HEADQUARTERS
UNITED STATES FORCES KOREA
APO AP 96205-0054

USFK Regulation
No. 40-562

Medical Services
IMMUNIZATION AND CHEMOPROPHYLAXIS POLICY

SUPPLEMENTATION: Issue of further supplements to this regulation by subordinate commands is prohibited unless prior approval is obtained from HQ USFK, ATTN: FKMD-OPS, APO AP 96205-0010.

1. PURPOSE. To provide a standardized guideline for the immunization and chemoprophylaxis of all USFK health care beneficiaries, including active-duty and reserve component personnel, civilian employees, and family members.

2. APPLICABILITY. This regulation applies to all USFK personnel in Korea on permanent assignment or temporary duty and those aboard Naval vessels that are making a port visit or are operating in the littorals of the Korean Theater of Operations (KTO) both during Armistice and transition to war.

3. REFERENCES. Required references are listed in Appendix A.

4. EXPLANATION OF ABBREVIATIONS AND SPECIAL TERMS. Abbreviations and special terms used in this regulation are explained in the glossary (Appendix B).

5. RESPONSIBILITIES.

a. Commander, United States Forces Korea (FKMD), will:

(1) Ensure that Force Health Protection Notices are published notifying all Unified Commanders of any new disease threat or an increased incidence of a known endemic disease.

(2) Ensure that the current disease threat list is validated and published semi-annually.

b. USFK Unit Commanders will ensure that their personnel have current immunizations/ chemoprophylaxis outlined in Appendix C as an integral part of force protection.

c. All USFK Medical Treatment Facility (MTF) Commanders will:

(1) Ensure, via medical in-processing and periodic record review, that all USFK personnel and civilian employees are in compliance with this policy. Specifically, in-processing

of new personnel must include a review of each individual's immunization/chemoprophylaxis history. Immunizations/chemoprophylaxis determined to be required as outlined in Appendix C will be given during in-processing. Immunizations not required at in-processing, but which will be required in the following 12 months, will be noted in order to recall the individual for immunization/chemoprophylaxis at the appropriate future date. Immunizations/chemoprophylaxis not specified in Appendix C will be given only with the concurrence of the USFK Preventive Medicine Consultant (FKMD-PM).

(2) Ensure all immunizations/chemoprophylaxis given have the date, vaccine/drug name, vaccine/drug lot number, amount, route of administration and responsible health care provider documented on SF 601, DD Form 2766C, or service appropriate form. This information should also be documented on the International Certificates of Vaccination (PHS-731), if available. Additionally, all immunizations/chemoprophylaxis must be entered into the automated tracking system in use by the respective service.

(3) Ensure USFK family members receive immunizations/chemoprophylaxis as recommended by the Advisory Committee on Immunization Practices, the American Academy of Family Practice, and the American Academy of Pediatrics. There are no additional immunizations/chemoprophylaxis recommended for USFK family members.

(4) Ensure those CONUS activities transferring personnel to USFK commands are notified of all immunization/chemoprophylaxis deficiencies noted during medical in processing in accordance with current service procedures. Significant trends in the number of these deficient personnel must be brought to the attention of the USFK Surgeon (FKMD-OPS).

(5) Ensure compliance with the guidelines provided in Appendix D and the references listed in Appendix A.

(6) Ensure compliance with evaluations of adverse events and prompt reporting of adverse events in accordance with Appendix E.

