Vaccinations Outside Recommended Ages — 2014; Six Immunization Information System Sentinel Sites

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CDC Immunization Information Systems Support Branch

American Immunization Registry Association National Meeting

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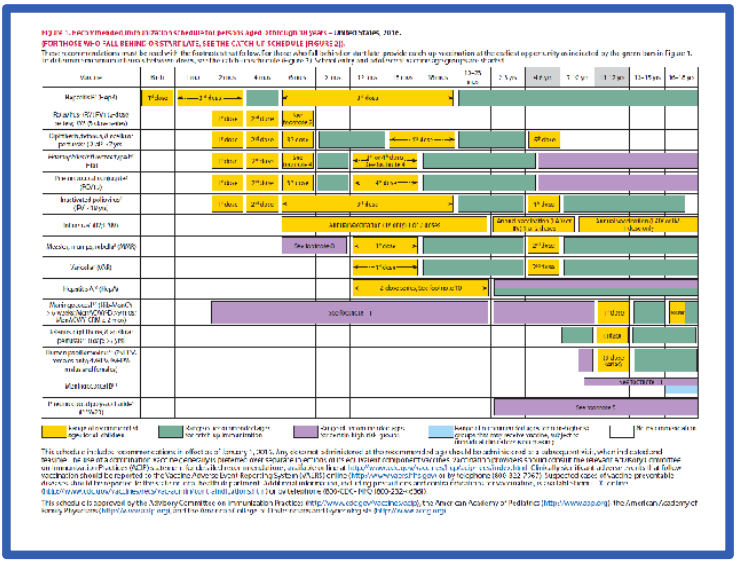
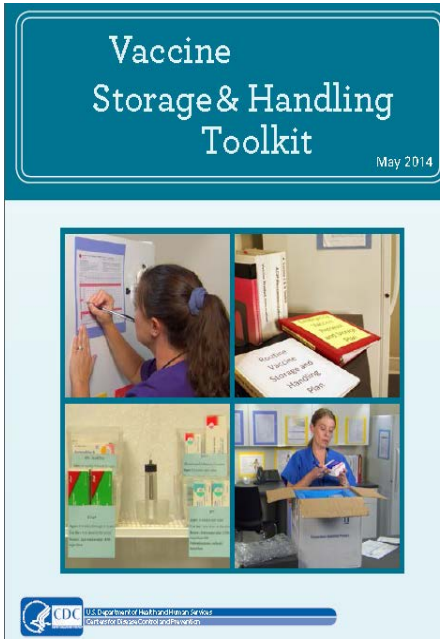
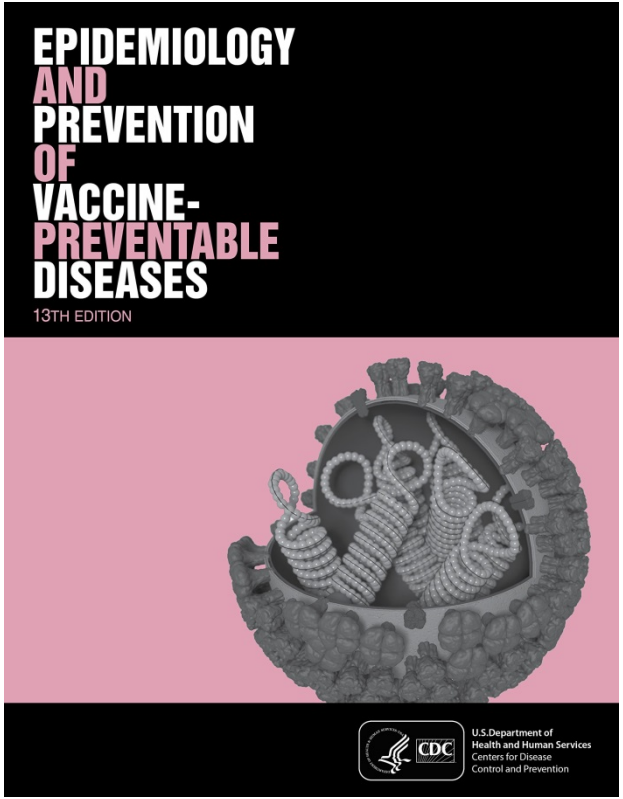
Guidance for Vaccination



