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FM COMDT COGARD WASHINGTON DC//G-WK//
TO ALCOAST

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UNCLAS //N06230//

ALCOAST 036/03

COMDTNOTE 6230

SUBJ: SMALLPOX VACCINATION PROGRAM (SVP) MEDICAL GUIDANCE

A. COMDT COGARD WASHINGTON DC R 141521Z ALCOAST 023/03, SMALLPOX VACCINATION PROGRAM (SVP)

B. DOC ASD(HA) 26NOV02, APMN ASD(HA) MEMO, SUBJ: CLINICAL POLICY FOR THE DOD SMALLPOX VACCINATION PROGRAM (SVP) (NOTAL)

1. THIS ALCOAST PROVIDES ADDITIONAL MEDICAL GUIDANCE REGARDING THE CG SMALLPOX VACCINATION PROGRAM (SVP) ORIGINALLY ANNOUNCED IN REF A. A SVP COMDTINST IS UNDER DEVELOPMENT THAT WILL SERVE AS DETAILED CG SMALLPOX VACCINE PROGRAM GUIDANCE. UNTIL IT IS PUBLISHED, USE THIS MSG AS THE MEDICAL PORTION OF THE CG INTERIM SMALLPOX IMPLEMENTATION POLICY AND READ IT IN ITS ENTIRETY.

2. POLICY GUIDANCE FOR MEDICAL PERSONNEL:

A. BECOME FAMILIAR WITH THE SVP POLICIES AND RESOURCES BY REVIEWING THE SVP WEBSITE AT WWW.SMALLPOX.ARMY.MIL. PARTICULAR ATTENTION SHOULD BE GIVEN TO THE EDUCATIONAL PRODUCTS AND THE "QUESTIONS AND ANSWERS" POSTED ON THE WEBSITE, SINCE THESE ARE THE MOST FREQUENTLY ASKED QUESTIONS BY OUR PERSONNEL AND THEIR FAMILIES. AS WITH OTHER VACCINE IMMUNIZATION PROGRAMS, EXPERIENCE SHOWS THAT EDUCATION IS PIVOTAL TO PROGRAM SUCCESS AND ACCEPTANCE.

B. ASSIST COMMANDING OFFICERS IN ENSURING THAT ALL PERSONNEL MANDATED TO RECEIVE THIS VACCINE ARE PROVIDED AN ORAL BRIEF BY MEDICAL PERSONNEL COVERING TOPICS USING THE INDIVIDUALS BRIEFING AT WWW.SMALLPOX.ARMY.MIL, (LOCATED UNDER THE EDUCATION TOOLKIT LINK). BRIEFERS SHOULD EMPHASIZE: VACCINATION SITE CARE, FREQUENT HAND WASHING WITH SOAP AND WATER TO PREVENT AUTOINOCULATION AND CROSS-INOCULATION, AND FREQUENT LAUNDERING OF CLOTHING AND PERSONAL LINENS (E.G., TOWELS, SHEETS) IN HOT WATER AND BLEACH. EVERY MEMBER ELIGIBLE FOR VACCINE SHALL BE PROVIDED THE TRIFOLD BROCHURE THAT CAN BE FOUND AT THE WEBSITE WWW.SMALLPOX.ARMY.MIL, (LOCATED UNDER THE EDUCATION TOOLKIT LINK). THE COMPLETE TRIFOLD WILL INCLUDE LOCAL INFORMATION/CONTACT NUMBERS FOR THE MEMBER IN THE EVENT HE/SHE EXPERIENCES AN ADVERSE REACTION.

