

*Cessation of routine oral polio vaccine (OPV)  
use after global polio eradication*

# Framework for National Policy Makers in OPV-Using Countries

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# Index

1. Introduction
2. Rationale for eventual cessation of oral polio vaccine (OPV) use in routine immunization after eradication
3. Risks associated with OPV cessation
4. Risk management before, during and after OPV cessation: implementing the prerequisites for OPV cessation
  - I Confirmation of interruption of wild poliovirus transmission globally
  - II Appropriate biocontainment of all polioviruses
  - III International stockpile of monovalent OPVs (mOPV)
  - IV Highly-sensitive surveillance for circulating polioviruses
  - V Procedure for internationally-simultaneous OPV cessation
  - VI Long-term routine polio immunization policy
5. Timetable for OPV cessation
6. Glossary of terms

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# 1. Introduction

## *Polio eradication - global overview as at 2005*

By early 2005, the annual number of polio cases reported globally had been reduced by over 99 % since the Global Polio Eradication Initiative was launched in 1988. In addition, endemic wild polioviruses had been eliminated from all but six countries in the world (Nigeria, India, Pakistan, Niger, Afghanistan and Egypt), demonstrating that the polio eradication strategies can work in all settings. Following the large polio epidemic of 2003-2004 in west and central Africa, which spread to 16 previously polio-free countries, a massive 'intensified' effort has been launched and is anticipated to stop polio transmission globally in the near future.

With the 'intensification' of the global polio eradication effort in 2004-2005, preparations are being made for simultaneous oral polio vaccine (OPV) cessation soon after assurance of the complete interruption of wild poliovirus transmission.

In 1988, World Health Assembly (WHA) resolution 41.28 established the goal of polio eradication as 'interruption of wild poliovirus transmission' globally. Since 1999, however, increasing scientific data demonstrate that polio eradication will also require the eventual cessation of OPV use in routine immunization programmes. Otherwise, the continued reintroduction of the attenuated polioviruses of OPV into a polio-free world will result in polio cases due to vaccine-associated paralytic polio, and polio outbreaks due to circulating vaccine-derived polioviruses<sup>1</sup>.

The international oversight bodies that guide the Global Polio Eradication Initiative concluded in 2003 and 2004 that OPV cessation should occur as soon as possible after the interruption of wild poliovirus transmission globally, while population

immunity against polio and surveillance sensitivity for acute flaccid paralysis remain high<sup>2</sup>. Minimizing the risks associated with stopping OPV requires careful preparation at the national and international levels and, eventually, simultaneous OPV cessation across all remaining OPV-using countries to ensure that no country is placed at risk of importing a vaccine-derived poliovirus from an area where OPV use continues.

This document has been developed to provide national health policy makers in OPV-using countries with an overview of the rationale, risks, prerequisites and potential timetable for the global cessation of OPV. Particular emphasis is given to those activities required at the country level during the ongoing 'OPV Cessation Preparatory Phase'.

**"After eradication of wild poliovirus, continued use of oral polio vaccine (OPV) would compromise the goal of a polio-free world." *Advisory Committee on Poliomyelitis Eradication (ACPE), Geneva, 21-22 September 2004***

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<sup>1</sup> *Conclusions and Recommendations of the Advisory Committee on Poliomyelitis Eradication (ACPE)*, Geneva, Switzerland, 21-22 September 2004

<sup>2</sup> WHO Informal Consultation on Identification and Management of Vaccine-derived Polioviruses. September 2003, Geneva, Switzerland.

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## 2. Rationale for eventual cessation of oral polio vaccine (OPV) use in routine immunization after eradication

OPV is the appropriate – and only recommended – polio vaccine for achieving the eradication of wild polioviruses worldwide<sup>3</sup>. However, OPV can also cause – in rare instances – paralytic polio cases. Consequently, once wild poliovirus transmission has been interrupted globally, the attenuated Sabin poliovirus strains used in OPV could continue to cause polio cases and outbreaks at a rare but predictable rate. Therefore, the continued use of OPV after the interruption of

transmission of wild poliovirus is increasingly considered inconsistent with eradication. Polio cases due to vaccine-associated paralytic poliomyelitis (VAPP) and outbreaks due to circulating vaccine-derived polioviruses (cVDPVs), are the two main reasons for eventually stopping the use of OPV for routine immunization in all countries.

