

DHCC

DEPLOYMENT HEALTH CLINICAL CENTER

Vaccine Safety and the Military Vaccine Program

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Vaccine Safety and the Military Vaccine Program *Objectives*



- ★ To describe the Vaccine Healthcare Centers Network - Here to help you and your patients
- ★ To discuss potential risks associated with vaccines
 - Prescription drugs with potential risks of administration
 - Deployment-related vaccines are no exception

Vaccine Safety and the Military Vaccine Program *Objectives (cont.)*



- ★ To explain reporting and management of vaccine adverse events (VAERS)
 - Safe and effective but rare serious VAERS occur
- ★ To identify tools available to assist with vaccine administration & adverse events management:
www.VHCinfo.org/AskVHC

World Health Organization

Weekly Epidemiological Record



15 October 1999 (www.who.int/wer)

Vaccine Safety Advisory Committee

“However, it is also recognized that there is no vaccine completely safe or protective in all vaccinated individuals. Differences in the way individual immune systems react to a vaccine account for rare occasions when people are not protected following immunization or experience side effects.”

Immunization Health Care

Standards of Care

Reducing Practice Variance



★ Congressional concerns

- How service members are screened for vaccine administration - barriers to medical exemptions when indicated?
- How service members are treated in the setting of an adverse event beyond a side effect?
 - Adequacy of evaluation, treatment and follow-up, outcomes
 - Adequacy of reporting: VAERS

★ Vaccine Healthcare Centers (VHC) Network

- New DoD Executive Agency – collaborating with CDC
- Support to health care workers, vaccinees, stakeholders

Vaccine Adverse Events



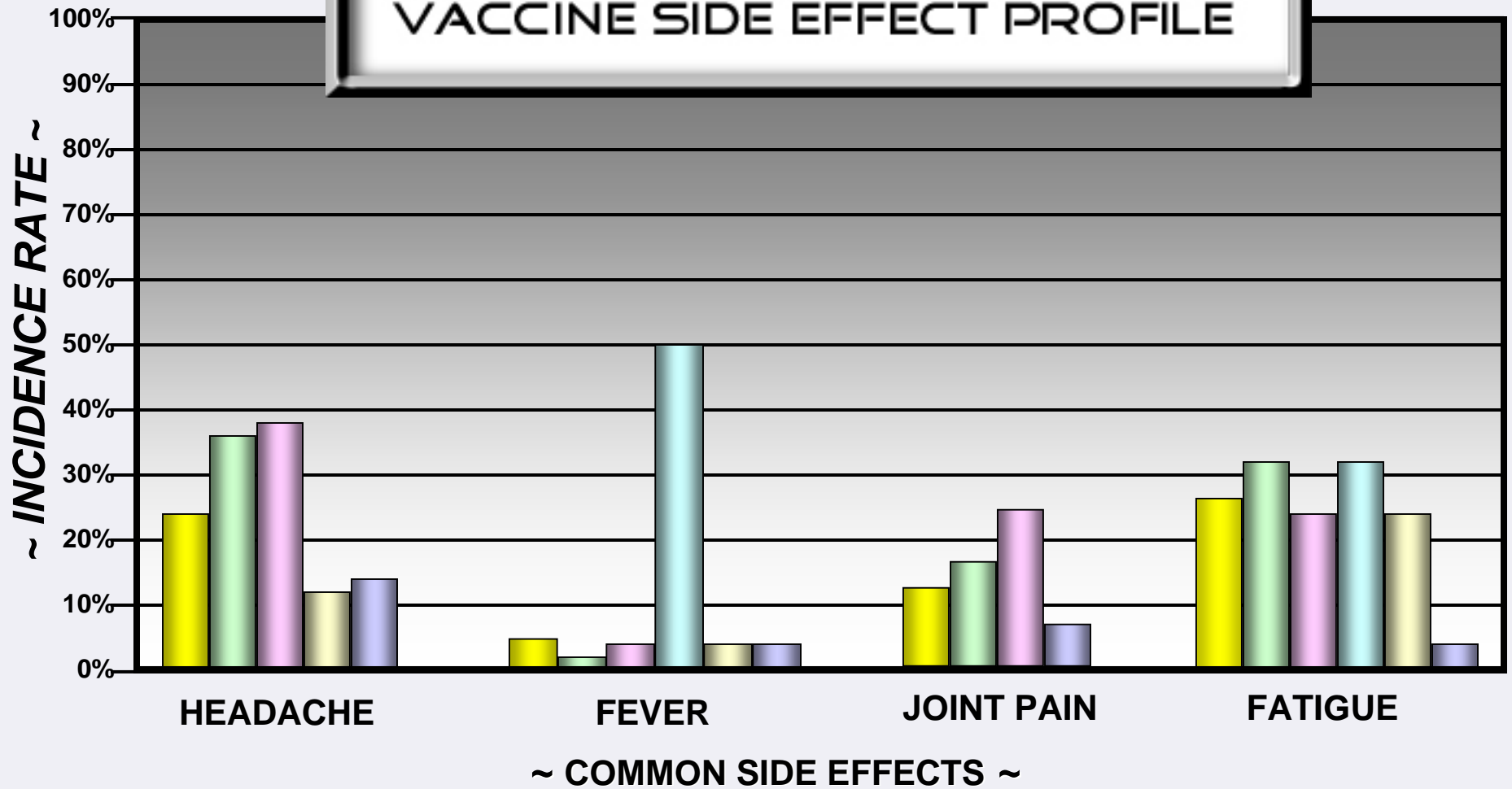
- ★ **Rare, previously unrecognized vaccine associated adverse events** may occur with a prolonged negative impact on patient quality of life in the absence of hospitalization
- ★ **Some of these AEs are unexpected:** e.g. intussusceptions with rotavirus vaccine
- ★ **Understanding of rare but serious AEs is needed to enhance public trust** in vaccine safety & address future disability claims issues
- ★ **NEED:** validate strategies for vaccine adverse events management & rechallenge benefit-risk

