

## INFORMATION PAPER

DHA-IHB  
3 May 2016

SUBJECT: Vaccinia Immune Globulin Intravenous (Human) (VIGIV)

1. Purpose. Define procedures for acquiring VIGIV

2. Facts.

a. The DoD requires smallpox vaccination of designated at-risk military personnel, DoD civilian personnel classified as emergency-essential per DoD Directive 1404.10, and members of CBRNE response teams (e.g., smallpox epidemic response teams, treatment teams, and public health teams). A small number of people may be at increased risk for side effects after receipt of, or exposure to, the smallpox vaccine. VIGIV is indicated for the treatment of certain adverse conditions induced by the smallpox vaccine.

b. In 2011, representatives from CBMS and the United States Army Medical Materiel Agency of the United States Army Medical Research and Materiel Command to establish a DoD VIGIV stockpile. Establishment of this stockpile allowed the DoD to pre-position stocks of VIGIV for more responsive worldwide administration of potentially life-saving treatments in response to emergencies. OCONUS stockpiles are maintained at Camp Foster, Okinawa Japan, USAMMC-K Korea, and USAMMC-E Pirmasens Germany. Prior to the receipt of this materiel, the DoD relied solely on the Strategic National Stockpile's continental U.S.-based VIGIV stocks for emergency purposes. VIGIV, manufactured by Cangene Corporation, is an FDA-licensed medical treatment for rare, but serious adverse events associated with smallpox vaccination.

c. Any Medical Director within the DHA-Immunization Healthcare Branch (IHB) is delegated by the Director of the IHB to act as final releasing authority for DoD owned VIGIV. The IHB will provide and coordinate professional consultation services to facilitate the diagnosis of a potential VIGIV-requiring vaccinia adverse event and the clinical use of VIGIV.

d. The DHA-IHB's Chief of the Clinical Operations Office or designee will coordinate with USAMMA the shipment of all VIGIV to CONUS and OCONUS locations.

3. Procedures

a. An experienced clinician identifies an individual with adverse reaction who may benefit from treatment with VIGIV. This would include but is not limited to: aberrant infections induced by vaccinia virus that include accidental implantation in eyes, mouth, or other areas where vaccinia infection would constitute a special hazard; eczema

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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. VIGIV is not indicated for isolated vaccinia keratitis or post-vaccinial encephalitis.

b. The attending physician will immediately begin the consultation process with the IHB by calling the DHA Immunization Healthcare Support Center at 877-438-8222, available 24 hours a day, 7 days a week.

c. Before Vaccinia Immune Globulin (VIGIV) is released, confirmation of vaccinia infection is required. This may be either through accepted clinical signs and symptoms, or through verification of infection (see IHB Vaccinia PCR Algorithm).

d. To assist in the indication verification, dose determination, and shipping processes, the following information is required from the attending physician:

- (1) Age
- (2) Weight
- (3) Clinical Condition (i.e., stable, guarded, critical)
- (4) In-patient status (i.e., Doctor's office, ED, hospitalized, ICU)
- (5) Percent skin involvement
- (6) History of eczematous skin conditions
- (7) History of immunocompromising conditions
- (8) Blood Rh factor (to determine VIGIV lot to be used)
- (9) Dermatology and ID consultant availability
- (10) Clinical specimens availability
- (11) Digital photos representing various lesions and total surface involvement
- (12) Obtain list of other potential contacts
- (13) Date of his last smallpox vaccination (primary or re-vaccinee)
- (14) Number of vials required  $[\text{wt}(\text{kg}) \times 6,000\text{U}/\text{kg} / 50,000\text{U}/\text{vial}]$
- (15) Mailing address (MTF 24 hr pharmacy) and receiving pharmacist's name and 24 hr contact number

e. The IHB physician will contact the United States Army Medical Materiel Agency (USAMMA) Emergency Operations Center (Phone: 301-619-4408) with the above information and begin the coordination process.

f. The attending physician must review the VIGIV package insert and be familiar with the indications, contraindications, complications, as well as all factors that affect the safe administration of this product. The IHB physician will coordinate any pre- and post-infusion labs, and management of any untoward VIGIV reactions with the attending clinician.

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4. References.

a. Advisory Committee on Immunization Practices. Smallpox Vaccinations and Adverse Reactions, MMWR 2003;52(RR04): 1-28:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm>

b. Centers For Disease Control and Prevention. Surveillance Guidelines for Smallpox Vaccine (Vaccinia) Adverse Reactions, MMWR 2006;55(RR01);1-16

c. Vaccinia Immune Globulin Intravenous (Human), Cangene Corporation, Package Insert:

<http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm179513.htm>

d. Guideline for Obtaining Vaccinia Polymerase Chain Reaction (PCR) Assay Testing at: [www.health.mil/smallpox](http://www.health.mil/smallpox)

e. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by the Defense Health Agency – Immunization Healthcare Branch:

[www.health.mil/smallpox](http://www.health.mil/smallpox)

IHB Education Office/ (877) 438-8222

Approved by: Chief, Clinical Services Office