Operational Framework
for
Monovalent Oral Poliovirus Type 2 (mOPV2)
deployment and replenishment
(during the endgame period)

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Contents:

Annex

Documents (These are examples of the types of documents which might be needed, along with the usual documentation that is used in countries in case of outbreak response.)

1. Introduction

Background on polio eradication. Since the launch of polio eradication at the World Health Assembly (WHA) in 1988, countries, through the Global Polio Eradication Initiative (GPEI), have reduced the global incidence of polio by more than 99% and the number of countries with endemic polio from 125 to 3. In May 2012, the WHA called on the Director-General of the World Health Organization (WHO) to develop and finalize a comprehensive polio end-game strategy. The Polio Eradication & Endgame Strategic Plan 2013-2018 [1] is the result of that request. As noted in that document, wild poliovirus (WPV) type 2 has been eliminated since 1999, and new diagnostic methods have shown that over 90% of circulating vaccine-derived polioviruses (cVDPVs) are type 2. Thus WHO's Strategic Advisory Group of Experts on Immunization (SAGE) recommended in 2012 the withdrawal of the type 2 component of oral polio vaccine (OPV) as soon as possible from routine immunization programmes in all countries, facilitated by the introduction of at least one dose of inactivated polio vaccine (IPV) [2]. These two steps would (1) promote more effective elimination of wild viruses types 1 and 3 using a bivalent (types 1 and 3) OPV,[1] and (2) eventually eliminate the major source of cVDPVs with the withdrawal of type 2 OPV. In addition, the IPV would reduce the risks of OPV2 withdrawal, help stop outbreaks if type 2 were reintroduced, and boost immunity to types 1 and 3 WPV.

Status and strategy of endgame. The endgame strategy has four main objectives: polio virus detection and interruption; immunization systems strengthening and OPV withdrawal; containment and certification; and legacy planning [1]. The withdrawal of type 2 OPV, the switch from use of trivalent OPV to bivalent OPV in all OPV-using countries, and the addition of IPV to the schedule are part of Objective 2, which is coordinated by WHO's Immunization Management Group and overseen by the SAGE. Objective 2 contains the following key milestones: (1) the achievement of at least a 10% year-on-year increase in diphtheria-tetanus-pertussis vaccine third dose coverage in the majority of worst-performing districts from 2014; (2) the introduction of at least one dose of IPV in all OPV-using countries in 2015; and (3) the withdrawal of OPV2 globally in 2016 [1]. Activities to assure the attainment of these milestones were begun in early 2013 and have involved several WHO partners (e.g. UNICEF, the GAVI Alliance, the Centers for Disease Control and Prevention, the Bill and Melinda Gates Foundation, Rotary International), and four clusters within WHO.

In order for the global withdrawal of OPV2 to take place [3] in a timely manner, readiness criteria need to be met in the areas of virus notification, surveillance, vaccine stockpiles, outbreak response and management of travelers. Given current priorities and achievements, the emphasis on needed activities is as follows [4]:

- mOPV2 stockpile and response capacity
- Surveillance, including enhanced environmental surveillance and immediate notification of any type 2 poliovirus
- Licensure of bivalent OPV and its availability for routine immunization

[1] Note that the last type 3 wild poliovirus infection was documented on 10 November 2012

- Solid implementation of at least one dose of IPV for all OPV-using countries
- Assurance of elimination of WPV2 and of type 2 containment for all regions.

The trigger event for OPV2 withdrawal, that is the event which would fix the date, would be the evidence for absence of all 'persistent' cVDPV2s for at least six months globally [5]. Thus, global readiness must be assured by the end of 2015 to meet the projected time frames for the withdrawal of OPV2 in mid-2016.

