

## Joint Trauma System Clinical Practice Guideline

### *Austere Resuscitative and Surgical Care*

30 October 2019

#### Summary of Recommendations and Guidelines

- The intent of this Clinical Practice Guideline is to provide guidance for Austere Resuscitative and Surgical Care (ARSC) teams, which often comprise conventional forces surgical units used in support of Special Operations missions.
- All ARSC teams should receive ARSC-specific, team-centric, predeployment readiness training to include medical aspects and operational aspects of ARSC, with the result that ARSC teams are capable of protecting themselves and their patients and function well in a tactical environment.
- The purpose of the ARSC team is to mitigate risk for the Operational Commander by providing surgical and resuscitative care for combat casualties. ARSC teams are smaller and more mobile than other conventional surgical assets and have less clinical capability and holding capacity. Realistic assessment of the risks and benefits of this capability must be clearly communicated to the Operational Commander.
- Limited resources and staffing require that medical decisions be made in the context of the following variables: time and distance to the next role of care, capability of the next role of care, availability of blood products, sterility, anticipation of additional casualties, evacuation capability, security, mobility, and patient-holding capacity.
- Patient care must focus on rapid triage, initial resuscitation with blood products, rapid control of hemorrhage and contamination with a damage-control approach, and subsequent transfer to higher echelon.
- Ultrasound of the chest and abdomen in patients with penetrating trauma to chest, abdomen, or pelvis or severe blunt trauma should be performed to rule out life-threatening injuries.
- A ruck-truck-house model, explained later in the guidelines, can help frame logistical considerations for planning purposes to maximize mobility and flexibility.
- Documentation (e.g., Joint Trauma System [JTS] Austere Trauma Resuscitation Record, operative note) must be completed for all patients treated by ARSC teams and submitted to the JTS or uploaded into the Theater Medical Data Store.

#### Introduction

The intent of the Clinical Practice Guideline (CPG) is to provide small, conventional surgical teams both operational and

clinical guidance for this unique Austere Resuscitative and Surgical Care (ARSC) environment. Small teams from every service have been tasked with the mission of supporting operational units (usually Special Operations Forces [SOF]) in far-forward environments. The ARSC environment uses surgical capability outside of the conventional doctrinal guidance. The development of this CPG is not indicative of Joint Trauma System (JTS) support for nondoctrinal use of ultrasmall teams with limited capabilities but rather to provide guidance for teams deployed in support of missions that require ARSC to facilitate the best outcomes for casualties managed by ARSC teams.

It is recognized that teams are working in the ARSC environment, frequently without specific training for the unique challenges, clinical and tactical, that these teams encounter. Small surgical teams have been increasingly used and have an evolving role in providing care to US and partner forces on the battlefield over the past two decades of global conflict. The Task Force Commanders or their designees will be referred to as the Operational Command to represent all services throughout this document. Operational forces place high value on the support of surgical capability in their area of operations and may be constrained by policy to perform forward military operations within defined evacuation rings. During the course of current conflicts, US Army Forward Surgical Teams (FST) and others were split into ever smaller elements and employed outside of published doctrinal concepts to meet operational demand for close surgical support,<sup>1-7</sup> often in support of SOF. The demand for smaller and more mobile surgical teams has continued to grow and many different models have emerged over the past two decades. Examples include the Joint Medical Augmentation Unit Surgical Resuscitative Team; Army Expeditionary Resuscitative Surgical Team and split Forward Resuscitative Surgical Team; the Air Force Ground Surgical Team and Special Operations Surgical Team; and Navy Damage Control Surgical Team and Expeditionary Resuscitation Surgical System.<sup>1-11</sup>

There is no standard definition or joint doctrine specifying the exact capabilities of these small surgical teams. Although this CPG has been developed on the basis of ground combat support, the concepts can be applied to maritime environments. Recently, the Austere Surgery Teams Subcommittee of the JTS Committee on Surgical Combat Casualty Care defined the care environment of these small teams as follows: “Austere Resuscitative and Surgical Care is advanced medical capability delivered by small teams with limited resources, often beyond traditional timelines of care, and bridging gaps in roles of care in order to enable forward military operations and mitigate

risk to the force.”<sup>12</sup> The goal of this guideline is to provide guidance for the leaders and personnel of ARSC teams who are tasked to deploy and provide advanced medical and surgical capability on the battlefield spanning the spectrum from point of injury (POI) up to conventional Role 2, noting that this environment of care has nuances from conventional/doctrinal surgical support. These teams often comprise conventional forces personnel in support of SOF missions and have a unique placement in the battlefield system of care; their ability to support these teams and remain small and agile relies on the proximity and capabilities of adjacent roles of care.

## ARSC Mission Readiness

Expertise in trauma care is the cornerstone for ARSC teams, and trauma training to achieve and sustain clinical expertise of all team members is foundational. Historical, abbreviated “just-in-time” training for trauma care is highly discouraged. Combat trauma patients already present the most demanding challenges to an experienced trauma team in the unconstrained environment. ARSC team members should be selected to possess a mission-first mindset, perform well under duress, work effectively as part of a team, and demonstrate resilience to periods of sustained levels of stress. Individual members should be proficient in Tactical Combat Casualty Care (TCCC) and their respective specialties of resuscitative, surgical, and post-operative care of critically ill trauma patients. Ideally, ARSC teams will achieve expertise by working routinely as a team in high-volume, high-quality trauma centers to develop trust, fluid team dynamics, and cross-train on key roles and tasks to maximize use of limited available hands.

It has been well recognized that certain teams supporting these missions may not maintain the appropriate clinical volume for skill sustainment. This fact emphasizes two elements of the current trauma system in the Department of Defense (DoD): (1) maintaining surgical trauma skills while not deployed and (2) keeping deployments short for individuals with life-saving critical skills that have been demonstrated to be perishable. It is important that deployed clinical and operational leadership recognize the value of personnel flexibility (e.g., intratheater rotations) to ensure providers get clinical exposure during deployments.

ARSC teams should be prepared to function outside of the boundaries of forward operating bases; therefore, success relies on proper integration with the operational mission. The ability to balance resuscitative trauma care within the tactical mission requirements and constraints is the greatest challenge. ARSC teams should undergo training to function in tactical environments, including training in survival, evasion, resistance, and escape, and be proficient in tactical communications and weapons management. Specific guidance from the supported ground force should guide the training requirements. Personnel must have the ability to defend themselves and their patients. Teams require expeditionary maneuverability with a compact resuscitative surgical package that is rapidly deployable and collapsible. Pre-mission tactical training for the team should be supported by hospital and ground force leaders and include technical skills and knowledge, team training, and professional development.

Using ad hoc teams without specialized equipment or more intensive, sustained predeployment and team-centric training

specific for this mission presents both a risk to mission and risk to force, and is highly discouraged.<sup>3,13,14</sup> Being an asset in the operational environment, not a liability, requires that ARSC team members have sufficient training to integrate with the supported operational force and throughout the entire en route chain of care. The smaller the ARSC team, the more technical and clinical expertise is required for all team members. Likewise, the farther forward the ARSC team deploys, the more tactical and clinical proficiency the team requires.

Mission planning is essential to effective use of the ARSC team and begins well before deployment. Surgeon involvement with ARSC leadership is essential. ARSC leadership elements include the officer in charge (OIC), senior surgeon, and senior enlisted member. They should be involved in all phases of the Joint Operations Planning Process. Communicate early and often with the line command to establish mutual trust and shared realistic expectations of the ARSC team’s capabilities, limitations, and requirements for each individual mission while deployed. The Operational Command must be advised by the OIC and/or senior surgeon of the decreased capability (as compared with a conventional Role 2) that ARSCs can deliver and accept the increased risk to their forces. The Command must be aware of the number of critically injured casualties that can be managed before personnel are overwhelmed or resources exhausted. Dedicated security from anticipated threats must be provided when the ARSC team is decisively engaged in patient care. Successful integration of resuscitative trauma care within the operational environment begins before the first patient contact.

## Operational Influences on Clinical Decision-Making

Expert clinical decision-making in the austere environment is the most important asset the ARSC provides. It is multifactorial and may differ from traditional Role 2 and Role 3 settings on the bases of the operational context and the time and distance to the next role of care. Availability of resources, personnel, blood products, sterility, anticipation of additional casualties, evacuation capability,<sup>15,16</sup> security, mobility, and patient-holding capacity must all be considered. In addition, the dynamic nature of the tactical environment may result in frequent changes; constant situational awareness is required. Assumptions on duration of transport and time to intervention at the next level of care may increase the risk for the patient, the team, and the mission. Therefore, in most cases, damage control surgery should be done before transport of a casualty. A patient should never be transported from this environment with any question of instability if there is any uncertainty of the transport timeline.

Surgeons are responsible to communicate real-time clinical risk assessments regarding tactical conditions, operational constraints, and potential impact on patient outcomes. However, surgeons must recognize that the operational commander retains legal decision-making authority to assume risk and to decide when operational objectives and tactical mission requirements supersede the recommended clinical course of action. Priorities may be weighed against the current threat situation, necessity for tactical maneuver, opportunities to accomplish mission objectives, and so forth. ARSC team integration in operational planning phases not only determines the medical plan but clarifies the overall tactical intent and the Operational Commander’s desired end state. This allows

the Operational Command and ARSC team to make timely decisions to accomplish objectives and maximize critical care capabilities.

