日医発第917号（健Ⅱ）
令和６年８月23日

都道府県医師会
感染症危機管理担当理事　殿

日本医師会感染症危機管理対策室長
笹本　洋一

世界的なポリオ根絶に向けた、不必要なポリオウイルスの廃棄について

今般、厚生労働省より各都道府県等衛生主管部（局）宛標記に係る通知２件がなされ、本会に対しても周知方依頼がありました。

急性灰白髄炎（ポリオ）については、世界保健機関（WHO）において根絶に向けた最終的な取り組みが進められており、2026年までに全ての型のウイルスを封じ込めることを目標としています。

第24回世界ポリオ根絶認証委員会会合（別添：概要報告書）では、国際的な根絶状況を踏まえ、封じ込め対象について、これまで対象であった２型（野生株・Sabin株）に加え、2019年に根絶が認証された３型の野生株、流行国を除く全ての国においては、１型の野生株も対象とする方針が示されました。

本件は、これを踏まえ、医療機関及び研究機関等に対し、今後の廃棄に係る対応について、周知及び協力要請をお願いするもので、概要は下記のとおりです。

なお、２型（野生株・Sabin株）についてはこの度、廃棄対象の定義が変更され、平成27年12月15日付(地Ⅲ186F)をもって貴会宛ご連絡した平成27年12月11日付け健感発1211第１号厚生労働省健康局結核感染症課長通知は廃止されました。

つきましては、貴会におかれましても本件についてご了知のうえ、郡市区医師会及び関係医療機関に対する周知方について、ご高配のほどよろしくお願い申し上げます。

記

○感染性のある１型、２型及び３型野生株ポリオウイルス及び変異型ワクチン由来ポリオウイルスを含む材料（各通知の別紙に掲げられているもの）については、速やかに廃棄すること。

- 廃棄の方法については、エンテロウイルス属ポリオウイルスとして、感染症法に規定する四種病原体等であることから、感染症法施行規則第31条の34第３項に規定する方法で滅菌の上、廃棄すること。感染性のある２型ワクチン株ポリオウイルスを含む材料（２型に係る通知の別紙の２に掲げられているもの）についても、同様の方法で廃棄することが望ましい。

○各通知の別紙に掲げられているものを継続して保有する必要があると考える場合は、令和６年12月末までに、その施設等の責任者から、厚生労働省健康・生活衛生局感染症対策部感染症対策課病原体等管理対策係（TEL:03-3595-3097、Mail:polio.nac@mhlw.go.jp）まで連絡すること。

（参考）
厚生労働省HP　世界的なポリオ根絶に向けた対応について：
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/kenkou/kekkaku-kansenshou/polio/index_00001.html

感感発０８２２第１号
令和６年８月２２日

各{都道府県 / 保健所設置市 / 特別区}衛生主管部（局）御中

厚生労働省健康・生活衛生局
感染症対策部感染症対策課長
（　公　印　省　略　）

世界的なポリオ根絶に向けた、不必要なポリオウイルス（１型及び３型）の廃棄について
（周知及び協力依頼）

急性灰白髄炎（以下「ポリオ」という。）については、昭和63年５月の世界保健総会における決議に基づき、世界保健機関（以下「WHO」という。）によるポリオ根絶に向けた取り組み（世界ポリオ根絶計画）が推進されているところです。

国内においては、昭和 56 年以降、野生株ポリオウイルスによる症例は報告されておらず、我が国を含むWHO西太平洋地域においても、平成12年以降、輸入例を除き、野生株ポリオウイルスによる症例の根絶状態が続いています。

また、世界全体でも野生株ポリオウイルスによる症例は７例（令和５年）まで減少し、令和６年８月13日時点で野生株ポリオウイルスの伝播が確認されているのは、アフガニスタン及びパキスタンの二ヵ国のみとなっています。

こうした現状を踏まえ、WHOでは、ポリオ根絶に向けた最終的な取り組みとして、「ポリオ根絶戦略2022-2026（Polio Eradication Strategy 2022-2026)」を進めており、2026年までに全ての型のポリオウイルスを封じ込めることを目標としています。

今般、「世界ポリオ根絶認証委員会」（別添：第24回世界ポリオ根絶認証委員会会合の概要報告書）にて、国際的な根絶状況を踏まえ、これまで封じ込め対象であった２型のポリオウイルス（野生株・Sabin株）に加え、2019年に根絶が認証された３型の野生株ポリオウイルスも封じ込め対象とすること、同様に、

１型の野生株ポリオウイルスについても、流行国を除く全ての国で、封じ込め対象とする方針が示されました。

つきましては、我が国においても、世界的なポリオ根絶に向けた取り組みを推進するため、上記の趣旨をご理解の上、貴管下市町村、医療機関及び研究機関等に対し、下記について周知及び協力要請をいただきますようお願いします。

記

1. 感染性のある１型及び３型野生株ポリオウイルス及び変異型ワクチン由来ポリオウイルスを含む材料（別紙に掲げられているもの）については、速やかに廃棄すること。

   なお、廃棄の方法については、エンテロウイルス属ポリオウイルスとして、感染症の予防及び感染症の患者に対する医療に関する法律（平成 10 年法律第 114 号）に規定する四種病原体等であることから、感染症の予防及び感染症の患者に対する医療に関する法律施行規則（平成 10 年厚生省令第 99 号）第 31 条の 34 第３項に規定する方法で滅菌の上、廃棄すること。

2. 別紙に掲げられているものを継続して保有する必要があると考える場合は、令和６年 12 月末までに、その施設等の責任者から、厚生労働省健康・生活衛生局感染症対策部感染症対策課まで連絡すること。

以上

【問い合わせ】
厚生労働省健康・生活衛生局感染症対策部
感染症対策課　病原体等管理対策係
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別紙

感染性のある１型及び３型の野生株ポリオウイルス及び変異型ワクチン由来ポリオウイルスを含む材料（※１）

- 1 型及び 3 型野生株ポリオウイルス（VDPV（※２）含む）の感染が確認された臨床検体
- 1 型及び 3 型野生株ポリオウイルス（VDPV 含む）の存在が証明された環境水あるいは水サンプル
- 1 型及び 3 型野生株ポリオウイルス（VDPV 含む）の細胞培養分離株と参照株
- 1 型及び 3 型の不活化ポリオワクチン生産に必要な種株およびその産物
- 1 型及び 3 型野生株ポリオウイルス（VDPV 含む）を感染させた動物（ヒトポリオウイルス受容体トランスジェニックマウスを含む）または感染動物に由来する検体
- Sabin 株より安全であることが証明されていない、1 型及び 3 型野生株ポリオウイルス由来のカプシドシークエンスを含む感染性ウイルス（※３ ※４）
- 1 型及び 3 型野生株ポリオウイルス（VDPV 含む）持続感染細胞

※１）Sabin 株を除く。

※２）VDPV(Vaccine-derived polioviruses):変異型ワクチン由来ポリオウイルス

※３）GAPIII から GAPIV への改訂にともなう野生株ポリオウイルスの定義の変更を反映し、「カプシドシークエンスを含む誘導体(derivative)」あるいは「核酸(full-length RNA or cDNA)」は、「カプシドシークエンスを含む感染性ウイルス(infectious viruses)」に改訂した。

※４）野生ポリオウイルスのカプシドシークエンスを含む新しい感染性ウイルスの安全性は、WHO が招集する専門家パネルによって評価され、Sabin 株と比較して（i）弱毒の程度と安定性；（ii）人から人への伝播の可能性；（iii）動物モデルにおける神経病原性が検討される必要がある。

別添

Summary Report from the Twenty-fourth Meeting of the Global Commission for Certification of Poliomyelitis Eradication

Geneva, Switzerland, 22-23 November 2023

World Health Organization

Members of the Global Commission for Certification of Poliomyelitis Eradication, Regional and Global Secretariats and GPEI partners

GCC members, left to right, front row: Professor Yagoub Al-Mazrou, Dr Arlene King, Professor Mahmudur Rahman, Professor David Salisbury, Professor Rose Leke, Dr Nobuhiko Okabe, photo taken at the 23rd meeting in Amman

