

Vaccination Errors Reported to the Vaccine Adverse Event Reporting System (VAERS), 2000-2013

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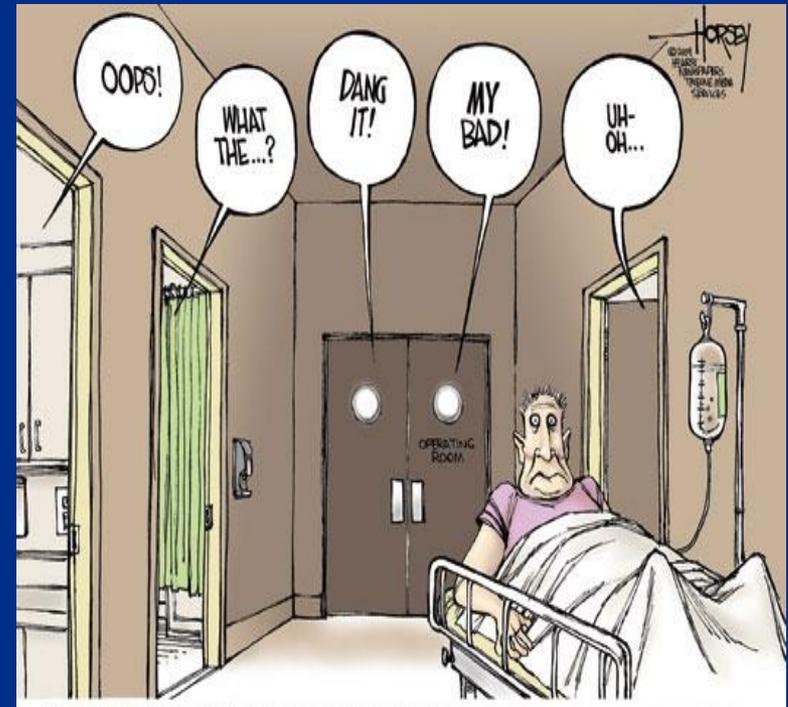
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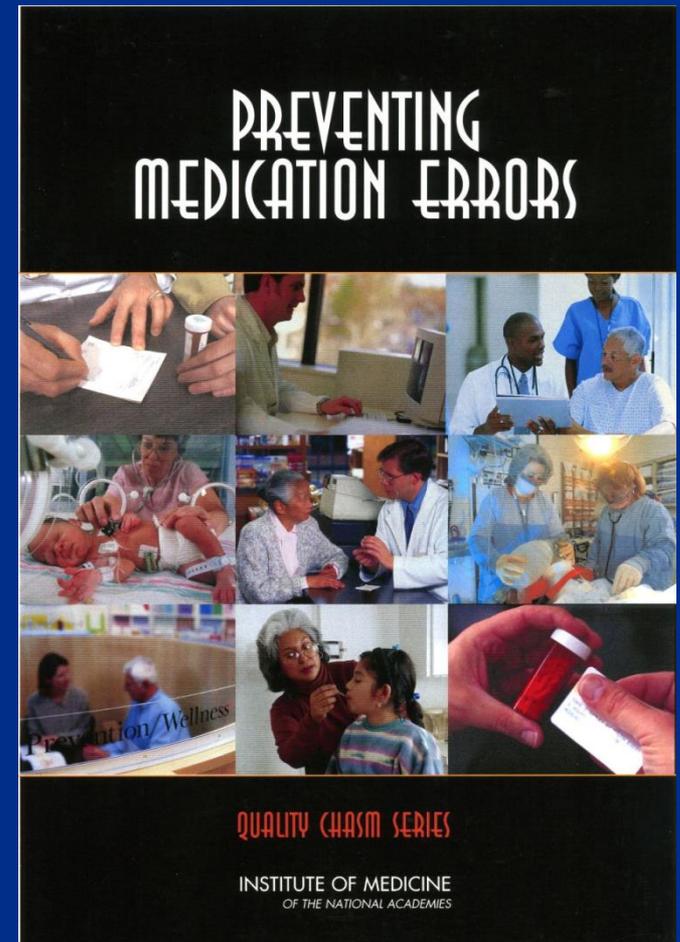
Overview