### Tactical Combat Casualty Care

The TCCC guidelines are foundational knowledge for austere providers at all levels of training, and, as of 2019, TCCC training is a requirement for all medical providers. Thorough knowledge of current TCCC guidelines not only will help surgical teams understand care provided at point of injury but also provide battle-tested options for care that are appropriate in austere environments, even for surgical teams. A thorough understanding of tourniquets, their associated complications, and recommendations for conversion to pressure dressings and removal in the austere environment is fundamental to TCCC and is not common knowledge for providers without prior tactical medical experience. TCCC airway management, pain management, and resuscitation recommendations have been implemented with a high degree of success.

Mass casualty (MASCAL) scenarios are especially challenging in resource-limited environments. A few casualties can quickly turn into a MASCAL for the austere team. Mastery of the concepts of TCCC will save lives in this setting.<sup>17-23</sup> Principles of dynamic triage must be used during all phases of care, including intraoperatively, and not be limited to the initial evaluation.<sup>13</sup> Proper triage results in the greatest good for the greatest number. This cannot be overstated. The burden of these decisions is heavy. Redundancy in triage and clinical skills is especially necessary for ARSC teams given that they do not have all the resources of a standard Role 2 and because every member will be task saturated. Realistic, challenging MASCAL and triage scenarios should be trained during predeployment to work through difficult decisions based on limited resources.

Austere teams should maximize the use of limited resources by restricting surgical interventions to damage control only, particularly when evacuation timelines are short. When evacuation timelines are delayed, more definitive or repeated surgeries may be required. For example, a vascular shunt may temporize arterial injury, but when evacuation is delayed beyond 24 hours, definitive vascular reconstruction or amputation may be indicated. When transferring patients to a host-nation facility, the capability for definitive surgical care may be absent or unknown. This highlights the wide and complex spectrum of clinical care in the austere setting and emphasizes the importance of understanding time and distance to the next level of care with a clear knowledge of the transport capability and the receiving facility's capability.

When evacuation is delayed and patients are held by a surgical team after the initial resuscitative care, the surgeon must weigh the risks of definitive surgery against the risks of ischemia and infection. There are currently not enough outcome data available to make firm recommendations for patients being treated for longer than 72 hours in an austere environment.

### Damage Control Procedures

ARSC teams exist for unstable patients who cannot tolerate transport to a Role 2 (or next level of care); their function in the battlefield continuum of care is for the provision of early damage-control resuscitation and surgery. ARSC teams should

focus damage-control principles as the primary approach for all surgical procedures, which minimizes time, resources, and personnel. This mindset and approach should be used for patient with traumatic injury and those without (e.g., appendicitis). There may be scenarios in which the ARSC team will be the definitive level of care for host-nation patients; however decision-making is still constrained by resource availability and by operational mission requirements.<sup>24</sup>

In most cases, emergency surgery for acute surgical diseases (e.g., acute cholecystitis and appendicitis) that do not clinically require a damage-control strategy should be temporized with antibiotics and expeditiously transferred to a higher level of care. If operational considerations require patients be held longer than 24 hours, or if the patient presents with sepsis or hemodynamic instability due to an intraabdominal source, surgery may be indicated.

For elective or semi-urgent cases, the evacuation chain should be used in communication with the operational commander and the theater trauma director. Give the significant resource limitations, only true emergencies should be considered at this level of care.

### Anesthesia and Intraoperative Monitoring

Delivering safe anesthesia in the austere environment must account for available medical capabilities and the tactical situation.

#### Patient Monitoring

Monitoring under anesthesia ideally includes understanding normal physiology of a patient and using your hands and eyes to monitor your patient. Adjuncts in this environment are additional cardiac monitoring, blood pressure, pulse oximetry, temperature, and, for a patient receiving ventilatory support, inspired oxygen analysis and end-tidal carbon dioxide (EtCO<sub>2</sub>) measurement.<sup>25</sup> A range of devices are available to monitor vital signs with minimal space and maintenance. However, honing clinical skills to manually assess vital signs is important because monitoring devices may not always be available.

**EtCO<sub>2</sub>:** EtCO<sub>2</sub> monitoring is an important capability as a physiologic indicator, even at the initial levels of care. The EtCO<sub>2</sub> value is relevant during resuscitation and in patients with traumatic brain injury, in addition to its established role in verifying airway placement and monitoring ventilation.<sup>25</sup> Under controlled ventilation, the EtCO<sub>2</sub> level can also be used to estimate changes in cardiac index or cardiac output over time.<sup>26</sup> This knowledge can be applied within the clinical context and can be used in cardiopulmonary resuscitation to predict patients who are more likely to achieve return of spontaneous circulation (EtCO<sub>2</sub> pressure >10mmHg).<sup>26</sup> As such, knowing the EtCO<sub>2</sub> can be useful during triage.

**Ultrasound:** The presence of sonographically identified cardiac activity at any point during trauma bay or intraoperative resuscitation is associated with increased survival to hospital admission.<sup>27</sup>

**Invasive pressure monitoring:** Small in-line devices (e.g., Centurion Compass®; Centurion Medical Products, <http://compass.centurionmp.com/>) have been used successfully for monitoring aortic occlusion during resuscitative endovascular

balloon occlusion of the aorta (REBOA). These can also be used to measure and trend central venous pressures, bladder pressures, or myofascial compartment pressures. See the guideline “JTS resuscitative endovascular balloon occlusion of the aorta (REBOA) for hemorrhagic shock CPG.”<sup>28</sup>

### Perioperative Anesthetic Considerations

Definitive airway control is challenging in the patient with trauma. It becomes increasingly difficult in the austere environment and requires a significant commitment of resources, such as the need for a ventilator, continuous monitoring, and sedation. When intubation is indicated, the timing should be optimized to conserve resources. Even with a depressed Glasgow Coma Scale score, if a patient remains spontaneously breathing, it may be preferable to support their respirations noninvasively while resuscitation is initiated. Resuscitation before induction of anesthesia in an unstable patient may prevent hemodynamic collapse. Alternative anesthetic techniques such as moderate sedation or peripheral nerve block may conserve resources. With respect to airway management, consider the capabilities of the transport personnel, their available respiratory and monitoring equipment en route, and the capability of the next level of care. In patients with a potential for airway compromise, ensure a definitive airway is established before transport. Considerations must be made for supplemental oxygen delivery, which can be challenging in this environment, an Austere Anesthesia CPG (under development) will address these issues specifically.

### Maintenance of Anesthesia

The means to administer inhaled agents for the maintenance of anesthesia is not likely to be available in the austere setting. Electrical power and inspired gases used to drive vaporizers are problematic resources to obtain. Draw-over methods could be considered; however, these can be challenging to titrate or administer when considering variables such as a nonspontaneously breathing patient or patient transportation. General anesthesia using a total intravenous anesthetic (TIVA) is a more effective way to provide adequate anesthesia and conserve equipment and resources. Practitioners should have an intimate knowledge of the benefits and limitations of intravenous (IV) anesthetic drugs available to allow for an effective, balanced anesthetic. Simple infusion pumps or quantitative drip sets can automate flow for prolonged infusions and providers should carefully select and train with their specific equipment. Because TIVA is commonly used in this environment, calculations and concentrations of the most commonly used drips have to be mastered by providers using this form of sedation and general anesthetic, and the drip rates of propofol, fentanyl, and ketamine have to be well understood.

### Regional Anesthesia Adjuncts

The capability to perform regional anesthetic techniques enhances the ARSC team mission. Experience in Iraq and Afghanistan has highlighted the value of early aggressive pain management in the combat casualty<sup>29</sup> and reinforced the importance of multimodal pain management in the perioperative setting.<sup>30,31</sup> The use of regional anesthesia, either in conjunction with or instead of general anesthesia, may reduce the resources and personnel required for operative, postoperative, and subsequent en route care. The risk of masking a developing compartment syndrome must be considered. Ultrasound or stimulator-based techniques can be used to perform a variety of nerve blocks. Intercostal nerve blocks can be used to

decrease respiratory pain associated with thoracostomy tube or thoracotomy or multiple rib fractures.<sup>32</sup> A transversus abdominis plane block can be used as a part of multimodal pain treatment to attempt early extubation after laparotomy, even in patients with a temporarily closed abdomen.<sup>33</sup>

### Blood Transfusion Capability

In addition to surgical hemorrhage control, resuscitation with warmed blood is the most important intervention the ARSC team can perform. Effective resuscitation of the patients with trauma who has sustained massive blood loss consists of simultaneous hemorrhage control along with resuscitation to correct trauma-induced coagulopathy, acidosis, and hypothermia.<sup>33</sup> Resuscitation with blood products rather than crystalloid or vasopressor administration is the standard in trauma care; calcium administration should be early during the resuscitation. Treatment of acute coagulopathy of trauma is addressed with transfusion of whole blood, plasma, cryoprecipitate, and platelets; however, blood products in the austere environment may be limited and platelets and cryoprecipitate will unlikely be available. Whole-blood administration, preferably stored, low-titer type O whole blood, provides the most balanced resuscitation and is easier to administer as a single product for minimally staffed ARSC teams. The capability to draw warm, fresh, whole blood from prescreened donors should be optimized. Also, the capability to warm blood products during massive resuscitation is required; although there is not always standardized equipment to support this requirement, every effort should be made to ensure these teams deploy with at least one rapid fluid infuser with warming capabilities. Effective rapid transfusion and warming devices are necessary and require adequate power to support.

