Immunization Safety Office Updates

Centers for Disease Control and Prevention

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

Topics

- Recent ISO contract awards
- October 2012 Advisory Committee on Immunization Practices (ACIP) meeting highlights
- CDC-Clinical Immunization Safety Assessment (CISA) Project working group response to an article on deaths following quadrivalent Human Papillomavirus (HPV) vaccination
- Selected publications

Recent ISO contract awards

- Vaccine Safety Datalink (VSD) contract awarded September 2012
- Clinical Immunization Safety Assessment (CISA) Project contract awarded September 2012
- Contract to conduct an enhanced evaluation of risk of narcolepsy associated with Pandemrix and Arepanrix awarded to the Brighton Collaboration in September 2012.

Oct 2012 ACIP meeting*: Vote on updated recommendations for Tdap in pregnant women†

- ACIP recommends that providers of prenatal care implement a Tdap immunization program for all pregnant women. Healthcare personnel should administer a dose of Tdap during each pregnancy irrespective of the patient's prior history of receiving Tdap. If not administered during pregnancy, Tdap should be administered immediately postpartum.
  - Guidance for use: Optimal timing for Tdap administration is between 27 and 36 weeks gestation to maximize the maternal antibody response and passive antibody transfer to the infant.
- ISO/CDC and FDA will monitor safety as this recommendation is implemented

†ACIP recommendations are provisional until published in the *MMWR*
Presented by J. Liang, CDC

* http://www.cdc.gov/vaccines/acip/meetings/slides-oct-2012.html

Oct 2012 ACIP meeting: Vote on MMR in persons with HIV*

- Persons with perinatal HIV infection who were vaccinated with MMR before effective antiretroviral therapy should be considered unvaccinated and should receive two appropriately spaced MMR vaccines once effective antiretroviral therapy has been established
- Two doses of MMR are recommended for all persons >=12 months with HIV infection who do not have evidence of current severe immunosuppression

*ACIP recommendations are provisional until published in the *MMWR*
Presented by H. McLean, CDC

Oct 2012 ACIP meeting: Immunization schedules and VFC vote*

- Vote on Immunization schedules*
  - Childhood immunization schedule for 2013 approved[1]
  - Adult immunization schedule for 2013 approved[2]
- Vote on Vaccine for Children (VFC)*
  - Resolution passed to change the term from Trivalent Inactivated Influenza Vaccine (TIV) to Inactivated Influenza Vaccine (IIV) in the VFC language to incorporate Quadrivalent Inactivated Influenza Vaccine (QIV) when licensed and available

*ACIP recommendations are provisional until published in the *MMWR*
1. Presented by I. Beysolow, CDC
2. Presented by C. Bridges, CDC

Oct 2012 ACIP meeting: Quadrivalent inactivated influenza vaccine

- **MedImmune Quadrivalent LAIV[1]**
  - Similar safety profile except higher rate of fever in children aged 2-8 years after 1st dose (QLAIV vs. TLAIV)
- **GSK Fluarix QIV[2]**
  - BLA submitted (>=3 years old)
  - Similar safety profiles to TIV and no difference in rate of fever
- **Sanofi Pasteur Fluzone QIV[3]**
  - BLA submitted (>=6 months old)
  - Comparable safety profiles for QIV vs. TIV and no increase in rate of fever

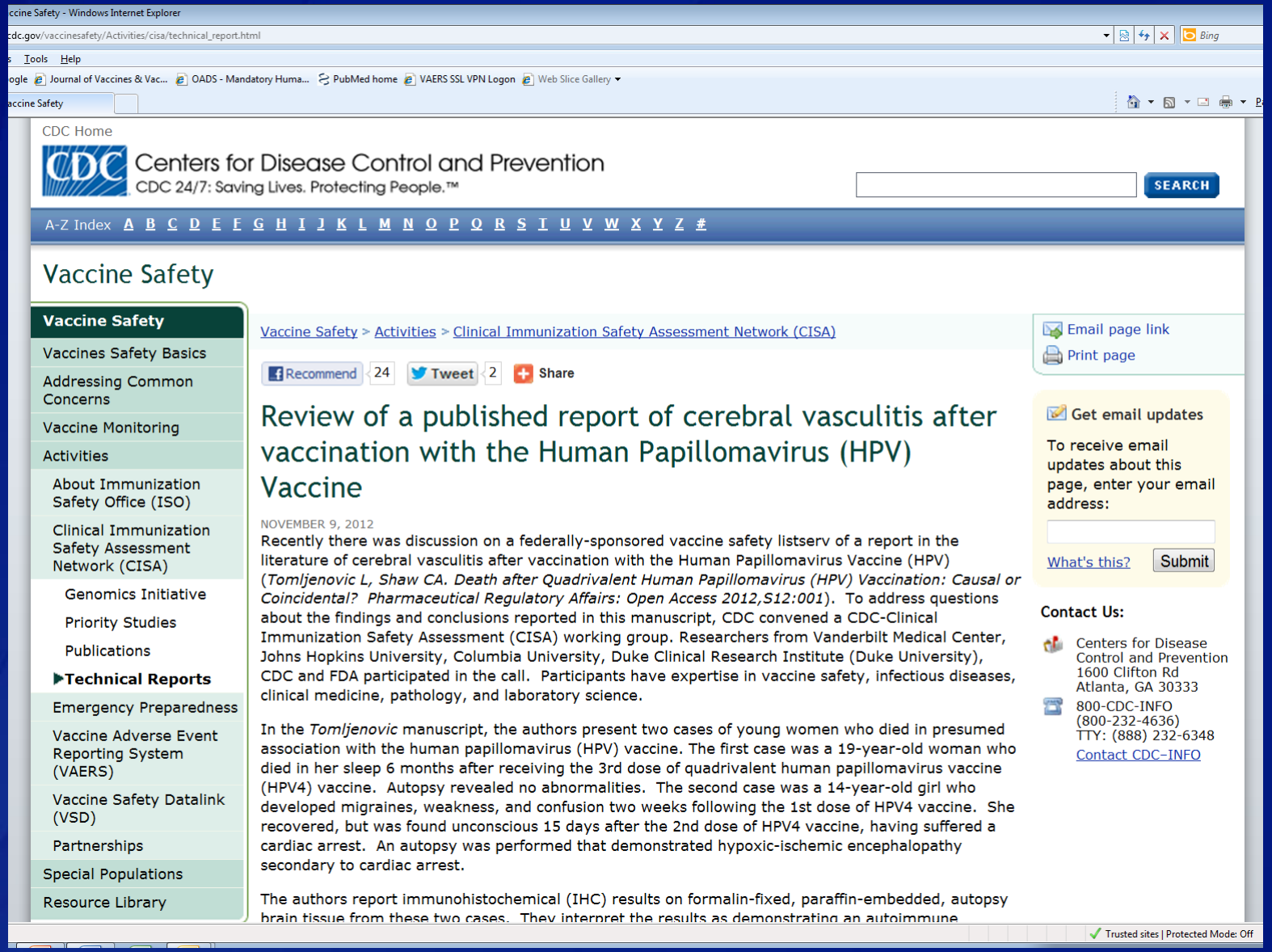
1. Presented by R. Mallory, MedImmune
2. Presented by V. Jain, GSK
3. Presented by D. Greenberg, Sanofi Pasteur

