THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP - 4 2008

The Honorable Carl Levin
Chairman, Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report responds to the requirement in Section 715 of the National Defense Authorization Act for Fiscal Year 2008, which requires the Secretary of Defense to provide a report on the policies of the Department of Defense (DoD) for administering multiple vaccinations to members of the Armed Forces.

This report includes assessments of DoD policies governing the administration of multiple near-concurrent vaccinations. In addition, it discusses how current DoD policies conform to Federal regulations and standards, DoD procedures for initiating investigations of deaths of Service members in which vaccinations have or may have played a role, and DoD procedures for sharing vaccine information and National Guard medical records to the Adjutants General of the various states and territories.

Thank you for your continued support of the Military Health System.

Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable John McCain
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP - 4 2008

The Honorable Ben Nelson
Chairman, Subcommittee on Personnel
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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The Honorable Lindsey O. Graham
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP - 4 2008

The Honorable Ike Skelton
Chairman, Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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cc:
The Honorable Duncan Hunter
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP - 4 2008

The Honorable Susan A. Davis
Chairwoman, Subcommittee on Military Personnel
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

The enclosed report responds to the requirement in Section 715 of the National Defense Authorization Act for Fiscal Year 2008, which requires the Secretary of Defense to provide a report on the policies of the Department of Defense (DoD) for administering multiple vaccinations to members of the Armed Forces.

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cc:
The Honorable John M. McHugh
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP - 4 2008

The Honorable Robert C. Byrd
Chairman, Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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Enclosure:
As stated

cc:
The Honorable Thad Cochran
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP - 4 2008

The Honorable Daniel K. Inouye
Chairman, Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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Ranking Member

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HEALTH AFFAIRS

SEP - 4 2008

The Honorable David R. Obey
Chairman, Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

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cc:
The Honorable Jerry Lewis
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP - 4 2008

The Honorable John P. Murtha
Chairman, Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Enclosure:
As stated

cc:
The Honorable C. W. Bill Young
Ranking Member

Department of Defense

Report to Congress on Multiple Vaccinations of Members of the Armed Forces National Defense Authorization Act for Fiscal Year 2008, Section 715

Table of Contents

INTRODUCTION

The National Defense Authorization Act for Fiscal Year 2008, Section 715 requires the Secretary of Defense to submit to the Armed Services Committees a report on the policies of the Department of Defense (DoD) for administering and evaluating multiple vaccinations to members of the Armed Forces. This section of the report informs the Congress on the concerns surrounding administration of multiple vaccinations in short periods of time, as well as the medical care, policies and procedures followed during administration of vaccinations to members of the Armed Forces.

An interim report was submitted to Congress in May 30, 2008. This final report provides more in-depth information as well as DoD procedures for providing the Adjutants General of the various states and territories with up-to-date information on vaccines required to be taken by National Guard members.

DoD knows the risk of infections makes it necessary to protect Service members with vaccines and other medical countermeasures. DoD routinely administers the following single and combination vaccines to active duty and reserve Component members. However, some of these vaccines are administered only in cases of deployment to specific high threat environments (e.g., anthrax, Japanese encephalitis, typhoid).

- Anthrax
- Hepatitis A
- Hepatitis B
- Human Papillomavirus (HPV)
- Influenza
- Japanese encephalitis
- Measles
- Meningococcal
- Mumps
- Measles, mumps, rubella (MMR)
- Measles-rubella (MR)
- Poliovirus
- Pneumococcal
- Rabies
- Rubella
- Smallpox (vaccinia)
- Tetanus–diphtheria (dT) (preferably with pertussis vaccine - dTP)
- Typhoid (Vi injectable or oral capsules)
- Varicella
- Yellow Fever

These vaccines and combination vaccines are not routinely administered to DoD adults:

- *Haemophilus influenzae* type b conjugate vaccine (HIB)
- *Haemophilus influenzae* and Hepatitis B combo vaccine (Hep B-Hib combo)
- Diphtheria, tetanus, pertussis and *Haemophilus influenzae* combo vaccine (DTaP-Hib)
- Measles, mumps, rubella, and varicella combo vaccine (MMRV)

DOD POLICIES GOVERNING ADMINISTRATION OF MULTIPLE NEAR-CONCURRENT VACCINATIONS

The policies and procedures for all military immunization practices are outlined in enclosure 1, DoD Joint Regulation, "Immunization and Chemoprophylaxis", updated and published September 2006 (http://www.vaccines.mil/documents/969r40_562.pdf). This joint regulation applies to all active duty, National Guard, and reserve members of the Uniformed Departments of the Army, Navy, Air Force, Marine Corps, and Coast Guard, as well as nonmilitary persons under military jurisdiction; selected Federal employees; selected employees of DoD contractors; and family members and other health care beneficiaries eligible for care within the military health care system. This joint regulation is applicable during mobilization; provides the directive requirements for the Military Immunization Program; clearly describes general principles, procedures, policies, and responsibilities for the immunization program to include administration of multiple near-concurrent vaccinations; and implements military and international health regulations and requirements.

This joint regulation for immunization and chemoprophylaxis appropriately establishes updated standards of care for the delivery of military vaccines. It establishes electronic immunization tracking systems as the preferred immunization record, provides guidance for lost immunization records and immunization credit for pre-existing immunity, and describes dividing initial entry immunizations into two clusters.

Any immunizing agent licensed by the Food and Drug Administration (FDA) may be delivered to Service members. Additionally, immunizing agents strictly compliant with applicable FDA and DoD regulations and guidance on investigational new drugs (INDs) or emergency use authorizations (EUAs) may be used. Privileged health care providers may make clinical decisions for individual patients to customize medical care or to respond to an individual clinical situation.

Military Vaccine Agency

DoD maintains a robust global vaccine monitoring system for the health care of its members. The Army, as Executive Agent for the Military Immunization Program and in cooperation with the military Services, manages the Military Vaccine Agency (MILVAX) and operates the Vaccine Healthcare Centers (VHC) Network to provide the

military Services with a coordinated source for information and education of vaccine–related activities.

