INFORMATION PAPER

Military Vaccine Agency
9 November 2007

SUBJECT: Intra-Venous Vaccinia Immune Globulin (IV-VIG)

1. Purpose. Define procedures for ordering IV-VIG

2. Facts.

a. Smallpox immunizations are provided to designated at-risk military personnel, DoD civilian personnel classified as emergency-essential, and other civilian personnel. Some people are at greater than usual risk for serious side effects from the smallpox vaccine. IV-VIG is indicated for the treatment or modification of certain conditions induced by the smallpox vaccine.

b. Under routine circumstances, the need for VIG shall be validated by a board-certified infectious-disease or allergy-immunology specialist before administration. The Vaccine Healthcare Centers (VHC) Network will provide and coordinate professional consultation services to optimize clinical use of IV-VIG, and then maintain a case file of patients treated with IV-VIG.

3. Procedures

a. Clinician identifies smallpox vaccinee with adverse reaction that may benefit from IV-VIG administration This would include but is not limited to: aberrant infections induced by vaccinia virus that include accidental implantation in eyes (except in cases of isolated keratitis), mouth, or other areas where vaccinia infection would constitute a special hazard; eczema vaccinatum; progressive vaccinia; severe generalized vaccinia; or vaccinia infections in people who have skin conditions such as burns, impetigo, varicella-zoster, or poison ivy; or in people who have eczematous skin lesions because of either the activity or extensiveness of such lesions.

b. Clinician consults with infectious-disease (ID) or allergy-immunology (AI) specialist physician. Long-distance consultations will be arranged via the Vaccine Healthcare Centers (VHC) Network's Vaccine Clinical Call Center (866-210-6469). VHC will notify the Military Vaccine (MILVAX) Agency of case specifics.

c. ID or AI, in consultation with the VHC and Centers for Disease Control and Prevention (CDC) physician, authorizes release of IV-VIG from CDC’s Strategic National Stockpile (SNS).

d. IV-VIG is requested directly from the CDC by calling the CDC Director's Emergency Operation Center (DEOC) at (770) 488-7100 and request to speak with the

Division of Bioterrorism Preparedness and Response (DBPR) on-call person. The CDC is the release authority for IV-VIG.

e. Requestor notifies VHC Network (telephone 866-210-6469, email askvhc@amedd.army.mil); MILVAX (telephone 877-GET-VACC, DSN 761-4245, email patrick.garman@us.army.mil).

f. The attending clinician reads package insert and case-report form while considering the patient's clinical situation. The clinician then obtains needed specialty consults and administers IV-VIG if warranted. Clinician draws serum specimens before infusion and then 5 days after each IV-VIG dose. Freeze serum vials at -20°C until ready to ship. Obtain patient's consent to release serum samples. Ship serum vials at -20°C and case-report form to CDC in accordance with detailed instructions in the serum processing kit that accompanies IV-VIG. Send copy of case-report form to VHC.

4. References.

a. Advisory Committee on Immunization Practices. Smallpox Vaccinations and Adverse Reactions, MMWR 2003;52(RR04): 1-28: www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm

b. CDC VIG information website: ww.bt.cdc.gov/agent/smallpox/vaccination/vig.asp

c. CDC disease information website. www.bt.cdc.gov/agent/smallpox/index.asp

d. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by Military Vaccine Agency: www.vaccines.mil/smallpox

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