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DC(uc)
SUBJECT: CLINICAL POLICY FOR THE ADMINISTRATION OF THE ANTHRAX VACCINE
ADSORBED(AVA)UPDATE
TEXT:
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MSGID/GENADMIN/BUMED WASHINGTON DC//NOV// SUBJ/CLINICAL POLICY FOR THE
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REF/G/DOC/SECNAV/29APR98// REF/H/DOC/AMEDD/16DEC08// NARR/REF A IS
ASD(HA)MEMORANDUM ON CLINICAL POLICY FOR THE ADMINISTRATION OF THE ANTHRAX
VACCINE ADSORBED. REF B IS BUMED MESSAGE ON ANTHRAX VACCINE CHANGE ROUTE OF
ADMINISTRATION AND CHANGE IN DOSING SCHEDULE.
REF C IS NAVADMIN 068/07 CONCERNING RESUMPTION OF MANDATORY ANTHRAX VACCINATION
IMMUNIZATION PROGRAM (AVIP). REF D IS MARADMIN 190/07 CONCERNING RESUMPTION OF
THE MANDATORY ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP). REF E IS ALNAV
072/07 CONCERNING CHANGE IN POLICY FOR PRE-DEPLOYMENT ADMINISTRATION OF ANTHRAX
AND SMALLPOX VACCINE. REF F IS BUMEDINST 6230.15A, MEDICAL SERVICES
IMMUNIZATIONS AND CHEMOPROPHYLAXIS. REF G IS SECNAVINST 6230.4, DEPARTMENT OF
THE NAVY (DON) ANTHRAX VACCINATION IMPLEMENTATION PROGRAM (AVIP). REF H IS
MILVAX AGENCY MEMORANDUM CONCERNING IMPLEMENTATION INSTRUCTIONS FOR CHANGE IN
ROUTE AND CHANGE IN DOSING SCHEDULE FOR THE ANTHRAX VACCINE ADSORBED (AVA) IN
THE DEPARTMENT OF DEFENSE ANTHRAX VACCINE IMMUNIZATION PROGRAM.// RMKS/1. THIS
MESSAGE HAS BEEN COORDINATED WITH THE COMMANDANT OF THE MARINE CORPS. THE
COMMANDANT HAS AUTHORIZED TRANSMISSION TO MARINE CORPS ACTIVITIES.
2. PER REF (A) THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS ASD(HA)
HAS UPDATED THE CLINICAL POLICY FOR THE ANTHRAX VACCINE ADSORBED (AVA). THIS
UPDATED CLINICAL POLICY CONSOLIDATES AND REPLACES SEVERAL LEGACY ASD(HA) ANTHRAX
POLICIES. ISSUES COVERED IN THE NEW POLICY INCLUDE:

A. RECENT FDA-APPROVED CHANGES IN DOSAGE SCHEDULE FROM A SIX-SHOT SERIES TO A FIVE-SHOT SERIES WITH ANNUAL BOOSTERS.
B. INJECTION SITE SELECTION AND CHANGE TO INTRAMUSCULAR INJECTION.
C. MEDICAL SCREENING BEFORE IMMUNIZATION.
D. PREGNANCY SCREENING.
E. EDUCATIONAL MATERIAL.
F. MEDICAL EXEMPTIONS.
G. ADVERSE EVENT MANAGEMENT.

3. REFS (B) THROUGH (G) ARE CURRENT NAVY AND MARINE CORPS REQUIREMENTS FOR THE ADMINISTRATION OF THE ANTHRAX VACCINE IMMUNIZATION PROGRAM AND MAY BE IMPACTED BY THIS CLINICAL UPDATE. MEDICAL DEPARTMENT PERSONNEL AUTHORIZED TO ADMINISTER THE ANTHRAX VACCINE SHALL ENSURE THAT THEY FOLLOW THE UPDATED CLINICAL REQUIREMENTS CONTAINED IN REF A. WHERE THERE IS A CONFLICT IN CLINICAL POLICY, REF A SHALL BE FOLLOWED. REF G IS IN THE PROCESS OF BEING UPDATED.

4. COPIES OF THE ASD(HA) CLINICAL POLICY FOR AVA AND OTHER USEFUL INFORMATION PERTAINING TO THE ANTHRAX VACCINATION IMMUNIZATION PROGRAM MAY BE OBTAINED AT: WWW.ANTHRAX.MIL AND WWW.MILVAX.MIL. PERSONNEL CAN ALSO OBTAIN THIS INFORMATION BY CONTACTING THE POCS LISTED OR THE MILITARY VACCINE AGENCY (MILVAX).