Immunization
You Call the Shots



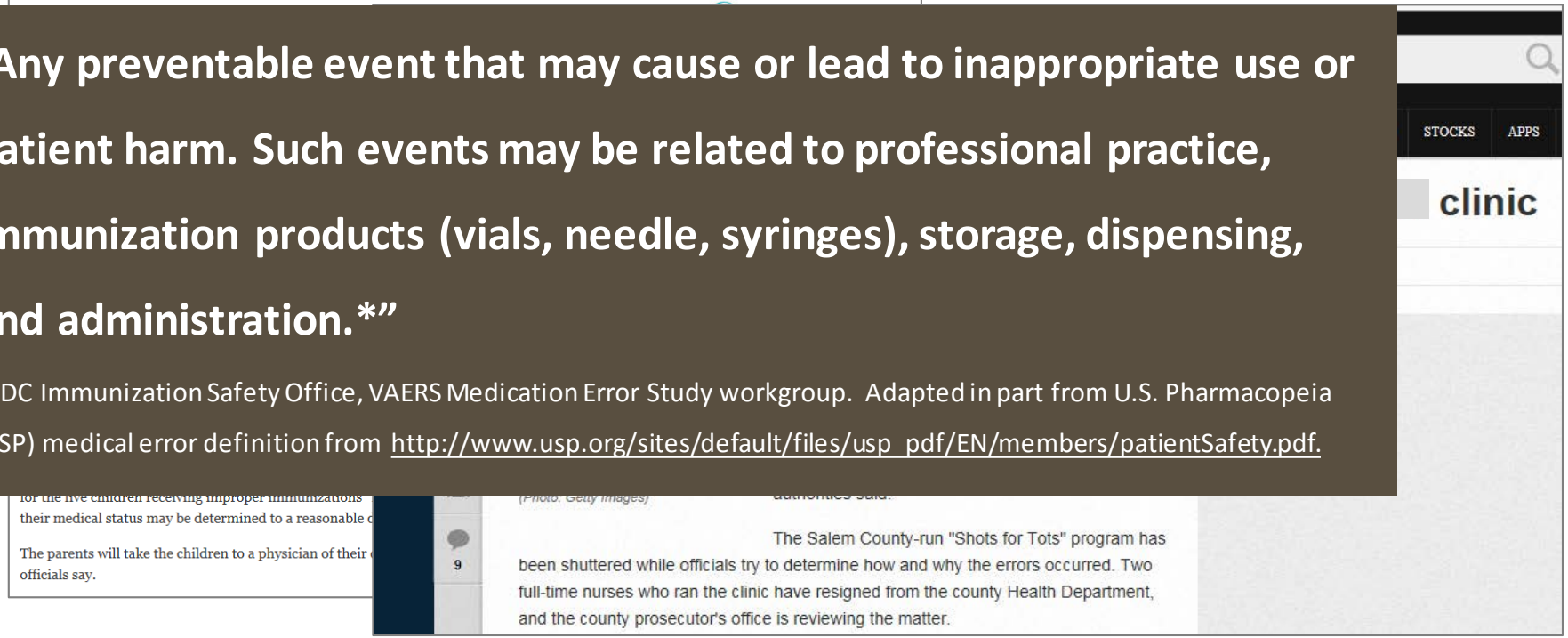


Vaccination Errors Happen

Children got wrong immunizations, including cervical cancer vaccine, at [redacted] County clinic, officials say

"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.*"

*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.



Vaccination Errors Can Be Costly

- Revaccination cost
- Wasted vaccine
- Reduced vaccine supply
- Staff time
- Healthcare practices and system
- Patient and caregivers inconvenienced
- Decreased public confidence
- Adverse health events
- Increased disease burden

National Organizations that Accept Reports of Vaccination Errors

- MedWatch [1]
- Vaccination Error Reporting Program [2]
- MEDMARX [3]
- Vaccine Adverse Event Reporting System (VAERS) [4]

[1] www.fda.gov/medwatch [2] www.verp.ismp.org [3] https://www.medmarx.com/ [4] www.vaers.hhs.gov

Vaccine Adverse Event Reporting System (VAERS)

- National post-marketing voluntary reporting system for adverse events occurring after receipt of US-licensed vaccines [1,2]
- Jointly administered by CDC and FDA
- Receives an average ~36,000 reports/year (2009–2013) .[3]
- Accepts vaccination error reports

[1] www.vaers.hhs.gov
[2] http://wonder.cdc.gov/vaers.html
[3] Number include both U.S. and foreign reports, primary and non-primary.

Vaccination Error Reports to VAERS, 2000–2013

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Vaccination errors reported to the Vaccine Adverse Event Reporting System, (VAERS) United States, 2000–2013

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ABSTRACT

Importance: Vaccination errors are preventable events. Errors can have impacts including inadequate immunological protection, possible injury, cost, inconvenience, and reduced confidence in the healthcare delivery system.
Objectives: To describe vaccination error reports submitted to the Vaccine Adverse Event Reporting System (VAERS) and identify opportunities for prevention.
Methods: We conducted descriptive analyses using data from VAERS, the U.S. spontaneous surveillance system for adverse events following immunization. The VAERS database was searched from 2000 through 2013 for U.S. reports describing vaccination errors and reports were categorized into 11 error groups. We analyzed numbers and types of vaccination error reports, vaccines involved, reporting trends over time, and descriptions of errors for selected reports.
Results: We identified 20,585 vaccination error reports documenting 21,843 errors. Annual reports increased from 10 in 2000 to 4324 in 2013. The most common error group was "Inappropriate Schedule" (5947; 27%); human papillomavirus (quadrivalent) (1516) and rotavirus (880) vaccines were most frequently involved. "Storage and Dispensing" errors (4983; 23%) included mostly expired vaccine administered (2746) and incorrect storage of vaccine (2202). "Wrong Vaccine Administered" errors (3372; 15%) included mix-ups between vaccines with similar antigens such as varicella/herpes zoster (shingles), DTaP/Tdap, and pneumococcal conjugate/polysaccharide. For error reports with an adverse health event (5204; 25% of total), 92% were classified as non-serious. We also identified 936 vaccination error clusters (i.e., same error, multiple patients, in a common setting) involving over 6141 patients. The most common error in clusters was incorrect storage of vaccine (582 clusters and more than 1715 patients).
Conclusions: Vaccination error reports to VAERS have increased substantially. Contributing factors might include changes in reporting practices, increasing complexity of the immunization schedule, availability of products with similar sounding names or acronyms, and increased attention to storage and temperature lapses. Prevention strategies should be considered.

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Vaccination Error Reports 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	