MILVAX oversees all DoD immunization programs and is dedicated to protecting and enhancing the health of all Service members and military beneficiaries against vaccine preventable diseases by ensuring the safe delivery of voluntary and mandatory vaccines, electronic tracking of immunizations, and treatment of any adverse events (possible side effects) from a vaccination with the best care available.

Vaccine Healthcare Centers Network

The VHC Network demonstrates DoD's commitment to better understanding rare and unusual adverse events after vaccination. DoD evaluates rare and unusual adverse events that follow vaccination through a network of specialty clinics. The VHC Network contains centers at Walter Reed Army Medical Center (Washington, District of Columbia), Naval Hospital Portsmouth (Virginia), Wilford Hall Air Force Medical Center (San Antonio, Texas), and Fort Bragg (Fayetteville, North Carolina). More information regarding the VHC Network can be found at www.vhcinfo.org. After receiving reports of any serious adverse events following vaccination, MILVAX and the VHC reassess procedures to ensure all of the necessary and appropriate steps in administering the program have been included.

The VHC Network supports Service member health care, emergency preparedness, and military readiness of the DoD by acting as a specialized clinical support system for the development and implementation of programs, research, consultation, and services that enhance vaccine safety, efficacy, and acceptability. It serves as a center for military vaccine health care support and case management of vaccine adverse events, providing global access to clinical expert consultation services, which are available at all times and in any emergency.

The VHC Network provides current, accurate, and comprehensive immunization education that is available at all times for routine and emergency preparedness of immunization personnel. In collaboration with government, private, and academic agencies, the VHC Network conducts and supports clinical research that enhances vaccine safety, efficacy, and acceptability. It works to improve DoD vaccine safety surveillance, reporting, and outcomes tracking, including use of the Vaccine Adverse Event Reporting System (VAERS), with follow-up for Service members and beneficiaries with persistent medical problems temporally related to a vaccine.

MILVAX and the VHC Network measure and analyze implementation of immunization policies as indicators of readiness, safety, and effectiveness; support quality of standardized automated immunization tracking systems; establish joint clinical quality standards for vaccine administration and for the education and training of

personnel; and review these standards annually and revises them as necessary. Each of the military Services provides immunization health care capability to deliver medical specialty consultation, case management, and clinical investigation and abides by these standards in routine immunization delivery.

Vaccine Adverse Event Reporting System

VAERS is a joint post-marketing safety surveillance program of the Centers for Disease Control and Prevention (CDC) and the FDA. It collects information about adverse events that occur after the administration of U.S. licensed vaccines. The National Childhood Vaccine Injury Act (NCVIA) of 1986 and other regulations set standards for certain immunizations. These requirements apply to U.S. vaccines containing diphtheria, tetanus, pertussis, MMR, poliovirus, hepatitis A, hepatitis B, Haemophilus influenzae type b, influenza, varicella, rotavirus, pneumococcal-conjugate antigens, and other vaccines recommended by the CDC for routine administration to children after the Secretary of the Department of Health and Human Services (HHS) publishes a notice of coverage. The National Vaccine Injury Compensation (NVIC) program requires all health care providers to report adverse events involving vaccines to the VAERS.

All vaccine providers (including DoD) record in a permanent health record or permanent office log or file, in either paper or electronic format, a detailed account of severe adverse events after administering immunizing agents or other medications. Mandatory information consists of identification, lot number, and manufacturer of the vaccine or other medication; date of administration; name and location of the medical facility; the type and severity of the event; treatment provided; and any exemption from additional doses.

In addition, VAERS directly accepts all reports of real or suspected adverse events occurring after the administration of any vaccine by any interested party. All DoD and U.S. Coast Guard (USCG) health care beneficiaries are eligible to file claims directly with the NVIC program, according to the program's procedures. If a patient wishes to submit a VAERS report, DoD health care personnel will assist the patient in completing the form, regardless of professional judgment about causal association to immunization.

The NCVIA requires the following events be reported to the VAERS:

a. Any event listed in the NVIC program's vaccine injury table that occurs within the time period specified or within seven days, if that is longer (http//www.hrsa .gov/vaccinecompensation/table.htm).
b. Any contraindicating event listed in a vaccine's package insert (that is, product labeling).

DoD health care personnel report adverse events resulting in hospitalization, a life-threatening event (e.g., anaphylaxis), time lost from duty more than 24 hours (i.e., more than one duty shift), an event related to suspected contamination of a vaccine vial, and an event warranting permanent medical exemption (i.e., a contraindicating event). At a minimum, reports are submitted for the following events: anaphylaxis, brachial neuritis, encephalopathy, encephalitis, rubella–associated chronic arthritis, thrombocytopenic purpura, vaccine–strain measles infection in an immunodeficient recipient, paralytic poliomyelitis, and any other entry in the vaccine injury table maintained by the NVIC program (http://www.hrsa.gov/osp/vicp/table.htm).

Further, DoD health care providers are encouraged to report other adverse events that the provider considers unexpected in nature or severity. DoD and USCG health care providers are also required to report adverse events involving other medications (e.g., immune globulins, chemoprophylaxis agents) to MedWatch, the FDA's Safety Information and Adverse Event Reporting System.

Reports of mild expected reactions to vaccines are not required (e.g., low-grade, self-limited fever of less than 24 hours duration; temporary local soreness, redness, or minor swelling at the site of immunization) because they are already expected, but such reports may be submitted if the clinician or patient wishes.

An adverse reaction to a DoD-directed immunization in Service personnel is considered a line of duty condition that protects the interest of both the individual concerned and the U.S. Government. Military treatment facility (MTF) commanders provide full access to Reserve Component members for evaluation and treatment of adverse events possibly related to DoD-directed immunizations. Reserve Component unit commanders inform their members that they may seek medical care for such adverse events with the unit providing assistance and information related to pay status and compensation issues. Each of the military Services provides an immunization health care capability to deliver medical specialty consultation, case management, and clinical investigation. Any necessary documentation, including line of duty determinations, is completed after the Guardsman or Reservist is evaluated and, if required, treated. In no case is such evaluation or treatment denied or delayed pending line of duty determination. If additional health care is required after the initial visit and a line of duty determination has established a Service connection, a notice of eligibility is completed in accordance with DoD Directives.

