

Summary of Key Points

Yellow Fever Vaccine: WHO Position on the Use of Fractional Doses, June 2017

**Addendum to WHO Yellow Fever Position Paper,
June 2013**



**World Health
Organization**

Background

- Theoretical basis for fractional Yellow fever vaccination:
 - Minimum potency recommended by WHO is 1000 international units (IU)/dose
 - Potency at release of YF vaccine standard doses is frequently many-fold higher.
- Previous studies suggest lower potency YF vaccine is equivalent to the standard dose with respect to immunological and virological parameters

Background

- In response to an outbreak during a global vaccine shortage in 2016, fYF doses were administered in Kinshasa, Democratic Republic of the Congo
 - 7.9 million people administered fYF vaccine
 - 1/5 of the standard dose given to individuals >2 years, excluding pregnant women
 - Potency still above minimum WHO threshold of 1000 IU/dose
 - No safety signals detected
- Observational study conducted in the context of the campaign found 98% seroconversion at 28 days among participants given fYF

WHO Position

- Recent outbreaks highlight critical importance of strong routine YF immunization programmes
- fYF vaccination can be used as part of an emergency response to an outbreak **if** there is a shortage of full-dose YF vaccine that exceeds the capacity of the global stockpile
 - As soon as the YF vaccine supply situation can meet the immediate need, the use of fYF vaccination should be replaced by standard full-dose YF vaccination.
- Children aged <2 years, pregnant women, and individuals known to be HIV-infected should preferentially be vaccinated using a standard dose.
- fYF vaccination does not meet YF vaccination requirements under the International Health Regulations (IHR),



WHO Position fYF Vaccine Specifications

- fYF is an off-label use
- Determining most suitable volume (i.e. 1/2 or 1/5 of a standard dose) should be done taking into consideration the available vaccine product and its release specifications
- Not recommended to use multi-dose vials with more than 10 standard 0.5 mL doses for fractional dose administration
- Should be reconstituted according to the manufacturer's specifications, and under no circumstances should it be diluted
- Recommendations from 2013 YF position paper on standard YF vaccination remain the same



WHO Position

Research Priorities

- Non-inferiority immunogenicity studies for all four WHO-prequalified YF vaccines, including in special populations
- Duration of protection with fYF vaccination, including the potential need for revaccination
- Safety and effectiveness assessments
 - Evaluation of potential programmatic errors related to fYF as well YF vaccine-associated neurologic and viscerotropic disease
 - fYF vaccination should be recorded using individual vaccination records and nominal registries to support evaluations



**For more information on the WHO
Yellow Fever position paper, please
visit the WHO website:**

www.who.int/immunization/documents/positionpapers



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