Japanese encephalitis and yellow fever vaccines workgroup update

Joseph A. Bocchini, Jr., M.D.
ACIP, Workgroup Chair

June 25, 2015

Japanese encephalitis (JE) vaccine in the U.S.

- Inactivated Vero cell culture-derived JE vaccine (JE-VC; Ixiaro) is the only JE vaccine available in the U.S.
- JE-VC is manufactured by Valneva (formerly Intercell) and distributed in the U.S. by Novartis
- Inactivated mouse brain–derived vaccine (JE-MB; JE-VAX) is no longer available in the U.S.

ACIP recommendations for use of JE-VC

2009: FDA licensed JE-VC for use in adults

2009: ACIP approved recommendations for primary series in adults

2010: Updated MMWR Recommendations & Reports from 1993

2011: ACIP approved recommendations for booster dose in adults and published policy note in MMWR

2013: ACIP approved recommendations for primary series in children and published policy note in MMWR

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 data
- Update MMWR Recommendations and Reports published in 2010

Updates to MMWR recommendations & reports

- Remove JE-MB vaccine information and recommendations
- Add booster dose recommendations for adults
- Add primary series recommendations for children

New JE-VC data to review and incorporate

- Post-licensure safety data
- Single primary dose in people who previously received JE-MB
- Increased and decreased intervals between two primary series doses usually administered 28 days apart
- Co-administration with rabies and meningococcal vaccines
- Duration of protection and additional booster dose recommendations

Additional expected data and events

- By end of 2015, DoD post-licensure safety study data may become available
- Manufacturer has requested meeting with FDA to discuss acceptability of data for alternate dosing schedule, co-administration, and booster dose indications; might submit proposed label changes in 2016

ACIP JE Vaccine Workgroup plans

- Present revised MMWR Recommendations & Reports to ACIP in October 2015 or February 2016
- Timeline will depend on availability of data
- Additional ACIP votes and policy notes may be needed in 2016-2017 as new indications approved by FDA

ACIP JE & YF Vaccines Workgroup members

ACIP

Joseph Bocchini, WG Chair

Lorry Rubin, 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

Technical advisors

Alan Barrett, Univ Texas Galveston

Lin Chen, Mount Auburn Hosp

Myron Levin, Univ Colorado

Tony Marfin, PATH

Cody Meissner, Tufts Univ

David Shlim, ISTM

Mary Wilson, Harvard Univ

CDC

Marc Fischer, DVBD

Mark Gershman, DGMQ

Susan Hills, DVBD

Mike McNeil, ISO

Hardeep Sandhu, GID

Erin Staples, DVBD