Abbreviations

Containment

CAG	Containment Advisory Group
CC	Certificate of Containment
CCS	Containment Certification Scheme to support GAPIII
CP	Certificate of Participation
CWG	Containment Working Group of the GCC
ICC	Interim Certificate of Containment
GAPIII	Global Action Plan for Poliovirus Containment, 3rd edition, 2014
NAC	National Authority for Containment
PEF	Poliovirus-Essential Facility

Certification

GCC	Global Commission for Certification of Poliomyelitis Eradication
NCC	National Certification Committee
RCC	Regional Commission for Certification of Poliomyelitis Eradication
AmRCC	RCC of the Americas
AfRCC	African RCC
EMRCC	Eastern Mediterranean RCC
EuRCC	European RCC
SEARCC	South East Asian RCC
WPRCC	Western Pacific RCC

Viruses and vaccines

IPV	Inactivated poliomyelitis vaccine
OPV	Oral poliomyelitis vaccine
bOPV	Bivalent oral poliomyelitis vaccine containing Sabin type 1 and 3
mOPV2	Monovalent oral poliomyelitis vaccine Sabin type 2
nOPV2	Novel oral poliomyelitis vaccine type 2
PV	Poliovirus (PV1 is PV type 1 etc)
VDPV	Vaccine-derived poliovirus
aVDPV	Ambiguous vaccine-derived poliovirus
cVDPV	Circulating vaccine-derived poliovirus
iVDPV	Immunodeficiency-associated vaccine-derived poliovirus
WPV	Wild poliovirus
WPV1	Wild poliovirus type 1
WPV2	Wild poliovirus type 2
WPV3	Wild poliovirus type 3

Others

AFP	Acute Flaccid Paralysis
BMGF	Bill and Melinda Gates Foundation
CDC	Centers for Disease Control (United States of America)
ES	Environmental surveillance
GPEI	Global Polio Eradication Initiative
IDP	Internally Displaced Persons
IMB	Independent Monitoring Board
KPI	Key Performance Indicator
LQAS	Lot Quality Assurance Sampling
PID	Primary Immunodeficiency Disorders
SAGE	Strategic Advisory Group of Experts on immunization
TAG	Technical Advisory Group
ToR	Terms of Reference
WHO	World Health Organization

Contents

Introduction

The 24th meeting of the Global Commission for Certification of Poliomyelitis Eradication (GCC) took place in Geneva on 22 – 23 November 2023, chaired by Professor David Salisbury. Commission Members are chairs of their respective Regional Commissions for Certification of Poliomyelitis Eradication (RCC):

Professor David Salisbury – WHO European Region,

Professor Yagob Al-Mazrou – WHO Eastern Mediterranean Region,

Dr Arlene King – WHO Region of the Americas, and Chair, GCC Containment Working Group,

Dr Nobuhiko Okabe - WHO Western Pacific Region,

Professor Mahmudur Rahman – WHO South-East Asian Region.

Professor Rose Leke Chair of the WHO African Region Certification Commission was unable to attend.

Aim and Objectives

The aim of the meeting was to ensure global certification of poliovirus eradication takes place in a timely manner with transparent processes.

The main objectives of the GCC meeting were:

- To review progress towards eradication of WPV, including the response to the outbreak of WPV1 in south-eastern Africa;
- To review progress towards stopping and preventing outbreaks of cVPDV2;
- To make recommendations regarding the criteria for certification of elimination of cVDPVs;
- To review progress on containment of polioviruses, focusing on timelines of PV2 containment in view of ongoing use of type 2 polio vaccines in response to cVDPV2 outbreaks, and make recommendations in this regard, and
- To review the outcomes of the mid-term review of the Global Polio Eradication Strategy 2022-2026, and make recommendations accordingly vis-à-vis certification of poliomyelitis eradication.

The agenda is included in appendix 1.

Session 1: Endemic Countries Update

Polio eradication in Afghanistan

The WHO Afghanistan polio team gave a detailed presentation covering:

- the current status of polio eradication in Afghanistan,
- efforts to stopping poliovirus transmission,
- surveillance performance and efforts to improve sensitivity,
- geographies and populations of concern for surveillance.

In summary, the Afghanistan polio team asserted that the situation represented the best opportunity ever to stop poliovirus transmission. Intense vaccination interventions were conducted to stop transmission in endemic areas and prevent establishment in the rest of the country. Limitations in SIA modality remains the key bottleneck to eradication. There is a functional community-based surveillance system achieving targets of global indicators. The surveillance system has inbuilt quality assurance mechanisms, and surveillance audits have identified gaps which were being addressed, primarily related to documentation. Identified areas and populations of concerns were under higher scrutiny.

Polio eradication in Pakistan

The WHO Pakistan polio team gave a detailed presentation covering:

- the WPV1 epidemiology,
- the polio surveillance system,
- main challenges,
- population immunity to stop transmission.

Endemic transmission (YB3C cluster) remains restricted to south KP, however, the intensity of transmission declined significantly in 2023. Repeated introduction of YB3A cluster strains has been detected in all provinces of Pakistan. There is evidence of local transmission of the imported YB3A strains in Karachi and Peshawar. The increased detection of YB3A strains across Pakistan during the last three months is consistent with known seasonal population movements and the high poliovirus transmission season. A massive repatriation of Afghani population from Pakistan increased the risk of further spread within Pakistan and cross-border

The surveillance system has been strengthened further since the previous GCC meeting in February 2023 - field surveillance and laboratory capacity improved significantly. Poliovirus transmission has been detected from even remote districts and detection matches with the recent population movement. The current surveillance system has the ability to detect even low-level transmission.

The programme has been able to build and maintain high population immunity except in a few access compromised areas. Maintaining high immunity in these difficult to

access populations and areas remains a big challenge.

Session 1 Conclusions

Pakistan / Afghanistan

1. GCC appreciates the detailed briefings provided by the Afghanistan and Pakistan polio teams, facilitated by the Eastern Mediterranean RCC and WHO EMRO.

2. GCC noted the ongoing WPV1 transmission in the endemic zones of Afghanistan and Pakistan, the eastern part of Afghanistan and southern Khyber Pakhtunhwa (KP) of Pakistan, respectively

3. Since quarter 2 of 2023, there is WPV1 spread from endemic zones to epidemiologically important areas like Kandahar in Afghanistan and Peshawar, Karachi and Quetta Block in Pakistan, detected mainly through environmental surveillance.

Session 1 Recommendation

Continuing to coordinate closely with the EMRCC concerning the situation in Afghanistan and Pakistan including surveillance quality, in order that certification remains high quality and robust.

Session 2: Global Surveillance and Certification

Update on iVDPV Surveillance and bOPV cessation

The GCC received a presentation on iVDPV surveillance from the GPEI working group on this topic. The aim of the presentation was to inform GCC about current status of iVDPV surveillance and plans for the future and to align the iVDPV portfolio with GCC's strategy on certification of VDPV eradication.

Field implementation of iVDPV surveillance is feasible and works. However "one size does not fit all" as countries have very different systems of immunology care with some centralized and others fragmented and the surveillance strategy needs to consider these differences. Sensitivity of surveillance will never be perfect as it is based on sentinel sites, and undetected iVDPV excretors will continue to exist. Setting up surveillance takes time and requires financing. The highest risk of iVDPV emergence and spread is in countries that use bOPV in RI, have a large population, have PID diagnostic and treatment capacity allowing PID patients to survive, have low RI coverage permitting iVDPV spread and have a high proportion of consanguine marriages

Regarding bOPV cessation planning, the presentation updated the GCC on planning for bOPV cessation in order to seek GCC's guidance on how to validate absence of persistent cVDPVs which is a pre-requisite for bOPV cessation.

The risks of failure to control cVDPVs following bOPV cessation are similar to those following the tOPV-bOPV switch. The main risk is undetected cVDPV1/3 circulation at the time of cessation. High population immunity for types 1 and 3 before bOPV cessation is the best prevention against failure and pre-cessation bOPV campaigns must focus on identified high-risk areas and consequential geographies. Outbreak capacity including type specific OPV vaccines must be established.

