Use of Medicare Data to Evaluate Adverse Events After Influenza Vaccine

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Food and Drug Administration

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Overview

- Collaborative project
  - Food and Drug Administration (FDA)
  - Centers for Medicare & Medicaid Services (CMS)
- Focus on influenza and pneumococcal vaccines
- Use controlled study designs to evaluate whether serious adverse events are associated with vaccination
Medicare Data

- Approximately 40 million Medicare beneficiaries
  - 34 million age 65 years or older
- Administrative data (enrollment; insurance claims)
  - Massive databases
  - Useful for exploratory analyses
- Medical record data (hospital records)
  - In-depth analysis of selected adverse events
  - Via quality review study by Medicare Peer Review Organization (Quality Improvement Organization)
Milestones to Date and Timeline

- Executed intra-agency agreement between FDA and CMS
- Awarded FDA contract to perform part of the data management
- Protocol approved by FDA internal review board
- Submitted data request to CMS
- Results of first in-depth evaluation(s) expected in 1 to 3 years
Feasibility Issues in Selecting Topics for In-Depth Evaluation

- Number of years of data needed
- Likelihood of inpatient management with acute onset
- Sensitivity and specificity of diagnosis codes (ICD-9-CM)
- Number of medical records needed to review to find an adequate number of cases
# Prioritization Matrix

## Feasibility

<table>
<thead>
<tr>
<th>Importance</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
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</thead>
<tbody>
<tr>
<td>High</td>
<td>High</td>
<td>Guillain Barre Syndrome (GBS)</td>
<td>Multiple sclerosis</td>
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<td></td>
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<td>Transverse myelitis</td>
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<td>Optic neuritis</td>
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<td>Peripheral neuropathy</td>
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<tr>
<td>Medium</td>
<td>Stevens Johnson Syndrome (SJS)/Toxic Epidermal Necrolysis (TEN)</td>
<td>Severe injection site reactions</td>
<td>Other cranial nerve disorders</td>
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<tr>
<td></td>
<td>Giant cell arteritis</td>
<td>Anaphylaxis Encephalitis</td>
<td>Frozen shoulder</td>
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<td></td>
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<td>Aseptic meningitis</td>
<td>Thrombocytopenia</td>
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<td>Herpes zoster</td>
<td>Asthma</td>
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<tr>
<td>Low</td>
<td>Events coded as poisoning (i.e., overdose or wrong substance)</td>
<td>Hemolytic anemia</td>
<td>Dermatomyositis</td>
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<tr>
<td></td>
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<td>Aplastic anemia</td>
<td>Angioimmunoblastic lymphadenopathy</td>
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Questions

• What is/are the central GBS study questions? E.g., whether any elevated risk exists, vs monitoring elevated risk over time, vs other?
• What is the minimum number of influenza seasons needed for a useful GBS evaluation? E.g., 1, 2, 3 or other?