Vaccines in the Military: A Department of Defense-Wide Review of Vaccine Policy and Practice

A Report for the Armed Forces Epidemiological Board
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The Infectious Diseases Control Subcommittee of the Armed Forces Epidemiological Board

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13. ABSTRACT *(Maximum 200 words)*
The Military Services have long recognized that the prevention of disease is a keystone of military readiness. The prevention of many diseases of military and civilian significance is best accomplished through the use of vaccines. In the four years since the publication of the last joint instruction on Immunizations and Chemoprophylaxis, new vaccines, new dosing, or different indications for old vaccines have been introduced. The speed with which these changes have occurred is such that many in the field who depend upon these policies to set the standard for medical care, express confusion regarding current immunization policies. In addition, the Infectious Diseases Control Subcommittee of the AFEB has received ongoing, multiple inquiries about new vaccines and new policies for the use of currently licensed vaccines. Hence the Infectious Diseases Control Subcommittee, with the support of the AFEB, performed a DoD-wide review of immunization policies among the Military Services, for recruits, active duty, reserve, special operations groups, and dependent/Tricare personnel. Recommendations resulting from the review have been forwarded to DoD(Health Affairs) and the Military Medical Departments.

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Foreword

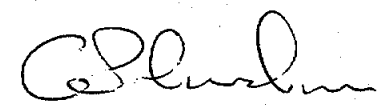
The Armed Forces Epidemiological Board has a long and important history of dealing with disease prevention issues, particularly in the area of vaccines, biologics, and immunization policy for the military. The Armed Forces also has great concern for this area, as it not only impacts the individual welfare of each and every soldier, airman and sailor, but also the military's overall readiness status.

As a result of the growing number of new vaccines and biologics, as well as the need for updated policy, the AFEB tasked the Infectious Diseases Control Subcommittee to perform a Department of Defense-wide review of vaccine use and policy, and to make recommendations that would also serve to aid and inform the drafting of a new and updated *Joint Instruction on Immunizations and Chemoprophylaxis*.

In accepting this report and its recommendations, the Armed Forces Epidemiological Board has focused upon the critical need for a comprehensive Department of Defense-wide document that updates vaccine and biologic use and policy for all those persons who depend upon these recommendations to guide military medical practice.

The Infectious Diseases Control Subcommittee appreciates the work of the contractor (Birch & Davis Associates, Inc.), the individual members of each of the military services who assisted us in our work, and the support of the immediate past and current Executive Secretary (Col. V. Fogelman and Col. B. Diniega, respectively) and immediate past and current President's (Dr. J. Fletcher and Dr. D. Perrotta, respectively) of the AFEB, without whom this work could not have been accomplished.

Finally, we appreciated the opportunity to have been of service to the men and women of our Armed Forces, whose health and welfare formed the always present singular focus of our work.



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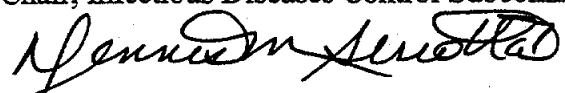

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EXECUTIVE SUMMARY AND RECOMMENDATIONS

The Military Services have long recognized that the prevention of disease is a keystone of military readiness. The prevention of many diseases of military and civilian significance is best accomplished through the use of vaccines. In the 4 years since the publication of the last Joint Instruction on Immunizations and Chemoprophylaxis, new vaccines, new dosing, or different indications for old vaccines have been introduced. The speed with which these changes have occurred is such that many in the field who depend upon these policies to set the standard for medical care, express confusion regarding current immunization policies. In addition, the Infectious Diseases Control Subcommittee (IDCS) of the AFEB has received ongoing, multiple inquiries about new vaccines and new policies for the use of currently licensed vaccines. Hence, the IDCS, with the support of the AFEB, performed a DoD-wide review of immunization policies among the military services, for recruits, active duty, reserve, special operations groups, and dependent/Tricare personnel.

From this work, the following conclusions and recommendations have resulted:

1. We urgently recommend that policies and practices that ensure the ready supply to the military of vaccines essential to its mission be developed. Vaccine supply, vaccine stocking logistics, and threats to the vaccine supply are crucial issues in the design and maintenance of a successful DoD immunization program. This is highlighted by the inability to obtain new stocks of adenovirus vaccine, and the near loss of the ability to obtain plague and anthrax vaccines. Serious consideration should be given to:

- Assigning specific "watchdog" organizations within DoD (such as DSCP, the USACHPPM, MRMC, etc.) to partner with vaccine manufacturers in projects that will allow funding and development of manufacturing facilities, research and development facilities, or storage facilities. This must be done to prevent the loss of manufacturing facilities for militarily strategic vaccines. If this is not done, existing manufacturing facilities, institutional knowledge and expertise will be lost and will not be easily assembled in time to alleviate a large outbreak or biological warfare attack.

- Providing funding for collaborative projects and development of DoD-identified strategically important vaccines that have limited markets.

- Addressing whether DoD might need its own manufacturing facility to ensure that militarily crucial vaccines will always be available to the DoD. In particular, BSL 3 facilities for the manufacture of vaccines such as Rift Valley Fever, and others are not now routinely available to the DoD, and hence the ability to manufacture these vaccines is being lost.

- The above issues might constructively be addressed in a joint planning meeting between the DoD, CDC, NIH (NIAID), and vaccine manufacturers.

2. We recommend that DoD further develop and expand the efforts towards standardized, computerized record-keeping and tracking of both adult and childhood immunizations provided to active duty, reserve forces, dependents and other TRICARE beneficiaries; within the framework of fully computerized medical records.

- In particular we recommend that DoD maintain and enhance the current effort to implement *standardized* requirements for automation across all services and agencies. Automated records, if properly maintained, will make it far easier to determine immunization status and force readiness and to identify individuals who may be susceptible to particular diseases because of missing immunizations. The ability to electronically access immunization records at all vaccine administration sites throughout DoD would be ideal. The new Joint Instruction, an increasing capability to monitor implementation electronically, and requirements that commanders routinely report on readiness issues, including immunization status, will foster continued efforts to ensure that the military services are prepared and protected against infectious diseases.

3. We recommend that each service measure and report up-to-date immunization rates as key indicators of medical care delivery and force readiness. Major benefits of such a task will be to make clear the resources and infrastructure necessary to perform such functions, and to make clear the urgency of improving these rates.

- Appendices F, G, and H; appended to this report, provide specific guidance and recommendations, as well as baseline data, in designing and operationalizing surveys in this regard.

4. We recommend that consideration be given to the concept of a "Vaccine and Immunobiologics Oversight Board". This oversight is proposed to come from the Joint PVNTMED Policy Group, with adjunct members consisting of "people in the field" who actually administer immunizations and immunization programs (including Allergists, Infectious Disease experts, Primary Care physicians, and Nurses). This is a small council chartered under the auspices of OASD(HA) charged with reviewing and reconciling diverse immunization policies among the Services.

- We recommend increasing involvement by the Reserves and National Guard in the central planning and funding of DoD immunization programs so that

special logistical and implementation problems encountered by the R/NG when not on active duty are better addressed.

5. We recommend that DoD develop and disseminate, as soon as practicable, a new Joint Instruction on Immunizations and Chemoprophylaxis. In developing the new Joint Instruction on Immunizations and Chemoprophylaxis, we recommend that the DoD:

- Consider adding anthrax., Lyme disease , and tick-borne encephalitis vaccines to those addressed by the Joint Instruction on Immunizations and Chemoprophylaxis
- Clarify the policy for boosting meningococcal vaccine
- Consider expanding the instructions for use of varicella vaccine
- Address policies for the use of INDs not only in the biological warfare defense section but also in the body of the Joint Instruction on Immunizations and Chemoprophylaxis, including requirements for informed consent
- Develop a policy for the introduction of new vaccines that may be utilized before a new Joint Instruction on Immunizations and Chemoprophylaxis is issued
- Address the issue of obtaining and storing informed consent (written or otherwise) for routine, IND, and non-IND vaccine use
- Revise jet injector use policy to address recent safety concerns and recent AFEB recommendations
- Revise the vaccine record-keeping requirements in light of the automation of records, e.g., what paper records need to be maintained, whether the PHS-731 must be maintained, etc. taking into consideration the period of transition before all records are automated
- Address the issue of differences in immunization policy and practice between the service branches
- Promulgate a policy for properly recording Federally-mandated vaccine administration information, and for reporting vaccine adverse events
- Address the issue of screening for immunity to vaccine-preventable diseases, particularly in recruit, reserve, and officer accessions

6. We recommend that DoD address whether current procedures and resources are sufficient to ensure that appropriate personnel are aware of what portions of official policy documents have been superseded. We recommend that DoD:

- Develop a web page and/or other communication devices that allow easy access to current military immunization policy, ACIP recommendations, and other relevant policy references. Some of these items could be accessed by hypertext linkages (the ACIP recommendations, for example, are available through the CDC web site).

7. We recommend that DoD be committed to fully informing every service member of the health risks, personal and military benefits, and proper use of all vaccines and other medical countermeasures. Each military member should be fully informed about both the licensed and IND vaccines that they receive, even though such vaccines are considered "required" or "mandatory." Specific recommendations include:

- DoD should develop vaccine risk communication plans for the military vaccine program and, as appropriate, for specific vaccines.
- DoD should provide military members with appropriate vaccine information statements during each vaccine service encounter, especially when vaccines are being administered to recruits, alert forces, and deploying forces.
- DoD should develop and issue general policies for the use of any IND vaccine product and for the off-label use of a vaccine product, including requirements for informed consent and documentation.
- DoD should develop orientation and training procedures to alert military members that they may be required to take vaccines not yet approved for commercial marketing, if the President approves a DoD request for a waiver of informed consent.
- DoD should conduct research among military populations that will inform better vaccine risk communication efforts in the future.

8. We recommend that DoD address issues of standardized training and proficiency of immunization delivery practice. Specific programs and policies regarding the following issues are needed:

- Training and licensure requirements for those providers actually delivering the injection. Given the broad differences in potentially applicable state laws, a central DOD training and licensure requirement should be spelled-out to ensure uniformity of best practice across the enterprise.

- Development of proficiency standards and ongoing continuing medical education (CME) requirements to ensure that shotgivers remain up-to-date with the rapidly changing landscape of vaccine science, delivery practices, and adverse reaction management & reporting.

- Address credentialing, licensing, and CME requirements for those providers responsible for vaccine ordering and supervision/oversight of shotgivers. Since vaccines are FDA-licensed materials to be dispensed by prescription only, better clarification in this area is needed.

- Better define the language in the Joint Instruction on Immunizations and Chemoprophylaxis regarding training of immunization personnel in resuscitative measures and the treatment of anaphylaxis. The minimum standards required to conduct immunization delivery in remote sites (i.e. away from the hospital or clinic) should be specifically outlined in regards to training of personnel and the availability of specialized resuscitative equipment.

9. We recommend that the DoD develop a vaccine policy and practice statement for the use of vaccines and immunobiologics in humanitarian missions. For example, tetanus immune globulin has little or no use within US military forces, but may have high utility in humanitarian operations in developing countries. Planning for the immunization of key segments of the civilian population in the event of a biological warfare attack may also be prudent.

10. We recommend maintaining the current centralized DSCP procurement system, while providing flexibility at the local level with the many other adjunct procurement systems. Centralized procurement of certain vaccines will ensure competitive prices for DoD while the current adjunct procurement systems will allow local levels to prioritize immunization missions on a timely basis.

11. We recommend that the DoD continue to participate in developing a comprehensive US Pandemic Influenza Planning document, and actively devise, disseminate and test a DoD-wide plan that would be activated world-wide once an influenza pandemic is declared.

12. Finally, we recommend that because of rapid changes in the vaccine field, the number of new vaccines expected on the market in the near future, and the rapidly changing geographic areas and hence disease risks within which DoD must operate that the AFEB review this document and its recommendations on an every two-three year basis.

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CHAPTER 1

INTRODUCTION AND PURPPOSE

This report attempts to review the recommendations, use, and administration of vaccines across the Department of Defense. A major goal of this report is to assesses immunization policy data specific to Army, Navy, Air Force, Marine Corps, Coast Guard, and TRICARE personnel. This information was collected by Birch & Davis Associates, Inc. (B&D). In conjunction with the Infectious Diseases Control Subcommittee (IDCS) of the Armed Forces Epidemiological Board (AFEB), B&D developed comprehensive questionnaires about immunization policies affecting five personnel groups: new accessions (both enlisted recruits and officer accessions), active duty personnel (both routine immunizations and those administered for travel to high risk areas), special operational and occupational groups, reserve forces, and dependents and other TRICARE beneficiaries.

To lessen the burden on the survey respondents, B&D encouraged them to complete the questionnaires by referencing and providing copies of policy letters, memoranda, messages, and other written communication. The IDCS and B&D had been provided with a copy of the Joint Instruction on Immunizations and Chemoprophylaxis dated 1 November 1995, but sought to collect information that interpreted or modified the Joint Instruction on Immunizations and Chemoprophylaxis. Although not originally the primary focus of the data collection effort, the over 95 documents collected from 113 survey respondents have proved to be critical sources of policy and procedure data. Thus the focus of the project was broadened from a sole emphasis on responses from key survey respondents to include written policy documents as well.

Throughout the project we relied on contacts from each of the services to review draft summaries of the information collected. The IDCS and B&D project team would like to thank the many representatives of the services who provided data and reviewed the summary tables. Any conclusions drawn about the data are the responsibility of the IDCS's and do not necessarily represent the opinions of the Department of Defense (DoD) or any of the military services. The data in this report however have been fully reviewed by the services, the members of the Infectious Diseases Control Subcommittee, and the full AFEB.

The purpose of this document is to report the findings from an analysis of the policy documents and questionnaire responses collected during the project period, identify policy gaps and inconsistencies, and present conclusions and recommendations concerning DoD practice and policy. The report is organized into the following sections:

- Introduction and Background
- Current Vaccine Recommendations

- Vaccine-specific policies for personnel groups in the military services:
  - Enlisted recruits and officer accessions
  - Active duty personnel
  - Special operational and occupational groups
  - Reserve forces
  - Dependents and other TRICARE beneficiaries

- Immunization Policy
  - Issues of Screening
  - Issues of Immunobiologics
  - Issues of Administration
  - Issues of Consent
  - Issues of Data Management
  - Issues of Research
  - Issues of Surveillance
  - Issues of Resources and Budget

- Conclusions and Recommendations

It is our hope that this document will serve three major purposes:

1. To aid and inform the writing of the next version of the Joint Instruction on Vaccines and Chemoprophylaxis.

2. To increase military readiness by decreasing time lost from training and work, as well as reducing the morbidity and mortality associated with vaccine-preventable diseases.

3. To provide recommendations that will provide a framework for addressing issues which impair accomplishment of the important task of protecting DoD personnel against vaccine-preventable diseases.

CHAPTER TWO

CURRENT VACCINE RECOMMENDATIONS

Immunization is the most effective and economical means of preventing hepatitis A and B, influenza, measles, mumps, rubella (MMR); polio; tetanus-diphtheria (Td); varicella; and other vaccine-preventable diseases. In the military, susceptibility to vaccine-preventable diseases can have devastating consequences. Military personnel who acquire vaccine-preventable disease not only suffer morbidity and mortality as a result of infection but also serve as vectors for transmitting disease to other personnel, and may substantially affect training schedules, security, and readiness.

A. Specific Vaccines Recommended by the United States Public Health Service's Advisory Committee on Immunization Practices (this section adapted from Poland GA, Haiduven DJ, Adult Immunizations in Infection Control and Applied Epidemiology, Mosby and Co, St. Louis, 1999, in press)

1. Hepatitis A

a) Vaccine Type: The first hepatitis A vaccine for use in the US was licensed in February, 1995 (HAVRIX™, SmithKline Beecham Biologicals). A similarly prepared and licensed vaccine is also available (VAQTA™, Merck Research Laboratories). Both vaccines undergo inactivation and purification procedures designed to inactivate all known viruses, and thus are inactivated whole virus preparations. Both vaccines appear to be equally efficacious and safe.

b) Indications: Hepatitis A vaccine is indicated for pre-exposure prophylaxis against hepatitis A infection for the groups listed below:

- Travelers to endemic countries (including military personnel)
- Male homosexuals
- Household and sexual contacts of persons infected with hepatitis A
- Daycare workers
- Health care workers having contact with active cases and laboratory workers who handle live hepatitis A virus
- Food handlers
- Illicit drug users
- Prisoners
- Staff and inmates of institutions for the mentally handicapped

- Chronic carriers of hepatitis B
- Native Americans
- Persons with other chronic liver diseases

c) Side Effects:

- All studies to date indicate the exceptional safety profile of the hepatitis A vaccines. In studies to date, side effects reported in up to 50% of recipients included pain and tenderness at the injection site, headache, diarrhea, and other non-specific symptoms of approximately equal frequency to placebo. [1]
- In a study of 151 health care workers, the most frequent reported side effect was transient soreness at the site of injection in 27% of recipients, with no major symptoms reported. [2]
- There is a single case report of encephalopathy temporally associated with the third dose of the SKB vaccine in a single individual, with uneventful recovery after 48 hours. [3]
- Slight, transient liver function abnormalities have occurred in some vaccine recipients.
- In one summary report of 104 studies utilizing the SKB vaccine involving > 50,000 subjects and > 120,000 doses of vaccine, a seroconversion rate of 100% was observed with no serious adverse events considered related to vaccination.[4]

d) Strategies for Administration: Mechanisms to ensure that two doses of vaccine are administered with appropriate spacing between doses are necessary. There is no apparent advantage to more than two doses of vaccine and more than two doses represent excess cost. Computerized tracking databases are optimal to ensure that the number of doses and dosing intervals are adhered to.

e) Spacing with Other Immunobiologics: The ability to initiate the hepatitis A vaccine series, while simultaneously providing immediate protection against infection for travelers to at-risk countries by administering immune globulin, is desirable.

- Studies to date generally indicate that immune globulin can safely be administered simultaneously (different anatomic sites, separate injections) with the hepatitis A vaccine, although the height of the antibody response may be slightly reduced.
- One study involving the SKB vaccine demonstrated a marked depressive effect on antibody response when the dose of gamma globulin was 5 mL, but little effect when the dose of immune globulin was 2 mL. [5,6]
- In another trial, 5 mL of immune globulin co-administered with the SKB vaccine resulted in twofold lower geometric mean titers compared to persons receiving only vaccine. [7]
- At the current time, it is recommended that immune globulin continue to be given at the same time as the first dose of hepatitis A vaccine for individuals who need immediate protection, and who are expected to require the longer term protection necessary for pre-exposure prophylaxis, such as travelers to endemic areas. Future research may well indicate the efficacy of a single dose of vaccine as pre-exposure prophylaxis in adult travelers.

f) Contraindications:

- The currently licensed hepatitis A vaccines are inactivated vaccines and cannot cause hepatitis A.
- The vaccine should be given during pregnancy only if clearly needed.
- There are no other known contraindications other than hypersensitivity to any of the known components of the vaccine.

g) Administration Schedule:

- Hepatitis A immunization requires a single dose in adults (with a later booster dose at 6-12 months to achieve maximum titers), and a two dose series in children/adolescents (with a later [third] booster dose).
- The antigen content of the vaccines is expressed in enzyme-linked immunosorbent assay units. For adults, the dose is 1 mL intramuscularly (1440 ELISA unit formulation) given at time 0, with a booster dose 6-12 months later. For persons > age 2 years, but < age 16 years, the dose is 0.5 mL (360 ELISA unit formulation) at time 0, and at 1 month, with a booster dose at 6-12 months.
- The vaccine is not approved for use in children younger than 2 years of age.
- Interrupting the administration schedule does not require restarting the series.
- The antigen content of the vaccines is expressed in enzyme-linked immunosorbent assay units. Dosages are as follows, adapted from [8]:

Age of Vaccinee (yrs)	Dose	Volume (mL)	Number of Doses	Schedule (mos)
HAVRIX				
2-18	720	0.5	2	0, 6-12
> 18	1,440	1.0	2	0, 6
VAQTA				
2-17	25	0.5	2	0, 6-18
> 17	50	1.0	2	0, 6

h) Post-vaccination Serologic Testing: Not typically performed or required.

i) Effectiveness and Safety:

- There are two large prospective studies demonstrating the efficacy of both hepatitis A vaccines. [9,10] The calculated efficacy of the SKB vaccine in a double-blind, randomized, controlled efficacy trial involving 40,119 Thai children, half of whom received vaccine, was 94%. [10]

- In the MSD trial involving children living in a closed religious community in Monroe County, New York, efficacy was 100% 21 days after immunization.[9] In fact, all studies to date indicate that these vaccines are highly immunogenic, with excellent safety profiles.[1]
- After a single dose of either vaccine, seroconversion rates exceeding 90% are routinely observed, with anti-HAV levels approximating those achieved by a 5 mL dose of immune globulin. [1]
- Specifically, after a single 1440 ELISA unit dose of vaccine in adults, 80-90% have protective levels of antibody after 15 days, and >96% seroconvert after 30 days.
- When a booster dose is given 6 months later, essentially 100% of recipients seroconvert. Protective antibody titers develop within 15 to 30 days after vaccination.

2. Hepatitis B

a) Vaccine Type:

- The two vaccines available in the U.S. are both recombinant subunit vaccines.
- The plasma-derived vaccine is no longer available in the U.S., but is available in other parts of the world.

b) Indications:

- Hepatitis B vaccine is recommended for pre- and/or post-exposure prophylaxis of all persons at risk of contact with blood, blood products, or bodily secretions.
- Serologic screening is not necessary prior to immunization. There are no known adverse effects to immunizing someone who may already be immune due to previous infection or immunization.

c) Side Effects:

- Mild soreness at the injection site lasting up to 1-2 days can occur in up to 20% of recipients.
- Occasionally nonspecific constitutional symptoms (low grade fever, myalgias, malaise, etc.) occur.
- No severe acute or chronic adverse effects have been demonstrated to be due to the vaccine.

d) Strategies for Administration:

- Ideally, immunization against hepatitis B should be completed prior to the risk of exposure.[11]

e) Spacing with Other Immunobiologics: Hepatitis B vaccine can be given at any time, in conjunction with any other vaccines, although at different anatomic sites and using separate syringes.

f) Contraindications: There are no contraindications other than demonstrated hypersensitivity to previous doses of hepatitis B vaccine, and allergy to thimerosal.

g) Administration Schedule:

- Immunization against hepatitis B requires three doses, administered intramuscularly in the deltoid muscle, regardless of the formulation.
- Adults should receive one 1-mL dose initially, which is repeated at 1 and 6 months.
- The vaccine concentrations as currently formulated are 20 mcg/mL for Engerix-B (SKB) and 10 mcg/mL for Recombivax HB (Merck). Higher doses (40 mcg/mL) are recommended to provide protection for dialysis and immunocompromised patients.
- The SKB vaccine is also licensed for use on a 0,1,2,12 month schedule.
- A 1 or 1.5 inch needle may be needed to ensure the vaccine is given intramuscularly in obese persons.[12]

h) Post-vaccination Serologic Testing:

- Routine serologic testing in all recipients is not necessary unless the vaccine was administered in the buttock rather than the deltoid muscle.
- Booster doses are not routinely recommended.
- **The ACIP does advise serologic testing for antibody in health care workers who are "at high risk of disease", and in recipients older than age 30 at the time of administration, or those with conditions expected to impair antibody response.**[13]
- An algorithm has been published dealing with the issues on nonresponse to hepatitis B vaccine in HCWs, with guidelines as to how and when to test for anti-hepatitis B antibody and what dose(s) of hepatitis B vaccine to administer, based on risk factors.[14]

i) Effectiveness and Safety:

- When properly administered, the three-dose series induces seroconversion in more than 90% of otherwise healthy, young adults.
- However, vaccine immunogenicity is related to several factors such as concomitant medical conditions, gender, age, body weight, and smoking status.
- The current vaccine does not protect against the hepatitis B "escape mutants" which have been recently reported.[15] Cases of hepatitis B due to this variant virus have not been reported in the U.S.
- Persons who initially respond to the vaccine with an appropriate antibody response, but who later have waning antibody levels (i.e. "non-protective") appear to be protected. Prospective studies in high risk populations have shown very low rates of asymptomatic seroconversion with exposure, and no evidence for chronic carriage of the virus.[16,17]

3. Influenza

a) Vaccine Type:

- Several different preparations of trivalent vaccine are available. This includes inactivated whole virus and split virus preparations. The immunogenicity of these preparations are identical.

- The vaccine normally contains three strains of influenza - two type A strains, and one type B strain. New vaccines are made every year because the strains causing diseases change yearly.
- At the current time there is no vaccine available for the H5N1 influenza strain recently isolated in Hong Kong.

b) Indications:

- Immunization against influenza virus is recommended for all health care workers who care for high-risk persons, the elderly, transplant recipients, or persons with acquired immunodeficiency syndrome (AIDS), and those with chronic medical conditions, (heart, lung, renal) diseases should receive the vaccine.
- Because of the high transmissibility of influenza, and historically documented outbreaks of influenza among military personnel and recruits; influenza vaccine is recommended in these groups, and for essential community workers.

c) Side Effects:

- The vaccine cannot "cause the flu". A randomized, double-blind, placebo-controlled, cross-over trial showed no difference in "side effects" between vaccine and placebo recipients.[18]
- Side effects to the vaccine are generally minimal and minor, rarely lasting up to 24 hours, and include low grade fever and injection site tenderness occurring in up to 20% of individuals.
- The 1976-77 "swine flu" vaccine was associated with an increased risk of Guillain-Barre syndrome (GBS). In 1990 a small excess of cases was seen in the 6 weeks following vaccination in adults < 65 years old. However, the population base rate of Guillain-Barre cases was lower than normal, making the significance of these observations unclear. Whether there is a true "cause and effect" relationship remains unclear. More recently an excess risk of approximately 1 case per million doses was determined for the 1992-1993 and 1993-1994 influenza vaccines.[19]

d) Strategies for Administration:

- New trivalent influenza virus vaccines are prepared every year, based on the anticipated infectious strains. One or more strains may be repeated in subsequent years, but re-immunization every year is recommended to achieve immunity.
- Candidates should be vaccinated before the peak season for influenza infection, which usually begins in December. October is the optimal month to begin immunization programs, but vaccination can take place as early as September, providing the most current vaccine is available, and continue as late as their are influenza outbreaks.
- It takes about 14 days after immunization for protective levels of antibody to be produced and circulate in high enough titer to protect against disease.
- A recent study demonstrated that healthy working adults who received influenza vaccine experienced significantly fewer upper respiratory infections, fewer days of sick leave from work, and less health-related direct costs.[20]
- The vaccine should only be given via the intramuscular route.[21]

e) Spacing with Other Immunobiologics: The vaccine can be given concomitantly with any other vaccine, although at different anatomic sites and using different syringes.

f) Contraindications:

- The vaccine is produced using chicken eggs. Hence persons with anaphylactic reactions to chicken eggs (not feathers!) should not receive this vaccine.
- Other allergic reactions to chicken egg proteins are also contraindications.
- Persons who developed Guillain-Barre syndrome or other neurologic syndromes *in temporal association* with receipt of influenza immunization should not receive further doses of vaccine.

g) Administration Schedule: The dose of this vaccine is 0.5 mL administered intramuscularly (deltoid) on an annual basis.

h) Post-vaccination Serologic Testing: Not applicable.

i) Effectiveness and Safety:

- Influenza vaccines are safe and do not cause the "flu".[22]
- A randomized, double-blind, placebo-controlled, cross-over trial demonstrated that side effects were no different among vaccine versus placebo recipients.[18]
- The most common side effect is minor injection site soreness lasting up to 1-2 days.
- No known clinically significant changes in concomitantly administered drug pharmacokinetics occurs (such as warfarin, theophylline, dilantin, etc.).
- The vaccine is highly effective in preventing clinical illness in young, healthy recipients.

4. Measles-Mumps-Rubella

a) Vaccine Type: Measles, mumps, and rubella vaccines are all live, attenuated viral vaccines. The vaccines are available as monovalent, bivalent, and as trivalent vaccines.

b) Indications:

- All persons working health care facilities should be immune to these diseases.[23] Additionally, it is reasonable to require proof of immunity in the medical setting even though persons born before 1957 have usually acquired immunity against measles due to wild virus exposure. Medical staff and hospital employees are at increased risk of acquiring measles, mumps, and rubella.[24-29]
- Proof may consist of documented vaccination with live measles virus vaccine on or after the first birthday, laboratory evidence of immunity, or history of physician-diagnosed measles. If such proof is not available, immunization with MMR provides long-lasting protection against all three diseases and is not harmful to persons already immune against one or more of its components.

- The dose of MMR or any of the monovalent component vaccines is 0.5 mL administered subcutaneously.
- Recent CDC recommendations include documentation of receipt of two doses of measles vaccine after the first birthday or other evidence of measles immunity in health care workers, including prior physician-diagnosed measles disease, laboratory evidence of measles immunity, or birth before 1957.[22]
- Persons are considered immune only if they were immunized with live virus vaccine on or after their first birthday or have laboratory evidence of immunity.
- Prior to immunization, serologic screening is not necessary unless the institution considers it cost effective or the health care worker specifically requests it.
- As with measles, mumps and rubella immunization is not harmful for persons already immune and consideration should be given to the use of trivalent MMR, rather than monovalent vaccine.
- Members of the military are at risk for measles, mumps, and rubella due to deployment to geographic areas where these diseases are widespread.

c) Side Effects:

- Fever greater than 103 F can occur in up to 15% of recipients.
- Transient vaccine-associated rashes occur in up to 5% of recipients.
- Both parotitis and encephalitis have rarely been reported after mumps immunization.
- As many as 40% of susceptible adult women may experience transient arthralgias or arthritis after rubella immunization. When these side effects occur, they generally occur 1-3 weeks after immunization and resolve within days to weeks.
- Short-lived peripheral neuritis and paraesthesias have been reported in association with rubella immunization of non-immune individuals.

d) Strategies for Administration:

- MMR is the preferred vaccine formulation. Immunization with MMR is not harmful to a recipient already immune to one or more of these viruses.
- Without proof of immunity, all HCWs should ideally receive two doses of MMR, spread apart by a minimum of one month between doses.

e) Spacing with Other Immunobiologics:

- Administration of measles vaccine causes temporary mild immunosuppression. Under routine use with the licensed vaccine, the only clinical significance of this effect is false-positive PPD skin tests for up to 6 weeks after immunization.
- The vaccine should be given 2 weeks before gamma globulin or other blood products, or up to 9 months after receipt, depending upon the dose of blood product received, for optimal immunogenicity.[30]
- Co-administration with other live viral vaccines (other than oral polio vaccine or varicella) should be avoided, and separated by at least 30 days.

f) Contraindications:

- Pregnant women or women anticipating conception in the 30 days after immunization
- Previous hypersensitivity reactions to the vaccine of any of its components
- Egg allergy
- Subjects immunocompromised for any reason (the one exception is that HIV-positives may receive the vaccine if they are not severely immunocompromised)

g) Administration Schedule:

- A second dose of vaccine should be given and documented for all HCWs born after 1957.
- Recently a clinical standard for measles immunization in HCWs was published.[31]
- Immunization is not necessary for those with documented immunity by serology, or by physician-diagnosed illness.
- The vaccine MUST be used within 8 hours of vaccine reconstitution.

h) Post-vaccination Serologic Testing: Not usually done. Testing for MMR antibody can be done to document immunity in HCWs who do not wish to receive a second dose of vaccine.

i) Effectiveness and Safety:

- These vaccines are safe and efficacious. Failure rates are in the 5% or less range.
- Seronegative recipients of rubella vaccine, especially adolescent and adult women, appear to have an increased risk of arthralgias and arthritis. The risk appears to be small, and generally short-lived. [32,33]
- Occasionally chronic arthritis has been reported. Rare, isolated cases of polyneuropathy have been reported after immunization with this vaccine or its components.
- Rare cases of optic neuritis, viral meningitis, parotitis, and orchitis have been reported following mumps immunization.

5. Pneumococcus

a) Vaccine Type:

- Pneumococcal vaccine is a polyvalent vaccine, which provides protection against the 23 types of pneumococci known to cause bacteremic disease.
- Two manufacturers currently produce the vaccine in the US (Merck and Lederle).

b) Indications: Although most members of the military are not at higher risk than the general adult population for acquiring pneumococcal disease, they may seek immunization because they fall into a high-risk category, or because of high-risk situations. For example, pneumococcal immunization is routinely delivered to USMC recruits in the San Diego depot because of ongoing problems with pneumococcal pneumonia. Additionally, the ACIP has

recently published recommendations for re-immunization in certain high-risk groups.[34] The following conditions are indications for pneumococcal vaccine:

- Age 65 years or more.
- Chronic illness that increases the risk of pneumococcal disease (e.g., functional cardiorespiratory impairment) or severity of disease (e.g., alcohol abuse).
- Asplenia or splenic dysfunction (e.g., sickle cell disease).
- Hodgkin's disease, other malignancies, and immunocompromising illnesses, or the use of immunocompromising drugs.
- In addition, vaccination of residents of closed communities in which infection may cause increased morbidity and mortality (e.g., nursing homes) is recommended to decrease the risk of mortality.
- The presence of a chronic CSF leak.
- Persons in certain social settings where pneumococcal disease is more prevalent (Native American reservations, military recruit barracks, etc.).

More recently, the Advisory Committee on Immunization Practices has published new guidelines and an algorithm for pneumococcal revaccination.[34]

- For those age 65 and older: Revaccination is recommended if $\geq$ 5 years have elapsed since the first dose and the patient is:
    - Immunocompromised
    - CRF/Nephrotic syndrome
    - Organ (BMT) transplant

- For those persons who received their first dose prior to age 65, revaccination is recommended if:
    - If the patient is age > 10 years, repeat if $\geq$ 5 years old and has splenic dysfunction
    - If the patient $\leq$ 10 years, repeat if $\geq$3 years old and has splenic dysfunction or is immunocompromised

c) Side Effects:

- Local injection site soreness and erythema may occur in up to 50% of recipients, but usually subsides within 24-48 hours after administration.
- Anaphylactoid reactions have occurred in persons receiving repeat doses of vaccine more often than the current recommendation repeat dosing 6 years after the first dose in high-risk individuals.
- Adverse effects on the fetus after vaccinating pregnant women have not been observed. Nonetheless, it is prudent to wait until after the first trimester of pregnancy before immunizing.
- The Lederle preparation uses thimerosal as a preservative, whereas the Merck preparation uses phenol.

d) Strategies for Administration:

- The American College of Physician's Task Force on Adult Immunization recommends that the 50th birthday be used as a date to review adult immunizations, and to determine specifically whether pneumococcal vaccine should be given. After age 50, 30% to 40% of persons have a high-risk condition for which they should receive the vaccine.[13]
- Persons at very high risk of complicated pneumococcal disease (severe COPD, asplenia) who received the 14-valent vaccine should be re-immunized with 23-valent vaccine.
- Persons with rapid loss of antibody (nephrotic syndrome, transplant patients, renal failure) should be re-immunized if they received their first vaccine 6 or more years earlier.
- Re-immunization of otherwise healthy adults is not necessary.

e) Spacing with Other Immunobiologics: The vaccine can be administered at any time, concomitantly with other vaccines, but at different anatomic sites and using separate syringes.

f) Contraindications:

- There are no known contraindications, other than a hypersensitivity reaction to a previous dose of vaccine.
- Re-immunization more frequently than recommended increases the probability of Arthus-like reactions.
- The Lederle vaccine contains thimerosal.

g) Administration Schedule: The dose of this vaccine is 0.5 mL administered intramuscularly or subcutaneously. Repeat dosing is advisable in the following situations:

- Persons with anatomic or functional asplenia
- Persons with rapid loss of antibody (nephrotic syndrome, chronic renal failure)
- Immunocompromised persons

h) Post-vaccination Serologic Testing: Not applicable.

i) Effectiveness and Safety:

- The vaccine is really 23 vaccines in one, with each serotype vaccine having its own failure rate.
- While there is some controversy regarding the efficacy of the vaccine, most experts feel it effectively reduces the incidence of pneumococcal bacteremia among elderly, high-risk persons. Recent case-control studies among elderly but otherwise healthy adults have shown efficacy rates of 50%-70%.
- Studies of younger, healthy adults show excellent protective efficacy against pneumococcal pneumonia and bacteremia.
- Other than mild local reactions, the vaccine is safe. No neurologic disorders have been causally linked to pneumococcal vaccine.

6. Polio

a) Vaccine Type:

- Two types of vaccine are available: a live, attenuated, oral vaccine (Sabin); and an enhanced-potency inactivated, parental whole virus vaccine (Salk). However, the ACIP has recently recommended an IPV only schedule for polio immunization within the United States.
- In some countries, including Canada, IPV (not enhanced-potency) is still available.

b) Indications: Polio vaccine is indicated for those at increased risk of exposure to polio viruses because of travel or occupation.

c) Side Effects:

- Oral Polio: Adults are at slightly greater risk for vaccine associated paralysis than children. For first dose recipients the risk is estimated at 1 case per 1.2 million doses given, plus an additional 1 case among contacts of recipients. The risk with subsequent doses is even less.
- Enhanced-Potency Inactivated Polio: No serious adverse effects have been documented due to this vaccine since 1955 when a lot of vaccine was inadvertently not inactivated. The vaccine can contain trace amounts of neomycin, streptomycin, or polymixin B. Hence individuals with known hypersensitivity to any of these components should not receive this vaccine.

d) Strategies for Administration:

- All HCWs should be immune to polio.

e) Spacing with Other Immunobiologics: No specific guidelines are necessary.

f) Contraindications:

- Oral polio vaccine should not be given to individuals who are immunocompromised, or to those individuals who have household contacts who are immunocompromised. Enhanced-potency inactivated polio vaccine can be given to these individuals.

g) Administration Schedule:

- Oral Polio: Primary series: 3 doses at time 0, 6-8 weeks, and 2-12 months.
- Enhanced-Potency Polio: 3 doses [0.5 mL SQ] given at time 0, 4-8 weeks, and 1-12 months later. Enhanced-potency vaccine is preferred in adults receiving a primary series.
- Persons who received an incomplete polio series can complete the series with either vaccine.
- Persons who received an incomplete oral polio series: A total of 3 doses of any mix of oral or inactivated parenteral vaccine is required.
- Persons who received an incomplete inactivated polio series: A total of 4 doses with either oral or inactivated vaccine is sufficient.

h) Post-vaccination Serologic Testing: Not applicable or usually done.

i) Effectiveness and Safety:

- Both vaccines are highly effective in preventing polio. Widespread use of oral polio vaccine has eliminated indigenous polio in North America.
- 98%-100% seroconversion occurs after 2 doses of this vaccine

7. Tetanus-Diphtheria- (Pertussis)

a) Vaccine Type:

- A parenteral toxoid vaccine produced by multiple manufacturers.
- In this category several vaccines are available for use in adults; diphtheria toxoid (D), tetanus toxoid (T), and tetanus-diphtheria toxoid (Td).
- The adult formulation of Td has less diphtheria toxoid component than the pediatric vaccine (DT), allowing for lower reactogenicity. Hence only Td should be used in adults.
- At the current time, there are no routine indications for the use of pertussis vaccines in adults.
- It is thought by many vaccine experts that the newer acellular pertussis vaccines may, in the future, be recommended as a "booster" dose for those at higher than baseline risk. To date the safety, immunogenicity, and efficacy trials of the acellular pertussis vaccines demonstrate that they are safe and effective, including in adult subjects.
- For tetanus toxoid, both fluid and adsorbed preparations are available. The adsorbed vaccine is adsorbed onto an aluminum adjuvant. This induces higher anti-toxin levels which persist for a longer period of time. The fluid form should only be used in the very rare person with hypersensitivity reactions to the aluminum adjuvant present in the adsorbed formulation.

b) Indications:

- Both toxoids (Td) are necessary to protect against tetanus and diphtheria.
- In particular, HCW's may be at increased risk of exposure to diphtheria due to outbreaks among several of the Newly Independent Russian states, and the amount of travel from these areas.
- Unless there is a compelling reason otherwise, all primary and booster doses of vaccine should include diphtheria (Td).

c) Side Effects:

- Common side effects include mild erythema, and local injection site pain and tenderness lasting up to a few days.
- Persons who are "over-immunized" and receive booster doses too frequently can develop more severe local and systemic Arthus-like reactions.

d) Strategies for Administration: Similar to any multi-dose vaccine.

e) Spacing with Other Immunobiologics:

- These vaccines can be given simultaneously with any other vaccine, using different syringes and injected at different anatomic sites.
- Tetanus and/or diphtheria vaccines should not be given until at least 3-4 weeks after receipt of tetanus or diphtheria antitoxin use, respectively.

f) Contraindications: The only contraindication is known hypersensitivity to any component of the vaccine. The vaccine does contain thimerosal.

g) Administration Schedule:

- Primary series: 0.5 mL IM (deltoid) at time 0, 4-8 weeks later, and a third dose 6-12 months later.
- Booster dose: Give 0.5 mL IM (deltoid) every 10 years. Persons who present with a tetanus-prone wound should receive a booster dose if greater than 5 years have elapsed since the last dose of vaccine, or if they previously received less than 3 doses of vaccine.
- More recently, the ACIP has stated that an acceptable alternative is to give one mid-life booster dose of Td (age 50), if a full primary series of Td has already been received. The usual protocol for booster doses in the case of injury remains in effect.

h) Post-vaccination Serologic Testing: Not routinely done.

i) Effectiveness and Safety:

- Td and its component toxoids are extremely effective vaccines with a long-standing safety record.

8. Varicella

a) Vaccine Type: Currently, one preparation of this live attenuated vaccine, "Varivax", is produced by Merck. It is a lypholilized preparation, initially isolated from a child named Oka, who had naturally occurring varicella. The name of the viral strain is Oka/Merck. [35]

b) Indications: The ACIP has published a statement on the use of varicella vaccine.[36] All members of the military should be immune to varicella. Varivax is indicated for protection against varicella. In adults, the indications are as follows: [35,37,38] Recommended for susceptible persons who will have close contact with persons at high risk for serious complications from varicella:

⇒ health care workers

⇒ susceptible family contacts of immunocompromised individuals

- Should be considered for vaccinating susceptible persons at high risk of exposure in the following groups:

⇒ teachers of young children, day care workers, and residents and staff of institutional settings (persons who live and work in environments with high likelihood of transmission)
⇒ college students, inmates and staff of correctional institutions, and military personnel (persons who live or work in environments in which varicella transmission may occur)
⇒ non-pregnant women of childbearing age (women should be advised to avoid pregnancy for 1 month after each dose of the vaccine)
⇒ international travelers who expect to have close personal contact with local populations, due to varicella endemnicity in most countries throughout the world

- Vaccination of other susceptible adolescents and adults may be offered at time of routine health care visits.

c) Side Effects:

- Approximately 1600 adolescents and adults who received 1 dose and 950 who received 2 doses were monitored for 42 days for adverse effects. Results[39] are summarized in Table VI.
- Injection site complaints include soreness, erythema, swelling, rash, pruritis, pyrexia, hematoma, induration, and numbness [35,37]

d) Strategies for Administration:

- Varicella immunity is recommended for all susceptible HCWs by the ACIP. [23,37]
- Serologic screening of personnel with negative or uncertain history of varicella is likely to be cost-effective prior to vaccination.[37] Those persons with clear histories of previous varicella infection can be assumed to be immune, as several studies show that 70%-99% of such individuals are immune.
- Policies for management of vaccinated healthcare workers should be developed for each institution. These policies should be added to those already in place for handling varicella exposures. There are numerous issues to be included in such policies such as definitions of exposure to varicella, serologic testing for immunity to varicella; whether to require or recommend vaccination to non-immune employees; how to manage vaccinated healthcare workers in the immediate post-vaccination period and in future exposures to wild varicella; whether to conduct any type of serologic testing in vaccinated employees; and how to handle patients and healthcare workers who develop vaccine rash. There are many questions to be considered in formulating these policies (See "k"-"Unresolved Issues") .

e) Spacing with Other Immunobiologics:

- Varivax can be given at the same time or within 30 days of MMR without increasing adverse reactions (Caution- use separate anatomic sites and syringes).
- ACIP guidelines state that the simultaneous administration of most widely used live attenuated and inactivated vaccines has not resulted in impaired antibody responses or increased adverse effects with this vaccine.[37]

- Varicella-Zoster Immune Globulin should not be given for at least 2 months following vaccination with varicella vaccine.
- Vaccination with varicella vaccine should be deferred for at least 5 months following administration of any immune globulin.[37]

f) Contraindications and Precautions :

- The vaccine is contraindicated in persons with a history of hypersensitivity to any component of the vaccine, including gelatin, and those with a history of anaphylactoid reaction to neomycin (Varivax contains trace quantities of neomycin).
- The vaccine is contraindicated in persons with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.
- The vaccine is not recommended for adults receiving immunosuppressive therapy (vaccination can result in a more extensive vaccine-associated rash or disseminated disease in persons on immunosuppressant doses of corticosteroids).
- Additional contraindications include persons with primary and acquired immunodeficiency states, including individuals with AIDS or other clinical manifestations of infection with HIV virus, cellular immune deficiencies; and hypogammaglobulinemic/dysgammaglobulinemic states.
- The vaccine is not recommended in persons with a family history of congenital or hereditary immunodeficiency unless immune competence of the potential vaccine recipient is demonstrated.
- Varicella vaccine should not be administered during a febrile respiratory illness, or other active febrile infection.
- Do not administer the vaccine to persons with active, untreated tuberculosis. However, tuberculosis skin testing is not a prerequisite for varicella vaccination.
- Do not administer the vaccine to pregnant women. Its possible effects on fetal development are unknown at this time. If vaccination of postpubertal females is undertaken, pregnancy should be avoided for 3 months following vaccination.
- Vaccination should be deferred for at least 5 months following blood or plasma transfusions.
- Vaccine recipients should avoid use of salicylates for 6 weeks after vaccination, as Reye's Syndrome has been reported following the use of salicylates during natural varicella infection.
- Vaccination of persons with severe illness should be postponed until recovery. The decision to delay vaccination depends largely on the severity of symptoms and on the etiology of the disease.
- As a precautionary measure, epinephrine injection (1:1000), should be available for immediate use should an anaphylactoid reaction occur.
- Reporting of adverse events- Although the National Vaccine Injury Act of 1986 does not apply to varicella virus vaccine, the ACIP recommends that these same recording and reporting requirements be used. Serious adverse events, regardless of whether they are suspected to have been caused by varicella virus vaccine, should be reported to the Vaccine Events Reporting Systems (VAERS). These forms can be found in the FDA Drug Bulletin

and the Physician's Desk Reference or the 24-hour VAERS information recording (1-800-822-7967) can be used. [40]

g) Administration Schedule (adults):

- A 0.5 mL dose of vaccine by subcutaneous administration at an elected date, and a second 0.5 mL dose 4 to 8 weeks later. The preferred site of administration is the deltoid muscle.
- Additional administration and handling information:
  - ⇒ Not for intravenous injection.
  - ⇒ Vaccine should be administered immediately-discard if reconstituted vaccine is not used within 30 minutes.
  - ⇒ Vaccine must be stored frozen before reconstitution at an average temperature of -15 degrees C or +5 degrees F.
  - ⇒ Diluent should be stored separately at room temperature or in a refrigerator.
  - ⇒ Duration of protection is unknown at present and the need for booster doses is not defined-additional studies are needed in this area.

h) Post-vaccination Serologic Testing:

- Testing for varicella immunity following two doses of vaccine is not considered necessary because 99% of persons are seropositive after the second dose and seroconversion does not always result in full protection against disease.
- Consideration can be given for testing vaccinees for seropositivity immediately after wild virus exposure to identify individuals who remain at risk for varicella.

i) Effectiveness and Safety

- Efficacy is defined as protection afforded by 2 doses of Varivax to adults or adolescents administered either 4 or 8 weeks apart, and subsequently exposed to varicella in a household setting. In 64 such adolescents and adults, 17 (27%) of vaccinees reported breakthrough chickenpox in 2 years of active follow-up.[37]
- In combined clinical trials of adolescents and adults who received 2 doses of Varivax, 42 (4%) later developed chickenpox; though cases were extremely mild or asymptomatic.
- According to the ACIP, the vaccine provides 70-90% protection against varicella infection and 95% protection against severe disease for 7-10 years after vaccination. In addition, it is anticipated that serious complications due to varicella will be reduced in vaccinees.
- Vaccinees may potentially be capable of transmitting vaccine virus to close contacts . This has occurred in vaccinees who developed a rash after vaccination. Vaccinated health care workers should therefore avoid close contact with susceptible high-risk individuals, such as newborns, pregnant women, and immunocompromised persons, especially if a rash develops in the vaccinated health care worker. [41] (See also-Strategies for Administration)
- Should inadvertent vaccination to a varicella-immune individual occur, the vaccine has been well-tolerated in seropositive individuals, with no serious adverse effects.
- A summary table of routine recommended immunizations is provided on the following page.

Immunization Schedule Recommended by the Advisory Committee on Immunization Practices for Routine Vaccines in Adults

Vaccine	Indication	Schedule
Hepatitis A	Exposure to active cases	1 mL IM at 0, 6 months
Hepatitis B	Occupational exposure to blood, blood products, or bodily secretions	3 doses of 1 mL IM at 0, 1, and 6-12 months
Influenza	Persons attending high-risk patients (e.g., elderly)	1 dose of 0.5 mL IM annually
MMR		
Measles	Adults born after 1957 without a history of physician-diagnosed measles, serologic immunity, or documentation of having received two doses of vaccine	0.5 mL SC at 0, and at least one month later
Mumps	Adults born after 1957 without a history of mumps, serologic immunity, or documentation of having received vaccine	0.5 mL SC once
Rubella	Unimmunized women of child bearing age and health care workers	0.5 mL SC once
Pneumococcus	Increased risk of infection and its complications (e.g., age >50 years)	Single dose of 0.5 mL IM or SC
Polio	Laboratory and other health care workers who come in contact with the virus	3 doses of 0.5 mL SC. First two doses separated by 4-8 weeks, and a third dose 6-12 months after the second dose
Td	Persons without a history, or an unknown history of Td immunization	Unimmunized: 3 doses of 0.5 mL IM at 0, 1-2, 6 months All Persons: booster dose of 0.5 mL IM every 10 years
Varicella	Non-immune adults	0.5mL SC at 0 and 4-8 weeks later

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B. Specific Vaccines Recommended by CINC Geographic Areas of Responsibility (AOR)

The United States military has assigned combatant commanders (CINC) geographic areas of responsibility (AOR) for all operations within their respective theaters. These areas vary as to endemic disease threats. All CINCs require personnel deploying to their AORs to have received all routine deployment related immunizations. Two CINCs have additional immunization requirements based on unique endemic threats.

The Central Command has directed all personnel deploying to their AOR for greater than 15 days to receive meningococcal vaccine every 5 years. If deploying to Saudi Arabia during the Hajj, immunization is required to be within 3 years.

The Pacific Command requires units at risk of Japanese encephalitis to be immunized prior to deployment. Units must individually assess their risk based on time of year and area of deployment, since the risk of Japanese encephalitis is not uniform throughout the AOR. Individuals who have received the primary series and are at risk of Japanese encephalitis require boosters every 3 years.

The European Command does not have routine immunization requirements for entry into the AOR, but tailor them for specific deployments. For operations in Bosnia, it was noted that tick-borne encephalitis vaccine (under IND protocol) should be considered for certain groups at high risk of exposure (special operations forces and search and rescue personnel), and outlined procedures to obtain vaccine.

For operations in Central Africa, meningococcal vaccine within 5 years is required.

Prior to deployments, units must currently check three locations for immunization requirements:

- Standard DoD immunization requirements for all deploying personnel (tetanus-diphtheria, hepatitis A, typhoid, influenza, MR/MMR, and polio).
- Service specific requirements, such as yellow fever, and hepatitis B
- Deployment specific requirements based on geographic locations and CINC requirements, such as Japanese encephalitis and meningococcal vaccines.

C. Specific Vaccine Recommendations Made by the Armed Forces Epidemiological Board

On an ongoing basis, and consistent with its formal charter, the AFEB, through its Infectious Diseases Control Subcommittee (IDCS), has made numerous formal recommendations to the Secretary of Defense-Health Affairs regarding vaccine policy and practices. These recommendations involve vaccines, other immunobiologics, vaccine administration devices, vaccine schedules and dosing, or other facets of vaccine policy. The most recent

recommendations pertaining to vaccines, vaccine dosing schedule and vaccine administration made by the AFEB are appended in Appendix E.

CHAPTER THREE

VACCINE-SPECIFIC POLICIES BY PERSONNEL GROUP

Based on a review of the policy documents collected during the project and the comments provided by key survey respondents, a series of summary charts of routinely administered immunizations was developed. This section presents the summary charts and discusses the vaccines to be administered for each personnel group and across services.

Each appendix contains the policies of a particular service in a series of charts: Appendix A presents the policies of the Army; Appendix B, the Navy and Marine Corps; Appendix C, the Air Force; and Appendix D, the Coast Guard. Each appendix contains charts of the policies reported by the survey respondents and summarizes briefly the policy documents provided by the military respondents. The charts address immunization requirements for enlisted recruits and officer accessions, active duty routine and high risk travel or deployment, special occupational and operational groups, and reserve forces. The following sections of the report present immunization requirements by personnel group.

A. Enlisted Recruits And Officer Accessions

Enlisted recruits undertake basic training at relatively few boot camp sites, while individuals may become officers through a number of routes. They may attend a service academy, which will have immunization requirements similar to those of other post-secondary schools. They may enter the service after college participation in a Reserve Officer Training Corps (ROTC) program or after professional training, for example, in medicine. They may attend Officer Candidate School or Commissioned Officer Training as new service members or as noncommissioned personnel moving into the ranks of commissioned officers.

Table 1 is a summary chart of the immunizations required for enlisted recruits and officer accessions by each of the services. For additional information on the policies related to each of the service's immunization schedule, please refer to the first chart in each of the four appendices.

TABLE 1
IMMUNIZATIONS ADMINISTERED TO ENLISTED RECRUITS AND OFFICER ACCESSIONS

VACCINE	USA	USN/USMC	USAF	USCG
Adenovirus 4&7	ER	ER	ER only for disease threat; not generally administered	ER
Anthrax	ER, OA	ER, OA	ER, OA	ER, OA
Hepatitis A	No	ER, OA Academy	ER, OA	No
Influenza	ER, OA	ER, OA year-round	ER year-round, OA OCT-MAR	ER, OA
MMR/MR	MR ER; OA without documentation ROTC before summer camp	MMR ER; OA without documentation	MR ER screened serologically; Academy screens record, then serology (measles and rubella); gives MMR. Other officer training: evaluate record; give MR.	MR: ER, OA MMR: Academy
Meningococcal	ER	ER	ER	ER, Academy
Pneumococcal	No	USMC-San Diego only	No	No
Polio	ER, OA	ER, OA	ER, OA	ER, OA
Tetanus-diphtheria	ER, OA ROTC before summer camp	ER, OA	ER, OA	ER, OA
Typhoid	No	NROTC for summer cruise to high risk area	No	No
Varicella	No	ER who are susceptible	Academy	No
Yellow Fever	No	ER, OA	No	ER,OA

KEY: ER =enlisted recruit; OA =officer accessions (includes Academy unless specified); Academy = service academy

The initial vaccines provided are generally those deemed to be protective during the training period, e.g., adenovirus and meningococcal vaccine for the enlisted recruits trained in close quarters, influenza vaccine for all new accessions. Other vaccines administered may also be needed for protection during the recruit training period, e.g., tetanus-diphtheria for all new accessions, typhoid for NROTC midshipmen on summer cruises to high risk areas. The Navy, Marines, Air Force, and Coast Guard also administer vaccines that are required for protection during active duty, e.g., hepatitis A (Navy, Marines, Air Force), yellow fever (Navy, Marines, Coast Guard). The Army administers vaccines required for active duty once the accessions move to their first active duty units.

Some, but not all, survey respondents report that enlisted recruits and officer accessions are screened for asplenia, which, if caused by chronic disease, is cause for separation from the service. If caused by trauma, asplenia is not cause for separation and the new accession is immunized against *Haemophilus influenzae* type b, pneumococcal disease, and meningococcal disease.

Pregnancy Testing

The Joint Instruction on Immunizations and Chemoprophylaxis requires that women be questioned about pregnancy prior to vaccination, and excluded or referred for evaluation if the answer is "yes" or "maybe." Personnel are immunized but counseled to avoid pregnancy for three months if the answer is "no" and a live virus vaccine is administered. Further, such counsel is to be documented in the chronological health record. The Joint Instruction on Immunizations and Chemoprophylaxis does not require a pregnancy test prior to immunization with live virus vaccines which could potentially be teratogenic. However, primarily because pregnancy is cause for separation from the service for an enlisted recruit, each service reports administering pregnancy tests early in the enlisted recruit training period. The Coast Guard tests for pregnancy again later in the basic training period. If a test result is positive for pregnancy, the woman is separated from the service. Most survey respondents reported that the test results are known prior to attendance at an immunization clinic, but this is not always the case.

Concerns About Vaccine Supplies

Three supply issues have been elucidated that could affect enlisted recruits and officer accessions:

1. Adenovirus vaccine is no longer manufactured. The services are seeking to conserve supplies by limiting vaccine administration to the time period of September through March. Some respondents expressed concerns about potential outbreaks in the close quarters of recruit training if the supply is exhausted before a new manufacturer can be found and the new vaccine approved by the Food and Drug Administration. However, the Marine Corps reports that, even though supplies were not available during the fall of 1997, there were no outbreaks of disease.

2. One survey respondent mentioned the potential cessation of manufacture of the measles-rubella vaccine. This would leave only the more expensive measles-mumps-rubella vaccine available, which could significantly impact Army, Air Force, and Coast Guard immunization budgets.

3. The Marine Corps recruit training site at Parris Island has had logistical problems with obtaining pediatric strength doses of hepatitis A vaccine (VAQTA™). When it is available, it is used for 17-year-old recruits; when it is unavailable they administer an adult dose. On the other hand, because of the numbers of recruits processed and to ensure greater protection of those immunized, the Navy's Great Lakes recruit training center has found it more efficient to administer adult doses of hepatitis A vaccine to all recruits.

Deviations from the Joint Instruction on Immunizations and Chemoprophylaxis

In several cases, immunization practice differs from what is currently prescribed in the Joint Instruction on Immunizations and Chemoprophylaxis. For example, the Joint Instruction on Immunizations and Chemoprophylaxis lists the recommendations of the Advisory Committee on Immunization Practices (ACIP) as required references for immunizations. It should be noted that hepatitis B vaccine, which is currently universally recommended for children and adolescents by the ACIP, is not provided to new accessions. The Joint Instruction on Immunizations and Chemoprophylaxis requires influenza vaccination year-round for both enlisted recruits and officer accessions in the Navy and the Marine Corps. The Navy and the Marine Corps report that there are often gaps in the summer when their supplies are exhausted before the next year's supply is available. The Marine Corps' San Diego training facility has added pneumococcal immunization to its schedule for enlisted recruits because of problems with pneumococcal outbreaks. Further, as noted above, the Navy, Marine Corps, and Coast Guard all administer yellow fever vaccine during basic training. Yellow fever is supplied in multi-dose vials; if all doses are not used within one hour of reconstitution, the vaccine must be discarded. Thus, administering the vaccine to large groups of recruits is an efficient approach to ensuring that all active duty members are immunized.

