IN SUPPORT OF THE

Global Polio Eradication Initiative

GUIDANCE NOTE ON

cold chain logistics and vaccine management during polio supplementary immunization activities

Annex-2 updated in May 2017

polio global eradication initiative

unicef



ACKNOWLEDGEMENTS
The UNICEF polio team developed this guidance note with inputs from immunization unit, health section/ programme division, supply division, UNICEF regional and country offices and GPEI partners.

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Health Section/ Programme Division
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Executive summary

The Global Polio Eradication Initiative (GPEI) was established in 1988 when there were an estimated 350,000 polio cases reported from 125 endemic countries. Since then there has been tremendous progress towards global polio eradication, and by September 2015 only two countries continued to have endemic transmission of wild polio virus: Afghanistan and Pakistan.

Building high population immunity to poliovirus infection through routine immunization as well as through supplementary immunization activities (SIAs) is key to polio eradication. UNICEF, as one of the spearheading partners of GPEI, is the lead agency for procuring, supplying and managing vaccine logistics in polio-affected countries. In 2014, UNICEF procured more than 1.7 billion doses of oral polio vaccine (OPV) and delivered those to over 60 countries for use in SIA and routine immunization. In addition, more than 8 million doses of inactivated polio vaccine (IPV) have also been delivered for SIAs primarily in the endemic countries and Nigeria.

The magnitude of annual vaccine procurement and utilization by GPEI and the urgency for achieving polio eradication has further underscored the need to rapidly develop clear guidelines and tools for improving vaccine management in the context of polio SIAs. This guidance note aims to summarize critical technical concepts and activities to be implemented before, during and after polio SIAs in the domain of cold chain logistics and vaccine management (CCL&VM). The guidance note was developed in consultation with experts in countries, regions and partner organizations. After a brief overview of SIA approaches in the context of the Polio Eradication and Endgame Strategic Plan 2013–2018, the guidance note highlights common challenges encountered in polio SIAs and consolidates key lessons learnt and available resources and tools.

We expect that application of these guidelines will help country immunization programmes manage a valuable resource like polio vaccines more efficiently and effectively. The guidance note also references examples demonstrating how polio eradication programme and routine immunization can mutually benefit each other.

We believe this guidance note would also contribute to the broader efforts made to strengthen overall immunization supply chain and cold chain and logistics including that for non-polio SIAs as part of the GPEI legacy.

We request your kind support in adapting and implementing this guidance note towards improving polio vaccine management. Polio programme staff remain readily available to extend support to countries and regions as we work together towards achieving global polio eradication.

> **The world has a historic opportunity to eradicate polio, once and for all. UNICEF is committed to playing a central role in this effort. As previously noted, doing our part in the global eradication effort is a top corporate priority and is to be treated by the whole organization with the same sense of urgency and importance as a 'Level 3' emergency**
>
> —Anthony Lake, UNICEF Executive Director

INTRODUCTION

In May 2012, the World Health Assembly formally declared polio eradication as a "programmatic emergency for global public health" and called for the development and finalization of a comprehensive polio endgame strategy. Efforts towards eradication involve many different actors at country, regional and global levels. At the centre of this effort is the Global Polio Eradication Initiative (GPEI), which was established in 1988 when there were an estimated 350,000 polio cases reported from 125 endemic countries. Considerable progress towards global polio eradication has since been made, and by September 2015 only two countries continue to have endemic transmission of wild polio virus: Afghanistan and Pakistan. However, due to significant gaps in immunity and high population movements, several polio-free countries were either re-infected, causing large outbreaks with extensive transmission, or remain at risk.

UNICEF is one of the leading partners in the GPEI along with the World Health Organization, Centers for Disease Control and Prevention, Rotary International and the Bill and Melinda Gates Foundation. Within the polio partnership, UNICEF is the lead agency for two specific areas:

1. Communication and social mobilization and
2. Vaccine supply, which includes procurement, effective vaccine management (VM) and cold chain logistics (CCL)

UNICEF's role in vaccine supply includes providing technical support to national governments, local authorities and partners to:

1. Forecast, procure and deliver vaccines and cold chain equipment
2. Manage in-country vaccine stocks, including effective vaccine management up to the point of service delivery, and
3. Maintain cold chain equipment (CCE) and strengthen logistics services

Purpose of a guidance note on CCL&VM in polio SIAs

As a leading agency in supporting immunization supply chain systems, UNICEF is expected within the GPEI to play a key role in supply chain, which includes procurement and delivery of vaccines to countries procuring through UNICEF, as well as in-country cold chain, vaccine management and logistics support. While procurement and supplies to country level are managed by UNICEF Supply Division (SD) at the global level, UNICEF Country Offices (CO) supported by UNICEF Regional Offices and Programme Division (PD) have a more direct role to play in supporting national immunization programmes in planning and managing their vaccine supplies in-country. This guidance note aims to provide UNICEF staff and consultants at global, regional and country levels as well as GPEI partners with a framework to guide and strengthen their role in implementing cold chain logistics and vaccine management activities, focusing on country-level activities.

Countries either manage their own procurement and supply of vaccines (at country or regional level) or depend on UNICEF-SD to do so. While this guidance note focuses on UNICEF vaccine supply management, many of the principles outlined here can also be adapted by other partner agencies and by country programmes that procure and manage their vaccines directly.

Scope of this guidance note

This guidance note focuses on cold chain logistics and vaccine management (CCL&VM) activities to be implemented before, during and after polio SIAs, and will help to:

- Explain the expected roles and responsibilities for UNICEF staff/ consultants to ensure that appropriate CCL&VM systems and mechanisms are in place at different levels before, during and after a polio SIA
- Outline the processes, tools and indicators available to support these efforts

Most countries in the world have experience in implementing mass immunization campaigns (supplementary immunization activities or SIAs) with oral polio vaccines (OPV), and some also have experience in implementing measles and tetanus SIAs. While most references in this guidance note pertain to using OPV in SIAs, as per GPEI guidance, the endemic countries are also conducting SIA rounds with Inactivated Polio Vaccine (IPV) in special situations. Implementing IPV SIAs poses a different set of operational and communication challenges from those encountered in OPV or measles SIAs. While this guidance note does not attempt to serve as detailed operational guidelines for IPV SIAs, we include a brief section on this area and provide a comparison of some of the operational (logistics) and communication issues that programme managers may need to consider before conducting an SIA round with OPV, IPV or measles vaccine (Table 1)

This guidance note may also be useful to any other staff working on cold chain and logistics. It is not expected, however, that this guidance note will cover all the details related to cold chain and logistics during polio SIAs. For additional information, relevant links and resources are included at the end of the document.

TABLE 1

OPV, measles and IPV campaigns: Key differences in technical, operational and communication domains

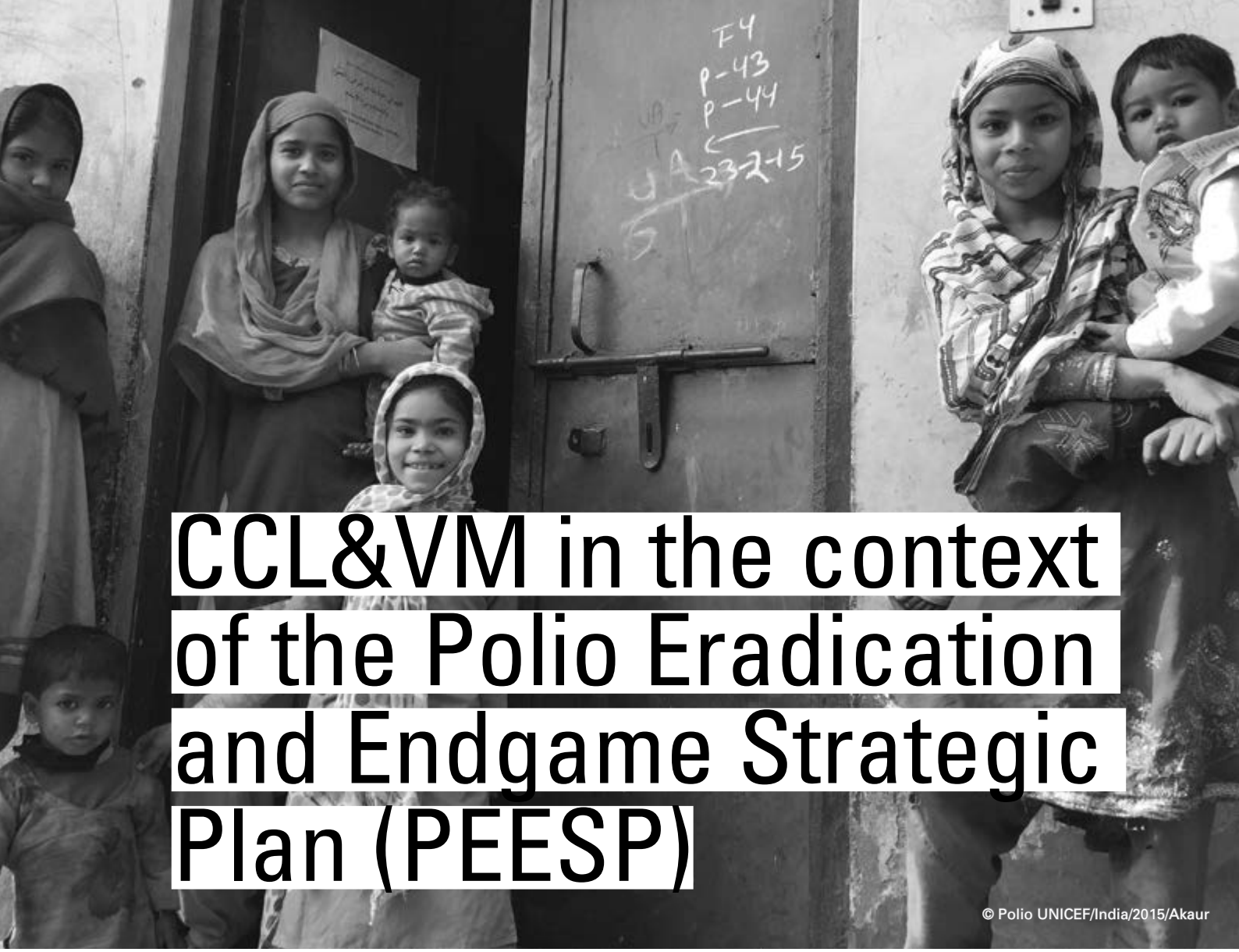
PARAMETER	ORAL POLIO VACCINE (OPV) CAMPAIGNS*	MEASLES VACCINE CAMPAIGNS	INACTIVATED POLIO VACCINE (IPV) CAMPAIGNS
Operational experience	Most countries have extensive experience	Many countries have experience	Very limited to no experience at country level
Target population	Target population usually 0–59 months (may be modified by local epidemiological situation/ outbreak response)	Target population variable: Usually lower limit is 6 or 9 months and upper limit is 5, 10 or 15 years	As per GPEI recommendations suitably adapted to local epidemiology and national/regional TAG recommendations
Duration of SIA	Usually completed in a few days to a week	May extend over 3–4 weeks	May extend over 3–4 weeks
Route of administration of vaccine	Oral	Sub-cutaneous (SC) injection. Also effective by intra-muscular (IM) route	Intra-muscular (IM) or SC injection
Storage requirement and precautions during transit	Vaccine vials can be stored until expiry date (usually 2 years) at –20 Degrees or at +2 to +8 Degrees Celsius for a maximum of 6 months. During shipment or in the field, vaccine may be thawed and refrozen.	Injectable vaccine with diluent for reconstitution: Freeze-dried vaccine can be stored at +2 to +8 Degree Celsius. Diluent stored at same temperature at least 24 hours before use and must not be frozen	Injectable liquid vaccine. Damaged by freezing. Occupies same compartment as other vaccines used in routine immunization (+2 to +8 Degree Celsius) and may pose storage constraints in IPV-OPV campaigns. Special precautions needed to ensure vaccines are not frozen during transit.
Bundling and supply to service delivery points	Supply with droppers	Supply with manufacturer's diluent, sterile syringe/needle for reconstitution and administration	Supply with sterile syringe/needles for administration
Use of opened multi-dose vials	Opened vials can be re-used for up to 28 days as per criteria laid down in WHO MDVP policy.	Reconstituted vaccine: Discard after 6 hours or end of session, whichever is earlier	Opened vials can be re-used for up to 28 days as per criteria laid down in WHO MDVP policy.