1. *Polio Cases due to Vaccine-Associated Paralytic Poliomyelitis (VAPP)*: the continued use of OPV will result in a predictable burden of polio disease due to VAPP.

VAPP cases will continue to occur at a rate of 2-4 cases per one million birth cohort, wherever OPV is used. If the OPV utilization patterns of 2005 continued after confirmation of the eradication of wild-type poliovirus, between 250 and 500 new VAPP cases would be expected to occur worldwide each year.

While the risk of polio due to wild poliovirus currently outweighs the risk of VAPP in most countries, this balance will change with confirmation of the interruption of wild poliovirus transmission globally.

2. *Polio Outbreaks due to circulating Vaccine-Derived Polioviruses (cVDPV)*: the continued use of OPV will result in a predictable rate of polio outbreaks due to cVDPVs.

Since 2000, four polio outbreaks due to cVDPVs have been documented in Hispaniola (in 2000-2001), the Philippines (in 2001), Madagascar (in 2002) and China (in 2004), resulting in a total of 31 polio cases. A fifth outbreak was described retrospectively in Egypt.

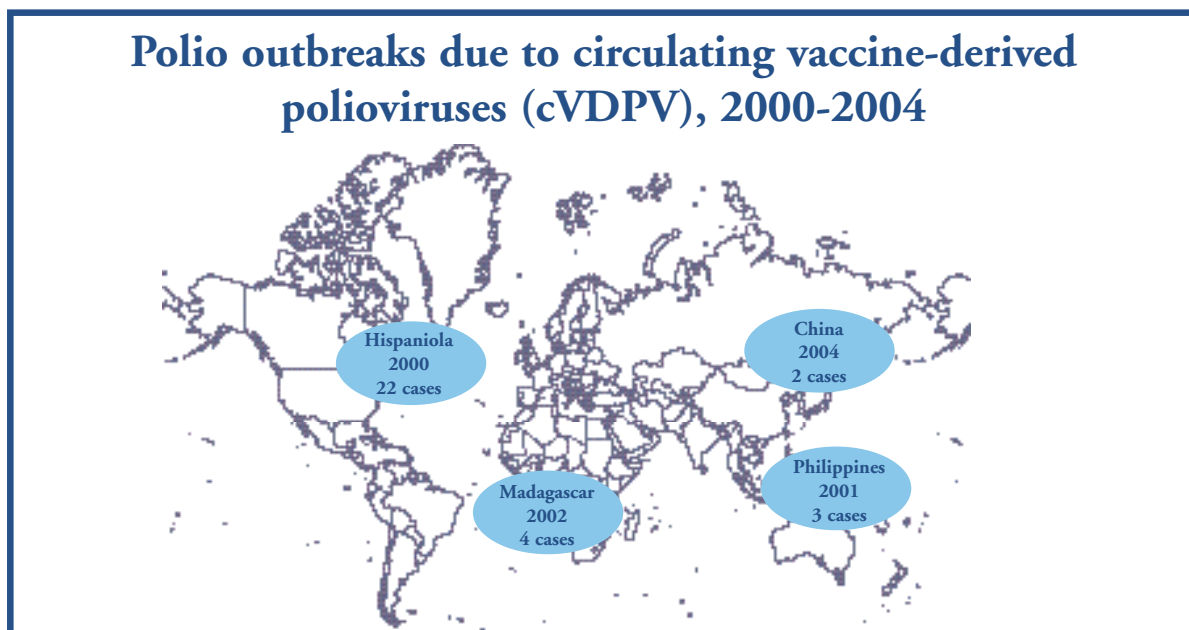
While low routine immunization coverage probably contributes to the conditions that give rise to cVDPVs, and mass campaigns with OPV eventually stopped each reported outbreak, it appears that even major improvements in routine polio immunization coverage would be unlikely to prevent future polio outbreaks due to such events. Unlike smallpox, the eventual cessation of OPV must be synchronized across all countries so that the risk of cVDPV decreases rapidly and uniformly throughout the world, thus ensuring that no country is placed at risk of importing a cVDPV from an area where OPV use continues.