6. POLICIES.

a. Immunizations and chemoprophylaxis are an integral part of DoD's overall Force Health Protection Program. It is imperative that all USFK personnel strive to maintain 100% readiness at all times. As such, this regulation provides guidelines that enhance immunity and health protection necessary to maintain readiness and will be given the appropriate level of support at all levels of command. This is a Commander's Program since it has a direct impact on force protection and readiness.

b. There is nothing in this regulation that precludes either the assignment or deployment of personnel to the KTO during Armistice or transition to war. Active duty service members and emergency essential civilians who are found to be medically exempt from further administration of a mandatory immunization will not be precluded from deploying or remaining in the theater based solely on the inability to receive such immunization. Other measures to protect these

individuals are available and will be implemented to the fullest extent to protect them. The emphasis of this regulation is to provide commanders at all levels the guidance necessary to appropriately protect their personnel from the known disease threats in the KTO.

c. This regulation does not establish new conditions of employment for civilian employees. Civilian employees, other than EECs, who refuse the required immunizations in this regulation, will be provided adequate education on the risks and benefits of immunizations. No adverse administrative consequences are to be placed on the employee other than those imposed by the host nation through the Status of Forces Agreement (SOFA).

The proponent for this regulation is the USFK Surgeon. Users are invited to send comments and suggested improvements on DA Form 2028. (Recommended changes to Publications and Blank Forms) to the Commander, USFK, ATTN: FKMD-OPS, APO AP 96205-0010.

FOR THE COMMANDER:

OFFICIAL:

CHARLES C. CAMPBELL
Lieutenant General, USA
Chief of Staff

E. ERIC PORTER
Colonel, USA
Adjutant General

4 Appendices
A. References
B. Glossary
C. Immunization & Chemoprophylaxis Requirements for Korea
D. Guidelines for the Administration of Immunizations & Chemoprophylaxis
E. Guidelines for Evaluation and Reporting of Adverse Events Related to Vaccinations and Chemoprophylaxis

DISTRIBUTION:
C

SPECIAL DISTRIBUTION:
100 - FKMD-OPS

APPENDIX A

REFERENCES

The following references have been used in the compilation of this regulation:

A. DODI 6205.2, Immunization Requirements

B. DODD 6205.3, DoD Immunization Program for Biological Warfare Defense

C. STANAG 3474, International Military Standardization Agreement on Immunizations

D. AR 40-562/AFJR 48-110/NAVMEDCOMINST 6230.15/CG COMDTINST M6320.4E, Immunizations and Chemoprophylaxis dated 01 NOV 1995.

E. AR 40-5, Preventive Medicine, dated 15 OCT 1990.

F. FM 8-33, Control of Communicable Disease Manual, 2000.

G. USFK Regulation No 690-1, dated 4 OCT 1994.

H. General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP), CDC, 2002.

I. Guide for Adult Immunization, 3rd edition, American College of Physicians, 1994.

J. Health Information for International Travel, CDC, 2001-2002 (and revised periodically).

K. Epidemiology & Prevention of Vaccine-Preventable Diseases, CDC, 7th edition, 2001.

L. Food and Drug Administration Vaccine Adverse Event Reporting System (VAERS) website: http://www.fda.gov/cber/vaers/vaers.htm

M. Vaccine Adverse Event Reporting System (VAERS) Form-1 http://www.fda.gov/cber/vaers/vaers1.pdf

N. Instructions for completing VAERS Form-1 http://www.fda.gov/cber/gdlns/vaers-1.pdf

APPENDIX B

GLOSSARY

The following is a glossary of abbreviations and terms used throughout this regulation:

ABBREVIATIONS:

ACIP	Advisory Committee on Immunization Practices
AMSA	Army Medical Surveillance Activity
AR	U.S. Army Regulation
AVIP	Anthrax Vaccine Immunization Program
CDC	Centers for Disease Control & Prevention, Atlanta
CONUS	Continental United States
DoD	Department of Defense
DODD	Department of Defense Directive
DODI	Department of Defense Instruction
DODDS	Department of Defense Dependent Schools
EEC	Emergency Essential Civilian (US)
Engerix-B	Hepatitis-B Virus vaccine manufactured by GlaxoSmithKline
FDA	U.S. Food and Drug Administration
FM	U.S. Army Field Manual
GG	Gamma Globulin
HAV	Hepatitis-A-Virus
HAVRIX	Hepatitis-A Virus vaccine manufactured by GlaxoSmithKline
HBsAB	Hepatitis-B Surface Antibody
HBV	Hepatitis-B Virus
IGIM	Immune Globulin Intramuscular
JEV	Japanese Encephalitis Vaccine
KATUSA	Korean Augmentee to the U.S. Army
Kg	Kilogram
KTO	Korean Theater of Operations
MEC	Mission Essential Civilian
MEDCOM	Medical Command
MMR	Measles, Mumps, and Rubella
M-M-R II	Measles, Mumps, and Rubella vaccine manufactured by Merck & Co., Inc.
MTF	Medical Treatment Facility
NCVIA	National Childhood Vaccine Injury Act of 1986
OPV	Oral Polio Vaccine
PHS-731	Public Health Service Form 731, International Certificates of Vaccination
RECOMBIVAX-HB	Hepatitis-B Virus vaccine manufactured by Merck & Co., Inc
ROK	Republic of Korea
SF 601	Immunization Record
SOFA	Status of Forces Agreement

STANAG	International Military Standardization Agreement
TB	Tuberculosis
US	United States
USFK	United States Forces, Korea
VAERS	Vaccine Adverse Events Reporting System
VAQTA	Hepatitis-A Virus vaccine manufactured by Merck & Co., Inc.

TERMS:

Chemoprophylaxis – The administration of a chemical, including antibiotics, to prevent the development of an infection or the progression of an infection to active manifest disease.

Force Health Protection – All measures taken to preserve and conserve the health of a fighting force.

Immunization – A substance administered to an individual that enables resistance to a particular disease, especially through preventing development of a pathogenic infection or by counteracting the effects of a microorganism.

International Certificates of Vaccination – A record of immunizations recognized worldwide that is required for international travel. It is better known as the “Yellow Shot Card” or PHS Form 731.

Korean Theater of Operations – The Korean peninsula and surrounding littoral waters.

Military Treatment Facility – Any facility in which a Service Member receives health care.

Providers – Licensed health care providers to include physicians, physicians assistants, and nurse practitioners.

APPENDIX C

IMMUNIZATION & CHEMOPROPHYLAXIS REQUIREMENTS FOR THE REPUBLIC OF KOREA

M=mandatory, R=recommended, HR*=high risk
A=available, N/A=not available

	Active Duty	KATUSA	EEC/MEC	DOD	DODDS	Family Members
Anthrax	**M**	N/A	**M**	N/A	N/A	N/A
Hepatitis A	**M**	**M**	R	A	A	A
Hepatitis B	**M**	HR	R	HR	HR	HR
Influenza	**M**	**M**	R	R	R	HR
Measles	**M**	**M**	R	R	R	R
Mumps	**M**	**M**	R	R	R	R
Rubella	**M**	**M**	R	R	R	R
Polio	**M**	**M**	R	R	R	R
Tetanus	**M**	**M**	**M**	R	R	R
Diphtheria	**M**	**M**	**M**	R	R	R
Typhoid	**M**	**M**	R	A	A	A
Japanese Encephalitis	A	A	A	A	A	A
Varicella**	HR	HR	HR	HR	HR	HR
Hemophilus influenzae type b ---------- R for < 2 y.o.						
Pneumococcal ---------- 23-valent R for > 65 y.o.						
7-valent R for young children						

* **Recommended** only for persons traveling on official orders to high-risk regions or for persons engaged in high-risk occupations. **Available** for recreational travel or persons not engaged in high-risk occupations.
** Required for healthcare workers who are not immune and recommended for those who have not had chickenpox as a child or who are not immune by serological screening. Recommended for all children at 1 year of age unless there is a history of prior disease.

NB: There is nothing in this regulation that precludes either the assignment or deployment of personnel to the KTO during Armistice or transition to war. Active duty service members and emergency essential civilians who are found to be medically exempt from further administration of a mandatory immunization will not be precluded from deploying or remaining in the theater based solely on the inability to receive such immunization. Other measures to protect these individuals are available and will be implemented to the fullest extent to protect them. The emphasis of this regulation is to provide commanders at all levels the guidance necessary to appropriately protect their personnel from the known disease threats in the KTO.

