DoD Military Vaccine (MILVAX) Programs & Policy Update

Presented to:

Defense Health Board

Colonel Randall G. Anderson
Director, Military Vaccine Agency

3 May 2007

UNCLASSIFIED
PURPOSE: To provide the Defense Health Board with an update on the Military Vaccine Agency mission, current immunization policies and ongoing initiatives with the Department of Defense.

1. MILVAX Mission

2. Anthrax Vaccination Program

3. Smallpox Vaccination Program

4. Other Vaccines

5. Initiatives / Challenges

6. Questions
Vaccines Are Different!
DoD Directive 6205.02E (dated 19 Sep 06) directs “The Secretary of the Army shall serve as Executive Agent for the military immunization program…”

Also…

“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.”
Immunizations and Chemoprophylaxis

AR 40–562, BUMEDINST 6230.15A, AFJI 48–110, CG COMDTINST M6230.4F (Approved 29 Sep 06)

- Role for the Military Vaccine Office (para 1-4d).
- Standards for military immunization delivery, including quality improvement mechanisms (para 2-1 and app B).
- Establishes that electronic immunization tracking systems are the preferred record for immunization data (para 2-7).
- managing lost immunization records (para 2-7c).
- Procedure for immunization during initial military training (para 3-1).
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
MILVAX REGIONAL ANALYSTS

17 Sites Worldwide

FT Lewis, WA
Glen Porter

Camp Pendleton, CA
Dave Cortez

Naval Base San Diego:
Joe Young

Ft Sam Houston, TX
Jim Knobel
John Seipp

Peterson AFB, CO
Terrance Wherry
(SPACECOM/NORTHCOM)

Scott AFB, IL
Suzy Walker
TRANSCOM)

Walter Reed AMC, DC
Troy Ricks

Norfolk, VA
Allen Wright

Camp Lejeune, NC
Cornelius Rowe

Ft Gordon, GA
Chin Wang
(SOUTHCOM)

Atlanta, GA
Ollie Thomas
(FORSCOM)

Mac Dill AFB, FL
Doug Phelps
(CENTCOM)
MILVAX ANALYSTS

Heidelberg, Germany
Carolyn Hurst
(EUCOM)

Seoul, Korea
Bill Nieding
(USFK)

Okinawa Japan
Tom Kanaris
(USFJ)

Tripler AMC, Hawaii
Lance Golder
(PACOM)
http://www.anthrax.mil

Your health and safety are our #1 concerns.

The anthrax vaccine is safe and effective.

The threat from anthrax is deadly and real.

Vaccination offers a layer of protection in addition to antibiotics and other measures needed for certain members of the Armed Forces.
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
Military Vaccine Agency (MILVAX) Overview

ANTHRAX VACCINATION PROGRAM

• Over 6 million doses to over 1.5 million personnel since March 1998
• FDA-approved vaccine production steady, inventory accumulating
• Safety: 26 published studies, on-going studies, plus concurrence of eight independent reviews
• Pending dose-reduction / Route change (FDA)

Cumulative Anthrax Vaccinations Since 01 Mar 98

DEERS data as of 25 Apr 07
- Smallpox is contagious, deadly, and would disrupt military missions.
- Smallpox vaccine prevents smallpox and we will use it carefully.
- Preserving the health and safety of our people is our top concern.
- The Defense Department’s smallpox vaccination program is part of our national strategy to safeguard Americans against smallpox attack.
SMALLPOX VACCINATION PROGRAM

• Policy: Reviewed – Remains deploying individuals to higher threat areas and special response teams

• Status:
  – Screened: 1,276,581  – Vaccinated: 1,176,573
  – Primary:  80%  – Male:  89%

• Exemption process working well
  – Eczema vaccinatum - 1  Progressive vaccinia - 0
  – VIG treatments more rare than expected - 6: Burn - 1, eye - 2,
    eczema vaccinatum - 1, unconfirmed eczema vaccinatum – 1,
    contact transmission - 1

• Education working well, but we can do better
  – Contact transfer vaccinia - 58:  Family - 25, intimate - 20,
    friend - 13, patient – 0  “Don’t let guard down at home.”
  – Myo-pericarditis -137

- data as of 21 March 2007
A CASE OF ECZEMA VACCINATUM

• On 8 Mar 07, the Vaccine Healthcare Center was consulted by physicians from the University of Chicago Children’s Hospital who identified a case of eczema vaccinatum (EV) in a 28-month-old male child and a less severe case of contact transfer in his mother.