B. Active Duty Personnel

Immunizations provided to active duty personnel fall into three broad categories:

- those provided routinely
- those provided only when needed for travel or deployment to high risk areas
- those provided to members of special operational or occupational groups

This section addresses routine vaccines and those for high risk travel. Special groups' immunization requirements will be addressed in the next section. The second chart in each appendix presents the services' policies for immunizing active duty personnel. **Table 2** is a summary chart of vaccine requirements for active duty personnel. It lists vaccines mentioned in

the Joint Instruction on Immunizations and Chemoprophylaxis as well as two that are not listed (i.e., anthrax and tick-borne encephalitis). It should also be noted that the Commanders in Chief of regional commands outside of the continental United States (OCONUS) can require other immunizations for personnel traveling to their command; these AOR (area of responsibility) requirements are separate and distinct from service requirements, add a significant additional layer of complexity to immunization requirements, and may or may not have undergone thorough medical review.

TABLE 2
IMMUNIZATIONS ADMINISTERED TO ACTIVE DUTY PERSONNEL

VACCINE	USA	USN/USMC	USAF	USCG
Anthrax	All active duty; priority to high risk forces.			
Cholera	Joint Instruction on Immunizations and Chemoprophylaxis: Only when required by host country. Survey Respondents report military does not use Per CDC, no country currently requires, though some local areas may			
Hepatitis A	AD	AD	AD	AD
Hepatitis B (See special groups)	HRA	HRA	HRA	HRA
Influenza	AD, annual	AD, annual	AD	AD
Japanese Encephalitis Virus	HRA	HRA	HRA	HRA
Meningococcal	HRA	HRA	AD, HRA	HRA
Plague	HRA; Rarely used			
Tetanus-diphtheria	AD	AD	AD	AD
Tick-borne Encephalitis	HRA	HRA	HRA	HRA
Typhoid	HRA, AF	HRA, AF	HRA, AF	HRA, AF
Yellow Fever	HRA, AF	AD	HRA, AF	HRA, AF

KEY: AD = routine active duty immunization; AF = alert forces; HRA = administered for travel to high risk area

C. Routine Active Duty Immunizations

Influenza vaccine (annual) and tetanus-diphtheria boosters (every 10 years) are routinely administered to active duty personnel in all of the services. Navy and Marine Corps personnel routinely receive booster doses of yellow fever vaccine every 10 years. DoD now requires that all active duty personnel be immunized against hepatitis A by 31 December 1998 and all of the services are working toward that goal.

All military recruits receive meningococcal vaccine during basic training. The Joint Instruction on Immunizations and Chemoprophylaxis indicates that the vaccine is to be boosted only when an assessment of disease transmission and risk indicates its advisability. One Air Force command, the Air Mobility Command (AMC), requires that AMC flying personnel, who travel frequently and on short notice, maintain meningococcal immunity with boosts every three years. The three year boost is to ensure that personnel who may need to travel to Saudi Arabia during the period of the religious pilgrimage (the Hajj) can meet the host country's requirement for this vaccine and boost interval. A few individual survey respondents not from the AMC indicated that meningococcal vaccine is regularly boosted.

D. Alert Forces Immunizations

The definitions of alert forces vary by service, but generally refer to personnel who must be ready to deploy soon after notification, e.g., within 30 days or less, or who are members of certain types of units whose mission is to be ready to deploy rapidly, e.g., within 24 hours of notification. Typhoid is administered and boosted for alert forces in the Army, Navy, Marine Corps, and Air Force. The boost interval may be two, three, or five years, depending on which vaccine is used. Yellow fever vaccine is administered to alert forces in the Army, Air Force, and Coast Guard.

E. Less Frequently Used Vaccines

Some vaccines are listed in **Table 2** because they are mentioned in the Joint Instruction on Immunizations and Chemoprophylaxis. While cholera vaccine is only to be used when required by the host country; survey respondents reported that the military does not currently use cholera vaccine. Hepatitis B is listed because it may be administered to personnel traveling to high risk areas. The primary uses of hepatitis B prophylaxis in the services appears to be for the special groups listed in the next section and for individuals diagnosed with a sexually transmitted diseases. The services advocate education and other measures for preventing Japanese encephalitis virus (JEV) and tick-borne encephalitis (TBE). Both JEV and TBE vaccines are administered only for travel, deployment, or assignment to endemic areas. TBE vaccine is an investigational new drug (IND), whose use is subject to strict protocols including informed consent requirements. The Joint Instruction on Immunizations and Chemoprophylaxis does not

directly address protocols for use of any INDs, except in the section on biological warfare defense.

F. Special Operational And Occupational Groups

Vaccines administered to persons in high risk operational and occupational groups in all services include the following:

- Anthrax—Forces at high risk, including chemical and biological incident response forces
- Hepatitis B—High-risk medical personnel, other health care workers, those who need to know first aid for their jobs and are potentially at risk (e.g., firefighters, base security personnel), and members of specified special warfare groups
- Measles-mumps-rubella—Medical personnel and other health care workers, if not immune
- Plague—Special operations groups, reportedly rarely used
- Rabies—Animal handlers; veterinary personnel; certain laboratory, field, and security personnel; personnel frequently exposed to potentially rabid animals in occupational or recreational settings
- Varicella—Listed in the Joint Instruction on Immunizations and Chemoprophylaxis for high-risk occupational groups

Service-specified special groups are listed in the third chart in each of the four appendices.

G. Reserve Forces

Reserve forces receive all of the basic training vaccines. Subsequent vaccination varies by service and by identified need, as presented in **Table 3** on the following page.

TABLE 3
IMMUNIZATIONS ADMINISTERED TO RESERVE FORCES

VACCINE	USA	USN/USMC	USAF	USCG
All Vaccines Indicated On Service Schedule	Called up for 30 days or more	**USN/USMC:** subject to short-notice deploy-ment **USN** called up for 10 days **USMC** called up for 30 days	Called up for 30 days or more	Called up for 30 days or more
Hepatitis A	Mobility status targeted for early deployment to high risk areas; selected reserve			High-risk travel. Specified units. Subsistence specialists; food handlers
Hepatitis B	If indicated by Army policy; see All Vaccines, above	If indicated by USN/USMC policy; see All Vaccines, above	High risk groups; Air Mobility Command (AMC) medical reserves	Health services personnel
Influenza	On active duty for 30 days or more during flu season	If indicated by USN/USMC policy; see All Vaccines, above	All reserve forces personnel annually	Reserves designated by district commander
Meningococcal	If indicated by Army policy; see All Vaccines, above	If indicated by USN/USMC policy; see All Vaccines, above	All deploying OCONUS. AMC reserves on active flying status, mobility.	If indicated by Coast Guard policy; see All Vaccines, above

Several reserve survey respondents noted barriers to immunizing reservists: the full schedule on drill weekends, the need to import immunization teams if the unit does not drill at a site with a

Medical Treatment Facility (MTF), reservists living too far away to come for immunizations except during the drill weekends, and funding for immunizations.

H. Dependents And Other TRICARE Beneficiaries

The DoD is implementing on a region-by-region basis TRICARE, a uniform health benefits program for active duty military personnel, dependents of military personnel, and other beneficiaries. TRICARE has four options: Prime, Standard, Extra, and Senior. The focus of the data collection on TRICARE was on immunization coverage policies for beneficiaries who are not members of the military services.

TRICARE was created to eliminate differences between areas of the country and between services provided directly by MTFs and those provided by CHAMPUS-reimbursed private providers. TRICARE Prime requires enrollment, costs the enrollee less than other options, and is a Health Maintenance Organization (HMO) program with a Primary Care Manager (PCM) in either the civilian sector or an MTF. TRICARE Senior is similar in enrollment requirements and benefits to Prime; currently the Senior option is available only on a demonstration basis at a few sites. TRICARE Standard is a fee-for-service program; those using this option can go to any doctor or to the MTF on a space-available basis. TRICARE Extra provides medical care through a Preferred Provider Organization (PPO), which is a network of providers. TRICARE Extra has the same benefits as TRICARE Standard, but with a financial incentive to use a network provider. Under all three options, there is no charge to immunize active duty dependents whose sponsors have permanent changes of station orders to overseas locations, although there may be an office visit copayment for immunizations provided outside of MTFs. Well-baby care is provided up to 24 months of age. TRICARE senior benefits are comparable to Medicare benefits.

TRICARE Prime benefits specify that age-appropriate doses and vaccines for specific diseases should be administered in accord with the recommendations of the Advisory Committee on Immunization Practices (ACIP), which advises the Centers for Disease Control and Prevention (CDC). The diseases are diphtheria, *Haemophilus influenzae* type b, hepatitis A, hepatitis B, influenza, measles, mumps, pertussis, pneumococcal disease, poliomyelitis, rubella, tetanus, and varicella. This list includes all 10 vaccines on ACIP's recommended schedule for childhood immunizations as well as three vaccines (hepatitis A, influenza, and pneumococcal disease) more commonly recommended for and administered to adults.

The Military Health System (MHS) has developed a report card for all MTFs, which includes 34 measures of access, quality, utilization, and health status based on surveys of DoD beneficiaries and inpatient data records. Immunization measures will be addressed by measuring childhood immunization status against the American Academy of Pediatrics, and the American Academy of Family Physicians standards. Data are not yet available on this measure. No adult immunizations are measured other than for active duty personnel, and no reports on adult immunization of

beneficiaries are currently required or submitted. There was no indication that DoD collects information on immunizations delivered to nonmilitary beneficiaries outside of MTFs.

CHAPTER FOUR

IMMUNIZATION POLICY DEVELOPMENT AND DISSEMINATION

The DoD makes immunization policy that is relevant to all services. Each service can also develop policy for its own personnel, so long as that policy is at least as restrictive as overall DoD policy and does not conflict with DoD policy. Services, commands within services, and local MTFs can and do develop operating procedures for implementing policy. Policy is disseminated through the types of documents collected during this project, i.e., Joint Instruction on Immunizations and Chemoprophylaxis developed by the services and issued at the DoD level; letters, memoranda, e-mail messages, and manuals developed and issued at any level. Thus, immunization policy is developed and disseminated top-down in the same manner as other military policy.

It also appears that horizontal (peer) and bottom-up communication take place, the first serving as a collegial, informal means of comparing observations regarding potential immunization needs or vaccine reactions, the second serving to alert higher authorities to the potential need for modifications or changes in policy. Thus immunization policy development does not appear to be a strictly top-down process. Outside influences observed include legislation and budgets (e.g., special funding for widespread hepatitis A vaccination, budgetary constraints that may limit adding vaccines such as hepatitis B to the routine schedule); vaccine research and development, vaccine availability (e.g., cessation of manufacture of adenovirus vaccine, withdrawal of immune globulin for hepatitis A from the market); emerging threats to the health of the military forces (e.g., use of an IND vaccine for tick-borne encephalitis in Bosnia); and recommendations from the Armed Forces Epidemiological Board.

Questionnaire responses were evaluated for information on several key, cross-cutting topics concerning immunization policy. This section addresses those topics.

A. Issues of Screening

1. Introduction

Dating from the inception of the US military forces, an aggressive approach to providing vaccines to protect our armed forces has been instituted. General George Washington ordered the variolation of the Continental Army-- the first army in history to be immunized by command directive. Since then, US Forces have been given a variety of vaccines, most intended to protect them against threats from military service outside of the continental US. However, before reaching the current levels of sanitation that we now enjoy, some vaccines, like typhoid, offered

protection against domestic threats as well. Still today many of the vaccines, especially those given to new accessions, are for the general public health as opposed to any military specific protection.

For the most part, it has been military policy to simply provide the vaccine. The default assumption for many years was that new recruits came into the service unvaccinated and hence was not protected naturally against disease threats. Recent advances in the availability and lowered cost of serology for determining a person's immune status, coupled with the increased costs of the vaccines themselves, have lead to an interest in pre-screening candidates for immunity against vaccine-preventable diseases in order to determine the need for vaccines. This screening may be 'paper-based'--determining that a valid medical record entry exists that the vaccine was previously administered-- or serologic—by actively determining the level of antibodies present.

The increased ease and lowered cost (volume and automation) of determining immune status along with the increased number of potential vaccines at ever-increasing cost per dose, drives the need to decide when to give vaccines universally versus screening to determine who is in need. The decision to institute screening before immunization is a complex one, and is based on knowledge (seroprevalence or best guess) of the expected level of immunity (natural or induced) in the population at hand.

As the public health of the nation's population improves, and as local and State laws require universal immunization of children prior to school attendance; the percentage of immune individuals presenting for military service is obviously increasing. This has been true for many years for some diseases. The military's (unstated) stance has been that a booster dose is worth providing. So, recruits continue to get doses of polio, measles and mumps vaccines. Recent serologic screening has provided some interesting (and not necessarily predictable) results.

An example is the current consideration of adding varicella vaccine to the recruit regimen. It is not yet clear whether it is cost-effective to simply add this on and give varicella vaccine to all recruits, or whether varicella immune screening could be added onto screening for immunity to MMR and immunize only those found to be susceptible.

Of all the vaccines routinely administered to military forces, only those mentioned above currently seem amenable to serologic screening. In time perhaps screening for immunity to hepatitis A and hepatitis B might be considered as more States require these vaccines for school attendance, increasing the prevalence of immunity among new accessions.

Currently, DoD does not as a matter of policy measure serologic response to vaccines. The one exception is the Navy's policy to perform post-vaccine verification of immunity for hepatitis B. There are no assignment policies that we are aware of that precludes a military assignment when immunity to hepatitis B is not established. In other words, when hepatitis B vaccine is

administered, the recipient is presumed to be protected, no verification of immunity is undertaken and no assignments are changed or withheld based upon immune status.

2. Pre-Immunization Serologic Screening Background

Military personnel are required to receive many immunizations to protect against diseases associated with training and deployment. Immunization programs are expensive; their costs include buying vaccine products, time for administration and tracking, and, rarely, morbidity from adverse reactions. Some service members may have pre-existing immunity which, if identified, may exempt them from receiving unnecessary immunizations and save medical resources. Serologic testing is the most objective method of screening for such immunity.

3. Vaccine-specific consideration

Not every vaccine-preventable disease is amenable to immunologic screening. To be useful, screening tests must be commercially available and provide reliable data about disease resistance. Such serologic tests exist for measles, mumps, rubella, varicella, hepatitis A, and hepatitis B. For these diseases, the following vaccine-specific considerations apply:

Measles is a very serious viral disease which has been targeted for elimination in the United States in the near future.(l) Although U.S. measles rates are now at an an-time low, it is important to recall measles outbreaks in the late 1980s among young adults, and the global threat of measles to our deploying forces.(2) To protect service members' health, and support the U.S. public health effort, it remains important to ensure that ALL troops are measles-immune. Published data on serologic testing of military recruits has revealed that 13 - 21% of these young adults have been susceptible to measles before beginning training.(3-6) More recent serologic data supports concern about a continued high rate of susceptibility to measles.(7) Any program which opts to screen for measles immunity prior to vaccination, must have safeguards built in to ensure that all susceptibles are vaccinated.

Mumps has been considered a relatively benign childhood illness, and the incidence of mumps has fallen dramatically in the U. S. since the introduction of vaccine. Unfortunately, young adults, including military members, continue to experience outbreaks and complications from mumps.(8-10) Among new military accessions, the prevalence of susceptibility to mumps has been documented as 11 -18'0/o.(3-6)

Rubella incidence has also declined in the U.S. since the introduction of vaccine more than 3 0 years ago. Although rubella can cause complicated illness in young adults, the chief purpose of any rubella immunization program should be to prevent congenital rubella syndrome in the children of non-immune women.(1) Among military accessions, regardless of gender, the prevalence of rubella susceptibility has been documented as 14 - 18%.(3,4,6)

It should be noted that whenever immunization is needed against measles, mumps, or rubella, the recommended vaccine is a combination product *(NMR)* which ensures coverage against all three diseases.(I) In fact, it is currently difficult to purchase a measles, mumps, or rubella vaccine in the monovalent or bivalent form This, too, must be considered when developing a serologic screening program for any or all of these vaccine-preventable diseases.

Varicella, immunization became available in 1995. Although varicella is typically considered a benign childhood illness, susceptible young adults can become infected, occasionally at great cost to military readiness. It is interesting to note that, while the incidence of reported varicella in the military has been variable (I 1- 12), serologic surveys report a fairly consistent prevalence of susceptibility at 7 - 8% among new accessions.(3,5,13) Pre-vaccine serologic screening is certainly an attractive option for varicella, given that the cost of vaccine is high and the prevalence of susceptibility is relatively low.

Hepatitis A vaccine has also become available in recent years, and is now a mandatory immunization for all military members. The prevalence of natural immunity among young adults born in the United States is extremely low, making pre-immunization screening unlikely to be cost-effective. Serologic testing should only be considered for those who have lived in countries where hepatitis A is endemic, or who have a known history of natural disease.(14)

Hepatitis B vaccine is currently recommended for all children and young adults in the United States, although it is not yet mandatory for all military members. Among those who receive vaccine, serologic testing is very unlikely to be cost-effective in persons who have no known history of past immunization or natural disease.

4. Site-specific consideration

Beyond vaccine-specific considerations, each military site must consider its ability to pay for, perform, and assess serologic testing before implementing a titer-directed immunization program. Most sites have likely used serologic testing on an occasional, case-by-case basis, yet only a few have been able to add pre-immunization screening on a large programmatic basis. Examples of such program-wide screening include the following:

> Lackland Air Force Base screens all Air Force recruits for measles and rubella immunity with a rapid serologic test at accessioning. Recruits who screen sero-negative on either test are given measles-rubella (MR) immunization. It is interesting to note that the Air Force and Army have determined that recruits will not be given mumps immunization, so no serologic test is formed at Lackland. This policy is based on cost-benefit analyses performed before the bivalent MR vaccine became difficult to purchase.(16) For simple availability reasons, the Air Force may begin giving the trivalent measles-mumps rubella (MMR) vaccine to recruits who screen negative to either measles or rubella.

Great Lakes Naval Training Center screens all Navy recruits for varicella immunity with a rapid serologic test at accessioning. Recruits who screen sero-negative receive the twodose varicella vaccine series. Great Lakes was able to demonstrate an immediate cost effectiveness of this program because of its history of caring for large numbers of varicella cases within the bootcamp.(13)

Air Force officer accessions are screened and vaccinated against varicella in much the same way as Navy recruits.(17) Both programs have opted against using the accessions' subjective history of chicken pox to pre-screen for varicella immunity, since this question had a poor sensitivity for identifying sero-negativity.

It may be important to note the experience of Great Lakes in attempting to implement a serologic screening program prior to giving MMR vaccine to recruits. Although preliminary review showed such a program to be cost-effective, feasibility runs showed that lab resources could not consistently support the rapid turnaround required on these accessioning tests.(7) There was concern that MMR vaccination could be delayed, and therefore not simultaneous with other live-virus vaccines given to recruits at in-processing. To ensure recruit protection, especially against measles, Great Lakes opted to continue giving MMR vaccine to all accessions without pre-immunization serologic testing.

5. Recommendations

The military must continue to protect all its members from vaccine-preventable diseases. Given this priority, some military sites may be safely able to reduce medical expenses by performing serologic screening prior to immunizing service members. Screening is most likely to be cost-effective at accession points, where mass immunization against measles, mumps, rubella, and/or varicella is provided. The decision to perform serologic screening should be made on a site-specific basis, using cost-benefit analyses, with oversight from the parent services. Such cost-benefit analyses should include, at least, consideration of:

a. Reliability of available serologic screening tests,
b. Costs of performing screening tests,
c. Efficiency and ease of performing such testing,
d. Prevalence of immunity within the screened population,
e. Costs associated with vaccination,
f. Costs associated with delayed or missed vaccination if serologic testing is imperfect.

Because many of these factors are dynamic, each military installation should review its serologic screening program (or potential to add such a screening program) at least annually.

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B. Issues of Immunobiologics

1. Recruits

Numerous studies have demonstrated that when recruits enter initial training they are at significantly increased risk of diseases transmitted through the respiratory route. All services administer immunizations as early as possible in recruit training to protect recruits against respiratory and other disease threats. Since the disease threats facing recruits are primarily respiratory, the initial series of immunizations should be limited to what is needed to protect recruits during recruit training. These initial immunizations should include: adenovirus 4 & 7 (while available) and where historic outbreaks have occurred; measles, mumps, rubella; meningococcal; influenza; pneumococcal; tetanus/diphtheria; and varicella for non-immune individuals (ideally determined by serology).

Other immunizations needed while on active duty can be administered in the latter part of recruit training or upon arrival at the next duty station. This serves several purposes. It helps in the transition from recruit to active duty service member, and prepares them for the threats they will face when they join their units. It also decreases the number of immunizations received at one time by a recruit. Since some vaccines are one time doses or have long intervals between doses, most recruits will need no additional doses during their enlistment. While it will increase the

manpower and time required to administer immunizations (another shot day is required), there is a cost savings from not administering vaccines to recruits who have already left recruit training. Administering military required vaccines at recruit training allows for initial series of vaccines to be started, and allows for some level of protection from the moment an individual arrives at their unit. These vaccines include: hepatitis A; hepatitis B; oral typhoid; oral polio; yellow fever; and anthrax (once Phase III is reached).

Recruit centers should try to review individual's civilian immunization records upon arrival to avoid administering unnecessary immunizations. This will be especially important since hepatitis B and other vaccines are now being required by many school districts, and newly arriving recruits can be expected to have completed their primary series prior to arrival.

2. Active Duty

All active duty military members require certain immunizations for routine health maintenance, as do their civilian counterparts. These include tetanus/diphtheria, hepatitis B, and influenza. Additionally, active duty service members are expected to deploy in support of military operations, often at short notice, and usually to overseas locations with a high risk of infectious disease threats. Each service defines who is considered in a rapid deployment category, a deployable category, or a shore-based category (one less likely to deploy). Immunizations for these groups are based on disease threats in deployed locations overseas and include: hepatitis A; typhoid; yellow fever; oral polio; and anthrax.

3. Reserves

Current Department of Defense policies reflect increased utilization of reserve personnel in deployment scenarios. Most active duty units have reserve units that provide critical specialties for certain deployments as well as additional manpower. To maintain proficiency and unit cohesion, reserve units often train with their active duty counterparts both in the United States and overseas. In light of their critical deployment roles, immunization requirements for reserve units should mirror the active duty units they support, e.g., if in support of a rapid deployable unit, all overseas deployment related immunizations should be maintained.

4. Healthcare workers

The Department of Defense provides all immunizations recommended for occupationally exposed civilian workers to military members working in similar circumstances. Of primary concern is providing hepatitis B to all military members occupationally exposed to blood and body fluids. This includes health care workers as well as security personnel and fire fighters. Other required immunizations for this occupational group include measles, mumps, rubella, and

varicella to non-immune individuals. Health care workers also maintain the routine military immunizations based on their deployment status.

5. Special Operations

Special Operations personnel are rapidly deployable to often classified locations under highly adverse conditions. They maintain all military immunizations for rapid deployment, and depending upon their geographic locations, may also receive Japanese encephalitis, meningococcal, plague, rabies, and anthrax vaccines.

6. Animal Handlers

Veterinary personnel as well as security personnel that have responsibilities for managing stray animals on military bases receive the pre-exposure rabies series.

7. Other Immunobiologics

Since the DoD has mandated immunization with hepatitis A for all military personnel, there will be little need for immune serum globulin. Military treatment facilities may have need of ISG for treating other military beneficiaries how have been exposed to an active case of hepatitis A.

Hepatitis B immune serum globulin is part of the routine treatment of contacts to a patient with hepatitis B, for hepatitis B vaccine non-responders, or unvaccinated individuals. Varicella immune globulin is also part of the routine treatment of a non-immune adult contact of a patient with varicella. Both products will be still be needed primarily in medical treatment facilities to prevent staff members from developing disease that may be transmitted to other staff or patients.

Since rabies pre-exposure vaccination is only routinely provided to very small numbers of military personnel, rabies immune globulin remains an integral part of management of animal bites post-exposure, as it is in the civilian community. Having access to a safe source of rabies vaccine and immune globulin should be a part of routine planning for medical care during an overseas deployment where the risk of exposure to a rabid animal increases.

Due to high routine tetanus coverage for military personnel, tetanus immune globulin is rarely indicated for military personnel. It may be necessary in humanitarian operations if health care is provided to local individuals.

C. Issues of Administration

1. Jet Injector Use

Please see Appendix E for AFEB recommendations specific to the current policy on jet injectors. Prior to the current moratorium on jet injector use, we questioned medical personnel at recruit training sites and at the service level about their use of jet injectors. Personnel authorized to use the injectors in addition to physicians and registered nurses included medical technicians, corpsmen, physician assistants, and licensed practical nurses. As required by the Joint Instruction on Immunizations and Chemoprophylaxis, all sites that used the injectors reported training personnel using a combination of formal classroom and on-the-job training. They reported their sterilization practices were consistent with the policy in the Joint Instruction on Immunizations and Chemoprophylaxis and with manufacturers' recommendations. Acetone or alcohol wipes were used to clean the tips after each inoculation, nozzles visibly contaminated with blood were replaced and sterilized before additional use, and all injector nozzles were cleaned and sterilized daily. All services reported using the injectors routinely. Vaccines administered by jet injection included hepatitis B, influenza, MMR/MR, meningococcal, tetanus-diphtheria, and yellow fever. Some Army recruit sites did not use the jet injectors. The Navy and Marine Corps reported that they did not use jet injectors on smaller ships because there were more doses in the vaccine vials than personnel to be immunized. The Coast Guard used its jet injector only for mass influenza inoculations.

Of note is that the AFEB made a site visit to the MTF at Parris Island and directly observed high volume recruit immunization using jet injectors. It was noted that jet injector nozzle's were frequently contaminated with blood, yet sterilization practices were frequently inadequate or not followed.

D. Issues of Vaccine Information and Consent

1. Introduction

Members of the military as a condition of their military service are required to receive specific vaccines. The Department of Defense (DoD) and the Services have established policies requiring immunization of all members of the Armed Forces. DoD Instruction 5205.2, Immunizations Requirements, requires "implementation of programs that minimize individual illness and disability, days lost from work, and impairment of operational capabilities from conditions that are preventable through immunization." The Services' Surgeons General have issued a joint instruction, Immunizations and Chemoprophylaxis, that identifies "mandatory vaccinations for military personnel." DoD Directive 6205.3, DoD Immunization Program for Biological Warfare Defense, provides vaccination guidance focused exclusively on defense against biological warfare threats.

The joint instruction assigns responsibility to commanders to "ensure all military and nonmilitary personnel under their jurisdiction receive all required immunizations." Individuals may be deferred from specific immunizations if they have hypersensitivity to a vaccine or vaccine component. Permanent immunization waivers may be granted only in the case of legitimate religious objections to immunization.

The Nation demands that military commanders do all in their power and authority to employ prudent medical countermeasures in the face of preventable disease threats, including those threats posed by biological warfare agents. The authority to direct the uniform use of vaccines without the specific consent of the individual military member is necessary to protect the health and lives of individual military members, to ensure the safety of their comrades who rely on them, and to the success of the military mission. The consequences of an action which leads to one or more military members foregoing a needed vaccine will lead to an unacceptable military operational setting in which the lives of military members and the accomplishment of mission are jeopardized.

In general, Service members who refuse to receive an immunization after receiving a lawful general order are subject to administrative or disciplinary actions. There is no DoD-wide policy directing a specific disposition when a Service member refuses a lawful military order to receive an immunization. The Military Services have also not enacted policies dictating a specific Service-wide response in these cases. Rather, in these instances, the Military Services apply the principles in the Uniform Code of Military Justice (UCMJ) and the guidance in the Manual for Courts-Martial and Service regulations that apply to other cases involving a refusal to obey a lawful order.

2. Vaccine Information

For military members, information on vaccine benefits and risks, especially related to their military "occupation," is currently limited in availability and scope. Military members and military health care providers administering vaccines frequently do not have ready access to information on the "military" rationale for the vaccine. There are no requirements to provide such information routinely to military members.

The joint immunization instruction identifies the required vaccines, the groups who should be immunized, and administrative requirements associated with immunization. The instruction does not provide any information on the benefits and risks of specific vaccines or the rationale for their use in military populations. The published recommendations of the Advisory Committee on Immunization Practices (ACIP) provide more detail on preventable disease burden and vaccine effectiveness and safety, but these documents are not written for a lay audience. In addition, the ACIP frequently does not address specific indications for immunization of military members because of military operations and environments.

Other sources of information available to military members include the vaccine information statements issued by the Centers for Disease Control and Prevention (CDC), material from other federal agencies such as the Food and Drug Administration (FDA) and National Institutes of Health (NIH), and manufacturers' package inserts that accompany vaccines. Oral communications from health care providers are an important source of information, but the providers' level of information may be limited. A variety of nonprofit, consumer, and veterans organizations provide information. Many of these information sources are on the Internet, including several civilian and veterans group sites with strong anti-vaccination positions.

The joint immunization instruction does require "all health care providers who administer any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella or polio to either children or adults (to) provide a copy of the most recent relevant vaccine information materials provided by the DHHS." The National Childhood Vaccine Injury Act (NCVIA), passed by Congress in 1986 and subsequently revised, now requires that all health care providers who administer vaccines containing diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, hepatitis B, *Haemophilus influenzae* type b, varicella, and rotavirus must provide a copy of the appropriate vaccine information statement (VIS) to the vaccine recipient, their parent or legal guardian prior to each dose.

The NCVIA applies to "childhood" vaccines that are administered to adults as well as to children. A VIS must be given with every vaccination, including each dose in a multi-dose series. The educational materials should be supplemented with visual presentations or oral explanations, as necessary. Although the law specifically applies to the listed "childhood" vaccines, NCVIA does recommend that vaccine providers use, and CDC has developed, VISs for "adult" vaccines (such as influenza, hepatitis A, and pneumococcal vaccines).

VISs are developed by the Centers for Disease Control and Prevention (CDC). VISs have been developed to comply with the requirements of the NCVIA. Each document contains a brief description of the disease as well as the risks and benefits of the vaccine. The content and form of these documents cannot be altered without permission of the CDC (except to add identifying information of state and local health departments). Health care providers are not required to obtain the signature of the vaccine recipient, parent or legal guardian acknowledging receipt of the VIS. However, to document that the VIS was given, health care providers must note in the patient's permanent medical record (1) the date printed on the VIS and (2) the date the VIS is given to the patient or legal guardian.

While the joint immunization instruction requires that VISs be given to adult vaccine recipients, the "childhood vaccine" language causes frequent confusion. The level of compliance with this requirement during immunization of military members is uncertain, but probably low. This Board's analysis of DoD immunization policy did not address the issue of vaccine information.

VISs, even if given to the military member, would not provide information on the military rationale for immunization.

3. Vaccine "Risk" Communication

The DoD has the challenge of "requiring" military men and women to receive numerous vaccines. Many of these vaccines are not routinely given to their civilian family members, friends, and neighbors. Many of these vaccines will protect them from diseases that they have never seen or do not understand. Some of these vaccines will produce side effects that may cause concern, discomfort, and rarely illness or disability.

In *Risk Communication and Vaccination: Summary of a Workshop* (National Academy Press, 1997), the Institute of Medicine (IOM) reviewed and summarized the role and challenges of health risk communication as related to vaccines. Although the science and practice of vaccine risk communication is in its infancy, understanding how risks are perceived and the inherent biases of both message providers and recipients are key to good risk communication. The risk communication challenges addressed by the IOM Vaccine Safety Forum apply to immunization of military members, but the military faces added challenges. The rarity of vaccine-preventable diseases in the vaccine era makes it more difficult to communicate the risks of these diseases. Within the military, beliefs, leadership, and culture within a unit may influence an individual's immunization decisions. Some people might prefer to do what a majority of others do and be vaccinated. Others might prefer to rely upon the protection afforded by high immunization rates and not be vaccinated. Still others may respond to a message that their vaccination would protect the health and readiness of their unit. Perceptions of disease risk and the ability to control those risks through other means may influence some to avoid vaccination. Others may prefer the risk of disease per se over risks (real and perceived) of the vaccine available to protect them.

Issues of mandatory vaccine versus informed consent, individual rights versus societal welfare, and trust or distrust of leaders, health care providers, peers, and other information providers all can affect how military men and women respond to military immunization requirements. The mandatory nature of the military vaccination program may damage trust and deter effective communication. Although military members may not be able to make voluntary decisions regarding vaccination, an informed military member who consents to immunization based on truly knowing the risks and benefits of the vaccine should be DoD's goal.

4. Anthrax Vaccine Communication Plan

On December 15, 1997, Secretary of Defense Cohen approved the plan to immunize the total force against anthrax contingent on the successful completion of four conditions. One of those conditions was approval of the Services' implementation plans that describe how they planned to administer their anthrax vaccine immunization program and communications plans to inform military personnel of the overall program. Although anthrax vaccine is a licensed vaccine, DoD

placed high priority on informing military members, health care providers, leaders, and the public of the reason for the vaccine program and the effectiveness and safety of the vaccine.

The Services developed a coordinated communication plan that had several elements. Tri-fold information sheets were to be given to each member before the first dose of vaccine was administered. Briefing materials were prepared for military members, health care providers, and commanders. Initial information on the anthrax vaccine program was posted on DefenseLINK, the DoD's website. A redesigned, more attractive, website has been developed. During initial implementation of the vaccine program, regional commanders used public service announcements and news reports through local military media channels to provide information. DoD continues to update and improve communications materials.

The communications effort is laudable. The anthrax vaccine program did face unique challenges because of the Gulf War experience and because this is the first vaccine routinely administered to protect military members against a biological warfare threat. DoD's commitment to vaccine risk communication should not be limited, however, to anthrax vaccine or future vaccines against BW threats. Structured vaccine risk communication programs should support all vaccine programs for the military population.

5. Investigational and Off-label Use of Vaccines

The DoD has used vaccines that have not been approved for commercial marketing in combat settings and peacekeeping missions as force health protection measures. The specific force protection measure may have been voluntary and administered with informed consent, as was the case with the use of tickborne encephalitis vaccine for soldiers in Bosnia-Herzegovina. Administration of the vaccine may have been mandatory, if the FDA approved DoD's request for a waiver of the requirement for informed consent. The decision to obtain or not obtain a waiver of informed consent has depended on the nature and degree of the threat to military men and women, the impact of that threat on accomplishing the military mission, the best interests of the military members at risk, and other factors. During the Gulf War, a waiver of informed consent was in effect for use of the botulinum toxoid vaccine. No such waivers have been in effect or requested since the Gulf War.

The decision to use investigational vaccines with or without the informed consent of the military member is complex. The implications of such decisions—ethical, organizational, operational, legal, and informational—are exceedingly complex. A detailed discussion of these issues is beyond the scope of this report. Two excellent reviews are (1) Annas G. Protecting soldiers from friendly fire: The consent requirement for using investigational drugs and vaccines in combat. Am J Law Med. 1998;24(2-3):245-60 and (2) Rettig R. Military use of drugs not yet approved by FDA for BW/CW defense: Lessons from the Gulf War. National Defense Research Institute, DRR(L)-1806-1-OSD. (In press).

Recently, Congress passed the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999. Section 731 provides that only the President may grant a waiver of the requirement that a military member provide prior consent to receive an investigational new drug or a drug unapproved for its applied use in connection with the member's participation in a particular military operation. The President must determine, in writing, that obtaining consent is (1) not feasible, (2) is contrary to the best interests of the member; or (3) is not in the interests of national security. DoD believes the President must be given a range of options—including the feasible use of "investigational" products—for providing credible medical protection against chemical and biological weapons. FDA and DoD are working together to establish "standards and criteria" for determining that informed consent is not feasible or contrary to the best interest of military personnel.

The joint immunization instruction briefly mentions the requirement to comply with Federal regulations on informed consent and established investigational new drug (IND) protocols when the only available vaccine for a biological warfare threat is an IND. This section is drawn directly from DoD Directive 6205.3. The joint immunization instruction is silent on the use of IND vaccines for other disease threats, and any related issues for vaccine administration, information, and documentation.

6. Recommendations

The DoD should be committed to fully informing every service member during orientation and training of the health risks, personal and military benefits, and proper use of all vaccines and other medical countermeasures. Each military member should be fully informed about both the licensed and IND vaccines that they receive, even though such vaccines are considered "required" or "mandatory." The commitment needs to apply both to vaccines that will protect the military member from biological and chemical warfare threats and to those vaccines that will protect them from infectious disease threats during military training and deployments and in the community. Specific recommendations include:

- DoD should develop vaccine risk communication plans for the military vaccine program and, as appropriate, for specific vaccines.
- DoD should provide military members with appropriate vaccine information statements during each vaccine service encounter, especially when vaccines are being administered to recruits, alert forces, and deploying forces.
- DoD should develop and issue general policies for the use of any IND vaccine product and for the off-label use of a vaccine product, including requirements for informed consent and documentation.
- DoD should develop orientation and training procedures to alert military members that they may be required to take vaccines not yet approved for commercial marketing, if the President approves a DoD request for a waiver of informed consent.

- DoD should conduct research among military populations that will inform better vaccine risk communication efforts in the future.

E. Issues of Data Management

The Services to date have recorded minimal information in the paper (hard-copy) medical record. Rarely do the entries reflect more than the date, vaccine, dose and point of service or provider. The recently promulgated Federal guidelines that require recording vaccine manufacturer and lot number have not yet been universally adopted in the military medical record.

This should change in the near future with the fielding and implementation of the Preventive Health Care Application (PHCA). This USAF-developed software will be the first fielded application of the second generation of the Composite Health Care System, known as CHCS II.

PHCA has an immunization recording module based on a COTS-product that provides much more than a simple place to record data. It has many features that enable it to be a true medical record entry and to guide and prompt the user through the proper use of vaccines and biological products. It would record not only the vaccines administered but also any adverse reactions that might result. One of the more attractive features of the PHCA is its ability to poll the patient's record and compare the recorded services against a predetermined list of requirements or immunization schedules and to prompt any provider viewing the record that certain defined elements are overdue or missing. In addition, for planning and scheduling purposes, it will have the ability to look forward and to provide a list (from a defined population such as a unit) of those who will come due for a service or immunization over a user- defined period of time. Finally, there is a logistics module, which assists the provider in stocking the proper amount of vaccines.

By recording immunization (and TST) data into an electronic file, the Services will be taking the first steps to being able to aggregate the data and to perform analyses of immune status of individuals and units. At the current time, each Service has a functioning 'interim' system into which it is entering, at a minimum, the anthrax immunization data. This data in turn is moved from the Service-specific system to the DEERS database where it is archived for retrieval and analysis. It is planned that as PHCA is implemented, all immunization data will be archived in this manner.

In addition to the ability to define 'readiness' from an immunologic standpoint, such an electronic file would facilitate product recall and alert messages in that the exact lot number and date of service would be readily available.

One other initiative that is under active investigation is the 'electronic dog tag' or PIC (personal information carrier). It is envisioned that, depending on the (ever increasing) capacity of these devices, pertinent medical information will be moved to such a device when the military member

deploys away from his home station. Medical services provided to that member in the field setting would also be added to this device and then rolled back into his 'permanent' record upon his return. The PHCA will be the DoD's primary point of entry of all vaccine and 'readiness' data elements. These will form the core of the medical data that is moved to the PIC.

1. Immunization Records And Tracking

Immunization record-keeping and tracking of immunization status are two rapidly changing fields, primarily because of automated medical records. The Joint Instruction on Immunizations and Chemoprophylaxis requires written records and only briefly mentions the automated systems that have become more commonplace in recent years. When this project began one year ago, one survey respondent stated that the only way to determine the proportion of individuals whose immunizations were up to date would be to search the medical records by hand. Others reported that they had developed their own local systems using a variety of readily available database and spreadsheet software applications. While both of these conditions are still true to a certain extent, it is apparent that all of the services are moving toward automated record-keeping. In fact, the Air Force reports that all MTFs have an automated system specifically designed to track and monitor their immunization programs. We view this as the most desirable of states for all of the services.

Two forms of records are required by the Joint Instruction on Immunizations and Chemoprophylaxis: the SF-601, Health Record—Immunization Record, and the PHS-731, International Certificate of Vaccination, known as the yellow shot card. We understand that the SF-601 form is being replaced by a preventive care flow sheet formatted on paper or automated. Automation will prompt the medical facility to enter the manufacturer and lot number of any vaccine administered, which will facilitate communication in the event of a question about a particular lot, and is in line with Federal regulations concerning the administration of these vaccines. The Army relies on the SF-601 and the PHS-731, which may be kept by the individual or placed in the medical record when the record is held by the unit rather than the MTF, and plans to use the automated Preventive Health Care System (PHCS). The Air Force, which relied primarily on the PHS-731 cards for individual immunization records, is now required to maintain immunization documentation in the medical record as well. The Air Force is using the automated Military Immunization Tracking System (MITS). The Navy and Marine Corps, which have automated systems (the Shipboard Automated Medical System, SAMS), no longer prepare PHS-731 cards as a matter of routine; if needed for individual travel, the cards can be produced from automated systems. Survey respondents inform us that Navy ship personnel often travel without passports or shot cards, but are cleared into other countries as a group by host country officials checking a printed roster listing HIV test results as well as the immunization status of those aboard.

2. Reporting Adverse Reactions

The survey respondents indicated appropriate knowledge of the processes for reporting adverse reactions through the chain of command and to the Vaccine Adverse Event Reporting System (VAERS). Each service has mechanisms for collecting adverse reaction reports centrally as well as submitting them to VAERS. Unfortunately, VAERS is a passive surveillance system, which is therefore unlikely to receive data on all reportable adverse events. In our review, survey respondents noted that adverse events were reported rarely. This is unfortunate, as it prevents adequate research into possible side effects associated with the administration of vaccines. Such data are useful in counseling subjects, and in determining cause and effect with regard to injuries due to vaccines.

F. Issues of Surveillance

Accurate surveillance is the key for determining vaccination policies. The Composite Health Care System (CHCS) collects information on patient encounters from military medical treatment facilities (MTF's). Several databases are created by the Corporate Executive Information System (CEIS) from CHCS that are available for analyzing the effects of vaccine preventable diseases. Appropriate fields used for analysis are date of event, appropriate patient demographics, and diagnosis by IDC-9.

Active duty hospitalized cases are captured through the Standard Inpatient Data Registry (SIDR) of CHCS. This database contains hospitalizations from all services beginning in January 1990. This data base is considered the "gold standard" for analysis purposes as it reflects severe morbidity and data entry is done by professional ICD coders .

Cases seen as outpatients are entered by the attending provider into the medical treatment facility's Ambulatory Data System, which is centrally collected into the Standard Ambulatory Data Registry (SADR). The SADR system is relatively new. Outpatient data was first entered into this system in January 1996. The completeness and accuracy of data from this source is currently being analyzed.

Additionally, each service independently collects reportable events through their respective reportable diseases surveillance systems. The Navy central hub is located at the Navy Environmental Health Center (NEHC) in Norfolk Virginia. Air Force reportable events are analyzed centrally at the Epidemiology Services Branch at Brooks AFB Texas. The Army hub for central collection and analysis of reportable diseases is located at the Army Medical Surveillance Activity (AMSA) located on the campus of Walter Reed Medical Center in Washington DC Reportable events are collected, transmitted, and analyzed similar to the program cooperatively run between the states and territories, and the Centers for Disease Control and Prevention.

Until recently, each service operated separate systems: each collecting different events, operating different software packages, with differing periods of historical data, and with varying quality control measures. In the fall of 1997, all services agreed to report on a selected group of events, including the following vaccine preventable diseases (Measles, Mumps, Rubella, Chickenpox (active duty only), Meningococcal Meningitis, Pneumococcal pneumonia, Hepatitis A, Hepatitis B, Anthrax, Diphtheria, H. influenzae type b (invasive), Pertussis, Plague, Polio, Rabies, Smallpox, Tetanus, Typhoid, Yellow fever). Consensus was reached on accurate case definitions, appropriate fields, and appropriate timelines.

Additionally the services agreed to adopt compatible, transaction based reportable events systems, which will be analyzed at each service hub, and centrally incorporated into the Defense Medical Surveillance System (DMSS, co-located with the Army Medical Surveillance Activity at Walter Reed Army Medical Center). This new system will begin collection of TriService events in the fall of 1998. Analysis for completeness and accuracy will be conducted on a regular basis once this system is firmly established.

The DMSS also maintains patient demographic data received from the Defense Manpower Data Center (DMDC) in Monterey, California. All data from the previously described MTF generated databases is checked against this demographic database. This assures not only the accuracy of the demographic data in any analysis, but also provides accurate longitudinal records on each service member since 1990.

G. Issues of Vaccine Supply

1. Current Status

- Vaccine supply needs: Ideally, the US military needs a vaccine program that recognizes all threats, identifies effective vaccines, procures them in the most cost effective and efficient manner, stores them appropriately, and delivers them on time. These functions fall into the core areas of R&D, acquisition, and supply.

- Vaccine supply system: Currently, the US Army Medical Materiel Agency (USAMMA, Fort Detrick, MD, a subordinate unit of the US Army Medical Research and Materiel Command [MRMC]) is the DoD lead agent for vaccine supply. The Navy and Air Force also have offices at USAMMA to coordinate their specific needs. Requirements for commercially available products are given to the Defense Supply Center, Philadelphia (DSCP), Philadelphia, PA, an agency of the Defense Logistics Agency (DLA).

- DSCP manages the procurement and distribution of various FDA licensed vaccines. DSCP manages a Prime Vender system that enables activities to order directly from the DSCP contracted Prime Vendor (e.g., Mckesson, Bergan) for certain commercial

products (those for which the manufacturer has entered into a Distribution and Pricing Agreement [DAPA] with DSCP). Some activities choose to place requisitions with DSCP's Direct Vendor Delivery Branch (for purchasing directly from the manufacturer). A few activities are supported by the Veterans Administration (VA) Prime Vendor system (e.g. Ft. Jackson and Ft. Sam Houston). Lastly, some activities buy vaccines directly from manufacturers. DSCP has visibility on purchases using DSCP programs, but not on the local purchase or the VA supported programs. Most pharmaceutical sales are supported by the Prime Vendor System.

- Most Depot-stocked vaccines are military unique in size or application, or are not available via the Prime Vendor distribution system. The following vaccines are currently stocked in the DLA depots:

  Adenovirus, types 4 (expired) & 7 (limited stock, expires Fall 99)
  Japanese Encephalitis, 10 Dose
  Meningococcal Vaccine, Quadravalent, 50 Dose
  Plague Vaccine, USP, 20 Ml
  Tetanus & Diphtheria Toxoids, 30 Ml
  Tetanus Toxoid Absorbed, 5 Ml
  Typhoid Vaccine Inj, Acellular, 20 Dose (Vi)
  Typhoid Vaccine Live Capsules, 4 Set
  Yellow Fever, 20 Dose
  Influenza Virus Vaccine, Adult, 10 Dose
  Influenza Virus Vaccine, Pediatric, 10 Dose

  Note that items like Polio, Measles, Mumps, Rubella, Cholera, Hepatitis A, Hepatitis B, and others are not stocked in the depot. Depot stockage is continually reviewed based upon customer requirements, prices, and availability.

2. Current Status of Selected Vaccines

Problems

- **Plague Vaccine** - has mostly military and some commercial applications. In 1990, Greer took over production from the former supplier, Cutter/Miles. The last of the FDA approved Greer Vaccine expires in November 1998. Discussions with the FDA Center for Biologics, Evaluation, and Research (CBER), Greer, CDC, and various DoD offices have occurred to try to ensure continued availability. Greer will be providing data to the FDA in early November which may allow them to continue manufacture. Usage has diminished since the early 1990s after a change in usage recommendation by the AFEB. Cost is over $1M per year for ~1200 20 ml vials.

- **Adenovirus Vaccine, Types 4 and 7** - Military unique item. The only approved use is for military basic training facilities. In 1994, Wyeth decided to abandon the manufacture of the product (enteric coated tablets embedded with live virus). Greer had shown interest in a technology transfer but no arrangements could be made. The problem escalated to DoD (Drs. Martin and Bailey) recently. Funding appears to be the major problem in getting a supplier. Currently, all type 4 vaccine has expired. Remaining stocks of type 7 vaccine have been extended until the fall of 1999 but the supply may not last through the winter of 1998-1999.

- **Influenza Virus Vaccine, Pediatric, 10 Dose** - Flu vaccine orders must be placed in March in order to insure an August/Sept delivery--the sooner the contract, the better the delivery. When there is a production problem with one or more of the firms, shortages and delays result. DSCP did not procure any 50 dose vials this year because of the uncertainty of the Jet Injector. In 1999, DSCP can offer pre-filled syringes.

Resolved Vaccine Issues

- **Meningoccocal** – This item was on backorder in July 1998 because the Connaught Labs product was held up by the CBER. Fresh stock reached the depot on 28 July 98 and all backorders were released. DSCP has been in sustained supply since that time. This military unique size item (50 dose vial) is scheduled to come out of the depot since it is designed to be used with a jet injector. The sole supplier (Connaught) has recommended that the commercial size be used with needles and syringes. This commercial size will be made available via Prime Vendors, and thus, probably not depot stocked. Connaught sees no problem in meeting the military needs through commercial distribution.

- **Typhoid Vaccine, Acellular/Inj (Typhoid VI)** – This is a single source vaccine, manufactured in France and supplied by Connaught in the US. This vaccine is preferred, from a clinical viewpoint, but is significantly more expensive than the old Wyeth phenol-killed vaccine that is still sporadically available on the commercial market. When available, the Wyeth vaccine has the majority of the market. Wyeth has had production problems. (The former military unique acetone-killed vaccine was discontinued by Wyeth in the early '90s). The Oral Vaccine has remained in sustained supply. The Navy and Air Force have advised that the Wyeth vaccine should not be used.

- **Hepatitis A** – DSCP is in the second year of a successful contract for Hep A Vaccine. It can be ordered via Direct Vendor Delivery or from the Prime Vendor. It is now $16 per dose from Merck after a competitive "winner take all" solicitation . When SKB's

product was first licensed, the price to DoD and the Federal Government was $33 per dose.

3. Changes – Vaccines Coming Out Of Depot.

Three of the below listed vaccines are being discontinued based upon the reported problems with the Jet Injection Apparatus.

- **Meningoccocal** - For use with the Jet Injector. Currently DSCP has several months of stock on hand and due in. Item should be out of the depot by June 1999, depending on whether DSCP orders the additional 5,000 vials Connaught has already manufactured. A 10 dose vial will be available through a DAPA and Prime Vendor and may not be stocked in the Depot.

- **Tetanus & Diphtheria Toxoids** - For use with Jet Injector. Approximately 3 months stock on hand,. Should be out of depot by early 1999. A 10 dose vaccine is currently available on DAPA and Prime Vendor

- **Yellow Fever Vaccine** - a military unique size (20 dose). Single source (Connaught) will discontinue in favor of a commercial size. Item should be out of depot by mid-1999.

- **Japanese Encephalitis Vaccine** - A commercial item imported by Connaught. Most demands are going directly to Connaught and bypassing the depot. DSCP has had excessive stocks on hand which will become outdated.

- **Measles/Rubella (MR)** – This military unique combination vaccine made by Merck will soon be discontinued by the manufacturer, as a business decision. DSCP will enter into negotiations with Merck (for M & R separately or MMR) based on the service's desires. Unless DOD's price for MMR remains the same as MR was, training posts may prefer to give M and R separately, versus giving MMR, given the fact that mumps vaccination is not cost-effective in trainees.

4. Vaccine Supply Problem - Issues

Cost

Clearly, funding issues are central to many vaccine supply problems. The current example is adenovirus vaccine, which will require an estimated $12-20M to make this vaccine available again. The Typhoid vaccines are also good examples. The Vi vaccine is more effective and less reactogenic than the Phenol Inactivated of Wyeth, but the cost per dose makes the Wyeth

Vaccine preferred by many activities. DSCP assigns a 50+% Cost Recovery Factor to depot stocked items. Thus, depot stocking increases price for some items.

Sole Source Suppliers
When DOD relies on a sole source for any product, an interruption in production or delivery can cause both immediate and lengthy shortages.

5. One Company Vaccines

For the most part, vaccines tend to be one company products. While there is competition between the major vaccine producers of the world with some vaccines, most have only one licensed producer and some of these are small companies without significant resources. This is especially true of the few military specific vaccines: plague, anthrax and adenovirus. DoD is in constant danger of being left without a supplier when the capability lies with only one firm without a backup plan. For example, DoD is without adenovirus vaccine because the manufacturer (Wyeth) decided not to upgrade their facility to meet FDA demands. This was purely a business decision—not a readiness decision.

Small Companies
Small companies are more susceptible to economic buffeting than are larger ones.

Military Unique Items
Vaccine manufacturers are naturally interested in return on investment. Where there is no civilian need, such as with adenovirus vaccine, all costs must be borne by DoD. Plague Vaccine is similar, with little DoD or civilian use. Companies need an advance commitment from DoD to produce these items in a sustained fashion.

DoD Is A Small Buyer
The DoD, as large as it is, does not contribute significantly to the world-wide demand for vaccines. DoD orders for military-specific products (plague, adeno vaccines) are not procuring sufficient doses to be an attractive customer. Moreover, DoD must compete with others for all products. Potential solutions to this dilemma are complex. Should DoD build and maintain its own internal capability for making certain vaccines? Should DoD have contracts requiring the continued production of designated products? Should DoD expect to pay more for relatively small quantities of military unique products? What is the responsibility of private industry to the military, particularly when the military does the research and development on a product that industry then produces? Short of declarations of national emergency, corporate decisions can and do override defense needs.

Foreign Manufacturers
Some items are manufactured overseas and exported to a US distributor. In such cases, the US firm may have little leverage with it's overseas parent. This is especially apparent with typhoid

vaccine, where DSPC's needs for the Connaught Vi vaccine are dependent upon Wyeth's production capabilities.

Vaccine Shelf Life
With the relatively short shelf life of most vaccines, overstocking can easily lead to waste by having stocks that expire. Manufacturers, distributors, including Prime Vendors, and DLA store quantities based upon anticipated demand. Vaccines are not extendable, with the exception of the special CBER provisions granted for Adenovirus Vaccines.

Inventory Tracking
When a vaccine's shelf life is short, it must be intensively managed (e.g., adeno). Tracking on-hand supplies in order to cross-level among users is sometimes done manually, which can be cumbersome and problematic.

Use and Stocking of IND Vaccines
DSCP only deals with FDA licensed products. IND vaccines are managed by the IND licensee. In an environment of increased scrutiny and accountability, the use of IND products becomes much more difficult and problematic.

'Just-in-Time' Logistics
DoD has made a conscious decision to move away from large military stockpiles and to shift the burden to 'just in time' (JIT) production and delivery of a myriad of items. Among these are vaccines and biologicals. Since that decision has been implemented, JIT has not yet failed DoD (with regards to vaccine supply) but this could happen.

Responsibility to Assure Supply
It is unclear whether there is one agency responsible to assure an uninterrupted supply of vaccines to DoD. Further clarification is needed in this regard.

6. Other Potential Threats to Vaccine Supply

Espionage/Subversion/Terrorism/Sabotage
These threats are ever present and should be considered by DoD, with a contingency plan in place.

Unrecognized Threats
Significant progress within the area of biological warfare (BW) vaccine policy and development has been made. The DoD has established policy, responsibilities, and procedures for stockpiling biological agent vaccines and determined which personnel should be immunized and when the vaccines should be administered. DoD has also identified which biological agents constitute critical threats, and determined the amount of vaccine that should be stocked for each. The department awarded a prime systems contract in November 1997 to manage advanced development of biologic defense products, obtain FDA licenses and produce vaccines using the

US pharmaceutical industrial base. The prime contract approach has the advantage of flexibility by allowing the market place to drive how and where the DoD requirement will be satisfied. R&D efforts are underway to develop vaccines against all validated threat agents.

With the Iraqi buildup of biological weapons, terrorism attacks in Japan, and a breakdown in security at Russia's advanced bioweapons center in Koltsovo near Novosibirsk, some experts believe that the United States should resume making smallpox vaccine to deal with the threat of biological warfare. This is one example of a potentially unrecognized or newly recognized threat.

Surge Demand
DSCP does have programs that ensure that pharmaceuticals are available for surge needs, but has not investigated vaccines. DSCP uses Stock Rotation contracts, Vendor Managed Inventory, and Prime Vendor Surge provisions. Vaccines have a fixed and long production lead time and a specific lot approval process. When a firm agrees, DSCP sometimes buy bulk vaccines that have longer dating in storage at the plant, and thus a much shorter production lead time.

7. Recommendations to DoD

Fix Responsibility
DoD should fix responsibility on one agency to ensure an uninterrupted vaccine supply of all DoD-required vaccines, or to track the supply and be able to warn of shortages. The adenovirus vaccine lapse appears to have occurred in part because of the absence of a single responsible DoD agent. This message was heard frequently throughout the development of our report, and forms the basis for one f our major recommendations.

Coordinating Body
One agency should be named to coordinate all vaccine issues, i.e., threat assessment and identification, R&D, acquisition and supply.

Use Free Market When Feasible
The free market should be used when possible to acquire vaccines as inexpensively as possible, so long as the supply will not be reasonably compromised.

Use Non-Market Methods As Necessary
When necessary, DoD should use non-free market methods to ensure constant vaccine supply.

Apply Cost-Effectiveness Analyses
Scientific analyses, accounting for all relevant factors (e.g., readiness, economics) should be applied to all vaccine use decisions.

H. Issues of Education and Quality Assurance in Vaccine Delivery Immunizations and the Military: Quality Assurance in Vaccine Delivery

1. Deficiencies of the Current Approach to the Delivery of Vaccines in the DoD

Background: **On a DoD wide level, there is NO cohesive approach to the training and certification of personnel delivering immunization and tuberculosis screening (PPD delayed type hypersensitivity or DTH skin testing) services.** The fund of knowledge and complexity of the information dealing with immune surveillance (DTH skin testing with a wide array of antigens) and vaccine and/or immunogen delivery is increasing at the same time as workload is increasing (increasing personnel requiring vaccines and increasing number of vaccines). In the face of decreasing personnel for the delivery of these services, the lack of consistent training opportunities for tasked personnel (e.g., limited educational travel funding) has seriously impacted on the mission as a whole.

