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
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