Continued >

TABLE 1 (CONTINUED) OPV, measles and IPV campaigns: Key differences in technical, operational and communication domains

PARAMETER	ORAL POLIO VACCINE (OPV) CAMPAIGNS*	MEASLES VACCINE CAMPAIGNS	INACTIVATED POLIO VACCINE (IPV) CAMPAIGNS
Vaccine wastage rate	5–15% on average	10–15% depending on vial size	Limited IPV SIA data available suggests <12%
Service delivery strategy	Usually house-to-house strategy or combination of fixed post and house-to-house strategy	Usually fixed vaccination posts	Usually fixed vaccination posts
Vaccinator skills	Volunteers can administer vaccine	Staff skilled in safe injection practices needed	Staff skilled in safe injection practices needed
Risk of adverse events following immunization	AEFI risk is extremely low	AEFI risk is low, but greater than for OPV	AEFI risk is low
Safety and bio-hazardous waste	Some waste generated (plastic – droppers and glass – vials)	Management of potentially hazardous waste (sharps) extremely important. Need for safety boxes or other safe methods of disposal.	Management of potentially hazardous waste (sharps) extremely important. Need for safety boxes or other safe methods of disposal.
Communication and social mobilization	Effective social mobilization important to ensure high attendance at fixed posts. Inter-personal skills critical for successful vaccination during house visits	Effective social mobilization critical to ensure high attendance at fixed vaccination posts	Effective social mobilization critical to generate demand for attendance at fixed vaccination posts and to ensure continued community uptake of stand-alone OPV when delivered after these campaigns
Availability of communication tool kits	Standardized messaging for communities/families has been developed at country level	Most countries that have done SIAs have developed communication tools and messages	UNICEF-HQ and endemic countries have developed communication tools to train Front Line Workers (FLW). Messaging regarding IPV should be carefully designed to avoid generating any negative perception regarding OPV

*The term OPV is used here to indicate two vaccines: Trivalent OPV (tOPV) containing serotypes 1, 2 and 3 and bivalent OPV (bOPV) containing serotypes 1 and 3 of Sabin strain of polioviruses. For logistics purposes and storage temperature conditions etc. both vaccines have the same requirements.



CCL&VM in the context of the Polio Eradication and Endgame Strategic Plan (PEESP)

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The Polio Eradication and Endgame Strategic Plan 2013–2018 was developed by the GPEI with inputs from national health authorities, scientific experts and partners. The plan has four major objectives:

1. Poliovirus detection and interruption of poliovirus transmission
2. Routine immunization strengthening, oral polio vaccine withdrawal and IPV introduction in routine immunization
3. Laboratory containment and polio-free certification
4. Legacy planning

Supplementary immunization activities (SIAs) remain a key operational strategy for rapidly improving population immunity against poliovirus in endemic, outbreak affected and at risk countries. Gains in population immunity made through SIAs can be sustained through high routine immunization coverage.

Well-planned and implemented vaccine supply and management activities that ensure adequate quantity and quality of vaccine and supplies for polio SIAs can also strengthen CCL&VM systems for both routine immunization and other non-polio SIAs. For example, the use of polio SIA micro-plans and vaccine distribution plans as well as staff training

on vaccine management in preparation for SIAs can directly improve routine immunization and remain a legacy of the polio eradication programme.

Additionally, installation of new cold chain equipment to accommodate the surge in supplies for polio SIAs, as well as improvements in vaccine utilization and safety management anticipated during the withdrawal of trivalent oral polio vaccine (tOPV) and introduction of inactivated polio vaccine (IPV) on a globally unprecedented scale, will be another opportunity for polio eradication to have a positive impact on routine immunization.

Strengthening vaccine management and logistics systems for polio SIAs is one of several ways that the polio eradication program can benefit routine immunization systems. (Abdelwahab, Jalaa', et al., 2014). Robust vaccine stock management systems necessary for handling large volumes of vaccine in polio SIAs also strengthen vaccine management systems in routine immunization. In some countries (e.g. Pakistan) polio social mobilization staff (COMNet) have supported making inventories of functional cold chain equipment.

Finally, the magnitude of annual vaccine procurement and utilization by GPEI (in 2014 UNICEF delivered 1.7 billion doses of OPV, worth USD 272 million) and the urgency for achieving polio eradication have further underscored the need to rapidly develop clear guidelines and tools for improving vaccine management in the context of polio SIAs.

At the global level, GPEI, through several of its working groups and task teams (e.g. Risk Assessment Task Team, SIA Options Task Team, Vaccine Supply Task Team etc.), as well as regional and country teams, undertakes a rigorous process of risk assessment to develop and approve a global GPEI SIA calendar on a six-monthly to annual basis. This process takes into account updated epidemiological information, mathematical modelling for immunity, surveillance information, historical experience, supply availability and other factors to come up with a number of alternate options for the global SIA calendar. With additional inputs on available finances from Finance Management Team (FMT), the alternate scenarios are then presented to the Eradication and Outbreak Management Group (EOMG). Finally, EOMG and Strategy Committee (SC) review the proposed options and a decision is made on the final calendar.

The global GPEI SIA calendar specifies the number of SIA to be implemented by country by month, the proportion of its population to be targeted and the type of vaccine (tOPV or bOPV) to be used. The initial projections are reviewed and revised in the event of outbreaks and as per other changing epidemiological needs including isolation of wild as well as vaccine derived polioviruses. From the logistics perspective, this is a critical planning tool to ensure timely supply of vaccines to all countries.

For countries which procure their polio SIA vaccines through UNICEF, UNICEF SD supports implementation of the approved global SIA calendar by issuing global tenders in accordance with

public procurement practices to meet organizational objectives and achieve best value for money.

Historically, OPV supply has been constrained and there has been a need to balance supply and demand taking into consideration all planned activities against projected and actual availability of vaccines from the manufacturers producing WHO prequalified vaccines. Managing supply lines is a dynamic process closely coordinated by UNICEF with performance indicators regularly reviewed by the programme including by the Polio Oversight board (POB). This includes maintaining a dynamic buffer stock of at least 30-40 million doses of each type of oral polio vaccine (tOPV and bOPV) at the global level. The vaccine product by a particular manufacturer has to be approved by the country's national regulatory authority (NRA) before it can be supplied to the country. Occasionally, in the interest of program implementation, countries have issued regulatory waivers for WHO pre-qualified vaccines supplied by UNICEF.

As global supplies of polio vaccines for UNICEF are limited and draw upon manufacturing capacities of WHO pre-qualified manufacturers, in-country vaccine wastage has to be minimized and demands for fresh vaccine supplies adjusted against available stock balances within countries. A global standard operating procedure for vaccine management (SOP-VM) to report on vaccine utilization has been designed (Annex 2). The May 2015 report of the International Monitoring Board (IMB) of GPEI has recommended that polio priority countries should apply the SOP-VM to optimize vaccine utilization (IMB, 2015).

Overview of CCL&VM systems in polio SIAs

Once vaccine stocks are received in a country, it is extremely important that the vaccine be stored, distributed and used optimally, maintaining proper cold chain temperatures. The data for in-country vaccine utilization and stock balances at national as well as sub-national levels should be recorded and communicated accurately, completely and in a timely way to national, regional and global levels.

A robust vaccine cold chain and logistics system including storage and transportation is the cornerstone of all in-country immunization programmes. Rigorous supply planning based on accurate data should enable such a

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system to have the right vaccines in the right place, at the right time, in the right quantities, in the right condition, and at the right cost (Wisner, 2012).

By and large, many components of in-country supply and cold chain infrastructure for routine immunization are the same as those being used for implementation of polio SIAs. However, the forecasting, funding, procurement and cold chain and logistics requirements at all levels are at a larger scale during polio SIAs than in routine immunization programme.

SIA campaigns involve the arrival, distribution, storage and use of large quantities of vaccine within a short period of time, which may involve various delivery strategies beyond those typically used for routine immunization. This may require additional surge capacities in storage, management and supply of vaccines from proximal to distal levels and in retrieving, accounting and managing stocks at the end of an SIA round. Innovative strategies like cross-docking[1] have been utilized in polio SIAs to cope with capacity constraints in proximal level stores.

1 Cross-docking: A continuous replenishment logistics process at a distribution centre, where incoming goods are sorted and/or consolidated, and then shipped out to their final destinations, without the need to store the goods.

Figure 1 is a schematic diagram depicting flow of vaccines and other ancillary equipment (bundling), as well as flow of information between different levels of the vaccine logistics chain. Both vaccine stocks and inventory information must be in the forward flow loop, whereas it is equally important that inventory information (balance stocks, utilization reports etc.) flow backward in the reverse loop with or without remaining vaccine stocks. The reverse flow loop for vaccine inventory information is often a weak link in country supply chains.