- ❑ Background
- ❑ Objective
- ❑ Methods
- ❑ Findings
- ❑ Summary
- ❑ Conclusions



Background Vaccination Errors

- ❑ Institute of Medicine (IOM) reports focused national attention on medical errors and medication errors^a
- ❑ Previous studies in VAERS 1990-2002 identified few reported errors (<100)^{b,c}



a Preventing Medication Errors IOM 2007, <http://www.nap.edu/>

b Varricchio F. Medication errors reported to the vaccine adverse event reporting system (VAERS). *Vaccine*. 2002 Aug 19;20(25-26):3049-51.

c Varricchio F, Reed J; Follow-up study of medication error reported to the vaccine adverse event reporting system (VAERS). *South Med J*. 2006 May;99(5):486-9.

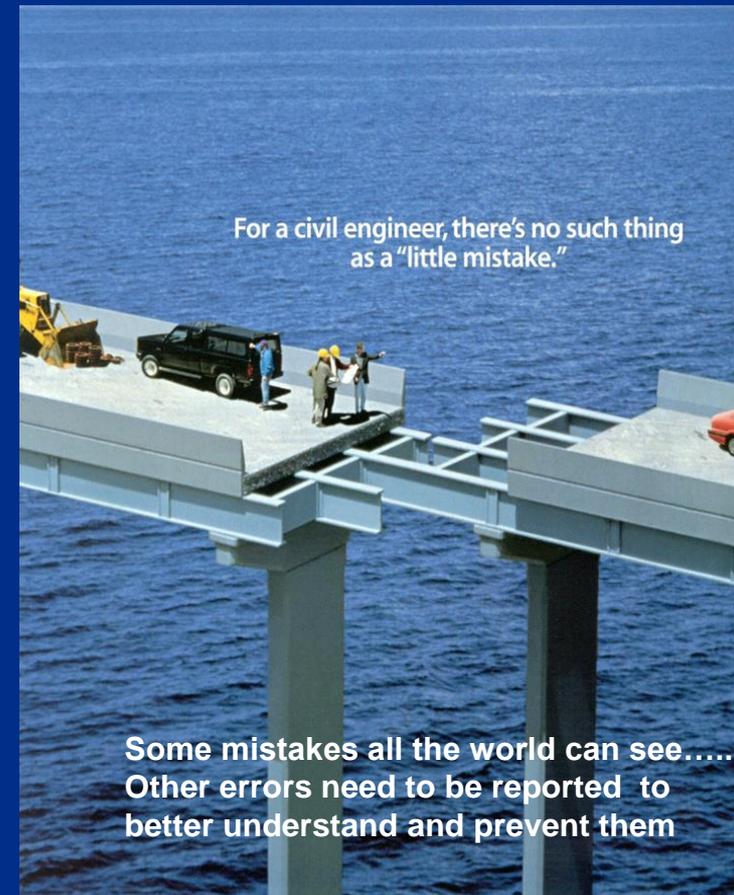
National Organizations that Accept Reports of Vaccination Errors

- ❑ **Vaccine Adverse Event Reporting System (VAERS)**
 - Accepts reports about adverse events following immunization www.vaers.hhs.gov

- ❑ **MedWatch**
 - Accepts reports about products regulated by the FDA, including drugs and medical devices www.fda.gov/medwatch

- ❑ **Institute for Safe Medication Practices (ISMP) and California Department of Public Health (CDPH)**
 - Vaccination Error Reporting Program (VERP) accepts reports related to vaccination errors <http://verp.ismp.org/>

- ❑ **MEDMARX**
 - Limited to hospitals that are part of their medication error program