• Child had a history of atopic dermatitis, a known risk factor for EV.

• Route of exposure - Father received smallpox vaccination on 26 Jan 07 at an Army Soldier Readiness Center. Due to a delay in deployment, he returned home from 16 – 20 Feb 07.
LESSONS LEARNED FROM A CASE OF ECZEMA VACCINATUM

• Screening is important – continuity training for clinicians is equally important

1. Do you NOW HAVE or have you EVER HAD Eczema or Atopic Dermatitis? (Usually this skin condition involves an itchy, red, scaly rash that lasts more than 2 weeks. It often comes and goes.)
   - Yes
   - No
   - Unsure

2. Do you LIKE or use any of the following medications: Roaccutane (oral acne skin rash)?
   - Yes
   - No
   - Unsure

5. Do you LIVE WITH anyone who NOW HAS or EVER HAD Eczema or Atopic Dermatitis? (Usually this skin condition involves an itchy, red, scaly rash that lasts more than 2 weeks. It often comes and goes.)
   - Yes
   - No
   - Unsure

• Education is vital – It has to be routinely reemphasized

• Vaccine Healthcare Centers are valuable assets for DoD’s unique vaccination programs

• Interagency cooperation requires education about military operational concerns
INFLUENZA VACCINATION PROGRAM

• Continue to protect the force – greater emphasis with pandemic concerns
• Status 2006-2007 season: 83%
• DoD sites used seasonal flu drive for “Mass Vaccination” training (pandemic preparedness – lessons learned)
• Vaccine procurement and distribution - Defense Supply Center Philadelphia (DSCP)
• FluMist® storage for 2007-2008 season more operationally supportive
Military Vaccine Agency (MILVAX) Overview

DoD Resumes Mandatory Anthrax Vaccinations for Select Groups

On 12 Oct 06, the DEPSECDEF directed a resumption of mandatory anthrax immunizations for higher threat areas and voluntary resumption of the anthrax immunization series in all Service members only partially immunized. DoD personnel will resume mandatory anthrax immunizations consistent with the FDA-licensed dose schedule (0, 2, and 4-weeks, and at 6, 12 and 18-months) and current standards for medical practice. On 6 Dec 06, the USD(P&R) issued Department of Defense implementation guidance. On 8 Feb 07, the ASD(HA) approved the Service implementation plans.

Mandatory vaccinations for all Services have been resumed.

Immunization Training Available

Register to become the local subject matter expert on DoD vaccination programs, including anthrax & smallpox. Learn about program implementation and administration within your unit, electronic tracking systems, adverse

FDA Licenses First H5N1 Influenza Vaccine

On 17 Apr 07, the FDA licensed the 1st influenza vaccine against H5N1 made by Sanofi Pasteur. This vaccine was produced under contract to the U.S. Department of Health and Human Services as part of national pandemic preparedness initiatives.

Influenza Virus Vaccine, H5N1, is indicated for active immunization of persons 18 through 64 years of age at increased risk of exposure to the H5N1 influenza virus subtype contained in the vaccine.

DoD Vaccine Price List

Review a consolidated price list for DoD vaccines, updated 05 Mar 07, to help ensure your organization is getting the best bang for their vaccine bucks. This summary list will help you identify quantity breaks, and other efficiencies when you purchase vaccines.

2006-07 Flu Season

Have fun learning about vaccines and vaccine preventable diseases with our monthly crossword puzzle, brought to you by Immunization University.

