

Report from the Polio WG Meeting (9-10 February, 2017)

**Dr.Yagob Al-Mazrou
Chair, SAGE Polio Working Group
25 April, 2017**



**World Health
Organization**

- Background
- Issues and WG Conclusion
- Proposed Recommendations by SAGE

Background: SAGE

Recommendations in October 2016

2016, 91, 561-584

No. 48



World Health Organization

Organisation mondiale de la Santé

Weekly epidemiological record
Relevé épidémiologique hebdomadaire

2 DECEMBER 2016, 91st YEAR / 2 DÉCEMBRE 2016, 91^È ANNÉE
No. 48, 2016, 91, 561-584
<http://www.who.int/weer>

Contents

561 Meeting of the Strategic Advisory Group of Experts on immunization, October 2016 – conclusions and recommendations

583 Monthly report on dracunculiasis cases, January–October 2016

Sommaire

561 Réunion du Groupe stratégique consultatif d'experts sur la vaccination, octobre 2016 – conclusions et recommandations

583 Rapport mensuel des cas de dracunculose, janvier–octobre 2016

Meeting of the Strategic Advisory Group of Experts on immunization, October 2016 – conclusions and recommendations

The Strategic Advisory Group of Experts (SAGE) on immunization¹ met on 18–20 October 2016. This report summarizes the discussions, conclusions and recommendations.²

Report from the WHO Department of Immunization, Vaccines and Biologicals

The report addressed 4 main themes: the progress and failures observed; the current and recurrent challenges; the actions taken to accelerate progress; and the role of WHO.

The contribution of vaccination to the global reduction of mortality in children aged <5 years, and the broader impact of immunization in economic and productivity gains as well as community benefits were noted. SAGE emphasized the need for stronger communication on these health and non-health benefits of immunization.

The report noted that an additional 5.9 million children need to be vaccinated to achieve the goal of 90% 3rd dose diphtheria-tetanus-pertussis vaccine (DTP3) coverage by 2020. It called for accelerating the use of pneumococcal conjugate vaccine (PCV) and rotavirus vaccine as both have led to substantial reductions in childhood mortality.

The report cautioned that as immunization programmes are becoming more

Réunion du Groupe stratégique consultatif d'experts sur la vaccination, octobre 2016 – conclusions et recommandations

Le Groupe stratégique consultatif d'experts (SAGE) sur la vaccination¹ s'est réuni du 18 au 20 octobre 2016. Le présent rapport résume les discussions, conclusions et recommandations auxquelles il est parvenu.²

Rapport du Département Vaccination, vaccins et produits biologiques de l'OMS

Le rapport présenté était axé sur 4 thèmes principaux: les progrès et les échecs observés; les difficultés existantes et récurrentes; les mesures prises pour accélérer les progrès; et le rôle de l'OMS.

Le rapport a évoqué la contribution de la vaccination à la réduction mondiale de la mortalité des enfants de <5 ans, ainsi que ses retombées positives plus générales sur l'économie, la productivité et le bien-être des communautés. Le SAGE a souligné la nécessité d'intensifier les efforts de communication pour mieux faire connaître les avantages de la vaccination, tant dans le domaine de la santé que dans d'autres domaines.

Le rapport a indiqué que 5,9 millions d'enfants supplémentaires devront être vaccinés pour atteindre l'objectif d'une couverture de 90% par la 3^e dose de vaccin antidiphtérique-antitétanique-anticoquelchueux (DTC3) d'ici 2020. Il a appelé à une utilisation accélérée du vaccin antipneumococcique conjugué (VPC) et du vaccin antirotavirus, qui ont tous deux contribué à la baisse substantielle de la mortalité de l'enfant.

Le rapport a fait valoir que face à la complexité croissante des programmes de vaccination,

¹ See <http://www.who.int/immunization/sage/en/index.html>; accessed October 2016.

² Presentations and background materials used for the SAGE meeting together with the list of SAGE members and summarized declarations of interests are available at <http://www.who.int/immunization/sage/meetings/2016/october/en/index.html>; accessed October 2016.

¹ Voir <http://www.who.int/immunization/sage/fr/index.html>; consulté en octobre 2016.

