



Update on Military Vaccination Programs: *Providing a Continuum of Care in Immunizations*

Presented to:

Defense Health Board

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Director, Military Vaccine Agency

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UNCLASSIFIED



BRIEFING OUTLINE

PURPOSE: To provide information on the Military Vaccine Agency's operations, current DoD policies and opportunities for training with Immunization University.

1. MILVAX Mission
2. Vaccine Healthcare Centers Network
3. Anthrax Vaccination Program
4. Smallpox Vaccination Program
5. Other Vaccines
6. Immunization University
7. Questions / Discussion



MILVAX MISSION

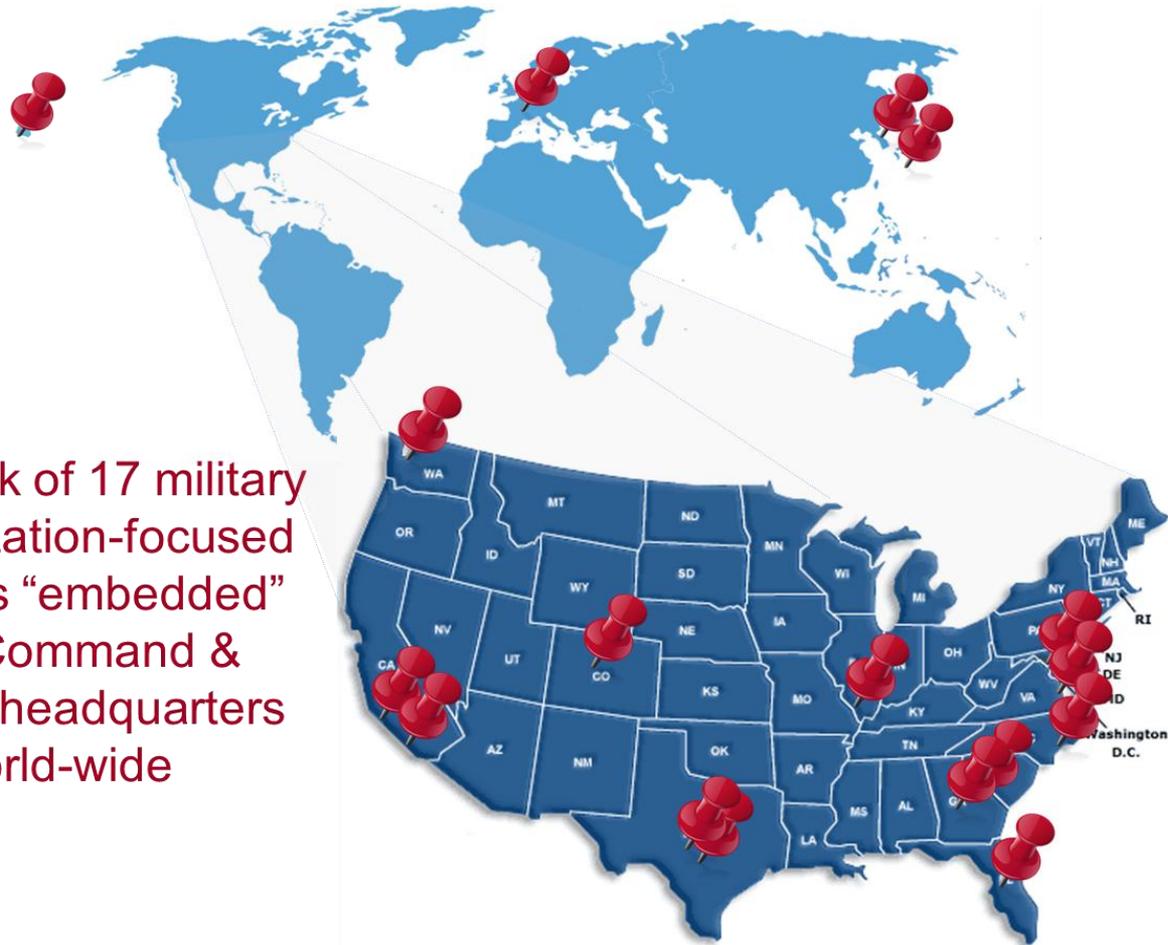


- Synchronize information, deliver education, and coordinate U.S. military immunization programs worldwide
- Assist senior leaders with policy development
- Promote quality in immunization delivery
- Enhance scientific understanding of vaccines
- Provide specialized clinical management of complex adverse events



