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General questions

1. Why did we need to revise the 2018 Post-Certification Strategy (PCS)?

Since the Polio Post-Certification Strategy (PCS) was noted at the World Health Assembly in 2018, the global landscape for polio eradication and global health more broadly has changed significantly: the COVID-19 pandemic disrupted routine immunization programmes globally; variant poliovirus type 2 (cVDPV2) outbreaks have expanded across the WHO African and Eastern Mediterranean Regions; and the novel oral polio vaccine type 2 (nOPV2) has been developed, rolled out and become the vaccine of choice for responding to outbreaks due to its enhanced genetic stability. A revision of the PCS, now titled *Sustaining a Polio-free World: A strategy for long-term success*, was launched in 2024 to meet these realities and provide a full and clear picture of what is required to achieve and sustain a polio-free world.

2. How is the new strategy for Sustaining a Polio-free World different from the 2018 PCS?

The strategy for *Sustaining a Polio-free World* includes new and updated approaches but remains focused on mitigating the risk of poliovirus re-emergence through three goals: protecting people through continued vaccination, detecting and responding to any polio event or outbreak, and containing polioviruses retained in laboratories for research and vaccine manufacturing. It also includes new chapters on possible governance and accountability structures and a 10-year global cost estimate.

As was done in 2018, the revision team convened experts across polio, immunization, health emergencies, finance, resource mobilization and communications, donors and other health initiatives to gather input on the latest poliovirus epidemiology, lessons learned from the 2016 global switch from trivalent oral polio vaccine (tOPV) to bivalent OPV (bOPV), and changes to the global immunization agenda, health security frameworks and the wider global health architecture. The final strategy will reflect insights from their expert consultations.

3. How does the strategy for Sustaining a Polio-free World fit into broader transition planning?

The <u>Polio Transition Strategic Framework</u> serves as a critical bridge between the strategy for *Sustaining a Poliofree World* and other global health frameworks, ensuring that polio-essential functions and activities are integrated into national health systems and contribute to broader public health goals.

The strategy for *Sustaining a Polio-free World* defines what technical standards must be maintained as polioessential functions are transitioned to national health systems (e.g. polio, immunization, surveillance, outbreak preparedness and response, and containment efforts). Broader transition planning and implementation, already underway through the Polio Transition Strategic Framework, support how countries sustain and repurpose polio investments to keep their communities polio-free while building stronger, more resilient and more equitable health systems. The goal of transition is for national health systems to fully assume these polio-essential functions.

4. How will fragile and high-risk countries be supported under this strategy?

Sustaining a Polio-free World anticipates the need for continued financial support for some high-risk countries that will not be able to transition and sustain key functions, like disease surveillance, within national health systems given limited domestic funding sources. As one way to mitigate this challenge, the strategy contains cost estimates for supporting such high-risk, fragile settings.

The Polio Transition Strategic Framework also recognizes that, given the challenging contexts in which the GPEI operates today, not all countries will be able to absorb polio-essential functions in the short to medium term. In these cases, standardized and routinely updated criteria will guide decisions around support to countries not able to fully finance polio-essential functions. GPEI partners, future owners of this strategy and the broader global health community will need to identify funding streams, likely requiring a variety of resource mobilization approaches, to support countries that cannot self-finance the maintenance of polio-essential functions.

5. How does the strategy for *Sustaining a Polio-free World* align with changes to the global health architecture?

While the strategy for *Sustaining a Polio-free World* defines the technical standards for mitigating the risk of polio re-emergence, implementation plans will need to be developed and integrated into the broader global health landscape. Wherever possible, the strategy details synergies with existing agendas and frameworks, including the International Health Regulations (IHR), the Health Emergency Preparedness, Response and Resilience Framework (HEPR), the Immunization Agenda 2023 (IA2030) and the Lusaka Agenda. Just as these and other global health structures and mechanisms will continue to evolve to meet future needs, implementation plans for the strategy will need to be adapted by existing and new owners. The strategy recommends an evolving governance and accountability model to remain responsive to future risks, including changes to implementation or funding mechanisms.

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Goal One: Protect populations

6. What is bOPV cessation and why is it necessary?

Oral polio vaccines (OPVs) are the most effective way to prevent person-to-person transmission of polio and are therefore key to eradication efforts. Because of their high effectiveness, low cost and easy administration, OPVs have been largely responsible for the 99% decline in polio cases worldwide over the last four decades.

However, all OPVs contain a live, weakened form of the poliovirus that, in rare instances and if allowed to circulate among under-immunized populations for long enough, can revert to forms that can cause paralysis, known as variant polioviruses. Today, following the recommendations of other technical bodies, including the Strategic Advisory Group of Experts on Immunization (SAGE), the types 1- and 3-containing bivalent OPV (bOPV) is still being used in many routine immunization programmes. Responsibly ending the use of bOPV is thus essential to eliminate any risk of new outbreaks emerging.

