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L:DISTRICT OF COLUMBIA,L:WASHINGTON,OU:SECNAV
WASHINGTON DC(uc)
SUBJECT: TRANSITION FROM CURRENT DRYVAX SMALLPOX VACCINE TO ACAM2000
SMALLPOX VACCINE
TEXT:
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FM SECNAV WASHINGTON DC

TO ALNAV

BT

UNCLAS

ALNAV 018/08

MSGID/GENADMIN/SECNAV WASHINGTON DC/-/FEB//

SUBJ/TRANSITION FROM CURRENT DRYVAX SMALLPOX VACCINE TO ACAM2000
SMALLPOX VACCINE//

REF/A/DOC/MILVAX DIRECTOR/23JAN2008//

REF/B/DOC/ASD (HA)/26NOV2002//

REF/C/MSG/CNO/(N09)/CNO WASHINGTON DC/091532ZJAN03//

REF/D/DOC/BUMEDINST 6230.15A/29SEP06//

REF/E/DOC/COMFLTFORCOM/NORFOLK VA//161133ZJAN03//

NARR/REF A IS DIRECTOR, MILITARY VACCINE AGENCY MEMO IMPLEMENTATION
INSTRUCTIONS FOR TRANSITION TO ACAM2000 IN THE DEPARTMENT OF DEFENSE
(DOD) SMALLPOX VACCINATION PROGRAM (SVP).

REF B IS ASD (HA) MEMO PROMULGATING CLINICAL POLICY FOR THE DOD SVP.

REF C IS CNO GENADMIN SVP FOR MILITARY TREATMENT FACILITIES. REF D IS
BUMEDINST 6230.15A MEDICAL SERVICES IMMUNIZATIONS AND CHEMOPROPHYLAXIS.

REF E IS COMFLTFORCOM SVP AMPLIFICATION//

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RMKS/

1. PER REFERENCE (A), DOD IS TRANSITIONING FROM WYETHS DRYVAX BRAND OF
SMALLPOX VACCINE TO ACAMBIS ACAM2000 BRAND OF SMALLPOX VACCINE.
ACAM2000 IS A VACCINE LICENSED AND APPROVED BY THE FOOD AND DRUG
ADMINISTRATION (FDA) FOR PROTECTION AGAINST SMALLPOX. THE FDA APPROVED
LICENSURE OF ACAM2000 ON 31 AUGUST 2007. SUBSEQUENTLY, WYETH (THE
MANUFACTURER OF DRYVAX) ANNOUNCED ITS PLANS TO WITHDRAW LICENSURE OF
DRYVAX VACCINE.

2. SMALLPOX VACCINATION PROGRAM (SVP) POLICY. NAVY AND MARINE CORPS
POLICY FOR THE SVP REMAINS THE SAME. THIS TRANSITION TO A NEW VACCINE
DOES NOT CHANGE THE POPULATION BEING VACCINATED OR THE PREVIOUS
REQUIREMENTS OF THE SVP.

3. ADMINISTRATION AND LOGISTICS TIMELINES:

A. IN JANUARY 2008 DRYVAX VACCINE AT HIGH VOLUME SITES WERE REPLACED
WITH ACAM2000.

B. ALL NAVY AND MARINE CORPS COMMANDS AND IMMUNIZATION CLINICS SHALL
STOP USING DRYVAX SMALLPOX VACCINE ON 29 FEBRUARY 2008 AND CONTINUE THE
SVP USING THE ACAM2000 VACCINE.

C. THE SUSPENSE DATE FOR ALL DOD DRYVAX SMALLPOX VACCINE AND DILUENT TO BE DESTROYED IS 31 MARCH 2008. PERSONNEL SHALL FOLLOW THE DESTRUCTION REQUIREMENTS THAT WILL BE PROVIDED BY U.S. ARMY MEDICAL MATERIAL AGENCY (USAMMA). DESTRUCTION REQUIREMENTS ARE FORTHCOMING VIA DOD MMQC MESSAGE. ALL NAVY AND MARINE CORPS COMMANDS SHALL ENSURE THAT DRYVAX DESTRUCTION PAPERWORK AND DOCUMENTATION IS FORWARDED DURING THE MONTH OF MARCH 2008 TO USAMMA AS DIRECTED.

