

MMRV

MMRV = One combined shot for Measles, Mumps, Rubella and Varicella

alternative to

MMR+V = Two shots, one for Measles, Mumps and Rubella and another for Varicella

No known difference in efficacy

MMRV Timeline

2005: FDA licensed the combined MMRV vaccine for use in children 12 months to 12 years of age.



2006: The CDC Advisory Committee on Immunization Practices recommended use of MMRV, with preference over separate MMR and Varicella vaccines.

Weekly Safety Surveillance

CDC's Vaccine Safety Datalink Rapid Cycle Analysis

Weekly Data from Electronic Health Records

First MMRV dose, at age 12-23 months

2007: Signal for an excess number of febrile seizures after ~26,000 doses

Seizure Signal

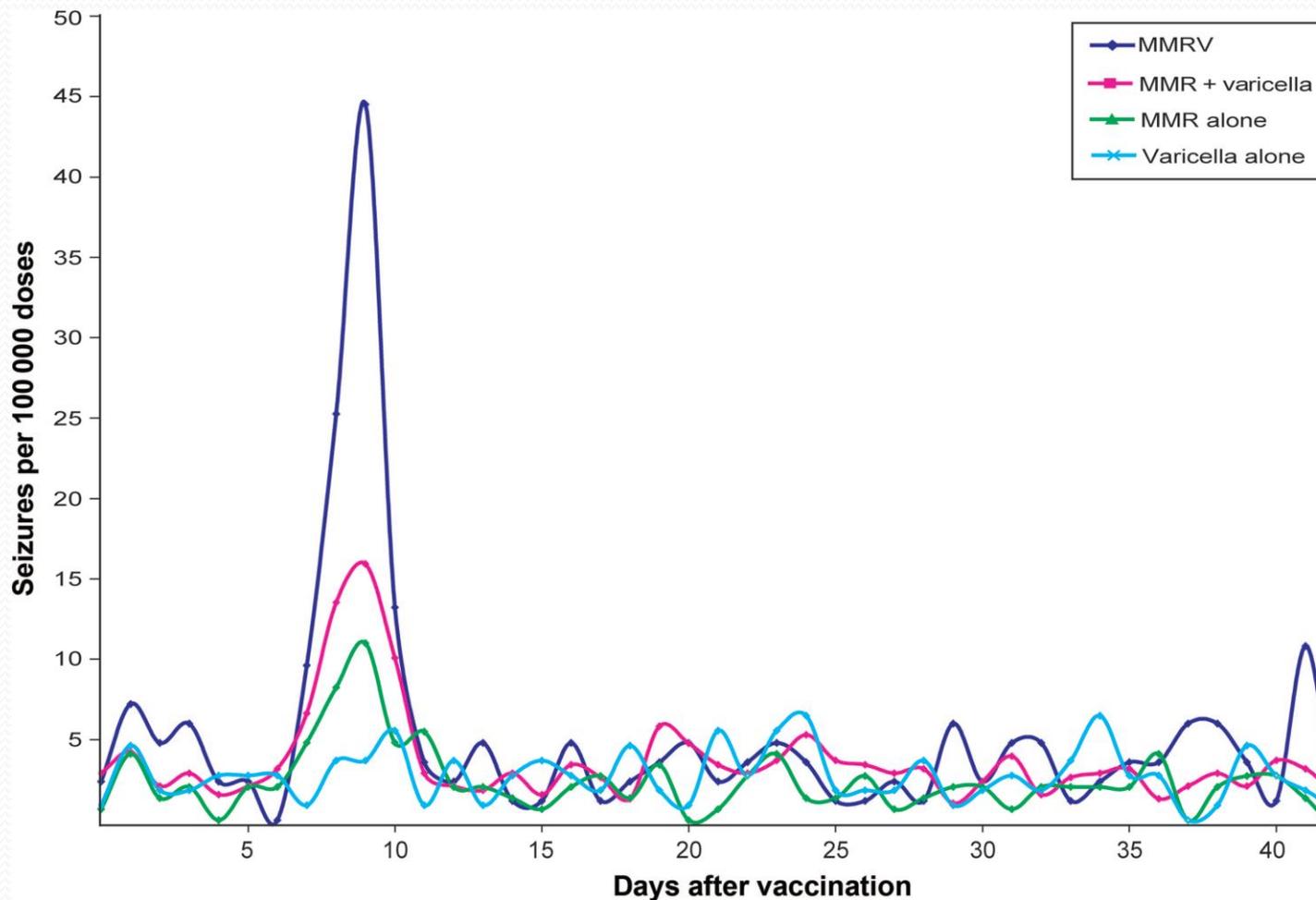
- For 12-23 month olds, seizure signal on February 11, 2007.
- Cumulative doses at that time: 25,779



	Observed	Expected	Relative Risk	LLR (critical value)
Number Seizures	59	38	1.57	5.17 (4.12)

Note: No seizure risk after second dose at age 4-6 years old

Postvaccination seizures among 12- to 23-month-olds according to vaccine received: VSD study population, 2000 –2008.