DoD Pandemic Influenza Resources
Anthrax is an acute infectious disease of animals that can be secondarily transmitted to humans. It is caused by a bacterium (Bacillus anthracis) that primarily affects sheep, horses, hogs, cattle, and goats and is almost always fatal in animals. The bacillus produces toxins that kill cells and cause fluid to accumulate in the body's tissues. Anthrax spores, which can survive for decades, are found in the soil, and animals typically contract the disease while grazing. Transmission to humans normally occurs through contact with infected animals but can also occur through eating meat from an infected animal or breathing air laden with the spores of the bacilli. The disease is almost entirely occupational, i.e., restricted to individuals who handle hides of animals (e.g., farmers, butchers, and veterinarians) or sort wool.
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<th>POLICIES</th>
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<tr>
<td>QUICK REFERENCE CHART</td>
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<td>Pertussis</td>
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<td>Shingles</td>
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<td>Smallpox</td>
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<td>Tetanus</td>
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<td>Tuberculosis (TB)</td>
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<td>Tularemia</td>
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<td>Yellow Fever</td>
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<td>Vaccine</td>
<td>Infectious Hazard</td>
<td>Disease Effects</td>
<td>Microbe</td>
<td>Common Vaccine Side Effects</td>
<td>Required in CENTCCOM.OR?</td>
<td>Dosing Schedule</td>
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<td>Anthrax (AVA, ANT)</td>
<td>Bioweapon</td>
<td>Skin infection, Death (common)</td>
<td>Bacillus anthracis (bacteria)</td>
<td>Injection-site swelling</td>
<td>As per DoD Policy</td>
<td>0, 2, 4W, 6, 12, 18m</td>
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<tr>
<td>Hepatitis A</td>
<td>Food- or water-borne</td>
<td>Liver infection, death (rare)</td>
<td>Hepatitis A virus</td>
<td>Sore arm</td>
<td>All countries</td>
<td>0 + 6-18 m liter</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Blood-borne</td>
<td>Liver infection, chronic illness, death (rare)</td>
<td>Hepatitis B virus</td>
<td>Sore arm</td>
<td>Medical forces</td>
<td>0, 1, 6 m</td>
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<tr>
<td>Influenza A&amp;B</td>
<td>Respiratory disease, especially in close quarters</td>
<td>Incapacitation, death (rare)</td>
<td>Influenza A and influenza B viruses</td>
<td>Sore arm</td>
<td>During fall-winter</td>
<td>each fall</td>
</tr>
<tr>
<td>Measles-mumps-rubella (MMR)</td>
<td>Respiratory diseases</td>
<td>Incapacitation, death (rare)</td>
<td>Measles virus, mumps virus, rubella virus</td>
<td>Sore arm</td>
<td>If missed in basic training</td>
<td>1 dose</td>
</tr>
<tr>
<td>Poliovirus inactivated (IPV)</td>
<td>Food- or water-borne, close to eradication</td>
<td>Paralysis, death (rare)</td>
<td>Polioviruses (3 types)</td>
<td>Sore arm</td>
<td>If missed in basic training</td>
<td>1 booster dose</td>
</tr>
<tr>
<td>Rabies</td>
<td>Threat from infected animals, including bats</td>
<td>Death (common)</td>
<td>Rabies virus</td>
<td>Sore arm</td>
<td>Veterinarians, Special Ops</td>
<td>Pre: 3 doses + boosters</td>
</tr>
<tr>
<td>Smallpox (Vaccinia)</td>
<td>Bioweapon</td>
<td>Incapacitation, scars, death (common)</td>
<td>Variola virus</td>
<td>Itching, swollen lymph nodes, rash</td>
<td>All countries</td>
<td>1 dose by DoD policy</td>
</tr>
<tr>
<td>Tetanus-diphtheria (Td)</td>
<td>T-spores in soil, D-Respiratory</td>
<td>Paralysis, death (rare)</td>
<td>Clostridium tetani, Corynebacterium diphtheriae (bacteria)</td>
<td>Sore arm</td>
<td>All countries</td>
<td>1 dose, every 10 y</td>
</tr>
<tr>
<td>Typhoid (Vi, injectable or oral capsules)</td>
<td>Water-borne</td>
<td>Diarrhea, dehydration, death (rare)</td>
<td>Salmonella typhi (bacteria)</td>
<td>Sore arm</td>
<td>All countries</td>
<td>IM, 2y; Caps, 5 y</td>
</tr>
<tr>
<td>Yellow fever (YF)</td>
<td>Mosquito-borne</td>
<td>Encephalitis, death (moderate)</td>
<td>Yellow fever virus - Virus</td>
<td>Sore arm</td>
<td>Horn of Africa</td>
<td>every 10 y</td>
</tr>
</tbody>
</table>
Informal 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 Systems
  - 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