From Side Effects to Rare Serious Adverse Events



- ★ Temporal association versus causality
- ★ Clinical management principles for adverse drug reactions
 - Should they apply to vaccines?
- ★ VAER
 - No barriers, low threshold to file

VACCINE SIDE EFFECT PROFILE



NOTE: ANTHRAX RATES DERIVED FROM COMBINED EXPERIENCE OF TAMC-600 SURVEY AND USAMRIID REDUCED DOSE STUDY

Vaccine Safety & Adult Immunizations Surveillance, Trust *DoD Challenges*



★ Vaccine Safety Concerns Based on Rare Cases

- Influenza: pericarditis, myocarditis syndrome
- Yellow fever: deaths reported in South America
- Anthrax vaccine: questions of risk raised
 - Pregnancy & birth defects
 - Optic neuritis
 - Rashes: some serious – Erythema multiforme
 - Tinnitus
 - Neurological symptoms: ulnar neuropathy, sequelae to large local inflammatory reactions validated by AVEC
 - Chronic fatigue-like syndromes

Clinical Guidelines



★ Local reactions

- Mild: 30-50 mm
- Subcutaneous nodules
- Moderate 50-120 mm above elbow
- Large Local above elbow . 120
- Large Local extending below elbow

★ Other local reactions

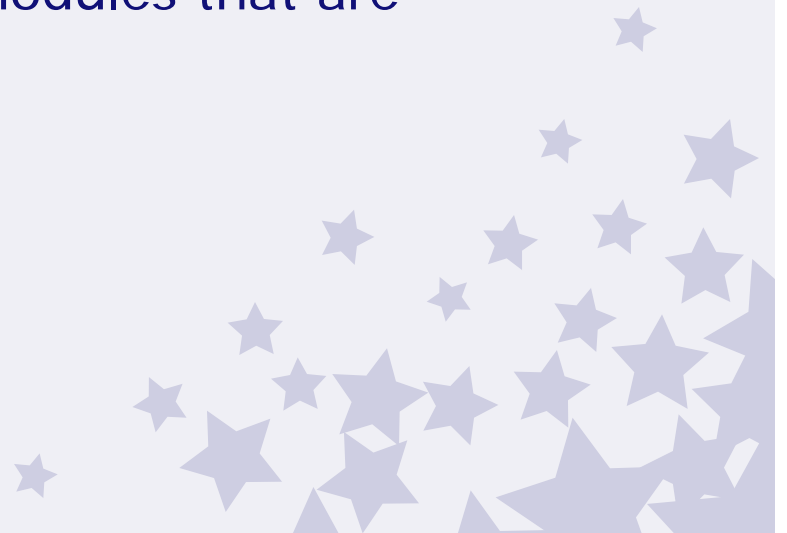
- Parasthesias, localized

Clinical Guidelines (cont.)



