Major Decisions for OPV2 Withdrawal:

Report from the Polio Working Group

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Overview

- Background
- Major issues for the WG meetings in July and October 2014.
- WG Discussion and Recommendations
- Summary

SAGE Recommendations in April 2014

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Meeting of the Strategic Advisory Group of Experts on immunization, April 2014 – conclusions and recommendations

The Strategic Advisory Group of Experts (SAGE) on immunization[1] met on 1–3 April 2014 in Geneva, Switzerland. This report provides a summary of the discussions, conclusions and recommendations.[2]

Report from the WHO Department of Immunization, Vaccines and Biologicals

The report focused on 3 key issues: (i) sustaining the momentum generated by the Decade of Vaccines (DoV)/Global Vaccine Action Plan (GVAP), (ii) ensuring efforts to effectively support country implementation are sufficient and (iii) identifying areas for more effective coordination and collaboration between WHO and its partners.

The upcoming 40-year anniversary of the WHO Expanded Programme on Immunization (EPI) was celebrated during World Immunization Week, 24–29 April 2014.

The report described the implementation of recent SAGE recommendations on yellow fever, hepatitis A and cholera vaccinations. In January 2014, the WHO Executive Board recommended a draft resolution for consideration by the World Health Assembly in May 2014, calling for an update of the relevant provisions in the *International Health Regulations* (Annex 7) to reflect the life-long protection conferred by 1 dose of yellow fever vaccine. The continued monitoring of the 1 dose hepatitis A vaccination programme in Argentina indicates the

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

Le Groupe stratégique consultatif d'experts (SAGE) sur la vaccination[1] s'est réuni du 1er au 3 avril 2014 à Genève (Suisse). Le présent rapport récapitule les discussions, ainsi que les conclusions et recommandations auxquelles il est parvenu.[2]

Rapport du Département OMS Vaccinations, vaccins et produits biologiques

Le rapport s'est axé sur 3 points essentiels: i) maintenir la dynamique suscitée par le Plan d'action mondial pour les vaccins (GVAP) dans le cadre de la Décennie de la vaccination, ii) veiller à ce que les efforts pour soutenir efficacement la mise en œuvre dans les pays soient suffisants et iii) déterminer les domaines pour une coordination et une collaboration plus efficaces entre l'OMS et ses partenaires.

Le 40e anniversaire du Programme élargi de vaccination (PEV) de l'OMS a été célébré lors de la Semaine mondiale de la vaccination, du 24 au 29 avril 2014.

Le rapport décrit la mise en œuvre des recommandations récentes du SAGE concernant les vaccins contre la fièvre jaune, l'hépatite A et le choléra. En janvier 2014, le Conseil exécutif de l'OMS a recommandé un projet de résolution à soumettre à l'Assemblée mondiale de la Santé en mai 2014 appelant à revoir les dispositions du *Règlement sanitaire international* (Annexe 7) pour y refléter la protection à vie conférée par une dose de vaccin antiamaril. Le suivi continu du programme de vaccination par 1 dose de vaccin contre l'hépatite A en Argentine indique toujours une absence

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[1] See http://www.who.int/immunization/policy/sage/en/
[2] The complete set of presentations and background materials used for the SAGE meeting of 1–3 April 2014 together with summarized declarations of interests provided by SAGE members are available at http://www.who.int/immunization/sage/meetings/2014/april/en/, accessed in April 2014.

[1] Voir http://www.who.int/immunization/policy/sage/en/
[2] La série complète des communications et des documents de travail de la réunion du SAGE tenue du 1er au 3 avril 2014, ainsi que les déclarations d'intérêt fournies par les membres de ce groupe sont disponibles à l'adresse suivante: http://www.who.int/immunization/sage/meetings/2014/april/en/, consultée en avril 2014.