*Don’t reinvent the wheel, learn from those around you…*
<table>
<thead>
<tr>
<th>Course</th>
<th>Competency</th>
<th>Course</th>
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<tbody>
<tr>
<td>Anthrax</td>
<td>Competency</td>
<td>Haemophilus Influenzae type b (HIB)</td>
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<td>Hepatitis A</td>
<td>Hepatitis B - Advanced</td>
<td>Hepatitis B - General</td>
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<td>Immune System 2</td>
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<td>Introduction to Vaccination</td>
<td>Japanese Encephalitis</td>
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<td>Mumps</td>
<td>Pneumococcal</td>
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<td>Polio</td>
<td>Rabies</td>
<td>Rubella</td>
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<tr>
<td>Smallpox Disease</td>
<td>Smallpox Administration</td>
<td>Smallpox Vaccine</td>
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<td>Tetanus-Diphtheria</td>
<td>Typhoid</td>
<td>Vaccine Storage and Handling</td>
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<tr>
<td>Varicella</td>
<td>Yellow Fever</td>
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</table>

>50 seat hours of CE credit: http://www.vhcinfo.org
https://www.projectimmunereadiness.amedd.army.mil/
<table>
<thead>
<tr>
<th>Clinic Self-Assessment Program</th>
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<tr>
<td><strong># Topic</strong></td>
<td><strong>Response</strong></td>
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<td>1</td>
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<td>2</td>
<td><strong>Information and Education</strong></td>
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<td>3</td>
<td><strong>Storage and Handling</strong></td>
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MILVAX TRAINING

MILVAX conducts CONUS and OCONUS, no-cost, on-site training:

– **Immunization Leaders Course** – 3 day
  (Four National Capital Region; Three Regional; Four OCONUS annually)

– **Immunization Basic Course** – 1 day

– Regional Analysts perform local **site visits** at military clinics and **information briefings** for Servicemembers and leaders
ACCESSION SCREENING AND IMMUNIZATION PROGRAM (ASIP)

AFEB recommended on 16 April 2004 that the Services screen for pre-existing immunity to vaccine-preventable diseases individualize immunizations administered at initial entry training locations.

Status: Air Force program working; Army implemented program in Nov 05 with standardizes screening and immunization delivery at Army Basic Combat Training posts (Ft. Benning, Ft. Sill, Ft. Jackson, Ft. Knox, and Ft. Leonard Wood); Navy program in consideration.

Importance of Initiative: Optimizes medical care by reducing unnecessary immunizations, and improves readiness through better use of medical resources. Provides significant estimated cost avoidance (For the Army, estimated $40M by end of FY11),
MILITARY VACCINE MONITORING SYSTEM (MVMS)

- Continue to refine application to best support passive surveillance of H5N1 vaccinees
- Pursuing redundant (back-up) data entry methods
• On 8 Nov 06 the DoD Force Health Protection Committee (FHPC) approved the alignment of the Vaccine Healthcare Centers Network under MILVAX

• Congressional interest - National Defense Authorization Act 2007, Sec 732: *Prohibits the SecDef from downsizing or restructuring the Vaccine Healthcare Centers during FY07 and requires that funding for the centers be provided by each Military Department.*