Frequently, allergy shot administration is an adjunctive function provided in immunization clinics; the performance of this service also represents an area of variable quality assurance standardization in personnel training and certification. Particularly Hymenoptera venom (stinging insect) immunotherapy has relevance to active duty and their readiness for deployment to high risk environments. All of the current Army basic training sites are in fire ant endemic areas. The availability of venom immunotherapy for active duty in Fort Benning, GA alone, since 1990, is estimated to have saved the service more than $2 million dollars in personnel costs. Although an extremely rare event, death as a complication of aeroallergen. immunotherapy makes the documentation of adequate training and supervision an additional concern. Finally, aeroallergen immunotherapy for allergic rhinitis which affects approximately 15-20% of the population, is first line therapy for many active duty personnel with special job requirements that make medication use less desirable or potentially interfering: the classic example for this is the aviator with severe allergic rhinitis not adequately controlled with nonsedating antihistamines and topical steroids. The value of this person, considering the cost of training, certainly favors treatment with immunotherapy as militarily relevant.

The performance of the mission (quality delivery of immunizations, allergy shots, particularly insect venom, travel related medical education, and disease screening services such as tuberculosis and anergy) is critical to military readiness worldwide and forms the cornerstone of preventive medicine. Enhancing immune defense ("immune readiness") at all possible levels will ultimately save health care dollars and will improve the quality of life and functionality of active duty service members and their dependents. The education of personnel and ultimately patients is an area of priority as we enter the 21st century. The organization of the tools necessary to carry out the mission successfully must include the development of improved methods to access and document quality training.

Although the **Immunization and Allergy Specialty Course,** coordinated by the Allergy-Immunology Department of Walter Reed Army Medical Center, has provided training on a TRISERVICE (plus VA) basis since 1973, many personnel needing training are unable to access this school. The course became an AMEDD C&S course 300-174 with official designator ASI 91BY8 established in 1975 (currently no longer utilized as a subspecialty designator) and has graduated over 1800 personnel. The Air Force became a full partner in 1981 and the Navy has actively participated since the 1980's. The school infrastructure costs have been solely supported by Walter Reed Command even though it has functioned as a de facto DoD immunization training course. Instructor personnel are provided by the Army, Air Force and Navy. Currently the school course structure includes 8 classes per year, 5 weeks in length to include 8 days of didactic training, 2 days of practical procedure training and 15 days of supervised rotations in clinic settings in the National Capital Region. The total number of graduates by service since 1984 alone are tabulated below.

AMEDD C&S 30OF4 Graduates FY 84-97:

Branch of Service	FY 84-97
ARMY	527
AIR FORCE	378
NAVY	56
Department of Defense	76
TOTAL	**1037**

Remote military health care facilities are having increasing difficulty supporting the travel and special duty funding necessary for participation in this needed course. There is a growing perception that we need to **train the trainers** in order to improve and expand the efficiency of education and certification delivery. In the past, immunization delivery required basic skills often adequately obtained by OJT (on the job training) utilizing minimally trained corpsmen. However, the landscape of immunization practice entering the 21" century is dramatically different with numerous biotechnology-derived vaccines now available and the high-complexity threat of biologic warfare. The immunization training of the near future will require specific advanced learning that will forever change the image of immunization delivery as "something that can be done by anyone." Distance learning modules to support this effort and assist local training efforts (reducing on-site school time and travel expenses) are an approach that offers unique opportunities to improve immunization delivery for the DoD as a whole.

2. Questions with Specific and Broader Applications:

In light of the complexity of vaccine delivery in the 2lst century, issues such as those listed below will need to be addressed at the DoD level:

- Some services use non-LPN' s for vaccine administration, others restrict the performance of these duties to RN's or LPN's only. Should non-RN/LPN personnel be administering pediatric or complex adult vaccines? Should non-RN/LPN personnel be administering investigational new drug status (IND) vaccines?

- What are the minimum requirements for continuing education in this area and how best do we document education, information updates? How do we incorporate new information from the Armed Forces Epidemiological Board (AFEB), the American College of Physicians and the Report of the Committee on Infectious Diseases as well as Center for Disease Control Updates via the Morbidity, Mortality Weekly Reports (MMWR)? Do military immunization clinics have timely access to these materials?

3. Proposed Solutions:

An initial summary of the types of initiatives that should be pursued in order to improve immunization delivery include the following:

- **Uniform Standard Operating Procedures** (SOPs) addressing critical elements of quality assurance in the operation of an immunization and tuberculosis screening service, allergy shot clinic, or a more complex travel medicine service are lacking, allowing for a high degree of variability in practices between facilities and between services. In some instances, due to a lack of trained personnel, this results in practices that may increase the risk of adverse events and decrease the quality of health care delivery.

- Immunization and immune screening services are increasing in complexity and form the cornerstone of military and general health or "immune" readiness. Qualified, well-trained support for these services at the level of local commands is limited and the cost of vaccine delivery is NOT centrally funded, putting it in competition with other competing demands within installations. **Individual medical treatment facilities need support to access uniform standards of training and proficiency testing for personnel assigned to deliver immunizations and other services such as tuberculosis screening, travel medicine services and allergy shot administration.**

- Multiple levels of training need to be available commensurate with the skill of the personnel to be trained and the needs of the overall mission. Examples are listed below in the following section.

Specific Proposed Solutions:

1. Establish a Department of Defense, TRISERVICE Health Affairs sponsored, specially tasked subject matter expert group with an active, on-going charter to monitor new developments in areas of interest, develop issues to present to the AFEB and other relevant organizations, provide a practical interface for the end users, and participate in education content development to address specific learning issues.Such a group should consist of experts with PRACTICAL EXPERIENCE from allergy-immunology, infectious disease, preventive medicine/occupational health, pediatrics, primary care providers, nursing involved in vaccine administration, and regular military representation to bring the issues of the customer perspective (commanders, soldiers, etc.) to the group. Such a diverse expert group could be involved in maintaining an active, interactive web site where vaccine delivery problems could be reported, where update bulletins could be made rapidly available, where the progress and updating on issues surrounding a central database could be addressed. Such a group could actively participate in the development and implementation of vaccine clinical research initiatives, particularly phase IV studies that address adverse reactions identified AFTER deployment of a new vaccine or immunizing material.

2. Develop a distance learning program for personnel of different levels of function and background. Establish a reliable way to test knowledge base - establish a rotating question bank so that relevancy and security are maintained. Knowledge base about proficiency testing as utilized by medical boards should be incorporated into DoD efforts at standardization of education and proficiency testing.

3. Use the most interested physician training programs (allergy-immunology, infectious disease, pediatrics, internal medicine) to develop ongoing review programs of both educational and informational products for continued process improvement.
    - The specialty of allergy-immunology in the military has a 25 year history of Tri-Service cooperation under the auspices of the AUSAI (Association of Uniformed Services Allergy-Immunologists). This group is made up of all active-duty Allergist-Immunologists with an executive committee consisting of representatives of each uniformed service. Because of this, Allergy-Immunology already has in place a unique paradigm for Tri-Service cooperation and can be effectively utilized as internal subject matter experts, providing an already established Tri-Service experience and perspective.

4. Partner with Uniformed Services University of the Health Sciences (USUHS) staff for product development.

4. Recommended Tracks For Training In Immunization Practices and Delivery By Experience and Education Level

Licensed Practitioner Nurse (LPN), Other Personnel Involved in Vaccine/Shot Delivery:

- **Beginning Course on Adult Active Duty Immunization Delivery and Basic Principles of Vaccine Handling, Storage, Administration Techniques:** Active duty military personnel vaccine delivery only with comprehensive education on basics of vaccine delivery, handling, storage issues, PPD skin testing, treatment of anaphylaxis, documentation requirements, when to refer for expert consultation, patient education requirements. Consider incorporating the development of improved learning material for enlisted training (91B & 91C level training).
- **Advanced Adult Immunizations for LPN/Corpsman/Other:** All adult immunizations, PPD and anergy panel skin testing, and introduction to travel medicine basics.
- **Basic Pediatric Immunizations** and delayed type hypersensitivity skin testing to include proper shot administration, complicating illnesses that affect vaccine strategies, etc.

Registered Nurse (RN), Nurse Practitioner or Physician Assistant Certification:

- **Beginners Course** covering the fundamental principles of vaccine delivery, adverse reactions, problem solving in vaccine administration, issues of documentation, etc. Focus of this course would be adult vaccines only as related to the military mission. Question: subdivide into pediatrics and adult, active duty and dependents?

- **Non-MD/DO Training in Allergy Shot Administration:** Allergy shots (Hymenoptera venoms, imported fire ant, other immunotherapy) both new prescriptions and maintenance shots with more extensive education on anaphylaxis and quality assurance of this service. Increasing sites for training military personnel are located in imported fire ant endemic areas where a high rate of sensitization of exposed personnel makes the cost of lost personnel if they are not desensitized in an expeditious manner a critical military impact issue. Failure to recognize this has resulted in serious shortages that can cost a local command as much as $25 to $30,000.00 dollars per soldier who is administratively separated rather than retained after a 2 week rush desensitization. The maintenance of these immunotherapy shots is like an immunization and interruptions in service due to scattered availability impacts adversely on the individual soldier as well as the organization.

- **Advanced Course** covering more detailed issues surrounding specific vaccine delivery, how to deal with problems surrounding vaccine delivery, exemptions to vaccine delivery, introduction to basic travel medicine patient education, etc. Question: subdivide into pediatrics and adult, active duty and dependents?

Physician Training and Certification:

- **Beginning Physician Training:** Licensed physician with NO specific background training in immunology, immunizations or travel medicine who needs fundamental training in the supervision of an immunization and allergy shot clinic. Potentially 2 modules of training: beginning and advanced training.

- **Comprehensive Physician Training:** Licensed physician with training in immunology and/or immunizations (allergy-immunology, infectious diseases, preventive medicine) who seeks certification and updating of new developments in vaccines, investigational vaccines, allergy shot administration issues, etc.

An example provided by the Clinical Work Group of the Anthrax Vaccine Immunization Program (AVIP) which directly addresses the critical issues raised in the delivery and monitoring of immunization programs is provided below:

FROM: COL Renata J. M. Engler, MC, USA
LTC Michael O'Connell, MC, USA

TO: COL Kim, Chief of Staff, NARMC
Ms. Lynn Slepski

Subject: NARMC AVIP WORKSHOP - Report of Clinical Work Group
9-10 December 1998

1. Four major categories of clinical "problem areas" were defined by the Clinical Work Group of the Anthrax Vaccine Immunization Program (AVIP) for the North Atlantic Regional Medical Command (NARMC) during the 1. 5 day meeting convened from 9 to 10 December 1998. Those issues identified by consensus of the working group are summarized in the paragraphs that follow. It was the consensus of the group, with broad clinical and geographic representation, that the forum provided was highly informative for all who attended and provided a necessary opportunity to define problems and possible solutions at different levels within the organization. The need for an ongoing, chartered immunization working group (consisting of ALL stakeholders to include nursing, preventive medicine, allergy-immunology, infectious disease, pediatrics, primary care and perhaps command representation) to address the broader concerns of quality immunization care delivery throughout the region and beyond was unanimously endorsed.

2. **Issue One:** Management of Adverse Reactions

   - **Background and Discussion:** There is a need to provide more detailed, expert recommendations for the categorization and management of adverse reactions to anthrax, focusing on detailed reporting that meets the data requirements of a VAERS report but also the clinical requirements of the organization. As new problems evolve, future management decisions must have a working network of communication in place for timely dissemination of experience as well as changing recommendations.
   - **Recommendations:** It was suggested by the group that an expert consultant document that is easy to use and provided clear algorithms of approach would be extremely helpful to delivery sites within the NARMC. Several members suggested that the production of a training video about adverse reactions, that could be used to educate both providers and patients, might be helpful. The possibility of adverse reactions, particularly if cutaneous or visible, being evaluated using Telemedicine tools already in place in Dermatology (VIRAMC) was suggested by COL Kim in response to this suggestion.
   - **Primary Office of Responsibility:** Immunization Consultant group facilitated by the NARMC staff and the Office of the Surgeon General. The need for a broad based clinical immunization working group would need to be chartered at the level of the OTSG or even DoD/HA.

3. **Issue Two:** Clinical Research on Adverse Reactors
   - **Background and Discussion:** There is a need to identify prospective methods of assisting in the evaluation of patients who develop adverse reactions to the anthrax vaccine and to develop standardized strategies for the management of these reactions. In this context and in the face of a need to increase reporting of adverse reactions, creating a climate that most vaccine reactions can be medically managed, centers of excellence for the critical and scientific evaluation of reactors need to be defined and supported within the NARMC. Funding research initiatives that include serologic assessment of immune response in collaboration with USAMRIID would be needed.
   - **Recommendations:** Since large local reactions are common with underreporting of morbidity to date, a research strategy to reduce the morbidity of these reactions while not interfering with vaccine efficacy would be beneficial to the program and its participants. Development of a formal multi-center research protocol is underway and should be supported by the NARMC.
   - **Primary Office of Responsibility:** Walter Reed Allergy-Immunology Department staff in conjunction with the WRAIR/USAMRIID staff (COL Pittman, COL Friedlander, etc.)

4. **Issue Three:** Guidelines for Waivers
   - **Background and Discussion:** The subject matter experts need to develop, in conjunction with clinical experience and feedback, detailed and consistent standards

for the application of waivers within the NARMC and beyond. Specialists in vaccine immunology and the management of adverse reactions should only grant permanent waivers. Temporary waivers can be granted until a full evaluation has been completed since immediate access to a specialist may not be available. There is a growing concern that the medical exclusion from anthrax vaccination may result in significant administrative adverse actions such as a Command directed MEB. Additionally, consistency of practice demands that waivers be dispensed equitably regardless of geographic location or rank.

- **Recommendations:** Although there is currently no official DoD position regarding restrictions on deployment of soldiers who receive a waiver from further vaccination, the logic of anthrax vaccination as a critical piece of force protection for deployment to certain high risk areas is widely advertised and has resulted in the perception that soldiers unable to receive the full anthrax immunization should not be deployed to high risk areas. The implications of these questions need to be reviewed and clearly addressed. There is a need to create of a waiver process algorithm for clinicians. This will include recommendations for subspecialty referral and should be distributed NARMC wide to ensure consistency in the waiver process.
- **Primary Office of Responsibility:** Immunization Consultant group facilitated by the NARMC staff and the Office of the Surgeon General.

5. **Issue Four:** Training of Personnel Providing Service and Medical Supervision
   - **Background and Discussion:** There are no centrally defined proficiency standards of training for personnel who deliver the immunizations, by what authority and under what supervision. Although there is a perception of sovereign immunity in federal facilities, multiple members of the group raised concerns that the standards of practice for the prescribing and administration of vaccines within the military facilities was NOT comparable to the nearby civilian community. Questions were raised regarding how to document training and proficiency for shot-givers and supervisors. The loss of the organizationally defined Y8 designator within the AMEDD was cited as an additional problem since many sites are using 91B level personnel. Questions raised included the liability concerns, licensing issues, and credentialing issues for providers. Vaccines are medications that require a physician prescription (according to the package insert) and only registered nurses or licensed practical nurses are authorized, by civilian standards, to administer medication by standing or verbal order. There is a great concern that 9 1 B's, particularly without the Y8 designator training experience, practicing in isolation with only very remote supervision may present a quality assurance risk to the organization.
   - **Recommendations:** The issues of defining proficiency standards and verification of clinical skills need to be addressed at the level of MEDCOM, OTSG, the AMEDD C&S and DoD (in order to assure uniformity of practices across service lines). In this context, there is an urgent need to support the formation of an OTSG immunization working group and develop tools to standardize training and testing of knowledge base

as well as clinical skills. The NARMC immunization sites to train personnel involved in immunization delivery should utilize the WRAMC Immunization-Allergy Technician School.

Primary Office of Responsibility: NARMC staff with coordination via the Office of the Surgeon General, MEDCOM, AMEDD C&S, TRADOC and DoD/HA.

I. Issues of Resources and Budget

Introduction/general statements

Resources and budgeting for immunizations in the Department of Defense are immunization dependent and service dependent. There are some specific vaccines or special missions where central procurement and centralized funding occur. However, even with a centrally procured vaccine, actual personnel and resources used to implement the immunization is accomplished by different services and different commands in a number of different ways. Tracking of the budgets and resources needed to implement many immunization programs are difficult within the current system because most immunization programs are implemented at the local level. While this may seem to be a disadvantage with regards to central accounting principles, this also allows local commands to prioritize resources and budgets for their most needed immunizations.

1. Central vs. Local Procurements

Procurements for most commercially available products are routed through the Defense Supply Center, Philadelphia (DSCP). See previous section on Vaccine Supply. If a vaccine is procured through DSCP, DSCP is able to capture the supply cost of the vaccine for the organization and is then able to tabulate the total cost of that centrally procured vaccine.

Organizations can also procure vaccine through the Prime Vendor system, the Direct Vendor Delivery Branch, the Veterans Administration Prime Vendor System, or directly from the manufacturer. See previous section on Vaccine Supply. DSCP is only able to tabulate the total cost of a vaccine if it was procured through a DSCP program. Since local procurements for specific vaccines are demand driven and usually based on recent historical usage of the vaccine, the total costs of vaccine procured through programs other than DSCP programs will vary from service to service and from vaccine to vaccine. Capturing the total cost of a vaccine that can be purchased outside of DSCP is best obtained from querying the local organizations or commands.

2. Personnel and Ancillary Costs

In addition to the actual vaccine, organizations must budget for personnel and ancillary supplies and other incidentals in order to implement immunization programs. Resources and budgets

must be set aside to purchase needles, syringes, sponges, hazardous waste disposal, refrigeration of vaccines, etc. Lastly, personnel and their salaries must be accounted for in tabulating total costs for immunization implementation. Except for very specific vaccines or specific programs, such as the Anthrax vaccine or Tick-Borne Encephalitis vaccine, total accounting for personnel and ancillary costs for immunization implementation is not possible within the current system.

3. Garrison Medical Support vs. Mission/Operation Medical Support

How organizations budget for personnel and ancillary supplies (like procurement) is based on priorities set at the local level. Immunization implementation at the local level can be described by comparing garrison medical support vs. mission/operation medical support.

In most garrison installations, there are medical organizations that have the mission to provide medical support to the organizations in that installation. Depending on the installation or the command, these medical organizations can be large tertiary hospitals, smaller hospitals, or clinics. These medical facilities normally have trained personnel and an operating budget dedicated to providing a variety of medical services. Some of these medical services are immunizations. There may be dedicated "immunization clinics" than can capture the total costs used to implement certain immunizations for that clinic but there are also Emergency Departments, Pediatric Clinics, Internal Medicine Clinics, etc. that provide immunizations in addition to other health services. The actual portion of personnel or supplies that these other clinics spend specifically for immunizations is not systematically captured. Compounding this problem is the fact that in some locations or situations, a service hospital may provide medical support (and immunizations) to Army, Air Force, Navy, National Guard and Reserve units that have access to that medical facility.

In addition to medical facilities that support installation organizations, there are medical personnel that are dedicated to serving specific missions or operations. These medical personnel may be organic to the mission or operation (or ship) or may be attached to it. The cost of the immunizations (supply, ancillary costs, and personnel costs provided by these medical personnel can be tabulated by that mission or operation. Again there is no systematic recording of routine immunizations unless it is a specific vaccine for a specific operation such as Tick-Borne Encephalitis vaccine during Operation Joint Endeavor in the Balkans.

B. Costs for Standard or Routine Immunizations

Supply costs and administration costs for most standard or routine vaccinations are taken from the operating budgets of garrison medical facilities or mission/operation medical support. Routine immunizations such as measles, mumps, OPV, rubella, tetanus-diphtheria, hepatitis B, influenza, and varicella are provided regularly to active duty soldiers, sailors, and airmen through various clinics during normal clinic hours by garrison medical facilities. These same immunizations may be offered by command for a mission/operation using medical personnel

organic/attached to the organization and are usually provided in the form of "unit readiness processing." During unit readiness processing, organic medical personnel can be and usually are supplemented by the garrison medical personnel. Often, vaccine supply costs, ancillary costs, and personnel costs of the supplemented unit readiness processing are borne by the operating budget of the garrison medical facility. They may receive supplementary funding at the end of the year to cover the unforeseen "unfinanced requirement" to support the mission/operation.

Reserve and National Guard (R/NG) soldiers who require standard or routine immunizations do not have regular access to immunizations compared to active duty soldiers, sailors, and airmen. As a result, they are often not as up-to-date with their immunizations. They may be able to obtain their immunizations in the following ways. Many of the routine immunizations are given during basic training. Since Reserves and National Guard are considered on active duty while in training, the cost for their routine immunizations are covered just like the immunizations for active duty soldiers described above. If the (R/NG) soldier requires the standard/routine immunizations but is not on active duty, he/she usually has no access to the medical facility and is therefore unable to get the immunization.

Immunization costs (for routine vaccines) for DoD civilians are covered by the operating budget of the installation medical facility's Occupational Medical Clinic or the Immunization Clinic or the Emergency Department. Routine immunizations for contractors are negotiated on a contractual basis.

Immunization costs (for routine vaccines) for dependent civilians are covered by the operating budget of the installation medical facility's many different clinics.

C. Costs for Pre-Deployment Immunizations.

When soldiers, sailors, and airmen deploy on individual assignments, they can obtain immunizations through the various medical clinics and those clinics assume the immunization costs. However, if there is a large mobilization for a specific mission/operation and there are also large numbers of R/NG forces, immunization costs assumed by the garrison medical facility are sometimes supplemented. The medical facility can attempt to bill the central medical command, which can then bill the mission/operation for the unfinanced requirement. Supplementary funding can come from the Major Command in charge of the operation or from the central Medical Command.

Pre-deployment immunizations for DoD civilians are usually performed by installation medical facilities. Since there are usually not a large number of deploying civilians, these immunization costs are usually not a problem for the installation medical facility to assume. Pre-deployment immunizations for contractors are negotiated. Often, since there are usually not a large number of contractors deploying, the immunizations are provided by the DoD installation medical

facility. In some instances, the negotiated contract states that the contractor is responsible for coordinating and assuming the cost of the immunizations.

D. Resourcing for Special Immunizations.

Sometimes depending on the mission and on the endemic or enemy threat, non-commercially available vaccines (such as Tick-Borne Encephalitis Vaccine or Botulinum Toxin) or infrequently available vaccines (Anthrax) must be purchased. When these situations occur, centralized procurement for both the vaccine and the ancillary supplies are accomplished from a centrally supplemented fund. Tracking of the vaccine supply cost and the ancillary supply costs are much more easily tabulated. Tracking of personnel costs will vary based on whether the healthcare personnel are dedicated to give the special immunization or whether they provide other healthcare services.

Reserves and National Guard forces are often included in planning the supply costs for the special vaccines. Unfortunately, the relatively infrequent nature of active duty training and the multiple and frequent sequence dosing often create problems for administering healthcare personnel. If the R/NG forces are close enough to a DoD installation, they can take advantage of full-time, active-duty health care personnel. Otherwise, the R/NG have to implement vaccinations by putting their people on active duty for a day or two to keep current with the sequence doses for anthrax as an example. Tracking those costs is probably impossible.

E. Crisis Resourcing Concerns

1. DoD important vaccines without a large US market.

It is important to note that the DoD budget and resourcing system is centralized enough (through DSCP procurements) to be able to negotiate competitive contract costs for specific vaccines, such as influenza, typhoid, hepatitis B, etc. On the other hand, there are enough adjunct procurement systems to allow local healthcare personnel to order specific vaccines on a faster timetable that is responsive to their needs. Despite the lack of centralized accounting for immunization costs, the adjunct procurement systems allow tremendous flexibility at the local level for prioritization of immunization purchases and implementation.

The biggest weakness with the system is the lack of a "vaccine watchdog" for certain vaccines that are not used in large quantities by DoD or the civilian community. Vaccines with large markets will continue to be funded by the demands from DoD and the civilian market. These vaccines such as influenza, hepatitis B, etc., will be available for DoD to negotiate prices with or for local levels in DoD to purchase as they see fit. Unfortunately, certain vaccines that do not have a large market can be neglected by the system.

Two good examples of neglected vaccines are adenovirus vaccine and anthrax vaccine. Adenovirus vaccine was eventually discontinued and anthrax vaccine was revitalized by DoD's Anthrax Vaccine Immunization Plan. Adenovirus vaccine does not have a civilian market. In fact, it is only licensed for use in DoD recruit populations. Eventually, because of its manufacturing facility maintenance costs, regulatory costs, dwindling profit margins, lack of a large market, etc., the sole producer eventually made the business decision to stop production of the vaccine. Because the vaccine had been so effective, DoD had grown complacent in assuming that the vaccine would be continually manufactured. When the warning came from the manufacturer, Wyeth-Ayerst, it was necessary to continually convene meetings and brief DoD decision-makers about the need for the vaccine, its safety and efficacy and its cost-effectiveness. In the end, because of DoD downsizing and ever decreasing budgets, the only adenovirus vaccine manufacturing facility was dismantled and there are currently no plans to invest capital expenditures to help build a new manufacturing facility. It may take a return to the large and disruptive epidemics that the Army experienced in the 60's before funding can be restored for adenovirus vaccine.

Another vaccine that did not have a large market was anthrax vaccine. Like adenovirus vaccine, there was not a large yearly demand for the vaccine, and hence for revitalization of the manufacturing facility. Until the Gulf War, DoD had not used or purchased enough anthrax vaccine to significantly support the manufacturer. In the interim years between the Gulf War and the creation of the Anthrax Vaccine Implementation Plan (AVIP), the manufacturing facility, Michigan Biologicals, was put up for sale. Interest in the vaccine and the plant increased with the AVIP and eventually, Bioport purchased the plant.

The two vaccine examples above are not the only vaccines in danger of being lost. Vaccines such as Junin, Rift Valley Fever, etc., may have their development stopped or curtailed because of research and development costs coupled with the absence of a large domestic U.S. market.

2. Stockpiling costs

For some vaccines, there may be an important strategic need to stockpile the vaccine in the event of a large outbreak or a biological warfare attack. But while DoD may request plans for a manufacturer to stockpile a vaccine or have contingency plans to rapidly increase production, DoD has no obligations to finance the stockpiling. In the meantime, the manufacturer has the onus of assuming the storage costs; the risk of the vaccine expiring before it is purchased; and the need to economically weather years of slow demand for the vaccine until such time as an outbreak or attack occurs. Secondary to this issue is the need to provide security for the strategic stockpile. Who is responsible for ensuring security and who will provide the funding?

3. Immunization resources during domestic crisis

Although there has been tremendous planning to fund and implement certain vaccines for DoD personnel or DoD affiliates, it is important to visualize the effects of our immunization plans in the event of domestic biological warfare such as an anthrax attack by terrorists. There would be an outcry to fund and allocate some of the specially procured vaccines originally slated for DoD personnel to civilian political leaders, civilian healthcare providers, police, firemen, etc. It would be wise to anticipate this outcry and demand and provide for contingency and prioritization plans for the immunization of certain segments of the civilian population. The 24 million doses of anthrax vaccine during a domestic scare would become a very scarce and valuable commodity that could cause disruption and unrest.

CHAPTER FIVE

SURVEY CAVEATS AND LIMITATIONS

This report has presented findings from the analysis of documents and survey responses provided by each of the military services and we have developed several conclusions from those findings. Several limitations in the data collection process may limit the general applicability of the findings and conclusions of this analysis. The survey respondents were a small sample of those responsible for dissemination and implementation of immunization policy. They were a convenience sample rather than necessarily a representative sample, consisting of individuals who were often recommended by name in a cascading process that began with service preventive medicine officers, who themselves are knowledgeable about service immunization policy. In addition, the collection of policy documents was not the initial focus of the project; some survey respondents who answered the questionnaires may not have referenced documents because that was only suggested, not required. We have addressed these limitations at least in part by requesting service-specific expert review of the results to ensure that the data collected are comprehensive, representative, and accurate.

Policy documents provided during this project indicate the evolving nature of immunization policy. The Joint Instruction on Immunizations and Chemoprophylaxis was frequently cited as the source of policy. In addition, survey respondents provided policy updates and procedural documents issued by the services through their routine channels, including e-mail for rapid dissemination; no survey respondent complained about not receiving information in a timely fashion.

The survey respondents contacted were, with few exceptions, well-informed and knowledgeable about existing policies. However, it may be difficult for the person removed from the policy development process to understand what policies are new and what policies have been rescinded. One survey respondent complained about the number and confusing nature of immunization-related messages received. Survey respondents provided some documents developed before the current Joint Instruction on Immunizations and Chemoprophylaxis. We noted that it was not always readily apparent, nor had the survey respondents marked the documents to indicate, which parts of those documents were still applicable and which no longer applied. At present, the Navy and the Air Force are in the process of issuing new, comprehensive instructions that will take into account changes in epidemiology, vaccines, and policies since the Joint Instruction on Immunizations and Chemoprophylaxis was issued on November 1, 1995. In addition we understand that a new Joint Instruction on Immunizations and Chemoprophylaxis will be developed in the near future. Efforts such as these to update and consolidate regulations and recommendations will doubtless be appreciated by those who must implement them.

APPENDIX A
ARMY IMMUNIZATION POLICIES

EXHIBIT A-1
ARMY IMMUNIZATION POLICY FOR ENLISTED RECRUITS AND OFFICER ACCESSIONS

VACCINE	ARMY ENLISTED RECRUITS	ARMY OFFICER ACCESSIONS
Adenovirus 4&7	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits • 10SEP96. Army Medical Command. *Restriction of Adenovirus Vaccine to Seasonal (Winter) Use Only.* Vaccine supply limited. Vaccinate 1SEP through 31MAR. Maintain surveillance for acute respiratory disease at BCT sites.	**No**
Anthrax	**Policy under development**	**Policy under development**
Hepatitis A	**No** • Joint Instruction on Immunizations and Chemoprophylaxis: Does not address recruits • 22MAY95. Army Medical Command. *Use of HAVRIX* • Hepatitis A not a threat during recruit training; therefore is administered as a readiness vaccine after basic training.	**No** • Joint Instruction on Immunizations and Chemoprophylaxis: Does not address officer accessions. • 22MAY95. Army Medical Command. *Use of HAVRIX* • Officer accessions training brief; become active duty quickly
Influenza	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: During flu season
MMR/MR	**Yes, MR** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits • MMR sometimes given, depending on vaccine availability. • MMR can be given if no history, but usually not given • Not currently screening serologically, but investigating its value and effectiveness	**Yes, MR** • Joint Instruction on Immunizations and Chemoprophylaxis: Officer accessions if there is no documentation • Army ROTC cadets receive before summer camp.
Meningococcal	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits	**No** • Joint Instruction on Immunizations and Chemoprophylaxis: Not required for ROTC or Service Academy.
Poliomyelitis (OPV)	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruit	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Officer accessions
Tetanus-	**Yes**	**Yes**

diphtheria	• Joint Instruction on Immunizations and Chemoprophylaxis: Recruits	• Joint Instruction on Immunizations and Chemoprophylaxis: Officer accessions • Army ROTC cadets receive before summer camp.
Varicella	**No** • Joint Instruction on Immunizations and Chemoprophylaxis: As directed • Considering adding to schedule, if proves cost-effective.	**No** • Joint Instruction on Immunizations and Chemoprophylaxis: As directed • Considering adding to schedule, if proves cost-effective.

EXHIBIT A-2
ARMY IMMUNIZATION POLICY FOR ROUTINE ACTIVE DUTY AND PERSONNEL TRAVELING OR DEPLOYING TO HIGH RISK AREAS

Note: Commanders in Chief for OCONUS regional commands (CINCs) can require other immunizations; these AOR (area of operations) requirements are separate and distinct from Army or other service requirements. For example, see tick-borne encephalitis policy of CINCEUR (CINC Europe).

VACCINE	ARMY ROUTINE ACTIVE DUTY	ARMY HIGH RISK TRAVEL OR DEPLOYMENT
Anthrax	**All active duty; priority to high risk forces** • Joint Instruction on Immunizations and Chemoprophylaxis: Does not address	**Yes, priority**
Cholera		**Not used by military** • Joint Instruction on Immunizations and Chemoprophylaxis: Only when required by host country. • DEC96. CDC's *Health Information for International Travel 1996-97.* "Currently no country or territory requires vaccination as a condition for entry. Local authorities, however, may "
Hepatitis A	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: As directed • 12AUG96. DoD\HA. *Policy for Use of Hepatitis A Virus Vaccine and Immune Globulin.* All active duty to be immunized by 31DEC98.	
Hepatitis B		**As directed** • Joint Instruction on Immunizations and Chemoprophylaxis: As directed • 4OCT94. HQDA. *Hepatitis B Vaccination.* All personnel PCS-ing to Korea.

Influenza	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Annual	
Japanese Encephalitis Virus		**High risk travel** • Joint Instruction on Immunizations and Chemoprophylaxis: High risk travel
Meningococcal		**High risk travel** • Joint Instruction on Immunizations and Chemoprophylaxis: High risk travel Boost q 5 yrs
Plague		**High risk travel** • Joint Instruction on Immunizations and Chemoprophylaxis: High risk travel • Rarely used
Tetanus-diphtheria	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: All active duty personnel • Boost q 10 yrs	
Tick-borne Encephalitis		**High risk travel** • Joint Instruction on Immunizations and Chemoprophylaxis: Does not address • 17OCT96. DoD\HA. *Policy for Tick-Borne Encephalitis Preventive Measures for DoD Personnel Deployed to Endemic Areas.* For Joint Endeavor personnel under Commander-in-Chief Europe. Do not routinely immunize; use personal preventive measures. However, personnel at high risk should be considered. Requests to be approved by USCINCEUR. Must comply strictly with Investigational New Drug protocol; informed consent required.
Typhoid		**High risk travel** • Joint Instruction on Immunizations and Chemoprophylaxis: Alert forces; high risk travel • Joint Instruction on Immunizations and Chemoprophylaxis: Army alert forces are members of active duty or reserve units required to be in a state of readiness for deployment within 30 days or less of notification.

		• Boost dependent on vaccine used: q 2, 3, or 5 yrs
Yellow Fever		**High risk travel** • Joint Instruction on Immunizations and Chemoprophylaxis: Alert forces; high risk travel • Boost q 10 yrs

EXHIBIT A-3
ARMY IMMUNIZATION POLICY FOR SPECIAL OPERATIONAL AND OCCUPATIONAL GROUPS

SPECIAL GROUP	VACCINES ADMINISTERED TO ARMY PERSONNEL IN ADDITION TO ROUTINE IMMUNIZATIONS
High risk occupational groups	Joint Instruction on Immunizations and Chemoprophylaxis. **Hepatitis B, MMR, plague (rare in practice), rabies, varicella**
Medical personnel and other health care workers if not immune	**Hepatitis B.** Joint Instruction on Immunizations and Chemoprophylaxis: OSHA requirements. **Hepatitis B.** 23OCT96. DoD\HA. Hepatitis B Immunization Policy for DoD Medical and Dental Personnel. All required to complete three-dose series unless documentation or contraindication. **MMR.** Joint Instruction on Immunizations and Chemoprophylaxis: Following ACIP requirements, those born before 1957 require proof of immunity.
Animal handlers; veterinary personnel; certain laboratory, field, and security personnel; personnel frequently exposed to potentially rabid animals in occupational or recreational setting	**Rabies.** Joint Instruction on Immunizations and Chemoprophylaxis. Preexposure series in accord with ACIP.
Army Special Operations Command requirements, USASOC Supplement 1 to AR 40-562. 19APR95	**Hepatitis A.** Two-dose primary series. Boost q 4yrs. **Hepatitis B.** Initial series. **Influenza.** Annual. Boost if in Southern Hemisphere APR-SEP. **JE Vaccine.** By geographic area. Boost q 3 yrs. **Measles.** Initial series; one adult dose if born after 1956. **Meningococcal.** Initial series. Boost q 5 yrs. **Plague.** Shots 1 and 2 of initial series. Boost if deployed to high-risk area and q 6 mos while in high-risk area. **Polio.** Initial series; one adult dose if born after 1956. **Rabies.** Initial series for AMEDD personnel in Special Forces Groups and personnel assigned, attached, or OPCON to an Operational Detachment - Alpha (ODA). **Td.** Boost q 10 yrs. **Typhoid.** Initial series. Boost q 3yrs injectable; boost q 5 yrs oral. **Yellow Fever.** Boost q 10 yrs.

EXHIBIT A-4 IMMUNIZATION POLICY
ARMY IMMUNIZATION POLICY FOR RESERVE FORCES

VACCINE	ARMY RESERVE FORCES POLICY
All Vaccines	• Joint Instruction on Immunizations and Chemoprophylaxis: Army reserve component personnel considered alert forces are subject to deployment within 30 days or less of notification; they thus receive the immunizations indicated for active duty or special occupational or operational groups as applicable. •
Influenza	• Joint Instruction on Immunizations and Chemoprophylaxis: Reserve component personnel on active duty for 30 days or more during influenza season receive influenza immunization.
Hepatitis A	• Joint Instruction on Immunizations and Chemoprophylaxis: As directed; does not address reserve forces • 12AUG96. DoD\HA. Policy for Use of Hepatitis A Virus (HAV) Vaccine and Immune Globulin (IG). Reserve personnel on mobility status who are targeted for early deployment to high risk areas.

APPENDIX B
NAVY AND MARINE CORPS IMMUNIZATION POLICIES

EXHIBIT B-1
NAVY AND MARINE CORPS IMMUNIZATION POLICY FOR ENLISTED RECRUITS AND OFFICER ACCESSIONS

VACCINE	NAVY AND MARINE ENLISTED RECRUITS	NAVY AND MARINE OFFICER ACCESSIONS		
		No • Joint Instruction on Immunizations and Chemoprophylaxis: Not required		
		Policy under development		
		Yes • Joint Instruction on Immunizations and Chemoprophylaxis: As directed • 6FEB97. FY97 Updated Guidance on Use of Hepatitis A Vaccine.. Administer to all Marine Corps officer accessions. All Naval Academy midshipmen to receive two doses by graduation. Midshipmen and Navy and Marine Corps ROTC students with summer assignments to Marine Corps expeditionary forces, Navy construction battalions, or SEAL, EOD, or other special warfare units.		
		Yes • Joint Instruction on Immunizations and Chemoprophylaxis: Officer accessions receive year-round		
		MMR • Joint Instruction on Immunizations and Chemoprophylaxis: Officer accessions if there is no documentation		

• 3JUN97. NROTC Administrative Manual. NROTC midshipmen must have documentation of MMR or equivalent single antigen immunizations or serologic evidence of immunity.		
No • Joint Instruction on Immunizations and Chemoprophylaxis: Not required for ROTC or Service Academy, though may be used based on risk		
No		
Yes • Joint Instruction on Immunizations and Chemoprophylaxis: Officer accessions		
Yes • Joint Instruction on Immunizations and Chemoprophylaxis: Officer accessions • 3JUN97. NROTC Administrative Manual. NROTC midshipmen must have documentation of Td within past 10 years. • 12JAN93. BUMED Notice 6230, Immunization Requirements_ Officer accessions to have one dose of Td unless born and attended elementary and secondary school outside the U.S.		
• **Joint Instruction on Immunizations and Chemoprophylaxis: Traveling or deploying to high risk areas** • 3JUN97. NROTC Administrative Manual. NROTC midshipmen may be required to have typhoid for summer cruise involving foreign travel.		
No • Joint Instruction on Immunizations and Chemoprophylaxis: As directed		
Yes • Joint Instruction on Immunizations and Chemoprophylaxis: Not required • 12JAN93. BUMED Notice 6230, Immunization Requirements_ Officer accessions should have one yellow fever with boosts as required.		

EXHIBIT B-2
NAVY AND MARINE CORPS IMMUNIZATION POLICY FOR ROUTINE ACTIVE DUTY AND PERSONNEL TRAVELING OR DEPLOYING TO HIGH RISK AREAS

Note: Commanders in Chief for OCONUS regional commands (CINCs) can require other immunizations; these AOR (area of operations) requirements are separate and distinct from Navy, Marine Corps, or other service requirements. For example, see tick-borne encephalitis policy of CINCEUR (CINC Europe).

VACCINE	USN AND USMC ROUTINE ACTIVE DUTY	USN AND USMC HIGH RISK TRAVEL OR DEPLOYMENT
Anthrax	**Yes, all active duty; priority to high-risk forces** • Joint Instruction on Immunizations and Chemoprophylaxis: Does not address	**Priority**
Cholera		• Joint Instruction on Immunizations and Chemoprophylaxis: Only when required by host country. • DEC96. CDC's *Health Information for International Travel 1996-97*. "Currently no country or territory requires vaccination as a condition for entry. Local authorities, however, may continue to require documentation of vaccination"
Hepatitis A	**Yes** • 6FEB97. FY97 Updated Guidance on Use of Hepatitis A Vaccine_ The following active duty forces are to receive: Marine Corps expeditionary forces; Navy construction battalions; special warfare units; Marine Corps security guards; Navy personnel and medial personnel mobilizing with Marine Corps expeditionary forces, Navy construction battalions, and special warfare units; all members of afloat units deployed or preparing for deployment; and military forces assigned to areas of high endemicity. • 12AUG96. Policy for Use of Hepatitis A Vaccine and Immune Globulin. Post-exposure prophylaxis with IG if given within two weeks of known foodborne or waterborne HAV disease.	

Hepatitis B		• Joint Instruction on Immunizations and Chemoprophylaxis: As directed (See also Special Groups, below)
Influenza	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Annual	
Japanese Encephalitis Virus		• Joint Instruction on Immunizations and Chemoprophylaxis: High risk travel • 16AUG96. Update on Use of Japanese Encephalitis Vaccine. All active duty personnel likely to experience field conditions in endemic areas. Should have primary series or booster before departure if possible; if not, complete upon arrival. Personnel on flight status routinely grounded 24 hours after JEV; with history of urticaria or hypersensitivity reactions, grounded 3 days after doses 1, 3, or booster and 5 days after dose 2.
Meningococcal		• Joint Instruction on Immunizations and Chemoprophylaxis: High risk travel • Boost q 5 yrs
Plague		• Joint Instruction on Immunizations and Chemoprophylaxis: High risk travel • See also Special Groups, below
Tetanus-diphtheria	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: All active duty personnel • Boost q 10 yrs	
Tick-Borne Encephalitis		• Joint Instruction on Immunizations and Chemoprophylaxis: Does not address • 17OCT96. DoD\HA. Policy for Tick-Borne Encephalitis Preventive Measures for DoD Personnel Deployed to Endemic Areas. For Joint Endeavor personnel under Commander-in-Chief Europe. Do not routinely immunize; use personal preventive measures. However, personnel at high risk should be considered. Requests to be approved by USCINCEUR. Must comply strictly with Investigational New Drug protocol; informed consent required.

Typhoid		• Joint Instruction on Immunizations and Chemoprophylaxis: Alert forces; high risk travel • Joint Instruction on Immunizations and Chemoprophylaxis: Alert forces are fleet units deployed on scheduled or situational basis to foreign country (except Canada); personnel subject to foreign deployment on short notice • Boost dependent on vaccine used: q 2, 3, or 5 yrs
Yellow Fever	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: All active duty • Boost q 10 yrs	

EXHIBIT B-3
NAVY AND MARINE CORPS IMMUNIZATION POLICY FOR SPECIAL OPERATIONAL AND OCCUPATIONAL GROUPS

SPECIAL GROUP	VACCINES ADMINISTERED TO NAVY AND MARINE PERSONNEL IN ADDITION TO ROUTINE IMMUNIZATIONS
High risk occupational groups	**Hepatitis B, MMR, plague, rabies, Varicella (Navy only).** Joint Instruction on Immunizations and Chemoprophylaxis.
Medical personnel and other health care workers	**Hepatitis A.** 6FEB97. BUMED FY97 Updated Guidance on Use of Hepatitis A Vaccine. All medical personnel mobilizing with Marine Corps expeditionary forces, Navy construction battalions, or special warfare units **Hepatitis B.** Joint Instruction on Immunizations and Chemoprophylaxis: OSHA requirements **Hepatitis B.** 23OCT96. DoD\HA. Hepatitis B Immunization Policy for DoD Medical and Dental Personnel. All required to complete three-dose series unless documentation or contraindication. **JE Vaccine.** 16AUG96 BUMED Update on Use of Japanese Encephalitis Vaccine. Medical personnel needs for immunization to be considered on case-by-case basis. **MMR.** Joint Instruction on Immunizations and Chemoprophylaxis: Following ACIP requirements, those born before 1957 require proof of immunity **Varicella.** 24JUN96. BUMED Interim Guidance on Use of Varicella
Marine Corps chemical and biological incident response forces (CBIRFs)	**Anthrax.** Reported by SURVEY RESPONDENT.
Marine Corps expeditionary forces Navy construction battalions All members of special warfare units Marine Corps security guards	**Hepatitis A.** 6FEB97. BUMED FY97 Updated Guidance on Use of Hepatitis A Vaccine
Animal handlers; veterinary personnel; certain laboratory, field, and security personnel; personnel frequently exposed to potentially rabid animals in occupational or recreational setting	**Rabies.** Joint Instruction on Immunizations and Chemoprophylaxis. Preexposure series in accord with ACIP
Susceptible adolescents and adults living or working closely with immunocompromised individuals	**Varicella.** 24JUN96. BUMED Interim Guidance on Use of Varicella.

(recommended strongly)	

EXHIBIT B-4
NAVY AND MARINE CORPS IMMUNIZATION POLICY FOR RESERVE FORCES

VACCINE	NAVY AND MARINE CORPS RESERVE FORCES POLICY
All Vaccines	• Joint Instruction on Immunizations and Chemoprophylaxis: Navy and Marine Corps reserve personnel subject to foreign deployment on short notice are considered alert forces and receive active duty, alert forces, and special occupational or operational group immunizations as applicable. • Joint Instruction on Immunizations and Chemoprophylaxis: Navy reserve personnel called to active duty for 10 days or more receive immunizations • Joint Instruction on Immunizations and Chemoprophylaxis: Marine Corps reserve personnel called to active duty for 30 days or more receive immunizations. • 23AUG96 COMRESFOR INSTRUCTION 6230.1B reiterates Joint Instruction on Immunizations and Chemoprophylaxis
Hepatitis A	• Joint Instruction on Immunizations and Chemoprophylaxis: As directed; does not address reserve forces • 6FEB97. BUMED. FY97 Updated Guidance on Use of Hepatitis A Vaccine. Reserve Navy personnel to be immunized if deploying or assigned to Marine Corps expeditionary forces, Navy construction battalions, or special warfare units • 12AUG96. DoD\HA. Policy for Use of Hepatitis A Virus (HAV) Vaccine and Immune Globulin (IG). Reserve personnel on mobility status who are targeted for early deployment to high risk areas.

APPENDIX C
AIR FORCE IMMUNIZATION POLICIES

EXHIBIT C-1
AIR FORCE IMMUNIZATION POLICY FOR ENLISTED RECRUITS AND OFFICER ACCESSIONS

VACCINE	AIR FORCE ENLISTED RECRUITS	AIR FORCE OFFICER ACCESSIONS
Adenovirus 4&7	**No** • Joint Instruction on Immunizations and Chemoprophylaxis: USAF only when evidence of active disease transmission	
Anthrax	**Policy under development**	**Policy under development**
Hepatitis A	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits not specified • 10SEP96, Policy for the Use of Hepatitis A Virus (HAV) Vaccine and Immune Globulin (IG), (ASD[HA] and Memo, 12AUG96). Notification to accelerate Hepatitis A immunization for total active duty and selected Reserve force by 31DEC98. Accessions and new recruits have been added to the priority list	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Officer accessions not specified • 10SEP96, Policy for the Use of Hepatitis A Virus (HAV) Vaccine and Immune Globulin (IG), (ASD[HA] and Memo, 12AUG96). Notification to accelerate Hepatitis A immunization for total active duty and selected Reserve force by 31DEC98. Accessions and new recruits have been added to the priority list
Influenza	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits • Administered year-round	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Officer accessions during flu season • Administered OCT-MAR at OTS, COT, ROTC, and Academy
MMR/MR	**MR** • Joint Instruction on Immunizations and Chemoprophylaxis: MR • Joint Instruction on Immunizations and Chemoprophylaxis: Serological screening only when feasible and cost-effective; document the results. Antibody testing must be cost-effective and an FDA-approved screening test must be used. • Recruits are screened serologically	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: MR • Academy screens record and serology; immunizes seronegatives • OTS, COT evaluate shot record
Meningococcal	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits	**No** • Joint Instruction on Immunizations and Chemoprophylaxis: Not required for officer accessions

Poliomyelitis (OPV)	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Officer accessions
Tetanus-diphtheria	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Officer accessions

Varicella	**No** • Joint Instruction on Immunizations and Chemoprophylaxis: As directed • 20SEP95. Re: AFEB Recommendations on the Use of Meningococcal and Varicella Vaccines. Varicella vaccine not recommended for universal immunization of military members or recruits. A serological study of current levels of immunity among recruits and selective immunization of non-immunes may be indicated. • Serological study has not been done	**Yes for Academy cadets** • Joint Instruction on Immunizations and Chemoprophylaxis: As directed • Academy screens all cadets and vaccinates susceptibles

EXHIBIT C-2
AIR FORCE IMMUNIZATION POLICY FOR ROUTINE ACTIVE DUTY AND PERSONNEL TRAVELING OR DEPLOYING TO HIGH RISK AREAS

Note: Commanders in Chief for OCONUS regional commands (CINCs) can require other immunizations; these AOR (area of operations) requirements are separate and distinct from Air Force or other service requirements. For example, see tick-borne encephalitis policy of CINCEUR (CINC Europe

VACCINE	AIR FORCE ROUTINE ACTIVE DUTY	AIR FORCE HIGH RISK TRAVEL OR DEPLOYMENT
Anthrax	**All active duty; priority is high risk travel** • Series not begun CONUS; administered in AOR	**Priority** • Series not begun CONUS; administered in AOR
Cholera		• Joint Instruction on Immunizations and Chemoprophylaxis: Only when required by host country. • DEC96. CDC's *Health Information for International Travel 1996-97*. "Currently no country or territory requires vaccination as a condition for entry. Local authorities, however, may continue to require documentation of vaccination"
Hepatitis A	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Alert forces; high risk travel • 10SEP96. ASD/HA. Policy for the Use of Hepatitis A Virus (HAV) Vaccine and Immune Globulin (IG). Immunize all active duty personnel.	
Influenza	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Annual	

Japanese Encephalitis Virus		• Joint Instruction on Immunizations and Chemoprophylaxis: High risk travel • 16AUG96. Update on Use of Japanese Encephalitis Vaccine. All active duty personnel likely to experience field conditions in endemic areas. Should have primary series or booster before departure if possible; if not, complete upon arrival. Personnel on flight status routinely grounded 24 hours after JEV; with history of urticaria or hypersensitivity reactions, grounded 3 days after doses 1, 3, or booster and 5 days after dose 2.
Meningococcal	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits; high risk travel • 26MAR97. Mobility Immunization Requirements (AMC) requires booster q 3 years for AMC and AMC-gained flying personnel. • 20SEP95, HQ USAF/SG – Re: AFEB Recommendations on the Use of Meningococcal. Routine booster q 5 years. (Note: this precedes Joint Instruction on Immunizations and Chemoprophylaxis, but was provided as policy by SURVEY RESPONDENT) • Deployment/travel to Saudi Arabia during Hajj requires boost within past 3 years (Saudi Arabia requirement)	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits; high risk travel • 20SEP95, HQ USAF/SG – Re: AFEB Recommendations on the Use of Meningococcal. Routine booster q 5 years. • 26MAR97. Mobility Immunization Requirements (AMC) requires booster q 3 years for AMC and AMC-gained flying personnel. (Note: this precedes Joint Instruction on Immunizations and Chemoprophylaxis, but was provided as policy by SURVEY RESPONDENT) • Deployment/travel to Saudi Arabia during Hajj requires boost within past 3 years (Saudi Arabia requirement)
Plague		• Joint Instruction on Immunizations and Chemoprophylaxis: High risk travel (See also Special Groups)
Tetanus-diphtheria	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: All active duty personnel	
Tick-borne Encephalitis		• Joint Instruction on Immunizations and Chemoprophylaxis: Does not address • 17OCT96. DoD\HA. Policy for Tick-Borne Encephalitis Preventive Measures for DoD Personnel Deployed to Endemic Areas. For Joint Endeavor personnel under Commander-in-Chief Europe. Do not routinely

		immunize; use personal preventive measures. However, personnel at high risk should be considered. Requests to be approved by USCINCEUR. Must comply strictly with Investigational New Drug protocol; informed consent required.
Typhoid		• Joint Instruction on Immunizations and Chemoprophylaxis: Alert forces; high risk travel
Yellow Fever		• Joint Instruction on Immunizations and Chemoprophylaxis: Required for all alert forces, active duty personnel, or reserve component traveling to yellow fever endemic areas. • Boost q 10 yrs

EXHIBIT C-3
AIR FORCE IMMUNIZATION POLICY FOR SPECIAL OPERATIONAL AND OCCUPATIONAL GROUPS

SPECIAL GROUP	VACCINES ADMINISTERED TO AIR FORCE SPECIAL GROUPS PERSONNEL IN ADDITION TO ROUTINE IMMUNIZATIONS
High risk occupational groups	Joint Instruction on Immunizations and Chemoprophylaxis. **Hepatitis B, MMR, plague, rabies, varicella**
Medical personnel and other health care workers	**Hepatitis B.** Joint Instruction on Immunizations and Chemoprophylaxis: Health care workers, OSHA standards. **Hepatitis B.** 23OCT96. DoD/HA. Hepatitis B Immunization Policy for DoD Medical and Dental Personnel. All required to complete three-dose series unless documentation or contraindication. **MMR.** Joint Instruction on Immunizations and Chemoprophylaxis. Following ACIP requirements, those born before 1957 require proof of immunity.
Animal handlers; veterinary personnel; certain laboratory, field, and security personnel; personnel frequently exposed to potentially rabid animals in occupational or recreational setting	**Rabies.** Joint Instruction on Immunizations and Chemoprophylaxis. Preexposure series in accord with ACIP.
Firefighters	**Hepatitis B.** 26MAR97. AMC Memo: Mobility Immunization Requirements.
Anyone who needs to know first aid as part of job description	**Hepatitis B**

EXHIBIT C-4
AIR FORCE IMMUNIZATION POLICY FOR RESERVE FORCES

VACCINE	AIR FORCE RESERVE FORCES POLICY
All Vaccines	• Joint Instruction on Immunizations and Chemoprophylaxis: Individuals called to active duty for 30 days or more immunized

	• All reservists go through basic training and technical school; receive vaccines administered to enlisted recruits and officer accessions
Hepatitis A	• Joint Instruction on Immunizations and Chemoprophylaxis: Alert Forces, Deploying to High Risk Areas • 10SEP96. ASD/HA. Policy for the Use of Hepatitis A virus (HAV) Vaccine and Immune Globulin (IG). Accelerate Hepatitis A immunization for total active duty and selected reserve force by 31DEC98. • 12AUG96. DoD/HA. Policy for Use of Hepatitis A Virus (HAV) Vaccine and Immune Globulin (IG). Reserve personnel on mobility status who are targeted for early deployment to high risk areas.
Hepatitis B	• Joint Instruction on Immunizations and Chemoprophylaxis: High risk occupational groups; as directed • 3JAN97. HQ, Air Mobility Command (AMC). Hepatitis B for Air Reserve Component medical healthcare facility and aeromedical personnel.
Influenza	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Reserves called to active duty for 30 days or more • 9SEP97. AFMOA. 97-98 Influenza Immunizations and Surveillance Program. Requires vaccination of reserve component personnel.
Meningococcal	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits, High risk travel • 3JAN97. HQ, Air Mobility Command (AMC). Identifies specific immunization requirements for AMC personnel. Air Force Reserve Component (ARC) on active flying status and in mobility positions. Initial series and booster every 3 years. • 12JUL96. HQ AFRES/SGP. Hepatitis A and Meningococcal Immunization Requirements for Air Force Reserve Personnel. Given fiscal constraints, sets priorities: (1) any Air Force Reserve member who deploys OCONUS must have, or be current in , both vaccines; (2) all personnel on flying status: (3) all medical personnel; and (4) all other reserve personnel
Varicella	• Joint Instruction on Immunizations and Chemoprophylaxis: High risk occupational groups; as directed

APPENDIX D
COAST GUARD IMMUNIZATION POLICIES

EXHIBIT D-1
COAST GUARD IMMUNIZATION POLICY FOR ENLISTED RECRUITS AND OFFICER ACCESSIONS

VACCINE	COAST GUARD ENLISTED RECRUITS	COAST GUARD OFFICER ACCESSIONS
Adenovirus	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: As directed	
Anthrax	**Not yet determined**	**Not yet determined**
Influenza	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits • 22JUL97, *Influenza Immunization Program.* Mandatory for recruits.	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: All officer candidate, recruit, and cadet populations during influenza season • 22JUL97, *Influenza Immunization Program.* Mandatory for officer accessions and cadets
MMR/MR	**MR** • Joint Instruction on Immunizations and Chemoprophylaxis: Measles and rubella, yes; mumps, as directed	**MR** • Joint Instruction on Immunizations and Chemoprophylaxis: Measles and rubella, yes; mumps, as directed • MMR required for Service Academy; MR for other officer accessions
Meningococcal	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits; as directed	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Does not require • Administered at Academy
Poliomyelitis (OPV)	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: All active duty personnel	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Officer accessions and Academy
Tetanus-diphtheria	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Officer accessions
Yellow Fever	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: All accessions

EXHIBIT D-2
COAST GUARD IMMUNIZATION POLICY FOR ROUTINE ACTIVE DUTY AND PERSONNEL TRAVELING OR DEPLOYING TO HIGH RISK AREAS

Note: Commanders in Chief for OCONUS regional commands (CINCs) can require other immunizations; these AOR (area of operations) requirements are separate and distinct from Coast Guard or other service requirements.