In general, an ARSC team should plan to ideally maintain at least 20 units of whole blood or red blood cells (RBCs) plus plasma (20 units of each blood component). Mission requirements will also dictate inventory levels of blood (mission support versus area support). The ARSC teams must be in regular communication with the theater Joint Blood Program Officer (JBPO) or Armed Service Blood Program Theater representative and keep their status updated (as much as possible) in the Theater Medical Data Store to facilitate resupply. ARSC teams must have a well-rehearsed walking blood bank (WBB) capability. At times, the WBB may rely on the host-nation blood supply, depending on the tactical and clinical environment. If using the host-nation blood supply, consideration must be given to endemic disease risk of donors and ability to perform rapid tests to mitigate risk. When supporting en route care missions, WBB is less feasible and stored blood is required, depending on operational activity. Frequent communication with the supporting Blood Support Detachment and JBPO is essential.

### Surgical Airway Management

Airway obstruction represents 8% of potentially preventable prehospital deaths.<sup>34</sup> Multiple attempts at orotracheal intubation should be avoided, and providers should maintain a low threshold to surgically manage the airway. Complex facial injuries require airway management and hemorrhage control for temporary stabilization<sup>35</sup> In this circumstance, obtaining an initial endotracheal tube or cricothyroidotomy is appropriate. As mentioned, consider the level of the transport capability. Transferring a patient with significant maxillofacial injuries

with a surgical airway as opposed to an orotracheal airway may be the safest option. It is important to have equipment for a surgical airway ready in the event orotracheal intubation is unsuccessful. Always confirm airway placement with EtCO<sub>2</sub>.<sup>36</sup> See the guidelines “JTS Airway Management of Traumatic injuries CPG.”<sup>37</sup>

## Neck Injuries

Hard indications for surgical neck exploration in the ARSC environment are no different than at the Role 2 or Role 3 and include “hard signs” of vascular injury with active hemorrhage or expanding or pulsatile hematoma. However, because of the lack of imaging, lack of resources, and the inherent challenge of these injuries, casualties without hard signs should be transferred to a higher level of care as long as they have an acceptable airway for transport (this could be their native airway or a definitive airway). In some cases, exploration is indicated when airway injury is suspected on the basis of subcutaneous emphysema or air bubbling through the wound<sup>38</sup>; however, many cases of tracheal injury can be temporarily managed with endotracheal intubation with the cuff inflated below the level of injury. Be ready to immediately perform a surgical airway in these patients, because a relatively stable patient may have significant airway disruption. Proximal and distal vascular control is difficult for injuries approaching the base of the neck or skull base. In this environment, most penetrating wounds to the neck without immediate life-threatening hemorrhage should be transferred to a higher level of care for additional diagnostic workup and subsequent formal surgical exploration. Although penetration of the platysma alone is not an indication for neck exploration in the austere environment in the current trauma system, multiple factors must be taken into consideration (e.g., transport time, capabilities at sending and receiving facilities, the trauma system) because the level of injury may be difficult to ascertain without imaging. Maintain a low threshold to secure the patient’s airway before transfer. In addition, communication to the higher level of care should be established to discuss the plan for these casualties.

## Traumatic Brain Injury

Non-neurosurgeons should be cautious when performing craniotomy or craniectomy in the austere setting; this is no different from a surgeon at a Role 2. However, in this far-forward environment, medical management and craniectomy have even more challenges. Lack of appropriate training and experience may make operative therapy more dangerous than medical management alone. In the austere setting, every attempt should be made to maximize medical management (e.g., EtCO<sub>2</sub> monitoring, hypertonic saline, bed positioning, airway management, sedation, paralysis, keeping the head elevated and midline). Discuss the patient with and transfer to a neurosurgeon as soon as clinically possible.<sup>39</sup> If transport is not possible, the provider should attempt to seek the guidance of a neurosurgeon in real time. In the absence of proper imaging, burr holes or needle drainage of suspected epidural hematomas are discouraged. See the “JTS Emergency Cranial Procedures by Non-neurosurgeons in Deployed Setting CPG.”<sup>40</sup>

## Ophthalmology

Trained ophthalmologists are never available in this environment and every attempt should be made to contact an

ophthalmologist at the Role 3; however, given the nature of the ARSC teams, communication is not always feasible. Injuries to the globe should be covered with an occlusive shield and parental antibiotics and antiemetics should be administered. These patients frequently experience severe nausea; oral medications should be avoided. It is imperative to avoid pressure to the globe, ensure nothing is directly touching the injured globe, and no intraocular medications are administered. See the “JTS Ocular Injuries and Vision-Threatening Conditions in Prolonged Field Care CPG.”<sup>41</sup> Lateral canthotomy and cantholysis should be performed if there is concern for retrobulbar hematoma or increased intraorbital pressure. In the rare circumstance that telemedicine support is available, it should be heavily used. Establish telemedicine consultation as soon as possible. AD.VIS.OR, the Advanced Virtual Support for Operational Forces system, offers 24/7/365, on-demand, real-time telemedicine consultations (<https://prolongedfieldcare.org/telemed-resources-for-us-mil>).

## Torso Trauma

Approximately 13% of combat casualty patients presented with injury patterns at risk of noncompressible torso hemorrhage (NCTH), and this was identified as a cause of death in 50% to 70% of patients assessed to have potentially survivable injuries in Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF).<sup>35,42–44</sup> Truncal injury was characterized as 36% thoracic and 64% abdominopelvic.<sup>35</sup> It is in this patient population that forward-positioned surgeons have the greatest potential to directly influence survival.<sup>45–48</sup> The ability to perform extended focused assessment with sonography for trauma (E-FAST) for identification of intrathoracic injury and intra-abdominal hemorrhage is required because X-ray and computed tomography (CT) scan may be unavailable. Ultrasound has its limitations and has higher false-positive and -negative rates in penetrating trauma. In one study looking at combat trauma, FAST only had a sensitivity of 12% for intraabdominal injury requiring laparotomy,<sup>49</sup> which underscores the use of training to improve diagnostic sensitivity, as well as the challenges of these teams that do not have any additional diagnostic imaging. Diagnostic peritoneal lavage and diagnostic peritoneal aspiration (DPL/DPA) can be used to augment diagnostic capability when FAST results are equivocal, although DPL/DPA are only limited to evaluation of the peritoneal cavity. ARSC teams have to optimize requirement for ultrasound capability and providers must have the appropriate ultrasound training. Ultrasound is limited for identification of pelvic or retroperitoneal hemorrhage; therefore, a high index of suspicion should be maintained when the injury mechanism indicates potential retroperitoneal bleeding.

Although not proven with prospective outcome data, REBOA has shown potential in the austere environment as a bridge to prompt surgical intervention, obtain rapid proximal vascular hemorrhage control, reduce blood transfusion requirements, improve exposure by reducing hemorrhage, facilitate rapid normalization of hemodynamics,<sup>50</sup> and as a force multiplier during MASCAL scenarios.<sup>51,52</sup> Early femoral arterial access (18 gauge A-line, 4Fr or 5Fr micropuncture) and monitoring can help identify patients who will die of hemorrhage earlier. Placing arterial access is strongly encouraged and does not require placement of a REBOA but improves monitoring. This can be upsized to the 7Fr femoral sheath for balloon occlusion should the patient deteriorate. The sheath may be left in situ

connected to a pressure monitor during evacuation to higher levels of care or if repeated catheterization is probable but comes at a risk of limb ischemia and even limb loss. Sheath complications are not uncommon and the sheath should be removed at the earliest time after the patient has demonstrated stability. After sheath removal the vascular must be evaluated to ensure that there is good distal perfusion. While the sheath is in place, distal pulses must be followed closely. See the "JTS Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Hemorrhagic Shock CPG."<sup>28</sup> All ARSC providers require REBOA training. There are multiple training courses available.

### Laparotomy

Concern for NCTH with hemodynamic instability requires surgical intervention at the earliest opportunity that resources and personnel permit; this is no different from other roles of care. Damage-control laparotomy is the standard in the unstable trauma patient and may be performed in forward environments.<sup>13,53</sup> In the deployed setting, damage-control surgery and temporary abdominal closure are recommended when significant intraabdominal injuries are found.

In OIF and OEF, the rate of nontherapeutic laparotomy was as high as 32%.<sup>54</sup> A nontherapeutic laparotomy is likely safer than a potentially prolonged transfer for a casualty who might have a missed injury. These decisions are very challenging, but succumbing to injuries in flight is never acceptable. Selective nonoperative management<sup>55</sup> should only be considered where CT scan and extended observation are possible.

### Thoracotomy

The incidence of thoracic trauma in modern conflict is approximately 5%, with the mortality rate ranging from 12% to 24%.<sup>44,56</sup> Patients with severe thoracic trauma have a significant survival advantage if they reach surgical capability within 1 hour.<sup>57,58</sup> Thoracotomy should be performed when indicated with the damage-control mindset and the goals of rapid control of hemorrhage and contamination. The chest may be temporarily packed and closed over chest tubes.

### Cardiac Injury

Imaging is usually limited to a handheld ultrasound device. Maintain a low threshold to perform a subxyphoid or transdiaphragmatic pericardial window if the injury pattern is concerning for mediastinal or cardiac injury. If there is blood in the pericardium, explore as indicated. See the "JTS Wartime Thoracic Injury CPG."<sup>59</sup> Rarely, some patients with hemopericardium may present with normal hemodynamics, which may represent a superficial injury to the myocardium, and sternotomy may be avoided if the pericardial space is irrigated with warmed fluid and the bleeding is noted to have stopped.<sup>60-62</sup> Place a closed suction drain and record output. A period of observation is recommended before transfer.

