Nursing Intervention in Prolonged Field Care (CPG ID: 70)

The intent of this guideline is to provide medical professionals who encounter extended casualty evacuation times in austere environments the evidence-based guidance for nursing interventions necessary to improve patient outcome.

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

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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 a higher level of care is not immediately possible. A provider of PFC first must be an expert in TCCC. The intent of this guideline is to provide medical professionals who encounter extended casualty evacuation times in austere environments the evidence-based guidance for nursing interventions necessary to improve patient outcomes. Recommendations follow a “minimum, better, best” format that provides alternate or improvised methods when optimal hospital options are unavailable.

Basic activities of daily living become impaired or nonexistent depending on the severity of wounds. Simple tasks such as brushing teeth, breathing, drinking, coughing, moving extremities, and turning become impossible for an injured or unconscious patient. Thus, the patient requires regular assessments and nursing interventions to monitor their condition and prevent the development of complications.

Nursing interventions may not appear important to the medical professionals caring for a patient, but such interventions greatly reduce the possibility of complications such as deep vein thrombosis (DVT), pneumonia, pressure sores, wound infection, and urinary tract infection. Critically ill and injured casualties are at high risk for complications that can lead to adverse outcomes such as increased disability and death. Nursing care is a core principle of PFC to reduce the risk of preventable complications and can be provided without costly or burdensome equipment.

Using a nursing care checklist assists with developing a schedule for performing appropriate assessments and interventions.

Cross-training all team members on these interventions prior to deployment will lessen the demand on the medic, especially when caring for more than one patient.

ASSESSMENT

After initial stabilization, every patient requires regular assessments. Document results on a PFC flowsheet (Appendix A) and monitor trends to identify signs of decompensation. Initiate nursing interventions early to prevent further harm.

- **Minimum**: Manual blood pressure (BP) cuff, stethoscope, thermometer, pulse oximeter, glucometer, urinary catheter, flashlight, watch
- **Better**: Digital, wrist BP cuff
- **Best**: Portable monitor providing continuous vital signs display and capnography capability, glucometer

**VITAL SIGNS**

- Obtain BP, heart rate, respiratory rate, temperature, oxygen saturation, end-tidal CO2 (when available), Glasgow Coma Scale score, pain score, and peripheral pulses.
- Inspect and Monitor Tubes
- Examine all tubes (e.g., endotracheal tube [ETT] or cricothyroid tube, nasogastric [NG] tube, intravenous [IV] line, chest tube, urinary catheter) for correct placement and appropriate function, and ensure they are secured properly.
High-volume burn resuscitation results in global edema and ETT/cricothyroid tube position must be closely monitored. Securing tubes with circumferential ties is required when burned skin weeps fluid.

**Caution:** NG tubes should only be placed when radiographic or intraoperative confirmation is available, or when the benefit outweighs the risk. Routine NG placement for unconscious or intubated patients is not recommended in austere environments.

### MONITOR INPUT AND OUTPUT

- Check IV drip rate or give oral fluids as needed.
- Ensure adult patients void an average of 30–50mL/h, or 100–200mL/h if exhibiting signs of rhabdomyolysis.
- Check drainage from wounds and tubes.

### INSPECT SKIN AND SPLINTS

Examine skin, including nares and mouth, for changes and ensure splints are fitted properly and pulses are present below splint. Monitor for allergic reactions to tape, developing erythema, excessive dryness, pressure indenting the skin, cracking, or breakdown.

**Nursing Interventions**

Applicable nursing interventions are identified and adjusted after every assessment is completed. Interventions are individualized on the basis of each patient’s illness or injury. Different interventions may be required depending on a patient’s level of consciousness, and a previously conscious patient may become unconscious. Positioning a patient in a comfortable position with head and injured extremities elevated is a basic and important intervention; one positioning method is to use a trifold lawn chair, or similar improvised support, to maintain elevation of the patient’s head and legs as needed.

