INFORMATION PAPER

Military Vaccine Agency
3 June 2011

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

1. Purpose. Define procedures for acquiring VIG-IV

2. Facts.

a. Smallpox immunizations are provided to designated military personnel, DoD civilian personnel classified as emergency-essential, and other civilian personnel. A small number of people are at an increased risk for side effects from the smallpox vaccine. VIG-IV is indicated for the treatment or modification of certain adverse conditions induced by the smallpox vaccine.

b. The Director of the Military Vaccine (MILVAX) Agency will act as final releasing authority for all Food and Drug Administration (FDA) licensed and DoD owned VIG-IV.

c. MILVAX is responsible for FDA required post-licensure safety surveillance activities for VIG-IV in coordination with the manufacturer.

c. Under routine circumstances, the need for VIG-IV will be validated by a board-certified infectious-disease or allergy-immunology specialist before administration. The Vaccine Healthcare Centers Network (VHCN), a division of MILVAX, will provide, and coordinate professional consultation services to optimize clinical use of VIG-IV

3. Procedures

a. Clinician identifies smallpox vaccinee with adverse reaction that may benefit from VIG-IV 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 will consult with infectious-disease (ID) or allergy-immunology (AI) specialist physician. Long-distance consultations will be arranged via the VHCN by calling the DoD Vaccine Clinical Call Center at (866-210-6469). VHCN or attending

physician will notify the Military Vaccine (MILVAX) Agency with case specifics. The ID or AI specialist, in consultation with the VHCN will request the release of VIG-IV.

c. MILVAX Agency (telephone 877-GET-VACC, DSN 761-4245, email Vaccines@amedd.army.mil) will coordinate the release and shipment of CONUS and OCONUS VIG-IV with the United States Army Medical Materiel Agency Distribution Operations Center (USAMMA-DOC). VIG-IV is prepositioned at USAMMA in Fort Detrick, MD, as well as at Hawaii (Tripler Army Medical Center), Okinawa, Japan (Camp Lester), Republic of South Korea (Brian Allgood Army Community Hospital), and Germany (USAMMC-Europe).

d. The attending clinician reads package insert and case-report form while considering the patient's clinical situation. The clinician then obtains needed specialty consultations and administers VIG-IV if warranted. Clinician draws serum specimens before infusion and 5 days after each VIG-IV 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 the Centers for Disease Control and Prevention in accordance with detailed instructions in the serum processing kit that accompanies VIG-IV. Send copy of case-report form to VHCN.

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: www.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 and www.smallpox.mil.

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