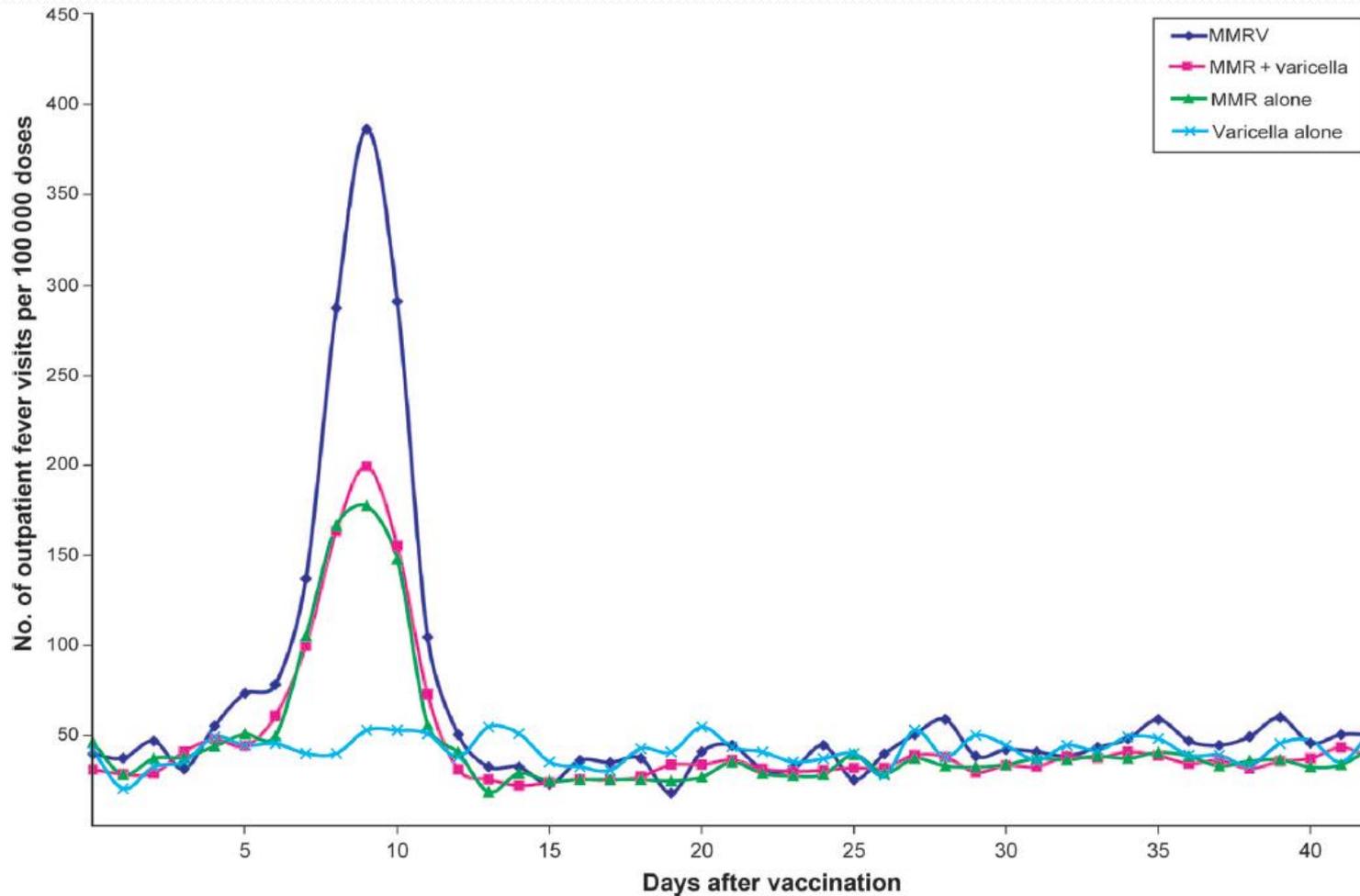
Klein N, Fireman B, Yih WK, Lewis E, Kulldorff M, Ray P, Baxter R, Hambidge S, Nordin J, Naleway A, Belongia E, Lieu T, Baggs J, Weintraub E, for the Vaccine Safety Datalink. Measles-Mumps-Rubella-Varicella Combination Vaccine and the Risk of Febrile Seizures, *Pediatrics*, 2010.

Risk for Febrile Seizures after MMRV Compared to MMR+V

Days After Vaccination	Analysis Incorporates Chart-Confirmation Rate?	RR (95% CI) ^a	<i>P</i>	Excess Risk per 10 000 Doses (95% CI)
7–10	No	1.98 (1.43–2.73)	<.0001	4.6 (2.8–5.9)
	Yes	2.04 (1.44–2.90)	<.0001	4.3 (2.6–5.6)

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Also excess in post-vaccination fever



MMRV Working Group Vote

2009



Four Options for the Vote, ages 12-47 months:

1. Both recommended, Preference for MMRV
 2. Both recommended, Equal preference
 3. **Both recommended, Preference for MMR+V**
 4. Only recommend MMR+V
1. Zero votes
 2. Minority
 3. **Majority**
 4. One vote

ACIP Vote

June 2009

Four Options for the Vote, ages 12-47 months:

1. Both recommended, Preference for MMRV
2. **Both recommended, Equal preference**
3. Recommend both, Preference for MMR+V
4. Only recommend MMR+V



1. Zero votes
2. **Majority**
3. Minority
4. Zero votes

CDC 2009 Recommendation

ACIP is only advisory. CDC decided:

- Either MMRV or MMR+V may be administered
- For dose 1 in children age 12-47 months, preference for MMR+V



Summary

- No known difference in efficacy between MMRV and MMR+V
- After first dose for children at ages 12-23 months, more febrile seizures after MMRV than MMR+V, ~ 1 per 2,300 doses
- After second dose at ages 4-6 years, no excess risk for febrile seizures

Proposed Recommendation

As there exist a safer equally effective alternative, the MMRV vaccine should not be administered to children under the age of 47 months.