The PFC nursing care plan (Appendix B) is a chart of nursing interventions with recommended intervals that the primary medical professional can fill out for the team to continue caring for a patient while the primary medical professional rests. Before deployment, medical professionals can use this tool to train teammates on nursing interventions so they can assist with patient care. Appendix C is an example of a completed chart with instructions.

### PLAN AND DOCUMENT NURSING INTERVENTIONS

**Minimum:** Nursing care checklist portion of the PFC flowsheet (Appendix A)

**Best:** PFC nursing care plan (Appendix B)

### FLUSH SALINE LOCKS

- **Minimum:** Empty 10mL syringe, needle, bag of normal saline (NS), alcohol pads
- **Best:** Prefilled 10mL NS syringes, needle (if applicable), alcohol pads

At least every 8 hours, flush saline locks with 10mL of NS.

1. Gather equipment.
2. Clean access port with alcohol pad.

3. Take prefilled 10mL syringe of NS and needle (if applicable) or attach syringe to port.

4. With constant pressure, inject NS into port to flush catheter to ensure line remains open.

5. If resistance is met, gently use pulsating pressure on end of syringe until NS flows freely.

6. Carefully observe the IV site for swelling or pain. Start a new IV if swelling or pain occurs.

7. Detach syringe and dispose; place needle in sharps container (if applicable).

If prefilled syringes are unavailable, draw up NS into unused, empty syringe from a bag of NS, then follow steps above.

**SUCTION ADVANCED AIRWAY**

- **Minimum:** Manual suction device or improvised suction device, such as a 25cm length portion of IV tubing connected to a 60mL syringe
- **Better:** Open suction tube, suction machine
- **Best:** Closed inline suction tube, suction machine

Perform airway suction only when needed, using sterile technique for advanced airways or clean technique for the mouth and throat. Humidify the air using a humidifier, moist gauze, or by boiling a pot of water.

1. Gather necessary equipment.

2. Ensure patient’s head is elevated.

3. Perform hand hygiene.

4. Place a clean towel under patient’s chin.

5. Don eye protection.


7. Perform appropriate suctioning with available equipment (ensuring suction is performed while withdrawing the catheter for no longer than 10 seconds at a time).

8. Allow at least 30 seconds before repeating suctioning, if needed.

9. Perform oral care as needed but at least every 4 hours.

**REPOSITION AND CHECK PADDING**

- **Minimum:** Extra clothing, soft items
- **Best:** Pillows, blankets, towels

Identify patients who cannot reposition themselves. Reposition patient and check padding at least every 2 hours. To prevent ischemic tissue injury and the formation of pressure sores, frequent movement of the patient
is necessary. Relieving pressure from superficial capillaries allows the skin to recover from the temporary ischemia.

1. Roll the patient onto one side (if concerned about spine injury, carefully log roll while maintaining spine stabilization).
2. Have an assistant remove pillows, blankets, or soft items being used for positioning and gently guide the patient down onto their back.
3. Using the same procedure, have assistant gently roll patient in the opposite direction.
4. Place pillows, blankets, or soft items under patient for positioning and have assistant guide patient back down.
5. Ensure the patient’s ankles, knees, and elbows are not resting on top of each other and arms are not resting on the abdomen, by placing padding between them.
6. Ensure the patient’s head and neck are in line with the spine.
7. Use additional padding items for bony prominences on hard surfaces.
8. Ensure creases and bumps in clothing, sheets, and blankets are smoothed out under the patient.
9. Be aware of the location of external equipment such as Foley catheter, IV tubing, and ventilator tubing to prevent dislodging during repositioning.
10. If any areas of nonblanchable erythema are noted, outline area with marker and prevent placing patient on the affected area until it recovers.
11. Burned and injured extremities should be slightly elevated and slightly flexed to optimize venous return and maintain adequate peripheral pulses.

