

GUIDELINES TO PREVENT INFECTION IN COMBAT-RELATED INJURIES

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Supersedes:	Guidelines to Prevent Infection in Combat-Related Injuries, 1 Mar 2010		
<input type="checkbox"/> Minor Changes (<i>or</i>)		<input checked="" type="checkbox"/> Changes are substantial and require a thorough reading of this CPG (<i>or</i>)	
<input type="checkbox"/> Significant Changes			

1. **Goal.** To provide rationale and guidance for the prevention of infection after combat-related injuries.
2. **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. Challenges unique to the theater include significant patient transfers between hospitals and teams, the challenging environment of theater medical care, and the difficulties arising during long distance aeromedical evacuation. High rates of infection with multi-drug resistant organisms have been reported in theater. Infection prevention and control practices must be able to effectively adapt to these challenges and support the prevention of spread of infection.
3. **Guidelines.**
 - a. Follow the general infection prevention and control practices noted below to the extent allowed by the operational environment to reduce nosocomial infections.

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

- b. Standard Precautions: CANNOT BE OVER-EMPHASIZED
 - 1) Hand washing: Use soap and water or alcohol-based sanitizer before and after each patient contact, even if gloves were worn. Monitor all personnel; ensure compliance. Of note, alcohol-based sanitizers are NOT effective against *C. difficile* spores.
 - 2) Gloves: Use when contact with non-intact skin or body fluids is anticipated. Gloves should be used for ALL dressing changes.
 - 3) Gowns: Use when changing dressings on open wounds or performing invasive procedures.
 - 4) Masks and eye protection: Use based on anticipated exposure.
 - 5) Contact Precautions: Gloves and gowns should be worn with all patients suspected or know to have multidrug-resistant organism (MDRO) colonization or infection or *C. difficile*-associated diarrhea. 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).

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- 6) Cohorting: Separate long-term (>72 hours) and short term (<72 hour stay) patients when possible to reduce the risk of cross-contamination with resistant hospital-associated organisms. Patients with known or suspected MDRO colonization or infection (i.e., C. difficile, MRSA), should be separated from the non-infected patients.
- 7) Skin care for patients: ICU patients should undergo a daily SAGE "bath". The reduction of skin flora with antimicrobial agents such as the chlorhexidine SAGE skin wipes in one theater ICU was associated with a 25% decrease in Acinetobacter skin colonization of arriving patients to Germany. (See [APPENDIX A](#), Sage Antiseptic Body Cleaning.)
- 8) Antibiotic Control:
 - a) Avoid unnecessary empiric use of broad spectrum antibiotics.
 - b) When available, use local antibiogram to guide empiric therapy.
 - c) 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.
- c. Care of combat-injured personal should be based on level (Role) of care (See [Table 1](#)).
 - 1) Infection Control questions can be fielded by the following established AKO teleconsultation program (infect.cntnl.consult@us.army.mil).
 - 2) Ideally, Level II and III facilities should have a designated Infection Control Officer (ICO) as an additional duty or a full-time position if supported by current manning levels. The "Infection Control in the Deployed Setting" course (AMEDD C&S course 6A-F22) is currently being conducted at Fort Sam Houston, Texas and is recommended for anyone who is/will be designated as the unit ICO. HQDA EXORD 328-10, "Infection Control Officers in Deploying Combat Support Hospitals," 27Sep10 requires deployed combat support hospitals (CSH) to identify and ensure adequate training of an ICO for each deployed location of the CSH.
 - 3) 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. (See [APPENDIX A](#).)

4. Performance Improvement (PI) Monitoring.

- a. Intent (Expected Outcomes).
 - 1) All patients with skin, soft tissue, with open fractures, exposed bone or open joint injuries, Cefazolin 2 gm IV q6-8 hrs or Clindamycin 600 mg IV q 8h will be initiated at the first level of surgical care.
 - 2) All patients with penetrating abdominal injuries with suspected/known hollow viscus injury, soilage and rectal/perineal Cefazolin 2 gm IV q6-8 hrs or Clindamycin 600 mg IV q 8h will be initiated at the first level of surgical care.

