JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)

Emergency General Surgery in Deployed Locations (CPG ID:71)

This CPG will guide providers in the evaluation and treatment of patients with acute general surgical needs in potentially austere locations

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TABLE OF CONTENTS

GOAL

The goal of this clinical practice guideline is to provide guidance on the treatment of acute surgical conditions in the deployed environment. These guidelines are not intended solely for clinical care, but to help unit commanders and supporting medical components to consider tactical and resource constraints relevant to the management of acute surgical conditions in order to optimize patient care in the expeditionary setting.

BACKGROUND

Austere surgical environments in a deployed setting can be significantly different from what medical personnel experience in garrison. The lack of diagnostic and treatment modalities can significantly limit management options. While deployed austere surgical capabilities are established for the primary purpose of trauma care and hemorrhage control, surgeons are still likely to deal with other urgent surgical issues.[1,2,3] The aim of this guideline is to provide surgeons in austere locations, as well as command staff, with decision support for the care of emergency general surgery patients.

EVALUATION

Depending on surgical team capabilities, a history and physical examination will be the mainstay of the diagnostic evaluation. In addition, the majority of surgical teams also have the capability for ultrasound and point of care blood analysis to allow for limited imaging and laboratory assessment. The most common non-traumatic surgical diagnoses to be encountered are shown in the table below:[1,2,3]

Table 1. List of Common Surgical Diagnoses

List of Common Surgical Diagnoses
Kidney stones
Appendicitis
Hernia
Testicular Torsion
Cholecystitis
Inflammatory bowel disease
Bowel obstruction
Ectopic pregnancy
Obstetric emergency
Ruptured ovarian cyst
Anorectal disorders (abscess, hemorrhoids, fissure)
Diverticulitis
Soft tissue infection/Abscess
Gastrointestinal bleeding

All the above diagnoses are familiar to general surgeons and history and physical examination alone will yield a high diagnostic accuracy.

In the non-deployed setting, the most important part of the evaluation is determination of the patient's clinical stability followed by timing of surgical intervention if warranted. In the resource-limited environment, many additional factors have to be considered in order to optimize the care of the patient with an acute surgical condition. Determining whether the patient is best served by having emergency surgery in an austere or resource-limited location or by transferring to a higher role of care is multifactorial.

