

Advisory Committee on Immunization Practices (ACIP): Measles, Mumps, Rubella and Varicella (MMRV) Vaccine Safety Working Group Update

ACIP Meeting on October 23, 2008

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Chair, MMRV ACIP Vaccine Safety Working Group**



MMRV Vaccine Safety Working Group Background – February 2008 ACIP Meeting

- Preliminary data from Vaccine Safety Datalink (VSD) Project and Merck postlicensure studies presented
 - Suggesting increased risk for febrile seizures during 1st–2nd week after 1st dose measles, mumps, rubella, and varicella (MMRV: ProQuad[®]) vaccine among children aged 12–23 months
- ACIP recommended
 - Removing the preference for MMRV vaccine over separate administration of MMR and varicella vaccines
 - Forming an ACIP MMRV Vaccine Safety Working Group
- Recommendations published in CDC's *Morbidity and Mortality Weekly Report (MMWR)*, March 2008



ACIP Recommendations for MMRV Use: Voted in February 2008

"Combination MMRV vaccine is approved for use among healthy children aged 12 months--12 years. MMRV vaccine is indicated for simultaneous vaccination against measles, mumps, rubella, and varicella. ACIP does not express a preference for use of MMRV vaccine over separate injections of equivalent component vaccines (i.e., MMR vaccine and varicella vaccine)."

¹CDC. Update: Recommendations from the Advisory Committee on Immunization Practices (ACIP) Regarding Administration of Combination MMRV Vaccine. MMWR. 57(10);258-260



MMRV Vaccine Safety Working Group Terms of Reference

1. Risk assessment (CDC Immunization Safety Office - lead)
 - To evaluate postlicensure safety data on risk of febrile seizures after MMRV vaccine, identify data gaps, and propose additional analyses or studies
 - To review encephalitis cases after MMRV vaccine
 - To communicate vaccine safety findings related to MMRV vaccine with ACIP and the public in a clear and transparent manner

In progress



MMRV Vaccine Safety Working Group Terms of Reference (cont.)

2. Risk management (CDC Division of Viral Diseases - lead)
 - To formulate policy options for use of MMRV vaccine for ACIP, considering benefit of vaccination and risks of vaccine adverse events
 - To identify and reconcile potential inconsistencies in ACIP statements, related to measles, mumps, rubella, varicella vaccination and febrile seizure prevention

To be started in November 2008
MMRV vaccine is not currently being distributed



MMRV Vaccine Safety Working Group Process: June 12 2008 – October 15, 2008

- Convened 16 hours of working group meetings
- Most WG time spent reviewing and interpreting data from VSD and Merck studies of MMRV vaccine and febrile seizure risk
- Consulted with numerous experts in areas of epidemiology, virology, immunology and vaccine safety
- By mutual agreement among WG members, Merck scientific staff and sponsored researchers participated in some meetings regarding discussion of VSD and Merck-sponsored study data interpretations
- Merck did not participate in WG evidence synthesis or policy-related discussions



MMRV Vaccine Safety Working Group

Progress: June 8, 2008 – October 15, 2008

(cont)

- Developed evidence framework to assess risk for febrile seizures after MMRV vaccine
 - Based on Institute of Medicine, World Health Organization and draft ACIP Evidence Based Working Group frameworks
- Synthesized the evidence for febrile seizure risk after MMRV vaccine
 - Focus on dose 1
- Proposed suggestions for further analyses to enhance the strength of evidence related to risk for febrile seizures after MMRV vaccine and inform policy



MMRV Vaccine Safety Working Group Members

ACIP

Jon Temte, Chair
H. Cody Meissner
Mark Sawyer

FDA

Sang Ahnn
Judy Beeler
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HRSA

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CDC

Karen Broder (Co-Lead)
Mona Marin (Co-Lead)
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Aisha Jumaan*
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Jim Sejvar
Jane Seward
Eric Weintraub



*Service on Working Group from June – September 2008

MMRV Vaccine Safety Working Group Members (cont)

Elizabeth Andrews	RTI International
Lawrence Brown	Children's Hospital of Philadelphia
Bruce Fireman	Kaiser Permanente Northern California (VSD)
Kathleen Gensheimer	Maine State Health Department, Council of State and Territorial Epidemiologists
Anne Gershon	Columbia University
Sam Katz	Duke University (Emeritus)
David Kimberlin	University of Alabama (AAP)
Nicola Klein	Kaiser Permanente Northern California (VSD)
Thomas Koinis	Duke Health (AAFP)
Martin Kulldorff	Harvard Medical School (VSD)
Tracy Lieu	Harvard Medical School (VSD)
Georges Peter	Brown University (Emeritus)
Katherine Yih	Harvard Medical School (VSD)



October 23, 2008: ACIP MMRV Vaccine Safety Session

Topic	Speaker	Time (min)
Measles, Mumps, Rubella, and Varicella (MMRV) Vaccine Safety Working Group Update	Dr. Temte, University of Wisconsin	5
Vaccine Safety Datalink (VSD) Project Safety Study of MMRV Vaccine: Review of Febrile Seizure Results Presented in February 2008	Mr. Weintraub, ISO/CDC	5
Merck Safety Study of ProQuad® (MMRV Vaccine): Febrile Seizure Results	Dr. Saddier, Merck	15
MMRV Vaccine Safety Working Group: Interim Synthesis of Evidence for Febrile Seizure Risk after MMRV Vaccination and Considerations for Future Activities	Dr. Broder ISO/CDC	30
Discussion	Dr. Temte	20



Thank You