Progress in Implementation of Global Polio Surveillance Action Plan

The GPEI Surveillance Group provided an update, comprising:

Surveillance indicators performance globally shows a system that is moderately sensitive.

In 2022 and 2023 YTD, 61% of priority countries have >80% of districts with a NPAFP >=2, which is above the certification target. There has been little change in stool adequacy from 2022 to 2023 with majority of countries meeting the indicator at the national level, but heterogeneity in performance at district (Admin 2) level.

Although new laboratory methods such as direct detection are still being piloted, improvements in logistics and transports of samples decreased the time to detection for key countries from 2022 to 2023 (YTD):

- –Somalia 85 days to 48 days
- –Madagascar 110 days to 80 days
- –DRC 90 days to 74 days

Most priority countries are unable to maintain a sensitive ES network with the majority of sites with EV detection rates below 50%. ES is a good tool but can only complement AFP surveillance and cannot be implemented everywhere; ES is limited by:

- the type of sewage system,
- density of population,
- type (high risk) population.

ES is not a population based surveillance system but rather it a "sentinel system" which should be used to cover high risk populations where possible. A high number of ES sites with limited sensitivity is costly and can be misleading through offering false reassurance. The negative predictive value of many sites is difficult to interpret-no detected poliovirus does not mean absence of virus. Results from a sensitive site should be interpreted only for the population it is draining and cannot be extrapolated to the general population. More data is needed to define a high quality ES site and ES system within a country. EV detection of 50% should be a minimum; 80% EV detection should be the standard for a sensitive site.

Criteria for Certification of WPV1 & cVDPVs Elimination

The GCC considered the position paper drafted by an expert working group to develop principles that should be applied to determine when cVDPV transmission has been eliminated. The paper in addition to discussing the principles also recommended that terminology be updated, in particular that the term **‘validation of absence’** for documenting the end of cVDPVs be replaced with ‘certification of elimination of cVDPV’.

Eradication is the permanent reduction to zero of the worldwide incidence of infection

caused by a specific pathogen, as a result of deliberate efforts, with no risk of reintroduction. No further actions are required, although interventions may be required for a buffer or transition period; eradication is permanent, barring release from containment laboratories maintaining stocks, genetic engineering to recreate the pathogen or other unforeseen events.

Elimination (or interruption of transmission) is the reduction to zero incidence of infection caused by a specific pathogen in a defined geographical area, with minimal risk of reintroduction, as a result of deliberate efforts. Actions to prevent re-establishment of transmission are required.

Interpretation of the definitions for live polioviruses

In the context of polio, **eradication** refers to all transmissible polioviruses, including cessation and eradication of all vaccine, vaccine-like, and vaccine-derived polioviruses (VDPVs). Eradication of VDPV cannot be achieved while OPV is in use, which represents a key distinction with WPV, for which high OPV coverage is the key to eradication.

Elimination of cVDPVs refers to interruption of circulation / transmission of all VDPV in a defined geographical area i.e. country or Region but does not include the absence of all OPV-related viruses such as iVDPV. Elimination of cVDPV is achieved by high coverage of OPV, while poor coverage is the main risk for generating new emergences of cVDPV. It remains critical therefore that all OPV using countries ensure and maintain high coverage in all areas and high risk groups to eliminate cVDPV, allowing OPV cessation.

Furthermore, the working group proposed the recommended terminology to describe the elimination of cVDPV and eradication of VDPV be used for the status of countries and Regions with regard to WPV. Thus, WPV2 and WPV3 have been *eradicated* from all Regions and countries as certified by the GCC; all Regions have *eliminated* WPV1 except the Eastern Mediterranean Region.

Principles for Certifying cVDPV Elimination

1. **Phases:** There are two phases in the certification of eradication of VDPV; the first phase being certification of elimination of cVDPVs, the second phase being global certification of the eradication of all VDPV.

2. **Roles and responsibilities:** As occurred for WPVs, certification of elimination of cVDPVs will be determined by each Regional Certification Commission (RCC) based on the criteria established by the GCC. After all Regions have certified elimination of cVDPV, global certification of the elimination of cVDPV by the GCC may occur, to be followed by certification of eradication of all VDPV. The GCC would advise the Director General WHO of the global eradication of the serotype specific PV.

3. **OPV Cessation:** Because of the risk of new VDPV being generated through use of OPV, certification will only be considered after all OPV use has ended, including use of OPV for outbreak response.

4. **Sequential process:** Certification of elimination of cVDPVs may be a sequential process for each poliovirus serotype, as it has been for WPV. This means cVDPV2 could be certified as eliminated at different times than cVDPV1 and cVDPV3.

5. **Period of non-detection:** The length of time since the last cVDPV detection to be

considered for certification of elimination of cVDPV may vary by poliovirus type and is yet to be determined, but should be a flexible period not less than two years, taking into account:

- the quality of surveillance in previously infected countries, including the risk in sub-population groups poorly or not reached by surveillance and/or immunization activities, and other data such as molecular analysis of the last chains of transmission, the incidence of orphan viruses or other evidence of missed transmission;
- the coverage of OPV prior to cessation and the length of time since OPV was last used in the Region;
- the previous use of Sabin versus novel OPV in the Region;
- the IPV coverage;
- additional data on sub-national population immunity;
- risks from neighboring or demographically linked geographies in other Regions (e.g. active cVDPV outbreaks, continued use of OPV)[1];
- the length of time since aVDPV was detected in the Region – aVDPV could be expected soon after cessation of all OPV use but would be unexpected later in the post cessation period;
- the status of iVDPV surveillance, including the quality/efficiency of regional mechanisms for identifying iVDPV excreters, maintaining a Regional or the global inventory and following up, performing risk assessment and mitigating measures to avert the risk of community transmission as well as the availability of treatment such as antivirals and monoclonal antibodies for identified cases in the Region;
- detection of iVDPV of the same serotype does **not** affect the certification of elimination of cVDPV.

6. **Surveillance and Containment:** Certification of elimination of cVDPVs should be conducted with the same standards of global surveillance and poliovirus containment[2] as the GCC described for WPV (see box 1 above). Respective RCCs and the GCC may consider additional in-depth review of surveillance quality among high-risk countries, sub-national geographies and populations while making the decisions on certification.

7. **Final Phase:** The period between global certification of cVDPV elimination and certification of eradication of all VDPV cannot yet be determined, principally because the precise effect of OPV cessation on the prevalence of VDPV especially iVDPV is unknown.

[1] recent examples of inter-regional spread of cVDPV2 include from Chad to Sudan and Egypt, Somalia to Ethiopia, Pakistan/Afghanistan to Tajikistan and Ukraine, and spread between Israel, UK, USA and Canada; there have been no recent events of inter-regional spread of cVDPV1 and cVDPV3

[2] There is a need to synchronize containment and certification processes with regard to continued generation of new materials for containment. Containment also cannot be finalized until OPV use stops.

Session 2 Conclusions

1. GCC agreed to maintain receiving regular reports from the iVDPV Working Group to ensure consistency with the certification criteria for VDPV and the surveillance of iVDPV.

2. GCC agreed that the processes of annual reporting by NCCs and RCCs would provide a useful input into the bOPV Cessation process, which aims to exclude with confidence any persistent transmission of cVDPV1 or cVDPV3

3. GCC endorsed the work of Expert Working Group on cVDPVs and accepted the draft principles with some amendments to improve clarity in this complex area of work. The final GCC approved principles are in annex 2.

Session 2 Recommendation

The GCC recommended that the draft principles be discussed at the Regional level, and feedback provided on any issues that may arise in application of these principles.

Session 3: Feedback from RCCs - current priorities and issues

Western Pacific Region

The presentation featured:
- Regional Assessment for Risk of Missed Poliovirus Transmission,
- Surveillance for Acute Flaccid Paralysis,
- Environmental surveillance in the Western Pacific Region in 2023,
- Countries with recent outbreaks,
- Poliovirus essential facilities (PEF) in the WPR-2023,
- Regional Assessment for Risk of Population Immunity, and
- Key outcomes of 28th meeting of RCC.

