

# VAERS Reports for Trivalent Inactivated Influenza Vaccine (TIV) in Infants/Toddlers

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# BACKGROUND:

## Influenza Deaths in Children Aged <18 Years 2003-2004

- 143 influenza-confirmed deaths through 4/5/04
- 58 (40%) in children aged < 2 years
- 110 (77%) had no high-risk medical condition
- 101 with known vaccination status of which 4 had been completely vaccinated

- July, 1983 the Advisory Committee on Immunization Practices (ACIP) recommended that all children with high-risk medical conditions  $\geq$  6 months of age be vaccinated with TIV.
- April, 2002 ACIP encouraged providers to vaccinate healthy children 6-23 months of age with TIV.
- Objective: Compare adverse events reported to VAERS in children aged  $<$  2 years before and after 2002 ACIP Guidance.

# Limitations of Data from VAERS

**Usually not possible to assess whether a vaccine caused the reported adverse event:**

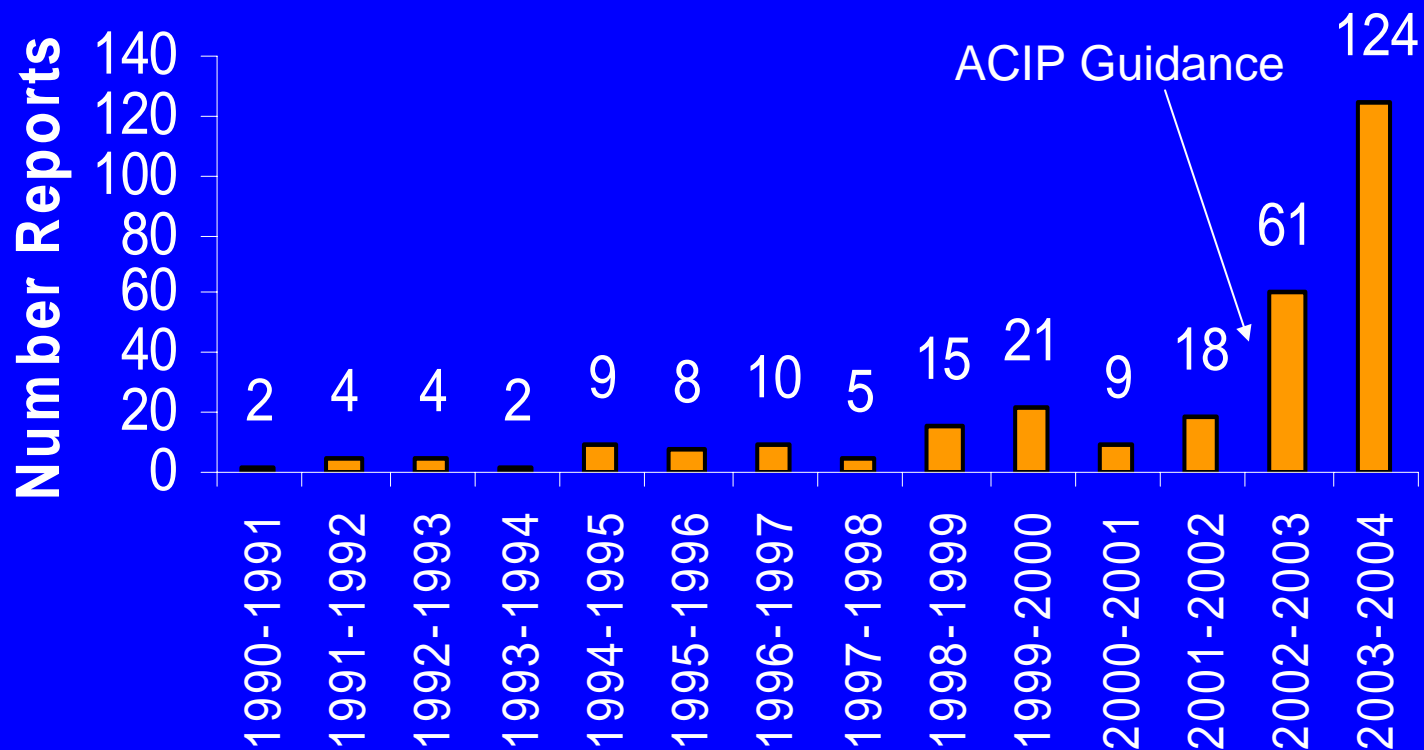
- Reported diagnoses are not verified
- Lack of consistent diagnostic criteria
- Wide range in data quality
- Underreporting
- Inadequate denominator data
- No unvaccinated control group

