Outbreak response in post-OPV2 withdrawal era

Strategic Advisory Group of Experts (SAGE) on immunization,

Geneva, 22 October 2014

World Health Organization

Request to SAGE

- Endorse the principles for outbreak response in post-OPV2 withdrawal era

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Overview

- Introduction and background
  - Assumptions
  - WHA resolution on outbreak control
  - Modelling
- Principles of outbreak response
- Outbreak tools
- Other supporting measures
- Summary

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Introduction

2014, 89, 1–20 No. 1

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Organisation mondiale de la Santé

Weekly epidemiological record
Relevé épidémiologique hebdomadaire

3 JANUARY 2014, 89th YEAR / 3 JANVIER 2014, 89e ANNÉE
No. 1, 2014, 89, 1–20
http://www.who.int/wer

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1 Réunion du Groupe stratégique consultatif d'experts sur la vaccination, novembre 2013 – conclusions et recommandations

Meeting of the Strategic Advisory Group of Experts on immunization, November 2013 – conclusions and recommendations

The Strategic Advisory Group of Experts (SAGE) on immunization[1] met on 5–7 November 2013 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 the scale up of immunization services required to reach the Global Vaccine Action Plan (GVAP) goal of 90% national coverage with 3 doses of diphtheria-tetanus-pertussis vaccine (DTP3) in all countries by 2015. This commitment will entail the vaccination of 9.3 million additional infants each year.

Recent successes such as the meningococcal A vaccine project and its impact on the burden of disease and carriage, as well as the delivery of the vaccine using the controlled temperature chain, were noted. Updates were also provided on site-specific results of phase 3 clinical trials of the malaria RTS,S vaccine candidate, the prequalification of the live SA 14-14-2 Japanese encephalitis vaccine as the first WHO prequalified Chinese vaccine, and the life course and integrated approaches to promote the delivery of vaccination with other relevant interventions to children, adolescents, and pregnant women.

Réunion du Groupe stratégique consultatif d'experts sur la vaccination, novembre 2013 – conclusions et recommandations

Le Groupe stratégique consultatif d'experts (SAGE) sur la vaccination[1] s'est réuni du 5 au 7 novembre 2013 à Genève (Suisse). Le présent rapport donne un résumé des discussions, ainsi que les conclusions et recommandations auxquelles il est parvenu.[2]

Rapport du Département OMS Vaccination, vaccins et produits biologiques

Le rapport s'est concentré sur l'extension des services de vaccination nécessaire pour atteindre l'objectif du Plan d'action mondial pour les vaccins (GVAP) d'une couverture nationale par 3 doses du vaccin antidiphtérique-antitétanique-anticoquelucheux (DTC3) de 90% dans tous les pays d'ici 2015. Cet engagement nécessitera de vacciner 9,3 millions de nourrissons en plus chaque année.

De récents succès, tels que le projet de vaccin contre le méningocoque A et son impact sur la charge de morbidité et le portage, ainsi que l'utilisation du vaccin dans le cadre de la chaîne sous température contrôlée, ont été signalés. Des mises à jour ont également été présentées concernant les résultats d'un essai clinique de phase 3 mené dans différents pays portant sur le vaccin candidat antipaludique RTS,S, la préqualification du vaccin vivant atténué SA 14-14-2 contre l'encéphalite japonaise qui devient ainsi le premier vaccin chinois préqualifié par l'OMS, et les approches intégrées, pour toutes les étapes de la vie, destinées à promouvoir la prestation de services de vaccination en même temps que d'autres interventions pertinentes ciblant les enfants, les adolescents, et les femmes enceintes.

[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 5–7 November 2013 together with summarized declarations of interests provided by SAGE members are available at: http://www.who.int/immunization/sage/meetings/2013/november/en/index.html accessed in November 2013.

[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 5 au 7 novembre 2013, ainsi que les résumés des déclarations d'intérêt fournies par les membres de ce groupe sont disponibles à l'adresse suivante: http://www.who.int/immunization/sage/meetings/2013/november/en/index.html, consultée en novembre 2013.

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- In November 2013, SAGE reviewed the type 2 response strategy and requested the WG to draft the protocol for review by SAGE

- Following the request, WHO Secretariat drafted a Protocol for notification, risk assessment & response.