Rotavirus vaccine after age 8 months

DTaP instead of Tdap

Vaccination Error Reports to VAERS, 2000–2013

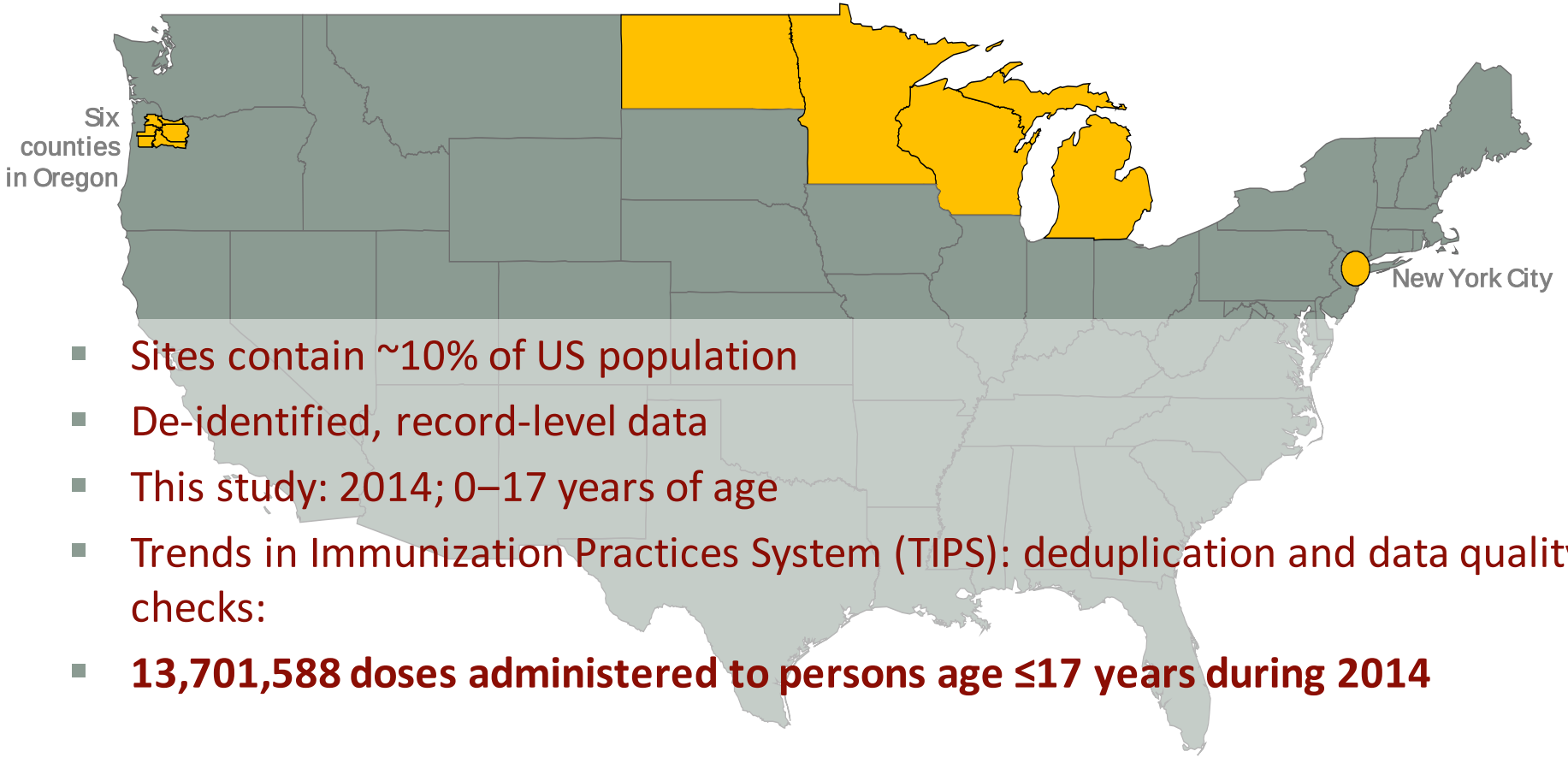
VAERS data are limited by

- Under-reporting
- Reporting bias
- Inconsistent data quality
- Coding practices

Objective

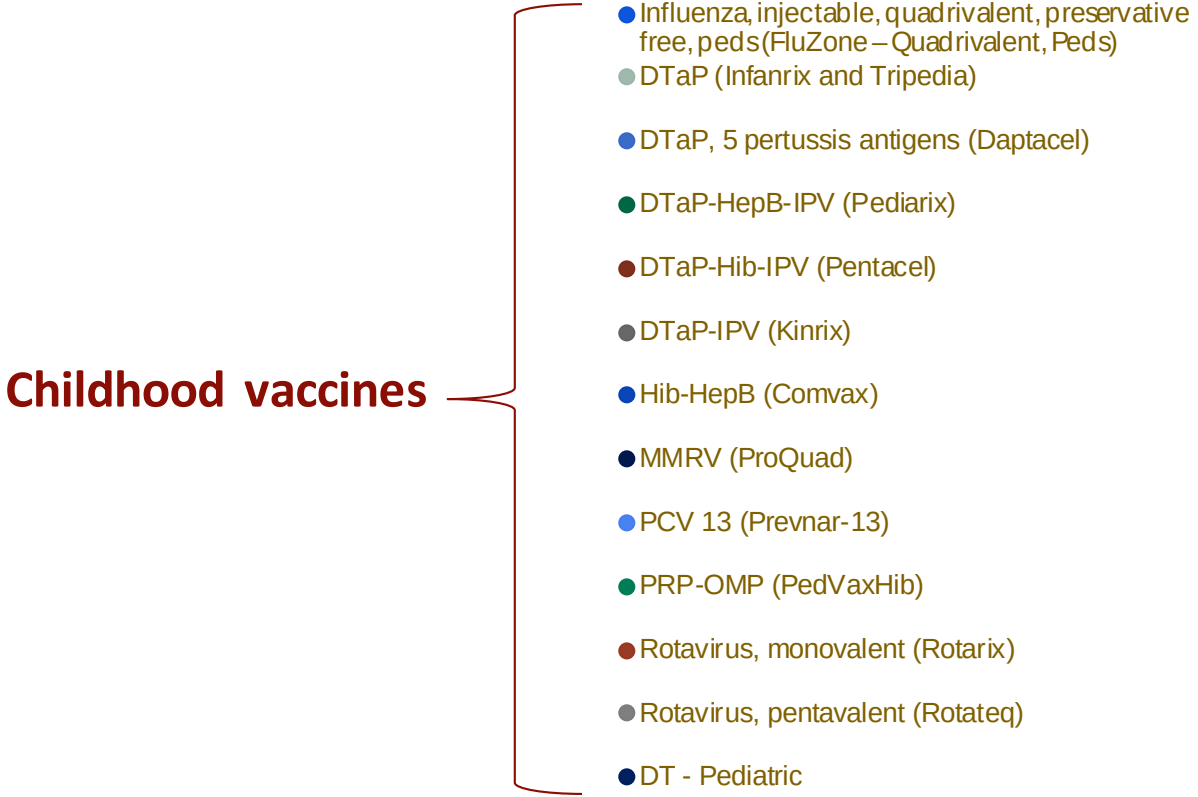
Use IIS Sentinel Site data to quantify how frequently vaccines are administered outside recommended ages.

