

Update on Yellow Fever Vaccine Supply in the U.S.

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ACIP Meeting
October 19, 2016



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Yellow Fever (YF) Overview

- ❑ Caused by YF virus (*Flavivirus*)
- ❑ Virus transmitted predominantly by *Aedes* mosquitoes
- ❑ Endemic in tropical Africa and South America
- ❑ Clinical disease ranges from mild febrile illness to severe disease with jaundice and hemorrhage
- ❑ In 2016, outbreaks occurred in areas of Africa where cases had not been reported for decades

YF Vaccine

- ❑ **Live attenuated viral vaccine produced in chick embryos**
- ❑ **Four WHO-prequalified vaccines available globally**
- ❑ **One vaccine licensed for use in U.S.**
 - **YF-VAX® (Sanofi Pasteur)**
 - **Not WHO-prequalified; not part of global supply**
- ❑ **YF vaccine is the only one for which proof of vaccination can be required by countries from arriving travelers under International Health Regulations 2005**

Global YF Vaccine Supply Issues - 2016

- ❑ 6 million doses placed in global emergency stockpile annually**
- ❑ Response to large outbreaks in Africa depleted the stockpile**
- ❑ Vaccine allotted for childhood and prevention campaigns rerouted for response**
- ❑ Fractional doses of YF vaccine used in DRC for preemptive vaccination of Kinshasa**

YF Vaccine Use in U.S.

- ❑ **Vaccinate people travelling internationally**
 - **To countries where there is risk of YF virus transmission**
 - **To countries with entry requirements for proof of YF vaccination**
- ❑ **Vaccinate laboratory workers potentially exposed to YF virus**

YF Vaccine Supply –U.S.

- ❑ Historically, intermittent manufacturing issues have led to temporary supply shortages**
- ❑ Since end of 2015, ongoing shortage with ordering restrictions in place**
- ❑ Anticipated additional demands on supply for Brazil Olympics**

Concerns about U.S. YF Vaccine Supply

- ❑ Given outbreaks and global supply issues, stakeholder discussions initiated in spring 2016**
- ❑ How to assure stable YF vaccine supply for travelers, military, and response personnel**
- ❑ Participants included CDC, Sanofi Pasteur, FDA, and DOD**

U.S. YF Vaccine Supply Options Reviewed

- ❑ Maintaining status quo relying on release of new YF-VAX[®] lots in production**
- ❑ Implementing Investigational New Drug (IND) application to allow for importation and use of YF vaccine licensed outside U.S.**
- ❑ Using fractional dosing of YF vaccine**

Status of Options – U.S. YF Vaccine Supply

- ❑ **YF-VAX[®] currently being produced is scheduled to be released before current inventory is exhausted**
 - Depletion of supply due to Olympics did not occur
 - Current ordering restrictions would remain in place
- ❑ **Contingency plan developed with submission of IND application to import and use YF vaccine licensed outside U.S.**
 - Application under 30-day review by FDA*
 - Protocol would be implemented should there not be adequate U.S. supply of YF vaccine
- ❑ **Fractional dosing not considered viable option based on limited data and many uncertainties**

* As of September 27, 2016

Conclusions

- ❑ In 2016, limitations in both global and U.S. YF vaccine supply
- ❑ Contingency plans are being developed for U.S. vaccine supply
- ❑ Plans will be enacted as needed based on demand & supply

JE and YF Vaccines Working Group Members

ACIP members

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Robert Atmar

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Thank You

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



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