Report from the Polio WG Meeting (22-23 August, 2016)

Dr.Yagob Al-Mazrou
Chair, SAGE Polio Working Group
18 October, 2016

World Health Organization

- Background

- Issues and WG Conclusion

- Proposed Recommendations by SAGE

Background: SAGE Recommendations in April 2016

World Health Organization
Organisation mondiale de la Santé

Weekly epidemiological record
Relevé épidémiologique hebdomadaire

Contents

EPIDEMIC FOCUS

GROS PLAN SUR LES ÉPIDÉMIES

- SAGE expressed its concern over the global supply shortage of Inactivated Poliovirus Vaccine (IPV), which will persist into 2017-18
- SAGE also requested the WG to present a high-level policy direction on future immunization policies in October 2016

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Background: Polio WG Discussions

Following up on the SAGE recommendations, the WG met on 22-23 August 2016 to review/discuss:

- cVDPV2/iVDPV epidemiology
- Remaining issues in OPV2 withdrawal (e.g. IPV shortage, catch-up vaccination, containment)
- Future immunization policy (bOPV campaigns before the OPV cessation and long-term IPV schedule)

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Circulating-VDPV2 After OPV2 Withdrawal

Tracking cVDPV2 Outbreaks

Report date: 27 September 2016

Year / Month

Outbreak, year of emergence	Source	State / Province	2014												2015												2016								
			Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.
Nigeria, 2005-08th	AFP	Borno			X																													
		Katsina									X																								
		Kano					X	X		X		X																							
		Jigawa										X																							
	ENV	Jigawa											X																						
		Kano				X	X	X	X	X	X	X																							
		Kaduna						X		X		X	X				X																		
		Katsina						X	X																										
		Sokoto		X		X	X	X	X	X																								
Chad, 2012	AFP	Adamawa																																	
		Borno		X	X	X	X	X			X																								
		Kano						X					X																						
		Jigawa										X																							
		Yobe										X	X																						
	Contact	Borno																																X	
	ENV	Borno	X	X	X	X	X																						X						
		Kano				X																													
Nigeria, KDS-1	AFP	FCT, Abuja																	X																
	ENV	Kaduna								X			X		X																				
Pakistan	AFP	Balochistan																																	
		FATA	X		X	X	X																												
		KP					X																												
		Sindh																																	
	ENV	Sindh																																	
Pakistan (recent emergences)	AFP	FATA	X	X				X								X																			
		KP					X									X																			
		Sindh												X																					
	ENV	Balochistan															X																		
		Sindh							X		X	X	X	X	X	X	X																			
South Sudan	AFP	Unity									X																								
Myanmar	AFP	Rakhine																X						X											
Guinea	AFP	Kankan								X											X		X	X		X									

Borno, Monguno
Spec date: 26-August-2016
37 nt change (ORPHAN at ~97%)

