Vaccine Safety

Epidemiology and Prevention of Vaccine-Preventable Diseases

National Immunization Program
Centers for Disease Control and Prevention
Revised January 2006

Importance of Vaccine Safety

• Decreases in disease risks and increased attention on vaccine risks
• Public confidence in vaccine safety is critical
  – higher standard of safety is expected of vaccines
  – vaccinees generally healthy (vs. ill for drugs)
  – lower risk tolerance = need to search for rare reactions
  – vaccination universally recommended and mandated

<table>
<thead>
<tr>
<th>Disease</th>
<th>Pre-vaccine Era*</th>
<th>2000</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria</td>
<td>31,054</td>
<td>1</td>
<td>-99</td>
</tr>
<tr>
<td>Measles</td>
<td>390,852</td>
<td>86</td>
<td>-99</td>
</tr>
<tr>
<td>Mumps</td>
<td>21,342</td>
<td>338</td>
<td>-99</td>
</tr>
<tr>
<td>Pertussis</td>
<td>117,998</td>
<td>7,867</td>
<td>-93</td>
</tr>
<tr>
<td>Polio (wild)</td>
<td>4,953</td>
<td>0</td>
<td>-100</td>
</tr>
<tr>
<td>Rubella</td>
<td>9,941</td>
<td>176</td>
<td>-98</td>
</tr>
<tr>
<td>Cong. Rubella Synd.</td>
<td>19,177</td>
<td>9</td>
<td>-99</td>
</tr>
<tr>
<td>Tetanus</td>
<td>1,314</td>
<td>35</td>
<td>-97</td>
</tr>
<tr>
<td>Invasive Hib Disease**</td>
<td>24,856</td>
<td>112</td>
<td>-99</td>
</tr>
<tr>
<td>Total</td>
<td>566,706</td>
<td>8,624</td>
<td>-98</td>
</tr>
<tr>
<td>Vaccine Adverse Events</td>
<td>0</td>
<td>13,497</td>
<td>+++</td>
</tr>
</tbody>
</table>

* Maximum cases reported in pre-vaccine era
+ Estimated because no national reporting existed in the prevaccine era
^ Adverse events after vaccines against diseases shown on Table = 5,296
** Invasive type b and unknown serotype

Prelicensure Vaccine Safety Studies

• Laboratory
• Animals
• Humans

Prelicensure Human Studies

• Phases I, II, III trials
• Common reactions are identified
• Vaccines are tested in thousands of persons before being licensed and allowed on the market
**Postlicensure Surveillance**
- Identify rare reactions
- Monitor increases in known reactions
- Identify risk factors for reactions
- Identify vaccine lots with unusual rates or types of events
- Identify signals

**Postlicensure Vaccine Safety Activities**
- Phase IV Trials
  - ~10,000 participants
  - better but still limited
- Large-Linked Databases
- Clinical Immunization Safety Assessment Network

**Vaccine Adverse Event Reporting System (VAERS)**
- National reporting system
- Jointly administered by CDC and FDA
- Passive (depends on healthcare providers and others to report)
- Receives ~15,000 reports per year

**Vaccine Adverse Event Reporting System (VAERS)**
- Detects
  - new or rare events
  - increases in rates of known side effects
  - patient risk factors
- Additional studies required to confirm VAERS signals
- Not all reports of adverse events are causally related to vaccine

**Adverse Event Classification**
- Vaccine-induced
- Vaccine-potentiated
- Programmatic error
- Coincidental

**Vaccine Safety Datalink (VSD)**
- Large-linked database
- Links vaccination and health records
- “Active surveillance”
  - 8 HMOs
  - ~2% of the U.S. population
- Powerful tool for monitoring vaccine safety
### Clinical Immunization Safety Assessment (CISA) Network
- Improve understanding of vaccine safety issues at individual level
- Evaluate persons who experience adverse health events
- Gain better understanding of events
- Develop protocols for healthcare providers

### Vaccine Injury Compensation Program (VICP)
- Established by National Childhood Vaccine Injury Act (1986)
- “No fault” program
- Covers all routinely recommended childhood vaccines
- Vaccine Injury Table

### The Provider’s Role
- Immunization providers can help to ensure the safety and efficacy of vaccines through proper:
  - Vaccine storage and administration
  - Timing and spacing of vaccine doses
  - Observation of contraindications and precautions

### The Provider’s Role
- Immunization providers can help to ensure the safety and efficacy of vaccines through proper:
  - Management of vaccine side effects
  - Reporting of suspected side effects to VAERS
  - Vaccine benefit and risk communication

### Contraindication
A condition in a recipient that increases the chance of a serious adverse reaction

### Precaution
A condition in a recipient that might
- Increase the chance or severity of an adverse reaction, or
- Compromise the ability of the vaccine to produce immunity
## Invalid Contraindications to Vaccination

- Minor illness
- Mild/moderate local reaction or fever following a prior dose
- Antimicrobial therapy
- Disease exposure or convalescence
- Pregnancy or immunosuppression in the household
- Premature birth
- Breastfeeding
- Allergies to products not in vaccine
- Family history (unrelated to immunosuppression)

## Benefit and Risk Communication

- Opportunities for questions should be provided before each vaccination
- Vaccine Information Statements (VISs)
  - must be provided before each dose of vaccine
  - public and private providers
  - available in multiple languages

## National Immunization Program

### Contact Information

- Telephone 800.CDC.INFO
- Email nipinfo@cdc.gov
- Website www.cdc.gov/nip