VACCINE	COAST GUARD ROUTINE ACTIVE DUTY	COAST GUARD HIGH RISK TRAVEL OR DEPLOYMENT
Cholera		• Joint Instruction on Immunizations and Chemoprophylaxis: Only when required by host country • DEC96. CDC's *Health Information for International Travel 1996-97*. "Currently no country or territory requires vaccination for entry. Local authorities, however, may"
Hepatitis A	• Joint Instruction on Immunizations and Chemoprophylaxis: As directed • Coast Guard to immunize active duty by 31DEC98	• Joint Instruction on Immunizations and Chemoprophylaxis: As directed • **Hepatitis A.** 8DEC95, *COMDINST 6230.8, Hepatitis A Immunizations and Prophylaxis.* Military personnel traveling or deploying for more than 90 days to high risk areas; likely to require repeated IG for repetitive high risk travel ; alert forces with a high likelihood of exposure to unsafe food or water sources, due to rapid deployment to high risk areas. Immunize unit after consultation with Commandant (G-KOM).
Influenza	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Alert forces, as directed	
Japanese Encephalitis Virus		• Joint Instruction on Immunizations and Chemoprophylaxis: As directed
Meningococcal		• Joint Instruction on Immunizations and Chemoprophylaxis: As directed

Poliomyelitis (OPV)	**Administered during recruit/accession training** • Joint Instruction on Immunizations and Chemoprophylaxis: All active duty personnel	
Tetanus-diphtheria	**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: All active duty personnel	
Typhoid		• Joint Instruction on Immunizations and Chemoprophylaxis: High risk travel
Yellow Fever		**Yes** • Joint Instruction on Immunizations and Chemoprophylaxis: Recruits, alert forces, required by host country • Boost q 10 yrs

EXHIBIT D-3
COAST GUARD IMMUNIZATION POLICY FOR SPECIAL OPERATIONAL AND OCCUPATIONAL GROUPS

VACCINE	VACCINES ADMINISTERED TO COAST GUARD SPECIAL GROUPS PERSONNEL IN ADDITION TO ROUTINE IMMUNIZATIONS
Hepatitis A	• Joint Instruction on Immunizations and Chemoprophylaxis: As directed **Hepatitis A.** 8DEC95, *COMDINST 6230.B,, Hepatitis A Immunizations and Prophylaxis.* Policy affects special groups: 1. Active duty and reserves personnel assigned to Port Security Units (PSUs), Harbor Defense Commands (HDCs), and Composite Naval Coastal Units (CNCUs). 2. All active duty and reserve subsistence specialists (SS) and food handlers.
Hepatitis B	• Joint Instruction on Immunizations and Chemoprophylaxis: High Risk Occupational Groups *and* As directed • 26AUG94, *COMDTINST M6220.9 Chapter 2, Section B.* Alien Migrant Interdiction Operations environment does not necessitate routine immunization for hepatitis B. Health services personnel shall be immunized and emergency medical technicians are strongly recommended to be immunized.
Rabies	• Joint Instruction on Immunizations and Chemoprophylaxis: As directed • Coast Guard does not have high-risk personnel groups who should receive preexposure rabies vaccination

EXHIBIT D-4
COAST GUARD IMMUNIZATION POLICY FOR RESERVE FORCES

VACCINE	COAST GUARD RESERVE FORCES
All Vaccines	• Joint Instruction on Immunizations and Chemoprophylaxis: Reserve personnel called to active duty for 30 days or more are immunized in accordance with service requirements in Joint Instruction on Immunizations and Chemoprophylaxis.
Hepatitis A	• Joint Instruction on Immunizations and Chemoprophylaxis: As directed • **Hepatitis A.** 8DEC95, *COMDINST 6230.B, Hepatitis A Immunizations and Prophylaxis.* Authorized for personnel with a high likelihood of repetitive travel to high risk geographic areas, who would otherwise require repetitive administration of IG; reserve personnel assigned to Port Security Units (PSUs), Harbor Defense Commands (HDCs), and Composite Naval Coastal Units (CNCUs); all reserve subsistence specialists (SS) and food handlers.
Hepatitis B	• Joint Instruction on Immunizations and Chemoprophylaxis: High Risk Occupational; As directed • 26AUG94, *COMDTINST M6220.9, Chapter 2, Section B.* Alien Migrant Interdiction Operations environment does not necessitate routine immunization for hepatitis B. Health services personnel shall be immunized and emergency medical technicians are strongly recommended to be immunized.
Influenza	• Joint Instruction on Immunizations and Chemoprophylaxis: Recruits, alert forces, as directed • **Influenza.** 22JUL97, *Influenza Immunization Program.* Mandatory for reserves designated by the district commander.

APPENDIX E

Copies of the Recent AFEB Recommendations Pertaining to Vaccine Use and Policy

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

THE EXECUTIVE SECRETARY
ARMED FORCES EPIDEMIOLOGICAL BOARD
OFFICE OF THE SURGEON GENERAL
DEPARTMENT OF THE ARMY
WASHINGTON, D.C. 20310
(202) 695-9115

DASG-AFEB 84-6

28 June 1984

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Hepatitis B Vaccine Use in the U.S. Disciplinary Barracks and Personnel Assigned to Korea

1. At the request of the Preventive Medicine Consultants Division, Office of the Army Surgeon General, the Armed Forces Epidemiological Board (AFEB), at its 22 June 1984 meeting was requested to provide recommendations concerning the administration of hepatitis B vaccine to staff and inmate personnel in the United States Disciplinary Barracks (USDB) and the advisability of hepatitis B immunization of U.S. military personnel assigned to Korea.

2. The experience with the hepatitis B vaccine, since its licensure in November 1981, has confirmed its safety, immunogenicity and efficacy. Hepatitis B vaccine is recommended for persons at high risk of infection. Potential consequences of hepatitis B infection include: (1) an acute illness with morbidity lasting several weeks to several months; (2) chronic active hepatitis that may be associated with a chronic carrier state; and (3) cirrhosis and/or primary cancer of the liver. Among the groups at high risk of infection for whom the vaccine is recommended are prisoners in the United States and persons likely to be exposed in areas of high endemicity.

3. Data provided to the Board for the period May 1982-June 1983 indicated that hepatitis B virus (HBV) infections are endemic in the USDB and that the incidence of intra-prison HBV transmissions was 1.7% per year. Because USDB prisoners are demonstrated to be at high risk to HBV the Board recommends that:

a. ALL PRISONERS BE IMMUNIZED WITH THE HEPATITIS B (HB) VACCINE AS SOON AFTER CONFINEMENT AS POSSIBLE. RECOMMENDATIONS AS TO VACCINE USE FOR STAFF PERSONNEL WILL BE PROVIDED BY THE BOARD FOLLOWING REVIEW OF SUSCEPTIBILITY AND INCIDENCE STUDIES PRESENTLY UNDER INVESTIGATION.

4. Information provided the Board for calendar year 1983 demonstrated that the risk of HBV infection among United States military personnel during a tour

DASG-AFEB 84-6

SUBJECT: Hepatitis B Vaccine Use in the U.S. Discplinary Barracks and Personnel assigned to Korea

in Korea was six (6) percent and that the majority of these infections occur during the early months of the tour. Due to this high rate of infection, the Board recommends that:

a. *PERSONNEL ASSIGNED TO KOREA BE IMMUNIZED WITH THE HB VACCINE WITH AT LEAST ONE TO TWO DOSES CONSISTENT WITH THE STANDARD SCHEDULE AND THE EXIGENCIES OF TIME PRIOR TO EMBARKATION.*

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

ROBERT F. NIKOLEWSKI
COL, USAF, BSC
Executive Secretary

CF:
Board Members
Cmd Surgeon, Military Airlift Cmd, USAF
Ch, Prev Med Div, OTSG-DA
Ch, Prev Med Div, OTSG-DAF
Dir, Occup & Prev Med Div, BUMED-DN
ASD (HA Spec Asst Prof Act)
Cmdr, US Army Med R&D Cmd

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

THE EXECUTIVE SECRETARY
ARMED FORCES EPIDEMIOLOGICAL BOARD
OFFICE OF THE SURGEON GENERAL
DEPARTMENT OF THE ARMY
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DASG-AFEB 85-5 5 March 1985

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Route of Administration and Dosage of the Currently Licensed Hepatitis B Vaccine

1. At the request of the Preventive Medicine Consultants Division, Office of the Army Surgeon General, the Armed Forces Epidemiological Board, at its 28 February - 1 March 1985 meeting, was asked to consider whether there is an alternative route of administration or dosage for mass inoculation of the currently licensed hepatitis B vaccine other than the standard of 1.0 ml (20 mcg) dose injected intramuscularly at zero, one and six months.

2. After discussion and comprehensive review by the Subcommittee on Disease Control, the Board reaffirms its recommendations of 28 June 1984 (DASG-AFEB 84-6) relative to immunization with the hepatitis B virus vaccine and further recommends that:

a. IN THE EVENT IT IS ECONOMICALLY NOT FEASIBLE TO ADMINISTER THE STANDARD REGIMEN AS PREVIOUSLY RECOMMENDED AND, BASED ON THE RECENT DATA PROVIDED THE BOARD BY SCIENTISTS AT THE WALTER REED ARMY INSTITUTE OF RESEARCH, A PROVISIONAL ALTERNATIVE WOULD BE INTRADERMAL ADMINISTRATION OF THE HEPATITIS B VACCINE. SUCH ADMINISTRATION SHOULD CONSIST OF THREE DOSES OF 0.1 ml (2 mcg per dose) OF HEPATITIS B VIRUS VACCINE AT ZERO, ONE AND TWO TO SIX MONTHS. AT LEAST TWO AND PREFERABLY THREE DOSES SHOULD BE ADMINISTERED PRIOR TO THE MOVEMENT OF PERSONNEL INTO HIGH-RISK AREAS.

b. THE OFFICE OF THE ARMY SURGEON GENERAL SHOULD UNDERTAKE TO EVALUATE THE USEFUL EFFICACY OF THIS ALTERNATIVE REGIMEN, ESPECIALLY AS IT RELATES

DASG-AFEB 85-5

SUBJECT: Route of Administration and Dosage of the Currently Licensed Hepatitis B Vaccine

TO ANTIBODY PRODUCTION IN INDIVIDUALS, AS WELL AS PROTECTION AGAINST CLINICAL DISEASE DUE TO THE HEPATITIS B VIRUS.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

ROBERT F. NIKOLEWSKI
COL, USAF, BSC
Executive Secretary

CF:

Board Members
Cmdr, HQ USAF Med Serv Ctr
Ch, Prev Med Div, OTSG-DA
Ch, Prev Med Div, OTSG-DAF
Dir, Occup & Prev Med Div, BUMED-DN
Dep ASD(HA) - PAQA
Cmdr, US Army Med R&D Cmd

DEPARTMENT OF THE NAVY
NAVAL MEDICAL COMMAND
WASHINGTON, D.C. 20372-5120

IN REPLY REFER TO
5420/1
Ser 241/0394
05 AUG 1985

From: Commander, Naval Medical Command
To: Executive Secretary, Armed Forces Epidemiological Board, Washington, DC 20310-2300
Via: Chief of Naval Operations (OP-093), Navy Department, Washington, DC 20350-2000

Subj: AGENDA ITEM FOR SEPTEMBER 1985 MEETING OF THE ARMED FORCES EPIDEMIOLOGICAL BOARD (AFEB)

1. It is requested that the following query be discussed at the September 1985 meeting (or subsequent meeting, if necessary) of the AFEB for the benefit of the uniformed services.

a. Asplenic individuals in the services can be categorized as follows:

- Congenital asplenics - recognized only incidentally
- Surgical asplenics - secondary to pre-service surgery
- Surgical asplenics - secondary to surgery following commencement of active duty.

b. An asplenic individual's increased susceptibility to various infections of military importance, and to the post-splenectomy sepsis syndrome (PSSS) requires that close attention be paid to those individuals' deployability and immunization requirements. In particular, the requirements for meningococcal vaccine, pneumococcal vaccine and possibly Haemophilus influenzae vaccine must be evaluated.

2. It is requested that the Board determine the immunization requirements for each of the three categories, and that immunization schedules, particularly addressing the temporal relationship between the splenectomy and the immunization, be recommended for the services.

3. The point of contact at this command is CAPT W. B. Mahaffey, MC, USN, MEDCOM-241, Autovon: 294-1338 or Commercial: (202) 653-1338.

J. S. CASSELLS

Copy to:
CO NAVENVIRHLTHCEN Norfolk, VA

DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
WASHINGTON, DC 20350-2000

IN REPLY REFER TO
5420
Ser 093(933)/1048
9 August 85

FIRST ENDORSEMENT on NAVMEDCOM ltr 5420/1 Ser 241/0394 of 5 Aug 85

From: Chief of Naval Operations
To: Executive Secretary, Armed Forces Epidemiological Board, Washington, DC 20310-2300

Subj: AGENDA ITEM FOR SEPTEMBER 1985 MEETING OF THE ARMED FORCES EPIDEMIOLOGICAL BOARD (AFEB)

1. Forwarded recommending inclusion in the subject agenda.

Lewis H. Seaton

LEWIS H. SEATON
Director, Naval Medicine

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

THE EXECUTIVE SECRETARY
ARMED FORCES EPIDEMIOLOGICAL BOARD
OFFICE OF THE SURGEON GENERAL
DEPARTMENT OF THE ARMY
WASHINGTON, D.C. 20310-2300
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DASG-AFEB 85-9

25 September 1985

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Immunization of Asplenic Personnel

1. At the request of the Commander, Naval Medical Command, Washington, D.C., the Armed Forces Epidemiological Board (AFEB) members and consultants considered a set of questions on asplenic military personnel (Enclosure 1) during the fall meeting of the Board at Parson's Island, Maryland.

2. Although asplenic individuals have been shown to produce lower levels of antibody in response to some antigenic stimuli than those with intact spleens, they withstand common infectious agents including viruses as well. However, asplenic individuals may fail to control infections by encapsulated bacteria such as Streptococcus pneumoniae, Neisseria meningitidis and Haemophilus influenzae. Vaccines for these infections are available. In addition, blood protozoal infections (malaria, babesiosis) may not be resisted as well as by the normal host. The post-splenectomy sepsis syndrome, however, is a rare event.

3. It has been reported that significantly higher antibody titers against pneumococci develop if vaccine is administered to traumatized persons before splenectomy than afterwards. There is an antibody response in either instance.

4. Based on the preceding information, the Board recommends:

a. ALL PERSONNEL KNOWN TO BE ASPLENIC SHOULD RECEIVE ONE DOSE OF PNEUMOCOCCAL POLYVALENT VACCINE. A SECOND DOSE NEED NOT BE GIVEN.

b. IT SHOULD BE ESTABLISHED THAT ALL ASPLENIC PERSONS HAVE RECEIVED QUADRIVALENT MENINGOCOCCAL VACCINE UPON ENTRY INTO THE SERVICE. IF NOT, THIS VACCINE SHOULD BE GIVEN.

DASG-AFEB 85-9

SUBJECT: Immunization of Asplenic Personnel

c. VACCINE AGAINST INFLUENZA B SHOULD BE ADMINISTERED TO ALL ASPLENIC INDIVIDUALS.

d. ACTIVE DUTY PERSONNEL WHO REQUIRE SPLENECTOMY SHOULD BE GIVEN THE PNEUMOCOCCAL AND H. INFLUENZAE VACCINE PRIOR TO REMOVAL OF THE TRAUMATIZED SPLEEN IF FEASIBLE.

e. ASPLENIC PERSONS SHOULD BE COUNSELED REGARDING THE IMPORTANCE FOR THEM TO COMPLY WITH ALL ANTI-MALARIAL MEASURES, ESPECIALLY THOSE RELATED TO THE USE OF PROPHYLACTIC DRUGS.

f. IN AREAS WHERE BABESIOSIS IS PREVALENT, ANTI-TICK MEASURES SHOULD BE EMPLOYED.

g. NO RESTRICTIONS ON DEPLOYMENT ARE NECESSARY FOR ASPLENIC PERSONNEL.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

THEODORE E. WOODWARD, M.D.
President, AFEB

ROBERT A. WELLS, Ph.D.
LTC(P), USA, MSC
Executive Secretary

Encl

CF:
Board Members
Cmdr, HQ USAF SGP
Ch, Prev Med Div, OTSG-DA
Ch, Prev Med Div, OTSG-DAF
Dir, Occup & Prev Med Div, BUMED-DN
Dep ASD(HA) - PAQA
Cmdr, US Army Med R&D Cmd

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

THE EXECUTIVE SECRETARY
ARMED FORCES EPIDEMIOLOGICAL BOARD
OFFICE OF THE SURGEON GENERAL
DEPARTMENT OF THE ARMY
WASHINGTON, D.C. 20310
(202) 695-9115

DASG-AFEB 86-3

18 APR 1986

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Additional Study, B Component, Armed Forces Influenza Vaccine

1. On 14 April 1986, the Disease Control Subcommittee of the AFEB reviewed appropriate data and subsequently rendered its recommendation for the Armed Forces influenza vaccine for the 1986-1987 flu season.

2. The data reviewed indicated that fifteen (15) micrograms of the B virus component of the 1985-86 vaccine (B/USSR/100/83) induced a poor antibody response to itself and an even poorer response to B viruses prevalent in 1985-86. Protection against influenza B disease was marginal in both civilian and military populations. In addition to substituting a more recent B strain (B Ann Arbor) in the vaccine as recommended in the 1986-87 formulation, it may be appropriate to increase the amount of this antigen in future vaccines if this can be achieved without a significant increase in adverse reactions. The AFEB therefore recommends that:

FURTHER STUDIES BE UNDERTAKEN TO EXAMINE THE ANTIBODY RESPONSE TO INCREASED AMOUNTS OF THE B ANN ARBOR INFLUENZA COMPONENT PRIOR TO THE 1987-1988 INFLUENZA SEASON.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Robert A. Wells

ROBERT A. WELLS, Ph.D.
Colonel, USA, MSC
Executive Secretary

Copies Furnished:

Board Members
Cmd Surgeon, Military Airlift Cmd, USAF
Ch, Prev Med Div, OTSG-DA
Ch, Prev Med Div, OTSG-DAF
Dir, Occup & Prev Med Div, BUMED-DN
ASD (HA Spec Asst Prof Act)

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

THE EXECUTIVE SECRETARY
ARMED FORCES EPIDEMIOLOGICAL BOARD
OFFICE OF THE SURGEON GENERAL
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WASHINGTON, D.C. 20310-2300
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DASG-AFEB 86-5 7 July 1986

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation on Japanese B Encephalitis Prevention

1. At the request of the Surgeon General, Air Force, the Armed Forces Epidemiological Board (AFEB) addressed the above issue at its 30 June - 1 July 1986 meeting.

2. The AFEB defers making a definitive recommendation of a specific vaccine for Japanese B Encephalitis awaiting further data on safety and effectiveness. In the meantime, it is recommended that the Armed Forces take steps to provide authority to procure the existing inactivated Japanese B Encephalitis vaccine distributed by the Centers for Disease Control to State Department personnel and other travelers to endemic areas for use by military personnel and dependents assigned to high-risk areas for this disease should such interim use be desirable.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

THEODORE E. WOODWARD, M.D.
President, AFEB

ROBERT A. WELLS, Ph.D.
Colonel, USA, MSC
Executive Secretary

Copies Furnished:

Board Members
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Ch, Prev Med Div, OTSG-DAF
Dir, Occup & Prev Med Div, BUMED-DN
ASD (HA Spec Asst Prof Act)
Cmdr, US Army Med R&D Cmd

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

THE EXECUTIVE SECRETARY
ARMED FORCES EPIDEMIOLOGICAL BOARD
OFFICE OF THE SURGEON GENERAL
DEPARTMENT OF THE ARMY
WASHINGTON, D.C. 20310-2300
(202) 695-9115

DASG-AFEB 86-6

7 July 1986

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Federal Malaria Vaccine Programs

1. Periodically, and not less frequently than once each year, the Board discusses the problem of malaria including measures aimed at its prevention and treatment. During its meeting of 30 June - 1 July 1986, the Board heard a series of presentations on malaria vaccine development programs within the federal sector. This was in response to a 28 May 1986 letter from Dr. J. Jarrett Clinton on behalf of the Assistant Secretary of Defense (Health Affairs). The central presentation was a comprehensive overview by Colonel Carter Diggs, coordinator of the Unified Armed Forces program. An in-depth review indicated that considerable concurrent activity has been effected since the program's inception in 1979. Agencies involved have included WRAIR, NAMRI, NIAID/NIH, CDC, USAID and WHO. It is clear that there has been significant coordination and collaboration among our federal organizations.

2. The Subcommittee on Disease Control met in executive session to examine the extensive information provided during the presentations. The Board subsequently endorsed recommendations concerning the four questions raised in Dr. Clinton's letter. Specifically, the following recommendations are provided:

a. *THE MILITARY SPONSORED RESEARCH ACTIVITIES FOR MALARIA VACCINE DEVELOPMENT ARE BOTH UNIQUE AND COMPLIMENTARY TO OTHER SIMILAR ACTIVITIES. TWO CANDIDATE CIRCUMSPOROZOITE ANTIGEN VACCINES ARE NOW AVAILABLE: A RECOMBINANT EXPRESSED ANTIGEN DEVELOPED BY WRAIR AND NIAID (INTRAMURAL) AND A SYNTHETIC ANTIGEN DEVELOPED BY NYU, USAID AND NIAID (EXTRAMURAL). THE AVAILABILITY OF TWO CANDIDATE VACCINES WITH DIFFERENT FORMULATIONS AND DIFFERENT INDUSTRIAL PRODUCERS IS TO BE COMMENDED.*

DASG-AFEB 86-6

SUBJECT: Federal Malaria Vaccine Programs

b. THE MILITARY RESEARCH ESTABLISHMENT SHOULD CONTINUE TO CONCENTRATE ON TWO MAJOR RESEARCH TOPICS: THE SEARCH FOR EFFECTIVE DRUGS FOR CHEMOPROPHYLAXIS AND TREATMENT; THE DEVELOPMENT AND TESTING OF VACCINES.

c. THE MILITARY'S RESEARCH PROGRAM IS ALREADY CLOSELY INTEGRATED WITH OTHER FEDERAL PROGRAMS, ALTHOUGH IT IS EVIDENT THAT THE MILITARY AND USAID HAVE SOMEWHAT DIFFERENT OBJECTIVES.

d. THE WRAIR/NIAID/CDC (AGENCY SPECIFIC) FIELD TRIALS PROPOSED FOR KENYA HAVE BEEN CAREFULLY PLANNED AND COULD SERVE AS A PROTOTYPE FOR TRIALS SPONSORED BY USAID, WHO OR OTHERS.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

Theodore E. Woodward

Robert A. Wells

THEODORE E. WOODWARD, M.D.
President, AFEB

ROBERT A. WELLS, Ph.D.
Colonel, USA, MSC
Executive Secretary

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DASG-AFEB 86-7

30 July 1986

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Revised Composition and Dosage of the 1986-1987 Influenza Vaccine

1. The infectous disease consultant membership of the AFEB was asked to render a decision regarding a supplemental A influenza vaccine. This request was through a 25 July 86 letter with supporting data from the U.S. Public Health Service addressing apparent recent antigenic drift in viral isolates collected from Southeast Asia. The information was forwarded by the Office of the Assistant Secretary of Defense (Health Affairs) with the knowledge/concurrence of key senior staff officers of the military medical departments. As a result of its deliberations, the Armed Forces Epidemiological Board recommends that:

a. The trivalent vaccine for 1986-1987 consisting of the A/Chile 1/83 (H_1N_1), A/Mississippi 1/85(H_3N_2) and the B Ann Arbor 1/86 components as contained in AFEB recommendation 86-2 be supplemented with a vaccine for A/Taiwan 1/86.

b. Contingent upon acquisitions and manufactruing requirements, the vaccine should preferably consist of a quadravalent vaccine containing fifteen (15) micrograms of each of the four components per dose.

c. If conditions do not permit the manufacture of a quadravalent vaccine, a supplemental vaccine for A/Taiwan 1/86 containing fifteen (15) micrograms per dose should be produced.

d. Whole or split vaccines should be utilized depending on contractural arrangements and supplies from the manufacturers.

DASG-AFEB 86-7

SUBJECT: Revised Composition and Dosage of the 1986-1987 Influenza Vaccine

e. Recruits and permanent party military should be immunized with single doses of the quadravalent vaccine or trivalent vaccine with a monovalent supplemnet, as conditions dictate.

f. In addition, the Board recommends that stockpiles of Amantadine be increased as a contingency measure prior to the upcoming influenza season.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

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DASG-AFEB 87-1

23 October 1986

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation on Japanese B Encephalitis Prevention

1. At the request of the Surgeon General, Air Force, the Armed Forces Epidemiological Board (AFEB) first addressed the above issue at its 30 June - 1 July 1986 meeting. At that time, the AFEB deferred final recommendations pending the availability of further data on safety and effectiveness.

2. The AFEB review on 16-17 October 1986 centered on field trials carried out in Thailand which evaluated the efficacy and safety of vaccines against Japanese encephalitis. Both the inactivated monovalent (Nakayama strain of virus) and the bivalent (Nakayama and Beijing strains) have shown excellent protection. Data available from the Centers for Disease Control indicate that these vaccines elicited adequate levels of neutralizing antibody in previously nonexposed adult Americans. Accordingly, the Board recommends that:

THE MILITARY SERVICES PROCURE EITHER THE MONOVALENT OR BIVALENT JAPANESE ENCEPHALITIS VACCINE FOR USE BY MILITARY PERSONNEL AND DEPENDENTS ASSIGNED TO HIGH-RISK AREAS FOR THIS DISEASE SHOULD SUCH USE BE DESIRABLE.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

THEODORE E. WOODWARD, M.D.
President, AFEB

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DASG-AFEB 87-2

23 October 1986

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation on Tetanus Toxoid Purity

1. At the request of the Chief, Preventive Medicine Consultants Division, Office of the U.S. Army Surgeon General, the Armed Forces Epidemiological Board (AFEB) considered the issue of minimal purity specifications for tetanus toxoids. A review of data, background information and comments by a representative from the Defense Medical Standardization Board were heard by the Board during its meeting of 16-17 October 1986.

2. During its review of this matter, the Board discovered that tetanus toxoid standards, which were intended primarily for the adult tetanus diphtheria toxoid (Td), had been extended to all vaccines for the military which contained tetanus toxoid as one of its components. Discussions of the problem related to tetanus toxoids focused on stock items such as Diphtheria and Tetanus Toxoids and Pertussis Vaccine, adsorbed (DTP). The Board recommends that:

a. THE TETANUS COMPONENT OF STOCK ITEMS, 6505-00-299-8296 (5 ml) AND 6505-00-864-5249 (30 ml) - TETANUS AND DIPHTHERIA TOXOIDS FOR ADULT USE, ADSORBED (Td) HAVE A LEVEL OF PURITY OF NOT LESS THAN 1200 Lf/mg-N.

b. THE TETANUS COMPONENT OF OTHER VACCINES SUCH AS DTP SHOULD MEET THE POTENCY AND PURITY REQUIREMENTS OF THE FOOD AND DRUG ADMINISTRATION.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

THEODORE E. WOODWARD, M.D.
President, AFEB

ROBERT A. WELLS, Ph.D.
Colonel, USA, MSC
Executive Secretary

DASG-AFEB 87-2

SUBJECT: Recommendation on Tetanus Toxoid Purity

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DASG-AFEB 87-6

20 April 1987

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Composition and Dosage of the 1987-1988 Influenza Vaccine

1. The infectious disease consultant membership of the AFEB has considered the formulation of the 1987-1988 influenza vaccine and proposes that this be consistent with recommendations made by the Public Health Service. Recent meetings of the U.S. Public Health Service and the World Health Organization have concluded that distinct antigenic variants have occurred requiring changes in two of the three components from the 1986-1987 vaccine. Based on this information, the Armed Forces Epidemiological Board recommends that:

a. THE TRIVALENT INFLUENZA VACCINE FOR 1987-1988 CONSIST OF THE A/TAIWAN 1/86 (H_1N_1), A/LENINGRAD 360/86 (H_3N_2), AND B/ANN ARBOR 1/86 COMPONENTS.

b. THE VACCINE SHOULD CONTAIN FIFTEEN (15) MICROGRAMS OF EACH OF THE THREE ANTIGENS PER DOSE.

c. WHOLE OR SPLIT VACCINES SHOULD BE UTILIZED DEPENDING ON CONTRACTUAL ARRANGEMENTS AND SUPPLIED FROM THE MANUFACTURERS.

d. RECRUITS AND ACTIVE DUTY PERSONNEL SHOULD BE IMMUNIZED WITH A SINGLE DOSE OF VACCINE.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

THEODORE E. WOODWARD, M.D.
President, AFEB

ROBERT A. WELLS, Ph.D.
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DASG-AFEB (15-1a) 88-4 21 March 1988

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Composition and Dosage of the 1988-1989 Influenza Vaccine

1. The infectious disease consultant membership of the AFEB has considered the formulation of the 1988-1989 influenza vaccine and proposes that this be consistent with recommendations made by the Public Health Service and the FDA's Vaccine and Related Products Advisory Committee. Based on this information, the Armed Forces Epidemiological Board recommends that:

a. THE TRIVALENT INFLUENZA VACCINE FOR 1988-1989 CONSIST OF THE A/SINGAPORE 6/86 (H_1N_1), A/SICHUAN 2/87 (H_3N_2) AND B/BEIJING 1/87 COMPONENTS.

b. THE VACCINE SHOULD CONTAIN FIFTEEN (15) MICROGRAMS OF EACH OF THE THREE ANTIGENS PER DOSE.

c. WHOLE OR SPLIT VACCINES SHOULD BE UTILIZED DEPENDING ON CONTRACTUAL ARRANGEMENTS AND SUPPLIES FROM THE MANUFACTURERS.

d. RECRUITS AND ACTIVE DUTY PERSONNEL SHOULD BE IMMUNIZED WITH A SINGLE DOSE OF VACCINE.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

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REPLY TO ATTENTION OF

30 AUG 1988

SGPS-PSP-D

MEMORANDUM FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

SUBJECT: Hepatitis B Immunization of Health Care Workers, Booster Immunizations, and Alternative Regimens for Administration of Hepatitis B Vaccine

1. Reference:

a. Publication, "Update on Hepatitis B Prevention," Morbidity and Mortality Weekly Report, Centers for Disease Control, 36:353-360, 366, 19 June 1987.

b. OSHA Instruction CPL 2-2-44, "Enforcement Procedures for Occupational Exposure to Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV), and Other Blood-borne Infectious Agents in Health Care Facilities," U.S. Department of Labor, 19 January 1988.

2. In view of the increasing incidence of hepatitis B over the last decade and the occupational risk to health care workers, the U.S. Public Health Service has recommended pre-exposure vaccination of health-care workers having potential blood or needle-stick exposures (Enclosure 1). In addition, vaccinated persons who experience percutaneous or needle exposure to HBsAg-positive blood should be serologically tested before a decision is made to receive hepatitis B immune globulin and/or a booster dose of hepatitis B vaccine.

3. The Department of Labor has also indorsed immunization of health care workers and has made the availability of hepatitis B vaccine an item of concern in future OSHA inspections of health care facilities. Occupations considered to be at high risk for blood-borne infections include but are not limited to surgeons, pathologists, dentists, dental technicians, phlebotomists, and emergency room, intensive care and operating room nurses and technicians. Housekeeping personnel, laundry workers, orderlies, and central supply personnel are considered to be at low risk, with ward clerks and administrators at virtually no risk of contact with blood and/or body fluids (Enclosure 2).

4. Considering the peacetime and wartime missions of medical personnel in all specialities and the risk of blood and/or body fluid exposure, should the Army adopt a mandatory program of hepatitis B vaccination for all health care providers, or should such a program be more occupationally selective, as recommended in paragraph 3 above?

5. Since declining titers of antibody will occur in previously vaccinated persons, should boosters be routinely administered to individuals at significant risk of exposure? If so, what should the interval between vaccinations be to insure protection? An interval of five years has been proposed.

6. For personnel needing long-term protection, can vaccine costs be further reduced with the intramuscular administration of smaller doses of recombinant or plasma-derived hepatitis B vaccine without significant reduction in immunity level?

7. Request that The Armed Forces Epidemiological Board address these questions at the fall meeting.

FOR THE SURGEON GENERAL:

William H. Bell LTC, MS

MICHAEL J. SCOTTI, JR.
Brigadier General, Medical Corps
Director, Professional Services

WILLIAM H. BELL
Lieutenant Colonel, MS
Executive to Director

DEPARTMENT OF DEFENSE
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AFEB (15-1a) 88-6 4 October 1988

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendations on Hepatitis B

1. At the request of the Department of the Army Surgeon General, The Armed Forces Epidemiological Board (AFEB) considered at its 29-30 September 1988 meeting, a request for the review of and advice on the Army's hepatitis B immunization program. A copy of the questions posed to the Board is provided at Enclosure 1.

2. a. Available medical data were examined regarding the question on vaccination of health care workers. Based on the Potential exposure of all military personnel to blood, it was recommended that:

> IMMUNIZATION AGAINST HEPATITIS B SHOULD BE PLANNED AND BECOME A PART OF THE BASIC IMMUNIZATIONS OF ALL MILITARY PERSONNEL. INITIAL EMPHASIS SHOULD BE PLACED ON THE IMMUNIZATION OF ALL HEALTH CARE WORKERS, WITH HIGHEST PRIORITY FOR THOSE LISTED BY THE DEPARTMENT OF LABOR TO BE AT GREATEST RISK.

b. Additional discussions took place concerning various hepatitis B immunization schedules and routes in order to advise the Army on these key issues. Available information indicated that reducing the intradermal dose of vaccine may evoke satisfactory antibody responses. However, if economic consideration preclude the administration of vaccine by the intramuscular route, it is recommended that:

> THE HEPATITIS B VACCINE BE ADMINISTERED BY THE INTRADERMAL ROUTE WITH A DOSE OF 0.1 ML. OF PLASMA DERIVED VACCINE USING A 0, 1, 2-6 MONTH SCHEDULE. RECOMBINANT VACCINE BY THE INTRADERMAL ROUTE MAY BE USED WHEN STUDIES INDICATE ANTIGENIC COMPARABILITY.

AFEB (15-1a) 88-6

SUBJECT: Recommendations on Hepatitis B

c. With reference to the issue of hepatitis B vaccine boosters, the Board advises that:

THE NEED FOR BOOSTER DOSES HAS NOT BEEN DEMONSTRATED.

3. a. Based on the available information and subsequent discussions, the AFEB further recommends that:

STUDIES BE CARRIED OUT AMONG THE PERSONNEL IMMUNIZED BY THE INTRADERMAL ROUTE TO DETERMINE IF SUBCLINICAL INFECTIONS OCCUR WITH SUBSEQUENT VIRUS CARRIER STATUS.

b. Regarding the recommendation in 3a above, it was noted that the hepatitis B carrier state which may result in chronic hepatitis, that cirrhosis of the liver and hepatoma and that these states have been associated with naturally acquired subclinical infections.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward

THEODORE E. WOODWARD, M.D.
President, AFEB

Robert A. Wells

ROBERT A. WELLS, Ph.D.
Colonel, USA, MSC
Executive Secretary

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AFEB (15-1a) 89-2

9 March 1989

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Composition and Dosage of the 1989-1990 Influenza Vaccine

1. At its meeting of 16 February, the Disease Control Subcommittee of the Armed Forces Epidemiological Board considered the formulation of the 1989-1990 influenza vaccine. In accordance with agreements made at that time, the membership bases its recommendations on guidelines of the United States Public Health Service and the World Health Organization. The Board recommends that:

a. **THE TRIVALENT INFLUENZA VACCINE FOR 1989-1990 CONSIST OF THE A/TAIWAN 1/86 (H_1N_1), A/SHANGHAI 11/87 (H_3N_2) AND B/YAMAGATA 16/87 COMPONENTS. THE SUITABILITY OF THE A/SHANGHAI COMPONENT WILL BE CONTINGENT UPON THE AVAILABILITY OF A HIGH YIELD RECOMBINANT STRAIN. SUCH A STRAIN IS BEING ACTIVELY DEVELOPED. SHOULD INSURMOUNTABLE TECHNICAL PROBLEMS ARISE, FURTHER GUIDANCE WILL BE PROVIDED AS APPROPRIATE.**

b. **THE VACCINE SHOULD CONTAIN FIFTEEN (15) MICROGRAMS OF EACH OF THE THREE ANTIGENS PER DOSE.**

c. **WHOLE OR SPLIT VACCINES SHOULD BE UTILIZED DEPENDING ON CONTRACTUAL ARRANGEMENTS AND SUPPLIES FROM THE MANUFACTURERS.**

d. **RECRUITS AND ACTIVE DUTY PERSONNEL SHOULD BE IMMUNIZED WITH A SINGLE DOSE OF VACCINE.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward

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AFEB (15-1a) 89-2
SUBJECT: Composition and Dosage of the 1989-1990 Influenza Vaccine

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REPLY TO
ATTENTION OF

SGPS-PSP

21 APR 1989

MEMORANDUM FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

SUBJECT: Typhoid Immunization

Recent studies have indicated that the Vi antigen of Salmonella typhi is an effective immunogen. The Vi antigen vaccine also appears to be associated with fewer side effects than the vaccine currently in use. Immunization with the Vi antigen allows for serological testing as an appropriate indicator of the immune status. Given the advances in typhoid fever vaccine development, the following question is posed to the Board:

Would the Vi antigen vaccine be an appropriate replacement for the standard whole cell vaccine currently in use?

FOR THE SURGEON GENERAL:

Joel C. Snyder, CA/MC
for MICHAEL J. SCOTTI, JR.
Brigadier General, MC
Director, Professional Services

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

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AFEB (15-1a) 89-4 30 May 1989

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation on Typhoid Fever Vaccine

1. As a sequel to its earlier deliberations, the AFEB met on 26 May 1989 to consider a request from the Army Surgeon General on typhoid fever vaccine (enclosure).

2. During the discussions on this topic, the Board recognized the fact that typhoid fever has not recently been a major health hazard for members of the military. However, there remains a potential problem if military operations are carried out in poorly sanitized areas. Preventive health measures appear to be critical although vaccine induced immunity is also important in protecting individuals. The current acetone killed vaccine provides 80% protection based on field and volunteer studies. It is inexpensive and stable but has a reputation of producing local and systemic reactions in some recipients.

3. In reviewing the new vaccine, the AFEB learned that the Vi antigen has been purified and field tested. As a potential replacement for the current killed vaccine, several factors were considered. Two field trials in endemic areas demonstrated protection rates comparable to AKD vaccine in one and reduced in the other. The vaccine was given as a single dose 25 mg. sc. Reactions were minimal. Antibody titers have been predictable with 85% of the recipients having a fourfold increase in titer. A potential protective level of Vi antibodies has been estimated based on the analysis of the field trials. The vaccine cost is not known. The product is stable and antibody titers persist for at least three years. As the Vi antigen is a polysaccharide preparation, there is a possible risk of local or systemic reaction upon revaccination in persons with circulating antibodies. This risk has not been assessed to date with the Vi antigen. This vaccine preparation is also not yet licensed and no manufacturer has publicly declared its intention to produce it.

AFEB (15-1a) 89-4

SUBJECT: Recommendation on Typhoid Fever Vaccine

4. Based upon information currently available, the AFEB states that:

THE Vi ANTIGEN DERIVED VACCINE IS WORTHY OF FURTHER CONSIDERATION AS A POTENTIAL CANDIDATE TO REPLACE THE VACCINE CURRENTLY IN USE AGAINST TYPHOID FEVER. INHERENT IN THIS STATEMENT IS THE RECOMMENDATION THAT APPROPRIATE ARMY PERSONNEL PURSUE THE DEVELOPMENT OF THIS VACCINE AND REPORT ON THE PROGRESS OF THIS PRODUCT TO THE BOARD.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward

Robert A. Wells

Encl

THEODORE E. WOODWARD, M.D.
President, AFEB

ROBERT A. WELLS, Ph.D.
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Executive Secretary

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REPLY TO
ATTENTION OF

SGPS-PSP-D

21 AUG 1989

MEMORANDUM TO THE ARMED FORCES EPIDEMIOLOGICAL BOARD

SUBJECT: Reduced Dose Regimen for the Recombinant Hepatitis B Vaccine

1. On 26 May 1989, Merck Sharpe & Dohme (MS&D), manufacturer of Recombivax-HB, received permission from the Food and Drug Administration to lower the recommended dosage of vaccine for infants, children, and adolescents up through the age of 19 to one-half of the previously recommended doses. This information will be a part of their marketing strategy that will be announced in September of this year.

2. In view of the fact that MS&D has now discontinued the manufacturing of their plasma-derived product Heptavax, other economical methods of immunizing the force besides intradermal administration of Heptavax must be identified. MS&D has agreed to have the data on dose reduction presented, including studies demonstrating probable protection in older age groups.

3. Request that the Armed Forces Epidemiological Board provide advice to the Army on the reduced dose schedule and its use in adults. Can soldiers up to the age of 30 be satisfactorily immunized under the reduced dose schedule?

4. As of the date of this memorandum, another vaccine production firm, Smith Kline & French Laboratories, has not received FDA approval of their recombinant vaccine, Engerix-B. FDA approval is anticipated soon, however. Because of their interest in hepatitis immunization in the military, they have been informed of the meeting and will be available to discuss the merits of their vaccine in military populations.

FOR THE SURGEON GENERAL:

Frederick Hudson COL, MC

for MICHAEL J. SCOTTI, JR.
Brigadier General, MC
Director, Professional Services

Encl

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

THE EXECUTIVE SECRETARY
ARMED FORCES EPIDEMIOLOGICAL BOARD
OFFICE OF THE SURGEON GENERAL
DEPARTMENT OF THE ARMY
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

AFEB (15-1a) 89-6 3 October 1989

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation on the Reduced Dose Regimens for Recombinant Hepatitis B Vaccines

1. During its meeting of 28-29 September 1989, the Armed Forces Epidemiological Board (AFEB) considered questions relating to the above topic. The questions posed are provided at enclosure 1.

2. Recombinant hepatitis B vaccines are not generic. Consequently, reduced doses of hepatitis B vaccines prepared by different manufacturers may or may not be equally immunogenic. Studies by various investigators have revealed that 1/4 (2.5 mcg.) to 1/2 (5 mcg.) of the currently recommended 10 mcg. doses of Merck, Sharp & Dohme's recombinant vaccine (Recombivax-HB) are highly immunogenic for adults up to the age of 30. As of this date, reduced dose data on the SmithKline Beecham vaccine (Engerix B) are not available. The AFEB therefore recommends that:

A REDUCED DOSE OF 5 mcg. OF THE MERCK RECOMBIVAX - HB VACCINE MAY BE USED FOR THE IMMUNIZATION OF ADULTS UP TO THE AGE OF 30. THE RECOMMENDED DOSE OF ENGERIX B SHOULD BE 20 mcg. UNTIL STUDIES INDICATE THAT A REDUCED DOSE IS IMMUNOGENIC AND EFFECTIVE.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Encl

THEODORE E. WOODWARD, M.D.
President, AFEB

ROBERT A. WELLS, Ph.D.
Colonel, USA, MSC
Executive Secretary

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Dir, Prof Svcs, OTSG-DA
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Deputy Cdr, Fleet Readiness & Supt, BUMED-DN
Dir, AFMIC

DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
WASHINGTON, D.C. 20372-5120

IN REPLY REFER TO

6230:5420/1
Ser 24/0455
21 Dec 89

MEMORANDUM FOR THE EXECUTIVE SECRETARY, ARMED FORCES EPIDEMIOLOGICAL BOARD

Subj: VARICELLA VIRUS VACCINE TRIAL IN NAVY RECRUITS - ACTION MEMORANDUM

Encl: (1) Proposed varicella virus vaccine trial protocol
(2) Data from Merck Sharp and Dohme w/scientific literature

1. In 1988 there were over 1500 cases of varicella in active duty Navy personnel, at an estimated cost of over $2 million for hospital admissions. Two active duty members died of severe varicella and its complications. Additionally, a Navy ship had to abort its mission when 11 percent of the crew of 994 developed varicella. The largest proportion of cases were seen at Naval Training Center, Great Lakes, Illinois which had 614 cases in 1988 and 520 cases so far in 1989.

2. The Commander, Naval Education and Training Command requested Naval Medical Department assistance. After due consideration, it was determined that the only practical intervention would be a vaccine trial using the Merck Sharp and Dohme (MSD) investigational vaccine, Varivax. Because the usual Varivax formulation, approximately 1000 pfu per dose, is less immunogenic in adolescents and young adults than in children, a regimen using higher doses and/or multiple doses appeared to be necessary.

3. We request that the Board convene a special session to review the issues of concern, and to advise us in time to begin the project in January 1990. We seek advice on four questions.

a. Does Varivax appear to demonstrate sufficient evidence of safety, probable immunogenicity, and potential efficacy to permit a vaccine trial in Navy recruits?

b. Is there sufficient evidence of a significant varicella problem among Navy personnel, especially recruits, to justify a vaccine trial in Navy personnel?

c. Should an attempt be made to initiate the trial this winter, 1989-90?

d. How long should the follow-up period last?

4. Enclosure (1) is the proposed vaccine trial protocol and enclosure (2) is data from MSD with pertinent scientific literature.

Subj: VARICELLA VIRUS VACCINE TRIAL IN NAVY RECRUITS - ACTION MEMORANDUM

5. My point of contact on this subject is Captain W. F. Bina III, MC, USN, Director, Occupational Health and Preventive Medicine Division, at 653-1788.

W. A. BUCKENDORF
Rear Admiral, Medical Corps
United States Navy
Assistant Chief for Fleet
Readiness and Support

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

SGPS-PSP-D (40)

23 JAN 1990

MEMORANDUM FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

SUBJECT: Immunization Program for Military Recruits

1. Reference. AR 40-562/NAVMEDCOMINST 6230.3/AFR 161-13/CG COMDTINST M6230.4D, Immunizations and Chemoprophylaxis, 7 October 1988.

2. The U.S. Army continues to immunize its recruit population with vaccines as outlined in reference above. Vaccines include measles-rubella (M-R), influenza (A and B), adenovirus types 4 and 7, oral polio, tetanus-diphtheria, meningococcal (A, C, Y, and W-135), and smallpox vaccines. These vaccines, with the exception of smallpox vaccine, are administered within the first three days of arrival at reception centers. Mumps vaccine is not administered to Army recruits.

3. Request that the Armed Forces Epidemiological Board (AFEB) review the current immunization schedule (enclosure 1) and provide advice on continuing or modifying the schedule. Specifically, should mumps be added to the vaccine regimen for recruits? Should the Army continue using oral poliovirus vaccine, or use the enhanced-potency inactivated poliovirus vaccine?

4. At the February AFEB meeting, serological prevalence data will be presented on recruits tested within the past year. This should assist the Board in advising the Army. The other services will also present data, based on recent serosurveys conducted in their recruit populations.

5. It should be noted that the Army does not administer typhoid, plague, or yellow fever vaccine to its recruits during basic training; these vaccines are given to personnel when assigned to designated alert forces units.

6. Request that the AFEB address these questions at the February meeting.

FOR THE SURGEON GENERAL:

Frederick Kuhlmann COL, MC
for MICHAEL J. SCOTTI, JR.
Brigadier General, Medical Corps
Director, Professional Services

Encl.

TABLE 1. VACCINATIONS FOR UNITED STATES MILITARY PERSONNEL*

Immunizing agent	Army	Navy	Air Force	Marine Corps	Coast Guard
Adenovirus (Types 4 and 7)	B	B	B	B	H
Cholera	F	F	F	F	F
Hepatitis B	E,G,H	E,G,H	E,G,H	E,G,H	G,H
Influenza	A,B,X	A,B,R	A,B,R	A,B,R	B,C,H
Measles	B,G	B,G	B,G	B,G	B,G
Meningococcal (A, C, Y, W135)	B,H	B,H	B,H	B,H	B,H
Mumps	G,H	G,H	G,H	G,H	G
Plague	C,D,E,G	D,G	E	A,G	E
Polio	A,R	A,R	A,R	A,R	A
Rabies	D,G,H	D,G,H	D,G,H	D,G,H	H
Rubella	B,G	B,G	B,G	B,G	B
Smallpox	B,H	B,H	B,H	B,H	B,H
Tetanus-diphtheria	A,B,R	A,B,R	A,B,R	A,B,R	A,B
Typhoid	C,E,H	H	C,E,H	H	E
Yellow fever	C,D,E	A,R	C,E	A,R	B,E

A--All active duty personnel
B--Recruits
C--Alert forces
D--Special Forces components
E--When deploying or traveling to high risk areas
F--Only when required by host country for entry
G--High risk occupational groups
H--As directed by the applicable surgeon general or Chief, Coast Guard Office of Health Services
R--Reserve Components
X--Reserve Component personnel on active duty for 30 days or more during the influenza season

* EXTRACTED FROM: ARMY, NAVY, AIR FORCE, AND COAST GUARD IMMUNIZATION REGULATION

TABLE 2. DOSAGES AND ROUTES OF ADMINISTRATION OF IMMUNIZING AGENTS FOR ADULT MILITARY PERSONNEL *

Immunizing Agent	Initial Dosages/Route	Booster Dose(s)/Route	Precautions/ Contraindications
Adenovirus (Types 4 and 7)	Single oral dose (enteric-coated tablet) for each.	None.	Hypersensitivity to vaccine components and pregnancy.
Cholera	Single dose: 0.5 ml subcutaneous (SC) or intramuscular (IM) for administrative purposes, if required for entry by a host country.	0.5 ml SC or IM for administrative purposes if required for entry by a host country; boosters every 6 months.	Hypersensitivity to vaccine components.
Hepatitis B	3 doses IM: 1.0 ml initially, then 1.0 ml IM at 1 and 6 months following initial dose. (Note: Other routes e.g., intradermal, must be approved by the appropriate surgeon general or Chief, Coast Guard Office of Health Services.)	None.	Hypersensitivity to vaccine components.
Immune globulin (IG) (Passive Immunization)	2.0 ml IM for travel < 3 months; 5.0 ml IM for travel > 3 months.	Every 5 months when in high-risk areas	None. Avoid administering live vaccines within 6 weeks of having received IG. (Exceptions: OPV and yellow fever).
Influenza	As directed annually.	Annually.	Hypersensitivity to vaccine components.
Japanese encephalitis	Two doses: 1.0 ml SC spaced at 1 to 2 weeks apart.	1.0 ml SC every 1 to 4 years based on risk.	Hypersensitivity to vaccine components and pregnancy.
Measles	Single dose SC, or as recommended by the manufacturer.	None.	Hypersensitivity to vaccine components and pregnancy.
Meningococcal (quadrivalent)	Single dose as recommended by the manufacturer.	Booster may be indicated every 3 to 5 years if assigned to high-risk area.	Hypersensitivity to vaccine components.

TABLE 2. DOSAGES AND ROUTES OF ADMINISTRATION OF IMMUNIZING AGENTS FOR ADULT MILITARY PERSONNEL (Cont.)

Immunizing Agent	Initial Dosages/Route	Booster Dose(s)/Route	Precautions/ Contraindications
Mumps	As recommended by the manufacturer.	None.	Hypersensitivity to vaccine components and pregnancy.
Plague	3 doses given IM: 1.0 ml initially, then 0.2 ml at 1 month and 3 to 6 months following second dose.	0.2 ml IM at 6 and 12 months following initial 3 dose series, then if required every 1 to 2 years.	Hypersensitivity to vaccine components.
Polio: OPV (Live poliovirus vaccine)	Single Dose of 0.5 ml orally unless there is reliable evidence of no previous polio immunization; if there has been no prior immunization, 2 doses 6 to 8 weeks apart and the third dose 12 months later.	None.	Hypersensitivity to vaccine components and pregnancy. OPV should not be given to immunocompromised persons or persons with immunocompromised family members. IPV is recommended in such situations.
Polio: IPV (Inactivated poliovirus vaccine)	1 dose SC for adults who have completed the primary series of IPV. If no history of immunization; administer as per ACIP or manufacturer's recommendation.	None.	Hypersensitivity to vaccine components and pregnancy.
Rabies: (pre-exposure)	As per ACIP** or manufacturer's recommendations.	As per ACIP** or manufacturer's recommendations.	Hypersensitivity to vaccine components.
Rabies: (post-exposure)	As per ACIP** or manufacturer's recommendations.	As per ACIP** or manufacturer's recommendations.	Hypersensitivity to vaccine components.
Rubella	Single dose as recommended by the manufacturer.	None.	Hypersensitivity to components of vaccine and pregnancy.
Smallpox	For primary vaccination, 1 drop of vaccine with 2-3 needle pressures of punctures. DO NOT SCRATCH.	No booster ordinarily required.	Hypersensitivity to components of vaccine and pregnancy.

TABLE 2. DOSAGES AND ROUTES OF ADMINISTRATION OF IMMUNIZING AGENTS FOR ADULT MILITARY PERSONNEL (Cont.)

Immunizing Agent	Initial Dosages/Route	Booster Dose(s)/Route	Precautions/ Contraindications
Tetanus-diphtheria toxoid (Td), adult type	If previously immunized, 1 dose 0.5 ml SC or IM. If there has been no prior immunization, 2 doses of 0.5 ml 4 to 8 weeks apart and a third of 0.5 ml 6 to 12 months later.	0.5 ml SC or IM every 10 years or as indicated for wound management.	Hypersensitivity to vaccine components and pregnancy.
Typhoid (Acetone-inactivated and phenol-treated vaccines)	Two doses: First dose of 0.5 ml SC then 0.5 ml SC 1 month later.	0.5 ml SC or IM every 3 years if entering or remaining in high risk areas, or as required.	Hypersensitivity to vaccine components and pregnancy.
Yellow fever	Single dose: 0.5 ml SC or IM.	0.5 cc SC or IM every 10 years.	Hypersensitivity to vaccine components and pregnancy. Should not be given within 3 weeks of having received cholera vaccine.

* Extracted From: Army, Navy, Air Force, and Coast Guard Immunization Regulation
** ACIP = Advisory Committee on Immunization Practices.

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

THE EXECUTIVE SECRETARY
ARMED FORCES EPIDEMIOLOGICAL BOARD
OFFICE OF THE SURGEON GENERAL
DEPARTMENT OF THE ARMY
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

AFEB (15-1a) 90-3 27 February 1990

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARIMENT OF THE ARMY
THE SURGEON GENERAL, DEPARIMENT OF THE NAVY
THE SURGEON GENERAL, DEPARIMENT OF THE AIR FORCE

SUBJECT: Recommendations on Immunization Programs for Military Recruits

1. Reference is made to the enclosed memorandum to the Armed Forces Epidemiological Board (AFEB) in which the Army Surgeon General requested guidance on the immunization program for Army recruits.

2. At its 22 February 1990 meeting the AFEB heard presentations by the three services on recent serosurveys of recruit populations and immunization strategies regarding vaccine-preventable diseases.

3. Given progress within the medical sciences, the improvement and changes in vaccines, the enhanced treatment of many diseases and the need to simplify immunization regimens, the Board recommends that:

a. **A WORKSHOP BE HELD INVOLVING THE PREVENTIVE MEDICINE OFFICERS OF THE SERVICES, AN AD HOC COMMITTEE OF THE BOARD AND REPRESENTATIVES OF THE CDC AND FDA TO REVIEW CURRENT KNOWLEDGE OF VACCINES AND THEIR EFFECTIVENESS AND TO REVIEW THE SUSCEPTIBILITIES OF INCOMING MILITARY PERSONNEL TO VACCINE-PREVENTABLE DISEASES AS THE BASIS FOR THE FORMULATION OF APPROPRIATE RECOMMENDATIONS.**

b. **THE BOARD COMMENDS THE SERVICES FOR THEIR ACTIVITIES DIRECTED TO DETERMINE THE SUSCEPTIBILITIES OF RECRUIT POPULATIONS WHICH WILL BE OF GREAT VALUE TO THIS WORKSHOP.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Encl

THEODORE E. WOODWARD, M.D.
President, AFEB

ROBERT A. WELLS, Ph.D.
Colonel, USA, MSC
Executive Secretary

AFEB (15-1a) 90-3

SUBJECT: Recommendations on Immunization Programs for Military Recruits

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Deputy Cdr, Fleet Readiness & Supt, BUMED-DN

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

THE EXECUTIVE SECRETARY
ARMED FORCES EPIDEMIOLOGICAL BOARD
OFFICE OF THE SURGEON GENERAL
DEPARTMENT OF THE ARMY
5109 LEESBURG PIKE
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AFEB (15-1a) 90-4

27 February 1990

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

Subject: Recommendations on Varicella Vaccine Trial in Navy Recruits

1. During its meeting of 22 February 1990 the Armed Forces Epidemiological Board (AFEB) met to consider a request from The Surgeon General, U.S. Navy concerning a proposed varicella virus vaccine field trial in Navy recruits. The request memorandum is provided at enclosure 1.

2. During the meeting, presentations by Navy and Army epidemiologists described the experiences of the military services concerning the clinical disease of this infection. A representative of Mercke Sharpe and Dohme provided pertinent data and other valuable information as the manufacturer of the candidate vaccine.

3. The Board is concerned over the increasing incidence of varicella in the services, especially in training centers, the deaths of two servicemen from complications of the disease and interference with unit missions caused by related epidemics. It was noted that the vaccine had been predominantly used on leukemic children who were in remission of their malignant disease, and that its use was free of adverse reactions; herpes zoster occurred after vaccinations less frequently than among unimmunized leukemic children infected with wild virus. In healthy children, the vaccine elicited specific antibodies in 96% of those evaluated and had an efficacy in preventing disease approaching 100% while 4-7% of the recipients developed a rash 2-3 weeks after vaccination, no clinical symptoms were noted among their contacts. Experience with adult recipients has not been as extensive with only 88% developing antibodies suggesting that a larger dose or second injection of this attenuated virus may be necessary. Those cases which did occur among those vaccinated were very mild. One healthy vaccinated adult developed mild herpes zoster three years after vaccination; however, the virus isolated from the lesions proved not to be vaccine derived, but a wild strain.

AFEB (15-1a) 90-4

SUBJECT: Recommendations on Varicella Vaccine Trial in Navy Recruits

4. In view of these facts, the Board recommends that:

a. VARIVAX, THE PROPOSED VACCINE, APPEARS TO DEMONSTRATE SUFFICIENT SAFETY, PROBABLE IMMUNOGENICITY AND POTENTIAL EFFICACY TO PERMIT A VACCINE TRIAL IN NAVY RECRUITS.

b. THERE IS ADEQUATE EVIDENCE THAT VARICELLA IS A SIGNIFICANT PROBLEM AMONG NAVY PERSONNEL, ESPECIALLY THOSE UNDERGOING TRAINING.

c. BASED ON THESE FACTORS, THE BOARD CONCURS THAT THE STUDY BE PERFORMED.

d. IT IS TOO LATE TO INITIATE TRIALS IN THE 1989-1990 SEASON. IT WOULD BE BEST TO INITIATE THE IMMUNIZATION PROGRAM 6-8 WEEKS BEFORE THE EXPECTED BEGINNING OF THE DISEASE OUTBREAK BASED ON THE EXPERIENCE OF PREVIOUS YEARS.

e. THE FOLLOWUP PERIOD FOR ANTIBODY STUDIES SHOULD BE ONE YEAR; CLINICAL FOLLOWUP THROUGH ALERTED DISEASE REPORTING FUNCTIONS SHOULD BE AS LONG AS POSSIBLE.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward

Robert A. Wells

Encl

THEODORE E. WOODWARD, M.D.
President, AFEB

ROBERT A. WELLS, Ph.D.
Colonel, USA, MSC
Executive Secretary

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

THE EXECUTIVE SECRETARY
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AFEB (15-1a) 90-5

27 February 1990

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation for the Composition and Dosage of the 1990-1991 Influenza Vaccine

1. At its 22 February 1990 meeting the Disease Control Subcommittee of the Armed Forces Epidemiological Board considered the formulation of the 1990-1991 influenza vaccine. In accordance with agreements made at that time, the membership bases its recommendations on guidelines of the United States Public Health Service and the World Health Organization. The Board recommends that:

a. **THE TRIVALENT INFLUENZA VACCINE FOR 1990-1991 CONSIST OF THE A/TAIWAN 1/86 (H_1N_1) LIKE, A/GUIZHOU 54/89 (H_3N_2) LIKE AND B/YAMAGATA 16/88 LIKE COMPONENTS.**

b. **THE VACCINE SHOULD CONTAIN FIFTEEN (15) MICROGRAMS OF THE HEMAGGLUTININ OF EACH OF THE THREE ANTIGENS PER DOSE.**

c. **WHOLE OR SPLIT VACCINES SHOULD BE UTILIZED DEPENDING ON CONTRACTUAL ARRANGEMENTS AND SUPPLIES FROM THE MANUFACTURERS.**

d. **RECRUIT AND ACTIVE DUTY PERSONNEL SHOULD BE IMMUNIZED WITH A SINGLE DOSE OF VACCINE.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward

THEODORE E. WOODWARD, M.D.
President, AFEB

Robert A. Wells

ROBERT A. WELLS, Ph.D.
Colonel, USA, MSC
Executive Secretary

AFEB (15-1a) 90-5

SUBJECT: Recommendation on Composition and Dosage of the 1990-1991 Influenza Vaccine

Copies Furnished:
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Dir, Prof Svcs, OTSG-DA
Dir, PA&QA, OTSG-DAF
Deputy Cdr, Fleet Readiness & Supt, BUMED-DN

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF
SGPS-PSP-D (40)

15 MAY 1990

MEMORANDUM FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

SUBJECT: Use of Primaquine for Malarial Chemoprophylaxis

1. For many years, the military has used primaquine hydrochloride for terminal malaria prophylaxis and treatment. Primaquine is particularly effective in eradicating the exoerythrocytic forms of malaria. The drug is available as 15 mg. tablets and in combination with chloroquine (500 mg. chloroquine and 45 mg. primaquine combination tablets).