APPENDIX D

GUIDELINES FOR THE ADMINISTRATION OF IMMUNIZATIONS & CHEMOPROPHYLAXIS

1. Reference D, Immunizations and Chemoprophylaxis, provides the direct requirements for the Armed Forces Immunizations Program, establishes general principles, procedures, policies, and responsibilities for the immunizations program, and implements References A through C; and international health regulations and requirements. This regulation guides commanders and health care providers in only those areas which Reference D leaves to the discretion of the USFK Surgeon or which have been superseded by DoD directive.

2. Vaccines can be grouped into two overlapping sets of two categories: viral, bacterial, live-attenuated, and inactivated. Examples of live viral vaccines include measles, mumps, rubella, polio, yellow fever, and varicella vaccines. Bacille Calmette-Guerin (BCG), oral typhoid, and oral cholera are examples of live bacterial vaccines. Live vaccines can be administered simultaneously at different sites, or be separated in time by at least four weeks. Live vaccines generally should not be given to women who are pregnant. No inactivated vaccines recommended for USFK personnel interfere with each other or with live vaccines. Contraindications to vaccines are summarized below:

Summary of Vaccine Contraindications

Condition	Contraindication to	
	Live Vaccine	Inactivated Vaccine
Severe allergy to component	YES	YES
Pregnancy	YES*	YES**
Immunosuppression	YES	NO
Severe Illness	YES	YES
Mild Illness (URI, OM, etc)	NO	NO
Recent blood product	YES	NO

*Except yellow-fever vaccine in certain situations
** Not a strict contraindication per ACIP, but DoD policy is to avoid immunization in those pregnant or possibly pregnant unless clearly needed.

3. Vaccines should be administered as close as possible to the recommended administration direction and schedule. Do not 'restart' a series if an intermediate dose is late. In general, increasing the time interval between doses of a multi-dose vaccine does not diminish the effectiveness of the vaccine. However, administering doses of a multi-dose vaccine at intervals less then that recommended may interfere with the immune response and not provide protection against disease.

4. Immunizations for USFK personnel and emergency essential employees are listed in Appendix C. This list is derived from Table 1 of Reference D, with DoD and USFK

Surgeon directives included. Health care workers, to include KATUSAs, are addressed in 21.3 (page 6) of Reference D.

5. Vaccines differ in many ways, to include their route of administration, duration of protection, contraindications, and side effects. Several aspects of the immunizations listed in Appendix C are discussed below, including the relative merits of screening to determine antibody status before immunizing versus empiric or universal immunization. Only vaccines of interest to USFK health care providers are discussed. Refer to the vaccine package insert, pharmacy, or the FKMD-PM Consultant for additional questions.

a. **Cholera.** The inactivated, injectable cholera vaccine is a poorly tolerated vaccine of low efficacy and short duration. It is no longer manufactured in the United States and is not recommended for Korea.

b. **Hepatitis-A Virus (HAV).** On 12 AUG 96, the DoD "...established the goal of achieving HAV immunization of the total Active Duty and Selective Reserve force by December 31, 1998." There are two brands of this inactivated virus vaccine. 'VAQTA' (Merck & Co., Inc.) and 'HAVRIX' (GlaxoSmithKline) are both well-tolerated vaccines of high efficacy. They are given as a two-shot series at 0 and >=6 months, conferring life-long immunity. Protective antibody is present in 70% of those immunized as soon as 14 days after the first immunization. The HAV vaccines may be used interchangeably.

c. **Hepatitis-B Virus (HBV).** HBV vaccine is required for all active-duty USFK service members and all health care providers in USFK MTFs. HBV is recommended for all children and adolescents as routine immunization and for all persons at high risk for hepatitis B to include:

- Persons with occupational risk of exposure to blood or blood-contaminated body fluids.
- Clients and staff of institutions for the developmentally disabled.
- Hemodialysis patients.
- Recipients of clotting-factor concentrates.
- Household contacts and sexual partners of those chronically infected with HBV.
- Family members of adoptees from countries where HBV infection is endemic, if adoptees are HBsAg+.
- Certain international travelers.
- Injecting drug users.
- Men who have sex with men.
- Heterosexual men and women with multiple sex partners or recent episode of a sexually transmitted disease.
- Inmates of long-term correctional facilities.
- All unvaccinated adolescents.

