OPV Cessation

Plan for tOPV Campaigns Immediately Prior to tOPV to bOPV Switch

(Draft version 14 October 2014)

DRAFT

RISK BASED APPROACH

Background

One of the recommended next steps from the 9th Meeting of the SAGE Polio Working Group held on July 30-31, 2014 was that GPEI develops a draft plan regarding tOPV SIAs to be conducted immediately before OPV2 withdrawal in areas identified as high risk for cVDPV2 emergence. This concept note provides a framework for risk assessment, and suggests list of areas to be considered for tOPV pre switch SIAs. This is a working document with revisions and refinements expected. All countries using tOPV in routine immunization and conducting SIAs should continue to use tOPV for planned preventive SIAs, particularly for national immunization days. Some countries may also benefit from additional tOPV SIAs to reduce the risks of cVDPV emergence following globally-coordinated cessation of type 2-containing OPV.

Risk Based Approach

This risk assessment of cVDPV 2 emergence post tOPV to bOPV switch is based on:

- Lessons learned, findings and conclusions from risk assessments on global and regional level
- Past cVDPV 2 epidemiological analysis
- Modelling of tOPV to bOPV switch
- Tier system for determination of risk of VDPV 2 emergence

Recent Risk Assessment Initiatives

Many recent initiatives have assessed risks to poliovirus eradication and the endgame strategy that provided valuable lessons relevant to OPV2 cessation risks. These initiatives include:

Group	Scope	Reporting to	Methodology	Ref.
Risk Assessment Task Team (RATT) – since 2013	The regions (AFRO, EMRO & SEARO) and select countries in EURO	Eradication Management Group (EMG), GPEI	Combined risk score by 3 agencies (WHO, CDC, IDM) – Countries individually ranked from low to high risk for WPV	1
Centers for Disease Control and Prevention (CDC) – since 2010	All countries reporting polio cases during 2009-14	Independent Monitoring Board (IMB)	Surveillance performance (NPAFP rate, stool adequacy, virology) and immunization status (NPAFP OPV status)	2
Regional risk assessment – since 2011	All countries in each region	Regional and global program, GPEI	Typically, risk scoring based on population immunity, surveillance quality, and other	3

			indicators (sanitation, routine immunization)	
Imperial College London	25 countries in Africa with WPV cases from 2003-2010	Regional and global program, GPEI	Regression model to estimate the cVDPV emergences based on routine coverage, NPAFP OPV doses, # of SIA and % of zero dose children	4
Kid Risk, Inc.	All OPV-using countries, Nigeria and India	Country, Regional and Global Program GPEI	Modelling of population immunity to transmission to estimate cases and time before WPV1 cessation and risks of cVDPV2 Estimation of the impact of different OPV/IPV immunization policies	5-12
Institute of Disease Modelling (IDM)	All countries in Africa, subnational country specific analysis for Nigeria and Pakistan	Regional and global program, GPEI	Regression model to estimate the cVDPV emergences based on population under 5, susceptible fraction, historical cVDPV cases and population density. Subnational assessments have primarily looked as WPV risk	n/a

Summary of published and unpublished analyses from these initiatives

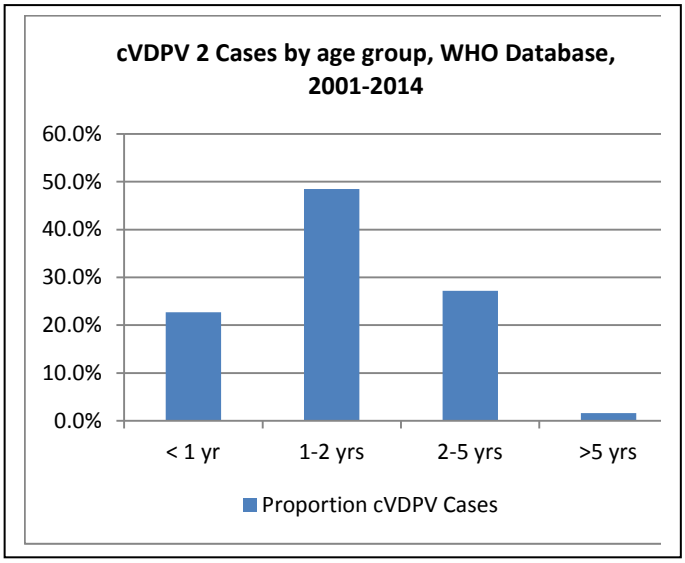
- Modelling and experience demonstrate that cVDPVs occur in areas using tOPV with low routine immunization coverage and insufficient SIA frequency and coverage. Low levels of vaccine coverage allow the vaccine virus to continue to circulate in the population [10-12].
- The risk of cVDPV emergence after coordinated OPV cessation comes from undetected OPV-related transmission chains seeded prior to cessation [5, 6, 10-12].
- Imperial College Risk Assessment (unpublished): Under some circumstances (poor RI, poor campaign coverage and/or vaccine efficacy), tOPV campaigns could increase risk of cVDPV2 emergence.
- The risk of introducing OPV2 virus into the environment through tOPV campaigns and subsequent emergence of VDPV2 is outweighed by the benefit of increasing population immunity, *although the SIAs must be of sufficient number and coverage to achieve high population immunity to prevent the cVDPV* [6, 10].
- SIAs with tOPV shortly before coordinated OPV2 cessation represent a key cVDPV2 emergence risk mitigation strategy in OPV-using areas [6].
- High population immunity is necessary for successful, coordinated OPV cessation [6].
- Modelling showed limited impact of IPV in RI on cVDPV2 emergence and transmission after OPV2 cessation, although IPV will protect children against poliomyelitis due to cVDPV2 [7].

- Following coordinated OPV2 cessation, modelling suggests the highest risk of emergence within approximately 12 months [6], with detection of the cVDPV depending on surveillance quality.
- Specific modelling of high-risk areas in northern India showed a low risk of cVDPV emergence after OPV2 cessation provided that nationwide tOPV SIAs are maintained until OPV2 cessation [8].
- Specific modelling of the high-risk area in northwest Nigeria showed that cVDPV2 persists unless the frequency of tOPV SIAs is increased (or SIA/RI coverage improves in underserved groups) and that even with an added tOPV SIA each year, cVDPV2 risk in Nigeria remains relatively high [9].

Epidemiology of past cVDPV 2 Outbreaks

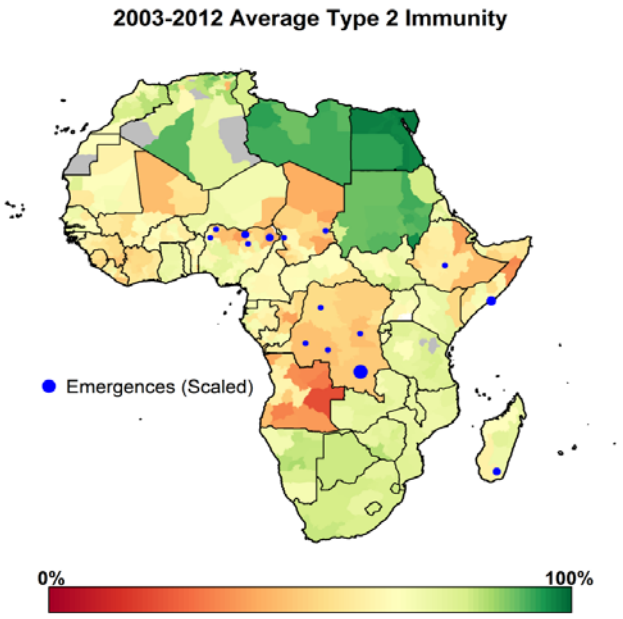
According to the WHO cVDPV database (2001-2014), 651 detected cases caused by cVDPV2 resulted from multiple cVDPV2 emergences in 14 countries, with 23 emergences detected in Nigeria alone between 2005 and 2011 [13]. Almost 85% of the cases occurred in 3 countries: Nigeria (61.3%), Pakistan (12.3%) and DR Congo (9.8%). Nearly all (98.4%) of cVDPVs occurred in children below 5 years of age, with 99.7% occurring in children below 10 years of age, and only one cVDPV2 case ever detected in an adult (22 years old).

Country	Cases	%
Afghanistan	18	2.8
Cameroon	4	0.6
Chad	17	2.6
China	2	0.3
DR Congo	64	9.8
Ethiopia	4	0.6
India	17	2.6
Kenya	3	0.5
Madagascar	8	1.2
Niger	7	1.1
Nigeria	399	61.3
Pakistan	80	12.3
Somalia	19	2.9
Yemen	9	1.4

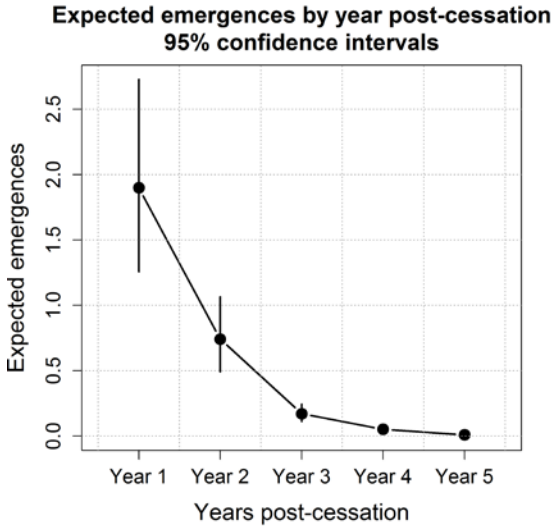


Results from the IDM modelling [unpublished]

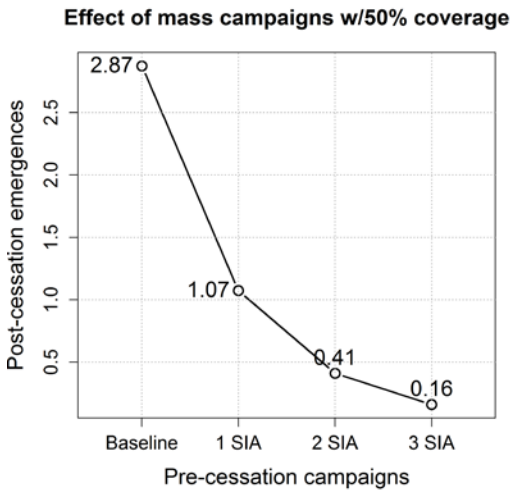
No cVDPV2 cases have been detected in any country that achieved and maintained for at least 3 years POL3 routine coverage of >80%. In Africa, all cVDPV2 emergences occurred in areas with relatively low immunity of children under 5 years to serotype 2.



Without any pre-switch tOPV SIAs, IDM estimates three cVDPV2 emergences will occur worldwide; two of which in the first year post switch.



Reducing susceptibility with pre-cessation tOPV SIAs can reduce risk (Note: the IDM model assumes only 50% SIA coverage and thus provides the worst-case scenario. In reality, we may achieve larger risk reduction with each SIA.)



Tier system for determination of risk of VDPV 2 emergence

Framework for tiering: The GPEI developed a framework for determination of risk of VDPV2 emergence to guide IPV introduction strategies that groups current tOPV using countries into Tiers 1-4.

To optimize the use of constrained tOPV resources in pre-OPV2 cessation additional tOPV SIAs, the risk assessment seeks to prioritize additional tOPV SIAs in the areas of highest risk. Most non-high risk countries with successful RI programs will not need any additional tOPV campaigns. For example, in Sri Lanka the RI DTP3/POL 4 coverage is >90%; recent seroprevalence survey in several age groups including adolescents showed PV2 protection $\geq$ 95%.

Rationale and Priorities for tOPV SIAs

The rationale for conducting tOPV SIAs prior to switch is to minimize the risk of VDPV2 emergence by rapidly increasing the population immunity to poliovirus type 2.

cVDPV2 occurs mostly in areas with a combination of low routine and SIA coverage. Other triggering factors (such as co-circulation of other human enteroviruses [HEV C]) may exist, but all cVDPV outbreaks have low population immunity in common. In these areas, low coverage levels give the vaccine virus the opportunity to start circulating but not high enough immunity to interrupt their transmission.

The priorities for risk mitigation are:

- *Priority 1:* achieve high population immunity for PV2 prior to switch— **key role of SIAs** & routine immunization
- *Priority 2:* enhance surveillance sensitivity
- *Priority 3:* ensure adequate response capability

Operational Assumptions for IDM Risk Assessment

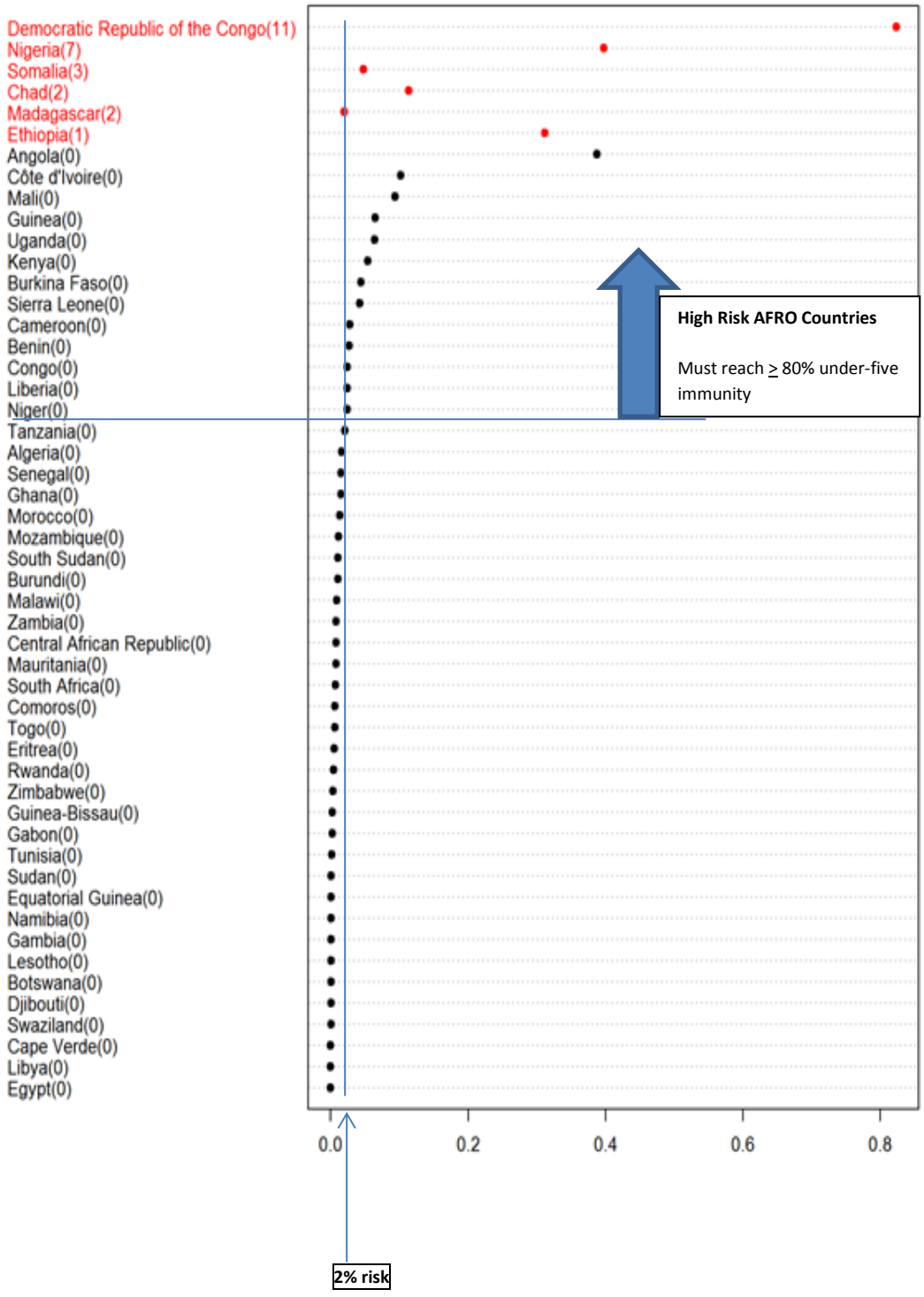
- All known cVDPV2 transmission chains will have stopped prior to the tOPV to bOPV switch
- Proportion of PV2 seronegative persons who seroconvert after one dose of tOPV depends on age (young infants may neutralize the vaccine with maternal antibodies), and on location (OPV efficacy is lower in densely populated areas of developing countries with poor sanitation). *Per dose efficacy of tOPV for PV 2 is estimated to be between 27-53%* [14-18]. **For our purposes, we estimated uniform efficacy of 40%**. This is one of the limitations.
- The evaluated SIA coverage will reach at least 80% in all areas and is homogenous (access is uniform to all children)
- The analysis assumes administration of tOPV for SIAs based on standard 4-week interval between doses.
- Waning of mucosal immunity to all poliovirus serotypes has been observed within 12 months [19].
- Any OPV used (in routine immunization and/or SIAs) implies introduction of the precursors to VDPVs with potential to start circulating in populations [20].
- IPV will be introduced to all OPV only using countries 6 months prior to the tOPV to bOPV switch, however, some models show that while IPV in RI will protect against paralysis caused by cVDPV2, it will not significantly reduce the risk of cVDPV2 emergence [7].
- PV2 immunity in children under 5 years is estimated from AFP data.
- Historical epidemiological experience with cVDPVs is predictive of future experience

Goal of the assessment: Reduce the risk of cVDPV2 emergence post switch by > 90% through achieving > 80% under-five population immunity against type 2 in all high risk areas by (1) identifying high risk areas for cVDPV2 emergence, (2) reviewing the existing plan for tOPV SIAs during 12 months preceding the switch, (3) determining if additional SIAs are needed in the high risk areas, and (4) determining other considerations (interval between rounds, target age group and timing).

1. <u>Identification of High Risk Areas</u>

- High risk areas of Tier 1 and 2 countries and other identified areas (High risk is defined as >2% risk of emergence of cVDPV post switch [IDM Figure below for Countries in AFRO])

Risk of cVDPV Emergence post switch in Africa; in (n) number of cVDPV Emergences in 2012 [IDM]



2. Review of existing plan for tOPV SIAs during 12 months preceding the switch

The table below shows the tOPV SIAs already planned in the period from April 2015-July 2015 and the **tentatively** planned tOPV SIAs from July 2015-March 2016, which will be **updated and finalized at later stage.** When calculating **ADDITIONAL** tOPV SIAs needed to achieve ≥80% under-five immunity against type 2 in high-risk areas, the IDM risk assessment assumes that this plan will be fulfilled with all rounds in this table conducted as indicated.

Table: Already planned tOPV SIAs between Nov 2014 and Switch date (N-National, SN-Sub-National; PROJECTED SIAs shown in grey [from July 2015])

	2014		2015												2016					
Country	**11**	**12**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**	**TOTAL SIAs**	**SIAs 12 mo Prior to Switch**	**SIAs 6 mo Prior to Switch**
Afghanistan				N			SN				N				SN	N	N	6	5	3
Angola	N				SN						SN							3	1	0
Benin					N						N							2	1	0
Burkina Faso					N						N							2	1	0
Cameroon			N		SN		SN				N					N	N	6	4	2
Cape Verde	N																	1	0	0
Central African Republic					N		N				N						N	4	3	1
Chad					N	SN					N		SN			N	N	6	5	3
Congo			N		N						N							3	1	0
Côte d'Ivoire					N													1	0	0
Djibouti	N	N																2	0	0
DR Congo	SN				SN						SN					SN	N	5	3	2
Egypt				SN	SN													2	0	0
Equatorial Guinea			N				N			N	N						N	5	4	1
Eritrea																		0	0	0
Ethiopia	N				SN						SN					SN	N	5	3	2
Gabon					N		N											2	1	0
Gambia	N																	1	0	0
Ghana	N																	1	0	0
Guinea					N						N						SN	3	2	1
Guinea Bissau	N																	1	0	0
India			N	N											N	N		4	2	2
Iran																		0	0	0
Iraq				N		N					SN						N	4	3	1
Israel																		0	0	0
Jordan	N			SN														2	0	0
Kenya					SN						SN					SN	N	4	3	2
Lebanon	N			SN		SN												3	1	0
Liberia					N	N					N							3	2	0
Madagascar																	SN	1	1	1
Mali					N						SN						N	3	2	1
Mauritania	N																	1	0	0
Niger		SN			N	SN					N		N			N	N	7	5	3
Nigeria	SN					SN	SN		SN		SN		SN			N	N	8	7	3
Pakistan				SN							N				SN	N	N	5	4	3
Palestine	N																	1	0	0
Senegal					N						N							2	1	0
Sierra Leone					N	N					N							3	2	0
Somalia			N		N		N			SN	N		N			N	N	8	6	3
South Sudan	N	N			N						N						N	5	2	1
Sudan	N				SN													2	0	0
Syria				N		N		N			N						N	5	4	1
Togo	N																	1	0	0
Turkey				SN		SN												2	1	0
Uganda	N	SN			SN													3	0	0
Yemen					N						N						N	3	2	1

3. Determination of number of tOPV SIAs to be conducted in each area

The number of SIAs in each identified high-risk area is determined by starting under-five immunity levels and by gain from each tOPV campaign. The gain is estimated using the table below.

Table: Achieved gain in under-five immunity after one round of tOPV SIA; (per dose tOPV efficacy for PV 2=40%)

Starting PV 2 Immunity (in under five-year olds)	PV 2 Immunity post tOPV SIA (with 80% evaluated coverage)
30%	52%
35%	56%
40%	59%
45%	63%
50%	66%
55%	69%
60%	73%
65%	76%
70%	80%
75%	83%
80%	86%

The approximation in the table above can be applied to areas in which access is homogenous and at either the national or subnational level.

IDM estimated the starting under-five immunity levels from AFP surveillance data [IDM Analysis] (see table in Annex 1). The estimates reflect a worst-case scenario, because they do not take into consideration secondary environmental exposure to PV2 (which is likely significant) and the analysis assumes the 2012 data represent the future.

As appropriate, the tOPV SIAs should target sub-national areas deemed at high risk. The level of heterogeneity of RI and SIA coverage within each country and historical review of any cohorts exposed primarily to mOPV or bOPV SIAs needs to be assessed. The focus should be on areas or population groups identified as high risk for PV2. In addition, differences in POL3 coverage between low risk and high risk areas of >30% than sub-national SIAs should be considered.

4. Other considerations

- The interval between rounds should be 28 days.
- SIAs should target children under-five years old unless evidence suggests the presence of immunity gaps in older individuals who may therefore contribute to cVDPV circulation.
- To maximize the risk mitigating effect, the additional SIAs should be conducted during the six months leading to the switch because of waning mucosal immunity.

IDM Risk Mitigation Estimate

IDM estimated that without doing any tOPV campaigns, at least one, and 2-3 emergences of cVDPV2 will most likely occur in the first year after the switch. **The strategy of additional tOPV campaigns (which includes already planned tOPV campaigns)** will significantly reduce the risk of cVDPV emergence (by around 90%). The existing tOPV plan for 2015 and 2016 may change. If that happens, it will be important that the total number of currently planned tOPV rounds is maintained in each high risk area.

Limitations

Significant uncertainties limit our ability to provide a more precise estimate for need of tOPV SIAs pre switch.