X At least one cVDPV2 reported per given month

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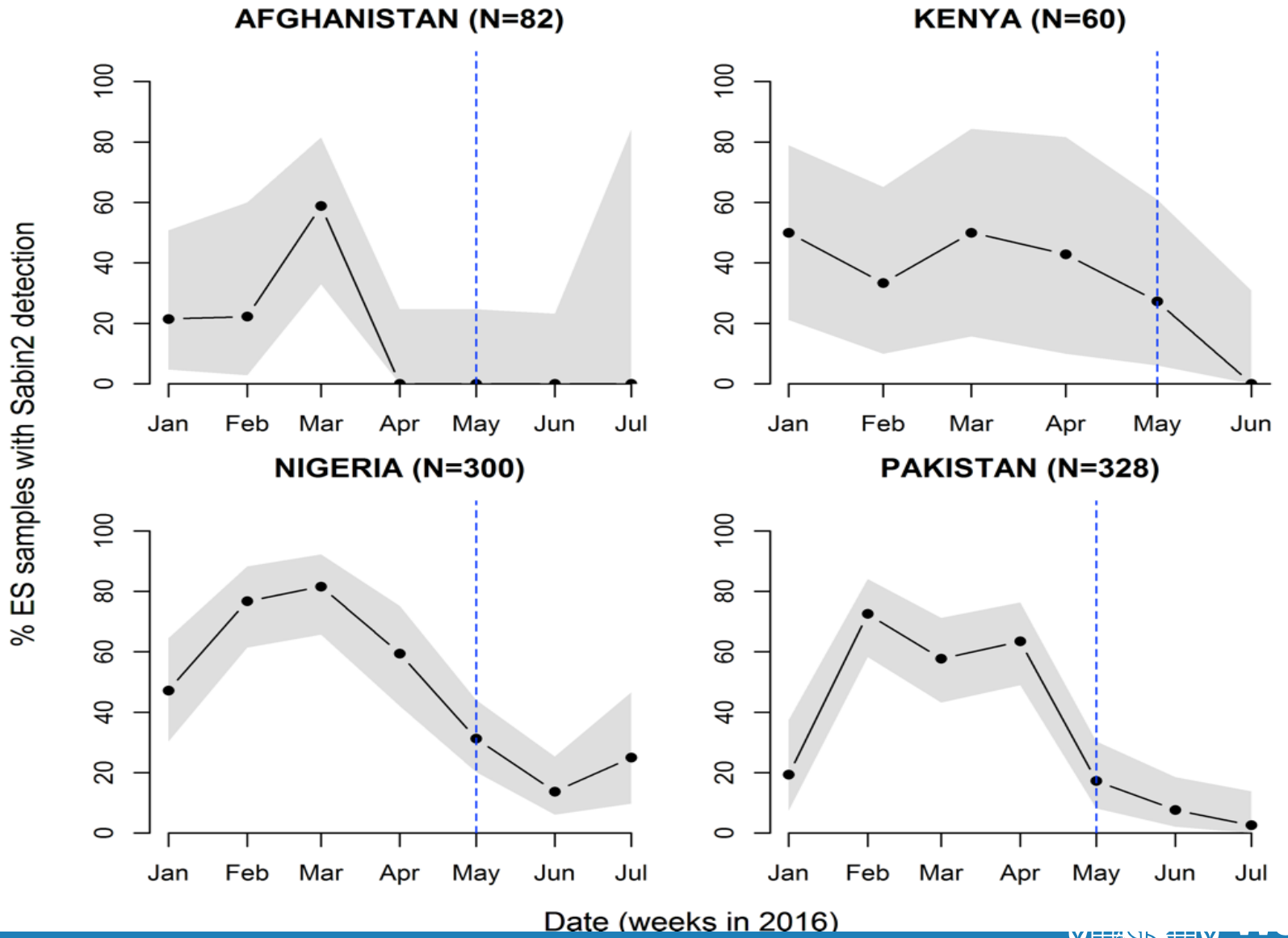
Sabin Type 2 in Environmental Samples (2016)



