Why is Vaccine Safety increasing in Importance?

As disease risks decrease, attention on vaccine risks increase

- Public confidence in vaccine safety is critical
- Higher than ever standard of safety for vaccines
- Vaccines generally healthy vs. consumers of other pharmaceuticals
Why is Vaccine Safety Increasing in Importance?

- Vaccinations universally recommended and mandated
- Lower risk tolerance means adverse reactions must be investigated thoroughly
Post licensure 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
Vaccine Adverse Event Reporting System (VAERS)

- Passive reporting system administered by the CDC and FDA
- Receives approximately 15,000 reports per year
- Must be reported to the BPH, Division of Immunization Services if state-supplied vaccine used or if administered in an LHD
VAERS

- VAERS detects
  - New or rare events
  - Increases in rates of known side effects
  - Patient risk factors

- VAERS signals confirmed through additional studies
- Not all reported vaccine reactions causally related to vaccine
Classification of VAEs

- Vaccine-induced
- Vaccine-potentiated
- Programmatic Error (Provider’s Role)
- Coincidental
Vaccine Safety Data Link Program

- Large database which links vaccination and health records
- An active surveillance system
- Populated by 10 HMOs, roughly 2% of the U.S. population
- Crucial to vaccine safety monitoring
Vaccine Injury Compensation Program

- Created in 1986 by the National Childhood Vaccine Injury Act
- “No fault” program
- Covers all routinely recommended childhood vaccines
- Basis of the Vaccine Injury Table
Role of the Provider

- Store and administer vaccines properly
- Adhere to guidelines for timing and spacing of vaccines
- Observation of contraindications and precautions
- Management of side effects
- Report suspected VAEs to VAERS
- Communicate vaccine benefits/risks
Contraindication vs. Precaution

- Contraindication: A condition in a recipient that increases the chance of a serious adverse event.

- Precaution: A condition that might increase the chance or severity of an adverse event or compromise the ability of the vaccine to produce immunity.
Contraindications and Precautions

- Only two conditions are considered permanent contraindications to vaccination:
  - **Severe (anaphylactic) allergic reaction** to a vaccine component or following a prior dose of vaccine
  - **Encephalopathy** not due to another identifiable cause within 7 days of vaccination
Contraindications and Precautions

- Two temporary contraindications to vaccination with *live* vaccines:
  - *Pregnancy*
  - *Immunosuppression*
Contraindications and Precautions

- Two conditions are temporary precautions to vaccination:
  * Moderate or severe acute illness (all vaccines)
  * Recent receipt of an antibody-containing blood product (MMR and Varicella only)

- Fever: $> 100.4 = \text{moderate or severe}$
Invalid Contraindications

- Minor illness
- Mild/moderate local reaction or fever following a prior dose
- Disease exposure or convalescence
- Pregnancy or immunosuppression in the household
- Antimicrobial therapy
Invalid Contraindications

- Premature birth
- Breastfeeding
- Allergies to products not in the vaccine
- Family history (unrelated to immunosuppression)
- *possibility that a family history of seizures could warrant a precaution to MMRV
Benefit and Risk Communications

- Providers should ask questions regarding any possible adverse reactions associated with previous vaccination(s)
- Opportunities for questions from recipient should be provided
- Vaccine information statements (VISs) must be provided before each dose of vaccine
What’s New in Immunization?

- 64CSR95 (Interpretive Rule)
- PCV13
- MMRV
- Rotavirus and Intussusception
- Data
Tdap and MCV4 vaccines will become requirements for 7th grade entry
MCV4 booster dose will be required at 12th grade entry
39 states and D.C. require a Td/Tdap dose for middle school
WV will become the 11th state to require MCV4 vaccine
PCV 13

- Children in mid-series of PCV7 should start receiving PCV13 instead
- Booster doses for children who completed PCV7 series:
  -- < 59 months and healthy
  -- 6-18 years at increased risk may receive one dose.
MMRV Vaccine

- Combined MMR & Varicella
- Slightly higher risk of febrile seizure w/ 1st dose
- ACIP expresses *no preference* between MMR/VAR and MMRV for 1st dose
- ACIP continues to *recommend* MMRV for 2nd dose
- Rare situation when family history may be considered as a precaution – (seizures)
Rotavirus

- Study in Mexico: 1.8 fold increase in intussusception 1-7 days after dose 1 of Rotarix vaccine
- No increase found in Brazil for Rotarix
- In the U.S.: No increase identified for either Rotarix or Rotateq (VSD). However, studies of the VSD or Merck data can rule out a slight increased risk
Rotavirus

Pre-Vaccine

- 400,000 doctor visits
- 200,000 ER visits
- 70,000 hospitalizations
- 20-60 deaths
Rotavirus

- **Now**
  - 85% decrease in rotavirus hospitalizations since vaccine was reintroduced
  - As of 2008, 40,000-60,000 fewer cases of rotavirus in the U.S. than in the pre-vaccine era.
- Recommendations unchanged
## Data – 2 Year Olds

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>U.S.</th>
<th>W.V.</th>
</tr>
</thead>
<tbody>
<tr>
<td>4:3:1:0:3:1:4*</td>
<td>70.5%</td>
<td>60.9%</td>
</tr>
<tr>
<td>Hep B (birth)</td>
<td>60.8%</td>
<td>53.7%</td>
</tr>
<tr>
<td>Hep A</td>
<td>46.6%</td>
<td>51.7%</td>
</tr>
<tr>
<td>Influenza (1)</td>
<td>41.5%</td>
<td>39.2%</td>
</tr>
<tr>
<td>Influenza (fully)</td>
<td>24.7%</td>
<td>24.1%</td>
</tr>
</tbody>
</table>

4 DTaP, 3 Polio, 1 MMR, 0 Hib, 3 Hep B, 1 Varicella and 4 PCV
## Data - Teens

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>U.S.</th>
<th>W.V.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Td or Tdap</td>
<td>76.2%</td>
<td>52.2%</td>
</tr>
<tr>
<td>Tdap</td>
<td>55.6%</td>
<td>40.5%</td>
</tr>
<tr>
<td>MCV4</td>
<td>53.6%</td>
<td>39.0%</td>
</tr>
<tr>
<td>HPV (3 doses) *</td>
<td>26.7%</td>
<td>27.0%</td>
</tr>
</tbody>
</table>

Sample: 13-17 year olds

* Females only
Data – Adult Influenza

Influenza
Age 19-49 HR 33.4%
Age 19-49 Non-HR 19.7%
Age 50-64 HR 51.5%
Age 50-64 Non-HR 34.2%
Age 65 and older 65.6%
HCP (any age) 52.4%
Questions?

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