MILVAX REGIONAL ANALYSTS

A network of 17 military immunization-focused analysts “embedded” with Command & Control headquarters world-wide





“Caring for Those Who Serve: Before & After Immunizations”

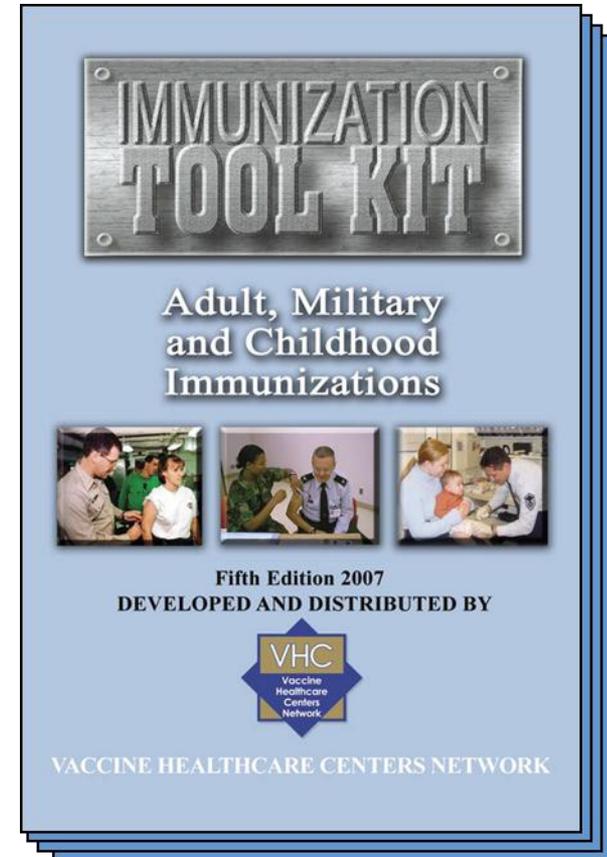
- Vaccine Clinical Support & Consultation Services
 - Adverse events & efficacy case management, medical exemptions
- Vaccine Safety
 - Surveillance, reporting & adverse events registry, long term follow-up
- Immunization Education
 - For Health Care Workers & Service Members, Beneficiaries, DoD, etc.
 - Integrate with Immunization University
- Support for Research
 - Clinical focus, post-licensure, to “enhances vaccine safety, efficacy & acceptability”
 - Adult military vaccine related gaps
- Advocacy
 - For quality immunization healthcare delivery
 - For care, compassion & fairness
- Outreach & Support
 - 24/7 Clinical Call Center
 - Secure Consultative E-mail



VACCINE HEALTHCARE CENTERS NETWORK

Education & Outreach

- 24hr DoD Call Center support
- Immunization Tool Kit
- Project Immune Readiness
- Immunization University
- VHC Network Website (vhcinfo.org)
- Secure web-based Q&A for patients & providers
- Knowledge, Attitudes & Beliefs Surveys





VACCINE HEALTHCARE CENTERS NETWORK

Challenges: Current & Future



- Complex (mandatory and voluntary) vaccination programs
 - **Service members AD/Reserve:** **2,400,000**
 - **DoD employees** **> 2,000,000**
 - **Beneficiaries** **> 6,000,000**
 - **Homeland defense support** **Millions++**
- Program Management and Policy Development
 - Increasing complexities
 - DOD global mission with evolving challenges
 - Competing resources to support missions
- Vaccine Safety, Efficacy and Acceptability
 - Increasing complexities: clinical, educational, science, etc
 - Changing perceptions towards diseases and vaccines
 - Surveillance: Life-Cycle, Ongoing
 - Expanding expectations with existing resources





ANTHRAX VACCINATION PROGRAM POLICY

- Start Mar 98; resume Sep 02; expand Jun 04
- Injunction Oct 04; Emergency Use Authorization (EUA) Jan 05; FDA issued Final Order Dec 05
- DoD Policy Review between Dec 05 – Oct 06

- **DEPSECDEF announced new policy on 12 Oct 06:**
 - **Mandatory anthrax vaccinations for personnel deploying to higher risk areas (U.S. Central Command and Korea) and for other select units with unique missions. Includes some emergency-essential contractors and DoD civilians**
 - **Voluntary anthrax vaccinations for family members; other U.S. civilians in higher risk areas; and anyone that received one or more doses since 1998**