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SAGE recommended:

- Countries with persistent cVDPV2 need to correct the mix of OPV being used in immunization campaigns

- The specifics of the approach for OPV2 withdrawal will be further elaborated by the Polio Working Group for SAGE review in October 2014

Scope of SAGE Polio WG Discussions

Background

- Follow up on SAGE recommendations:
  - WG met in July 2014 to review the status of cVDPV epidemiology and the progress towards OPV2 withdrawal
  - WG had a conference call in October 2014 to follow up some remaining items

Pre-conditions for OPV2 withdrawal

Trigger for OPV2 withdrawal: absence of 'persistent' cVDPV2s globally for at least 6 months

Criteria for judging OPV2 withdrawal readiness:

1) status of IPV introduction into OPV-using countries;
2) access to bOPV licensed for routine immunization;
3) surveillance & response protocols for type 2 poliovirus;
4) phase 1 containment, with appropriate handling of type 2 materials;
5) affirmation of wild poliovirus type 2 global eradication.

WG Discussions/Recommendations

Categories	Discussion Topics	Presentation at SAGE
Trigger	• Optimum vaccine mix in countries with persistent cVDPV2 • Risk mitigation strategy to reduce cVDPV2 emergence at time of OPV2 withdrawal	Hamid
1. IPV introduction	• Status of IPV introduction in priority countries • Operational guidelines for OPV2 withdrawal	Michel
2. bOPV licensure	• Status of bOPV label change in producing countries • Proposal for the global licensure framework for bOPV use in routine immunization	Michel

WG discussions/recommendations

Categories	Discussion Topics	Presentation at SAGE
3. surveillance & response	• Key principles of type 2 response after OPV2 withdrawal	Roland
	• Key principles of management and use of mOPV2 stockpile • Plan for environmental surveillance expansion	Peter
4. Containment	• New containment strategy, aligned with Polio Endgame Plan	Peter

WG discussion and Recommendations:

mOPV stockpile

Key Objectives of mOPV2 Stockpile

Key objectives of mOPV2 stockpile:

- Rapid deployment of vaccines for countries with a type 2 outbreak
- Outbreak response capacity for emergency vaccination against any type 2 poliovirus.

Approaches to mOPV2 stockpile:

- mOPV2 is a global stock: universal access and safe use
- Timely arrival for an effective outbreak response, decision should be made within 24 hours after notification
- The proposed criteria for release include:
  - "Confirmed" or "probable" poliovirus circulation
  - Decision by the Director-General of WHO on advice of a standing expert advisory group.
- Maintain a minimum stock of 100 million doses of mOPV2 in filled and finished form* and 400 million doses of bulk

* Assuming 5 million doses/campaign, 3 rounds of campaigns/outbreak, maximum of 3 outbreaks, and 50% buffer

Proposed Membership of Standing Expert Advisory Group

- Chair SAGE Polio WG
- SAGE Polio WG members
- Experts in emergency response
- Experts in vaccination strategies
- WHO Secretariat

mOPV2 Stockpile: Key Recommendations

The WG reviewed the proposed approach of mOPV2 stockpile and recommends:

- Director-General of WHO to make the decision on the use of the stockpile with advice from the standing expert advisory group within 24 hours of notification
- An initial stockpile should contain 100 million doses of finished mOPV2 product, and replenish when 50% is used
- National stockpiles are to be discouraged to minimize the risk of re-introduction of Sabin type 2 viruses.
- National authorities should be encouraged to facilitate emergency import and use of mOPV2 from the global stockpile

WG discussion and Recommendations:
Surveillance Expansion

Objectives of Expanding Environmental Surveillance

Rationale for expanding environmental surveillance:

- Currently, environmental surveillance is used primarily to supplement AFP surveillance to detect wild poliovirus and cVDPV2
- Following OPV2 withdrawal, the program needs to detect Sabin 2 viruses and AFP surveillance alone is not sufficient to detect virus
- Environmental surveillance also provides supportive data for the certification of polio eradication

