US Immunization Safety;
CDC monitoring, assessment and response

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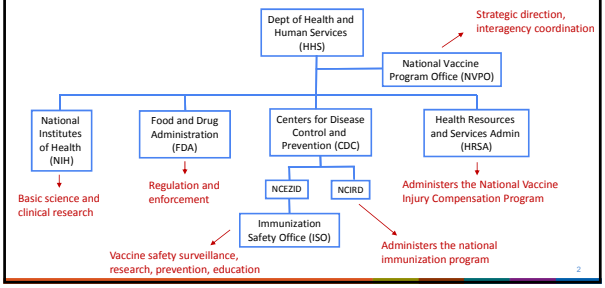
No conflicts of interest to declare.

The findings in this report are those of the author(s) and do not necessarily represent the official position the Centers for Disease Control and Prevention.

Primary U.S. Dept. of Health and Human Services organizations engaged in vaccine safety activities



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Rationale for post-licensure vaccine safety monitoring

- Safety standards for vaccines are high
- Pre-licensure clinical trials are typically not designed to
  - Detect rare adverse events (numbers enrolled too small)
  - Monitor vaccine safety in a real-world environment
  - Assess safety in special populations (often excluded)
  - Evaluate adverse events with delayed onset

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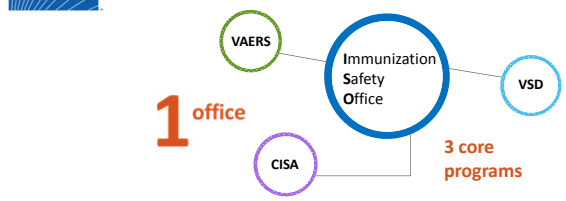
CDC vaccine safety monitoring



VAERS: Vaccine Adverse Event Reporting System
VSD: Vaccine Safety Datalink
CISA: Clinical Immunization Safety Assessment Project

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Vaccine safety monitoring

VAERS

Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

http://vaers.hhs.gov

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Vaccine Adverse Event Reporting System (VAERS)

Strengths

- National data
- Accepts reports from anyone
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

Limitations

- Reporting bias
- Inconsistent data quality and completeness
- Lack of unvaccinated comparison group
- Generally cannot assess causality

- VAERS is a spontaneous reporting (passive surveillance) system
- VAERS accepts all reports from all reporters without making judgments on causality or judging clinical seriousness of the event
- As a hypothesis generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

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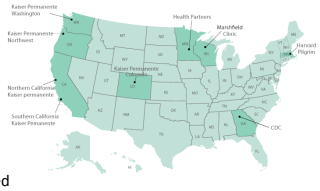
Vaccine safety monitoring

VSD

Vaccine Safety Datalink



8 participating integrated healthcare organizations

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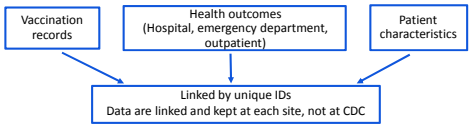
Vaccine Safety Datalink (VSD)

- Established in 1990
- Collaboration between CDC and several integrated healthcare plans
- Medical care and demographic data on over 12.1 million persons per year (~3.7% of U.S. population)
- Links vaccination data to health outcome data
- Used for surveillance (active) and research



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VSD methods for surveillance and research

- Near real-time surveillance (Rapid Cycle Analysis [RCA])
- Traditional epidemiologic studies – observational designs; can be planned safety studies and studies to follow up on statistical signals detected in RCA
  - Cohort
  - Case-control
  - Self-controlled
  - Case only

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Vaccine safety monitoring

CISA

Clinical Immunization Safety Assessment

7 participating medical research centers*

vaccine safety experts

- assist U.S. healthcare providers with complex vaccine safety questions about their patients CISAeval@cdc.gov†
- conduct clinical research

*Boston Medical Center, MA; Cincinnati Children's Hospital Medical Center, OH; Columbia University, NY; Duke University, NC; Johns Hopkins University, MD; Kaiser Permanente Northern California, CA; Vanderbilt University TN