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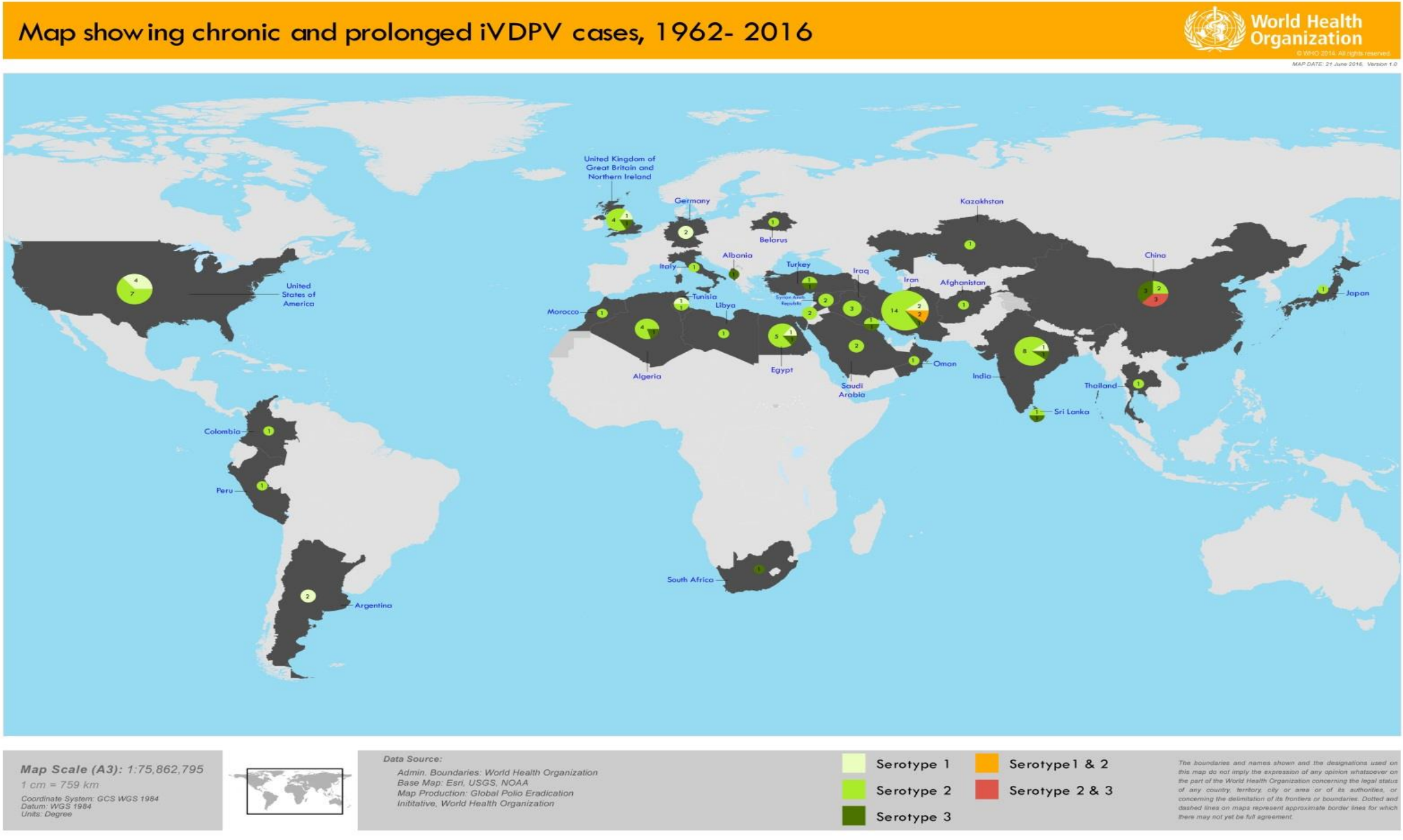
cVDPV2 Epidemiology: WG Conclusion

- It is encouraging that Sabin type 2 is disappearing from the environment/AFP samples after OPV2 withdrawal
- However, the WG expressed concern over the missing circulation of persistent cVDPV2 and WPV1 in Nigeria
- The WG reiterated the importance of monitoring surveillance quality especially in access-limited areas

Distribution of iVDPV Cases



iVDPV Epidemiology: WG Conclusion

- WG noted a significant shift in reported iVDPV cases from high to middle income countries, which constitutes a risk in seeding communities and triggering outbreaks

- The WG endorsed the proposed approach to expand AFP surveillance to detect more iVDPV cases (by screening AFP cases for primary immunodeficiency)