COMMANDS WILL BE ABLE TO OBTAIN DESTRUCTION REQUIREMENTS BY MONITORING THE MILITARY VACCINE WEBSITE AT [WWW.VACCINES.MIL](http://www.vaccines.mil). IN ADDITION, NAVY AND MARINE CORPS ACTIVITIES AUTHORIZED TO GIVE SMALLPOX AND ANTHRAX VACCINES SHALL SUBSCRIBE AND RECEIVE DOD MMQC MESSAGES FROM THE FOLLOWING SITE: [HTTP://WWW.USAMMA.ARMY.MIL](http://www.usamma.army.mil) CLICK ON "SUBSCRIBE TO MMQC MESSAGES."

D. ACAMBIS ACAM2000 WILL BE FULLY IMPLEMENTED AS THE DODS SMALLPOX VACCINE ON 1 APRIL 2008.

4. CLINICAL REQUIREMENTS:

A. ACAM2000 IS ADMINISTERED SIMILAR TO THE DRYVAX VACCINE BY PERCUTANEOUS ROUTE (SCARIFICATION) USING A BIFURCATED NEEDLE. LIKE DRYVAX VACCINE ACAM2000 SHALL NOT BE ADMINISTERED BY THE INTRADERMAL, SUBCUTANEOUS, INTRAMUSCULAR, OR INTRAVENOUS ROUTE.

B. ACAM2000 WAS EVALUATED AGAINST DRYVAX SMALLPOX VACCINE IN SIX PRELICENSURE CLINICAL STUDIES AND FOUND TO HAVE A COMPARABLE SIDE-EFFECT PROFILE. THE MOST COMMON SIDE-EFFECTS FOLLOWING VACCINATION WITH ACAM2000 INCLUDES: ITCHING, SWOLLEN LYMPH NODES, SORE ARM, FEVER, HEADACHE, BODY ACHE, MILD RASH, AND FATIGUE. THERE WAS NO STATISTICAL DIFFERENCE IN THE INCIDENCE OF SERIOUS ADVERSE EVENTS (MYOCARDITIS OR PERICARDITIS) BETWEEN ACAM2000 VACCINE AND DRYVAX VACCINE.

C. COMMANDERS SHALL CONTINUE TO ENSURE THAT ALL MEDICAL DEPARTMENT PERSONNEL WHO ADMINISTER THE ACAM2000 VACCINE ARE PROPERLY TRAINED PRIOR TO ADMINISTERING THE VACCINE PER REFS (C) AND (D), AND THAT THEY FOLLOW THE MANUFACTURERS, DOD, NAVY, AND MARINE CORPS REQUIREMENTS FOR PROPER ADMINISTRATION AND DOCUMENTATION OF THE VACCINE. ADDITIONAL TRAINING RESOURCES CAN BE FOUND AT [WWW.SMALLPOX.MIL](http://www.smallpox.mil). THE MILVAX AGENCY CONDUCTS IMMUNIZATION TRAINING FOR MEDICAL PERSONNEL, SEE [WWW.VACCINES.MIL](http://www.vaccines.mil) FOR ADDITIONAL INFORMATION. PERSONNEL WHO ADMINISTER THE SMALLPOX VACCINE SHALL BE IMMUNIZED PER THE REQUIREMENTS OF REF B. RECOMMEND DEPLOYING UNITS CONSIDER THE PROXIMITY OF THE NEAREST MILITARY TREATMENT FACILITY PRIOR TO ADMINISTERING THE VACCINE IN ORDER TO FACILITATE TREATMENT AND CASEVAC OF POTENTIAL ADVERSE REACTIONS POST INNOCULATION PER REF (E).

D. THE BOTTLE OF DILUENT SUPPLIED WITH THE ACAM2000 VACCINE KIT CONTAINS MORE LIQUID THAN IS NEEDED TO RECONSTITUTE THE VACCINE. CLINIC PERSONNEL MUST FOLLOW THE MANUFACTURERS PACKAGE INSERT TO PREVENT FROM OVERPRESSURING THE VACCINE VIAL AND TO ENSURE THAT THE CORRECT AMOUNT IS USED.

E. PRIOR TO VACCINATION, COMMANDERS MUST VERIFY THAT THOSE BEING VACCINATED ARE ON ORDERS OR HAVE BEEN DESIGNATED TO DEPLOY WITHIN 120 DAYS TO OVERSEAS LOCATIONS DESIGNATED FOR THE SMALLPOX VACCINATION PROGRAM, OR THEY ARE REQUIRED/AUTHORIZED(VOLUNTARY) TO RECEIVE THE SMALLPOX VACCINATION BASED ON CURRENT DOD, NAVY, OR MARINE CORPS SVP POLICY GUIDELINES.