2. In April 1990, the Army was informed that the only FDA-licensed manufacturer of primaquine in the U.S. (Winthrop Laboratories) had interrupted their production of primaquine. Winthrop is unable to manufacture additional primaquine until 1st QTR CY-91. Based on the current rates of utilization and stockpile levels, the military may not have sufficient primaquine on hand to meet all requirements prior to new stocks being received.

3. In view of this situation, request that the Armed Forces Epidemiological Board provide guidance on how primaquine might best be prescribed. Specifically,

a. Are there malarious areas of the world where terminal primaquine prophylaxis does not need to be routinely administered following suppressive chemoprophylaxis?

b. Are there malarious areas or situations where the risk of contracting vivax and/or ovale malaria is so high as to warrant routine terminal primaquine chemoprophylaxis for all travelers?

c. Is eight weeks of terminal chemoprophylaxis with the chloroquine-primaquine combination tablet necessary, or can this weekly schedule be shortened?

4. Request that the AFEB address these questions at its next meeting.

FOR THE SURGEON GENERAL:

for MICHAEL J. SCOTTI, JR.
Brigadier General, Medical Corps
Director, Professional Services

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

AFEB (15-1a) 90-6

24 July 1990

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendations Pertaining to the Use of Primaquine as a Chemoprophylaxis for Malaria

1. At its 29 June 1990 meeting the Armed Forces Epidemiological Board (AFEB) considered three questions raised by the Director, Professional Services, Office of The Surgeon General, U.S. Army. The questions, noted in Enclosure 1, addressed an announcement by Winthrop Laboratories that they could no longer manufacture Primaquine, a chemoprophylaxis for malaria, due to the inability to acquire necessary chemical ingredients. As a result of the cessation of manufacture, a potential shortage of Primaquine could occur between now and the first quarter of calendar year 1991.

2. In answer to the first two questions regarding whether there are any geographical areas where terminal Primaquine prophylaxis is or is not routinely required, the AFEB concluded that there are no major malaria-endemic regions where Plasmodium vivax and/or P. ovale is not sufficiently prevalent to constitute a significant health threat to forces deployed in the region following termination of suppressive chemoprophylaxis. Data is insufficient to calculate specific risks of infection due to P. vivax for any of these areas. Therefore, the Board recommends:

a. **THAT TERMINAL PRIMAQUINE PROPHYLAXIS, EITHER 45 MG. WEEKLY FOR EIGHT WEEKS OR 15 MG. DAILY FOR FOURTEEN DAYS BE CONTINUED FOLLOWING DEPARTURE FROM MALARIA-ENDEMIC AREAS FOR AS LONG AS THE SUPPLIES OF PRIMAQUINE LAST.**

b. **THAT IN COOPERATION WITH WINTHROP LABORATORIES AND THE CENTER FOR DISEASE CONTROL, THE SITUATION WITH RESPECT TO THE SUPPLY OF RAW MATERIALS NECESSARY FOR PRIMAQUINE PRODUCTION BE INVESTIGATED WITH A VIEW TOWARD MORE DEFINITIVE DETERMINATION OF THE FUTURE AVAILABILITY OF PRIMAQUINE.**

AFEB (15-1a) 90-6

SUBJECT: Recommendations Pertaining to the Use of Primaquine as a Chemoprophylaxis for Malaria

c. **THAT DEVELOPMENT AND TESTING OF THE NEW RING-SUBSTITUTE ANALOG OF PRIMAQUINE, WR260568, BE EXPEDITED TO THE MAXIMUM EXTENT POSSIBLE SO AS TO HAVE THIS ALTERNATIVE CHEMOPROPHYLAXIS DRUG AVAILABLE IF THE SUPPLY OF PRIMAQUINE IS EXHAUSTED.**

3. The AFEB recognizes that the currently recommended chemoprophylaxis regimen of Primaquine is based on data derived from studies in volunteers infected with so-called "Chesson" strain of P. vivax from Korea which apparently was relatively more refractory to a radical course with Primaquine than other P. vivax strains, however, the AFEB is not aware of data to suggest that shorter courses of Primaquine will suffice as terminal chemoprophylaxis for other P. vivax strains or of data regarding the geographical distribution of chesson-like strains. Therefore, the AFEB recommends:

THAT THE CURRENTLY RECOMMENDED EIGHT-WEEK TERMINAL CHEMOPROPHYLAXIS REGIMEN OF CHLOROQUINE-PRIMAQUINE NOT BE SHORTENED.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

THEODORE E. WOODWARD, M.D.
President, AFEB

WILLIAM M. PARSONS, Ph.D.
Colonel, USA, MSC
Executive Secretary

Enclosure

Copies Furnished:
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DEPARTMENT OF THE ARMY
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

AFEB (15-1a) 91-2

7 March 1991

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation for the Composition and Dosage of the 1991-1992 Influenza Vaccine

1. At its 1 March 1991 meeting the Disease Control Subcommittee of the Armed Forces Epidemiological Board considered the formulation of the 1991-1992 influenza vaccine. Final recommendations were proposed by the World Health Organization and the United States Public Health Service on 6 March 1991. Accordingly, the Board recommends that:

a. **THE TRIVALENT INFLUENZA VACCINE FOR 1991-1992 CONSIST OF THE A/TAIWAN/1/86 (H_1N_1) LIKE; A/BEIJING/353/89 (H_3N_2) LIKE; AND B/PANAMA/45/90 LIKE COMPONENTS.**

b. **THE VACCINE SHOULD CONTAIN FIFTEEN (15) MICROGRAMS OF THE HEMAGGLUTININ OF EACH OF THE THREE ANTIGENS PER DOSE.**

c. **WHOLE OR SPLIT VACCINES SHOULD BE UTILIZED DEPENDING ON CONTRACTUAL ARRANGEMENTS AND SUPPLIES FROM THE MANUFACTURERS.**

d. **RECRUIT AND ACTIVE DUTY PERSONNEL SHOULD BE IMMUNIZED WITH A SINGLE DOSE OF THE VACCINE.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward

THEODORE E. WOODWARD, M.D.
President, AFEB

W. M. PARSONS, Ph.D.
Captain, Medical Service Corps,
United States Navy
Executive Secretary

AFEB (15-1a) 91-2

SUBJECT: Recommendation for the Composition and Dosage of the 1991-1992 Influenza Vaccine

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

AFEB (15-1a) 91-3

15 May 1991

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation on the Use of Oral Live-Attenuated Ty21a Typhoid Vaccine

1. The Department of Defense (DOD) currently uses a parenteral heat-acetone-inactivated vaccine to immunize personnel against typhoid fever. Parenteral inactivated vaccines produce several systemic and local adverse reactions including fever (14%-29%), headache (9%-30%), severe local pain and/or swelling (6%-40%). These adverse reactions have been known to incapacitate personnel with resulting absenteeism and degraded job performance. These side reactions may be of importance in certain categories of military personnel.

2. The Ty21a oral vaccine has been shown by extensive testing to be a safe and effective vaccine without eliciting the undesirable side reactions of the parenteral typhoid vaccines. In view of the above, the Armed Forces Epidemiological Board recommends:

a. **THAT DOD ADOPT THE USE OF THE ORAL LIVE-ATTENUATED Ty21a TYPHOID VACCINE.**

b. **THAT THE Ty21a VACCINE BE PHASED IN ACCORDING TO INDIVIDUAL SERVICE POLICY AND USAGE OF CURRENT STOCKS OF THE PARENTERAL TYPHOID VACCINES.**

c. **THAT DOSAGE SCHEDULES BE CONSISTENT WITH THOSE RECOMMENDED BY THE IMMUNIZATION PRACTICES ADVISORY COMMITTEE (ACIP) AS PUBLISHED IN MMWR 39: No. RR-10 OF JULY 13, 1990, PAGES 1-5.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward

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President, AFEB

W. M. PARSONS, Ph.D.
Captain, Medical Service Corps,
United States Navy
Executive Secretary

AFEB (15-1a) 91-3

SUBJECT: Recommendation on the Use of Oral Live-Attenuated Ty21a Typhoid Vaccine

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
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AFEB (15-1a) 91-5

5 September 1991

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE, HEALTH AFFAIRS
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: DOD Vaccine and Immunization Review - Recommendation Concerning Ordering of Bulk Quantities

1. The Armed Forces Epidemiological Board meeting of 18-19 June 1991 addressed DOD vaccine and immunization policies. The Board limited its discussions to those infectious diseases of potential endemic threat and did not address biological warfare agents as a subject of this review.

2. During this meeting the issue of the high cost of biological products was considered. It was pointed out that these high costs could be minimized if procurements were coordinated, or consolidated, with those of other government agencies. Accordingly, the AFEB provides the following recommendation:

THAT PROCUREMENT OF REQUIRED VACCINES BE CONSOLIDATED WITH U. S. PUBLIC HEALTH SERVICE REQUIREMENTS TO REDUCE COSTS.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward MD

THEODORE E. WOODWARD, M.D.
President, AFEB

W. M. PARSONS, Ph.D.
Captain, Medical Service Corps
U. S. Navy
Executive Secretary

AFEB (15-1a) 5 September 1991
SUBJECT: DOD Vaccine and Immunization Review - Recommendation Concerning Ordering of Bulk Quantities

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DEPARTMENT OF DEFENSE
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AFEB (15-1a) 91-6 5 September 1991

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE, HEALTH AFFAIRS
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: DOD Vaccine and Immunization Review - Recommendations Concerning Combined Vaccines

1. The Armed Forces Epidemiological Board meeting of 18-19 June 1991 addressed DOD vaccine and immunization policies. The Board limited its discussions to those infectious diseases of potential endemic threat and did not address biological warfare agents as a subject of this review.

2. During this meeting the issue of combined vaccines was considered. Evidence indicates that combining antigens does not interfere with development of immunity, and that there are advantages to be derived assuming there is no incompatibility in antigens or substrates. Where feasible, combining vaccines offers reduced costs and logistical burdens, and minimizes time away from duty for the recipient. Additionally, it was noted that hepatitis A and hepatitis B vaccines are likely candidates for being combined into a single vaccine. Accordingly, the AFEB provides the following recommendations:

a. **THAT MANUFACTURERS OF VACCINES BE ENCOURAGED TO PURSUE THE DEVELOPMENT OF COMBINED VACCINES.**

b. **THAT A HIGH PRIORITY BE GIVEN TO DEVELOPING A COMBINED HEPATITIS A AND HEPATITIS B VACCINE FOR USE BY ALL MILITARY PERSONNEL.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward mp

THEODORE E. WOODWARD, M.D.
President, AFEB

W. M. PARSONS, Ph.D.
Captain, Medical Service Corps
U. S. Navy
Executive Secretary

AFEB (15-1a)
SUBJECT: DOD Vaccine and Immunization Review - Recommendations Concerning Combined Vaccines

5 September 1991

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DEPARTMENT OF DEFENSE
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AFEB (15-1a) 91-8

5 September 1991

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE, HEALTH AFFAIRS
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: DOD Vaccine and Immunization Review - Recommendations Concerning Adenovirus Vaccine

1. The Armed Forces Epidemiological Board meeting of 18-19 June 1991 addressed DOD vaccine and immunization policies. The Board limited its discussions to those infectious diseases of potential endemic threat and did not address biological warfare agents as a subject of this review.

2. During this meeting the issue of adenovirus vaccines was considered. The Board noted the efficacy of the adenovirus vaccine in preventing acute respiratory disease in recruit training centers. Accordingly, the Board provides the following recommendations:

a. **THAT ADENOVIRUS VACCINE BE GIVEN TO ALL RECRUITS ON REPORTING TO THE RECRUIT TRAINING ACTIVITY.**

b. **THAT WHERE CLOSE SURVEILLANCE IS POSSIBLE, THE ADMINISTRATION OF ADENOVIRUS VACCINE MAY BE RESERVED UNTIL ADENOVIRAL INFECTIONS ARE DETECTED.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward

THEODORE E. WOODWARD, M.D.
President, AFEB

W. M. PARSONS, Ph.D.
Captain, Medical Service Corps
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Executive Secretary

AFEB (15-1a) 5 September 1991
SUBJECT: DOD Vaccine and Immunization Review - Recommendations Concerning Adenovirus Vaccine

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ARMED FORCES EPIDEMIOLOGICAL BOARD
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AFEB (15-1a) 91-9

5 September 1991

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE, HEALTH AFFAIRS
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: DOD Vaccine and Immunization Review - Recommendations Concerning Administration of Measles-Mumps-Rubella Vaccine

1. The Armed Forces Epidemiological Board meeting of 18-19 June 1991 addressed DOD vaccine and immunization policies. The Board limited its discussions to those infectious diseases of potential endemic threat and did not address biological warfare agents as a subject of this review.

2. During this meeting the issue of the administration of Measles-Mumps-Rubella vaccine was considered. The Board recognizes that there are some activities which have chosen to test for antibody levels and recommends:

a. **THAT MMR SHOULD BE GIVEN TO ALL RECRUITS WHEN BUDGETARILY FEASIBLE.**

b. **WHERE LABORATORY FACILITIES ARE AVAILABLE TO TEST FOR LEVELS OF IMMUNITY, THEN IMMUNIZATIONS MAY BE GIVEN TO COVER THOSE DISEASES TO WHICH THE INDIVIDUAL IS SUSCEPTIBLE.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

THEODORE E. WOODWARD, M.D.
President, AFEB

W. M. PARSONS, Ph.D.
Captain, Medical Service Corps
U. S. Navy
Executive Secretary

AFEB (15-1a) 5 September 1991
SUBJECT: DOD Vaccine and Immunization Review - Recommendations Concerning Administration of Measles-Mumps-Rubella Vaccine

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DEPARTMENT OF DEFENSE
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AFEB (15-1a) 91-10 5 September 1991

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE, HEALTH AFFAIRS
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: DOD Vaccine and Immunization Review - Recommendations Concerning Administration of Plague Vaccine

1. The Armed Forces Epidemiological Board meeting of 18-19 June 1991 addressed DOD vaccine and immunization policies. The Board limited its discussions to those infectious diseases of potential endemic threat and did not address biological warfare agents as a subject of this review.

2. During this meeting the issue of the administration of plague vaccine was considered and the Board offers the following recommendations:

a. **THAT ROUTINE IMMUNIZATION AGAINST PLAGUE BE DISCONTINUED.**

b. **THAT PLAGUE VACCINE BE ADMINISTERED TO PERSONNEL WHO ARE LIKELY TO BE ASSIGNED TO AREAS WHERE THE DISEASE IS ENDEMIC AND THE RISK OF EXPOSURE IS HIGH.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward

THEODORE E. WOODWARD, M.D.
President, AFEB

W. M. PARSONS, Ph.D.
Captain, Medical Service Corps
U. S. Navy
Executive Secretary

AFEB (15-1a) 5 September 1991
SUBJECT: DOD Vaccine and Immunization Review - Recommendations Concerning Administration of Plague Vaccine

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
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AFEB (15-1a) 91-11

5 September 1991

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE, HEALTH AFFAIRS
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: DOD Vaccine and Immunization Review - Recommendations Concerning Administration of Pneumococcal Vaccine

1. The Armed Forces Epidemiological Board meeting of 18-19 June 1991 addressed DOD vaccine and immunization policies. The Board limited its discussions to those infectious diseases of potential endemic threat and did not address biological warfare agents as a subject of this review.

2. During this meeting the issue of the administration of pneumococcal vaccine was considered. The Board notes that Streptococcus pneumoniae is a significant cause of pneumonia in adults, and that recent outbreaks of pneumococcal pneumonia have occurred in military personnel. The current pneumococcal vaccine (Pneumovax) has been shown to be a safe and effective vaccine for the prevention of pneumonia in adults of military age. Accordingly, the Board recommends:

a. **THAT PNEUMOCOCCAL VACCINE BE GIVEN AT BASES WHICH EXPERIENCE AN INCREASED PREVALENCE OF PNEUMONIA.**

b. **THAT, IN ACCORDANCE WITH AFEB RECOMMENDATION 85-9, A SINGLE DOSE OF PNEUMOCOCCAL VACCINE BE GIVEN TO ALL PERSONNEL KNOWN TO BE ASPLENIC. A SECOND DOSE IS NOT REQUIRED.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward

THEODORE E. WOODWARD, M.D.
President, AFEB

W. M. PARSONS, Ph.D.
Captain, Medical Service Corps
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Executive Secretary

AFEB (15-1a) 5 September 1991
SUBJECT: DOD Vaccine and Immunization Review - Recommendations Concerning Administration of Pneumococcal Vaccine

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
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AFEB (15-1a) 91-12

5 September 1991

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE, HEALTH AFFAIRS
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: DOD Vaccine and Immunization Review - Recommendation Concerning Varicella Vaccine

1. The Armed Forces Epidemiological Board meeting of 18-19 June 1991 addressed DOD vaccine and immunization policies. The Board limited its discussions to those infectious diseases of potential endemic threat and did not address biological warfare agents as a subject of this review.

2. During this meeting the issue of varicella vaccine was considered. The Board noted that varicella outbreaks have a significant potential to adversely impact on military operations and training activities. Accordingly, the Board recommends:

THAT DOD PURSUE APPROPRIATE AVENUES TO ACCELERATE THE DEVELOPMENT OF A VARICELLA VACCINE FOR ADULT USE.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward MD

THEODORE E. WOODWARD, M.D.
President, AFEB

W. M. PARSONS, Ph.D.
Captain, Medical Service Corps
U. S. Navy
Executive Secretary

AFEB (15-1a) 5 September 1991
SUBJECT: DOD Vaccine and Immunization Review - Recommendation Concerning Varicella Vaccine

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
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AFEB (15-1a) 91-13

5 September 1991

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE, HEALTH AFFAIRS
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: DOD Vaccine and Immunization Review - Recommendations Concerning Typhoid Vaccine

1. The Armed Forces Epidemiological Board meeting of 18-19 June 1991 addressed DOD vaccine and immunization policies. The Board limited its discussions to those infectious diseases of potential endemic threat and did not address biological warfare agents as a subject of this review.

2. During this meeting the issue of typhoid vaccines was considered. The Board has heard presentations and considered data regarding the safety and efficacy of the Oral Typhoid Ty21a Vaccine and recommended its use by DOD in AFEB Recommendation 91-3. Noting that both parenteral and the oral typhoid Ty21a vaccines are licensed for use by the Food and Drug Administration, the Board recommends:

a. **THAT EITHER PARENTERAL OR ORAL TYPHOID TY21a VACCINES ARE SUITABLE FOR USE BY THE ARMED FORCES.**

b. **THE TY21a HAS SIGNIFICANTLY REDUCED SIDE EFFECTS. WHEN THE ORAL TYPHOID TY21a VACCINE IS USED, FOUR SEPARATE DOSES ARE REQUIRED IN ACCORDANCE WITH FDA REQUIREMENTS.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

THEODORE E. WOODWARD, M.D.
President, AFEB

W. M. PARSONS, Ph.D.
Captain, Medical Service Corps
U. S. Navy
Executive Secretary

AFEB (15-1a) 5 September 1991
SUBJECT: DOD Vaccine and Immunization Review - Recommendations Concerning Typhoid Vaccine

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
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AFEB (15-1a) 91-14

5 September 1991

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE, HEALTH AFFAIRS
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: DOD Vaccine and Immunization Review - Recommendation Concerning Oral Polio Vaccinations

1. The Armed Forces Epidemiological Board meeting of 18-19 June 1991 addressed DOD vaccine and immunization policies. The Board limited its discussions to those infectious diseases of potential endemic threat and did not address biological warfare agents as a subject of this review.

2. During this meeting the issue of oral polio vaccinations was considered. The difficulty of ascertaining immunization status prior to reporting for active service was noted. Accordingly the Board recommends:

THAT ORAL POLIO VACCINE BE GIVEN TO ALL MILITARY PERSONNEL UNLESS THERE IS HEALTH DEPARTMENT OR PHYSICIAN CERTIFICATION THAT IMMUNIZATIONS HAVE BEEN PREVIOUSLY RECEIVED.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

THEODORE E. WOODWARD, M.D.
President, AFEB

W. M. PARSONS, Ph.D.
Captain, Medical Service Corps
U. S. Navy
Executive Secretary

AFEB (15-1a) 5 September 1991
SUBJECT: DOD Vaccine and Immunization Review - Recommendation Concerning Oral Polio Vaccinations

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
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AFEB (15-1a) 92-1

8 April 1992

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation for the Composition and Dosage of the 1992-1993 Influenza Vaccine

1. At its 20 February 1992 meeting, the Armed Forces Epidemiological Board considered the formulation of the subject vaccine. Final recommendations were proposed by the United States Public Health Service on 16 March 1992. Accordingly, the Board recommends that:

a. **THE TRIVALENT INFLUENZA VACCINE FOR 1992-1993 CONSIST OF THE A/TEXAS/36/91 (H_1N_1) LIKE; A/BEIJING/353/89 (H_3N_2) LIKE; AND B/PANAMA/45/90 LIKE COMPONENTS.**

b. **THE VACCINE SHOULD CONTAIN FIFTEEN (15) MICROGRAMS OF THE HEMAGGLUTININ OF EACH OF THE THREE ANTIGENS PER DOSE.**

c. **WHOLE OR SPLIT VACCINES SHOULD BE UTILIZED DEPENDING ON CONTRACTUAL ARRANGEMENTS AND SUPPLIES FROM THE MANUFACTURERS.**

d. **RECRUIT AND ACTIVE DUTY PERSONNEL SHOULD BE IMMUNIZED WITH A SINGLE DOSE OF THE VACCINE.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

WALTER R. DOWDLE, Ph.D.
President, AFEB

W. M. PARSONS, Ph.D.
Captain, Medical Service Corps
U. S. Navy
Executive Secretary

DEPARTMENT OF THE ARMY
ARMED FORCES EPIDEMIOLOGICAL BOARD
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AFEB (15-1a) 92-4

26 June 1992

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

SUBJECT: Continuation of the Influenza Study at the University of Colorado

1. The Armed Forces Epidemiological Board addressed the issue of continuation of the U. S. Army Influenza Vaccine Monitoring Program at its 20-21 February 1992 meeting. The contract with the University of Colorado will expire 30 September 1993. The Board was pleased to acknowledge the 40-year contribution of the University of Colorado laboratory and particularly the dedication and leadership of Dr. Gordon Meiklejohn. The work of Dr. Meiklejohn's laboratory has greatly contributed to the control of respiratory diseases in the armed forces.

2. The Board endorsed the objectives of the monitoring program and noted the continued military importance of respiratory disease. With the anticipated closing of Lowry Air Force Base, the Air Force Surgeon General has approved continuing the surveillance program in personnel assigned to the United States Air Force Academy. The adequacy and relevancy of this new surveillance population has raised some concern by Board members regarding the importance of evaluating this type of selected personnel.

3. In view of the above, the Board makes the following recommendations:

a. IN ANTICIPATION OF THE 1993 EXPIRATION OF THE CONTRACT WITH THE UNIVERSITY OF COLORADO, THAT THE ARMY, AS LEAD AGENT FOR INFECTIOUS DISEASES, USE THE JTCG-2 OF THE ASBREM TO COORDINATE WITH THE OTHER SERVICES TO CAREFULLY REVIEW MID- AND LONG-TERM NEEDS FOR RESPIRATORY DISEASE SURVEILLANCE, PARTICULARLY IN RECRUITS, AND THE RELEVANCE OF THIS STUDY IN MEETING THOSE NEEDS.

b. IN THE EVENT THE SERVICES DETERMINE THAT A REQUIREMENT EXISTS TO CONTINUE SUCH A SURVEILLANCE STUDY, THAT PROPOSALS WITH CAREFULLY DEFINED OBJECTIVES BE SOLICITED FROM QUALIFIED LABORATORIES.

AFEB (15-1a) 92-4 26 June 1992
SUBJECT: Continuation of the Influenza Study at the University of Colorado

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

WALTER R. DOWDLE, Ph.D.
President, AFEB

W. M. PARSONS, Ph.D.
Captain, Medical Service Corps
U. S. Navy
Executive Secretary

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Dir, Med Plans, Policy and Ops, OP-932, DN
Dir, Env & Life Sci, OUSDA, ATTN: Dr. J. Osterman
Cmdr, HSHA-Z, Brooks AFB
Deputy Cdr, Fleet Readiness & Supt, BUMED-DN

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

AFEB (15-1a) 93-2

03 December 1992

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: U. S. Navy Question - Risk Assessment for Japanese Encephalitis in Enzootic Areas.

1. The Navy is commended on its excellent seroepidemiological studies to date. Military preventive medicine units are encouraged to continue seroepidemiological studies. When JE is known to be seasonally transmitted, blood samples taken to estimate infection should be obtained from unimmunized individuals immediately after the transmission season, e.g. October in Okinawa, September in Japan and Korea. Using this strategy, JE IgM positive samples will yield a fairly accurate measure of JE infection rates during the test year. Alternatively, antibodies in pre-deployment sera can be compared with antibody prevalence in post-deployment sera through use of the specimen repository.

2. The AFEB recommends:

a. **THAT ALL PERSONNEL AND DEPENDENTS ASSIGNED TO OKINAWA AND OTHER ENZOOTIC AREAS BE PROVIDED INFORMATION ON JAPANESE ENCEPHALITIS (JE), INCLUDING INFORMATION ON RISK FACTORS AND PERSONAL PROTECTIVE MEASURES. ALL PERSONNEL AND DEPENDENTS SHOULD BE OFFERED VACCINE. IF VACCINE AVAILABILITY IS LIMITED, VACCINE SHOULD BE OFFERED IN THE FOLLOWING PRIORITY ORDER:**

1. **ACTIVE DUTY PERSONNEL ASSIGNED TO AREAS WITH WELL-ESTABLISHED RISK, e.g. MARINES AT CAMP HANSEN (PRIOR TO DEPLOYMENT).**

2. **OTHER PERSONNEL AND DEPENDENTS WITH POTENTIAL EXPOSURE TO HIGH RISK AREAS, e.g. OTHER MARINES AND CAMPERS (PRIOR TO DEPLOYMENT).**

3. **DEPENDENTS AND OTHER PERSONNEL WITHOUT POTENTIAL HIGH-RISK EXPOSURE, AS DEFINED ABOVE, WHO DESIRE VACCINE AFTER ARRIVAL (AFTER DEPLOYMENT).**

b. **THAT EXCLUSION OF VACCINE ADMINISTRATION ON THE BASIS OF AN ALLERGIC HISTORY SHOULD BE CONSIDERED IN GROUPS 2 and 3.**

AFEB (15-1a) 93-2 03 December 1992
SUBJECT: U. S. Navy Question - Risk Assessment for Japanese Encephalitis in Enzootic Areas.

c. **THAT SHORT TERM VISITORS IN THE OFF SEASON NEED NOT BE IMMUNIZED.**

d. **THAT THE IMMUNOGENICITY OF THE CURRENT VACCINE BE STUDIED WITH A VIEW TOWARD REDUCING THE NUMBER OF DOSES REQUIRED TO IMMUNIZE INDIVIDUALS.**

In response to the specific questions, the AFEB recommends:

e. **THAT DECISIONS TO VACCINATE SHOULD NOT BE BASED SOLELY ON GEOGRAPHIC LOCATIONS AND ECOLOGICAL CONSIDERATIONS IN A RELATIVELY GEOGRAPHICALLY-CONFINED AREA SUCH AS OKINAWA. EVERYONE ASSIGNED TO OKINAWA IS AT SOME LEVEL OF RISK.**

f. **THAT IMMUNIZATION SHOULD BE MADE AVAILABLE AFTER DEPLOYMENT AS IN a.3. ABOVE. THE CONCEPT OF IMMUNIZING ONLY THOSE WITH ANTICIPATED NIGHTTIME EXPOSURE IN RURAL AREAS PRESENTS AN UNACCEPTABLE RISK OF EXPOSURE.**

g. **THAT A NUMERICAL INFECTION RATE SHOULD NOT BE A CONSIDERATION IN AREAS WHERE A SOURCE OF VIRUS (e.g. IN PIGS) IS KNOWN TO BE PRESENT.**

h. **THAT THESE GUIDELINES SHOULD APPLY IN OKINAWA AND ANY OTHER AREAS WHERE JAPANESE ENCEPHALITIS IS PROVEN TO BE ENZOOTIC.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

WALTER R. DOWDLE, Ph.D.
President, AFEB

MICHAEL R. PETERSON, DVM, MPH, DrPH
Colonel, USAF, BSC
Executive Secretary

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
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FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

AFEB (15-1a) 93-5

03 March 1993

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation for the Composition of the 1993-1994 Influenza Vaccine

At its 25 February 1993 meeting, the Armed Forces Epidemiological Board considered the formulation of the subject vaccine. Final recommendations were proposed by the United States Public Health Service on 26 January 1993. Accordingly, the Board recommends that:

a. **THE TRIVALENT INFLUENZA VACCINE FOR 1993-1994 CONSIST OF THE A/BEIJING/32/92(H3N2); A/TEXAS/36/91(H1N1); B/PANAMA/45/90 COMPONENTS.**

b. **THE VACCINE SHOULD CONTAIN FIFTEEN (15) MICROGRAMS OF THE HEMAGGLUTININ OF EACH OF THE THREE ANTIGENS PER DOSE.**

c. **WHOLE OR SPLIT VACCINES SHOULD BE USED DEPENDING ON CONTRACTUAL ARRANGEMENTS AND SUPPLIES FROM THE MANUFACTURERS.**

d. **RECRUIT AND ACTIVE DUTY PERSONNEL SHOULD BE IMMUNIZED WITH A SINGLE DOSE OF THE VACCINE.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

WALTER R. DOWDLE, Ph.D.
President, AFEB

MICHAEL R. PETERSON, DVM, MPH, DrPH
Colonel, USAF, BSC
Executive Secretary

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

AFEB (15-1a) 93-8

22 June 1993

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Tick-Borne Encephalitis (TBE) Vaccine

1. The U. S. Army Medical Research Institute of Infectious Diseases (USAMRIID) holds an Investigational New Drug (IND) Permit for the TBE vaccine manufactured by the Austrian firm, Immuno AG. The vaccine has been used extensively in Austria and has been used by the U. S. Army Medical Department for several years to immunize at-risk soldiers and Department of Defense civilians on weapons inspection teams traveling to the former USSR.

2. Based on efficacy data presented at the 25 February 1993 and 3-4 June 1993 meetings of the AFEB:

THE BOARD SUPPORTS THE USE OF THE TBE VACCINE UNDER IND PROTOCOL WITH INFORMED CONSENT FOR USE IN MILITARY PERSONNEL/UNITS AND CIVILIAN BENEFICIARIES DETERMINED BY THE SERVICES TO HAVE SIGNIFICANT POTENTIAL FOR EXPOSURE TO TBE IN ENDEMIC AREAS.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

WALTER R. DOWDLE, Ph.D.
President, AFEB

MICHAEL R. PETERSON, DVM, MPH, DrPH
Colonel, USAF, BSC
Executive Secretary

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Cmdr, U. S. Army Med R&D Cmd
Dir, Prof Svcs, OTSG-DA
Dir, Env & Life Sci, OUSDA, ATTN: Dr. J. Osterman
Cmdr, HSHA-Z, Brooks AFB

AFEB (15-1a) 94-2

13 December 1993

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendations Concerning Tuberculosis (TB) Skin Testing of Armed Forces Personnel

Available data indicate that the TB prevention programs of the Services have kept the annual number of cases requiring hospitalization and the rate of hospital admissions for active TB relatively low. Based on this information, no major changes are needed in the Services' TB control programs to prevent active TB disease (as reflected by admissions for TB). However, the Armed Forces Epidemiological Board (AFEB) recommends the following steps be taken to refine DoD policy on TB skin testing of active duty personnel:

a. **DOD-WIDE GOALS OF THE TB SKIN TESTING PROGRAM SHOULD BE CLEARLY SET FORTH.**

b. **THE MANTOUX TEST, USING INTERMEDIATE STRENGTH PPD, SHOULD BE USED FOR ALL TB SKIN TESTING IN DoD, EXCEPT IN TIME OF EMERGENCY WHEN RAPID SCREENING OF LARGE NUMBERS OF PERSONNEL DICTATES USE OF THE MONO-VACC MULTIPLE PUNCTURE TEST.**

c. **THE MOST RECENT AMERICAN THORACIC SOCIETY (ATS)/ CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) CRITERIA FOR A POSITIVE MANTOUX TEST SHOULD BE USED TO EVALUATE THE INITIAL (BASELINE) SKIN TEST. FOR MOST ACTIVE-DUTY PERSONNEL, INDURATION OF 15 MM OR GREATER WOULD BE CLASSIFIED AS A POSITIVE SKIN TEST. THEREAFTER, AN INDIVIDUAL SHOULD BE CONSIDERED A SKIN TEST CONVERTER IF THERE IS AN INCREASE OF 10 MM OR MORE FOR INDIVIDUALS UNDER AGE 35 (15 MM OR MORE FOR INDIVIDUALS AGE 35 OR GREATER) IN THE DIAMETER OF INDURATION OF THE SKIN TEST COMPARED TO THE BASELINE TEST.**

AFEB (15-1a) 94-2 13 December 1993
SUBJECT: Recommendations Concerning Tuberculosis (TB) Skin Testing of Armed Forces Personnel

d. SINCE EVEN REGULAR TB SKIN TESTING WILL NOT IDENTIFY ALL PERSONNEL INFECTED WITH TB, INDIVIDUALS LIVING OR WORKING IN CONFINED ENVIRONMENTS (WHERE THE RISK OF TRANSMISSION OF INFECTIOUS DISEASES IS INCREASED) AND THEIR SUPERVISORS SHOULD BE MADE AWARE OF THE NEED TO SEEK EARLY MEDICAL ATTENTION FOR SYMPTOMS CONSISTENT WITH TB OR OTHER INFECTIOUS DISEASES (E.G., PERSISTENT COUGH, UNEXPLAINED WEIGHT LOSS, ETC.)

e. THE DoD SHOULD CONSIDER COLLECTING THE DATA NEEDED TO EVALUATE THE COST/BENEFITS OF CURRENT POLICY AND TO REFINE IT WHERE INDICATED. THIS WOULD REQUIRE TRACKING OF THE RATES OF TB DISEASE AND TB SKIN TEST CONVERSION AMONG ACTIVE DUTY PERSONNEL AND ANALYSIS TO IDENTIFY HIGH RISK SUBGROUPS AND GEOGRAPHIC AREAS.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

WALTER R. DOWDLE, Ph.D.
President, AFEB

MICHAEL R. PETERSON, DVM, MPH, DrPH
Colonel, USAF, BSC
Executive Secretary

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COL J. Pitt Tomlinson, USA, MC
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COL Peter Lutter, RAMC
CDR Gordon Clifford, CFMS

AFEB (15-1a)

13 December 1993

MEMORANDUM FOR THE SURGEON GENERAL, DEPARTMENT OF THE ARMY

SUBJECT: Armed Forces Epidemiological Board (AFEB) Recommendations Concerning Tuberculosis (TB) Skin Testing of Armed Forces Personnel

1. The AFEB considered the questions at enclosure 1 from Mr. Richards, Executive Officer to the Assistant Secretary of Defense for Health Affairs, at its June and October 1993 meetings. The Board's recommendations, in response to Mr. Richards' questions, are at enclosure 2.

2. The recommendations are forwarded for your review, concurrence and/or comment preparatory to their being forwarded to Mr. Richards.

3. Please provide this office with your response not later than 31 January 1993. Please contact Colonel Peterson at (703) 756-8012 if you or your staff have any questions.

4. The Army's point of contact for this action is Colonel Erdtmann.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

WALTER R. DOWDLE, Ph.D.
President, AFEB

MICHAEL R. PETERSON, DVM, MPH, DrPH
Colonel, USAF, BSC
Executive Secretary

2 Encls
1. Ltr. Question
2. Rec 94-2

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

AFEB (15-1a) 94-7

03 August 1994

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

SUBJECT: Biological Warfare Vaccines

In accordance with DoD Directive 6205.3, the Armed Forces Epidemiological Board (AFEB) met on 3 August 1994 to review two vaccines available to protect against validated biological warfare threat agents and makes the following recommendations:

a. **THE LICENSED ANTHRAX VACCINE IS SUITABLE FOR USE IN PERSONNEL ASSIGNED, PRE-DESIGNATED OR SCHEDULED FOR DEPLOYMENT TO AREAS WITH A VALIDATED HIGH THREAT UNDER ITS APPROVED INSTRUCTIONS.**

b. **THE INVESTIGATIONAL BOTULINUM TOXOID VACCINE IS SUITABLE FOR USE UNDER THE CURRENT PROTOCOL IN PERSONNEL WITH RISK AS DEFINED ABOVE. THE BOARD STRONGLY ENCOURAGES PURSUIT OF FDA APPROVAL OF THIS PRODUCT.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

LEWIS H. KULLER, M.D., DrPH
President, AFEB

MICHAEL R. PETERSON, DVM, MPH, DrPH
Colonel, USAF, BSC
Executive Secretary

CF: CO, USAMRDALC

3 AUG 1994

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF
DASG-RDZ (40-562)

MEMORANDUM FOR ARMED FORCES EPIDEMIOLOGICAL BOARD (AFEB)

SUBJECT: Special Meeting of the AFEB

1. References:

a. Meeting, AFEB, 8 Jul 94, subject: Program Review.

b. Department of Defense (DoD) Directive 6205.3, DoD Immunization Program for Biological Warfare Defense, 26 Nov 93.

2. The AFEB met 8 Jul 94 and agreed to conduct a subgroup meeting to support the implementation of the DoD Immunization Program for Biological Warfare Defense.

3. Request:

a. The AFEB meet 3 Aug 94.

b. Review specific biological defense immunization recommendations.

c. The Chair of the AFEB identify vaccines available to protect against biological threat ageents designated by the Chairman of the Joint Chiefs of Staff and recommend appropriate immunization protocols.

4. Point of contact for this action is MAJ William Klenke, DASG-HCO, DSN 289-8185 or commercial (703) 756-8185.

FOR THE SURGEON GENERAL:

Russ Zajtchuk

RUSS ZAJTCHUK
Brigadier General, MC
Assistant Surgeon General

CF:
SGPS-PSP
JPO-BD
SGRD-PLD
DASG-HCO

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

AFEB (15-1a) 94-8

09 August 1994

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

SUBJECT: Recommendation on the Use of Meningococcal Vaccine

In response to your request for telephonic advice on the use of meningococcal vaccine for DoD personnel deployed in Rwanda and Zaire, the Board recommends the following:

a. **THE BOARD CONCURS WITH THE CDC RECOMMENDATION THAT ALL DoD PERSONNEL DEPLOYED TO RWANDA AND ZAIRE SHOULD BE IMMUNIZED WITH THE MENINGOCOCCAL POLYSACCHARIDE VACCINE, QUADRIVALENT A,C,Y, W-135, LICENSED FOR USE IN THE UNITED STATES.**

b. **THERE IS NO AVAILABLE SCIENTIFIC DATA THAT DEMONSTRATES THE EFFICACY OF BOOSTER DOSES OF THE VACCINE. HOWEVER, IF IN THE JUDGMENT OF THE MEDICAL AUTHORITIES SUPPORTING THE INVOLVED CINC THERE IS SIGNIFICANT RISK OF EXPOSURE TO DoD PERSONNEL, A BOOSTER DOSE IS RECOMMENDED. A BOOSTER DOSE AT 3-5 YEARS, AS WAS RECOMMENDED DURING OPERATIONS DESERT SHIELD AND DESERT STORM, SEEMS REASONABLE.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Michael R. Peterson

LEWIS H. KULLER, M.D., DrPH
President, AFEB

Michael R. Peterson

MICHAEL R. PETERSON, DVM, MPH, DrPH
Colonel, USAF, BSC
Executive Secretary

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

AFEB (15-1a) 94-9

11 October 1994

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendations Concerning Administration of Plague Vaccine and Antibiotic Prophylaxis

1. At its 6-7 October 1994 meeting, the Armed Forces Epidemiological Board was asked to reevaluate the DoD plague immunization policy.

2. During this meeting the issue of plague prevention was considered and the Board offers the following recommendations:

a. **THAT ROUTINE IMMUNIZATION AGAINST PLAGUE NOT BE DONE.**

b. **THAT PLAGUE VACCINE BE ADMINISTERED TO PERSONNEL WHO ARE LIKELY TO BE ASSIGNED TO AREAS WHERE THE RISK OF ENDEMIC TRANSMISSION OR OTHER EXPOSURE IS HIGH.**

c. **VACCINE MAY NOT BE EFFECTIVE IN THE PREVENTION OF AIRBORNE INFECTION. THE ADDITION OF ANTIBIOTIC PROPHYLAXIS IS RECOMMENDED FOR SUCH SITUATIONS.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Michael R. Peterson
for LEWIS H. KULLER, M.D., DrPH
President, AFEB

Michael R. Peterson
MICHAEL R. PETERSON, DVM, MPH, DrPH
Colonel, USAF, BSC
Executive Secretary

Copies Furnished:
(See Page 2)

AFEB (15-1a) 94-9 11 October 1994

SUBJECT: Recommendations Concerning Administration of Plague Vaccine and Antibiotic Prophylaxis

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CO NACMEDRSCHDEVCOM
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Dir, Med Resources, Plans & Policy Div. (N931)
Dir, Env & Life Sci, OUSDA, ATTN: Dr. J. Osterman
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Head, Epi Dept., NEPMU 5
COL J. Pitt Tomlinson, USA, MC
CDR Timothy J. Ungs, USPHS
COL Robert Leitch, RAMC
CDR Gordon Clifford, CFMS

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

AFEB (15-1a) 95-1

28 February 1995

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendations Concerning Adenovirus Vaccine Program

At its 23-24 February 1995 meeting, the Armed Forces Epidemiological Board was briefed on issues regarding the adenovirus vaccine program. Although a short term critical supply problem appears to have been resolved, the Board has concerns about the long term success of this program. To assist you in prioritizing this program, we discussed these issues and provide the following general comments:

a. **THE RISK AND IMPACT OF ADENOVIRUS INFECTIONS TO MILITARY OPERATIONS ARE CONSIDERED OF HIGHEST SIGNIFICANCE AT PRESENT AND FOR THE THE FORESEEABLE FUTURE.**

b. **ASSURING CONTINUING AND TIMELY AVAILABILITY OF THE CURRENT VACCINE SHOULD BE GIVEN THE HIGHEST PRIORITY IN FACILITATING ACQUISITION.**

c. **ALTERNATIVE SCENARIOS FOR THE USE OF VACCINE SUCH AS OUTBREAK CONTROL SHOULD BE CONSIDERED AND RESEARCH TO DETERMINE THE RELATIVE EFFICACY OF SUCH PROGRAMS SHOULD BE CONDUCTED.**

d. **LONG TERM ARRANGEMENTS TO ASSURE A STABLE AND RELIABLE SOURCE OF VACCINE SHOULD BE PURSUED VIGOROUSLY.**

e. **EPIDEMIOLOGIC SURVEILLANCE ACTIVITIES INCLUDING DIAGNOSTIC CAPABILITIES SHOULD BE STRENGTHENED IN THE MILITARY.**

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

AFEB (15-1a) 95-2

28 February 1995

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendations Regarding the Use of the Newly Licensed Hepatitis A Vaccine in Military Personnel

1. In response to your request for recommendations regarding the use of the newly licensed hepatitis A vaccine in military personnel, the Board reviewed available data on clinical trials at its recent meeting and provides the following conclusions:

a. **HEPATITIS A VACCINE IS SAFE AND HIGHLY EFFICACIOUS AND OFFERS CERTAIN DISTINCT ADVANTAGES OVER IMMUNE GLOBULIN FOR PREVENTION OF HEPATITIS A:**

1) **THE SCHEDULE FOR ADMINISTRATION OF VACCINE IS NOT TIED TO THE TIME OF DEPLOYMENT AND WILL SIGNIFICANTLY ENHANCE READINESS.**

2) **RECENTLY EXPERIENCED SHORTAGES OF IG CAN BE EXPECTED TO CONTINUE FOR THE FORESEEABLE FUTURE.**

3) **ACQUISITION COSTS OF IG ARE EXPECTED TO INCREASE.**

4) **VACCINE PRODUCES RAPID (2-3 WEEKS AFTER A FIRST DOSE) AND LONGER LASTING (AT LEAST 4 YEARS) ACTIVE IMMUNITY**

b. **THE COST OF VACCINE IS CURRENTLY HIGHER THAN IG BUT VACCINE MAY BE MORE COST EFFECTIVE DEPENDING ON RISK AND LOGISTICAL FACTORS.**

c. **BASED ON THE LIMITED DATA PRESENTED, CONCURRENT USE OF THE VACCINE WITH OTHER VACCINES USED IN MILITARY PERSONNEL APPEARS TO HAVE NO RECOGNIZED ADVERSE EFFECTS OR INTERFERENCE WITH IMMUNE RESPONSES. INDEED, A COMBINATION HEPATITIS A AND B VACCINE MAY BE COST EFFECTIVE.**

28 February 1995

SUBJECT: Recommendations Regarding the Use of the Newly Licensed Hepatitis A Vaccine in Military Personnel

d. IN OUTBREAK SITUATIONS, IG IS THE PREVENTIVE MEASURE OF CHOICE. IF PROVIDING LONG TERM PROTECTION IS DESIRABLE, VACCINE MAY BE GIVEN SIMULTANEOUSLY.

e. BASED ON THESE FINDINGS, USE OF HEPATITIS A VACCINE IN MILITARY PERSONNEL IS RECOMMENDED. SPECIAL PRIORITY CAN BE GIVEN TO USE IN THE FOLLOWING GROUPS IN DESCENDING ORDER:

1) MILITARY FORCES ASSIGNED OR DEPLOYED TO GEOGRAPHIC AREAS WITH KNOWN HIGH RISK.

2) DEPLOYABLE FORCES, ACTIVE AND RESERVE, FOLLOWING ALERT LEVEL RANKING.

3) FAMILY MEMBERS AND DOD CIVILIANS ASSIGNED ABROAD OR WITH RECURRENT TRAVEL TO HIGH RISK AREAS.

4) ALL OTHER FORCES.

f. USE OF THE VACCINE IN DEPENDENTS INCLUDING CHILDREN, FOOD HANDLERS, AND DAY CARE WORKERS SHOULD FOLLOW ACIP RECOMMENDATIONS, WHICH WILL BE ISSUED IN THE NEAR FUTURE.

g. SCREENING TO DETECT PREEXISTING IMMUNITY MAY BE COST EFFECTIVE IN UNITS WITH HIGH PREVALENCE OF ANTIBODY TO HA. STUDIES TO DETERMINE THE VALUE OF SCREENING OF NEW UNIT MEMBERS AND RECRUITS ON AN ONGOING BASIS ARE RECOMMENDED.

2. A second vaccine preparation is expected to be licensed. At that time, these recommendations will be reviewed and modified, if necessary.

LEWIS H. KULLER, M.D., DrPH
President, AFEB

MICHAEL R. PETERSON, DVM, MPH, DrPH
Colonel, USAF, BSC
Executive Secretary

Col MC

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AFEB (15-1a) 95-2 28 February 1995

SUBJECT: Recommendations Regarding the Use of the Newly Licensed Hepatitis A Vaccine in Military Personnel

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

AFEB (15-1a) 95-3

24 July 1995

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation Concerning Varicella Vaccine

1. Varicella represents a limited but potentially disruptive infection in recruit populations. In the face of background immunity of >90%, universal immunization of recruits is not recommended. To determine the proper role for the newly licensed varicella vaccine in military settings, the Board recommends the following:

AN UNCONTROLLED PILOT PROJECT SHOULD BE CONDUCTED TO ASSESS THE PREVENTIVE EFFECTIVENESS OF SEROLOGIC SCREENING OF ALL RECRUITS FOR VARICELLA ANTIBODY FOLLOWED BY IMMUNIZATION OF NONIMMUNES WITH THE STANDARD TWO-DOSE REGIMEN. THE RELIABILITY OF A HISTORY OF CHICKENPOX SHOULD BE DETERMINED IN THIS STUDY WITH THE GOAL OF POSSIBLY LESSENING THE NEED FOR SEROLOGIC TESTING IN THE FUTURE.

2. Results of this study will allow development of a consistent service-wide policy for the use of varicella vaccine.

LEWIS H. KULLER, M.D., DrPH
President, AFEB

FRANCIS L. O'DONNELL
Colonel, USA, MC
Preventive Medicine Staff Officer
Acting, AFEB Executive Secretary

DEPARTMENT OF DEFENSE
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REPLY TO
ATTENTION OF

AFEB (15-1a) 95-4

24 July 1995

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation on the Use of Meningococcal Vaccine

1. Meningococcal disease continues to be a problem in military settings such as basic training. Current vaccine formulations provide significant protection against serogroups A, C, Y and W 135, but infections continue to occur after the widespread use of vaccine.

2. The duration of vaccine-induced protection is not well known but may be very long and frequent boosters may not be required. In the face of these uncertainties, the Board makes the following recommendations:

a. **All meningococcal isolates should be grouped and group B organisms typed by a reference laboratory to assess the current prevalence of strains in the military population. B typing information may be useful if the group B OMP vaccine becomes an option. The vaccine history of individuals with meningococcal disease should be determined.**

b. **A longitudinal study of antibody persistence for 3 to 10 years should be conducted using samples from the DoD Serum repository. The effects of current booster regimens should be assessed in a separate prospective study.**

3. The results of these studies will allow us to recommend optimal vaccine formulations and booster intervals. In the meantime, a consistent service-wide policy of a five-year booster interval is reasonable.

LEWIS H. KULLER, M.D., DrPH
President, AFEB

FRANCIS L. O'DONNELL
Colonel, USA, MC
Preventive Medicine Staff Officer
Acting, AFEB Executive Secretary

DEPARTMENT OF DEFENSE
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REPLY TO
ATTENTION OF

AFEB (15-1a) 96-1

05 December 1995

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation for Tick Borne Encephalitis (TBE) and Hepatitis A Vaccine Use in DoD Personnel Deployed to Bosnia

In response to your request to the Armed Forces Epidemiological Board (AFEB) for advice regarding the use of vaccines in U.S. troops deployed to Bosnia, the AFEB Disease Control Subcommittee held a teleconference on 04 December 1995 and makes the following recommendations:

a. **THE COMMITTEE REAFFIRMS ITS RECOMMENDATION FOR GENERAL USE OF THE LICENSED HEPATITIS A VACCINE IN DEPLOYED TROOPS. EXCEPTIONS TO THIS WOULD BE ALLOWED FOR VALID LOGISTICAL REASONS. ROUTINE USE OF IMMUNE SERUM GLOBULIN IS NOT RECOMMENDED AND WOULD COMPOUND AND PERPETUATE THE SERIOUS SUPPLY DIFFICULTIES THAT SUCH USE HAS CREATED IN THE CIVILIAN COMMUNITY.**

b. **WITH REGARD TO THE QUESTION OF TICK-BORNE ENCEPHALITIS (TBE) VACCINE, THE COMMITTEE RECOMMENDS THAT THE VACCINE NOT BE GIVEN TO TROOPS PRIOR TO DEPLOYMENT PENDING FURTHER REVIEW. THE TICK SEASON IS SEVERAL MONTHS AWAY, AND FURTHER INFORMATION CAN BE OBTAINED PRIOR TO THE RISK PERIOD TO ASSIST US IN MAKING A MORE INFORMED DECISION. SUCH INFORMATION WOULD INCLUDE RECENT DATA ON DISEASE OCCURRENCE IN BOSNIA, EXPERIENCE OF THE U.N. FORCES, TICK ACTIVITY INFORMATION FOR RECENT YEARS, A BETTER DEFINED VIEW OF "HOT SPOTS" OF TBE VERSUS AREAS OF U.S. TROOP ASSIGNMENT, CLASSIFICATION OF TROOPS INTO FIELD EXPOSURE GROUPS, ETC.**

c. **THE COMMITTEE RECOMMENDS A FACE-TO-FACE MEETING OF A FEW OF ITS MEMBERS WITH SERVICE REPRESENTATIVES WHO CAN PROVIDE THE ABOVE INFORMATION PRIOR TO THE NEXT BOARD MEETING, PERHAPS IN THE BEGINNING OF FEBRUARY.**

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
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REPLY TO
ATTENTION OF

AFEB (15-1a) 96-2

21 February 1996

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation for Tick-Borne Encephalitis (TBE) Vaccine Use in DoD Personnel Deployed to Bosnia

1. In response to the question of the risk of tick-borne encephalitis (TBE) and use of vaccine in U.S. troops deployed to Bosnia, the Board offers the following evaluation:

a. **BASED ON CURRENT AND HISTORICAL DATA, TICK-BORNE ENCEPHALITIS REPRESENTS A POTENTIAL RISK THAT IS DIFFICULT TO QUANTIFY, BUT WHICH COULD RESULT IN LESS THAN 10 TO MORE THAN 20 CLINICAL CASES IN U.S. TROOPS IN THE SPECIFIC AREAS OF HUNGARY, CROATIA, AND BOSNIA WHERE THEY ARE CURRENTLY DEPLOYED. THE SPECIFIC RISK IN BOSNIA CAN ONLY BE ASSESSED. INDIRECTLY BUT APPEARS TO BE PRESENT, ALBEIT AT LOWER LEVELS, AS AN EXTENSION FROM THE HIGHLY ENDEMIC REGIONS TO THE NORTH. DISRUPTION OF HABITAT AND MOVEMENT OF ANIMALS AND PEOPLE DURING RECENT CONFLICTS MAY HAVE INCREASED THE RISK IN BOSNIA AND OTHER AREAS OF POTENTIAL DEPLOYMENT.**

b. **IT IS ANTICIPATED THAT THE RISK OF TBE WILL INCREASE SHARPLY IN THE SPRING BEGINNING IN MARCH, PEAKING IN JULY, AND LASTING UNTIL OCTOBER. DUE TO SHORT ATTACHMENT TIMES FOR INFECTION BY TICKS AND INFECTION OF ALL STAGES OF TICKS, INDIVIDUAL PROTECTIVE MEASURES MAY NOT BE COMPLETELY EFFECTIVE IN PREVENTING EXPOSURE.**

c. **THE ACUTE CLINICAL ILLNESS OF TBE IS MORE SEVERE IN ADULTS AND HENCE CAN BE SERIOUS IN A MILITARY SETTING. TBE CAN BE FOLLOWED OCCASIONALLY BY LONG-TERM, PERMANENT NEUROLOGIC SEQUELAE. PROPER MANAGEMENT OF ACUTE INFECTIOUS NEUROLOGIC DISEASES IN THE FIELD IS DIFFICULT, AND TBE, BECAUSE OF ITS BIPHASIC COURSE, CAN BE A PARTICULAR PROBLEM.**

AFEB (15-1a) 96-2 21 February 1996

SUBJECT: Recommendation for Tick-Borne Encephalitis (TBE) Vaccine Use in DoD Personnel Deployed to Bosnia

d. TBE VACCINE IS USED ROUTINELY IN SEVERAL COUNTRIES IN EUROPE IN HIGH RISK GROUPS SUCH AS FORESTRY WORKERS AND THE MILITARY AND IS A ROUTINE CHILDHOOD IMMUNIZATION IN AUSTRIA. OVER 26 MILLION DOSES OF THE CURRENT VACCINE HAVE BEEN ADMINISTERED THROUGHOUT EUROPE. THE ESTIMATED EFFICACY IS OVER 90%. ALTHOUGH NOT LICENSED IN THE UNITED STATES, THE VACCINE WOULD APPEAR TO HAVE EQUIVALENCE WITH U.S.PRODUCTS IN THE STANDARDS FOR ITS MANUFACTURE AND SAFETY. THE MANUFACTURER IS PREPARED TO PROVIDE SUFFICIENT VACCINE ON SHORT NOTICE TO IMMUNIZE ALL TROOPS IN THE AREA.

e. THE ACCELERATED SCHEDULE OF IMMUNIZATION ON DAYS 0,7,AND 28 IN THE CURRENT IND PROTOCOL APPEARS TO GIVE RAPID AND STRONG IMMUNITY BASED ON ANTIBODY RESPONSES. SOME DEGREE OF CROSS-PROTECTION TO RUSSIAN SPRING-SUMMER ENCEPHALITIS WILL DEVELOP AFTER TBE VACCINE.

f. TBE IS CLASSICALLY FOUND IN STABLE ENVIRONMENTAL FOCI. IDEALLY, IMMUNIZATION COULD BE TARGETED TO INDIVIDUALS WHO WILL BE DEPLOYED IN AREAS OF ESTABLISHED RISK. HOWEVER, ACCURATE INFORMATION ON CURRENT FOCI OF TBE ACTIVITY IS NOT AVAILABLE, AND LOCATIONS OF TROOP DEPLOYMENT MAY UNEXPECTEDLY CHANGE OVER TIME. THEREFORE, SELECTIVE IMMUNIZATION BASED ON CURRENT DEPLOYMENT PLANS WOULD NOT PROVIDE ANY PROTECTION TO UNITS WHO WILL SUBSEQUENTLY BE MOVED TO AREAS OF RISK.

g. SIDE EFFECTS FOR TBE VACCINE INCLUDE LOCAL PAIN AND/OR REDNESS IN 3-5% OF VACCINEES. TEMPORALLY ASSOCIATED TOTAL ADVERSE REACTIONS HAVE BEEN REPORTED AT A RATE OF 1 IN 33,000 AND SERIOUS REACTIONS, INCLUDING SIGNIFICANT NEUROLOGIC PROBLEMS, AT A RATE OF APPROXIMATELY 1 IN 170,000 IN THE 26 MILLION PERSONS IMMUNIZED IN EUROPE. THESE REPORTS ARE BASED ON A PASSIVE SURVEILLANCE SYSTEM AND ARE SIMILAR TO THOSE REPORTED WITH OTHER WIDELY USED VACCINES.