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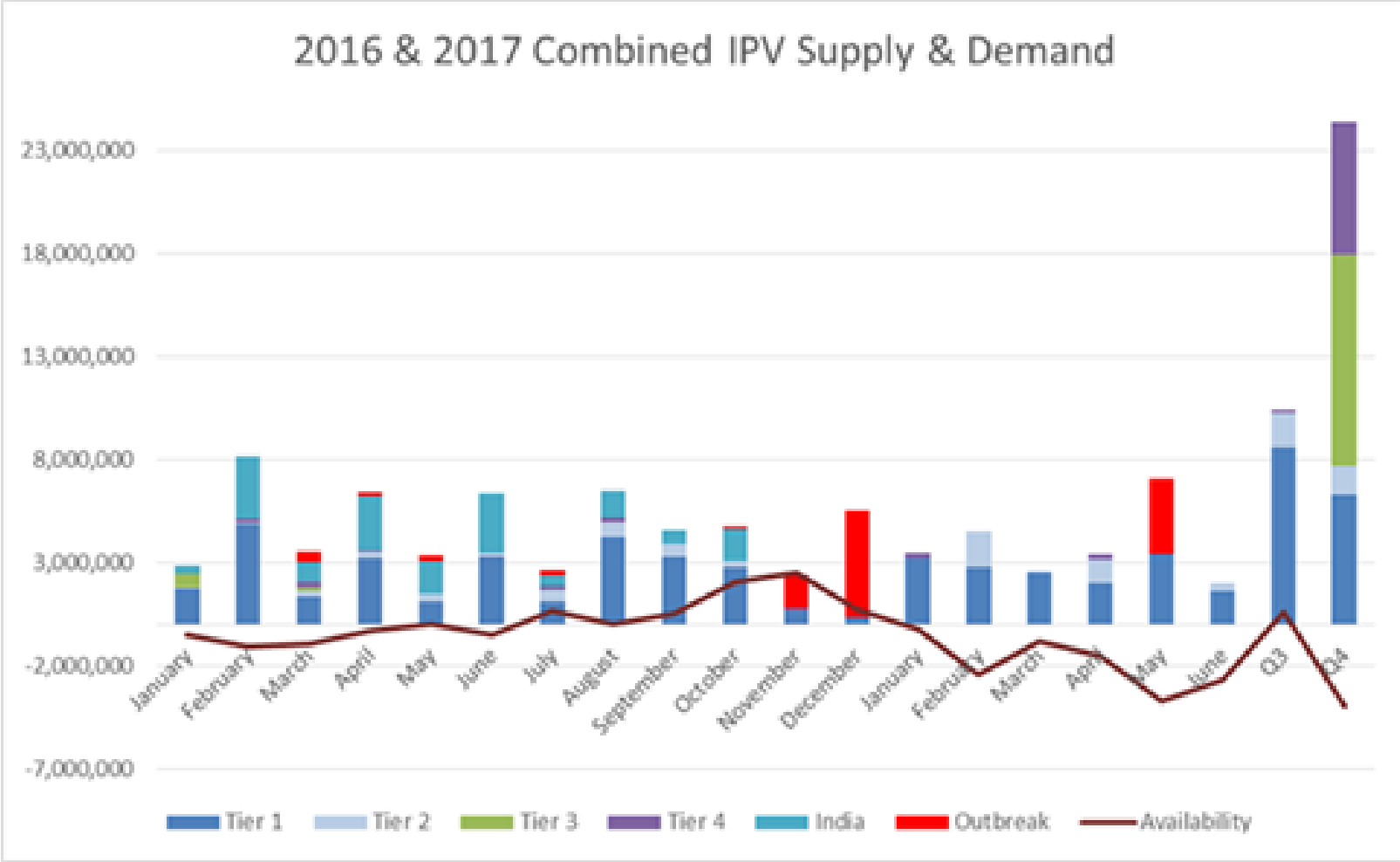
IPV Supply and Demand Situations