• GAO review of VHC out-brief scheduled for 11 May 07
FOCUSED EFFORTS

• Ensure immunizers are trained and providing the best vaccinations services possible

• Develop education outreach products that optimize the benefits of technology

• Change the leadership culture about exemptions

• Educate DoD and healthcare providers about the Vaccine Healthcare Center (VHC) and their services

• ACAM2000 Pharmacovigilance Plan w/ Acambis/JVAP/CDC/FDA (~Dec 07)

• Improve standardized immunization tracking and readiness reporting
CONCLUSION

• The threat continues
• Key leader support is critical to continued success
• Documentation is essential
• Education, risk communication, and continuous quality assurance are key
• Up-to-date vaccinations improve Force Readiness and are combat multipliers
QUESTIONS
QUESTIONS
Endemic Disease Threats (universal, occupational, +/- or geographic)

- Hepatitis A
- Hepatitis B
- Influenza A & B
- Japanese Encephalitis
- Measles, Mumps, Rubella
- Meningococcal A,C,Y,W-135
- Papillomavirus (HPV)
- Poliomyelitis
- Rabies
- 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
- AIDS
- ... Et cetera
The 2007 Medical Command Training Guidance is now available on AKO.

The CTC outlines a number of individual training requirements.

**AKO – My Medical Readiness**

According to the Medical Protection System (MEDPROS), you are being reported as not having a Medical Non-Deployable Profile. If this information is incorrect, please contact your unit MEDPROS Data Entry Clerk to have your status updated.

**GREEN: Dental Readiness**
- View Detailed Information

**GREEN: HIV**
- Your next HIV Test is due 11/26/2007.
- View Detailed Information

**GREEN: Immunization Profile**
- According to the Medical Protection System (MEDPROS), you are current on all of your Routine Adult Immunizations. You can download your Electronic Immunization Record (DD Form 2766C) after clicking on the View Detailed Information link located in the Immunization Alert. If the information on the DD Form 2766C is incorrect, please contact your unit MEDPROS Data Entry Clerk to have your status updated. You may be asked to provide copies of paper immunization records to support requested changes.
- View Detailed Information

**GREEN: Limited Duty Profile**
- According to the Medical Protection System (MEDPROS), you are being reported as not having a Limited Duty Profile that would preclude you from deploying. If this information is incorrect, please contact your unit MEDPROS Data Entry Clerk to have your status updated.
- View Detailed Information

**GREEN: Physical Readiness**
- Your next Physical Exam is due 4/5/2007. Your expected PULTRC code is...
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.
Army Executive Agent Responsibilities

The Executive Agent shall (continued):

- In cooperation with the other Military Services, **develop metrics** to assess implementation of the military immunization program. These metrics shall be developed as indicators of readiness, effectiveness, safety, and compliance with overall policies.

- In cooperation with the other Military Services, **establish joint clinical quality standards** for immunization delivery, for immunization healthcare, and for the education and training of personnel involved in immunization healthcare. The goals of these standards are to promote clinical excellence and decrease practice variability.

- Periodically **report to the ASD(HA) and the AFEB** on the status of the military immunization program.
Immunization Capture Points

- "One Stop" In/Out Processing Centers
- Ships
- Gunad/Reserve Home Station via FEDS_HEAL & Unit Medics
- Troop/Branch Medical Clinics
- Hospital Immunization Clinic
- Readiness Processing Centers Mob/Demob Deploy/Redeploy
- Unit Aid Stations

Network of military facilities and systems:
- ARMY MEDPROS MFRAME & RIDES
- USMC SAMS MRRS
- NAVY SAMS
- NAVY SAMS
- USMC SAMS
- AFCITA
- NAVY SAMS
- MEDPROS
- AHLTA
- USCG MRS
- USMC SAMS
- ARMY MEDPROS MFRAME & RIDES
- MEDPROS
- MFRAME & RIDES
- MFRAME & RIDES
- MFRAME & RIDES