There are two brands of genetically engineered HBV vaccine for use in adults. 'RECOMBIVAX' (Merck & Co., Inc.) and 'ENGERIX-B (GlaxoSmithKline) are both well-tolerated vaccines of high efficacy. They are given as a three-shot series on a 0, 1, >6 months schedule which confers life-long immunity. These two HBV vaccines may be

used interchangeably, after adjusting for microgram content. It is not cost effective to determine the HBV immune status of US service members. It is, however, felt to be cost effective to determine the HBV immune status in KATUSA and Korean national health care workers. Those Korean health care workers who are HBsAb-positive require no HBV immunization. Those who have no evidence of exposure to HBV should be immunized.

d. **Immune Globulin Intramuscular (IGIM, 'gamma globulin,' GG).** IGIM is no longer recommended for passive immunity against HAV. HAV vaccine is now used to provide active immunity against HAV. Health care workers who wish to use IGIM for post-exposure prophylaxis (e.g., with HAV or measles) should contact the FKMD-PM Consultant.

e. **Japanese Encephalitis virus (JEV).** JEV vaccine is an inactivated vaccine derived from infected mouse brain. It is given in a three-dose series on a 0, 7, and 30-day schedule. While JEV is enzootic in Korea, it present no significant impact on force readiness as documented by lack of US military disease burden. JEV may be required if conditions change.

f. **Measles, Mumps, and Rubella (MMR).** Although measles, mumps, and rubella vaccines are all available as individual vaccines, the most common preparation, 'M-M-R II' (Merck & Co., Inc.), contains all three live viruses. Two doses of MMR vaccine, given at least one month apart, is felt to provide life-long immunity (by immunization or natural infection) against measles and mumps. For adults, one dose is sufficient.

g. **Rabies.** No variance with Reference D.

h. **Tetanus-diphtheria (Td).** A Td booster should be given to everyone every 10 years. Patients with dirty (contaminated) wounds should receive a booster if their last Td immunization was greater than 5 years before the injury.

i. **Typhoid.** No variance with Reference D. Frequency of booster requirement and appropriate age for administration differs by vaccine type and manufacturer.

j. **Varicella (Chickenpox).** Current ACIP recommendations will be followed regarding the use of varicella immunization. All health care workers will either have documented evidence of immunity or will receive varicella immunization. Evidence of immunity will consist of a physician's diagnosis of varicella, a reliable history of the disease, or serologic evidence of immunity. Varicella vaccine is recommended for the following personnel:

- All children at 1 year of age unless there is a history of prior disease.
- Persons of any age without a reliable history of varicella disease or vaccination, or who are seronegative for varicella.
- Susceptible adolescents and adults living in households with children.
- All susceptible health care workers.
- Susceptible family contacts of immunocompromised persons.

· Susceptible persons in the following groups who are at high risk for exposure:
- persons who live or work in environments in which transmission of varicella is likely
(e.g., teachers of young children, day care employees, residents and staff in institutional settings) or can occur (e.g., college students, inmates and staff of correctional institutions, military personnel)
- nonpregnant women of childbearing age
- international travelers

6. Chemoprophylaxis. Other policies or regulations generally cover chemoprophylaxis recommendations, such as Malaria, TB, and Hepatitis. Programs of interest to USFK health care workers are discussed below. Chemoprophylaxis of other infectious diseases are described in Reference D, and shall be carried out in accordance with FM 8-33, Control of Communicable Diseases Manual) in consultation with FKMD-PM.

a. **Malaria.** The USFK Surgeon issues anti-malarial chemoprophylaxis recommendations on an as-needed basis. Malaria in the ROK at this time is entirely due to *Plasmodium vivax* and is sensitive to chloroquine. Terminal prophylaxis with primaquine is required for all those who were felt to be at great enough risk to institute chloroquine therapy. G6PD deficiency will be checked prior to anyone being started on primaquine.

