## JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE

# En Route Care (ERC) Patient Packaging

This guideline provides an overview of packaging a patient for en route care and presents a standardized approach in the preparation of patients for ERC transfer through the continuum of medical care.


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# En Route Combat Casualty Care Patient Packaging



## Preparation & Planning

### Sending Team

- Develop the 9-line/MIST
- Gather meds, personal items, ID, travel orders, documentation
- Complete time/resource intensive intervention prior to ERC arrival

### En Route Care Team

Review 9-line and MIST for:

- Number and criticality of casualties
- Tactical situation

On arrival:

- Assess the casualty using the MARCH acronym (Appendix B)
- "Do now" any immediate interventions
- "Take with" supplies & equipment needed for "What if" situations (Appendix C)
- Determine the amount of consumables/medications/O2 needed to cover 2-3x the transport time

## PEARLS for Packaging

- **A difficult airway on the ground will NOT be easy en route**
- Secure the airway and vent support prior to transport
- Decrease FiO2 requirements on the ground in controlled setting
- Assess ventilation/BVM compliance
- Roll casualty & investigate all junctional areas
- Time-saving measures pre-mission:
  - Pre-draw/pre-mix meds
  - Prime blood tubing
  - Pre-place needed supplies near casualty
- Early antibiotics
- Dedicate IV line for Meds with accessible port
- Solid baseline assessment with MARCH
- Separate securing straps for casualty and monitors
- Keep it simple!

### Packaging the Casualty-Appendix A

- Access to relevant interventions/view of monitors
- Monitors attached to litter device securely
- NO EQUIPMENT RESTING ON CASUALTY
- Casualty secured with min of 2 strap devices
- Tubing/wires secured with litter straps
- PPE: eyes/hearing/hypothermia
- Four-person litter team
- Ensure litter/sled is secured and re-assess after each movement

METRICS

Document:

- Packaging measures
- Clinical procedures completed prior to transport
- MIST report from initiating team to transport team

This information is pulled from the evidence-based JTS En Route Combat Casualty Care Patient Packaging Clinical Practice Guideline (CPG). JTS CPGs can be found at the JTS CPG website or the JTS Deployed Medicine site.

# BACKGROUND

Patient movement is the process which provides a continuum of care and coordinates the movement of patients from the site of injury or onset of disease, through successive roles of care, to and between medical treatment facilities (MTFs) that can meet the needs of the patient. Patients are moved only as far rearward as the tactical situation dictates and as clinical needs warrant. Prompt movement of patients to the required level of clinical care is essential to prevent morbidity and mortality. Each Service component has medical evacuation (MEDEVAC) or casualty evacuation (CASEVAC) capability to do so. Patient movement consists of three components:

- medical regulating
- patient evacuation
- en route care (ERC)

En Route Care (ERC) is defined in Joint Publication (JP) 1-02, Department of Defense (DoD) Dictionary of Military and Associated Terms and JP 4-02 as the continuation of the provision of care during movement (evacuation) between the health service support capabilities in the roles of care, without clinically compromising the patient's condition. ERC involves the provision of transitory medical care, patient holding, and staging capabilities during transport from the point of injury or onset of disease throughout the continuum of care.

To ensure the safe transport of casualties during evacuation to definitive care, patients must be adequately prepared for evacuation. The purpose of this Clinical Practice Guideline (CPG) is to provide a ready resource for those who are responsible for preparing a patient for en route care.

# PATIENT PREPARATION

The goal of ERC casualty preparation is to provide the continued level of medical support as the casualty is transported throughout the battlespace and differing roles of care. Considerations for planning during transport can be categorized into groups of concerns: 1)safety, 2) access, and 3) organization. When planning for any casualty transfer, **the transport team should prepare for 2-3 times longer transport time than initially projected (i.e. If the transport is anticipated to take 2 hours, plan for 4-6 hours).**

Transport safety includes the safety of both the casualty and the ERC team's interaction with the casualty. All casualties should be provided thermal regulation, visual protection, and auditory protection from the transport environment. Casualty preparation for transport can be divided into two phases: ground preparation and transport team preparation.