†More information about clinical consults available at http://www.cdc.gov/vaccinesafety/Activities/CISA.html

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CISA sites

- Boston Medical Center
- Cincinnati Children's Hospital Medical Center
- Columbia University
- Duke Clinical Research Institute
- Johns Hopkins University
- Kaiser Permanente Northern California
- Vanderbilt Medical Center

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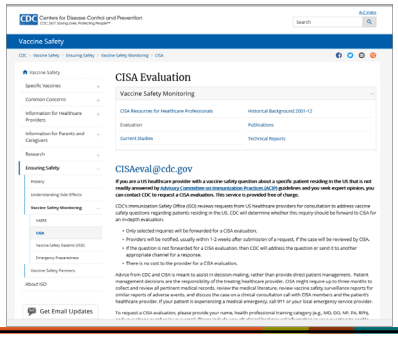

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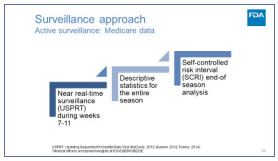
Selected FDA vaccine safety monitoring activities

Active surveillance for Guillain-Barré syndrome following influenza vaccination in Medicare data*



*https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2018-06/flu-04-Shimabukuro-508.pdf

FDA's Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program†

ORIGINAL REPORT

The Food and Drug Administration's Post-Licensure Rapid Immunization Safety Monitoring program: strengthening the federal vaccine safety enterprise

†Nguyen M et al. The Food and Drug Administration's Post-Licensure Rapid Immunization Safety Monitoring program: strengthening the federal vaccine safety enterprise. Pharmacoepidemiol Drug Saf. 2012;21 Suppl 1:291-7.

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Summary

- CDC and FDA continuously monitor the safety of vaccines
- Passive and active monitoring systems are in place to detect statistical signals for possible safety problems
  - VAERS, VSD, FDA monitoring in Medicare data
- Research studies in VSD or other systems can be planned studies to evaluate specific outcomes or vaccines or in response to detection of statistical signals in surveillance
- CISA conducts clinical research and clinical case reviews of complex vaccine adverse events to evaluate individual risk factors

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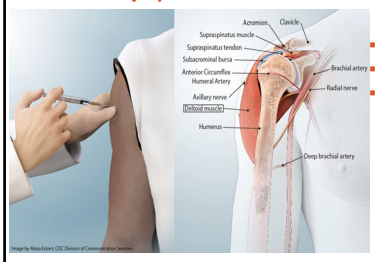
Immunization Technique: Shoulder Injury Related to Vaccine Administration (SIRVA)



- **Pain; reduced range of motion**
- Beginning **within 48 hours**
- Includes deltoid bursitis, other misdirected injection sites

Image by Alissa Eckert, CDC Division of Communication Services

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CDC activities around SIRVA

- Joint review (with HRSA) of SIRVA injury claims to the National Vaccine Injury Compensation Program (VICP)
  - **In progress**
- VAERS review of reports of atypical shoulder pain and dysfunction following inactivated influenza vaccine (IIV)
  - Reports with signs and symptoms that could be indicative of shoulder injuries following IIV are **uncommon and do not appear to be increasing** over time
- VSD study of risk of deltoid bursitis following IIV
  - Incidence is **uncommon**, **adult** condition, preliminary results indicate attributable risk of ~2.5 additional cases/million influenza vaccines administered
- Education and outreach on proper vaccine administration and SIRVA prevention

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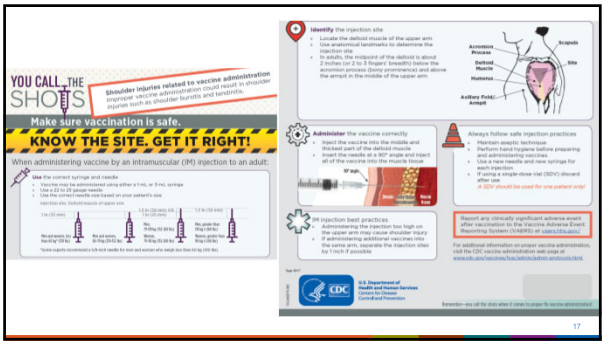