Effective and efficient vaccine management for SIAs includes:

- Planning, procuring, storing and supplying (to and from each level of the supply chain) appropriate and fully potent vaccines in right quantities down to the service delivery levels
- Ensuring that vaccine supplied is properly administered and accounted for with appropriate record maintenance at all levels
- At the end of an SIA round, proper inventory management and storage and/or reverse shipment of unutilized vaccine and information transfer regarding stock utilization and balances

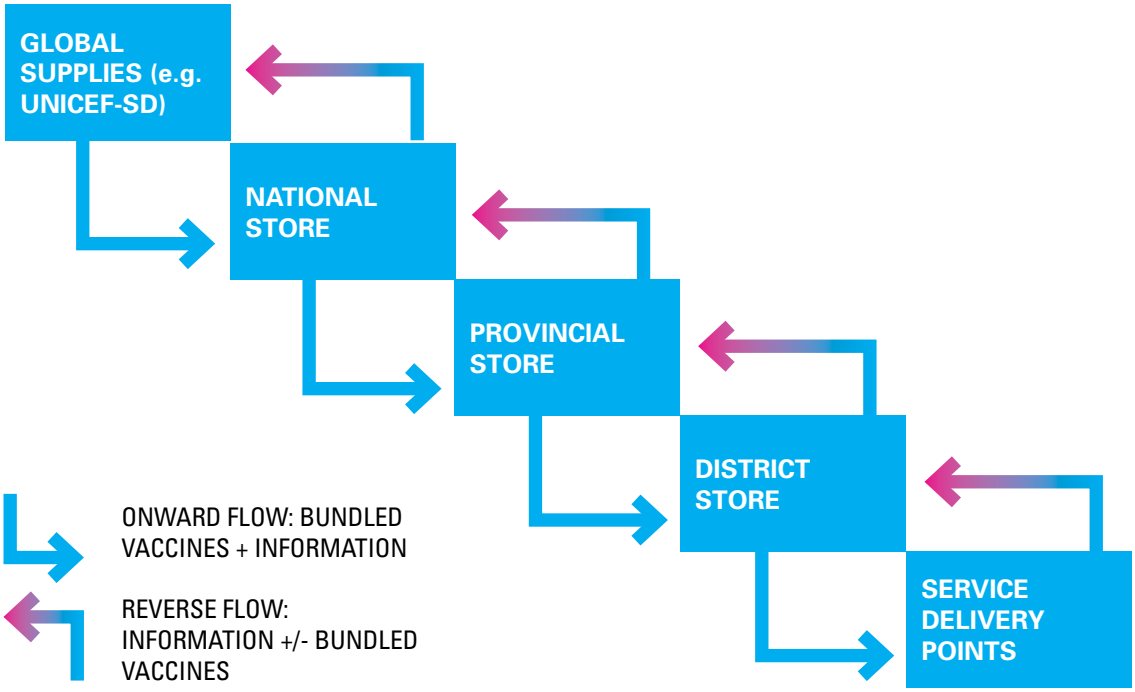
Data needed for CCL&VM are often available at the peripheral level and collected along with operational data such as number of children vaccinated. With the support of both WHO and UNICEF, local programmes should be able to ensure and streamline the collection, submission and use of this information.

For SIAs, the cold chain logistics and vaccine management activities can be divided into three phases: pre-campaign, intra-campaign and post-campaign. There are specific tasks, requirements and indicators (see Annexes) at national, regional and global levels for each phase of the campaign. Country immunization programmes should have well-laid-

Reverse cold chain for stool shipment in surveillance

Stool samples from acute flaccid paralysis (AFP) cases should be transported to the laboratory for virus isolation under cold chain temperature conditions similar to vaccines in order to keep any potential polio virus viable. This is referred to as 'reverse cold chain'. Ideally, only specimen carriers kept aside for this purpose should be used for these shipments. Sometimes, when such specimen carriers are not available, vaccine carriers can be used for this purpose. However, a vaccine carrier, once used for transport of stool specimens, should never again be used to store or transport vaccines. The materials and equipment used to transport stool specimens for poliovirus isolation can become contaminated with the virus. Therefore these materials should be destroyed or disinfected after each use and clearly marked out and segregated from other equipment used for vaccine storage and transport. Vaccine carriers should not be used to ship biological specimens nationally or internationally by air (WHO, 2004).

Figure 1: Bundled vaccines and vaccination equipment* as well as information for inventory control must flow up and down the logistics chain



* e.g. droppers, auto-disable syringes, safety-boxes etc.

out policies regarding both onward and reverse shipment and utilization of vaccines before, during and after SIAs.

It is also important to ensure that other equipment/materials needed for quality campaign activity and post-campaign monitoring (PCM), such as finger markers etc., are adequately planned. Ensuring good PCM is essential if we are to be sure that campaigns have been properly carried out.

The data generated and compiled on CCL&VM are critical to guide programme management as well as advocacy efforts by UNICEF and the GPEI in discussions with community members, local partners and authorities as well as governments and external partners, to ensure that gaps are well identified and addressed in a timely manner.

Strengthening in-country vaccine logistics and management for polio SIAs would also likely have a positive impact on the overall vaccine management for the routine immunization programme.

Common challenges observed in CCL&VM in polio SIAs

Assessments made during SIAs in polio priority countries have highlighted some of the challenges in cold chain logistics and vaccine management systems:

- Significant differences exist in the operational target for SIAs (denominator) and official population figures at country level which can create difficulties in determining the precise target populations and immunization coverage.
- Cold chain equipment: There are absolute or relative deficiencies (due to maldistribution) in cold chain equipment needed to cater to the large population targeted in an SIA, causing problems in vaccine distribution, storage and management. Often financing is inadequate to address these deficits.
- Data on vaccine stocks, distribution and utilization are not regularly collected, updated and analysed in order to rationalize vaccine supplies and avoid stock-outs or overstock.
- Even when an SIA round has been agreed upon in the global SIA calendar of the GPEI, and supply quantities secured with manufacturers, countries need to communicate vaccine supply requirements to UNICEF-SD early enough, taking into account shipment lead times:
  - Vaccines are shipped by UNICEF-SD to countries by air. The

vaccines are made ready for dispatch within approximately 2–3 weeks from placement of the purchase order with the supplier, and then a further 1–3 weeks are needed to make the necessary arrangements for shipment by air. Once air shipment starts, according to WHO guidelines, the consignment should not take longer than 48 hours to reach final destination while maintaining approved temperature range (WHO, 2005a).

- Immunization devices, on the other hand, are shipped by sea owing to their bulkiness, with a shipment lead time of approximately 3–4 months.
- In some circumstances, either due to faulty training, logistical and operational challenges, or inefficient vaccine management practices, vaccine wastage rates have been observed to be substantially higher than the expected rate of 5–15 per cent for OPV.
- Conversely, vaccine wastage may be unrealistically low owing to reporting errors in numerator (e.g. children vaccinated reported higher than actual) or denominator (e.g. reported vaccine doses utilized lower than actual) and other data quality issues.
- Micro-plans are not updated regularly to adequately reflect status and gaps in cold chain equipment or vaccine storage capacity, especially at the peripheral level. Preparing micro-plans for a polio SIA is an excellent opportunity to identify and update gaps and advocate for corrective measures through the various existing polio structures.
- Distribution plans (for both onward and reverse flow) for vaccines are not always laid out explicitly and clearly.
- Vaccination teams are often not managed and coordinated well during campaigns to ensure real-time redistribution of vaccines and supplies as needed.
- Significant differences remain between the vaccine doses required per the updated micro-plan and distribution plans and the requested and final number of doses administered.
- Human resources for CCL&VM positions at various levels either are vacant, or filled positions are not provided regular training and supervision, particularly at provincial/regional or district stores.

Points to keep in mind in SIA vaccine management

- Vaccines are expensive. Detailed written plans for delivery and distribution of bundled vaccines should be developed for every level.
- Bundled vaccine movement through the logistics system during an SIA is several times the annual routine immunization requirement (for all vaccines) in a very short period and may quickly overwhelm logistics management systems if not planned properly.
- During SIAs, proximal level stores often have space constraints for vaccine storage, while distal level stores often face challenges in preparing larger numbers of ice packs in a short period.
- If proximal level stores lack adequate space to accommodate larger quantities of vaccines required for SIA, alternate stores and supply routes should be planned for (Figure 2).
- Vaccines and supplies may be delivered directly to distal stores, bypassing proximal stores with space constraints during SIAs. All such alternative supply routes should be included in the distribution plan and not done in an ad-hoc manner.
- Alternately, if a proximal level store has no constraints in vaccine storage space but a distal level store has space constraints, the proximal (larger) store may supply the distal store in smaller but more frequent shipments before and during the SIA.
- Managing vaccine utilization and stocks properly before, during and after SIAs is important. Post-SIA vaccine inventory management is often neglected. Detailed plans should be made and policies laid out for return and use of opened vials as per the WHO multi-dose vial policy (MDVP).
- Vaccine wastage at the service delivery level is expected to be less in SIAs (as compared to routine immunization).
- Vaccine waste generated during SIAs should be properly managed according to global guidelines and national regulations in place.

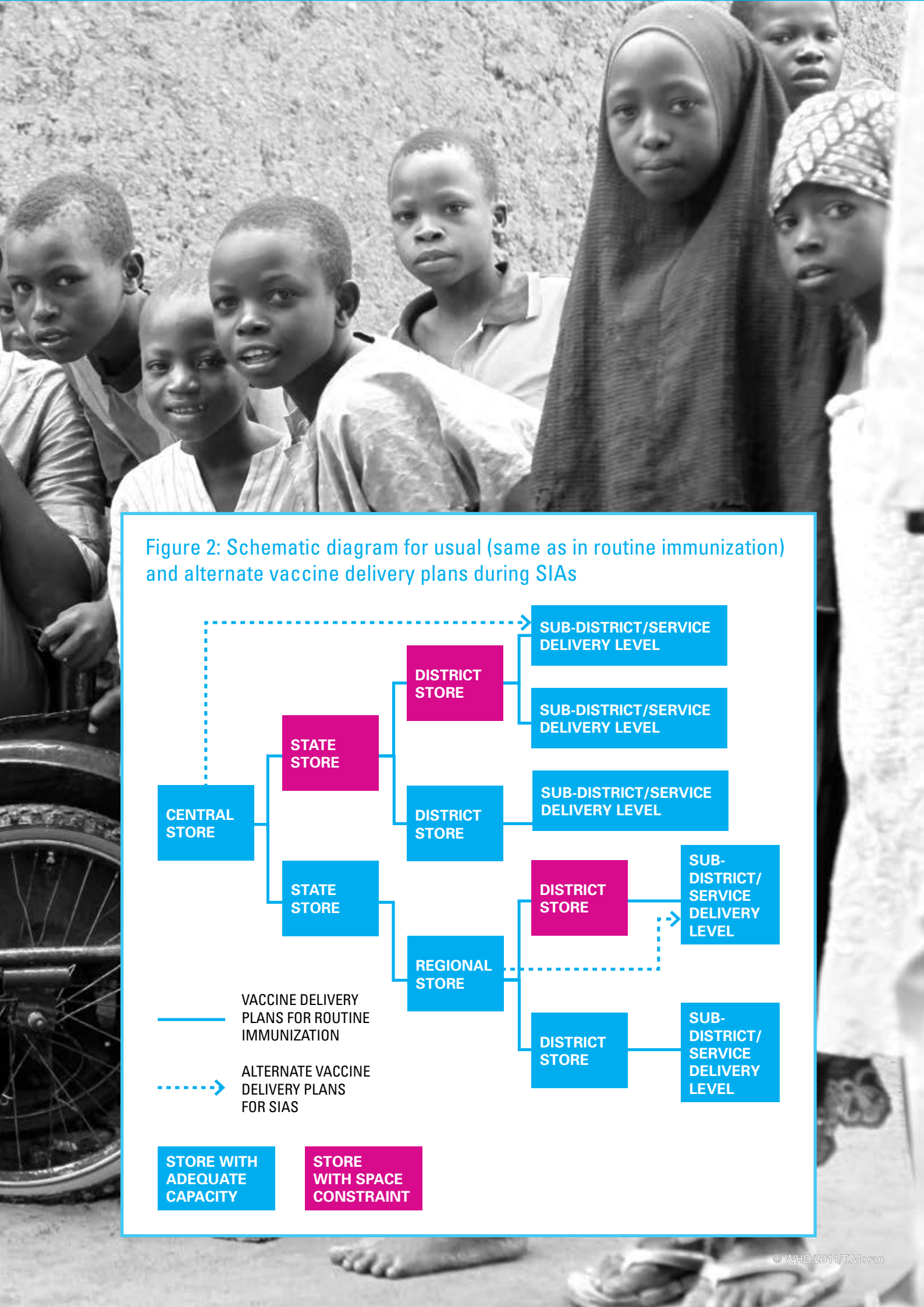


Figure 2: Schematic diagram for usual (same as in routine immunization) and alternate vaccine delivery plans during SIAs

Vaccine usage, wastage and multi-dose vial policy (MDVP)

Optimal vaccine management entails maximizing coverage through high vaccine usage while minimizing wastage. It is convenient to consider vaccine usage first to understand vaccine wastage. Vaccine usage rate has been defined as below (WHO, 2005b):

Vaccine wastage rate (%) can be considered as 100 – Vaccine usage rate. Vaccine wastage can occur in both opened as well as unopened vials. Some examples are cited in Table 2.

