
Role 1 and Role 2 without surgical support (IIa)	Post-injury antimicrobials	• Provide intravenous antimicrobials for open wounds (Appendix B) as soon as possible (within 3 hours). • Provide tetanus toxoid and immune globulin as appropriate. • Gram negative coverage with aminoglycoside or fluoroquinolone not recommended. • Addition of penicillin to prevent clostridial gangrene or streptococcal infection is not recommended. • Redose antimicrobials if large volume blood product resuscitation • Use only topical antimicrobials for burns.
	Debridement and irrigation	• Irrigate minor wounds to remove gross contamination with normal saline, sterile, or potable water without additives. • Debridement and irrigation of large wounds should be done at a surgical facility (Role IIb or III). • Do not attempt to remove retained deep soft tissue fragments if criteria met. Provide Cefazolin 2 gm IV x 1 dose.
Role 2 with surgical support and Role 3	Post-injury antimicrobials	• Provide intravenous antimicrobials (Appendix B) as soon as possible (within 3 hours). • Provide tetanus toxoid and immune globulin as appropriate. • Gram negative coverage with aminoglycoside or Fluroquinolone not recommended. • Addition of penicillin to prevent clostridia gangrene or streptococcal infection is not recommended. • Redose antimicrobials if large volume blood product resuscitation. • Use only topical antimicrobials for burns • Antimicrobial beads or pouches may be used. • Provide post splenectomy immunizations if indicated.
	Debridement and irrigation	• Irrigate wounds to remove contamination with normal saline or sterile water using bulb irrigation, gravity irrigation, or pulse lavage without additives. For open fractures, use 3 L for each type I, 6 L for each type II, and 9 L for each type III extremity fractures. • Repeat debridement and irrigation every 24-48 hours until wound is clean and all devitalized tissue is removed. • Do not attempt to remove retained deep soft tissue fragments if criteria met.† Provide Cefazolin 2 gm IV x 1 dose. • Do not obtain cultures unless infection is suspected.
	Other surgical management	• Surgical evaluation as soon as possible. • Only dural and facial wounds should undergo primary closure. • Negative pressure wound therapy (NPWT) can be used. • External fixation (temporary spanning) of femur/tibia fractures. • External fixation (temporary spanning) OR splint immobilization of open humerus/forearm fractures.

LEVEL OF CARE*	CARE CATEGORY	RECOMMENDATIONS
Role 4	Post-injury antimicrobials	• Complete course of post-injury antimicrobials (Appendix B) • Antimicrobial beads or pouches may be used • Provide post splenectomy immunizations if indicated
	Debridement and irrigation	• Irrigate wounds to remove contamination with normal saline or sterile water using bulb • Irrigation, gravity irrigation, or pulse lavage without additives. For open fractures, use 3L for each type I, 6 L for each type II, and 9 L for each type III extremity fractures. • Repeat debridement and irrigation every 24-48 hours until wound is clean and all devitalized tissue is removed. • Do not attempt to remove retained deep soft tissue fragments if criteria met.† Provide Cefazolin 2 gm IV x 1 dose • Do not obtain cultures unless infection is suspected
	Other surgical management	• Wounds should not be closed until 3-5 d post-injury when wound is clean and all devitalized tissue is removed. • Only dural and facial wounds should undergo primary closure. • Negative pressure wound therapy (NPWT) can be used. • External fixation (temporary spanning) of femur/tibia fractures. • External fixation (temporary spanning) OR splint immobilization of open humerus/forearm fractures.

Criteria for allowing retained fragments to remain behind: entry/exit wounds < 2 cm; no bone, joint, vascular, body cavity involvement; no high risk etiology (e.g., mine); no obvious infection; assessable by x-ray.

