COVID-19 Vaccination

Country Readiness and Delivery:
Supply and Logistics Guidance
(November 2020)

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ACKNOWLEDGEMENTS
TO COME

ACRONYMS

ACT	Access to COVID-19 Tools	LMIC	Lower Middle-Income Countries
AEFI	Adverse Events Following Immunization	LMIS	Logistics Management Information System
CCEOP	Cold Chain Equipment Optimisation Platform	MoH	Ministry of Health
CCE	Cold Chain Equipment	NDVP	National Deployment and Vaccination Plan
CCI	Cold Chain Inventory	NGO	Non-Governmental Organization
COVID-19	Novel Coronavirus SARS-CoV-2	NLWG	National Logistics Working Group
COVAX	COVID-19 Vaccines Global Access	MoH	Ministry of Health
CCT	Cold Chain Technician	NMS	National Medical Store
CNCC	COVAX National Coordinating Committee	PAHO	Pan American Health Organization
CTWG	COVAX Technical Working Group	PCM	Phase Change Material
CTC	Controlled temperature Chain (during immunization and outreach sessions)	PPE	Personal Protective Equipment
DNA	Deoxyribonucleic acid	PPM	Planned Preventive Maintenance
EPI	Expanded Programme on Immunization	RNA	Ribonucleic acid
ESAVI	Events Supposedly Attributable to vaccination	SDD	Solar Direct Drive
EUL	WHO Emergency Use Listing	SMT	Stock Management Tool
Gavi	Gavi, the Vaccine Alliance	SN	Sub-National Store
GDP	Good Distribution Practices	SOP	Standard Operating Procedure
GEVIT	Global Ebola Vaccine Implementation Team	UCC	Ultra-low temperature cold chain
GTIN	Global Trade Item Number	ULT	Ultra-Low Temperature
HMIS	Health Management Information System	UNICEF	United Nations Children's Fund
IPC	Infection Prevention and Control	VVM	Vaccine Vial Monitor
ILR	Ice Lined Refrigerator	vLMIS	virtual Logistics Management Information System
IFRC	International Red Cross and Red Crescent Movement	VIRAF/T	Vaccine Introduction Readiness Assessment Framework and Tool
iSC	Immunization Supply Chain	WICR	Walk in Cold Room
		WHO	World Health Organization

1. CONTEXT

The COVID-19 pandemic is causing unprecedented human and economic costs in all the countries and societies in the world. The permanent solution to save more lives will likely be brought through development and deployment of:

- an effective and safe vaccine against the virus;
- specialized diagnostics technologies; and
- effective therapeutics.

The COVID-19 Vaccine Global Access (COVAX) Facility aims to accelerate equitable access to appropriate, safe and efficacious vaccines to all countries.

Many vaccine candidates are under development; as of November 2020, over 45 vaccine candidates in clinical trials that are part of the COVAX portfolio. The London School of Hygiene & Tropical Medicine has developed an interactive tool[1] that allows you to track the progress on the candidate vaccines in real-time. It is recommended to verify the status of the vaccines development progress, profiles and potential controlled-temperature chain (CTC) frequently.

Given the pandemic context, the vaccines may not be prequalified at the time of their initial periods of use; they will be released under WHO's Emergency Use Listing (EUL: link) procedures. The EUL process was developed by WHO to expedite the availability and use of unlicensed medical products needed in public health emergency situations.

In this context, it is possible that some vaccine profile characteristics will not be established by the time they are labelled for use. For example, expiry date and vaccine vial monitor (VVM) category may not be established. Consequently, strict supply, distribution, logistics and management procedures and practices must be applied throughout the vaccination deployment.

The minimum label information (shown below) and package insert in 6 UN languages are under consideration. The label may include a manufacturing date rather than an expiry date and the expiry date could be updated through real-time stability data accessible via a barcode that would direct users to a website. This characteristic represents new requirements of vaccine management activities that need to be handled appropriately in the field.

Figure 1: COVID-19 vaccine label information

COVID-19 VACCINE	**COVAX SUPPLY**
[Insert Mode of Admin, IM etc.]	[Insert Total Volume]
[Insert Storage conditions]	[Insert strength / dosage]
[Insert Multidose vial (number of doses x volume)]	[Insert QR code and/or Web site]
[Insert Manufacturing date]	
[Insert Lot #]	[Insert Manufacturer]

[1] COVID-19 vaccine tracker, Vaccine Center, London School of Hygiene & Tropical Medicine: link to TRACKER

The goal of the COVAX allocation framework for vaccines is to protect public health and minimize societal and economic impact by reducing COVID-19 mortality. Priority target groups are identified as:

- Frontline workers in health and social care:
  - it is projected that countries receive doses to cover 3% of their population to cover frontline workers involved in health and social care in most countries.
- Elderly (adult over 65 years old), adults with comorbidities and others based on local relevant risk factors:
  - it is projected that countries receive additional doses to cover a total of 20% of their population (in tranches).
- Additional populations:
  - if countries purchase or receive additional doses over their 20% population threshold, they could decide to prioritize other at-risk populations.