Immunization intervals

Nationally recommended immunization schedules are not compressed by DoD vaccine providers. Immunizations given at an interval shorter than the recommended interval may not provide adequate immune response and are not counted as part of a primary series, unless part of a nationally recognized catchup schedule accepted by the

CDC. An immunization series is generally completed once it has been started unless a medical contraindication exists or the person is no longer susceptible or unlikely to be exposed to the pathogen in question. Restarting an immunization series or adding extra doses is not necessary when an initial series of a vaccine or toxoid is interrupted because increasing the interval between doses in a series does not diminish the ultimate immunity obtained. Instead, delayed doses are given as soon as feasible.

DoD observes national norms regarding simultaneous administration of vaccines (multiple near-concurrent vaccinations). To minimize injection-site discomfort, generally no more than five vaccine injections are given on the same day. Other required immunizations are then given at an appropriate later date; no set time interval for inactivated vaccines and four or more weeks between live-virus immunizations. The five-injection threshold may be exceeded in cases, for example, where the vaccine recipient is deploying beyond the reach of deployable medical resources, where exceptional personal exposure to infectious diseases exists, in basic military training sites due to training schedules, or when authorized by the physician responsible for the immunization service.

Priority of immunization is based on the relative likelihood of Service member exposures to the various microbial threats and the existence of any vaccine-to-vaccine, vaccine-to-antibody, or vaccine-to-drug interactions. A starting point for prioritizing immunizations for an individual would consider microbes: (1) most likely to be encountered (for example, typhoid, hepatitis A, influenza), (2) of greatest severity if encountered (for example, anthrax, smallpox, meningitis, yellow fever, Japanese encephalitis, rabies), or (3) of long-standing risk (for example, hepatitis B, tetanus, diphtheria, pertussis, poliovirus, varicella, measles, mumps, and rubella). In military training centers, contagious respiratory diseases would typically represent the most imminent threats.

For some vaccine-preventable diseases, serologic or other tests will be used to identify preexisting immunity from prior infection or immunization that may eliminate the need for unnecessary immunization. Such testing is adopted where it offers advantages in terms of improved care or medical economics such as in military recruit training centers.

DoD procedures for reviewing individual medical histories prior to the administration of vaccines

Before administration of any vaccine, all Active and Reserve Component members (individually or collectively) are asked about general food and drug allergies, health status, previous adverse events before immunization, and allergy to any specific component of the vaccine or its packaging (for example, eggs, gelatin, preservatives, latex) and provided an opportunity to ask questions about potential contraindications.

Each vaccine recipient is provided Vaccine Information Statements (VISs) about benefits and risks associated with each pending immunization. VISs are produced by the CDC and explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of each vaccine. This information is culturally appropriate and at an appropriate age level. Two sample VISs for chickenpox and anthrax are provided at enclosures 2 and 3, respectfully, and found at http://www.cdc.gov/vaccines/pubs/vis/default.htm#multi). DoD provides an additional informational brochure to anthrax vaccinees (enclosure 3). For smallpox vaccination, additional detailed educational brochures are provided. The DoD smallpox educational packet at enclosure 4 contains the Smallpox VIS, the ACAM2000 (newest smallpox vaccine) Medication Guide, smallpox informational brochure for the Service member, smallpox informational brochure for household members, and the DoD Smallpox Vaccination Initial Note (screening form).

Federal law (NCVIA) requires that VISs be handed out before each dose to either the adult recipient or to the child's parent/legal representative whenever a health care provider vaccinates a child or an adult with a dose of any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, Haemophilus influenzae type b (Hib), varicella (chickenpox), influenza, or pneumococcal conjugate vaccine. VISs are recommended but not currently required by Federal law for these vaccines: smallpox, anthrax, Japanese encephalitis, yellow fever, HPV, meningococcal, pneumococcal polysaccharide, and rotavirus, as well as various vaccines used primarily for international travelers. Use of VISs for HPV, meningococcal, and rotavirus vaccines will become mandatory at a later date.

Review of the Service member's medical history is an important part of DoD's quality immunization programs. Individuals with reported hypersensitivity are deferred from immunization or chemoprophylaxis and referred to an appropriate medical specialist for evaluation, unless the health record documents prior consultation or a specialist's recommendations. Hypersensitivity to any vaccine, vaccine component or medication is documented on the individual's health record (Chronological Record of Medical Care, Standard Form 600) and on the health record problem list. Exemptions from further immunization are entered in the individual's deployable health record (i.e., Department of Defense Form 2766 Adult Preventive and Chronic Care Flowsheet), DoD or USCG-approved electronic immunization tracking systems, on the International Certificate of Vaccination or Prophylaxis (PHS Form 731), or in other relevant paper-based immunization records.

For all Service members, civilian employees, and other health care beneficiaries, the DoD-approved electronic immunization tracking systems are the preferred record for maintaining immunization data and include date, immunization given, dose, and identification of the person administering the vaccine. Clinics and other activities administering immunizations transmit electronic records and exemption information to (and receive updates from) a DoD-centralized repository at least weekly. Transcription

of historical data from official records occurs concurrently with the implementation of electronic tracking.

The Service's immunization tracking systems comply with the requirements of the NVIC Program. DoD-directed levels of security, certification, and redundancy, and the requirements of the Health Insurance Portability and Privacy Act of 1986 are incorporated to preclude unauthorized access to personal medical information and to survive hardware or software malfunction. The various DoD electronic immunization tracking systems include:

- Army Medical Protection System (MEDPROS)
- Navy Shipboard Non-Tactical Automatic Data Processing Program (SNAP) Automated Medical System (SAMS)
- Navy Reserve/Marine Corps Medical Readiness Reporting System (MRRS)
- Air Force Complete Immunization Tracking Application (AFCITA)
- Coast Guard Medical Readiness System (MRS)

During deployment, information regarding immunizations and chemoprophylaxis including date, product given, dose, and initials of person administering are transferred to the deployable health record (DD Form 2766) or other approved form, either by computer-generated report or by hand. Upon return from deployment, entries are transferred from the deployment record into the appropriate immunization tracking systems or other electronic record system.