# What is a serious report?

A “Serious” Report has one or more of the following:

1. Patient died
2. Life threatening illness
3. Required hospitalization
4. Resulted in prolongation of hospitalization
5. Resulted in permanent disability

# NUMBER VAERS REPORTS PER YEAR IN CHILDREN <2 YEARS OF AGE AFTER TIV\* (Through April 7, 2004)

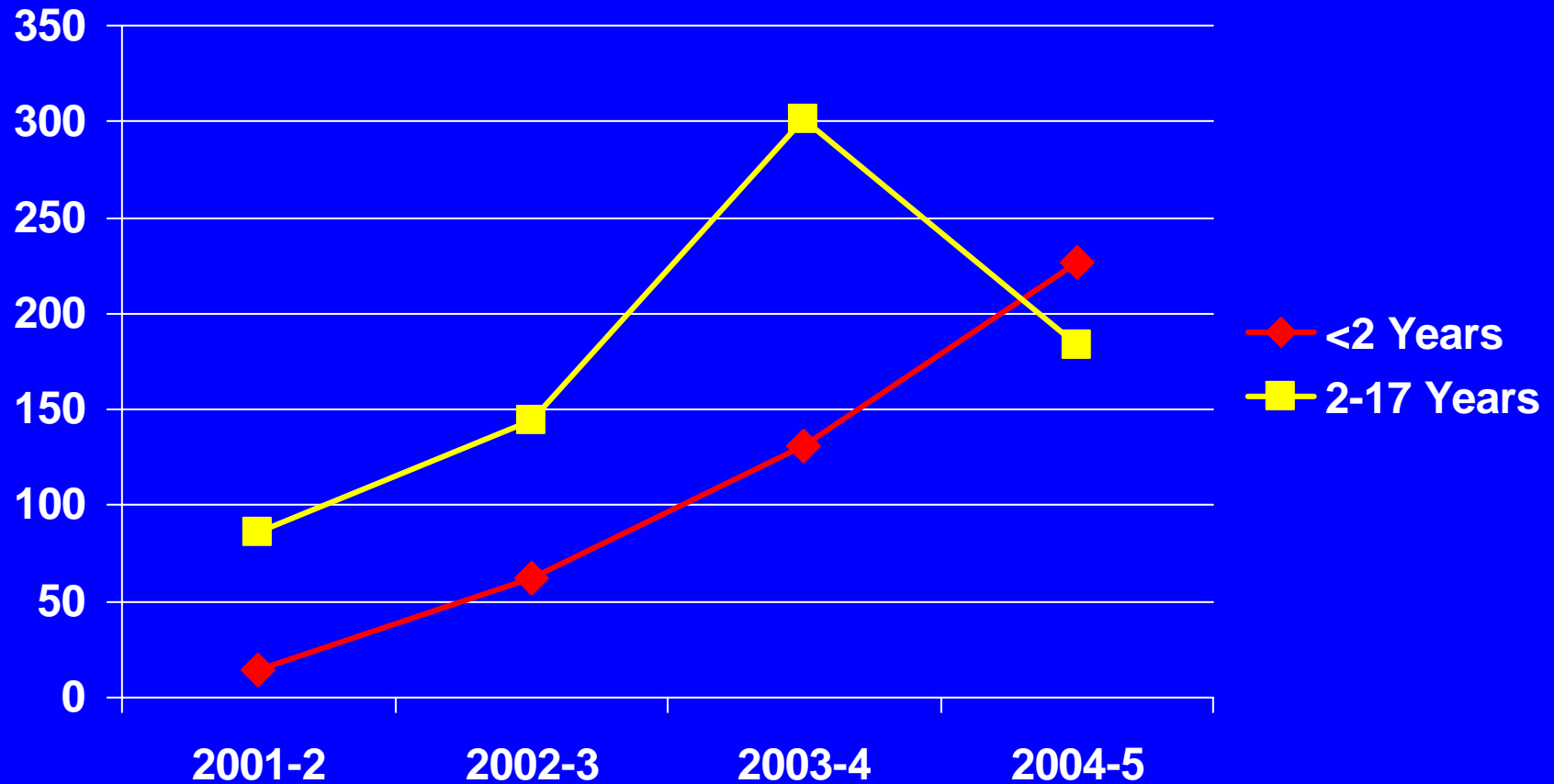


\*Increase in reporting >2002 probably secondary to increase in number of vaccinees, but the number of doses distributed to this age group is unknown.



# TIV VAERS Reports in Children

Vaccinated and Report Received July 1-February 24