### Vascular

Like every deployed surgeon, the ARSC surgeon should have training and experience in expeditious exposure of all named vessels to identify and control hemorrhage. The initial damage control and stabilization of injured vessels include control of exsanguinating hemorrhage, recognition of extremity ischemia, rapid restoration of flow to the ischemic limb with vascular shunts, and fasciotomies to treat or prevent compartment

syndrome.<sup>13,62</sup> All of these are exceptionally more difficult in the ARSC environment, which emphasizes the importance of readiness and training for this skill set before deployment.

Shunt placement is a required skill set. When placing a shunt, thrombectomy of the distal vessel should be performed before shunt placement if vigorous back-bleeding is not present. Secure all shunts with suture as close to the vascular injury as possible to preserve native vessel length. Leaving all vessel loops used for proximal and distal control loosened and in place will allow the next surgeon to quickly identify relevant anatomy and provides rapid control of a vessel if the shunt dislodges in transport. Cover the operative field with dressings and consider a temporary skin closure to protect the shunt. Primary patency rates are high for proximal shunts (86%) and low for distal shunts (12%).<sup>62</sup> Primary repair of partially injured vessels, such as large veins, is preferable if greater than 50% stenosis can be avoided. Shunting of large veins is preferable to ligation when primary repair is not feasible and may increase patency rates of associated arterial shunts. Definitive reconstruction such as vein graft should be delayed to a higher level of care when possible.<sup>13</sup> If the vascular repair is associated with a fracture, immobilization with an external fixator is recommended; external fixation before definitive vascular shunting is recommended if the warm ischemia time allows. In the case of popliteal and femoral artery injuries, the use of shunts, as opposed to primary amputation, even in an unstable patient, does not increase risk of death and improves overall amputation-free survival.<sup>63,64</sup> Balloon catheters (REBOA or Fogarty) can be used to provide temporary vascular control. Refer to the "JTS Vascular Injury."<sup>65</sup>

### Subclavian Vessels

This injury pattern carries a high mortality rate. Most venous bleeding and some arterial bleeding can be controlled with wound packing. A temporary skin closure over the packing may improve tamponade. Maneuvers to obtain proximal vascular control include intrathoracic exposures such as sternotomy, supraclavicular, clavicular resection, trap-door approaches, and retrograde placement of a Fogarty catheter through the brachial artery or through the zone of injury. In addition, inflating a Foley balloon within the wound track may provide tamponade, particularly if able to maintain compression against the clavicle or chest wall. A chest tube should be placed on the same side as the subclavian vascular injury if there is a concern for intrathoracic hemorrhage.

### Inguinal Vessels

Contralateral placement of a REBOA catheter with aortic occlusion in zone 3 is a rapid and effective way to obtain temporary proximal control of a junctional groin injury. Extraperitoneal control of the iliac vessels above the level of the inguinal ligament also achieves proximal control of the injured vessel outside of the zone of injury, but a low threshold for intraabdominal proximal control should be applied, given the often unpredictable trajectories of combat injuries.

### Fasciotomy

Maintain a low threshold to perform fasciotomies for the combat-injured extremity.<sup>13</sup> Delay in diagnosis of compartment syndrome can occur due to multiple patient handovers during the transport process.<sup>13</sup> Be proficient with techniques for the upper and lower extremity, especially the common pitfalls: missing the deep posterior compartment in the lower extremity and

not coming all the way across the carpal tunnel in the upper extremity. Even without evidence of compartment syndrome, early prophylactic fasciotomy may be considered in the setting of vascular injury with a temporary repair and may improve limb salvage rate, especially in patients who are going to be transported and do not have immediate access surgical care.<sup>66</sup>

## Extremity Trauma

Extremity trauma is the most common injury on the battlefield. Having proficiency with bony, soft tissue and vascular techniques in the extremities is extremely important for the ARSC surgeon—and not always thoroughly trained in general surgery residencies. The surgeon in an austere environment must be familiar with all open surgical and nonsurgical techniques to control hemorrhage and reperfuse injured limbs. Transport of a patient with a tourniquet should be avoided. When tourniquets are left in place for more than 4 to 6 hours, the risk of severe rhabdomyolysis, kidney failure, limb loss, and death are high.<sup>67</sup> Closed reduction, splinting and/or traction are often adequate temporary stabilization techniques of long-bone fractures if these procedures adequately align the bony injury.

### External Fixation

For combined orthopedic and vascular injuries, consider external fixation of long-bone fractures after shunting and before definitive repair. Pelvic binder placement is effective for temporary control of most pelvic hemorrhage.<sup>68</sup> In delayed evacuation scenarios, pelvic binders optimally should remain in place no longer than 48 to 72 hours.

### Mangled Extremity

Every effort should be made to temporize the mangled extremity and transfer the patient to a higher level of care. However, when blood product and resource availability are limited, limb salvage may not be feasible. Initial management of the mangled extremity includes hemorrhage control, irrigation, and debridement of clearly nonviable tissue. Traumatic amputations should not be formalized in the austere setting, though familiarity with formal amputations is required to anticipate future soft tissue coverage needs. Wounds should be left open in anticipation of repeated exploration and debridement. See “JTS Amputation: Evaluation and Treatment CPG.”<sup>69</sup>

### Soft Tissue Wounds

Early debridement of soft tissue wounds and burns improves outcomes and morbidity. However, the ability to fully debride soft tissue wounds may be limited in the ARSC setting because of limited access to surgical energy devices, blood products, sterility, and irrigation fluid. Aggressive management of soft tissue injuries should be weighed against the available resources and operational considerations such as resupply and overall sustainment of the mission. In general, the ARSC team is not resourced to treat large soft tissue wounds that require serial debridement. Potable water is as effective as sterile fluid for surgical irrigation.<sup>70</sup> Sharp debridement is the standard of practice for soft tissue wounds. Commercial negative-pressure dressings are unlikely to be available in the ARSC environment. Standard gauze (or hemostatic gauze) or occlusive dressings over closed suction drains are suitable for transport. See “JTS Initial Management of War Wounds CPG”<sup>70</sup> and “JTS Acute Traumatic Wound Management in the Prolonged Field Care Setting CPG.”<sup>71</sup>

## Additional Considerations

### Resuscitation

Large-bore IV access is one of the most critical components of initial resuscitation. On insertion of IV access, blood is used for typing on an Eldon Card. All team members should be proficient in peripheral IV and intraosseous (IO) placement. Initial resuscitation through an IO catheter can be a bridge to IV catheter placement. The damage-control resuscitation CPG algorithm should be followed. See “JTS Damage Control Resuscitation.”<sup>72</sup> Ultrasound-guided peripheral IV placement is another useful option. It also is recommended to become familiar with conversion of peripheral IV catheters to rapid infusion catheters (e.g., Arrow RIC<sup>®</sup>; Teleflex Inc, <https://teleflex.com/usa/en/>). Central catheter access should be considered only when peripheral IV or IO access is limited or when multiple sites for infusion are not readily available. Most patients can be rapidly resuscitated through large-bore peripheral IV or IO access. Rapid blood typing as part of the WBB, blood product storage, transfusion, and efficient blood warming is essential capabilities of ARSC teams.

### Burns

Protect the airway early; early intubation is necessary in patients with greater than 40% total body surface area burns, facial burns, or if there is any concern for inhalation injury. Video laryngoscopy (e.g., GlideScope<sup>®</sup>; Verathon, <https://www.verathon.com/glidescope/>) should be heavily used to obtain an early definitive airway and may help diagnose inhalational injuries in patients with facial burns. Burn resuscitation should be started as early as possible using the rule of 10s. See “JTS Burn Care CPG.”<sup>73</sup> The volume of IV resuscitation fluid available may be limited. Plasma may be used to supplement resuscitation fluid. Patients with significant burns should be transferred rapidly to the next level of care. Maintain a low threshold to perform escharotomy early in the transport process, especially with circumferential full-thickness burns. Silverlon<sup>®</sup> (Argentum Medical, <https://www.silverlon.com/>) is a lightweight burn dressing that can stay in place 3–5 days and is useful for other abrasions and shallow wounds. When burn dressings are not available, avoid debridement of blistered partial-thickness burns and cover burns with dry sterile dressings. Maintain normothermia because patients with burns are susceptible to hypothermia even in the warmest environments. Notify the US Army Institute of Surgical Research Burn Center as early as possible (DSN 312-429-2876) or email: burntrauma.consult.army@mail.mil.

### Hypothermia

Maintenance of normothermia is crucial for survival of combat casualties. Active warming or cooling devices such as heaters or air conditioners have significant electrical power or fuel requirements and will not be available in the ARSC environment. Hypothermia management kits (HPMKs) should be used frequently; they contain chemical warming blankets that generate heat on exposure to air. These blankets should not be placed directly on the skin, however, due to the risk of thermal burns. Hypothermia in the patient with trauma is directly related to degree of blood loss. Hypothermia will continue until adequate blood volume is restored.

### Pediatrics

ARSC teams may be required to care for pediatric patients including neonates, depending on the medical rules of eligibility.

This is a significant challenge for these teams; however, even though non-doctrinal, the unique mission requirements of these teams may result in them caring for pediatric patients. If this is the case, ensure age-specific medical supplies and equipment are available, such as pediatric monitors, catheters, tubes, and medications. Although a Broselow bag may be too large to carry in this environment, the contents can be broken down and specific elements such as airway adjuncts and a Broselow™ tape can be carried to assist with caring for the pediatric population.

### Obstetrics

Pregnant patients may present who meet medical rules of engagement for care. ARSC providers should be familiar with the anatomic changes that occur during pregnancy due to the gravid uterus. Ultrasound can be used to evaluate the fetus. Fetal distress is associated with a fetal heart rate of fewer than 100 bpm and is an indication of the need for continued maternal resuscitation or even emergent fetal delivery. ARSC providers should be familiar with emergent obstetric procedures, including cesarean delivery and surgical management of postpartum hemorrhage. ARSC providers should contact an obstetrician for guidance as able.

### K9 Damage Control

Injured military working dogs (MWDs) may require urgent surgical stabilization. The MWD CPG<sup>74</sup> outlines the unique clinical considerations for these patients. Always apply a muzzle (or improvised muzzle) early for safety. Consider having hair clippers and larger endotracheal tubes (9Fr–11Fr) available for canine use, as well as larger laryngoscopes (e.g., Miller blade size 4). The canine handler, unless injured, will help manage the care and will have a card with weight-based medication doses specific to their canine. Standard tourniquets may be used for severe canine limb injuries; however, elastic pressure dressings are typically effective and, in some cases, the tourniquets may not adjust to a small enough circumference to occlude blood flow. Predeployment, MWD-specific medical training is strongly recommended and currently is a Central Command theater requirement. New recommendations regarding the K9 WBB exist and these teams (as well as all Role 2 and Role 3) should contact a theater veterinarian when arriving in theater. If K9 blood is held on-site, it must be in a separate cooler and location than human blood.

### Ventilator Management

All team members should be facile with the use of the particular ventilator available. Refillable oxygen storage containers (liquid or gas) are heavy and a challenge to maintain and refill. Portable battery-powered oxygen concentrators are an option but require power for continuous use. Additional ventilator management, such as setting up an oxygen reservoir for a ventilator, will be addressed in a future Austere Anesthesia CPG.

### Imaging

X-ray or cross-sectional imaging may not be available in the austere environment. Portable sonography may be the only imaging tool and miniaturized devices are available. Readiness and training for this skill set are required before deploying to an ARSC environment. Ultrasound will provide the ability to evaluate the torso for injuries (E-FAST), guide resuscitation, guide vascular access, assess for vascular flow, and perform regional anesthetic techniques.

### External Electrical Power

The ability to provide quality care will depend heavily on electrical power. Early initiation of warmed blood products and patient normothermia are vital components of a successful trauma resuscitation. Maintenance of blood refrigeration and active warming and cooling devices (e.g., heaters, air conditioners, blood warmers, plasma thawing devices) draw significant electrical power requirements. Regular maintenance and fuel requirements for power generators must be preplanned and communicated with the ground-force commander, but are ultimately the responsibility of the surgical team.

### Chemical, Biological, Radiological, and Nuclear

ARSC teams should be prepared to protect and decontaminate themselves, and there must be a plan for the patients and incoming casualties. Although ARSC teams must have a treatment plan in place should they encounter a patient with chemical, biological, radiological, and nuclear (CBRN) exposure, they may not be equipped to treat this patient population. It is imperative to communicate with the Operational Command that an ARSC team is not equipped or staffed for large-scale patient decontamination, that care timelines will extend during a CBRN event, and triage decisions may change significantly (Table 1).

**TABLE 1** CBRN Considerations for Austere Resuscitative and Surgical Care Teams

• Develop a hasty and deliberate decontamination plan (on arrival to a new site with all parties).
• Conduct individual and team drills to practice donning personal protective equipment.
• May use nitrile gloves x3 for protection; change outer glove if it becomes sticky or gummy.
• Identify the nearest resource that has CBRN detection capabilities.
• Identify a large water source (55-gal drum or similar, with hose).
• Ample supply of rapid skin-decontamination lotion
• Do not bring casualty into clinical facility until decontamination is complete. This is an element of proper triage. Anticipate loss of supplies and equipment used on patients before decontamination, and plan accordingly.
• See JTS CBRN Injury Part I: Initial Response to CBRN Agents CPG <sup>75</sup>

Abbreviations: CBRN, chemical, biological, radiological, and nuclear; CPG, clinical practice guideline; JTS, Joint Trauma System.

### Blood Use in the ARSC Environment

Blood is a resource that cannot be improvised and must be communicated to operational leadership as a mission-critical requirement. Logistical factors with the ARSC team must be considered even more so than at the Role 2 or Role 3. ARSC teams do not have dedicated personnel to manage the blood supply, storage, temperature regulation, accounting, and resupply. Blood supply and resupply must be considered early and often. This is often managed through medical operations channels and requires close coordination with the combatant command blood program and regional blood logistic process. Maintaining stored blood products within a narrow temperature range and subsequently warming them in a timely manner are two of the greatest challenges of austere trauma medicine.<sup>13,50</sup> In an unstable and critically ill combat casualty, early, balanced blood resuscitation (ideally, whole blood) improves 72-hour mortality rate.<sup>4,13,76–79</sup> ARSC teams must anticipate blood requirements, work with the theater blood program

manager to meet those requirements, plan for their own WBB, and prepare for contingencies.<sup>13,58</sup>

Fresh whole blood (FWB) use in the combat casualty setting is associated with improved survival when compared with administration of packed red blood cells (PRBCs) and fresh frozen plasma (FFP) alone.<sup>80</sup> FWB eliminates the need for blood cooling, storage, and rewarming equipment but carries increased risk of transmissible disease, and FWB donors may be limited in some operational environments. It is recommended, and will be doctrinal in an upcoming DoD Instruction, that anti-A and anti-B titer levels be collected from all deploying personnel with type O blood in addition to FDA-recommended infectious disease testing. This strategy provides a constant blood-donor pool for contingencies. For US casualties, FWB donors should be US personnel, rarely from coalition forces, and from local nationals only in the most extreme cases. See the JTS Whole Blood Transfusion CPG<sup>81</sup> for detailed guidance. Point-of-care testing for some transmittable diseases exist (e.g., human immunodeficiency virus), but the required time for interpretation may be prohibitive in patients in severe hemorrhagic shock. Have a plan in place for patients and donors who test positive for such diseases, and recognize that there may be significant cultural implications with local nationals and partner nation forces who test positive for such diseases.

The need to remain light and mobile further increases the challenge of retaining an adequate supply of blood products for mission support.<sup>50</sup> Portable battery-operated blood refrigerators and freezers are available (e.g., HemaCool<sup>®</sup>) but require mobility platforms to move over long distances, and mechanical failures in hot and dusty environments may occur. Refrigerators and freezers require a constant and reliable power source, further increasing the team's weight and footprint and reducing maneuverability. Mission requirements for increased mobility may limit the size and number of refrigeration equipment and thus blood availability,<sup>13</sup> and vice versa.

PRBCs and frozen plasma are readily available at Role 2, Role 3, and ARSC teams, but supply of platelet components is limited despite increasing use of cold-stored platelets. Stored low-titer type O whole blood and never-frozen liquid plasma are increasingly available via the ASBP theater blood distribution system. Freeze-dried plasma may be available for some ARSC missions supporting SOF. Options for acquiring blood outside official supply and resupply channels include WBB drives (requires blood typing capability such as Eldon cards as well as citrate bags) and blood from the local area, such as local hospitals, for use on host-nation casualties should be considered when appropriate. Inform the theater JBPO if considering local host-nation supply of blood products.

## Blood Warming

Conventional warming techniques for blood transfusion such as the Belmont<sup>®</sup> Rapid Infuser (Belmont Medical Technologies, <https://www.belmontmedtech.com/>) or plasma-thawing devices draw substantial power and may be unavailable in the austere setting. Battery-operated, in-line products are easily packed; however, flow rates are inversely proportional to infusion temperature and may be inadequate for the patient with trauma who is in severe hemorrhagic shock. Plasma-thawing devices may be available in some equipment sets but may not

be suitable for small, highly mobile surgical teams or in the ARSC environment. There is no light, portable, approved plasma-thawing device. Portable water heaters and thermometers can be used to create a 30–37° C bath of water to thaw FFP and warm PRBCs to the appropriate temperature of 37° C; however, they are not FDA approved for this use. Approximately 10% of FFP bags may break during thawing and this should be factored into the supply. Prethawing frozen plasma saves time in the acute setting, but once thawed, plasma must be used within 5 days.

## Walking Blood Bank

Every ARSC team member must be trained to draw and transfuse FWB and must be able to recognize and treat transfusion reactions. Recruitment and blood typing of potential blood donors may take time, so early initiation of a WBB is recommended for patients with the suspected need for massive transfusion. Fresh whole-blood transfusion must be type specific unless the donor has been predesignated low-titer type O by laboratory testing. All low-titer type O donors must provide documentation of titer testing before donation. See the “JTS Whole Blood Transfusion CPG.”<sup>81</sup> Standard equipment sets should contain blood-collection kits. Ensure Eldon cards and point-of-care infectious disease testing kits are available and team members are trained in their use. Ensure a reliable system for marking and numbering (1) individual donors, (2) blood-donor bags, and (3) Eldon cards.