7. When will bOPV cessation occur and who will be responsible?

Since 2023, the GPEI's bOPV Cessation Team (BOCeT) has been reviewing lessons learned from the 2016 global switch from tOPV to bOPV and supporting the development of global policy for eventual bOPV cessation. To safely and responsibly phase out the use of bOPV from countries' routine immunization programmes, the timing of bOPV cessation must be constantly assessed to incorporate changes within programmatic and epidemiological realities. Policies for bOPV cessation are being carefully considered under the close advisement of technical experts and stakeholders, including SAGE.

BOCeT will continue to develop policy recommendations for endorsement by SAGE. An accountability framework and a decision-making body will be established with clear guidelines of what needs to be reviewed ahead of bOPV cessation, who will provide data to inform decision-making, and who will be tasked with making the decision to proceed or not. Additionally, implementation plans will be developed through engagement with WHO Member States as conditions for cessation approach. Cessation planning, implementation and monitoring will require training, capacity-building, communication and coordination across the global and local levels.

8. What immunity levels will be needed for bOPV cessation?

SAGE recommends countries reach a 95% coverage for a second dose of the inactivated polio vaccine (IPV2). However, it is unlikely all OPV-using countries can reach this target, particularly those with inaccessible and conflict-affected populations. National and global stakeholders should continue to aim for high routine coverage as part of broad system strengthening while monitoring delivery to hard-to-reach, under-immunized populations. In countries that do not reach IPV2 coverage of at least 80%, SAGE recommends targeted campaigns using bOPV to boost immunity ahead of its cessation.

9. Will pre-bOPV cessation campaigns be supported by the GPEI?

Under its 2022–2029 Eradication Strategy, the GPEI remains committed to protecting all children from polio. This includes implementing far-reaching vaccination campaigns using bOPV in the last two countries facing endemic transmission of wild poliovirus type 1 – Pakistan and Afghanistan – and those countries experiencing outbreaks of variant poliovirus types 1 and 3. The GPEI is also coordinating with broader immunization partners through the Big Catch-Up (BCU) to boost routine immunization among children across the world, including for polio. By the end of 2024, the GPEI agreed to fund 54 million doses of bOPV in 24 countries. Through these efforts, the GPEI is helping to build the population immunity needed to end all forms of polio for good and set the stage for bOPV cessation.

Dedicated pre-cessation campaigns are included in the cost estimate of the strategy for *Sustaining a Polio-free World*. Future planning will include recommendations on pre-cessation campaigns based on country risk and an accountability framework to support success.

10. What information will drive critical decisions about protecting populations before and after bOPV cessation?

Recent poliovirus transmission, immunization coverage with IPV and overall population immunity are all important factors that will impact decisions made in each of the periods surrounding bOPV cessation. Continued high-quality modelling will be essential to ensuring advisory groups are well prepared with data for action. Modelling efforts are also ongoing with BOCeT and SAGE to inform all bOPV cessation decisions. Modelling is continuously updated to reflect the current situation, and the GPEI regularly publishes this work in peer-reviewed journals that are publicly available. The Polio Research and Analytics Group (PRAG) and its Subgroup on Analytics and Modelling (SAM) coordinate these research efforts.

11. What is the GPEI doing to ensure sufficient vaccine supply?

To ensure a healthy supply of polio vaccines, the GPEI developed the Polio Vaccine Security Framework that draws upon lessons from past shortages (e.g. IPV and type 2-containing vaccines) to define the coordinated planning and communications, economic incentives and risk mitigation strategies needed to ensure uninterrupted vaccine supply. Further modelling of vaccine stockpile requirements will be required during the implementation planning phase of the strategy for *Sustaining a Polio-free World*, and supply requirements will be communicated to manufacturers two to three years before the start of this strategy.

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Goal Two: Detect and respond

12. What is the status of nOPV1 and nOPV3 development? How do these new vaccines factor into this strategy?

The clinical development of novel oral polio vaccines for types 1 and 3 (nOPV1 and nOPV3), as well as a trivalent version of the novel vaccine (tnOPV), are ongoing with anticipated WHO pre-qualification assessment in 2028/2029. If they are approved, stockpiles of the vaccines will be maintained to respond to any new outbreaks of variant poliovirus following bOPV cessation.

13. What guidance on surveillance activities is included in this strategy and who will be responsible for them?

Surveillance activities outlined in the strategy for *Sustaining a Polio-free World* focus on ensuring the prompt detection of any poliovirus in a human or in the environment through a sensitive surveillance system. This includes guidance on establishing and maintaining an integrated surveillance system and sustaining adequate laboratory infrastructure and information systems capacity. Future surveillance will need to be actively monitored globally, but details of how this will be implemented and who will be responsible will be determined in a future phase of planning. The strategy acknowledges that further implementation planning will be required, especially related to strengthening the integration of polio surveillance into existing vaccine-preventable disease (VPD) surveillance systems.