8. Biological Warfare Defense.

a. In SEP 1998, USFK implemented the Anthrax Vaccine Immunization Program (AVIP) for all service members and EECs. Korea has been identified as a high-threat area, and as such, requires all personnel be immunized accordingly. The anthrax vaccine is an inactivated bacterial vaccine licensed by the FDA in 1970. It is given in a six-shot series on a 0, 2, 4 week; 6, 12, 18-month schedule. Annual boosters are required after the initial six-shot series. For initial series and boosters, subsequent doses of vaccines will be administered based on the date the last dose was given, not when it was originally scheduled, in order to avoid the possibility of administering the vaccine closer than the recommended interval from the previous dose. Anthrax vaccine will not be given during pregnancy, except under post-exposure or emergency conditions.

b. The USFK Surgeon on an as needed basis will provide recommendations on other biological warfare defense issues in consonance with Reference B.

APPENDIX E

GUIDELINES FOR EVALUATION AND REPORTING OF ADVERSE EVENTS RELATED TO VACCINATIONS AND CHEMOPROPHYLAXIS

1. The Vaccine Adverse Event Reporting System (VAERS) is a Cooperative Program for Vaccine Safety of the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). VAERS is a post-marketing safety surveillance program, collecting information about adverse events (side effects) that occur after the administration of US licensed vaccines. Reports are welcome from all concerned individuals: patients, parents, health care providers, pharmacists, and vaccine manufacturers. VAERS accepts reports of adverse events that may be associated with U.S. licensed vaccines from health care providers, manufacturers, and the public. The FDA continually monitors VAERS reports for any unexpected patterns or changes in rates of adverse events. The report of an adverse event to VAERS is not proof that a vaccine caused the event. More than ten million vaccinations per year are given to children less than one year old, usually between 2 months and 6 months of age. At this stage of development infants are at risk for a variety of medical events and serious childhood illnesses. These naturally occurring events include fevers, seizures, sudden infant death syndrome (SIDS), cancer, congenital heart disease, asthma, and other conditions. Some infants coincidentally experience an adverse event shortly after a vaccination. In such situations an infection, congenital abnormality, injury, or some other provocation may cause the event. Because of such coincidences, it is usually not possible from VAERS data alone to determine whether a particular adverse event resulted from a concurrent condition or from a vaccination - even when the event occurs soon after vaccination. Doctors and other vaccine providers are encouraged to report adverse events, whether or not they believe that the vaccination was the cause. If the VAERS data suggest a possible link between an adverse event and vaccination, the relationship may be further studied in a controlled fashion.

2. Providers will become familiar with the processes associated with the VAERS Reporting System. IAW DoD policy for any immunization, providers will document in detail severe local or systemic reactions in the individual's medical record. Mandatory information consists of identification of the biological agent, the lot number and manufacturer, the date of administration, the name and location of the medical facility, and the type and severity of the reaction. Providers will report all severe and systemic adverse reactions by FAX to the 121st General Hospital Clinical Pharmacy, 737-6895. The Health and Human Services VAERS Form-1 (ANNEX 1) must be used.

3. VAERS reports are usually submitted by health care providers, vaccine manufacturers, and vaccine recipients (or their parents/guardians). Any one can report to VAERS. Patients, parents, and guardians are encouraged to seek the help of a health-care professional in reporting to VAERS. Although NCVIA only requires reporting of the post-vaccination adverse events identified in Annex A of this guideline,

VAERS encourages **all** reporting of **any** clinically significant adverse event occurring after the administration of **any** vaccine licensed in the United States.