AFEB (15-1a) 96-2 21 February 1996

SUBJECT: Recommendation for Tick-Borne Encephalitis (TBE) Vaccine Use in DoD Personnel Deployed to Bosnia

2. Based on these factors and others contained in the TBE memo prepared by USACHPPM, the Board recommends:

a. **PERSONAL PROTECTIVE MEASURES TO MINIMIZE TICK EXPOSURE, INCLUDING LONG LASTING UNIFORM IMPREGNATION, MUST BE IMPLEMENTED BY COMMANDERS IN THE FIELD.**

b. **TBE VACCINE IS RECOMMENDED FOR ALL TROOPS DEPLOYED TO THE HUNGARY, CROATIA AND BOSNIA AREAS WITHOUT RESPECT TO ACTIVITY OR UNIT OF ASSIGNMENT. PRIORITY SHOULD BE GIVEN TO HAVE THE FIRST DOSE ADMINISTERED TO UNITS AT THE HIGHEST RISK OF EXPOSURE BY MARCH 15.**

c. **THE PROCEDURES REQUIRED TO USE THIS PRODUCT UNDER IND PROTOCOL, INCLUDING OBTAINING INFORMED CONSENT AND MAINTAINING ADEQUATE DOCUMENTATION, WILL REQUIRE ADDITIONAL RESOURCES SO AS NOT TO SLOW ITS DELIVERY TO TROOPS IN THE FIELD AND INCREASE THEIR RISK OF CONTRACTING TBE.**

d. **MEASURES FOR RODENT EXCLUSION SHOULD BE IMPLEMENTED TO REDUCE THE RISK OF THIS AND OTHER VECTOR-BORNE AND RODENT ASSOCIATED DISEASES, E.G., HANTAVIRUS, CRIMEAN-CONGO HEMORRHAGIC FEVER, AND LYME DISEASE.**

e. **INGESTION OF RAW MILK OR ANY UNPASTEURIZED LOCAL DAIRY PRODUCTS FROM CATTLE, SHEEP OR GOATS SHOULD BE PROHIBITED.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Michael S. Ascher

MICHAEL S. ASCHER, M.D.
Chairman, Disease Control

Vicky L. Fogelman

VICKY L. FOGELMAN
Colonel, USAF, BSC
AFEB Executive Secretary

Copies Furnished:
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AFEB (15-1a) 96-2

21 February 1996

SUBJECT: Recommendation for Tick-Borne Encephalitis (TBE) Vaccine Use in DoD Personnel Deployed to Bosnia

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
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FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

AFEB (15-1a) 96-3

14 March 1996

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation on Timing of Booster Dose for Japanese Encephalitis Vaccine

1. The Armed Forces Epidemiological Board (AFEB) was asked to provide an opinion on whether it would be reasonable to administer the booster dose three years after the primary 3-dose series for Japanese encephalitis vaccine. The Board reviewed the FDA approved package insert and the ACIP statement, and reviewed data from a small study of 39 individuals revaccinated three years after the primary series. There was only a slight decline in antibody titers between 6 months and 3 years after the primary series. Two individuals at each time, 16 months and 3 years, had titers below the protective level of 1:10.

2. The vaccine is also believed to cause serious urticarial reactions in approximately 1-100 per 10,000 doses; the reactions may or may not occur following a booster dose.

3. Given these considerations, the AFEB recommends:

CHANGING TO A 3-YEAR SCHEDULE, BUT OBTAINING MORE DATA ON ANTIBODY DECLINE AT 3 YEARS BY OBTAINING SERUM SPECIMENS PRIOR TO THE BOOSTER. INFORMATION SHOULD ALSO BE OBTAINED ON ANY INTERVENING BOOSTERS OR TRAVEL IN ENDEMIC AREAS. RESULTS OF THE SEROLOGIC STUDY SHOULD BE REPORTED TO THE AFEB WITHIN ONE YEAR.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Gerald F. Fletcher MD

GERALD F. FLETCHER, M.D.
AFEB President

Vicky L. Fogelman

VICKY L. FOGELMAN
Colonel, USAF, BSC
AFEB Executive Secretary

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AFEB (15-1a) 96-3 14 March 1996

SUBJECT: Recommendation on Timing of Booster Dose for Japanese Encephalitis Vaccine

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REPLY TO
ATTENTION OF

AFEB (15-1a) 97-1

22 January 1997

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation for the Use of Hepatitis A Vaccines Produced by Different Manufacturers

The Armed Forces Epidemiological Board (AFEB) Infectious Disease Subcommittee met on 13 December 1996 to review the question of whether hepatitis A vaccine produced by two different manufacturers could be used in the same individual to complete the two dose immunization series. The following recommendation was proposed by the subcommittee and approved by the full Board:

a. **ALTHOUGH PERTINENT DATA ARE LIMITED, FROM A PRACTICAL POINT OF VIEW, THE HEPATITIS A VACCINES FROM THE TWO MANUFACTURERS CAN BE CONSIDERED TO BE COMPARABLY IMMUNOGENIC AND INTERCHANGEABLE. EITHER VACCINE CAN BE USED TO COMPLETE AN IMMUNIZATION SERIES BEGUN WITH THE OTHER.**

b. **WHEN EQUIVALENT PRODUCTS, SUCH AS HEPATITIS A VACCINE, ARE PRODUCED BY TWO MANUFACTURERS, DUAL SOURCE CONTRACTS OFFER THE ADVANTAGES OF SUPPORTING THE LONG-TERM VACCINE MANUFACTURING CAPABILITY OF BOTH MANUFACTURERS AND PROVIDING A SAFEGUARD SHOULD ANY ONE MANUFACTURER EXPERIENCE AN INTERRUPTION IN ITS ABILITY TO SUPPLY VACCINE. THUS, THE AFEB RECOMMENDS THAT THE DOD DEVELOP A DUAL SOURCE STRATEGY FOR THE PURCHASE OF HEPATITIS A VACCINE.**

C. **ANTICIPATING THE USE OF HEPATITIS A VACCINE FROM TWO MANUFACTURERS, THE AFEB RECOMMENDS A STUDY BE PERFORMED OF THE SAFETY AND IMMUNOGENICITY OF MIXING THE TWO VACCINES IN THE COMPLETION OF THE TWO DOSE VACCINATION SERIES. THE RESULTS OF SUCH A STUDY WOULD BE OF VALUE BOTH TO THE DOD AND THE CIVILIAN POPULATION.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

AFEB (15-1a) 97-1 22 January 1997

SUBJECT: Recommendation for the Use of Hepatitis A Vaccines of Different Manufacturers

GERALD F. FLETCHER, M.D.
AFEB President

WILLIAM SCHAFFNER, II, M.D.
Chairman, Disease Control Committee

VICKY L. FOGELMAN, COL., USAF, BSC
AFEB Executive Secretary

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
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REPLY TO
ATTENTION OF

AFEB (15-1a) 98-1

09 January 1998

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation for the Use of Reduced Dose of Hepatitis B Vaccines in Military Recruits

1. The Centers for Disease Control and Prevention now recommends universal vaccination against hepatitis B virus for all adolescents aged 11-21 years in the United States. The Armed Forces Epidemiological Board (AFEB), Infectious Disease Control Subcommittee, met on 11 December 1997 to review the data on immune responses to reduced doses of hepatitis B vaccines, and their possible application for universal immunization of all military recruits. Responses to recombinant hepatitis B vaccines are highly age dependent with dependably vigorous responses observed in persons <30 years of age. Obesity and smoking are noted to reduce immune response to hepatitis B vaccine. Responses to reduced doses of the two licensed vaccines (5 μg of Recombivax HB or 10 μg of Engerix B) administered intramuscularly are adequate to provide protection in the vast majority (>95%) of recruits. Data show that peak antibody response to hepatitis B vaccine is increased when the third dose (booster) is given more than six months after the first dose. Therefore, the following recommendations were proposed:

a. **ALL MILITARY RECRUITS <30 YEARS OF AGE WHO HAVE NOT PREVIOUSLY RECEIVED A DOCUMENTED PRIMARY SERIES OF HEPATITIS B VACCINE SHOULD BE IMMUNIZED AGAINST HEPATITIS B.**

b. **A REDUCED DOSE OF HEPATITIS B VACCINE (5 μg OF RECOMB VIVAX HB OR 10 μg OF ENGERIX B) MAY BE USED TO IMMUNIZE RECRUITS. THE REDUCED DOSE MAY ALSO BE USED IN OTHER MILITARY PERSONNEL <30 YEARS OF AGE PROVIDED THEY ARE NON-SMOKERS AND NOT OBESE.**

c. **THE THIRD DOSE MAY BE GIVEN AT AN INTERVAL LONGER THAN SIX MONTHS AFTER THE FIRST DOSE.**

AFEB (15-1a) 98-1 09 January 1998
SUBJECT: Recommendation for the Use of Reduced Dose of Hepatitis B Vaccines in Military Recruits

2. This recommendation was discussed and approved by the Infectious Disease Subcommittee on 11-12 December 1997 and endorsed by the full Board on 12 December 1997.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

GERALD F. FLETCHER, M.D.
AFEB President

VICKY L. FOGELMAN
Colonel, BSC, USAF
AFEB Executive Secretary

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REPLY TO
ATTENTION OF

AFEB (15-1a) 98-2

09 January 1998

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation for Japanese Encephalitis Vaccine

1. In a 14 March 1996 memorandum, the Armed Forces Epidemiological Board (AFEB), in response to a request to consider whether it was reasonable to increase the interval between the Japanese encephalitis (JE) vaccine primary series and booster dose from two to three years made the following recommendations:

a. Changing to a three-year schedule.
b. Obtaining more data on JE antibody level decline at three years.
c. That the results of the above study be reported back to the AFEB.

2. At its 11 December 1997 meeting, the Board was briefed on the results of a retrospective cohort serosurvey of 68 active-duty Marines who had received a three-dose primary series of JE vaccine between 1 and >4 years previously, and had antibody titers performed. The results of this study as presented are confusing, but fit best with an interpretation that either recent lots of JE vaccine are significantly less immunogenic than older lots of vaccine, or that in recent years JE vaccine is being improperly handled/stored/administered. In addition, the Board heard anecdotal evidence that the latter concern was justified.

3. Based on this information, the Board makes the following recommendations:

a. **THE NAVY BE TASKED WITH CONDUCTING A HIGH QUALITY, COMPREHENSIVE, RETROSPECTIVE COHORT SEROSURVEY WITH ADEQUATE POWER AND APPROPRIATE STUDY DESIGN TO DETERMINE WHETHER A SIGNIFICANT DECLINE IN JE ANTIBODY TITERS TO NON-PROTECTIVE LEVELS OCCURS AT THREE YEARS COMPARED TO TWO YEARS AFTER THE PRIMARY SERIES, ACROSS AGE AND GENDER CATEGORIES.**

AFEB (15-1a) 98-2 09 January 1998
SUBJECT: Recommendation for Japanese Encephalitis Vaccine

b. EFFECTIVE IMMEDIATELY, THAT A MEMORANDUM BE ISSUED TO ALL DOD SITES THAT ADMINISTER JE, VACCINE REVIEWING:

1) PROPER STORAGE AND HANDLING OF JE VACCINE.
2) PROPER ADMINISTRATION AND DOSING OF JE VACCINE, WITH PARTICULAR EMPHASIS ON THE FACT THAT THE VACCINE IS TO BE ADMINISTERED SUBCUTANEOUSLY.

c. THAT THE FDA AND MANUFACTURER BE NOTIFIED OF THE PRESENT SEROSURVEY RESULTS AND FORMALLY QUERIED ABOUT POSSIBLE PROBLEMS WITH LOT TO LOT VARIABILITY, CHANGES IN IMMUNOGENICITY, POTENCY AND STABILITY OVER THE LAST FOUR YEARS, AND/OR CHANGES IN VACCINE SHELF LIFE OVER THIS TIME PERIOD.

d. THE RESULTS OF THE ABOVE PROPOSED SEROLOGIC STUDIES SHOULD BE REPORTED BACK TO THE AFEB WITHIN 12 MONTHS.

4. The above recommendation was proposed and discussed by the Infectious Disease Subcommittee on 11-12 December 1997, and endorsed by the full Board on 12 December 1997.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

GERALD F. FLETCHER, M.D.
AFEB President

VICKY L. FOGELMAN
Colonel, BSC, USAF
AFEB Executive Secretary

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
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REPLY TO
ATTENTION OF

AFEB (15-1a) 98-3

09 January 1998

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation for a Research Study on Pneumococcal Vaccine

1. To assess whether a single dose of the 23 valent pneumococcal polysaccharide vaccine should be recommended for routine use in military recruits, data are needed on the likely impact of the vaccine. Factors which make the pneumococcal vaccine likely to be useful in the recruit/training setting include:

a. Documented outbreaks of pneumococcal disease in recruits (i.e. Camp Pendleton, Rangers).

b. Data showing substantial pneumonia morbidity based on medical record review, with morbidity particularly increased during the initial recruit period. While definitive diagnosis of most pneumonias is difficult, many of these cases may be of pneumococcal etiology.

c. A controlled vaccine trial of the pneumococcal vaccine is a way to estimate what proportion of pneumonia is preventable in recruits by use of pneumococcal vaccine, as well as the expected impact on pneumonia, sick days, and costs.

d. Increasing antimicrobial resistance in pneumococcal isolates worldwide, including the United States, is substantially increasing the risk and cost of treating pneumococcal disease.

2. Therefore, the Infectious Disease Subcommittee, with the approval from the full Board of the AFEB, recommends that:

A CONTROLLED STUDY OF THE IMPACT OF PNEUMOCOCCAL POLYSACCHARIDE VACCINE IN RECRUITS BE UNDERTAKEN. CAREFUL ATTENTION SHOULD BE GIVEN IN DESIGNING THE STUDY TO ADDRESS POTENTIAL EFFECTS OF SEASONALITY, COINCIDENT OUTBREAKS OF OTHER RESPIRATORY DISEASES, IMPACT OF OTHER VACCINES SUCH AS ADENOVIRUS AND INFLUENZA, AND THE POSSIBLE HERD EFFECT OF VACCINATION.

AFEB (15-1a) 98-3 09 January 1998
SUBJECT: Recommendation for a Research Study on Pneumococcal Vaccine

3. This recommendation was approved by the full Board on 12 December 1997.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

GERALD F. FLETCHER, M.D.
AFEB President

VICKY L. FOGELMAN
Colonel, BSC, USAF
AFEB Executive Secretary

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REPLY TO
ATTENTION OF

AFEB (15-1a) 98-4

09 January 1998

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation for the Use of Adenovirus Vaccine

1. The Infectious Disease Control Subcommittee of the Armed Forces Epidemiological Board (AFEB) has had the opportunity to examine adenovirus surveillance data and outbreak epidemiologic data. Based on (a) the known risk of recurrent adenovirus outbreaks, and (b) the substantial morbidity of adenovirus outbreaks, including disruption of recruit training, and (c) the substantial costs in treating adenovirus infections and the associated follow-on respiratory infections (e.g. increased risk of streptococcal and pneumococcal infections), the Infectious Disease Subcommittee recommends that:

a. **EVERY REASONABLE EFFORT BE MADE TO INSURE ADEQUATE AVAILABILITY OF ORAL ADENOVIRUS VACCINE BY:**

1) **SEEKING AN EXTENSION OF EXPIRATION ON THE CURRENTLY HELD ADENOVIRUS VACCINE LOTS TO THE SPRING OF 1999.**

2) **IDENTIFYING A MANUFACTURER TO PRODUCE ADEQUATE SUPPLIES OF ADENOVIRUS VACCINE.**

b. **CONCOMITANT WITH THE ABOVE, THE INFECTIOUS DISEASE SUBCOMMITTEE RECOMMENDS THAT ALL RECRUITS RECEIVE THIS VACCINE IN TRAINING SETTINGS WITH KNOWN OUTBREAKS OF ADENOVIRUS ILLNESS ON A YEAR-ROUND BASIS WHEN VACCINE IS AVAILABLE.**

c. **THAT CONTINUED AND ONGOING SURVEILLANCE OF ADENOVIRUS SEROTYPES BE CARRIED OUT IN RECRUIT TRAINING SETTINGS.**

d. **THAT ADDITIONAL DISEASE CONTROL METHODS FOR THE PREVENTION OF ADENOVIRUS OUTBREAKS BE PURSUED.**

AFEB (15-1a) 98-4 09 January 1998
SUBJECT: Recommendation for the Use of Adenovirus Vaccine

2. The above recommendation was approved by both the Infectious Disease Subcommittee and the full Board on 12 December 1997.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

GERALD F. FLETCHER, M.D.
AFEB President

VICKY L. FOGELMAN
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REPLY TO
ATTENTION OF

AFEB (15-1a) 98-5

09 January 1998

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation for Typhoid Vaccine

1. At the current time, there are three typhoid vaccines licensed in the United States. These vaccines include a parenteral heat-phenol-inactivated vaccine (two doses requiring four weeks), an oral live attenuated Ty21a vaccine (four doses requiring one week), and a newly licensed parenteral polysaccharide vaccine (Typhim-Vi, one dose).

2. The parenteral heat-phenol-inactivated vaccine causes substantially more adverse reactions, yet is no more effective than the other two available vaccines. Therefore, the following recommendations were proposed by the Infectious Disease Subcommittee and approved by the full Board on 12 December 1997:

a. **ONLY THE POLYSACCHARIDE (TYPHIM-Vi) OR ORAL (Ty21a) TYPHOID VACCINES SHOULD BE USED.**

b. **THAT THE DOD DISCONTINUE USE OF THE HEAT PHENOL-INACTIVATED PARENTERAL VACCINE AND REMOVE IT FROM THE NATIONAL STOCK NUMBER LIST.**

3. This recommendation was approved by the full Board on 12 December 1997.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

GERALD F. FLETCHER, M.D.
AFEB President

VICKY L. FOGELMAN
Colonel, BSC, USAF
AFEB Executive Secretary

CF:
(See Page Two)

AFEB (15-1a) 98-5 09 January 1998
SUBJECT: Recommendation for Typhoid Vaccine

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AFEB (15-1a) 98-10

28 April 1998

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE(HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Armed Forces Epidemiological Board Recommendation on Jet Injectors

1. At the Armed Forces Epidemiological Board (AFEB) meeting, 14 April 1998, the Infectious Disease Control Subcommittee re- viewed its December 1997 recommendation regarding the use of jet injectors to administer vaccines. Representatives of each of the services were present and reviewed the impact of this recommendation on their current recruit immunization programs. In addition, the Committee heard extensive presentations regarding the development of new prototype needleless injection technology.

2. In view of the obvious benefits, practicality, efficiency, and economy of using high workload needleless injectors in the military, the Committee recommends the following:

a. **THAT DOD HEALTH AFFAIRS AND THE ARMY MEDICAL RESEARCH AND MATERIEL COMMAND DEFINE THE FUNCTIONAL REQUIREMENTS FOR, AND FACILITATE THE DEVELOPMENT AND TESTING OF NEW GENERATION NEEDLELESS INJECTION TECHNOLOGY.**

b. **FURTHER, THE COMMITTEE RECOMMENDS THAT NEWLY DEVELOPED PROTOTYPES UNDERGO APPROPRIATE SAFETY TESTING AND IMMUNOGENICITY TESTING TO ENSURE EQUIVALENCE WITH STANDARD NEEDLE INJECTION.**

3. The above recommendations were unanimously approved by the subcommittee.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

GREGORY A. POLAND
Chairman, Infectious
Disease Subcommittee

VICKY L. FOGELMAN
Colonel, BSC, USAF
AFEB Executive Secretary

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AFEB (15-1a) 98-10 28 April 1998

SUBJECT: Armed Forces Epidemiological Board Recommendation on Jet Injectors

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AFEB (15-1a) 98-11 28 April 1998

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE(HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Armed Forces Epidemiological Board Recommendation Regarding Deviation from the Anthrax Vaccine Policy

1. At the Armed Forces Epidemiological Board (AFEB) meeting on 15 April 1998, the Infectious Disease Control Subcommittee reviewed a draft of a DoD policy for deviation from the anthrax vaccine immunization schedule. In addition, the subcommittee reviewed the extant data available on this issue, including the original FDA licensure trials and two post Gulf War studies (one small, one large) of post-immunization antibody levels.

2. These studies demonstrated that by day 35 after three doses of vaccine, 90-95% of all individuals had developed presumptively protective levels of antibody. Further, a single booster dose given one to two years after initial receipt of one to three doses produced rapid antibody responses; 99.3% of volunteers responded 30 days after administration of this booster dose with a greater than four-fold increase in titer, and 95% of subjects demonstrated an anthrax PA titer of 1:10,000. In the largest prospective study of DOD personnel (n=604), reported on 24 October 1997, the investigators concluded that it would be "reasonable to prime with two or three doses of anthrax vaccine and boost at some reasonable interval or when deployment or travel demands it."

3. Full immunization with anthrax vaccine adsorbed requires six doses, referred to as the primary series, administered over 18 months. Doses are administered according to the following FDA approved schedule: 0, 2 and 4 weeks; 6, 12 and 18 months. Yearly boosters are administered thereafter to maintain immunity. This schedule is the only regimen shown to protect humans against anthrax. Although the effect of specific deviations from this schedule on the efficacy of the vaccine is unknown, in general, the greater the deviation the less certain the protective effect in humans.

AFEB (15-1a) 98-11 28 April 1998
SUBJECT: Armed Forces Epidemiological Board Recommendation Regarding Deviation from the Anthrax Vaccine Policy

4. Repeating all or part of the primary series is rarely indicated. In accordance with the guidelines of the Advisory Committee on Immunization Practices, U.S. Public Health Service, an interruption in the immunization schedule does not generally require reinstitution of the entire series of a vaccine. For anthrax vaccine, this approach is supported by unpublished data in humans that shows a robust antibody response to anthrax vaccine one to two years after a partially completed primary series. However, the subcommittee recognizes that the consequences of inhalation anthrax area severe, and the correlation between serum anthrax and antibody titers and protection in humans is uncertain.

5. After consideration and discussion of these studies, the Subcommittee made the following recommendations based on the available data:

a. DO NOT ADMINISTER DOSES OF THE VACCINE ON A COMPRESSED OR ACCELERATED SCHEDULE (FOR EXAMPLE, SHORTER INTERVALS BETWEEN DOSES OR MORE DOSES THAN REQUIRED).

b. FOR LATE OR MISSED DOSES, THE FOLLOWING PROCEDURE, MAY BE FOLLOWED FOR INDIVIDUAL VARIATION FROM THE STANDARD IMMUNIZATION SCHEDULE.

1) IF ONLY ONE DOSE HAS BEEN RECEIVED, AND MORE THAN TWO YEARS HAVE ELAPSED, RESTART THE PRIMARY SERIES WITH THE FIRST DOSE. IF TWO OR FEWER YEARS HAVE ELAPSED, CONTINUE THE PRIMARY SERIES WITH THE SECOND DOSE.

2) IF TWO OR MORE DOSES HAVE BEEN RECEIVED, THE PRIMARY SERIES DOES NOT NEED TO BE RESTARTED, BUT MAY SIMPLY RESUME WITH ADMINISTRATION OF THE NEXT DOSE IN THE SERIES.

3) IF AN ANNUAL BOOSTER IS NOT RECEIVED ON TIME, ADMINISTER THE BOOSTER DOSE AT THE EARLIEST POSSIBLE DATE, ADJUSTING THE SUBSEQUENT BOOSTER DOSE SCHEDULE ACCORDINGLY. ONCE THE PRIMARY SERIES OF SIX DOSES IS COMPLETE, THE PRIMARY SERIES IS NEVER REPEATED, EVEN IF MORE THAN THREE YEARS HAVE ELAPSED BETWEEN BOOSTER DOSES.

AFEB (15-1a) 98-11 28 April 1998
SUBJECT: Armed Forces Epidemiological Board Recommendation Regarding Deviation from the Anthrax Vaccine Policy

c. **FURTHER, THE COMMITTEE STRONGLY RECOMMENDS THAT STUDIES BE DESIGNED AND INITIATED TO DETERMINE THE IMMUNOGENICITY OF AN ABBREVIATED IMMUNIZATION SCHEDULE AND THE OPTIMAL TIME INTERVAL AND NEED FOR BOOSTER DOSES OF VACCINE.**

6. The above recommendation was unanimously approved by the Subcommittee.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

GREGORY A. POLAND, M.D.
Chairman, Infectious
Disease Subcommittee

VICKY L. FOGELMAN
Colonel, BSC, USAF
AFEB Executive Secretary

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DEPARTMENT OF THE ARMY
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AFEB (15-1a) 98-12

28 April 1998

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE(HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Armed Forces Epidemiological Board Recommendation Regarding G-6-PD

1. At its 15 April 1998 meeting, the Infectious Diseases Control Subcommittee reviewed the results of an Army decision analysis and cost benefit study of G-6-PD screening in recruits. In addition, G-6-PD screening policies for the other services were reviewed and discussed. On the basis of these discussions, the Committee recommends the following:

a. **PRIOR TO DEPLOYMENT TO A P. VIVAX ENDEMIC AREA, ALL PERSONNEL FOR WHOM PRIMAQUINE IS INDICATED FOR PROPHYLAXIS/TREATMENT SHOULD UNDERGO G-6-PD SCREENING. SUCH SCREENING MAY TAKE PLACE DURING RECRUIT TRAINING OR AFTER RECRUIT TRAINING BUT PRIOR TO DEPLOYMENT TO P. VIVAX ENDEMIC AREAS.**

b. **THE RESULTS OF G-6-PD SCREENING ASSAYS SHOULD BE RECORDED WITHIN THE PAPER AND ELECTRONIC MEDICAL RECORDS OF EACH INDIVIDUAL IN SUCH A MANNER AS TO BE IMMEDIATELY AVAILABLE TO MEDICAL PERSONNEL AT THE TIME OF MALARIA PROPHYLAXIS/TREATMENT DECISION MAKING.**

2. The above recommendations were unanimously approved by the Subcommittee.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

GREGORY A. POLAND
Chairman, Infectious
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VICKY L. FOGELMAN
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AFEB Executive Secretary

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AFEB (15-1a) 98-12 28 April 1998
SUBJECT: Armed Forces Epidemiological Board Recommendation Regarding G-6-PD

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DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
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REPLY TO
ATTENTION OF

AFEB (15-1a) 99-2

25 May 1999

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE(HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Armed Forces Epidemiological Board (AFEB) Recommendation for Lyme Disease

1. At its April 1999 meeting, the Board considered the issue of the appropriate use of Lyme vaccine in members of the armed services. After reviewing the literature, and examining the impact of Lyme disease on the military, the Board makes the following recommendations:

a. **LYME VACCINE IS ONLY ONE ADJUNCT TO THE PREVENTION OF LYME DISEASE. PERSONAL TICK PREVENTION MEASURES SHOULD BE ENCOURAGED AND COMPLIANCE STRENGTHENED AS THE PRIMARY, AND MOST EFFECTIVE, METHOD OF PREVENTING LYME DISEASE.**

b. **THE BURDEN OF LYME DISEASE IN THE MILITARY IS UNCLEAR. STUDIES EXAMINING THE PREVALENCE OF LYME DISEASE, AS WELL AS STUDIES EXAMINING THE INCIDENCE OF LYME INFECTION AS A SPECIFIC FUNCTION OF MILITARY DUTIES SHOULD BE INITIATED. THESE STUDIES SHOULD INCLUDE DATA ON IXODES DISTRIBUTION, AND THE PREVALENCE OF BORRELIA INFECTION OF IXODES TICKS ON MILITARY INSTALLATIONS.**

c. **IN THE INTERIM, THE BOARD RECOMMENDS CONSIDERATION OF USE OF LYME VACCINE UNDER THE FOLLOWING CONDITIONS:**

1) **CONDITIONS SPECIFIED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES DOCUMENT ON THE PREVENTION OF LYME DISEASE.**

AFEB (15-1a) 99-2 25 May 1999
SUBJECT: Armed Forces Epidemiological Board (AFEB) Recommendation for Lyme Disease

2) FOR SELECTED OCCUPATIONAL GROUPS CONSIDERED TO BE AT HIGH RISK BECAUSE THEIR MILITARY DUTIES PLACE THEM IN HIGH RISK ENVIRONMENTS WHERE FREQUENT AND PROLONGED EXPOSURE TO BORRELIA-INFECTED IXODES TICKS MIGHT BE ANTICIPATED. UNDER THIS CONDITION, VACCINE SHOULD BE USED IN ADVANCE OF ANTICIPATED EXPOSURE. LOCAL CONDITIONS AND RISK INFORMATION SHOULD BE USED IN DETERMINING RISK.

2. The above recommendations were unanimously approved by the Subcommittee.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

GREGORY A. POLAND
Chairman, Infectious
Disease Subcommittee

BENEDICT M. DINIEGA
Colonel, USA, MC
AFEB Executive Secretary

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REPLY TO
ATTENTION OF

AFEB (15-1a) 99-3

25 May 1999

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE(HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Armed Forces Epidemiological Board Recommendation Regarding Varicella Vaccine.

1. At the Armed Forces Epidemiological Board (AFEB) April 1999 meeting, the Board considered the issue of use of varicella vaccine among military personnel. After hearing reports from military Preventive Medicine officers, it is clear that varicella disease can and does disrupt military training and readiness. With this in mind, the Board recommends the following:

a. **THAT ALL PERSONNEL UNDERSTAND THAT WHILE VARICELLA VACCINE CAN AND DOES PREVENT DISEASE AND EPIDEMIC SPREAD OF DISEASE, IT CANNOT PREVENT DISEASE DUE TO INCUBATING INFECTION, SUCH AS OCCURS IN THE EARLY TIME PERIOD AFTER ACCESSION.**

b. **THE BOARD DOES NOT RECOMMEND THE INSTITUTION OF AUTOMATIC UNIVERSAL IMMUNIZATION OF ALL MILITARY ACCESSIONS. HOWEVER, IMMUNIZATION OF ALL SUSCEPTIBLES IS RECOMMENDED. BECAUSE UNIVERSAL SEROLOGIC SCREENING IS THE MOST SENSITIVE METHOD OF IDENTIFYING SUSCEPTIBLES, THIS IS RECOMMENDED WHERE IT IS FEASIBLE TO DO SO. IF THIS IS NOT FEASIBLE, SUSCEPTIBILITY MAY BE IDENTIFIED BY SEROLOGICALLY SCREENING ONLY THOSE WITH NEGATIVE OR UNCERTAIN VARICELLA DISEASE HISTORIES, WITH VACCINE PROVIDED TO THOSE WHO ARE SERONEGATIVE.**

c. **IN ORDER TO HAVE THE GREATEST POSSIBLE BENEFIT, SCREENING FOR SUSCEPTIBLES SHOULD BE DONE AS EARLY IN THE ACCESSION PROCESS AS POSSIBLE. IN ORDER TO DECREASE COSTS AND LABORATORY IMPACT, IDEALLY THIS SHOULD BE DONE IN CONJUNCTION WITH OTHER ACCESSION TESTING. FOR EXAMPLE, SUCH SCREENING MIGHT OPTIMALLY BE DONE DURING MEPS PROCESSING.**

d. FOR ALL OTHER MILITARY PERSONNEL, THE RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES SHOULD BE FOLLOWED.

2. The above recommendations were unanimously approved by the Subcommittee.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

GREGORY A. POLAND
Chairman, Infectious
Disease Subcommittee

BENEDICT M. DINIEGA
Colonel, USA, MC
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REPLY TO
ATTENTION OF

AFEB (15-1a) 99-4

25 May 1999

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE(HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Armed Forces Epidemiological Board Recommendation on the Use of Inactivated Polio Vaccine.

1. At its April 1999 meeting, the Board considered the issues regarding the use of oral versus parental inactivated polio vaccine. Based on our review and discussion, the Board makes the following recommendations:

a. **THAT THE PRESENT POLICY OF A SINGLE UNIVERSALLY ADMINISTERED 'BOOSTER' DOSE OF TRIVALENT ORAL POLIO VACCINE IN ALL ENLISTED ACCESSIONS AND OFFICER CANDIDATES/CADETS BE CONTINUED, UNLESS A PREVIOUS ADULT BOOSTER IS DOCUMENTED.**

b. **THAT INACTIVATED POLIO VACCINE (IPV) BE USED AS AN ALTERNATIVE TO TRIVALENT ORAL POLIO VACCINE (TOPV) IN SELECTED INDIVIDUALS ACCORDING TO THE RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.**

c. **THAT IPV BE USED IN ALL MILITARY ACCESSIONS THAT DO NOT HAVE A HISTORY OF HAVING RECEIVED A FULL PRIMARY POLIO SERIES. THIS HISTORY MAY BE ORAL OR WRITTEN.**

d. **THAT THIS POLICY BE REVIEWED AS CHANGES IN POLIO VACCINE AVAILABILITY OCCUR DUE TO THE POSSIBILITY THAT MANUFACTURERS DISCONTINUE MAKING ORAL POLIO VACCINE IN FAVOR OF IPV.**

AFEB (15-1a) 99-4 25 May 1999
SUBJECT: Armed Forces Epidemiological Board Recommendation on the Use of Inactivated Polio Vaccine.

2. The above recommendations were unanimously approved by the Subcommittee.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

GREGORY A. POLAND
Chairman, Infectious
Disease Subcommittee

BENEDICT M. DINIEGA
Colonel, USA, MC
AFEB Executive Secretary

Copies Furnished:
The Surgeon General, USA
The Surgeon General, USAF
The Surgeon General, USN
Board Members
DASG-ZH
AFMOA/CC
AFMOS/SGOP
Ch, Prev Med Div, OTSG-DA
DASG-HS-PM
HQ, USMC, PMO, LCDR Ann P. Fallon
Dir. Occup Hlth & Prev Med Div, BUMED-DN
CDR, WRAIR
CDR, USAMEDCOM, ATTN: MCCS-FC
CDR, USACHPPM, ATTN: MCHB-DC-C
CDR, USAMRMC
Navy Env. Health Center
Dir, Med Resources, Plans & Policy Div. (N931)
Head, Epi Dept., NEPMU 5
CDR Mark Tedesco, USPHS
COL Andrew S. Warde, BvetMed Msc MRCVS
LCOL Frank Souter, CFMS

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

AFEB (15-1a) 99-5

25 May 1999

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

SUBJECT: Armed Forces Epidemiological Board Recommendations for Biological Warfare Vaccines

1. In accordance with DOD Directive 6205.3, "DOD Immunization Program for Biological Warfare Defense," the Armed Forces Epidemiological Board (AFEB) met on 24 May 1999 at the Institute for Defense Analyses, Alexandria, VA to review vaccines available to protect against the validated biological warfare (BW) threat agents.

2. After review of the Biologic Threat Matrix and the above directive, the AFEB makes the following comments and recommendations:

a) THE AFEB CONTINUES TO STRONGLY ENDORSE THE CURRENT DOD ANTHRAX VACCINE IMMUNIZATION PROGRAM. FURTHER, THE BOARD RECOMMENDS THAT DOD AGGRESSIVELY PURSUE CLINICAL INVESTIGATIONS NECESSARY TO REVISE AND/OR ACCELERATE THE CURRENT ANTHRAX VACCINATION SCHEDULE (ACCELERATED SCHEDULE, FEWER DOSES, IM VS. SC ADMINISTRATION, ETC.).

b) REGARDING THE USE OF VACCINES AND BIOLOGICS TO PROTECT AGAINST BW AGENTS, THE AFEB RECOMMENDS THAT THE PRIORITIZATION FOR VACCINE DEVELOPMENT, AND THE USE OF RESOURCES BE DIRECTED IN THE FOLLOWING MANNER:

TIER I (INTENT: HIGHEST PRIORITY TO RAPIDLY ACCELERATE AND IMMEDIATELY ESTABLISH VACCINE PRODUCTION CAPABILITY). AGENTS LISTED UNDER TIER I INCLUDE SMALLPOX, PLAGUE, ANTHRAX, AND STAPHYLOCOCCAL ENTEROTOXIN B.

TIER II (INTENT: HIGH PRIORITY CANDIDATES FOR VACCINE DEVELOPMENT AS SOON AS POSSIBLE). AGENTS INCLUDE RICIN, BOTULINUM, TULAREMIA, HEMORRHAGIC FEVER VIRUSES, ENCEPHALITIS VIRUSES, Q FEVER, BRUCELLOSIS, AND SHIGELLOSIS.

TIER III (INTENT: WARRANTS FURTHER RESEARCH AND CLOSE OBSERVATION FOR SCIENTIFIC DEVELOPMENTS OR VALIDATED NEW

THREATS THAT WOULD MOVE IT INTO TIER I OR TIER II). ALL OTHER BIOLOGIC AGENTS.

c) THE BOARD STRONGLY FELT THAT A COMPLETE RESPONSE TO THE VALIDATED BIOLOGIC WARFARE THREAT MATRIX INVOLVES MORE THAN VACCINE RECOMMENDATIONS PER SE. THEREFORE, WE RECOMMEND A REVIEW OF DOD DIRECTIVE 6205.3, AND THAT IT BE REVISED WITH ATTENTION TO THE FOLLOWING ISSUES:

1) THE BOARD RECOGNIZES THAT PRIORITIZATION OF BW THREATS IS CURRENTLY ONLY INTELLIGENCE-BASED, WITH NO CONSIDERATION OF MEDICAL RISK-BASED MEASURES. THE BOARD STRONGLY FELT THAT A MEDICAL RISK ANALYSIS IS A VITAL PIECE OF DATA NEEDED FOR PRIORITIZATION OF ADMINISTERING AND DEVELOPING NEW VACCINES. SUCH INPUT WILL INSURE THAT THE PROPER NUMBER OF DOSES ARE RECOMMENDED FOR STOCKPILING, (FOR USE IN DOD PERSONNEL, ESSENTIAL CIVILIANS, CONTRACTORS, ETC.). FORMAL MEDICAL RISK-ANALYSES SHOULD BE CONDUCTED FOR ALL VALIDATED AGENTS. PRIORITY SHOULD BE GIVEN TO A HIGHLY TRANSMISSIBLE SCENARIO SUCH AS SMALLPOX.

2) THE BOARD HIGHLY RECOMMENDS A REVIEW OF THE CURRENT DOD VACCINE STOCKPILING NUMBERS THAT WOULD TAKE INTO ACCOUNT HIGH-RISK POPULATIONS, AND COMMUNICABILITY OF THE BW AGENT. THIS IS ESSENTIAL TO DECISIONS ABOUT NUMBERS OF DOSES OF VACCINE AND RESOURCE USE.

3) THE BOARD RECOMMENDS THAT A REVIEW OF TEMPORARY/INTERIM COUNTERMEASURES BE PERFORMED SUCH AS TAKING INTO ACCOUNT FACTORS SUCH AS TREATMENT AVAILABILITY, PRE-VERSUS POST-EXPOSURE PROPHYLAXIS, AND STOCKPILING OF CURRENTLY AVAILABLE PHARMACEUTICALS, AS WELL AS PRIORITIES FOR PHARMACEUTICAL R&D AGAINST VALIDATED BIOLOGIC WARFARE THREATS.

4) THE BOARD RECOMMENDS A FORMAL REVIEW OF THE EFFECTIVENESS OF CURRENT MEDICAL SURVEILLANCE AS AN "EARLY DETECTOR" FOR EXPOSURE TO BIOLOGIC WARFARE AGENTS.

AFEB (15-1a) 99-5
SUBJECT: Armed Forces Epidemiological Board Recommendations for Biological Warfare Vaccines

5) THE BOARD RECOMMENDS A FORMAL REVIEW OF THE RAPID DIAGNOSTICS AVAILABLE TO SUPPORT MEDICAL SURVEILLANCE AS AN EARLY DETECTOR FOR EXPOSURE TO BIOLOGIC WARFARE AGENTS.

d) THE BOARD ENDORSES, AND URGES RAPID DEPLOYMENT OF THE PLANNED JOINT TRI-SERVICE SOFTWARE PROGRAMS CAPABLE OF RECORDING AND REPORTING ADMINISTRATION OF ANY DOSE OF VACCINE (LICENSED OR IND) ADMINISTERED TO DOD PERSONNEL.

e) LASTLY, THE BOARD RECOMMENDS THAT HIGH QUALITY EDUCATION AND MARKETING PROGRAMS BE DEVELOPED FOR EACH VACCINE DEPLOYED AGAINST BIOLOGIC WARFARE AGENTS AND RECOMMENDED FOR USE IN DOD PERSONNEL. IDEALLY, THIS WOULD BE DEVELOPED BY EXPERTS BOTH INSIDE AND OUTSIDE OF THE DOD.

3. The above recommendations were unanimously by the Board.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

DENNIS M. PERROTTA, PH.D.
President, AFEB

GREGORY A. POLAND, M.D.
Chairman, Disease Control Committee

BENEDICT M. DINIEGA, COL, MC, USA
AFEB Executive Secretary

CF:
The Surgeon General, Army

APPENDIX F

ARMED FORCES EPIDEMIOLOGICAL BOARD DEPARTMENT OF DEFENSE IMMUNIZATION PROGRAM ANALYSIS AND DESIGN FOR STUDY OF IMMUNIZATION COVERAGE

Report on the Pretest

ARMED FORCES EPIDEMIOLOGICAL BOARD DEPARTMENT OF DEFENSE IMMUNIZATION PROGRAM ANALYSIS AND DESIGN FOR STUDY OF IMMUNIZATION COVERAGE

Report On The Pretest

Submitted To:

Vicky L. Fogelman, Col, USAF, BSC
Executive Secretary
Armed Forces Epidemiological Board

Prepared By:

Birch & Davis Associates, Inc.
Under Prime Contract Number DASW01-95-D-0026
Modification 1
Delivery Order Number 0081

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June 8, 1998

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APPENDICES

EXHIBITS

EXECUTIVE SUMMARY

The Department of Defense (DoD) is beginning to implement an automated system to record and track immunizations of military service members. The Armed Forces Epidemiological Board (AFEB) has also requested information on immunization policies and procedures. Birch & Davis Associates, Inc., (B&D), developed a single survey methodology to provide the DoD with a pre-automation baseline for comparison with post-automation results and the AFEB with limited data on the outcomes of DoD policies and procedures expressed as immunization coverage rates. To pretest the survey methodology, B&D identified 12 military units for on-site sampling of immunization status. They included active duty units that are likely to deploy outside the United States, active duty units unlikely to deploy, reserve units, and a National Guard unit. The focus of the data collection effort was four vaccines (influenza, tetanus-diphtheria, yellow fever, and typhoid) that are required by the Army, Navy, Air Force, and Marine Corps for all alert duty forces and may be required for other military personnel. In this document, B&D presents its findings from the pretest data collection and analysis effort as well as recommendations for future surveys.

1.0 DATA ANALYSIS

In accordance with the "Preliminary Study Design," immunization data were collected from as many as four sources for each service member included in the survey: medical records, PHS-731 forms (yellow shot cards), automated record systems, and mass immunization rosters (e.g., for influenza). Four principal components of these data were analyzed:

- Up-to-date (UTD) Immunization Rates—The proportion of surveyed records that indicated UTD status. For each surveyed vaccine, the team calculated two UTD rates by (1) using the most recent date provided by *any* data source to develop an aggregate UTD rate and (2) determining the UTD rate indicated by *each* data source. Next, the team calculated the aggregate proportions of unit members UTD for any two or all three vaccines that could be assessed, i.e., influenza and tetanus-diphtheria, influenza and yellow fever, tetanus-diphtheria and yellow fever, all three of these vaccines. (Typhoid UTD rates could not be reliably calculated because the records lacked data on the vaccine used and the route of administration.) UTD rates were calculated for each unit as of the date the unit was surveyed and 95 percent confidence intervals were calculated for the UTD rates.

- Comparison of UTD Coverage Rates with Service- and Unit-specific Requirements—Documented immunization rates for units surveyed compared to DoD and service-specific immunization requirements.

- Records Sampled—Comparison of records that were surveyed versus those that were not surveyed, as well as an assessment of any bias introduced because of the sampling process.

- Stratification—UTD percentages stratified by rank (officer versus enlisted), longevity of service, and longevity in unit.

2.0 CONCLUSIONS

As expected, the scope and nature of the pretest limited the number and strength of the conclusions that could be reached, particularly with regard to stratifications and correlations. However, based on the pretest results, the project team reached the following conclusions:

- Units likely to deploy were, in general, better immunized than the others, and active duty units were better immunized than reserves.

- Every unit surveyed had some members whose immunizations, as recorded, were lacking with respect to the unit's medical and readiness requirements.

- When UTD coverage rates were calculated for more than one vaccine, the rates were lower than for individual vaccines, indicating that some unit members were not up-to-date for all vaccines surveyed.

- Data sources tended to be inconsistent and no one source proved reliable and valid for all vaccines for any service. Automated records were no more reliable than other data sources.

- Members of some units surveyed deploy as individuals or small groups even when the unit is considered unlikely to deploy. Thus the association between units' likelihood of deployment and their members' immunization status was somewhat less clear than anticipated.

- To the extent that any pattern analysis was possible using this sample, unit turnover rates, rank (officer versus enlisted), and longevity in service seemed to have little predictive value for whether the individual was immunized. It should be noted that the resulting sub-sample sizes, particularly for officers, were too small to permit any conclusions about rank and immunizations.

3.0 RECOMMENDATIONS

The immunization survey was intended to establish a pre-automation baseline of immunization data in order to compare the results with post-automation findings. B&D recognizes the

importance of such comparisons to determine the benefits realized through the investment in information technology. We recommend that the units surveyed during this pretest, particularly those that had not yet fully automated their records, be surveyed again once their systems are well established. A follow-up survey will provide potentially rich, comparative data to serve as an indicator of the impact of automation on documentation of immunizations administered.

Another purpose of the pretest survey was to test the study design. As anticipated, the inclusion of only one unit of each type (e.g., deployable, active duty) per service resulted in two key limitations. First, it prevented comparisons of rates and estimates of variance across units of an individual service. Second, it limited the broad applicability of survey results among services. Therefore, B&D recommends that (1) further surveys be conducted to better assess military immunization status, (2) active duty and reserve/Guard forces be surveyed separately for each service, and (3) the samples consist of individual service members selected randomly from a random selection of units across a range of commands and bases. To achieve a sample size that can support development of a 95 percent confidence interval, we recommend surveying 533 individuals for each service's active duty force and 533 individuals for each service's reserve/Guard force.

We recommend that future surveys employ the following protocol, regardless of the survey scale or focus:

- Unit Data—Collect data on unit and individual members' deployment status, unit strength, and points of contact. Since unit rates of entry and departure proved inconsequential in relationship to immunization status, do not collect these data in the future.

- Individual Data—Collect immunization dates, presence or absence of vaccine manufacturer names and lot numbers, and typhoid vaccines and routes of administration from all available data sources. Collect rank, which can generally be provided by the medical treatment facility. Collect data on deployability status and deployments within the previous 36 months only for the individuals surveyed. Do not collect length of time in the service, length of time in the unit, or the pay grade, as these require extensive unit effort.

- Vaccines—In addition to data on influenza, tetanus-diphtheria, yellow fever, and typhoid vaccines, consider measuring compliance with recent DoD and service directives by collecting data on all anthrax and hepatitis A vaccinations administered to the individuals surveyed.

- Data Analysis—Calculate aggregate UTD rates and UTD rates by data source, as well as rates for both single and multiple vaccines. Continue to assess by service whether a single source will produce reliable UTD coverage rates.

The lack of recorded data on typhoid vaccines prevented determination of typhoid booster due dates. It was also observed that data on vaccine manufacturers and lot numbers were lacking for other vaccines as well. Although the number of reported adverse reactions to vaccines is quite small, DoD regulations, Federal law, and clinical practice standards require that providers keep track of what they have administered to persons in their care. Therefore, we recommend that the DoD consider ways to increase compliance in this matter. For example, automated systems may include prompts that require vaccine data entry before the record can be closed.

Finally, we recommend that the revised Joint Instruction address the impact of automation on record-keeping, e.g., what paper records need to be maintained, whether the PHS-731 must be maintained, and how to manage period of the transition before all records are automated.

REPORT ON THE PRETEST

1.0 INTRODUCTION

The Department of Defense (DoD) is beginning to implement an automated system to record and track immunizations of military service members. The Armed Forces Epidemiological Board (AFEB) has also requested information on immunization policies and procedures. Birch & Davis Associates, Inc., (B&D), developed a single survey methodology to provide the DoD with a pre-automation baseline for comparison with post-automation results and the AFEB with limited data on the outcomes of DoD policies and procedures expressed as immunization coverage rates. To pretest the survey methodology, B&D identified 12 military units for on-site sampling of immunization status. In this document, B&D presents its findings from the pretest data collection and analysis effort.

The sample was designed to include active duty units that are likely to deploy outside the United States, active duty units unlikely to deploy, reserve units, and a National Guard unit. In a previous deliverable, entitled "Preliminary Study Design," submitted on January 20, 1998, B&D presented the methodology for this study, including the criteria for selecting units to be visited and the data elements to be collected. The methodology used was an "establishment survey," following the methods developed for such surveys as the Current Employment Survey administered by the Bureau of Labor Statistics where organizations are the units sampled, and individuals are sampled within each organization. The analysis is then performed using the organization as the unit of analysis. For this study, a military unit is the unit of analysis.

The focus of the data collection effort was four vaccines that are required by the Army, Navy, Air Force, and Marine Corps for all alert duty forces and that may be required for other military personnel also. These include influenza, which is administered every year; tetanus-diphtheria, which is boosted every 10 years; and yellow fever, which is boosted every 10 years. The fourth immunization, typhoid, should be boosted at two, three, or five years, depending on which vaccine is administered. The typhoid vaccines boosted at two and three years are injected; the vaccine boosted at five years is administered orally. The most recent recorded immunization date was collected for each of the four vaccines; in addition the type of vaccine and/or route of administration was collected for typhoid vaccine. Other data elements collected on individual service members included rank and pay grade, length of time in the Service, and length of time in the unit. Units provided data on unit deployments and readiness exercises within the previous 36 months.

This report presents the implementation of the study design, including characteristics of the units selected for the survey, data collection procedures, the results of an analysis of survey findings, conclusions, and recommendations for future immunization surveys.

2.0 IMPLEMENTATION OF THE STUDY DESIGN

This section describes the units selected for the study and the data collection process used for the pretest. It concludes with a discussion of limitations encountered in the data collection process.

2.1 Characteristics Of Units Surveyed

The pretest was conducted in accordance with the plan presented in the "Preliminary Study Design," which established the criteria for selection of units to be surveyed. The selection criteria, and the degree to which the units surveyed met those criteria are presented below.

- Eight active duty units, including four units considered likely to deploy and four units considered unlikely to deploy. Although the project team originally arranged for this mix of active duty units, one site replaced a less deployable unit with a more deployable unit. Thus, the final set of active duty units included five deployable units and three that were considered less likely to deploy.

- Non-medical units. No medical units were surveyed.

- Representative of Army, Navy, Air Force, and Marine units. Two active duty units from each of the four services were surveyed.

- Representative of both active duty (eight units) and reserve units (four units). This was the mix of units surveyed.

- Co-located (on the same site) with other units selected from the same service, although active duty and reserve units could be at different sites if necessary. Active duty units within the same service were co-located; the three reserve and one Guard unit were at separate sites. Thus, eight site visits were required to survey 12 units.

- Located within approximately 200 miles of the Washington, D.C., area. Six units were in Virginia, three in Maryland, two in Delaware, and one in Washington, D.C.

- Selected by their respective services. Service points of contact assisted in identifying and recruiting units to be surveyed.

- Willing to participate in the survey. All units agreed to participate.

- Historically reliant primarily on written immunization records, i.e., only recently or not fully automated. The Navy reserve unit, two Marine Corps active duty units, and Air Force active duty and reserve units had automated their records

recently, in most cases immediately prior to the site visit. The Air National Guard (ANG) unit was in the process of automating immunization records. Records were not automated at the Army active duty and reserve sites nor fully automated at the ANG unit. Only the two Navy active duty units' records had been automated longer, in both cases for approximately nine years. It is our understanding that the status of automation in these units approximates that of their services.

Exhibit 1 summarizes key characteristics of the surveyed units, which ranged in strength from approximately 100 to 1,000. It should be reiterated that this was a convenience sample of units. All were willing to be surveyed and were within 200 miles of Washington, D.C. Therefore, as stated in the study design, the units surveyed cannot be considered representative of their services as a whole and all analyses from this pretest should be considered indicative, not conclusive.

EXHIBIT 1
UNIT CHARACTERISTICS

Unit	Unit Type	Likely To Deploy	Unit Strength	Avg Yrs in Unit	Avg Yrs in Service	Mission
Army (#1)	Transport	Y	285	2.6	6.1	Provide transportation
Army (#2)	Training	N	845	2.4	16.2	Instruct in and administer Security Assistance Program
Navy (#1)	Transport	Y	1090	2.1	8.0	Load, transport, and land troops and their vehicles
Navy (#2)	Transport	N	1042	1.7	7.5	Load, transport, and land troops and their vehicles.
Air Force (#1)	Transport	Y	390	2.6	7.2	Transport equipment and personnel
Air Force (#2)	Infra-structure	Y	205	2.2	8.9	Provide infrastructure, ordnance disposal, environmental protection
USMC (#1)	Rapid Deploy	Y	250	1.3	3.5	Conduct anti-terrorist activities
USMC (#2)	Staff	N	250	1.8	9.6	Provide administrative support, security
Army Reserve	Transport Terminal	N	139	.9	15.3	Manage cargo traffic
Navy Reserve	Command Support	N	118	3.2	15.0	Provide administrative support
Air Force Reserve	Transport	N	220	9.6	15.0	Inspect, prepare, load and unload aircraft cargo
Air National Guard	Airlift	Y	100	6.3	12.0	Transport equipment and personnel

2.2 Data Collection Process

For each unit selected, the team obtained appropriate authorizations from medical officials on-site, the office of the service Surgeon General, and/or the reserve command. Appendix A contains a sample authorization letter. Prior to the visit, the team requested information about unit characteristics using the instrument contained in Appendix B. During the visit, the team ensured that medical records were held confidentially and were constantly secured; no identifying data were removed from the site.

The objective was to obtain 50 records for each unit, sampled at random throughout the roster. To achieve this objective there was an individualized sampling plan based on reported unit strength for each unit surveyed. Exhibit 2 presents the unit strength, the records sought from that unit's roster, the number of records finally collected, and the sources of data for each unit.

EXHIBIT 2
SURVEY PROCESS

Unit	Unit Size	Records Sought From Roster	Records Collected	Source: Medical Record	Source: PHS-731 Card	Source: Automated System
Army (#1)	285	Every 4th	50	x	x	
Army (#2)	845	Every 9th	35	x	x	
Air Force (#1)	390	Every 6th	50		x	x
Air Force (#2)	205	Every 3rd	54		x	x
Navy (#1)	1,090	Every 9th	53	x		x
Navy (#2)	1,042	Every 9th	50	x		x
USMC (#1)	250	Every 4th	58	x		x
USMC (#2)	250	Every 4th	55	x		x
Army Reserve	139	All odd #	54	x	x	
Navy Reserve	118	Skip every 3rd	65	x		x*
Air Force Reserve	220	Every 3rd	76	x**	x	**
Air National Guard	100	Skip every 3rd	60	x	x	x***

*Interoperable with the personnel system computer.
**In this case the medical record was derived from an automated system.
***To be interoperable with the personnel system computer; however, data source was not available during survey.

The team requested all available data sources for each unit surveyed. The plan was to collect data from up to four record forms (i.e., written service medical record, yellow PHS-731 immunization card, automated immunization record, mass immunization roster) for each of the individuals in the sample at each unit. For each unit, there were two routinely used data sources, which were provided for the survey. One unit provided a mass immunization roster, which was unusable for the survey because it included 1,600 names listed in the order in which individuals presented for influenza vaccination rather than in alphabetical or Social Security Number (SSN) order. Thus no data were collected from mass rosters.

The team determined during the first site visit that collecting data from more than one source would provide the most nearly accurate picture of the unit's immunization coverage. Therefore, an individual's record was considered "complete" only if both data sources were available during the site visit. If one of the data sources was not present for an individual selected from the roster according to the sampling plan, the team selected the next individual on the roster and continued through the roster until a complete record was located Once that complete record was collected, the team returned to using the selection intervals in the sampling plan. The process continued until the team had a sufficient number of complete records or there were no more unit members remaining to sample. In all but one case, the sample size equaled or exceeded 50 records selected at random. The sample size in one unit was limited to 35 by the number of PHS-731 cards available.

The team recorded data using a standard form, which is provided at Appendix C. While on-site, the team used unit members' names and/or SSNs to match medical data to personnel data such as rank and time in unit. At the end of the visit, to protect individuals' privacy, the team returned all identifying information to medical records personnel, keeping only the collection forms.

2.3 Limitations Encountered In The Data Collection Process

For several reasons, it was not possible to collect data for every unit member identified on the roster by the unit sampling plan. Only records that were complete (i.e., for which both data sources used by the unit were present) were collected. In several instances the unit did not provide a full set of records; in other instances, although the unit provided all records, some individuals' records were missing and could not be surveyed. In some cases, the rosters provided were in alphabetical order while in other cases the rosters were in SSN order. It was not possible to account for the potential impact of selection bias (i.e., whether the records that were provided or available differed from the records not provided or missing). However, since the available records appeared without pattern throughout the rosters, all unit samples could be considered randomly distributed.

Variations among services' record-keeping practices were greater than anticipated. Although the Joint Instruction on Immunizations and Chemoprophylaxis (Joint Instruction) specifies that SF-601, Health Record—Immunization Record, and PHS-731 forms are to be completed for each service member, there was considerable variation among units and services with regard to what records were used. Army practice adhered to the Joint Instruction. Navy and Marine Corps units no longer routinely prepare PHS-731 forms. The Air Force had historically relied on the PHS-731 as the primary source of immunization data, although the Joint Instruction specifies the use of AF Form 3922, Adult Preventive Care—Flow Sheet. Under current Air Force automation efforts, data for the automated records are initially derived from the PHS-731 forms; printouts may be inserted into the medical record. Units likely to deploy, units unlikely to deploy, reserve forces, and Guard units follow the practices of their services.

