

# The world needs to prepare now to prevent polio resurgence post eradication

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## URGENT NEED FOR POLIO VACCINE INCENTIVES

Despite some setbacks in 2022, there has been tremendous progress in the fight to eradicate polio from the world. Following a reduction from 140 cases of wild poliovirus (wPV) in 2020<sup>1</sup> to just 6 cases in 2021, we have seen over 30 cases in the first 11 months of 2022.<sup>2</sup> Twenty of these new cases surfaced in Pakistan and eight in East Africa—a region which was declared wild polio free in 2020. Further concerns have been raised owing to polio being detected in an unvaccinated individual from Rockland County, New York (USA)<sup>3</sup> and positive sewage samples reported from London (UK)<sup>4</sup> and Kolkata (India),<sup>5</sup> countries that have been polio free for many years. The increase in cases in 2022 shows the fragility of the fight against polio and the importance of continued efforts to capitalise on the advances to finally eradicate polio, while taking steps to ensure the world remains polio-free post-eradication.

Ensuring an adequate supply of appropriate polio vaccines will be key to prepare for the world post-polio. After eradication, the WHO recommends cessation of oral polio vaccines (OPV) to eliminate spread of vaccine-derived polio viruses. The world will then rely exclusively on inactivated polio vaccine (IPV) for the next decade or more to prevent the risk of recurrence of polio.

A modelling exercise conducted by Routine Immunisation to Secure Eradication<sup>6</sup> estimated the projected demand and supply for IPV as countries implement WHO's recommendations. The modelling suggests a risk of serious shortages of IPV post-eradication unless existing manufacturers make investments to increase production and new entrants invest in establishing polio vaccine production capacity. However, the polio vaccine market is unpredictable given polio will be only the second human disease ever to

## SUMMARY BOX

- ⇒ The authors of this paper earlier published a commentary on polio vaccine investment, in *BMJ Global Health*: Batson A, *et al*. Polio eradication vaccine investment: how do we ensure polio vaccines are available to keep the world polio-free after transmission of wild poliovirus (wPV) has been interrupted? *BMJ Global Health* 2021;**6**:e006447. In that commentary the authors argued about the need to encourage investments to ensure the world has adequate supply of appropriate polio vaccines post eradication.
- ⇒ The authors have since deliberated on a possible mechanism to motivate polio vaccine decision makers as well as suppliers to make these investments to secure vaccine supply for the future.
- ⇒ After a positive year in 2021—no cases of wild polio virus in the entire world for 7 months—the manner in which the polio landscape has evolved in 2022 mirrors the fragility of the battle against this disease.
- ⇒ In July, a case of paralytic polio was reported from New York, USA. The virus detected in the USA is genetically linked to the strain detected in environmental samples collected in early June in New York, Greater Jerusalem, Israel and London, UK.
- ⇒ Therefore, we need to prepare now to make sure that all children are protected against polio.
- ⇒ The mechanism proposed by the authors is a risk-sharing advance guarantee that will incentivise investment in inactivated polio vaccine (IPV) production and mitigate the risk of mid-term to long-term shortages of IPV stand-alone and IPV-containing hexavalent vaccines.
- ⇒ The financial guarantee mechanism would provide national and global health policy makers with the confidence to adopt IPV and IPV-containing hexavalent vaccines and prevent recurrence of polio, secure in the knowledge that manufacturers would scale up production for surge in demand in the future.

be eradicated (smallpox was the first) and the only one to have continued immunisation for another decade. The uncertainty this creates for both stand-alone IPV and IPV-containing

hexavalent vaccines post-eradication makes investments by firms unlikely, unless future demand becomes clearer.

A simple, risk-sharing advance guarantee mechanism could be the solution to incentivise investment in IPV production and mitigate the risk of mid-term to long-term shortages of IPV stand-alone and hexavalent vaccines. A guarantee could provide vaccine producers with the assurance they appear to need to invest in expanding production capacity to meet the predicted future demand for polio vaccines. The value of this guarantee may initially be tested for IPV-containing hexavalent vaccines and once proven, extended to include other paediatric vaccines with unpredictable future markets.

Global polio vaccine stakeholders must act soon to put in place the safeguards needed to assure continued, adequate supply of IPV even after the world's attention shifts from polio to other priority health goals. After decades of effort and billions of dollars invested in polio eradication, any risk of resurgence post-eradication is much too high a price to pay.

## BACKGROUND

There were only 6 cases of wPV and 698 cases of circulating vaccine-derived poliovirus (cVDPV)<sup>7</sup> reported in 2021 as compared with 140 cases of wPV<sup>8</sup> and 1113 cases of cVDPV in all of 2020.<sup>9</sup> In this last stage before eradication of wPV, most low-income and middle-income countries use stand-alone IPV—one or two doses per child per year, complemented by OPV in some countries.

Polio is expected to be declared eradicated 3 years after the last case of wPV is detected but immunisation will need to continue for many years to prevent cVDPV cases.<sup>10</sup> New wPV and cVDPV cases in 2022<sup>11</sup> may push back the timeline of eradication but it does not change the fact that the global health community needs to prepare now for that day.

The Global Polio Eradication Initiative (GPEI) strategy 2022–2026 focuses on stopping transmission of both wPV and cVDPV. Eradication will likely happen in two phases—first of wPV, followed by the vaccine-derived poliovirus that causes cVDPV. The first phase of eradication requires adequate supplies of both OPV and IPV. However, once wPV is eradicated, OPV will cease to be used as it contains attenuated live virus and the second phase of eradication will rely solely on IPV (stand-alone or in combination).

Currently, GPEI recommends that every child should receive at least two doses of IPV to prevent any recurrence of wPV or cVDPV,<sup>12</sup> a goal that is supported by Gavi, the Vaccines Alliance.<sup>13</sup>

In a meeting of the WHO's Strategic Advisory Group of Experts (SAGE) on Immunisation, held in October 2021, 'SAGE acknowledged that countries have different epidemiological risks and supported the use of IPV-only schedules in countries in polio-free regions with high routine immunisation coverage...that decide to withdraw bivalent OPV before certification of eradication'.<sup>12</sup> During

the same meeting, and confirmed in the last Dec 2021 Weekly Epidemiological Record, the SAGE also made recommendations on how to use appropriate hexavalent vaccines in these countries pending first wP hexavalent WHO prequalification.

SAGE also observed that once adequate IPV supply is available, countries could consider adopting hexavalent (six-in-one) vaccines as part of the Expanded Programme on Immunisation, by increasing the IPV regimen from two to three or more doses.

Immunisation schedules with IPV stand-alone vaccines will mean additional injections at a time when COVID-19 is already putting stress on vaccination systems around the world; the same systems that immunise children from childhood diseases often have to deal with adult and child COVID-19 immunisation. Health providers need simple, easy-to-use techniques that conserve system resources, in which families are able to access immunisation for multiple diseases.

IPV-containing hexavalent vaccines, which prevent six diseases with one injection, have been shown in South Africa to reduce the number of injections from 10 to 7, despite increasing the number of childhood vaccines from 25 in 2009 to 30 in 2015.<sup>14</sup> Combination vaccines have also helped save around an average of US\$8 per child and US\$3 of additional savings in healthcare labour cost and parents' time saving; consequently, saving around US\$10 per child in South Africa.<sup>15</sup> However, IPV stand-alone does cost less than IPV within a hexavalent, so the savings must be viewed alongside the additional manufacturing cost of the new vaccines.

## THE PROBLEM

Shortages of IPV in 2017 and 2018 resulted from underestimating the complexity of scaling up IPV production.<sup>16</sup> Manufacturers estimate it takes roughly 5–7 years to bring a new production facility online from conception to production. In addition, the technology required to produce hexavalent vaccines that meet all the required standards is also extremely complex. In fact, shortages of the five-in-one (pentavalent) vaccine existed for the first 15 years of its use globally.

While decisions on manufacturing plans must be made up to 5–7 years ahead of the first production, procurement plans by purchasing organisations tend to run on much shorter cycles of 2–3 years. Vaccines are purchased by governments, groups of governments or international organisations. None procure far enough in advance or with firm enough commitments to generate the investment required now. This means that there is no clear certainty of demand for manufacturers making, for example, a production-related investment decision in 2023 for doses to be used in 2030 or later. For both existing and potential new manufacturers, this mismatch in timing between when investment decisions must be made and when procurement signals of demand are issued is very challenging.

## THE SOLUTION

Learning from existing financing mechanisms, there is an opportunity to establish a simple solution without disrupting existing procurement mechanisms. A clearer, longer-term outlook on future demand can be established to ensure timely investment in production of IPV stand-alone and IPV-containing hexavalent vaccines.

This new solution can both provide adequate incentives for existing manufacturers and create the conditions to enable new entrants, thereby promoting greater competition and better prices. Planning to avoid shortages in 2026, when GPEI expects eradication to be achieved<sup>17</sup>—requires urgent action now.

The proposed mechanism is an advance volume guarantee. A group of donors would assure a guaranteed, multi-year purchase of a minimum number of doses at a price that would be derived from publicly available international agreements with international purchasers.

The guarantee does not entail any initial fiscal outlay—the mechanism would only pay out if demand falls below agreed levels up to a certain agreed maximum volume. For example, if the demand in a given year were for 400 million (mn) doses rather than the predicted 500 mn, the payout to the supplier would be calculated for a percentage of the 100 mn doses based on their market share. Of course, given public projections of likely demand, the expected demand will exceed supply and there will be no payout. However, the existence of the guarantee provides suppliers with the certainty that if demand is lower than predicted, they will be compensated for their investment.

The guarantee mechanism is not intended to generate additional revenue; it is a transitory way of addressing the tender-manufacturing timeline mismatch by guaranteeing demand until the market is robust and predictable enough to justify investment on its own. For polio, it will assure that post-eradication supply needs are met without disruption, which should happen by the end of the decade.

Parallel action will also be required by implementing countries, donors and development finance institutions to assure sustainable financing for routine immunisation (RI).

## FOUR VARIATIONS OF THE GUARANTEE MECHANISM

The guarantee mechanism can have four variations, some or all of which could be incorporated into the overall scheme

- ▶ **New entrant incentive:** To encourage new entrants to the market recognising it may take 5–7 years for a new production facility to be established.
- ▶ **Regional incentive:** To encourage entry and expansion of manufacturers in a specific region (eg, Africa and Asia).

- ▶ **Price/certainty trade-off:** To ensure that the higher the level of certainty, the lower the price and the lower the level of uncertainty, the higher the price.
- ▶ **Accelerated production incentive:** To accelerate production if there is higher demand for IPV and IPV-containing hexavalent vaccines than expected.

## CONCLUSION

Given the current progress in eliminating wPV, polio eradication is likely to happen sooner than thought possible a few years ago. Demand for IPV-containing hexavalent vaccines is likely to increase well beyond manufacturers' ability to respond based on their current investments but they will not invest more unless that demand is guaranteed.

The financial guarantee mechanism described above would provide national and global health policy makers with the confidence to adopt hexavalent vaccines and prevent recurrence of polio, secure in the knowledge that manufacturers would scale up production for the surge in demand.

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