C. ENSURE EACH MEMBER DESIGNATED TO RECEIVE SMALLPOX VACCINE COMPLETES THE SMALLPOX VACCINATION INITIAL NOTE SF-600, (LOCATED UNDER THE RESOURCE LINK AT WWW.SMALLPOX.ARMY.MIL) TO DETERMINE VACCINE ELIGIBILITY. EMPHASIZE THE IMPORTANCE OF HOUSEHOLD CONTACT INFORMATION IN DETERMINING VACCINE ELIGIBILITY. SOME BARS (CONTRAINDICATIONS) ARE: IMMUNOSUPPRESSION, ECZEMA OR OTHER DERMATOLOGICAL (SKIN) CONDITIONS, PREGNANCY, BREASTFEEDING, AND KNOWN ALLERGIES TO ANY COMPONENT OF THE VACCINE INCLUDING DIHYDROSTREPTOMYCIN SULFATE, NEOMYCIN SULFATE, CHLORTETRACYCLINE HYDROCHLORIDE, OR POLYMYXIN B SULFATE. MEMBERS MUST HAVE ACCESS TO HEALTHCARE PROVIDERS TO ANSWER ANY QUESTIONS OR CONCERNS. WOMEN WILL BE QUESTIONED, IN AS PRIVATE A SETTING AS POSSIBLE, ABOUT WHETHER THERE IS ANY POSSIBILITY THEY ARE PREGNANT. AN ANSWER OF YES OR UNSURE REQUIRES A PREGNANCY TEST. IF THE TEST IS NEGATIVE, VACCINATION OF THE INDIVIDUAL MAY PROCEED. ALL MEMBERS BEING SCREENED WILL HAVE IN THEIR MEDICAL RECORDS DOCUMENTATION THAT THE HIV TEST IS UP-TO-DATE PER CG POLICY.

D. SINCE THIS IS A LIVE VIRUS VACCINE, THERE IS A SLIGHT BUT REAL RISK THAT THE VACCINIA VIRUS (NOT SMALLPOX VIRUS) CAN BE TRANSFERRED FROM ONE PERSON TO ANOTHER. ALL VACCINE RECIPIENTS SHALL BE GIVEN DETAILED INSTRUCTIONS ON HOW TO PROPERLY CARE FOR THE VACCINE SITE IN ORDER TO NEGATE THIS SLIGHT RISK. SOME POTENTIAL RECIPIENTS MAY BE EXEMPTED DUE TO RISK FACTORS IN HOUSEHOLD/INTIMATE CONTACTS. EMPHASIS ON PRE-VACCINATION SCREENING

IS CRITICAL TO ADDRESS TEMPORARY OR PERMANENT CONTRAINDICATIONS IN SERVICE MEMBERS AND LIVING QUARTERS/HOUSEHOLD CONTACTS. IF HOUSEHOLD CONTACTS HAVE CONTRAINDICATIONS THE SERVICE MEMBER SHALL NOT BE IMMUNIZED UNLESS HE/SHE CAN BE HOUSED SEPARATELY DURING THE 21 DAYS FOLLOWING SMALLPOX IMMUNIZATION. ALTERNATIVELY, THIS COULD NECESSITATE IMMUNIZING FORCES UPON DEPLOYMENT. IN MILITARY-UNIQUE BERTHING SETTINGS, MEDICALLY EXEMPT INDIVIDUALS SHALL NOT SHARE OR ALTERNATE USE OF COMMON SLEEPING SPACE (E.G., COT, BUNK, BERTH) WITH PEOPLE WHO HAVE BEEN RECENTLY VACCINATED. MEDICALLY EXEMPT INDIVIDUALS SHALL BE EXEMPT FROM DUTIES THAT POSE THE LIKELIHOOD OF CONTACT WITH POTENTIALLY INFECTIOUS MATERIALS (E.G., CLOTHING, TOWELS, LINEN FROM RECENTLY VACCINATED PEOPLE). GIVEN THAT THIS RISK OF TRANSFER IS IN SETTINGS OF INTIMATE CONTACT, IT IS NOT EXPECTED THAT PERSONNEL IN ROUTINE WORK PLACE SETTINGS ARE AT INCREASED RISK REGARDLESS OF THEIR UNDERLYING MEDICAL CONDITION(S). IF A CHILD UNDER ONE YEAR OF AGE LIVES IN THE HOUSEHOLD, THE MEMBER SHOULD EXERCISE GREAT DILIGENCE IN VACCINATION SITE CARE/COVERAGE AND THOROUGH AND FREQUENT HAND WASHING. A HOUSEHOLD CONTACT UNDER THE AGE OF ONE IS NOT A CONTRAINDICATION, BUT GREATER VIGILANCE IS WARRANTED BY MEMBERS IN THIS CATEGORY.

E. CONSIDER THE STAGGERING OF VACCINATION OF PERSONNEL TO MINIMIZE IMPACT OF EXPECTED MILD REACTIONS (E.G., SORE ARM, FEVER, HEADACHE, BODY ACHE, AND FATIGUE) WHICH MAY PEAK 8-10 DAYS FOLLOWING VACCINATION. SOME INDIVIDUALS MAY BE SIQ FOR 1-2 DAYS AS A RESULT. IF POSSIBLE, A FEASIBLE APPROACH MAY BE TO VACCINATE GROUPS AT 14-21 DAY INTERVALS TO DIMINISH IMPACT ON MISSION READINESS.

F. THOROUGHLY UNDERSTAND THE CLINICAL ASPECTS OF THIS VACCINE AND THE POTENTIAL FOR ADVERSE EVENTS AFTER VACCINATION (REF B). MEDICAL PERSONNEL MUST KNOW HOW TO MANAGE THE SPECTRUM OF ADVERSE EVENTS, INCLUDING THE REQUIREMENT TO SUBMIT VACCINE ADVERSE EVENT REPORTS (VAERS). MEDICAL PERSONNEL WILL FAMILIARIZE THEMSELVES WITH SMALLPOX WEBSITE RESOURCES, ESPECIALLY THE CLINICIANS TOOLKIT LINK (LOCATED UNDER THE EDUCATION TOOLKIT LINK) AT WWW.SMALLPOX.ARMY.MIL.

G. MEDICAL PERSONNEL WHO ADMINISTER THE SMALLPOX VACCINE WILL BE SPECIFICALLY DESIGNATED, IN WRITING, BY THE COMMAND AS QUALIFIED TO DO SO. PERSONNEL WHO ATTENDED THE 4-DAY DOD SMALLPOX PREPAREDNESS TRAINING CONFERENCE AND THE HANDS-ON VACCINATION TRAINING ARE ELIGIBLE FOR CERTIFICATION TO ADMINISTER THE VACCINE WITHOUT ADDITIONAL TRAINING. OTHER MEDICAL PERSONNEL WHO WILL BE VACCINATORS MAY BE SO DESIGNATED BY THE COMMAND AFTER COMPLETING THE 4 HOUR VACCINATOR TRAINING (LOCATED UNDER THE EDUCATION TOOLKIT LINK) FOUND AT WWW.SMALLPOX.ARMY.MIL. AS A CHECK ON PROPER VACCINATION TECHNIQUE, MEDICAL OFFICERS SHALL ENSURE THAT EACH VACCINATOR HAS A TAKE RATE ABOVE 90 PERCENT.

H. ENSURE APPROPRIATE UNIT MEDICAL PERSONNEL ARE TRAINED IN COAST GUARD HUMAN RESOURCES MANAGEMENT SYSTEM (CGHRMS) MEDICAL READINESS SYSTEM (MRS) IMMUNIZATION TRACKING PROCEDURES AND HAVE A CURRENT PASSWORD TO ACCESS MRS. IMMUNIZATION TRACKING IS VITAL FOR ALL ACTIVE AND RESERVE PERSONNEL, IN ADDITION TO RECORDING MEMBER DATA, UNIT DATA, VACCINE LOT NUMBER, INJECTION SITE/ROUTE AND TAKE READING IN MRS (NOTE THAT THE TAKE READING IS RECORDED IN THE MEDICAL READINESS PANEL VICE THE IMMUNIZATION PANEL), RECORD THIS SAME INFORMATION IN MEMBERS HEALTH RECORD AND ON YELLOW SHOT CARD (PHS 731).

I. ADDITIONAL DETAILED CLINICAL GUIDANCE IS AVAILABLE IN REF B AT WWW.SMALLPOX.ARMY.MIL, (LOCATED UNDER EDUCATION TOOLKIT LINK). GUIDANCE INCLUDES MEDICAL SCREENING BEFORE VACCINATION, PREGNANCY SCREENING, INCLUDING COUNSELING VACCINATED WOMEN ABOUT AVOIDING PREGNANCY FOR 4 WEEKS, INJECTION-SITE SELECTION. VACCINATION/REVACCINATION PROCEDURES, SITE CARE, MEDICAL EXEMPTIONS, ADVERSE EVENTS MANAGEMENT, AND BLOOD DONOR DEFERRAL.

SMALLPOX VACCINE INITIAL NOTE, SMALLPOX VACCINE ADVERSE EVENT DIARY REPORT CARDS, AND SMALLPOX IMMUNIZATION FOLLOW-UP NOTE FORMS ARE AVAILABLE ON THE DOD SVP WEBSITE. THESE FORMS MUST BE ADDED TO MEDICAL RECORDS.

J. MEMBERS CONSIDERED FOR MEDICAL EXEMPTIONS SHALL BE REFERRED TO APPROPRIATE HEALTH CARE PERSONNEL FOR EVALUATION PRIOR TO ASSIGNMENT OF ANY MEDICAL EXEMPTION CODE IN MRS. MEDICAL TEMPORARY CODE IN MRS WILL BE ASSIGNED TO MEMBERS WITH HOUSEHOLD CONTACTS HAVING CONTRAINDICATIONS TO SMALLPOX VACCINATION. ALL CONTRAINDICATION INFORMATION WILL BE RECORDED ON THE SMALLPOX VACCINATION INITIAL NOTE. MEMBERS WITH SMALLPOX VACCINATION EXEMPTIONS ARE STILL DEPLOYABLE.

K. VACCINE SHALL BE ADMINISTERED ACCORDING TO FDA LABEL REQUIREMENTS. 6-8 DAYS FOLLOWING VACCINATION, A TAKE READING MUST BE RECORDED ON THE INITIAL SMALLPOX VACCINE IMMUNIZATION NOTE AND IN MRS. A SUCCESSFUL, EXPECTED RESPONSE TO THE SMALLPOX VACCINATION IS A PUS-FILLED BLISTER AT THE VACCINATION SITE AND IS RECORDED AS A MAJOR RESPONSE. AN EQUIVOCAL RESPONSE OR NO RESPONSE WILL REQUIRE REVACCINATION PER REF B. COMMAND SPECIFIC INFORMATION ON SEEKING APPROPRIATE MEDICAL CARE IN THE EVENT OF AN ADVERSE REACTION SHOULD BE PROVIDED TO EACH VACCINE RECIPIENT.

L. VERY RARELY, SMALLPOX VACCINE CAN CAUSE SERIOUS SIDE EFFECTS, EVEN DEATH IN 1 OR 2 PEOPLE PER MILLION VACCINATED. THE CG AND DOD WILL MINIMIZE SERIOUS SIDE EFFECTS BY CAREFULLY SCREENING AND EXEMPTING PERSONNEL WHO SHOULD NOT GET THE SMALLPOX VACCINE, EDUCATING THOSE WHO DO ON PROPER VACCINATION SITE CARE, AND MONITORING FOR ADVERSE REACTIONS. MANY OF THESE SERIOUS ADVERSE REACTIONS WILL BE TREATED WITH VACCINIA IMMUNE GLOBULIN (VIG) OR CIDOFOVIR, USING INVESTIGATIONAL NEW DRUG (IND) PROTOCOLS. IF A VACCINE RECIPIENT IS SUSPECTED OF HAVING A SERIOUS REACTION TO THE VACCINE, HE/SHE SHOULD BE IMMEDIATELY REFERRED FOR EVALUATION BY AN INFECTIOUS DISEASE, DERMATOLOGY, ALLERGY-IMMUNOLOGY OR INTERNAL MEDICINE PHYSICIAN, PREFERABLY AT A MILITARY MTF. ONCE A DEFINITE OR PROBABLE DIAGNOSIS OF A SPECIFIC SERIOUS ADVERSE REACTION HAS BEEN MADE BY A QUALIFIED PROVIDER (E.G., INFECTIOUS DISEASE, DERMATOLOGY, ALLERGY-IMMUNOLOGY PHYSICIAN), THEY MAY REQUEST USE OF VIG OR CIDOFOVIR FOR A NAMED PATIENT BY TELEPHONING U.S. ARMY MEDICAL RESEARCH INSTITUTE FOR INFECTIOUS DISEASES (USAMRIID) AT 1-888-USA-RIID OR 301-619-2257. ALTERNATELY, PAGE THE USAMRIID STAFF DUTY OFFICER AT 301-631-4393 OR THE U.S. ARMY MEDICAL RESEARCH MATERIEL COMMAND (USAMRMC) STAFF DUTY OFFICER AT 301-619-6092. USAMRIID WILL COORDINATE WITH SPECIALIZED TREATMENT TEAMS, WHICH WILL TRAVEL TO THE MEDICAL TREATMENT FACILITY (MTF) CARING FOR THE DIAGNOSED PATIENT. IND SPECIFIC PROCEDURES WILL BE FOLLOWED IN DETAIL.

M. MEDICAL OFFICERS (SMOS FOR CLINICS AND DMOAS FOR SICK-BAYS) SHOULD INFORM LOCAL HEALTH DEPARTMENTS OF THE NUMBER OF SMALLPOX VACCINATIONS THAT HAVE BEEN ADMINISTERED AND, IF REQUESTED, PROVIDE FURTHER INFORMATION THAT IS CONSISTENT WITH MEDICAL CONFIDENTIALITY AND OPSEC. IN GENERAL, A PHONE CALL INFORMING THEM THAT THE CG CLINIC HAS GIVEN (OR WILL GIVE) XX NUMBER OF SMALLPOX VACCINES THAT DAY WILL SUFFICE. YOU MAY ALSO PROVIDE GENERIC INFORMATION SUCH AS EACH MEMBER WAS SPECIFICALLY TRAINED IN PROPER CARE OF THE VACCINE SITE, ETC IF ASKED.

N. AT TIME OF RECONSTITUTION, RECORD DATE ON VIAL. RECONSTITUTED DRYVAX MAY BE USED FOR 60 DAYS IF STORED AT 2-8 DEGREES CENTIGRADE (36-46 DEGREES FAHRENHEIT) WHEN NOT IN ACTUAL USE. SEE [HTTP://WWW.SMALLPOX.ARMY.MIL/MEDIA/PDF/WYETH.PDF](http://www.smallpox.army.mil/media/pdf/wyeth.pdf) FOR DOCUMENTATION AUTHORIZING THE 60 DAY STANDARD.

O. UNTIL 1 AUG 03, WHEN COMPLETED, VACCINATING SITES WILL MAKE A COPY OF EACH SMALLPOX VACCINATION INITIAL NOTE AND SMALLPOX VACCINATION FOLLOWUP NOTE. THESE COPIES WILL BE SENT TO: COMMANDANT, G-WKH-1, 2100 SECOND ST., SW, WASHINGTON, DC 20593.

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P. VACCINATING SITES WILL TRACK AND REPORT WEEKLY (NEGATIVE REPORTS NOT REQUIRED), VIA EMAIL TO SMALLPOX(AT)COMDT.USCG.MIL, THE FOLLOWING:

- (1) NUMBER OF PERSONS EVALUATED FOR VACCINATION
- (2) NUMBER OF TEMPORARY EXEMPTIONS (MEMBER)
- (3) NUMBER OF TEMPORARY EXEMPTIONS (HOUSEHOLD CONTACT)
- (4) NUMBER OF PERMANENT EXEMPTIONS
- (5) NUMBER OF VACCINATIONS GIVEN (PRIMARY/REVACCINATION)

3. LOGISTICAL GUIDANCE:

A. ENSURE UNIT MEDICAL LOGISTICS SUPPORTING ELEMENT HAS SUFFICIENT REFRIGERATION CAPACITY TO PRESERVE VACCINE INTEGRITY WITHIN FDA LABEL TEMPERATURE RANGE OF 2-8 DEGREES CENTIGRADE/36-46 DEGREES FAHRENHEIT (DO NOT PUT VACCINE IN DIRECT CONTACT WITH ICE. DO NOT FREEZE). SUPPORT INCLUDES TWICE DAILY MONITORING OF TEMPERATURE AND BACK-UP POWER SUPPLY. IDEALLY, A 24 X 7 ALARM SYSTEM SHOULD NOTIFY APPROPRIATE MEDICAL PERSONNEL.