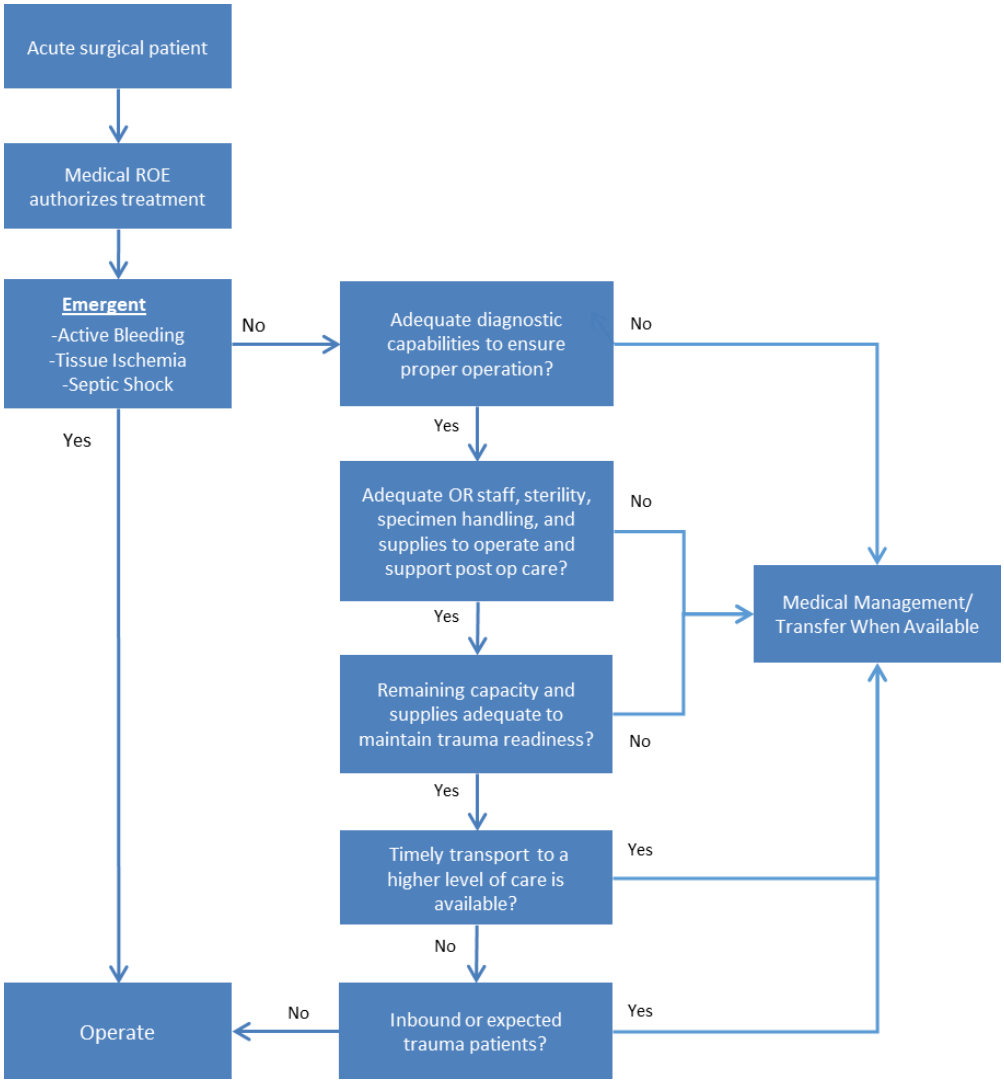
The deployed surgeon must consider complex tactical and clinical data in decision-making for clinically urgent situations. The surgeon must determine if the patient is emergent, requiring immediate intervention (e.g., ongoing bleeding, suspected tissue ischemia, or evidence of septic shock) or is nonemergent (localized findings, mild systemic symptoms). The clinical determination of stability is the most challenging for the deployed surgeon and their command staff alike. Except for gastrointestinal bleeding and tissue ischemia (e.g., testicular torsion, strangulated hernia), most patients with the previously mentioned surgical diagnoses will tolerate a delay of several hours with antimicrobial therapy before surgical intervention without increased morbidity or mortality. Therefore, these patients can be considered nonemergent.[4] While this delay in surgical treatment may not be ideal, it may be well within the standard of care. Some non-emergent invasive surgical procedures may be indicated in the austere environment depending on time to transport and complexity of the proposed intervention. For example, drainage of a soft tissue abscess may be indicated if transport to higher level of care will take multiple days.

DECISION MATRIX

Austere surgical environments and acute care surgery conditions are diverse and strict rules to cover every conceivable diagnosis would be inappropriate to a surgeon and commander. In all cases, the final clinical decision should rely on the surgeon at the forward location to act in the best interest of the patient. In real-world situations, the difference between emergent and nonemergent conditions can be clinically ambiguous when a host of additional factors are considered.

A graphical representation of considerations is presented above and discussed along with additional factors below.

Figure 1. Decision Matrix



1. Non-coalition patients: Patients may include local nationals, partner nation forces, contractors, foreign citizens, etc. Theater medical rules of eligibility (ROE) will dictate what care may be rendered, what transport resources will be available for use, and where these patients are to be transported for follow-on care. The principles of care should be equivalent to those provided to US/Coalition/enemy combatant patients, although operative decisions must be made in the context of the system of care in which that patient will be managed. Understanding of the medical ROEs and knowledge of the capabilities of the relevant systems of care are paramount.