² Les communications et les documents de travail utilisés pour la réunion du SAGE, ainsi que la liste des membres du SAGE et une synthèse de leurs déclarations d'intérêts sont disponibles à l'adresse: <http://www.who.int/immunization/sage/meetings/2016/october/en/index.html>; consulté en octobre 2016.

- SAGE reiterated its concern over the global supply shortage of Inactivated Poliovirus Vaccine (IPV), which will persist into 2017-18.
- SAGE strongly recommended that: countries should start preparing for a fractional intradermal 2-dose IPV schedule, e.g. at 6 and 14 weeks, in lieu of a single intramuscular full dose at 14 weeks.
- SAGE also reviewed the Polio WG discussion on future polio immunization policy and requested the WG present its recommendations on future immunization policies for consideration by SAGE in April 2017.



World Health Organization

Background: Polio WG Discussions

Following up on the SAGE recommendations, the WG met on 9-10 February 2017 to:

- Review the GPEI programme update, including the IPV supply situation
- Review scientific data on the use of IPV in polio eradication, outbreak response and routine immunization
- Make a proposal on future immunization policy (including duration of vaccination with IPV after OPV withdrawal (i.e. post-OPV immunization schedule) for the April 2017 SAGE meeting.

- Background
- Issues and WG Conclusion
 - cVDPV2/iVDPV epidemiology
 - Benefit of IPV in eradication, outbreak response and routine immunization
 - Future immunization policy
- Proposed Recommendations by SAGE

Circulating-VDPV2 After OPV2 Withdrawal

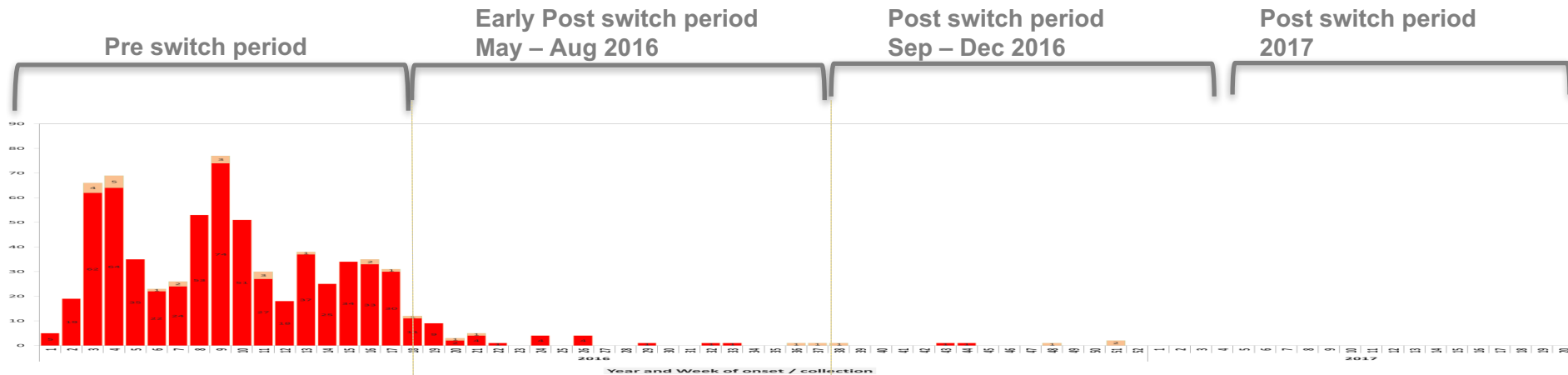
Tracking cVDPV2 Outbreaks			Year / Month																																					
Outbreak-emergence	Source	State / Province	2014												2015												2016												2017	
			Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.	Jan.	Feb.
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																																						
	ENV	Borno	X	X	X	X	X																																	
		Kano				X																																		
Nigeria, KDS-1	AFP	FCT, Abuja																X																						
	ENV	Kaduna								X			X	X																										
Nigeria, (new)	AFP	Sokoto																																			X			
	Contact	Sokoto																																		X				
Pakistan, KAb-1	AFP	FATA	X		X	X	X																																	
		KP					X																																	
Pakistan (NWz-2, NWz3, KHI-1 & KP-1)	AFP	FATA	X	X			X												X																					
		KP					X											X																						
		Sindh										X																												
	ENV	Balochistan																		X																				
Sindh							X		X	X	X	X	X	X	X	X	X																							
Pakistan, Quetta-1	AFP	Balochistan																																		X				
	ENV	Balochistan																															X	X	X					
South Sudan	AFP	Unity							X																															
Myanmar	AFP	Rakhine															X																							
Guinea	AFP	Kankan							X											X		X	X		X															