Eastern Mediterranean Region

The presentation featured:
- Stopping WPV1 transmission
- Stopping all cVDPV outbreaks
- Consequential geographies: Somalia and Yemen
- Stopping other outbreaks: Egypt, Djibouti, Sudan
- Highly sensitive poliovirus surveillance (AFP, ES, iVDPV) supported by a strong regional lab network to guide interruption of transmission and underpin certification
- Risk assessments and mitigation and prevention of outbreaks through strengthening routine immunization; preparedness for outbreaks, and more integrated campaigns.

South-east Asian Region

The presentation focussed on the recommendations from the SEARCCPE:

Certification process

- Secretariat to continue to make efforts to gather information from DPR Korea and Myanmar on immunization and surveillance performance and share with SEARCCPE when available
- Secretariat to develop and share guidelines related to membership of NCCPEs with all countries
- NCCPEs continue to meet at least twice in a year

Surveillance

- Involve all sectors of health system including NGOs and private sector for reporting AFP cases
- On-site accreditation visits to polio laboratories every three years
- Countries with low/decreasing NPEV isolation should investigate the reasons

Population Immunity

- Countries that have not yet implemented IPV2 introduction or schedule optimization, should do so in accordance with SAGE guidance that was approved by the SEAR-ITAG (August 2023)
- NCCPEs should closely review the coverage of IPV2 and recommend appropriate actions based on local context to improve coverage
- Targeted immunization program for missed children including outreach efforts for hard-to-reach areas and additional strategies such as risk communication and communication message to reduce hesitancy wherever it is present

Containment

- Countries with PEFs should prepare exposure response plan and conduct containment breach exercise

Outbreak Preparedness

- Subnational risk assessment and take actions to strengthen immunization and surveillance systems with a subnational focus
- Conduct polio outbreak simulation exercises (POSE) at least once in three years

European Region

The EuRCC noted that the polio outbreaks in the Region were well managed and evidence suggests transmission has stopped.
Urgent action is needed by all countries to protect against importation of cVDPV2 through high population immunity and strong surveillance, AFP and supplemental.
The EuRCC noted continued gaps in polio containment in the Region and welcomed additional advocacy with Romania.
RCC expressed concerns about the considerable challenges that remain in Ukraine.

African Region

The Region is on track to meet its Phase I milestone of ending WPV1 and cVDPV1 outbreaks in Southern Africa, with no new case in more than 12 months.

With the availability of adequate vaccine stockpile for outbreak response, now is the time to move quickly and end ongoing outbreaks. The Region has been ramping up response to cVDPVs in the second half of 2023 and is focused on ending all ongoing active outbreaks by end of 2024 and addressing any remnant risk in 2025

Nigeria and the Lake Chad basin countries, and DRC have contributed the highest number of cases and have been the source of international spread; focus will be on maintaining pressure on the virus through the end of 2023 and accelerating response in early 2024

Madagascar has seen sustained transmission of poliovirus type 1; country has implemented 4 major rounds including subnational rounds targeting all age groups; with the aim of ending transmission all together by end of 2024, response efforts to be maintained next year.

Coordinated response in the Horn of Africa to the outbreak in Somalia that has spilled over to Kenya and may further spread to Ethiopia planned.

West African and Southern African countries have seen a resurgence of poliovirus type 2 outbreaks, response to ongoing outbreaks on track; to address risk to other countries in the sub-region, surveillance and outbreak response preparedness being enhanced.

Poliovirus type 1 risk increasing; population immunity declining; current plans inadequate to address risk; essential immunization systems strengthening coupled with regular preventive supplementary immunizations targeting missed cohorts required

Region of the Americas

Vulnerable, hard-to-reach, and vaccine-hesitant populations.
- To identify their interconnections with other similar communities both within the country and elsewhere.

Vaccination and Surveillance.
- All countries to achieve high vaccination coverage in all districts and strengthen AFP surveillance.

Detection of the VDPV1 case in Peru.
- Countries and adjacent districts in the Amazonian region to achieve high vaccination coverage and strengthen surveillance.

TAG and previous RCC recommendations.
Review vaccination against polio and AFP surveillance and continue with their implementation.

Session 3 Conclusions

1. The GCC noted the different challenges in the six WHO Regions, and the key role of RCCs in documenting and supporting countries in addressing these challenges.

2. The GCC concluded that all five certified Regions continue to be free of indigenous wild polio transmission, recognizing the WPV1 outbreak in southeastern Africa was due to an importation from Pakistan.

Recommendation

The GCC recommended that all Regions and countries continue to address surveillance gaps, population immunity, polio outbreak preparedness and planning and poliovirus containment so that the world is in the best possible position to certify global WPV eradication no later than 2026.

Session 4: Poliovirus Containment

There has been much progress achieved with implementing the commitments in resolution WHA 71.16 (2018) Poliomyelitis– Containment of Polioviruses[3] and GCC recommendations over the years.

As of November 2023, 22 countries host 69 facilities retaining polioviruses:
- Romania and China are the only two countries that have yet to establish a NAC
- 42 of the 69 facilities retaining polioviruses have valid GCC-countersigned CPs and are officially in the CCS
- Four countries, Australia, China, Serbia and Romania have yet to submit CP applications for their facilities.
- Four countries, Canada, France, Republic of Korea and USA have progressed to the ICC phase where five facilities have been awarded a GCC-countersigned ICCs.

Several key containment issues were raised which included:
1. Need for increased advocacy to reduce the number of facilities retaining polioviruses globally.
2. Need for capacity building opportunities to support national stakeholders in performing their functions, including implementation of containment guidance documents, to be provided using the most feasible modality.
3. Need to complete the revision of containment guidance documents as soon as possible, including GAPIV, CCS and PIM Guidance.
4. Lack of standardized and globally harmonized reporting and indicators to monitor progress with implementation of poliovirus survey and inventory activities. Survey and inventories activities are required if WPV or VDPV is in circulation or OPV is in use. Such activities are resource intensive and do not provide the expected assurance that all PV materials have been identified and are appropriately managed.
5. Limited capacity of CWG with an increasing workload associated with the review of CCS applications.
6. Challenges of national-level candidate auditors to meet the qualifying requirements to become an auditor as described in the CCS. This was addressed by a GCC recommendation in 2021 enabling countries to submit to CWG for prior approval, national ICC plans utilizing in-country auditors with experience and relevant expertise.

The lack of alignment of poliovirus containment timelines with WPV eradication will likely persist as goals 1 and 2 of the Eradication Strategy 2022 – 2026[4] have been assessed to be off-track and likely to miss the end-2023 timelines[5] for the interruption of WPV1 transmission and for the last detection of cVDPV2. The dependence of containment on WPV eradication, absence of cVDPV2 and cessation of OPV, will also impact the current containment

[3] Seventy- First World Health Assembly Resolution WHA 71.16 Poliomyelitis – containment of polioviruses. Available at: https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R16-en.pdf
[4] Polio Eradication Strategy 2022-2026: Delivering on a Promise. Available at: https://polioeradication.org/gpei-strategy-2022-2026/
[5] 22nd Report of the Independent Monitoring Board (IMB) and Mid-Term Review: Closing in on Zero. Available at: https://polioeradication.org/wp-content/uploads/2023/09/22nd-Report-of-The-Independent-Monitoring-Board-IMB.pdf

requirements[6] for the certification of WPV eradication.

Other issues presented include variable data quality associated with surveys and inventories across the WHO regions; poor and incomplete survey and inventory activities associated with potentially infectious materials, poliovirus (PV PIM); long-term containment requirements for handling of novel poliovirus strains and the lack of oversight of facilities retaining PV PIM.

Session 4 Conclusions (Poliovirus Containment Certification)

GCC Conclusions: GCC acknowledged the progress made in containment since the last meeting as several ICCs have been awarded. GCC noted that the provision of necessary guidance, tools, and capacity building opportunities to stakeholders to perform their functions is important to ensure sustained progress in poliovirus containment. GCC also noted the dependence of containment on the WPV eradication milestone and cessation of OPV and the impact on the current containment requirements for the certification of WPV eradication4.

GCC noted that to meet the containment requirements for the certification of WPV eradication by end -2026, that WPV3, certified eradicated in 2019, and VDPV3, must be handled/stored in containment effective immediately. Similarly, although not yet eradicated, WPV1/VDPV1 must be handled/stored in containment in all but endemic countries effective immediately. The containment requirements for WPV/VDPV of any serotype are described in the biorisk management standard of the WHO Global Action Plan for Poliovirus Containment, 4th edition, 2022 (GAPIV)[7].

Recommendations:

To ensure sustained poliovirus containment progress, GCC recommends:
4.1 Timelines to meet the containment requirements for the certification of WPV eradication by end-2026 will remain in-place independent of the status of WPV eradication.

4.2 WPV3/VDPV3 holding facilities must apply for an ICC immediately. These facilities are expected to achieve a Containment Certificate (CC) or an Interim Containment Certificate (ICC) with a clear end-point for obtaining a CC agreed with the CWG / GCC by end-2026[8].

4.3 Facilities retaining WPV1/VDPV1 in all countries, other than the endemic countries, must apply for an ICC immediately. These facilities are expected to achieve a Containment

[6] Safe and secure containment of WPV retained in facilities, such as laboratories and vaccine manufacturing facilities - all facilities retaining WPVs should have a Containment Certificate, or an Interim Containment Certificate, with a clear end-point for obtaining a CC agreed with the GCC. In addition, at the time of global WPV certification, GCC will consider the status of biorisk management of PIM and readiness to respond to containment breaches. Report from the Seventeenth Meeting of the GCC, Geneva, Switzerland, 26-27 February 2018. Avalable at: https://polioeradication.org/wp-content/uploads/2018/04/polio-eradication-certification-17th-meeting-global-commission-for-certification-of-poliomyelitis-eradication-20180412.pdf

[7] WHO-Global-Action-Plan-for-Poliovirus-Containment-GAPIV.pdf (polioeradication.org)

[8] Source: Report of the 17th meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis, 26-27 February 2018, Geneva, Switzerland. Available at: https://polioeradication.org/wp-content/uploads/2018/04/polio-eradication-certification-17th-meeting-global-commission-for-certification-of-poliomyelitis-eradication-20180412.pdf)

Certificate (CC) or an Interim Containment Certificate (ICC) with a clear end-point for obtaining a CC agreed with the CWG / GCC by end-2026.

Session 4 Conclusions (Poliovirus Survey and Inventory)

GCC acknowledges the importance of survey and inventory activities as an important prerequisite to containment "certification". GCC also acknowledges the efforts made by the RCCs and containment regional focal points in ensuring data is collected and made available in alignment with the qualitative and quantitative indicators previously agreed to by GCC. However, variability in indicator definitions, data quality and availability still vary significantly between the different WHO regions.

Recommendations:

4.4 Noting the importance of considering poliovirus survey and inventory completion as a prerequisite to containment certification, GCC recommends that survey and inventory completion criteria be added to the current containment requirements for WPV eradication certification and requests that the WHO containment team collaborate with the containment regional focal points and the RCCs to develop the said criteria. These criteria should be shared with the GCC for approval.

4.5 To ensure a standardized and globally harmonized set of indicators to monitor the implementation of survey and inventory activities, GCC recommends a revision of the previously agreed qualitative and quantitative indicators be carried out by the containment team at WHO headquarters in collaboration with the containment regional focal points, RCCs and possibly NCCs and NPCCs to ensure data harmonization across all WHO regions. These indicators should be shared with the GCC for approval.

Session 4 Conclusions (Containment of Novel Poliovirus Strains and Potentially Infectious Materials, Poliovirus)

As the global oversight body for poliovirus containment, GCC notes the lack of compliance verification of facilities retaining novel poliovirus strains for specific uses with the terms of the 'temporary waiver' ('conditional usage') as recommended by CAG[9] . GCC notes that survey and inventory activities and collected data for PV IM are more robust and complete compared to those addressing PV PIM. In addition, GCC notes that currently there is a lack of an accountability framework for facilities retaining OPV/Sabin PIM against the risk mitigation strategies described in the PIM Guidance, 2nd edition 2021, and possibly WPV/VDPV PIM following the revision of the PIM Guidance as per CAG recommendation 5.

[9] Sixth meeting of the Poliovirus Containment Advisory Group, 25th, 26th and 27th January 203, Geneva, Switzerland. Available at: https://polioeradication.org/wp-content/uploads/2023/05/CAG6-Jan-2023-Report-EN-FINAL.pdf

Recommendations:

Novel Poliovirus Strains

4.6 GCC reminds all relevant national oversight bodies of reporting requirements of facilities retaining novel poliovirus strains as per the 2022 recommendation[10]

4.7 GCC recommends that a mapping exercise be carried out to determine the number and country location of facilities (research, manufacturing, etc.) retaining novel poliovirus (nOPV1, nOPV2, nOPV3, tnOPV, S19 (all serotypes with and without N18S), CAVA strains). In addition, understanding the specific activities being conducted with these strains and the risk mitigation measures currently in place for their handling novel poliovirus strains in such facilities will be important to determining an appropriate compliance verification structure.

Potentially Infectious Materials Poliovirus

4.8 GCC recommends that a 'White Paper' on the containment of PV PIM be developed with the aim of presenting evidence on the likelihood of the presence of PV in PV PIM and assessing the risk of a release of poliovirus from facilities retaining PV PIM. This will provide a better understanding into the level of oversight needed (national or global), the mechanism for this oversight, and the way forward for the GCC to use these data (if at all) for the certification of eradication.

[10] GCC recommends that WHO maintains an inventory of facilities retaining novel poliovirus strains, with the collection of the same information as that which is provided in the Certificate of Participation (CP). This information should be provided by the facility to its National Authority for Containment (NAC) where one exists, or to its National Polio Containment Coordinator and processed onwards to the CWG Secretariat. Report of the 22nd meeting of the Global Commission for the Certification of Eradication of Poliomyelitis, Geneva, Switzerland, 28 - 29 June 2022. Available at: https://polioeradication.org/wp-content/uploads/2022/09/22nd-GCC-report-20220907.pdf

Annex 1: Meeting Agenda

Global Commission for the Certification of Poliomyelitis Eradication

22 -23 November

DRAFT AGENDA

Wednesday 22 November		
Coffee - 10.45		
Session 1: ENDEMIC COUNTRIES UPDATE		
11.00	Opening remarks	Aidan O'leary - Director WHO HQ/POL David Salisbury
11.05	Polio Eradication in Afghanistan (Epidemiology and surveillance – progress, challenges and way forwar	Dr Mandeep Rathee, WHO/AFG
11.50	Discussion	
12.05	Polio Eradication in Pakistan (Epidemiology and surveillance – progress, challenges and way forward)	Dr Zainul A Khan, WHO/PAK
12.50	Discussion	
13.15 - Lunch		
Session 2: Global surveillance and Certification		
14.15	iVDPV surveillance	Ondrej Mach
14.30	Progress in implementation of the GPSAP	Stephanie Kovacs
15.00	Update on virology: GPLN Working paper 5	Ousmane Diop
15.30	outcomes of the GPEI strategy mid-term assessment	Aidan O'leary
15.45	Discussion	
Coffee break - 16.00		
16.15	Report back from cVDPV GCC WG	David Salisbury
16.30	Discussion	
17.00	Draft Recommendations for day 1	GCC members
17.15	*End*	
Thursday 23 November		
09.00	Review draft recommendations	all
Session 3: Feedback from RCCs - current priorities and issues		
09.30	Eastern Mediterranean Update	EMRO
09.50	Western Pacific Update	WPRO
10.10	South East Asian Update	SEARO
10.30	European Region Update	EURO
Coffee break - 10.50		
11.10	Region of the Americas Update	PAHO
11.30	African Update including feedback from ARCC WG	AFRO
12.00	Discussion	
Lunch - 12:30		
Session 4: Global Containment		
13.30	Global containment progress and gaps	CNT
14.00	Strategic issues: surveys and inventories; minimum dataset; PIM oversight	CNT
14.30	Containment trajectory: timelines and scope - guidance needed	CNT
15.00	Discussion	
Coffee break - 15.30		
16.00	Recommendations from day 2 and wrap up	David Salisbury
16.30	End	

Annex 2: Final Version of the Principles for Certification of Elimination of cVDPV

GCC Principles for the Global Certification of Eradication of Polio Associated with Vaccine Polioviruses

This document sets out the GCC principles for the certification of eradication of vaccine derived polioviruses after global cessation of all use of oral poliovirus vaccine (OPV). These principles resulted from discussions by an expert working group (or working group of polio experts) convened March through October 2023 that were presented to the GCC at its November 2023 meeting. The principles outlined here have relevance also for the terminology of the certification of wild polioviruses (annex 1).