**ORAL CARE**

- **Minimum:** Gloves, gauze, lip moisturizer
- **Better:** Mouth wash, mouth moisturizer, gloves, gauze, tongue depressor, tape, lip moisturizer
- **Best:** Oral cleansing and suction system, lip moisturizer

Good oral hygiene reduces oropharyngeal colonization, which is associated with ventilator-acquired pneumonia. Patients who are conscious and able should brush their teeth a minimum of every 12 hours. For unconscious patients, perform oral care at least every 4 hours. Ensure some type of suction is available (e.g., manual suction device, syringe with IV tubing).

- To keep the patient’s mouth open, make a padded tongue depressor by wrapping gauze around one end of it and securing with tape.
- If available, use swab and chlorhexidine gluconate rinse from oral cleansing and suction system. Make sure not to oversaturate the swab to avoid aspiration of fluid. Clean teeth and oral cavity for approximately 1 minute. If the system is unavailable, use a 2×2 gauze wrapped around pointed gloved finger and hold firmly with the rest of hand. Moisten the gauze with mouthwash (ensuring not to oversaturate) and gently clean the teeth and mouth cavity. Multiple gauze swabs may be needed depending on the level of contamination in the mouth. Follow up with mouth moisturizer if available.
• Apply lip moisturizer.

**FOLEY CATHETER CARE**

**Minimum**: Basin, warm water, nonirritating soap, linen saver pad, towels

Perform Foley care once a day or as needed for excessive drainage.

1. Wash hands thoroughly with soap and water, apply gloves, and place linen-saver pad or dry towels under patient.

2. Using mild soap and water, clean genital area.

3. For male patient: retract the foreskin, if needed, and clean the area, including the penis.

4. For female patient: separate the labia, and clean the area from front to back.

5. Clean urethra (urinary opening), where the catheter enters the body.

6. Clean the catheter from where it enters the body and then down, away from urethra. Hold the catheter at the point it enters the patient so that tension is not placed on it.

7. Rinse the area well, dry gently, and replace linen-saver pad under patient.

**WASH AND DRY SKIN, APPLY LOTION**

- **Minimum**: Water, gauze, or well rinsed “baby” wipes

- **Better**: Bowl, baby or mild wash, unscented lotion, 2×2 and 4×4 gauze pads, gloves, tongue depressor, tape

- **Best**: Basin, linen-saver pads, disposable wash cloths, compression stockings, trifold lawn chair, nasal mist, pillows, padding, urine test strips, toothbrush and toothpaste, oral cleansing and suctioning kit, tongue depressor, gauze, tape

At least once per day or as needed, wash, dry, and apply lotion to skin. Cleaning the skin is an opportunity to evaluate additional injuries and visualize any new areas of erythema.

1. Prepare basin or bowl with warm water and a small amount of baby wash.

2. Obtain multiple 4×4 gauze pads or clean washcloths and place in water

3. Expose body part to be washed, keeping the rest of the patient covered, and place linen-saver pad under the area to absorb water.

4. Take one gauze or washcloth out of the basin and wring out excess water. Wash skin a little bit at a time, throwing away used gauze or washcloths until clean. DO NOT place contaminated gauze or washcloths back into basin or bowl.

5. Wash face first and genitalia last. (Cleaning genitalia is detailed under Foley care.)

6. Ensure the skin is thoroughly dried, including all skin folds, and apply lotion.
**Caution:** If baby wipes or skin wipes are used to wash the skin, the wipes should be thoroughly rinsed with water first, because most contain alcohol and residues that can irritate the skin.

**CHANGE INTRAVENOUS BAG AND TUBING**

Every 72 hours if possible, replace infusing bag of fluids and tubing with new equipment. If fluids infusing at a to-keep-open rate and a bag has been up for 72 hours, ensure a fresh bag and tubing are hung and marked with new time and date.

**CHECK BLOOD GLUCOSE LEVEL**

If available, check blood glucose level (BGL) every 8 hours or more frequently as dictated by patient status. A low BGL (less than 80 mg/dL) must be treated immediately with oral sugar or juice or IV glucose. A high BGL (greater than 200 mg/dL) is less dangerous than low glucose, but may be treated if the capability is available.