Definitions

❑ Vaccination Error

- Any preventable event that may cause or lead to inappropriate use or patient harm. Such events may be related to professional practice, immunization products, (vials, needle, syringes), storage, dispensing and administration*

❑ Vaccine Adverse Health Events

- Health effects that occur after immunization that may or may not be causally related to the vaccination

*CDC Immunization Safety Office, VAERS Medication Error Study workgroup. Adapted in part from U.S. Pharmacopeia (USP) medical error definition from http://www.usp.org/sites/default/files/usp_pdf/EN/members/patientSafety.pdf

Vaccine Adverse Event Reporting System (VAERS)

- ❑ Authorized by National Childhood Vaccine Injury Act of 1986
- ❑ Jointly administered CDC and FDA
- ❑ National, post-marketing, passive reporting system for adverse events occurring after receipt of US-licensed vaccines
- ❑ Began receiving reports in 1990
- ❑ Receives average ~36,000* reports/year (2009-2013)
- ❑ Data available to the public at wonder.cdc.gov/vaers.html and vaers.hhs.gov/data/data

*Numbers include both US and foreign reports, primary and non-primary

Vaccine Adverse Event Reporting System (VAERS) (co-managed CDC and FDA)*

Strengths

- ❑ National data; accepts reports from anyone
- ❑ Rapid signal detection; rare adverse events (AE)
- ❑ Collects information about vaccine, characteristics of vaccinee, adverse event
- ❑ Data available to public

Limitations

- ❑ Under-reporting
- ❑ Reporting bias
- ❑ Inconsistent data quality and completeness
- ❑ Generally cannot assess if vaccine or error caused an adverse health event
- ❑ VAERS coding practices can affect types and numbers of errors reported

* VAERS website: <http://vaers.hhs.gov>

Objective

- ❑ **To describe reports of vaccination errors to VAERS during 2000-2013***
 - **Types and frequency**
 - **Adverse health events**

Methods

Total VAERS Reports 2000-2013

Vaccination Error Reports*

Types of errors
classified into 11 error
groups

Top 3 error
groups

5% random
sample for
each group
clinically
reviewed

Contraindication
reports

All reports
clinically
reviewed

Errors and adverse
health events

Error no health
event
documented

Error with
health event

“Non-serious”
reports

“Serious”
reports

All reports
clinically
reviewed

“Cluster” errors involving
multiple individuals
same location

All reports
clinically
reviewed

* VAERS U.S. primary reports analyzed using Medical Dictionary for Regulatory Activities (MedDRA) codes describing vaccination errors and SAS version 9.2 (SAS Institute Inc., Cary, NC)

Groupings of Vaccine Error Codes (N=11 Groups)

Accidental

- Accidental exposure
- Accidental exposure to product
- Accidental needle stick

Administration errors

- Drug administered at inappropriate site
- Drug administration error
- Incorrect drug dosage form administered
- Incorrect drug administration duration
- Incorrect route of drug administration
- Multiple use of a single-use product
- Wrong technique in drug usage process

Contraindication

- Contraindication to vaccination
- Documented hypersensitivity to administered drug
- Labeled drug-drug interaction medication error

Equipment

- Injury associated with device
- Medical device complication
- Needle issue
- Syringe issue

General

- Medication error
- Vaccination error

Inappropriate schedule

- Inappropriate schedule of drug administration
- Drug administered to patient of inappropriate age

Incorrect dose

- Accidental overdose
- Drug dose omission
- Extra dose
- Incorrect dose administered
- Underdose
- Overdose
- Multiple drug overdose

Product quality

- Product contamination,
- Product contamination microbial
- Product contamination physical
- Product quality issue

Product labeling/packaging

- Drug name confusion
- Product label confusion
- Product name confusion
- Product container issue
- Product label issue
- Product label on wrong product
- Product outer packaging issue
- Product packaging issue
- Product packaging confusion