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<sup>3</sup> Hull HF, Lee JW. Sabin, Salk or sequential? The Lancet. March 1996

In addition to these primary reasons for eventually stopping routine OPV immunization, continued use of the vaccine would, rarely, lead to prolonged excretion (> 6 months) of a VDPV from a person with a severe primary immunodeficiency syndrome. Theoretically, these 'iVDPVs' could then reintroduce poliovirus into the general population. In 40 years of OPV use, 28 iVDPVs had been documented by end-2004, though none had been shown to cause secondary cases. Four of these were 'chronic' iVDPVs (excretion > 36 months), all of which occurred in high-income countries.

Once eradication of wild poliovirus has been confirmed, the public health benefits of routine immunization with OPV will no longer outweigh the burden of disease due to VAPP and cVDPVs. Despite these shortcomings of OPV, successful eradication depends on maintaining high coverage with this vaccine until the point of simultaneous OPV cessation. Decreases in OPV immunization coverage prior to the time of OPV cessation would put polio-free countries at risk of wild poliovirus importations and cVDPVs.



#### *OPV Facts*

If the worldwide OPV utilization patterns of 2005 continued after confirmation of the eradication of wild-type poliovirus, it is expected that there would be:

- 250 to 500 cases of VAPP per year,
- Up to one polio outbreak due to a cVDPV per year.

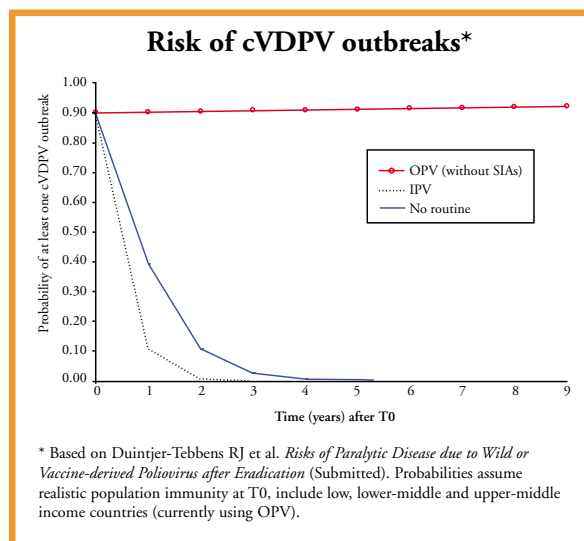
Once eradication of wild poliovirus has been confirmed, the public health benefits of routine immunization with OPV may no longer outweigh the burden of disease due to VAPP and cVDPVs.

### 3. Risks associated with OPV cessation

Although the burden of disease caused by VAPP and cVDPVs will eventually outweigh the benefits of routine OPV immunization, OPV cessation is associated with risks that must be managed appropriately.

For most OPV-using countries, the risks associated with OPV cessation can be summarized in two main categories:

**1. Immediate risk of cVDPV emergence:** once countries simultaneously stop using OPV, there will be a time-limited, rapidly decreasing risk that a vaccine-derived poliovirus could regain neurovirulence and begin to circulate, which would require an outbreak response. For any individual country, the risk of such an outbreak is remote and diminishes rapidly over the 12-24 month period immediately following simultaneous OPV cessation. This risk will be lowest in countries with high routine immunization coverage at the time of OPV cessation. Although the risk of a cVDPV outbreak is low for individual countries, there is an estimated 65-90% chance of such an outbreak occurring somewhere in the world during the first year after simultaneous OPV cessation. This risk will fall to 5-15% by the end of the second year if OPV cessation can be implemented simultaneously worldwide, and will reduce further to 1-5% by the end of the third year.



