

ESTABLISHMENT OF INTERNATIONAL REFERENCE STANDARD FOR SABIN IPV (sIPV)

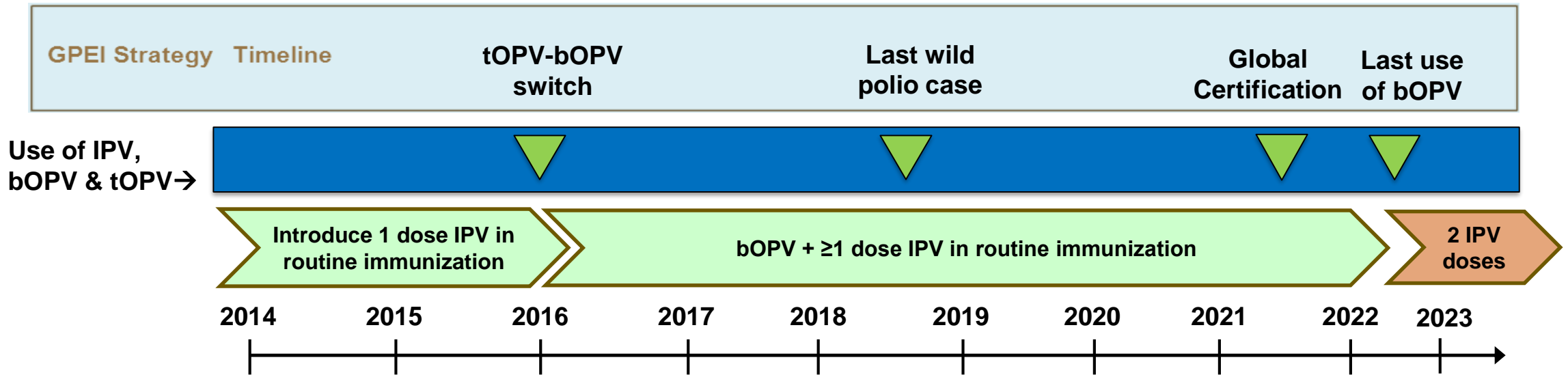
October 31, 2018

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Bill & Melinda Gates Foundation