cVDPV2 de
in Nigeria a
Pakistan in
2016

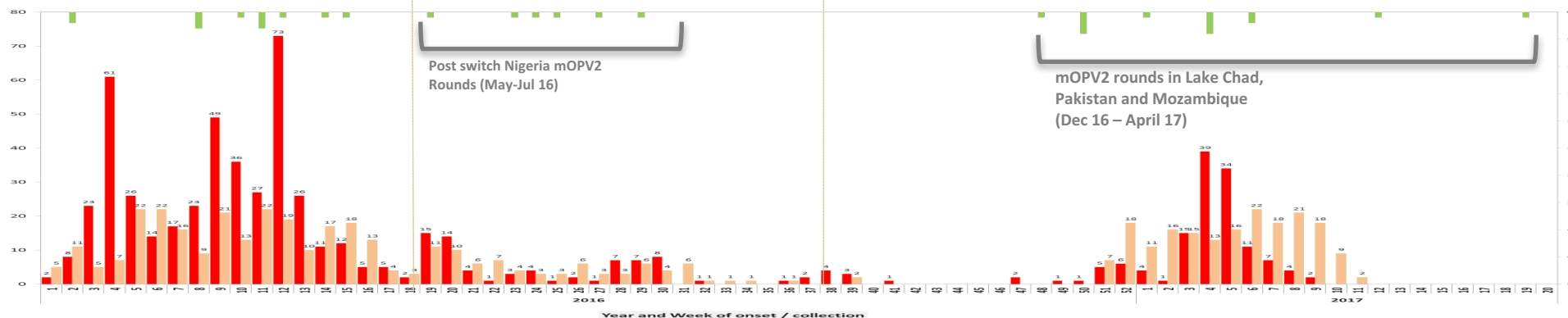
cVDPV2 detected in Nigeria and Pakistan in Q4 2016

Sabin Type 2 Detection in All countries

Countries without mOPV2 use



Countries with mOPV2 use after May 2016



cVDPV2 Epidemiology: WG

Conclusion

- It is encouraging that Sabin type 2 has disappeared from the environment/AFP samples after OPV2 withdrawal outside countries with mOPV2 use (i.e. Afghanistan, Cameroon, Chad, Mozambique, Niger, Nigeria, Pakistan)
- In endemic countries with co-circulation of WPV and cVDPV, stopping cVDPV2 outbreak should have a higher priority than WPV 1 elimination, because of the increasing risk of significant type 2 outbreaks
- The WG remains concerned about the ongoing IPV shortage and the increasing number of children without any immunity against type 2 (esp. in countries with type 2 iVDPVs, high risk of importation and circulation of VDPV)
- The WG expressed concern over the large number of facilities nominated to retain poliovirus type 2 (Polio Essential Facilities; PEFs) (e.g. ~80 facilities in 29 countries)

- Background
- Issues and WG Conclusion
 - cVDPV2/iVDPV epidemiology
 - Benefit of IPV in eradication, outbreak response and routine immunization
 - Future immunization policy
- Proposed Recommendations by SAGE

Role of IPV: Background

- Given the significant IPV shortage, the GPEI should optimize the use of the limited quantities of IPV. In this regard, the WG reviewed different perspectives on the benefit of IPV in:
 1. Achieving WPV1 eradication
 2. Outbreak response against cVDPV2, and
 3. Routine immunization to provide protection against type 2
- The WG benefited from presentations by experts in epidemiology, vaccinology, virology and diseases modelling

Role of IPV in Eliminating WPV/cVDPV

- A few clinical studies showed IPV does reduce the prevalence and duration of faecal shedding following challenges in previously OPV vaccinated children
- However, a single dose of IPV administered to children un-primed by a prior dose of OPV containing type 2 has minimal effect on faecal shedding
- The disease modelling results on the role of IPV in addition to OPV compared to using OPV alone is mixed
- The WG concluded that
 - The effect of IPV depends on coverage, OPV status (naive vs. OPV-vaccinated with waning intestinal immunity), OPV take, and adequacy and timing of OPV use
 - In addition, the WG raised questions about the implications of using IPV in addition to OPV in SIAs on coverage