VACCINE USAGE RATE (%)

$$\text{Vaccine usage rate (\%)} = \frac{\text{Number of doses correctly administered}}{\text{Number of doses issued}} \times 100$$

TABLE 2 Examples of vaccine wastage*

Vaccine wastage in unopened vials	Vaccine wastage in opened vials
➔ Expiry ➔ VVM indication ➔ Heat exposure ➔ Freezing (e.g. IPV) ➔ Breakage ➔ Missing inventory ➔ Theft ➔ Discarding unused vials returned at end of day's SIA activity	In addition to the types listed in the previous column: ➔ Discarding remaining doses at end of day's SIA activity (e.g. not applying multi-dose vial policy for opened vials) ➔ Not being able to administer the number of doses indicated on the label of the vial ➔ Submergence of opened vials in water damaging the labels ➔ Suspected contamination

*Adapted from World Health Organization, *Monitoring Vaccine Wastage at Country Level: Guidelines for programme managers*, WHO, Geneva, 2005.

While vaccine wastage in stores should be kept at a minimum (less than 1 per cent), a higher wastage level may have to be accepted at service delivery level. Operationally, at service delivery level, it is convenient to calculate vaccine wastage in an SIA round by the following formula:

While calculating vaccine requirements for an SIA target population taking wastage into account, it is necessary to multiply the target population with a Wastage Factor or a Wastage Multiplication Factor (WMF).

VACCINE WASTAGE RATE (%)

$$\text{Vaccine wastage rate (\%)} = \frac{\text{Number of doses used - Children immunized}}{\text{Number of doses used}} \times 100$$

where, 'Number of doses used' includes doses used for immunization and all doses discarded or lost for any reason (including expiry, VVM indication, cold chain failure, freezing, missing inventory or routine discard of open vials of vaccine at the end of a session or campaign activity).

WASTAGE FACTOR (WF) OR WASTAGE MULTIPLICATION FACTOR (WMF)

$$\text{WMF} = \frac{100}{100 - \text{Vaccine wastage rate}}$$

Note that WMF is a number and not a percentage.

Vaccine requirement calculations and buffer quantity

Based on target population, the formula to calculate vaccine requirement for one round of polio SIA is the product of target population, WMF and target coverage.

Since for planning purposes the target coverage is usually 100 per cent (or 1 as a proportion), the formula works out to be a simple product of target population and WMF.

TABLE 3 Wastage rate, wastage multiplication factor and vaccine requirement

Wastage rate (%)	WMF	Vaccine doses required for a target population of 1,000 (rounded)
5%	1.05	1,050
10%	1.11	1,110
15%	1.18	1,180

VACCINE REQUIREMENT FOR ONE ROUND OF SIA WITH TARGET COVERAGE OF 100%

Vaccine requirement (doses)=Target population × WMF

Unlike in routine immunization, no buffer quantity is usually added to this calculated vaccine requirement for an SIA round for most countries. However, for endemic countries a buffer quantity is added to the estimated annual SIA requirement. This buffer quantity usually refers to vaccine quantities that are above what is detailed and requested for the planned SIAs and other regular immunization activities (including transit point strategy, International Health Regulations, etc.). This buffer is based on the estimated need for the country to implement immunization activities that cannot be planned and forecast in advance such as case response rounds and mop-up activities, and it is usually based on previous country specific experience in the polio eradication programme.

Some useful norms for logistics calculations are included in Table 4.

While multi-dose vials save on cost per dose and storage space, they also lead to some degree of unavoidable operational wastage of unutilized vaccine doses in opened vials. For OPV, wastage at service delivery level in SIAs usually ranges between 5–15 per cent and tends to be lower than in a routine immunization setting. For further details on calculating different kinds of vaccine wastage the reader is referred to reference cited above (WHO 2005b).

For WHO pre-qualified vaccines procured by UNICEF, WHO published a revision of its multi-dose vial policy (MDVP) in 2014, allowing use of multi-dose vials up to 28 days after opening the vial provided the following criteria are met (WHO, 2014):

1. The vaccine is currently prequalified by WHO
2. The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO and as published on its website <www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/index.html>
3. The expiry date of the vaccine has not passed
4. The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer- recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing

As noted above, when all these criteria are fulfilled, opened vials of WHO pre-qualified OPV may be used for up to 28 days after opening. This practice can reduce vaccine wastage in opened vials significantly. At the service delivery level, health workers should be trained to note the date and time of opening of vials to enable application of MDVP.

TABLE 4

Useful norms for calculating vaccine and other logistics requirements for OPV and IPV campaigns*

Activity / Unit	Norm
Vaccine wastage rate (%)	(Number of doses used – Number of children immunized) ×100 / (Number of doses used), where , 'Number of doses used' includes doses used for immunization and all doses discarded or lost for any reason (including expiry, VVM indication, missing inventory, cold chain failure, freezing, or discarding of open vials of vaccine at the end of a session or campaign activity).
Wastage Multiplication Factor (WMF)	100/(100 – Vaccine wastage rate)
Vaccine doses required for one round of SIA	Target population × WMF × Target coverage For SIAs Target coverage is usually 100%
Vaccine vials (and droppers) required	Vaccine doses required / vial size; Number of droppers for OPV = number of vials.
Auto disable syringes (ADS) required	Target population × WMF for ADS For service delivery points, ADS = Vaccine doses supplied
Safety boxes (5 ltr) required (for IPV)	(Number of AD Syringes)/100 or at least one per session site (whichever is greater)
Vaccine storage space	IPV: 10-dose vial – 2.5 cubic centimetre/dose (cc/dose) 5 dose vial – 4.0 cc/dose OPV: 10-dose vial – 2.0 cc/dose 20-dose vial – 1.0 cc/dose
Cold chain space required for routine immunization (RI)	Varies according to country immunization schedule. Each country should calculate this in cubic centimetres (cc) per child and mother for all vaccines to be given in one year and derive volume requirements as per supply periodicity and buffer requirement for supply chain level. While calculating SIA cold chain requirement, cold chain space for RI vaccines should first be set aside.
Indelible ink marker pens	1 pen per 300 children or at least 1 per session site (whichever is greater). Higher for OPV-IPV or other combined campaigns needing >1 finger mark per child.

*The norms mentioned here are generic. Actual figures may vary according to national policies or local context.
Note: Dry storage for droppers and/or syringes should be calculated separately. Additional information on vaccine storage and ice pack freezing capacities can be downloaded at <www.who.int/immunization_standards/vaccine_quality/pqs_catalogue>.

IPV campaigns

Objective 2 of PEESP has the target of introducing at least 1 dose of IPV in routine immunization (RI) in all countries that do not currently use IPV in RI. This will be a major global new vaccine introduction in the context of strengthening routine immunization.

Despite repeated SIAs with oral polio vaccines, wild poliovirus transmission has persisted in some of the reservoir areas of endemic countries. Evidence from serological studies (Estívariz, Concepción, et al., 2012; Moriniere, Bernard J., et al., 1993; John, T. Jacob, et al., 2014) shows that IPV administered to persons who have previously received OPV can significantly boost their serologic and gut immunity to polioviruses helping to interrupt transmission. Recent studies have shown that, especially in settings where OPV is less immunogenic, a supplemental dose of IPV can close the immunity gap more effectively than another dose of OPV.

Although IPV requires skilled personnel to administer the vaccine at fixed sites, as opposed to a house-to-house approach, it lends itself well to being integrated into polio plus or integrated child health day activities such as health camps, permanent transit points and other SIAs with injectable vaccines (e.g. measles and tetanus campaigns). Unlike OPV, IPV is damaged by freezing and combined IPV-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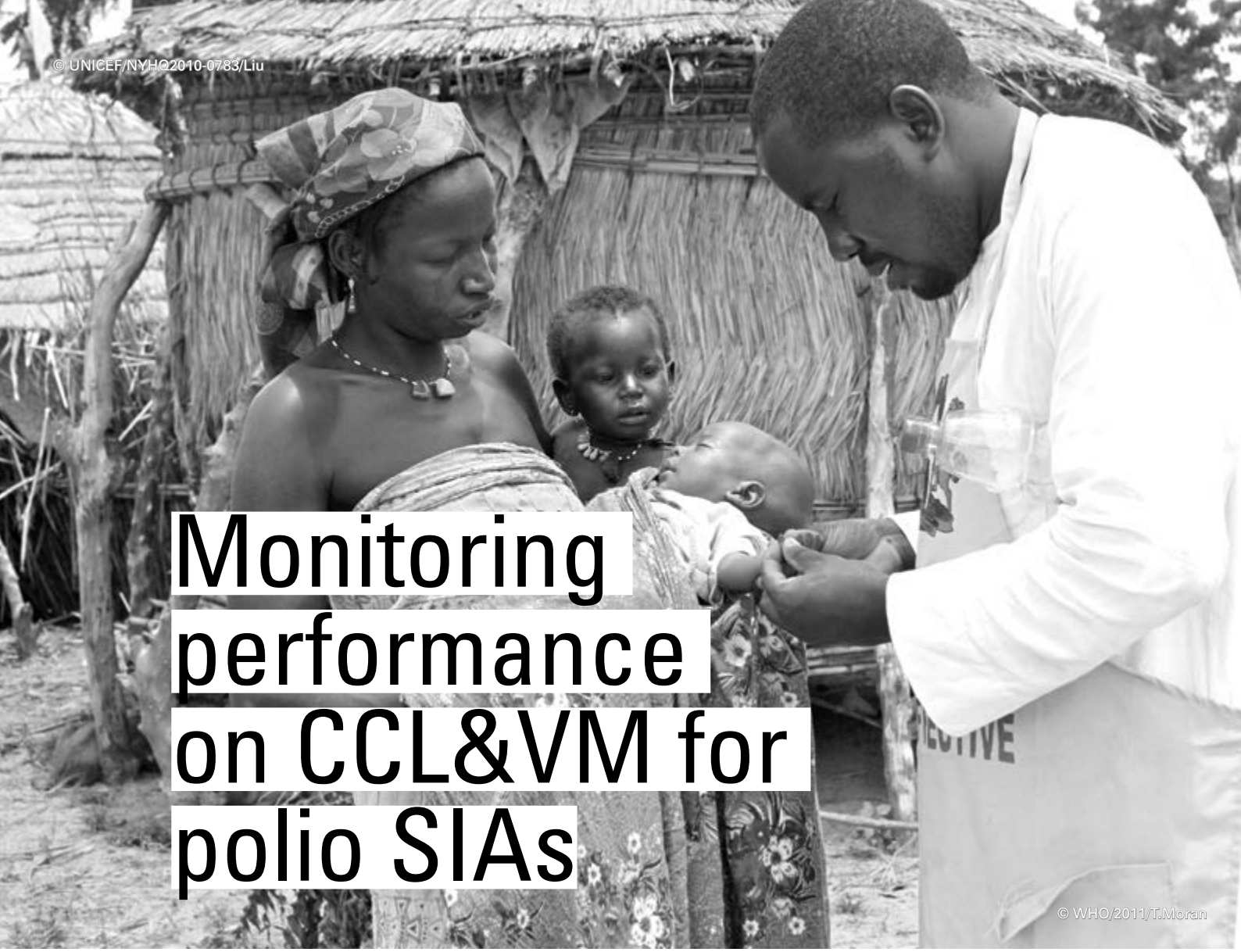
OPV campaigns should maintain proper cold chain for both vaccines.