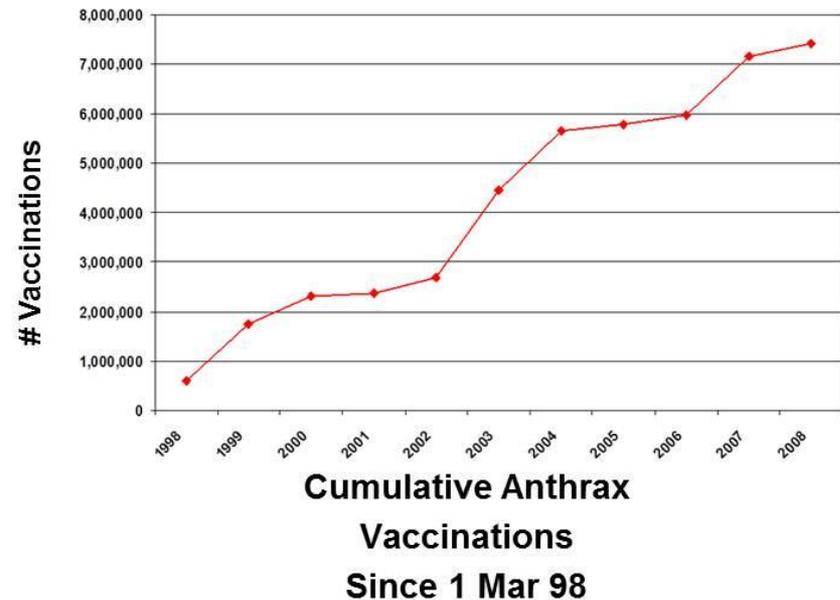
- ASD(HA) approved Service plans on 8 Feb 07
- The USD(P&R) approved a change in policy for the pre-deployment administration of anthrax and smallpox vaccinations from 60 to 120 days in Sep 07.





Anthrax Vaccinations

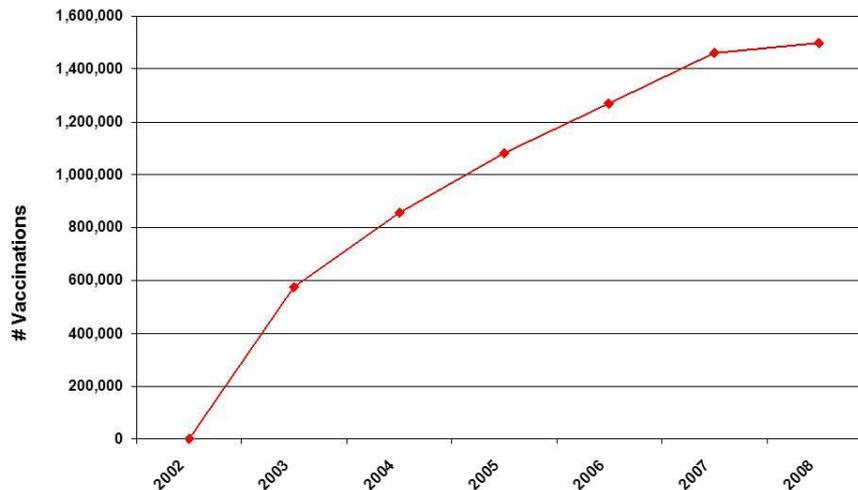
- **Over 7.4 million doses to over 1.9 million personnel since 1998**
- **FDA-approved vaccine production steady; Strategic Stockpile**
- **Safety: 26 published studies, on-going studies, plus concurrence of eight independent reviews**
- **Pending dose-reduction / Route change (FDA)**





SMALLPOX VACCINATION PROGRAM

- Over 1.6 million personnel screened; 1.5 million vaccinated since 2002
- Policy: Those at highest risk – CENTCOM; Korea; Special Units/Teams
- Safety: 3 cases eczema vaccinatum; 61 cases contact transfer; 168 cases myo-pericarditis (suspect -26, probable - 137, confirmed – 5)