Background

The GCC applied the criteria for certification of WPV in Box 1 below in 2015 for global certification of WPV2 eradication[1] and in 2019 for the global certification of WPV3 eradication[2], with the exception of full containment of WPV3.

Box 1: Criteria to certify eradication of WPV

1. No WPV transmission detected from any population source[1] for the previous three years, and
2. Adequate global poliovirus surveillance[2], and
3. Safe and secure containment[3] of WPV retained in facilities, such as laboratories and vaccine manufacturing facilities

[1] Population sources are humans (both AFP cases and healthy individuals) and environmental sources composing of human waste-water, and do not include other sources such as laboratories and vaccine manufacturing facilities; conversely non-population sources include known WPV stocks in facilities. Detection of WPV from a human or the environment resulting from a containment breach will not be considered from a population source, unless there is sustained transmission in the surrounding population.

[2] Adequate global surveillance is defined as:
AFP surveillance that meets the minimum standard of non-polio AFP rate in the under 15 population of ≥ 1 per 100,000 with a stool adequacy of ≥ 80% (collected within 14 days of onset and arriving in good condition), and

- clear evidence of a sufficiently well-functioning surveillance system in all high-risk areas and special populations-of-concern to detect transmission, as determined by additional surveillance indicators, or
- in countries with strong healthcare systems, with evidence of high population immunity for all poliovirus serotypes; presence of a national surveillance system capable of detecting poliovirus including through the use notifiable disease surveillance, or supplemental surveillance systems such as environmental and enterovirus surveillance, shall be deemed adequate.

[3] All facilities retaining WPVs should have a Containment Certificate (CC), or an Interim Containment Certificate (ICC), with a clear end-point for obtaining a CC agreed with the GCC. In addition, at the time of global WPV certification, the GCC will consider the status of bio-risk management of potentially infectious materials and readiness to respond to containment breaches.

Discussing type 1 WPV (WPV1) at its twenty-second meeting in February 2023, the GCC recommended the change in the period of non-detection in Box 2.

Box 2: Amended criterion on the period of non-detection for WPV1

No WPV transmission detected from any population source for a flexible period, but not less than two years, taking into account the quality of surveillance in endemic countries, the risk in sub-population groups poorly or not reached by surveillance, and other data such as molecular analysis of the last chains of transmission.

[1] https://polioeradication.org/wp-content/uploads/2016/07/1Report.pdf,
[2] https://polioeradication.org/wp-content/uploads/2016/07/20th-meeting-of-the-Global-Commission-for-the-Certification-of-Eradication-of-Poliomyelitis-17-18-October-2019.pdf

WHO Definitions[3]

Eradication is the permanent reduction to zero of the worldwide incidence of infection caused by a specific pathogen, as a result of deliberate efforts, with no risk of reintroduction. No further actions are required, although interventions may be required for a buffer or transition period; eradication is permanent, barring release from containment laboratories maintaining stocks, genetic engineering to recreate the pathogen or other unforeseen events.

Elimination (or interruption of transmission) is the reduction to zero incidence of infection caused by a specific pathogen in a defined geographical area, with minimal risk of reintroduction, as a result of deliberate efforts. Actions to prevent re-establishment of transmission are required.

Certification implies a high degree of certainty that specific criteria have been met; requires strict procedures (e.g. documentation process by every country, oversight and vetting by regions, and then oversight and vetting globally), which could provide high confidence that transmission has stopped.

Interpretation of the definitions for live polioviruses

In the context of polio, eradication refers to all transmissible polioviruses, including eradication of all vaccine, vaccine-like, and vaccine-derived polioviruses (VDPVs) and cessation of use of all OPV vaccines including bOPV and novel OPV. Eradication of VDPV cannot be achieved while any OPV is in use, which represents a key distinction with WPV, for which high OPV coverage is the key to eradication.

Elimination of cVDPVs refers to interruption of transmission of all cVDPV in a defined geographical area, but does not include the absence of all OPV-related viruses. Elimination of cVDPV is achieved by high coverage of OPV, while poor coverage is the main risk for generating new emergences of cVDPV. It remains critical therefore that all OPV using countries ensure and maintain high coverage in all areas and high risk groups to eliminate cVDPV, allowing OPV cessation.

Although the GCC previously discussed the concept of the **validation of absence** for documenting the end of cVDPVs, the GCC agreed that the terminology was not useful and that the GCC, RCCs and GPEI should use the term 'certification.'

Polio epidemiology as of October 2023

Since global withdrawal of OPV2 from routine immunization in 2016, cVDPV2 transmission has been detected in 52 countries and caused over 3100 cases of paralysis (as of Oct 2023). OPV2 used for outbreak response has led to emergence of new cVDPV2 strains responsible for the majority of these paralytic polio cases. The risk of seeding new VDPVs appears to be lower with nOPV2 use than with Sabin OPV2 use, based on experience with emergences of nOPV2 origin cVDPV2 outbreaks to date, although the same issues of low coverage and the nature of OPV have led to reported cases of cVDPVs caused by nOPV2. The number of unique VDPV detections and emergences according to poliovirus type and classification is given in table 1 below. In 2023, all first detections of VDPV2 have nt changes less than or equal to 13, indicating less than two years since emergence, assuming a rate of 10 nt changes per year (see annex 2).

[3] Global Framework for Multi-disease Elimination (unpublished) accessed 12 October 2023 at https://www.who.int/docs/default-source/ntds/leprosy/global-consultation-on-global-leprosy-strategy-2021-2030/08-global-framework-multi-disease-elimination.pdf

Table 1: aVDPV detections, cVDPV emergence groups and iVDPV detections according to serotype since 1 Jan 2017

	type 2	type 1	type 3
Ambiguous VDPV	350	33	19
cVDPV emergence groups	88	13	3
Immunodeficient VDPV *	3	8	8

** the number of iVDPV is likely underestimated due to limited surveillance, and the case definition refers to AFP cases only. Data source: GPEI Polio Information System (PolIS), data exported on 24 Oct 2023*

Status of OPV2 cessation

Sabin OPV2 was withdrawn globally from routine immunization programmes in April 2016. Currently, OPV2 is only being used for responding to cVDPV2 outbreaks and cVDPV high-risk events with the special authorization of the WHO Director General and under stringent vaccine management measures.

The Strategic Advisory Group of Experts on Immunization (SAGE) also recommended flexibility for the use of only IPV for responding to cVDPV2 outbreaks in IPV exclusive countries (countries using only IPV and no OPV in their routine immunization) with high level of sanitation. This option, however, is recommended if transmission is confined to a well-defined population group or geographical area. In 2022 and 2023, United Kingdom, Israel and United States implemented IPV-only responses to cVDPV2.

Status of OPV1 / OPV3 cessation

While elimination of cVDPV1 and cVDPV3 requires high coverage with OPV1 and OPV3, **certification** of elimination of cVDPV1 and cVDPV3 will only be considered after the cessation of all live type-1 and type-3 oral polio vaccines, including bivalent OPV, monovalent OPV1 and OPV3 as well as any novel live OPV1 and OPV3 vaccines (currently under development). Current GPEI strategic plans focus on coordinated bOPV cessation (i.e. stopping both types 1 and 3 OPV at the same time everywhere), which itself can only occur after the GCC certifies the eradication of WPV1. The timing of WPV1 eradication and its certification remain uncertain as of October 2023, and will depend on the timing of regional certification of elimination in the WHO Eastern Mediterranean Region. If WPV1 transmission is interrupted in 2024, certification of WPV eradication may occur as early as 2026, allowing for bOPV cessation in 2027 and onwards.

The date and location of the most recent detection and OPV usage in each WHO Region since 2016 (as at October 2023) is given in table 2 below.

