

**Summary of Syncope Reports to Vaccine Adverse
Event Reporting System (VAERS)
January 1, 2005 – July 31, 2007**

**Advisory Committee on Immunization Practices
Atlanta, GA
October 25, 2007**

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Vasovagal Syncope

- Transient loss of postural tone and consciousness with spontaneous recovery
 - Bradycardia, vasodilatation or hypotension resulting in decreased brain perfusion
 - Due to abnormal sympathetic reflex
- Elicited by a variety of stimuli in settings of fear or emotional distress
- Occurs after medical procedures, including vaccinations

General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)¹

“..., although syncopal episodes are uncommon ... vaccine providers should strongly consider observing patients for 15 minutes after they are vaccinated. If syncope develops, patients should be observed until symptoms resolve.”

¹MMWR 2006; 55 (No. RR-15)

Vaccine Adverse Event Reporting System (VAERS)

- National passive surveillance system
- Jointly operated by CDC and FDA since November 1990
- Covering all U.S. licensed vaccines
- Receives >15,000 reports per year
- Subject to well-described limitations including underreporting and reporting bias

Objectives

- Describe trends in syncope events reported to VAERS
- Characterize post-immunization syncope
- Identify potential areas for further research

Published VAERS Data on Syncope

- Serious injuries with at least one fatality have occurred¹
- 89% occurred within 15 minutes²
- VAERS data, 1990-2004³
 - Total number of reports: 3,168
 - 35% were among persons aged 10-18 years
 - 14% resulted in hospitalization for injury or medical evaluation

¹Woo EJ et al. Arch Pediatr Adolesc Med 2005; 159: 1083

²Braun MM et al. Arch Pediatr Adolesc Med 1997; 151: 255-9

³MMWR 2006; 55 (No. RR-15)

Methods

- Population:
 - VAERS reports received Jan 1, 2005 – Jul 31, 2007
- Case definition:
 - MedDRA[®] coding terms¹ - “syncope” or “syncope, vasovagal”
 - Case-patients aged ≥ 5 years
 - Syncope onset < 1 day after immunization
 - Vaccines involved in syncope reports
- Available records reviewed for selected reports

¹Medical Dictionary for Regulatory Activities

Adverse Events* Reported to VAERS, 2002 – 2007

Adverse events	Year 2002 – 2004		Year 2005 – 2007	
	No.	(%)	No.	(%)
Syncope	203	(1)	463	(2)**
Serious+ syncope	20	(10)††	33	(7)††