2. Diagnostic capability: When conditions permit, the same preoperative, intraoperative, and postoperative standards of care should be provided to patients in a deployed location as in the United States. If a patient is non-emergent, reasonable attempts should be made to obtain appropriate diagnostic tests prior to surgical intervention, even if that requires transport to a higher role of care.

3. Operative team and supplies: Austere conditions are potentially not sterile and operative personnel may lack the subspecialty expertise for certain procedures or may be lacking the most appropriate supplies or

equipment needed. When conditions permit, procedures performed should be within the scope of practice of the deployed surgeon or should be done in close consultation with the appropriate subspecialist. In addition, specimens should be handled appropriately. Incidental neoplasms, while uncommon, do occur. Resected tissue should be evaluated by a pathologist and should be preserved appropriately for evaluation.

4. Holding capacity: If an operation is performed, the patient will have to be cared for postoperatively until transport or discharge is possible. If holding capacity is limited, a plan for transfer or discharge should be in place prior to the arrival of trauma patients.

5. Mission readiness: Non-emergent operations should not compromise the primary mission of the deployed team or the team's readiness to receive trauma patients.

6. Transport/receiving capability: If considering transport of the patient, the capability of transport vehicles and personnel may vary as well as the capabilities of receiving facilities. Knowledge of these capabilities and transport times are critical to making safe decisions. To the extent possible, communication with the transport team and the receiving provider should be made for patient safety and continuity of care.

7. Minor Procedures: If a procedure can be done in a clinic room, it can likely be done in an austere setting (i.e. thrombosed hemorrhoids, simple incision and drainage). Elective procedures should not be performed in the deployed setting. Elective minor procedures such as routine skin or soft tissue biopsies should not be done at a Role 3 unless in-house pathology is available as specimens can become lost or dry out while in transit for pathologic evaluation.

8. Teleconsultation: Whenever possible, particularly when surgical intervention for nonemergent conditions is being considered or when it is uncertain whether the condition is emergent or nonemergent, teleconsultation should be obtained with the surgeon at the next higher role of care if it is expected that the patient will require transfer postoperatively.

With the above listed considerations in mind, if the patient's clinical status is such that a delay in surgical treatment is likely to result in death or significant morbidity, they should be considered emergent and an operation performed. If not, strong consideration should be made to transfer the patient to a higher level of care unless, after considering the above points, in the surgeon's opinion the benefits outweigh the risks.

TREATMENT

The best interest of the patient is always the focus of decision-making for the surgeon; however, commanders are required to keep the tactical environment and risks aligned with the overall mission goals. In a setting of limited medical assets, determining the patient's clinical stability for transport as well as the availability of transport are extremely important factors to consider when determining the best treatment. The determination of emergent or nonemergent surgical status is therefore paramount and that decision may be appropriately influenced by availability and timing of transport to higher level of care. This distinction is based on the judgement of the surgeon on the ground, but emergent usually involves patients with tissue ischemia, ongoing bleeding, or evidence of septic shock. Emergent surgery should be done with treatment rendered based on damage control principles rather than in-garrison standards of care.[5] As in trauma, principles of surgical care should prioritize controlling sources of contamination and bleeding, with definitive care (e.g., anastomoses or ostomies) deferred for Role 3 or 4 facilities. In addition, heavily contaminated wounds should be left open for further washouts in a more sterile environment, if applicable.

Patients classified as nonemergent should be treated with the best available medical therapy and await transportation to a level of care that can definitively treat and hold patients for the perioperative period (See Decision Matrix; likely Role 3 or 4). This allows the austere surgeon to conserve supplies, equipment, and manpower for future emergent patients. Medical management may consist of broad spectrum antibiotics, resuscitation with fluids, pain control and supportive care as indicated. For some commonly encountered acute surgical diagnoses, medical management with ongoing close surgical observation may actually constitute definitive therapy.[6-10] The austere surgeon and the command element should have an awareness of the treatment options and how they fit into the multifactorial decision making. Treatment may entail medical management and observation within the forward surgical setting, transfer to higher level of care for definitive diagnosis, or disposition to quarters with a medical or non-medical attendant. Commanders and patients should be aware of these options with the associated risks. Clinical observation always carries the risk of deterioration requiring surgical intervention, therefore transfer to a higher level of care may be indicated even when non-operative management is selected.