Although DoD electronic immunization tracking systems provide ready access to the health status of Active Component members, some Reserve Component members receive their routine health care by personal civilian providers or contractors in the Reserve Health Readiness Program (RHRP, previously Federal Strategic Health Alliance, FEDS_HEAL) which may have limited or no connectivity to the electronic health record.

The RHRP is administered in conjunction with the DoD to support deployment readiness requirements. The RHRP provides a robust specially trained and credentialed health care provider network that delivers medical and dental services to Reserve Component members in all 50 states and territories providing an extensive array of services, seven days a week, at provider locations or at other specified locations, such as military installations.

DoD studies on multiple, near-concurrent vaccinations

An extensive 2004 review (enclosure 5) by the Armed Forces Epidemiological Board (AFEB, now the Defense Health Board) and a 2007 study published by the CDC Vaccine Analytic Unit (enclosure 6) of multiple near-concurrent immunizations

administered to DoD Service members concluded there is no evidence of increased risk of adverse events for those receiving multiple near-concurrent vaccinations.

The AFEB met to address the issue of multiple, near-concurrent immunizations and reported on April 16, 2004 (paragraph 8, page 3):

> *At the current time, decades of experience and extant data do not demonstrate serious or long-term adverse health effects causally related to multiple, concurrent immunizations, and there is no reason to deviate from current [national] consensus guidelines for adult immunization. Standard clinical practice and the recommendations of multiple scientific and professional medical societies currently support the practice of concurrent immunizations.*

Finally, the AFEB concluded (paragraph 8, page 3):

> *For these reasons, and the demonstrated positive health effects of widespread immunity to infectious diseases that can seriously impair readiness, the current practice of multiple, concurrent immunizations should be continued in the Armed Services.*

This AFEB report (http://www.vaccines.mil/documents/477AFEB2004.pdf) made several significant recommendations including spreading out immunizations over time during recruit training to minimize discomfort to vaccinated personnel without sacrificing the individual and population benefits of widespread vaccine-induced immunity to infectious diseases. Consequently, the 2006 DoD Joint Regulation, "Immunization and Chemoprophylaxis," was updated to include provisions for scheduling immunizations in two or more clusters such that not more than five vaccine injections will generally be given on the same day to minimize injection-site discomfort.

The AFEB also recommended strategies to reduce overall vaccine use including (1) serologic screening in appropriate settings when immunity is likely to be high (e.g., measles-mumps-rubella vaccine after recruit training) and vaccinating only susceptible individuals, and (2) employing a risk-based approach for vaccines where risk is limited to specific geographic areas (e.g., yellow fever vaccine). As an example, the Air Force consequently reduced its use of yellow fever vaccine by 81 percent with a change in policy requiring a risk-based requirement before vaccination. The choice of strategies takes into account the prevalence of immunity against specific diseases, the feasibility and costs of selective versus universal vaccination, and the likelihood and risks of missing susceptible persons.

Peer-reviewed epidemiological research also supports the safety of the nationally accepted standards and DoD policies for administration of multiple near-concurrent vaccinations. The CDC's Vaccine Analytic Unit published a study in 2007 investigating

whether the receipt of multiple near-concurrent vaccinations (two or more vaccinations during a two-day period) is associated with a higher risk of hospitalization among U.S. Service members.

In this CDC study, the following vaccine combinations were the 10 most frequently administered simultaneously by DoD between 1997-2004 in decreasing order of frequency (smallpox and anthrax vaccines were included in this study):

- Hepatitis A + Typhoid
- Hepatitis A + Influenza
- Hepatitis A + Tetanus–diphtheria
- Hepatitis A + Influenza + Tetanus–diphtheria
- Hepatitis A + Hepatitis B
- Hepatitis A + Yellow fever
- Hepatitis A + Tetanus–diphtheria + Typhoid
- Tetanus–diphtheria + Typhoid
- Influenza + Typhoid
- Influenza + Hepatitis A + Typhoid

Analyses for individuals receiving only one vaccination served as the reference point in this study. Multivariable analyses were performed on demographic, occupational, vaccination, and hospitalization data reported to the Defense Medical Surveillance System (DMSS) from January 1, 1998, through December 31, 2003. The DMSS integrates data on U.S. Service members from MTFs, vaccination centers, and personnel offices worldwide.

The study cohort of 117,876 Active Component U.S. Service members had one or more vaccinations. Out of this cohort population, the records of 19,743 Service members with multiple near-concurrent vaccinations were analyzed. The results of this well controlled, large independent study of U.S. military personnel found no statistically significant evidence of increased hospitalization risk between the 120-day pre-exposure and post-exposure intervals. There was no association with subsequent hospitalizations even for members receiving five or more multiple near-concurrent vaccines. Finally, there was no difference in hospitalization risk between those receiving multiple near-concurrent vaccinations and those receiving a single vaccination. This study is available at www.ncbi.nlm.nih.gov/pubmed/17574864 (Concurrent Vaccinations and U.S. Military Hospitalizations, Payne et al, Annals of Epidemiology, 2007).

Established in 1970 under the charter of the National Academies, the Institute of Medicine (IOM) provides independent, objective, science-based advice to policymakers, health professionals, the private sector, and the public on biomedical science, medicine, and health. In 2002, the IOM reviewed the safety of multiple vaccinations for healthy

infants, whose immune systems are less mature than adults' immune systems. The IOM committee concluded the epidemiological evidence (i.e., from studies of vaccine-exposed populations and their control groups) favors rejection of a causal relationship between multiple immunizations and increased risk for infections and for type 1 diabetes. The epidemiological evidence regarding risk for allergic disease, particularly asthma, was inadequate to accept or reject a causal relationship. The IOM recommended no change was needed in current national policies involving multiple immunizations. This IOM report can be found at http://www.nap.edu/catalog.php?record_id=10306#toc (Immunization Safety Review: Multiple Immunizations and Immune Dysfunction).