APPENDIX B: POST-INJURY ANTIMICROBIAL AGENT SELECTION AND DURATION BASED UPON INJURY PATTERN

INJURY	PREFERRED AGENT(S)	ALTERNATE AGENT(S)	DURATION
EXTREMITY WOUNDS (INCLUDES SKIN, SOFT TISSUE, BONE)			
Skin, soft tissue, no open fractures	Cefazolin, 2 gm IV q6-8h†‡	Clindamycin (300-450 mg PO TID or 600 mg IV q8h)	1-3 days
Skin, soft tissue, with open fractures, exposed bone, or open joints	Cefazolin 2 gm IV q6-8h†‡§	Clindamycin 600 mg IV q8h	1-3 days
THORACIC WOUNDS			
Penetrating chest injury without esophageal disruption	Cefazolin, 2 gm IV q6-8h†‡	Clindamycin (300-450 mg PO TID or 600 mg IV q8h)	1 day
Penetrating chest injury with esophageal disruption	Cefazolin 2 gm IVq 6-8h†‡ PLUS metronidazole 500 mg IV q8-12h	Ertapenem 1 gm IV x 1 dose, OR moxifloxacin 400 mg IV x 1 dose	1 day after definitive washout
ABDOMINAL WOUNDS			
Penetrating abdominal injury with suspected/known hollow viscus injury and soilage; may apply to rectal/perineal injuries as well	Cefazolin 2 gm IV q 6-8h†‡ PLUS metronidazole 500 mg IV q8-12h	Ertapenem 1 gm IV x 1 dose, OR moxifloxacin 400 mg IV x 1 dose	1 day after definitive washout
MAXILLOFACIAL AND NECK WOUNDS			
Open maxillofacial fractures, or maxillofacial fractures with foreign body or fixation device	Cefazolin 2 gm IV q6-8h†‡	Clindamycin 600 mg IV q8h	1 day
CENTRAL NERVOUS SYSTEM WOUNDS			
Penetrating brain injury	Cefazolin 2 gm IV q6-8h.†‡ Consider adding metronidazole 500 mg IV q8-12h if gross contamination with organic debris	Ceftriaxone 2 gm IV q24h. Consider adding metronidazole 500 mg IV q8-12h if gross contamination with organic debris. For penicillin allergic patients, Vancomycin 1 gm IV q12h PLUS ciprofloxacin 400 mg IV q8- 12h	5 days or until CSF
Penetrating spinal cord injury	Cefazolin 2 gm IV q6-8h.†‡ ADD metronidazole 500 mg IV q8-12h if abdominal cavity is involved	As above. ADD metronidazole 500 mg IV q8- 12h if abdominal cavity is involved	5 days or until CSF leak is closed, whichever is longer
EYE WOUNDS			
Eye injury, burn or abrasion	Topical: Erythromycin or Bacitracin ophthalmic ointment QID and PRN for symptomatic relief Systemic: No systemic treatment required	Fluoroquinolone 1 drop QID	Until epithelium healed (no fluoroescein staining)

INJURY	PREFERRED AGENT(S)	ALTERNATE AGENT(S)	DURATION
Eye injury, penetrating	Levofloxacin 500 mg IV/PO once daily. Prior to primary repair, no topical agents should be used unless directed by ophthalmology		7 days or until evaluated by an ophthalmologist
BURNS			
Superficial burns	Topical antimicrobials with twice daily dressing changes (include mafenide acetate** or silver sulfadiazine; may alternate between the two), OR silver impregnated dressing changed q3-5d, OR Biobrane	Silver nitrate solution applied to dressings	Until healed.
Deep partial thickness burns	Topical antimicrobials with twice daily dressing changes, OR silver impregnated dressing changed q3-5d, PLUS excision and grafting	Silver nitrate solution applied to dressings PLUS excision and grafting	Until healed or grafted
Full thickness burns	Topical antimicrobials with twice daily dressing changes PLUS excision and grafting	Silver nitrate solution applied to dressings PLUS excision and grafting	Until healed or grafted
POINT OF INJURY/DELAYED EVACUATION††			
Expected delay to reach surgical care	Moxifloxacin 400 mg PO x 1 dose. Ertapenem 1 g IV or IM if penetrating abdominal injury, shock, or unable to tolerate PO medications	Levofloxacin 500 mg PO x 1 dose. Cefotetan 2 g IV or IM q12h if penetrating abdominal injury, shock, or unable to tolerate PO medications	Single dose therapy

*Post-injury antimicrobial agents are recommended to prevent early post-traumatic infectious complications, including sepsis, secondary to common bacterial flora. Selection is based on narrowest spectrum and duration required to prevent early infections prior to adequate surgical wound management. This narrow spectrum is selected to avoid selection of resistant bacteria. The antimicrobials listed are not intended for use in established infections, where multidrug-resistant (MDR) or other nosocomial pathogens may be causing infection.