★ Long term complications

- Rare but seen
 - Bilateral ulnar neuropathy from severe local reactions to anthrax vaccine – note change in location of administration and route if needed
 - Persistent (months-years) nodules that are painful



www.VHCinfo.org

VHC Network

A Clinical Support
Resource

Education

Consultation

Case Management

Registry Support

www.vaccines.mil

MilVax Agency

A Policy & Procedure
Support Resource

MANAGING ADVERSE EVENTS AFTER VACCINATION

Service Member Receives Vaccine

*If in yellow or red zone, avoid simultaneous administration with other vaccines.

(proof copy,
13 Dec 00)



Clinical guidelines for managing adverse events after vaccination: Version 1 January 2001. This document provides general guidance, to adapt to individual clinical cases. Use with companion tables. Patients may present with symptoms corresponding to more than one category. Revisions to this document will be disseminated via medical command channels and posted on AVIP site, www.anthrax.osd.mil. The probability of events on this chart is not uniform: some are quite common and some are rare. See cover sheet for details.

Submit Form VAERS-1 as warranted. Must be submitted for hospitalization, loss of duty ≥ 24 h, or suspected vial contamination. Other events may also be reported. Forms available at www.anthrax.osd.mil/vaers/vaers.htm.



Large Local Reaction

>12cm

Confusion with
Cellulitis
Actually
Immune Inflammation

Severe Local Reaction Post-Vaccinia



2003 Apr 9 AskVHC

27 y/o Primary Vaccinee

Presented to Texas Hospital

Plan: take patient to OR for surgical
debridement!

Robust Primary Vaccinia Rxn

Observe, resolved w/o Surgery

Adverse Events & Vaccines

Side Effects



★ Duration and impact

- Short term, no impact on function or quality of life (QOL)
- Prolonged or severe, impact on QOL
- Long term with disability implications

Adverse Events & Vaccines

Side Effects (cont.)



- ★ Possible mechanisms of symptoms, injury
 - IgE – immediate hypersensitivity reaction
 - Direct mast cell activator
 - Traumatic or mechanical injury
 - Delayed local reactions
 - Arthus-like, immune complex mediated
 - Delayed type hypersensitivity reaction
 - Secondary complication: hematoma, cellulitis



Systemic Adverse Reactions

- ★ "Flu-Like" systemic reactions
- ★ Anaphylaxis
- ★ Serum sickness
- ★ Neurologic disease
- ★ Generalized skin reaction
- ★ Other systemic disease
- ★ The unexpected and ill-defined...