#### Two main risk-categories associated with OPV cessation:

1. Immediate risk of cVDPV emergence
2. Medium and long-term risks of poliovirus re-introduction from a vaccine manufacturing site, research facility or diagnostic laboratory

**2. Medium and long-term risks of poliovirus re-introduction:** once it has been verified that OPV is no longer being used in routine immunization anywhere, the greatest risks to a polio-free world will be the inadvertent re-introduction of a wild, vaccine-derived or Sabin strain of poliovirus from a polio vaccine manufacturing site, a research facility or a diagnostic laboratory. This risk is low, as documented poliovirus re-introductions were rare even prior to the adoption of international guidelines for the containment of polioviruses by the World Health Assembly in 1999. This risk will diminish further as all countries fully implement appropriate biocontainment of polioviruses and verify that achievement. Achieving appropriate containment of all polioviruses will be extremely important given that the potential harmful consequences of a poliovirus re-introduction will increase substantially as polio-susceptible individuals accumulate after OPV cessation. The risk of reintroduction of a vaccine-derived poliovirus from an iVDPV is still lower, for the reasons noted in section 2 above.

Although the risks associated with stopping OPV use in routine immunization are relatively small, these risks can be further reduced through international implementation of appropriate risk management strategies before, during and after OPV cessation. Implementation of these risk management strategies – or prerequisites – will involve close oversight by National Policy Makers.

## 4. Risk management before, during and after OPV cessation: implementing the prerequisites for OPV cessation

### Six prerequisites for simultaneous OPV cessation:

- I Confirmation of interruption of wild poliovirus transmission globally
- II Appropriate biocontainment of all polioviruses
- III International stockpile of monovalent OPV (mOPV)
- IV Highly-sensitive surveillance for circulating polioviruses
- V Procedure for internationally-simultaneous OPV cessation
- VI Long-term routine polio immunization policy (i.e. national IPV decisions)

The strategies needed to minimize and manage the risks associated with eventual OPV cessation are considered 'prerequisites' for stopping routine immunization with this vaccine. The six prerequisites that have been established for OPV cessation are:

#### I CONFIRMATION OF INTERRUPTION OF WILD POLIOVIRUS TRANSMISSION GLOBALLY

**Issue:** because of the ongoing risk of poliovirus importations into polio-free areas, the interruption of wild poliovirus transmission must be confirmed in every country in the world prior to the cessation of routine polio immunization anywhere.

**Status:** in 1995 the Global Commission for the Certification of Poliomyelitis Eradication (GCC) established the criteria for confirming the interruption of wild poliovirus transmission. As of end-2004, 135 countries in three WHO Regions had been certified polio-free (WHO regions of the Americas, Europe and Western Pacific).

**Next Steps:** intensified efforts are being made to interrupt the remaining chains of

wild poliovirus transmission in the last six polio-endemic countries and the six countries where poliovirus transmission was re-established following importations in 2003-2004. All countries in regions yet to be certified as polio-free must demonstrate zero polio cases for a minimum of three years, in the presence of 'certification standard' surveillance, prior to OPV cessation.

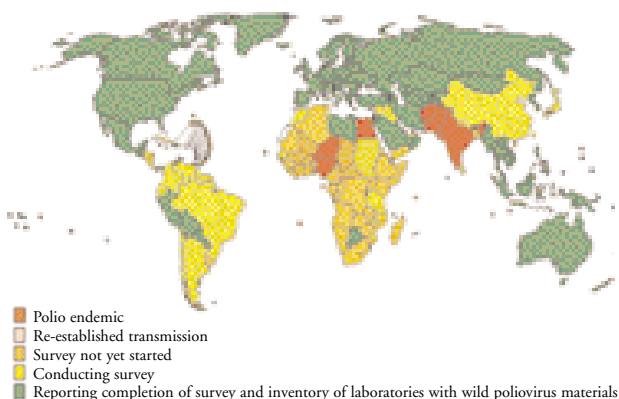
#### II APPROPRIATE BIOCONTAINMENT OF ALL POLIOVIRUSES

**Issue:** all wild, vaccine-derived and Sabin polioviruses must be placed under appropriate biocontainment levels on a timely basis to minimize the risk of re-introduction into a polio-free world.