**CHANGE TAPE**

1. Once a day, change tape on patient’s skin (except for peripheral IV sites, which can be changed every 72 hours to avoid exposing puncture site to contaminants). Daily tape changes decrease the potential for skin breakdown. This intervention may be accomplished after patient’s daily wash.

2. For ETT or cricothyroid tube, gently remove tape. If tape is strongly adhered, use an alcohol swab to moisten the top of the tape. As the tape is lifted back, use the alcohol swab and gently rub across the skin at the junction with tape to loosen, ensuring not to dislodge tube placement.

3. For ETT, after tape is removed, gently move the tube to the opposite side of the mouth, again ensuring not to dislodge it or rest on lip.

4. Apply new tape to a section of skin next to where tape was previously removed. To give skin a break, do not place over the same area.

**LOWER EXTREMITY MASSAGE, DVT PREVENTION**

If available, compression stockings, or elastic bandages (wrapped starting from the toes upward) should be placed on immobile or unconscious patients, ensuring toes remain exposed for capillary refill assessment. Patients who are conscious and able may perform the following exercises, completing 10 repetitions of each exercise every hour while awake. This may be done in burned extremities or in the presence of open wounds, but should be avoided when fractures or severe extremity injuries are present.

- **Foot pumps.** Have the patient stretch toes up and back, flexing feet, and hold for a few seconds. Then point toes and hold before repeating.

- **Ankle circles.** Have patient raise both feet and trace a circle or each letter of the alphabet with their toes

- **Leg raises.** With left leg straight, have the patient raise foot off the bed or floor, then lower. Repeat with right leg. Alternatively, slowly have patient lift left knee up to chest, then bring foot back to the bed or floor; repeat with right leg.

- **Thigh stretches.** While patient is lying on their back with straight legs, have them raise one leg to 90°. Instruct patient to pull the leg gently toward the head and hold for up to 30 seconds. Slowly bring leg back down to a flat position, and repeat with other leg.
Shoulder rolls. Although developing a clot in the upper body is not likely, blood still needs to keep flowing. Have the patient raise shoulders and circle them back and down five times. Then reverse direction for five more repetitions.

Perform DVT prevention for unconscious patients at least every 2 hours.

- **Ankle plantarflexion-dorsiflexion.** Hold the ankle and heel of one foot and alternately bend the foot forward into plantarflexion and then push the foot upward into dorsiflexion. Hold each position for 5–10 seconds.

- **Lower extremity massage.** Using both hands and starting at the ankle, apply consistent pressure, massaging the leg in an upward motion through the thigh. (Items such as a plastic bottle may be used to roll the skin toward the head.) Ensure deep pressure is avoided when massaging behind the knee or over bony prominences. Alternate legs (to simulate walking) for five times on each leg.

**RANGE OF MOTION EXERCISES**

At least every 8 hours, perform range of motion exercises on all movable joints such as ankles, knees, hips, wrists, fingers, elbows, and shoulders, except where joint mobility is restricted by injury.

**TURN, COUGH, DEEP BREATHE**

1. For a conscious patient, encourage them to turn, cough, and take deep breaths to prevent atelectasis.

2. Instruct the patient to breathe in deeply and slowly through their nose, expanding lower rib cage, and letting abdomen move forward.

3. Hold for a count of 3 to 5.

4. Instruct patient to breathe out slowly and completely through pursed lips.

5. Have patient rest and repeat 10 times every hour.

6. Code Brown: Unconscious Patient Bowel Movement Recommend leaving unconscious patients unclothed from the waist down and covered with a sheet or blanket, with linen-saver pad or towel under the buttocks for easy bowel movement clean up. During assessment, check if the unconscious patient has had a bowel movement and clean if needed.