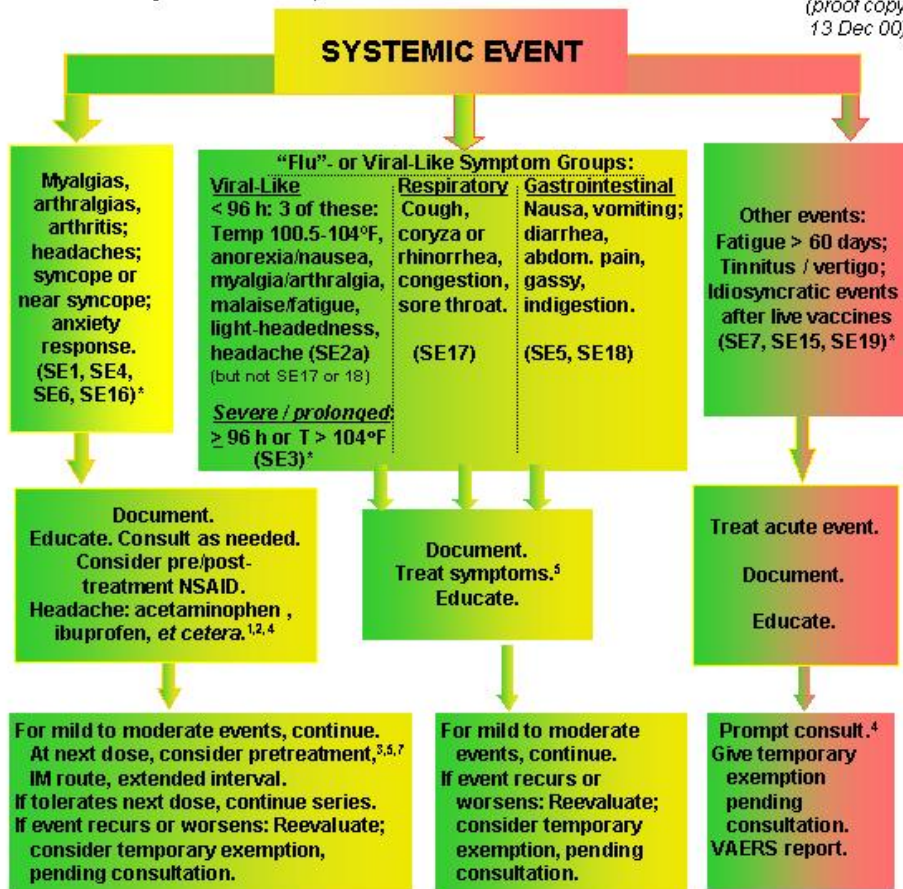
Vaccine safety as a new clinical specialty
Growing complexity with new challenges

Systemic Adverse Events

MANAGING ADVERSE EVENTS AFTER VACCINATION

Service Member Receives Vaccine

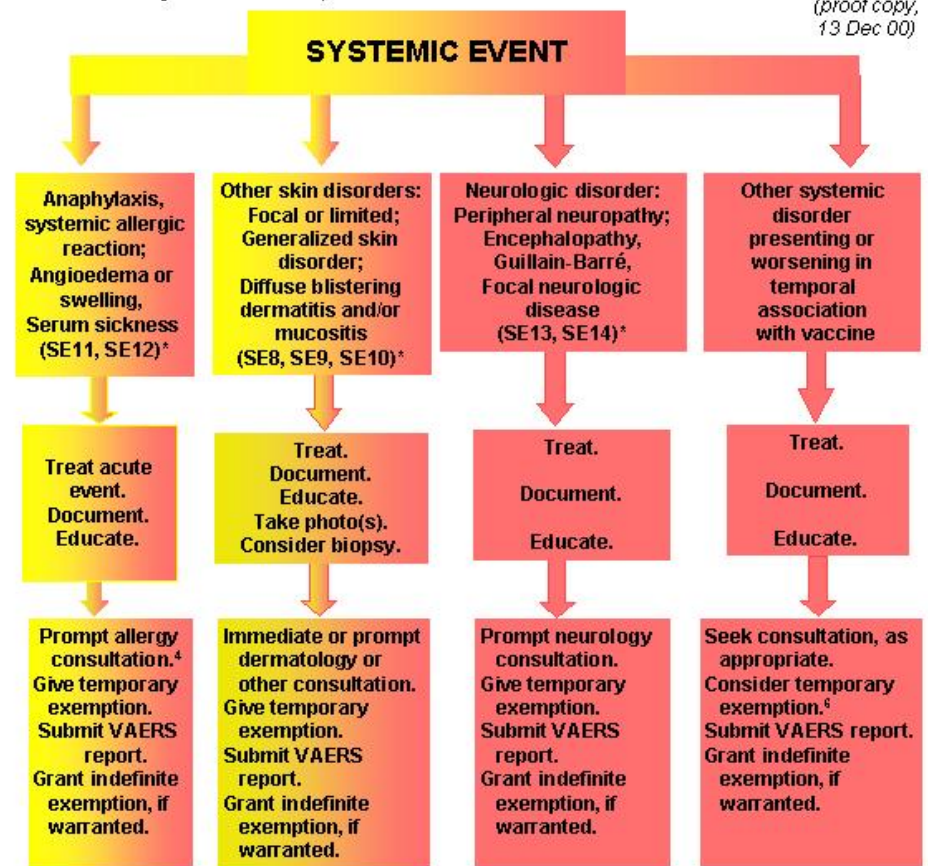
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Adverse Events and Vaccines