Why a stockpile is needed. In the face of withdrawal of one of the three serotypes found in trivalent OPV, there is a need for an outbreak response capacity upon the detection of ANY circulating type 2 poliovirus, because both the wild type and vaccine strains have been associated with outbreaks and continued circulation of type 2 virus. The primary risks the stockpile is designed to address are thus (1) cVDPV2s emerging anywhere in the world during or after the withdrawal of OPV2 in routine immunization and (2) circulation of WPV2 released, accidentally or intentionally, from a laboratory or an IPV production facility. The withdrawal of one serotype of poliovirus can serve as a 'dress rehearsal' for withdrawal of all OPV immunization (i.e., of bOPV) once eradication is certified, and the lessons learned with the mOPV2 stockpile can ultimately allow OPV cessation to proceed more smoothly and effectively.

Scope of the Operational Framework. This document describes the mechanisms for vaccine procurement, storage and release, roles and responsibilities of WHO, UNICEF, national regulatory authorities (NRAs), manufacturers and advisers, as well as the operational steps for vaccine deployment to respond effectively to a polio type 2 outbreak and for the ongoing management of the stockpile.

2. The stockpile, its procurement and governance

WHO and UNICEF developed in 2009 a Memorandum of Understanding that led to a Request for Proposals (RFP) for supply of bulk mOPV2 for the stockpile [6]. The RFP spelled out the main points of stockpile governance, procurement, management, containment, and qualities. Based on this, bulk OPV stockpile contracts are being developed with two European manufacturers for the period from contract signing until 31 December 2018. An RFP is being developed for finished product procurement.

The Objectives of the stockpile are to ensure 1) rapid access of vaccines for countries experiencing epidemics; and 2) outbreak response capacity for an emergency vaccination against any type 2 polio, in case of either a) circulation of VDPV2 during or after withdrawal of OPV2, or circulation of WPV2 accidently or intentionally released from a laboratory or manufacturing facility

Keys to stockpile use: speed and appropriateness. Effective outbreak response demands speed. This means that instances of circulating type 2 poliovirus must be detected and notified as quickly as possible, and analyzed for actions to be taken within 24 hours of notification. These time frames will be further developed in part 3. Appropriateness means that the outbreak response is appropriate to the speed of detection, the number of years since OPV2 has been withdrawn from use, the type of circulation and the immune status of the surrounding population (Annex1), [7]. Figure 1 below shows schematically how outbreak response is affected by these factors.

FIGURE 1 (from Annex 1). Outbreak Response Determinants after OPV2 Cessation

Zone 1: Clear history of sustained WPV or reported cVDPV2 since 2000; OR affected community with other risks for low immunity or high mobility to susceptible communities
Zone 2: Consistently low DTP3 coverage <80% in the previous 3 years; OR history of imported WPV or any cVDPV in the previous 3 years; OR with DTP3 coverage <90% and adjacent to affected area
Zone 3: DTP3 coverage consistently >80%; affected community with few risk factors for sustained transmission

Matrix for WPV/cVDPV response after OPV2 cessation (Preliminary Draft)

	Zone 1	Zone 2	Zone 3
Phase 1 (within 2 years post OPV2 withdrawal)	- Target population (TP) 1million minimum - Age group up to 10 years minimum - Minimum 3 rounds SIA	- TP 1million minimum - Age group up to 5 yrs minimum - Minimum 3 rounds SIA	- TP dependent on situation - Age group up to 5 yrs minimum - Minimum 3 rounds SIA
Phase 2 (within 3-5 years post OPV2 withdrawal)	- TP minimum 1 million - Age group up to 10 years minimum - Minimum 3 rounds SIA	- TP 1million minimum - Age group up to 10 years minimum - Minimum 3 rounds SIA	- TP dependent on situation - Age group dependent on situation - Minimum 3 rounds SIA
Phase 3 (after 5 years post OPV2 withdrawal)	- TP minimum 2 million - Age group up to 15 yrs minimum - Min 5 rounds SIA	- TP minimum 1 million - Age group up to 10 years minimum - Minimum 4 rounds SIA	- TP minimum 1 million - Age group up to 10 years minimum - Minimum 3 rounds SIA

