JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)

Blunt Abdominal Trauma, Splenectomy, and Post-Splenectomy Vaccination (CPG ID:09)

To provide guidance on the management of combat casualties who sustain blunt abdominal trauma.

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BACKGROUND

Unlike penetrating abdominal injuries where the decision to operate is relatively straight forward, those combat casualties that sustain Blunt Abdominal Trauma (BAT) offer more of a diagnostic and clinical challenge. With the improvements in body armor, truncal injury has decreased despite increasingly more lethal weapon systems. With the advent of Improvised Explosive Devices (IEDs), however, more casualties are presenting with evidence of BAT. While Computed Tomography (CT) scans are available to assist the provider in decision making at a Role 3 facility, providers at far forward surgical units must decide to operate based on a physical and a focused assessment with sonography for trauma (FAST) exam.[1]

It is incumbent on the senior surgeon at each facility to ensure the staff understands their resource limitations and the inherent limitations associated with the use of the FAST exam to diagnose a hemoperitoneum. For hemodynamically unstable trauma patients with a positive FAST, exploratory laparotomy should be undertaken immediately. Rarely, patients with a positive FAST and/or CT scan may be managed non-operatively if they are already at a Role 3 facility that can ensure adequate clinical follow-up and evaluation. Patients who have a positive FAST exam and/or evidence of hemoperitoneum through CT at a surgical facility should not be transferred until any and all ongoing intraabdominal hemorrhage is completely assessed and controlled. The benefits of non-operative management do not outweigh the risks of an in-flight hemorrhagic emergency with no potential for therapeutic surgical intervention. Patients who evolve peritonitis by physical exam or continue to consume blood products in order to maintain blood pressure warrant exploratory laparotomy. An algorithmic approach to the blunt trauma patient is presented in Appendix A.

Splenic injury grading is presented in Table 1 below. All grade IV-V splenic injuries should undergo splenectomy due to the high risk of failure of non-operative management with or without splenic embolization[2] and the need for prolonged transportation out of theater. Lacerated spleens of any grade with active hemorrhage encountered during laparotomy for any reason are best managed by splenectomy. If the tactical situation permits stable grade III splenic injuries without active extravasation, pseudo aneurysm, hemoperitoneum on CT scan or other indications for laparotomy that may include, but are not limited to associated injury may undergo attempt of non-operative management under the direct supervision of an experienced trauma surgeon.[3] Ideally, patients undergoing attempted splenic salvage should be monitored in the Role 3 facility for at least 48 hours prior to strategic evacuation out of theater. In Role 3 facilities with interventional radiology capabilities, embolization of grade III splenic injuries may be considered as an adjunct to non-operative management. Embolization is not definitive treatment for splenic injuries so these patients must also be monitored for 48 hours following the procedure and prior to strategic aeromedical evacuation from theater.

Table 1. Organ Injury Scaling Spleen

Grade	Injury Description	AIS 90
I	Subcapsular Haematoma, <10% surface area Laceration Capsular tear, <1cm parenchymal depth	2 2
II	Subcapsular Haematoma, 10-50% surface area Intraparenchymal, <5cm diameter Laceration 1-3cm parenchymal depth not involving a parenchymal vessel	2 2
III	Subcapsular Haematoma, >50% surface area or expanding. Ruptured subcapsular or parenchymal haematoma. Intraparenchymal haematoma >5cm Laceration >3cm parenchymal depth or involving trabecular vessels	3 3
IV	Laceration of segmental or hilar vessels producing major devascularization (>25% of spleen)	4
IV	Laceration Completely shattered spleen Vascular Hilar Vascular Injury which devascularized spleen	5 5
	Advance one grade for multiple injuries to same organ up to Grade III.	