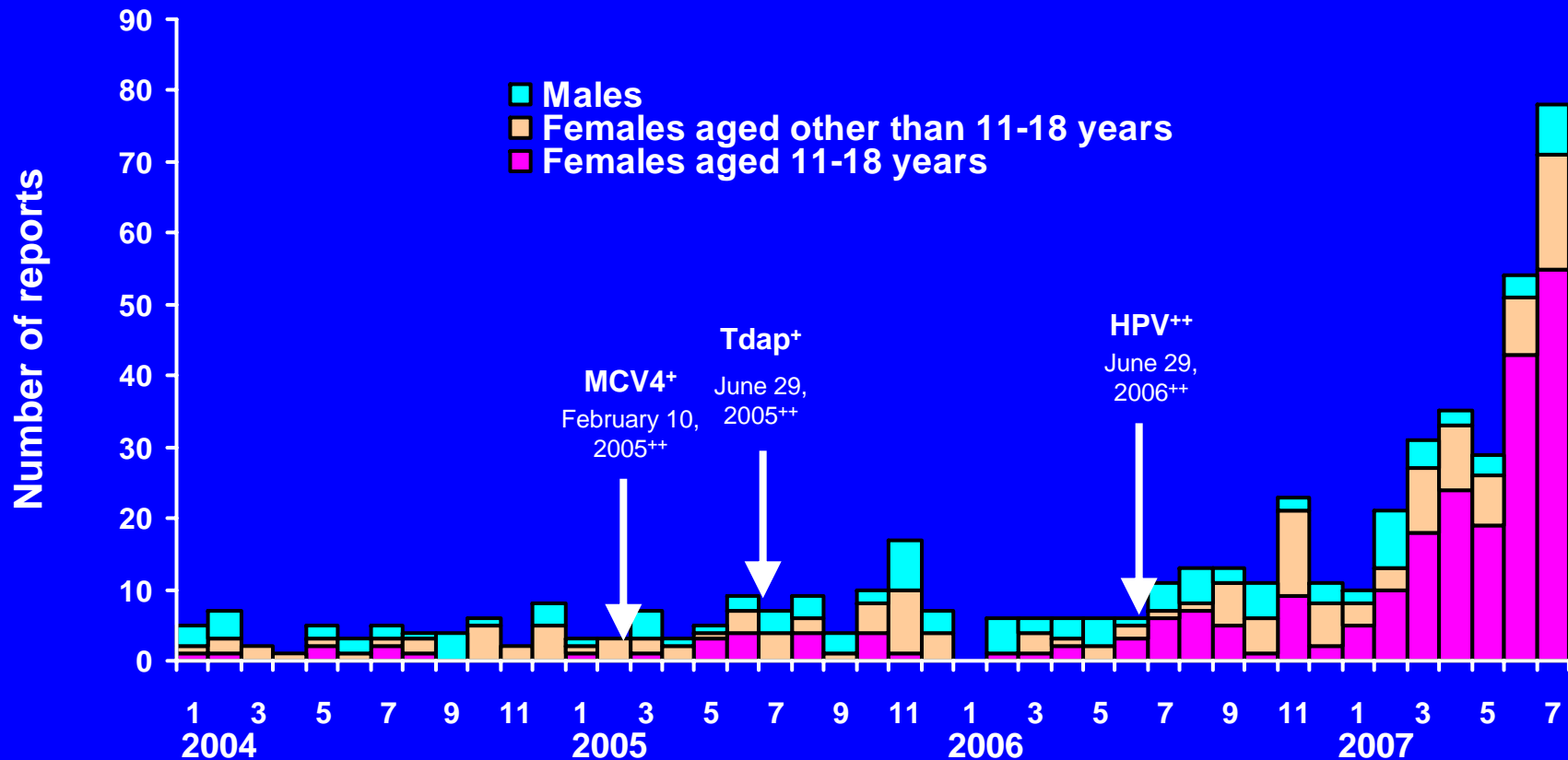
*Case-patients aged ≥ 5 years

** Significant increase in syncope reports in 2005—2007, $p=0.0001$

+Defined by FDA as resulting in death, life-threatening illness, hospitalization, or disability; according to information provided by the reporter of the adverse event

††Proportion of serious reports among all syncope reports, $p=0.2758$ ⁸

Syncopal* reported to VAERS, January 1, 2004 - July 31, 2007



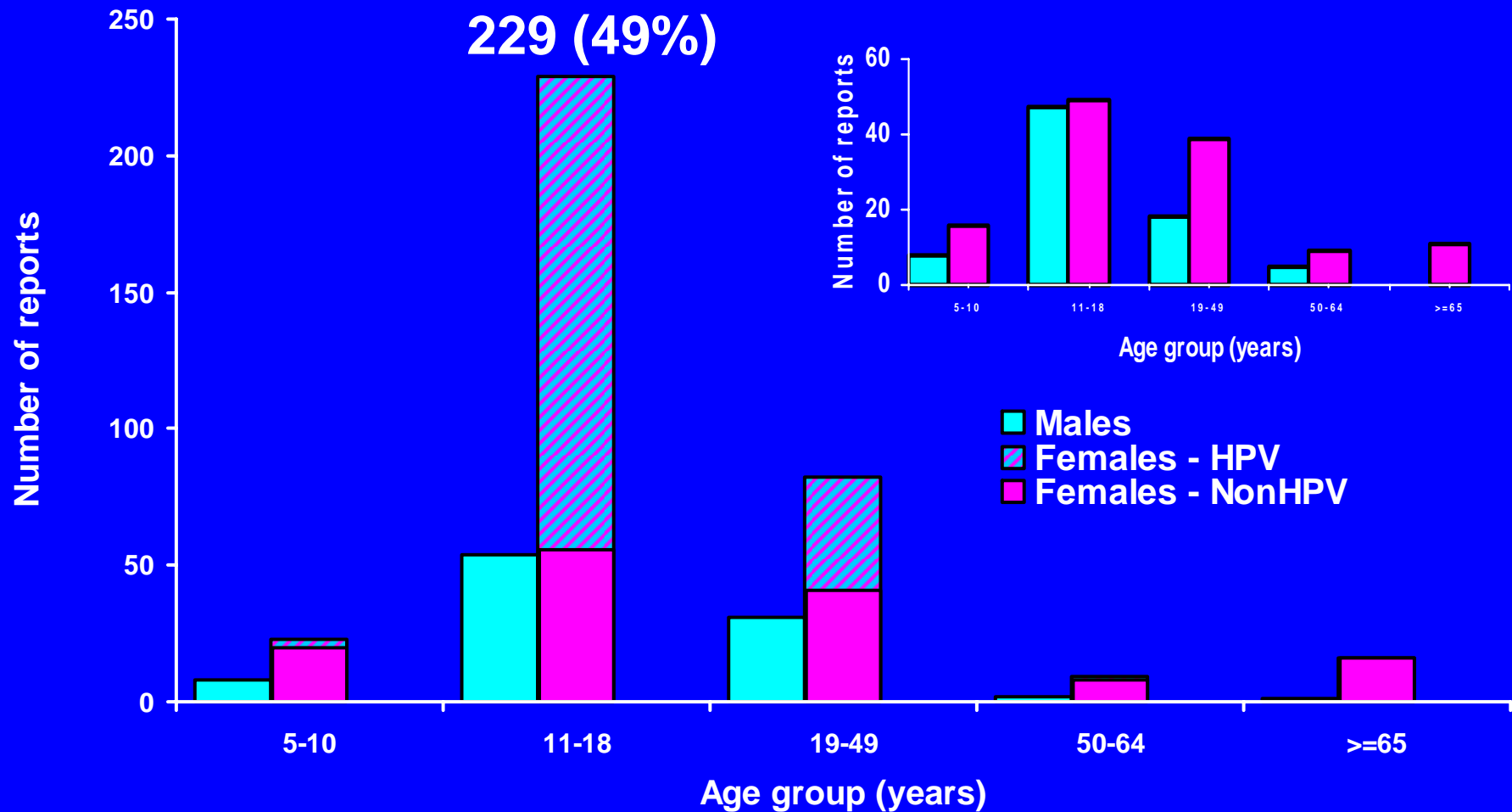
*Case-patients aged ≥5 years Date of report received (month)

