

DoD Military Vaccine (MILVAX) Programs & Policy Update

Presented to:

Defense Health Board

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Director, Military Vaccine Agency

3 May 2007

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BRIEFING OUTLINE

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!









Executive Agent Responsibilities

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."



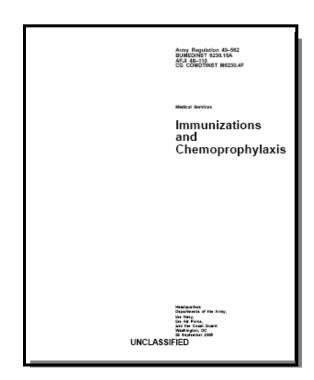
Military Vaccine Agency (MILVAX) Overview



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



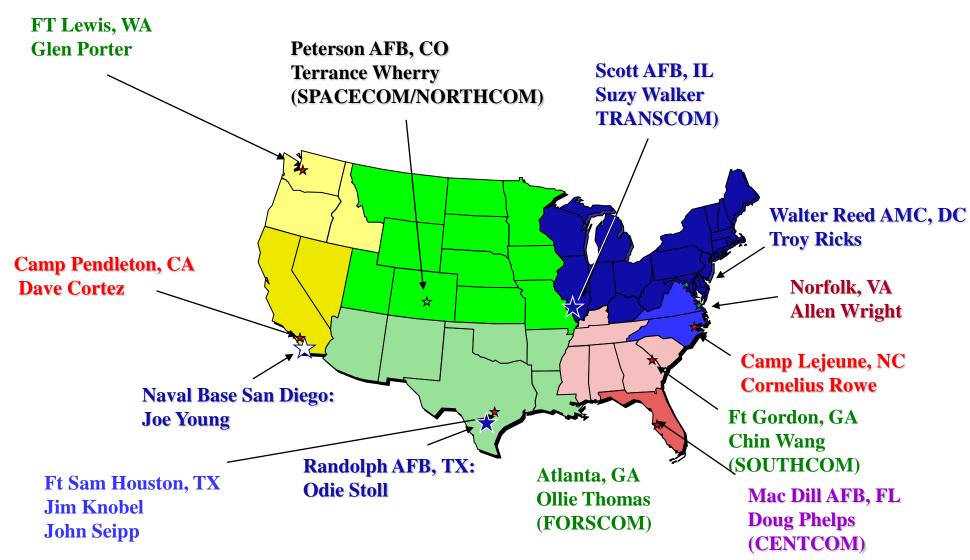






MILVAX REGIONAL ANALYSTS

17 Sites Worldwide

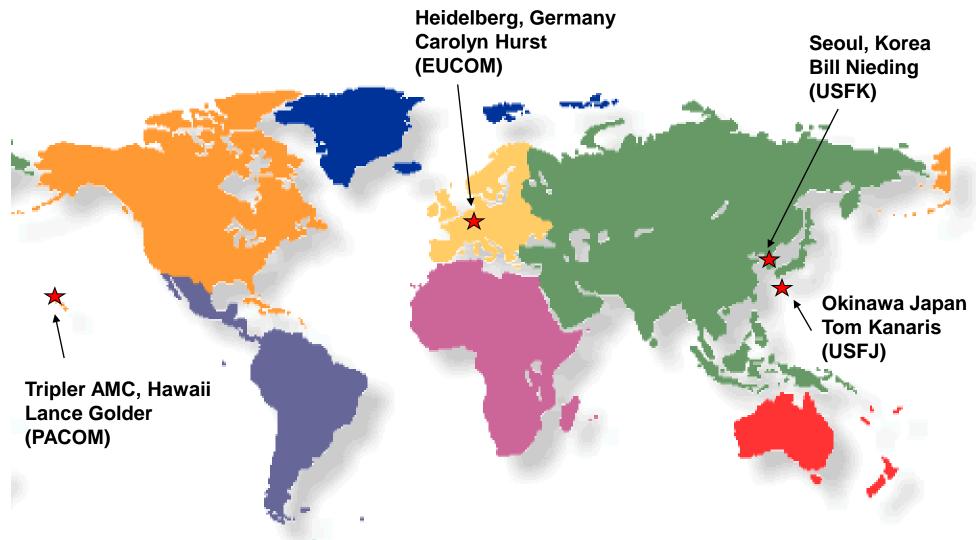








MILVAX ANALYSTS









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



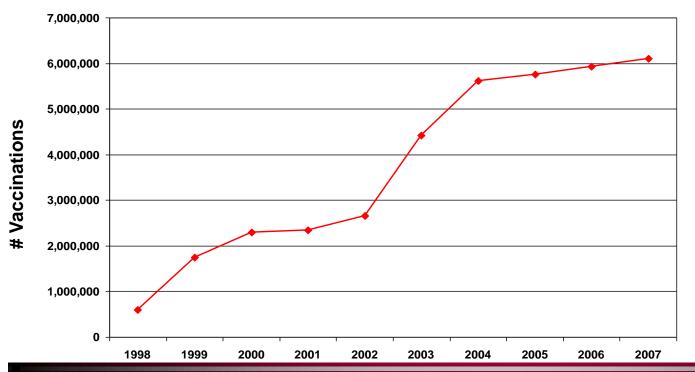






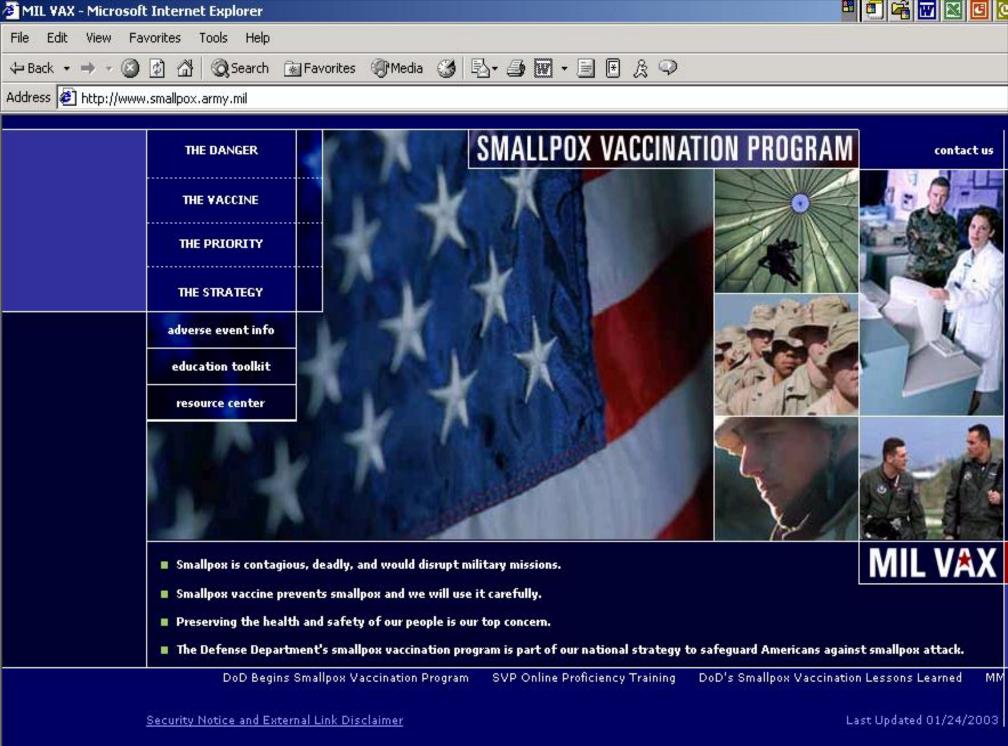
ANTHRAX VACCINATION PROGRAM

- 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 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 1Progressive 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.