DoD vaccination policies for Active and Reserve Component members

The DoD policies, procedures, and standards of care for delivery of military vaccines are provided in the DoD Joint "Immunization and Chemoprophylaxis" regulation and are the same for all Active and Reserve Component members, including National Guard, and Reserve members of the uniformed Departments of the Army, Navy, Air Force, Marine Corps, and Coast Guard. Military Services abide by these standards in routine immunization delivery.

The AFEB report (enclosure 5) noted that the Reserve Component forces may more commonly receive multiple near-concurrent vaccines with higher numbers of vaccine doses than the Active Component. Recently revised DoD procedures should minimize just-in-time delivery of preparatory countermeasures. First, increasing the frequency of medical-readiness reviews spreads out the number of vaccines needed for force protection. Second, implementation of an annual individual medical readiness requirement for Reserve Component forces has further decreased just-in-time delivery of preparatory countermeasures including vaccines.

CONFORMANCE OF DOD POLICIES ON MULTIPLE NEAR-CONCURRENT VACCINATIONS TO FEDERAL AND NON-FEDERALLY ACCEPTABLE STANDARDS

The U.S. nationally accepted standards for administering all single, multiple, or multiple near-concurrent vaccinations are determined by the CDC and the Advisory Committee on Immunization Practices (ACIP). It is DoD policy (DoD Joint Regulation, "Immunization and Chemoprophylaxis", Chapter 2.1) to follow the recommendations of the CDC and the ACIP for administering all single, multiple, or multiple near-concurrent vaccinations for its Active and Reserve Component members, unless there is a militarily relevant reason to do otherwise (e.g., deploying beyond the reach of deployable medical resources).

The ACIP consists of 15 national and international experts in fields associated with immunization who have been selected by the HHS Secretary to provide advice and

guidance to the Secretary, the Assistant Secretary for Health, and the CDC on the control of vaccine-preventable diseases.

DOD PROCEDURES FOR INITIATING DEATH INVESTIGATIONS IN WHICH VACCINATIONS MAY HAVE PLAYED A ROLE

The Armed Forces Medical Examiners (AFME) System, under the Armed Forces Institute of Pathology, investigates all DoD Service member deaths and maintains the DoD Medical Mortality Registry. The AFME Medical Mortality Surveillance Division detects mortality due to unexplained infectious diseases and analyzes all active duty deaths for trends and preventable or modifiable risk factors.

The AFME receives notification of the deaths of all Service members on active duty and inactive duty for training, including those recently retired if the death was the result of an injury or illness incurred while such a member was on a period of active duty. Each Military Department maintains a Service casualty office serving as the primary liaisons for families concerning personnel recovery and accounting. Each Service casualty office is required to notify the AFME within four hours of an active duty Service member's death. Medical, casualty, mortuary, law enforcement, and other similar personnel of the Military Departments expeditiously report all such deaths to the AFME. However, notification may be delayed if the death occurs, for example, in a civilian hospital.

The death of a Reserve Component member while not in a military status or not on a military installation is under the purview of civilian authority. Once a unit is informed of the death (typically by a family member), the Reserve Component chain of command up to the Joint Forces Headquarters (JFHQ) is notified of the member's death. The JFHQ obtains a copy of the death certificate for military records. If the civilian authorities, the military command or the family feel that there is any possible connection to military service, there is a subsequent investigation. Deaths among Reserve Component members are possibly missed if occurring while in a civilian status. The DoD Medical Mortality Registry database only includes deaths that occurred while on active duty.

Forensic pathology investigations

The AFME System is governed by Sections 176, 1565a, 1471, and 2012 of Title 10, United States Code and DoD Instruction 5154.30 ("Armed Forces Institute of Pathology Operations", March 18, 2003), which specifically refer to forensic pathology investigations.

The AFME may conduct a forensic pathology investigation (may or may not include an autopsy) to determine the cause or manner of death of a deceased person if

such an investigation is determined to be justified under at least one of the following circumstances:

- It appears that the decedent was killed or that, whatever the cause of the decedent's death, the cause was unnatural;
- The cause or manner of death is unknown;
- There is reasonable suspicion that the death was by unlawful means;
- It appears that the death resulted from an infectious disease or from the effects of a chemical, biological, radiological, or other hazardous material, that may have an adverse effect on the military installation or community involved; or
- The identity of the decedent is unknown.

In addition, one of the following circumstances must be met to justify a forensic pathology investigation:

- The decedent was found dead or died at an installation garrisoned by units of the Armed Forces that is under the exclusive jurisdiction of the United States;
- The decedent was a member of the Armed Forces on active duty or inactive duty for training;
- The decedent was recently retired under chapter 61 of this Title as a result of an injury or illness incurred while a member on active duty or inactive duty for training;
- The decedent was a civilian dependent of a member of the Armed Forces and was found dead or died outside the United States;
- In any other authorized DoD death investigation when a determination of the cause and manner of death is necessary; or
- In any other authorized investigation being conducted by the Federal Bureau of Investigation, the National Transportation Safety Board, or any other Federal agency, when an authorized official of such agency with authority to direct a forensic pathology investigation requests that the AFME conduct such an investigation.

Consent of the next-of-kin is not required for any forensic pathology investigation carried out under DoD regulations (DoD Instruction 5154.30) or any other applicable compulsory authority.

If a Service member dies after being hospitalized in a DoD or civilian hospital fewer than 24 hours, a forensic autopsy will normally be conducted. On any autopsy performed in a DoD medical facility, the AFME has the authority to review all pertinent

medical and dental records, investigative reports, photographs, evidence, x-rays, and retained pathologic materials.

An in-hospital death after 24 hours as an inpatient is generally not considered a forensic death; hence, a routine voluntary hospital autopsy is less likely to be requested and the AFME loses authority to investigate. Although attempts to gather some details of a non-forensic death are generally successful, the AFME cannot compel a civilian hospital to turn over records to DoD. However, the AFME can respectfully demand an autopsy if there is sufficient evidence to warrant a forensic pathology investigation.

An autopsy report typically describes the circumstances of death. For example, the manner of being found is reported (e.g., "24 year old enlisted male found face down in his berthing rack aboard ship"). The external and internal exam findings are reported in detail including tattoos, personal effects, evidence of medical intervention (e.g., intubation tube, intravenous lines, etc.). The examiner likely will report the typical smallpox scar as well as toxicology results, histopathology, and subspecialist evaluations. Finally, a summary opinion describes the suspected cause and manner of death. Some medical examiners will not be speculative at all, while others will offer a little more exploration in the summary opinion.

Before the beginning of Operation Enduring Freedom in 2001, the AFME routinely conducted approximately 1,000 autopsies per year. In 2006, the AFME performed more than 2,000 autopsies including battlefield casualties; in 2007, more than 1,900 autopsies were conducted. All combat deaths are ruled homicides and warrant autopsies. Non-combat related autopsies still average approximately 1,000 per year. Leading causes of non-combat related deaths from 2003 to 2004 were accidents, natural causes, and suicide.

Quick notification of a Service member's death in which an infectious etiology is suspected is critical for the medical examiner so proper tests and tissue samples can be collected. The AFME office often contacts the civilian pathologist conducting an autopsy for necessary specimens in these cases. Suspicion of an infectious etiology is usually a judgment call made after an investigation is begun.

It is sometimes learned during an investigation that the deceased had recently received vaccination(s) but this is not routinely queried. Any autopsy finding of myocarditis, however, always targets vaccines as a causative element. This finding usually is detected after formalin fixation of autopsy specimens so infectious etiologies are rarely found, especially viruses.

If a Service member's death is possibly thought to be vaccine-related, the information is sent from the AFME to the MILVAX, and then to the DoD VHC Network where vaccination databases of active duty personnel can be accessed.

Family member access to death investigations

Family members of deceased active duty personnel can always get a copy of an autopsy report if one is performed by a DoD pathologist. Limitations may occur, however, if an autopsy is performed by civilian authorities.

The primary jurisdiction for the investigation of a death may rest with a state or a local government of the state, or in the case of a death in a foreign country, by that foreign country under any applicable treaty, status of forces agreement, or other international agreement between the U.S. and that foreign country. If another government having concurrent jurisdiction waives or declines jurisdiction, fails to conduct an autopsy, or otherwise fails to conduct a complete investigation, the DoD AFME may order a forensic pathology investigation, including an autopsy. In these cases, the family member would be allowed copies of the autopsy reports from the AFME. Otherwise, the family member will have to request copies of autopsy reports directly from the jurisdictional authority.

Since 2001, over 3,200 autopsy results have been given to family members including detailed reports, pictures, etc. Note, however, Naval Criminal Investigative Service (NCIS) reports are not made available to family members.

Service member deaths investigated by DoD since May 18, 1998, for the potential role of vaccine administration, including those deaths alleged or determined to have involved more than one vaccine administered in a given 24-hour period

Several million doses of vaccines are administered to the U.S. Armed Forces annually to protect Service members against natural disease and bioterror threats. More than 2 million members of the Armed Forces have been vaccinated against anthrax, and more than 1.5 million have been vaccinated against smallpox.

It is not possible to identify the number of deaths of members of the Armed Forces since May 18, 1998, that DoD has investigated for the "potential role" of vaccine administration. There are likely numerous times over the past 10 years where the role of vaccines was entertained but quickly ruled out due to lack of supporting evidence. However, there have been four extensive investigations for deaths possibly related to vaccination.

On November 19, 2003, the DoD announced findings of two independent review panels of medical experts who evaluated the possibility of a relationship between vaccination and the illnesses or deaths of four Service members. Among the four cases, the panels concluded vaccination may have contributed to an illness that led to death in one case. In the review of the three other cases, the panels found no causal association

with vaccination. The patient diagnoses in these three non-vaccine related cases were drug overdose, pulmonary embolism, and atrial fibrillation.

In the single vaccine-related case from April 2003, the expert panel members made a divided decision that there was "possibly" or "probably" a causal link between multiple vaccinations and an illness that ultimately led to the death of a 22-year-old Army Reserve medical technician who received several vaccinations while being mobilized for active duty. Although the two review panels determined that evidence favored a possible or probable causal relationship, the evidence was not conclusive. Each panel said that it was unable scientifically to identify a specific vaccination as the possible cause since several near-concurrent vaccinations were administered.

This soldier received five vaccinations (anthrax, hepatitis B [dose 2], MMR [measles, mumps, rubella], smallpox [vaccinia], and typhoid) on March 2, 2003, at Fort McCoy, Wisconsin, where she and her unit were preparing for overseas deployment. She had received multiple vaccinations previously all without complications, such as when she entered into military basic training six years earlier where she received measles, rubella, influenza, and oral live polio vaccines, and four to five months earlier where she received hepatitis A and hepatitis B [1st doses], diphtheria and tetanus vaccines. The MMR and smallpox vaccines are live-virus vaccines. The others are inactivated vaccines. She also received a tuberculin skin test on the same day. Other deploying soldiers in her unit and other military units received similar vaccinations.

This soldier was physically healthy and medically cleared to receive the vaccinations that she received in March 2003. She provided all requested information during pre-vaccination screening procedures. Neither DoD nor the soldier knew any reason not to vaccinate her.

Thirty-three days following vaccination and after progressively worsening illness, she developed a complex set of pulmonary, neurological, and other symptoms and died while being treated at the Mayo Clinic in Rochester, Minnesota. She died due to a severe inflammatory process affecting her lungs, findings consistent with a diagnosis of systemic lupus erythematosus. She was unaware she had an underlying immune system disorder, nor did any of her physicians.

The DoD sought the expert panels' reviews as part of the process designed to identify possible adverse effects of vaccinations. The two panels were convened at the request of the Assistant Secretary of Defense for Health Affairs under the auspices of the HHS as part of DoD's vaccine safety surveillance program.