5. APPLICABILITY. PER CURRENT DEPARTMENT OF DEFENSE (DOD) POLICY AVA IS MANDATORY FOR UNIFORMED PERSONNEL, EMERGENCY-ESSENTIAL AND EQUIVALENT CIVILIAN PERSONNEL OR CONTRACTORS DEPLOYED TO U.S. CENTRAL COMMAND (USCENTCOM) OR KOREAN AREAS OF RESPONSIBILITY FOR 15 OR MORE CONSECUTIVE DAYS. AVA IS ALSO MANDATORY FOR CERTAIN UNIFORMED PERSONNEL ASSIGNED TO SPECIAL UNITS OR UNITS WITH BIO-DEFENSE RELATED MISSIONS. UNIFORMED ACTIVE DUTY, SELECTED RESERVES, AND U.S. GOVERNMENT CIVILIAN PERSONNEL WHO PREVIOUSLY RECEIVED AT LEAST ONE DOSE OF AVA AND ARE NO LONGER DEPLOYED TO AREAS WITHIN USCENTCOM OR KOREA MAY CONTINUE THE SERIES ON A VOLUNTARY BASIS. VACCINATIONS ARE ALSO VOLUNTARY FOR U.S. CITIZEN ADULT FAMILY MEMBERS WHO ARE 18 TO 65 YEARS OF AGE AND ARE ACCOMPANYING DOD MILITARY CIVILIAN OR CONTRACTOR PERSONNEL FOR 15 OR MORE CONSECUTIVE DAYS TO AREAS WITHIN USCENTCOM OR KOREA. REF E AUTHORIZES VACCINATIONS TO BEGIN 120 DAYS BEFORE DEPLOYMENT.

6. DOSAGE SCHEDULE. THE NAVY AND MARINE CORPS SHALL ADHERE TO THE FDA-APPROVED FIVE DOSE PRIMARY VACCINATION SERIES SCHEDULE. ADMINISTER AVA VIA 0.5 ML INTRAMUSCULAR (IM) DOSES AT DAY 0, 4 WEEKS, 6 MONTHS, 12 MONTHS, AND 18 MONTHS, WITH A REQUIREMENT FOR ANNUAL BOOSTERS. DO NOT COMPRESS OR ACCELERATE THIS DOSING SCHEDULE. IF DOSING INTERVALS EXCEED THE RECOMMENDED INTERVALS, RESUME THE REGIMEN WITH THE ADMINISTRATION OF THE NEXT DOSE IN THE SERIES. ADMINISTER SUBSEQUENT DOSES OF VACCINE AT INTERVALS BASED ON THE DATE THE LAST DOSE WAS GIVEN, NOT WHEN IT WAS ORIGINALLY SCHEDULED. DO NOT RESTART THE SERIES. THIS PREVAILING MEDICAL PRACTICE IS CONSISTENT WITH THE RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICE AND IMPLICIT IN THE FDA-APPROVED DOSING SCHEDULE. IF AN ANNUAL BOOSTER HAS NOT BEEN ADMINISTERED ON TIME, ADMINISTER THE BOOSTER AT THE EARLIEST POSSIBLE DATE AND ADJUST THE SUBSEQUENT BOOSTER SCHEDULE ACCORDINGLY. ONCE THE FIVE DOSE PRIMARY REGIMEN IS COMPLETE, THE PRIMARY SERIES IS NEVER REPEATED.

7. INJECTION SITE SELECTION. AVA IS ADMINISTERED VIA THE IM ROUTE AND THE PREFERRED INJECTION SITE IS THE DELTOID MUSCLE REGION OF THE UPPER ARM. THE CENTERS FOR DISEASE, CONTROL, AND PREVENTION (CDC) CONDUCTED A LARGE HUMAN CLINICAL TRIAL INVESTIGATING THE SAFETY AND EFFICACY OF A DOSE REDUCTION AND ROUTE CHANGE FOR AVA. STUDY RESULTS SHOWED THAT AVA ADMINISTERED BY IM INJECTION OVER THE DELTOID REGION OF THE UPPER ARM AFFORDS THE SAME PROTECTION AGAINST ANTHRAX WITH SIGNIFICANTLY LESS LOCAL EDEMA AND DISCOMFORT AT THE INJECTION SITE. UNUSUALLY LEAN PERSONNEL MAY FURTHER REDUCE THE RISK OF INJECTION SITE REACTIONS BY VACCINATION IN THE ANTEROLATERAL THIGH. IMMUNIZATION PROVIDERS SHOULD ROTATE INJECTION SITES AND EXERCISE APPROPRIATE CLINICAL JUDGMENT.

8. MEDICAL SCREENING AND EDUCATION MATERIAL. APPROPRIATELY TRAINED MEDICAL DEPARTMENT PERSONNEL WILL PROVIDE EDUCATION AND SCREENING BEFORE THE ADMINISTRATION OF THE ANTHRAX VACCINE TO IDENTIFY MEDICAL CONDITIONS WHICH COULD WARRANT A DEFERRAL OR INITIATE FURTHER MEDICAL EVALUATION. NAVY MEDICAL DEPARTMENT PERSONNEL WILL DISTRIBUTE THE ANTHRAX VACCINE BROCHURE TO VACCINEES AND USE IT FOR EDUCATION SESSIONS. ADDITIONAL COPIES MAY BE OBTAINED AT WWW.ANTHRAX.MIL/EDUCATION. BROCHURES ARE SHIPPED WITH VACCINE ORDERS THROUGH THE UNITED STATES ARMY MEDICAL MATERIEL AGENCY OR THEY MAY BE ORDERED BY EMAIL MESSAGE AT VACCINES@AMEDD.ARMY.MIL. OTHER EDUCATIONAL MATERIALS ARE POSTED IN THE MILITARY VACCINE (MILVAX) WEBSITE: WWW.ANTHRAX.MIL, OR WWW.VACCINES.MIL/ANTHRAX.