Role of IPV in Routine Immunization

- The review of a large body of scientific studies demonstrated that IPV is highly effective in inducing individual protection.
- However, there is insufficient evidence that IPV induces community protection (e.g. mucosal immunity).
- The IPV-OPV switch experience in Israel and Yogyakarta, Indonesia suggest that high IPV coverage in areas with relatively low faecal-oral transmission may have some impact on preventing the generation of new cVDPVs from imported parent Sabin viruses (with lower force of infection than WPVs)

Benefit of IPV: WG Conclusion

- In recognition of the severe global supply constraints, IPV supply should be prioritized for routine immunization (especially in Tier 1 and 2 countries)
 - The WG re-emphasized that the primary vaccine of choice to eliminate WPVs and respond to cVDPVs is OPV (bOPV1&3 and mOPV2) while IPV may offer additional benefit in stopping poliovirus WPV/cVDPV transmission.
 - However, the WG agreed that IPV has a significant role in RI in protecting children against poliomyelitis caused by cVDPV2 in countries using bOPV for routine immunization
 - IPV use is increasingly important as population immunity for type 2 is decreasing since the time of the switch. Access to IPV in RI is also important from an equity perspective
- The WG endorsed the following proposed IPV allocation over the next six months (April to October):
 - Prioritize available supply for routine immunization, especially to Tier 1 and 2 countries.
 - No IPV for SIAs in endemic countries or type 2 outbreaks over the next six months

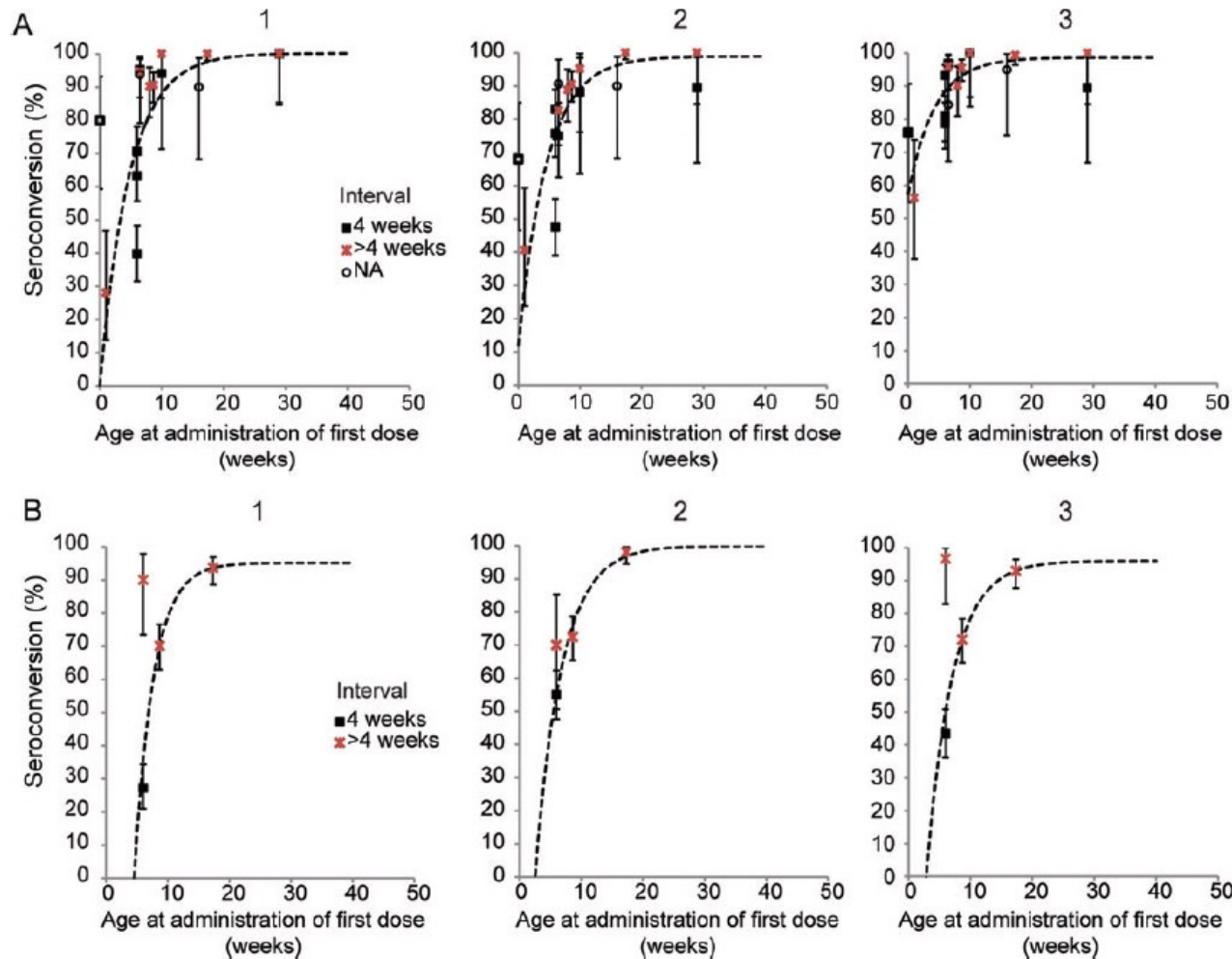
- Background
- Issues and WG Conclusion
 - cVDPV2/iVDPV epidemiology
 - Benefit of IPV in eradication, outbreak response and routine immunization
 - Future immunization policy
- Proposed Recommendations by SAGE

