POST-SPLENECTOMY VACCINATION

Original Release/Approval		March 2012	Note: This CPG requires an annual review.	
Reviewed:		Approved for PACOM :	DEC 2014	
Supersedes:	**This is a new CPG and must be reviewed in its entirety**.			
Minor Changes (or)		Changes are substantial and require a thorough reading of this CPG (or)		
Significant Changes				

1. **Goal.** All post-splenectomy and functionally asplenic trauma patients in the PACOM AOR will receive appropriate and timely vaccination. All vaccinations will be documented in the longitudinal medical record and include date/time of physician order and date/time of administration by medical staff.

2. **Background.** Overwhelming post-splenectomy sepsis (OPSS) is a rare but devastating complication with a case mortality rate in most studies approaching 50%.[1] OPSS represents a life-long risk, with the incidence in trauma patients estimated to be < 0.5%.[2] It is estimated that splenectomized individuals are up to 540 times more susceptible to lethal sepsis than the general population.[3] The majority of trauma surgeons provide some sort of post-splenectomy vaccination to their patients, although to date, there is no consensus on timing of initial vaccination, vaccination regimen, or future re-vaccination. In 2002, Shatz conducted a survey of trauma surgeons regarding their vaccination practices in post-splenectomy patients. Of 261 active surgeons, 99.2% immunized their splenectomized patients: 1) All but two provided the pneumococcal vaccine, 2) 62.8% advocated the meningococcal vaccination, 3) 72.4% added the H.influenzae vaccine, and 4) 56.7% gave all three vaccines. The timing of vaccination ranged from the immediate post-operative period to six weeks following surgery.[4]

   Within the PACOM AOR, most moderate to severe splenic injuries are managed by total splenectomy. Since these patients are at risk for OPSS, there must be a standardized process to provide post-splenectomy vaccination, accurate documentation, and life-long tracking to identify outcomes (See Appendix A for additional clinical background).

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

4. **Dosing.**

   a. Pneumococcal (Pneumovax 23): Single dose.[5]

      1) Approved abbreviation: PPSV23.

      2) One-time revaccination after 5 years is recommended for persons aged 19 through 64 years with functional or anatomic asplenia (splenectomy).

   b. Haemophilus influenzae type B. (ActHIB, PedvaxHIB, or Hiberix): Single dose.[5]

      1) Approved abbreviation: Hib.

c. Meningococcal (Menactra or Menveo): Single dose.[5]

1) Approved abbreviation: MCV4.

2) One-time revaccination after 5 years is recommended for persons aged 19 through 64 years with functional or anatomic asplenia (splenectomy).

5. Timing.

a. All US forces and all patients for aeromedical evacuation (AE) to Role IV or Role V: Administer all three vaccines in the immediate postoperative period at the first Level III facility. Vaccinations may be given at a Role II if they are available. For patients evacuated directly from Role II to a Role IV or Role V facility, vaccinate at the Role IV or Role V facility.

b. Host nation and other patients NOT for AE to Role IV or Role V: Administer all three vaccines in the immediate postoperative period at the first Role III facility, but no later than the 14th postoperative day.

6. Documentation.

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

b. Vaccine administration documentation on the medication administration record (MAR) will include date, time, dose, lot number/lot sticker, manufacturer, and nurse signature for each of the three vaccines. If any or all of the three 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.

c. 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.

7. Performance Improvement (PI) Monitoring.

a. Intent (Expected Outcomes). To ensure all patients in the PACOM AOR who are rendered asplenic by trauma and/or surgery are completely vaccinated against OPSS.

b. Performance/Adherence Measures.

1) All patients undergoing splenectomy and those who are functionally asplenic received all three post-splenectomy vaccines.

2) All post-splenectomy vaccinations are documented in the physician orders and nursing MARs.

3) All documentation is complete and accurate to include date, time, dose, lot number/lot sticker, manufacturer, and nurse signature for each of the three vaccines administered.

c. Data Source.