While many countries have extensive experience in conducting OPV campaigns and some experience in measles campaigns, very few countries have experience in conducting IPV campaigns.

Combined IPV+OPV SIAs have been recently used by the programme with a more focused and targeted scope to rapidly build population immunity and interrupt poliovirus transmission in areas with persistent circulation (despite high quality SIAs with OPV) or limited windows of opportunity for access.

Further detailed guidance on IPV SIAs is available at <www.polioeradication.org/Portals/0/Document/Aboutus/Governance/IMB/11IMBMeeting/2.5_11IMB.pdf>.

Other IPV-related technical material also available at <www.who.int/immunization/diseases/poliomyelitis/inactivated_polio_vaccine/en>.



Monitoring performance on CCL&VM for polio SIAs

Efforts to strengthen oversight and accountability in vaccine supply for polio SIAs have resulted in the development of specific indicators (e.g. the Polio Oversight Board indicators) to monitor the availability of vaccine and the ability to respond to unexpected increases in demand by maintaining a notional buffer level of vaccine stock at the global level (Table 5).

Comparable monitoring activities and indicators have not always been available or implemented at country level. Consequently, indicators have been added to national emergency action plans and polio monitoring cells. UNICEF has also developed polio management dashboard indicators which are primarily used in endemic and polio priority countries to monitor progress on vaccine availability, vaccine wastage, utilization, stock reporting and cold chain capacity.

Table 6 includes a list of key indicators that are being used by UNICEF senior management to monitor SIA performance on CCL&VM in endemic countries.

Table 7 lists some additional indicators which may be adapted by country programmes for monitoring performance on CCL&VM in polio SIAs.

Annex 1 has a list of additional activities, processes, expected results and indicators which can be used at country, regional and global levels for detailed performance monitoring before, during and after polio SIA campaigns (Table 8, Table 9 and Table 10).

TABLE 5 Polio Oversight Board (POB) indicators on CCL&VM: measured on a quarterly basis and reviewed at the global level

INDICATOR	DEFINITION	TARGET	SOURCE
Proportion of planned* SIAs that were cancelled, postponed or reduced in size, in priority countries (endemic, outbreak, active transmission / other), during the previous 6 months due to gaps in vaccine supply ***Planned as per the Financial Resource Requirement (FRR), or related to rounds not in the FRR, but for which vaccine was ordered on basis of consensus and at least 6 weeks before the campaign**	Numerator is the number of planned SIAs cancelled, postponed or reduced in priority countries during the previous 6 months due to gaps in vaccine supply Denominator is the number of SIAs planned in priority countries during the previous 6 months Based on the current plan and original plan (based on the FRR from the Sept/Oct of the previous year)	<5%	UNICEF
Proportion of weeks with a minimum of 15 consecutive days, in the plan for the next 6 months, for which the global forecasting graph goes below the agreed buffer level, but remains above zero for each type of OPV	Numerator is number of weeks forecasting graph goes below the agreed buffer for next six months' supply Denominator is the number of weeks forecasting six months' supply Based on the current plan and original plan (based on the FRR from September/October of the previous year)	<15% (<4 weeks out of 25 weeks)	UNICEF-SD
Proportion of weeks with a minimum of 15 consecutive days, in the plan for the next 6 months, for which the forecasting graph goes below the agreed buffer level, and also goes below zero for each type of OPV	Numerator is the number of weeks forecasting goes below zero, next 6 months' supply Denominator is the number of weeks forecasting 6 months' supply Based on the current plan and original plan (based on the FRR from September/October of the previous year)	<10% (<2.5 weeks out of 25 weeks)	UNICEF-SD

TABLE 6

UNICEF management dashboard indicators for programme monitoring CCL&VM in SIA in endemic countries

INDICATOR	DEFINITION (FOR ENDEMIC COUNTRIES)[2]	TARGET	SOURCE
Delays in OPV supply	Percentage of High Risk Districts (HRD) out of total HRD, that did NOT receive polio vaccine supply at least 3 days before the planned starting date of campaign	0%	Polio control room/EPI Cell/ Emergency Operations Centre
Stock reporting	Percentage of High Risk Districts out of total HRD, which reported on balance of SIA vaccine stocks after last SIA round	>=80%	Polio control room/EPI Cell/EOC
OPV wastage rate	Percentage of High Risk Districts out of total HRD where OPV wastage rate in SIAs is between 5% and 15%	>90%	Summary tally sheet data
Cold chain functional status	Percentage of High Risk districts out of total HRD where at least 90% of active (e.g. electric, solar, kerosene) cold chain equipment are functional (maintaining optimal temperature range)	>90%	Micro-plan data or other Cold Chain Equipment assessment

[2]The definitions given here are generic for endemic countries. Precise definitions of UNICEF dashboard indicators are adapted to country context for some endemic countries and for outbreak countries.

TABLE 7

Additional indicators for monitoring CCL&VM performance in polio SIAs at sub-national level

INDICATOR	DEFINITION (MAY BE ADAPTED TO COUNTRY CONTEXT)	TARGET	SOURCE
Percentage of micro-plans with CCL&VM, CCE and transportation component updated	Micro-plans with updated CCL&VM, CCE and transportation components/ total number of micro-plans	>=80%	Micro-plans
Percentage of subnational and peripheral sites with an updated vaccine distribution plan	Sites with an updated vaccine distribution plan/total number of sites with vaccine distribution plans	>90%	Micro-plans
Percentage of stores at the subnational and peripheral levels that received appropriate amount of vaccine in good quality (VVM at usable stage) in a timely manner as per the micro-plan	Stores that received appropriate amount of vaccine in good quality (VVM at usable stage) in a timely manner per the micro-plan/total number of stores that were expected to receive vaccine as per the micro-plan	100%	Micro-plans/ vaccine store records
Percentage of vaccine store records updated by vaccine type (bOPV, tOPV, IPV), segregated by RI and SIA	Vaccine store records updated by vaccine type and segregated by RI and SIA/total number of vaccine store records	>=80%	Micro-plans/ vaccine store records
Percentage of sites by sub-national administrative level with unused vaccine returned to vaccine stores at the end of the campaign as per national policy	Sites with unused vaccine that is returned to vaccine stores at the end of the campaign as per national policy /total number of sites with unused vaccine at the end of the campaign	>=80%	Vaccine store records
Percentage of supervisors and teams trained	Supervisors and teams trained (including handling of vaccine and understanding VVM) before the campaign/total number of supervisors and teams monitored	>=90%	Campaign monitoring
Percentage of sub-national level stores / teams with stock-out of vaccine impacting activity	Stores / teams with stock-out during polio SIA divided by total number of stores / teams (or teams monitored)	0%	Campaign monitoring or SIA data
Percentage of teams using a vial with VVM in unusable stage	Number of teams using a vial with VVM in unusable stage/total number of teams monitored	0%	Campaign monitoring

Standard Operating Procedures for SIA polio vaccine management (SOP-VM)

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In its 9th report the IMB had noted the importance of stringent vaccine management and reporting on balance vaccine stocks by countries for better management of global vaccine supplies. Capturing vaccine utilization data as well as stock balances for vaccines used in polio SIAs is a challenge for both GPEI and country programmes. However, such information is essential to rationalize vaccine supplies within the country as well as globally. It is especially important to capture such information from the endemic countries because of the large quantities of polio vaccines being used there.

In order to initiate a standardized process of collecting this information, UNICEF had worked with GPEI partners in the vaccine supply task team to develop a standard operating procedure for vaccine management incorporating two simple data collection tools. This was circulated by GPEI in early 2015.

Taking a cue from the 9th IMB report, countries of the UNICEF Western and Central Africa Region had applied the SOP-VM, which helped reduce oral polio vaccine demand by 2.5 million doses over two months across nine countries (IMB, 2015).

> **SIMPLE DROPS OF VACCINE**
> **Vaccine is precious, and there is considerable scope for countries, supported by partners, to further improve its judicious management. The IMB recommends that in the endemic and priority countries, vaccine wastage be urgently reduced to 15% as an absolute maximum in every subnational area, starting by full implementation of the programme's standard operating procedure for reporting on vaccine utilization and stock balance.**
>
> — 11th report of International Monitoring Board of GPEI (May 2015)

The current version of the SOP and tools are included in Annex 2. Based on the SOP-VM it is expected that endemic countries will be submitting the vaccine stock reports along with new vaccine supply requests. Similarly, endemic countries are expected to provide a monthly update on vaccine utilization based on implemented activities to UNICEF Programme Division for analysis and feedback.

While endemic countries are being prioritized for using these tools, all country programmes implementing polio SIAs are encouraged to make use of them with support from their respective regional offices. Electronic vaccine logistics systems will facilitate capturing such information.

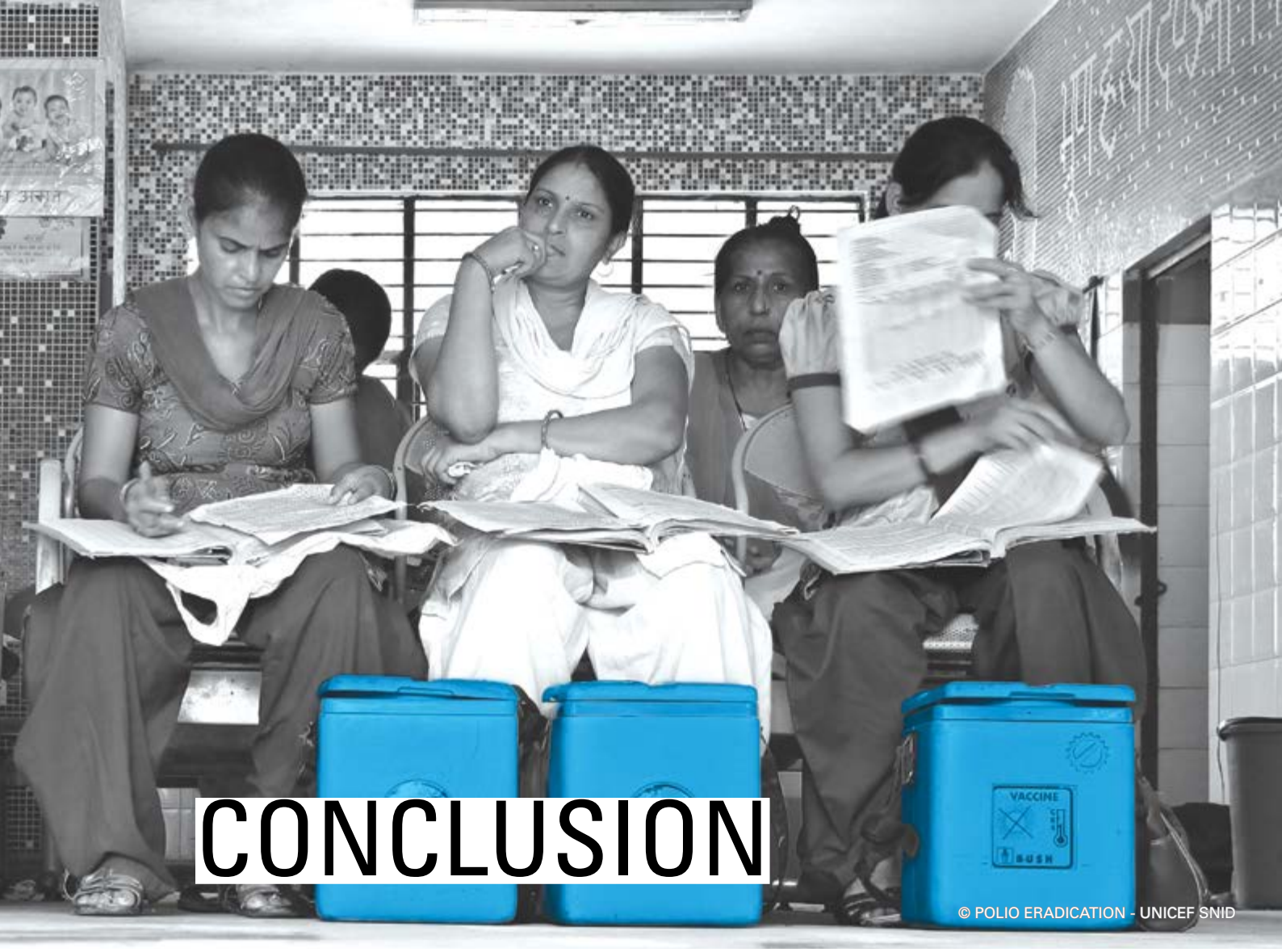
In its 11th report (May 2015) the IMB has recommended applying the SOP-VM to monitor vaccine utilization at national as well as sub-national levels in endemic and polio priority countries. The current version of SOP-VM and the tools will therefore be updated to help support countries to capture, analyse and report data on vaccine utilization from sub-national levels for optimizing vaccine usage.