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Outbreak protocol for post OPV2 era

Protocol for notification, risk assessment, and response following detection of poliovirus type 2 following globally-coordinated cessation of serotype 2-containing oral polio vaccine

(Draft version 14 October 2014)

- Detection
- Notification
- Risk assessment
- Response strategy and scope of response

B Burkholder & RAP

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Assumptions

- *Having achieved:*
  - elimination of "persistent" cVDPVs
- *Maintaining*:
  - sensitive surveillance systems (globally)
  - outbreak response capacity
  - emergency funding in hand
- *Access to*:
  - a stockpile of adequate quantities of monovalent type 2 OPV (mOPV2) & access to substantial quantities of IPV
  - a rapid release / shipping mechanism for stockpile vaccine
  - emergency regulatory procedures for use

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Background

- Resolution WHA 59.1 (2006) outlines the principles for outbreak control
- K Thompson et al (2006) demonstrated that *speed trumps quality*:
  - "We find that delay in response represents a crucial risk factor for occurrence of large outbreaks and we characterize the tradeoffs associated with delaying the initial response to achieve better population coverage."
- K Thompson et al (2014) suggest that the risk of *new cVDPV emergence* in areas with mass control activities is very low
- With Sabin type 2 withdrawal, new cohorts will have no (much reduced) mucosal immunity – time since OPV2 withdrawal becomes important
- IPV introduction will mitigate the risk of paralysis, but may have little impact on transmission