†Cefazolin may be dosed based on body mass: 1 gram if weight < 80 kg (176 lbs), 2 grams if weight 81-160 kg (177-352 lbs), 3 grams if weight > 160 kg (>352 lbs); doses up to 12 grams daily are supported by FDA-approved package insert.

‡Pediatric dosing: cefazolin, 20-30 mg/kg IV q6-8h (maximum, 100 mg/kg/day); metronidazole, 7.5 mg/kg IV q6h; clindamycin 25-40mg/kg/day IV divided q6- 8h; ertapenem, 15 mg/kg IV or IM q12 (children up to 12 years) or 20 mg/kg IV or IM once daily (children over 12 years; maximum, 1 gm/day); ceftriaxone, 100 mg/kg/day IV divided q12-24h (dosing for CNS injury); levofloxacin, 8 mg/kg IV or PO q12h (levofloxacin is only FDA-approved in children for prophylaxis of inhalational anthrax in children > 6 months of age, but this dose is commonly used for other indications); vancomycin 60 mg/kg/day IV divided q6h (dosing for CNS injury); ciprofloxacin, 10mg/kg IV (or 10-20mg/kg PO) q12h.

§These guidelines do not advocate adding enhanced Gram negative bacteria coverage (i.e., addition of fluoroquinolone or aminoglycoside antimicrobials) in type III fractures.

**Mafenide acetate is contraindicated in infants less than 2 months of age.

††Post-injury antimicrobial therapy as suggested by the Committee on Tactical Combat Casualty Care (CoTCCC).

APPENDIX C: POST EXPOSURE MANAGEMENT OF PERSONNEL AFTER OCCUPATIONAL PERCUTANEOUS AND MUCOSAL EXPOSURE TO BLOOD OR ANY BODY FLUIDS

(Morb Mortal Wkly Rep. 2013;62:1)

Healthcare Personnel Status	Postexposure testing		Postexposure prophylaxis		Postvaccination serologic testing †
	Source patient (HBsAg)	HCP testing (anti-HBs)	HBIG*	Vaccination	
Documented responder § after complete series (≥3 doses)	**No action needed**				
Documented non-responder ٩ after 6 doses	Positive/unknown	_ **	HBIG x2 separated by 1 month	_	No
	Negative	**No action needed**			
Response unknown after 3 doses	Positive/unknown	‹ 10 mIU/mL **	HBIG x1	Initiate revaccination	Yes
	Negative	‹ 10 mIU/mL	None		
	Any result	≥ 10 mIU/mL	**No action needed**		
Unvaccinated/incompletely vaccinated or vaccine refusers	Positive/unknown	_ **	HBIG x1	Complete vaccination	Yes
	Negative	_	None	Complete vaccination	Yes

Abbreviations: HCP – Healthcare Personnel; HBsAg – Hepatitis B surface antigen; anti-HBs – antibody to Hepatitis B surface antigen; HBIG – Hepatitis B immune globulin.

* HBIG should be administered intramuscularly as soon as possible after exposure when indicated. The effectiveness of HBIG when administered ›7 days after percutaneous, mucosal, or nonintact skin exposures is unknown. HBIG dosage is 0.06 mL/kg.

† Should be performed 1-2 months after the last dose of the HepB vaccine series (and 4-6 months after administration of HBIG to avoid detection of passively administered anti-HBs) using a quantitative method that allows detection of the protective concentration of anti-HBs (≥10 mIU/mL)

§ A responder is defined as a person with anti-HBs ≥10 mIU/mL after ≥3 doses of HepB vaccine.

٩ A nonresponder is defined as a person with anti-HBs ‹10 mIU/mL after ≥6 doses of HepB vaccine.

** HCP who have anti-HBs ‹10 mIU/mL, or who are unvaccinated or incompletely vaccinated, and sustain an exposure to a source patient who is HBsAg positive or has unknown HBsAG status, should undergo baseline testing for HBV infection as soon as possible after exposure, and follow-up testing approximately 6 months later. Initial baseline tests consist of total anti-HBc; testing at approximately 6 months consists of HBsAG and total anti-HBc.