1) Patient Record

2) Department of Defense Trauma Registry (DoDTR)

3) Nursing MAR

d. 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 Theater Trauma System (JTTS) Director, JTTS Program Manager, and the Joint Trauma System (JTS) Performance Improvement Branch.

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

9. References.

[1] Prevention of pneumococcal disease: recommendations for the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 1997; 46:12-15.

[2] Crivitz W. Overwhelming postsplenectomy infection. *Am J Hematol*. 1977; 2:193- 201.

[3] O'Neal BJ, McDonald JC. The risk of sepsis in the asplenic adult. *Ann Surg*. 1981; 194:775-778.

[4] Shatz David V. Vaccination practices among North American trauma surgeons in splenectomy for trauma. *J Trauma*. 2002; 53:950-956.

[5] Recommended Adult Immunization Schedule: UNITED STATES 2011, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP); www.cdc.gov/vaccines.

Approved by PACOM JTTS Director, JTS Director and PACOM SG

APPENDIX A

TIMING OF VACCINATION AFTER SPLENECTOMY

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22 Dec 2008

Overwhelming post-splenectomy sepsis is an uncommon, but rapidly life-threatening complication of splenectomy, occurring at the rate of approximately 1 per 1000 patient-years. Immunization with vaccines protective against encapsulated organisms (e.g. Streptococcus pneumonia, Nisseria meningitis, Hemophilus influenzae) drops this risk to approximately 1 per 106 patient-years. Appropriate prophylactic immunization of injured warriors undergoing splenectomy was not reliably occurring until the recent development of a Clinical Practice Guideline suggesting immunization with appropriate vaccines immediately after splenectomy. During the most recent two months of evaluation, immunization rates are 100%. At issue is the effectiveness of vaccination at this time period. A literature search was performed with recent pertinent references listed below.

A summary of the pertinent studies is included in Table 1 below. The Surgical Infection Society recommends that patients who cannot be immunized prior to splenectomy receive vaccination two weeks after splenectomy (Grade D recommendation: expert opinion). In summary, antibody responses to vaccination in humans after splenectomy have been shown to be improved if there is a two week delay in immunization. Likely due to the very low incidence of overwhelming post-splenectomy sepsis, there is no evidence to support an outcome benefit related to this delay.

Table 1, Summary of Pertinent Studies

Reference	Species	Endpoint	Notes
Shatz	Human (splenectomy)	Antibody response	Improved Ab response at 2 weeks (= normal controls) after splenectomy compared to 1 day, 1 week
Werner	Rat (splenectomy)	Antibody response	Improved response 1 week, 1 month post-splenectomy
Schreiber	Rat (splenectomy, *S pneumo* challenge)	Survival	No difference in survival in early (1 day) vs. late (42 d) immunization. Both better than unimmunized controls
Clayer	Rat (splenectomy)	Antibody response	Ab response decreased early (1 d) and late (1 y) after splenectomy compared to normal controls
Werner	Rat (Hem shock, then splenectomy)	Antibody response	No difference in Ab response 1 d vs. 28 d s/p splenectomy plus shock

Currently there is little evidence that patients requiring immunization are not receiving them. Of patients receiving splenectomy as part of their treatment in theater between Jan and Dec of 2011, 30/31 received appropriate immunization (Figure 2 and Figure 1).

While it appears that antibody response to immunization is improved in humans when waiting two weeks post-injury, there is no evidence to suggest that this delay is protective for overwhelming post-splenectomy sepsis. The current process of immunization at the time of splenectomy is yielding appropriate immunizations in warfighters requiring splenectomy and will be continued.