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- 3) All patients with penetrating brain injury, Cefazolin 2 gm IV q6-8 hrs or Clindamycin 600 mg IV q 8h will be initiated at the first level of surgical care.
- 4) All patients admitted to the ICU will have Sage antiseptic body cleaning daily
- b. Performance/Adherence Measures.
 - 1) Cefazolin 2 gm IV or Clindamycin 600 mg IV was initiated at the first level of surgical care on patients with skin, soft tissue, open fractures, exposed bone or open joint injuries.
 - 2) Cefazolin 2 gm IV or Clindamycin 600 mg IV was initiated at the first level 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 or Clindamycin 600 mg IV was initiated at the first level of surgical care on patients with penetrating brain injury.
 - 4) Sage antiseptic body cleaning was performed on ICU patient daily.
- c. Data Source.
 - 1) Patient Record
 - 2) Joint Theater Trauma Registry (JTTR)
- d. System Reporting & Frequency.

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

The system review and data analysis will be performed by the Joint Theater Trauma System (JTTS) Director, JTTS Program Manager, and the Joint Trauma System (JTS) Performance Improvement Branch.

5. **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.
 - a. All Health Care Providers will:
 - 1) Become familiar with the guidelines for infection prevention and control.
 - 2) Use recommended standard precautions
 - 3) Provide feedback on these guidelines and suggestions for changes to the CPG to the JTS.

References.

1. Hospenthal DR, Murray CK, Andersen RC, Bell RB, Calhoun JH, Cancio LC, Cho JM, Chung KK, Clasper JC, Colyer MH, Conger NG, Costanzo GP, Crouch HK, Curry TK, D'Avignon LC, Dorlac WC, Dunne JR, Eastridge BJ, Ficke JR, Fleming ME, Forgione MA, Green AD, Hale RG, Hayes DK, Holcomb JB, Hsu JR, Kester KE, Martin GJ, Moores LE, Obrebsky WT, Petersen K, Renz EM, Saffle JR, Solomkin JS, Sutter DE, Tribble DR,

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Wenke JC, Whitman TJ, Wiesen AR, Wortmann GW. Guidelines for the prevention of infections associated with combat-related injuries: 2011 update. J Trauma 2011;71:S210-S234.

2. Hospenthal DR, Green AD, Crouch HK, English JF, Pool J, Yun HC, Murray CK, and the Prevention of Combat-related Infections Guidelines Panel. Infection prevention and control in deployed military medical treatment facilities. J Trauma 2011;71:S290-S298.
3. Hospenthal DR, Crouch HK, English JF, Leach F, Pool J, Conger NG, Whitman TJ, Wortmann GW, Murray CK, Cordts PR, Gamble WB. Response to infection control challenges in the deployed setting: Operations Iraqi and Enduring Freedom. J Trauma 2010;69:S94-S101.

Approved by CENTCOM JTTS Director,
JTS Director and CENTCOM SG

Opinions, interpretations, conclusions, and recommendations are those of the authors and are not necessarily endorsed by the Services or DoD.

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Table 1. Recommendations to prevent infections associated with combat-related injuries based on level of care

Level of Care*	Care Category	Recommendations
Role 1/Level I (Prehospital)	Initial care in the field	<ul style="list-style-type: none">• Bandage wounds with sterile dressings (avoid pressure over eye wounds)• Stabilize fractures• Transfer to surgical support as soon as feasible
	Post-injury antimicrobials	<ul style="list-style-type: none">• Provide single dose point of injury antimicrobials (Table 2) if evacuation is delayed or expected to be delayed
Role 1/Level I and Role 2/Level II without surgical support (IIa)	Post-injury antimicrobials	<ul style="list-style-type: none">• Provide intravenous antimicrobials for open wounds (Table 2) as soon as possible (within 3 hours)• Provide tetanus toxoid and immune globulin as appropriate• Gram negative coverage with aminoglycoside or fluoroquinolone <u>not</u> recommended• Addition of penicillin to prevent clostridial gangrene or streptococcal infection is <u>not</u> recommended• Redose antimicrobials if large volume blood product resuscitation• Use only topical antimicrobials for burns
	Debridement and irrigation	<ul style="list-style-type: none">• 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 (Level IIb or III)• Do not attempt to remove retained deep soft tissue fragments if criteria met.† Provide cefazolin 2 gm IV x 1 dose

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Table 1. Recommendations to prevent infections associated with combat-related injuries based on level of care

