Annex 1: Trigger, Prerequisites, Readiness, & Other Important Considerations → Standards, Evaluation, Implications & Lessons for bOPV Withdrawal						
Trigger		Element	Standard	Evaluation	Implication „Did it matter?“	Lessons for bOPV withdrawal
Validation of elimination of persistent cVDPV type 2 and confirmation of WPV2 eradication	**T1**	Validation of elimination of “persistent” cVDPV2	No “persistent” cVDPV2 before SWITCH	**NOT MET** -cVDPV2 in Borno, Nigeria detected – 4/28/2016 reported	Outbreak response with mOPV2 → seeding of new cVDPV2 outbreaks	Anticipate with contingency plans + plan to deal with silent cVDPV circulation
	T2	Confirmation of WPV2 eradication	Global Certification Committee (GCC) resolution	**ACHIEVED** -20-21 September 2015 14th Meeting of GCC Bali, Indonesia		
Prerequisites **REF a**						
An OPV type 2 stockpile and response capacity	P1	OPV type 2 stockpile	Initial plan requirement: 750 mio doses; procured 519 mio doses including 100 mio in vials and rest in bulk	**NOT MET**	Stockpile plan target not achieved – rapid depletion in 1st year required bulk fill & finish contracts– eventually stock out	Stockpile assumptions too optimistic, must be tested – margin of error must be large -- **RISK**
	P2	Response capacity	Outbreak response SOPs + credible organization	**NOT MET** – Not possible to implement SOPs re required number of rounds and vaccines	Protocol revised several times – number of SIA rounds decreased [adjusted down because of IPV & mOPV2 constraints] **KEY to overall failure**	Eventually some countries did not adhere to guidelines [delayed outbreak control]-- **RISK**
Surveillance capacity and an international notification requirement for all Sabin, Sabin-like	P3	Surveillance capacity	Standard ≥2 AFP rate + ≥80% stool collection + ≥90% of cVDPV2 (≤1% nt divergence) for Region or Sub-Regions	**NOT MET** -7 silent cVDPV2s at switch time -Somalia cVDPV2 emergence circulates	Undetected (i.e., silent) cVDPV2 seeded new outbreaks in increasingly susceptible populations	To avoid failure in future, surveillance must cover all inaccessible communities; **RISK**

and cVDPV type 2 viruses	P4	International notification requirement for all Sabin, Sabin-like and cVDPV type 2 viruses	All type 2 poliovirus included in mandatory IHR reporting	**ACHIEVED**		Need to include all poliovirus serotypes in mandatory HR reporting, including novel viruses
Sufficient bOPV products for all OPV-using countries	P5	Sufficient bOPV products for all OPV-using countries	No stock-outs or supply constraints	**ACHIEVED**	All OPV vaccine producers stopped type 2 bulk production and switched to bOPV	Provide adequate multi-year lead time for global change -- **RISK**
Affordable IPV option(s) for all OPV-using countries	P6	Affordable IPV option(s)	-Gavi-eligible countries only -Some middle-income countries (MICS	**ACHIEVED**	-Gavi IPV support window for 73 countries (Board 1-2 June 2013) – all applied -9 MICs supported by GPEI (6 WPRO, 3 PAHO) for IPV procurement & operational costs associated with IPV introduction	One size does not fit all. India received $50 mio for one-time introduction support – to ensure meeting IPV introduction timeline
	P7	Affordable IPV option(s) for all OPV-using countries	≥1 IPV dose for OPV-using countries	**NOT MET [REF d]** -49 countries without IPV (20 delayed, 29 in stock-out) -only 50% IPV required supplies available	a) lack of IPV led to decreased population immunity → vulnerable to outbreaks; b) IPV basically not available for outbreak response (contrary to initial outbreak response SOPs) **KEY to overall failure**	If vaccine is required, must ensure sufficient quantities – multiple producers; robust production capacity; production must continue after withdrawal -- **RISK**
Phase II biocontainment for all cVDPV type 2 and WPVs	P8	Phase II biocontainment for all cVDPV type 2 and WPVs	Phase II (inventories) achieved in all countries	**NOT MET** -large quantities of type-2-containing vaccine remained in storage	Unlikely to be a major issue for overall switch failure	Only one outbreak can definitely assigned to tOPV left over vaccine