In October 2015, the Strategic Advisory Group of Experts (SAGE) has recommended implementing the global switch from tOPV to bOPV in April 2016. Application of the SOP-VM to monitor stock levels of tOPV will be of critical importance for a successful 'switch'.

Roles and responsibilities in supporting CCL&VM activities for polio SIA

Successful CCL&VM requires the efforts of teams at all levels; however, members of the national operational team are particularly important for monitoring progress, identifying gaps and instituting corrective measures. Coordination committees at national, provincial and peripheral levels as well as technical working groups are vital in this process.

National immunization programmes often set up logistics working groups to provide operational guidance and technical support for the overall cold chain and logistics system for the Expanded Program on Immunization (EPI) and are also particularly important during SIAs. Specifically, logistics working groups or similar functional groups are critical for the management of vaccine stocks for SIAs as well as the distribution, utilization and oversight for SIA vaccine management data at all levels. As we move closer towards global polio eradication and implementation of the GPEI PEESP, ensuring high quality, functioning logistics working groups will become even more important in supporting the surge in cold chain and logistics activities related to the oral polio vaccine switch from trivalent OPV (tOPV) to bivalent OPV (bOPV), avoiding overstocking of tOPV and initial supplies of bOPV, integrating inactivated polio vaccine into routine immunization, and improving vaccine safety and waste management.



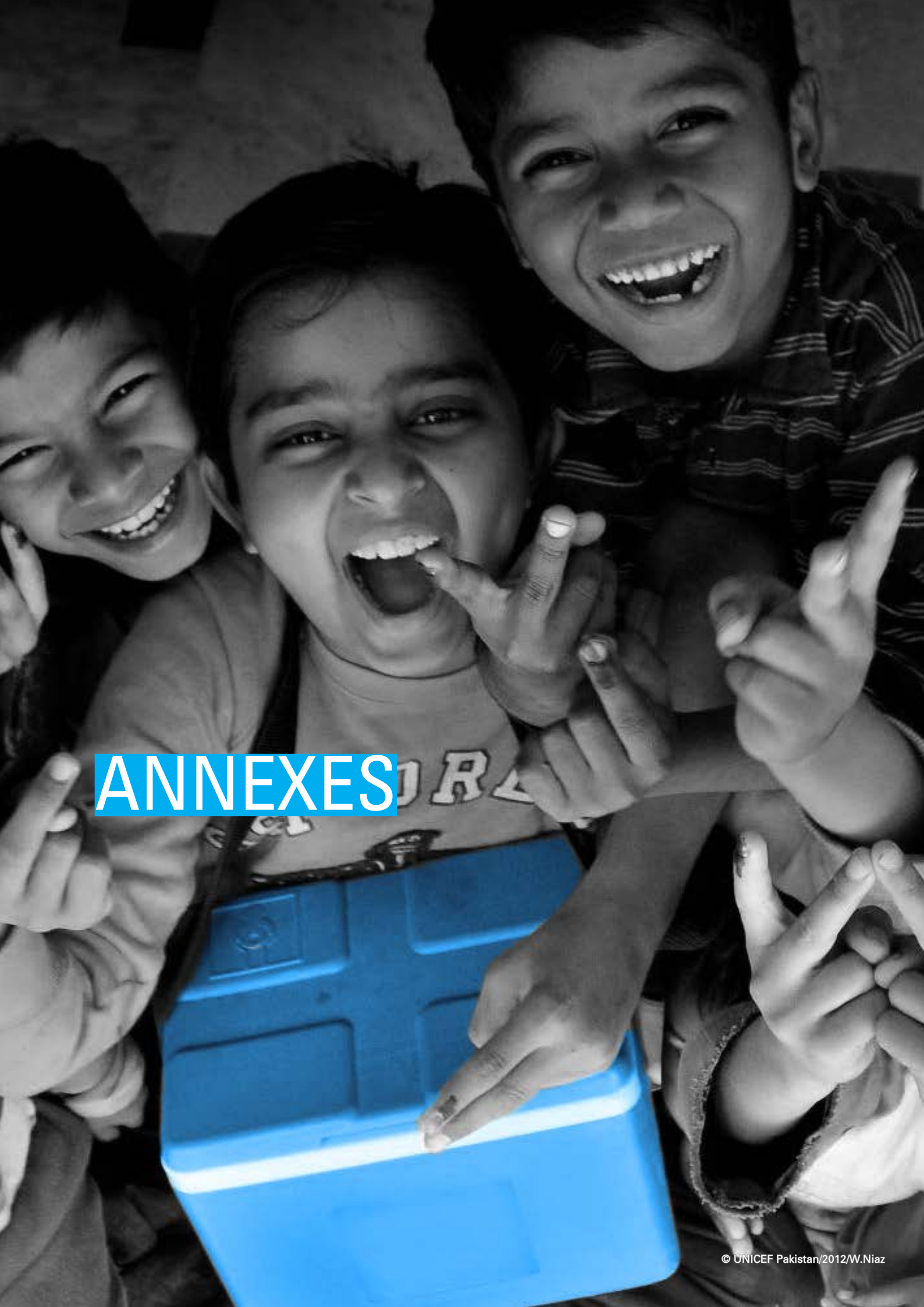
CONCLUSION

To ensure that the world achieves and sustains polio eradication through global certification, country programmes must implement high quality SIAs, maintaining integrity of the cold chain throughout the logistics cycle.

The projected global SIA schedule for countries needs to be coordinated well in advance so that global manufacturing, procurement and supply of polio vaccines to countries can support successful implementation of the planned polio SIAs. At the service delivery level, in-country vaccine management should ensure optimal use of polio vaccines and efficient use of resources.

We hope the overall guidance regarding processes, activities and indicators provided in this note will help improve cold chain logistics and vaccine management at global, regional and country levels.

ANNEXES



Annex 1: Key activities, processes, results and indicators for CCL&VM performance in polio SIAs at national, regional and global levels

The following tables (8 - 10) set out generic timelines and lists of key activities that should be completed before, during and after SIA campaigns. Country programmes need to adapt these timelines and activities to their specific contexts.

Note that these timelines do not apply to polio outbreak situations where many activities will have to be completed within a shorter timeframe as per global Standard Operating Procedures for polio outbreaks.

TABLE 8 **National level:** Key activities, processes, results and indicators for CCL&VM before, during and after polio SIA rounds

National level: Pre-campaign (completed 8–12 weeks before the start of the campaign)			
KEY ACTIVITY	PROCESS	EXPECTED RESULT	INDICATOR
Estimate and order the quantity of OPV and other related supplies	Start planning with appropriate type of vaccine, target age group and percentage of population to be covered by reviewing Technical Advisory Group (TAG) recommendations and global SIA calendar. Communicate any discrepancy between the global SIA calendar and country plans to WHO and UNICEF regional offices along with background and justification for changes. Estimate target population size from various sources (e.g. recent census data, population estimates and previous campaigns coverage) and the vaccine doses required. Inventory: Review in-country balance stock of vaccines and adjust vaccine demand accordingly. Present the planned and needed vaccine requirements to the Vaccine Management/Logistics committee and get endorsement by Government, WHO/GPEI and other partners as needed to secure supplies.	Adequate quantity of vaccine and other ancillary materials available in country in a timely manner	Percentage of states/ districts where a planned and approved SIA campaign was cancelled, postponed or delayed because of delayed vaccine supply. (Target: 0%)

Continued >

TABLE 8 (CONTINUED) **National level**: Key activities, processes, results and indicators for CCL&VM before, during and after polio SIA rounds

National level: Pre-campaign (completed 8–12 weeks before the start of the campaign)			
KEY ACTIVITY	PROCESS	EXPECTED RESULT	INDICATOR
	Submit request of official estimated needs of vaccine along with the reports on vaccine stock and utilization to UNICEF-Supply Division, copying UNICEF Programme Division as per SOP-VM. Review vaccine type for registration and licensing requirements, which could impact vaccine availability. Coordinate with the National Regulatory Authority and WHO for expediting waivers for importation, if needed.		
Review CCL, Cold Chain Equipment (CCE) and transportation resource requirements	Review CCL and CCE resource and transportation requirements at national, subnational and peripheral levels to ensure that there is adequate cold chain storage, logistics and ice pack freezing capacity at all levels. , Ensure availability of power for active equipment. Review availability of funding for vaccines and Cold Chain Equipment (CCE) and advocate for domestic or local funding for existing gaps. Use multiple sources including outcome of most recent campaigns, EVMa, CCEM inventory and other assessments, reviews and lessons learned to identify gaps which need to be addressed prior to next campaign, and advocate with the government and partners for corrective action. Support country to ensure SIA micro-plans and mapping exercise includes updated information on CCL, CCE and transportation needs at each level.	CCL and CCE and transportation needs identified and addressed Available data is used to drive advocacy efforts with government and partners to address gaps.	Percentage of districts where at least 90% of active (e.g. electric, solar, kerosene) cold chain equipment are functional. (Target: >90%) Percentage of districts with adequate cold chain storage space for polio SIA vaccines (Target: >90%)

Continued >

TABLE 8 (CONTINUED)

National level: Key activities, processes, results and indicators for CCL&VM before, during and after polio SIA rounds

National level: Pre-campaign (completed 8–12 weeks before the start of the campaign)