# Comparison of VAERS Reports Before\* and After\*\* 2002 ACIP Guidance

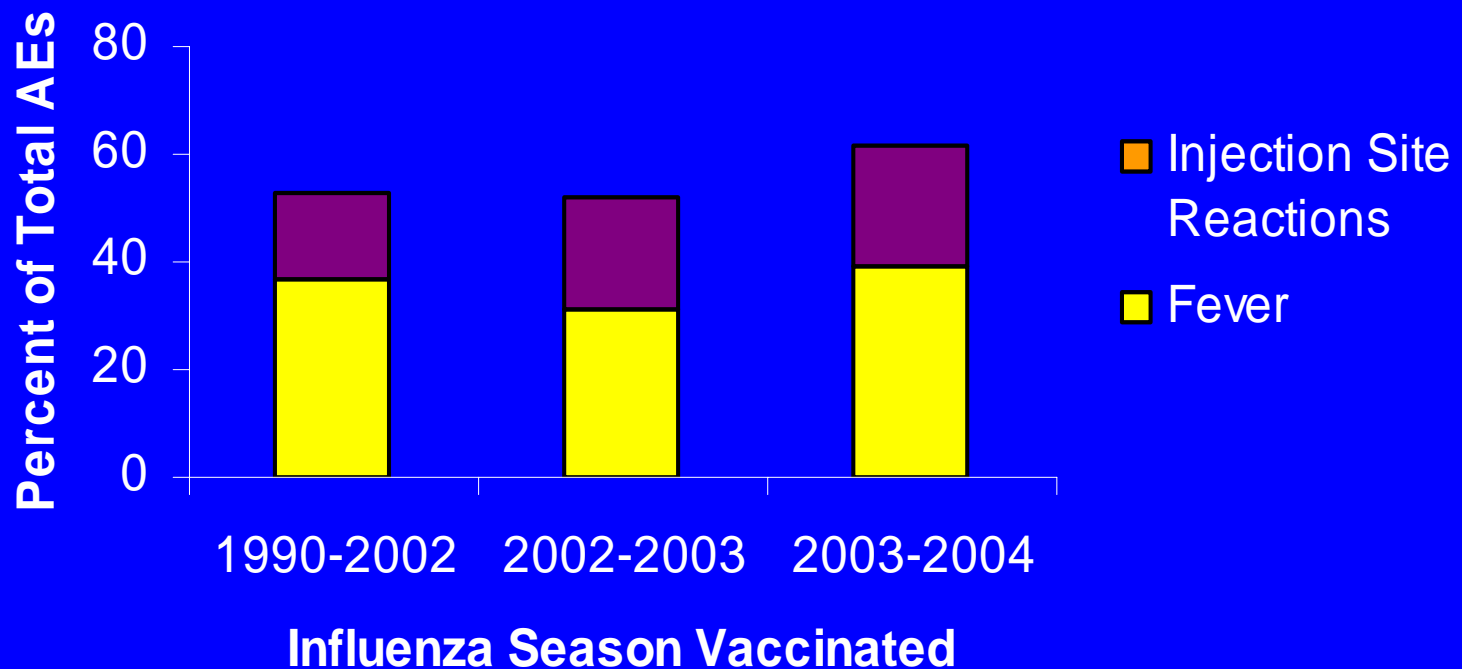
- Most characteristics of VAERS reports after TIV in children < 2 years were the same before and after the 2002 ACIP Guidance:
  - Median age in months 13
  - 45-46% female subjects
  - Median days from vaccination to onset of event 1
  - 14% reports “serious”
  - 2-3% report subjects died
- One characteristic slightly different:
  - 43% report subjects received TIV alone before the guidance versus 34% after the guidance