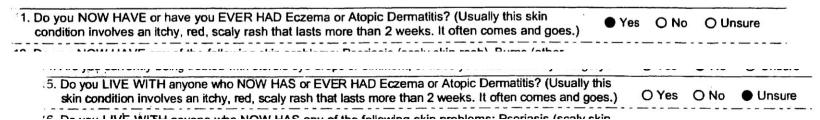






LESSONS LEARNED FROM A CASE OF ECZEMA VACCINATUM

 Screening is important – continuity training for clinicians is equally important



- 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

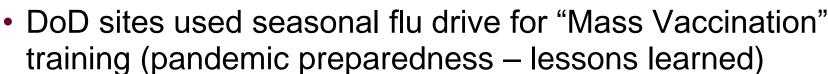






INFLUENZA VACCINATION PROGRAM

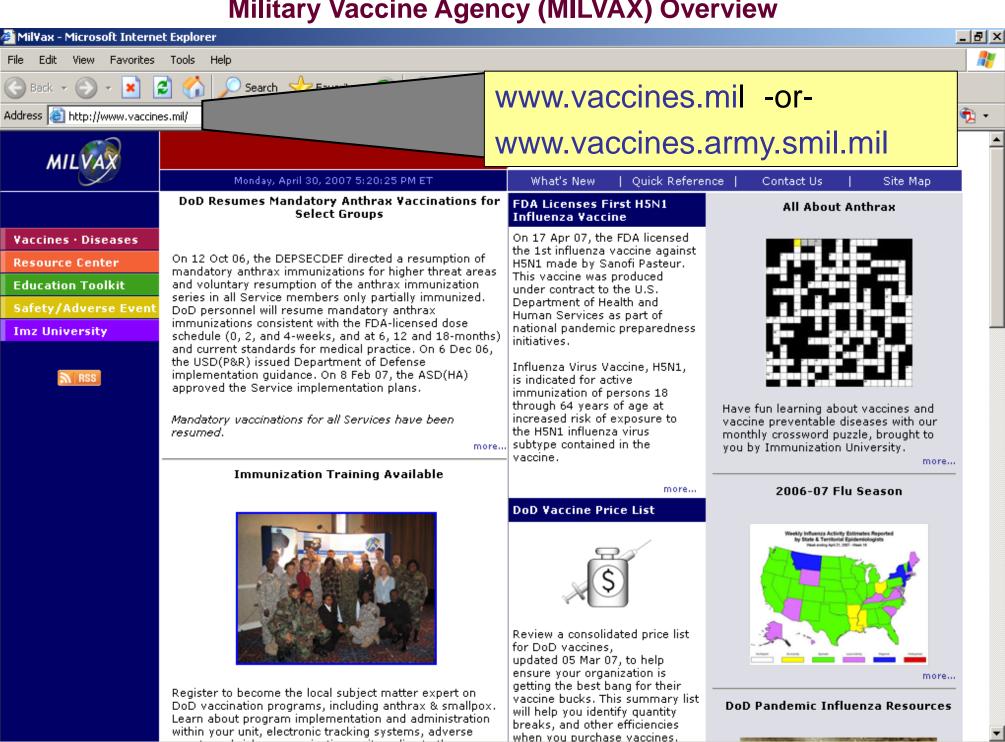
- Continue to protect the force –
 greater emphasis with pandemic concerns
- Status 2006-2007 season: 83%



- Vaccine procurement and distribution Defense Supply Center Philadelphia (DSCP)
- FluMist® storage for 2007-2008 season more operationally supportive



Military Vaccine Agency (MILVAX) Overview





Wednesday, August 09, 2006 8:51:04 AM ET

quick reference

site map

Home

Vaccines · Diseases

General Vaccine

Haemophilus B

Hepatitis A

Hepatitis B

Human Papillomavirus

Influenza (pandemic)

Influenza (seasonal) Japanese encephalitis

Lyme Disease

contact us

Anthrax

Bacillus anthracis



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.



stain of anthrax



NEWS • Reuters 31 Jul 06

Western Canada anthrax outbreak worst in decades

 Washington Post 08 Jun 06 Anthrax Victim Says He's Ready to Perform

POLICIES

more...

more...