Table 2: most recent cVDPV and OPV use per WHO Region as at October 2023

Region	Last cVDPV2	OPV2 last used	Last cVDPV1	Last cVDPV3	bOPV use
AFR	Ongoing	Ongoing	Ongoing	None	Ongoing
AMR	USA (20 Oct 2022)	April 2016	None	None	Ongoing
EMR	Ongoing	Ongoing	YEM (21 Mar 2021)	OPt (15 Mar 2022)	Ongoing
EUR	ISR (13 May 2023)	TJK (Sept 2021)	None	ISR (16 May 2022)	Ongoing
SEAR	INO (23 Feb 2023)	INO (May 2023)	MMR (21 Aug 2019)	None	Ongoing
WPR	PHP (16 Jan 2020)	PHP (May 2020)	MYS (13 Mar 2020)	China (25 Feb 2021)	Ongoing

Principles for Certifying cVDPV Elimination

1. **Phases:** There are two phases in the certification of eradication of VDPV; the first phase being certification of elimination of cVDPVs, the second phase being global certification of the eradication of all VDPV.

2. **Roles and responsibilities:** As occurred for WPVs, certification of elimination of cVDPVs will be determined by each Regional Certification Commission (RCC) based on the criteria established by the GCC. After all Regions have certified elimination of cVDPV, global certification of the elimination of cVDPV by the GCC may occur, to be followed by certification of eradication of all VDPV. The GCC would advise the Director General WHO of the global eradication of the serotype specific PV.

3. **OPV Cessation:** Because of the risk of new VDPV being generated through use of OPV, certification of cVDPV elimination and subsequently eradication of VDPV will only be considered after all OPV use has ended, including use of OPV for outbreak response.

4. **Sequential process:** Certification of elimination of cVDPVs may be a sequential process for each poliovirus serotype, as it has been for WPV. This means cVDPV2 could be certified as eliminated at different times than cVDPV1 and cVDPV3.

5. **Period of non-detection:** The length of time since the last cVDPV detection to be considered for certification of elimination of cVDPV may vary by poliovirus type and is yet to be determined, but should be a flexible period of not less than two years, taking into account:

- the quality of surveillance in previously infected countries, including the risk in sub-population groups poorly or not reached by surveillance and/or immunization activities, and other data such as molecular analysis of the last chains of transmission, the incidence of orphan viruses or other evidence of missed transmission
- the coverage of OPV prior to cessation and the length of time since OPV was last used in the Region;
- the previous use of Sabin versus novel OPV in the Region;
- the IPV coverage;
- additional data on sub-national population immunity;
- risks from neighboring or demographically linked geographies in other Regions (e.g. active cVDPV outbreaks, continued use of OPV)[4];
- the length of time since aVDPV was detected in the Region – aVDPV could be expected soon after cessation of all OPV use but would be unexpected later in the post-cessation period;
- the status of iVDPV surveillance, including the quality/efficiency of regional mechanisms for identifying iVDPV excreters, maintaining a Regional or the global inventory and following up, performing risk assessment and mitigating measures to avert the risk of community transmission as well as the availability of treatment such as antivirals and monoclonal antibodies for identified cases in the Region;
- detection of iVDPV of the same serotype does **not** affect the certification of elimination of cVDPV.

[4] recent examples of inter-regional spread of cVDPV2 include from Chad to Sudan and Egypt, Somalia to Ethiopia, Pakistan/Afghanistan to Tajikistan and Ukraine, and spread between Israel, UK, USA and Canada; there have been no recent events of inter-regional spread of cVDPV1 and cVDPV3

6. **Surveillance and Containment:** Certification of elimination of cVDPVs should be conducted with the same standards of global surveillance and poliovirus containment[5] as the GCC described for WPV (see box 1 above). Respective RCCs and the GCC may consider additional in-depth review of surveillance quality among high-risk countries, sub-national geographies and populations while making the decisions on certification.

7. **Final Phase:** The period between global certification of cVDPV elimination and certification of eradication of all VDPV cannot yet be determined, principally because the precise effect of OPV cessation on the prevalence of VDPV especially iVDPV is unknown.

Pending Issues

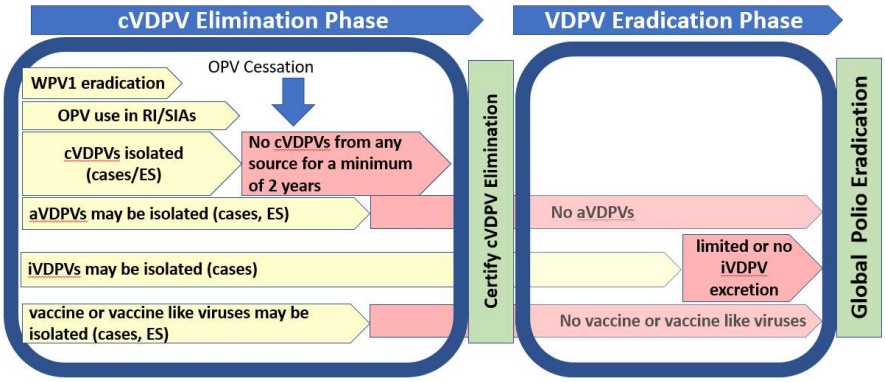
Detection of cVDPV in a certified region indicates either:

- a new emergence, or
- an importation event, or
- missed transmission of a pre-certification emergence group, or
- seeding of a cVDPV outbreak from an infectious iVDPV carrier.

Response protocols for responding to cVDPV in certified regions will need to be developed according to the source, as well as criteria for determining that a region is no longer certified due to either evidence of missed transmission, reintroduction of OPV use and/or reestablished transmission of a cVDPV for a period of more than 12 months.

For example, the ideal scenario could be that current cVDPV2 outbreaks end, allowing cessation of use of novel OPV2 for outbreak use, and after an appropriate amount of time (to be determined) after the last cVDPV2 is detected in each Region, that Region is certified as having eliminated cVDPV2. Similarly, after a period of non-detection of cVDPV1 and cVDPV3 and OPV cessation, Regions could be certified as having eliminated cVDPV1 and cVDPV3. Deviation from this ideal scenario could occur, with the epidemiology at the time dictating application of these principles for certification.

Figure 1: The ideal scenario (no time scale) TO BE REVISED



[5] There is a need to synchronize containment and certification processes with regard to continued generation of new materials for containment. Containment also cannot be finalized until OPV use stops.

Application of 'Elimination' and 'Eradication' terminology to WPVs.

At present, there is a mixture of terms used by Regions to define their current poliovirus status for WPVs and VDPVs. Because WPV2 and 3 have been certified as eradicated by GCC, by definition, each Region can define those viruses as eradicated although their responsibilities had been to report confirmation of interruption of transmission i.e. elimination to GCC. As a consequence, Regions have used terminology such as being 'polio-free' with respect to all three wild poliovirus types, except for the EMR and WPV1. Being 'polio-free' is confusing when there has been an importation with limited transmission (AFR in 2021 – 22), and if there has been transmission, the use of the term 'indigenous' can also lack clarity.

It is therefore proposed the recommended terminology to describe the elimination of cVDPV and eradication of VDPV be used for the status of countries and Regions with regard to WPV. Thus, WPV2 and WPV3 have been eradicated from all countries as certified by the GCC; all countries have eliminated WPV1 except AFG and PAK.

As an example, Kuwait has been certified as having eradicated WPV2 and WPV3, and as having eliminated WPV1 by the EMRCC. Yemen's status is the same irrespective of the ongoing transmission of cVDPV2.

This situation becomes more complex when there is consideration of cVDPV. Transmissible polioviruses are detected and there may be paralysis (US 2022) or transmission with no paralytic cases detected (UK 2022). In those circumstances, to continue the use of the term 'polio-free' may be unhelpful (Region of Americas RCC Review 2023). For example, in 2023, the Region of the Americas would be categorized as having eliminated WPV1, eradicated WPV2 and WPV3. No region has yet formally certified the elimination of VDPV – all remain uncertified.