APPENDIX D: SAGE ANTISEPTIC BODY CLEANING

(Adopted from LRMC Policy)

Policy: The Sage Antiseptic Body Cleaning Washcloths will be used on all Intensive Care Unit OIF/OEF patients unless a patient declines or has any known sensitivities to ingredients.

Purpose: To reduce the risk of hospital associated infection by decreasing bacterial colonization that can cause skin infection.

Applicability: The Antiseptic Body Cleaning Washcloths policy is applicable to all healthcare workers assigned to provide bedside bathing to patients in the medical facility.

Responsibility: It is the responsibility of the Nursing Managers to ensure that this policy is implemented correctly and consistently.

Exclusion: Avoid facial area, open wounds, and areas of 2nd or 3rd degree burned skin.

PROCEDURE

1. **When the patient arrives to the unit first bathe patient with soap/water add 30 cc of hibiclens 4 % to the basin and bathe patient to remove all visible dirt.**

2. **Wait 6 hours after initial bath and bathe patient with Antiseptic Body Cleaning Washcloths once a day.**

3. **Warming the Antiseptic Body Cleaning Washcloths (if warmer not available)**
    a. Warm package in the dedicated microwave settings: 1000 watts for 30 seconds.
    b. Consult package for complete indications, ingredients, and warnings.

4. **Bathing a patient with antiseptic body cleaning washcloths**
    a. Wash hands prior to the procedure and don a pair of gloves and a gown.
    b. Explain the procedure to the patient.
    c. Ensure the patient has privacy. Have patient remove gown or assist in the removal as needed. Use a towel or sheet to cover the patient appropriately.
    d. Peel back the label on the package and test the temperature by touching the top washcloth. Remember, gloves diminish your sensitivity to heat. If temperature is acceptable, proceed to the next step.
    e. Remove #1 washcloth.
        i. Test washcloth to back of patient's hand or inside wrist/forearm area.
        ii. Ask patient if the temperature is acceptable.
            - If acceptable, proceed with next step.
            - If NOT acceptable, STOP the procedure until temperature is acceptable to the patient.
            - Continue to monitor patient's comfort level with the temperature as the bath progresses.

Wash Cloth Sequence

Cloth	Areas*	Action
***DO NOT USE ON FACE**		
1	Both arms and chest	Discard
2	Perineum	Discard
3	Right Leg	Discard
4	Left Leg	Discard
5	Back	Discard
6	Buttocks	Discard

f. For incontinence care, clean using terrycloth towels, soap and water, followed by wiping the involved skin with as many chlorhexidine cloths as necessary.

g. Apply clean gown, reposition and cover the patient.

h. Discard all disposables as general waste.

NOTE: *Do not flush Antiseptic Body Cleaning Washcloths in the toilet!*

i. Document procedure in progress notes.

5. What To Do

a. Do use chlorhexidine (CHG) baths in place of daily bathing with soap and water.

b. Do massage firmly into skin to bind skin proteins and prevent bacteria for 24 hours.

c. Only use CHG-compatible lotions.

d. Use over superficial wounds, including stages 1 and 2 decubitus ulcers.

6. What NOT To Do

a. Do NOT use above jaw line.

b. Do NOT rinse or wipe off CHG. Let air dry.

c. Do NOT flush CHG cloths (discard in trash, not toilet or commode)

d. Do NOT include patients who are allergic to CHG.

REFERENCES

1. Michael O. Vermon, DrPH; Mary K. Hayden, MD et al. Chlorhexidine Gluconate to Cleanse Patients in a Medical Intensive Care Unit. The effectiveness of Source Control to Reduce the Bioburden of Vancomycin-Resistant Enterococci. Archives of Internal Medicine. Volume 166, February 13, 2006.

2. Internet Citation: Universal ICU Decolonization: An Enhanced Protocol. September 2013. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/systems/hospital/universal_icu_decolonization/index.html

APPENDIX E: 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.