- Continuation of the Anthrax Vaccine Immunization Program (AVIP) PDF 22 Dec 05 Author: Winkenwerder
- 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 the Emergency Use Authorization (EUA)

 $\mathbf{R}\mathbf{x}$ clinical

more...

- . 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

AC ACIP GUIDELINES

more...

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

AFEB RECOMMENDATIONS

more...

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

QUICK REFERENCE CHART	POLICIES	POLICIES VACCINE RECOMMENDATIONS				
GIAN		RECOMMENDATIONS				
	DoD	Army	Navy	Marines	Air Force	Coast Guard
General Vaccine	×	×	×		X	×
Adenovirus						
Anthrax	×	×	X	X	X	×
Botulism						
Chickenpox	×	×				
Diphtheria	×					
DTaP, Td, Tdap		X				
Haemophilus B						
Hepatitis A	X	X				
Hepatitis B	X	X			X	
Human Papillomavirus						
Influenza (pandemic)	X					
Influenza (seasonal)	X	X	X		X	
Japanese encephalitis						
Lyme Disease						
Measles		X				
Meningococcal						
Mumps						
Pertussis		X				
Plague						
Pneumococcal						
Polio	X					
Rabies						
Rotavirus		X				
Rubella		X				
Shingles						
Smallpox	×	X	X	×	X	X
Tetanus	X	X				
Tuberculosis (TB)		X				
Tularemia						
Typhoid						
Yellow Fever						

QUICK REFER	RENCE	POLICIES	SERVICE MESSA	GES RE	VACCINE COMMENDA		s				
DoD Vaccine Requirements for US Central Command Area of Responsibility (29 APR 05)											
CENTO	СОМ	EUCO	М	USFK			By Age		Ву	Military Seg	ment
Vaccine	Infectious Hazard	Disease Effects	Microbe	Common Vaccine Side Effects	Required CENTCOMA		Dosing Schedule	Manufac	turer	Vaccine Type	License Status
Anthrax (AVA, ANT)	Bioweapon	Skin infection, Death (common)	Bacillus anthracis (bacteria)	Injection- site swelling	As per DoE Policy)	0, 2, 4w, 6, 12, 18m	BioPort		Inactivated	FDA Licensed
Hepatitis A	Food- or water- borne	Liver infection, death (rare)	Hepatitis A virus	Sore arm	All countrie	es	0 + 6-18 m later	GSK, Me	erck	Inactivated	FDA Licensed
Hepatitis B	Blood- borne	Liver infection, chronic illness, death (rare)	Hepatitis B virus	Sore arm	Medical for	rces	0, 1, 6 m	GSK, Me	erck	Inactivated	FDA Licensed
Influenza A&B	Respiratory disease, especially in close quarters	Incapacitation, death (rare)	Influenza A and influenza B viruses	Sore arm	During fall- winter	-	each fall	SP, Chir MedImm	on; nune	Inactivated or Live	FDA Licensed
Measles- mumps- rubella (MMR)	Respiratory diseases	Incapacitation, death (rare)	Measles virus, mumps virus, rubella virus	Sore arm	If missed in basic traini		1 dose	Merck		Live	FDA Licensed
Meningococcal A, C, Y, W- 135 (MGC)	Respiratory disease, outbreaks in mid- Africa, Arabia	Meningitis, death (moderate)	Neisseria meningitidis (bacteria) (4 types)	Sore arm	African countries o CENTCOM	of	1 dose within 3 y	SP		Inactivated	FDA Licensed
Poliovirus inactivated (IPV)	Food- or water- borne, close to eradication	Paralysis, death (rare)	Polioviruses (3 types)	Sore arm	If missed in basic traini		1 booster dose	SP		Inactivated	FDA Licensed
Rabies	Threat from infected animals, including bats	Death (common)	Rabies virus	Sore arm	Veterinaria Special Op		Pre: 3 doses + boosters	SP, Chir	on	Inactivated	FDA Licensed
Smallpox (Vaccinia)	Bioweapon	Incapacitation, scars, death (common)	Variola virus	Itching, swollen lymph nodes, rash	All countrie	es	1 dose, by DoD policy	Wyeth		Live	FDA Licensed
Tetanus- diphtheria (Td)	Tspores in soil, D Respiratory	Paralysis, death (rare)	Clostridium tetani, Corynebacterium diphtheriae (bacteria)	Sore arm	All countrie	es	1 dose, every 10 y	SP		Inactivated	FDA Licensed
Typhoid (Vi injectable or oral capsules)	Water- borne	Diarrhea, dehydration, death (rare)	Salmonella typhi (bacteria)	Sore arm	All countrie	es	IM, 2y. Caps, 5 y.	SP; Berr	na	Inactivated or Live	FDA Licensed
Yellow fever (YF)	Mosquito- borne	Encephalitis, death (moderate)	Yellow fever virus	Sore arm	Horn of Afr	rica	every 10 y	SP		Live	FDA Licensed