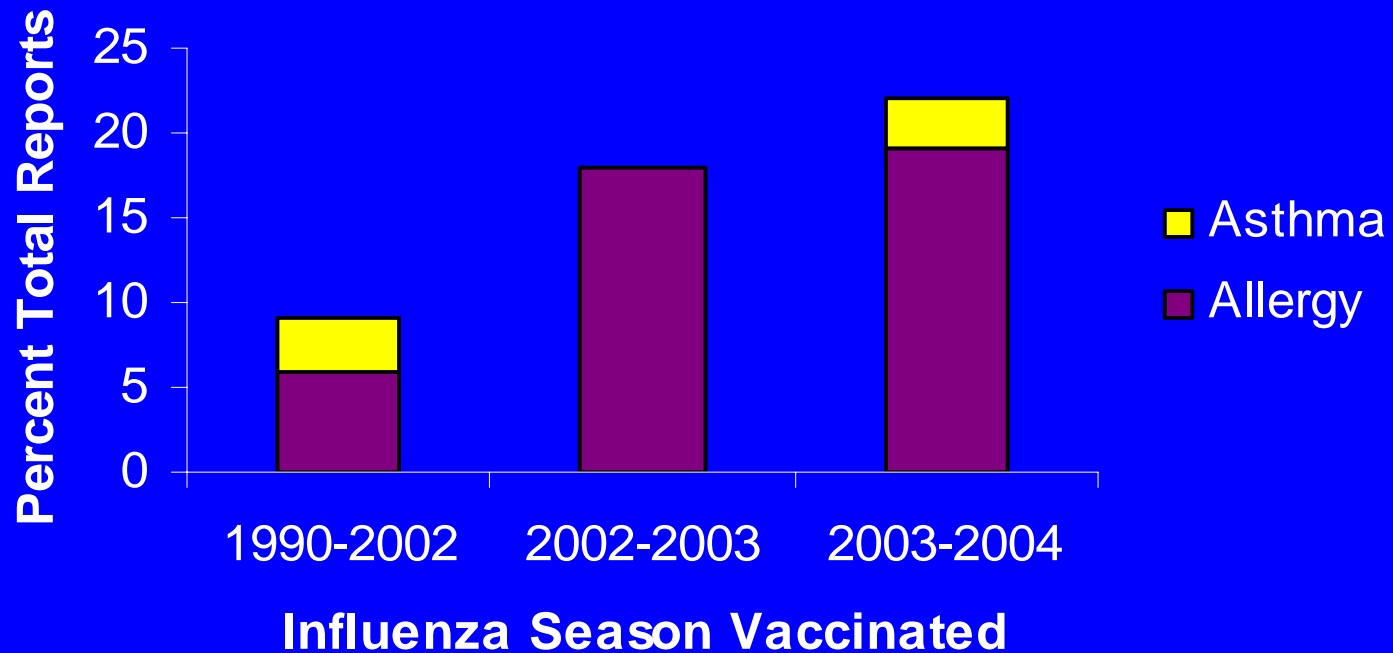
\*N= 107

\*\*N= 186

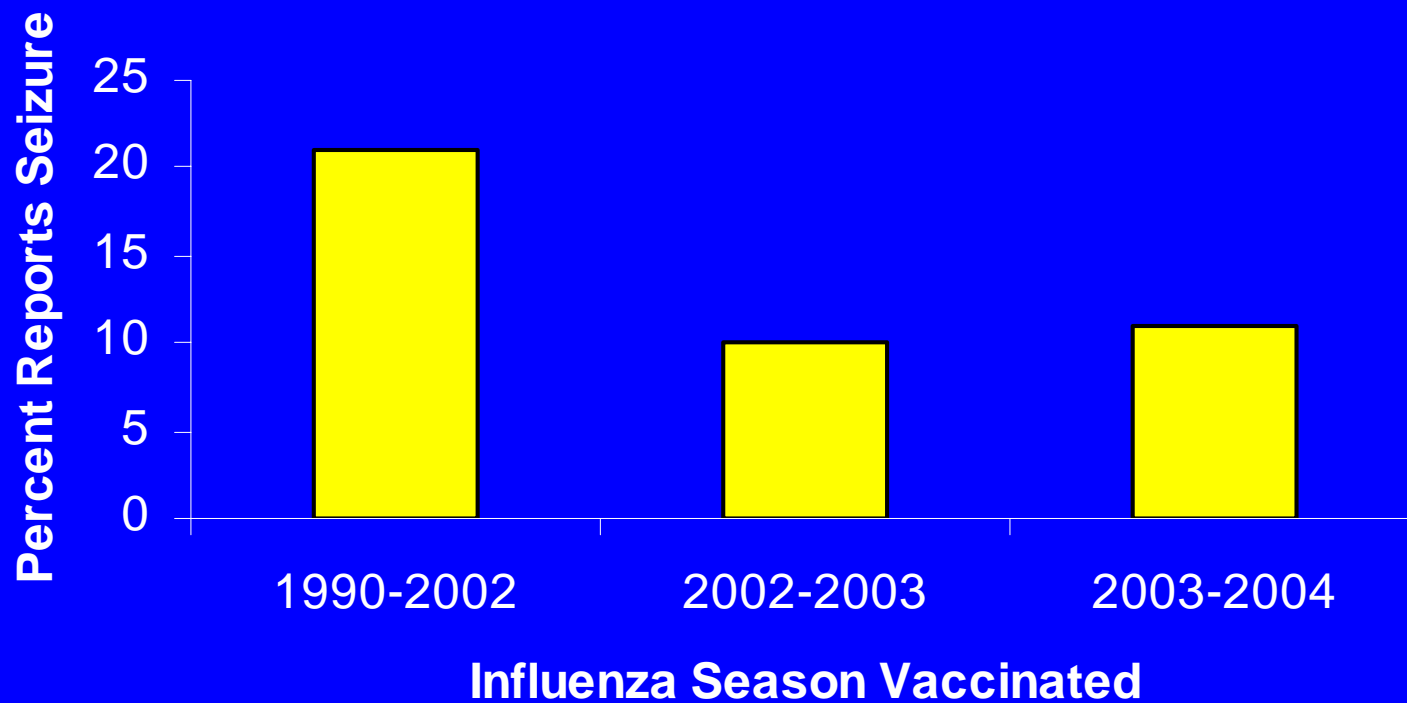
# The Majority of Reports Were of Fever and Injection Site Reactions