14. How will the development of national preparedness and response plans be supported under this strategy?

Currently, countries annually update national preparedness and response plans, which are endorsed in-country and by regions through the Regional Certification Commissions with support from the GPEI. The policies, standards and guidelines established for the post-cessation era will also need to be maintained by countries, ensuring that detailed response protocols for polio align with standard operating procedures (SOPs) for outbreak response. The SOPs will complement the guidelines laid out in the Emergency Response Framework (ERF) and will be made available to countries before bOPV cessation. Regional offices and high-risk countries will also be trained in the development of national preparedness plans, and these plans will be tested through regionally-led polio outbreak simulation exercises.

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Goal Three: Contain polioviruses

15. How does this strategy address the risk of containment breaches post-eradication?

To mitigate the consequences of potential breaches, the strategy for *Sustaining a Polio-free World* draws upon both the biorisk management requirements for poliovirus-essential facilities (PEFs), as outlined in the fourth edition of *WHO Global Action Plan for Poliovirus Containment* (GAPIV), and the global governance and oversight mechanisms for poliovirus containment, as outlined in the *Containment Certification Scheme* (CCS).

GAPIV and the CCS work together to support safe and secure poliovirus containment. The CCS provides a process for certifying facilities retaining poliovirus as PEFs through the coordination of national authorities for containment (NACs) and the Global Commission for Certification of the Eradication of Poliomyelitis (GCC), with secretariat support from WHO. GAPIV outlines safeguards required of facilities and requirements for PEF-hosting countries to mitigate the consequences of a facility-associated release of poliovirus, which include population immunity requirements and environmental control measures.

Furthermore, GAPIV Emergency Response and Contingency Planning requires that facilities establish riskmitigating structures and mechanisms that range from physical requirements to routine scenario-based testing to communications and decision-making protocols for use in the event of a breach. GAPIV requires that these structures and mechanisms be aligned with the Public Health Management of Facility-Related Exposure to Live Poliovirus, as well as the legal framework for reporting public health events involving polioviruses as set forth in Annex 2 of the IHR (2005).

16. What will governance and oversight of containment look like under this strategy?

The governance structure for containment leading up to the post-certification period and beyond will depend upon the oversight bodies and structures that exist at each point. At present, the GCC holds authority for certifying global poliovirus containment. Future oversight for containment will be decided by WHO Member States, with either the GCC continuing to provide global oversight or the mandate being given to WHO to assess facilities retaining poliovirus infectious material.

17. Will Global Polio Laboratory Network (GPLN) labs be required to become poliovirus-essential facilities (PEFs) and undergo containment certification under this strategy?

Today, most GPLN laboratories are non-PEFs and must follow specific guidance for short-term retention of poliovirus potentially infectious material (PIM). Once the presence of poliovirus in these materials is confirmed, infectious materials must be transferred to a PEF or destroyed. This arrangement is likely to remain in place in the post-cessation period unless the containment requirements and associated oversight for the retention of poliovirus PIM changes. Some GPLN laboratories (25 of 146) have been designated as PEFs by their host countries and must follow GAPIV guidance and achieve containment certification. Only these laboratories will be allowed to retain polioviruses requiring containment.

It is expected that in the longer term, the GPLN will evolve to ensure a minimum level of diagnostic capacity that will be key to the sustainability of core laboratory surveillance functions. Such testing needs may diminish as time progresses but will be essential to maintain a polio-free world.

Governance and accountability

18. Who is responsible for implementing the strategy for Sustaining a Polio-free World?

As a technical strategy, *Sustaining a Polio-free World* outlines the essential functions and requirements to achieve and maintain eradication. The strategy also outlines a roadmap for phased implementation planning. The required governance, accountability and funding mechanisms will need to be defined in subsequent planning phases, expected to begin after the strategy's presentation to the World Health Assembly in 2026.

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Cost estimate

19. Will the strategy for Sustaining a Polio-free World have its own budget? How will that be determined?

All global costs for polio-essential functions are estimated in this strategy, including costs for the preparatory investments required before the launch of the strategy, such as bOPV pre-cessation campaigns and vaccine stockpiles. The cost estimates for this strategy are not included in the current budget for the GPEI Eradication Strategy. Budgets will need to be developed after a governance and accountability model is established so partners can begin planning for the future costs to achieve and sustain a polio-free world.

20. The strategy only includes global costs. How will country-level costs of the strategy and transition be accounted for?

The cost estimate for this strategy is intended to provide a rough order of magnitude of the global resources required to sustain eradication gains over a period that extends for 10 years after bOPV cessation. Additional global cost modelling will be required as the funding picture becomes clearer and as country readiness is further assessed.

Separate country-level costing is already underway in some countries that are revising or implementing their transition plans. The process will be led by countries and regions as part of transition planning and through the development of national health plans. When the strategy for *Sustaining a Polio-free World* starts, countries will need to review where they are in relation to the current policy of Gavi, the Vaccine Alliance, as well as available domestic resources to support functions like surveillance.

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