Six IIS Sentinel Sites



- Sites contain ~10% of US population
- De-identified, record-level data
- This study: 2014; 0–17 years of age
- Trends in Immunization Practices System (TIPS): deduplication and data quality checks:
- **13,701,588 doses administered to persons age ≤17 years during 2014**

Childhood Vaccines Given Too Late



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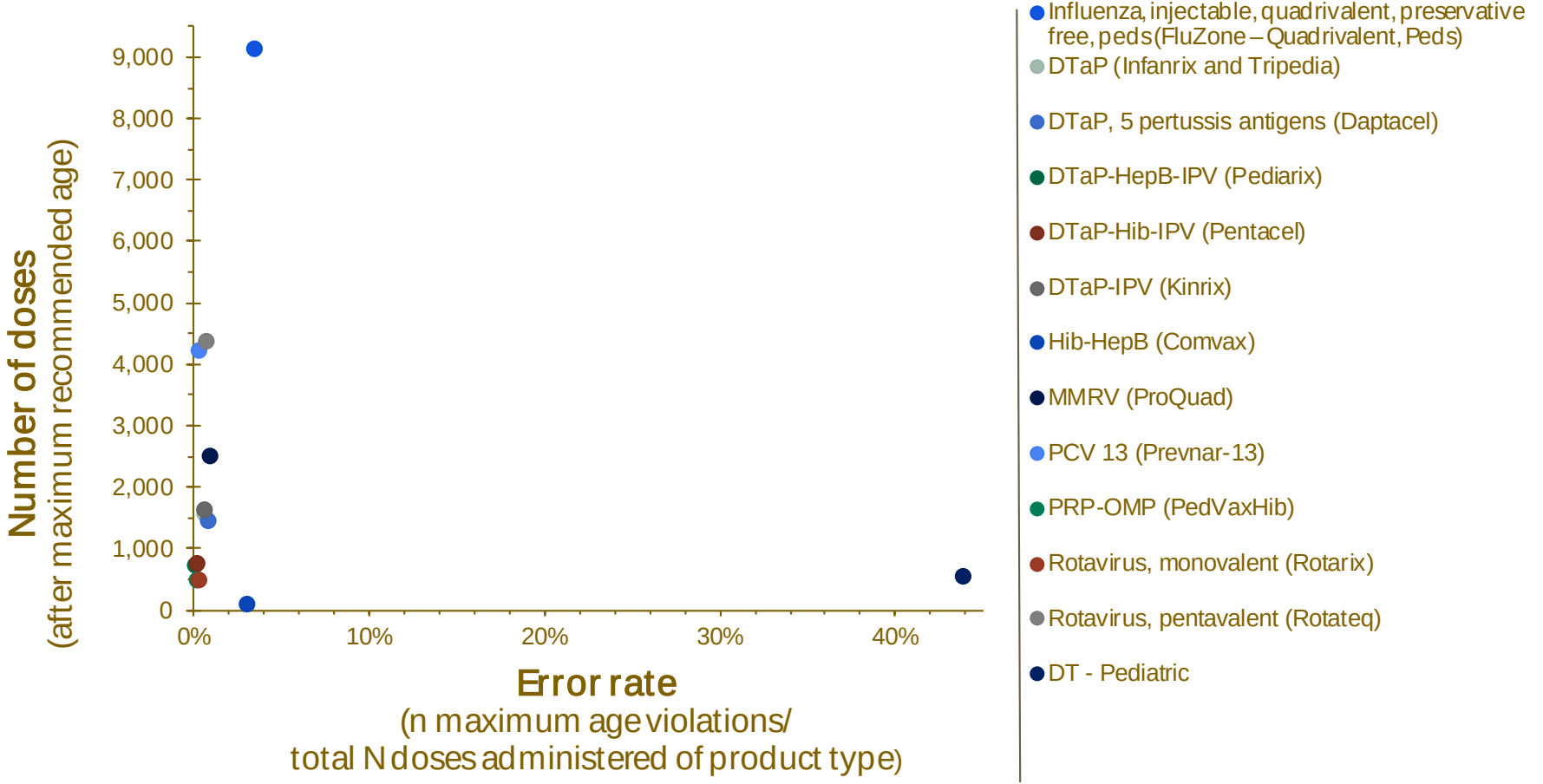

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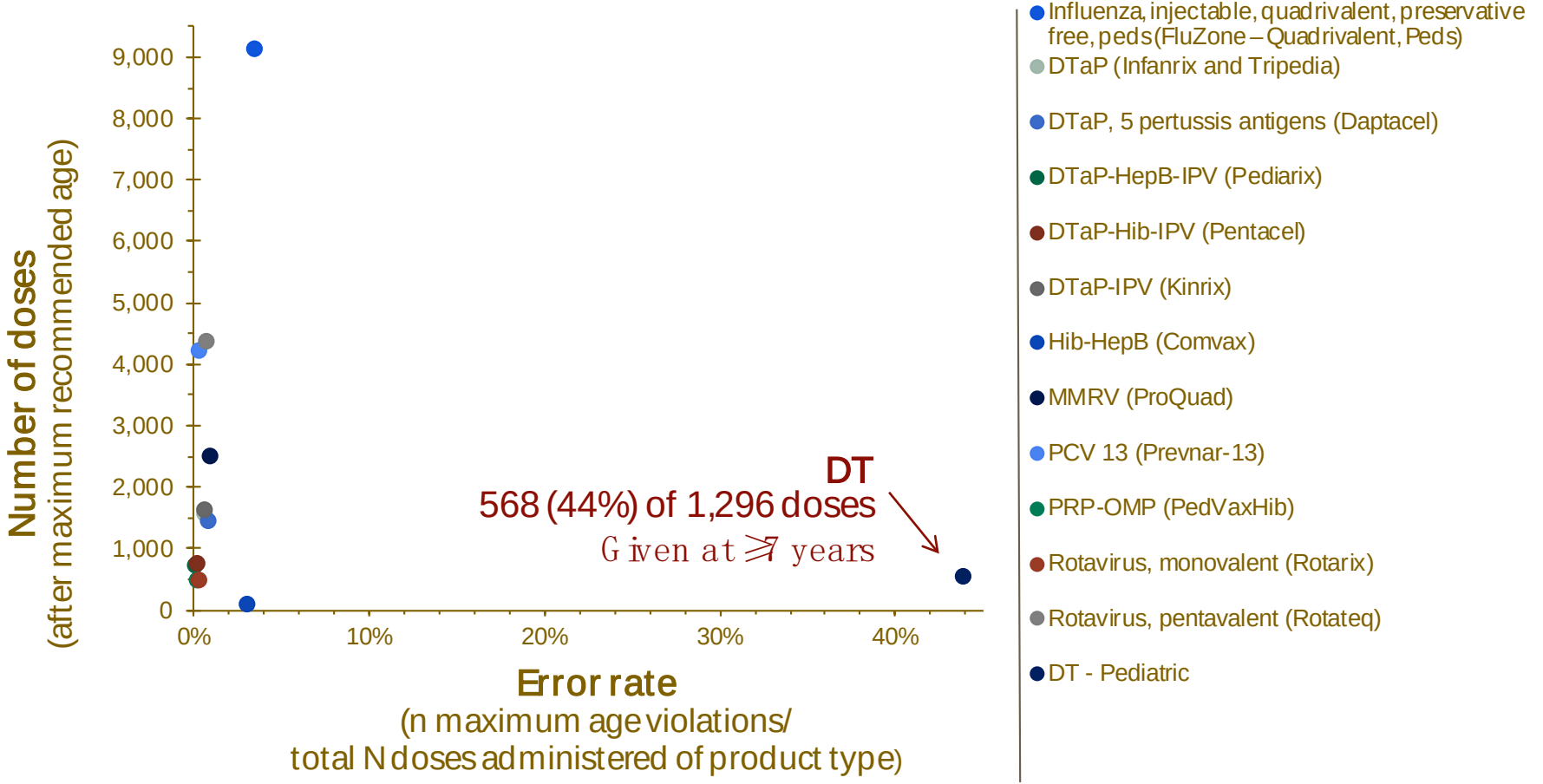

