

Advisory Committee on Immunization Practices Immunization Safety Update, February 27, 2008

Title	Presenter	Alloted time
Introduction	John Iskander (ISO/OCSO)	5 minutes
Overview of VSD rapid cycle analysis (RCA)	Tracy Lieu (ACIP, Harvard Pilgrim)	15 minutes
RCA results for MMRV vaccine	Nicola Klein (Northern California Kaiser)	15 minutes
Phase IV results for MMRV vaccine	Patricia Saddier (Epidemiology Group, Merck)	15 minutes
Summary and Vote	Mona Marin (DVD/NCIRD)	25 minutes



Combination Measles, Mumps, Rubella and Varicella Virus Vaccine (MMRV)

- **FDA licensed combined MMRV in 2005 for use in children 12 months to 12 years of age**
- **ACIP recommended use of MMRV in 2006 for the first and second dose for measles, mumps, rubella, and varicella vaccination**



MMRV safety: Pre-licensure studies

- The safety of MMRV was compared with the safety of MMR+V administered separately at the same visit
- Among children age 12–23 months, two systemic vaccine-related adverse events occurred at a significantly higher rate among MMRV recipients 5-12 days following vaccination
 - Fever ($\geq 102^{\circ}\text{F}$): 21.5% vs. 14.9%
 - Measles-like rash: 3.0% vs. 2.1%
- Fever and rash usually occurred within 5-12 days after vaccination, were of short duration and resolved without complication (Shinefield et al PIDJ 2005)



MMR and V Safety: previous post-licensure studies

- **MMR vaccine is associated with febrile seizures 8-14 days post-vaccination; Attributable risk of approximately 1 additional febrile seizure for every 3,000 to 4,000 doses administered (Barlow et al NEJM 2001)**
- **Varicella vaccine is not associated with increased risk for febrile seizures, after adjusting for the concomitant administration of MMR (Black et al PIDJ 1999)**