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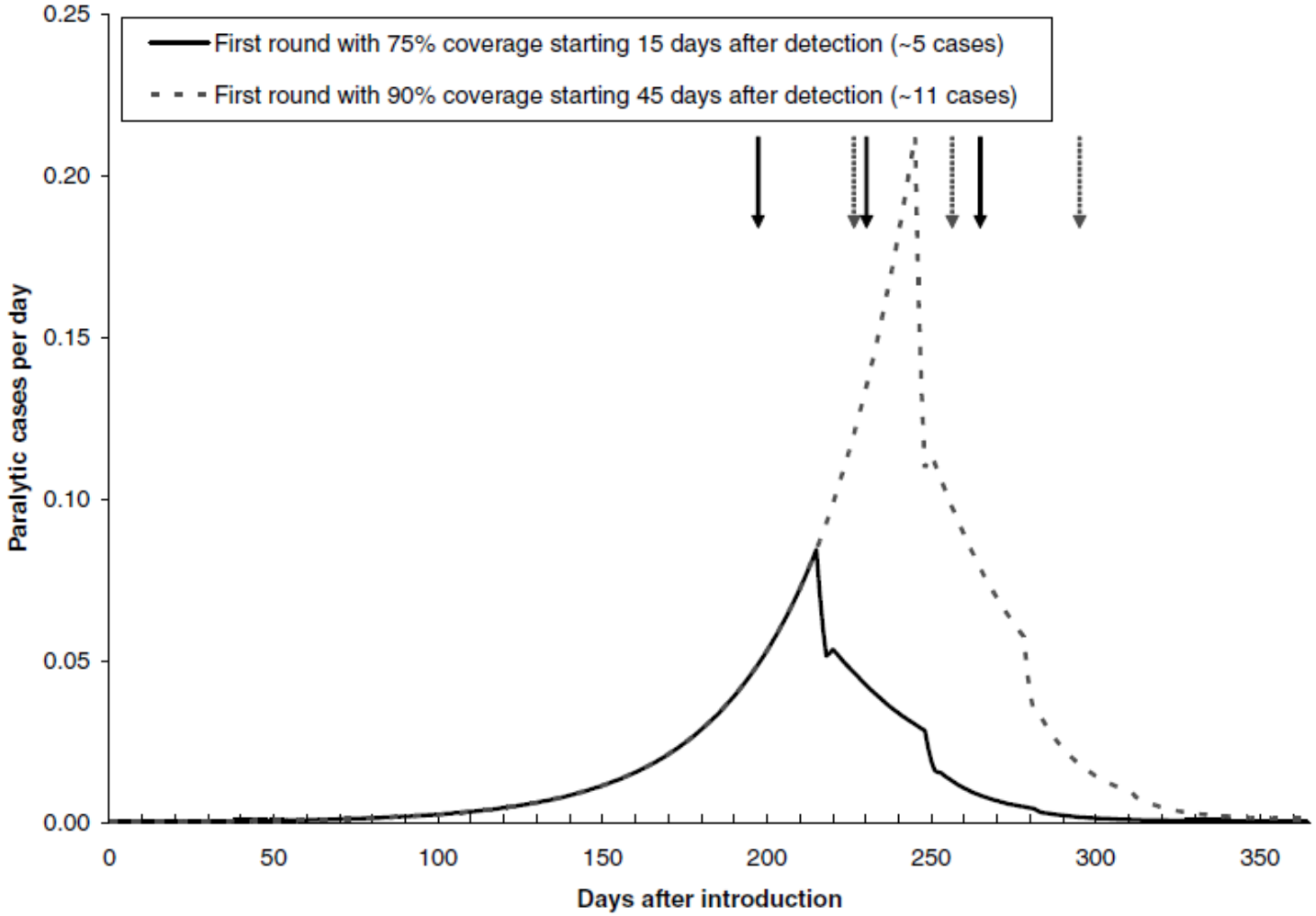
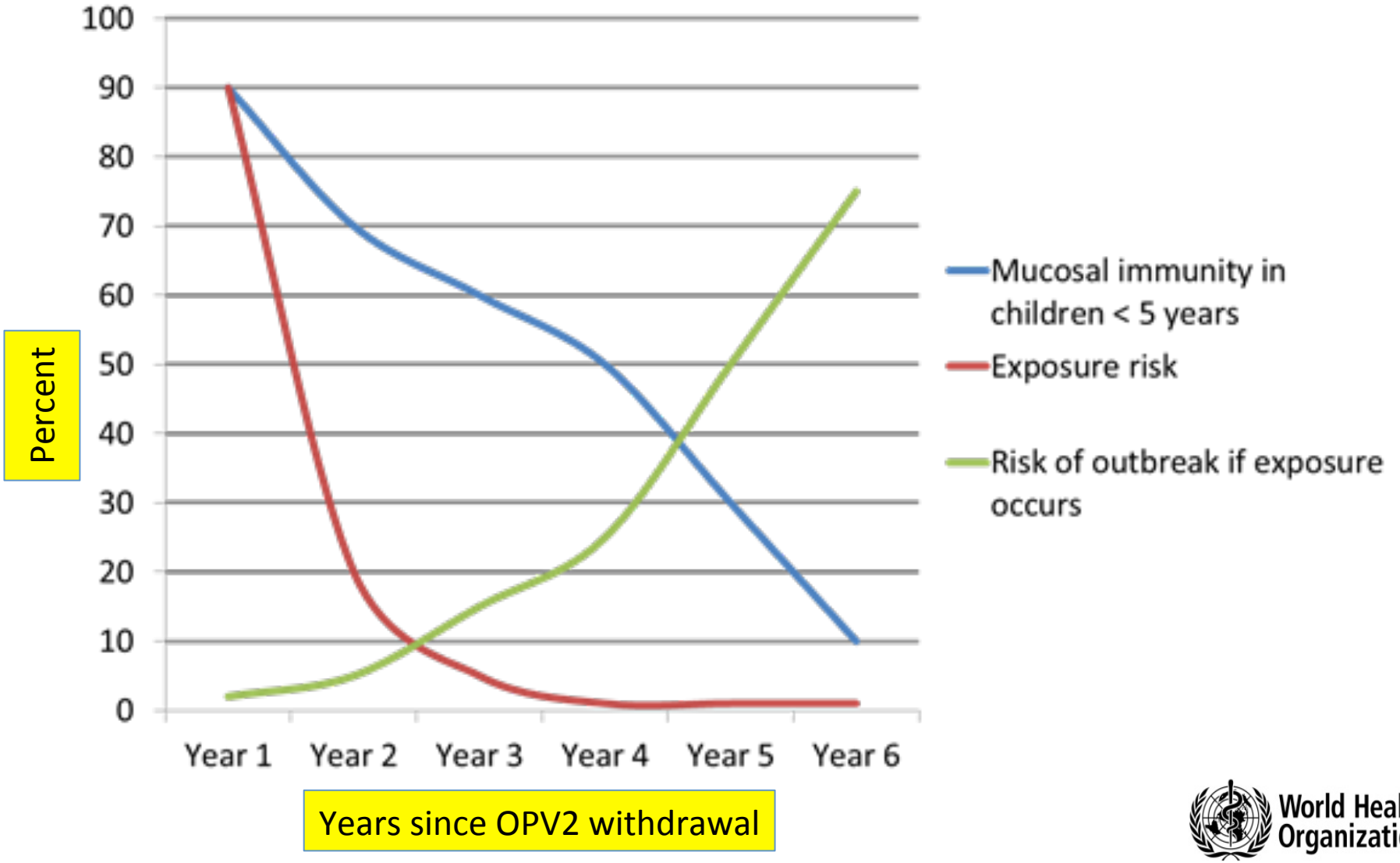


Fig. 2. Impact of a pre-OPV cessation response scenario with rapid first round in a low-income country with 10 million people, 50% routine OPV vaccination coverage, acute flaccid paralysis surveillance, and low-medium R_0 (=10), which conducted no supplemental immunization activities in the three years prior to the outbreak. Both response scenarios target children less than five years of age with mOPV and occur at 30-day intervals with the second and third rounds achieving 90% coverage. Arrows indicate the timing of response rounds.