Readiness REF c						
At least one dose of IPV in OPV-using countries	R1	At least one IPV dose in OPV-using countries	**SEE P6-7**	**NOT MET**		
bivalent oral poliovirus vaccine (bOPV) licensed for routine immunization	R2	bivalent oral poliovirus vaccine (bOPV) licensed for routine immunization	Regulatory approval in all countries for RI use of bOPV	**ACHIEVED** -national licensure -WHO prequalification -emergency approval	Multi-year effort with bOPV manufacturers required for success approval	Start obtaining regulatory approval as early as possible for nOPV2, ntOPV, etc. -- **RISK**
Appropriate containment and handling of residual type 2 materials	R3		**SEE P8 + O3**			
Type 2 poliovirus surveillance and response protocols and monovalent OPV (mOPV) stockpile	R4	Type 2 poliovirus surveillance and response protocols	**SEE P2-3**			
	R5	monovalent OPV (mOPV) stockpile	**SEE P1**			
Verification of global eradication of wild poliovirus type 2	R6	Verification of global eradication of wild poliovirus type 2	**SEE T2**			
Other important considerations						
	O1	Complete cessation of use of all tOPV globally must occur by a fixed date	Cessation of all OPV2 during 2-week period end of April 2016	**ACHIEVED** -Egypt needed to postpone to May because outbreak control	Policy & implementation globally coordinated	Key area for bOPV withdrawal

	O2	Cessation should be coordinated across all countries using tOPV	**SEE O1**	**ACHIEVED**		
	O3	All remaining stocks of tOPV at the time of cessation must be collected and destroyed (within 3 mos)	No tOPV remaining in country storage >3 mos after switch	**NOT MET** – multiple countries had tOPV ≥3 mos after switch	HIghly important – likely seeded a number of cVDPV2 outbreaks; **KEY to overall failure**	Key issue for bOPV withdrawal – **SEE R5**
	O4	The process must be documented	Each important area must be documented	**ACHIEVED**	Multiple journal supplements + articles in peer-reviewed journals	
Other key Issues		**Issue**	**What was done**	**Deficiencies / achievements**	**Supporting**	**Implications**
	I1	Global Plan of Action 2013-2018	Planning started in 1990s, oversight & guidance provided by TCG, ACPE, and SAGE; plan of action 2013-2018 outlined principles, prerequisites & trigger point for switch & ambitious RI target	-no plan B -no definition of failure -no detailed risk analysis -some contingencies not exercised -overly ambitious containment (leading to Sabin type 2 bulk production discontinuation)	Key WHO leadership position changed during critical phase – Director of POL changed in 12 Dec 2014, and again in early 2016 (similar changes in UNICEF)	New switch plan must address missing elements from 2016 SWITCH, should alos avoid leadership changes during most critical period
	I2	Routine immunization target	10% increase in RI coverage per year (in 10 highest risk countries) – **NOT MET**	Target too ambitious	Reliance on & cooperation with IVB was aspirational	Don´t include unrealistic goals in areas that are not controlled by GPEI

	I3	Country national switch plans	10 high-risk countries supported for national plans development & implementation (approx. $10 mio extra funding)	Too few countries, too narrow activities, too little funding	In many countries only a small proportion of tOPV storage site (10-20%) were actually inspected	Proper plan preparation & implementation requires adequate support
	I4	Oversight – GPEI leadership	WHO DG [M Chen] removed GPEI Head [BA] on 12 Dec 2014 [during POB meeting]; appointed on same day new GPEI Head [HJ] who stayed until 31 Jan 2016, and was replaced by [MZ] from 1 Feb 2016 [until 31 Dec 2020]	In the critical phase of the switch, new leadership was in charge of GPEI	Since plan definition of failure was not specified, new POL Directors had no guidance when to change course	Next withdrawal plan should address deficiencies from I1, and not change leadership during critical phase
	I5	Oversight – Role of technical oversight committee	Numerous meetings of SAGE Pol WG and SAGE provided guidance (usually 2 SAGE POL WG + 2 full SAGE meetings per year	Technical oversite didn´t identify key plan deficiencies	Given the importance of the SWITCH for global public health, additional review processes seem desirable	Global plans need to include team B approach to identify potential issues & problems
	I6	“Insurance”	Plan required >1 dose of IPV for all tOPV-using countries	Only about 50% of required IPV doses available at switch	However, insurance SUCCESSFUL, >50K children walk today (Ref c)	Insurance should be included in future plans

References:

a. Strategic Plan 2013-2018
b. SAGE Recommendations

c. Thompson KM, Kalkowska DA, Badizadegan K. Looking back at prospective modelling of outbreak response strategies in managing global type 2 oral poliovirus vaccine (OPV2) cessation. Front Public Health 2023 March 24:11:1098419. Doi: 10.3389/pubh.2023:1098419. eCollection 2023. PMID: 37033033.
d. Hampton LM, Farrell M, Ramirez-Gonzalez A, Menning L, Shendale S, Lewis I; Rubin J, Garon J, Harris J, Hyde T, Wassilak S, Patel M, Nandy R, Chang-Blanc D, Immunization Systems Management Group of the Global Polio Eradication Initiative. Cessation of Trivalent Oral Poliovirus Vaccine and Introduction of Inactivated Poliovirus Vaccine — Worldwide, 2016. Morb Mortal Wklz Rep 2016; 65(35);934–938.