## GROUND PREPARATION

1. Prepare the patient for the transport team to arrive.
2. Sending facility develops the 9-Line casualty request and M.I.S.T. (Mechanism of injury, Injuries sustained, Signs/symptoms, Treatment given) report
3. Gather the casualty's medications, personal effects, identification, travel orders, and documentation.
4. Complete any time or resource intensive interventions prior to ERC team arrival to optimize transport requirements and minimize delays.

## TRANSPORT (ERC) TEAM PREPARATION

Consists of planning and execution phases.

### Planning Phase

This phase begins upon receipt of the 9-line medical evacuation request and M.I.S.T. report. Each aspect of the 9-Line request is important for the transport team, but **emphasis is placed on the number and criticality of casualties, as well as**

**the tactical situation.** Accuracy is key - as the incoming ERC team must ensure that the casualty load will not overwhelm their resources or capabilities. The ERC team's clear understanding will lead to their arrival with the correct resources and the patient disposition to the appropriate medical facility.

## Execution Phase

During this phase, time is of the essence. Upon arrival at the initiating facility, the ERC team should contact the provider requesting the evacuation. The goal is to decrease the amount of time spent preparing the patient and rapidly move to transport. The ERC team will assign tasks to ensure that each member is appropriately utilized. Tasks that should be completed by the team include receiving report, assessing the patient, validating the movement of the casualty, verifying correct packaging in preparation for departure, packaging the patient for transport, and development of the en route plan.

## 1. Report and Patient Assessment

The ERC team will guide the report and assessment process. The use of the MARCH acronym (Appendix B) can assist both the sending and transport teams in communicating the appropriate information in the least amount of time. Often the priorities of the sending team differ from those of the ERC team. The ERC team should receive report, ask questions pertinent to the status and transfer of the patient, and then provide an opportunity for the sending team to provide additional information. If hand off must occur in high ambient noise environments such as engines running on/off-load or helicopter hot-load sending, provider should point to each wound(especially areas of controlled or suspected hemorrhage) with confirmation of receiving team of wounds/injuries. Use of a communication device (such as the Atlantic Signal Tactical Medic Intercom) that allows sending and receiving team aircraft-side verbal communication is hugely beneficial and units/teams should coordinate this beforehand.

Once the report has been completed, an assessment will be performed to confirm findings and interventions. This assessment will develop the "Do Now" status of the casualty. **The "Do Now" criteria are the current MARCH findings from the report and the assessment that need immediate intervention to prepare for transport.** As each of the "Do Now" criteria are identified, secondary logistic supply needs and assessment needs are developed.

## 2. Validate the Movement of the Casualty

The findings of the ERC casualty assessment assist in the validation of the decision to transport the casualty. The JTS CPG on the Interfacility Transport of Casualties Between Theater MTFs gives clear guidance on the resuscitation goals that should be followed to identify when a casualty is safe to transfer. **If one or more of these goals is not met, a plan must be developed to optimize the casualty in accordance with resources and tactical situations.**

## 3. Verify Correct Packaging in Preparation for Departure

Once the casualty is validated for movement, **supply needs can be filed under the "Take With" portion of casualty transport planning.** The goal of this portion of the planning process is to **ask the "what if" question** for each of the casualty's interventions. This item list will include back-up support devices and batteries, dressing reinforcement supplies, next step interventions, medications for continued treatment, and documentation.

## 4. Packaging the Patient for Transport

Package the casualty to ensure safety of the casualty and team, access to all relevant interventions, and organization of resources. Monitors should be placed on the litter structure or attached to a litter device to ensure that **NO EQUIPMENT IS RESTING ON THE CASUALTY**, it is fully secure to the litter system, and that all team members have access to and can view the monitors. Securing devices, such as litter straps used for equipment, should not be used for the casualty. All casualties should be secured with a minimum of two strap style devices. It is also recommended that any tubing or wires be secured with litter straps to prevent snaring or disconnection during movement.