# Proportion of Reports of Allergy, but not Asthma Increased



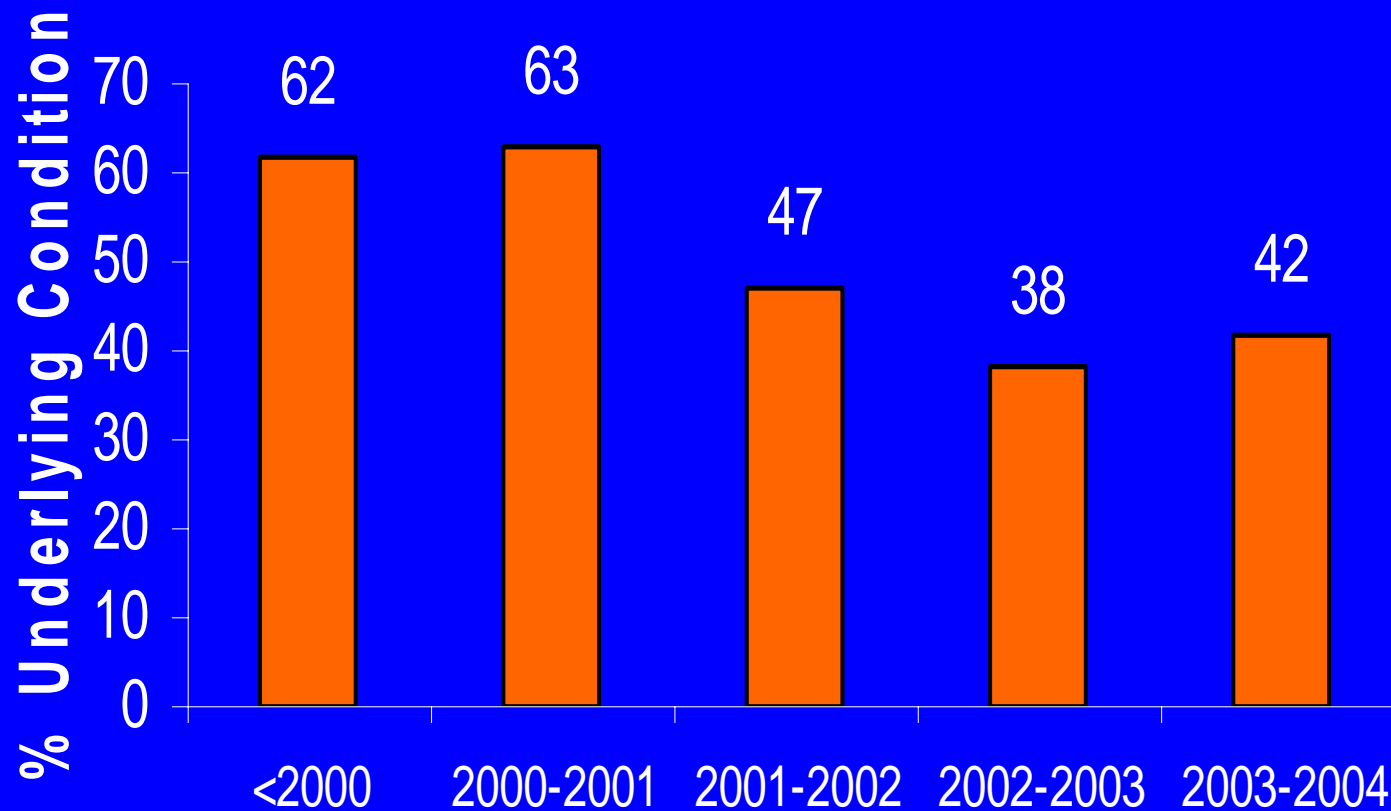
# Proportion of Reports of Seizure Decreased



