

# Seasonal Influenza Vaccine Safety Monitoring 2010-2011

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# Passive Surveillance

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- Purpose: to detect signals of unanticipated events that may deserve further follow-up
- Primary Limitation: Usually can not determine if event is caused by vaccine or coincidental
  - Lack of good denominator and comparison (unvaccinated) group
  - Potential Bias (under-reporting, incomplete reporting, etc).

# Vaccine Adverse Event Reporting System (CDC/FDA)

- US population, self-reported, from many sources including healthcare providers and the public
- Similar to last year's H1N1 monitoring
  - Will focus on identifying deviations from prior seasonal (and H1N1) influenza monitoring
  - Three analysis methods:
    1. Automated – certain events reported daily
    2. Clinical review – medical officers will review daily reports, serious cases classified by body system
    3. Data mining –assesses for patterns of disproportionate reporting
  - Will have less staff commensurate with anticipated need this season. Can have additional capacity if necessary.



# Real-Time Immunization Monitoring System (CDC/Johns Hopkins)

- Automated real-time/web-based active surveillance
  - Vaccinees either give permission to be contacted for follow-up at time of immunization or choose to complete an online questionnaire within 42 days
  - Potential for several million persons from healthcare sites
  - Can target subpopulations, particularly healthcare workers, children, and pregnant women
  - Analyzed in real time using rule-based algorithm
  - Only information on vaccinees; lacks comparison group (so while active surveillance still primarily for signal generation)

# Active Surveillance

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- Purpose: Assess associations
- Primary Limitation: size (which impacts speed for moderate to rare events)



# Rapid Cycle Analysis

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- Developed by VSD to monitor pre-specified outcomes in near real-time
- Compares rates of outcomes in pre-specified time windows among vaccinees to comparison group (rates of same event during same post-vaccination time window among persons receiving flu vaccine in previous years)
- Potential adverse events are based on data from pre-licensure vaccine studies, early VAERS analyses, and concerns published in scientific articles



# Pre-specified Outcomes

- Guillain-Barré Syndrome
- Demyelinating disease
- Disorders of the peripheral nervous system and neuropathies
- Seizures (epilepsy, convulsions)
- Narcolepsy/cataplexy (under development)
- Select pregnancy outcomes (SAb, pre-eclampsia, stillbirth)
- Encephalitis, myelitis, encephalomyelitis
- Bell's Palsy
- Other cranial nerve disorders (Facial/Trigeminal nerve disorders)
- Ataxia (other cerebellar ataxia, ataxia)
- Anaphylaxis
- Angioneurotic edema, Allergic Reaction, Urticaria
- Myocarditis and pericarditis (LAIV only)
- Hemorrhagic stroke
- Ischemic stroke (excludes transient ischemic attack)
- Wheezing (LAIV only)
  - Asthma, wheezing, respiratory distress/insufficiency, other diseases of trachea/bronchi
  - Multiple definitions with and without bronchiolitis
- TP/ITP (some systems)

# Vaccine Safety Datalink (CDC)

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- Active surveillance, near real-time
  - ~9 million people in 8 linked MCOs
  - Can study subpopulations
  - Can add adverse events if signals arise from other source
  - Rapidly conduct chart review if needed
- Two-year VSD pilot expansion focused on influenza safety monitoring



# Influenza Awareness System (IHS)

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- Moderate size population from 21 sites
  - ~350,000 people from all life phases of the American Indian and Alaska Native community
  - Unified system, chart-review capable
  - Will predominantly focus on Bell's Palsy, ITP, GBS, and febrile seizures



# Centers for Medicare and Medicaid Services (CMS)

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- Utilizes Medicare data
  - Very large database
    - Expect ~14 million vaccinations this year
  - Predominantly ages 65 years and older
  - Focus on GBS and pilot analysis on anaphylaxis



# Defense Medical Surveillance System (DoD)

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- Large study population (@ 1 million)
- Healthy adults, limited ages represented
- Chart-review capable
- Will predominantly focus on Bell's Palsy, GBS, and TP/ITP



# Dept. of Veterans Affairs (VA)

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- Large study population
  - ~5 million persons
  - Captures elderly and Federal employees (other than DoD)
- Chart-review capable
- Predominantly focused on Bell's Palsy, GBS, anaphylaxis, and TP/ITP



# PRISM: Post-licensure Rapid Immunization Safety Monitoring (FDA/CDC/NVPO)

- Very large study population
  - ~14 million persons in healthcare plans linked to immunization registries in about 8 states
  - People from all life phases
- Can capture vaccinations not in medical records
- Chart-review capable but slower than other systems
- Currently working to develop infrastructure for the FDA's Sentinel Initiative as part of the FDA Amendment's Act of 2007.
  - Will not contribute to seasonal influenza monitoring this season as in previous year
  - May be possible to do a quarterly data update if needed



# Federal Immunization Safety Task Force (ISTF) H1N1 Working Group

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- Includes representatives from all agencies within HHS with assets in vaccine safety, DoD, and VA
- Will review all influenza vaccine safety data regularly



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