Contents. Informed by modelling and precedent [8, 9, 10], UNICEF has proceeded with contracting for a mOPV2 stockpile. At present it is to be composed of about 500M doses of bulk mOPV2 equally supplied by the two contractors. Further contracting will proceed for up to 100M doses in finished product form, which will be available in 2016.Products from at least two manufacturers will form part of the stockpile and these products will be licensed and under the oversight of the appropriate competent regulatory authorities and the WHO prequalification team. At least one mOPV2 has already been licensed and prequalified [11]; an additional product is in the licensing process (expected date of licensing by Q3 2015). The shelf

life of the bulk form of the vaccine the is 30 years according to stability data and stored at -70 ºC

Location, management and governance of the stockpile. The stockpile will be held at the manufacturing sites of the manufacturers under contract to supply it [6]. There will be at least two sites; if there is only one manufacturer, that manufacturer will have two separated sites. UNICEF will procure and WHO will maintain ownership of the stockpile. The roles and responsibilities of each party (manufacturer(s), NRA(s), WHO and UNICEF) are outlined in the RFP [6] which builds on the Memorandum of Understanding between WHO and UNICEF establishing stockpile governance. The sites will be equipped with appropriate containment facilities as outlined in relevant sections of the WHO document GAP-III (*insert reference from website*).

Manufacturers are contractually obligated to manage quality assurance, production and control, appropriate storage, inventory, monitoring and maintaining contracted amounts of the polio bulk and finished product stockpiles, assure valid national licensing and continued WHO prequalification, and to report regularly [6] to their respective NRA, WHO and UNICEF.

Decision making for replenishment of the stockpile. As noted above, manufacturers are responsible for maintaining the contracted amounts of the stockpile, based on use. Because the outbreak response depends first and foremost on the time since OPV2 withdrawal (Figure 1), decisions about the deployment and replenishment of the mOPV2 stockpile are tied to these time frames. For example, in the first three years after OPV2 withdrawal, WHO expects to respond to an average of three outbreaks per year vaccinating 5M children per round, thus planning for 45M doses per year (3 outbreaks, 3 rounds, 5M children).

Currently 500M doses in bulk and 100M doses in filled form are planned for the mOPV2 stockpile. Based on the expected response of using 45M doses in the first and second year, the stock of vaccines in filled form will need to be replenished after the first year to ensure having enough filled form for year three.

After a five year period after withdrawal, without outbreaks from PV2, the susceptible population will have increased. Therefore a larger quantity of mOPV2 will be needed and replenishment of the stockpile needs to be considered of vaccines in both the filled and bulk form.

➔ There is a need for a process for decision making as to how many outbreaks would lead to a need to reinstate OPV2 immunization.

International nature of stockpile. Although the principle of building an international stockpile is generally agreed, there are some moves, for example, in the United States [10], to develop national stockpiles. The WHO stockpile is for all countries, whether or not they have previously received vaccines through UNICEF. Since the mOPV2 supply will be finite, there are risks associated with development of national stockpiles, including possible limited availability of doses to countries that need them, inconsistency of use with the possibility of flawed outbreak response, and

containment issues. Every additional site for storage of OPV2 after its withdrawal is a potential site for intentional or unintentional release of PV2 into the environment. Thus the GPEI recommends that there be only an international mOPV2 stockpile. The major reasons for establishing an international stockpile are:

- *Rapid response*: an international stockpile will facilitate a rapid and coherent response to circulating poliovirus;
- *Universal access*: an international stockpile will ensure that vaccine can be available, if necessary, to any country in the world within 48 hours;
- *Enhanced safety*: an international stockpile will reduce the risk of poliovirus into an increasingly polio susceptible world.

