

FDA/CBER Role in Smallpox Vaccine Safety

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Center for Biologics Evaluation and Research

Office of Vaccine Research and Review
License and Release Dryvax Lots
License Next Generation Vaccines

Office of Blood Research and Review
Regulate VIG

Office of Biostatistics and Epidemiology
Vaccine Safety Branch
VAERS
Follow-up
Controlled Studies of Safety Concerns

Smallpox Vaccine Safety

Mission: Vaccine Safety Branch

- *To rapidly detect and rigorously research safety problems for licensed vaccines and to facilitate regulatory and risk communication actions to mitigate these problems*
- Information obtained from smallpox vaccine safety surveillance and research can influence development of next generation vaccines

Smallpox Vaccine Safety Surveillance Through VAERS

- Collaborative effort with CDC
- Review smallpox vaccine adverse event reports on a daily basis
- Analyze VAERS data, conduct follow-up and controlled studies to evaluate safety concerns
- Communicate results to health professionals and public

Smallpox Vaccine Safety

Viral Determinants of Virulence Project

PI: Ann McMahon MD, MPH

- Hypothesis: Vaccinia virus genotype is associated with virulence in humans and mice
- Study Design
 - Obtain swabs of lesions from cases of eczema vaccinatum and vaccinia necrosum (~10-20 cases among 500,000 vaccinees)
 - Compare sequences of viral isolates from cases and 20 controls to investigate possible genetic polymorphisms
 - Study virulence of viral isolates from cases and 20 controls by murine inoculation
- Use information for making safer next generation smallpox vaccine

FDA/CBER Smallpox Vaccine Safety Contacts

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