

National Vaccine Advisory Committee
H1N1 Vaccine Safety Risk Assessment
Working Group (VSRAWG)

Report

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VSRAWG Members

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VSRAWG Charge

To conduct independent, rapid reviews of available federal immunization safety monitoring data for the 2009 H1N1 influenza vaccines

VSRAWG Methodology

- Created on October 30, 2009
- In-person meeting reviewed
 - Influenza vaccine safety literature from 1967 to 2009
 - Protocols/analytic plans from each vaccine safety monitoring system
 - Clinical trials data
- Ongoing Process
 - Bi-weekly calls through vaccine program, then monthly
 - Received vaccine safety data from each system via the Federal Immunization Safety Task Force (ISTF)
 - Discussed and interpreted data
 - 20 total meetings

VSRAWG Reports

- Reports included
 - Summary of data
 - Assessment of data strengths and limitations
 - Considerations for follow-up studies
- 6 VSRAWG reports were provided to the NVAC
 - December 16, 2009, January 20, 2010, February 26, 2010, March 23, 2010, April 23, 2010, June 2, 2010,
- NVAC reports transmitted to the ASH who forward to ASPR, CDC, FDA, NIH, IHS, CMS, DoD, VA & International Partners
- Available on NVPO website at:
<http://www.hhs.gov/nvpo/nvac/reports/index.html>
- This Report includes detailed methods and all available end-of-season data

VSRAWG Conclusion

Idiopathic Thrombocytopenic Purpura (ITP)

- Three systems initially detected a weak signal for ITP
- All three systems were either newly developed or had undergone accelerated development for H1N1
- After chart review & analyses to identify true incident ITP, no significant association found

VSRAWG Conclusion: No association between H1N1 vaccination and ITP

Bell's Palsy (BP)

- Two systems initially detected a weak signal of increased risk for BP
 - Concluded due to seasonal differences between when H1N1 vaccine was administered and historical and/or concomitant controls
 - Inconsistent findings across analysis

VSRAWG Conclusion: No association between H1N1 vaccination and BP

Guillain-Barré Syndrome (GBS)

- Initially EIP detected a statistically significant association between GBS and H1N1 vaccination
- VSD also detected an elevated risk when compared to historical data and self-controlled case series and case-centered analyses (case-centered analysis showed a non-significant trend).
- Non-statistically significant trends suggesting increased risks were noted in the primary analyses in other systems
- Results from meta-analysis across systems revealed an increased risk of 1-3 excess cases of GBS per 1 million doses of vaccine.

VSRAWG: There was an increased risk of GBS following H1N1 vaccine but that risk was very small

Other Findings

- Hypersensitivity reactions might be more common with H1N1 vaccine compared with seasonal influenza vaccines
- Methods of surveillance of pregnant women are not optimal and should be enhanced
- Continued methodological development of data mining approaches for signal detection is warranted
- Reports of administration errors (not associated with adverse events) suggest the need to explore opportunities to reduce such errors

Discussion

VSRAWG would like NVAC to
accept report and transmit it to
the Assistant Secretary for
Health