Immunization Safety Update: Combination Measles, Mumps, Rubella and Varicella (MMRV) Vaccine - Proposed Vote -

> Mona Marin, MD Division of Viral Diseases, NCIRD, CDC ACIP meeting, February 27, 2008





MMRV Vaccine Supply and Safety Update

- Supply: MMRV not distributed in the US since June 2007
 - Not expected to be available until 2009
 - Some providers might have supplies in stock
- Post-licensure safety monitoring
 - October 23, 2007: MMRV vaccine label updated to include "convulsion" and "febrile seizure" among adverse reactions post-vaccination
 - February 27, 2008: Preliminary vaccine safety study results on MMRV vaccine and febrile seizures presented to ACIP*



*ACIP presentations by Dr. Klein, CDC Vaccine Safety Datalink Project and Dr. Saddier, Merck Research Laboratories



Current ACIP Recommendations for Prevention of Varicella and Measles, Mumps, Rubella

Schedule: 2 vaccine doses

- 1st dose: 12-15 months
- 2nd dose: 4-6 years
- Catch-up vaccination for older children, adolescents and adults

Vaccination options

- Simultaneous: Varicella vaccine and MMR vaccine at separate sites and with separate syringes
- Non-simultaneous: Varicella vaccine and MMR vaccine
 ≥4 weeks apart

Combination MMRV vaccine (age 12 months-12 years)



ACIP General Recommendations on Combination Vaccines

"Use of combination vaccines can reduce the number of injections required at an office visit. Licensed combination vaccines can be used whenever any components of the combination are indicated and its other components are not contraindicated and if licensed by the Food and Drug Administration (FDA) for that dose in the series. Use of licensed combination vaccines is preferred to separate injection of their equivalent component vaccines to reduce the number of injections and missed opportunities to protect through vaccination."



CDC. General Recommendations on Immunization. MMWR 2006;55(No. RR-15), pg. 6.



Current ACIP Recommendations for MMRV Vaccine Use

"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. Whenever any components of the combination vaccine are indicated and the other components are not contraindicated, use of licensed combination vaccines, such as MMRV vaccine, is preferred over separate injection of equivalent component vaccines."

CDC. Prevention of Varicella. MMWR 2007;56(No. RR-4), pg 23.





Proposed Changes to the ACIP Recommendations for MMRV Use

Replace the preference for use of MMRV vaccine over simultaneous administration of MMR and varicella vaccines with no preference in the Varicella ACIP statement

 Proposed language: "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 combination MMRV vaccine over separate administration of MMR and varicella vaccines."







Next Steps

- Communication materials on CDC website
 - Health-care provider fact sheets to inform providers on preliminary findings and changes approved
 - Vaccine Information Statement (VIS) for MMR and varicella vaccines - updated "seizures caused by a fever have been reported after MMRV vaccine"
 - Q&A's
- MMWR Notice-to-readers
 - Present preliminary findings
 - Inform on no preference for use of combination MMRV vaccine
- ACIP workgroup to continue to evaluate MMRV vaccine safety findings and vaccination policy options