4. The VAERS Form-1 (ANNEX 1) can also be downloaded from the Internet at the following uniform resource locator: http://www.fda.gov/cber/vaers/vaers1.pdf. Instructions for completion of the VAERS Form-1 can be downloaded from the Internet at the following uniform resource locator: http://www.fda.gov/cber/gdlns/vaers-1.pdf. There is a toll-free VAERS information line **1-800-822-7967** to obtain copies of VAERS forms or to receive assistance from a VAERS staff member in filling out the VAERS form. Other services include general information on VAERS, information about vaccines from a health care professional and mailed copy of the Reportable Events Table.

5. All VAERS forms will be submitted to the 121st General Hospital Clinical Pharmacy, FAX 737-6895. VAERS reports will be submitted in conjunction with all regularly reported adverse drug reactions at the regularly scheduled P&T Committee meeting. Completed VAERS Form-1 will then forwarded to the FDA's Vaccine Adverse Event Reporting System, PO Box 1100, Rockville, MD 20849-1100.

6. Vaccine adverse events are also reportable to the Army Medical Surveillance Activity as part of Tri-Service Reportable Conditions. The 121st General Hospital Clinical Pharmacy will forward a copy of all VAERS forms to the USFK Preventive Medicine Consultant (FKMD-PM) (FAX 736-3028) for reporting to the AMSA.

7. Any patient with a vaccine adverse event for whom an exemption from further administration of the vaccine is contemplated will be referred to the immunology/allergy consultant at the 121st General Hospital. The immunology/allergy consultant will be the final medical authority to determine the medical indications for either temporary or permanent exemption from further immunizations of the offending vaccine.

8. The 18th MEDCOM Pharmacy and Therapeutics (P&T) Committee will provide oversight of VAERS reports to detect any trends, implement appropriate control measures, and to recommend courses of action for identified problem vaccinations.

3 Annexes
1 – Form VAERS-1
2 – Anthrax Vaccine Adverse Event Supplemental Form
3 – Post-Vaccination Events Requiring Reporting by NCVIA

VAERS

ANNEX 1 - VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number _____
Date Received _____

Patient Name:
Last First M.I.
Address
City State Zip
Telephone no. (____) _____

Vaccine administered by (Name):
Responsible Physician _____
Facility Name/Address
City State Zip
Telephone no. (____) _____

Form completed by (Name):
Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other
Address *(if different from patient or provider)*
City State Zip
Telephone no. (____) _____

1. State
2. County where administered
3. Date of birth mm / dd / yy
4. Patient age
5. Sex ☐ M ☐ F
6. Date form completed mm / dd / yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
☐ Patient died (date mm / dd / yy)
☐ Life threatening illness
☐ Required emergency room/doctor visit
☐ Required hospitalization (_____days)
☐ Resulted in prolongation of hospitalization
☐ Resulted in permanent disability
☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination mm / dd / yy
Time _____ AM PM

11. Adverse event onset mm / dd / yy
Time _____ AM PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
☐ Private doctor's office/hospital ☐ Military clinic/hospital
☐ Public health clinic/hospital ☐ Other/unknown

16. Vaccine purchased with:
☐ Private funds ☐ Military funds
☐ Public funds ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medial conditions(specify)

20. Have you reported this adverse event previously?
☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

Only for children 5 and under

22. Birth weight _____ lb. _____ oz.

23. No. of brother and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/Immunization project

24. Mfr./imm. proj. report no.

25. Date received by mfr./imm.proj.

26. 15 day report? ☐ Yes ☐ No

27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

Form VAERS-1(FDA)

"**Fold in thirds, tape & mail - DO NOT STAPLE FORM"**

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

BUSINESS REPLY MAIL

FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE

VAERS
P.O. Box 1100
Rockville MD 20849-1100

DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed)

GENERAL

Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)

Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.

Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.