Thompson K et al. Risk Analysis, Vol. 26, No. 6, 2006 DOI: 10.1111/j.1539-6924.2006.00843.x

cVDPV emergence and consequences



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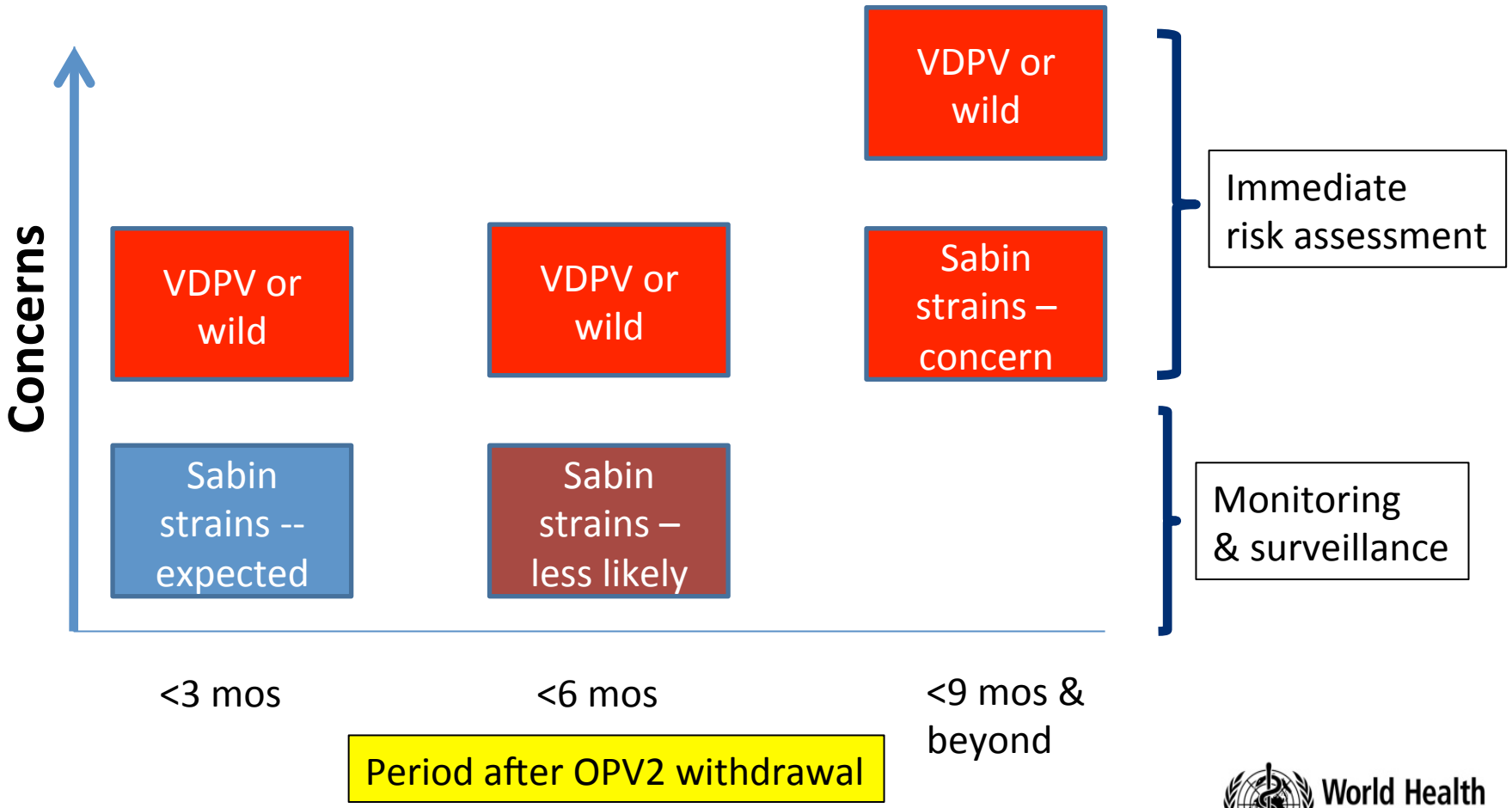
Transition after OPV withdrawal



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Outbreak response

Existing (WHA 59.1 - 2006)