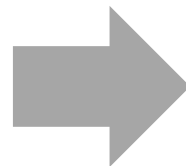
19th Annual DCVMN General Meeting

THE POLIO ERADICATION ENDGAME



Current WHO IPV Recommendation

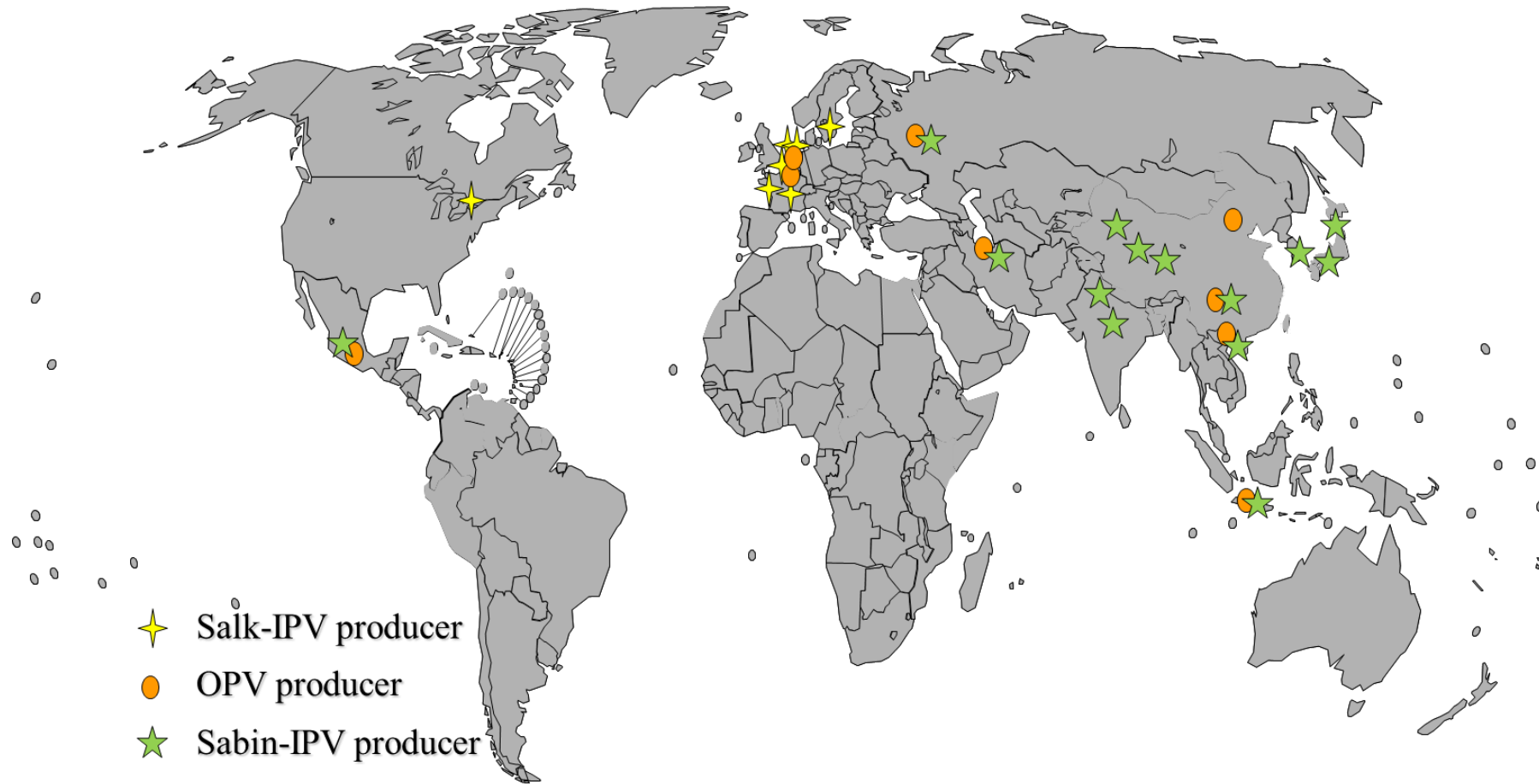
- For IPV only -using countries: 3 doses of IPV
- For OPV-using countries: at least 1 dose of IPV at 14 weeks



SAGE Recommendation for Post-OPV Cessation Era

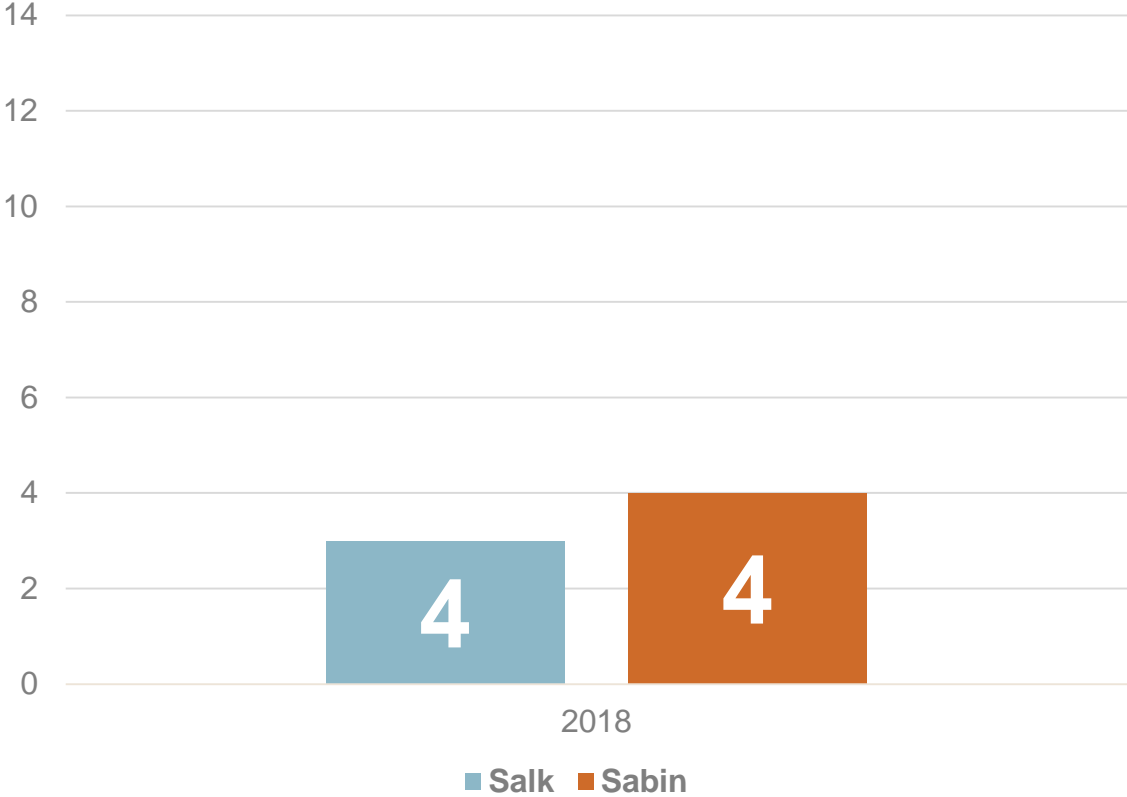
- Two IPV doses at 14 weeks (or 2nd DTP) and 9 months (or with MCV)
- Either full dose or fractional dose IPV
- Minimum of 10 years for countries not hosting polio essential facilities (PEP)