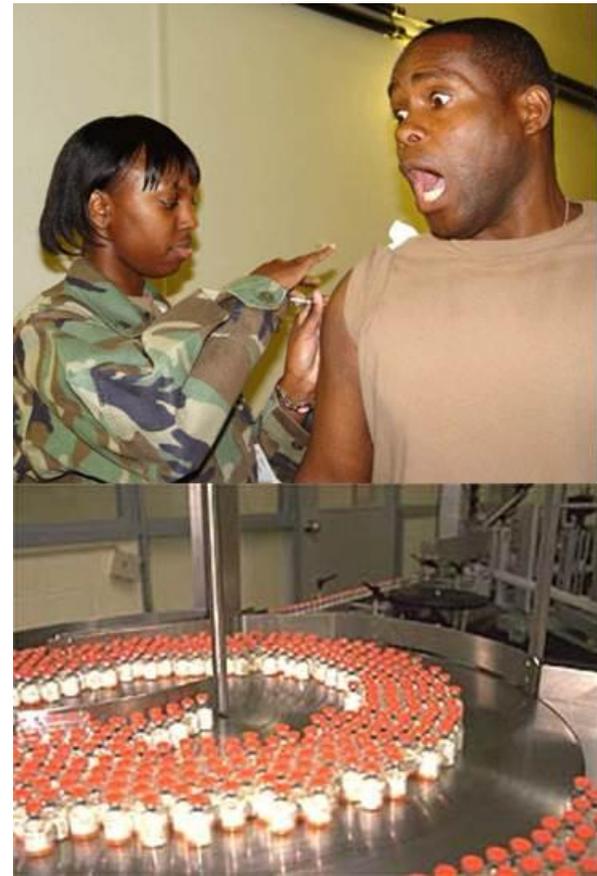
**Cumulative Smallpox
Vaccinations
Since 2002**

DEERS data as of 12 Apr 08



INFLUENZA VACCINATION PROGRAM

- Continue to protect the force – greater emphasis with pandemic concerns
- Status 2007-2008 season: over 90%
- Vaccine procurement and distribution - Defense Supply Center Philadelphia (DSCP); 3.5M doses for 2007-2008
- DoD sites used seasonal flu drive for “Mass Vaccination” training (pandemic preparedness – lessons learned)
- Change in intranasal vaccine (FluMist®) storage for 2007-2008 season
- New civilian health care personnel policy



PANDEMIC INFLUENZA VACCINE

- A/H5N1 vaccine: DoD owns 1.6M doses @ 90 mcg from Sanofi Pasteur, based on 2004 virus from Vietnam (“1203 vaccine”) – clade 1
 - FDA licensed vaccine on 17 Apr 07
 - About 1.1M doses bottled
- Smaller clade-2 purchase and clade-3 vaccines under development & testing
- Assistant Secretary of Defense (Health Affairs) approved the “DoD Pre-pandemic Influenza Vaccine Policy” on 10 Aug 07
- Concept: Lab Workers; Begin immunizing others at WHO Phase 4





U.S. MILITARY IMMUNIZATION – TODAY

Endemic Disease Threats

- (universal, occupational, +/- or geographic)
- Hepatitis A
- Hepatitis B
- Influenza A&B
- Japanese encephalitis (**replacement**)
- Measles, mumps, rubella
- Meningococcal A,C,Y,W-135

Papillomavirus (HPV)

- Poliomyelitis
- Rabies
- Rotavirus (infants)
- Tetanus, diphtheria, **pertussis**
- Typhoid fever
- Varicella (chickenpox)
- Yellow fever

Bioweapon Threats

- Anthrax
- Smallpox (vaccinia)

Desirable:

- Adenovirus types 4, 7
- Botulism
- Meningococcal group B
- Plague
- Malaria
- ...*Et cetera*

- Collection of resources to enhance the skills of professionals and paraprofessionals. “Imz U” offers training through distance learning and on-site classes.
- Training Resources
 - Project Immune Readiness (50 hours)
 - Immunization-Allergy Technician Course
 - Immunization Toolkit
 - Immunization Tracking System Training
 - Instructional Video Presentations
 - *et cetera*
- Clinic Quality Improvement Program (CQIP)
- “Six-Sided” Training & Competency Files
- Policies & Procedures (prototype SOPs)
- Communication Tools
- Clinical Guidelines for Managing Adverse Events
- Directory of Immunization Clinics





MILVAX Website

Address <https://www.vaccines.mil> -or- www.vaccines.army.smil.mil

Thursday, April 17, 2008 4:24:19 PM ET

What's New | Quick Reference | Contact Us | Site Map

Streaming Smallpox Briefings Now Available



DoD Smallpox Briefings are now available in a streaming multimedia format wherever you see the Red, White & Blue MULTIMEDIA button. Healthcare providers are encouraged to register for a MyImzU account to receive credit.

