Immunization Safety Office Updates

Centers for Disease Control and Prevention

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Advisory Commission on Childhood Vaccines (ACCV)
September 6, 2012

Topics

- Planned influenza vaccine safety monitoring activities for the 2012-2013 influenza season
- June 2012 Advisory Committee on Immunization Practices (ACIP) meeting highlights
- Selected recent publications

Planned Influenza Vaccine Monitoring for 2012-2013

- **VAERS routine surveillance**
  - Automated data analysis to identify potential signals
  - Reporting trends over 10 years for all reports, serious* adverse events, deaths, and Guillain–Barré syndrome (GBS)
  - Data mining per FDA
- **VAERS enhanced surveillance**
  - Fluzone® Intradermal TIV (2nd season of use)
  - Fluzone® High-Dose TIV (3rd season of use)
  - Anaphylaxis with egg allergy (2nd season following change in TIV recommendations for egg allergic patients)
- **VSD surveillance**
  - Active surveillance for selected conditions, including seizures and GBS, following TIV and LAIV using automated data

*Defined by Code of Federal Regulations (FDA CFR 1997) if at least one of the following was reported: death, hospitalization, life-threatening illness, disability and /or prolonged hospitalization

June 2012 ACIP meeting vaccine safety highlights*

- Continued to observe disproportionate reporting for febrile seizures in young children following Fluzone® in VAERS data mining for 2011-12, as was first seen in 2010-11
  - Not unexpected given no formulation change for 2011-12
  - Possibility of stimulated reporting
- Elevated relative risk observed for seizures following TIV in children age 6-23 months in VSD surveillance of automated data for 2011-12
  - Magnitude of risk consistent with risk observed in 2010-11
  - No increased risk in children 24-59 months old
- No disproportionate reporting for GBS following TIV or LAIV in VAERS data mining for 2011-12
- No elevated risk for GBS following TIV or LAIV in VSD surveillance of automated data for 2011-12

*Slides available at: http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-jun-2012/03-influenza-Shimabukuro.pdf

Summary of GBS results from U.S. 2009 H1N1 vaccine safety surveillance systems*

Vaccine safety system	Study design†	RR/OR (95% CI)	Risk Diff (95% CI) Additional cases per million doses
EIP GBS surveillance	Unvaccinated control	1.57 (1.02, 2.21)	0.74 (0.04, 1.56)
	Self control (var. window)	2.1 (1.2, 3.5)	1.5 (0.3, 3.4)
	Self control (fixed window)	3.0 (1.4, 6.4)	2.8 (0.6, 7.4)
VSD	Self control	4.4 (1.3, 14.2)	5.0 (0.5, 9.5)
	Case-centered	2.0 (0.5, 8.1)	3.4 (-6.4, 7.6)
PRISM	Self control	2.50 (0.42, 15.0)	Estimated at 2-3 additional cases per million doses
	Case-centered	1.15 (0.07, 18.6)	
CMS	Self control	2.41 (1.14, 5.11)	2.84 (0.21, 5.48)
DoD	Self control	1.90 (0.63, 5.72)	
VA	Historic control	3.89 (0.44, 14.04)	
	Self control	3.86 (0.00, ∞)^	

* Adapted from Vellozi at ICPE 2011 and Sandhu at VRBPAC 2011; † All cases chart confirmed;
^ Upper bound undetermined due to a small number of cases

June 2012 ACIP meeting vaccine safety highlights*

- Allergy/anaphylaxis
  - Recommendations for egg allergic patients updated for 2011-12†
  - No increase in reports of allergy or anaphylactic reactions in VAERS from 2010-2011 to 2011-2012
- High-dose and intradermal TIV
  - No new safety concerns identified

*http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-jun-2012/03-influenza-Shimabukuro.pdf
†http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6033a3.htm

June 2012 ACIP meeting general updates

- **Recommendations for 13-valent pneumococcal conjugate vaccine (PCV13) use among immunocompromised adults**
  - **ACIP voted (passed) to recommend PCV13 for adults with immunocompromising conditions and functional or anatomic asplenia, CSF leaks or cochlear implants.**
  - **Adults 19 years of age or older with immunocompromising conditions and who have <u>not</u> previously received PCV13 or PPSV23 should receive a single dose of PCV13 followed by a dose of PPSV23 at least 8 weeks later.***
  - **Adults 19 years of age or older with immunocompromising conditions who have <u>previously received</u> one or more doses of PPSV23 should receive a dose of PCV13 one or more years after the last PPSV23 dose was received. For those that require additional doses of PPSV23, the first such dose should be given no sooner than 8 weeks after PCV13 and at least 5 years since the most recent dose of PPSV23.***

***Adults with CSF leaks and cochlear implants can receive up to 2 lifetime doses of PPSV23, 1 dose 8 weeks after their dose of PCV13 (which should be shortly after they are diagnosed) and 1 more dose when they turn 65 years old. For all of the other immunocompromising conditions (e.g., HIV), it is up to 3 lifetime doses of PPSV23, 1 dose 8 weeks after PCV13, 1 dose 5 years later, then 1 more dose at 65 years of age.**

Selected publications

- Rowhani-Rahbar A, et al. Immunization and Bell's Palsy in Children: A Case-Centered Analysis. Am J Epidemiol. 2012 May 1;175(9):878-885.
  - No association between immunization and Bell's palsy in children
- Cano M, et al. Bell's palsy cases following administration of influenza A (H1N1) 2009 monovalent vaccine reported to the Vaccine Adverse Event Reporting System (VAERS). J Vaccines Vaccin 2012, 3:2. http://dx.doi.org/10.4172/2157-7560.1000134
  - No pattern in the demographic and clinical characteristics to suggest an increased risk of Bell's palsy after 2009-H1N1 vaccination
  - Higher reporting rate of Bell's palsy to VAERS following receipt of 2009-H1N1 vaccine compared to seasonal influenza vaccine may be due to stimulated reporting

Selected publications

- Zheteyeva, YA, et al. Adverse event reports after tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccines in pregnant women. Am J Obstet Gynecol. 2012;207:59.e1-7. [Epub ahead of print]
  - During a time when Tdap was not routinely recommended in pregnancy, review of reports to VAERS in pregnant women after Tdap did not identify any concerning patterns in maternal, infant, or fetal outcomes
- Rowhani-Rahbar A, et al. Biologically plausible and evidence-based risk intervals in immunization safety research. Vaccine. 2012 Jul 24. [Epub ahead of print]
  - Provided a systematic process to define biologically plausible and evidence-based risk interval estimates for two specific adverse events following immunization, febrile seizures and acute disseminated encephalomyelitis

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Thank You

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