Major uncertainties exist around:

- Estimates of PV 2 per dose efficacy of tOPV
    - Both population immunity and number of tOPV doses are sensitive to tOPV per dose efficacy
- Estimates of PV 2 starting immunity levels in under-fives is based on 2012 AFP data
- Risk of cVDPV emergence is based on 2012 data
- Immunity level that prevents emergence and subsequent circulation of cVDPVs is estimated to be 80%. This is a theoretical level that we used for this task. It is likely that in places such as Northern Nigeria 80% immunity among under-five year olds has been achieved while cVDPV circulation persists.
- Heterogeneity of access to population at high risk is not considered
    - ***Sub-national plan must be developed for each country as appropriate; the proposed table below assumes 50% of national target to be in high risk areas***
- Plan for tOPV SIAs after June 2015

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Table 1: Tier 1 and 2 Countries [plus high-risk countries] and recommendation regarding ADDITIONAL tOPV SIAs six months pre switch (assuming 50% of national target in high risk areas)

	Country	<5 Population	# tOPV SIAs already planned 12 mo prior to switch	Additional tOPV SIAs needed to achieve 80% immunity in under-fives	tOPV doses needed for additional SIAs (assuming 20% wastage)
Tier 1	Afghanistan	7,516,420	5	0	0
	Nigeria (all country)	34,806,010	2	0	0
	Nigeria (North)	17,500,000	7	0	0
	Pakistan (all country)	23,991,570	3	0	0
	Pakistan (high risk areas)	5,000,000	4	0	0
	Cameroon	3,667,945	4	0	0
	Chad	2,689,955	5	0	0
	Kenya (Garissa, Dadaab)	300,000	3	0	0
	DRC (High risk)	15,307,570	1	1	9,184,542
	Ethiopia (High Risk)	13,123,940	3	0	0
	Madagascar (High Risk)	4,051,450	1	0	0
	Niger	4,373,220	5	0	0
	Somalia	2,283,280	6	0	0
	Yemen	5,010,980	2	0	0
	China	78,186,755		0	0
	India	133,556,330	2	0	
				TIER 1	9,184,542
Tier 2	Azerbaijan	903,010	0	0	0
	Cambodia	1,555,070	0	0	0
	Central African Republic	819,285	3	0	0
	Dominican Republic	1,055,160	0	0	0
	Equatorial Guinea	139,900	4	0	0
	Gabon	220,860	1	0	0
	Guinea (high risk areas)	2,065,155	1	1	1,239,093
	Haiti	1,321,065	0	0	0
	Indonesia	20,796,050	0	0	0
	Iraq	6,116,185	3	0	0
	Lao	693,990	0	0	0
	Mali (high risk areas)	3,909,535	1	1	2,345,721
	Mauritania	611,860	0	0	0
	Mozambique	4,612,415	0	0	0
	Myanmar	3,990,915	0	0	0
	Papua New Guinea	1,071,215	0	0	0
	Philippines	12,093,045	0	0	0
	South Sudan	897,600	2	0	0
	Timor-Leste	244,130	0	0	0
Other High Risk Countries	*Angola (high risk areas)*	*3,965,000*	*1*	*2*	*4,758,000*
	Benin (high risk areas)	*1,631,000*	*1*	*2*	*1,957,200*
	Burkina Faso (high risk areas)	*2,932,000*	*1*	*2*	*3,518,400*
	Congo (high risk areas)	*722,100*	*1*	*2*	*866,520*
	Cote d'Ivoire (high risk areas)	*3,088,000*	*0*	*2*	*3,705,600*
	Liberia	*677,900*	*2*	*0*	*0*
	Sierra Leone	*928,000*	*2*	*1*	*556,800*
	Uganda n(high risk areas)	*6,939,000*	*0*	*2*	*8,326,800*
			TIER 2 and other High Risk		27,274,134
				TOTAL	**36,458,676**