3.0 ANALYSIS RESULTS

This section presents findings from an analysis of the data, as presented in the data analysis plan in Section 4.0 of "Preliminary Study Design." The section concludes with findings about the survey process itself. In accord with the study design, the project team analyzed the following:

- Up-to-date (UTD) Immunization Rates—The proportion of surveyed records that indicated UTD status. For each surveyed vaccine, the team calculated two UTD rates by (1) using the most recent date provided by *any* data source to develop an aggregate rate and (2) determining the UTD rate indicated by *each* data source. Next, the team calculated the aggregate proportions of unit members UTD for any two or all three vaccines that could be assessed, i.e., influenza and tetanus-diphtheria, influenza and yellow fever, tetanus-diphtheria and yellow fever, all three of these vaccines. (Typhoid UTD rates could not be reliably calculated because the records lacked data on the vaccine used and the route of administration.) UTD rates were calculated for each unit as of the date the unit was surveyed and 95 percent confidence intervals (95% CI) were calculated for the UTD rates[1].

- Comparison of UTD Coverage Rates with Service- and Unit-specific Requirements—Documented immunization rates for units surveyed compared to DoD and service-specific immunization requirements.

- Records Sampled—Comparison of records that were surveyed versus those that were not surveyed, as well as an assessment of any bias introduced because of the sampling process.

- Stratification—UTD percentages stratified by rank (officer versus enlisted), longevity of service, and longevity in unit.

[1] The confidence interval is a way to represent the degree of certainty or confidence in the reported results. A 95 percent CI means that if one were to take a large number of samples of the same size from the population in question, one would expect that 95 percent of these intervals would include the true value of the number being estimated. Intervals with higher confidence levels are wider, as higher confidence requires a sacrifice of precision. The 95% CI in the tables is calculated by the widely used formula for the CI of a proportion: if p is the proportion actually observed, the CI for the true proportion is [p - 1.96 sqrt((p(1-p)/n))], [p + 1.96 sqrt((p(1-p)/n))]. Here "sqrt" means the square root of the term in parentheses ((p(1-p)/n)), and n is the number in the sample. When the proportion is close to 100 percent or 0, the interval is truncated, as proportions greater than 100 percent or less than 0 are impossible. When the proportion is exactly 100 percent or 0, the CI is not defined since it is computed using the variation in the sample, and samples with proportions of 100 percent or 0 have no variation. There are, in fact, more exact methods; however, they are harder to compute and interpret. In addition, these rather small samples from small numbers of units do not support more exact conclusions.

As anticipated in the study design, not all of these statistics could be calculated meaningfully using the available data. Further, the numbers of units sampled by service and by deployability status were too small to permit useful discussion of statistical significance of differences between units.

3.1 Service And Unit Immunization Requirements

Each service has established immunization requirements for all active duty personnel, for alert forces and those on high-risk travel, and for reserve forces. All members of active duty units that are likely to deploy are required to be UTD for all four vaccines surveyed.

Army, Air Force, and Marine Corps reserve personnel, as well as the Guard forces, receive the same vaccines as active duty personnel when called up for 30 days or more (with the exception that Air Force and Air National Guard are required to have influenza immunizations every year). Navy reservists are immunized as active duty personnel when called up for 10 days or more. Reserve forces are also immunized with all vaccines indicated on the service schedule when they are subject to short-notice deployments outside of the United States.

Even in "non-deployable" active duty or reserve units, individuals or small groups may deploy outside of the United States and thus require specific immunizations. Although units provided data on recent deployments, it was not possible to link individual unit members with deployment-specific immunization requirements to determine whether they were immunized as required. Thus it was not possible to determine fully which unlikely-to-deploy active duty units or unit members, reservists, or reserve units were in compliance with requirements and which were not. The individual nature of deployments may influence the coverage rates seen for reserve units and those considered unlikely to deploy.

3.2 Survey Findings Compared With Influenza Immunization Requirements

Influenza immunization is required annually for all active duty personnel, Air Force reservists, and Air National Guard members, irrespective of deployment or mobility status. It is required for Army reserve forces called up for 30 days and for Navy reserve forces called up for 10 days. As presented in Exhibit 3, surveyed records indicated that aggregate UTD rates for units required to have annual influenza immunizations ranged from 42.9 percent to 96.3 percent. UTD rates for units not routinely required to have annual influenza immunizations ranged from 0 to 4.6 percent.

EXHIBIT 3
IMMUNIZATION RATES FOR INFLUENZA BY UNIT

Units Likely To Deploy	Sample Size	UTD %	(95% CI)	Out-of-Date	No Date Given
Army (#1)*	50	70%	(57.3%, 82.7%)	28%	2%
Navy (#1)*	53	90.6%	(83.4%, 98.6%)	5.7%	3.8%
Air Force (#1) *	50	94.0%	(87.3%, 100%)	6%	0%
Air Force (#2) *	54	96.3%	(90.7%, 100%)	3.7%	0%
USMC (#1)*	58	89.7%	(81%, 97%)	10.3%	0%
Air National Guard*	60	80%	(69.8%, 90.1%)	15%	5%
Units Unlikely To Deploy	**Sample Size**	**UTD %**	**(95% CI)**	**Out-of-Date**	**No Date Given**
Army (#2) *	35	42.9%	(26.5%, 59.4%)	57.1%	0%
Navy (#2) *	50	90%	(81.8%, 98.2%)	6%	4%
USMC (#2)*	55	81.8%	(71.8%, 92.2%)	18.2%	0%
Army Reserve **	54	0%	N/A	44.4%	55.6%
Navy Reserve **	65	4.6%	(.9%, 10.9%)	70.8%	24.6%
Air Force Reserve *	76	92.1%	(85.9%, 98%)	7.9%	0%

* = Influenza immunization required for this unit.
** = Influenza immunization not required for this unit unless called up, as specified by service.
N/A = No confidence interval is calculated for a rate of 0% or 100%.
No Date Given = There was no date provided for this immunization in any of the data sources surveyed.

3.3 Survey Findings Compared With Tetanus-Diphtheria Immunization Requirements

Tetanus-diphtheria immunization is required for all active duty personnel irrespective of deployment or mobility status. It is required for Army and Air Force reserve and Guard forces called up for 30 days and for Navy reserve forces called up for 10 days. As shown in Exhibit 4, UTD rates for the nine surveyed units required to have tetanus-diphtheria immunizations ranged from 90 to 100 percent, with six of the nine units having rates higher than 96 percent and three of the six having rates of 100 percent.

EXHIBIT 4
IMMUNIZATION RATES FOR TETANUS-DIPHTHERIA BY UNIT

Units Likely To Deploy	Sample Size	UTD %	(95% CI)	Out-of-Date	No Date Given
Army (#1) *	50	100%	N/A	0%	0%
Navy (#1) *	53	98.1%	(94.2%, 100%)	1.9%	0%
Air Force (#1) *	50	100%	N/A	0%	0%
Air Force (#2) *	54	100%	N/A	0%	0%
USMC (#1) *	58	98.3%	(94.5%, 100%)	1.7%	0%
Air National Guard*	60	90%	(82.4%, 97.6%)	1.7%	8.3%
Units Unlikely To Deploy	**Sample Size**	**UTD %**	**(95% CI)**	**Out-of-Date**	**No Date Given**
Army (#2) *	35	91.4%	(81.6%, 100%)	8.6%	0%
Navy (#2) *	50	98%	(94.2%, 100%)	2%	0%
USMC (#2) *	55	96.4%	(90.9%, 100%)	3.6%	0%
Army Reserve **	54	33.3%	(20.5%, 45.5%)	37%	29.6%
Navy Reserve **	65	86.2%	(77.5%, 94.4%)	9.2%	4.6%
Air Force Reserve **	76	90%	(82.4%, 97.6%)	1.7%	8.3%

* = Tetanus-diphtheria immunization required for unit.
** = Tetanus-diphtheria immunization not required for this unit unless called up, as specified by service.
N/A = No confidence interval is calculated for a rate of 0% or 100%.
No Date Given = There was no date provided for this immunization in any of the data sources surveyed.

3.4 Survey Findings Compared With Yellow Fever Immunization Requirements

Yellow fever vaccine is required for all Navy and Marine Corps active duty personnel and for deployable active duty personnel in the other services. Reserve or Guard forces called up for 30 days are required to be immunized for yellow fever, with the exception of the Navy reserves, who are immunized when called up for 10 days. As presented in Exhibit 5, of the eight units required to have yellow fever vaccine, all had UTD rates higher than 88 percent and two had rates of 100 percent.

EXHIBIT 5
IMMUNIZATION RATES FOR YELLOW FEVER BY UNIT

Units Likely To Deploy	Sample Size	UTD %	(95% CI)	Out-of-Date	No Date Given
Army (#1) *	50	90%	(81.8%, 98.2%)	0%	10%
Navy (#1) *	53	100%	N/A	0%	0%
Air Force (#1) *	50	100%	N/A	0%	0%
Air Force (#2) *	54	94.4%	(87.7%, 100%)	3.7%	1.9%
USMC (#1) *	58	96.6%	(92.7%, 100%)	0%	3.4%
Air National Guard*	60	88.3%	(79.8%, 96.2%)	5%	6.7%
Units Unlikely To Deploy	**Sample Size**	**UTD %**	**(95% CI)**	**Out-of-Date**	**No Date Given**
Army (#2) **	35	65.7%	(50.3%, 81.7%)	25.7%	8.6%
Navy (#2) *	50	96%	(90.5%, 100%)	4%	0%
USMC (#2) *	55	96.4%	(90.9%, 100%)	1.8%	1.8%
Army Reserve **	54	0%	N/A	20.4%	79.6%
Navy Reserve **	65	80%	(70.2%, 89.8%)	13.8%	6.2%
Air Force Reserve **	76	77.6%	(68.5%, 87.4%)	11.8%	10.5%

* = Yellow fever immunization required for unit.
** = Yellow fever immunization not required for this unit unless called to alert duty, per service requirements, or traveling to high-risk locations.
N/A = No confidence interval is calculated for a rate of 0% or 100%.
No Date Given = There was no date provided for this immunization in any of the data sources surveyed.

3.5 Survey Findings Compared With Typhoid Immunization Requirements

Typhoid vaccine is required for deployable, alert forces and for those traveling to high-risk areas. It is also required for Army and Air Force reserve forces called up for 30 days, Navy reserve forces called up for 10 days, and Guard forces called up for 30 days. Personnel traveling to high-risk areas should also receive typhoid vaccine.

It was not possible to determine a definitive UTD rate for typhoid vaccine for any unit surveyed. The Joint Instruction cites the Federal law requiring that records include, among other data, the manufacturer and lot number for vaccines administered to all persons. However, the team observed that these data were generally not recorded. For typhoid vaccine, the lack of data on the vaccine used made it impossible to determine up-to-date status, since there are three different boost intervals, depending on the vaccine used. The route of administration, if oral, would have indicated the need for a boost at five years; however, 97 percent of medical records and 90 percent of shot cards contained no data on route of administration. Therefore, Exhibit 6 presents rates for all three potential cases, i.e., boost intervals of two, three, or five years.

As could be anticipated, the estimated UTD rates increased, markedly in several cases, for longer boost intervals. Units required to have typhoid immunization had rates ranging from 60 percent for two-year boost intervals to 100 percent UTD for five-year boost intervals. However, it is not possible to draw conclusions about these rates because of the inadequacy of the data.

EXHIBIT 6
ESTIMATED TYPHOID IMMUNIZATION FOR DIFFERENT BOOST INTERVALS

NOTE: The typhoid boost interval is two, three, or five years, depending on the vaccine used. Over 90 percent of records were missing the name or type of typhoid vaccine administered. Therefore, it was impossible to calculate actual typhoid coverage rates. This exhibit presents estimated typhoid coverage rates based on potential boost intervals of two, three, or five years.

Units Likely To Deploy	Sample Size	If Two-year Boost Interval %UTD (95% CI)	If Three-year Boost Interval %UTD (95% CI)	If Five-year Boost Interval %UTD (95% CI)
Army (#1) *	50	76% (64.2%, 87.8%)	84% (74%, 94.2%)	98% (94.3%, 100%)
Navy (#1) *	53	67.9% (55.5%, 80.5%)	90.6% (83.4%, 98.6%0	98.1% (94.3%, 100%)
Air Force(#1) *	50	60% (46.5%, 73.5%)	92% (84.6%, 99.5%)	100% (N/A)
Air Force (#2) *	54	92.6% (86.1%, 99.8%)	98.1% (94.3%, 100%)	100% (N/A)
USMC (#1) *	58	91.4% (83.6%, 98.4%)	96.6% (92.7%, 100%)	96.6% (91%, 100%)
Air National Guard**	60	28.3% (16.6%, 39.4%)	41.7% (28.7%, 53.3%)	81.7% (72.4%, 91.6%)
Units Unlikely To Deploy	**Sample Size**	**If Two-year Boost Interval %UTD (95% CI)**	**If Three-year Boost Interval %UTD (95% CI)**	**If Five-year Boost Interval %UTD (95% CI)**
Army (#2) **	35	20% (6.6%, 33.3%)	65.7% (50%, 81.7%)	91.4% (81%, 100%)
Navy (#2) **	50	86% (76.4%, 96%)	96% (90.5%, 100%)	98% (94.3%, 100%)
USMC(#2) **	55	65.5% (51.5%, 77.5%)	89.1% (80.8%, 97.2%)	94.5% (89.3%, 100%)
Army Reserve **	54	7.4% (0.1%, 13.9%)	7.4% (0.1%, 13.9%)	13% (3.9%, 22%)
Navy Reserve **	65	30.8% (19.8%, 42.2%)	49.2% (36.8%, 61.2%)	73.8% (63.4%, 84.6%)
Air Force Reserve **	76	75% (65.4%, 84.6%)	85.5% (78.4%, 93.6%)	81.7% (72.4%, 91.6%)

* = Typhoid immunization required for unit.
** = Typhoid immunization not required for this unit unless called up, per service requirements, for alert duty or high-risk travel.
N/A = No confidence interval is calculated for a rate of 0% or 100%.

3. 6 Up-To-Date Coverage Rates For More Than One Vaccine Compared With Requirements

Calculations of coverage rates for individual vaccines, while useful, provide an incomplete picture of the readiness status of military units. It is also useful to determine the proportion of unit members who are UTD for all surveyed vaccines. To facilitate comparisons across the previous exhibits, Exhibit 7 presents the aggregate UTD rates for individual vaccines, as well as the aggregate rates for more than one vaccine. It should be noted again that not all of these vaccines are required for all service members whose records were surveyed.

Exhibit 7 demonstrates that the proportions of unit members who were fully UTD for two or three vaccines were generally lower than the proportion of unit members who were UTD for single vaccines. While the differences in proportions did not necessarily achieve significance, as more vaccines were added there was a notable overall downward trend in coverage. Some individuals were UTD for one vaccine, some for two vaccines, some for all three. Units required to have both influenza and tetanus-diphtheria vaccines had rates as high as 100 percent for a single vaccine; however, only 42.9 percent of one unit's members had both of those immunizations. Among units required to have all three vaccines, UTD rates for all three ranged from 60 percent to 94 percent. The exhibit again demonstrates that UTD rates for units considered likely to deploy were higher than for those considered unlikely to deploy.

EXHIBIT 7
PROPORTION UP-TO-DATE AND 95% CONFIDENCE INTERVAL FOR INDIVIDUAL AND MULTIPLE VACCINES

Units Likely To Deploy	Influenza	Tetanus-diphtheria	Yellow Fever	Influenza & Td	Influenza & Yellow Fever	Td & Yellow Fever	Influenza, Td & Yellow Fever
Army (#1)	70% (57.3%, 82.7%)	100% N/A	90% (81.8%, 98.2%)	70% (57.3%, 82.7%)	68% (55.1%, 80.9%)	90% (81.8%, 98.2%)	68% (55.1%, 80.9%)
Navy (#1)	90.6% (83.4%, 98.6%)	98.1% (94.2%, 100%)	100% N/A	88.7% (80.6%, 97.4%)	90.6% (83.4%, 98.6%)	98.1% (94.3%, 100%)	88.7% (80.6%, 97.4%)
Air Force (#1)	94.0% (87.3%, 100%)	100% N/A	100% N/A	94.0% (87.3%, 100%)	94% (87.3%, 100%)	100% (N/A)	94% (87.3%, 100%)
Air Force (#2)	96.3% (90.7%, 100%)	100% N/A	94.4% (87.7%, 100%)	96.3% (90.7%, 100%)	90.7% (83.4%, 98.6%)	94.4% (87.7%, 100%)	90.7% (83.4%, 98.6%)
USMC (#1)	89.7% (81%, 97%)	98.3% (94.5%, 100%	96.6% (92.7%, 100%)	87.9% (79.6%, 96.4%)	86.2% (76.9%, 95%)	94.8% (89.3%, 100%)	84.5% (74.6%, 93.4%)
Air National Guard	80% (69.8%, 90.1%)	90% (82.4%, 97.6%)	88.3% (79.8%, 96.2%)	71.7% (60.6%, 83.3%)	68.3% (56.2%, 79.8%)	76.7% (66.4%, 87.6%)	60% (47.7%, 72.3%)
Units Unlikely To Deploy	**Influenza**	**Tetanus-diphtheria**	**Yellow Fever**	**Influenza & Td**	**Influenza & Yellow Fever**	**Td & Yellow Fever**	**Influenza, Td & Yellow Fever**
Army (#2)	42.9% (26.5%, 59.4%)	91.4% (81.6%, 100%)	65.7% (50.3%, 81.7%)	42.9% (26.5%, 59.4%)	28.6% (13.9%, 44.1%)	62.9% (46.9%, 79%)	28.6% (13.9%, 44.1%)
Navy (#2)	90% (81.8%, 98.2%)	98% (94.2%, 100%)	96% (90.5%, 100%)	88% (78.9%, 97%)	86% (76.4%, 95.6%)	94% (87.3%, 100%)	84% (73.8%, 94.2%)
USMC (#2)	81.8% (71.8%, 92.2%)	96.4% (90.9%, 100%)	96.4% (90.9%, 100%)	78.2% (67%, 88.9%)	76.4% (64.6%, 87.4%)	92.7% (86.3%, 99.7%)	76.4% (64.6%, 87.4%)
Army Reserve	0% N/A	33.3% (20.5%, 45.5.%)	0% N/A	0% N/A	0% N/A	0% N/A	0% N/A
Navy Reserve	4.6% (.9%, 10.9%)	86.2% (77.5%, 94.4%)	80% (70.2%, 89.8%)	4.6% (.9%, 10.9%)	4.6% (.9%, 10.9%)	78.5% (69%, 89%)	4.6% (.9%, 10.9%)
Air Force Reserve	92.1% (85.9%, 98%)	92.1% (85.9%, 98%)	77.6% (68.5%, 87.4%)	86.8% (79.4%, 94.6%)	68.4% (57.4%, 78.6%)	69.7% (58.6%, 79.4%)	69.7% (58.6%, 79.4%)

N/A = No confidence interval is calculated for a rate of 0% or 100%.

3.7 Up–To–Date Status As Recorded In Different Data Sources

This survey relied on immunization records rather than serological testing to estimate the immunization status of members of the surveyed units. One matter of interest was which data sources would prove to be the most valid for determining immunization coverage rates. If one data source were found to be consistently valid, it would be possible to design future studies to focus only on that single data source, which could vary by service. As stated earlier, the team revised its original plan because of the difficulties encountered in defining, across services, what data sources should be expected to be present, i.e., constitute a "complete" record for each unit. However, it was possible to compare the proportions up-to-date for each immunization according to the data sources that were available for each unit and to compare these proportions to the aggregate UTD rate derived by using in each case the record that showed the most recent immunization. Exhibits 8, 9, and 10 present the rates obtained for influenza, tetanus-diphtheria, and yellow fever, respectively, from medical records, shot cards, and automated records, as well as the aggregate UTD rate from all sources combined.

EXHIBIT 8
INFLUENZA IMMUNIZATION STATUS BY UNIT BY DATA SOURCE

Units Likely To Deploy	Sample Size	UTD % Medical Record	UTD % Shot Card	UTD % Automated Record	UTD % Combined Data Sources
Army (#1) *	50	14%	66%	No data	70%
Navy (#1) *	53	41.5%	0%	86.8%	90.6%
Air Force (#1) *	50	No data	84%	94%	94%
Air Force (#2) *	54	No data	90.7%	96.3%	96.3%
USMC (#1) *	58	84.5%	0%	86.2%	89.7%
Air National Guard *	60	31.7%	78.3%	No data	80.0%
Units Unlikely To Deploy	**Sample Size**	**UTD % Medical Record**	**UTD % Shot Card**	**UTD % Automated Record**	**UTD % Combined Data Sources**
Army (#2) *	35	17.1%	34.3%	No data	42.9%
Navy (#2) *	50	74%	0%	90%	90.0%
USMC (#2) *	55	74.5%	14.5%	74.5%	81.8%
Army Reserve **	54	0%	0%	No data	0%
Navy Reserve **	65	3.1%	No data	4.6%	4.6%
Air Force Reserve *	76	84.2%	85.5%	No data	92.1%

* = Influenza immunization required for unit.
** = Influenza immunization not required for this unit unless called up, per service requirements.
No data = Data source was not available for this unit.

EXHIBIT 9
TETANUS-DIPHTHERIA IMMUNIZATION STATUS BY UNIT BY DATA SOURCE

Units Likely To Deploy	Sample Size	UTD % Medical Record	UTD % Shot Card	UTD % Automated Record	UTD % Combined Data Sources
Army (#1) *	50	100%	90%	No data	100%
Navy (#1) *	53	96.2%	7.5%	92.5%	98.1%
Air Force (#1) *	50	No data	100%	100%	100%
Air Force (#2) *	54	No data	92.6%	98.1%	100%
USMC (#1) *	58	98.3%	8.6%	98.3%	98.3%
Air National Guard *	60	0%	90%	No data	90%
Units Unlikely To Deploy	**Sample Size**	**UTD % Medical Record**	**UTD % Shot Card**	**UTD % Automated Record**	**UTD % Combined Data Sources**
Army (#2) *	35	88.6%	80%	No data	91.4%
Navy (#2) *	50	98%	6%	94%	98%
USMC (#2) *	55	96.4%	32.7%	90.9%	96.4%
Army Reserve **	54	31.5%	7.4%	No data	33.3%
Navy Reserve **	65	81.5%	No data	78.5%	86.2%
Air Force Reserve *	76	82.9%	85.5%	No data	92.1%

* = Tetanus-diphtheria immunization required for unit.
** = Tetanus-diphtheria immunization not required unless called up, per service requirements.
No data = Data source was not available for this unit.

EXHIBIT 10
YELLOW FEVER IMMUNIZATION STATUS BY UNIT BY DATA SOURCE

Units Likely To Deploy	Sample Size	UTD % Medical Record	UTD % Shot Card	UTD % Automated Record	UTD % Combined Data Sources
Army (#1) *	50	82%	74%	No data	90%
Navy (#1) *	53	100%	11.3%	96.2%	100%
Air Force (#1) *	50	No data	100%	94%	100%
Air Force (#2) *	54	No data	87%	92.6%	94.4%
USMC (#1) *	58	96.6%	8.6%	96.6%	96.6%
Air National Guard *	60	1.7%	88.3%	No data	88.3%
Units Unlikely To Deploy	**Sample Size**	**UTD % Medical Record**	**UTD % Shot Card**	**UTD % Automated Record**	**UTD % Combined Data Sources**
Army (#2) *	35	54.3%	48.6%	No data	65.7%
Navy (#2) *	50	96%	6%	94%	96%
USMC (#2) *	55	96.4%	27.3%	89.1%	96.4%
Army Reserve **	54	0%	0%	No data	0%
Navy Reserve **	65	75.4%	No data	72.3%	80%
Air Force Reserve *	76	72.4%	73.7%	No data	77.6%

* = Yellow fever immunization required for unit.
** = Yellow fever immunization not required unless called up, per service requirements.
No data = Data source was not available for this unit.

Every sampled unit had more than one data source for immunizations. These sources did not necessarily agree with one another; nor did any of the sources for a unit necessarily agree with the aggregate UTD rate. Initial observations indicated the following:

- There was a notable discrepancy among Army sources for influenza and yellow fever data.

- The medical records of the Navy (#1) unit, considered likely to deploy, yielded the same UTD rate for yellow fever as the aggregate record. For the Navy (#2) unit, considered unlikely to deploy, rates from the automated record for influenza and the medical record for yellow fever agreed with the aggregate record.

- For Air Force (#1), a deployable unit, UTD rates from both the automated records and the shot cards were equal to the aggregate UTD rate, the rate from the automated record agreed with the aggregate rate for influenza immunizations, and the rate from the shot

cards agreed with the aggregate rate for yellow fever immunizations. The rate from automated records for the Air Force (#2) unit, also deployable, agreed with the aggregate rate for influenza immunizations. It should be noted that both Air Force units' records had been automated immediately prior to the site visit, a process that involved collecting all available data on immunizations for the computerized record.

- Rates from the medical records of both Marine Corps units agreed with the aggregate rates for tetanus-diphtheria and yellow fever immunization. The automated records of the deployable Marine Corps unit (#1) yielded the same rate as the aggregate rate for tetanus-diphtheria and yellow fever.

- The UTD rate for influenza from the Naval Reserve unit's automated record matched the aggregate rate.

- The UTD rates for tetanus-diphtheria and yellow fever from the Air National Guard unit's shot cards (PHS-731 forms) matched the aggregate UTD rates for those vaccines.

Thus there appeared to be no consistently valid single source for data on all immunizations. It should be noted that, since Navy and Marine Corps units are not required to keep shot cards, the differences between the shot cards and other data sources for these units are meaningless. Similarly, the Air National Guard unit relied historically on shot cards rather than medical records for tracking immunizations, so the fact that the shot cards are more valid data sources is not surprising.

After making the initial observations, the team assessed the statistical significance of the differences between data sources and between each data source and the aggregate UTD rate, with the following results:

- There were some statistically significant differences between data sources, but these differences were not consistent for all vaccines, i.e., the differences varied according to vaccine.

- No single, comprehensive data source could be identified for any service. Thus, for all units and services surveyed, it was necessary to collect and analyze data from multiple sources to calculate the most accurate UTD coverage rates.

3.8 Records Sampled

During the pretest the study team observed large variability in coverage rates. The worst case UTD rate (for sample size) was approximately 50 percent for required immunizations. The rate of return on records sought, i.e., the percentage of "complete" records found, was approximately 75 percent.

Assessing the importance of the completeness or absence of records did not prove to be informative as it was impossible to estimate any bias introduced by sampling only complete records. As discussed in Section 2.3 above, units provided different data sources and not all units used the forms specified in the Joint Instruction. To standardize the approach to data collection, two data sources were required for each individual surveyed. However, the differences across services and limitations on the records available prevented the development of a consistent definition of "complete" immunization records that would be applicable to all services.

3.9 Stratification Of Up–To–Date Percentages By Rank And Longevity

The study was designed to allow stratification of results by rank and longevity, provided sufficient information was available. For most of the units sampled, the number of officers included in the sample was too small for stratification or meaningful statistical analysis. Thus it was not possible to form any conclusions about the immunization status of officers versus enlisted personnel.

Correlation analyses of longevity in service versus up-to-date status (coded as 1 if the individual was shown as up-to-date in at least one data source, 0 otherwise) yielded no statistically significant correlations. Contingency tables dividing units between individuals with less than five years of service versus those with five years or more tended to put most of a unit's members into one class: the units highly likely to deploy had few members with five years or more in service, while the others had few members with less than five years. Therefore, it was not possible to perform a meaningful analysis of this variable with the data collected.

3.10 Findings About The Survey Process

Identifying convenient units that were willing to participate and obtaining permission to visit each service's units was a lengthy, often cumbersome process, even though the services' Surgeons General were helpful in facilitating the approval process and the initial points of contact for each service were already familiar with the survey plans. Arranging the visits to the reserve and Guard units was particularly challenging, as the process involved introducing the project to four separate chains of command, each with its own requirements and concerns.

Collecting immunization data, the service member's rank, and a general assessment of the deployment status of the unit generally involved interaction only with the medical unit. When the shot cards were held in the unit they could be readily provided by the unit. When the shot cards were held by individuals, however, the unit had to work in advance to collect them. In some instances, collecting data on length of time in the service and in the unit for each individual required extensive efforts by the unit personnel officials. As shown in Exhibit 1, only two units had automated immunization records systems that were interoperable with their personnel data systems.

The on-site process worked well. The amount of time required to survey a unit varied with the length of time and number of officials involved in the in-brief, whether the unit had all records available when the team arrived, whether an out-brief was requested, and the number of questions posed in the out-brief. It was faster to check automated records than to hand-search medical records, particularly when the unit members had been in the service a long while and had thick records. The allocation of one day for collecting 50 records from a unit worked well for a two- or three-person team. In some cases in which two units' records were in the same location, the team was able to survey two units (approximately 100 records) in one day.

4.0 DISCUSSION

The small number and convenient nature (proximity to Washington, D.C., and willingness to participate) of units, as well as the relatively small sample sizes for each unit, limited the number and strength of the conclusions the team could draw, especially with regard to stratifications and correlations. However, a number of discussion points should be highlighted:

- Units likely to deploy were, in general, better immunized than the others, and active duty units were better immunized than reserves. The two active duty Navy units appeared very similar, despite the difference in their likelihood of deployment, because both had recently returned from deployment when they were sampled.

- When UTD coverage rates were calculated for more than one vaccine, the rates were lower than for individual vaccines, indicating that some unit members were not up-to-date for all vaccines surveyed

- Every unit surveyed had some members whose immunizations, as recorded, were lacking with respect to the unit's medical and readiness requirements.

- Data sources tended to be inconsistent and no one source proved reliable and valid for all vaccines for any service. Automated records were no more reliable than other data sources. However, it should be noted that, for all but the Navy units, no unit had been automated for even six months. The Air Force units appeared to have stepped up their automation efforts for the site visits.

- Members of some units surveyed deploy as individuals or small groups even when the unit is considered unlikely to deploy. Thus the association between units' likelihood of deployment and their members' immunization status was somewhat less clear than anticipated.

- The units were requested to provide data on officer and enlisted departures from and entries into the units over the past year. Rates of departure from and entry into units

calculated from the data provided by the units did not correlate with immunization status, the deployability of the unit, or longevity.

- To the extent that any pattern analysis was possible using this sample, rank (officer versus enlisted) and longevity in service seemed to have little predictive value for whether the individual was immunized. It should be noted that the resulting sub-sample sizes, particularly for officers, were too small to permit any conclusions about rank and immunizations.

- Members of units less likely to deploy tended to have greater time in service, and members of reserve units generally had considerably more time in service than members of active duty units. These were the types of units with generally lower immunization rates as well. However, it is not possible to conclude from this small sample of units whether there is a strong association between the type of unit, its members' longevity in service, and immunization rates.

- Six units were required to have influenza, tetanus-diphtheria, and yellow fever vaccines. Three of these units had rates over 90 percent for all three single vaccines. In only two instances was a single vaccine rate 80 percent or lower.

- Four units (the Army unit likely to deploy, the Navy unit likely to deploy, and the two Air Force units) showed 100 percent UTD coverage for at least one immunization required by service policy (tetanus-diphtheria for the Army unit and both Air Force units, yellow fever for the Navy unit and one Air Force unit).

5.0 RECOMMENDATIONS

Based on the findings derived from this analysis of survey results, B&D has developed recommendations for future surveys of immunization coverage and for immunization documentation and record-keeping practices.

5.1 Recommendations For Future Surveys Of Immunization Coverage

The immunization survey was intended to establish a pre-automation baseline of immunization data in order to compare the results with post-automation findings. B&D recognizes the importance of such comparisons to determine the benefits realized through the investment in information technology. We recommend that the units surveyed during this pretest, particularly those had not yet fully automates their records, be surveyed again once their systems are well established. A follow-up survey will provide potentially rich, comparative data to serve as an indicator of the impact of automation on documentation of immunizations administered.

Another purpose of the pretest survey was to test the study design. As anticipated, the inclusion of only one unit of each type (e.g., deployable, active duty) per service resulted in two key limitations. First, it prevented comparisons of rates and estimates of variance across units of an individual service. Second, it limited the broad applicability of survey results among services. Therefore, B&D recommends that (1) further surveys be conducted to better assess military immunization status, (2) active duty and reserve/Guard forces be surveyed separately for each service, and (3) the samples consist of individual service members selected randomly from a random selection of units within a representative range of commands and bases.

Taking into account the potential for low coverage rates and the rate of return found among the units surveyed during the pretest, we recommend that a sample size of 533 be collected. To achieve a 95 percent confidence level and a 5 percent acceptable error will require an effective sample size of 400 (William G. Cochran, *Sampling Techniques*, 1953, John Wiley & Sons, New York). Since the return rate is projected to be 75 percent, it will be necessary to collect original sample sizes of 533 for active duty forces and 533 for reserve/Guard forces for each service to obtain that effective sample size.

As a result of findings about data that appeared to correlate with immunization status, and in an effort to limit data collection only to those elements deemed critical to understanding military immunization processes, we recommend that future surveys employ the following protocol, regardless of the survey scale or focus:

- Unit Data—Collect data on unit and individual members' deployment status, unit strength, and points of contact. Since unit rates of entry and departure proved inconsequential in relationship to immunization status, do not collect these data in the future.

- Individual Data—Collect immunization dates, presence or absence of vaccine manufacturer names and lot numbers, and typhoid vaccines and routes of administration from all available data sources. Collect rank, which can generally be provided by the medical treatment facility. (On occasion rosters are produced by the unit, but this is a standardized, routine matter.) Rather than requesting that the unit provide a listing of all recent deployments and readiness exercises, we recommend that the unit be asked only about whether the individual members surveyed are considered likely to deploy or have deployed within the past 36 months. Do not collect length of time in the service, length of time in the unit, or the pay grade, as these require extensive unit effort.

- Vaccines—In addition to data on influenza, tetanus-diphtheria, yellow fever, and typhoid vaccines, consider collecting data on all anthrax and hepatitis A vaccinations administered to measure compliance with DoD and service directives.

- Data Analysis—Calculate aggregate UTD rates and UTD rates by data source, as well as rates for both single and multiple vaccines. Continue to assess by service whether a single source will produce reliable UTD coverage rates.

5.2 Recommendations Relating To Immunization Records

This survey found that the lack of recorded data on typhoid vaccines prevented determination of typhoid booster due dates. It was also observed that data on vaccine manufacturers and lot numbers were lacking for other vaccines as well. Although the number of reported adverse reactions to vaccines is quite small, DoD regulations, Federal law, and clinical practice standards require that providers keep track of what they have administered to persons in their care. Therefore, we recommend that the DoD consider ways to increase compliance in this matter. For example, automated systems may include prompts that require vaccine data entry before the record can be closed.

Finally, as recommended in the "Report on the Analysis of Department of Defense Immunization Policy," submitted on March 25, 1998, we urge that the revised Joint Instruction address the impact of automation on record-keeping, e.g., what paper records need to be maintained, whether the PHS-731 must be maintained, and how to manage period of the transition before all records are automated.

APPENDIX A
SAMPLE LETTER AUTHORIZING MEDICAL RECORDS REVIEW

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS AIR FORCE MEDICAL OPERATIONS AGENCY
BROOKS AIR FORCE BASE, TEXAS

16 JAN 1998

MEMORANDUM FOR AFEB
ATTN: COL FOGELMAN

HQ AFMOA/SGOI
2510 Kennedy Circle, Ste 208
Brooks AFB, TX 78235-5121

SUBJECT: Request for Access to Medical Records for Immunization Coverage Survey

We have reviewed your request for access to medical and immunization records for the [redacted] and the [redacted] Your request is hereby approved.

As stated in you request, the following conditions will be met by the reviewers:

1. Information taken from United States Air Force medical records will be treated according to the ethics of the medical and dental profession.
2. The identities of people mentioned in the records will not be divulged without permission. Medical record review does not include the use of photographs of people or any exterior portion of a patient's body; but should that ever occur, they would not be released without consent.
3. The Armed Forces Epidemiological Board understands that permission to study the records does not imply approval of the project or field of study by the United States Air Force.
4. All identifying entries about a person will be deleted from abstracts or reproduced copies of the records.
5. Any published material or lectures on the particular project or study will contain the following statement: "The use of United States Air Force medical records in the preparation of this material is acknowledged, but it is not to be construed as implying official United States Air Force approval of the conclusions presented."

When requesting access to the records at [redacted], show this approval letter allowing access to the records to the proper authority at the facility.

If we can be of any further assistance, please contact Ms. Debi Yowell at (210) 536-4081 or e-mail at yowell_d@msa01.brooks.af.mil.

LANE A. ONGSTAD, Col, USAF, MSC
Chief, Patient Informatics
Office of the Surgeon General

APPENDIX B
PRE-VISIT SURVEY FORM

APPENDIX B – UNIT DATA COLLECTION: PREVISIT QUESTIONNAIRE

Please complete this form and return to Jamerson Pender, Birch & Davis Associates, Inc., before our visit to your unit. Fax: 703-578-1890. Phone: 703-824-3471. Thank you.

UNIT/COMMAND NAME	

CONTACT INFORMATION

BASE COMMANDER Name/Rank/Position	
Address	
Telephone (commercial)	
Fax (commercial)	
E-mail	
UNIT COMMANDER Name/Rank/Position	
Address	
Telephone (commercial)	
Fax (commercial)	
E-mail	
POINT OF CONTACT Name/Rank/Position	***Person completing this form***
Address	
Telephone (commercial)	
Fax (commercial)	
E-mail	

UNIT DESCRIPTION

Unit mission	
Unit function(s)	

DEPLOYMENT/READINESS INSPECTION HISTORY

Deployments within past 3 years (include exercises)	
Date of last unit readiness inspection	
Comments on last unit readiness inspection	

UNIT STRENGTH

Current unit strength	

DEPARTURES FROM UNIT WITHIN PAST 12 MONTHS

Number of enlisted personnel departing	
Number of officers departing	

ENTRIES INTO UNIT WITHIN PAST 12 MONTHS

Number of enlisted personnel entering	
Number of officers entering	

APPENDIX C
ON-SITE DATA COLLECTION FORM

APPENDIX C - IMMUNIZATION SURVEY

IMMUNIZATION SURVEY Site: _____ Record ID: _____

Site: Roster:

Unit: Unit ID: Record ID:

Date: / / MM / DD / YY Data Collector: Initial

Date Entered Service: / / MM / DD / YY Date Entered Unit: / / MM / DD / YY

Rank:

Pay Grade: O-10 O-9 O-8 O-7 O-6 O-5 O-4 O-3 O-2 O-1 E-9 E-8

E-7 E-6 E-5 E-4 E-3 E-2 E-1 W-5 W-4 W-3 W-2 W-1

Remark:

Written Record:

Vaccine	Date of Last Imm.	If missing, Check Here
Influenza		
Yellow Fever		
Tetanus-Diphtheria		
Typhoid: See Below		
Typhoid- Vivotif Berna (Swiss Serum & Vaccine Institute)	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Typhoid- Parenteral Inactivated (Wyeth-Ayerst)	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Typhoid- Typhim Vi- ViCPS (Pasteur Merieux)	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Typhoid- Acetone - Inactivated Parenteral	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Remark:		

Shot Record:

Vaccine	Date of Last Imm.	If missing, Check Here
Influenza		
Yellow Fever		
Tetanus-Diphtheria		
Typhoid: See Below		
Typhoid- Vivotif Berna (Swiss Serum & Vaccine Institute)	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Typhoid- Parenteral Inactivated (Wyeth-Ayerst)	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Typhoid- Typhim Vi- ViCPS (Pasteur Merieux)	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Typhoid- Acetone - Inactivated Parenteral	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Remark:		

Mass Vaccination Roster:

Vaccine	Date of Last Imm.	If missing, Check Here
Influenza		
Yellow Fever		
Tetanus-Diphtheria		
Typhoid: See Below		
Typhoid- Vivotif Berna (Swiss Serum & Vaccine Institute)	Dosage:_____ _ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Typhoid- Parenteral Inactivated (Wyeth-Ayerst)	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Typhoid- Typhim Vi- ViCPS (Pasteur Merieux)	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Typhoid- Acetone - Inactivated Parenteral	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Remark:		

Automated Record:

Vaccine	Date of Last Imm.	If missing, Check Here
Influenza		
Yellow Fever		
Tetanus-Diphtheria		
Typhoid: See Below		
Typhoid- Vivotif Berna (Swiss Serum & Vaccine Institute)	Dosage:_____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Typhoid- Parenteral Inactivated (Wyeth-Ayerst)	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Typhoid- Typhim Vi- ViCPS (Pasteur Merieux)	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Typhoid- Acetone - Inactivated Parenteral	Dosage: _____ Route: Oral Intramuscular Subcutaneous Intradermal/Percutaneous	
Remark:		

APPENDIX G

ARMED FORCES EPIDEMIOLOGICAL BOARD DEPARTMENT OF DEFENSE IMMUNIZATION PROGRAM ANALYSIS AND DESIGN FOR STUDY OF IMMUNIZATION COVERAGE

Revised Design for Immunization Coverage Study

ARMED FORCES EPIDEMIOLOGICAL BOARD DEPARTMENT OF DEFENSE IMMUNIZATION PROGRAM ANALYSIS AND DESIGN FOR STUDY OF IMMUNIZATION COVERAGE

REVISED DESIGN FOR IMMUNIZATION COVERAGE STUDY

Submitted To:

Vicky L. Fogelman, Col, USAF, BSC
Executive Secretary
Armed Forces Epidemiological Board

Prepared By:

Birch & Davis Associates, Inc.
Under Prime Contract No. DASW01-95-0026
Delivery Order No. 0081

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May 14, 1998

CONTENTS

REVISED DESIGN FOR IMMUNIZATION COVERAGE STUDY

1.0 INTRODUCTION

The Department of Defense (DoD) is implementing an automated system to record immunizations of military service members. Concurrently, the Armed Forces Epidemiological Board (AFEB) is reviewing immunization policies and procedures. A single survey methodology can provide the DoD, the Services, and the AFEB with useful information regarding immunization coverage rates so they can measure the impacts of policies, procedures, and systems.

Birch & Davis Associates, Inc. (B&D), presents such a methodology in this document. It is a revision of the methodology presented in "Preliminary Study Design" submitted January 20, 1998. The revision reflects the findings and recommendations presented in "Report on the Analysis of Department of Defense Immunization Policy" submitted March 25, 1998, and in "Report On The Pretest" submitted April 10, 1998. The revision entails balancing statistical theory with practical realities: it minimizes the surveying effort while still allowing the drawing of statistical inferences regarding a population.

This document addresses the theoretical and practical aspects of the study design in the following areas:

- Survey objectives and the resulting ramifications
- Original and effective sample size
- Stratification and clustering
- Data collection and analysis
- Recommendations for study design options

2.0 SURVEY OBJECTIVES AND THE RESULTING RAMIFICATIONS

Developing the sampling frame is a stepwise process that entails answering critical questions about the objectives for the study. This section presents the survey objectives and the impact of the objectives on the sampling frame for study implementation.

First, defining the survey objectives includes developing a clear and explicit answer to the composite question *What is to be measured about what population for what purpose?* The objectives of the survey presented in this document are:

- Measure up-to-date (UTD) rates for immunizations among highly likely to deploy and not routinely deployed personnel. This objective remains the same as for the pretest.

- Assess the quality of the immunization records by comparing the coverage rates represented by different types of data sources. Marked differences between data sources in the pretest, as well as the changing environment for immunization record-keeping in DoD and the addition of a six-dose primary series of vaccinations for anthrax, make exploration of data quality and data source documents a matter of interest.

The second step in developing the sampling frame is to define the *universe* by answering the question *What population?* In this case, the *universe* is described as the personnel of units that are highly likely to deploy and of units that are not routinely deployable. Third, because findings and recommendations can relate statistically by inference only to the *working*, or *restricted universe*, the *working universe* must be defined consistently throughout the study. For this study, the original *universe* should be further restricted to the members of the active duty, reserves, and Guard forces of each specific military Service (and the Coast Guard, if interest and funding are present) that reside in the continental United States (CONUS). Furthermore, because of suspected biases, medical units should be excluded.

Finally, the definition of the ultimate sampling unit (USU) derives from the definition of the working universe. For this survey, the USU is defined as the man or woman belonging to the *working universe* Military units are, from the statistical point of view, clusters (or, in some special cases, strata) of USUs. Therefore, it is possible to analyze findings about military units, but because it would take a very large number of military units to provide results generalizable to any individual service, individual men or women rather than military units are the USUs.

Based on the previously defined *working universe*, the sampling frame will be Service-specific lists of the population elements from which the sample will be drawn, starting from the Service of interest, through commands, bases, and units, to individual USUs. As discussed in Section 4.0, the goal of the study should be to sample from a range of commands, bases, and units selected on a Service-by-Service basis to represent the Service population. The sampling frame is not a list of all the names of USUs, but a means of obtaining a list of USUs that is complete, free of duplicates, accurate, and current. Differences between the sampling frame and the *working universe* must be documented. For example, rosters for random selection will be generated ahead of the data collection and the report on the analysis; any discussion of survey findings should include an analysis of the implications of the differences of these dates on the working universe and the sampling frame.

The observation unit, that is, the unit about which data is collected, is defined as the immunization record of the USU. The immunization record is (depending on availability and applicability) the electronic immunization record, and/or the PHS 731 immunization card, and/or the written Service medical record, and/or information from mass immunization rosters. To achieve the study objectives, the study team should collect all available data from all sources and document the source for each piece of data collected.

3.0 ORIGINAL AND EFFECTIVE SAMPLE SIZE

During the pretest the study team observed large variability in coverage rates. The worst case (for sample size) of a 50% coverage rate cannot be disregarded and the return rate on information requests, 75%, must be considered also in determining the sample size for this study. Thus, achieving a 95% confidence level and a 5% acceptable error will require an effective sample size of 400 (William G. Cochran, *Sampling Techniques*, 1953, John Wiley & Sons, New York). Since the return rate is projected to be 75%, it will be necessary to collect an original sample size of **533** in order to obtain that effective sample size.

4.0 STRATIFICATION AND CLUSTERING

The universe contains mutually exclusive and exhaustive groups called strata. The units within a stratum are more homogeneous than units across strata. Strata are not sampled; rather, all strata are surveyed. In general, stratification improves the quality of a study because it improves the coverage of the universe. In this study, the sample size should be allocated to strata in direct proportion to stratum size; the exception should be special cases of small strata for which at least minimal coverage must be achieved. For this study, a logical scheme would be to stratify by:

- Geographical location of the military unit to which the USU belongs
- Size of military unit to which the USU belongs and/or of the USU's location (base)
- Likelihood of deployment

Within each stratum there are clusters of USUs. In general, clustering (sampling by choosing a few clusters) reduces cost and increases convenience, however, it introduces biases and limits the ability to generalize results. Clustering should be avoided as much as possible within the practical limitations of the study.

5.0 DATA COLLECTION AND ANALYSIS

The pretest of the preliminary study design was conducted with a convenience sample of units, some of whom did not make all records available to the study team. While these factors did not have an important impact on the analysis of the *processes* involved in the study, both factors

limited the generalizability of study results. This section presents recommended changes in data collection and analysis procedures.

5.1 Data Collection

The study team was aware of the burden placed on site points of contact by having to collect all records for an entire unit in a central location for review. Therefore, under the revised plan:

- The study team would select the sites to be surveyed randomly from lists developed with the individual Services.

- Selected sites would provide lists of units, identified as likely or unlikely to deploy in advance to the study team. The study team would randomly select the units from which USUs would be selected and request lists of USUs in advance. These lists would be kept under lock and key during the study and shredded mechanically prior to disposal at the end of the study.

- Using a non-systematic, random selection process, the study team would select the USUs to be surveyed.

- The selected sites would provide all immunization records and other requested data (see below) only for the selected USUs. In the case of missing records, the sites would contact the study team to select a replacement USU and collect data prior to the site visit.

- The study team would visit the site to ensure that the sample provided was as requested and collect the data from the immunization records.

Making these changes to the pretested study design will help to ensure that the results will be able to withstand scrutiny and be perceived as unbiased, representative, and generalizable. In addition, data collection and analysis will address explicitly the following items:

- The impact of deploying within the last three years. For each USU, the study team will request a list of OCONUS deployments within the 36 months prior to the site visit.

- The possible difference in immunization coverage between officer and enlisted personnel. The study team will request the rank for each USU sampled.

5.2 Data Analysis

The study team will analyze the collected data by computing the following statistics for each Service surveyed:

- UTD coverage rates for each vaccine surveyed by data source
- UTD coverage rates aggregated across data sources to create a "best-case" rate
- UTD coverage rates by strata to the extent statistically feasible; strata are likely to include membership in units that are likely vs. unlikely to deploy, actual deployments OCONUS within the past 36 months vs. not deployed within that time frame, officers vs. enlisted personnel, size of location and/or unit surveyed (large, medium, small)
- Agreement among data sources

6.0 RECOMMENDATIONS FOR STUDY DESIGN OPTIONS

There are two key types of study design options for consideration, which relate to the vaccines to be surveyed and the populations for study. This section presents recommendations for both types of options.

6.1 Vaccines

The pretest surveyed for coverage for influenza, tetanus-diphtheria, yellow fever, and typhoid vaccines. These four vaccines represent a mix of intervals between dosages, ranging from one year for influenza; two, three, or five years for typhoid, depending on the vaccine used; and 10 years for tetanus-diphtheria and yellow fever vaccines. Further, this set of vaccines represents both those that are required for all active duty forces and many reserves, as well as those provided primarily to alert forces or forces deploying to high-risk areas. We recommend that the survey address all four vaccines for all USUs in the study.

Two vaccines have been added to the schedule relatively recently. Adding these two vaccines to the survey can provide the DoD and the Services with valuable information about the implementation of the new requirements.

- Hepatitis A—A two-dose primary series is required for all active duty forces. If hepatitis A is added to the study, we recommend that both doses be recorded for assessment of compliance with the required number and spacing of doses.
- Anthrax—The requirements for anthrax vaccination present the Services with the logistical and record-keeping challenges of providing a six-dose series over an 18-month period. If anthrax is added to the study, we recommend that all doses be recorded for assessment of compliance with the immunization series schedule.

6.2 Populations

The Services differ sufficiently in requirements and organization such that a single sample cannot adequately address immunization coverage. Therefore, we recommend that the study be conducted by Service. Individual Services could implement the study design on their own; however, it would be more efficient to survey all participating Services in the same study. This would promote cost-effective travel, as USUs from all of the Services could be surveyed in certain locations, for example, Southern California. The goal would be to balance the need for random sampling for each Service with the need to conserve travel dollars.

We also recommend that active duty personnel in each Service be sampled independent of a sample of reserve and Guard personnel in each Service. This approach would effectively double the number of USUs sampled and thereby increase the resources required for the survey. However, the differences in routine immunization requirements for reserve forces/Guard personnel and active duty personnel are sufficiently great that they constitute two virtually separate populations. We recommend that the study of reserve and Guard forces focus primarily on those units and USUs that have deployed within the past three years and are likely to deploy as a unit.

7.0 SUMMARY

The pretest of the original study design provided information about immunization coverage rates in a convenience sample of Services' active duty, reserve, and Guard units. However, the fact that the sample of individuals was drawn in a sometimes nonrandom manner from a convenience, non-representative sample of units limits the generalizability of the results. A revised study design that addresses the limitations of the pretest can provide the Services with information about which Service members may be at greater or lesser risk for inadequate immunization coverage. Further, such a study can provide more reliable estimates of the readiness of deployable forces and the steps necessary to prepare both deployable and unlikely-to-deploy forces in the event that they are required OCONUS. A study that tracks implementation of new hepatitis A and anthrax requirements can also provide feedback to planners and policy makers about the progress of new vaccine initiatives, data that could prove useful in the short term as well as in planning for other additions to the schedule.

APPENDIX H

ARMED FORCES EPIDEMIOLOGICAL BOARD DEPARTMENT OF DEFENSE IMMUNIZATION PROGRAM ANALYSIS AND DESIGN FOR STUDY OF IMMUNIZATION COVERAGE

Report on the Analysis of Department of Defense Immunization Policy

ARMED FORCES EPIDEMIOLOGICAL BOARD
DEPARTMENT OF DEFENSE IMMUNIZATION ANALYSIS AND DESIGN FOR STUDY OF IMMUNIZATION COVERAGE

Report on the Analysis of Department of Defense Immunization Policy

Submitted To:

Vicky L. Fogelman, Col, USAF, BSC
Executive Secretary
Armed Forces Epidemiological Board

Prepared By:

Birch & Davis Associates, Inc.
Under Prime Contract No. DASW01-95-D-0026
Modification 1
Delivery Order No. 0081

Birch & Davis Associates, Inc.
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June 8, 1998

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EXHIBITS

EXHIBITS

REPORT ON THE ANALYSIS OF DEPARTMENT OF DEFENSE IMMUNIZATION POLICY

1.0 INTRODUCTION

This report assesses immunization policy data collected from the Army, Navy, Air Force, Marine Corps, Coast Guard, and TRICARE offices by Birch & Davis Associates, Inc. (B&D). For the Armed Forces Epidemiological Board (AFEB), B&D developed comprehensive questionnaires about immunization policies affecting five personnel groups: new accessions (both enlisted recruits and officer accessions), active duty personnel (both routine immunizations and those administered for travel to high risk areas), special operational and occupational groups, reserve forces, and dependents and other TRICARE beneficiaries.

To lessen the burden on the points of contact (POCs) identified to respond to the questionnaires, B&D encouraged them to complete the questionnaires by referencing and providing copies of policy letters, memoranda, messages, and other written communication. B&D had been provided with a copy of the Joint Instruction on Immunizations and Chemoprophylaxis dated 1 November 1995, but sought to collect information that interpreted or modified the Joint Instruction. Although not originally the primary focus of the data collection effort, the over 95 documents collected from 113 POCs have proved to be critical sources of policy and procedure data. Thus the focus of the project has shifted from a sole emphasis on responses from key POCs to include written policy as well.

Throughout the project B&D has relied on POCs from each of the services to review draft summaries of and comments on the information collected. The B&D project team would like to thank the many representatives of the services who provided data and reviewed the summary tables. Any conclusions drawn about the data are the team's and do not necessarily represent the opinions of the Department of Defense (DoD) or any of the military services. Most data in this report have not been fully reviewed by the services, who will be asked again to review the report prior to the final briefing for the AFEB on this project.

The purpose of this document is to report the findings from an analysis of the policy documents and questionnaire responses collected during the project period, identify policy gaps and inconsistencies, and present conclusions and recommendations concerning DoD immunization policy. The report is organized into the following sections:

- Vaccine-specific policies for personnel groups in the military services:
  - Enlisted recruits and officer accessions
  - Active duty personnel
  - Special operational and occupational groups
  - Reserve forces

- Dependents and other TRICARE beneficiaries

- Cross-cutting policy topics
  - Immunization policy development and dissemination
  - Record-keeping and tracking
  - Reporting adverse reactions
  - Jet injector use

- Conclusions and recommendations

2.0 VACCINE-SPECIFIC POLICIES BY PERSONNEL GROUP

Based on a review of the policy documents collected during the project and the comments provided by key POCs, the B&D team has developed a series of summary charts of vaccinations to be administered. This section presents the summary charts and discusses the vaccinations to be administered for each personnel group and across services. The services are reviewing these data.

Each appendix contains the policies of a particular service in a series of charts: Appendix A presents the policies of the Army; Appendix B, the Navy and Marine Corps; Appendix C, the Air Force; and Appendix D, the Coast Guard. Each appendix contains charts of the policies reported by POCs and summarizes briefly the policy documents that the POCs provided. The charts address immunization requirements for enlisted recruits and officer accessions, active duty routine and high risk travel or deployment, special occupational and operational groups, and reserve forces. The following sections of the report present immunization requirements by personnel group.

2.1 Enlisted Recruits And Officer Accessions

Enlisted recruits undertake basic training at relatively few boot camp sites, while individuals may become officers through a number of routes. They may attend a service academy, which will have immunization requirements similar to those of other post-secondary schools. They may enter the service after college participation in a Reserve Officer Training Corps (ROTC) program or after professional training, for example, in medicine. They may attend Officer Candidate School or Commissioned Officer Training as new service members or as noncommissioned personnel moving into the ranks of commissioned officers.

Exhibit 1 is a summary chart of the immunizations required for enlisted recruits and officer accessions by each of the services. For additional information on the policies related to each of the service's immunization schedule, please refer to the first chart in each of the four appendices.

EXHIBIT 1
IMMUNIZATIONS ADMINISTERED TO ENLISTED RECRUITS AND OFFICER ACCESSIONS

VACCINE	USA	USN/USMC	USAF	USCG
Adenovirus 4&7	ER	ER	ER only for disease threat; not generally administered	ER
Anthrax	Policy under development	USN: ER USMC: Policy under development?	Policy under development	Not yet determined
Hepatitis A	No	ER, OA Academy	ER, OA	No
Influenza	ER, OA	ER, OA year-round	ER year-round, OA OCT-MAR	ER, OA
MMR/MR	MR ER; OA without documentation; ROTC before summer camp	MMR ER; OA without documentation	MR ER screened serologically; Academy screens record, then serology (measles and rubella); gives MMR. Other officer training: evaluate record; give MR.	MR: ER, OA MMR: Academy
Meningococcal	ER	ER	ER	ER, Academy
Pnuemococcal	No	USMC-San Diego only	No	No
Polio	ER, OA	ER, OA	ER, OA	ER, OA
Tetanus-diphtheria	ER, OA ROTC before summer camp	ER, OA	ER, OA	ER, OA
Typhoid	No	NROTC for summer cruise to high risk area	No	No
Varicella	No	ER (susceptibles)	Academy	No
Yellow Fever	No	ER, OA	No	ER,OA

KEY: ER =enlisted recruit; OA =officer accessions (includes Academy unless specified); Academy = service academy

The initial vaccines provided are generally those that will be protective during the training period, e.g., adenovirus and meningococcal vaccine for the enlisted recruits trained in close quarters, influenza vaccine for all new accessions. Other vaccines administered may also be

needed for protection during the recruit training period, e.g., tetanus-diphtheria for all new accessions, typhoid for NROTC midshipmen on summer cruises to high risk areas. The Navy, Marines, Air Force, and Coast Guard also administer vaccines that are required for protection during active duty, e.g., hepatitis A (Navy, Marines, Air Force), yellow fever (Navy, Marines, Coast Guard). The Army administers vaccines required for active duty once the accessions move to their active duty units.

Some, but not all, POCs report that enlisted recruits and officer accessions are screened for asplenia, which, if caused by chronic disease, is cause for separation from the service. If caused by trauma, asplenia is not cause for separation and the new accession is immunized against *Haemophilus influenza* type b and pneumococcal disease as well as meningococcus.

2.1.1 Pregnancy Testing

The Joint Instruction requires that women be questioned about pregnancy prior to vaccination, excluded or referred for evaluation if the answer is "yes" or "maybe," and immunized but counseled to avoid pregnancy for three months if the answer is "no" and a live virus vaccine is administered. Further, the counsel is to be documented in the chronological health record. The Joint Instruction does not require a pregnancy test prior to immunization with live virus vaccines, which could potentially affect fetal development. However, primarily because pregnancy is cause for separation from the service for an enlisted recruit, each service reports administering pregnancy tests early in the enlisted recruit training period. The Coast Guard tests for pregnancy again later in the basic training period. If a test result is positive for pregnancy, the woman is separated from the service. Most POCs report that the test results are known prior to attendance at an immunization clinic.

