Progress of a WHO-led Initiative

Global Collaborative Vaccine Safety Network

Presented by:
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Background

• Multiple H1N1 influenza vaccines developed/distributed worldwide for pandemic
• H1N1 vaccines used extensively in population groups not often vaccinated against influenza
• Limited capacity for epidemiological vaccine safety studies in many countries
  ➢ Often rely on passive surveillance for post-marketing safety
• H1N1 vaccine safety concerns provided opportunity to demonstrate feasibility of a global collaborative vaccine safety consortium
International Study on GBS and H1N1: A Proof-of-concept

• Immediate objectives:
  ➢ To pilot-test a WHO-coordinated international collaborative approach towards the implementation of a simple and reliable epidemiological study methodology
  ➢ To investigate the association between GBS and H1N1 pandemic vaccines

• Final Goal:
  ➢ After pilot phase, approach should be generalizable to other countries and should become part of the standard WHO vaccine safety monitoring toolbox
Why GBS?

• GBS was associated with the 1976 Swine Flu vaccine and is of concerns for most countries.

• The Brighton collaboration has developed a widely accepted case definition which can be used to standardize assessment.

• In most countries GBS cases are hospitalized and thus can be ascertained in an unbiased manner from hospital records.

• GBS is a rare outcome, few countries have sufficient population to perform a valid study on their own.
Self-Controlled Case Series (SCCS)

• Requires only cases, estimates RR
  - No population denominators needed
• Controls implicitly for all fixed confounders
• An international team of advisors is performing simulations to define the most efficient SCCS method to address seasonality and vaccination contraindication post GBS:
  ➢ classical SCCS
  ➢ cases-only approach
  ➢ pseudolikelihood
Standard SCCS Method

- Example, individual i, observation period: 10/15/09-4/15/10 (day 1 to 183), vaccination: 11/15/09 (day 32), risk window: day 1-42, season cut off: 1/12/09 (day 90), diagnosis: 1/5/10 (day 83)
Including Seasonality
Identify all ICD9/ICD10 GBS cases hospitalized during study period

Confirm or discard cases (Brighton)

No GBS
   Discard

GBS
   Onset, H1N1 vaccination, intervals, covariates
   Send tabulated case data to WHO

Case classification (Vaccinated? Risk/non risk?)
Final Analysis (WHO)
**Status: Country Data**  
*(VAESCO Project not included)*

<table>
<thead>
<tr>
<th>Country</th>
<th>Site/System</th>
<th>GBS Case *</th>
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<tr>
<td></td>
<td></td>
<td>Total</td>
<td>Received H1N1</td>
<td>Received seasonal flu</td>
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<td><strong>135</strong></td>
<td><strong>26</strong></td>
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</tr>
</tbody>
</table>

* Includes all cases reported to WHO as of January 31, 2011. Depending on country-specific observation periods, some cases may not be included in analysis.
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