## Logistical Considerations

Packing for ARSC missions can be framed usefully by the Ruck-Truck-House model developed by SOF medics.<sup>82</sup> This is a modular approach to mission planning based on cube and weight constraints. As building blocks, each phase of this supply model builds on the previous phase, with Ruck capabilities intrinsic to Truck, and Truck capabilities intrinsic to House. The term Ruck-Truck-House refers to the cube and weight of the mission equipment and not necessarily to the mobility platform. For example, Ruck missions may be performed from a truck, and Truck missions are often conducted via rotary wing platforms.

Specific team-member composition of each team is based on multiple variables, and specific staffing recommendations are outside the scope of this practice guideline. Generally, ARSC teams should be prepared to scale their team size according to mission requirements dictated by the Operational Command. A Ruck team may have the fewest personnel of any given ARSC team that still provides a minimal, functional capability, and a House team may comprise the maximum number of personnel with maximal capability. Limitations of scaled teams must be clearly articulated to the Operational Command to accurately communicate inherent risk.

## Ruck

The Ruck model is the most mobile pack out because supplies and equipment are limited to what can be carried on each team member's back. It is well understood that this is not the ideal environment for surgical care; however, mission requirements occasionally dictate this capability. When it comes to surgical intervention, or no intervention and likely casualty death, this substandard option becomes a mission requirement. Because

of its inherent limitations on resources, the Ruck model requires the highest levels of clinical skill, tactical proficiency, and teamwork, and personnel must be highly trained in all these areas for mission success. Medical planners and the surgeon must clearly communicate the clinical and other limitations to mission planners and the supported Operational Command to conduct appropriate risk mitigation. The Ruck model fits on most transportation platforms. Although emergency surgery may be performed with this model, it is generally capable of providing temporary support for only one critical patient and has no capacity to hold critically ill patients for any length of time. Blood products are extremely limited and the lack of power and electricity prevents use of blood storage and cooling, blood warming, and electronic warming devices. As a result of these limitations, rapid patient evacuation to the next level of care is vital and urgent resupply must occur to continue the mission. Alternatively, the plan may include performance of en route care and return to base upon mission completion. In addition, communications are limited to personal radios, and team security must be provided by the supported unit during clinical care.

### Truck

The Truck model is also very mobile, capable of set up or collapse within minutes, and can be transported to a fixed location. Although this model may have greater capability than the Ruck model, its limitations must be carefully considered and communicated to planners and commanders in order not to fail expectations placed upon it. It includes each team member's ruck and as many additional supplies and equipment that can fit onto the mission's mobility platforms, depending on the mission need. This model may be able to treat and sustain more patients but is also limited by power and electricity, blood storage, and fluid volume. Although supplies are increased, the Truck model still depends on a rapid evacuation and resupply chain if heavy casualties are encountered or the team is intended to perform a static mission.

### House

The House model is far less mobile. It refers to a fixed location where the full equipment loadout of an ARSC team can be established and is only feasible to be maintained at a team house, firebase, or other mission-support site. This model provides the highest level of care organic to the team and has a greater patient capacity. Continuous operations may be sustainable with casualty evacuation and resupply of blood and other Class VIII materiel. Additional requirements for full operational capability include power and electricity for blood cooling and storage, blood warming and infusion, patient warming, water for steam sterilization and hygiene, and other requirements. Open communication of requirements, capabilities, and limitations to planners and commanders will enable mission success.

In all three models, challenges are magnified with supply and resupply limitations, blood availability, and prolonged hold time, transport time to next level of care, personnel available to help, and more. It is understood that this is not the ideal environment in which to care for surgical patients and that certain severe injuries will not be survivable. As emphasized, the limited capabilities of these teams have to be understood by mission planners and operational commanders. Clinical

experts, including the senior surgeon, should be involved in medical planning of mission support to ensure critical supply requirements and limitations are addressed, clearly articulated, and solutions are developed within mission constraints. Involve planners and the Operational Command early and often in mission planning to understand command requirements, mitigate risks, and shape expectations for success. See Appendix A for sample packing lists for each model.

Many mission variables affect what is ultimately packed into the finite cube and weight requirements for each model. See Table 2 for some of the variables to consider when planning for logistical support of ARSC missions.

**TABLE 2** Variables to Consider When Planning Logistical Support for ARSC Missions

Variable	Considerations
ARSC team composition	<ul style="list-style-type: none"> <li>Number and type of medical personnel on the ARSC team</li> <li>Team members' specialties, experiences, capabilities, preferences</li> </ul>
Patient variables	<ul style="list-style-type: none"> <li>Types of patients (e.g., friendly combatants, enemy, civilian, pediatric, geriatric, MWDs)</li> </ul>
Mission	<ul style="list-style-type: none"> <li>Operational Command intent</li> <li>Security situation (i.e., expected tactical risk to medical personnel)</li> <li>Length of mission</li> <li>Number of expected casualties, number of troops at risk</li> <li>Communication capabilities of medics and next levels of care</li> <li>Space available for equipment</li> <li>Maximum/minimum equipment weight requirements</li> <li>Security element for the ARSC team</li> <li>Task force composition (joint, combined) and service, state, or national caveats</li> <li>Team sustainment requirements</li> </ul>
Evacuation	<ul style="list-style-type: none"> <li>Capability, time, distance from forward medics</li> <li>Capability of the evacuation platform (CASEVAC vs MEDEVAC vs CCATT)</li> <li>Capability, time, distance to next level of care</li> </ul>
Environmental	<ul style="list-style-type: none"> <li>AO-specific medical concerns</li> <li>Night versus day operations</li> <li>Cold versus hot environments</li> <li>Indoors versus outdoors</li> <li>Physical and human terrain</li> <li>Security environment</li> </ul>
Resupply	<ul style="list-style-type: none"> <li>Emergent and routine time and processes for resupply of blood products and Class VIII materiel</li> </ul>

Abbreviations: ARSC, Austere Resuscitative and Surgical Care; CASEVAC, casualty evacuation; CCATT, Critical Care Air Transport Team; MEDEVAC, medical evacuation; MWD, military working dog.

### Resupply

Resupply should be categorized as Mission Critical, Mission Essential, and Mission Enhancing for planning and communicating purposes. The category of medical supply or equipment items may change depending on the mission.

- **Mission Critical:** There is high risk of mission failure without these items.
- **Mission Essential:** There may still be significant impact but less risk of mission failure if lacking these items.
- **Mission Enhancing:** There is low risk of mission failure if lacking these items.

The following subsets may require separate and deliberate logistical planning.

- **Mission Critical, consumable:** There simply are not ways to improvise shortfalls of a few things (e.g., blood products, citrate bags, IV calcium, key anesthetic medications).
- **Mission Critical, durable with lifespan:** replacement instruments, litters, replacement medical electronics, such as ventilators, monitors, ultrasound, Doppler probe, suction.
- **Frequent high use:** may be improvised: laparotomy sponges, TCCC equipment, operating room towels and drapes, dressings, flushes, syringes, IV catheters, IV tubing, HPMKs, suture, lines, tubes, pain medications, antibiotics, and so forth

A best practice is to plan with the supported unit's logistical support personnel to increase available assets for resupply and shorten the time required to execute. Educate the supported unit on movement requirements and limitations of critical supplies to facilitate timely and accurate decisions if a medical representative is not available at the higher level of command. Establish push-and-pull rapid-resupply packages, often called "speed balls," at the resupply base with focus on medications and expendables rather than durable equipment. Establish and practice supporting procedures for resupply to function well, and maintain abundant medical supply stocks for unexpected requirements. Depending on the mission, consider incorporating non-US resupply resources into medical logistics planning, including intergovernmental organizations, nongovernmental organizations, and host-nation facilities and services. Such schemes may optimize coalition or advise, assist, and accompany missions where the population at risk may be primarily host or foreign country nationals.

## Specific Logistical Concerns

### Surgical Sets

Traditional Role 2 surgical sets are bulky, difficult to access, and redundant.<sup>3,83</sup> Surgeons and surgical technologists should work together to design sets that support their specific mission. In general, hold and evacuation times are directly proportional to the degree of care to be rendered and, subsequently, the amount of equipment required. See Appendix A for packing considerations organized by the Ruck-Truck-House model.

### Anesthesia Equipment

Equipment should be mobile and adaptable to a variety of surgical cases. TIVA and regional anesthetic strategies are mobile and light. In addition, regional anesthetics will decrease requirements for systemic pain medication and lessen the concern for airway compromise and management. The use of regional anesthesia in patients at risk for compartment syndrome is controversial; although the data are sparse, there is no evidence that peripheral nerve blocks delay the diagnosis.<sup>84</sup>

### Nursing Equipment

Nursing equipment is often single use, disposable, and requires frequent resupply (e.g., IV catheters, IV tubing, syringes). Careful reuse of nursing items for the same patient will minimize waste. Long-term nursing supplies are not necessary, because the ARSC teams do not have holding capacity and rely heavily on expeditious transport to the next level of care.

### Instrument Sterilization

There are three principal methods to sterilize instruments: autoclave or steam sterilization, exposure to dry heat, and chemical antiseptics. Boiling is regarded as unreliable.<sup>85</sup> Mechanical- or steam-sterilizing devices are large, require high power input, and require several hours to clean, dry, and cool instruments. If sterilization devices are not available on site, instrument sets may be autoclaved or steam sterilized at a base of operations and turned over between missions. Careful planning should be used in packaging instrument sets so not all instruments are opened and contaminated at once.<sup>83</sup> The minimum standard for instrument decontamination is application of enzymatic cleaner followed by disinfection with an antiseptic, which can be achieved solutions such as formaldehyde, glutaraldehyde (Cidex®; Johnson & Johnson, <https://www.jnj.com/>), or chlorhexidine. Refer to the manufacturer's standards for time of solution contact and other considerations. To preserve resources, certain disposable items such as surgical staplers, clip applicators, or cautery pencils may be disinfected in chemical solution. Cautery grounding pads may be cleaned and reused with germicidal wipes; although not ideal, this is the reality of the ARSC environment.

### Power Requirements

The medical team must communicate power requirements to the supported element. Medical electronics and blood storage require power. Planning considerations include the size of the generator, voltage output (i.e., 110V versus 220V), maximum ampere load, optimal and maximum wattage operating ranges, type of fuel used, amount of fuel required for the mission, and maintenance plans. Other considerations include the total power required for all electrical equipment, the daily fuel consumption, and the capacity in amperes of the largest available circuit breaker needed to power a heating element or other high energy device. Power outputs and devices (110V versus 220V) must be carefully matched to provide adequate power to medical equipment and prevent destruction of critical electronic equipment. Be careful to maintain an ample supply of fuses for important electronic equipment. Note that each piece of equipment has unique and specific fuses that are not universal to each other and are prohibitively difficult to find on the local economy in most deployed locations. Table 3 lists mission-critical tasks and equipment that require power.

### Medical Waste Disposal

The estimated field-hospital medical waste per patient per day averages 1.5 to 3 kg.<sup>86</sup> ARSC planners should anticipate considerably more waste in the ARSC setting, given the critical nature of patients with wartime injuries. Team members should be sensitive to local religious customs when disposing of anatomic waste.<sup>86</sup> The World Health Organization recommends appropriate disposal of potentially infectious biological waste by either steam sterilization or high temperature incineration.<sup>85</sup> Burying waste is an option, but consideration should be given to avoid pollution of the environment and water sources.<sup>85,86</sup> Establish a safe system to dispose of sharps. The International Committee of Red Cross Manual of Medical Waste Management is an excellent resource and provides specific guidance.<sup>86</sup>

### Documentation

Accurate and complete documentation promotes patient safety and facilitates patient transfer, handover, and continuity of care. Documentation is required at all levels of care and can

**TABLE 3** *Mission Critical Tasks and Equipment That May Require Power*

Model	Function or Task	Equipment
Ruck	Patient warming	HPMK, ready heats, wool or space blankets
	Blood cooling	Person-portable preconditioned coolers
	Blood warming	Small, battery-powered in-line products
	Medical electronics	Battery-powered portable ventilator, monitors, and ultrasound
	Electrical power	Plan for person-portable, battery-operated equipment
	Lights	Battery-operated head lamps (consider equipment that uses standard batteries such as C123, AA, or AAA, as opposed to nonstandard, rechargeable lithium batteries, because replacement batteries are more easily acquired)
	Communications	Battery-powered radios
	Personal electronics	Minimal battery power only
Truck	Patient warming	HPMK, ready heats, wool or space blankets
	Blood cooling	Coolers with wet ice for blood or dry ice for plasma; battery-powered man-portable blood refrigerators (e.g., HemaCool®)
	Blood warming	Recommend Belmont® Rapid Infuser or plasma-thawing devices if power capability allows; if unable to support Belmont, use in-line device
	Medical electronics (monitors)	Battery power with recharging cords (stress awareness of 110V versus 220V)
	Electrical power	Plan for generator size 5kW–20kW and associated fuel requirement
	Lights	Battery-operated head lamps; person-portable, free-standing, LED spot lights
	Communications	Vehicle-mounted radio
	Personal electronics	Minimal rechargeable
House	Patient warming	HPMK, ready heats, wool blankets, Bair hugger, consider wall space- or area-heating units with understanding that these have tremendous power requirement
	Blood cooling	Multiple battery-powered, portable blood refrigerators (e.g., HemaCool®), ensure backup power source is available should primary power source fail
	Blood warming	Recommend Belmont® Rapid Infuser or plasma-thawing devices if power capability allows; if unable to support Belmont, use in-line device
	Medical electronics (monitors)	In-line power (stress awareness of 110V versus 220V)
	Electrical power	Central power versus large generator
	Lights	Battery-operated head lamps; person-portable, free-standing spot lights; wall-mounted lights
	Communications	Nonclassified IP router network, or secret IP router network or WiFi (choice)
	Personal electronics	Choice

Abbreviations: HPMK, hypothermia management kit; IP, Internet protocol; LED, light-emitting diode.

be challenging. In the ARSC environment, documentation is essential not just as part of a clinical standard but secondary to the need to further define, refine, and understand the limitations of this battlefield capability. The relatively low volume of casualties these teams have managed, combined with the paucity of documentation received for performance improvement (PI) analysis makes understanding the true capability and capacity of ARSC teams a challenge. In addition, appropriate and reliable analysis requires accurate and complete data, which will then allow more appropriate medical planning. In some cases, documentation and transmission are challenging due to a lack of communication equipment that enables reliable communications with higher levels of medical care. The ARSC environment is resource and personnel limited, and time must be committed to complete documentation on all patients. Experience has shown that in the setting of a MASCAL (when taking time to document seems the most challenging), proper documentation aids communication, decreases redundant evaluations, avoids errors, and ensures complete care. Consider language barriers with documentation. In unconventional warfare and depending on the unit the ARSC team is supporting, using patient identifiers may not be permitted. If caring for host-nation casualties, using

non US forms in their native language may be beneficial medically and practically.

The JTS MASCAL/Austere Trauma Resuscitation Record and an operative note and anesthesia record for surgical patients are the minimum required documentation for all patients. Minimum documentation includes mechanism of injury, injuries identified, signs and symptoms, treatments, vital signs data, neurologic status, medications, and interventions provided. Follow the Combatant Command or regional standard naming convention for trauma pseudonyms and maintain one consistent name for each patient during transfers. This improves continuity of care, patient tracking, blood resupply, and outcome analysis. In the operational setting, include ethnicity, unit affiliation, and geographic location of injury, as able. Use the JTS Burn Resuscitation Flow Sheet for major burns and Prolonged Field Care Flow Sheet for prolonged care. When evacuating to a higher level of care, records should be transferred with the patient. A photograph or copy of the record should be kept by the surgical team in the event the record is lost. When documentation cannot be completed before patient evacuation, complete the documentation immediately after evacuation and send it electronically to the next level of care as

soon as able. Submit patient records to the DoD Trauma Registry (DoDTR) via the USArmy.JBSA.MEDCOM-AISR.List.JTS-Trauma-Registry@mail.mil or to the closest Role 3 or 4 medical treatment facility patient administration as soon as able. Keep a log of all trauma patients and submit to the DoDTR.

## Performance Improvement Monitoring

**Patient population:** All patients treated by ARSC team

### Intent (Expected Outcomes)

- ARSC teams will receive ARSC-specific, team-centric, predeployment readiness training to include medical aspects and operational aspects of ARSC.
- Documentation is completed for all patients treated by ARSC teams (e.g., using the JTS Austere Trauma Resuscitation Record and an operative note) and submitted to the JTS or uploaded into the Theater Medical Data Store.
- Ultrasound of the chest and abdomen is performed and documented for patients with penetrating trauma to chest, abdomen, or pelvis, or severe blunt trauma in order to rule out life threats.

### Performance Adherence Measures

- All ARSC teams receive ARSC-specific training through a designated course or unit-specific training.
- Documentation is received by the next role of care and JTS for all patients treated by ARSC teams to include:
  - Trauma Resuscitation Record
  - Operative note, if applicable
  - Anesthesia record, if applicable
  - An ultrasound of chest and abdomen is documented for all patients with penetrating trauma to chest, abdomen, or pelvis (e.g., gunshot wound or blast) or severe blunt trauma.
  - Tourniquet times are documented (placement and removal times).
  - All tourniquets are removed and bleeding controlled before transfer from a surgical capability.

### Data Sources

- Patient record
- DoDTR

### System Reporting And Frequency

The aforementioned bulleted points constitute 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, JTS program manager, and the JTS PI Branch.

### Responsibilities

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

### Acknowledgments

**Defense Committee on Surgical Combat Casualty Care (CoSCCC)**

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## APPENDIX A: AUSTERE RESUSCITATIVE AND SURGICAL CARE EQUIPMENT CONSIDERATIONS

The following equipment lists are not complete packing lists. Teams should pack according to mission requirements, with expected numbers and types of patients significantly influencing quantities of medications and supplies.

For specific surgical instrument recommendations, please refer to: Hale DF, Sexton JC, Benavides LC, et al. Surgical instrument sets for Special Operations expeditionary surgical teams.

*J Spec Oper Med.* 2017;17(3):40–45. <https://www.jsomonline.org/JournalArticles/20173.php#Article708>

### Disclosure

This clinical practice guidelines (CPG), the US Air Force, US Army, US Navy, and US Department of Defense do not endorse or promote any specific products.