Systemic Side Effects & Adverse Events



- ★ Clinical guidelines are a work in progress
 - Extrapolated from broad clinical immunology experience; currently only applies to non-live vaccines...a work in progress
- ★ Outcomes data for degrees of severity of side effects and/or duration not well defined
- ★ Many challenges in perceptions
 - "Safe and effective"
 - "No serious reactions"
 - Medical exemptions: measure of Provider concern

Adverse Events & Vaccines

Ranking Side Effect Severity



- ★ TAMC 601 Study: J Occup Environ Med. 2003;45:222-233
- ★ Classification of systemic side effects
 - No symptoms
 - Symptoms can be ignored
 - Symptoms affect activity but can still perform
 - Symptoms affect activity, relieved by medication
 - Symptoms not relieved by meds, cannot perform
- ★ 5 VAERS events reported from a total of 3069 immunizations in the 601 vaccinees

Adverse Events & Vaccines

Symptoms Not Relieved by Meds, Cannot Perform Duties

	Male-Female
• Muscle aches	2.0% - 3.0%
• Fatigue	1.2% - 2.0%
• Headache	1.4% - 2.5%
• Joint ache	1.4% - 1.4%
• Loss of appetite	0.2% - 0.5%
• Nausea and vomiting	0.6% - 1.4%
• Fever	1.1% - 4.5%
• Itching over entire body	0.5% - 0.6%
• Chills	0.3% - 0.8%
• Diarrhea	0.3% - 0.8%
• Shortness of breath	0.3% - 0.2%

Anthrax Vaccine Safety Surveillance



- ★ >3.5 million doses of anthrax vaccine administered to >960,000 people
- ★ Soreness, redness, itching, swelling at injection site:
 - 30% of men, 60% of women
- ★ Lump at injection site common, lasting a few weeks, goes away on its own

Anthrax Vaccine Safety Surveillance (cont.)



- ★ Symptoms beyond injection site – muscle or joint aches, headaches, rashes, chills, low-grade fever, nausea – 5% to 35%, like other vaccines
- ★ No apparent differences between pre-renovation and post-renovation lots
- ★ National Academy of Sciences: Side effects “comparable to those observed with other vaccines regularly administered to adults”

Serious Adverse Events



- ★ Critical elements to assessment and review
 - History: accurate and detailed
 - Details like a medical student evaluation
 - Detective work required – time, patient participation, validation process
 - Physical and laboratory data
 - Detail required with precise documentation
 - Consideration of differential diagnosis
 - Plan for further evaluation, treatment
 - Medical exemption or strategy for protection
 - Connect to the available resources & support
 - DoD Vaccine Call Center 24/7 – 1-866-210-6469
 - AskVHC@amedd.army.mil

DoD Smallpox Vaccination Program as of 17 Dec 03



- ★ Response teams, hospital workers, operational forces
 - Screened: 605,000
 - Vaccinated: 530,315
 - Primary: 71%
 - Male: 88%
- ★ Exemption rates vary by location and setting:
 - Exemption: Personal 4.9-7.8%, Personal+household: 11-34%
- ★ Take: Primary, 3 jabs: 96% Revaccination, 15 jabs: 96%
- ★ Adverse Events: Expected temporary symptoms seen
 - Sick leave: Hospital staff: 3% In theater: 0.5%

Avg: 1.5 days

DoD Smallpox Vaccination Program as of 17 Dec 03 (cont.)



- ★ Noteworthy Adverse Events: *JAMA* 2003;289:3278-82
 - Generalized vaccinia-35
 - Inadvertent infection-Skin: Self-51, Contact-26
 - Inadvertent infection-Eye: Self-11, Contact-2
 - Contact transfer: Family-13, intimate contact-7, friend-8
 - Eczema vaccinatum-0 Progressive vaccinia-0
 - VIG treatments: Burn-1, eye-1 Encephalitis-1
 - Myo-pericarditis: Suspect-0, probable-66, confirmed-3
 - Deaths: Possible-1 (lupus-like illness), Unrelated-4