Three Groups of Countries for Future IPV Policy

Category	Description of IPV policy in post-OPV era	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*)	After the OPV cessation, GAP III requires: <ul style="list-style-type: none"> • 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”

Future Immunization Policy: Schedule



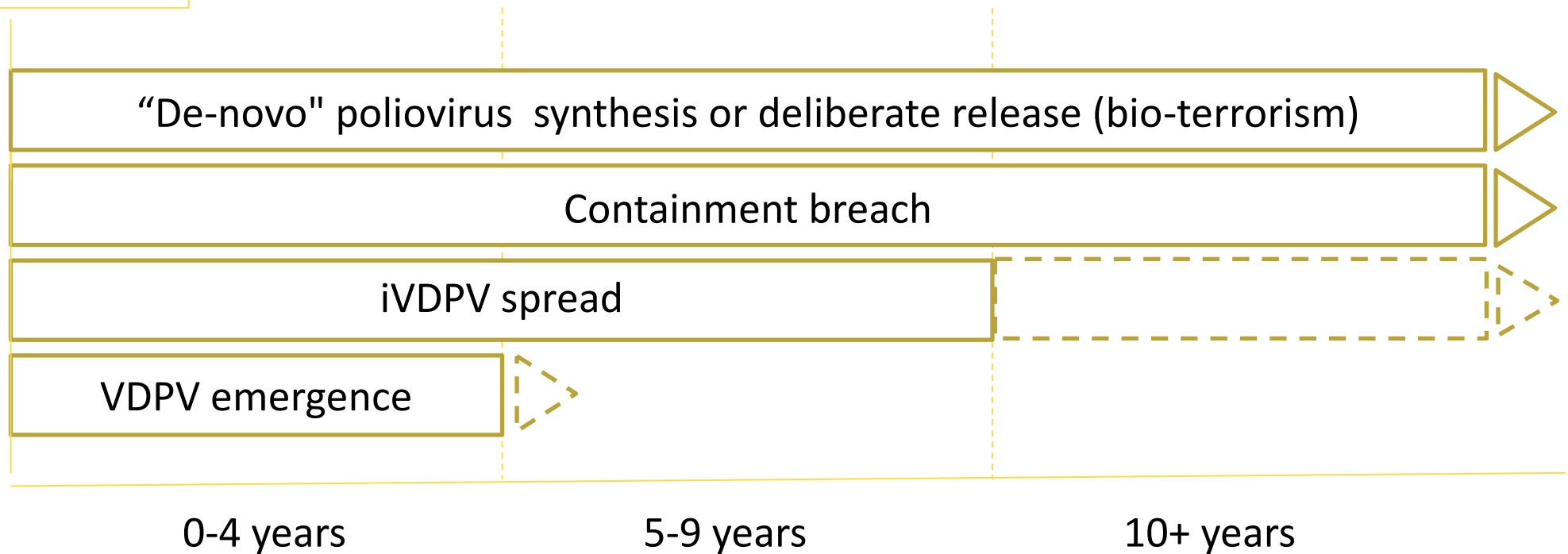
- Studies indicate two fractional or two full IPV doses (for prime and boost) can achieve 90% or more seroconversion, if:
 - the first IPV dose is given at 14 weeks or later; and
 - the interval between this and the second dose greater than 4 months
- However, there is only one study (Cuba) assessing the immunogenicity of two fIPV doses given at 4 and 8 months, with additional data expected within 1-2 years