Level of Care*	Care Category	Recommendations
Role 2/Level II with surgical support (IIb) and Role 3/Level III	Post-injury antimicrobials	<ul style="list-style-type: none">• Provide intravenous antimicrobials (Table 2) 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• Antimicrobial beads or pouches may be used• Provide postsplenectomy immunizations if indicated
	Debridement and irrigation	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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

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Table 1. Recommendations to prevent infections associated with combat-related injuries based on level of care

Level of Care*	Care Category	Recommendations
Role 4/Level IV	Post-injury antimicrobials	<ul style="list-style-type: none">• Complete course of post-injury antimicrobials (Table 2)• Antimicrobial beads or pouches may be used• Provide postsplenectomy immunizations if indicated
	Debridement and irrigation	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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

IV, intravenous; PSI, pounds per square inch

*Role of care, level of care, and echelon of care are considered synonymous with role currently the preferred US military term. Definitions of role/level/echelon of care: **Role 1** - self-aid, buddy aid, combat lifesaver, and combat medic/corpsman care at the point of injury; physician/physician assistant care at battalion aid station (BAS, US Army (USA)) or shock trauma platoon (US Marine Corps (USMC)); no patient holding capacity; **Role 2** - medical company (includes forward support medical company, main support medical company, and area support medical company in USA) or expeditionary medical support (EMEDS, US Air

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Force (USAF)); 72 hour patient holding capacity, basic blood transfusion, radiography and laboratory support. May be supplemented with surgical assets (2b) (forward surgical team, USA; mobile field surgical team, USAF; forward resuscitative surgical system, USMC); **Role 3** - combat support hospital (CSH, USA), Air Force theater hospital (AFTH, USAF), or casualty receiving ships (US Navy (USN)); full inpatient capacity with intensive care units and operating rooms; **Role 4** - regional hospital (Landstuhl Regional Medical Center, Germany) or USNS hospital ships (USN), typically outside of the combat zone; general and specialized inpatient medical and surgical care; **Role 5** - care facilities within US, typically tertiary care medical centers

†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

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Table 2. 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 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
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

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Table 2. Post-injury antimicrobial agent selection and duration based upon injury pattern*

INJURY	PREFERRED AGENT(S)	ALTERNATE AGENT(S)	DURATION
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 leak is closed, whichever is longer
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 fluorescein staining)
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

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Table 2. Post-injury antimicrobial agent selection and duration based upon injury pattern*

INJURY	PREFERRED AGENT(S)	ALTERNATE AGENT(S)	DURATION
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

IV, intravenous; PO, orally; IM, intramuscularly; TID, three times daily; QID, four times daily; PRN, as needed; CSF, cerebrospinal fluid

*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.

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†Cefazolin may be dosed based on body mass: 1 gram if weight \leq 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 Tactical Combat Casualty Care Committee.

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APPENDIX A

SAGE ANTISEPTIC BODY CLEANING

(Adopted from LRMC Policy)

1. **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.
2. **Purpose.** To reduce the risk of hospital associated infection by decreasing bacterial colonization that can cause skin infection.
3. **Applicability.** The Antiseptic Body Cleaning Washcloths policy is applicable to all healthcare workers assigned to provide bedside bathing to patients in the medical facility.
4. **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.

5. 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.
 - (1) Test washcloth to back of patient's hand or inside wrist/forearm area.
 - (2) Ask patient if the temperature is acceptable.
 - (a) If acceptable, proceed with next step.
 - (b) **If NOT** acceptable, **STOP** the procedure until temperature is acceptable to the patient.

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- (c) Continue to monitor patient's comfort level with the temperature as the bath progresses.

Key Points

- Follow the bathing procedure in sequential order, shown in the following table, while gently rubbing in a back and forth motion on the skin. This reduces the chance of cross-contamination by providing a clean cloth for separate areas of the body, while maximizing appropriate use of the product to prevent waste.
 - Use caution around dressings and intravascular lines.
-

Wash Cloth Sequence

Wash Cloths	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.

Do not flush Antiseptic Body Cleaning Washcloths in the toilet!

- i. Document procedure in progress notes.

6. References.

- ¹ Michael O. Vernon, 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 Author: Robert Garcia, Enhanced Epidemiology © 2004 Enhanced Epidemiology
- ³ Modified: Guilene Derisma RN BSN, LRMC Infection Prevention and Control Department October 2006

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APPENDIX B

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

1. 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.

2. 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.

3. 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.

4. Additional Procedures.

- a. 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.
- b. 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.
- c. 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.