Vaccine Healthcare Centers Network



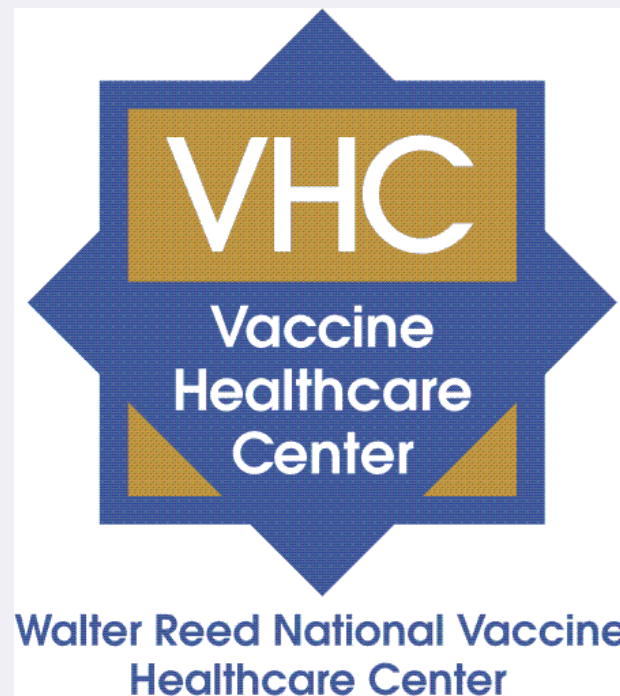
- ★ DoD registry for myo/pericarditis cases: suspect, probable and confirmed
 - Detailed history & physical documented
 - Case manager interviews
 - Records review
 - Provider interviews
- ★ DoD guidelines issued, work in progress
- ★ Standardize follow-up & document
 - Objective measures of recovery or persistent symptoms, loss of function

Vaccine Healthcare Centers Network

Vision



Develop a network of regional VHC's that support continuous quality improvement of immunization healthcare delivery, education, research and case management of complex adverse events for DoD beneficiaries

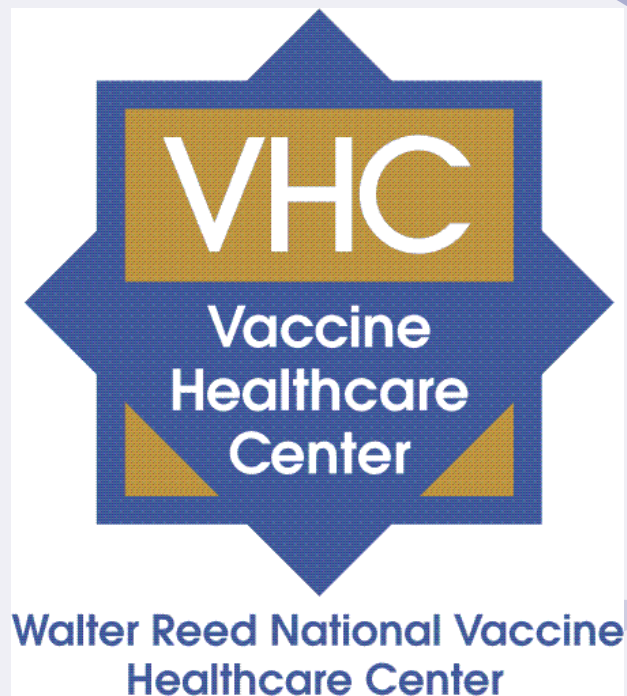


Vaccine Healthcare Centers Network

Mission and Goals



To provide clinical, educational, research & quality assurance leadership for immune readiness through outreach in support of the goals of enhanced vaccine safety, efficacy, knowledge, trust and services to include diagnosis & management of adverse events





Walter Reed National Vaccine
Healthcare Center

Assuring Quality Patient Care For Adverse Events “Quality Improvement”

The Right Response

The Right Way

At the Right Time with

The Right Education & VAERS

The Right Access to Care

The Right Exemption

VHC Points of Contact



To take or not to take . . .

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Regional VHCs

- Walter Reed
- Fort Bragg
- Portsmouth
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Adult, Military
and Childhood
Immunizations



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Website: www.VHCinfo.org

Distance Learning Tools: Go To **Project Immune Readiness**
Clinical Consultations, Help, Advocacy Support for Service Members
AskVHC@amedd.army.mil

Questions, Information, Assistance



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