# SEIZURE REPORTS FOLLOWING TIV IN CHILDREN <2 YEARS OF AGE 1/1/1990-4/7/2004

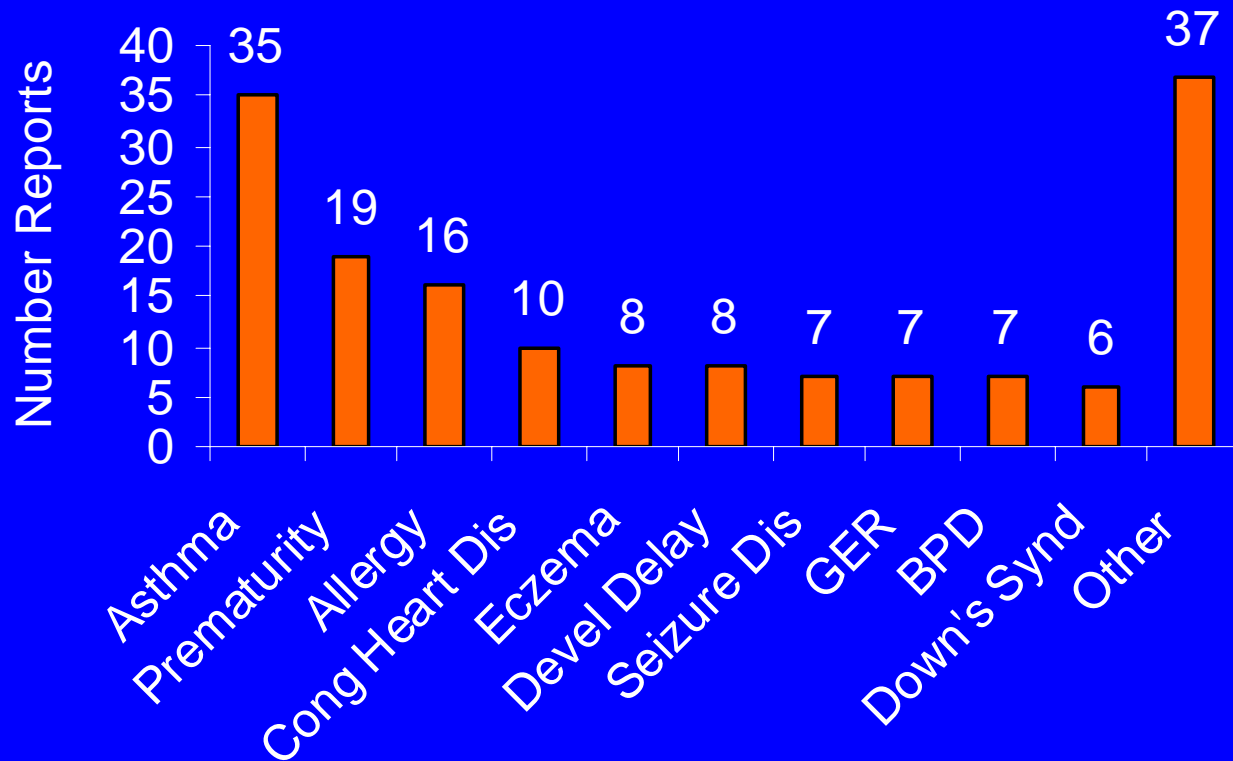
- 18/42 (43%) seizure reports with TIV alone
- 26/42 (62%) unexplained seizure with fever within 2 days of vaccination (3 h/o seizures, 1 of those febrile)
- 7 reports of seizure without fever within 1 day post-vaccination (1 h/o seizures) of which 3 received TIV alone
- 5 reports of seizure without fever after TIV alone
- 14/39 (36%) serious reports seizure
  - 11/14 with fever
  - 7/14 with TIV alone

# Percent Report Subjects with Underlying Medical Condition



# Underlying Medical Conditions in Reports of <2 year olds after TIV

January 1, 1990- April 7, 2004



# Summary of Death Reports

- 8 deaths reported to VAERS in children aged <2 years after TIV before April 7, 2004
- 5 of 8 had definitive causes of death unrelated to vaccine
- 3 of 8 did not have definitive causes of death, but all had underlying illnesses
  - 1 with Joubert's Syndrome and apnea
  - 1 with complex congenital heart disease
  - 1 with recurrent pneumonia of unknown etiology; Birth history: meconium aspiration, 36 week GA



# CONCLUSIONS: VAERS REPORTS IN CHILDREN AGED <2 YEARS AFTER TIV

- The safety profile of TIV in children aged <2 years appears similar before and after Pediatricians were encouraged to vaccinate healthy children in this age group.
- The number of VAERS reports dramatically increased, most likely due to an increase in number of doses administered (do not have denominators for both before and after periods).
- The percentage of report subjects with underlying medical condition decreased in the last 3 years, but remains at 40%.
  - Asthma is the most frequent underlying medical condition.



# CONCLUSIONS: SEIZURES IN AGED <2 YEARS

- Ongoing monitoring of seizure in <2 year olds after TIV
  - Approximately one-third of serious reports 1990-2004 were of seizure
  - Most seizure reports were of seizure with fever
  - The proportion of all reports that are of seizure in 2002-2004 is half of that previously.

# CONCLUSIONS: ONGOING ACTIVITIES

- October, 2003, ACIP recommended universal immunization for 6-23 month olds started in 2004-2005
- With increasing numbers of TIV vaccinees, there will continue to be ongoing surveillance with appropriate follow-up for all adverse events following TIV in children aged less than 2 years.

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