ANNEX 1: IDM Estimate of PV 2 Immunity

Country	AFP Count 2003-2012	Immunity 2003-2012	AFP Count 2012	Immunity 2012
Africa.Algeria	304	79.9%	53	75.4%
Africa.Angola	1432	51.1%	188	43.7%
Africa.Benin	660	65.7%	87	49.4%
Africa.Botswana	101	80.9%	7	80.5%
Africa.Burkina Faso	1145	64.2%	192	55.3%
Africa.Burundi	433	67.1%	50	58.3%
Africa.Cameroon	1116	66.7%	138	45.4%
Africa.Cape Verde	15	81.5%	1	71.0%
Africa.Central African Republic	659	66.8%	46	48.7%
Africa.Chad	1218	53.6%	253	44.2%
Africa.Comoros	13	52.6%	1	0.0%
Africa.Côte d'Ivoire	1653	56.0%	209	33.0%
Africa.Democratic Republic of the Congo	8277	50.0%	962	50.9%
Africa.Djibouti	23	77.9%	4	91.2%
Africa.Egypt	6980	97.2%	738	96.8%
Africa.Equatorial Guinea	30	69.3%	0	No Data
Africa.Eritrea	329	74.4%	24	76.3%
Africa.Ethiopia	4393	59.1%	427	63.4%
Africa.Gabon	108	66.5%	6	33.5%
Africa.Gambia	135	77.3%	27	70.0%
Africa.Ghana	1220	72.2%	122	69.6%
Africa.Guinea	783	55.7%	118	47.8%
Africa.Guinea-Bissau	47	66.8%	4	58.0%
Africa.Kenya	1777	69.2%	316	64.5%
Africa.Lesotho	78	79.0%	6	79.2%
Africa.Liberia	305	60.1%	35	41.1%
Africa.Libya	264	91.6%	31	90.0%
Africa.Madagascar	833	72.5%	132	69.5%
Africa.Malawi	430	74.1%	61	75.4%
Africa.Mali	845	61.0%	146	52.3%
Africa.Mauritania	270	65.4%	41	50.8%
Africa.Morocco	526	74.1%	43	79.3%
Africa.Mozambique	721	74.2%	140	75.6%
Africa.Namibia	125	78.2%	7	80.7%
Africa.Niger	2001	71.2%	271	62.5%
Africa.Nigeria	35352	61.9%	5275	70.7%
Africa.Republic of Congo	358	60.9%	23	39.2%
Africa.Rwanda	598	76.1%	74	58.8%

Africa.Senegal	832	68.7%	68	44.8%
Africa.Sierra Leone	736	53.8%	114	46.8%
Africa.Somalia	1188	59.4%	125	69.4%
Africa.South Africa	1194	78.5%	152	72.4%
Africa.South Sudan	1375	70.8%	253	77.4%
Africa.Sudan	2287	89.7%	229	92.8%
Africa.Swaziland	87	80.8%	8	80.0%
Africa.Tanzania	1883	75.8%	367	68.9%
Africa.Togo	441	69.2%	59	59.2%
Africa.Tunisia	255	78.8%	36	83.5%
Africa.Uganda	2260	66.4%	314	56.6%
Africa.Zambia	719	74.0%	85	76.0%
Africa.Zimbabwe	483	77.5%	80	71.0%
Asia.Afghanistan	7879	91.5%	1174	83.2%
Asia.Bahrain	33	80.6%	7	85.2%
Asia.Bangladesh	8746	96.0%	851	97.1%
Asia.Bhutan	18	84.2%	2	85.2%
Asia.East Timor	6	61.0%	3	50.7%
Asia.India	238885	92.9%	33037	93.2%
Asia.Indonesia	6924	77.1%	913	77.4%
Asia.Iran	2916	84.6%	382	87.8%
Asia.Iraq	2891	80.2%	309	79.4%
Asia.Jordan	182	85.4%	18	92.5%
Asia.Kuwait	86	87.0%	13	91.5%
Asia.Lebanon	72	67.7%	9	69.1%
Asia.Myanmar	1402	77.0%	160	77.0%
Asia.Nepal	2009	85.4%	296	80.5%
Asia.North Korea	649	81.9%	52	76.2%
Asia.Oman	149	88.5%	14	85.1%
Asia.Pakistan	28965	90.2%	3465	72.0%
Asia.Palestina	68	89.2%	5	91.8%
Asia.Qatar	34	84.4%	9	83.5%
Asia.Saudi Arabia	802	81.6%	85	86.6%
Asia.Sri Lanka	337	84.1%	21	84.5%
Asia.Syria	811	82.2%	47	80.6%
Asia.Thailand	882	85.3%	83	82.8%
Asia.United Arab Emirates	91	79.1%	19	79.9%
Asia.Yemen	2169	67.1%	298	70.3%