

Use of Medicare Data to Evaluate Adverse Events After Influenza Vaccine

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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

Importance

	High	Medium	Low
High		Guillain Barre Syndrome (GBS)	Multiple sclerosis Transverse myelitis Optic neuritis Peripheral neuropathy
Medium	Stevens Johnson Syndrome (SJS)/Toxic Epidermal Necrolysis (TEN) Giant cell arteritis	Severe injection site reactions Anaphylaxis Encephalitis Aseptic meningitis Herpes zoster	Other cranial nerve disorders Frozen shoulder Thrombocytopenia Asthma Dermatomyositis Angioimmunoblastic lymphadenopathy Pemphigus/Pemphigoid
Low	Events coded as poisoning (i.e., overdose or wrong substance)	Hemolytic anemia Aplastic anemia	Other vasculitis Inflammatory arthritis Cerebellar ataxia Myocarditis



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?