Ruck model: Plan for 1–2 surgical patients with 80% of combat trauma injury patterns	
TCCC equipment	<ul style="list-style-type: none"> <li>Litter</li> <li>Tourniquets</li> <li>Dressings, splints (e.g., Combat Gauze®, ACE, medical tape, Coban™, Kerlix™)</li> <li>Needle decompression catheters</li> <li>Airway equipment (e.g., oropharyngeal airways, nasopharyngeal airways, definitive airways, AMBU bag)</li> <li>Muzzle and large ETTs for MWD use</li> </ul>
Nursing equipment	<ul style="list-style-type: none"> <li>Personal protective equipment</li> <li>IV start kits, IO devices, extension tubing, blood tubing</li> <li>Syringes/flushes</li> <li>IV fluids</li> <li>Assorted catheters/tubes/drains</li> <li>Walking blood bank supplies (e.g., citrate bags, Eldon cards)</li> </ul>
Airway and anesthesia equipment	<ul style="list-style-type: none"> <li>Airway instrumentation</li> <li>Ventilation equipment</li> <li>Regional anesthetic block needles</li> <li>Dial-a-flow (infusion set)</li> <li>Centurion pressure transducer</li> <li>Nonelastic bougie</li> </ul>
Medications	<ul style="list-style-type: none"> <li>Tranexamic acid</li> <li>IV calcium</li> <li>Anesthetics</li> <li>IV and PO analgesics</li> <li>IV and PO antibiotics</li> <li>ACLS medications</li> <li>Antiepileptics</li> <li>IV fluids (including hypertonic saline for traumatic brain injury)</li> <li>Assorted “sick call” medications</li> </ul>
Surgical instruments	<ul style="list-style-type: none"> <li>Major instrument set</li> <li>Chest set with rib spreader and Lebsche knife</li> </ul>
	<ul style="list-style-type: none"> <li>Limited vascular set: a few fine instruments and vascular clamps</li> <li>Orthopedic bone saw (Gigli wires are intended to be single use, are fragile, and difficult to resterilize)</li> </ul>
Suture material	<ul style="list-style-type: none"> <li>Absorbable suture, given high likelihood of contaminated wounds</li> </ul>
	<ul style="list-style-type: none"> <li>Heavy PDS for fascia</li> </ul>
	<ul style="list-style-type: none"> <li>Fine Prolene for vascular repair</li> </ul>
	<ul style="list-style-type: none"> <li>Fine PDS for urologic and airway repairs</li> </ul>
	<ul style="list-style-type: none"> <li>Absorbable free ties for ligation of small vessels</li> </ul>
	<ul style="list-style-type: none"> <li>Heavy silk to secure tubes/drains</li> </ul>
	<ul style="list-style-type: none"> <li>Umbilical tape</li> </ul>
	<ul style="list-style-type: none"> <li>Heavy chromic for hepatic repairs</li> </ul>
	<ul style="list-style-type: none"> <li>Bone wax for amputations</li> </ul>
	<ul style="list-style-type: none"> <li>Vessel loops, large and small</li> <li>Pledgets</li> </ul>

Ruck model: Plan for 1–2 surgical patients with 80% of combat trauma injury patterns (cont.)			
Other surgical equipment	<ul style="list-style-type: none"> <li>Head lamps</li> <li>Cricothyroidotomy kit</li> <li>GIA staplers with reloads</li> <li>Topical hemostatic agents</li> <li>Surgical sponges (an ample supply of sponges cannot be overstated or overemphasized)</li> <li>Vascular shunts</li> <li>REBOA catheter and introducer kit</li> <li>Chest tubes, chest seals, and Heimlich valves</li> <li>Skin staplers</li> <li>Temporary abdominal closure device (e.g., Ioban)</li> </ul>		
	Electronics	<ul style="list-style-type: none"> <li>Portable, battery-powered EtCO<sub>2</sub> monitor</li> <li>Video laryngoscope (GlideScope®)</li> <li>Portable, battery-powered pulse oximeter</li> <li>Portable, battery-powered vital signs monitor</li> <li>Blood-cooling container (e.g., golden hour box)</li> <li>Hand-held Doppler device</li> <li>Hand-held ultrasound device</li> <li>Portable ventilator</li> <li>In-line IVF/blood-warming device</li> <li>Clippers for MWD use</li> </ul>	
		Operational equipment	<ul style="list-style-type: none"> <li>Internal and external communication equipment (e.g., hand-held encrypted radios, Peltors)</li> <li>Eye protection, ear protection</li> <li>Night-vision equipment</li> <li>Headlamp capable of red/green/blue light</li> <li>Navigation tool(s) (e.g., lenzatic compass, GPS)</li> <li>Survival equipment (e.g., blood chit, escape and evasion kit)</li> <li>Tactical protective equipment (body armor), IFAK</li> <li>Personal weapons and ammunition</li> </ul>

Abbreviations: ACLS, advanced cardiac life support; EtCO<sub>2</sub>, end-tidal carbon dioxide; ETT, endotracheal tube; GPS, global positioning system; IFAK, individual first aid kit; IO, intraosseous; IV, intravenous; MWD, Military working dog; PO, per os (by mouth); TCCC, Tactical Combat Casualty Care.

<b>Truck model:</b> Pack for 2–5 surgical patients with 80% of injury patterns. Includes increased quantities of all Ruck items.	
Added TCCC equipment	<ul style="list-style-type: none"> <li>• Litters</li> <li>• MASCAL kit</li> <li>• CBRNE kit</li> </ul>
Added anesthetic equipment	<ul style="list-style-type: none"> <li>• Oxygen</li> <li>• OG tubes</li> <li>• RIC catheters</li> </ul>
Added surgical instruments	<ul style="list-style-type: none"> <li>• Consider two or more of each instrument set</li> <li>• Limited external fixator set</li> </ul>
Other surgical equipment	<ul style="list-style-type: none"> <li>• Operating table/litter stands and arm boards</li> <li>• Broselow bag</li> </ul>
Added electronics	<ul style="list-style-type: none"> <li>• Point-of-care laboratory testing (iSTAT requires regular maintenance including calibration and cartridges must be temperature controlled)</li> </ul>
	<ul style="list-style-type: none"> <li>• Battery-powered blood refrigerators and/or freezers</li> </ul>
	<ul style="list-style-type: none"> <li>• Belmont Rapid Infuser</li> </ul>
Added operational equipment	<ul style="list-style-type: none"> <li>• Person-portable generator to power electronics with maintenance kit</li> </ul>
	<ul style="list-style-type: none"> <li>• Space heater</li> </ul>
	<ul style="list-style-type: none"> <li>• Fuel for generator</li> </ul>
	<ul style="list-style-type: none"> <li>• Tentage to set up patient care space</li> </ul>

Abbreviations: CBRNE, chemical, biological, radiological, nuclear, and explosive; MASCAL, mass casualty; RIC, rapid infusion catheter; TCCC, Tactical Combat Casualty Care.

<b>House model:</b> This model may allow for true surgical sets. The number of sets required will depend on how many simultaneous OR tables the site is intended to provide. Consider frequency and time required to resterilize instruments. Includes increased quantities of all Truck items.	
Anesthetic equipment	<ul style="list-style-type: none"> <li>• MAC catheters</li> </ul>
Medications	<ul style="list-style-type: none"> <li>• Increased IV fluids</li> </ul>
Surgical instruments	<ul style="list-style-type: none"> <li>• Consider several of each instrument set above</li> </ul>
	<ul style="list-style-type: none"> <li>• Craniotomy set</li> </ul>
	<ul style="list-style-type: none"> <li>• Several external fixator sets</li> </ul>
	<ul style="list-style-type: none"> <li>• Surgical suction and tubing</li> </ul>
	<ul style="list-style-type: none"> <li>• Surgical energy device (e.g., Bovie)</li> </ul>
Other surgical equipment	<ul style="list-style-type: none"> <li>• Consider larger capacity blood refrigeration equipment</li> </ul>
	<ul style="list-style-type: none"> <li>• Litters</li> </ul>
	<ul style="list-style-type: none"> <li>• More than 1 OR table/litter stands ± arm boards</li> </ul>
	<ul style="list-style-type: none"> <li>• Overhead free-standing lighting</li> </ul>
	<ul style="list-style-type: none"> <li>• Plasma thawer OR Belmont Rapid Infuser</li> </ul>
	<ul style="list-style-type: none"> <li>• Instrument sterilizer</li> </ul>
	<ul style="list-style-type: none"> <li>• More robust MASCAL kit</li> </ul>
<ul style="list-style-type: none"> <li>• Additional litters</li> </ul>	
Electronics	<ul style="list-style-type: none"> <li>• Arterial catheter pressure-monitoring equipment</li> </ul>
Operational equipment	<ul style="list-style-type: none"> <li>• Larger generator(s) with required fuel, wiring, circuit panels</li> </ul>
	<ul style="list-style-type: none"> <li>• Multiple space heaters</li> </ul>
	<ul style="list-style-type: none"> <li>• Wall-mounted lighting</li> </ul>

Abbreviations: IV, intravenous; OR, operating room.

## APPENDIX B: ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CLINICAL PRACTICE GUIDELINES

### Purpose

The purpose of this Appendix is to ensure an understanding of Department of Defense (DoD) policy and practice regarding inclusion in clinical practice guidelines (CPGs) of “off-label” uses of US 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 US 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. Furthermore, it does not imply that the Military Health System requires that use by DoD healthcare 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 healthcare practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for

the clinical judgment of the responsible healthcare practitioner within the practitioner-patient relationship.

### Additional Procedures

#### Balanced Discussion

Consistent with this purpose, CPG discussions of off-label uses specifically state they are uses not approved by the FDA. Furthermore, 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: (1) that the use is not approved by the FDA; (2) the reasons why a DoD healthcare practitioner would decide to use the product for this purpose; and (3) the potential risks associated with such use.