Storage and dispensing

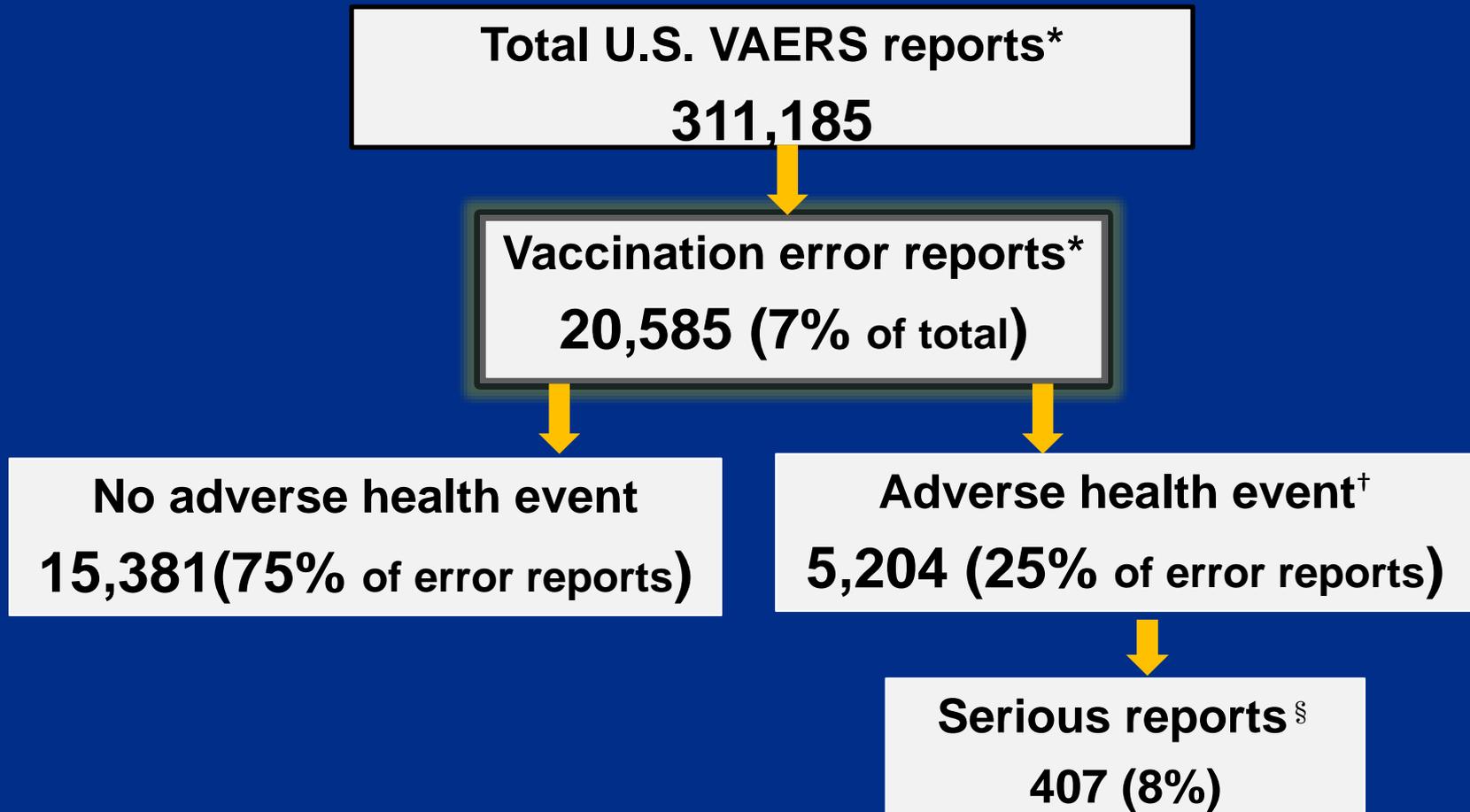
- Drug dispensing error
- Expired drug administered
- Incorrect product storage
- Incorrect storage of drug
- Poor quality drug administered
- Product reconstitution issue