### 5. Development of the "En Route" Plan

Develop the assessment protocol for your casualty while in transport. This is an opportunity for the team to clearly subdivide tasks and ensure that all aspects of casualty care will be met. It is key to remember that vital signs should be checked regularly. This will create a pattern repetition or "battle rhythm" for the transport period.

Documentation and report are developed from the "en route" portion of the casualty transport plan. Depending upon the status and required effort of casualty care during transport, documentation on the DD1380 or DA4700 may prove to be difficult to maintain. **It is imperative that, the team monitor, and document vital signs regularly as required by patient acuity, administer, and document medications, and perform and document any interventions in order that they have been completed in the casualty care record.**

## PEARLS OF PREPARATION

1. A difficult airway on the ground will NOT be easy to maintain en route. Secure the airway and ventilator support as needed prior to transport.
2. Decrease FiO2 requirements on the ground in a controlled setting to ensure proper O2 levels and allocation of limited resources en route.
3. Predrawn/premixed medications, primed blood tubing, taping of reinforcement bandages near wound, pelvic binders, and preplaced tourniquets are all examples of time saving measures to be optimized on the casualty prior to transport. Time is an enemy in the provider resource constrained transport environment.
4. Early antibiotics can prevent long-term complications, ensure your casualty has antibiotic coverage or have a plan to initiate coverage when appropriate.
5. Dedicate an intravenous line for medication administration. Separate, mark, and place the administration port somewhere accessible to all team members during the transport.
6. During assessment, ensure that the casualty is rolled, all junctional areas are investigated for injuries, and that all team members auscultate lung fields, palpate chest for expansion, and assess compliance of bag valve mask ventilation.
7. Establish a solid baseline assessment with your team using the MARCH acronym. This will act as supporting problem solving battle rhythm for your team en route.
8. Keep it simple! Use practical and manageable interventions to optimize your casualty en route.
9. Use separate securing straps and devices for the casualty and any monitors. Remember casualty safety and security is the priority.

## EQUIPMENT

En route care of patients requires adequate equipment to ensure safe and successful transport. Certain information such as length of flight, number of patients to be transferred, and severity of patient condition should be taken into consideration when deciding the type and number of equipment to be used. The goal of preparing equipment for patient transport is to ensure all necessary items are accounted for, both consumable and non-consumable.

In general, each patient will require:

1. Vital signs monitoring device with both invasive and non-invasive capabilities
2. External suction machine
3. A ventilator, depending on the patient's respiratory status

Models of these pieces of equipment may vary between each service depending on availability. Additional items should be available so that for each possible equipment failure or for deterioration of the patient there is a backup plan and the proper materials available for these plans. For example, if the external suction machine fails, a manual suction should be available.

The length of the transport will determine the amount of medication and number of consumables that should be brought with the ERC team**. At minimum, twice the length of the transport should be planned for when packing items. Oxygen needs and consumption rate should be calculated prior to transport to ensure enough supply is available for all legs of the transport**. For example, the flight time may be 15 minutes, but the ground transport time from the landing zone to the next echelon of care may be an additional 20 minutes.

Consumable equipment is that which expires or cannot be reused on another patient. **For all non-consumable items, fully charging batteries and performing any function checks should be ensured before transport.** Although some platforms have the ability to charge the equipment, it is not guaranteed on every platform. These items must be properly inspected by biomedical per the maintenance requirement recommended by the company of each respective piece of equipment.

Non-consumable equipment should be secured on the patient litter or transportation device so that the ERC team members can view them during transport. Equipment may be secured down by litter straps, ratchet straps, tape, or other securement devices. Consumables may be carried by the ERC team members via bag or backpack or may be prestaged in the transport platform.

Guidance on equipment, consumables, medications, and fluids can be found in Appendix A. Quantities of each have been left out as it will vary by transport. Although not all items on the list will need to be included for every transport, supplies needed for potential emergencies during transport should be considered.

### ERC CONSIDERATIONS

At minimum, twice the length of the transport should be planned for when packing items.

