

ACIP Japanese Encephalitis (JE) and Yellow Fever (YF) Vaccines Work Group

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Today's YF Vaccine Session

- ❑ **GRADE and Work Group conclusions regarding YF vaccine booster dose**
 - **J. Erin Staples, MD, PhD., NCEZID, CDC**
- ❑ **Discussion**
- ❑ **Vote**

Overview of Key Issues

- ❑ Since 1965, International Health Regulations (IHR) allowed countries to require a YF vaccine dose within past 10 years for entry
- ❑ In April 2013, the Strategic Advisory Group of Experts (WHO) concluded single dose of YF vaccine is sufficient to confer sustained immunity and lifelong protection
 - Booster doses are not needed
 - Identify specific risk groups which might benefit from second dose or booster dose

YF Vaccine and IHR

- ❑ YF vaccine is only vaccine covered by IHR
- ❑ IHR stipulate that YF vaccine provides protection against infection for 10 years
- ❑ Requiring proof of vaccination (i.e., certificates) from travelers is at discretion of each country
 - Certificate of vaccination valid for 10 years
- ❑ In May 2014, WHO World Health Assembly adopted an amendment to IHR that extends YF vaccine protection to the life of the person vaccinated
 - Change to IHR will be official in June 2016

ACIP Recommendations for YF Vaccine - 1

- ❑ Updated in 2009, published in 2010
- ❑ YF vaccine recommended for:
 - Persons aged ≥ 9 months traveling to or living in areas at risk for YF virus transmission in South America or Africa
 - Laboratory workers exposed to virulent virus strains
- ❑ Per IHR, YF vaccine may be required by a country for entry at intervals of 10 years

ACIP Recommendations for YF Vaccine - 2

- ❑ Because of risk of serious adverse events, health-care providers should vaccinate only persons who are at risk for exposure to YF virus or require proof of vaccination for country entry
- ❑ “IHRs require revaccination at intervals of 10 years to boost antibody titer. Evidence from multiple studies demonstrates that YF vaccine immunity persists for many decades and might provide life-long protection”

YF Vaccines

- ❑ **Live attenuated vaccine developed in 1930s**
- ❑ **Only YF vaccine available in U.S. is 17D-204 strain vaccine (YF-VAX) manufactured by Sanofi Pasteur (Swiftwater, PA)**
- ❑ **>540 million doses of YF vaccine administered worldwide**

YF Vaccine Efficacy and Correlate of Protection

- ❑ No human studies performed to determine efficacy or identify a correlate of protection for YF vaccine
- ❑ One study established minimal level of neutralizing antibodies needed to protect monkeys against virulent YF virus as \log_{10} neutralization index (LNI) ≥ 0.7
- ❑ No correlate determined with more the commonly used plaque reduction neutralization test (PRNT)
 - Not known whether lack of detectable antibody in previously immunized person indicates susceptibility

ACIP JE and YF Vaccines Work Group Activities

- ❑ Reformed JE Vaccine Work Group to include YF vaccine in October 2013**
- ❑ Met 12 times to discuss YF vaccine booster doses**
 - Reviewed duration of immunity following YF vaccine and safety of YF vaccine booster doses**
 - Performed GRADE analysis**
 - Reviewed epidemiology of YF vaccine in travelers**
 - Developed proposed recommendations**
- ❑ Two previous presentations to ACIP on this topic**
 - October 2013: Work group charge and plans**
 - February 2014: YF and YF vaccine background information**

JE and YF Vaccines Work Group Members

ACIP members

Joseph Bocchini (Chair)

Lorry Rubin

Liaison representatives

Cody Meissner (AAP)

Robert Schechter (AIM)

CDC Leads

Erin Staples (NCEZID/DVBD)

Marc Fischer (NCEZID/DVBD)

Ex Officio members

Doran Fink (FDA)

Jesse Geibe (DoD)

Michael Holbrook (NIH)

Lewis Markoff (FDA)

Pat Repik (NIH)

Invited consultants

Elizabeth Barnett

Alan Barrett

Lin Chen

Myron Levin

Mary Wilson