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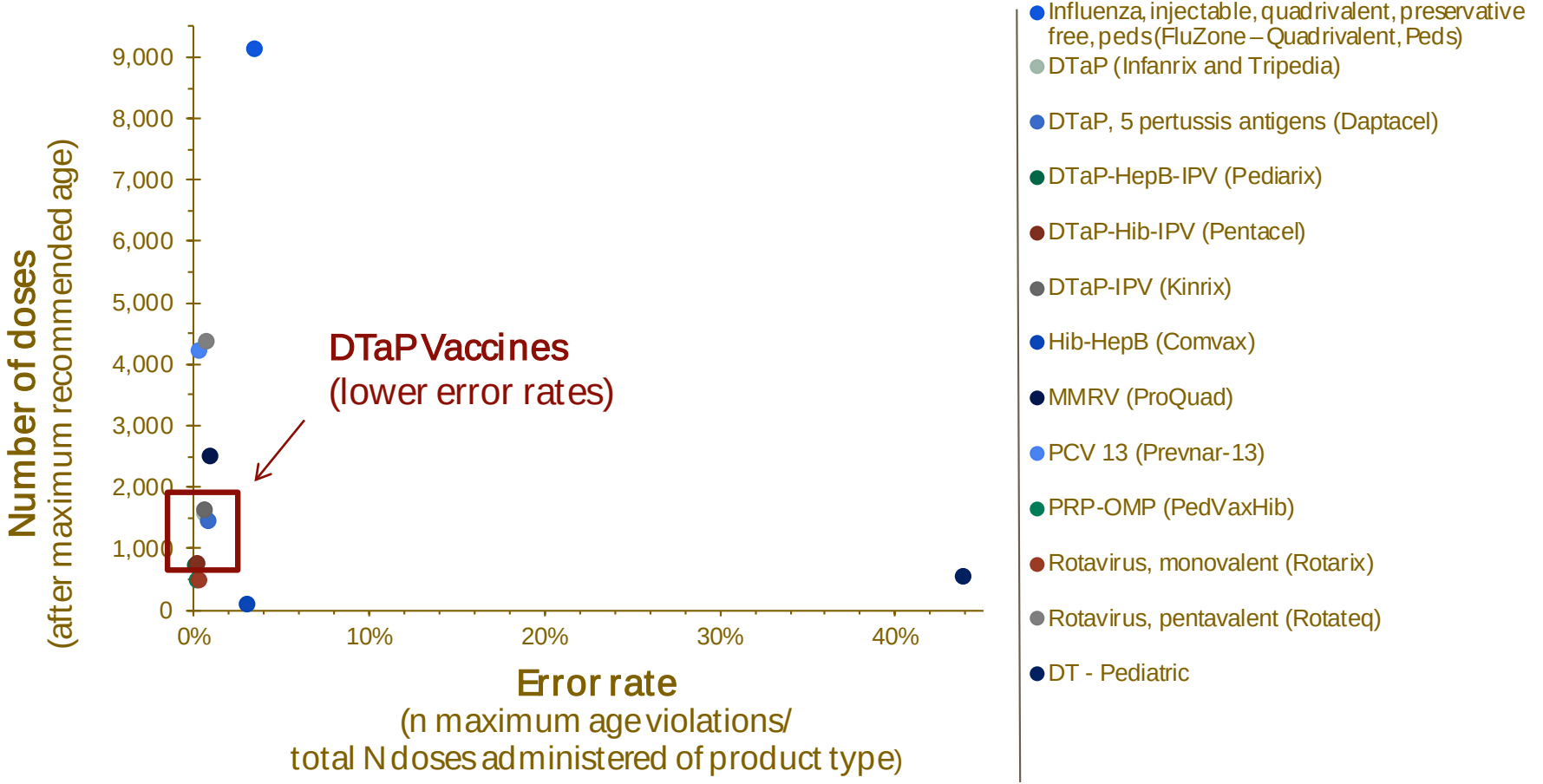