+MCV4: meningococcal conjugate vaccine; Tdap: tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine; HPV: quadrivalent human papillomavirus vaccine

++Date of ACIP Vaccines For Children (VFC) Program vote

Syncope reported to VAERS, by age and sex, January 1, 2005 - July 31, 2007 (N = 463)

Syncope reported to VAERS, 2002-2004



*Age or sex unknown (N = 5) are not included

Vaccines Associated with Syncope Reports in VAERS, 2005 - 2007

	One vaccine given N = 302		Multiple vaccines given concurrently N = 161	
	No.	(%)	No.	(%)
HPV	156	(52)	63	(39)*
MCV4	15	(5)	75	(47)*
Tdap	11	(4)	53	(33)*
HPV, MCV4 and/or Tdap	182	(60)	109	(68)
Other vaccine(s)	120	(40)	52	(32)

*Not mutually exclusive categories

Syncope Associated with Injuries in VAERS Reports, 2005 – 2007 (N = 41*)

- Adolescent (11-18 years), N = 31
 - Females, N = 22 (71%)
 - Males, N = 9 (29%)
- Syncope onset after immunization:
 - 20 (49%) within 5 minutes
 - 33 (80%) within 15 minutes
- Serious⁺ cases, N = 10 (24%)

*Excludes 14 cases with unknown onset intervals

⁺Defined by FDA as resulting in death, life-threatening illness, hospitalization, or disability; according to information provided by the reporter of the adverse event

Example of injury related to post-vaccination syncope

A 13-year-old girl fainted within 10 minutes of receiving HPV and MCV. She fell backward, hit her head on carpeted floor of the clinic and was admitted to the pediatric intensive care unit because of skull fractures and subarachnoid hemorrhage.

Cases Aged ≥ 50 Years with Syncope Onset ≤ 12 Hours after Immunization, 2005 - 2007

	Ages ≥ 50 years, n=20	
	No.	(%)
Gender*		
Females	16	(80)
Males	3	(15)
Pre-existing medical conditions	14	(70)
Onset time		
≤ 5 MIN	5	(25)
≤ 15 MIN	6	(30)
Serious** cases (2 deaths)	8	(40)
Associated with influenza vaccines	12	(60)

*One report with missing information was not included

** Defined by FDA as resulting in death, life-threatening illness, hospitalization, or disability; according to information provided by the reporter of the adverse event

Limitations

- Cannot calculate syncope incidence rate based on VAERS data
 - Underreporting of adverse events
 - Lack of data on vaccine doses administered
- VAERS MedDRA[®] coding terms may not reflect diagnosis accurately
- Most non-serious reports were not reviewed
- Cannot determine if syncope related to vaccine (e.g., HPV), targeted age group or both

Conclusions

- Since 2005, increase seen in number of VAERS syncope reports among:
 - Females aged 11-18 years
 - Non-serious reports
 - Reports associated with vaccines recommended for adolescents
- Syncope-related injury rarely occurred, can be serious, and may be preventable

Areas for Research

- Address age-specific incidence of syncope associated with immunization
- Evaluate adherence to waiting period
- Evaluate effectiveness of waiting period and other measures to prevent secondary injury
- Provide evidence-based interventions for use by clinicians to predict/prevent syncope after immunization

Recommendations

Remind Vaccine Providers of Current Recommendations

- Advisory Committee on Immunization Practices, 2006¹

“..., vaccine providers should strongly consider observing patients for 15 minutes after they are vaccinated.”
- American Academy of Pediatrics, 2006²

“Personnel should be aware of presyncopal manifestations and take appropriate measures to prevent injuries...”

“... having vaccine recipients sit or lie down for 15 minutes after immunization could avert many syncope episodes and secondary injuries.”

¹MMWR 2006; 55 (No. RR-15) ²American Academy of Pediatrics. 2006 Red Book: Report of the Committee on Infectious Diseases, 27th ed.

Acknowledgements

- CDC - ISO
 - Karen Broder
 - Julianne Gee
 - John Iskander
 - Tanya Johnson
 - Elaine R. Miller
 - Laura Leidel
- CDC - NCHHSTP
 - Lauri Markowitz
- CDC – NCIRD
 - Andrew Kroger
- FDA – CBER
 - Robert Ball
 - M. Miles Braun
 - Hector Izurietta
 - Andrea Sutherland
 - Emily J. Woo