The first panel was the Smallpox Vaccine Safety Working Group (SVSWG), a joint subcommittee of the CDC's ACIP and the AFEB, a panel of civilian physicians and scientists that advises the DoD. SVSWG reported that "the weight of available evidence favors acceptance of a causal relationship between the immunization experience and the disease" in this case. The panel did not find that the evidence conclusively established an actual causal relationship nor implicated a particular vaccine.

The second panel was the Clinical Expert Immunization Committee (CEIC), a group of expert private, academic physicians convened by the Health Resources and Services Administration (HRSA), an agency of Department of Health and Human Services (DHHS). The CEIC members reviewed two of the four cases, including the Fort McCoy soldier's death. Three CEIC members characterized the relationship between the vaccinations and the death as "possible," while two other members considered it "probable."

DoD invited both independent review panels because each brought complementary expertise to the review process. SVSWG has monitored adverse-event information about the U.S. smallpox vaccination program since the program's inception in December 2002. CEIC is the successor to the Anthrax Vaccine Expert Committee (AVEC), an experienced panel that reviewed adverse events reported after anthrax vaccination between 1998 and 2001.

The key findings leading to a conclusion of a "possible" or "probable" causal association by the CEIC include the soldier at Fort McCoy having an unusual pattern of antibodies called anti-Ro antibodies that have been associated with lupus in some patients with the disease. These antibody tests have to be interpreted with care, because most people who test positive do not go on to develop symptoms of lupus. Those people simply carry the antibody for years and without causing problems. A very small proportion of people who carry the antibody may experience some kind of "trigger" that sets in motion a lupus reaction. This lab finding leads some to conclude that the vaccines this soldier received may have triggered her lupus; but as can be seen in her case, she had received multiple vaccinations in the past without problems.

DoD considered whether a medical diagnostic test known as an Antinuclear Antibodies (ANA) test might have been helpful in preventing this soldier's death. The ANA test measures "antinuclear antibodies" which are proteins that bind to components inside of cells. However, this test produces false-positive results so often that it would not be a useful screening test for healthy populations, such as our deploying Service members. False-positive test results indicate the presence of a medical condition when that condition does not really exist.

The medical literature includes a small number of case reports of autoimmune disease occurring after vaccination, but these cases do not provide scientific proof of a cause-and-effect association. The medical literature also includes several studies showing some common vaccines (e.g., influenza, hepatitis B) to be generally safe in people with autoimmune diseases. Scientific knowledge is incomplete in this area, and more work is needed to better understand rare events that happen after vaccination. DoD is committed to its ongoing collaboration with CDC and other partners in evaluating adverse events after vaccination.

The Fort McCoy soldier's death certificate included mention of pericarditis, inflammation of the sac around the heart. The CEIC review panel noted that her inflammation was not like other cases of inflammation sometimes seen following smallpox vaccination. CEIC noted that pericarditis developed late in this soldier's case and did not seem to be the main reason for her illness. Hence, this soldier's case is unlike the small series of myo-pericarditis cases seen following smallpox vaccination.

An important conclusion of both expert groups is that nothing was discovered that indicates the DoD vaccine screening programs could have prevented the illness and ultimate death of this soldier, who appears to have had an underlying undiagnosed autoimmune disorder. DoD continues to carefully administer their vaccination programs, including carefully monitoring for adverse events that follow administration. Though it appeared no screening procedure could have averted her illness, DoD subsequently asked the AFEB in 2004 to review the long-standing tradition of administering simultaneous vaccinations. The AFEB's recommendations have previously been discussed.

As a result of this single case, the two review panels did not recommend any changes to current screening processes that would be useful in preventing similar rare cases in the future. From the beginning of the DoD Smallpox Vaccination Program, the same screening and exemption criteria adopted by the CDC, FDA, and similar authorities were adopted by DoD. These processes are regularly reevaluated to see if the DoD can do better. After any serious adverse event following vaccination, these procedures are routinely reassessed.

Based on the findings of these panels, DoD reemphasized its message to all vaccinees to seek prompt medical care if they experience medical problems after vaccination. DoD continues to pursue careful screenings, immunization procedures, and close monitoring for adverse events.

Determining causality between vaccination and adverse events

The following information is from the National Network for Immunization Information (NNii) at http://www.immunizationinfo.org/vaccine_safety_detail.cfv?id=67.

Most adverse events following immunization (AEFIs) are not unique clinical illnesses or syndromes (i.e., AEFIs also occur in people who do not receive the vaccine). Epidemiological studies such as randomized clinical trials comparing rates of the AEFI in vaccinated and non-vaccinated groups provide the most reliable way to determine whether an adverse event is causally related to vaccination. A higher risk among vaccinated persons could mean that the vaccine possibly caused the adverse event. However, large trials are needed to assess very rare events and post-marketing surveillance systems are required to identify events potentially related to vaccination.

When large populations are vaccinated, some serious events that occur rarely with or without vaccination will be observed coincidentally following vaccination. However, epidemiologic studies cannot absolutely prove coincidence (reject causation) because there can always be very rare occurrences that were not detected in the study population, or because the vaccine only accounted for a very small proportion of the adverse events. When the risk for vaccinated personnel cannot be distinguished from the risk for unvaccinated personnel, the strongest interpretation that can be made is that the evidence favors rejection of causation.

Investigating causality of serious AEFIs requires fulfilling certain established epidemiological criteria. However, published studies of AEFIs often do not fulfill the criteria needed to draw conclusions about vaccine safety with any degree of certainty.

Certain studies of AEFIs published in the medical literature over the past few years have resulted in controversy (e.g., vaccines and autism). While generating provocative hypotheses, these studies have generally not fulfilled the criteria that would be needed to be able to draw conclusions about vaccine safety with any degree of certainty. Yet these reports have had a major influence on public debate and opinion-making. When this debate spills over to the political arena, to policy-making and to determining the public acceptance of a vaccine by balancing the known benefits against possible but unverified risks, it is clear that a correct assessment of causality is vital.

World Health Organization (WHO) criteria for investigating vaccine adverse event causality

The WHO Global Advisory Committee on Vaccine Safety (GACVS) uses the following generally established criteria inferred from epidemiological studies for investigating vaccine adverse event causality:

(1) Consistency. The association of a purported adverse event with the administration of a vaccine should be consistent, i.e., the findings should be replicable in different localities, by different investigators not unduly influencing one another, and by different methods of investigation, all leading to the same conclusion(s). The more

studies that show similar results using different populations and differing study methods, the more likely there is a causal relationship.