F. PRIOR TO RECEIVING A VACCINATION WITH ACAM2000, ALL VACCINEES SHALL RECEIVE A COPY OF THE FDA APPROVED MEDICATION GUIDE AND THE MOST CURRENT COPY OF THE DOD SMALLPOX VACCINE INFORMATION TRIFOLD BROCHURE. THESE TWO DOCUMENTS ARE SHIPPED TO COMMANDS AT NO COST IN THE SAME QUANTITY AS THE ORDERED VACCINE. ADDITIONALLY, COMMANDS AND CLINICS MAY REQUEST ADDITIONAL COPIES THROUGH THE MILITARY VACCINE AGENCY

(MILVAX) BY PHONE 877-GET-VACC OR VACCINES(AT)AMEDD.ARMY.MIL. THESE PRODUCTS ARE ALSO AVAILABLE ONLINE FOR DOWNLOADING AT WWW.VACCINES.MIL/ACAM2000 OR WWW.SMALLPOX.MIL.

G. ALL PERSONNEL SHALL BE PROPERLY MEDICALLY SCREENED (INCLUDES HOUSEHOLD CONTACTS) AND EDUCATED PRIOR TO RECEIVING THE VACCINATION. VACCINEES SHALL BE INSTRUCTED ON PROPER VACCINATION SITE CARE AS WELL AS WHAT ACTIVITIES AND PEOPLE TO AVOID FOR FOUR WEEKS, AND UNTIL THE VACCINATION SITE HAS HEALED. VACCINEES SHALL BE EDUCATED ON WHAT TO DO IF THEY DEVELOP SYMPTOMS AFTER RECEIVING THE SMALLPOX VACCINE AND TO ENSURE THAT WHEN THEY SEEK MEDICAL ATTENTION THEY INFORM THEIR HEALTH CARE PROVIDER THAT THEY RECENTLY RECEIVED THE SMALLPOX VACCINE. VACCINEES SHALL BE INSTRUCTED TO RETURN TO MEDICAL FOR A FOLLOW-UP VISIT WITHIN 6-8 DAYS FOLLOWING VACCINATION BY SCARIFICATION TO ENSURE THE VACCINE HAS TAKEN.

H. PERSONNEL WHO ARE MEDICALLY OR ADMINISTRATIVELY EXEMPT (DETERMINED BY PRE-VACCINATION SCREENING) SHALL NOT BE REQUIRED TO RECEIVE THE SMALLPOX VACCINATION. ACAM2000 CONTAINS A SMALL AMOUNT OF NEOMYCIN AND POLYMYCIN B. INDIVIDUALS ALLERGIC TO THESE AND OTHER COMPONENTS MAY BE AT A HIGHER RISK FOR ADVERSE EVENTS AFTER VACCINATION.

I. AFTER PROPER MEDICAL SCREENING, PERSONNEL RECEIVING ACAM2000 (PRIMARY VACCINEES AND RE-VACCINEES) SHALL RECEIVE 15 JABS WITH A BIFURCATED NEEDLE (DO NOT REUSE THE NEEDLES AND ENSURE THEY ARE PLACED IN AN APPROVED BIOHAZARDOUS WASTE SHARPS CONTAINER). PERSONNEL HANDLING OR ADMINISTRATING ACAM2000 SHALL WEAR GLOVES AND CHANGE THEM BETWEEN EVERY VACCINE RECIPIENT.

J. IMMUNIZATION RECORD KEEPING PROCEDURES. THERE IS NO CHANGE TO THE IMMUNIZATION RECORD KEEPING REQUIREMENTS. EVERY VACCINATION SHALL BE PROPERLY ENTERED INTO A DOD APPROVED ELECTRONIC IMMUNIZATIONS TRACKING SYSTEM AND INTO THE PATIENTS MEDICAL RECORD.

K. CIVILIAN EMPLOYEES AND CONTRACT PERSONNEL SHALL BE GIVEN A COPY OF THEIR IMMUNIZATION RECORD (DD FORM 2766C) BY THE MILITARY TREATMENT FACILITY (MTF) WHERE THEY ARE IMMUNIZED.

