ESTABLISHMENT OF INTERNATIONAL REFERENCE STANDARD FOR SABIN IPV (sIPV)

October 31, 2018

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19th Annual DCVMN General Meeting
THE POLIO ERADICATION ENDGAME

GPEI Strategy    Timeline

Use of IPV, bOPV & tOPV

Introduce 1 dose IPV in routine immunization
bOPV + ≥1 dose IPV in routine immunization

2 IPV doses


Current WHO IPV Recommendation
- For IPV only - using countries: 3 doses of IPV
- For OPV-using countries: at least 1 dose of IPV at 14 weeks

SAGE Recommendation for Post-OPV Cessation Era
- Two IPV doses at 14 weeks (or 2nd DTP) and 9 months (or with MCV)
- Either full dose or fractional dose IPV
- Minimum of 10 years for countries not hosting polio essential facilities (PEP)
WHO – POLIO EN DGAME PLANS FOR 2014-2021
Note: The chart includes standalone as well as combination IPV vaccine manufacturers
**BACKGROUND**

- Wild virulent poliovirus strains have been used to produce conventional IPV (cIPV) for >50 years
- IPV potency is measured by a validated ELISA, suitable reference and expressed as D-Ag units
- cIPV International Standard (IS) 12/104 is used to calibrate such references
- The standard human dose for cIPV consists of the following D-Ag units:
  - 40 for poliovirus type 1
  - 8 for poliovirus type 2
  - 32 for poliovirus type 3
Currently, sIPV has no such reference and no defined requirements in terms of specific D-Ag units/human dose.

sIPV products vary in D-Ag units/dose, which have been based on clinical studies undertaken by each manufacturer.

Manufacturer specific references are not calibrated against IS, therefore it is difficult to assess D-Ag units between manufacturers and across sIPV products.

With more sIPV manufacturers moving towards licensure, these variations in D-Ag units may cause scientific and regulatory challenges for new sIPV product licenures.
FIRST COLLABORATIVE STUDY DESIGN WITH cIPV STANDARD

- **Aim:** To evaluate whether the current WHO IS for cIPV (12/104) is a suitable reference to measure the D-Ag content of sIPV products

- **Samples in collaborative study:**
  - sIPV products from several manufacturers
  - cIPV products: IS 12/104 and 08/143

- **Reagents for ELISA assay:**
  - In-house reagents
  - Common reagents (NIBSC reagents):

- **Determination of D-Ag potency in three independent assays using 12/104 vs in-house reference**