IMMUNIZATION UNIVERSITY

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...



Military Vaccine Agency (MILVAX) Overview



PROJECT IMMUNE READINESS



IMMUNE READINESS LMS

Version 1.3

Monday, April 30, 2007

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🕻 About Immune Readiness					
🕻 Goals and Objectives					
◆ Target Audience					
Courses					

AVAILABLE COURSES

<u>Anthrax</u>	Competency	Haemophilus Influenzae type b (HIB)
<u>Hepatitis A</u>	Hepatitis B - Advanced	Hepatitis B - General
Immune System 1	Immune System 2	<u>Influenza</u>
Introduction to Vaccination	Japanese Encephalitis	<u>Measles</u>
<u>Meningococcal</u>	<u>Mumps</u>	<u>Pneumococcal</u>
<u>Polio</u>	Rabies	Rubella
Smallpox Disease	Smallpox Administration	Smallpox Vaccine
Tetanus-Diphtheria	Typhoid	Vaccine Storage and Handling
<u>Varicella</u>	Yellow Fever	

>50 seat hours of CE credit: http://www.vhcinfo.org https://www.projectimmunereadiness.amedd.army.mil/



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CLINIC QUALITY IMPROVEMENT PROGRAM

-	,				,
	Clinic Self-Assessment Program				
	date:				
#	Topic	Response		Comment	Tools, References, Resources
1	Immunization Availability				
	What are your usual hours of operation? Which days of the week				
2	Information and Education				
a.	Show me the VISs you give to troops and beneficiaries.		a	If clinic personnel cannot show you these forms, it indicates need to either gather them or educate staff member on where the forms are located. Forms can be photocopied for distribution or laminated and placed on bulletin board.	http://www.cdc.gov/nip/public ations/VIS/default.htm
3	Storage and Handling		Ï		
i.	What does your SOP say about Mass vaccination? What does it say about pre-drawing of vaccines into syringes and storage during the vaccination process?		i	Pre-drawing is not prefered, but can be done if certain conditions are met	http://www.usamma.army.mil/ anthrax/info.htm
4	Indications and contraindications to immunization				
a.	What questions do you ask people		a	How do you feel today? Have you had prior adverse reactions to vaccinations?	http://www.immunize.org/catg

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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.