**Status:** in 2003, high level biosafety requirements were internationally agreed for vaccine-derived and wild-type polioviruses<sup>4</sup>. By end-2004, 152 countries had initiated a survey for wild-type and vaccine-derived poliovirus infectious and potentially infectious materials, covering over 200,000 facilities. Approximately 850 facilities were identified with relevant infectious materials. These materials will either be destroyed or placed under appropriate biocontainment conditions.

**Next Steps:** by the time wild poliovirus

#### Wild poliovirus containment: progress with Phase I - Survey & Inventory, 2004



<sup>4</sup> WHO Global Action Plan for Laboratory Containment of Wild Polioviruses (GAP II), Second edition. World Health Organization, Geneva, Switzerland, 2003. (WHO/V&B/03.11)

transmission is interrupted globally, all countries must have completed a national survey and inventory of facilities holding wild or vaccine-derived polioviruses. The process of destroying or properly containing those materials must be completed twelve months later. At an international level, consensus must be established on appropriate future biosafety containment levels for Sabin viruses, the timing of the implementation of such activities and the mechanisms for verification. The development and licensure of IPV-produced from Sabin strains (SIPV) will continue to be pursued to further reduce the number of sites generating high volumes of high titre wild polioviruses for IPV production.

### III INTERNATIONAL STOCKPILE OF MONOVALENT OPV (MOPV)

**Issue:** an international stockpile of types 1, 2 and 3 monovalent OPV is needed particularly to allow a 'type-specific' response during the process of OPV cessation (thereby enhancing the impact of the outbreak response while preventing the re-introduction of other polioviruses).

**Status:** in 2004, all producers of WHO-prequalified OPV and their respective national regulatory agencies were invited to collaborate with WHO on the development, licensure and production of monovalent type 1, type 2 and type 3 OPV. Working estimates have been established for the number of doses required of each mOPV type, development timelines have been elaborated, and the Global Alliance for Vaccines and Immunization (GAVI) will review a stockpile investment case for funding. As the result of an accelerated vaccine development project, two mOPV type 1 vaccines were licensed in early 2005 and are undergoing large-scale field evaluation.

**Next Steps:** the development, production and procurement of mOPV for the stockpile is scheduled to begin in 2006. The mechanisms and criteria for the future use of the stockpile must be completed and

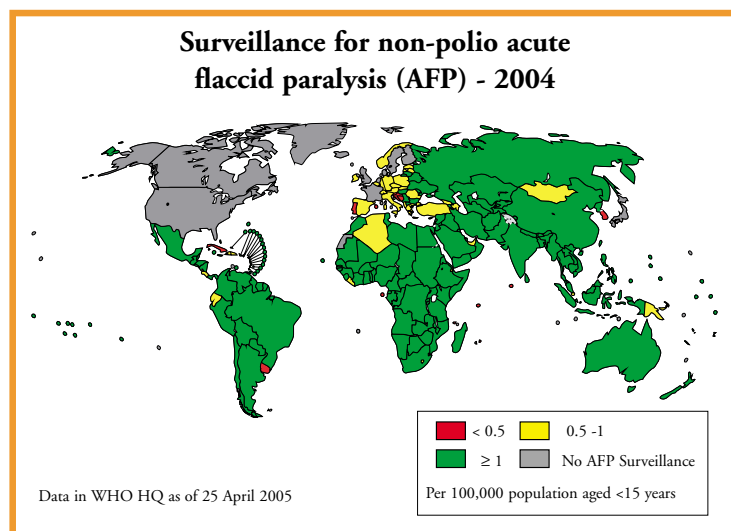
internationally-agreed in a World Health Assembly resolution. The potential role of IPV, and possibly antivirals, in outbreak response must also be fully elaborated.

### IV HIGHLY-SENSITIVE SURVEILLANCE FOR CIRCULATING POLIOVIRUSES

**Issue:** highly sensitive surveillance is required before, during and after OPV cessation to confirm interruption of wild poliovirus transmission, document the elimination of Sabin strains, and rapidly detect the potential re-introduction of any poliovirus.