DoD Transitioning to New Smallpox Vaccine

In early 2008, DoD is transitioning from Wyeth's Dryvax brand of smallpox vaccine to Acambis' ACAM2000 brand of smallpox vaccine. ACAM2000 is a vaccine licensed and approved by the FDA for protection against smallpox.

Maintaining optimum health and well-being of Service members is our top priority. Smallpox disease is contagious, deadly, and would disrupt military readiness. Smallpox vaccination is the best protection against the threat of smallpox. The DoD's smallpox vaccination program is part of our national defense strategy to safeguard Americans against a biological attack.

The current DoD policy remains unchanged, smallpox vaccinations are still mandatory for those in higher risk areas.

DoD Resumes Mandatory Anthrax Vaccinations for Select Groups

FDA Approves New Vaccine to Prevent Gastroenteritis Caused by Rotavirus

On 3 Feb 08, the FDA announced the approval of Rotarix, the second oral U.S. licensed vaccine for the prevention of rotavirus, an infection that causes gastroenteritis (vomiting and diarrhea) in infants and children. Rotarix is a liquid and given in a two-dose series to infants from 6 to 24 weeks of age.

Vaccine-Only MMQC Listserv Now Available

You can now register to receive only vaccine-related MMQC messages. USAMMA has just modified their Listserv rules to allow you to sign up for specific message threads, including Vaccines.

Log on & register, or change your subscription preferences now.

2008 Recommended Immunization Schedule for Persons Age 0-18 Years Released

The childhood and adolescent immunization schedule and the catch-up immunization schedule for 2008 have been approved by Advisory Committee on Immunization Practices (ACIP), American Academy of Family Physicians (AAFP), and the American Academy of Pediatrics

National Infant Immunization Week



National Infant Immunization Week is an annual observance to highlight the importance of protecting infants from vaccine-preventable diseases and celebrate the achievements of immunization programs in promoting healthy communities. Since 1994, NIIW has served as a call to action for parents, caregivers, and healthcare providers to ensure that infants are fully immunized against 14 vaccine-preventable diseases.

Vaccine Healthcare Centers Network



Are you a Vaccinee with a medical problem caused by a vaccine? Do you have questions about medical exemptions? Are you a Health Care

Over 1200 Unique Visitors per Day





MILVAX Website Cont'd.

31 DISEASES

MILVAX

Wednesday, August 09, 2006 9:51:04 AM ET quick ref

Home

Vaccines - Diseases

General Vaccine

Adenovirus

Anthrax

Botulism

Chickenpox

Diphtheria

DTaP, Td, Tdap

Haemophilus B

Hepatitis A

Hepatitis B

Human Papillomavirus

Influenza (pandemic)

Influenza (seasonal)

Japanese encephalitis

Lyme Disease

Measles

Meningococcal

Mumps

Pertussis

Plague

Pneumococcal

Polio

Rabies

Rotavirus

Rubella

Shingles

Smallpox

Tetanus

Tuberculosis (TB)

Tularemia

Typhoid

Yellow Fever

ANthrax

Bacillus anthracis

www.anthrax.mil **AVIP**

Anthrax is an acute infectious disease of animals that can be secondarily caused by a bacterium (Bacillus anthracis) that primarily affects sheep, and is almost always fatal in animals. The bacillus produces toxins that kill and accumulate in the body's tissues. Anthrax spores, which can survive for animals typically contract the disease while grazing. Transmission to humans contact with infected animals but can also occur through eating meat from air laden with the spores of the bacilli. The disease is almost entirely individuals who handle hides of animals (e.g., farmers, butchers, and veterinarians).

NEWS

- Reuters 31 Jul 06: Western Canada anthrax outbreak worst in decades
- Washington Post 08 Jan 06: Anthrax Victim Says He's Ready to Perform

POLICIES

- Continuation of the Anthrax Vaccine Immunization Program (AVIP) PDF 22 Dec 05
Author: Winklerwerder
- DoD Immunization Program for Biological Warfare Defense AFEB 2005-06 PDF 22 Aug 05
Author: Armed Forces Epidemiological Board
- Exception to Policy for Anthrax Vaccination PDF 16 Aug 05
Author: Chu
- Exception to Policy for Anthrax Vaccination of Forwarded Deployed Naval Forces (FDNF) and III Marine Expeditionary Force (III MEF) in the Resumption of the Anthrax Vaccination Program (AVIP) under Emergency Use Authorization (EUA)

Rx CLINICAL

- Safety Review PDF 06 Mar 06
Detailed Safety Review of Anthrax Vaccine Adsorbed
- Anthrax Basics 29 Jan 04
- The National Academy of Sciences: The Anthrax Vaccine: Is It Safe? Does It 28 Jan 04

ACIP GUIDELINES

- Use of Anthrax Vaccine in the United States PDF 15 Dec 00
Recommendations of the Advisory Committee on Immunization Practices (ACIP)

AFEB RECOMMENDATIONS

- DoD Immunization Program for Biowarfare Defense 22 Aug 05
Recommendations of the Armed Forces Epidemiological Board (AFEB)

www.health.mil

U.S. Department of Defense
Military Health System

In the News: Wall Street Journal: Pentagon Seeks Battlefield Device to Diagnose Brain Injury Stars and

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All

- Marine Amputee Diver Posted On: 4/21/2008
- Regenerative Medicine Announcement: Part 1 of 2 Posted On: 4/21/2008
- Regenerative Medicine Announcement: Part 2 of 2 Posted On: 4/20/2008
- Col. Loree Sutton on the RAND Study Posted On: 4/18/2008
- Surgeons General Testify Posted On: 4/18/2008
- SecDef Comments Posted On: 4/16/2008
- Honoring Our Heroes - Bataan Memorial Death March Posted On: 4/15/2008
- Medical Simulator

Influenza and You

Did you know that seasonal flu affects up to 5 million people each year? Learn about the different strains and symptoms of influenza- and the vaccines developed to combat them. For more info, visit Vaccines.mil.

Category: Quick Clips
Posted On: 3/4/2008
Source: Military Vaccine Agency

Smallpox Healthcare Provider's Briefing - Microsoft Internet Explorer

Address: https://training.vaccines.mil/pshp/

MILVAX Screening

All potential vaccinees must be screened

- Carefully read & complete screening form; medical professionals available to explain in layman's terms
- Ask for clarification if unsure how to answer screening questions
- Contact family members who may know about childhood history of recurrent rashes like eczema
- Talk to close contacts and family members about the vaccination program and safety precautions
- Ask for assistance at any point, if you or your Family members have safety concerns

Screening form image showing various fields and instructions.

Smallpox Healthcare Provider's Briefing - Andrew Brown, Medical Agency

Outline Notes

Sensitization should be verified and completed before the screening form. The help assembly document that is used to administer the vaccine.

Family members of vaccinees who may have a history of recurrent rashes like eczema should be contacted and advised of the vaccination program and the safety precautions that need to be observed.

Talk to close contacts and family members about the vaccination program and safety precautions.

WWW.VACCINES.MIL * WWW.ANTHRAX.MIL * WWW.SMALLPOX.MIL





TOP FIVE INITIATIVES

- Transition to ACAM 2000 Smallpox Vaccine
- Anthrax Vaccine (New Distribution/Dose Reduction/Route Change)
- Immunization Tracking Systems (AHLTA Module)
- Outreach to 100% Personnel Providing DoD Immunizations
- DoD Basic Standards for Immunization Training

QUESTIONS?



ARMY EXECUTIVE AGENT RESPONSIBILITIES

DoD Directive 6205.02E (dated 19 Sep 06)

- **The Secretary of the Army shall serve as Executive Agent for the military immunization program, funded through the centralized Defense Health Program. The Executive Agent shall:**
 - Establish a **MILVAX Office** to synchronize, integrate, and coordinate efforts in immunization services for all DoD Components. The purpose of these efforts is to facilitate and promote the quality of immunization policy, implementation, education, distribution, risk communication, administration, clinical services, safety surveillance, and program evaluation.
 - Provide a comprehensive access point for information, education resources, and coordination of immunization-related activities for the Military Services.
 - Monitor resources used in performing assigned responsibilities and functions.
 - Develop uniform procedures to identify, report, and evaluate vaccine-associated adverse events.





CONTINUUM OF CARE IN IMMUNIZATION MODEL