Polio status in the proposed updated framework:

Virus	Americas	Africa	Eastern Mediterranean	European	South East Asia	Western Pacific
WPV1	eliminated	eliminated	endemic	eliminated	eliminated	eliminated
WPV2	globally eradicated					
WPV3	globally eradicated					
VDPV1	uncertified	uncertified	uncertified	uncertified	uncertified	uncertified
VDPV2	uncertified	uncertified	uncertified	uncertified	uncertified	uncertified
VDPV3	uncertified	uncertified	uncertified	uncertified	uncertified	uncertified

An appendix to the Principles

For the years 2017 – June 2023 a recent analysis of the period between a new VDPV2 emergence and detection showed that:

- New VDPV2 emergences have a median 8 nt changes when detected.
    - cVDPV2s are first detected with more nt changes (median 9) compared with aVDPV2s (median 7)
- 95% new VDPV2 detections had ≤20 nt changes and 99% were detected with ≤30 nt changes.
- Novel emergences were detected with fewer nt changes (median 7) than Sabin emergences (median 9).
- The upper limit of nt changes has fallen from a peak in 2019 of 64 nt changes to 17 nt changes in 2023 (table 3)
- Importantly, assuming a rate of 10 nt changes per year, all novel OPV2 origin emergences were detected in the WHO African Region within two years (all nt changes ≤13).

Table 3: median and range of nucleotide changes for first detection of VDPV2 viruses 2017 – June 2023

	2017	2018	2019	2020	2021	2022	2023
N	23	30	94	69	93	20	26
Median	7	8	8	7	7	7	8
Range	6-38	6-27	6-64	6-32	6-29	6-28	6-17

Table 4: Nucleotide changes at first detection of cVDPV2 emergence group by region (importations excluded)*

	AFR (Sabin)	AFR (novel)	AMR	EMR	EUR	SEAR	WPR
N	56	8	0	20	1	1	2
Median	10	7	-	7	6	25	39
Range	6-24	6 – 13	-	6-38	6-6	25-25	13-64*

* The circulating emergence group with 64 nt changes in 2019 was PHL-NCR-1 in the Philippines. It was the only emergence group with a first detection of >40 nt changes.

感感発０８２２第１１号
令和６年８月２２日

各{都道府県 / 保健所設置市 / 特別区}衛生主管部（局）御中

厚生労働省健康・生活衛生局
感染症対策部感染症対策課長
（　公　印　省　略　）

世界的なポリオ根絶に向けた、不必要なポリオウイルス（２型）の廃棄について
（周知及び協力依頼）

急性灰白髄炎（以下「ポリオ」という。）については、昭和63年５月の世界保健総会における決議に基づき、世界保健機関（以下「WHO」という。）によるポリオ根絶に向けた取り組み（世界ポリオ根絶計画）が推進されているところです。

国内においては、昭和56年以降、野生株ポリオウイルスによる症例は報告されておらず、我が国を含むWHO西太平洋地域においても、平成12年以降、輸入例を除き、野生株ポリオウイルスによる症例の根絶状態が続いています。

また、世界全体でも野生株ポリオウイルスによる症例は７例（令和５年）まで減少し、令和６年８月13日時点で野生株ポリオウイルスの伝播が確認されているのは、アフガニスタン及びパキスタンの二ヵ国のみとなっています。

こうした現状を踏まえ、WHOでは、ポリオ根絶に向けた最終的な取り組みとして、「ポリオ根絶戦略2022-2026（Polio Eradication Strategy 2022-2026)」（以下「根絶戦略」という。）を進めており、2026年までに全ての型のポリオウイルスを封じ込めることを目標としています。

２型のポリオウイルス（野生株・Sabin株）については既に、「世界的なポリオ根絶に向けた、不必要なポリオウイルスの廃棄について」（平成27年12月11日付け健感発1211第１号厚生労働省健康局結核感染症課長通知）により廃棄をお願いしているところですが、根絶戦略の改訂にあわせ、廃棄対象の定義を変

更しましたので、貴管下市町村、医療機関及び研究機関等に対し、下記について改めて周知いただきますようお願いします。

なお、「世界的なポリオ根絶に向けた、不必要なポリオウイルスの廃棄について」（平成27年12月11日付け健感発1211第１号厚生労働省健康局結核感染症課長通知）については、本通知をもって廃止します。

記

1. 感染性のある２型野生株ポリオウイルス及び変異型ワクチン由来ポリオウイルスを含む材料（別紙の１に掲げられているもの）については、速やかに廃棄すること。

   なお、廃棄の方法については、エンテロウイルス属ポリオウイルスとして、感染症の予防及び感染症の患者に対する医療に関する法律（平成 10 年法律第 114 号）に規定する四種病原体等であることから、感染症の予防及び感染症の患者に対する医療に関する法律施行規則（平成 10 年厚生省令第 99 号）第 31 条の 34 第３項に規定する方法で滅菌の上、廃棄すること。

   なお、感染性のある２型ワクチン株ポリオウイルスを含む材料（別紙の２に掲げられているもの）についても、同様の方法で廃棄することが望ましい。

2. 別紙に掲げられているものを継続して保有する必要があると考える場合は、令和６年 12 月末までに、その施設等の責任者から、厚生労働省健康・生活衛生局感染症対策部感染症対策課まで連絡すること。

以上

【問い合わせ】
厚生労働省健康・生活衛生局感染症対策部
感染症対策課　病原体等管理対策係
TEL ： 03-3595-3097
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別紙

感染性のある２型ポリオウイルスを含む材料

１．感染性のある 2 型の野生株ポリオウイルス及び変異型ワクチン由来ポリオウイルスを含む材料

- 2 型野生株ポリオウイルス（VDPV（※１）含む）の感染が確認された臨床　　検体
- 2 型野生株ポリオウイルス（VDPV 含む）の存在が証明された環境水あるいは水サンプル
- 2 型野生株ポリオウイルス（VDPV 含む）の細胞培養分離株と参照株
- 2 型の不活化ポリオワクチン生産のための種ウイルス株および不活化ポリオワクチン生産から生じた感染性産物
- 2 型野生株ポリオウイルス（VDPV 含む）を感染させた動物（ヒトポリオウイルス受容体トランスジェニックマウスを含む）または感染動物に由来する検体
- Sabin 株より安全であることが証明されていない、2 型野生株ポリオウイルス由来のカプシドシークエンスを含む感染性ウイルス（※２※３）
- 2 型野生株ポリオウイルス（VDPV 含む）持続感染細胞

※１）VDPV(Vaccine-derived poliovirus):変異型ワクチン由来ポリオウイルス

※２）GAPIII から GAPIV への改訂にともなう野生株ポリオウイルスの定義の変更を反映し、「カプシドシークエンスを含む誘導体(derivative)」あるいは「核酸(full-length RNA or cDNA)」は、「カプシドシークエンスを含む感染性ウイルス(infectious viruses)」に改訂した。

※３）野生ポリオウイルスのカプシドシークエンスを含む新しい感染性ウイルスの安全性は、WHO が招集する専門家パネルによって評価され、Sabin 株と比較して（i）弱毒の程度と安定性；（ii）人から人への伝播の可能性；（iii）動物モデルにおける神経病原性が検討される必要がある。

2. 感染性のある 2 型ワクチン株ポリオウイルスを含む材料

- 2 型ワクチン株ポリオウイルス（Sabin2）の細胞培養分離株と参照株
- 経口ポリオ生ワクチン生産のための種ウイルス株および経口ポリオ生ワクチン生産から生じた感染性産物
- 2 型ワクチン株ポリオウイルス（Sabin2）の存在が証明された環境水あるいは水サンプル
- 平成 24 年 9 月以前に、経口ポリオ生ワクチン被接種者から採取された糞便や気道分泌物で、2 型ワクチン株ポリオウイルスの存在が証明されているもの
- 2 型ワクチン株ポリオウイルスを感染させた動物（ヒトポリオウイルス受容体トランスジェニックマウスを含む）または感染動物に由来する検体
- 2 型ワクチン株ポリオウイルス（Sabin2）由来のカプシドシークエンスを含む研究室材料
- 2 型ワクチン株ポリオウイルス（Sabin2）由来のカプシドシークエンスを有したポリオウイルス持続感染細胞