3. Decision making for release

FIGURE 2. Process for decision making

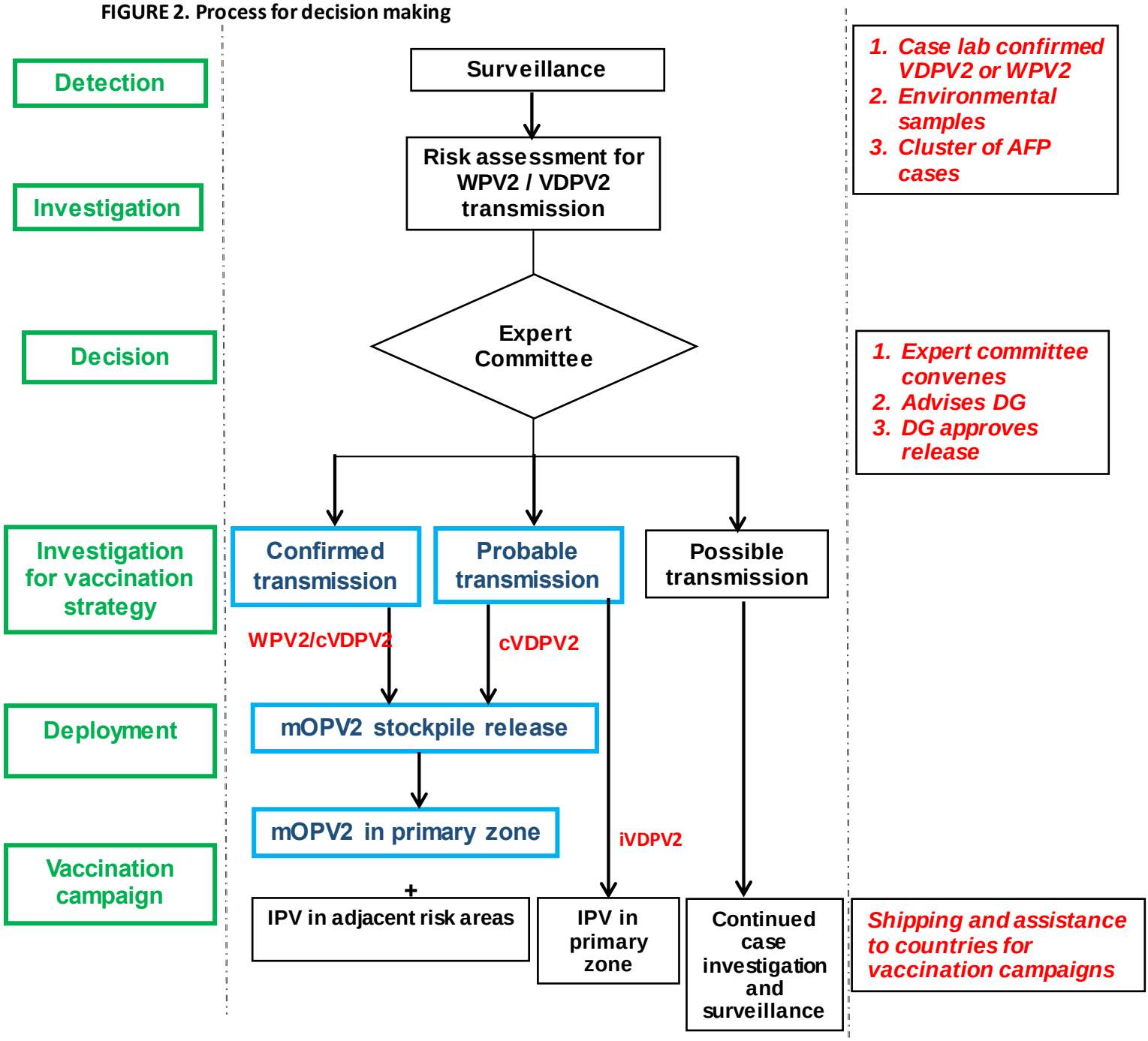

Table 1. Classifications of type 2 poliovirus transmission

Transmission of detected poliovirus	Evidence
Confirmed	detection of an infected individual –WPV or VDPV-without documented physical exposure to a virus in a laboratory or a vaccine production facility
Probable	detection of genetically related viruses from 2 or more environmental samples over time and space consistent with circulation in the population (e.g. cVDPV) or detection of an iVDPV
Possible	isolation of a type 2 virus in a single environmental sample or in an individual with

	documented exposure[2]