2. Purpose of this document

The purpose of this document is to provide guidance to countries to:

- develop and strengthen supply chain strategies to receive, store, distribute and manage COVID-19 vaccines and their ancillary products;
- distribute COVID -19 vaccines from port of entry up to the most remote vaccination sites;
- ensure the quality, efficacy, proper tracking, reporting of vaccine utilization and safety of COVID-19 vaccines throughout the supply chain;
- implement appropriate waste management mechanisms to safely treat and dispose the waste while protecting the environment and the populations;
- strengthen cold chain & logistics requirements to the context including reverse logistics; and
- provide tools to support country readiness activities.

KEY MESSAGES
• Supply chain readiness is key to efficiently deploying COVID-19 vaccine to the target populations in line with defined vaccination strategies
• Due to potential variations in storage temperature requirements of the different COVID-19 vaccine products, countries will need to compile information on the available cold chain capacity, including surge capacity from other government agencies and private sector, to develop the vaccine deployment strategy and to mobilize resources to fill the identified gaps.
• Countries will need to ensure adequate human resources capacity (including through training) for the management of the vaccine cold chain and supply chain in implementing the procedures according to Standard Operating Procedures (SOPs).
• Establish management protocols to ensure quality and integrity of the COVID-19 vaccines and ancillary products throughout the supply chain.
• Vaccines with ultra-low temperature cold chain (UCC) profile, would pose several challenges for many lower-middle-income countries (LMIC), because of the lack of existing UCC within the health/immunization systems; countries that will receive COVID-19 vaccine requiring ultra-low temperature storage temperatures (e.g. - 60°C to -80°C) should explore, as a quick alternative, the ability of logistic service providers (national, regional or global) to support the deployment plan of the UCC equipment based on the vaccine characteristics and the vaccination strategy to equitably reach the target population.
• First batches of COVID-19 vaccines may be scarce with a short shelf life; some vaccines may not have vaccines vials monitors (VVM), so cold chain equipment (CCE) temperature monitoring, vaccine distribution, inventory management and monitoring mechanism will need to be particularly rigorous and efficient.
• Robust mechanism to ensure the traceability of the COVID-19 vaccines, should be in place to avoid a risk of diversion and falsification of the vaccines.

- Procedures of reverse logistics need to be strengthened or implemented to allow tracking of the vaccines during the vaccination.
- Ensure safety plans to safeguard stock at the national and sub national stores and during the distribution of products.
- Establish security arrangements to ensure the integrity of COVID-19 vaccines and ancillary products throughout the supply chain; ensure availability of plans to safeguard the security of staff as well as security at the central and/or regional storage facility and for in-transit of products in a situation of high demand but limited stocks.
- COVID-19 vaccination campaigns are expected to generate unusually large amount of health care waste. Countries should ensure that safe and effective waste management plan, budget for training, employment of waste handlers, bins and treatment technologies are in place prior to vaccine deployment including the option of outsourcing to the private sector.

The table below illustrates how to use this document.

Table 1 – Document structure

Section	Goal	Key guidance
1 – Context	Introduce country teams to the COVAX Facility. It also informs on the characteristics of the candidate vaccines and how it might affect the supply and logistics activities	. Context of the pandemic . Suggested priority groups . Label example
2 - Purpose	Inform country on how this guidance might support their preparation and deployment operations	. Main activities covered by this guidance
3 - Vaccine profiles and scenarios	Inform country teams on challenges that the candidate vaccines will bring in terms of supply and logistics	. Vaccines development scenario . Challenges they might bring . Characteristics . Tools in selecting the right vaccine
4 - Cold chain and supply strategies	. Orient the country teams on how to organize a COVAX technical working group. . Provide Supply and Logistics guidance in preparation for COVID-19 vaccination . Inform country teams on Security and budget activities to support the campaign	. COVAX Technical Working Group (CTWG) . Guidance in: ➢ Preplanning: core functions and logistics ➢ Deployment operations ○ Reception of products ○ Storage ○ Repackaging ○ Coolant packs ○ Transportation ○ Reverse Logistics ○ Management of information ➢ Tracking of products ➢ Vaccination campaign security ➢ Budget
5 – Vaccines' store infrastructure & Power	. Guide the country teams on understanding the challenges that candidate COVID-19 vaccines might bring in terms of cold chain & dry storage requirement	. Store infrastructure . Ultra-low temperature cold chain (UCC) equipment system . Power Requirement . Dry storage
6 – Waste Management	. Orient country teams on best practices to manage hazardous and medical waste during the COVID-19 vaccination campaign	. Practical steps are described to prepare a waste management plan . A guide on how to dispose of syringes, vials and other COVID waste

