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

JE-VC immunogenicity in adults ≥65 years of age: Workgroup summary

- One observational study in adults aged ≥65 years
  - At 42 days after second dose
  - 65% (128/197) seroprotected
  - Neutralizing antibody GMT = 37
- Previous licensure study in younger adults
  - At 28 days after second dose
  - 96% (352/365) seroprotected
  - Neutralizing antibody GMT = 243

JE-VC immunogenicity in adults ≥65 years of age: Workgroup assessment

- Lower seroprotection rates and GMTs following 2-dose primary series compared to younger adults
- No data on safety, immunogenicity, or optimal timing of a possible 3rd primary series dose or early booster dose
- Data submitted to FDA but no change expected in recommended dosing schedule for adults aged ≥65 years

JE-VC immunogenicity in adults ≥65 years of age:
Options considered by Workgroup

1. Off-label recommendation for a 3rd primary series dose or early booster dose for adults ≥65 years of age before further exposure to JE virus

2. No off-label recommendation but incorporate data into updated MMWR Recommendations & Reports to make information available for vaccine providers

JE-VC immunogenicity in adults ≥65 years of age: Workgroup conclusions and recommendations

- Data not sufficient to support an off-label recommendation
- Incorporate the data into updated MMWR Recommendations & Reports
- Reevaluate if new data become available

JE-VC accelerated primary series:
Workgroup summary

- One randomized controlled trial in adults aged 18–65 years
- Accelerated primary series non-inferior to conventional dosing schedule
  - 99% (203/206) seroprotected after two doses administered 7 days apart
  - 100% (49/49) seroprotected after two doses administered 28 days apart

JE-VC accelerated primary series:
Workgroup assessment

- Limited safety and immunogenicity data in ~200 adults with 2-dose primary series administered 7 days apart
- No data in children <18 years or adults ≥65 years
- Data have not been submitted to FDA and it is not known if or when this will occur

JE-VC accelerated primary series:
Options considered by Workgroup

1. Off-label recommendation for an accelerated primary series of two JE-VC doses administered 7 days apart in adults aged 18–65 years

2. No off-label recommendation but incorporate data into updated MMWR Recommendations & Reports

JE-VC accelerated primary series: Workgroup conclusions and recommendations

- Data are promising for use of an accelerated 2-dose primary series but should be submitted for FDA review
- No off-label recommendation requested
- Incorporate the data into updated MMWR Recommendations & Reports

Additional new JE-VC safety and immunogenicity data for review at ACIP meeting in February 2016

- Duration of protection following primary series and booster dose in adults
- Duration of protection and booster doses in children
- Updated post-licensure safety data

Remaining ACIP JE Vaccine Workgroup objectives to be addressed at ACIP meeting in June

- 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

Updates to MMWR Recommendations & Reports

- Remove mouse brain-derived JE vaccine information and recommendations
- Incorporate previously published recommendations for JE-VC pediatric primary series and booster dose in adults
- Update traveler risk data
- Update JE-VC distributor, safety, immunogenicity, co-administration, and dosing schedule data

ACIP JE & YF Vaccines Workgroup members

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