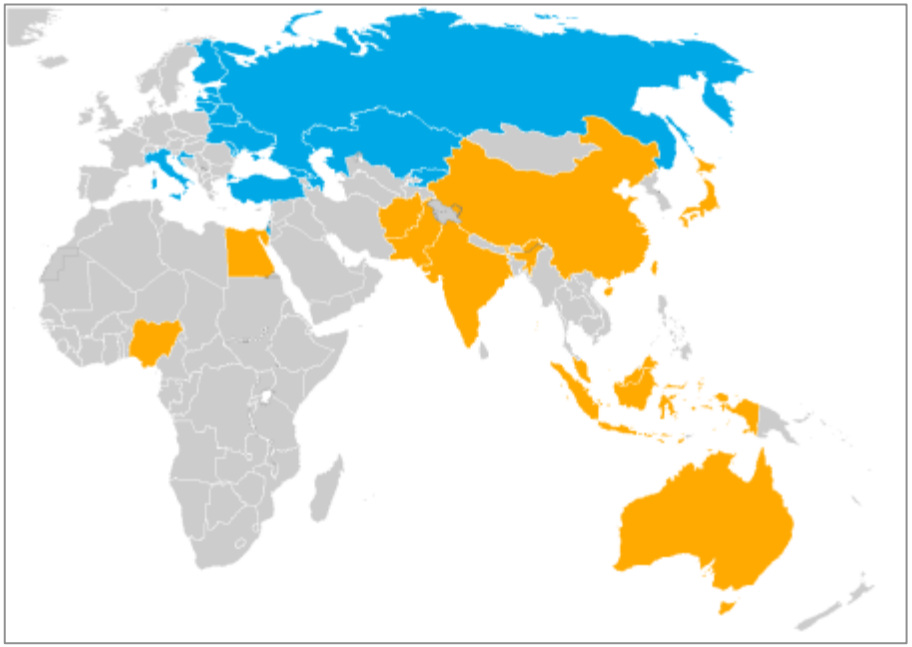
Priorities in new environmental surveillance strategy:

The new Polio Endgame Strategy (2013-18) proposes to establish at least 15-20 additional environmental surveillance sites with particular focus on:

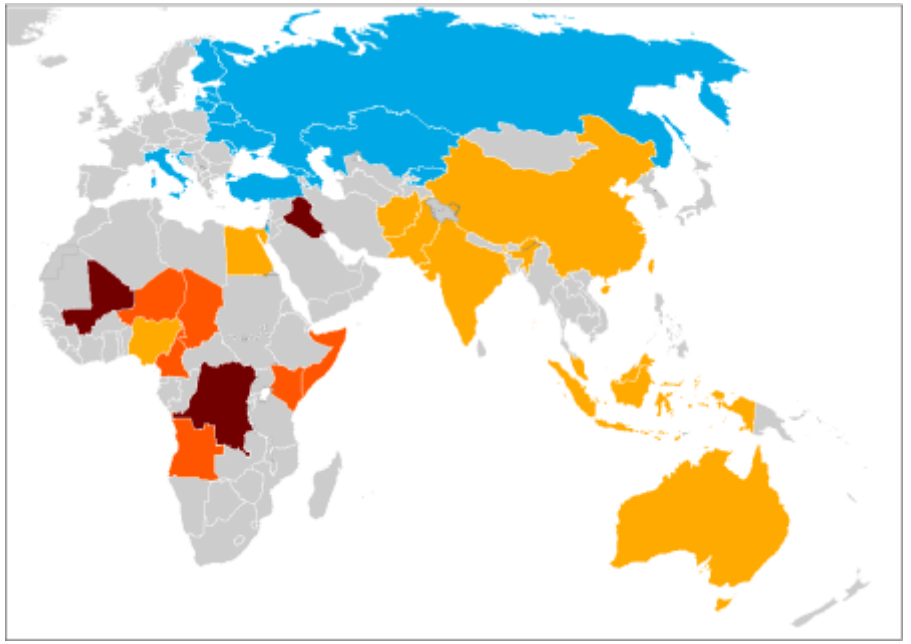
- Sustaining sites in endemic areas and expanding to capture "silent" areas within endemic countries (e.g. South Afghanistan)
- Establishing sites in priority countries along overland known virus exportation routes (e.g. Cameroon, Chad, Niger, Mali)
- Establishing sites in areas at risk for cVDPV emergence (e.g. Kenya, Somalia)