9. PREGNANCY SCREENING. IT IS DOD, AND NAVY AND MARINE CORPS POLICY, REF F, TO SCREEN FEMALES OF CHILDBEARING AGE FOR PREGNANCY AND DEFER ROUTINE ANTHRAX VACCINATION UNTIL AFTER PREGNANCY. AT A MINIMUM, WOMEN OF CHILDBEARING AGE ARE TO BE QUESTIONED/SCREENED FOR PREGNANCY BEFORE RECEIVING IMMUNIZATIONS. WOMEN WHO ARE UNCERTAIN OF PREGNANCY STATUS SHALL BE MEDICALLY EVALUATED FOR PREGNANCY BEFORE IMMUNIZATION PER REF F.

10. MEDICAL EXEMPTIONS. SOME ACUTE OR CHRONIC PRE-EXISTING MEDICAL CONDITIONS MAY REQUIRE TEMPORARY OR PERMANENT MEDICAL EXEMPTIONS FROM ANTHRAX IMMUNIZATION. GRANTING MEDICAL EXEMPTIONS WILL ONLY BE DONE BY A PRIVILEGED HEALTHCARE PROVIDER. HEALTHCARE PROVIDERS SHOULD FAMILIARIZE THEMSELVES WITH THE PACKAGE INSERT PRESCRIBING INFORMATION AND BALANCE EXEMPTIONS WHEN MEDICALLY WARRANTED WHILE BALANCING POTENTIAL BENEFITS WITH RISKS AND THREAT ASSESSMENT. MEDICAL EXEMPTIONS AND CODES ARE DESCRIBED IN REF F.

11. MANAGING ADVERSE EVENTS. AS WITH ANY VACCINE, SOME INDIVIDUALS RECEIVING AVA WILL EXPERIENCE SIDE EFFECTS OR ADVERSE EVENTS. DOD EXPERIENCE ALONG WITH PUBLISHED PEER REVIEWED RESEARCH STUDIES HAS SHOWN THAT SERIOUS ADVERSE EVENTS ARE NO MORE LIKELY WITH AVA THEN WITH OTHER COMMONLY ADMINISTERED VACCINES. MANAGE POTENTIAL AVA RELATED EVENTS PER REFERENCE (F). VACCINE ADVERSE EVENT REPORTING SYSTEMS (VAERS) REPORTS SHALL BE FILED USING CURRENT NAVY REPORTING PROCEDURES FOR THOSE ADVERSE EVENTS RESULTING IN HOSPITAL ADMISSION, LOST WORK/DUTY TIME OVER 24 HOURS, OR WHEN AN ADVERSE EVENT IS SUSPECTED TO HAVE RESULTED FROM VACCINATION VIAL CONTAMINATION. HEALTHCARE PROVIDERS ARE ENCOURAGED TO REPORT OTHER POTENTIAL AVA-RELATED ADVERSE EVENTS THEY MAY OBSERVE. VAERS REPORT FORMS MAY BE ACCESSED AT THE MILVAX WEBSITES: WWW.ANTHRAX.MIL OR WWW.VACCINES.MIL/ANTHRAX, OR WWW.VAERS.ORG OR BY CALLING VAERS AT 1-800-822-7967.

12. THE ANTHRAX VACCINE IMMUNIZATION PROGRAM REMAINS A COMMANDERS FORCE HEALTH PROTECTION RESPONSIBILITY. MEDICAL DEPARTMENT PERSONNEL SHALL ASSIST COMMANDERS IN COMPLYING WITH THIS RESPONSIBILITY BY ENSURING PERSONNEL ARE PROPERLY IDENTIFIED, SCREENED, AND EDUCATED PRIOR TO VACCINATION; THROUGH PROPER ADMINISTRATION AND DOCUMENTATION AT VACCINE ADMINISTRATION; AND BY ENSURING APPROPRIATE MEDICAL EVALUATIONS FOR ALL VACCINE-RELATED ADVERSE EVENTS.

13. THIS POLICY IS EFFECTIVE IMMEDIATELY AND SHOULD BE COMMUNICATED TO APPROPRIATE COMMANDERS, HEALTHCARE PROVIDERS, AND OTHERS INVOLVED IN THE DOD'S ANTHRAX VACCINE IMMUNIZATION PROGRAM. REQUEST WIDEST DISSEMINATION TO ALL MEDICAL ACTIVITIES, FLEET SURGEONS, SENIOR MEDICAL DEPARTMENT REPRESENTATIVES, IMMUNIZATION CLINICS, AND PREVENTIVE MEDICINE DEPARTMENTS BOTH ASHORE AND AFLOAT.

14. RELEASED BY VADM A. M. ROBINSON, JR., MC, USN.//

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