Criteria for vaccine release

Trigger events. Through the detection and verification of rumours (WHO's surveillance system), WHO is alerted if: 1) a laboratory confirmed case of VDPV2 or WPV2; 2) positive environmental samples; or 3) suspected cluster of AFP cases are detected.

Any of the above trigger events should initiate an immediate investigation within 48 hours to confirm, characterize the outbreak and assess the risk of transmission as rapidly as possible. Detailed steps for the required epidemiologic field investigation and enhanced surveillance review are outlined in recent GPEI guidelines for investigation and responding to a polio outbreak. (Annex 1).The initial investigation of a WPV or VDPV requires a similar approach.

Beyond confirming the outbreak, the investigation should include a risk assessment to confirm a sustained transmission and preparation for an immunization response of appropriate scope.

The risk assessment will lead to a decision whether to release mOPV2 from the stockpile, to estimate the target population or ensure further investigation:

1. **Confirmed sustained transmission of circulating** VDPV2 or WPV2. A release of the mOPV2 stockpile will be recommended by the Expert Committee plus administration of IPV in adjacent areas

2. **Probable sustained transmission of circulating** VDPV2 or WPV2. A release of the mOPV2 stockpile will be recommended by the Expert Committee plus administration of IPV in adjacent areas

3. **Possible sustained transmission** that will need continued case investigation and surveillance before any decision can be made.

The risk of a type 2 outbreak will be determined by 1) the time since OP withdrawal; 2) the nature of the virus (e.g. wild vs. Sabin virus); geographic location and proximity to high risk communities with immunity gaps; and 4) the population characteristics (e.g. underserved, mobile, conflict-affected, history of virus importation). It should be noted that an isolated WPV or cVDPV2 importation event involving a single AFP case proven to have originated from outside the country or in a single environmental sample would not yet be considered evidence of active poliovirus transmission [12].

In-country preparations for a potential response will begin immediately once a laboratory-confirmed circulating poliovirus, a cluster of clinically compatible poliomyelitis cases in a susceptible population, and/or a breach of containment with community exposure to WPV has been defined regardless if the event will be defined as a public health emergency of international concern (PHEIC), (Annex 1).

[2] When an individual is known to be significantly exposed to the contaminated material (e.g. exposed to highly concentrated vaccine bulk in the vaccine production facility.

Decision process.

As indicated above, the discovery of any type 2 poliovirus isolate should initiate and immediate investigation.

Roles and responsibilities in the decision process.

The responsibility for initiating assessment lies with the WHO Secretariat. If a confirmed case is detected with circulating VDPV2 or WPV2 poliovirus and/or the event is a potential PHEIC, arrangements would be made for a consultation with the expert committee within 48 hours, and the manufacturer(s) managing the stockpile, UNICEF and their respective NRAs would be notified.

The expert committee, consisting of representatives from the SAGE Working Group (WG) including the chair from the SAGE WG, emergency response as well as vaccine strategies experts, will evaluate the request to release mOPV2 from the Stockpile and make their decision within two days after receipt. The expert committee provides advice to the Director General who will make the final decision for action, based on the recommendations of the Expert Committee. It is critical that the requested vaccines are rapidly released from the Stockpile and shipped quickly. The decision makers are selected based on their technical expertise and availability.