**Status:** in 2004, 66 polio-endemic or recently-endemic countries met or exceeded the surveillance performance standards established by the GCC, including most countries that are affected or recovering from conflict such as Afghanistan, Angola, the Democratic Republic of the Congo and Somalia. However, declining rates of acute flaccid paralysis (AFP) surveillance in a number of countries that have been certified polio-free, and the recent detection in Africa of polioviruses that were missed due to suboptimal AFP surveillance, re-affirms the need to strengthen surveillance and maintain the full certification surveillance criteria everywhere.

**Next Steps:** all countries must strengthen AFP surveillance to ensure it can be sustained at certification standard throughout the three-year plus period of OPV cessation and verification of the elimination of Sabin- and vaccine-derived polioviruses. In addition, high- and middle-



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income countries should screen for iVDPVs among individuals with primary immunodeficiency syndromes. At the international level, event-based reporting for 'suspect polio' will need to be fully incorporated into the new *International Health Regulations*. New diagnostic tools for the OPV cessation phase, particularly IgM assays and direct molecular detection techniques, must be fully evaluated and integrated into the polio laboratory network.

## V PROCEDURE FOR INTERNATIONALLY-SIMULTANEOUS OPV CESSATION

**Issue:** all countries will need to simultaneously stop the use of OPV for routine immunization to ensure that no country is inadvertently put at risk of importing a cVDPV from a country that continues to use OPV.

**Status:** the international bodies providing oversight to the Global Polio Eradication Initiative have endorsed the need for eventual simultaneous OPV cessation. WHO has begun the process of developing and pilot testing guidelines for the withdrawal of OPV from routine immunization programmes. These guidelines will emphasize the need to maintain the highest possible level of OPV coverage until the actual time of simultaneous OPV cessation.

**Next Steps:** all remaining polio-infected countries must interrupt wild poliovirus transmission as rapidly as possible to allow the development of a firm timeline for OPV cessation. A World Health Assembly Resolution outlining the precise timing and process for simultaneous OPV cessation by all OPV-using countries could be required as early as 2006. At the national level, detailed plans for the withdrawal and destruction of all trivalent OPV stocks, from all levels of the country, will need to be developed and national immunization policies revised accordingly. Following OPV cessation, documentation of the destruction of remaining trivalent OPV stocks will need to be verified in each country.

## VI LONG-TERM ROUTINE POLIO IMMUNIZATION POLICY

**Issue:** each OPV-using country must decide whether to stop all routine immunization against

polio after OPV cessation (after OPV cessation, IPV will be the only option for those countries which decide to continue routine immunization).

**Status:** based on an evaluation of the costs and benefits of continued polio immunization after OPV cessation, and the needs of other disease priorities, WHO is recommending that OPV-using countries do not routinely introduce IPV at that time. WHO is, however, assisting those polio-free countries that have requested support to evaluate the potential role of IPV in their national immunization programme. To facilitate national decision-making on IPV, WHO published an IPV Position Paper in 2004 summarizing the characteristics, efficacy and potential role of the vaccine. A separate WHO study detailed the major programmatic implications of IPV introduction, many of which are not immediately apparent, for most OPV-using countries (e.g. the need to increase cold chain capacity, change the pertussis component of combination vaccines, use vaccines with a different preservative)<sup>5</sup>. Initial results from modelling studies commissioned by the Global Polio Eradication Initiative suggest that for most low-income countries, the introduction of IPV for routine immunization would only marginally reduce the already small risks associated with OPV cessation.

**Next Steps:** any OPV-using country which is considering the potential introduction of IPV should systematically evaluate the risks and benefits of continuing polio immunization following OPV cessation, including the impact this could have on other priority disease control programmes. WHO will continue to review the potential role of IPV as additional data are collected on the risks associated with OPV cessation.

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<sup>5</sup> WHO presentation at 3rd WHO/UNICEF Informal Consultation with IPV and OPV Manufacturers. June 2004, Geneva, Switzerland.