L. THE TRANSITION MMQC FOR ACAM2000 CAN BE FOUND AT ACAM2000 MMQC-08-1036. REFRIGERATION, STORAGE, AND HANDLING PROCEDURES ARE DISCUSSED IN THIS MMQC AND ALSO IN THE MANUFACTURER'S PACKAGE INSERT.

5. SUPPLY/LOGISTICS:

A. NSN: 6505-01-559-0815, SMALLPOX (VACCINA) VACCINE, LIVE WITH DILUENT, SYRINGES, AND NEEDLES. DOD USES THE SAME FDA APPROVED VACCINE THAT IS MAINTAINED IN THE STRATEGIC NATIONAL STOCKPILE. THEREFORE ALL DOD STOCK WILL HAVE THE STRATEGIC NATIONAL STOCKPILE USE ONLY PRINTED ON ITS LABEL. THIS VACCINE IS APPROVED FOR USE IN THE DOD. EXPIRY LABELS WILL BE PROVIDED FOR EACH ACAM VIAL ORDERED. THE EXPIRY LABELS SHALL BE IMMEDIATELY APPLIED TO EACH INDIVIDUAL VIAL AS THEY ARE RECEIVED BY THE COMMAND. AS WITH THE CURRENT DRYVAX VACCINE THE USAMMA DISTRIBUTION OPERATIONS CENTER WILL CONTINUE TO COORDINATE ALLOCATION AND DISTRIBUTION OF THE SMALLPOX VACCINE WITH THE MILITARY VACCINE AGENCY (MILVAX), COMMANDS, AND THE NAVY MEDICAL LOGISTICS COMMAND.

B. THE SMALLPOX VACCINE IS CENTRALLY FUNDED BY THE PROGRAM EXECUTIVE OFFICE FOR CHEMICAL BIOLOGICAL DEFENSE (PEOCBD). THE VACCINE IS NOT A DEFENSE SUPPLY CENTER PHILADELPHIA, STOCK ITEM.

C. ORDERS FOR SMALLPOX VACCINE SHOULD BE SUBMITTED THROUGH THE USAMMA DOCS SECURE ONLINE ORDER WEBSITE. ACTIVITIES MUST PRE-REGISTER ONLINE ON THE USAMMA WEBSITE IN ORDER TO PLACE VALID ORDERS FOR SMALLPOX VACCINE. ACTIVITIES WHO HAVE PREVIOUSLY REGISTERED REQUESTING ANTHRAX OR SMALLPOX VACCINE DO NOT NEED TO RE-REGISTER. USE THE SAME USER NAME AND PASSWORD PREVIOUSLY ASSIGNED. ACTIVITIES WHO HAVE NOT PREVIOUSLY REGISTERED GO TO WWW.USAMMA.ARMY.MIL/VACCINES/SMALLPOX/INDEX.CFM AND

SELECT SMALLPOX VACCINE REQUEST FORM TO REGISTER. BE CERTAIN TO RECORD THE SECURE WEBSITE ADDRESS AND YOUR USER NAME AND PASSWORD FOR FUTURE ORDERING NEEDS. THE USAMMA DOC SMALLPOX VACCINE WEBSITE MAY BE ACCESSED DIRECTLY OR THROUGH THE USAMMA HOMEPAGE:

[HTTP://WWW.USAMMA.ARMY.MIL](http://www.usamma.army.mil) SELECT VACCINES AND TEMPERATURE SENSITIVE MEDICAL PRODUCTS, AND THEN SELECT SMALLPOX VACCINATION PROGRAM.

D. NAVY AND MARINE CORPS ASSISTANCE FOR ORDERING THE SMALLPOX VACCINE AND OTHER LOGISTICAL INFORMATION CAN BE DONE BY CONTACTING MRS. LOUISE MCLUCAS AT NAVY MEDICAL LOGISTICS COMMAND: TELEPHONE COM: (301)619-8054 OR DSN: 343 EMAIL:

VACCINES(AT)NMLC.MED.NAVY.MIL.

6. POC FOR THIS MESSAGE IS CDR MARCUS LARKIN AT (202)762-3437 or MARCUS.LARKIN(AT)NAVY.MIL AND EDMOND FEEKS/CDR/HQMC/-/COMM/(240)857 3189/EMAIL/EDMOND.FEEKS(AT)USMC.MIL.

7. RELEASED BY THE HONORABLE DONALD C. WINTER, SECRETARY OF THE NAVY.//

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