- Composition of the expert committee needs to be finalized
- TORs for expert committee need to be developed

Time frames for decision making. All reported events are immediately assessed by the WHO Secretariat. If the risk of a circulating type 2 poliovirus cannot be immediately excluded, the Director-General is informed, UNICEF, the manufacturer(s) and NRA(s) are notified, and a consultation of the Expert Committee is convened. Within 48 hours of the WHO assessment, the WHO Secretariat and the Expert Committee are expected to either:

1. Advise the DG release vaccine immediately (if the vaccine request is complete)
2. Request more information (if the request is incomplete) review the event and decide on further action,
3. Continue monitoring and evaluating the event providing recommendations
4. Discard the event

Further actions in the case of a recommendation to monitor would be made on a case-by-case basis.

The final decision for action is made by the Director-General. If the decision is to release mOPV2 from the stockpile, the Director General will immediately inform the Ministry of Health of the requesting countri(es) of the decision, UNICEF will inform the manufacturer(s) and NRA(s), requesting shipment within 48 hours, and the receiving countri(es) will finalize all preparations for reception and use of the vaccine.

Within 24 hours of taking a decision, the Director-General shall issue a Note Verbale to Member States of the mOPV2 release and the expected time and place of use.

Even if the reported event is not deemed to be a PHEIC, especially in the first three years after VP2 withdrawal, this does not imply that investigation activities will stop or that the event will be ignored.

4. Outbreak response immunization

Strategies. In general, the outbreak response immunization strategies should not differ from those used currently for GPEI [16]. However, depending on the length of time since confirmed transmission of type 2 poliovirus and since withdrawal of OPV2, the size of the target population and number of rounds of the immunization campaign may be larger. Considerations are given in Annex 1.

Requested amounts based on figure 1. According to WHA59.1 [17], the requested amount of vaccine should be based on the target population, the number of rounds of vaccination, and the wastage factor, 1.20. The number of vials is calculated by dividing by 20, as the stockpile is likely to be in 20-dose vials. Countries requesting release of vaccine should be prepared to describe planned immunization strategies, requested numbers of doses, and the disposition of these doses on a regular basis. The WHO Secretariat will track this information and provide information to the Expert Committee and Director-General on a regular basis. Information should be recorded on standard forms to be developed (see *Documents*).

5. Logistics

Vaccine release. Once UNICEF has contacted the manufacturers to request vaccines from the stockpile (after approval for release from WHO's DG), the manufacturer(s) will make the vaccines ready for pickup by UNICEF's freight forwarders within 48 hours. As the product is not in regular use, there should be stocks of product in finished ready-to-ship form, released by both manufacturer and NRA, stored at -20°C. The contract will specify how frequently and on what basis the manufacturers will replenish the finished product stocks. Specified in the contract will be mechanisms for releasing and labelling the finished products.[3]

[3] It is expected that the vaccine will be stored and shipped without expiry date and without Vaccine Vial Monitors; this would be part of the contract terms, and will be determined by the WHO Prequalification Team in collaboration with UNICEF.

Shipping. Emergency shipping procedures would be specified in the contract and are not expected to differ from current emergency procedures already in place with freight forwarders.

Documentation. Documentation required to accompany shipping would normally include all paperwork specified in the contract and again is not expected to differ from current procedures, with the possible exception of the lack of expiry date and Vaccine Vial Monitors on the finished vials of vaccine. WHO will approve the label and label wording. Some countries have special requests for documentation that may need to be formally waived. Potency tests to establish the stability of the product under the stockpile storage conditions would be performed by the manufacturers and assessed by the NRAs and the WHO prequalification team at regular intervals specified in the contract to ensure that vaccines would meet all applicable WHO guidelines.

Containment. The "WHO Global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of routine OPV use (GAPIII)" covers the kind of containment facilities and practices that should be in place for stockpile storage as well as the changes that might occur as the situation evolves. The safeguards that should be in place for OPV2 components around the period of OPV2 withdrawal up to the point where polio is eradicated would include primary safeguards to meet facility containment specifications, and secondary safeguards including high national population immunity in countri(es) hosting the production and storage facility. Requirements for gaining and maintaining accreditation for containment on the national and international levels are specified in the contract. Figure 3 shows the type and timing of containment safeguards for OPV manufacturers.