Wrong drug

- Drug dispensed to wrong patient
- Wrong drug administered

Results

Vaccination Error Reports to VAERS 2000-2013

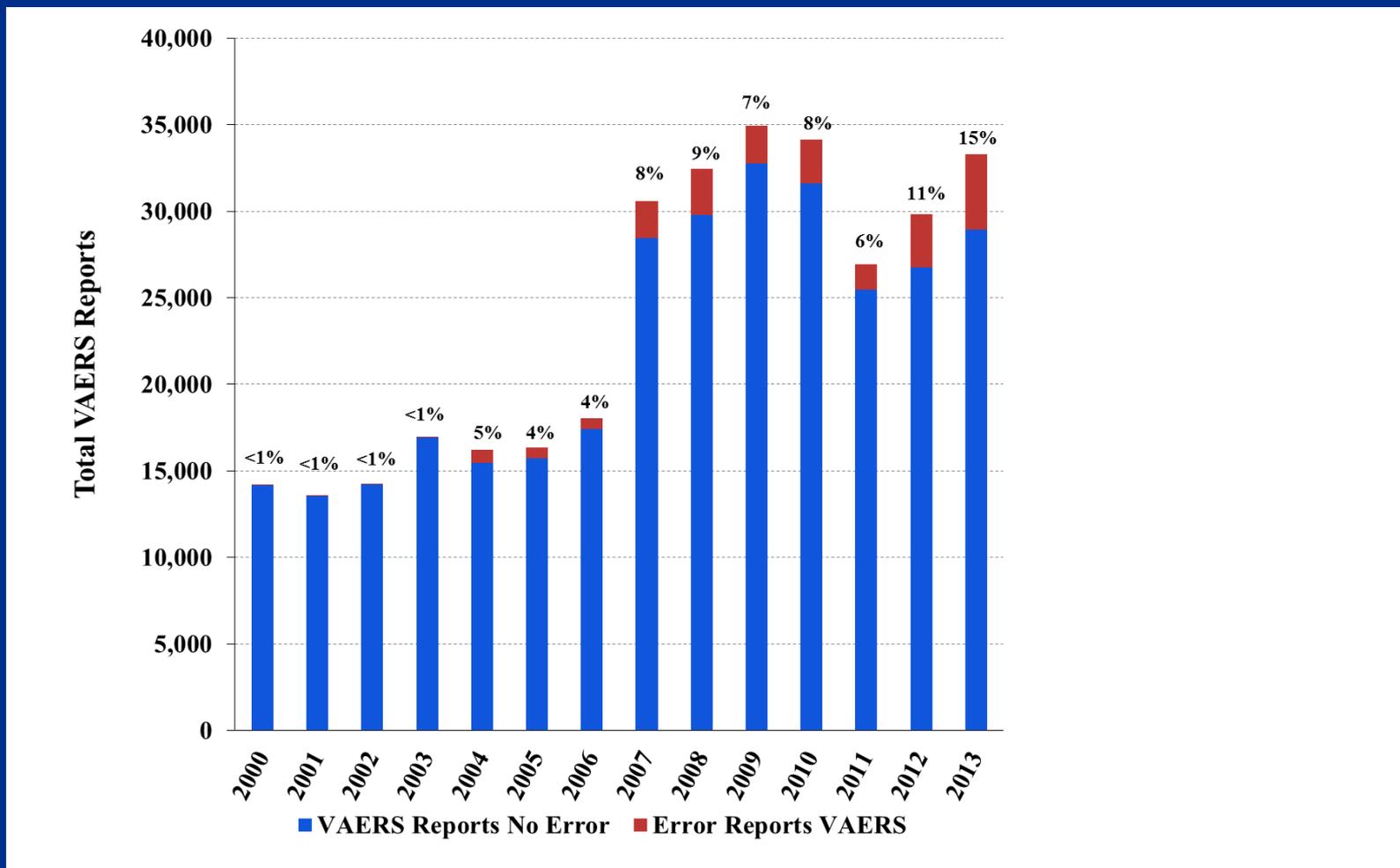


* Primary U.S. reports with one or more codes describing adverse health events or vaccination errors

