

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

June 25, 2008

**Jonathan Temte, MD, PhD
University of Wisconsin
Chair, ACIP MMRV Vaccine Safety Working Group**



MMRV Vaccine Safety Working Group Background – February 2008 ACIP Meeting

- Preliminary data presented suggesting increased risk for febrile seizures after measles, mumps, rubella, and varicella (MMRV) 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



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



MMRV Vaccine Safety Working Group

Terms of Reference (cont.)

2. Risk management (CDC National Center for Immunization and Respiratory 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



MMRV Vaccine Safety Working Group Expertise

- Vaccine safety
- Epidemiology and vaccines for measles, mumps, rubella and varicella
- Statistics and pharmacoepidemiology
- Pediatric neurology
- Pediatric infectious diseases
- Primary care
- Vaccinology
- Vaccine policy



MMRV Vaccine Safety Working Group Members

ACIP

Jon Temte, Chair

Tracy Lieu

Mark Sawyer

FDA

Sang Ahnn

Judy Beeler

Hector Izurieta

CDC

Karen Broder (Co-Lead)

Mona Marin (Co-Lead)

Elizabeth Skillen (Coordinator)

Aisha Jumaan

Preeta Kutty

Jim Sejvar

Jane Seward

Eric Weintraub



MMRV Vaccine Safety Working Group Consultants

Elizabeth Andrews	RTI International
Lawrence Brown	Children's Hospital of Philadelphia
Bruce Fireman	Kaiser Permanente Northern California
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 at Birmingham, American Academy of Pediatrics
Nicola Klein	Kaiser Permanente Northern California
Martin Kulldorff	Harvard Medical School
H. Cody Meissner	Tufts University School of Medicine
Georges Peter	Brown University (Emeritus)



MMRV Vaccine Safety Working Group Proposed Timeline

Date	Topic
June 2008	Working Group (WG) - Introductory calls
June 25, 2008*	ACIP Meeting - Update
June – Oct 2008	WG – Presentation and discussion on Vaccine Safety Datalink and Merck postlicensure MMRV safety studies
Oct 22 – 23 2008*	ACIP Meeting - Update on vaccine safety studies
Nov 2008 – Feb 2009	WG - Presentation and discussion on policy options for MMRV use
Feb 25 – 26, 2009*	ACIP Meeting - MMRV policy option discussion
Spring 2009	WG - Additional calls as needed

*Meetings open to the public



Thank you