2.1.2 Concerns About Vaccine Supplies

Three supply issues have been mentioned that could affect enlisted recruits and officer accessions. First, adenovirus vaccine is no longer manufactured. The services are seeking to conserve supplies by limiting administration to September through March. Some have expressed concerns about potential outbreaks in the close quarters of recruit training if the supply is exhausted before a new manufacturer can be found and the new vaccine approved by the Food and Drug Administration. However, the Marine Corps reports that, even though supplies were not available during the fall of 1997, there were no outbreaks of disease. Second, one POC mentioned the potential cessation of manufacture of the measles-rubella vaccine. This would leave only the more expensive measles-mumps-rubella vaccine available, which could significantly impact Army, Air Force, and Coast Guard immunization budgets. Third, the Marine Corps recruit training site at Parris Island has had logistical problems with obtaining pediatric strength doses of hepatitis A vaccine (Vaqta). When it is available, it is used for 17-year-old recruits; when it is unavailable they administer an adult dose. (Because of the numbers of recruits processed and to ensure greater protection of those immunized, the Navy's Great

Lakes recruit training center has found it more efficient to administer adult doses of hepatitis A vaccine to all recruits.)

2.1.3 Joint Instruction

In some cases, practice differs from what is prescribed in the Joint Instruction. For example, the Joint Instruction lists the recommendations of the Advisory Committee on Immunization Practices (ACIP) as required references for immunizations. It should be noted that Hepatitis B vaccine, which is currently recommended for children and adolescents by the ACIP, is not provided to new accessions. One question for the services is whether administration of this relatively expensive, three-dose vaccine is cost-effective. The Joint Instruction requires influenza vaccination year-round for both enlisted recruits and officer accessions in the Navy and the Marine Corps. The Navy and the Marine Corps report that there are often gaps in the summer when their supplies are exhausted before the next year's supply is available. The Marine Corps at the San Diego training facility has added pneumococcal immunization to its schedule for enlisted recruits because of an earlier outbreak there. Further, as noted above, the Navy, Marine Corps, and Coast Guard all administer yellow fever vaccine during basic training. Yellow fever is supplied in multi-dose vials; if all doses are not used within one hour of reconstitution, the vaccine must be discarded. Thus, administering the vaccine to large groups of recruits is an efficient approach to ensuring that all active duty members are immunized.

2.2 Active Duty Personnel

Immunizations provided to active duty personnel fall into three broad categories: those provided routinely, those provided only when needed for travel or deployment to high risk areas, and those provided to members of special operational or occupational groups. This section addresses routine vaccines and those for high risk travel. Special groups' immunization requirements will be addressed in the next section. The second chart in each appendix presents the services' policies for immunizing active duty personnel. Exhibit 2 is a summary chart of vaccine requirements for active duty personnel. It lists vaccines mentioned in the Joint Instruction as well as two that are not listed, anthrax and tick-borne encephalitis. It should also be noted that the Commanders in Chief of regional commands outside of the continental United States (OCONUS) can require other immunizations for personnel traveling to their command; these AOR (area of responsibility) requirements are separate and distinct from service requirements.

EXHIBIT 2
IMMUNIZATIONS ADMINISTERED TO ACTIVE DUTY PERSONNEL

VACCINE	USA	USN/USMC	USAF	USCG
Anthrax	All active duty; priority to high risk forces.			
Cholera	Joint Instruction: Only when required by host country. POCs report military does not use Per CDC, no country currently requires, though some local areas may			
Hepatitis A	AD	AD	AD	AD
Hepatitis B (See special groups)	HRA	HRA	HRA	HRA
Influenza	AD, annual	AD, annual	AD	AD
Japanese Encephalitis Virus	HRA	HRA	HRA	HRA
Meningococcal	HRA	HRA	AD, HRA	HRA
Plague	HRA; Rarely used			
Tetanus-diphtheria	AD	AD	AD	AD
Tick-borne Encephalitis	HRA	HRA	HRA	HRA
Typhoid	HRA, AF	HRA, AF	HRA, AF	HRA, AF
Yellow Fever	HRA, AF	AD	HRA, AF	HRA, AF

KEY: AD = routine active duty immunization; AF = alert forces; HRA = administered for travel to high risk area

2.2.1 Routine Active Duty Immunizations

Influenza vaccine (annual) and tetanus-diphtheria boosters (every 10 years) are routinely administered to active duty personnel in all of the services. Navy and Marine Corps personnel routinely receive booster doses of yellow fever vaccine every 10 years. DoD now requires that all active duty personnel be immunized against hepatitis A by 31 December 1998 and all of the services are working toward that goal. As noted in the chart, the Department of Defense (DoD) and the services are developing policy and procedures for routine administration of anthrax vaccine.

All military recruits receive meningococcal vaccine during basic training. The Joint Instruction indicates that the vaccine is to be boosted only when an assessment of disease transmission and risk indicates its advisability. One Air Force command, the Air Mobility Command (AMC), requires that AMC flying personnel, who travel frequently and on short notice, maintain meningococcal immunity with boosts every three years. The three year boost is to ensure that personnel who may need to travel to Saudi Arabia during the period of the religious pilgrimage (the Hajj) can meet the host country's requirement for this vaccine and boost interval. A few individual POCs not from the AMC indicated that meningococcal vaccine is regularly boosted.

2.2.2 Alert Forces Immunizations

The definitions of alert forces vary by service, but generally refer to personnel who must be ready to deploy soon after notification, e.g., within 30 days or less, or who are members of certain types of units whose mission is to be ready to deploy rapidly, e.g., within 24 hours of notification. Typhoid is administered and boosted for alert forces in the Army, Navy, Marine Corps, and Air Force. The boost interval may be two, three, or five years, depending on which vaccine is used. Yellow fever vaccine is administered to alert forces in the Army, Air Force, and Coast Guard.

2.2.3 Less Frequently Used Vaccines

Some vaccines are listed here because they are mentioned in the Joint Instruction. Cholera vaccine is only to be used when required by the host country; POCs report that the military does not currently use cholera vaccine. Hepatitis B is listed because it may be administered to personnel traveling to high risk areas. The primary uses of hepatitis B prophylaxis in the services appear to be for the special groups listed in the next section and for individuals diagnosed with a sexually transmitted disease. The services advocate education and other measures for preventing Japanese encephalitis virus (JEV) and tick-borne encephalitis (TBE). Both JEV and TBE vaccines are administered only for travel, deployment, or assignment to endemic areas. TBE vaccine is an investigational new drug (IND), whose use is subject to strict protocols including informed consent requirements. The Joint Instruction does not directly address the protocols for INDs, except in the section on biological warfare defense.

2.3 Special Operational And Occupational Groups

Vaccines administered to persons in high risk operational and occupational groups in all services include the following:

- Anthrax—Forces at high risk, including chemical and biological incident response forces
- Hepatitis B—High-risk medical personnel, other health care workers, those who need to know first aid for their jobs and are potentially at risk (e.g., firefighters, base security personnel), and members of specified special warfare groups
- Measles-mumps-rubella—Medical personnel and other health care workers, if not immune
- Plague—Special operations groups, reportedly rarely used

- Rabies—Animal handlers; veterinary personnel; certain laboratory, field, and security personnel; personnel frequently exposed to potentially rabid animals in occupational or recreational settings

- . Varicella—Listed in the Joint Instruction for high-risk occupational groups

Service-specified special groups are listed in the third chart in each of the four appendices.

2.4 Reserve Forces

Reserve forces receive basic training vaccines; subsequent vaccination varies by service and by identified need, as presented in Exhibit 3.

EXHIBIT 3
IMMUNIZATIONS ADMINISTERED TO RESERVE FORCES

VACCINE	USA	USN/USMC	USAF	USCG
All Vaccines Indicated On Service Schedule	Called up for 30 days or more	**USN/USMC:** subject to short-notice deploy-ment **USN** called up for 10 days **USMC** called up for 30 days	Called up for 30 days or more	Called up for 30 days or more
Hepatitis A	Mobility status targeted for early deployment to high risk areas; selected reserve			High-risk travel. Specified units. Subsistence specialists; food handlers
Hepatitis B	If indicated by Army policy; see All Vaccines, above	If indicated by USN/USMC policy; see All Vaccines, above	High risk groups; Air Mobility Command (AMC) medical reserves	Health services personnel
Influenza	On active duty for 30 days or more during flu season	If indicated by USN/USMC policy; see All Vaccines, above	All reserve forces personnel annually	Reserves designated by district commander
Meningococcal	If indicated by Army policy; see All Vaccines, above	If indicated by USN/USMC policy; see All Vaccines, above	All deploying OCONUS. AMC reserves on active flying status, mobility.	If indicated by Coast Guard policy; see All Vaccines, above

Some reserve POCs noted barriers to immunizing reservists: the full schedule on drill weekends, the need to import immunization teams if the unit does not drill at a site with a Medical

Treatment Facility (MTF), reservists living too far away to come for immunizations except during the drill weekends, and funding for immunizations.

2.5 Dependents And Other TRICARE Beneficiaries

The DoD is implementing on a region-by-region basis TRICARE, a uniform health benefits program for active duty military personnel, dependents of military personnel, and other beneficiaries. TRICARE has four options: Prime, Standard, Extra, and Senior. The focus of the data collection on TRICARE was on immunization coverage policies for beneficiaries who are not members of the military services.

TRICARE was created to eliminate differences between areas of the country and between services provided directly by MTFs and those provided by CHAMPUS-reimbursed private providers. TRICARE Prime requires enrollment, costs the enrollee less than other options, and is a Health Maintenance Organization (HMO) program with a Primary Care Manager (PCM) in either the civilian sector or an MTF. TRICARE Senior is similar in enrollment requirements and benefits to Prime; currently the Senior option is available only on a demonstration basis at a few sites. TRICARE Standard is a fee-for-service program; those using this option can go to any doctor or to the MTF on a space-available basis. TRICARE Extra provides medical care through a Preferred Provider Organization (PPO), which is a network of providers. TRICARE Extra has the same benefits as TRICARE Standard, but with a financial incentive to use a network provider. Under all three options, there is no charge to immunize active duty dependents whose sponsors have permanent changes of station orders to overseas locations, although there may be an office visit copayment for immunizations provided outside of MTFs. Well-baby care is provided up to 24 months of age. TRICARE senior benefits are comparable to Medicare benefits.

TRICARE Prime benefits specify that age-appropriate doses and vaccines for specific diseases should be administered in accord with the recommendations of the Advisory Committee on Immunization Practices (ACIP), which advises the Centers for Disease Control and Prevention (CDC). The diseases are diphtheria, *Haemophilus influenza* type B, hepatitis A, hepatitis B, influenza, measles, mumps, pertussis, pneumococcal disease, poliomyelitis, rubella, tetanus, and varicella. This list includes all 10 vaccines on ACIP's recommended schedule for childhood immunizations as well as three vaccines (hepatitis A, influenza, and pneumococcal disease) more commonly recommended for and administered to adults.

The Military Health System (MHS) has developed a report card for all MTFs, which includes 34 measures of access, quality, utilization, and health status based on surveys of DoD beneficiaries and inpatient data records. Immunization will be addressed by measuring childhood immunization status against the American Academy of Pediatrics, and the American Academy of Family Physicians. Data are not yet available on this measure. No adult immunizations are measured other than for active duty personnel, and no reports on adult immunization of

beneficiaries are currently required or submitted. There was no indication that DoD collects information on immunizations delivered to nonmilitary beneficiaries outside of MTFs.

3.0 CROSS-CUTTING POLICY TOPICS

Questionnaire responses were evaluated for information on several key, cross-cutting topics concerning immunization policy. This section addresses those topics.

3.1 Immunization Policy Development And Dissemination

The DoD makes immunization policy that is relevant to all services. Each service can also develop policy for its own personnel, so long as that policy is at least as restrictive as DoD policy and does not conflict with DoD policy. Services, commands within services, and local MTFs can and do develop operating procedures for implementing policy. Policy is disseminated through the types of documents collected during this project, i.e., joint instructions developed by the services and issued at the DoD level; letters, memoranda, e-mail messages, and manuals developed and issued at any level. Thus, immunization policy is developed and disseminated top-down in the same manner as other military policy.

It also appears that horizontal (peer) and bottom-up communication take place, the first serving as a collegial, informal means of comparing observations of potential immunization needs or vaccine reactions, the second serving to alert higher authorities to the potential need for modifications or changes in policy. Thus immunization policy development does not appear to be a strictly top-down process. Outside influences observed include legislation and budgets (e.g., special funding for widespread hepatitis A vaccination, budgetary constraints that may limit adding vaccines such as hepatitis B to the routine schedule); vaccine research and development, vaccine availability (e.g., cessation of manufacture of adenovirus vaccine, withdrawal of immune globulin for hepatitis A from the market); and emerging threats to the health of the military forces (e.g., use of an IND vaccine for tick-borne encephalitis in Bosnia).

3.2 Immunization Records And Tracking

Immunization record-keeping and tracking of immunization status are two rapidly changing fields, primarily because of automated medical records. The Joint Instruction requires written records and only briefly mentions the automated systems that have become more commonplace in recent years. When this project began one year ago, one POC stated that the only way to determine the proportion of individuals whose immunizations were up to date would be to search the medical records by hand. Others reported that they had developed their own local systems using a variety of readily available database and spreadsheet software applications. While both of these conditions are still true to a certain extent, the services are moving toward automated record-keeping. In fact, the Air Force reports that all MTFs have an automated system specifically designed to track and monitor their immunization programs.

Two forms of records are required by the Joint Instruction: the SF-601, Health Record—Immunization Record, and the PHS-731, International Certificate of Vaccination, known as the yellow shot card. The B&D team understands that the SF-601 form is being replaced by a preventive care flow sheet format on paper or automated. Automation will prompt the medical facility to enter the manufacturer and lot number of any vaccine administered, which will facilitate communication in the event of a question about a particular lot. The Army relies on the SF-601 and the PHS-731, which may be kept by the individual or placed in the medical record when the record is held by the unit rather than the MTF, and plans to use the automated Preventive Health Care System (PHCS). The Air Force, which relied primarily on the PHS-731 cards for individual immunization records, is now required to maintain immunization documentation in the medical record as well. The Air Force is using the automated Military Immunization Tracking System (MITS). The Navy and Marine Corps, which have automated systems (the Shipboard Automated Medical System, SAMS), no longer prepare PHS-731 cards as a matter of routine; if needed for individual travel, the cards can be produced from automated systems. POCs informed the team that Navy ship personnel often travel without passports or shot cards, but are cleared into other countries as a group by host country officials checking a printed roster listing HIV test results as well as the immunization status of those aboard.

3.3 Reporting Adverse Reactions

POCs' responses indicated appropriate knowledge of the processes for reporting adverse reactions through the chain of command and to the Vaccine Adverse Event Reporting System (VAERS). Each service has mechanisms for collecting adverse reaction reports centrally as well as submitting them to VAERS. Unfortunately, VAERS is a passive surveillance system, which is considered unlikely to receive data on all reportable adverse events. However, POCs noted that adverse events were reported rarely.

3.4 Logistics

MTFs order vaccines from DoD or directly from prime vendors. Although some respondents stated that advance planning ensures that vaccine supplies remain adequate, others complained that the delivery time for DoD-supplied vaccines is highly variable and unpredictable, ranging from a few days to several weeks. Several POCs said that vaccines were costly and one complained that DoD-supplied vaccines had a high markup. One noted that the prime vendor system was quicker to use than the DoD supply system. However, while all vaccines available through the prime vendor system are licensed, we understand that MTFs using the prime vendor system are not provided with guidance about which vaccines are preferable for military use. Further, the greatest consideration for MTFs may be cost, outweighing both efficacy and reactogenicity. These concerns were demonstrated by the earlier situation with phenol-inactivated typhoid vaccine, which proved to be highly reactive, a situation that was uncovered through peer communication across services. Discussions also revealed that some MTFs have been more successful than others at containing the costs of vaccines through cost comparisons, though it

may be that those were larger MTFs that could benefit from bulk pricing. Other POCs mentioned the difficulty of maintaining adequate supplies in the field given the limited amount of cold storage that may be available.

3.5 Jet Injector Use

Prior to the current moratorium on jet injector use, we questioned POCs at recruit training sites and at the service level about their use of jet injectors. Personnel authorized to use the injectors in addition to physicians and registered nurses included medical technicians, corpsmen, physician assistants, and licensed practical nurses. As required by the Joint Instruction, all sites that used the injectors reported training personnel using a combination of formal classroom and on-the-job training. Their sterilization practices were consistent with the policy in the Joint Instruction and with manufacturers' recommendations. Acetone or alcohol wipes were used to clean the tips after each inoculation, nozzles visibly contaminated with blood were replaced and sterilized before additional use, and all injector nozzles were cleaned and sterilized daily. All services reported using the injectors routinely. Vaccines administered by jet injection included hepatitis B, influenza, MMR/MR, meningococcal, tetanus-diphtheria, and yellow fever. Some Army recruit sites did not use the jet injectors. The Navy and Marine Corps reported that they did not use jet injectors on smaller ships because there were more doses in the vaccine vials than personnel to be immunized. The Coast Guard used its jet injector only for mass influenza inoculations.

4.0 CONCLUSIONS AND RECOMMENDATIONS

This report has presented findings from the analysis of policy data collected during the project period. This section presents conclusions and recommendations developed as a result of the analysis.

4.1 Conclusions

This report has presented findings from the analysis of documents and POC responses provided and we have developed several conclusions from those findings. Several limitations in the data collection process may limit the general applicability of the findings and conclusions of this analysis. The POCs were a small sample of those responsible for dissemination and implementation of immunization policy. They were a convenience sample rather than representative, consisting of individuals who were often recommended by name in a cascading process that began with service preventive medicine officers, who themselves are knowledgeable about service immunization policy. In addition, the collection of policy documents was not the initial focus of the project; some POCs who answered the questionnaires may not have referenced documents because that was only suggested, not required. We have addressed these limitations at least in part by requesting service expert review of the results to ensure that the data collected are comprehensive, representative, and accurate.

Policy documents provided during this project indicate the evolving nature of immunization policy. The Joint Instruction was frequently cited as the source of policy. In addition, POCs provided policy updates and procedural documents issued by the services through their routine channels, including e-mail for rapid dissemination; no POC complained about not receiving information in a timely fashion.

The POCs contacted were, with few exceptions, well-informed and knowledgeable about existing policies. However, it may be difficult for the person removed from the policy development process to understand what policies are new and what policies have been rescinded. One POC complained about the number and confusing nature of immunization-related messages received. POCs provided some documents developed before the current Joint Instruction. We noted that it was not always readily apparent, nor had the POCs marked the documents to indicate, which parts of those documents were still applicable and which no longer applied. At present, the Navy and the Air Force are in the process of issuing new, comprehensive instructions that will take into account changes in epidemiology, vaccines, and policies since the Joint Instruction was issued on November 1, 1995. In addition we understand that a new Joint Instruction will be developed in the near future. Efforts such as these to update and consolidate regulations and recommendations will doubtless be appreciated by those who must implement them.

4.2 Recommendations

Based on the findings and conclusions we recommend that DoD develop and disseminate, as soon as practicable, a new Joint Instruction. In developing the new Joint Instruction, we recommend that the DoD:

- Consider adding anthrax and tick-borne encephalitis vaccines to those addressed by the Joint Instruction
- Clarify the policy for boosting meningococcal vaccine
- Consider expanding the instructions for use of varicella vaccine
- Address policies for the use of INDs not only in the biological warfare defense section but also in the body of the Joint Instruction, include requirements for informed consent, and define a methodology for developing policy for the use of new vaccines that may be developed before a new Joint Instruction is issued
- Revise jet injector use policy as needed to address recent safety concerns

- Address the impact of automation of records, e.g., what paper records need to be maintained, must the PHS-731 be maintained, taking into consideration the period of transition before all records are automated

We recommend that the services consider whether current procedures are sufficient to ensure that personnel are aware of what portions of policy documents have been superseded in the event that the document is not completely superseded. The scope of this project was insufficient to determine the nature and extent of this potential problem. We recommend that DoD develop a web page to allow easy access to current military immunization policy, ACIP recommendations, and other relevant policy references. Some of these items could be accessed by hypertext linkages; the ACIP recommendations, for example, are available through the CDC web site.

We recommend that DoD track both adult and childhood immunizations provided to dependents and other TRICARE beneficiaries.

Automated records, if properly maintained, will make it far easier than it has been to determine immunization status and force readiness and to identify individuals who may be susceptible to particular diseases because of missing immunizations. The new instruction, an increasing capability to monitor implementation electronically, and requirements that commanders routinely report on readiness issues, including immunization status, will foster continued efforts to ensure that the military services are prepared and protected. We recommend that DoD maintain the current effort to implement standardized requirements for automation across all services and agencies.

APPENDIX A
ARMY IMMUNIZATION POLICIES

EXHIBIT A-1

ARMY IMMUNIZATION POLICY FOR ENLISTED RECRUITS AND OFFICER ACCESSIONS

VACCINE	ARMY ENLISTED RECRUITS	ARMY OFFICER ACCESSIONS
Adenovirus 4&7	**Yes** • Joint Instruction: Recruits • 10SEP96. Army Medical Command. *Restriction of Adenovirus Vaccine to Seasonal (Winter) Use Only.* Vaccine supply limited. Vaccinate 1SEP through 31MAR. Maintain surveillance for acute respiratory disease at BCT sites.	**No**
Anthrax	**Policy under development**	**Policy under development**
Hepatitis A	**No** • Joint Instruction: Does not address recruits • 22MAY95. Army Medical Command. *Use of HAVRIX* • Hepatitis A not a threat during recruit training; therefore is administered as a readiness vaccine after basic training.	**No** • Joint Instruction: Does not address officer accessions. • 22MAY95. Army Medical Command. *Use of HAVRIX* • Officer accessions training brief; become active duty quickly
Influenza	**Yes** • Joint Instruction: Recruits	**Yes** • Joint Instruction: During flu season
MMR/MR	**Yes, MR** • Joint Instruction: Recruits • MMR sometimes given, depending on vaccine availability. • MMR can be given if no history, but usually not given • Not currently screening serologically, but investigating its value and effectiveness	**Yes, MR** • Joint Instruction: Officer accessions if there is no documentation • Army ROTC cadets receive before summer camp.
Meningococcal	**Yes** • Joint Instruction: Recruits	**No** • Joint Instruction: Not required for ROTC or Service Academy.
Poliomyelitis (OPV)	**Yes** • Joint Instruction: Recruits	**Yes** • Joint Instruction: Officer accessions
Tetanus-diphtheria	**Yes** • Joint Instruction: Recruits	**Yes** • Joint Instruction: Officer accessions • Army ROTC cadets receive before summer camp.
Varicella	**No** • Joint Instruction: As directed • Considering adding to schedule, if proves cost-effective.	**No** • Joint Instruction: As directed • Considering adding to schedule, if proves cost-effective.

EXHIBIT A-2
ARMY IMMUNIZATION POLICY FOR ROUTINE ACTIVE DUTY AND PERSONNEL TRAVELING OR DEPLOYING TO HIGH RISK AREAS

Note: Commanders in Chief for OCONUS regional commands (CINCs) can require other immunizations; these AOR (area of operations) requirements are separate and distinct from Army or other service requirements. For example, see tick-borne encephalitis policy of CINCEUR (CINC Europe).

VACCINE	ARMY ROUTINE ACTIVE DUTY	ARMY HIGH RISK TRAVEL OR DEPLOYMENT
Anthrax	**All active duty; priority to high risk forces** • Joint Instruction: Does not address	**Yes, priority**
Cholera		**Not used by military** • Joint Instruction: Only when required by host country. • DEC96. CDC's *Health Information for International Travel 1996-97.* "Currently no country or territory requires vaccination as a condition for entry. Local authorities, however, may... "
Hepatitis A	**Yes** • Joint Instruction: As directed • 12AUG96. DoD\HA. *Policy for Use of Hepatitis A Virus Vaccine and Immune Globulin.* All active duty to be immunized by 31DEC98.	
Hepatitis B		**As directed** • Joint Instruction: As directed • 4OCT94. HQDA. *Hepatitis B Vaccination.* All personnel PCS-ing to Korea.
Influenza	**Yes** • Joint Instruction: Annual	
Japanese Encephalitis Virus		**High risk travel** • Joint Instruction: High risk travel
Meningococcal		**High risk travel** • Joint Instruction: High risk travel Boost q 5 yrs
Plague		**High risk travel** • Joint Instruction: High risk travel • Rarely used

Tetanus-diphtheria	**Yes** • Joint Instruction: All active duty personnel • Boost q 10 yrs	
Tick-borne Encephalitis		**High risk travel** • Joint Instruction: Does not address • 17OCT96. DoD\HA. *Policy for Tick-Borne Encephalitis Preventive Measures for DoD Personnel Deployed to Endemic Areas.* For Joint Endeavor personnel under Commander-in-Chief Europe. Do not routinely immunize; use personal preventive measures. However, personnel at high risk should be considered. Requests to be approved by USCINCEUR. Must comply strictly with Investigational New Drug protocol; informed consent required.
Typhoid		**High risk travel** • Joint Instruction: Alert forces; high risk travel • Joint Instruction: Army alert forces are members of active duty or reserve units required to be in a state of readiness for deployment within 30 days or less of notification. • Boost dependent on vaccine used: q 2, 3, or 5 yrs
Yellow Fever		**High risk travel** • Joint Instruction: Alert forces; high risk travel • Boost q 10 yrs

EXHIBIT A-3
ARMY IMMUNIZATION POLICY FOR SPECIAL OPERATIONAL AND OCCUPATIONAL GROUPS

SPECIAL GROUP	VACCINES ADMINISTERED TO ARMY PERSONNEL IN ADDITION TO ROUTINE IMMUNIZATIONS
High risk occupational groups	Joint Instruction. **Hepatitis B, MMR, plague (rare in practice), rabies, varicella**
Medical personnel and other health care workers if not immune	**Hepatitis B.** Joint Instruction: OSHA requirements. **Hepatitis B.** 23OCT96. DoD\HA. Hepatitis B Immunization Policy for DoD Medical and Dental Personnel. All required to complete three-dose series unless documentation or contraindication. **MMR.** Joint Instruction: Following ACIP requirements, those born before 1957 require proof of immunity.
Animal handlers; veterinary personnel; certain laboratory, field, and security personnel; personnel frequently exposed to potentially rabid animals in occupational or recreational setting	**Rabies.** Joint Instruction. Preexposure series in accord with ACIP.
Army Special Operations Command requirements, USASOC Supplement 1 to AR 40-562. 19APR95	**Hepatitis A.** Two-dose primary series. Boost q 4yrs. **Hepatitis B.** Initial series. **Influenza.** Annual. Boost if in Southern Hemisphere APR-SEP. **JE Vaccine.** By geographic area. Boost q 3 yrs. **Measles.** Initial series; one adult dose if born after 1956. **Meningococcal.** Initial series. Boost q 5 yrs. **Plague.** Shots 1 and 2 of initial series. Boost if deployed to high-risk area and q 6 mos while in high-risk area. **Polio.** Initial series; one adult dose if born after 1956. **Rabies.** Initial series for AMEDD personnel in Special Forces Groups and personnel assigned, attached, or OPCON to an Operational Detachment - Alpha (ODA). **Td.** Boost q 10 yrs. **Typhoid.** Initial series. Boost q 3yrs injectable; boost q 5 yrs oral. **Yellow Fever.** Boost q 10 yrs.

EXHIBIT A-4 IMMUNIZATION POLICY
ARMY IMMUNIZATION POLICY FOR RESERVE FORCES

VACCINE	ARMY RESERVE FORCES POLICY
All Vaccines	• Joint Instruction: Army reserve component personnel considered alert forces are subject to deployment within 30 days or less of notification; they thus receive the immunizations indicated for active duty or special occupational or operational groups as applicable. •
Influenza	• Joint Instruction: Reserve component personnel on active duty for 30 days or more during influenza season receive influenza immunization.
Hepatitis A	• Joint Instruction: As directed; does not address reserve forces • 12AUG96. DoD\HA. Policy for Use of Hepatitis A Virus (HAV) Vaccine and Immune Globulin (IG). Reserve personnel on mobility status who are targeted for early deployment to high risk areas.

APPENDIX B
NAVY AND MARINE CORPS IMMUNIZATION POLICIES

EXHIBIT B-1
NAVY AND MARINE CORPS IMMUNIZATION POLICY FOR ENLISTED RECRUITS AND OFFICER ACCESSIONS

VACCINE	NAVY AND MARINE ENLISTED RECRUITS	NAVY AND MARINE OFFICER ACCESSIONS
Adenovirus 4&7	**Yes** • Joint Instruction: Recruits. • 30JUL96. BUMED Administrative Message, Cessation of Adenovirus Vaccine...Administer 1SEP to 31MAR to conserve supplies. • 12JAN93. BUMED Notice 6230, Immunization Requirements... Administer as early as possible in recruit training. Not necessary after recruit training. • USMC, Parris Island, administers adenovirus to male recruits only (male and female recruits trained separately).	**No** • Joint Instruction: Not required
Anthrax	**Navy: Yes** **Marine Corps: Policy under development**	**Policy under development**
Hepatitis A	**Yes** • Joint Instruction: As directed • 6FEB97. FY97 Updated Guidance on Use of Hepatitis A Vaccine. All Navy and Marine recruits to receive primary dose during last half of recruit training. • USN administers adult dose to all (efficient; more protective) • USMC San Diego administers pediatric dose to recruits under 17; Parris Island currently has only adult doses	**Yes** • Joint Instruction: As directed • 6FEB97. FY97 Updated Guidance on Use of Hepatitis A Vaccine.. Administer to all Marine Corps officer accessions. All Naval Academy midshipmen to receive two doses by graduation. Midshipmen and Navy and Marine Corps ROTC students with summer assignments to Marine Corps expeditionary forces, Navy construction battalions, or SEAL, EOD, or other special warfare units.
Influenza	**Yes** • Joint Instruction: Recruits receive year-round • USN gives from arrival of vaccine in Sep until supply exhausted or 30APR at latest	**Yes** • Joint Instruction: Officer accessions receive year-round
MMR/MR	**MMR** • Joint Instruction: Recruits • Joint Instruction: Antibody testing must be cost-effective and an FDA-approved screening test must be used. • 12JAN93. BUMED Notice 6230, Immunization Requirements... Serological screening only when feasible and cost-effective; document the results.	**MMR** • Joint Instruction: Officer accessions if there is no documentation • 3JUN97. NROTC Administrative Manual. NROTC midshipmen must have documentation of MMR or equivalent single antigen immunizations or serologic evidence of immunity.

Meningococcal	**Yes** • Joint Instruction: Recruits • 12JAN93. BUMED Notice 6230, Immunization Requirements... Not necessary after recruit training	**No** • Joint Instruction: Not required for ROTC or Service Academy, though may be used based on risk
Pneumococcal	**No** **Yes, at San Diego MCRD** • Policy recommendation from NEPMU-5 in response to pneumonia outbreaks among recruits in San Diego	**No**
Poliomyelitis (OPV)	**Yes** • Joint Instruction: Recruits	**Yes** • Joint Instruction: Officer accessions
Tetanus-diphtheria	**Yes** • Joint Instruction: Recruits • 12JAN93. BUMED Notice 6230, Immunization Requirements... One dose of Td unless born and attended elementary and secondary school outside of the U.S. , in which case receive a two-dose primary series.	**Yes** • Joint Instruction: Officer accessions • 3JUN97. NROTC Administrative Manual. NROTC midshipmen must have documentation of Td within past 10 years. • 12JAN93. BUMED Notice 6230, Immunization Requirements... Officer accessions to have one dose of Td unless born and attended elementary and secondary school outside the U.S.
Typhoid		• **Joint Instruction: Traveling or deploying to high risk areas** • 3JUN97. NROTC Administrative Manual. NROTC midshipmen may be required to have typhoid for summer cruise involving foreign travel.
Varicella	**Yes** • Joint Instruction: As directed • Note 1724JUN96. BUMED Interim Guidance... All susceptible Navy recruits to receive a two-dose regimen... • Navy reports serological screening two days prior to immunization with varicella; only seronegatives immunized.	**No** • Joint Instruction: As directed
Yellow Fever	**Yes** • Joint Instruction: Does not require for recruits	**Yes** • Joint Instruction: Not required • 12JAN93. BUMED Notice 6230, Immunization Requirements... Officer accessions should have one yellow fever with boosts as required.

EXHIBIT B-2
NAVY AND MARINE CORPS IMMUNIZATION POLICY FOR ROUTINE ACTIVE DUTY AND PERSONNEL TRAVELING OR DEPLOYING TO HIGH RISK AREAS

Note: Commanders in Chief for OCONUS regional commands (CINCs) can require other immunizations; these AOR (area of operations) requirements are separate and distinct from Navy, Marine Corps, or other service requirements. For example, see tick-borne encephalitis policy of CINCEUR (CINC Europe).

VACCINE	USN AND USMC ROUTINE ACTIVE DUTY	USN AND USMC HIGH RISK TRAVEL OR DEPLOYMENT
Anthrax	**Yes, all active duty; priority to high-risk forces** • Joint Instruction: Does not address	**Priority**
Cholera		• Joint Instruction: Only when required by host country. • DEC96. CDC's *Health Information for International Travel 1996-97.* "Currently no country or territory requires vaccination as a condition for entry. Local authorities, however, may continue to require documentation of vaccination..."
Hepatitis A	**Yes** • 6FEB97. FY97 Updated Guidance on Use of Hepatitis A Vaccine... The following active duty forces are to receive: Marine Corps expeditionary forces; Navy construction battalions; special warfare units; Marine Corps security guards; Navy personnel and medial personnel mobilizing with Marine Corps expeditionary forces, Navy construction battalions, and special warfare units; all members of afloat units deployed or preparing for deployment; and military forces assigned to areas of high endemicity. • 12AUG96. Policy for Use of Hepatitis A Vaccine and Immune Globulin. Post-exposure prophylaxis with IG if given within two weeks of known foodborne or waterborne HAV disease.	
Hepatitis B		• Joint Instruction: As directed (See also Special Groups, below)

Influenza	**Yes** • Joint Instruction: Annual	
Japanese Encephalitis Virus		• Joint Instruction: High risk travel • 16AUG96. Update on Use of Japanese Encephalitis Vaccine. All active duty personnel likely to experience field conditions in endemic areas. Should have primary series or booster before departure if possible; if not, complete upon arrival. Personnel on flight status routinely grounded 24 hours after JEV; with history of urticaria or hypersensitivity reactions, grounded 3 days after doses 1, 3, or booster and 5 days after dose 2.
Meningococcal		• Joint Instruction: High risk travel • Boost q 5 yrs
Plague		• Joint Instruction: High risk travel • See also Special Groups, below
Tetanus-diphtheria	**Yes** • Joint Instruction: All active duty personnel • Boost q 10 yrs	
Tick-Borne Encephalitis		• Joint Instruction: Does not address • 17OCT96. DoD\HA. Policy for Tick-Borne Encephalitis Preventive Measures for DoD Personnel Deployed to Endemic Areas. For Joint Endeavor personnel under Commander-in-Chief Europe. Do not routinely immunize; use personal preventive measures. However, personnel at high risk should be considered. Requests to be approved by USCINCEUR. Must comply strictly with Investigational New Drug protocol; informed consent required.
Typhoid		• Joint Instruction: Alert forces; high risk travel • Joint Instruction: Alert forces are fleet units deployed on scheduled or situational basis to foreign country (except Canada); personnel subject to foreign deployment on short notice • Boost dependent on vaccine used: q 2, 3, or 5 yrs
Yellow Fever	**Yes** • Joint Instruction: All active duty • Boost q 10 yrs	

EXHIBIT B-3
NAVY AND MARINE CORPS IMMUNIZATION POLICY FOR SPECIAL OPERATIONAL AND OCCUPATIONAL GROUPS

SPECIAL GROUP	VACCINES ADMINISTERED TO NAVY AND MARINE PERSONNEL IN ADDITION TO ROUTINE IMMUNIZATIONS
High risk occupational groups	**Hepatitis B, MMR, plague, rabies, Varicella (Navy only).** Joint Instruction.
Medical personnel and other health care workers	**Hepatitis A.** 6FEB97. BUMED FY97 Updated Guidance on Use of Hepatitis A Vaccine. All medical personnel mobilizing with Marine Corps expeditionary forces, Navy construction battalions, or special warfare units **Hepatitis B.** Joint Instruction: OSHA requirements **Hepatitis B.** 23OCT96. DoD\HA. Hepatitis B Immunization Policy for DoD Medical and Dental Personnel. All required to complete three-dose series unless documentation or contraindication. **JE Vaccine.** 16AUG96 BUMED Update on Use of Japanese Encephalitis Vaccine. Medical personnel needs for immunization to be considered on case-by-case basis. **MMR.** Joint Instruction: Following ACIP requirements, those born before 1957 require proof of immunity **Varicella.** 24JUN96. BUMED Interim Guidance on Use of Varicella
Marine Corps chemical and biological incident response forces (CBIRFs)	**Anthrax.** Reported by POC.
Marine Corps expeditionary forces Navy construction battalions All members of special warfare units Marine Corps security guards	**Hepatitis A.** 6FEB97. BUMED FY97 Updated Guidance on Use of Hepatitis A Vaccine
Animal handlers; veterinary personnel; certain laboratory, field, and security personnel; personnel frequently exposed to potentially rabid animals in occupational or recreational setting	**Rabies.** Joint Instruction. Preexposure series in accord with ACIP
Susceptible adolescents and adults living or working closely with immunocompromised individuals (recommended strongly)	**Varicella.** 24JUN96. BUMED Interim Guidance on Use of Varicella.

EXHIBIT B-4
NAVY AND MARINE CORPS IMMUNIZATION POLICY FOR RESERVE FORCES

VACCINE	NAVY AND MARINE CORPS RESERVE FORCES POLICY
All Vaccines	• Joint Instruction: Navy and Marine Corps reserve personnel subject to foreign deployment on short notice are considered alert forces and receive active duty, alert forces, and special occupational or operational group immunizations as applicable. • Joint Instruction: Navy reserve personnel called to active duty for 10 days or more receive immunizations • Joint Instruction: Marine Corps reserve personnel called to active duty for 30 days or more receive immunizations. • 23AUG96 COMRESFOR INSTRUCTION 6230.1B reiterates Joint Instruction
Hepatitis A	• Joint Instruction: As directed; does not address reserve forces • 6FEB97. BUMED. FY97 Updated Guidance on Use of Hepatitis A Vaccine. Reserve Navy personnel to be immunized if deploying or assigned to Marine Corps expeditionary forces, Navy construction battalions, or special warfare units • 12AUG96. DoD\HA. Policy for Use of Hepatitis A Virus (HAV) Vaccine and Immune Globulin (IG). Reserve personnel on mobility status who are targeted for early deployment to high risk areas.

APPENDIX C
AIR FORCE IMMUNIZATION POLICIES

EXHIBIT C-1
AIR FORCE IMMUNIZATION POLICY FOR ENLISTED RECRUITS AND OFFICER ACCESSIONS

VACCINE	AIR FORCE ENLISTED RECRUITS	AIR FORCE OFFICER ACCESSIONS
Adenovirus 4&7	**No** • Joint Instruction: USAF only when evidence of active disease transmission	
Anthrax	**Policy under development**	**Policy under development**
Hepatitis A	**Yes** • Joint Instruction: Recruits not specified • 10SEP96, Policy for the Use of Hepatitis A Virus (HAV) Vaccine and Immune Globulin (IG), (ASD[HA] and Memo, 12AUG96). Notification to accelerate Hepatitis A immunization for total active duty and selected Reserve force by 31DEC98. Accessions and new recruits have been added to the priority list	**Yes** • Joint Instruction: Officer accessions not specified • 10SEP96, Policy for the Use of Hepatitis A Virus (HAV) Vaccine and Immune Globulin (IG), (ASD[HA] and Memo, 12AUG96). Notification to accelerate Hepatitis A immunization for total active duty and selected Reserve force by 31DEC98. Accessions and new recruits have been added to the priority list
Influenza	**Yes** • Joint Instruction: Recruits • Administered year-round	**Yes** • Joint Instruction: Officer accessions during flu season • Administered OCT-MAR at OTS, COT, ROTC, and Academy
MMR/MR	**MR** • Joint Instruction: MR • Joint Instruction: Serological screening only when feasible and cost-effective; document the results. Antibody testing must be cost-effective and an FDA-approved screening test must be used. • Recruits are screened serologically	**Yes** • Joint Instruction: MR • Academy screens record and serology; immunizes seronegatives • OTS, COT evaluate shot record
Meningococcal	**Yes** • Joint Instruction: Recruits	**No** • Joint Instruction: Not required for officer accessions
Poliomyelitis (OPV)	**Yes** • Joint Instruction: Recruits	**Yes** • Joint Instruction: Officer accessions
Tetanus-diphtheria	**Yes** • Joint Instruction: Recruits	**Yes** • Joint Instruction: Officer accessions

Varicella	**No** • Joint Instruction: As directed • 20SEP95. Re: AFEB Recommendations on the Use of Meningococcal and Varicella Vaccines. Varicella vaccine not recommended for universal immunization of military members or recruits. A serological study of current levels of immunity among recruits and selective immunization of non-immunes may be indicated. • Serological study has not been done	**Yes for Academy cadets** • Joint Instruction: As directed • Academy screens all cadets and vaccinates susceptibles

EXHIBIT C-2

AIR FORCE IMMUNIZATION POLICY FOR ROUTINE ACTIVE DUTY AND PERSONNEL TRAVELING OR DEPLOYING TO HIGH RISK AREAS

Note: Commanders in Chief for OCONUS regional commands (CINCs) can require other immunizations; these AOR (area of operations) requirements are separate and distinct from Air Force or other service requirements. For example, see tick-borne encephalitis policy of CINCEUR (CINC Europe

VACCINE	AIR FORCE ROUTINE ACTIVE DUTY	AIR FORCE HIGH RISK TRAVEL OR DEPLOYMENT
Anthrax	**All active duty; priority is high risk travel** • Series not begun CONUS; administered in AOR	**Priority** • Series not begun CONUS; administered in AOR
Cholera		• Joint Instruction: Only when required by host country. • DEC96. CDC's *Health Information for International Travel 1996-97.* "Currently no country or territory requires vaccination as a condition for entry. Local authorities, however, may continue to require documentation of vaccination..."
Hepatitis A	**Yes** • Joint Instruction: Alert forces; high risk travel • 10SEP96. ASD/HA. Policy for the Use of Hepatitis A Virus (HAV) Vaccine and Immune Globulin (IG). Immunize all active duty personnel.	
Influenza	**Yes** • Joint Instruction: Annual	

Japanese Encephalitis Virus		• Joint Instruction: High risk travel • 16AUG96. Update on Use of Japanese Encephalitis Vaccine. All active duty personnel likely to experience field conditions in endemic areas. Should have primary series or booster before departure if possible; if not, complete upon arrival. Personnel on flight status routinely grounded 24 hours after JEV; with history of urticaria or hypersensitivity reactions, grounded 3 days after doses 1, 3, or booster and 5 days after dose 2.
Meningococcal	**Yes** • Joint Instruction: Recruits; high risk travel • 26MAR97. Mobility Immunization Requirements (AMC) requires booster q 3 years for AMC and AMC-gained flying personnel. • 20SEP95, HQ USAF/SG – Re: AFEB Recommendations on the Use of Meningococcal. Routine booster q 5 years. (Note: this precedes Joint Instruction, but was provided as policy by POC) • Deployment/travel to Saudi Arabia during Hajj requires boost within past 3 years (Saudi Arabia requirement)	**Yes** • Joint Instruction: Recruits; high risk travel • 20SEP95, HQ USAF/SG – Re: AFEB Recommendations on the Use of Meningococcal. Routine booster q 5 years. • 26MAR97. Mobility Immunization Requirements (AMC) requires booster q 3 years for AMC and AMC-gained flying personnel. (Note: this precedes Joint Instruction, but was provided as policy by POC) • Deployment/travel to Saudi Arabia during Hajj requires boost within past 3 years (Saudi Arabia requirement)
Plague		• Joint Instruction: High risk travel (See also Special Groups)
Tetanus-diphtheria	**Yes** • Joint Instruction: All active duty personnel	
Tick-borne Encephalitis		• Joint Instruction: Does not address • 17OCT96. DoD\HA. Policy for Tick-Borne Encephalitis Preventive Measures for DoD Personnel Deployed to Endemic Areas. For Joint Endeavor personnel under Commander-in-Chief Europe. Do not routinely immunize; use personal preventive measures. However, personnel at high risk should be considered. Requests to be approved by USCINCEUR. Must comply strictly with Investigational New Drug protocol; informed consent required.
Typhoid		• Joint Instruction: Alert forces; high risk travel
Yellow Fever		• Joint Instruction: Required for all alert forces, active duty personnel, or reserve component traveling to yellow fever endemic areas. • Boost q 10 yrs

EXHIBIT C-3
AIR FORCE IMMUNIZATION POLICY FOR SPECIAL OPERATIONAL AND OCCUPATIONAL GROUPS

SPECIAL GROUP	VACCINES ADMINISTERED TO AIR FORCE SPECIAL GROUPS PERSONNEL IN ADDITION TO ROUTINE IMMUNIZATIONS
High risk occupational groups	Joint Instruction. **Hepatitis B, MMR, plague, rabies, varicella**
Medical personnel and other health care workers	**Hepatitis B.** Joint Instruction: Health care workers, OSHA standards. **Hepatitis B.** 23OCT96. DoD/HA. Hepatitis B Immunization Policy for DoD Medical and Dental Personnel. All required to complete three-dose series unless documentation or contraindication. **MMR.** Joint Instruction. Following ACIP requirements, those born before 1957 require proof of immunity.
Animal handlers; veterinary personnel; certain laboratory, field, and security personnel; personnel frequently exposed to potentially rabid animals in occupational or recreational setting	**Rabies.** Joint Instruction. Preexposure series in accord with ACIP.
Firefighters	**Hepatitis B.** 26MAR97. AMC Memo: Mobility Immunization Requirements.
Anyone who needs to know first aid as part of job description	**Hepatitis B**

EXHIBIT C-4
AIR FORCE IMMUNIZATION POLICY FOR RESERVE FORCES

VACCINE	AIR FORCE RESERVE FORCES POLICY
All Vaccines	• Joint Instruction: Individuals called to active duty for 30 days or more immunized • All reservists go through basic training and technical school; receive vaccines administered to enlisted recruits and officer accessions
Hepatitis A	• Joint Instruction: Alert Forces, Deploying to High Risk Areas • 10SEP96. ASD/HA. Policy for the Use of Hepatitis A virus (HAV) Vaccine and Immune Globulin (IG). Accelerate Hepatitis A immunization for total active duty and selected reserve force by 31DEC98. • 12AUG96. DoD/HA. Policy for Use of Hepatitis A Virus (HAV) Vaccine and Immune Globulin (IG). Reserve personnel on mobility status who are targeted for early deployment to high risk areas.
Hepatitis B	• Joint Instruction: High risk occupational groups; as directed • 3JAN97. HQ, Air Mobility Command (AMC). Hepatitis B for Air Reserve Component medical healthcare facility and aeromedical personnel.
Influenza	**Yes** • Joint Instruction: Reserves called to active duty for 30 days or more • 9SEP97. AFMOA. 97-98 Influenza Immunizations and Surveillance Program. Requires vaccination of reserve component personnel.
Meningococcal	**Yes** • Joint Instruction: Recruits, High risk travel • 3JAN97. HQ, Air Mobility Command (AMC). Identifies specific immunization requirements for AMC personnel. Air Force Reserve Component (ARC) on active flying status and in mobility positions. Initial series and booster every 3 years. • 12JUL96. HQ AFRES/SGP. Hepatitis A and Meningococcal Immunization Requirements for Air Force Reserve Personnel. Given fiscal constraints, sets priorities: (1) any Air Force Reserve member who deploys OCONUS must have, or be current in , both vaccines; (2) all personnel on flying status: (3) all medical personnel; and (4) all other reserve personnel
Varicella	• Joint Instruction: High risk occupational groups; as directed

APPENDIX D
COAST GUARD IMMUNIZATION POLICIES

EXHIBIT D-1
COAST GUARD IMMUNIZATION POLICY FOR ENLISTED RECRUITS AND OFFICER ACCESSIONS

VACCINE	COAST GUARD ENLISTED RECRUITS	COAST GUARD OFFICER ACCESSIONS
Adenovirus	**Yes** • Joint Instruction: As directed	
Anthrax	**Not yet determined**	**Not yet determined**
Influenza	**Yes** • Joint Instruction: Recruits • 22JUL97, *Influenza Immunization Program.* Mandatory for recruits.	**Yes** • Joint Instruction: All officer candidate, recruit, and cadet populations during influenza season • 22JUL97, *Influenza Immunization Program.* Mandatory for officer accessions and cadets
MMR/MR	**MR** • Joint Instruction: Measles and rubella, yes; mumps, as directed	**MR** • Joint Instruction: Measles and rubella, yes; mumps, as directed • MMR required for Service Academy; MR for other officer accessions
Meningococcal	**Yes** • Joint Instruction: Recruits; as directed	**Yes** • Joint Instruction: Does not require • Administered at Academy
Poliomyelitis (OPV)	**Yes** • Joint Instruction: All active duty personnel	**Yes** • Joint Instruction: Officer accessions and Academy
Tetanus-diphtheria	**Yes** • Joint Instruction: Recruits	**Yes** • Joint Instruction: Officer accessions
Yellow Fever	**Yes** • Joint Instruction: Recruits	**Yes** • Joint Instruction: All accessions

EXHIBIT D-2
COAST GUARD IMMUNIZATION POLICY FOR ROUTINE ACTIVE DUTY AND PERSONNEL TRAVELING OR DEPLOYING TO HIGH RISK AREAS

Note: Commanders in Chief for OCONUS regional commands (CINCs) can require other immunizations; these AOR (area of operations) requirements are separate and distinct from Coast Guard or other service requirements.

VACCINE	COAST GUARD ROUTINE ACTIVE DUTY	COAST GUARD HIGH RISK TRAVEL OR DEPLOYMENT
Cholera		• Joint Instruction: Only when required by host country • DEC96. CDC's *Health Information for International Travel 1996-97.* "Currently no country or territory requires vaccination...for entry. Local authorities, however, may"
Hepatitis A	• Joint Instruction: As directed • Coast Guard to immunize active duty by 31DEC98	• Joint Instruction: As directed • **Hepatitis A.** 8DEC95, *COMDINST 6230.8, Hepatitis A Immunizations and Prophylaxis.* Military personnel traveling or deploying for more than 90 days to high risk areas; likely to require repeated IG for repetitive high risk travel ; alert forces with a high likelihood of exposure to unsafe food or water sources, due to rapid deployment to high risk areas. Immunize unit after consultation with Commandant (G-KOM).
Influenza	**Yes** • Joint Instruction: Alert forces, as directed	
Japanese Encephalitis Virus		• Joint Instruction: As directed
Meningococcal		• Joint Instruction: As directed
Poliomyelitis (OPV)	**Administered during recruit/accession training** • Joint Instruction: All active duty personnel	
Tetanus-diphtheria	**Yes** • Joint Instruction: All active duty personnel	
Typhoid		• Joint Instruction: High risk travel
Yellow Fever		**Yes** • Joint Instruction: Recruits, alert forces, required by host country • Boost q 10 yrs

EXHIBIT D-3
COAST GUARD IMMUNIZATION POLICY FOR SPECIAL OPERATIONAL AND OCCUPATIONAL GROUPS

VACCINE	VACCINES ADMINISTERED TO COAST GUARD SPECIAL GROUPS PERSONNEL IN ADDITION TO ROUTINE IMMUNIZATIONS
Hepatitis A	• Joint Instruction: As directed **Hepatitis A.** 8DEC95, *COMDINST 6230.B,, Hepatitis A Immunizations and Prophylaxis.* Policy affects special groups: 1. Active duty and reserves personnel assigned to Port Security Units (PSUs), Harbor Defense Commands (HDCs), and Composite Naval Coastal Units (CNCUs). 2. All active duty and reserve subsistence specialists (SS) and food handlers.
Hepatitis B	• Joint Instruction: High Risk Occupational Groups *and* As directed • 26AUG94, *COMDTINST M6220.9 Chapter 2, Section B.* Alien Migrant Interdiction Operations environment does not necessitate routine immunization for hepatitis B. Health services personnel shall be immunized and emergency medical technicians are strongly recommended to be immunized.
Rabies	• Joint Instruction: As directed • Coast Guard does not have high-risk personnel groups who should receive preexposure rabies vaccination

EXHIBIT D-4
COAST GUARD IMMUNIZATION POLICY FOR RESERVE FORCES

VACCINE	COAST GUARD RESERVE FORCES
All Vaccines	• Joint Instruction: Reserve personnel called to active duty for 30 days or more are immunized in accordance with service requirements in Joint Instruction
Hepatitis A	• Joint Instruction: As directed • **Hepatitis A.** 8DEC95, *COMDINST 6230.B, Hepatitis A Immunizations and Prophylaxis.* Authorized for personnel with a high likelihood of repetitive travel to high risk geographic areas, who would otherwise require repetitive administration of IG; reserve personnel assigned to Port Security Units (PSUs), Harbor Defense Commands (HDCs), and Composite Naval Coastal Units (CNCUs); all reserve subsistence specialists (SS) and food handlers.
Hepatitis B	• Joint Instruction: High Risk Occupational; As directed • 26AUG94, *COMDTINST M6220.9, Chapter 2, Section B.* Alien Migrant Interdiction Operations environment does not necessitate routine immunization for hepatitis B. Health services personnel shall be immunized and emergency medical technicians are strongly recommended to be immunized.
Influenza	• Joint Instruction: Recruits, alert forces, as directed • **Influenza.** 22JUL97, *Influenza Immunization Program.* Mandatory for reserves designated by the district commander.

APPENDIX I

WHITE PAPER: IMMUNIZATION COVERAGE STUDIES AND ANALYSES IN THE MILITARY SERVICES

BACKGROUND

The Department of Defense (DoD) is beginning to implement an automated system to record and track immunizations of military service members. The Armed Forces Epidemiological Board (AFEB) has requested information on immunization policies and procedures. Birch & Davis Associates, Inc., (B&D), developed a single survey methodology to provide the AFEB with a pre-automation baseline for comparison with post-automation results and provided limited data on the outcomes of DoD policies and procedures expressed as immunization coverage rates.

Pretest Survey Results

To pretest the survey methodology, B&D identified a convenience sample of 12 military units and randomly sampled approximately 50 records from each unit. The sampled units included active duty units that considered likely to deploy outside the United States, active duty units considered unlikely to deploy, reserve units, and a National Guard unit. The military unit was the unit of analysis for the pretest.

The focus of the data collection effort was four vaccines (influenza, tetanus-diphtheria, yellow fever, and typhoid) that are required by the Army, Navy, Air Force, and Marine Corps for all alert duty forces and may be required for other military personnel. The vaccine name and route of administration were collected for typhoid because the boost interval for typhoid can be two, three, or five years, depending on vaccine type and whether it is injected or administered orally. Immunization data were collected from all sources that the unit could provide, including medical records, PHS-731 forms (yellow shot cards), and automated records. Other data collected included the individual's rank (officer or enlisted), time in service, and time in the unit as well as unit deployments and readiness inspections within the previous 36 months. As expected, the scope and nature of the pretest limited the nature and strength of the conclusions that could be reached. However, several key findings are of interest.

Coverage Rates Varied. Units considered likely to deploy were better immunized than the others, and active duty units were better immunized than reserves. Greater proportions of individuals surveyed were up to date for individual vaccines than for sets of two or three vaccines. Unit rates ranged from 43 percent to 100 percent for single required vaccines, with most units' rates at 90 percent or greater. Rates for personnel having influenza, tetanus-diphtheria, and yellow fever vaccines all up-to-date ranged from 60 percent to 94 percent. Unit turnover rates, rank (officer versus enlisted), and longevity in the service or unit seemed to have little predictive value for immunization; however, there were too few officers to draw definitive conclusions.

Critical Vaccine Data Were Missing. Over 90 percent of the data sources on typhoid vaccine did not include the name of the vaccine or the route of administration. Thus, it was not possible to determine the proportion of those surveyed who were up to date for typhoid vaccine.

Service Records Policies Differed. The Joint Instruction on Immunization and Chemoprophylaxis, issued 1 November 1995, requires a written medical form and PHS-731 card (yellow shot card) for each service member, but service policies and practices vary. These differences seem to reflect the status of service record automation, which has come about primarily since the Joint Instruction was issued. No one data source provided complete data for units or services.

Service Members May Deploy As Individuals. Members of some surveyed units deploy as individuals or small groups even when the unit is considered unlikely to deploy. Thus, using unit deployment data alone to assess compliance with immunization policy does not necessarily provide valid data on whether deploying individuals were adequately immunized.

RECOMMENDATIONS

Conduct Expanded Baseline (Pre-Automation) Survey for All Military Services

The small number of units limited the applicability of survey results. Therefore, B&D recommends that DoD conduct a larger study to establish a valid, reliable baseline for each service. B&D also recommends collecting data from all possible sources but using only the data elements shown in the pretest to be essential. Focusing on individuals rather than military units as the units of analysis would limit the number of site visits required to collect a statistically satisfactory sample. Based on survey findings about missing records and other factors, B&D recommends collecting 533 records from each service and personnel group (active duty, reserve/Guard). Individuals should be randomly

selected from units randomly selected from a range of representative commands and bases. The process of selecting bases and commands should balance concerns about minimizing selection bias with the need to conserve travel dollars.

The most cost-effective approach to developing a valid baseline would be to survey jointly both active duty and reserve/Guard forces for all four services. Surveying the active duty and reserve/Guard forces for a single service in a similar manner would decrease the cost effectiveness. Additional cost reductions could be achieved by surveying only one personnel group (active duty or reserve/Guard).

Follow-up Surveys Of Pretested Units Could Provide Pre- and Post-Automation Data

B&D recommends that the units surveyed during this pretest, particularly those that had not fully automated their records, be surveyed again once their systems are well established. A follow-up survey could provide potentially rich, comparative data on the impact of automation on documentation of immunizations administered.

Revisions to the Joint Instruction Should Address Automation and Other Record-Keeping Issues

Finally, B&D recommends that the Joint Instruction, which we understand is to be revised in the near future, address the impact of automation on record-keeping, including which paper records need to be maintained, whether the PHS-731 must be maintained, and how to manage period of the transition before all records are fully automated.

For additional information, please contact Len Fogelsonger, B&D Principal and Project Director, at (703) 824-3468. The Government Project Officer for the Pre-Survey was Col Vicky Fogelman, USAF, BSC, AFEB Executive Secretary, who can be reached at (703) 681-8014.

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