Oxygen needs and consumption rate should be calculated prior to transport to ensure enough supply is available for all legs of the transport.

For all non-consumable items, fully charging batteries and performing any function checks should be ensured before transport.

Non-consumable equipment should be secured on the patient litter or transportation device so that the ERC team members can view them during transport

## PATIENT SAFETY

Moving a patient from one echelon of care to another requires mitigation of safety risks through the use of personal protective equipment (PPE). PPE is determined, in part, by the mode of transportation and terrain. PPE must be applied prior to transport. Land, sea, and air are possible transport environments via ruck, truck, boat, or ship, rotary or fixed wing platforms. Critical thought must be used when considering the appropriate protective equipment which may include but not limited to:

1. Hearing protection (single or double)
2. Eye protection (may or may not be ballistic grade)
3. Cranial protection (helmet or cranial)
4. Personal flotation device or life preserver unit
5. Hypothermia, commercial or standard warming (i.e. Hypothermia Prevention Management Kit (HPMK), wool blankets)
6. Securing straps to transport device.

Patient safety considerations also must be exercised when moving the patient to, from, and within the transportation platform. The patient must be properly secured to the litter or sled prior to movement. The securing devices must be reassessed after each movement to ensure all interventions are still in place. Consideration must also be given to have adequate numbers of personnel to move the patient from one echelon to another. A four-person litter team, directed by a

medic, is the safest option when moving patients on a NATO litter. After the patient is transferred to a platform for transport, the final consideration is to ensure the litter or sled is secured to the conveyance. Though optimal, this final consideration may be omitted for the operational environment. If transporting via aircraft, work with air crew to determine the best patient position and securement method.

# PERFORMANCE IMPROVEMENT (PI) MONITORING

## INTENT (EXPECTED OUTCOMES)

1. Patient packaged to mitigate secondary injury (e.g., hypothermia prevention, hearing & eye protection, pressure injury prevention).
2. Completion of lifesaving interventions prior to transport.
3. MIST report given by the initiating team to the transport team.
4. All lines and tubes secured (e.g., endotracheal tube, intravenous line, Foley catheter, chest tube).
5. Vascular access immediately available.

## PERFORMANCE / ADHERENCE MEASURES

1. Complete documentation of patient packaging measures.
2. Complete documentation of clinical procedures completed prior to transport.
3. Documentation of MIST report from the initiating team to the transport team.

## DATA SOURCE

1. Patient record DD FORM 1380 or other relevant patient document.
2. Department of Defense Trauma Registry

## SYSTEM REPORTING & FREQUENCY

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

The system review and data analysis will be performed by the JTS Chief and the JTS PI team.

## RESPONSIBILITIES

It is the ERC team leader's responsibility to ensure familiarity, appropriate compliance, and PI monitoring at the local level with this CPG.

# REFERENCES

1. Joint Health Services, Joint Publication 4-02. Dec 11, 2017.
2. U.S. Department of the Air Force. Aeromedical Evacuation Equipment Standards (AFI10-2909). Jul 23, 2013.
3. Headquarters Department of the Army. Medical Evacuation (ATP 4-02.2) Army Techniques Publication No. 4-02.2 Aug 12, 2014.
4. Headquarters Department of the U.S. Army. Casualty Evacuation (ATP 4-25.13) Army Techniques Publication No. 4-25.13, Feb 9, 2013.
5. U.S. Department of the Air Force. En Route Care and Aeromedical Evacuation Medical Operations (AFI 41-307). Jan 7, 2017.
6. JTS: Interfacility Transport of Patients Between Theater Medical Treatment Facilities

## APPENDIX A: PATIENT PACKAGING CHECKLIST

Source: U.S. Army Aeromedical Evacuation Standard Medical Operating Guidelines, CY24 Version, Published 1 Feb 2024

# PRE-FLIGHT CHECKLIST

(for Critical Care and Post-Surgical Transfers)