KEY ACTIVITY	PROCESS	EXPECTED RESULT	INDICATOR
Update and monitor the implementation of vaccine distribution as per plan	Review and update distribution plans with the national logistics/vaccine management working committee to ensure that the plan for the receipt and storage of vaccine at the national level, and distribution of vaccine to the peripheral level, is available and is cross-checked with micro-plans to ensure that vaccine being shipped is of adequate quantity and quality Monitor vaccine distribution at different levels to ensure vaccine stocks are cross-checked at departure and arrival for quantity, quality and required additional materials such as droppers for OPV campaigns and syringes and safety boxes for IPV campaigns. Investigate, document and report any significant damage to the received vials and communicate it to Supply Division and Programme Division.	Delivery plan completed to ensure on-time distribution of adequate quantity and type of vaccines from the national to the subnational and peripheral storage sites	Percentage of stores at subnational and peripheral levels that received appropriate amount of vaccine of good quality (usable VVM and within expiry date) in a timely manner. (Target: 100%) Timeliness for different levels defined by country context as per logistics micro-plan. Percentage of vaccine storage points having updated records by vaccine type (bOPV, tOPV, IPV) separately for SIA (Target: >=80%)
Conduct need based CCL&VM training for national, subnational and peripheral level staff and consultants	Train storekeepers, vaccinators, and supervisors on the roles and responsibilities, and on best practices for CCL&VM in SIAs, with quality training on necessary skills.	Storekeepers, vaccinators and supervisors trained on best practices in CCL&VM	Percentage of supervisors and vaccinators trained (Target: >=90% of those in need of training)

Continued >

TABLE 8 (CONTINUED)

National level: Key activities, processes, results and indicators for CCL&VM before, during and after polio SIA rounds

National level: Intra-campaign (during the campaign activity days)			
KEY ACTIVITY	PROCESS	EXPECTED RESULT	INDICATOR
Supervise and monitor progress on vaccine distribution, utilization and waste management during the campaign	Visit vaccine stores and vaccination teams, reviewing records, temperature monitoring and noting progress and challenges at vaccination storage facilities and in the field with vaccination teams; provide corrective measures and advocate for changes as needed Visit health facilities to cross-check vaccine distribution and management plans, including reliable micro-plans, cold chain capacity and record keeping and practice of MDVP. Collect, collate and review CCL&VM campaign data including polio control room data	Supply line maintained with no stock-outs Vaccine wastage kept within reasonable limits (for OPV 5%-15%) and MDVP policy followed. Feedback provided for immediate corrective action to sites visited and to management level as needed Daily vaccine management data analysed to identify inconsistencies and corrective measures taken to improve the indicators	Percentage of provinces/districts with stock-out during campaign (Target: 0%) Percentage of provinces/districts where vaccine wastage rate during activity is within acceptable limits (Target: >90%)
National level: Post-campaign (2–4 weeks after the campaign)			
Analyse the overall campaign CCL&VM data and reports	Review vaccine distribution and utilization during SIA against dashboard indicators Identify discrepancies between the amount of vaccine delivered, used and returned Vaccine utilization record (for national level initially, later to include sub-national levels) submitted to UNICEF PD as per protocol laid out in SOP-VM. Feedback provided to take corrective measures.	Vaccine wastage kept within reasonable limits (for OPV 5%-15%) and MDVP policy followed.	Percentage of provinces/districts where vaccine wastage rate at end of activity is within acceptable limits (Target: >90%)
Manage left over polio vaccine stock	Conduct a physical inventory of left over vaccine stocks, recording VVM status, location and storage capacity	Polio vaccine stocks accounted for, adequately stored and available for next activity	Percentage of sites by administrative level reporting on vaccine utilization and balance vaccine stocks (Target: >=80%)

TABLE 9

Regional level: Key activities, processes, results and indicators for CCL&VM before, during and after polio SIA rounds

Regional level: Pre-campaign (completed 4–6 weeks before the start of the campaign for respective countries)			
KEY ACTIVITY	PROCESS	EXPECTED RESULT	INDICATOR
Review regional vaccine supply and demand requirements for upcoming SIAs	Provide input to the process of updating the global SIA calendar and represent country programmes. Disseminate the updated SIA calendar to all countries in the Region as soon as it is approved. Review updated global SIA calendar provided by the SIA options Task Team with country offices and WHO regional offices. Consolidate and share joint regional input (WHO-UNICEF) with UNICEFHQ on any changes based on available information from country offices and WHO Regional offices Participate in discussions and calls with Programme Division and Supply Division as needed	Country and regional offices have updated global SIA calendar with estimates of required OPV by type, schedule and location reflecting any agreed upon changes	Percentage of countries in the region where a planned and approved SIA campaign was cancelled, postponed or delayed because of delayed vaccine supply. (Target: 0%)
Support the capacity building of regional and national staff and consultants	Support to train staff and consultants at regional and national level on the roles and responsibilities, best practices and innovative approaches to CCL&VM in SIAs	UNICEF staff and consultants (and other GPEI partners) trained (as per need) on the roles and responsibilities on CCL&VM at regional and national level	Percentage of staff and consultants trained (Target: 100%) out of those that need training
Regional level: Intra-campaign (during the campaign) for priority countries			
Monitor progress of the campaign and provide ongoing support and collate information as needed			

Continued >

TABLE 9 (CONTINUED) **Regional level:** Key activities, processes, results and indicators for CCL&VM before, during and after polio SIA rounds

Regional level: Post-campaign (2–4 weeks after the campaign)			
KEY ACTIVITY	PROCESS	EXPECTED RESULT	INDICATOR
Tracking of CCL&VM campaign data	Review vaccine supplies and utilization reports from the campaign provided by country offices Provide feedback to country programmes as well as share information with GPEI stakeholders Share finalized vaccine utilization and stock balances from the countries of the region with UNICEF PD/SD as per SOP-vaccine management. (Note that endemic countries will send this information directly to HQ with RO in loop.)	Vaccine wastage rate kept within acceptable limits at national and sub-national levels and regular stock balance information sent at end of each round	Percentage of countries with SIA vaccine wastage rate for OPV between 5–15% (Target: >95%) Percentage of countries including stock balance report with vaccine requests for new SIA round (Target: >90%)

TABLE 10

Global level: Key activities, processes, results and indicators for CCL&VM before, during and after polio SIA rounds

KEY ACTIVITY	PROCESS	EXPECTED RESULT	INDICATOR
Global level: Pre-campaign - tracking pre-campaign preparations in countries			
Review global vaccine supply/ demand for upcoming SIAs	The GPEI Risk Assessment Task Team produces quarterly polio risk assessments to help prioritize countries and inform decision making to manage the limited available resources (financial and supplies) The GPEI Vaccine Supply Task Team reviews global vaccine supply and SIA calendar at the quarterly vaccine planning meetings and provides a mapping of available vaccines against current demands The GPEI SIA Options Task Team, in consultation with WHO/UNICEF regional offices, builds on the outcome from the risk assessment and supply mapping and, in consultation with the finance group of the GPEI, develops 3–4 SIA options to update the SIA calendar The updated SIA calendar is endorsed by the Eradication and Outbreak Management Group (EOMG) and the Strategy Committee (SC) of GPEI and circulated to the regional focal points for further dissemination.	Updated global SIA calendar finalized with inputs from regional and country offices. All resources (vaccines, finance, and human resources) are in place for planned SIA rounds.	Per cent of countries that have incorporated approved SIA calendar in country SIA plans (Target: 100%) Per cent of countries in which all resources are available in time for planned SIA rounds. (Target 100%)
Global level: intra-campaign for priority countries			
Monitor progress of the campaign and provide ongoing support and collate information as needed			

Continued >

TABLE 10 (CONTINUED) Global level: Key activities, processes, results and indicators for CCL&VM before, during and after polio SIA rounds

Global level: Post-campaign (2–4 weeks after the campaign) – for endemic and priority countries			
KEY ACTIVITY	PROCESS	EXPECTED RESULT	INDICATOR
Tracking of campaign CCL&VM data	Programme Division/UNICEF-HQ reviews and collates vaccine utilization record from the campaign provided by regional and country offices Programme Division/UNICEF-HQ analyses information on vaccine utilization, vaccine supplies and stock balance from national and sub-national levels and provides regular feedback to regional offices and country offices as well as sharing information with GPEI stakeholders.	Vaccine wastage rate at national and sub-national levels kept within acceptable limits. Countries provide stock balance information at the time of requesting for new vaccines for SIA	Percentage of countries with vaccine wastage rate for OPV between 5% and 15% at national level (Target: >95%) Percentage of districts by country having vaccine wastage rate for OPV between 5% and 15% (Target >90%) (If district level data are available) Percentage of countries reporting on balance SIA vaccine stocks at the time of requesting new supplies (Target: 100% for endemic countries)

Annex-2 Forms and instructions for reporting vaccine utilization and stock balances in Polio Supplementary Immunization Activities (updated in May 2017)

Background

Countries and the Global Polio Eradication Initiative (GPEI) partners have a programmatic and financial accountability to use vaccine supplies efficiently, achieving high coverage while minimizing wastage. Country programmes also need to report on vaccine utilization and stock balances.

With the aim to support the national authorities in the vaccine management for polio Supplementary Immunization Activities (SIAs), and to get a better oversight of vaccine usage and wastage, UNICEF proposes countries to use two forms: the Vaccine Balance Stock Information (VBSI) and the Vaccine Utilization Report version 2 (VUR-2). These two data tools summarize information that is already being captured by most country polio SIA information systems at national and sub-national levels and would therefore not lead to substantial additional workload on country teams.

Vaccine Balance Stock Information and Vaccine Utilization Report preparation instructions

All countries receiving polio SIA vaccines through UNICEF Supply Division (SD) are requested to:

- Report on available polio SIA vaccine stock balances in their central and first sub-national level stores when requesting polio SIA vaccine supplies from UNICEF SD. Countries are required to use the **Vaccine Balance Stock Information (VBSI)** form (Annex-1) for this.
- Submit the **Vaccine Utilization Report version 2 (VUR-2)** to designated focal points in UNICEF and WHO-HQ i) monthly (Annex-2) for countries conducting regular and frequent polio SIA rounds, or ii) immediately on completion of an SIA round for countries conducting polio SIA rounds less frequently.

Supply, distribution, utilization and stock balance information for vaccines supplied for polio SIAs should always be maintained and reported separately from vaccines supplied and used for routine immunization even if it is the same vaccine (e.g. bOPV).

Additional details on the process of sending this information in VBSI and VUR-2 forms are described below.

I. Vaccine Balance Stock Information (VBSI) form - Annex 1

- The VBSI form gives a snapshot of the polio SIA vaccine balance stock in the country at the point in time when a new vaccine request is being made for polio SIAs. This will help countries and UNICEF Programme Division (PD) and SD to rationalize vaccine supplies for SIAs.
- The VBSI form must accompany all vaccine requests to UNICEF SD for polio SIAs.
- One VBSI form should accompany each supply request for one particular type of polio vaccine.
- If the supply request is for more than one type of polio vaccine, then separate VBSI forms should be submitted for each type of polio vaccine requested capturing balance stock for each type separately.

The VBSI form has five sections – identifier, target population, detailed balance stock information, vaccine doses requested, and sign-off.