(2) Strength of the association. The association should be strong in the magnitude of the association and in the dose-response relationship of the vaccine with the adverse effect. The greater the difference in rates between the vaccinated and unvaccinated, the more likely there is a causal relationship.

(3) Specificity. The association should be distinctive—the adverse event should be linked uniquely or specifically with the vaccine concerned, rather than its occurring frequently, spontaneously or commonly in association with other external stimuli or conditions.

(4) Temporal relation. There should be a clear temporal relationship between the vaccine and the adverse event, in that receipt of the vaccine should precede the earliest manifestation of the event or a clear exacerbation of an ongoing condition. For example, an anaphylactic reaction seconds or minutes following immunization would be strongly suggestive of causality; such a reaction several weeks after vaccination would be less plausible evidence of a causal relation.

(5) Biological plausibility. The association should be coherent; that is, plausible and explicable biologically according to known facts in the natural history and biology of the disease.

DOD PROCEDURES FOR PROVIDING ADJUTANTS GENERAL (AGs) WITH VACCINE INFORMATION

The DoD does not have a procedure specifically in place to provide the Adjutants General (AGs) of the various states with vaccine-related up-to-date information on the effectiveness and potential allergic reactions and side effects. However, the DoD does provide this information to all DoD Active and Reserve Components through MILVAX. Reserve Components include the Army National Guard of the United States, Army Reserve, Air National Guard of the United States, Air Force Reserve, Naval Reserve, Marine Corps Reserve, and Coast Guard Reserve.

In cooperation with the military Services, including the Reserve Components, MILVAX works to enhance military medical readiness and protect human health, by coordinating and delivering information and education of vaccine-related activities, enhancing scientific understanding, promoting quality, and coordinating military immunization programs worldwide.

Education and outreach is a core focus of MILVAX. All vaccine package inserts; CDC VISs; special reports (e.g., CDC Morbidity and Mortality Weekly Report); and DoD's vaccination policies, including up-to-date information on the effectiveness and potential allergic reactions and side effects of vaccines required to be taken by all military Service members (including Reserve Component personnel), are distributed to all Active and Reserve Components and are posted publicly at MILVAX Web site (www.vaccines.mil).

MILVAX also hosts a monthly videoconference to provide updates regarding all vaccines. This videoconference is attended by the Uniformed Departments of the Army, Navy, Air Force, and Coast Guard (including the Active and Reserve Components of each Service).

Procedures allowing Adjutants General to retain updated medical records

All Reserve Components have automated (electronic) health readiness records which are permanent archives available at any time during the members' service and is retained beyond separation, retirement, and death. As an example, the Army National Guard's health readiness records have data uploaded from the Army MEDPROS that provides reporting and tracking information for dental and medical readiness and includes a soldier's permanent or temporary medical profiles (i.e., soldier's physical limitations), line of duty determinations, and individual immunization status. All immunization data is entered directly into MEDPROS at the point of service or within 24 hours. The health readiness records are always available to the AGs and their staffs.

The paper Soldier Treatment Record (STR) and health readiness records are sent to the mobilization station (MOBSTA) with the member for review during in-processing. Prior to the administration of an immunization, the STR, MEDPROS, and any civilian documents made available by the soldier are consulted to determine the need for an immunization. The Reserve Component unit retains the paper STR at the MOBSTA for use until overseas departure. When a unit departs, it takes only their Adult Preventive and Chronic Care Flowsheet (DD 2766) as their "deployment health record." The paper STR is returned to the State STR Custodian while the member is overseas. Upon redeployment, the contents of the DD 2766 documenting health care during deployment are incorporated into the STR and health readiness records for historical purposes.

Because Reserve Component personnel often receive health care by civilian contractors in the Reserve Health Readiness Program (previously FEDS_HEAL), current immunization data and other medical data may not have direct connectivity to the electronic health readiness records.

ACRONYMS

ACIP	Advisory Committee on Immunization Practices
ADP	Automatic Data Processing
AEFIs	Adverse events following immunization
AFCITA	Air Force Complete Immunization Tracking Application
AFEB	Armed Forces Epidemiology Board
AFME	Armed Forces Medical Examiners
AGs	Adjutants General
ANA	Antinuclear Antibodies
AVEC	Anthrax Vaccine Expert Committee
CDC	Centers for Disease Control and Prevention
CEIC	Clinical Expert Immunization Committee
DHHS	Department of Health and Human Services
DMSS	Defense Medical Surveillance System
DoD	Department of Defense
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FEDS_HEAL	Federal Strategic Health Alliance
GACVS	Global Advisory Committee on Vaccine Safety (WHO)
HRSA	Health Resources and Services Administration
HIB	Haemophilus influenzae type b
HHS	Department of Health and Human Services
IND	Investigational New Drug
IOM	Institute of Medicine
JFHQ	Joint Forces Headquarters
MEDPROS	Medical Protection System (Army)
MILVAX	Military Vaccine Agency
MMR	Measles, mumps, rubella
MOBSTA	Mobilization station
MRRS	Medical Readiness Reporting System (Navy Reserve/Marine Corps)
MRS	Medical Readiness System (Coast Guard)
MTF	Medical treatment facility
NB	NarroBand
NCIS	Naval Criminal Investigative Service
NCVIA	National Childhood Vaccine Injury Act
NVIC	National Vaccine Injury Compensation
PHS	Public Health Service
RHRP	Reserve Health Readiness Program
SAMS	SNAP Automated Medical System (Navy)
SNAP	Shipboard Non-tactical Automated data processing Program (Navy)
STR	Soldier Treatment Record
SVSWG	Smallpox Vaccine Safety Working Group

USCG	United States Coast Guard
VAERS	Vaccine Adverse Event Reporting System
VHC	Vaccine Healthcare Centers
VIS	Vaccine Information Statement
WHO	World Health Organization