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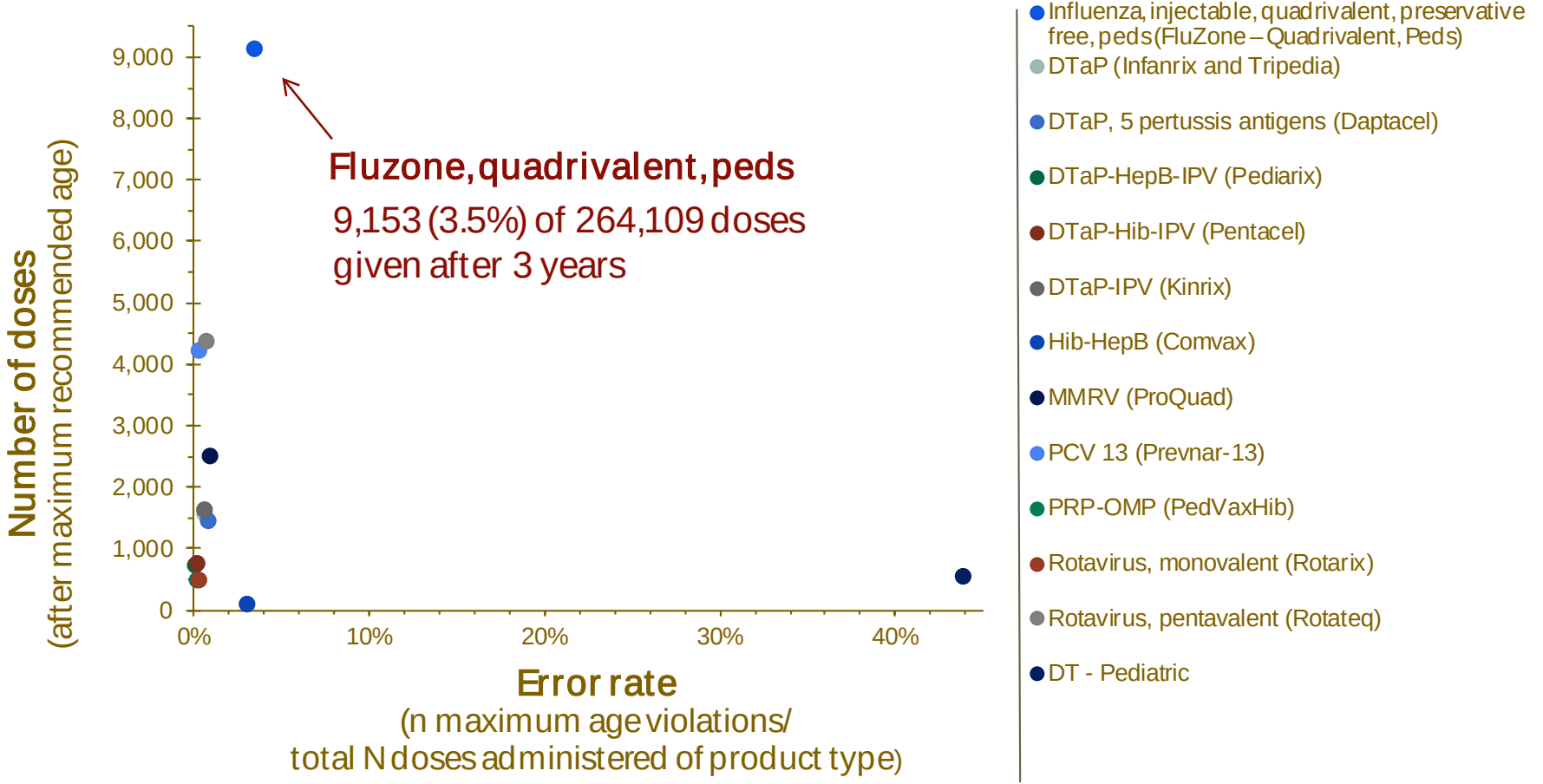

