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FM PTC WASHINGTON DC//ALARACT//

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\*\*\*\*\* THIS IS A COMBINED MESSAGE \*\*\*\*\*

SUBJ: ALARACT 013/2006

THIS MESSAGE HAS BEEN SENT BY THE PENTAGON TELECOMMUNICATIONS CENTER ON BEHALF OF DA WASHINGTON DC//DAMO-AOC//

SUBJ: ADOPTION OF NEW TETANUS-DIPHThERIA-ACELLULAR PERTUSSIS (TDAP) VACCINE

REF/A/REG/HQDA/ARMY REGULATION 40-562, IMMUNIZATIONS AND CHEMOPROPHYLAXIS, 1 NOV 95//

NARRATIVE: ON 10 JUN 05, THE FOOD AND DRUG ADMINISTRATION (FDA) LICENSED A TETANUS TOXOID/REDUCED-DOSE DIPHThERIA TOXOID/REDUCED-DOSE ACCELLULAR PERTUSSIS VACCINE (TDAP, TEE-DAP) FOR ADOLESCENTS AND ADULTS 11 TO 64 YEARS OLD, MANUFACTURED BY SANOFI PASTEUR, USING THE TRADE NAME ADACEL. ON 3 MAY 05, THE FDA LICENSED ANOTHER TDAP VACCINE FOR ADOLESCENTS 10 TO 18 YEARS OLD, MANUFACTURED BY GLAXO SMITHKLINE, USING THE TRADE NAME BOOSTRIX. THIS MESSAGE PROVIDES GUIDANCE ON HOW TO ADOPT THESE VACCINES IN MILITARY TREATMENT FACILITIES. BY LARGELY REPLACING ADULT-STRENGTH TETANUS-DIPHThERIA (TD) TOXOIDS, TDAP OFFERS THE ADVANTAGE OF PREVENTING A HIGHLY CONTAGIOUS RESPIRATORY INFECTION. TDAP DIRECTLY PROTECTS THE INDIVIDUAL VACCINATED AND IS EXPECTED TO PROVIDE INDIRECT BENEFIT BY REDUCING THE RISK OF TRANSMITTING THE INFECTION TO AN INFANT.

1. (U) TDAP FOR MILITARY PERSONNEL AND OTHER ADULTS.

1A. (U) ON 27 OCT 05, THE ACIP RECOMMENDED ROUTINE USE OF A SINGLE DOSE OF TDAP FOR ADULTS 19 TO 64 YEARS OF AGE TO REPLACE THE NEXT BOOSTER DOSE OF TETANUS AND DIPHThERIA TOXOIDS VACCINE (TD).

1B. (U) EFFECTIVE IMMEDIATELY, ARMY MILITARY TREATMENT FACILITIES WILL BEGIN TRANSITIONING FROM TD TO TDAP FOR BOOSTER IMMUNIZATION OF MILITARY PERSONNEL AND OTHER HEALTHCARE BENEFICIARIES 11 TO 64 YEARS OF AGE, USING THE STANDARD EVERY-10-YEAR DOSING INTERVAL. SELECT ADACEL OR BOOSTRIX BASED ON THE AGE RANGES REFLECTED IN THE PRODUCTS LICENSED INDICATIONS.

1C. (U) ARMY BASIC COMBAT TRAINING CENTERS WILL TRANSITION FROM TD TO TDAP FOR BASIC TRAINEES AS SOON AS PRACTICAL.

1D. (U) SOLDIER READINESS PROCESSING SITES WILL TRANSITION FROM TD TO TDAP USING THE STANDARD EVERY-10-YEAR DOSING INTERVAL AS SOON AS PRACTICAL. THIS APPLIES EQUALLY TO ACTIVE COMPONENT AND RESERVE COMPONENT PERSONNEL.