† Adverse health event (health problem) following vaccination

§ Based on the Code of Federal Regulations a report is classified as serious if one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization or permanent disability

Vaccine Error Reports* Number and Percentage † of all VAERS reports‡ by year, 2000-2013



* 20,585 total vaccination error reports, primary U.S. VAERS 2000-2013

† Percent of vaccination error reports among all primary U.S. VAERS reports by year

‡ 311,185 total primary U.S. VAERS reports 2000-2013

Number of Reports by Error Group Reported to VAERS, 2000-2013

Vaccine Error Group*	N	%
Inappropriate schedule	5,947	27%
Storage/Dispensing	4,983	23%
Wrong vaccine	3,372	15%
General error	2,526	12%
Incorrect dose	2,002	9%
Administration error	1,951	9%
Accidental exposure	373	2%
Product Quality	239	1%
Contraindication	215	1%
Equipment	205	1%
Product Labeling/Packaging	30	<1%
Total Errors†	21,843	

* Some groupings contain more than 1 MedDRA Code; error groups are not mutually exclusive

† Total primary reports with errors = 20,585; an individual report may be associated with more than 1 vaccination error or error group depending on assigned Medical Dictionary for Regulatory Activities (MedDRA) terms

Top Three Vaccination Errors

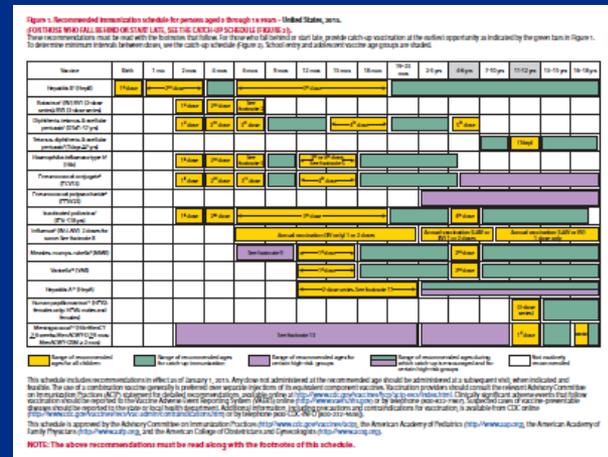
1. “Inappropriate Schedule” errors (wrong age, wrong timing between doses) (5,947; 27%)

- Most common age - Children 0-1 year, (53% of the 0-18 age group)



❑ Wrong Timing (most common vaccines)

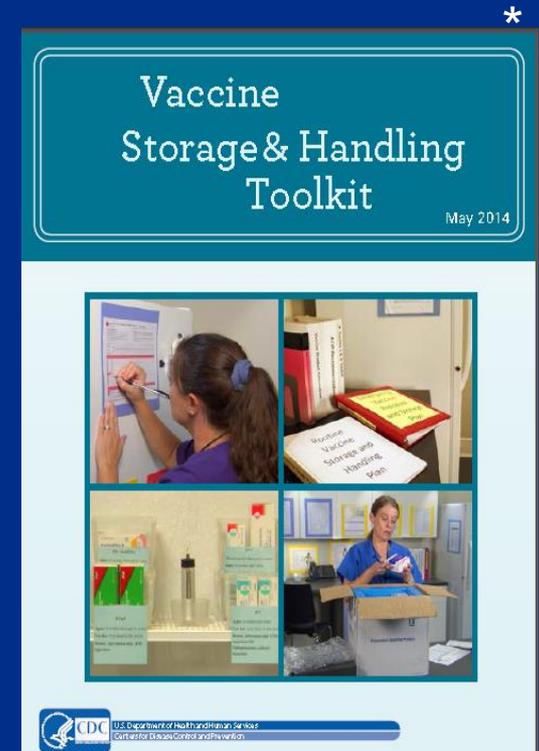
- Quadrivalent Human Papillomavirus (1,516)
 - Delays between dose 1 and dose 2*
 - 3rd dose given too soon (12 wk minimum)*
- Rotavirus vaccine (880)
 - First dose given late > 15 wks*
 - Last dose given after 32 week cut off*