*Once the decision is made to transfer a patient and an accepting physician has been obtained, the following steps will be taken to prepare the patient for transport:*

| Initials | Evaluation Steps |
|---|---|
| | 1. Sending location/physician: _____Accepting location/physician:_____<br>Flight nurse called: name / time: _____ |
| | 2. Anesthesia called: intubation if indicated. ETT secured/marked |
| | 3. Patient meets criteria for en route critical care transport: risk documented by sending physician **(POST-OPERATIVE and CC INTRAFACILITY TRANSFER, Pre-Transfer Patient Status Requirements)** |
| | **Preparation Steps** |
| | **Positioning and Proper Monitoring:** |
| | 1. Patient moved to litter (collapsible handles), positioned, padded, strapped, equipment (with necessary attachments) added and secured. |
| | 2. For head-injured patients, a pre-sedation neurologic examination will be performed. GCS and neurological exam documented on the en route care form, suggest placing patient sitting at 30°-45°. (For eye injured patients, fox shield in place. For burn patients, **JTS burn sheet initiated**.) |
| | 3. Ventilator switched to PMI vent at least 20-30 min prior to flight and set with transfer settings ordered by physician. |
| | 4. IV / IO access verified, patent, and secured. |
| | 5. Arterial line inserted and secured, if indicated. Transducer accessible. |
| | 6. Ventilator tubing checked to be free from obstruction, with $ETCO_2$ and secondary lines attached. |
| | 7. Orogastric or nasogastric tube is inserted (unless contraindicated), placement verified with chest x-ray, and attached to low-intermittent suction. |
| | 8. Chest tubes to water seal/suction (place Heimlich valve for non-atrium chest drainage systems). |
| | 9. Wound vacuum disconnected and stowed. |
| | 10. Foley catheter secured, urine output measured and documented. |
| | **Equipment, Medication, Chart, and Personnel Preparation:** |
| | 11. Medications needed for flight prepared and organized. |
| | 12. Flight equipment bag obtained and checked. Backup pulse oximeter readily available. |
| | 13. Complete chart photocopied (including x-ray cd), patient belongings bagged and tagged. Transfer Document, or other theater / unit approved transfer document, has been initiated. |
| | 14. Earplugs and eye protection for patient and flight nurse. |
| | 15. If facility sends medical attendant, attendant must have relevant personal protective equipment. In a combat environment this includes: Uniform, Kevlar, IBA, Weapon, ID Card, and equipment for transport. |
| | **Ventilator Management:** |
| | 16. Blood gas (preferably ABG) obtained, 15 min after initial settings and ventilator changes. All efforts will be made to have a documented blood gas within 30 minutes prior to flight time. |
| | 17. Adjust ventilator settings and check $O_2$ tank for length of flight. Resuscitator bag under patient's head with tubing connected to $O_2$ source, vent tubing free from obstruction. |
| | **Final Verification:** |
| | 18. Transferring Physician, Flight Paramedic, ECCN (or Flight Provider) verbally agrees to flight care plan. |
| | 19. Critical Care Transfer Orders reviewed and signed by transferring physician.**(STANDARD ORDER SET for CRITICAL CARE TRANSFERS)** |
| | 20. Enroute CC Transfer Document with completed preflight and enroute care data handed over to and confirmed by receiving provider / facility. **(CENTCOM Transfer Document)** |

# APPENDIX B: M A R C H

## MASSIVE HEMORRHAGE

- Address major hemorrhage threats and sending interventions
- Mark all bleeding on dressings
- Pre-stage loose tourniquet above prior arterial bleed for easy application during transport if re-bleed occurs

## AIRWAY

- Ensure that the airway is secured for flight with bilateral lung sounds and EtC02 monitoring.
- Cuff inflated and confirmed with manometer/ secured appropriately
- Prepare emergency airway device (BVM with mask, re-intubation, supraglottic, surgical airway)

## RESPIRATION

- Perform Breathing assessment
- Check recent arterial blood gas and compare results against current $ETCO_2$ monitoring

***Ensure collaborative assessment for chest expansion and bag valve compliance*

- Placing the patient on the transport ventilator should be weighed with oxygen consumption.