- *Starting point*: isolation of wild poliovirus or cVDPV
- *Initial investigation*: <72 hours
- *Principles*: ≥3, type-specific, large-scale SIAs rounds, <5 years, 2-5 million minimum, ≥95% coverage, 2 rounds after last case
- *Surveillance*: >2 cases/100,000 <15 yrs (duration + 12 mos afterwards)
- *Routine immunization coverage:* >80%

New (post-OPV2 withdrawal)

- *Starting point*: circulation of poliovirus
- *Risk assessment*: <48 hours
- *Principles*: Similar, but vaccine choice, age group dependent on epidemiology/assessment
- *Vaccine*: DG release mOPV2, advice of independent committee
- *Quarantine and/or travel restrictions*: Possible
- *Ring vaccination*: Outside outbreak area: Likely (IPV)

Substantially different

Notification

- *Sensitive surveillance* & rapid notification are critical
- *Follow-up laboratory investigations*, especially sequencing guide outbreak control measures (Sabin, VDPV, iVDPV, cVDPV)
- *International Health Regulations:*
  - detection of any type 2 poliovirus must be reported
- *WHA 2015 resolution* to further emphasize rapid detection & reporting

Classification of poliovirus type 2 circulation

	Risk assessment	Potential risk for further transmission
Confirmed	detection of infected individual (s) –WPV or VDPV- without documented physical exposure to a virus in a laboratory or production facility	High
Probable	detection of genetically related viruses from ≥2 environmental samples consistent with circulation in the population	Medium
Possible	isolation of a type 2 virus in a single environmental sample or from an individual with documented exposure	Low

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Control tools

- *Vaccines (active immunization)*:
  - mOPV2 (mucosal immunity), IPV (boosting of mucosal immunity in previously OPV-vaccinated + humoral immunity in naïve)
- *Antivirals:*
  - Post-exposure prophylaxis, clearing of chronic infection (iVDPV), adjunct to other tools
- *Antibodies (passive immunization):*
  - Immediate protection against paralysis (monoclonal antibodies)

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Response Strategy

Strategy	Confirmed	Probable		Possible
Assessment	Rapid assessment/response planning			Rapid assessment
Response	OPV in primary zone + IPV in adjacent risk areas	**(cVDPV)** OPV in primary zone+ IPV in adjacent risk areas	**(iVDPV)** IPV in primary response zone	Based on assessment
Surveillance	Enhance surveillance			Continue investigation and enhance surveillance

Scope of Outbreak Response

Phase	Zone 1: Clear history of sustained WPV or reported cVDPV2 since 2000; OR affected community with other risks for low immunity or high mobility to susceptible communities				Zone 2: Consistently low DTP3 coverage <80% in the previous 3 years; OR history of imported WPV or any cVDPV in the previous 3 years; OR with DTP3 coverage <90% and adjacent to affected area				Zone 3: DTP3 coverage consistently >80%; affected community with few risk factors for sustained transmission			
	Min age group (yrs.)	Min Target pop	Geographic scope beyond primary zone	Min # of SIA	Min age group (yrs.)	Min Target pop	Geographic scope beyond primary zone	Min # of SIA	Min age group (yrs.)	Min Target pop	Geographic scope beyond primary zone	Min # of SIA
Phase 1 (<2 years)	0-10	1 million	Extend widely to adjacent communities	3	0-5	1 million	Extent depends on links and risk factors of adjacent areas	3	0-5	Depend on situation	Extent depends on links and risk factors of adjacent areas	3
Phase 2 (3-5 years)	0-10	1 million		3	0-10	1 million		3	0-5			3
Phase 3 (6+ years)	0-15+	2 million		5	0-10	1 million		4	0-10	1 million		3

Other supplemental measures

- *Ring vaccination:*
  - Improve immunity around affected areas to decrease risk of generating new VDPVs
- *Vaccination for travellers:*
  - National & international travellers from outbreak area should be vaccinated before leaving
- *Quarantine:*
  - Measure of last resort (more feasible for exposed laboratory or vaccine production staff)
- *Surge / communications*

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Summary & conclusions

- The time-tested and successful principles for outbreak control should be applied
- Population immunity, especially mucosal immunity begins to decrease, choice of vaccine, geographic areas, target age groups, also change with time
- The re-introduction risk of an eradicated agent (poliovirus type 2) must be weighted against the possible benefits & needs
- In general, a conservative approach to outbreak response appears warranted

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Request to SAGE

- SAGE requested to endorse these principles for outbreak response in post-OPV2 withdrawal era

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Thank you so much for your attention!

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