Childhood Vaccines Given Too Soon

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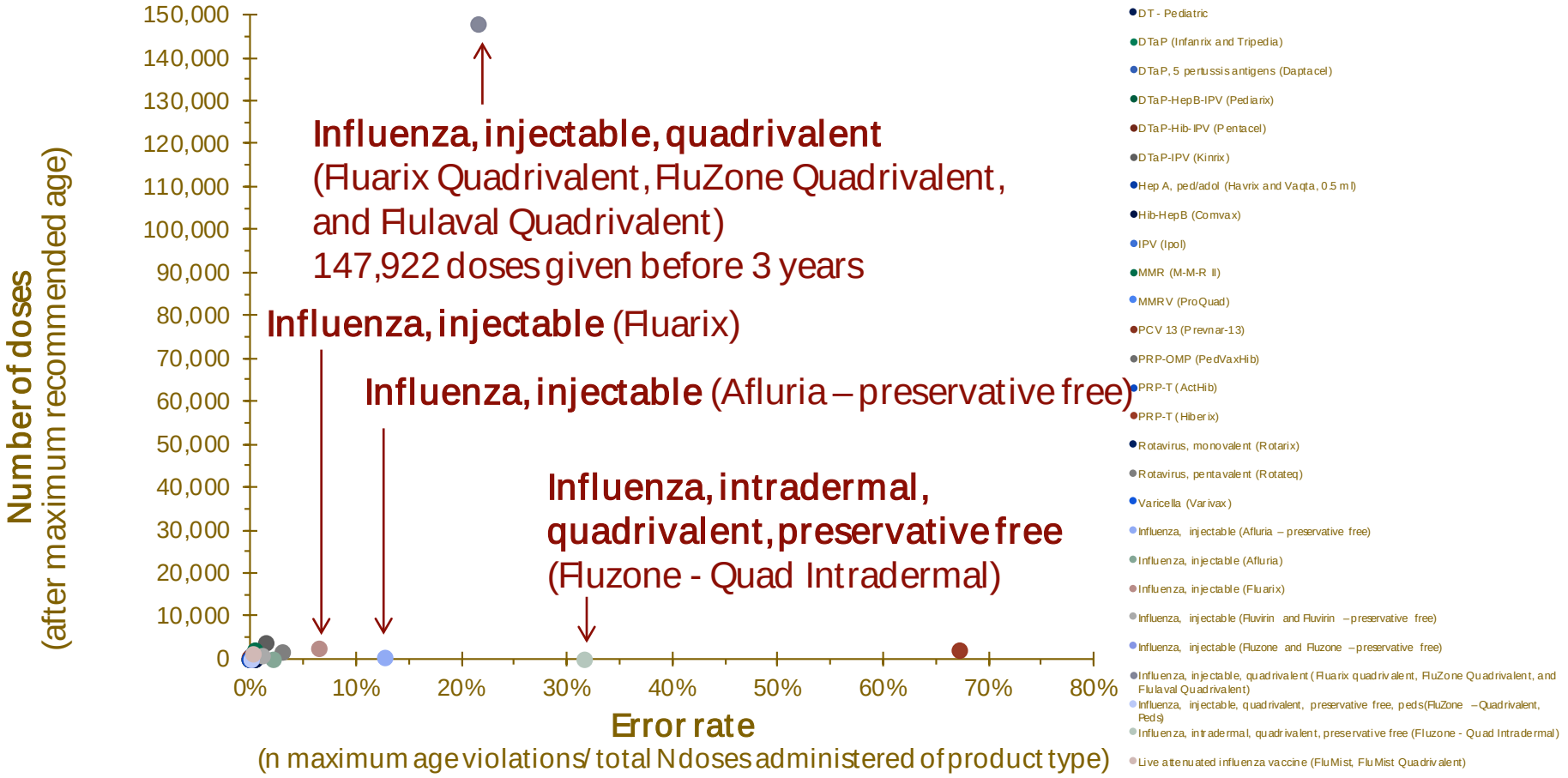
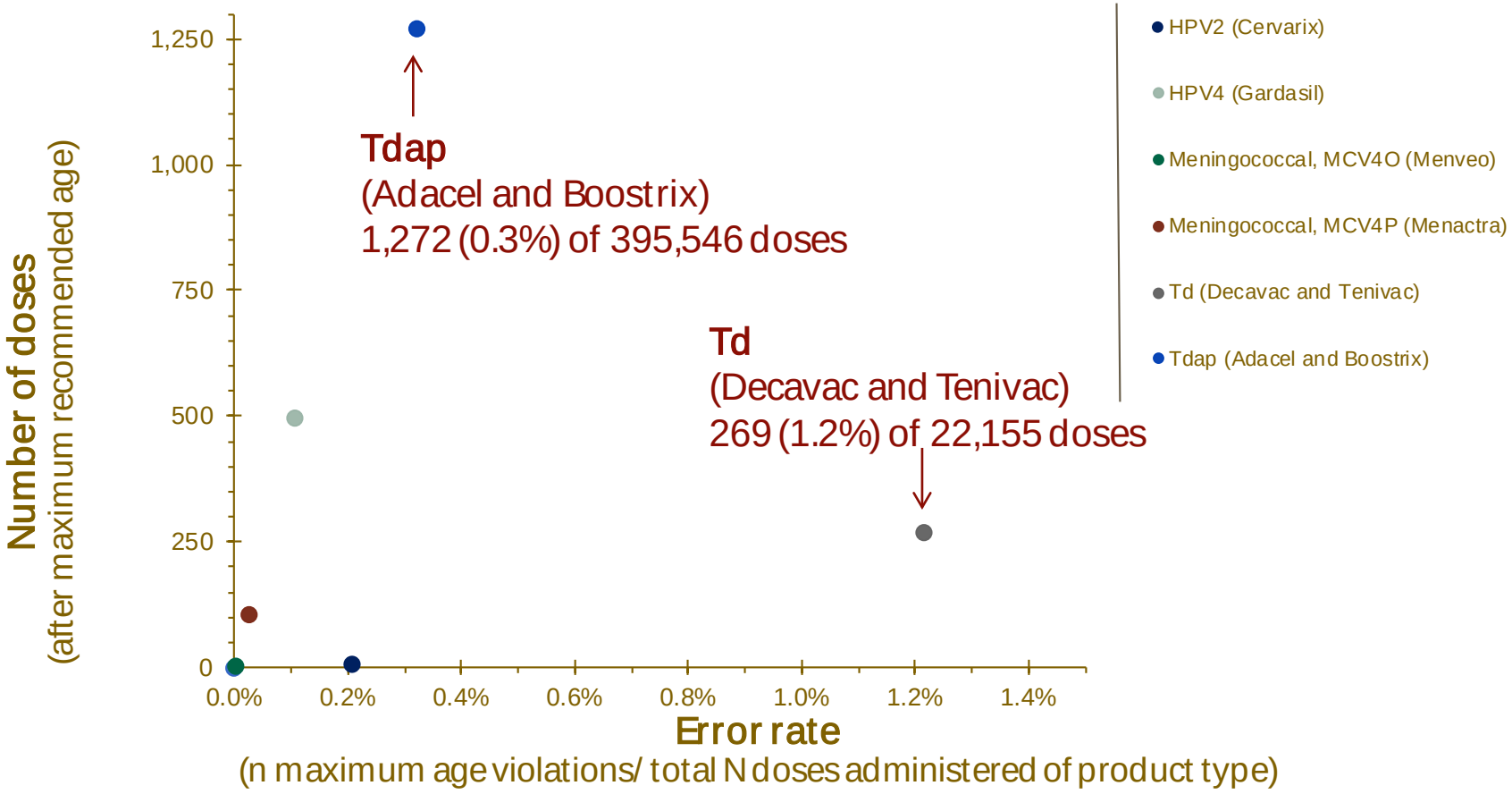
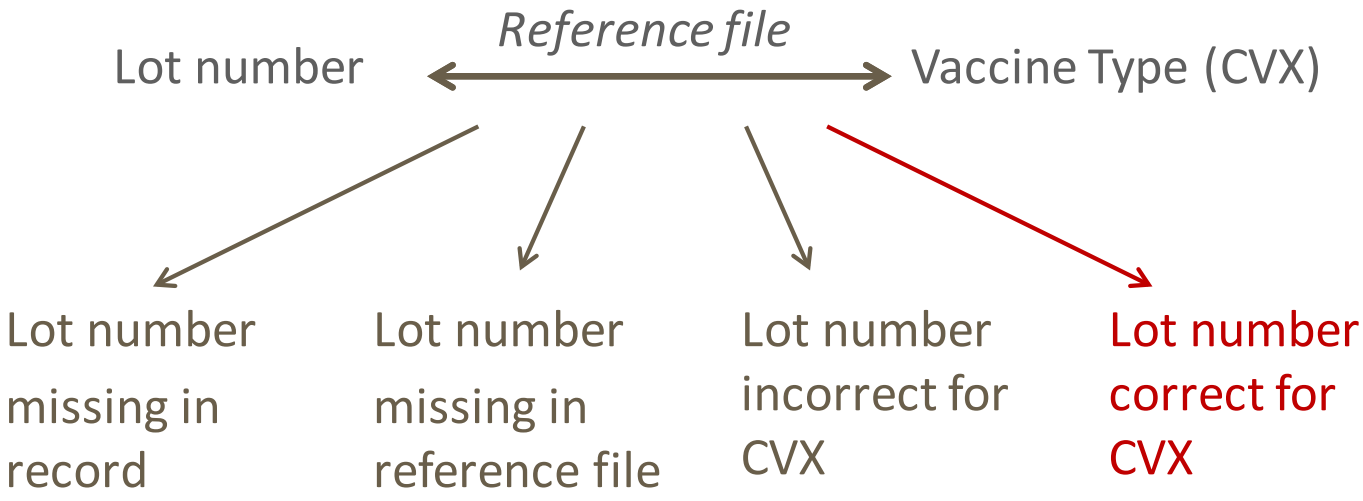


Adolescent Vaccines Given Too Soon



Reporting Error vs Clinical Error

- **Was the vaccine that was administered the same as the one reported?**
- **Conduct analyses among "verified" vaccines.**