A contrast CT scan should be obtained at 48 hours (and before aeromedical evacuation out of the Role 3 to assess for complications such as pseudonaneurysm formation on all patients undergoing non-operative management of splenic injury.[4] Indicators of failure of non-operative management of the spleen include but are not limited to any need for blood transfusion and any hypotensive episode. For Grade I-III splenic injuries success rate of non-operative management with embolization reach 99-100%. Patients who fail non-operative management of the spleen require splenectomy at the Role 3 prior to aeromedical evacuation. It must be stressed that placing a patient in the aeromedical environment is akin to discharge from the facility ***without activity restriction*** and without the option of re-admission during the complete inter-facility transport between theaters which must be assumed to be a minimum of 12 hours. Additionally, the patient's history should be discussed between the referring and accepting surgeons prior to evacuation. Patients with Grade III splenic injury and Traumatic Brain Injury (TBI) should undergo splenectomy due to the fact that hypotension with TBI will double mortality.[5] Angiography and embolization for blunt injuries of other visceral organs may be used as an adjunctive procedure and should be determined on a case by case basis.

OVERWELMING POSTSPLENECTOMY SEVERE INFECTION (OPSI)

In a review of post-splenectomy patients from 1966-96, with a median follow-up of 6.9 years, invasive infection occurred in 2.3% of trauma patients with a 49% mortality rate.[6] Patients present with nonspecific flu-like symptoms rapidly progressing to fulminant sepsis, consumptive coagulopathy, bacteremia, and untimely death within 12-48 hours. The infections are typically caused by encapsulated organisms including Streptococcus pneumoniae, Haemophilus Influenzae type B, and Neisseria meningitidis, for which there are effective vaccines. One study demonstrated that only 56.7% of patients receive all vaccines needed.[7] Since these patients are at risk for OPSI, there must be a standardized process to provide post-splenectomy vaccination, accurate documentation, and life-long tracking to identify outcomes.

VACCINE CANDIDATES

All splenectomized patients and those deemed to be functionally asplenic (e.g., <51% normal architecture and/or vascularization in the remaining splenic segment).

VACCINE DOSING

PNEUMOCOCCAL

1. Prevnar 13® (PCV13) AND Pneumovax 23® (PPSV23) are both recommended.[8]
2. Single dose of PCV13 should be given to patients who have not previous received PCV13.
3. PPSV23 should be given 8 weeks after PCV13 for those who have not previously received PPSV23.
4. One-time revaccination of PPSV23 should be administered 5 years after the first dose.

HAEMOPHILUS INFLUENZAE TYPE B (HIB)

Single dose of any Hib conjugate vaccine (PedvaxHIB®, ActHIB®, or Hiberix®) is recommended for those who have not previously been vaccinated for Hib.[9]

MENINGOCOCCAL

1. Vaccination for serogroup B (MenB) as well as serogroups A, C, W, and Y (MenACWY) is recommended.[10,11,12]
2. For those not previously vaccinated for MenB, either Bexsero® (2 dose series) or Trumenba® (3 dose series) may be given.
3. For those not previously vaccinated for MenACWY, either Menveo® or Menactra® should be administered as a 2 dose primary series. After the primary series, a booster dose is recommended every 5 years.
4. For those that have been vaccinated for MenACWY within 5 years, no booster is needed. If vaccinated beyond 5 years, a booster dose should be administered.
5. If Menactra® is the only MenACWY vaccine available and the patient also is recommended to get Prevnar 13®, Menactra® should be administered 4 weeks after Prevnar 13®.

VACCINATION ADMINISTRATION TIME

All patients for Aeromedical Evacuation: Administer recommended vaccines in the immediate postoperative period at the first facility that can do so. See above for timing if patient is recommended for both Prevnar 13® and Menactra®. Role 3 and Role 4 facilities should not assume that vaccination have occurred prior to arrival.

Host nation and other patients NOT evacuated out of theater: Administer recommended vaccines in the immediate postoperative period at the first available opportunity but no later than the 14th postoperative day.