## CIRCULATION

- Roll the casualty to assess posterior prior to transport!
- Visually inspect perineal area for hemorrhage and injury.
- Assess all junctional areas for bleeding.
- Assess and mark all distal and central pulses, consider doppler prior to transport if necessary.
- Ensure a minimum of two IV access and flush saline locked sites to ensure patency. If using IO, ensure continuous security of the device.

***Place pelvic binder or junctional tourniquets for all thoracic and abdominal injuries, as well as any traumatic lower leg amputations.*

- If necessary, ensure arterial catheter security and continuity, and arterial pressure monitoring system. Best practice to be secured with suture and adequate dressing.

## HYPOTHERMIA

Ensure wet clothing is removed and place patient in an Absorbent Patient Litter System or HPMK if available. If only sheets or blankets are available, place one underneath and on top of patient for full coverage.

| **Interventions all patients:** | **Interventions, if indicated:** |
|---|---|
| ▪ Complete Focused Neuro Exam, GCS, and pupil assessment.<br>▪ Apply transport monitors.<br>▪ Level/zero/calibrate all lines and censors.<br>▪ Apply hypothermia prevention (HPMK, blankets, etc.).<br>▪ Provide/apply ear + eye protections for all patients, including intubated patients.<br>▪ Review transport orders with sending team. | ▪ Ensure Foley Catheter is in place and check for patency, initiate I&O documentation.<br>▪ Secure chest tube and place Heimlich valves or confirm pleuravac to suction or water seal.<br>▪ Place nasogastric or orogastric for abdominal decompression and with all intubated patients.<br>▪ Reenforce tape on dressings and intervention sites.<br>▪ Check for bag-valve-mask compliance.<br>▪ Administer antibiotics.<br>▪ Administer Tranexamic acid.<br>▪ Administer seizure prophylaxis.<br>▪ Assess need for calcium with blood administration.<br>▪ Secure 3x travel period of sedation, analgesia, and paralytic medication.<br>▪ Measure/mark abdominal girth.<br>▪ Apply blanket rolls or head blocks to assist with airway stabilization.<br>▪ Apply c-collar if needed for known or suspected c- spine injury.<br>▪ Apply/secure spinal immobilization and/or extremity splints. |

# APPENDIX C: EN ROUTE EQUIPMENT LIST

## EQUIPMENT

- Vitals monitor
- Suction
- Ventilator
- Oxygen tanks
- Consolidated PT support system (alternate to all above equipment)
- Blood/fluid warming system
- Defibrillator (if not part of vitals monitor)
- IV Pumps

| Capability | Good | Better | Best |
|---|---|---|---|
| Vital sign monitoring | manual blood pressure cuff SpO2 Finger Probe Thermometer | Good+ EtCO2 | integrated monitor with SpO2, EtCO2, ECG, invasive pressure monitoring, thermometer |
| Suction | manual suction | manual suction | commercial mechanical suction device |
| Ventilator | BVM (For emergency use only) | Limited capability automated ventilator (SAVe II) | Full capability ventilator (Zoll 731, Hamilton T1, Eagle 754) |
| Oxygen source | Transport (D) Cylinder | Transport (D) Cylinder | oxygen generation or LOX |
| Blood/fluid warming | | | commercial warming device |
| Defibrillator | automated external defibrillator | | integrated with monitor |
| *NOTE: Commercial devices that integrate one or more of above functions may suffice (i.e. MOVES)* | | | |

## CONSUMABLES

- Endotracheal Tubes
- NPA
- OPA
- Cricothyrotomy kit
- 10cc Syringe
- Soft tip suction (or in-line suction if available)
- Suction tubing
- BVM
- LMA
- Extra O2 Tubing
- Tension Pneumothorax needles
- Heimlich valve
- Scalpel
- IV start kits
- 10cc NS flushes
- Chux pads
- Tourniquets
- Pressure bag
- IV tubing
- Blood tubing
- Blood warmer with tubing
- Back up handheld suction
- Commercial Blood container/Vampire box if traveling with blood
- APLS or HPMK
- Thermal Blanket
- Eye protection
- Ear protection
- Tape
- Transfer needles