FIGURE 3. GAP III containment safeguards [18]

	Poliovirus type 2 containment period	Final poliovirus containment period	
	All type 2 polioviruses	All OPV/Sabin polioviruses	All wild polioviruses
1° safeguards: Prevent infection & release of contaminated materials			
Operator protection[4]	Yes	Yes	Yes
Decontamination of materials/equipment	Yes	Yes	Yes
Dedicated effluent treatment plant	No[5]	No[3]	Yes[6]
Air/exhaust treatment	No	No	Yes[7]
2° safeguards: Population immunity in country hosting the facility			
IPV doses	≥ 1	≥ 1	≥ 3
IPV coverage	= DTP3 coverage[8]	= DTP3 coverage	>90%[9]
3° safeguards: Environment & location			
Siting of facilities in areas with low transmission potential (R_o) for wild polioviruses	No	No	Yes

[4] Since the operator is considered to be one of the sources of release of poliovirus from the facility, specific measures of protection are required, including e.g. the use of PPE, the use of primary containment devices, and vaccination

[5] Untreated release into closed sewage system with secondary effluent treatment in facility location (Note: all waste from facilities, potentially containing live poliovirus, should be inactivated prior to release through adequate and validated inactivation procedures. For facilities without a dedicated effluent treatment plant, this would normally be done through the application of heat or chemicals as part of a validated treatment process. Under no circumstances should raw poliovirus containing effluents be discharged to drains, unless the effluent treatment plant has been designed and validated to handle such effluents, effectively acting as part of the primary containment system)

[6] Facility effluent treatment before release into closed sewage system with secondary or greater effluent treatment in facility location

[7] HEPA (high efficiency particulate arresting) filtration on exhaust air

[8] Diphtheria-tetanus-pertussis (DTP3) immunization coverage (World Health Organization)

[9] (World Health Organization, 2013)

Disposal of unused stocks. Once the outbreak response immunization is over, vaccines must again be contained. Within two weeks of the last day of immunization in the last round, countries must report to WHO on the remaining stock. The final disposition of remaining vaccine will be decided case by case after evaluating the risks and benefits, depending on the quantities, country, storage conditions, re-importation and regulatory procedures/approvals. Should the quantity remaining be more than 1M doses of unopened vials, documented to have been properly stored, decisions on destruction or return to the global stockpile will be made by WHO and UNICEF.[10] For quantities of less than 1M doses, instructions will be provided for secure disposal [19]; for example, by exposure to high temperatures. Opened vials should be disposed of securely at the local level, and instructions will be provided for this destruction. All destruction procedures will need to follow WHO recommendations for vaccine disposal.

6. Vaccine specifications and storage

Storage, inspection, quality assurance. mOPV2 products will be securely stored in bulk at -40°C,[11] or below and as finished product in 20 dose vials at -20°C until shipping, or as specified in the contracts. It is probable that the finished vials will be supplied without Vaccine Vial Monitors and expiry dates to facilitate their use in emergency situations; however these considerations will be developed with the WHO prequalification team and UNICEF and included within the contracts. The contracts will specify manufacturer, NRA, UNICEF and WHO responsibilities in inspection of storage facilities and quality assurance of stockpiles and stockpiled products. The manufacturer will test potency of the stockpiled products as specified in the contract but at least every five years, and the results will be reviewed by the relevant NRA and by WHO. Inventory of the stock will fall under the responsibility of the manufacturers and UNICEF.

[*As part of the transmission process of this document for comments, the current status of contracting will be included, available from UNICEF SD.*]

Adding new suppliers. In the event that additional suppliers (either producers or fillers) are needed, this would mean that the contracting process would have to be restarted.