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Injection Safety Errors during Immunization

- Frequent
- Completely preventable
- Significant negative outcomes for patients

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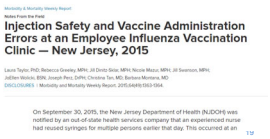
Employee Influenza Vaccination Clinic, 2015

- NJ DoH notified used syringes reused at employee influenza vaccination clinic
  - Out-of-state health services company
  - Nurse arrived with 3 multi-dose vials instead of prefilled syringes specified
- Nurse reported using two syringes to inject 67 employees
- Urgent Public Health response included bloodborne pathogen testing, counseling and offers to revaccinate



Injection Safety and Vaccine Administration Errors at an Employee Influenza Vaccination Clinic — New Jersey, 2015

On September 30, 2015, the New Jersey Department of Health (NJDOH) was notified by an out-of-state health services company that an experienced nurse had reused syringes for multiple persons earlier that day. This occurred at an

Colorado Pediatric Clinic, April 2011 Patient Notification due to Syringe Reuse

- **Medical assistant administered flu vaccine from one syringe to multiple patients**
  - Children between age 6 months and 35 months put at risk
- **Patient notification conducted; bloodborne pathogen testing advised**

April 12, 2011

Children told to be tested for HIV after flu vaccines reused

10:00 PM, Apr 12, 2011 | comments

FOX 59 NEWS VIDEOS MORNING TRAFFIC COMMUNITY CONTESTS PODCASTS ON-AIR TEAM SPORTS WEATHER 74°

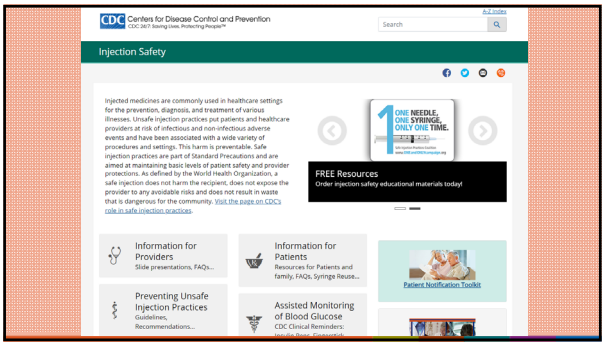
Officials warn vaccinations given in Indiana, Kentucky and Ohio may be causing infections

POSTED 1:29 PM, FEBRUARY 2, 2019, BY FOX59 WEB, *UPDATED AT 05:34PM, FEBRUARY 2, 2019*

FRANKFORT, Ky. – Health officials say vaccinations given out at various businesses in Indiana, Kentucky and Ohio may be causing infections because of contamination.

Kentucky's Department of Public Health (DPH) said Friday that the provider "Location Vaccination" had been giving the vaccinations at businesses since Sept. 1, 2018…

…multiple people have developed infections associated with the vaccines and those infected have experienced redness, pain or tenderness, swelling, and the development of hard lumps, or nodules, at the injection site.


CDC Centers for Disease Control and Prevention
Search
Injection Safety
Injected medicines are commonly used in healthcare settings for the prevention, diagnosis, and treatment of various illnesses. Unsafe injection practices put patients and healthcare providers at risk of infectious and non-infectious adverse events and have been associated with a wide variety of procedures and settings. This harm is preventable. Safe injection practices are part of Standard Precautions and are aimed at maintaining basic levels of patient safety and provider protections. As defined by the World Health Organization, a safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in waste that is dangerous for the community. Visit the page on CDC's role in safe injection practices.
ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.
FREE Resources
Order injection safety educational materials today!
Information for Providers
Slide presentations, FAQs...
Information for Patients
Resources for Patients and family, FAQs, Syringe Reuse...
Patient Notification Toolkit
Preventing Unsafe Injection Practices
Guidelines, Recommendations...
Assisted Monitoring of Blood Glucose
CDC Clinical Reminders:

Thank you!


HELP ENSURE PATIENT SAFETY.
MAKE EVERY INJECTION A SAFE ONE.
ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.