B. ALL REQUESTS FOR SMALLPOX VACCINE WILL BE SUBMITTED USING U. S. ARMY MEDICAL MATERIEL AGENCY (USAMMA) ONLINE REQUEST FORM. ONCE THE REQUEST IS ELECTRONICALLY SUBMITTED IT WILL BE VALIDATED BY APPROPRIATE MLC(K) AND THEN HEADQUARTERS (G-WKH-1) TO ENSURE COMPLIANCE WITH THIS GUIDANCE. MEDICAL PERSONNEL RESPONSIBLE FOR ORDERING THE SMALLPOX VACCINE SHALL REGISTER TO USE THE U. S. ARMY MEDICAL MATERIEL AGENCY (USAMMA) SECURE WEBSITE. INSTRUCTIONS FOR REGISTERING CAN BE FOUND AT

[HTTP://WWW.USAMMA.ARMY.MIL/ANTHRAX/ANTXHOME.HTM](http://www.usamma.army.mil/anthrax/antxhome.htm). CG CLINICS SHOULD ENSURE THAT AT LEAST 2-3 PERSONNEL ARE REGISTERED TO USE THE ONLINE REQUEST FORM. VACCINE IS SHIPPED IN 100 DOSE VIALS. EVERY EFFORT SHOULD BE MADE TO VALIDATE NEED FOR VACCINE SO THAT DOSE WASTAGE IS KEPT TO AN ABSOLUTE MINIMUM. IF NECESSARY, TO REDUCE THE CHANCE OF WASTAGE, DIRECT COORDINATION WITH OTHER CG OR DOD FACILITIES IS AUTHORIZED IN ORDER TO TRANSFER REMAINING DOSES OF VACCINE PRIOR TO EXPIRATION.

C. G-WKH WILL LIAISON WITH THE U.S. ARMY MEDICAL MATERIEL AGENCY (USAMMA) TO COORDINATE DISTRIBUTION OF VACCINE FROM THE NATIONAL PHARMACEUTICAL STOCKPILE. SMALLPOX VACCINE WILL BE PROVIDED AT NO COST TO UNITS. ANCILLARY SUPPLIES ARE THE RESPONSIBILITY OF THE RECEIVING ACTIVITY. THE CURRENT CONTRACT INCLUDES DISTRIBUTION TO FIRST DESTINATION. REFER TO THE USAMMA WEBSITE FOR MORE INFORMATION AT [WWW.ARMYMEDICINE.ARMY.MIL/USAMMA/SMALLPOX/INDEX.HTM](http://www.armymedicine.army.mil/usamma/smallpox/index.htm). ALL CG CLINICS SHOULD HAVE PASSWORD ACCESS AUTHORIZATION TO USAMMA'S SECURE WEBSITE FOR ORDERING ANTHRAX AND SMALLPOX VACCINES. CLINIC PHARMACIES WILL COORDINATE WITH SUPPORTED SICKBAYS FOR NECESSARY DISTRIBUTION.

D. GIVEN VACCINE AVAILABILITY, CG HEALTH CARE FACILITIES WILL VACCINATE MEMBERS OF OTHER MILITARY SERVICES WHO MEET THE STAGE CLASSIFICATIONS ABOVE.

4. HQ POCS FOR THIS MESSAGE ARE CAPT MARK TEDESCO AT 202-267-0528 AND CDR SHARON LUDWIG AT 202-267-1725. MLCP(K) POC IS CAPT CALDWELL AT 510-437-3442 AND MLCA(K) POC IS CDR CANTON AT 757-628-4333. CG SVP INFORMATION IS ALSO AVAILABLE AT [HTTP://WWW.USCG.MIL/HQ/G-W/G-WK/SMALLPOX/INDEX.HTM](http://www.uscg.mil/hq/g-w/g-wk/smallpox/index.htm).

5. MBRS WHO ARE UNABLE TO ACCESS THE INTERNET SHOULD CONTACT THE POCS IN PARA 4 FOR GUIDANCE.

6. INTERNET RELEASE AUTHORIZED.

7. RELEASED BY REAR ADMIRAL JOYCE M. JOHNSON, DIRECTOR OF HEALTH AND SAFETY.

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