Figure 1, Post Splenectomy Patients Receiving Vaccines 2003 - 2010

	2003	2004	2005	2006	2007	2008	2009	2010
Splenectomies	6	18	35	49	38	14	19	27
Pt Receiving vaccines	0	0	1	5	3	8	16	25

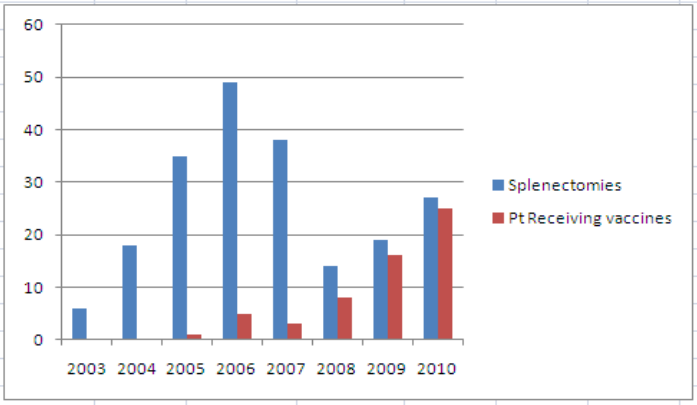
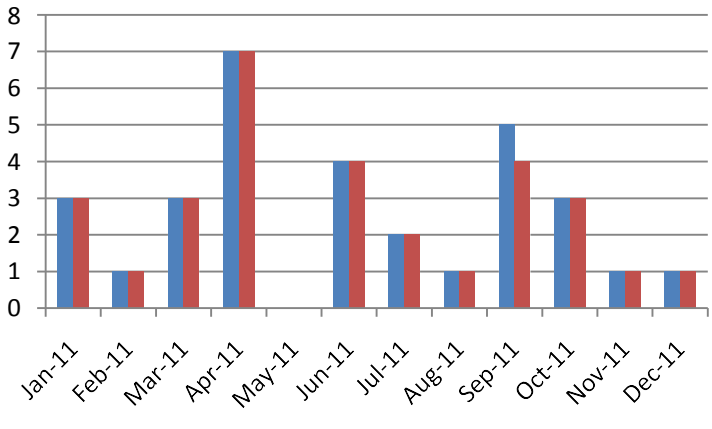


Figure 2, Post Splenectomy Patients Receiving Vaccines 2011



	Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11	Oct-11	Nov-11	Dec-11
Patients receiving splenectomies	3	1	3	7	0	4	2	1	5	3	1	1
Patients receiving vaccines	3	1	3	7	0	4	2	1	4	3	1	1

Abbreviated Reference List.

[1] Shatz DV, Schinsky MF, Pais LB, Romero-Steiner S, Kirton OC, Carlone GM., Immune responses of splenectomized trauma patients to the 23-valent pneumococcal polysaccharide vaccine at 1 versus 7 versus 14 days after splenectomy. J Trauma. 1998 May;44(5):760-5; discussion 765-6

[2] Werner AM, Solis MM, Vogel R, Southerland SS, Ashley AV, Floyd JC, Brown C, Ashley DW. Improved antibody responses to delayed pneumococcal vaccination in splenectomized rats. Am Surg. 1999 Sep;65(9):844-7; discussion 847-8.

[3] Schreiber MA, Pusateri AE, Veit BC, Smiley RA, Morrison CA, Harris RA. Timing of vaccination does not affect antibody response or survival after pneumococcal challenge in splenectomized rats. J Trauma. 1998 Oct;45(4):692-7; discussion 697-9

[4] Clayer MT, Drew PA, Jamieson GG. Antibody responses following splenectomy: implications for the timing of prophylactic vaccination. Aust N Z J Surg. 1992 Feb;62(2):142-6.

[5] Werner AM, Katner HP, Vogel R, Southerla SS, Ashley AV, Floyd JC, Brown C, Ashley DW. Delayed vaccination does not improve antibody responses in splenectomized rats experiencing hypovolemic shock. Am Surg. 2001 Sep;67(9):834-8.

[6] Howdieshell TR, Heffernan D, Dipiro JT; Therapeutic Agents Committee of the Surgical Infection Society. Surgical infection society guidelines for vaccination after traumatic injury. Surg Infect (Larchmt). 2006 Jun;7(3):275-303.

APPENDIX B

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

1. 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.

2. 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.

3. 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.

4. Additional Procedures.

a. 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.

b. 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.

c. 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.