

JE Vaccine Workgroup

Summary and Plans

Susan Hills, MBBS
Medical Epidemiologist
Centers for Disease Control and Prevention
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ACIP JE Vaccine Workgroup objectives

- Review newly available safety and immunogenicity data for JE-VC
- Review epidemiology and risk of JE in travelers
- Review ACIP recommendations for use of JE vaccine in consideration of updated safety, immunogenicity, and traveler risk data
- Update MMWR Recommendations and Reports published in 2010

Duration of protection in adults following JE-VC primary series and a booster dose

- ACIP JE-VC booster dose recommendation (2011)
 - If the primary series of JE-VC was administered >1 year previously, a booster dose may be given before potential JE virus exposure

Data supporting booster dose recommendation

- At 12-15 months after the 2-dose primary series, 58% -83% seroprotected (3 studies)
- At 24 months after the 2-dose primary series, 48%-82% seroprotected (2 studies)

Duration of protection following JE-VC primary series in adults: Workgroup summary

- At 5 years, 82% (124/152) subjects seroprotected
- Neutralizing antibody GMT = 43
- Seroprotection rates and GMTs higher if tick-borne encephalitis (TBE) vaccine administered after commencement of JE-VC vaccination
 - Seroprotection rates at 24–60 months
 - TBE vaccine group: 94-100%
 - No TBE vaccine group: 64-72%
 - GMTs in TBE vaccine group significantly higher at 24, 36, and 48 months

Duration of protection following JE-VC primary series in adults: Workgroup assessment

- After a 2-dose primary series, long term seroprotection rates and GMTs are lower in those not administered TBE vaccine compared with those administered TBE vaccine
 - TBE vaccine is not available in the United States and other flavivirus vaccines (e.g., yellow fever) are not routinely administered with JE-VC

Duration of protection following JE-VC primary series in adults: Options considered by Workgroup

1. No change to current booster dose recommendations
2. Strengthen the existing permissive ACIP recommendation (2011)

Duration of protection following JE-VC primary series in adults: Workgroup conclusions and recommendations

- Consideration of a strengthened booster dose recommendation
 - If the primary series of JE-VC was administered >1 year previously, a booster dose should be given before potential JE virus exposure

Duration of protection following a booster dose in adults: Workgroup summary

■ One observational study

- At ~ 6 years after booster dose, 96% (64/67) subjects seroprotected
- Neutralizing antibody GMT = 148
- Conducted in areas where TBE vaccine not routinely administered

■ Modeling study

- Estimated 75% subjects seroprotected \geq 10 years

Duration of protection following a booster dose in adults: Workgroup assessment

- After a 2-dose primary series and a booster dose, high seroprotection rates for at least 6 years
- No FDA recommendation for 2nd booster dose as no immunogenicity and safety data

Duration of protection following a booster dose in adults: Options considered by Workgroup

1. Off-label recommendation for a 2nd booster dose
2. No off-label recommendation but incorporate data into updated MMWR Recommendations & Report to make information available for vaccine providers

Duration of protection following a booster dose in adults: Workgroup conclusions and recommendations

- Data not sufficient to support an off-label recommendation for a 2nd booster dose
- Incorporate the data into updated MMWR Recommendations & Reports

Duration of protection following 2-dose primary series in children (non-endemic countries): Workgroup summary

- Long term study cohort included 23 children:
 - 1 child in 2 month–2 year age group (0.25mL dose)
 - 3 children in 3–11 year age group (0.5mL dose)
 - 19 children in 12–17 year age group (0.5mL dose)
- At 36 months 89% (17/19) children seroprotected;
GMT = 58
- Seroprotection rates and GMTs similar at months 6–36

Duration of protection following 2-dose primary series: comparison of pediatric and adult data Workgroup summary

- In the long term duration of protection studies, seroprotection rates at 36 months higher in pediatric study compared with adult study
 - 89% (17/19) children seroprotected
 - 72% (41/57) adults seroprotected*

*No TBE vaccination group

Duration of protection following 2-dose primary series in children (endemic countries): Workgroup summary

- At 36 months after 2-dose primary series
 - Overall, 90% (128/142) children seroprotected; GMT = 59
 - In all age groups, $\geq 81\%$ children seroprotected
- At 24 months after a booster dose, 100% (143/143) children seroprotected; GMT = 350

Need for a booster dose in children: Workgroup assessment

- Limited safety and immunogenicity data on need for a booster dose in children
- Available data suggest high seroprotection rates at 3 years following a 2-dose primary series
- Data have been submitted to FDA and are under review

Need for a booster dose in children: Options considered by Workgroup

1. Off-label recommendation for a booster dose while awaiting FDA review of data
2. No off-label recommendation but incorporate data into updated MMWR Recommendations & Reports and await FDA review of data

Need for a booster dose in children: Workgroup conclusions and recommendations

- No off-label recommendation requested
- Incorporate the data into updated MMWR Recommendations & Reports to make information available for providers

Remaining ACIP JE Vaccine Workgroup objectives to be addressed at future ACIP meetings

- Updated post-licensure safety data
- Review epidemiology and risk of JE in travelers
- Review ACIP recommendations for use of JE vaccine in consideration of updated safety, immunogenicity, and traveler data
- Present draft of updated MMWR Recommendations & Reports

ACIP JE & YF Vaccines Workgroup members

ACIP

Lorry Rubin, WG Chair*

Emmanuel Walter, ACIP

Ex Officio

Doran Fink, FDA

Mike Holbrook, NIH

Lewis Markoff, FDA

Pat Repik, NIH

Eric Sergienko, DoD

ACIP liaisons

Elizabeth Barnett, AAP

Robert Schechter, AIM

CDC

Marc Fischer, DVBD

Mark Gershman, DGMQ

Susan Hills, DVBD

Mike McNeil, ISO

Hardeep Sandhu, GID

Erin Staples, DVBD

Technical advisors

Alan Barrett, Univ Texas Galveston

Joseph Bocchini, Louisiana State Univ

Lin Chen, Mount Auburn Hosp

Myron Levin, Univ Colorado

Tony Marfin, PATH

Cody Meissner, Tufts Univ

David Shlim, ISTM

Mary Wilson, Harvard Univ

*New Workgroup chair to be identified

