Specifics of vaccine Pharmacovigilance

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DCVMN training on PV, May 2017
Definition vaccine PV

- “Vaccine pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and communication of adverse events following immunization and other vaccine- or immunization-related issues, and to the prevention of untoward effects of the vaccine or immunization.”

CIOMS working group on vaccine pharmacovigilance 2012
What is different in PV for vaccines?

- Vaccines are primarily a public health asset
- Universal mass vaccination leads to huge exposure numbers (almost everyone exposed)
- Some specific questions
- Very low tolerance for most AEs
- Events of concern/interest mostly rare to very rare
Public health asset (but too successful?)

<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>4</td>
<td>99.99</td>
</tr>
<tr>
<td>Measles</td>
<td>390,852</td>
<td>81</td>
<td>99.98</td>
</tr>
<tr>
<td>Mumps</td>
<td>161,500</td>
<td>323</td>
<td>99.80</td>
</tr>
<tr>
<td>Pertussis</td>
<td>117,998</td>
<td>6,755</td>
<td>95.40</td>
</tr>
<tr>
<td>Polio (wild)</td>
<td>4,953</td>
<td>0</td>
<td>100.00</td>
</tr>
<tr>
<td>Rubella</td>
<td>9,941</td>
<td>152</td>
<td>99.70</td>
</tr>
<tr>
<td>Cong. Rubella Synd.</td>
<td>19,177</td>
<td>7</td>
<td>99.10</td>
</tr>
<tr>
<td>Tetanus</td>
<td>246</td>
<td>26</td>
<td>98.00</td>
</tr>
<tr>
<td>Invasive Hib Disease</td>
<td>18,556</td>
<td>167</td>
<td>99.10</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>754,277</strong></td>
<td><strong>7,515</strong></td>
<td><strong>98.67</strong></td>
</tr>
</tbody>
</table>

| Vaccine Adverse Events    | 0               | 13,497^ | +++  |

Ref: (1)
Maximum cases reported in pre-vaccine era and year
^ Adverse events after vaccines against diseases shown on Table = 5,296
Large (near universal) exposure
Specific concerns to be monitored for vaccines

- transmission of infectious agent, especially for live viral vaccines (eg rotavirus, varicella, polio)
- genetic stability
- epidemiological shifts of prevented disease: eg pneumococcal serotypes
- safety in special groups such as premature children, immunocompromised
Very low tolerance

Family’s pain as girl, 13, dies just five days after cancer jab having been sent home from hospital hours earlier

Investigation launched into claims tragic Shazel was by done as a ‘lucky child’

Gardasil Vaccine Hoax: Vaccine Side Effect Risks Higher than Cervical Cancer Risks

No Gardasil!

Duty to Warn: Gardasil and Cervical Cancer: Are We Witnessing a Hoax in the Making?

(Exploring Big Pharma’s Assertion that Gardasil Will Prevent/Cervical Cancer)
Events of concern/interest mostly rare to very rare

“Eleven cases of the Guillain–Barré syndrome were reported, for a rate of 0.1 per 1 million doses, which is lower than the background rate in China. “(2)
Other specifics of vaccines (PV)

• Overlap between age of vaccination and high frequency some diseases (eg Intussusception, sudden infant deaths)
• Errors in vaccine handling (transport, storage, administration)
• Combination vaccines: which antigen is to blame fro the AE (or the adjuvant, the excipient, the solvent etc)?
• Co-administration: which vaccine is to blame for the AE?
• Lot specific analyses
• Generic analyses (eg all live viral, all adjuvanted, all influenza etc)
References

• (1): Chen et Orenstein in Infectious Disease Epidemiology


• + CIOMS : Definition and Application of Terms for Vaccine Pharmacovigilance (Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance)