Proposed Recommendations for OPV2 Withdrawal:

Report from the Polio Working Group

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April 14, 2014

Overview

- Background
- WG Discussion and Recommendations
  - Strategies to eliminate Persistent cVDPV2
  - Mitigating risk of emergence of new cVDPV2
  - Response to new cVDPV2
  - Verification process of poliovirus containment

Background: SAGE Recommendations in October 2014

2014, 89, 561-576 No. 50

World Health Organization
Organisation mondiale de la Santé

Weekly epidemiological record
Relevé épidémiologique hebdomadaire

12 DECEMBER 2014, 89th YEAR / 12 DÉCEMBRE 2014, 89e ANNÉE
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Meeting of the Strategic Advisory Group of Experts on immunization, October 2014 – conclusions and recommendations

The Strategic Advisory Group of Experts (SAGE) on immunization[1] met on 21–23 October 2014 in Geneva, Switzerland. This report summarizes the discussions, conclusions and recommendations.[2]

Report from the WHO Department of Immunization, Vaccines and Biologicals

The report focused on: (i) WHO's contribution to the Global Vaccine Action Plan (GVAP) and the process and timelines for developing WHO's vision and mission and prioritizing work on vaccines and immunization from 2015 to 2025 in the context of the GVAP, (ii) regional achievements, challenges, and priorities, (iii) feedback on selected work streams of importance to SAGE including integration, data quality, typhoid conjugate vaccine, maternal immunization, World immunization week, and (iv) SAGE working processes and projected agenda items.

For the future, SAGE requested that WHO give special attention to facilitating greater participation of Civil Society Organizations (CSOs) in immunization activities.

SAGE congratulated the Regions on progress in adapting the GVAP and developing regional vaccine action plans, with regional vaccine action plans already adopted by the European and Western Pacific Regional Committees. The African Region currently faces new challenges due to the Ebola crisis, which adversely affects health programmes, especially in the 3 most heavily Ebola-affected countries

Réunion du Groupe stratégique consultatif d'experts sur la vaccination, octobre 2014 – conclusions et recommandations

Le Groupe stratégique consultatif d'experts (SAGE) sur la vaccination[1] s'est réuni du 21 au 23 octobre 2014 à Genève (Suisse). Le présent rapport résume les discussions, conclusions et recommandations auxquelles il est parvenu.[2]

Rapport du Département OMS Vaccination, vaccins et produits biologiques

Le rapport était axé sur: i) la contribution de l'OMS au Plan d'action mondial pour les vaccins (GVAP), ainsi que sur le processus et les échéances pour élaborer la vision et la mission de l'OMS et pour définir les priorités du travail sur les vaccins et la vaccination de 2015 à 2025 dans le contexte du GVAP; ii) les réalisations, les difficultés et les priorités au niveau régional; iii) le retour d'information sur certains axes de travail importants pour le SAGE, parmi lesquels l'intégration, la qualité des données, le vaccin conjugué contre la typhoïde, la vaccination maternelle, la Semaine mondiale de la vaccination; et iv) les méthodes de travail du SAGE et les points prévus pour discussion dans un bref avenir.

Le SAGE a demandé qu'à l'avenir, l'OMS accorde une attention spéciale aux organisations de la société civile pour faciliter leur plus grande participation aux activités de vaccination.

Le SAGE a félicité les Régions pour les progrès accomplis dans l'adaptation du GVAP et l'élaboration de plans d'action régionaux pour les vaccins, dont deux ont déjà été adoptés par les Comités régionaux de l'Europe et du Pacifique occidental. La Région africaine est actuellement confrontée à de nombreuses difficultés dues à la crise du virus Ebola, qui a des répercussions négatives sur les programmes de santé, en particulier dans les 3 pays les plus

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[1] See http://www.who.int/immunization/sage/en/index.html
[2] The complete set of presentations and background materials used for the SAGE meeting of 21–23 October 2014 together with summarized declarations of interests provided by SAGE members are available at http://www.who.int/immunization/sage/meetings/2014/october/en/, accessed in October 2014.

[1] Voir http://www.who.int/immunization/sage/en/index.html
[2] La série complète des communications et des documents de travail de la réunion du SAGE tenue du 21 au 23 octobre 2014, ainsi que les résumés des déclarations d'intérêt fournies par les membres de ce groupe sont disponibles à l'adresse: http://www.who.int/immunization/sage/meetings/2014/october/en/, consulté en octobre 2014.

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- SAGE confirmed that preparations for OPV2 withdrawal in early 2016 are on track and recommended that WHO Member States be formally apprised of this through WHO's governing bodies to accelerate preparations and facilitate international coordination.

- Nigeria and Pakistan should ensure that sufficient tOPV SIAs are implemented to interrupt persistent* cVDPV2 by mid-2015

*evidence of ≥6 months circulation

Background: Important Dates

- Proposed date of OPV2 withdrawal: **April 2016**
- Decision on OPV2 withdrawal: **October 2015**
- Most recent persistent cVDPV2 case onset:
  - Nigeria: November 2014
  - Pakistan: December 2014
- Most recent positive environmental sample
  - Nigeria: March 2015
  - Pakistan: February 2015

WG discussions

Elimination of cVDPV2

- Strategies to eliminate persistent cVDPV2 in Nigeria and Pakistan and contingency actions to enable OPV2 withdrawal on the planned date of April 2016
- Plans to reduce the risk of new cVDPV2 emergence in other countries
- Response strategies to newly emerged cVDPV2

Facility containment of Polioviruses

- Verification process of poliovirus containment in essential facilities

WG discussion and Recommendations:

Strategy to eliminate persistent cVDPV2 in Nigeria and Pakistan

cVDPV Elimination Strategy in Nigeria

- Strong progress in Nigeria with improvements in quality of SIAs and surveillance
- Persistent cVDPV2 cases not detected since November 2014, following:
  - IPV + tOPV campaigns in high-risk areas of Borno (June), Yobe (June) and Kano (November) states
  - August and Nov. tOPV campaigns in northern states
- One positive environmental sample March 2015

Persistent cVDPV2 in Nigeria

• AFP case

x ES

tOPV campaigns completed

tOPV campaigns planned

tOPV+IPV campaigns completed

Nigeria: persistent cVDPV2 outbreaks by state, month and lineage

As of 9 April 2015

Viral grouping	Source	State	2014 Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	2015 Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	2016 Jan	Feb	Mar	Apr
Nigeria-Old	AFP	Borno			•																									
		Katsina									•																			
		Kano					•	•		•		•																		
		Jigawa										•																		
	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																				
Nigeria-Chad	AFP	Borno		•	•	•	•	•			•																			
		Kano							•				•																	
		Jigawa										•																		
		Yobe										•	•																	
	ENV	Borno	x	x	x	x	x	x																						
		Kano				x																								

- Mop up in Kaduna
- IDPs in Borno, Adamawa, Gombe, Nasarawa, Benue, Taraba and FCT will be targeted with tOPV+IPV per ERC recommendations

The "Nigeria-Chad" lineage has not been isolated since November 2014.
The "Nigeria-Old" lineage was isolated from ES in March 2015 (last case in October)

cVDPV Elimination Strategy in Nigeria

- Aggressive mop-up of any cVDPV2 isolate
- 7 tOPV SIAs from March 2015 - March 2016
  - March, April, July, October 2015
  - January, February, March 2016
- IPV introduced in Routine Immunization in February 2015

cVDPV2 Elimination Strategy in Pakistan

- Improving access and coverage of children
- In 2014, two “old” lineages circulated mostly in FATA and adjacent districts of KP
  - ➢**These strains not detected since June 2014**
- A new ‘persistent’ strain emerged in Gadaap, Karachi, in July 2014
  - Most recent case detection in December 2014
  - Most recent positive environmental sample in February 2015

Persistent cVDPV2 in Pakistan

• AFP case
x ES
tOPV campaigns completed
tOPV+IPV campaigns completed
tOPV campaigns planned

Pakistan: persistent cVDPV2 outbreaks by province, month and lineage

As of 9 April 2015

Year / Month

Viral grouping	Source	Province	2014 Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	2015 Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	2016 Jan	Feb	Mar	Apr
Pakistan: 2 'old' groupings	AFP only	FATA	•	•	•	•	•																							
			•	•				•																						
		KP					•																							
							•																							
Pakistan-New	AFP	Sindh												•																
	ENV	Sindh							x		x	x	x	x	x	x														

tOPV+IPV campaigns planned for high-risk UCs of Balochistan, FATA, Punjab and Sindh from April-June

- The “old” lineages not detected since June 2014
- A new persistent lineage emerged in Karachi in July 2014

cVDPV2 Elimination Strategy in Pakistan

- 8 tOPV campaign rounds from March 2015 to March 2016:
  - March, April, May (x2), Sept, Nov. 2015
  - February, March 2016
- Aggressive mop-up of any cVDPV2 isolate
- IPV to be introduced in Routine Immunization in July 2015

Summary: Persistent cVDPV2 in Nigeria and Pakistan

- Improved immunization & surveillance in both countries
- Progress towards interruption of transmission:
  - The "Nigeria-Chad" lineage not isolated since Nov 2014. The "Nigeria-Old" lineage isolated from ES in March 2015 (last case in November 2014)
  - The two "old lineages" in Pakistan not detected since June 2014. The case from new lineage was last detected in December 2014 (latest isolate from ES was in Feb 2015)
- Multiple tOPV SIAs, together with IPV implemented and planned in both countries
- Response plans in place in both countries
- IPV introduction in Routine Immunization

Elimination of Persistent cVDPV2 before OPV2 Withdrawal

- In June 2015, the WG will review strategies to rapidly eliminate any persistent cVDPV2 detected before or after October 2015
- In September 2015, the WG will review progress toward elimination of persistent cVDPV2
- In October 2015, the WG will recommend to SAGE April 2016 as the date for OPV2 withdrawal only if it has a high level of confidence in elimination of persistent cVDPV2 before OPV2 cessation

Persistent cVDPV2 Elimination Strategy: WG Recommendations

The WG recommends that SAGE:

Endorse: Strategies to eliminate cVDPV2 in Nigeria and Pakistan

Persistent cVDPV2 Elimination Strategy: WG Recommendations - 2

The WG recommends that SAGE:

Request WG to:

- Review in June the strategies and contingency plans to rapidly eliminate persistent cVDPV2
- Assess progress in September to ensure that cVDPV2 elimination is on track before OPV2 withdrawal in April 2016

Detection of Persistent cVDPV2 after October 2015: Contingency Plan

- The WG will:
  - Immediately review the epidemiological situation
    - quality of surveillance & immunization, access to children
  - Review emergency response plans & their feasibility
  - Assess challenges and risk of continued transmission
  - Consider impact of delaying OPV2 withdrawal
    - potential disruption in planned tOPV to bOPV switch in 156 countries
  - Recommend OPV2 withdrawal continue as planned, OR, be delayed if risk of spread is judged to be high

Detection of Persistent cVDPV2 after October 2015: WG Recommendations on Contingency Plan - 3

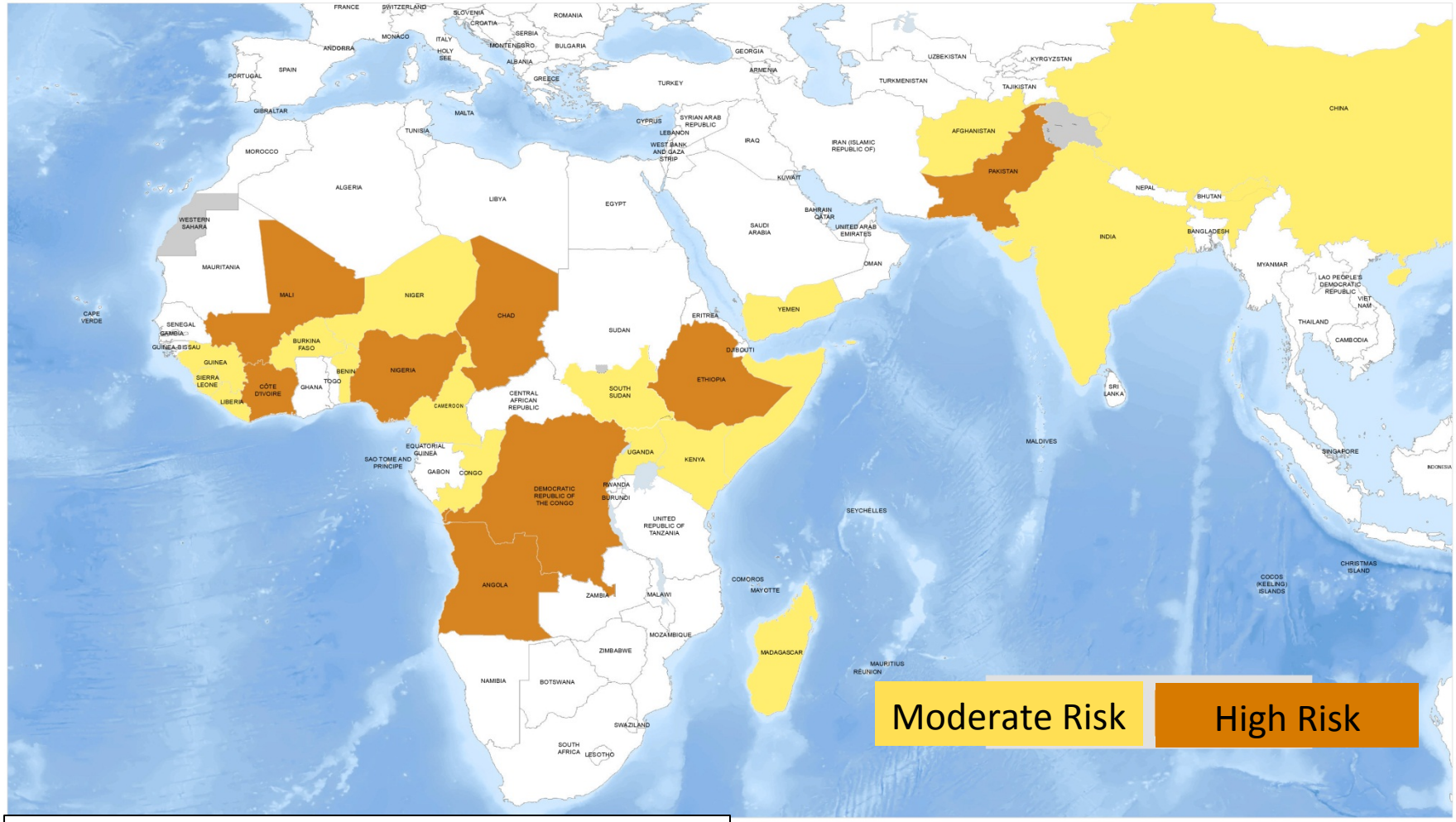
The WG recommends that SAGE:

- **Agree:** If SAGE at its October 2015 meeting confirms April 2016 as the date for OPV2 withdrawal, the switch should proceed as planned, given the serious implications of delay for all countries involved in OPV2 withdrawal
- Consider delaying OPV2 withdrawal if the WG reports in October 2015 that the risk of continued cVDPV2 transmission is judged to be high.

WG discussion and Recommendations:

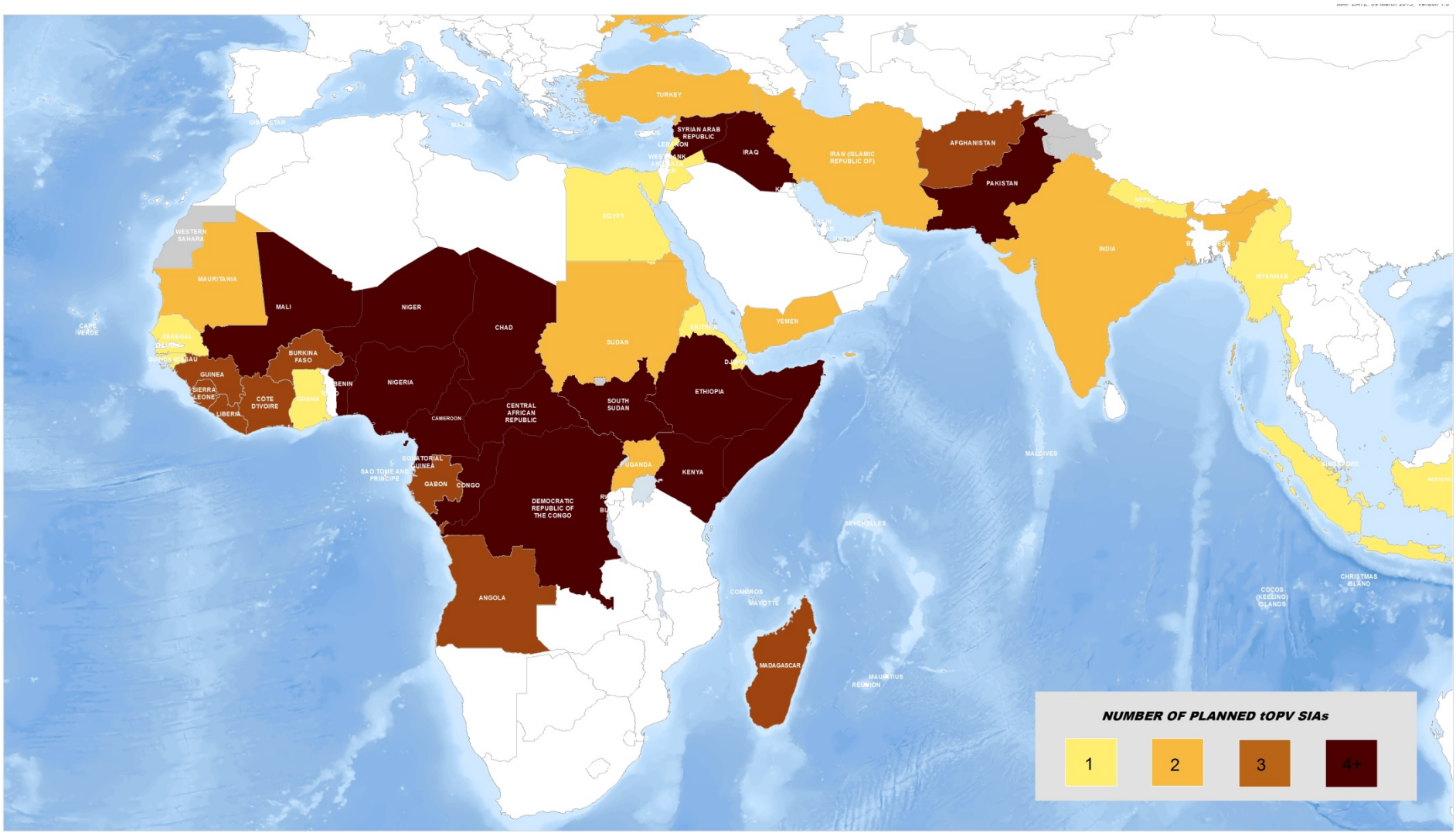
Mitigating the Risk of emergence of new cVDPV2

Risk* of cVDPV2 Emergence in Countries: Tier 1 Countries or Risk Moderate to High



*The probability of any cVPDV2 emergences post-switch based on modeling cVDPV2 emergences as a function of type 2 immunity and population size and assuming declining risk over time (IDM modelling work).

Planned tOPV SIAs 12 months prior to switch (April 2015-March 2016)



Map Scale (A3): 1:40,000,000
1 cm = 400 km
Coordinate System: GCS WGS 1984
Datum: WGS 1984
Units: Degree

Data Source:
Admin. Boundaries: World Health Organization
Base Map:GEBCO
Map Production: Global Polio Eradication Inititative, World Health Organization
Each sNID is considered as one round.

Additional tOPV SIAs since October 2014 SAGE

			SAGE Oct 2014		Approved Calendar (as of 9 April)		
	Country	<5 Population	# tOPV SIAs previously planned 12 mths prior to switch	Additional tOPV SIAs needed to achieve 80% immunity in under-fives	# tOPV SIAs NOW planned 12 mths prior to switch	Comments	Incremental doses vs. SAGE October 2014 recommendation
Tier 1	Cameroon	3,667,945	4	0	**5**	3 N, 2 SN	2,640,920
	Chad	2,689,955	5	0	**6**	4 N, 2 SN	3,227,946
	Kenya (Garissa, Dadaab)	300,000	3	0	**5**	Additional SN in high-risk areas	360,000
	DRC (Nationwide)	15,307,570	1	1	**4**	2 N, 2 SN	38,575,076
	Ethiopia (High Risk)	13,123,940	3	0	**6**	1 N, 5 SN (<50% scope)	-
	Madagascar (High Risk)	4,051,450	1	0	**4**	3 N, 1 SN	12,154,350
	Niger	4,373,220	5	0	**6**	3 N, 3 SN, additional SN in high-risk areas	-
	Somalia	2,283,280	6	0	**6**	5 N, 1 SN	-
	South Sudan	897,600	2	0	**5**	3 N, 2 SN	1,788,019
	Yemen	5,010,980	2	0	**4**	3 N, 1 SN	9,019,764
	India	133,556,330	2	0	**2**	2 N	-
Tier 2	Central African Republic	819,285	3	0	6	Multiple SN, given implementation challenges	983,142
	Equatorial Guinea	139,900	4	0	5	5 N	167,880
	Gabon	220,860	1	0	3	3 N	530,064
	Guinea (high risk areas)	2,065,155	1	1	4	4 N	4,956,372
	Indonesia	20,796,050	0	0	1	1 SN	4,991,052
	Iraq	6,116,185	3	0	5	2 N, 3 SN	3,669,711
	Mali (high risk areas)	3,909,535	1	1	4	1 N, 3 SN	2,345,721
	Mauritania	611,860	0	0	2	2 N	1,468,464
	Myanmar	3,990,915	0	0	1	1 SN	2,394,549
Other High Risk Countries	*Angola (high risk areas)*	*3,965,000*	*1*	*2*	*3*	*1 N, 2 SN*	-
	Benin (high risk areas)	*1,631,000*	*1*	*2*	*5*	*5 N*	3,914,400
	Burkina Faso (high risk are	*2,932,000*	*1*	*2*	*4*	*3 N, 1 SN*	1,759,200
	Congo (high risk areas)	*722,100*	*1*	*2*	*4*	*4 N*	866,520
	Cote d'Ivoire (high risk are	*3,088,000*	*0*	*2*	*3*	*2 N, 1 SN*	1,852,800
	Liberia	*677,900*	*2*	*0*	*4*	*4 N*	1,626,960
	Sierra Leone	*928,000*	*2*	*1*	*4*	*4 N*	1,113,600
	Uganda (high risk areas)	*6,939,000*	*0*	*2*	*3*	*1 N, 2 SN, additional SN in high-risk areas*	-

proposed calendar in line with SAGE October 2014 recommendation

proposed calendar > than SAGE October 2014 recommendation

incremental doses over Oct 2014 SAGE recommendation **100,000,000**

Reducing Risk of New cVDPV2 Emergence

- SAGE Oct 2014 endorsed the risk-based approach for use of tOPV SIAs to prevent emergence of new cVDPV in high-risk areas
- Additional SIA activities included to address both WPV and cVDPV emergence risks
- WG reviewed and found the number of campaigns adequate; recommended that SIAs are implemented with sufficient quality

WG discussion and Recommendations:

Responding to new cVDPV2 emergence in countries other than Nigeria and Pakistan

Background: Summary of epidemiology of 15 cVDPV2 outbreaks (2010-2015)*

cVDPV2 outbreaks in other countries are mostly small-scale and short-lived

- Median duration of outbreaks is 1.2 months and 87% (13/15) of outbreaks stopped within 6 months
- 33% (5/15) were single-case events and median number of cases was 2
- 93% (14/15) stopped after 4 or fewer SIAs
  - 47% (7/15) stopped spontaneously
  - 80% (12/15) stopped after 3 or fewer SIAs

* Excluding Nigeria and Pakistan

Risk-Based Approach for VDPV2 Response

- Three risk parameters to determine the response to cVDPV2 emergence:
  - *Evidence of circulation (cVDPV vs. aVDPV)*
  - *Risk of emergence and spread (Risk Tier of country)*
  - *Timing of emergence (Proximity to OPV2 withdrawal)*

Risk-based Programme Response to VDPV2
(excluding Nigeria & Pakistan)

VDPV2	April - Sept 2015	Oct 15 - Mar 16
"New" cVDPV2 *- Tier 1 country*	• Intensified mop-up with tOPV • Fully implement planned tOPV campaigns	• Expand scope, age groups, shorten interval of mop-up rounds, add IPV
"New" cVDPV2 *- Tier 2-4 country*	• Fully implement planned tOPV campaigns • Mopping-up	• Aggressive mop-up, expand scope based on risk, short interval SIAs

- VDPV2 detection from any source will result in a detailed epidemiologic investigation & risk assessment that will inform the nature of the response
- Mopping up will be conducted if investigation of an aVDPV2 indicates risk of circulation (e.g. Tier 1 country, high risk population, proximity to OPV2 withdrawal date)

Response to Emergence of New cVDPV2: WG Recommendations

The WG recommends that SAGE:

- **Endorse** the programme's strategies to respond to new cVDPV2 emergence
  - Between now and September 2015
  - From October 2015 to March 2016

WG discussion and Recommendations:

Verification process of poliovirus containment

Proposed Verification of Compliance with GAPIII

Background

- International oversight of containment is necessary
- WHO does not have the mandate to certify containment; will verify compliance on behalf of Regional Certification Commissions (RCCs)

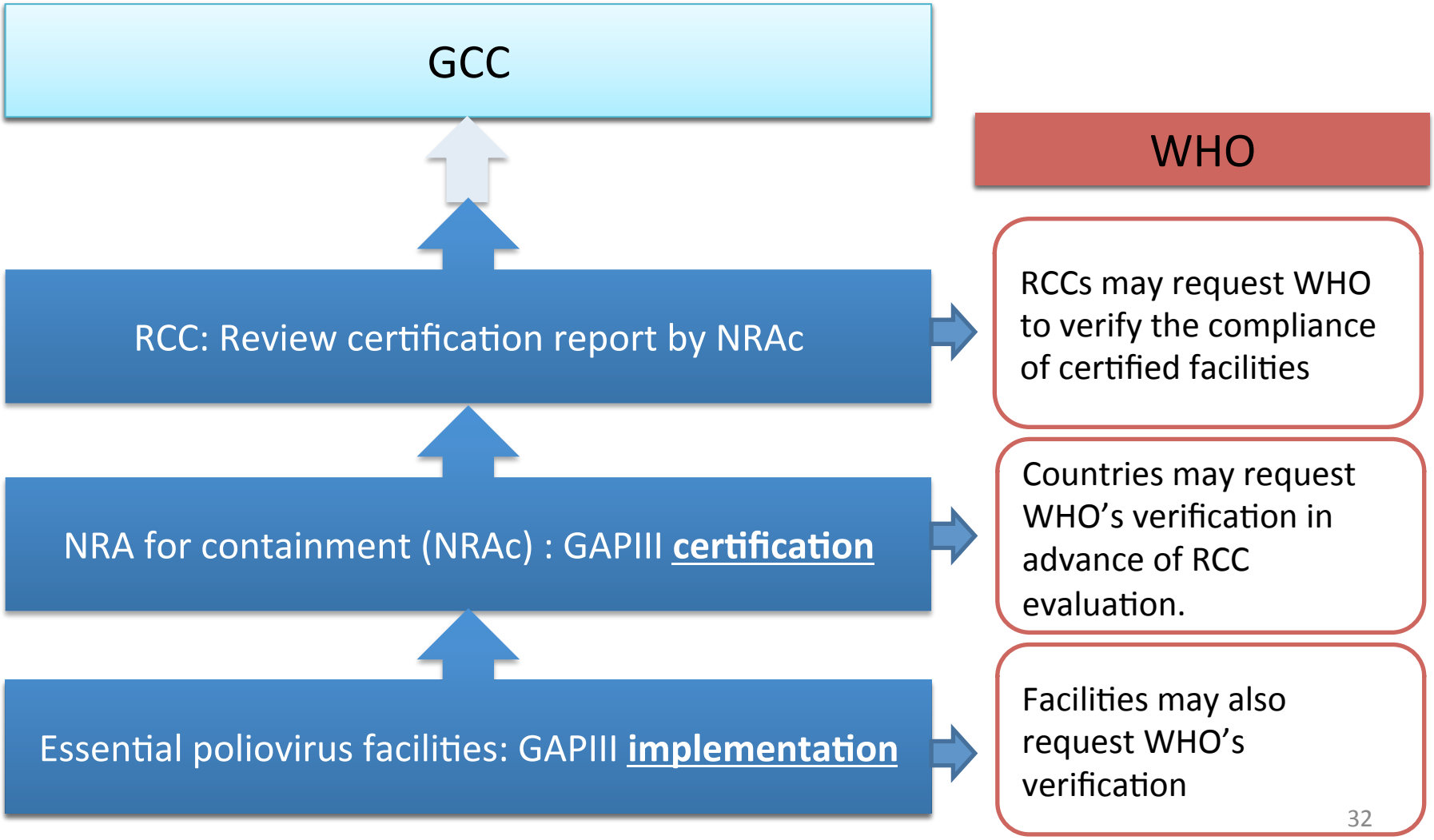
Proposed containment implementation, certification and verification

1. Facilities implement GAPIII
2. National Regulatory Authorities for containment (NRAc) certify facilities based on GAPIII. Certification reports are submitted to RCC.
3. RCCs may request WHO to verify compliance of certified facilities based on GAPIII. Countries or concerned facilities may also request verification, in advance of RCC's evaluation
4. WHO verification reports are submitted to RCCs and shared with concerned parties (facilities, NRAc and WHO).