5,789,276 (42%) of 13,701,588 doses verified

Reducing the Effect of Reporting Errors

Vaccine type (trade name)	Recommended maximum age	All doses administered at age 0-17 years			Verified doses administered at age 0-17 years		
		Total	Administered after recommended maximum age		Total	Administered after recommended maximum age	
		N	n	%	N	n	%
DT - Pediatric	6 years	1,296	568	43.8%	293	21	7.2%
DTaP (Infanrix and Tripedia)	6 years	257,833	1,587	0.6%	189,800	928	0.5%
DTaP, 5 pertussis antigens (Daptacel)	6 years	178,421	1,459	0.8%	102,707	454	0.4%
DTaP-HepB-IPV (Pediarix)	6 years	591,414	751	0.1%	416,712	381	0.1%
DTaP-Hib-IPV (Pentacel)	4 years	471,501	757	0.2%	196,105	232	0.1%
DTaP-IPV (Kinrix)	6 years	259,470	1,633	0.6%	198,141	1,058	0.5%
Hib-HepB (Comvax)	5 years	3,883	116	3.0%	1,489	10	0.7%
MMRV (ProQuad)	12 years	261,727	2,531	1.0%	0	0	0.0%
PCV 13 (Prevnar-13)	4 years	1,455,954	4,223	0.3%	613,578	1,508	0.2%
PRP-OMP (PedVaxHib)	4 years	386,478	512	0.1%	254,868	216	0.1%
PRP-T (ActHib and Hiberix)	4 years	475,297	909	0.2%	194,255	264	0.1%
Rotavirus, monovalent (Rotarix)	8 months	197,959	501	0.3%	32,463	65	0.2%
Rotavirus, pentavalent (Rotateq)	8 months	661,963	4,379	0.7%	401,617	2,016	0.5%
Influenza, injectable, quadrivalent, preservative free, peds (FluZone – Quadrivalent, Peds)	3 years	264,109	9,153	3.5%	69,189	667	1.0%

Conclusions

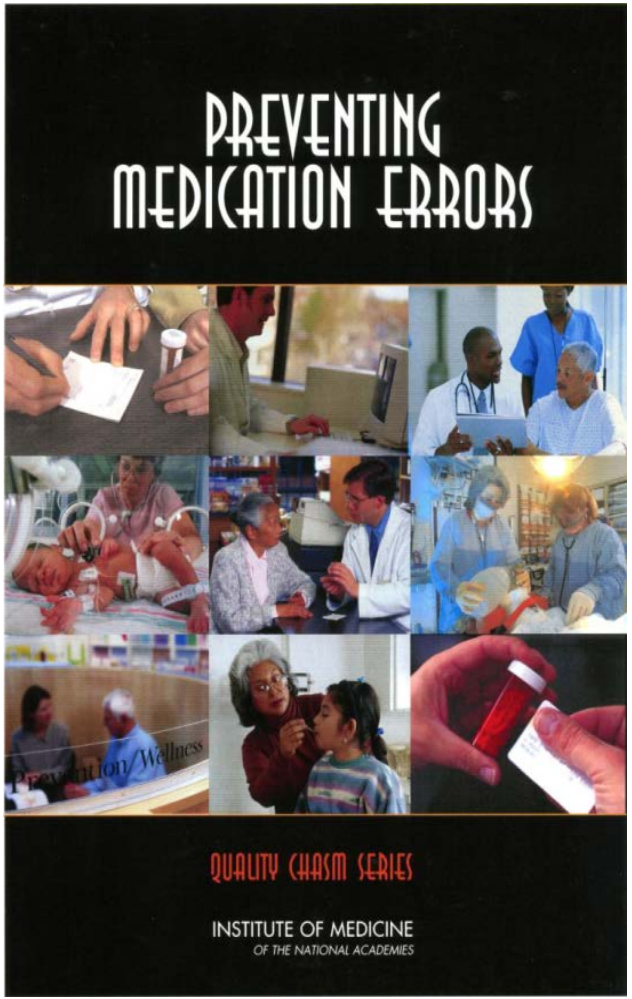
- Most vaccines are administered within recommended ages.
- Small percentage of vaccinations are given outside recommended ages, but the numbers are substantial.
- Most frequent errors:
  - products with recommendations unique within vaccine group
  - Quadrivalent pediatric Fluzone given after 3 years (other flu vaccines have higher maximum age)
  - Influenza, injectable, quadrivalent (Fluarix quadrivalent, FluZone Quadrivalent, and Flulaval Quadrivalent) given before 3 years

Errors Were Most Common for Vaccine Groups with Complex Recommendations

Trade Name	Recommended Age Range
FLUMIST	≥2 yrs to < 50 yrs
FLUZONE - HIGH DOSE	≥65 yrs
FLUARIX	≥3 yrs
FLUVIRIN - PRESERVATIVE FREE	≥4 yrs
FLUZONE - PRESERVATIVE FREE	≥3 yrs
FLUZONE - PRESERVATIVE FREE	≥6 mo to <3 yrs
AFLURIA - PRESERVATIVE FREE	≥9 yrs
FLUVIRIN	≥4 yrs
FLUZONE	≥6 mo
AFLURIA	≥5 yrs to < 65 yrs
FLULAVAL	≥18 yrs
FLUZONE - INTRADERMAL	≥18 yrs to < 65 yrs
FLUMIST - QUADRIVALENT	≥2 yrs to < 50 yrs
FLUARIX - QUADRIVALENT	≥3 yrs
FLUZONE - QUADRIVALENT	≥3 yrs
FLULAVAL - QUADRIVALENT	≥3 yrs
FLUCELVAX	≥18 yrs
FLUBLOK	≥18 yrs to < 50 yrs
FLULAVAL - QUADRIVALENT	≥3 yrs
FLUZONE - QUADRIVALENT, PEDS	≥6 mo to <3 yrs
FLUZONE - QUAD INTRADERMAL	≥3 yrs

Strategies for Reducing Medication Errors

- Reducing reliance on memory
- Protocols and checklists
- Differentiating among look-alike and sound-alike products.
- Monitoring error frequencies, and correct system problems associated with errors.
- Ensuring availability of pharmaceutical decision support



Institute of Medicine. Preventing medication errors 2007. http://www.nap.edu

Strategies for Reducing Vaccination Errors

- Providers education and outreach
- Reduce reliance on memory
- Clinical support tools:
  - Forecasting
  - Interoperability
- Labeling
- Impact analysis

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