7. Gather a basin with warm, soapy water; rolled linen-saver pad or towel; gloves; and washcloths.

8. Have assistant log roll the patient toward them.

9. Start cleaning from top of patient toward soiled linen-saver pad or towel, obtain a new washcloth when current one is completely used.

10. When patient is cleaned as far as can be reached on that side, roll soiled pad or towel on itself to contain fecal matter and start to unroll new linen-saver pad, keeping clean one under dirty one.

11. Gently log roll patient to the other side and have assistant finish cleaning soiled area; dry completely.

12. Discard soiled pad or towel and finish unrolling clean pad, ensuring there are no folds under patient.

13. Gently roll patient to previous position of comfort and cover.
14. For nursing assessment and intervention packing list, see Appendix D.

15. Hospital clinical rotations are an excellent opportunity to learn and practice nursing assessments and interventions. The recommended nursing skills checklist for clinical rotations is included in Appendix E.

DATA SOURCES

- Patient Record
- Department of Defense Trauma Registry (DoDTR)
- Morbidity and Mortality Conference Reports
| CPG ID: 70 | Guideline Only/Not a Substitute for Clinical Judgment |

**Nursing Interventions in Prolonged Field Care**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Description</th>
<th>Notes</th>
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<tbody>
<tr>
<td>IV Therapy</td>
<td>Administration of intravenous fluids, medications, or blood products</td>
<td>Must ensure patency of IV line</td>
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<tr>
<td>Oxygen Therapy</td>
<td>Administration of supplemental oxygen</td>
<td>Monitor patient's oxygen saturation levels</td>
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<tr>
<td>Nutrition Support</td>
<td>Feeding tubes, enteral nutrition, or total parenteral nutrition</td>
<td>Consider patient's nutritional needs and tolerance</td>
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<tr>
<td>Pain Management</td>
<td>Medications, physical therapy, or behavioral interventions</td>
<td>Evaluate patient's pain levels and adjust interventions accordingly</td>
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<tr>
<td>Skin Care</td>
<td>Bathing, moisturizing, or wound care</td>
<td>Monitor for skin integrity issues</td>
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<tr>
<td>Catheter Care</td>
<td>Urinary or fecal catheters</td>
<td>Monitor for infection risk</td>
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<tr>
<td>Monitoring Equipment</td>
<td>Blood pressure, heart rate, or oxygen saturation monitors</td>
<td>Ensure proper calibration and function</td>
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</tbody>
</table>

**Special Considerations**

- **Patient Education**: Teach patients about their condition, treatment options, and self-care practices.
- **Interdisciplinary Collaboration**: Ensure effective communication and coordination among healthcare providers.
- **Patient Safety**: Implement safety protocols to prevent errors and incidents.

*Note: This guideline is not intended to replace clinical judgment and should be used in conjunction with professional medical advice.*
### APPENDIX B: PFC NURSING CARE 12/24 HR - BLANK

<table>
<thead>
<tr>
<th>Extra</th>
<th>Gastrointestinal</th>
<th>Integumentary</th>
<th>Respiratory</th>
<th>MEE/IT</th>
<th>Pains/Stimulation</th>
<th>IN/OUTS</th>
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<td>Extra Stuff</td>
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<td>Intravenous</td>
<td>Respiratory</td>
<td>H2ENT</td>
<td>Pain/Dysphagia</td>
<td>In/Outs</td>
<td>Vital's</td>
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*Guideline Only/Not a Substitute for Clinical Judgment*
## APPENDIX C: PFC NURSING CARE PLAN - EXAMPLE

<table>
<thead>
<tr>
<th>Extra Stuff</th>
<th>Gastrointestinal</th>
<th>Integumentary</th>
<th>Respiratory</th>
<th>NS/INF</th>
<th>Pain/Sedation</th>
<th>In/Outs</th>
<th>Vitals</th>
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*Guideline Only/Not a Substitute for Clinical Judgment*
APPENDIX D: ASSESSMENT AND INTERVENTION PACKING LIST

The following list incorporates equipment categorized as “Best” although item substitutions categorized as “Minimum” may be described throughout performance steps.