CDC response to article on deaths following quadrivalent HPV vaccine

- Tomljenovic and Shaw (2012)* described two case reports of death in young females following quadrivalent human papillomavirus (HPV4) vaccine
- Authors reexamined the cases and concluded that patients died of autoimmune cerebral vasculitis related to HPV4 vaccination
- CDC staff and the Clinical Immunization Safety Assessment (CISA) working group identified key deficits in the data provided to support the conclusions of the authors
- The CISA working group, in consultation with CDC, drafted a response, in the form of a technical report, for the CDC website

*Tomljenovic L, Shaw CA. Death after Quadrivalent Human Papillomavirus (HPV) Vaccination: Causal or Coincidental? Pharmaceutical Regulatory Affairs: Open Access 2012,S12:001

CDC response to article on deaths following quadrivalent HPV vaccine



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Review of a published report of cerebral vasculitis after vaccination with the Human Papillomavirus (HPV) Vaccine

NOVEMBER 9, 2012

Recently there was discussion on a federally-sponsored vaccine safety listserv of a report in the literature of cerebral vasculitis after vaccination with the Human Papillomavirus Vaccine (HPV) (*Tomljenovic L, Shaw CA. Death after Quadrivalent Human Papillomavirus (HPV) Vaccination: Causal or Coincidental? Pharmaceutical Regulatory Affairs: Open Access 2012,S12:001*). To address questions about the findings and conclusions reported in this manuscript, CDC convened a CDC-Clinical Immunization Safety Assessment (CISA) working group. Researchers from Vanderbilt Medical Center, Johns Hopkins University, Columbia University, Duke Clinical Research Institute (Duke University), CDC and FDA participated in the call. Participants have expertise in vaccine safety, infectious diseases, clinical medicine, pathology, and laboratory science.

In the *Tomljenovic* manuscript, the authors present two cases of young women who died in presumed association with the human papillomavirus (HPV) vaccine. The first case was a 19-year-old woman who died in her sleep 6 months after receiving the 3rd dose of quadrivalent human papillomavirus vaccine (HPV4) vaccine. Autopsy revealed no abnormalities. The second case was a 14-year-old girl who developed migraines, weakness, and confusion two weeks following the 1st dose of HPV4 vaccine. She recovered, but was found unconscious 15 days after the 2nd dose of HPV4 vaccine, having suffered a cardiac arrest. An autopsy was performed that demonstrated hypoxic-ischemic encephalopathy secondary to cardiac arrest.

The authors report immunohistochemical (IHC) results on formalin-fixed, paraffin-embedded, autopsy brain tissue from these two cases. They interpret the results as demonstrating an autoimmune

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Selected publications

- Abedi et al. Adverse events following a third dose of measles, mumps, and rubella vaccine in a mumps outbreak. Vaccine. 2012 Nov 19;30(49):7052-8.
  - Third dose of MMR vaccine administered in an outbreak setting is safe, with injection site reactions reported more frequently than systemic reactions. However, to assess risk for rare or serious adverse events after a third dose of MMR vaccine, longer term studies would be required.
- O'Leary et al. Febrile seizures and measles–mumps–rubella–varicella (MMRV) vaccine: What do primary care physicians think? Vaccine. 2012 Nov 6;30(48):6731-6733.
  - After receiving data regarding febrile seizure risk after MMRV, few physicians report they would recommend MMRV to a healthy 12–15-month-old child.

Selected publications

- **Moro et al. Safety of seasonal influenza and influenza A (H1N1) 2009 monovalent vaccines in pregnancy. Expert Rev Vaccines. 2012 Aug;11(8):911-21.**
  - **Data from surveillance systems and observational studies did not identify any pattern of adverse events of concern in vaccinated pregnant women or their infants. Although live attenuated influenza vaccines are not indicated during pregnancy, it is reassuring to know that inadvertent exposure to this vaccine in pregnant women did not result in unexpected reactions.**

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Thank You

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