Table 2. Guide for the Vaccine Naïve Patient

Guide for the Vaccine Naïve Patient (*If patient has previously received one or more of the listed vaccines, see text for guidance.*)				
Bacteria	**Vaccine**	**Dose and Timing***		
Streptococcus pneumoniae	Prevnar 13®	Single Dose		
	Pneumovax 23®	One dose ≥8 weeks after Prevnar 13®	Second dose 5 years after first dose	
Nesseria meningitidis	Bexsero® or Trumemba® (serogroup B)	Dose #1	Dose #2 one month after first dose	If using Trumemba®, Dose #3 five months after Dose #2
	Menactra® or Menveo® (serogroups A, C, W, and Y)	Dose #1 (if using Menactra®, give 4 weeks after Prevnar 13®)	Dose #2 one month after first dose	Booster dose given every 5 year interval
Haemophilus influenza type b	PedvaxHIB® **or** ActHIB® **or** Hiberix®	Single Dose		

**Vaccines should be administered as soon as the patient is clinically stable post-operatively*

VACCINATION DOCUMENTATION

A dated, timed, and signed physician order for recommended vaccines will be documented on the physician order form. If any recommended vaccines are not ordered, there must be clear documentation indicating the rationale for why one or more vaccines were not ordered. Doing so will facilitate clear communication along the continuum of care.

Vaccine administration documentation on the medication administration record (MAR) will include date, time, dose, lot number/lot sticker, manufacturer, and nurse signature for each vaccine. If any or all of the vaccines are ordered, but not administered (for any reason), the ordering physician must be notified, and there must be clear documentation indicating this and the rationale for why one/more vaccines were not administered. Also, document which provider was notified. This facilitates clear communication along the continuum of care.

Documentation in the electronic medical record for the physician order, dispensing from the pharmacy or immunization clinic, and nursing administration is preferred when possible. Documentation of vaccination is highly recommended in the service specific vaccination tracking systems (MEDPROS for Army, MRRS for Navy/Marine/Coast Guard, and ASIMS for Air Force) if available at the treating facility or operating base.

PERFORMANCE IMPROVEMENT (PI) MONITORING

POPULATION OF INTEREST

All trauma patients with blunt trauma injury type ***and*** any AIS-abdominal code.

INTENT (EXPECTED OUTCOMES)

1. Hemodynamically unstable (SBP < 90) blunt trauma patients with positive FAST undergo laparotomy (unless documented reason to delay/avoid).

2. All patients with grade IV and V splenic injuries requiring long-range evacuation undergo splenectomy or reason for non-operative management is documented.

3. Selective non-operative management of hemodynamically stable Grade I-III blunt splenic injury is performed at Role 2E, 3 or 4.

4. All patients who undergo splenectomy receive splenectomy vaccinations.

PERFORMANCE/ADHERENCE METRICS

1. Number and percentage of patients in population of interest with SBP <90 and positive FAST on arrival to a surgical capability who undergo exploratory laparotomy at the same level of care.

2. Number and percentage of patients with grade IV and V splenic injuries who undergo splenectomy.

3. Number and percentage of patients with each grade of splenic injury who are managed non-operatively.

4. Number and percentage of patients who undergo splenectomy who have documentation of pneumococcal and **HAEMOPHILUS** influenza vaccines.

DATA SOURCES

- Patient Record
- Department of Defense Trauma Registry (DoDTR)

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 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.

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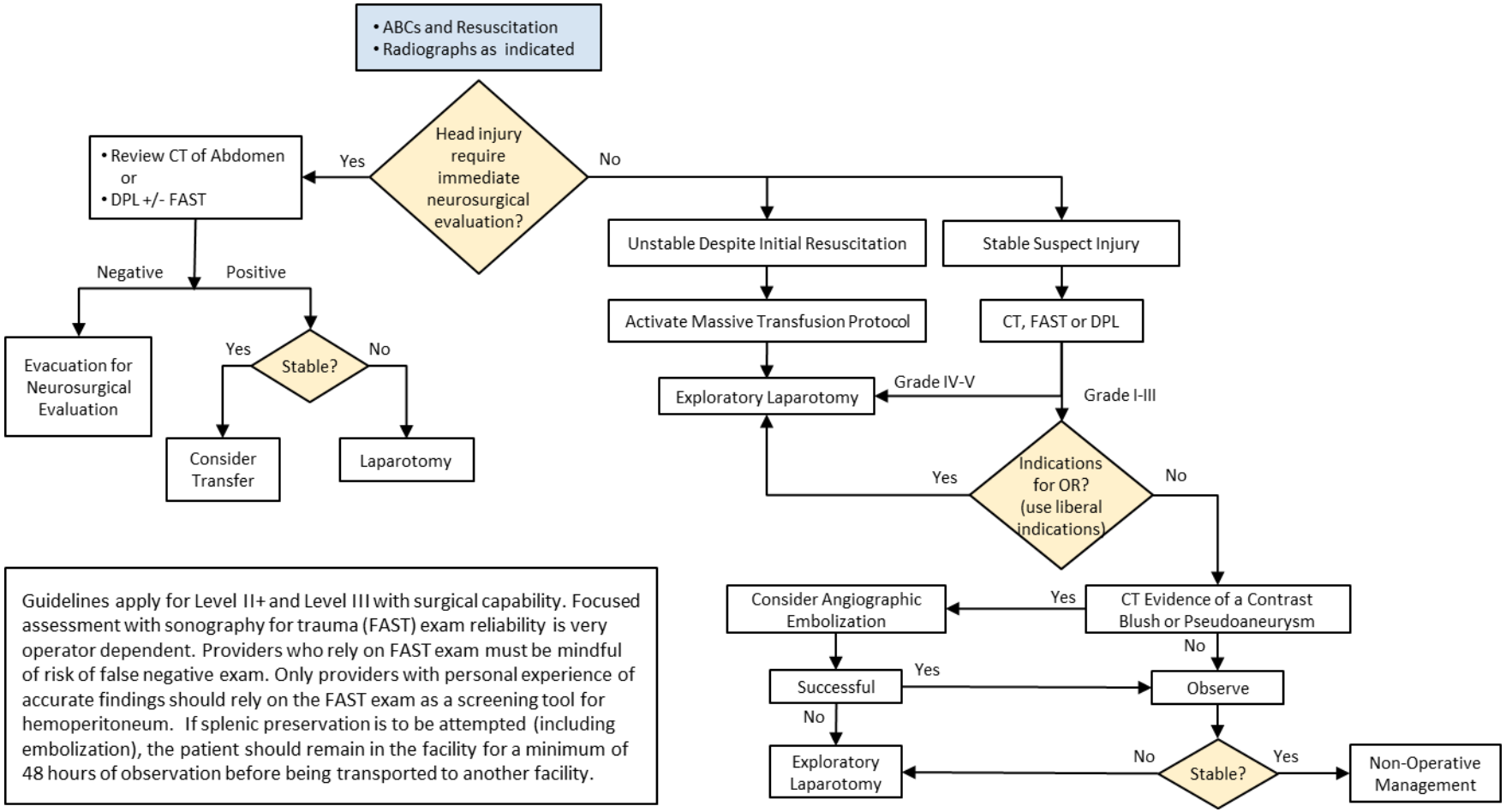
APPENDIX A: ALGORITHM FOR EVALUATING BLUNT ABDOMINAL TRAUMA



Guidelines apply for Level II+ and Level III with surgical capability. Focused assessment with sonography for trauma (FAST) exam reliability is very operator dependent. Providers who rely on FAST exam must be mindful of risk of false negative exam. Only providers with personal experience of accurate findings should rely on the FAST exam as a screening tool for hemoperitoneum. If splenic preservation is to be attempted (including embolization), the patient should remain in the facility for a minimum of 48 hours of observation before being transported to another facility.

APPENDIX B: 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.