☐ Portable Monitor
☐ Blood Pressure Cuff/Stethoscope/pulse oximeter
☐ Gloves
☐ Thermometer
☐ Urinary catheter
☐ Linen-saver pads
☐ Watch
☐ Oral Cleansing and Suctioning Kit/Toothbrush/Toothpaste/Mouthwash/Tongue depressor
☐ Lip balm
☐ Nasal mist
☐ Baby/mild wash
☐ Unscented lotion
☐ Compression stockings
☐ Pillows/Blankets/HPMK/Padding
☐ Basin/Bowl
☐ Suction device
☐ Tri-fold lawn chair
☐ Flashlight or headlamp
☐ Syringes (various sizes)
☐ Skin marker
☐ Gauze pads (2x2, 4x4)/Washcloths
☐ Glucometer
☐ Medical tape
☐ Urine test trips
☐ Saline flushes
## APPENDIX E: RECOMMEND NURSING SKILLS CHECKLIST FOR CLINICAL ROTATION

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<thead>
<tr>
<th>Perform and document physical exam</th>
<th>Apply eye ointment/drops</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perform vital sign monitoring</td>
<td>Brush teeth</td>
</tr>
<tr>
<td>Radial, DP/PT pulse check: manually/Doppler probe</td>
<td>Change all tape</td>
</tr>
<tr>
<td>Perform finger stick blood sugar</td>
<td>Adjust ventilator settings: understand FiO2, TV, PS, PEEP, etc.</td>
</tr>
<tr>
<td>Perform phlebotomy</td>
<td>Auscultate lungs</td>
</tr>
<tr>
<td>Manually titrate IV fluid drip rates</td>
<td>Measure compartment pressures (extremities, abdominal)</td>
</tr>
<tr>
<td>Monitor hourly urine output</td>
<td>Perform wound care (trauma, burn)</td>
</tr>
<tr>
<td>Perform US dipstick</td>
<td>Irrigate wounds</td>
</tr>
<tr>
<td>Measure gastric residual</td>
<td>Debride wounds</td>
</tr>
<tr>
<td>Insert Foley; perform Foley care</td>
<td>Auscultate and palpate abdomen</td>
</tr>
<tr>
<td>Flush PRN IV locks</td>
<td>Provide appropriate nutrition</td>
</tr>
<tr>
<td>Start peripheral IV</td>
<td>Perform escharotomy (animal lab, simulation)</td>
</tr>
<tr>
<td>Administer IV/oral medications</td>
<td>Insert IO (simulation: sternum, humerus, tibia)</td>
</tr>
<tr>
<td>Monitor GCS/pain (1 – 10 or nonverbal pain scale)/sedation levels (RASS scale)</td>
<td>Perform neuro exam</td>
</tr>
<tr>
<td>Effectively titrate analgesics</td>
<td>Calculate total burn size (Rule of nines, Lund-Brower)</td>
</tr>
<tr>
<td>Effectively titrate sedatives/daily wake up for neuro evaluation</td>
<td>Calculate burn resuscitation: starting volume (Rule of 10’s), total volume (Ivy Index)</td>
</tr>
<tr>
<td>Insert OG/NG tube</td>
<td>Titrate burn resuscitation fluid to meet target urine output</td>
</tr>
<tr>
<td>Perform Cric (Trach) care</td>
<td>Perform ultrasound FAST exam</td>
</tr>
<tr>
<td>Endotracheal suctioning</td>
<td>Perform blood typing using Eldon Card</td>
</tr>
<tr>
<td>Perform oral suctioning</td>
<td>Perform blood donor screening procedure</td>
</tr>
<tr>
<td>Perform nasal care</td>
<td>Reduce/splint fractures (Simulation)</td>
</tr>
<tr>
<td>Perform oral care</td>
<td>Convert tourniquet (Simulation)</td>
</tr>
<tr>
<td>Apply lip balm</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX F: 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.