WHO – POLIO ENDGAME PLANS FOR 2014-2021

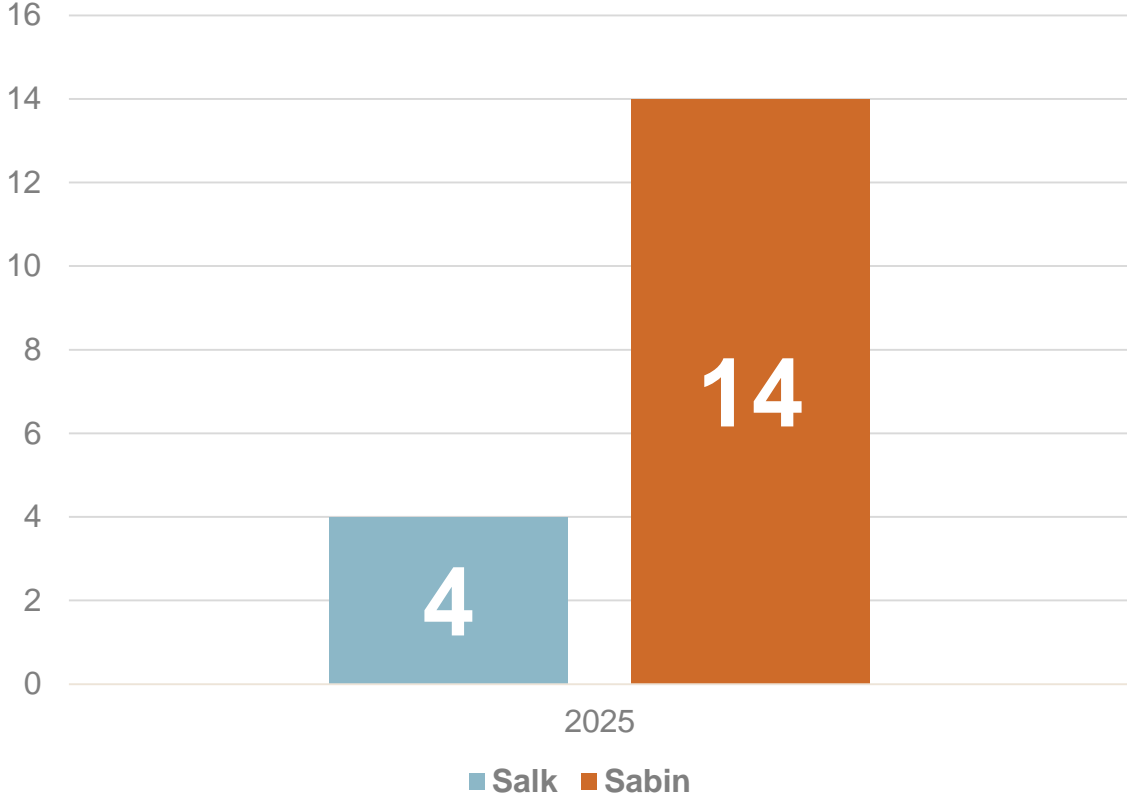


ANTICIPATED sIPV MANUFACTURERS

Licensed Salk vs Sabin IPV Manufacturers in 2018



Expected Licensed Salk vs Sabin IPV Manufacturers in 2025



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
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IPV MADE FROM SABIN STRAINS - sIPV

- 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.

Serotype	Sabin Producers			Salk
	A	B	C	
1	30	10	3	40
2	32	16	100	8
3	45	32	100	32

- 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 licensures.
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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
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