Source: Grassly NC. *J Infect Dis* 2014; 210 Suppl 1: S439-46

Future Immunization Policy: Duration

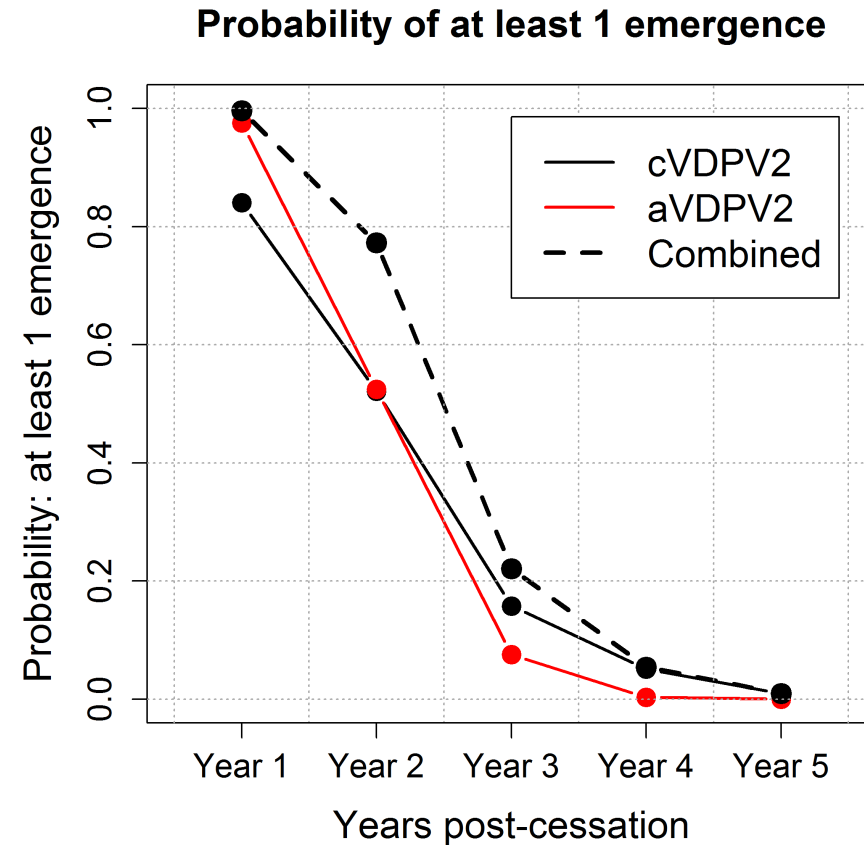
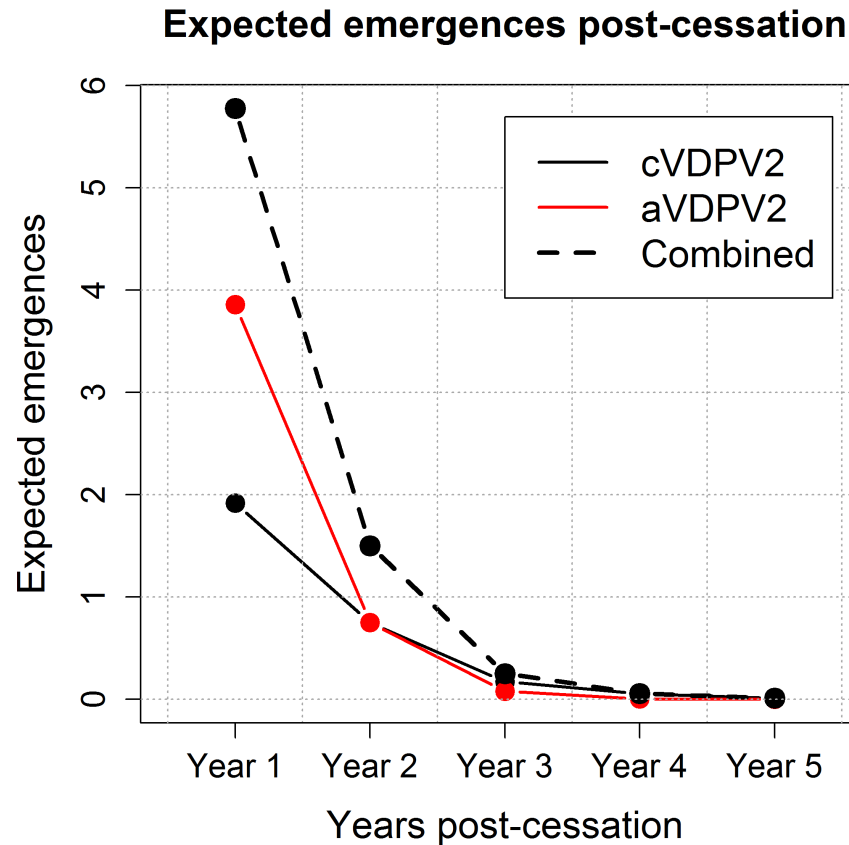
Expected poliovirus risk after the OPV Cessation