1E. (U) ADULTS WHO DESIRE PROTECTION AGAINST PERTUSSIS AND WHO RECEIVED A DOSE OF TD FEWER THAN 10 YEARS EARLIER MAY RECEIVE A DOSE OF TDAP, RECOGNIZING THAT A SHORTER INTERVAL COULD BE ASSOCIATED WITH AN ELEVATED RISK OF INJECTION-SITE SWELLING OR SYSTEMIC (E.G., FEVER) ADVERSE EVENTS. SHORTER INTERVALS WOULD BE APPROPRIATE IN PEOPLE AT INCREASED RISK OF PERTUSSIS INFECTION OR WHO HAVE OR ANTICIPATE CLOSE CONTACT WITH AN INFANT. THE SAFETY OF AN INTERVAL AS SHORT AS TWO YEARS BETWEEN TD AND TDAP IS SUPPORTED BY A CANADIAN STUDY AMONG 6,000 CHILDREN AND ADOLESCENTS.

2. (U) TDAP FOR ADOLESCENTS.

2A. (U) ON 30 JUN 05, THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP) RECOMMENDED ADOLESCENTS 11 TO 18 YEARS OF AGE

RECEIVE A SINGLE DOSE OF TDAP (EITHER ADACEL OR BOOSTRIX), INSTEAD OF TD, IF THOSE ADOLESCENTS COMPLETED THE RECOMMENDED DIPHTHERIA-TETANUS-PERTUSSIS (DTP) PEDIATRIC IMMUNIZATION SERIES. THE PREFERRED AGE FOR ADOLESCENT TDAP IMMUNIZATION IS 11 TO 12 YEARS. ADOLESCENTS AGED 11 TO 18 YEARS WHO RECENTLY RECEIVED TD ARE ENCOURAGED TO RECEIVE A SINGLE DOSE OF TDAP TO PROVIDE PROTECTION AGAINST PERTUSSIS. AN INTERVAL BETWEEN TD AND TDAP OF AT LEAST FIVE YEARS IS ENCOURAGED, HOWEVER AN INTERVAL AS SHORT AS TWO YEARS MAY BE CONSIDERED IF THE POTENTIAL BENEFIT OF IMMUNIZATION (IN THOSE AT INCREASED RISK OF PERTUSSIS EXPOSURE) JUSTIFIES AN INCREASED RISK OF LOCAL AND SYSTEMIC REACTIONS.

2B. (U) MILITARY TREATMENT FACILITIES (MTFS) WILL ADOPT ACIP GUIDELINES FOR ROUTINE ADMINISTRATION OF TDAP AS A SUBSTITUTE FOR TD AMONG ADOLESCENTS, AS DESCRIBED ABOVE.

2C. (U) FOR ADOLESCENTS FOR WHOM MENINGOCOCCAL CONJUGATE VACCINE (MENACTRA, SANOFI PASTEUR, WHICH CONTAINS DIPHTHERIA TOXOID) IS ALSO INDICATED, THE ACIP RECOMMENDS BOTH VACCINES BE GIVEN DURING THE SAME VISIT IF FEASIBLE.

3. (U) CLINICAL.

3A. (U) ADACEL AND BOOSTRIX ARE ADMINISTERED AS SINGLE INTRAMUSCULAR DOSES.

3B. (U) PREGNANCY. PREGNANCY IS NOT A CONTRAINDICATION TO TDAP OR TD IMMUNIZATION. GUIDANCE ON THE USE OF TDAP DURING PREGNANCY IS UNDER CONSIDERATION BY ACIP.

3C. (U) IN PATIENTS WITH A HISTORY OF INCOMPLETE DTP VACCINATION, COMPLETE A 3-DOSE TD SERIES, REPLACING ANY ONE OF THOSE THREE DOSES (PREFERABLY THE FIRST) WITH TDAP.

3D. (U) PEDIATRIC FORMULATIONS OF DIPHTHERIA-TETANUS-ACELLULAR PERTUSSIS (DTAP) VACCINE WILL CONTINUE TO BE USED AS THE PRIMARY VACCINE FOR INFANTS AND CHILDREN UNTIL THEIR SEVENTH BIRTHDAY.