Planned Expansion of Environmental Surveillance

Existing Sites (end-2013)



Proposed Plan (by end-2015)



- EUR: 15 countries Azerbaijan, Belarus, Georgia , Kyrgyzstan , Kazakhstan, Latvia, Lithuania, Republic of Moldova, Russian Federation, Turkey, Ukraine, Italy, Estonia, Finland and Croatia
- ES established by 2013 end: Afghanistan, Australia, China, Egypt, India, Indonesia, Israel, Malaysia, Nigeria, Japan and Pakistan
- Expanded ES by 2014 end: Angola ,Chad, Cameroon, Kenya, Niger and Somalia
- Expanded ES by 2015 end: DR Congo, Iraq and Mali

Environmental Surveillance: Key Recommendations

The WG concluded that ES is a fundamental strategy for early detection and confirming interruption of cVDPV2s after OPV2 withdrawal and recommended:

- **In the short term** (post-OPV 2 withdrawal), ES should be established in areas at high risk of cVDPV2 emergence and circulation, no later than Q3 2015
- **In the longer-term** (post-all OPV cessation), ES sites should include facilities retaining polioviruses (e.g. IPV production sites)
- GPEI should develop diagnostic technology to facilitate rapid virus detection in environmental and clinical samples to identify and investigate outbreaks

WG discussion and Recommendations:
Containment

Key Changes in the Containment Strategy

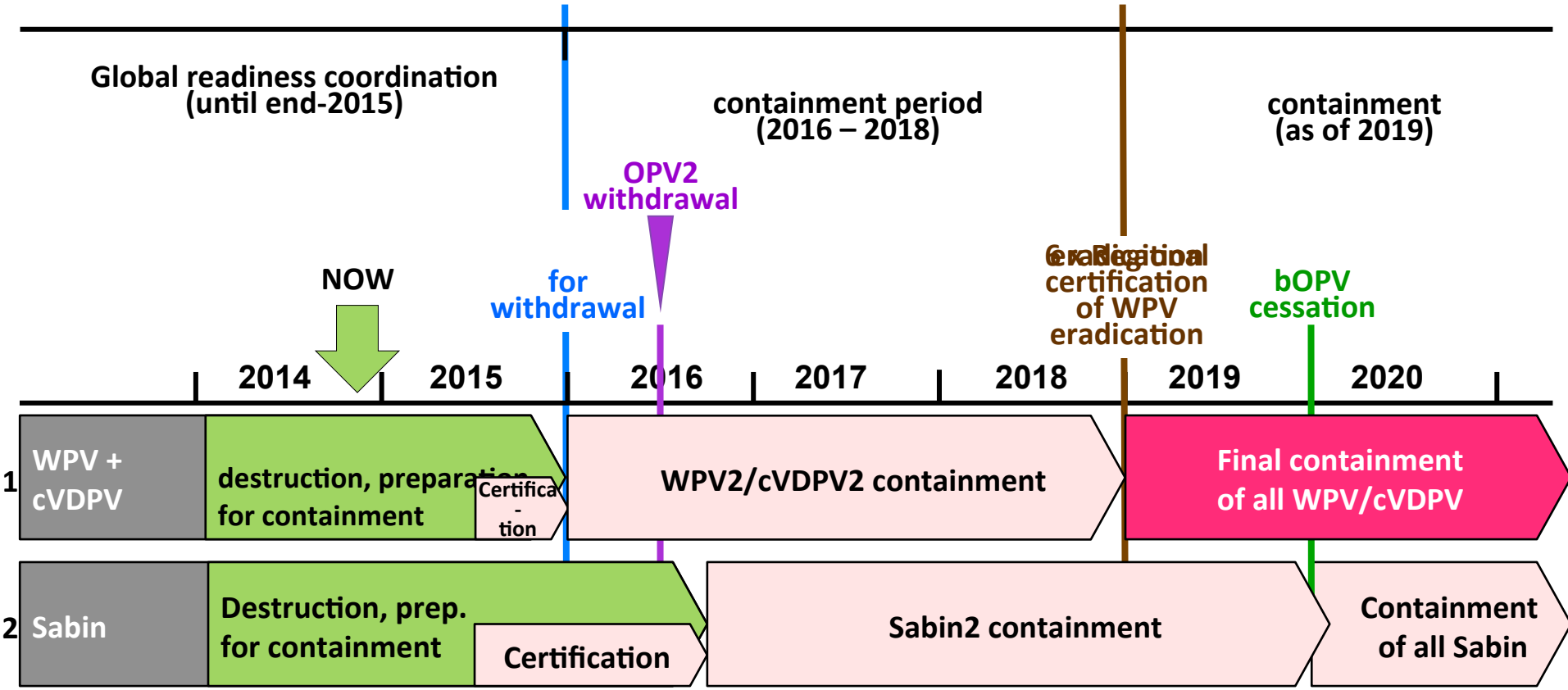
Major changes in eradication strategy since 2009 (when the initial GAP-III draft was published)