OPV cessation



- The risk of poliovirus may continue for 10 or more years

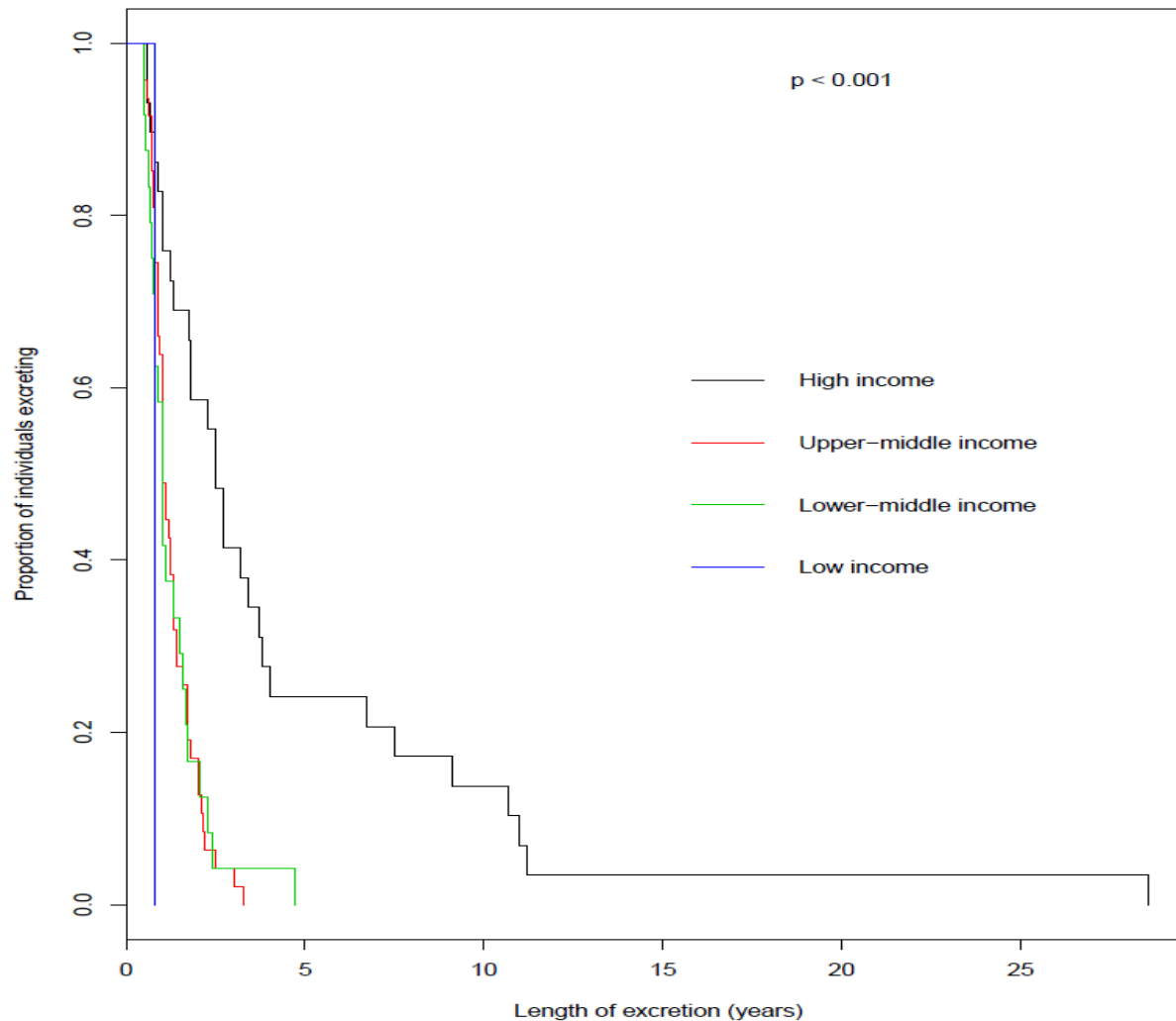
Future Immunization Policy: Duration



- VDPV may emerge 0-4 years after the global cessation of OPV

Source: Analysis by Institute for Disease Modelling

Length of iVDPV excretion



- Analysis of WHO iVDPV registry indicated that iVDPVs could excrete for up to 5 years in middle income countries and for 10+ years in high income countries.

Future Immunization Policy: Other Considerations

- There is not clear commitment from the donor community to support IPV after OPV withdrawal (anticipated earliest in 2021). There are significant benefits but also opportunity costs associated with continued long-term use of IPV given other competing investments in public health.
- There is a risk of IPV shortage continuing into the long-term, especially if the market after the global cessation is limited. The recommendation of the use of IPV for 10+ years should encourage vaccine suppliers to continue IPV supply in the pre and post eradication periods.
- The primary justification for the use of IPV for 10-year is the insurance against the remaining risks of poliovirus, not cost-effectiveness analysis

Future Immunization Policy: WG

Conclusion

- Studies indicated two fractional or two full IPV doses (for prime and boost) are required to achieve 90% or more seroconversion (individual protection), with the first dose after 14 weeks and the interval greater than 4 months
- The risk of reintroduction of polioviruses may continue more than 10 years after OPV cessation

-
- Background
 - Issues and WG Conclusion
 - Proposed Recommendations by SAGE

Proposed SAGE

Recommendations: (1/3)

Epidemiology of VDPV2

- Countries should adopt fractional IPV in their routine schedule to mitigate the global supply shortage
- WHO should review its tier classification of countries with respect to prioritization of IPV to take into account the size of the population with no IPV protection and the recent type 2 VDPV events