3E. (U) PRODUCTION OF TD CONTINUES.

3F. (U) AT THE POINT OF CARE, PRIVILEGED HEALTHCARE PROVIDERS MAY MAKE A CLINICAL DECISION TO PROVIDE THE BEST POSSIBLE CARE FOR THEIR PATIENTS. HEALTHCARE PROVIDERS MAY PRESCRIBE MEDICATION USE OUTSIDE LABELED INDICATIONS, IN AN INDIVIDUAL, HEALTHCARE PROVIDER-PATIENT RELATIONSHIP. HOWEVER, IN DOING SO, THEY MUST DOCUMENT THEIR RATIONALE FOR USING A MEDICATION OFF-LABEL IN THE HEALTH RECORD.

3G. (U) ALTHOUGH NO INFORMATION IS YET AVAILABLE TO GUIDE DECISIONS ABOUT ADMINISTERING MORE THAN ONE DOSE OF TDAP, SUCH INFORMATION WILL BECOME AVAILABLE OVER TIME. THE DURATION OF IMMUNITY TO PERTUSSIS AFTER IMMUNIZATION WITH TDAP IS NOT YET KNOWN.

3H. (U) REPORT ADVERSE EVENTS AFTER IMMUNIZATION TO THE VACCINE ADVERSE EVENT REPORTING SYSTEM, [WWW.VAERS.HHS.GOV](http://www.vaers.hhs.gov). VACCINE SAFETY SCIENTISTS ARE ESPECIALLY INTERESTED IN CASES OF EXTENSIVE LIMB SWELLING (EG, FROM SHOULDER OR DELTOID TO ELBOW), ARTHUS REACTIONS OR OTHER EXTENSIVE INJECTION-SITE REACTIONS, PARTICULARLY THOSE GREATER THAN 5 CM (2 IN) IN DIAMETER AFTER TDAP. ANY CLINICALLY SIGNIFICANT ADVERSE EVENT, EVEN IF A CAUSAL RELATIONSHIP TO IMMUNIZATION IS UNCERTAIN, SHOULD BE REPORTED.

4. (U) EDUCATION.

4A. (U) GENERAL. DETAILED CLINICAL AND LAY INFORMATION ABOUT ADACEL AND BOOSTRIX ARE AVAILABLE AT [WWW.VACCINES.MIL/PERTUSSIS](http://WWW.VACCINES.MIL/PERTUSSIS).

4B. (U) HANDOUTS. THE CENTERS FOR DISEASE CONTROL & PREVENTION (CDC) ISSUED A VACCINE INFORMATION STATEMENT (VIS) FOR TDAP. THIS SHEET WILL BE THE ARMY STANDARD FOR PATIENT-LEVEL INFORMATION ABOUT TDAP, AND IS AVAILABLE AT [WWW.CDC.GOV/NIP/PUBLICATIONS/VIS/VIS-TDAP.PDF](http://WWW.CDC.GOV/NIP/PUBLICATIONS/VIS/VIS-TDAP.PDF).

4C. (U) ACIP RECOMMENDATIONS FOR TDAP WILL BE PUBLISHED IN THE

MORBIDITY & MORTALITY WEEKLY REPORT IN COMING MONTHS.

5. (U) RESOURCE IMPLICATIONS.

\*\*\*\*\* START OF SECTION 2 \*\*\*\*\*

5A. (U) FY06. MTFs SHOULD PURCHASE THESE VACCINES VIA PRIME VENDOR USING CURRENT PROGRAMS. REGIONAL MEDICAL COMMANDS MAY SUBMIT UNFUNDED REQUIREMENT (UFR) REQUESTS FOR INTERIM BUDGET REVIEW. THE DOD VACCINE AND ANTIBODY PRICE LIST APPEARS AT: [WWW.VACCINES.MIL/PRICELIST](http://WWW.VACCINES.MIL/PRICELIST) . PHARMACY AND MEDICAL LOGISTICS STAFF SHOULD COMPARE THIS PRICE LIST TO LOCAL PROCUREMENT PRACTICES, TO ASSURE THAT THE MOST COST-EFFECTIVE PACKAGE SIZES OF ALL VACCINES ARE PURCHASED.