7. Legal considerations

Indemnification. UNICEF, under normal circumstances as a matter of course, includes indemnification in the contracting process [6] which requires that the manufacturer indemnify UNICEF, the governments receiving the vaccines and all parties making a financial contribution to the purchase of the vaccines from and against claims arising out of the contract or breach of contract. In the case of the smallpox vaccine emergency stockpile, its Framework Document [14] contains a requirement for indemnification of WHO and the manufacturer(s), without which

[10] Note that without VVM this policy could risk returning less than fully potent vaccines to the stockpile.
[11] At -40° C, the potency of bulk vaccine is stable for at least 40 years

vaccine will not be shipped. In the case of the mOPV2 stockpile, the situation is slightly different as the vaccines involved will be licensed and prequalified; thus it seems that usual contracting specifications on this issue would prevail. This means that in case of vaccines that are licensed in both the producing and recipient countries, the manufacturer is responsible and accepts all liability for the use of the vaccine. If the vaccine is not licensed in the recipient country, the government, or the requesting party, accepted liability. This is included as part of the terms and conditions on the vaccine request form (Document 3).

International Health Regulations. All procedures described in this document are intended to be in accord with the International Health Regulations [13] Under these regulations, countries are required to report promptly incidents that could lead to a PHEIC with PV2. WHO will then respond promptly to reduce risks and resolve the PHEIC.

8. Regulatory considerations

Role of National Regulatory Authorities in licensing and oversight. The roles and responsibilities of the manufacturer's NRA have been spelled out in the RFP [6]. It is the responsibility of the manufacturer to ensure that the vaccine is licensed by the reference NRA and where needed and that the license is renewed to cover the period of the stockpile contract. In the case of recipient countries that require national licensing of vaccines, these NRAs should take steps to license the stockpile product to prevent delays should the product be needed, or to put in place a waiver or a procedure for Emergency Use Authorization. In case of specific regulations in countries, or groups of countries, that might prohibit entry of mOPV2 from the stockpile across their borders, to avoid delay in the case of a Polio type 2 outbreak, special arrangements must be made.

Prequalification. It is intended that the mOPV2 products in the stockpile be WHO-prequalified, which could expedite their licensing and acceptance in countries. As specified in the contracts, the manufacturers are responsible for submission for WHO prequalification and for maintaining the prequalification status to cover the period of the stockpile contract.

9. Financing. Already more than $48M has been set aside for the original mOPV2 bulk stockpile.

➔ Clarification is needed on the sources of funding for various aspects of the development, management and deployment of the mOPV2 stockpile.

Areas where financing options are needed. Additional funds and precisions on who would be responsible for payment are needed in the areas of:

- Finished product stockpile contracting and bulk and finished product stockpile contracting
- Stockpile management, inspections, governance by the WHO secretariat
- Event assessments

- WHO field investigation in country outbreak response activities
- Operational costs for outbreak response activities and vaccination campaigns
- Monitoring and evaluation of the outbreak response

Potential financial interventions. There are two major sources of funding for the above activities, the WHO budget and external funding. GPEI has depended to a large extent on external funding, including for the initial investments for stockpile acquisition. It might be envisioned that stockpile contracting and management could be covered under such funding sources. WHO field investigation and operational costs would normally come from WHO programme and country budgets. However, in the case of a re-emergence of Polio type 2, WHO will request using funds from the HQ Rapid Response Account under the Emergency Response Framework. It is possible that the same mechanism could be used for events arising from polio type 2 event assessments and activities arising from mOPV2 stockpile deployment.

Revolving fund A revolving fund could be set up to allow for the purchasing of mOPV2 to replenish the stocks if no other funds are available. After an organization or a country receives the requested mOPV2, it reimburses the revolving fund for the vaccines and for any associated costs, such as shipping, of the vaccines. Reimbursed funds in the revolving fund are used to purchase more vaccines for the mOPV2 stockpile.

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