Top 3 Errors- cont

2. “Storage errors” (4,983, 23%)

- ❑ **Expired vaccine administered (2,746; 55%)**
 - Seasonal live attenuated influenza (LAIV) (978; 36%)
- ❑ **Incorrect storage of vaccine (2,202; 44%)**
 - Vaccines kept outside of proper storage temperatures (88%)[†]
 - Patient receiving vaccine (95%)
 - Refrigerator/freezer was not holding proper temperatures (74%)



*CDC Vaccine Storage and Handling Tool Kit available at www.cdc.gov/vaccines/recs/storage/toolkit/

[†]Based on 5% random sample review of reports

Top Three Vaccination Errors- cont

3. “Wrong vaccine administered” (3,372; 15%)

- Occurs among vaccines with similar: names, acronyms, antigens

Common Wrong Vaccine Mix-ups*		
Varicella	with	Herpes zoster
Diphtheria, tetanus and pertussis (DTaP)	with	Tetanus, diphtheria and pertussis (Tdap)
Trivalent inactivated influenza vaccines (IIV)	with	Another IIV of different age indications
Pneumococcal conjugate	with	Pneumococcal polysaccharide
Hepatitis A	with	Hepatitis B

* Vaccine mix ups can be either combination (e.g. varicella vaccine instead of herpes zoster vaccine or herpes zoster vaccine instead of varicella vaccine)

“Contraindication” Errors

- **Most common, drug exposure during pregnancy (56%)**
 - 111/120 (93%) involved live attenuated influenza vaccine
 - Adverse health events described in 18 (15%) of these reports;
 - 7 adverse health events were pregnancy related:
 - spontaneous abortion (6)
 - Vaginal bleeding (1)

- **Other common contraindication errors reported**
 - Live vaccines given to persons with immunodeficiency conditions
 - Vaccines given to persons with a history of an allergic reaction to a vaccine component
 - Live attenuated influenza administered to persons with asthma

Adverse Health Events and Errors, 5204 (25%)

- **Most common adverse health events (AHEs);**
 - Injection site erythema (680; 13%), injection site pain (593; 11%) and pyrexia (569; 11%)
 - Serious reports* 407(8%), all clinically reviewed;
 - injection site reactions (103; 25%), musculoskeletal (e.g. shoulder pain) (52;13%) neurological (e.g., headache) (50;12%)

- **Error groups and reported AHE's**
 - “Administration Errors” (e.g. wrong site, wrong technique, incorrect route) had the highest percent of AHEs for its group (1,176 of 1,951 error reports; 60%)

* Based on the Code of Federal Regulations a report is classified as serious if one of the following is reported: death, life-

Error Clusters

Same error, multiple individuals, same location



- ❑ 936 error clusters
 - Cluster size 2-501 patients (median 5)
 - 110 clusters involved 10+ patients
 - 586 clusters, the specific number of patients affected stated as “unknown, or several”

- ❑ Storage errors most common (72%)
 - Incorrect product storage (582 clusters, 1715 patients)
 - Expired vaccine administered (96 clusters, 1340 patients)
 - LAIV (45 clusters, 990 patients)

Who is Reporting Errors to VAERS?