- Countries should try to limit the number of Polio Essential Facilities (PEFs) to the extent possible

Benefit of IPV

- In recognition of the severe global supply constraints, IPV supply should be prioritized for routine immunization (especially in Tier 1 and 2 countries)

Proposed SAGE Recommendations (2/3)

Future immunization policy

- All countries should continue using at least one dose of IPV after the coordinated bOPV withdrawal. If IPV supply and funding allows, countries should adopt a two dose IPV schedule as a preferred option to ensure adequate individual protection against potential reintroduction of wild or vaccine-derived poliovirus.
- If a country, currently using OPV, is to adopt a two dose IPV schedule after bOPV withdrawal:
 - Two doses of IPV should be given at or after 14 weeks (e.g. with the 2nd or 3rd dose of DTP-containing vaccine) and at 9-12 months (e.g. with measles).
 - Ideally, two full doses IM should be given, but two fractional doses may provide a similar level of seroconversion based on the available results of clinical trials.
 - No data provide information on the duration of protection (e.g. sufficient antibody) following the receipt of 2 fractional or full IPV doses.

Proposed SAGE Recommendations (3/3)

Future immunization policy (continued)

- Countries with Poliovirus Essential Facilities (PEFs) should continue the use of IPV as long as mandated by Global Action Plan (GAP III).
- Countries without PEFs should maintain IPV in their routine immunization schedule for at least 10 years after global OPV withdrawal, to address: immediate (VDPVs), intermediate (iVDPV) and longer-term (containment failure and bioterrorism) risks.
- If there is no external funding for IPV available, countries need to decide how to prioritize available resources given other pressing public health needs.
- WHO should review the secondary safeguard requirements in the Global Action Plan (GAP III) to ensure adequate protection in countries with PEFs

Thank you very much!