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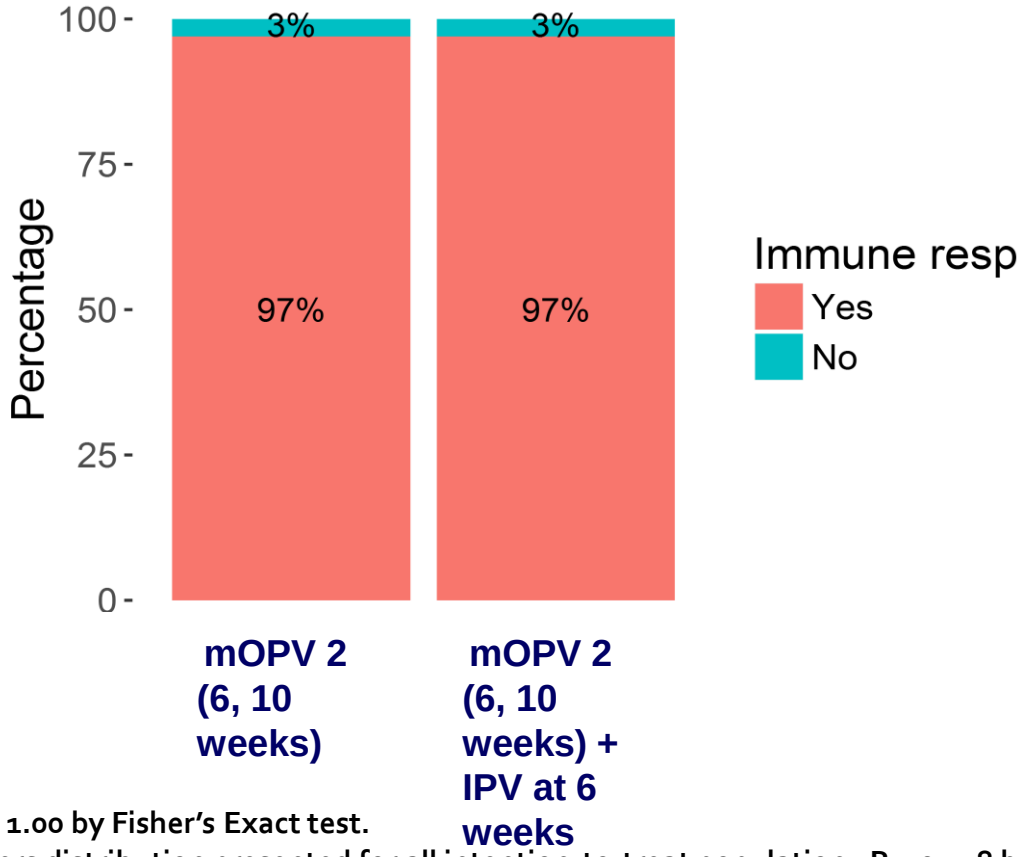
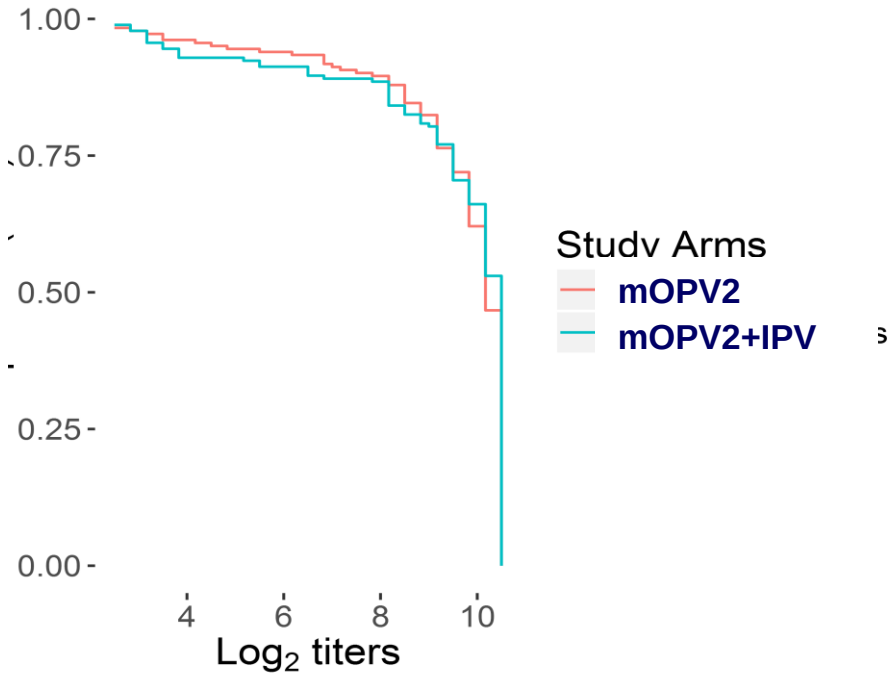
IPV Supply Situation: WG Conclusion

- WG expressed strong concern over the continued IPV supply shortage and the possibility of further supply reductions
- WG noted despite the SAGE recommendation in April 2016, only India and Sri Lanka have implemented fractional-dose IPV (fIPV) in routine immunization
- WG encouraged WHO/UNICEF to advocate more vigorously for alternative dose-sparing options (e.g. fIPV SIAs for eradication, use of fractional dose devices with IPVs)

Role of IPV in Type 2 Outbreak Response

CDC Study in Bangladesh on type 2 immune response and antibody titres after 2 doses of mOPV2 with or without IPV





p = 1.00 by Fisher's Exact test.

Titers distribution presented for all intention-to-treat population. P = 0.758 by Kruskal-Wallis test.

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Implications of Bangladesh Study in Type 2 Outbreak Response

Finding in study	WG Conclusions
• 1 dose of mOPV2 achieves high immune response in susceptible infants; short intervals non-inferior	• Fewer mOPV2 are needed than the originally proposed rounds (i.e. minimum of 5 in zone 1 and 2, and 4 in zone 3 to 2-3, depending on the coverage achieved and transmission risk (zone)
• Addition of IPV does not appear to significantly improve humoral immunity w/ mOPV2 (among non-primed 6wk olds).	• mOPV2 is the primary choice of vaccine in outbreak areas. The addition of 1 fractional IPV dose may be considered in the outbreak affected area during SIA2 or SIA3 in combination with mOPV2, if 1) operationally feasible and 2) mOPV2 SIA coverage not compromised. • In response to an aVDPV or in surrounding areas, responding with one SIA using ID fractional IPV may be considered for highly OPV primed populations