## MEDICATIONS & FLUIDS

- Blood Products (Best: Whole Blood, Better: 1:1:1 if available, Good: pRBC, plasma)
- IV Fluids – Lactated Ringer's and normal saline
- 3% NaCL
- Analgesia, sedation, antiemetic medications (consider use of rigid case to carry medication vials and syringes to avoid accidental waste)
- Calcium

## APPENDIX D: TELEMEDICINE / TELECONSULTATION

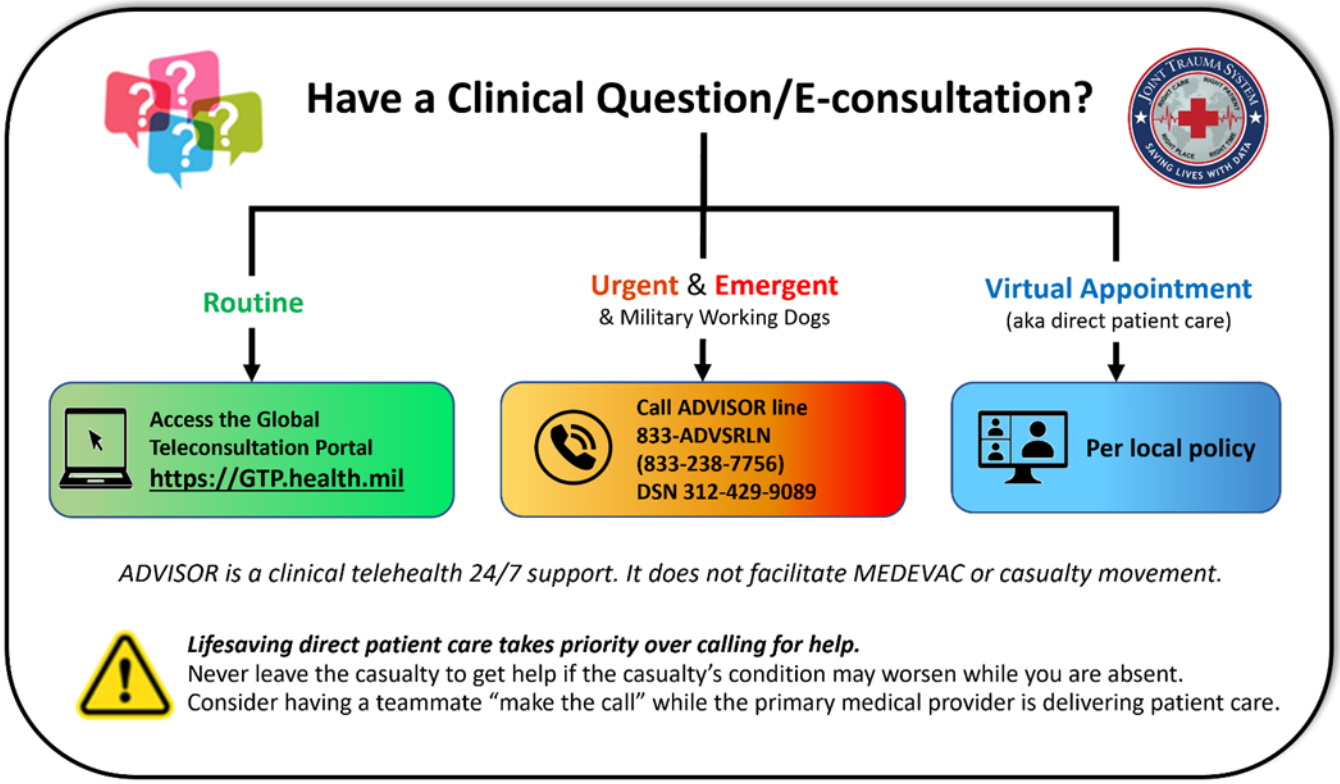


*Illustration by Raymond Samonte*

*GTP: https://GTP.health.mil*

# APPENDIX E: 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.