5B. (U) FY07 AND BEYOND. FOR FY07 BUDGET PLANNING, THE MILITARY VACCINE AGENCY DEVELOPED PLANNING FACTORS RELATED TO THE POSSIBLE LICENSURE OF A ROTAVIRUS VACCINE FOR INFANTS, A SHINGLES VACCINE FOR ELDERLY, AND A PAPILLOMAVIRUS VACCINE FOR ADOLESCENTS AND ADULTS. CONTACT THE MILITARY VACCINE AGENCY FOR MORE INFORMATION.

6. (U) DOCUMENTATION.

6A. (U) ALL IMMUNIZATIONS GIVEN TO MILITARY AND DA CIVILIAN EMPLOYEES WILL BE IMMEDIATELY RECORDED INTO THE MEDICAL PROTECTION SYSTEM (MEDPROS), THE HQDA STANDARD FOR TRACKING ALL INDIVIDUAL MEDICAL READINESS INDICATORS IN THE ACTIVE AND RESERVE COMPONENTS. THE MEDPROS CODE FOR TDAP IS 115 OR TDP. LEADERS AT ALL LEVELS CAN TRACK INDIVIDUAL AND UNIT COMPLIANCE USING MEDPROS ON THE INTERNET AT [WWW.MODS.ARMY.MIL](http://WWW.MODS.ARMY.MIL). USERS MAY REQUEST A LOGON ID DIRECTLY FROM THE WEBSITE OR BY CALLING THE MODS HELP DESK AT DSN 761-4976 OR 1-888-849-4341 FOR ASSISTANCE. COMMANDERS WILL ASSIGN DESIGNATED PERSONNEL TO ROUTINELY ACCESS MEDPROS TO KEEP THEIR UNITS CURRENT. INDIVIDUALS CAN PRINT OUT THEIR PERSONAL ELECTRONIC IMMUNIZATION RECORD VIA ARMY KNOWLEDGE ONLINE AT ITS MY MEDICAL READINESS SECTION.

6B. (U) ALL IMMUNIZATIONS WILL ALSO BE RECORDED PROMPTLY IN INDIVIDUAL HEALTH RECORDS.

7. (U) LOGISTICAL DETAILS. THE MANUFACTURERS ARE READY TO SHIP THESE VACCINES TO MTFs VIA PRIME VENDOR IN EARLY 2006.

7A. (U) ADACEL IS ORDERED BY MTFs VIA THEIR PRIME VENDOR WHOLESALER. THE FEDERAL SUPPLY SCHEDULE PRICE IS \$25.09 PER 0.5-ML DOSE. THE NATIONAL DRUG CODE (NDC) NUMBER FOR A PACKAGE OF 10 SINGLE-DOSE VIALS IS 49281-0400-10.

7B. (U) BOOSTRIX IS ORDERED BY MTFs VIA THEIR PRIME VENDOR WHOLESALER. THE FEDERAL SUPPLY SCHEDULE PRICE IS \$24.70 PER 0.5-ML DOSE. THE NDC NUMBER FOR A PACKAGE OF 10 SINGLE-DOSE VIALS IS 58160-0842-11. THE CODE FOR A PACKAGE OF FIVE SINGLE-DOSE SYRINGES IS 58160-0842-46.

8. (U) POCS: LTC STEVE FORD, 703-681-5101 OR DSN 761-5101, OR EMAIL: [VACCINES@OTSG.AMEDD.ARMY.MIL](mailto:VACCINES@OTSG.AMEDD.ARMY.MIL)

9. (U) EXPIRATION DATE FOR THIS AUTHORIZATION CANNOT BE DETERMINED.

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