- Phased removal of Sabin virus (type 2 first)
- Universal IPV introduction
- Availability of mOPV2 stockpile

Key updates in the containment strategy

- Phased containment of type 2 virus
  - Phase I (Global coordination for readiness)
  - Phase II (Global Type 2 containment)
  - Phase III (Long-term containment)
- In Phase II, all type 2 poliovirus (both Sabin and wild) will be contained with primary and secondary safeguards.
- In phase III, safeguards against wild poliovirus will be strengthened (e.g. effluent and air exhaust treatment, higher population immunity required, addition of tertiary safeguards) while Sabin viruses may be contained with the same safeguards as in phase II

(2014-2020)



The timeline of containment is aligned with the schedule of OPV withdrawal

Overview of Containment Safeguards

	Poliovirus type 2 containment period	Final poliovirus containment period	
Primary safeguards	All type 2 polioviruses	All OPV/Sabin polioviruses	All wild polioviruses
Operator protection	Yes	Yes	Yes
Decontamination of materials/ equipment	Yes	Yes	Yes
Dedicated effluent treatment plant	No	No	Yes
Air/exhaust treatment	No	No	Yes
Secondary safeguards			
IPV doses	≥1	≥1	≥3
IPV coverage	=DTP3 coverage	=DTP3 coverage	> 90%
Tertiary safeguards			
transmission potential (R_0) for wild polioviruses	No	No	Yes

WPV has enhanced containment requirements in "final containment period"

Containment Strategy: Key Recommendations

The WG reviewed the proposed containment strategy and recommends:

- Proceed with the proposed approach to align GAPIII with the Polio Endgame strategy and timelines, particularly the provisions to:
  - phase the containment in line with the planned withdrawal of OPV serotypes (i.e. beginning with type 2), and
  - establish specific containment requirements for 'Poliovirus Type 2 Containment Period' (i.e. 2016-2018).
- Complete phase 1 inventory activities (including for Sabin 2 viruses) in all countries and WHO Regions by end-2015
- Establish a process to review merits and risk-benefit of any

WG Discussion: Summary and Conclusion

  - Environmental surveillance expansion
  - Revision of GAP III document (for bio-containment)
  - Post-OPV2 withdrawal outbreak response
  - IPV introduction/access to bOPV
- At the same time, there is a significant risk of delay in the elimination of persistent cVDPVs by early 2015. WG urges GPEI to consider:
  - More tOPV in campaigns
  - tOPV campaigns to prevent cVDPV2 emergence post OPV2 withdrawal