Certification of Containment Implementation: WG Conclusion


GAPIII Containment Certification Scheme (CCS) 4 October 2016

GAPIII Containment Certification Scheme

Containment Certification Scheme (CCS) to support the certification of facilities against the *WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use (GAPIII, Annex 2 and Annex 3)*

- The WG welcomed the development of GAPIII Containment Certification Scheme (CCS)
- The CCS describes a scheme for adoption by countries in the conduct of containment certification of Poliovirus-Essential Facilities (PEFs)
- Global Certification Commission (GCC) will oversee the scheme
- The CCS will supersede Annex 4 of GAP III

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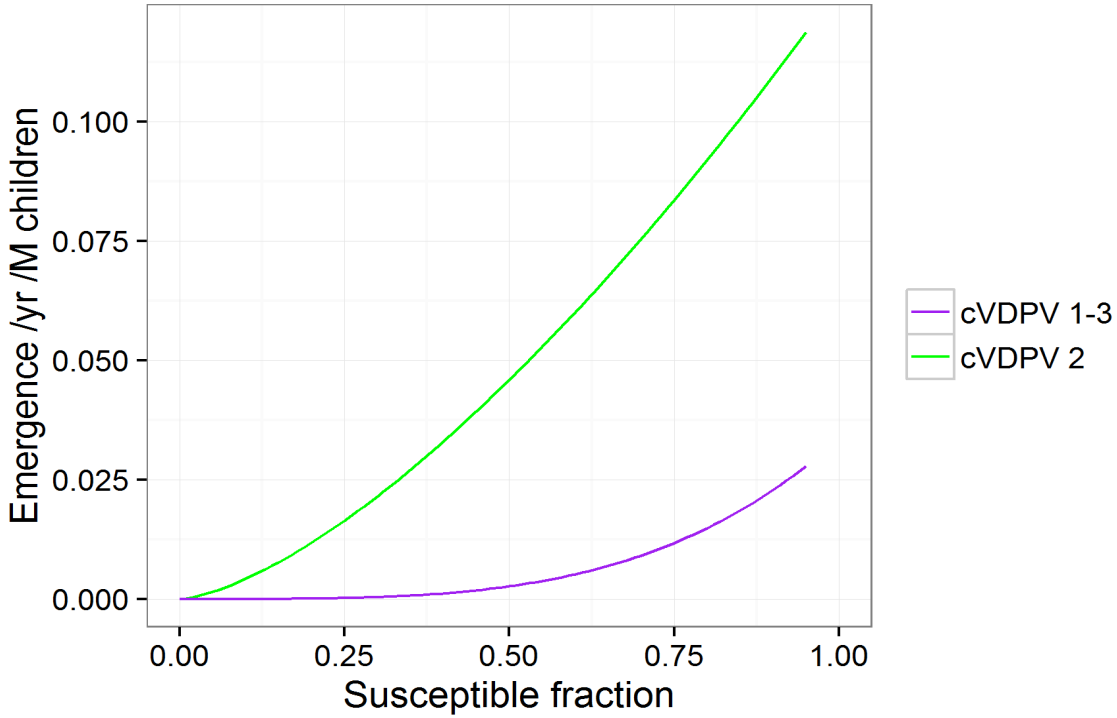
Risks Associated with Full OPV Withdrawal: WG Conclusion

Risk of cVDPV emergence as a function of non-immune fraction (Modelling by IDM)*



- The risk of cVDPV 1 and 3 emergence after bOPV cessation is likely to be low in most countries, with bOPV and IPV in routine immunization
- Therefore, most countries will not require additional bOPV campaigns prior to the bOPV cessation, except for areas with high force of infection and low RI coverage (e.g. areas with under-vaccinated and/or inaccessible sub-populations)

* Compile all known cVDPV emergences, and calculate immunity using NP-AFP data in Africa, South-East Asia, and Middle-East. Regress the rate of emergences as a function of the susceptible fraction, population under 5, at the province level

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Three Groups of Countries for Post-OPV IPV Policy