## 5. Timetable for OPV cessation

The timetable for OPV cessation can be divided into three distinct periods correlating with the evolution of the major polio risks and risk management strategies. The precise timing of these phases will depend on the date of interruption of wild poliovirus transmission globally and progress towards achieving the six prerequisites outlined earlier.

**Regional Certification & OPV Cessation Preparatory Phase:** this phase has already begun and will continue for three years after the last case of polio caused by wild-type poliovirus is detected anywhere in the world. The major risk during this period will be undetected wild poliovirus transmission due to suboptimal AFP surveillance. The national polio eradication priorities during this phase are outlined in Box 1.

**OPV Cessation & Verification Phase:** this phase will begin with the simultaneous cessation of OPV worldwide and will continue for at least three years thereafter, until verification of the disappearance of Sabin poliovirus strains from the human population globally, as well as

the absence of cVDPVs. The major risk during this period will be the emergence of a cVDPV (which would trigger a type-specific outbreak response with the appropriate mOPV).

**Post-OPV Era:** this period will begin with the verification of the disappearance of Sabin-strain polioviruses, as well as the absence of cVDPVs. This period will continue indefinitely. The major risks during this period (in decreasing order of potentially-damaging consequences) would be the re-introduction of a wild, vaccine-derived or Sabin-strain poliovirus.

**Potential timeline and priority activities for eventual cessation of oral polio vaccine (OPV) for routine immunization**

Interruption of wild poliovirus	Phase of OPV cessation work		
	Certification & Preparation for OPV Cessation	OPV Cessation & Verification	'Post OPV' Era
	Certify interruption of wild virus transmission	Simultaneously stop all routine use of OPV	Maintain surveillance
	Contain wild & vaccine-derived polioviruses	Contain Sabin strain polioviruses	Maintain stockpile
	Develop mOPV stockpile & criteria for use	Verify the absence of cVDPV & Sabin virus	Verify containment
	Establish national policy on IPV use	Fully integrate poliovirus surveillance into IHR	
-1 0	1 2 3	4 5 6	7 8
Years after last circulating wild poliovirus			

### Box 1: Priorities for National Policy Makers in OPV-Using Countries OPV Cessation Preparatory Phase

- Strengthen polio (AFP) surveillance to guide interruption of wild poliovirus transmission, certify eradication, and detect potential importations and cVDPVs.
- Fully implement – and verify – appropriate containment of wild and vaccine-derived polioviruses and prepare for Sabin-virus containment.
- Raise routine immunization coverage (target >90%) to minimize the risk of spread of an imported poliovirus and the risk of cVDPV emergence.
- Decide - based on analysis of risks, benefits and opportunity costs - whether to stop all routine immunization against polio after OPV cessation (when inactivated polio vaccine will be the only option for continued routine immunization).
- Conduct an iVDPV ‘risk assessment’ and establish a case management plan, if needed.
- Establish national plans and mechanisms for the eventual cessation of all OPV use in routine immunization programmes and destruction of remaining trivalent OPV stocks (note: standard template will be available 12-24 months beforehand).

*Further information and technical support is available from WHO country and regional offices, as well as from the Global Polio Eradication Initiative, WHO Geneva.*

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## 6. Glossary of terms

ACPE	Advisory Committee on Poliomyelitis Eradication
AFP	acute flaccid paralysis
cVDPV	circulating vaccine-derived polioviruses
GAVI	Global Alliance for Vaccines and Immunization
GCC	Global Commission for the Certification of Poliomyelitis Eradication
IHR	International Health Regulations
IPV	inactivated polio vaccine
iVDPV	immunodeficient excretors of vaccine-derived polioviruses
mOPV	monovalent oral polio vaccine
OPV	oral polio vaccine
S-IPV	inactivated polio vaccine produced from Sabin strains
tOPV	trivalent oral polio vaccine
VAPP	vaccine-associated paralytic poliomyelitis
VDPV	vaccine-derived polioviruses
WHA	World Health Assembly
WHO	World Health Organization



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