While tailored antimicrobial therapy may be preferred for some diagnoses, this may not be possible given limited medication options in most austere packs as well as diagnostic uncertainty. Antibiotics should default to broad spectrum agents such as ertapenem given its widespread availability in austere surgical team packs, ease of administration and broad coverage. Given the low cross reactivity with penicillin-allergic patients, this common allergy should not dissuade surgical teams from administering ertapenam to patients with penicillin allergy.[11] Alternatives are disease specific, but consideration should be given to broad coverage from the onset of care. Lack of microbiology, culture and basic lab capability, combined with virulent local pathogens in many austere settings dictate this approach.

Unique to the military surgical environment is the need for maintain mission-readiness for the patient and their deployed unit. With mission requirements of foremost importance, the possibility of treating common surgical diseases, such as appendicitis and cholecystitis, non-operatively in an austere surgical setting should be considered and a high likelihood of success may be expected.[7,12] In-theater surgical treatment in austere locations with rapid return to duty may also be acceptable if resources and mission requirements permit. While patients are commonly instructed to limit physical activity for 6 weeks, there is little evidence-based support for this practice.[13] In cases of soft tissue abscesses and uncomplicated appendicitis, the expected post-operative morbidity would likely be low and the patient potentially safely and well-managed in the austere setting. However, for a nonemergent patient with suspected appendicitis seen in the Role 2 setting, strong consideration should be given to transferring the patient to a higher level of care in order to confirm the diagnosis with CT scan or if laparoscopic capability is available.

Nonemergent patients with acute cholecystitis should not be operatively managed at the Role 2 unless laparoscopic equipment, the appropriate operating room table and the ability to perform a cholangiogram (either flat plate or C-arm) is available as this is the standard of care and very rarely does a patient with acute cholecystitis require an emergent open cholecystectomy.

Although surgical site infections have been reported to be similar to civilian outcomes in one published experience, the surgical site infection rates are not negligible and other non-infectious perioperative complications may occur.[14] While transfer to a location that can deal with post-operative complications most effectively would be ideal, if the austere surgical team can safely and effectively perform the operation and manage perioperative complications an operation may be considered. Additionally, return to duty status should be taken into consideration along with long term post-operative morbidity such as hernia formation, the need for advanced pain management requirements (difficult in the austere or combat environment) and immediate post-operative complications.

PERFORMANCE IMPROVEMENT (PI) MONITORING

INTENT (EXPECTED OUTCOMES)

- Initial treatment with antibiotics if infectious diagnosis (appendicitis, cholecystitis, abscess, diverticulitis).
- Emergency general surgery cases are done at Role 3 or Role 4; if done at Role 2, the indication to proceed with surgery rather than evacuate to higher level of care should be clearly documented.

POPULATION

All patients who undergo surgery for non-trauma diagnoses by deployed surgical teams.

PERFORMANCE/ADHERENCE MEASURES

- Antibiotics are given for infectious diagnoses.
- Emergency general surgery cases are done at Role 3 or Role 4; if done at Role 2, the indication to proceed with surgery rather than evacuate to higher level of care is clearly documented.

DATA SOURCES

- Patient Record
- Department of Defense Trauma Registry (DoDTR)
- Morbidity and Mortality Conference Reports

SYSTEM REPORTING & FREQUENCY

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

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

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APPENDIX A: ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

PURPOSE

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of "off-label" uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

BACKGROUND

Unapproved (i.e. "off-label") uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing "investigational new drugs." These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the "standard of care." Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

ADDITIONAL PROCEDURES

Balanced Discussion

Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

Quality Assurance Monitoring

With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

Information to Patients

Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.