Category	Description	Duration of IPV use
Voluntary	Some countries will voluntarily continue IPV in their routine schedule because of national security concern or people's demand	Indefinite
Statutory (Countries with Polio Essential Facilities*)	GAP III requires: • Countries with OPV/Sabin poliovirus facility to provide at least one dose of IPV (=DTP 3 coverage) • Countries with wild poliovirus facility to provide at least three dose of IPV (greater than 90% coverage)	Indefinite
Other countries	Other countries will decide their immunization policy based on cost, risk and other needs	5, 10 or more years

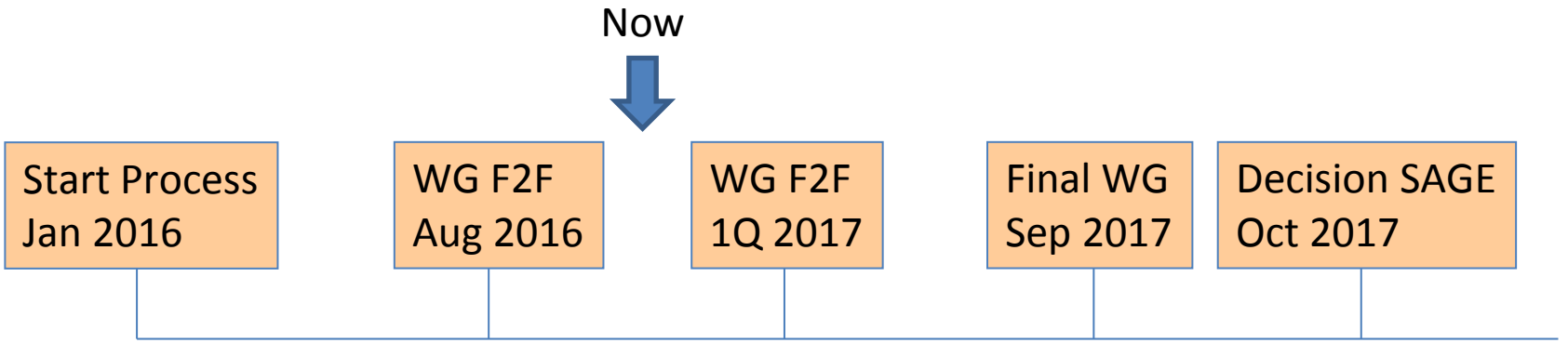
SAGE recommendations will be made to these "other countries"

* These 20+ countries (inc. China, India, Indonesia) will likely have more than 50% of global birth cohorts

Post-OPV Immunization Schedule: WG Conclusion to Date

- The WG agreed that countries should continue IPV in the routine immunization, which aims to achieve at least 90% seroconversion
- This would require at least two IPV doses (either fractional or full doses) (“prime and boost”)
- The WG will further discuss the immunization schedule and provide the more detailed recommendations (e.g. the minimum duration of IPV use, schedule and dosing), based on:
  - Immunogenicity of different schedule
  - Expected IPV supply
  - Feasibility of fractional IPV doses
  - Cost-effectiveness of different schedules

Timeline for review and decision-making



In the next SAGE in April 2017, the WG will provide more detailed recommendations on:

- Minimum duration of IPV use
- IPV schedules
- Fractional vs. full doses

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- Background
- WG Discussion and Recommendations
- Proposed Recommendations by SAGE

Proposed SAGE Recommendations: (1/2)

Remaining issues in OPV2 withdrawal

- WHO/UNICEF should continue to explore options to mitigate IPV shortage, including :
  - **Short term**: fIPV for outbreak use, SIA to eradicate WPV, and routine immunization
  - **Medium term**: supporting new IPV manufacturers, adjuvanted IPV
- Countries with delayed IPV introduction should provide catch-up vaccination of the missed children when sufficient supplies of IPV become available
- WHO should pilot an expanded AFP surveillance system to detect more iVDPV patients (without paralysis)

Proposed SAGE Recommendations (2/2)

Remaining issues in OPV2 withdrawal (continued)

- National authorities for containment (NACs) should start preparing for containment certification based on Containment Certification Scheme (CCS), which supplements and supersedes Annex IV of Global Action Plan (GAP III)

Future immunization policy

- Countries should consider additional bOPV campaigns prior to OPV cessation in areas where population immunity remains low
- The Polio WG should make more detailed recommendations (e.g. minimum duration, options for IPV schedule) for the post-OPV immunization schedule (aiming to achieve at least 90% seroconversion) in SAGE in April 2017

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Thank you very much!

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