These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine orthat person's legal representativewill not be made available tothe public, but may be available to the vaccinee or legal representative.

Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms diagnosis, treatment and recovery should be noted.

Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.

Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please

Item 11: indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.

Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.

Item 13: List ONLY those vaccines given on the day listed in Item 10.

Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.

Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.

Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.

Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).

Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.

Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one priorvaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.

Item 26: This space is for manufacturers' use only.

ANNEX - 2 Anthrax Vaccine Adverse Event Supplemental Form

SSN of recipient: _____ Date of adverse event: _____

Service: O USA O USN O USAF Date of vaccination: _____
O USMC O Other

Location (facility) of adverse event: _____
_____

Meets criteria for required reporting: O Yes O No

Patient hospitalized: O Yes O No

Patient on quarters > 24hrs: O Yes O No

Classification of reaction:
O Mild local reaction
O Moderate local reaction
O Large local reaction
O Systemic reaction

Suspected lot contamination: O Yes O No If yes, lot number: _____

Form submitted by: O AMSA O NEHC O IERA/RSRH

Date form submitted to AMSA: _____

Comments:
_____
_____
_____
_____
_____
_____
_____
_____

The above information on anthrax vaccine adverse event reports (VAERS) is to be completed by the reportable disease project officer located at AMSA (Army), NEHC (Navy) and IERA/RSRH (Air Force). This supplemental form should be submitted along with a copy of the Form VAERS-1 report to AMSA [Ph: (202) 782-0471, Fax: -0612, DSN: 662-].

ANNEX - 3

Post-Vaccination Events Requiring Reporting by NCVIA

Source: US Food and Drug Administration
http://www.fda.gov/cber/vaers/eventtab.htm

Vaccine / Toxoid	Event	Onset Interval
Tetanus in any combination; DTaP, DTP, DTP-HiB, DT, Td, TT	A. Anaphylaxis or anaphylactic shock	7 days
	B. Brachial Neuritis	28 days
	C. Any sequela (including death) of above events	No limit
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	see package insert
Pertussis in any combination; DTaP, DTP-HiB, P	A. Anaphylaxis or anaphylactic shock	7 days
	B. Encephalopathy (or encephalitis)	7 days
	C. Any sequela (including death) of above events	No limit
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	see package insert
Measles, mumps and rubella in any combination; MMR	A. Anaphylaxis or anaphylactic shock	7 days
	B. Encephalopathy (or encephalitis)	15 days
	C. Any sequela (including death) of above events	No limit
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	see package insert
Rubella in any combination; MMR, MR,R	A. Chronic arthritis	42 days
	B. Any sequela (including death) of above events	No limit
	C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	see package insert
Measles in any combination; MMR, MR,M	A. Thrombocytopenic purpura	30 days
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient	6 months
	C. Any sequela (including death) of above events	No limit
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	see package insert

ANNEX - 3

Post-Vaccination Events Requiring Reporting by NCVIA

Source: US Food and Drug Administration
http://www.fda.gov/cber/vaers/eventtab.htm

Oral Polio (OPV)	A. Paralytic polio --in a non-immunodeficient recipient --in an immunodeficient recipient --in a vaccine-associated community case	 30 days 6 months No limit
	B. Vaccine-Strain Polio Viral Infection --in a non-immunodeficient recipient --in an immunodeficient recipient --in a vaccine-associated community case	 30 days 6 months No limit
	C. Any sequela (including death) of above events	No limit
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	see package insert
Inactivated Polio(IPV)	A. Anaphylaxis or anaphylactic shock	7 days
	B. Any sequela (including death) of above events	No limit
	C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	see package insert
Hepatitis B	A. Anaphylaxis or anaphylactic shock	7 days
	B. Any sequela (including death) of above events	No limit
	C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	see package insert
Hemophilus influenzae type b	A. Early-onset Hib disease	7 days
	B. Any sequela (including death) of above events	No limit
	C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	see package insert
Varicella	A. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	see package insert