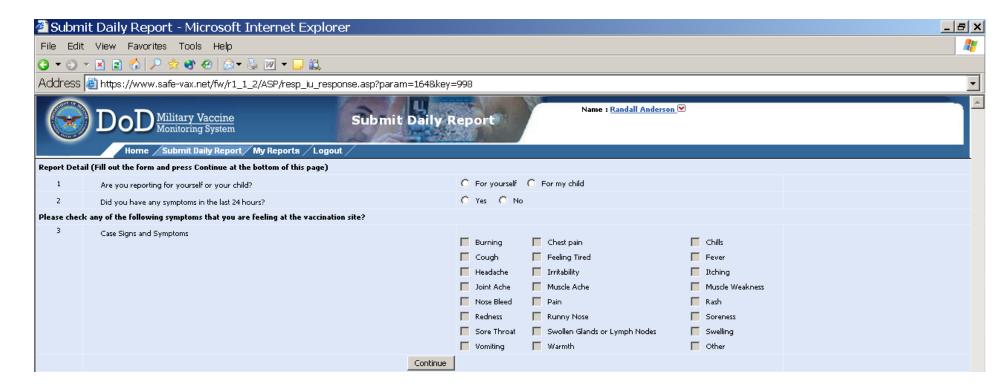
Status: Air Force program working; Army implemented program in Nov 05 with standardizes screening and immunization delivery at Army Basic Combat Training posts (Ft. Benning, Ft. Sill, Ft, Jackson, Ft. Knox, and Ft. Leonard Wood); Navy program in consideration.

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),





- Continue to refine application to best support passive surveillance of H5N1 vaccinees
- Pursuing redundant (back-up) data entry methods







NETWORK



- 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

Pvt. Murphy's Law by Master Sgt. Mark Baker www.pvtmurphy.com







BACKUP SLIDES







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

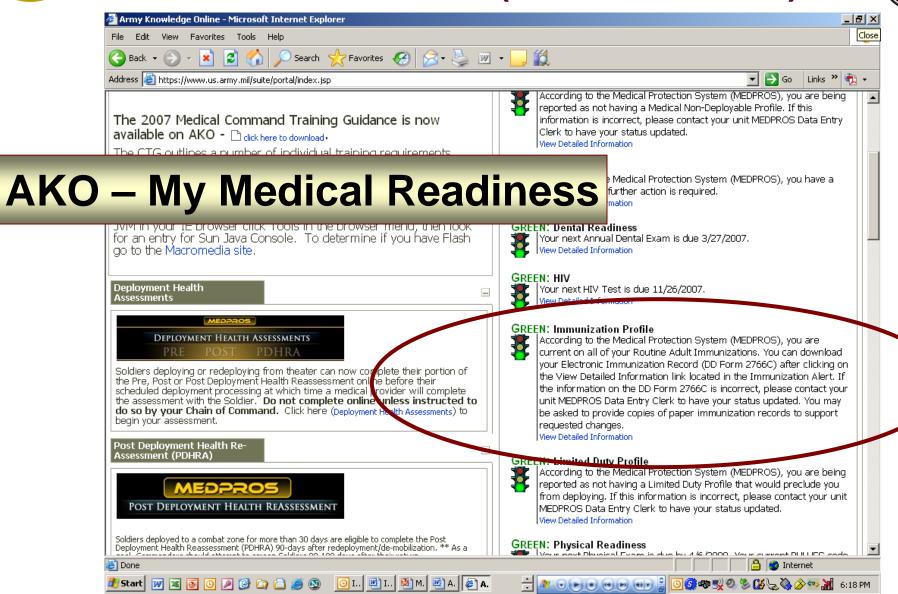
AIDS

... Et cetera



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On-line Shot Record (DD Form 2766C)

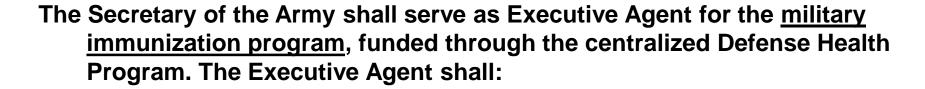






Army Executive Agent Responsibilities

DoD Directive 6205.02E (dated 19 Sep 06)



- 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.

UNCLASSIFIED

Develop uniform procedures to identify, report, and evaluate vaccineassociated 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.



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