Proposed Response to Verification Findings

1. Facilities: Identified non-compliances will be addressed within a timeframe agreed by concerned parties
2. Follow-up reporting and additional visits should the severity of the issue justify such measures
3. NRAc: Verification results will inform the decision of the national authority to revoke or maintain certification
4. RCC: The RCC will respond to verification reports and decide whether the essential facilities in the concerned country comply with GAPIII.

Proposed Approach for Certification and Verification of Poliovirus containment



Containment Strategy: WG Recommendations

The WG recommends that SAGE:

- **Endorse** the proposed approach to containment verification

WG Recommendations: Summary (1/3)

The WG recommends that SAGE:

- **Endorse:** cVDPV2 elimination strategies in Nigeria and Pakistan
- **Request:** WG to Review in June the strategies and contingency plans to rapidly eliminate persistent cVDPV2
- Assess progress in September 2015 to ensure that cVDPV2 elimination is on track before OPV2 withdrawal in April 2016

WG Recommendations: Summary (2/3)

The WG recommends that SAGE:

- **Agree:** If SAGE at its October 2015 confirms April 2016 as the date for OPV2 withdrawal, the switch should proceed as planned, given the serious implications of delay for all countries involved in OPV2 withdrawal
- Consider delaying OPV2 withdrawal if the WG reports in October 2015 that the risk of continued cVDPV2 transmission is judged to be high.

WG Recommendations: Summary (3/3)

The WG recommends that SAGE:

- **Endorse** the programme's strategies to respond to new cVDPV2 emergence
  - Between now and September 2015
  - From October 2015 to March 2016

  the proposed approach to containment verification

Extra Slides

Prevention of New cVDPV2 Emergence

tOPV SIA Calendar

National

Sub-National

Transmission zone / Country	2015									2016			tOPV SIAs 12 mos prior to switch	tOPV SIAs 6 mos prior to switch
	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar		
West/South Asia														
Afghanistan							N			SN		N	3	3
Pakistan		SN				N		SN		SN		N	5	3
India										N	N		2	2
Nepal	SN												1	
Bangladesh														
West/Central Africa														
Nigeria	SN			SN			SN			SN	N	N	6	4
Chad	SN					N	N	SN			N	N	6	4
Niger	SN					N	SN		SN		N	N	6	4
Mali						SN	SN				SN	N	4	3
Burkina Faso						N	SN				N	N	4	3
Benin	N					N	N				N	N	5	3
Cameroon		SN				N		SN			N	N	5	3
DR Congo						SN		SN			N	N	4	3
Central African Republic	SN	SN						SN	SN		N	N	6	4
Gabon		N				N						N	3	1
Equatorial Guinea		N				N	N				N	N	5	3
Congo		N		N							N	N	4	2
Liberia	N					N					N	N	4	2
Sierra Leone	N					N					N	N	4	2
Guinea	N					N					N	N	4	2
Côte d'Ivoire	N					SN						N	3	1
Mauritania						N						N	2	1
Ghana						SN							1	
Senegal	N												1	
Gambia														
Guinea Bissau						N							1	
Togo														
Cape Verde														
Horn of Africa														
Somalia	N	SN				N		N			N	N	6	3
Ethiopia		SN				SN		SN	SN		SN	N	6	4
Kenya	SN					SN		SN			SN	N	5	3
South Sudan							SN	N	N		SN	N	5	5
Sudan							SN					SN	2	2
Uganda						SN					SN	N	3	2
Djibouti						N							1	
Eritrea						N							1	
Tanzania														
Yemen						N		SN			N	N	4	3
Middle East														
Syria	N		N			N					N	N	5	2
Egypt	N							SN					2	1
Jordan	SN												1	
Lebanon	SN												1	
Iraq	N		SN			SN		SN				N	5	2
Iran	SN	SN											2	
Libya						SN		SN					2	1
Palestine														
Turkey						SN	SN						2	1
Israel														
Other														
Angola				SN		N						SN	3	1
Tajikistan														
Ukraine				N	N								2	
Madagascar	N	SN		N								N	4	1
Myanmar												SN	1	1
Indonesia												SN	1	1