1. **Identifier section:** The user has to enter country name, date of request and type of polio vaccine requested in this section.
2. **Target population and type of activity:** The user will fill in target population size and age-group, and the type and start date of activity, for which the request is being made. If the request is for building a buffer stock for a future case response, transit point activity or vaccinating travellers (IHR), then start date of activity is not required.
3. **Detailed balance stock information:**
   This section captures
   - Balance stock of vaccine doses available in the country (for the vaccine type requested) at national and first sub-national level stores for all types of polio SIAs.
   - The completeness of the information by noting the count and proportion (%) of stores from which the information has been collected out of those expected to report.
4. **Vaccine doses requested:** In this section, the user will enter net doses requested. Net doses requested is equal to the doses needed for the activity in question **minus** the doses available for polio SIAs in the country. The information on available doses is a summary of the information available in the previous section.
5. **Sign-off, notes and comments section:** This last section is for signing off by an accountable person on behalf of the national programme and for adding any explanatory remarks, should that be needed.

Note that once the VBSI form along with SIA vaccine request reaches UNICEF SD, there is no change from existing procedures in actual processing of vaccine requests. The main purpose of the additional information collected through the VBSI form is to rationalize supplies.

To give UNICEF SD adequate lead time for ordering and delivering vaccines, it is critical to send the VBSI form sooner rather than later, even when it is incomplete.

II. Vaccine Utilization Report Form version 2 (VUR-2) –Annex 2

The VUR-2 is a simple spreadsheet to capture information on vaccine utilization in polio SIAs by type of activity, target population, children immunized, and vaccine doses used by type of vaccine. It enables countries as well as the global partnership to monitor vaccine utilization at national and sub-national levels and to cross-check against reported stock balances available in country.

- The form collects vaccine utilization data from national and 1st sub-national levels which is already available in the countries as part of SIA reports.
- It focuses on outlier values of OPV/IPV wastages (<5% OR >=15%)
- Each row in the form captures a distinct period of completed activity, usually an SIA round with distinct start and end dates.
- When there are different types of activities happening in the country at the same time, e.g. an SNID in one part and a SIAD in another part of the country, then each separate activity should be captured in a separate row of the form.
- Activities occurring at the same time with different types of vaccines (bOPV/mOPV2/IPV) should be captured in different rows of the form according to the type of vaccine used.
- Some activities may be of a continuing nature (e.g. transit point vaccination) which may not have distinct start and end dates. For such activities, countries should report by calendar months (first and last day of the month).
- **To reduce workload on country data systems** new information should be added as additional rows at the bottom of the last VUR-2 submitted. A new form should however be filled in at the beginning of each year with the first SIA starting on or after 1 January of the year. The cut-off date will be the starting date of the SIA round.

UNICEF PD will analyse the information collected with VBSI and VUR-2 forms and feed it back to GPEI Vaccine Task Team and country programmes. Comparing the data on these forms cumulatively will give a realistic picture of vaccine balance stocks, utilization patterns and wastage rates in countries. This will be increasingly critical moving towards OPV cessation.

Table 1: Key operational procedures and use of VBSI and VUR-2 forms[1]

	VBSI	VUR-2
Purpose of the report	To report on available polio SIA vaccine stock balances in their central and first sub–national level stores when requesting SIA vaccine supplies from UNICEF SD	To capture information on vaccine utilization in polio SIAs by type of activity, and type of vaccine at national and first sub-national levels
Main source of data	Vaccine stock registers at national and sub-national levels	Tally sheet data + Vaccine stock registers
Principal partner for technical support	UNICEF CCL&VM staff	For data on children immunized and vaccine doses used - WHO polio staff. For data on balance stock – UNICEF CCL&VM staff
Who sends	UNICEF polio focal point	UNICEF polio focal point
To Whom	UNICEF SD: Andisheh Ghazieh (aghazieh@unicef.org); UNICEF PD: Ahmet Afsar (aafsar@unicef.org), WHO HQ: Eduardo Vargas (vargasgarciae@who.int)	UNICEF SD: Andisheh Ghazieh (aghazieh@unicef.org); UNICEF PD: Ahmet Afsar (aafsar@unicef.org), WHO HQ: Eduardo Vargas (vargasgarciae@who.int)
CC to	Regional polio focal points – WHO and UNICEF; Polio Programme focal points of WHO and UNICEF Country teams as decided by respective country offices.	Regional polio focal points – WHO and UNICEF; Polio Programme focal points of WHO and UNICEF Country teams as decided by respective country offices
At what frequency	With every new SIA vaccine request	By the 7th of every month or after every SIA round (see text)
Mode of reporting	E-mail	E-mail
File nomenclature protocol	<VBSI – Country Name - Date of Vaccine Request as YYYY-MM-DD> Ex: <VBSI-PAK-20140130>	<VUR-2 – Country Name - Date of Reporting as YYYY-MM-DD> Ex: <VUR-2-PAK-20140307>
Form template download link	https://www.dropbox.com/s/uc4blq0k5i6bsmy/VBSI%20Template%20v2.1.xlsx?dl=0	https://www.dropbox.com/s/2rte5z5mrvy3yjp/VUR-2%20Template%202.1.xlsx?dl=0
Analysis and Feedback will be provided from	UNICEF-HQ-PD/Polio.	
Shared with	Country Programme focal points and Regional focal points and GPEI	
Expected actions and impact	At country level: national polio eradication programme (EOC/polio control room) will utilize the information to take corrective actions and monitor vaccine utilization more closely. At global level UNICEF PD and SD will be able to monitor and manage vaccine supplies to countries more effectively.	

[1] Recently published "**Technical Guidance on mOPV2 vaccine management, monitoring, removal and validation**" requires using Form A for collecting mOPV2 stock information. Countries should not delay reporting with Form A while preparing VUR-2.

Annex 1: Vaccine Balance Stock information form (VBSI)

POLIO VACCINES: BALANCE STOCK INFORMATION - TO ACCOMPANY REQUEST FOR NEW SUPPLIES
(One sheet - One type of vaccine - One request)

PAGE _____ OF _____

COUNTRY IDENTIFIER: VACCINE TYPE, DATE OF REQUEST AND COUNTRY

Polio Vaccine Type: _____ Date of request: _____ COUNTRY: _____

TARGET POPULATION AND ACTIVITY TYPE

Target population age-group: _____ Target population size: _____ Activity Type (pick from the list): _____ If other, please specify: _____ Start date of activity (NA if request is for SIA Buffer or for RI): _____

DETAILS OF BALANCE STOCK IN COUNTRY (NATIONAL AND 1ST SUB-NATIONAL LEVEL STORES) AND COMPLETENESS OF REPORTING

Balance stock (DOSES) in stores at national level (N): _____ Number of national level stores in country: _____ Number of national level stores from which information included in this report: _____

Balance stock (DOSES) in stores at 1st sub-national level (SN): _____ Number of 1st sub-national level stores in country: _____ Number of 1st sub-national level stores from which information included in this report: _____

Combined Balance stock (DOSES) in country (National + 1st SN levels) T = N + SN: 0 Balance stock (DOSES) that cannot be used for this round (earmarked for other activities) - "E": _____ Please specify for which activities this stock has been earmarked: _____ **Net balance stock available for this activity B = T-E**: 0

SUMMARY INFORMATION ON VACCINE DOSES REQUESTED

Number of doses needed for this SIA round (A)	**Wastage Mutiplication factor used**	**Number of doses in balance stock that can be used for this activity (B)**	**Number of doses requested (C = A-B)**	**Explanatory comments (if any)**
			0	

SIGN-OFF, NOTES AND COMMENTS

Name of person making request: _____

Designation of person making request: _____

Signature with official seal: _____

Annex 2: Sub-national Vaccine Utilization Report (VUR-2)

POLIO SIAs - VACCINE UTILIZATION REPORT (with 1st SUB-NATIONAL LEVEL SUMMARY)
Country:

Line Number	Date of report (DD-MMM-YYYY)	Activity Start Date (DD-MMM-YYYY)	Activity End Date (DD-MMM-YYYY)	SIA /Activity Type	Vaccine Type (One row for one type of vaccine)	Target Population (Leave blank if PTP or other non-target based activity)	Number of children Immunized	Number of vaccine doses used	Number of 1st level sub-national areas where activity took place during period of reporting	Number of 1st level sub-national areas included in this report	Number of 1st level sub-national areas with <5% vaccine wastage	Number of 1st level sub-national areas with >=15% vaccine wastage	Percent 1st level SN area included in report	Percent 1st level SN area with outlier values (<5% + >=15%)	Aggregate coverage national level (%)	Aggregate vaccine wastage national level (%)
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
	Date	Date	Date	Text	Text	Number Entry	Number Entry	Number Entry	Number Entry	Number Entry	Number Entry	Number Entry	Formula K/J%	Formula (L+M)/K%	Formula H/G%	Formula (I-H)/I%
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12																

Annex 3: Tools and resources

As this guidance note is not meant to be exhaustive, links to some additional information on cold chain, logistics and vaccine management are given below.

- Overview of Global Polio Eradication Initiative and Endgame Strategic Plans
  <www.polioeradication.org>
  <www.polioeradication.org/Resourcelibrary/Strategyandwork.aspx>
- Overview of immunization supply chain and logistics from WHO-Immunization, Vaccine and Biologicals
  <www.who.int/immunization/programmes_systems/supply_chain>
- Overview of supplies and logistics from UNICEF-HQ
  <www.unicef.org/supply/index_68367.html>
- Information on WHO pre-qualified vaccines
  <www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en>
- Catalogue of WHO pre-qualified equipment for EPI
  <www.who.int/immunization_standards/vaccine_quality/pqs_catalogue>
- Technical network for strengthening immunization services including cold chain and logistics
  <www.technet-21.org>
- Cold chain technical guidelines from UNICEF
  <www.unicef.org/supply/files/Cold_Chain_Technical_Reference_Guide.pdf>
- Effective Vaccine Management (EVM) initiative programme from WHO
  <www.who.int/immunization/programmes_systems/supply_chain/evm/en>
- Detailed guidance on monitoring vaccine usage and wastage at country level
  Ordering code: WHO_V&B_03.18.
- WHO modules for training for mid-level managers (MLM)
  <www.who.int/immunization/documents/mlm/en>
- WHO Multi-dose Vial Policy (MDVP) – Revision 2014
  <http://apps.who.int/iris/bitstream/10665/135972/1/WHO_IVB_14.07_eng.pdf>
- GPEI note on implementation of IPV SIAs
  <www.polioeradication.org/Portals/0/Document/Aboutus/Governance/IMB/11IMBMeeting/2.5_11IMB.pdf>

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WORLD HEALTH ORGANIZATION. DEPT. OF IMMUNIZATION VACCINES AND BIOLOGICALS. 2014. *WHO Policy Statement: Multi-dose Vial Policy (MDVP) Revision 2014*, Geneva, World Health Organization.

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NOTES





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For additional information on polio SIA and technical support, please contact:

Jalaa' Abdelwahab
Senior Health Adviser
Deputy Polio Team Leader
jabdelwahab@unicef.org

Ahmet Afsar
Cold Chain and Logistics Specialist (Polio)
aafsar@unicef.org

Ryan McWhorter
Supply Chain Manager
rmcwhorter@unicef.org

For additional information on polio vaccine procurement and supply, please contact:

Ann Ottosen
Senior Contracts Manager (Polio)
aottosen@unicef.org

Andisheh Ghazieh
Contracts Manager (Polio)
aghazieh@unicef.org

United Nations Children's Fund (UNICEF)
3 United Nations Plaza
New York, NY 10017
USA

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