Reporter Type*	Error Reports Frequency/ Percent	All VAERS Reports Frequency/ Percent
Vaccine Manufacturer	13,106 (64%)	71,450 (23%)
Vaccine Provider	4,356 (21%)	127,518 (41%)
Other	2,635 (13%)	68,235 (22%)
Patient/Parent	460 (2%)	34,299 (11%)
Missing No data	28 (<1%)	9,683 (3%)
Total	20,585	311,185

*Reporter type is selected by the VAERS Reporter from specified options listed on form, VAERS primary report data 2000-2013

Potential Strategies for Reducing Vaccination Errors

- ❑ Education and training on vaccine timing, spacing and proper administration technique
- ❑ Improve monitoring of vaccine storage temperatures
- ❑ Increase awareness and establish procedures to monitor the relatively short expiration of live attenuated influenza vaccine
- ❑ Improvements in differentiating vaccines and other products with similar sounding names and acronyms
- ❑ Implementation and enforcement of procedures to properly screen for vaccines contraindicated for an individuals, such as live vaccines in pregnant women.

Summary

- ❑ **Vaccination Error reports comprised 6-15% of all reports to VAERS in recent years**
 - **The number and percentage of vaccination error reports have increased significantly in VAERS during the period 2000-2013**
- ❑ **Three-fourths of vaccination error reports have no reported adverse health event**
 - **However, errors can affect cost, convenience, effectiveness, and confidence in vaccination programs**

Acknowledgements

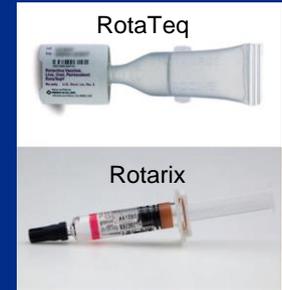
- ❑ Pedro Moro MD, MPH
- ❑ Paige Lewis MPH
- ❑ Elaine Miller RN, MPH
- ❑ Tom Shimabukuro MD, MPH, MBA

Other Errors Reported to VAERS of Interest

Rotavirus Errors 2006- 2013 VAERS

❑ Oral Rotavirus Vaccine Injected* (39)

- Rotarix (33), RotaTeq (6)
- Adverse health events (19;49%), irritability, injection site reactions
- Reasons for Error- misinterpreted instructions, confused Rotarix vial for Injectable vaccine, inadequate training, not reading package insert



❑ Eye splashes* (27)

- Eye splash following oral rotavirus vaccines with infant coughing, sneezing or spitting the vaccine into eyes
 - Healthcare providers most commonly affected (80%)
 - Adverse health events in (21;78%) included eye irritation, hyperemia, pruritus, blurred vision

❑ Proper administration- use the manufacturers' oral applicator devices (squirt gently and slowly into the child's cheek),



* Hibbs BF, Miller ER, Shimabukuro T. Centers for Disease Control and Prevention (CDC). Notes from the field: rotavirus vaccine administration errors-United States, 2006-2013. *MMWR Morb Mortal Wkly Rep.* 2014; 63(4):81

Administration of Expired Live Attenuated Influenza Vaccine (LAIV)*

- ❑ **Reports of administration of expired LAIV flu vaccine 866 (18.4% of all LAIV reports to VAERS) July 1, 2007, through June 30, 2014 to VAERS,**
 - LAIV generally has an 18 week shelf life, Inactivated influenza vaccine generally lasts until the end of flu season (June 30th)
- ❑ **No health event documented in 98% of the reports**
- ❑ **In 95% of expired LAIV reports the vaccination occurred after the first week in November which is approximately 18 weeks from July 1st.**

* Haber P, Schembri CP, Lewis P, Hibbs B, Shimabukuro T. Notes from the Field: Reports of Expired Live Attenuated Influenza Vaccine Being Administered -United States, 2007–2014. *MMWR Morb Mortal Wkly Rep.* 2014; 63(35):773.

Conclusions

- ❑ **Vaccination Errors are an important area in vaccine safety research and surveillance**
- ❑ **Continued study will be key in understanding risk factors and developing prevention strategies**
- ❑ **Focus of continued study in VAERS:**
 - **Vaccination errors that occur frequently**
 - **Errors that may be associated with an adverse health outcome**
 - **Prevention of vaccination errors**

Questions?