JE Vaccine Workgroup
Summary and Plans

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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 ≥ 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
1. Off-label recommendation for a 2\textsuperscript{nd} 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 2\textsuperscript{nd} 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, ≥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
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*New Workgroup chair to be identified*