7 – Human Resources	. Provide guidance on how to ensure staff availability, safety and security	. Strategy on staffing . Capacity building
8 – Country preparedness indicators	. Inform the country teams of key activities suggested on the COVAX country vaccine readiness assessment. . It also provides some indicators to help country teams measure their readiness	. Key activities are listed along with indicators and timelines
9 - Country readiness tools	. Provide guidance to country teams on tools for ensuring supply chain readiness for effective vaccine deployment	. The tools are presented according to their functions: ➢ Overview & scope of the supply chain (SC) ➢ Analyze readiness and identify SC needs ➢ Support effective vaccine deployment ➢ Monitor and evaluate supply chain operations and performance . Tool recommendations are made for each function, using a country-focused methodology
Annex	. Provide tools, procedures and templates that could be useful to country teams	. Tools Decision matrix . Guidance on UCC . Country Readiness self-assessment . Vaccine accountability monitoring reporting form (Reverse Logistics) . Reported waste form

3. VACCINES: SCENARIOS AND PROFILES

As of November 2020, the development of the COVID-19 vaccines is on-going, and given the absence of clinical trial data, the three core scenarios below can be used to help prepare and support delivery planning.

Table 2: Vaccines development scenarios

	Q4 2020 end of Q1 2021 ("First batch")	**Q2 2021 - Q4 2021** ("Second batch")
Scenario 1a	First doses may be available Q4 2020, month tbc ➢ 120 million doses available Viral Vector, 2 dose regimens at 2 to 8°C	Assumes 4 different vaccines available ➢ 1 billion doses available in Q3 2021 from at risk manufacturing Majority of vaccines are 2 dose regimens at 2 to 8°C
Scenario 1b	First doses may be available Q4 2020, month tbc ➢ Unconfirmed number of doses mRNA, 2 dose regimens at -70°C +/- 10	First doses may be available Q4 2020 ➢ Small number of doses available mRNA, 2 dose regimens at -70°C +/- 10
Scenario 2	First doses may be available Q4 2020, month tbc 2 different vaccines platforms, ➢ 120 million doses available Viral Vector, 2 dose regimens at 2 to 8°C mRNA, 2 dose regimens at -70°C +/- 10	Assumes 4 different vaccines available 2 different vaccines platforms, ➢ 650 million doses available Viral Vector, 2 dose regimens at 2 to 8°C mRNA, 2 dose regimens at -70°C +/- 10
Scenario 3	No vaccines available	First doses may be available Q2 2021 ➢ 1 billion doses available Q2 2021 from at risk manufacturing Majority of vaccines are 2 dose regimens at 2 to 8°C

- It is a good practice to verify the development of the candidate vaccines as they progress through the development pipeline using the COVID-19 London School of Hygiene & Tropical Medicine tracker[2].
- It is expected that more than 95% of the doses produced will required 2 to 8°C storage conditions.

3.1 Candidate COVID-19 vaccines profiles

Not all candidate vaccines are guaranteed to succeed and no single manufacturer has the capacity to supply the global volume required which mean that initially, countries may not have a wide variety of vaccine type to choose from (if any), but as supply increases, then countries can choose the right vaccine type based on product profiles, characteristics and cold chain requirements.

The data in table 3 are provided to inform decision-makers for planning and delivering vaccines.

Table 3: Candidate COVID-19 vaccines profiles (as of November 2020)

Characteristics	COVID vaccine A mRNA (liquid)	COVID vaccine B Viral vector (liquid)	COVID vaccine C Viral vector lyophilized	COVID vaccine D Protein subunit (liquid)
Efficacy	tbc	tbc	tbc	tbc
Safety	tbc	tbc	tbc	tbc
Dose Regimen	2	2	2	2
Duration of immunity	12-18 months (tbc)	12-18 months (tbc)	12-18 months (tbc)	12-18 months (tbc)
Duration between doses	4 weeks (tbc)	4 weeks (tbc)	4 weeks (tbc)	4 weeks (tbc)
Cold Chain Req.	- 70°C (Pfizer) & -20°C (Moderna)	2-8°C (AstraZeneca)	2-8°C (tbc)	2-8°C (tbc)
Stability at 2-8°C	5 days (Pfizer) 30 days (Moderna)	tbc	tbc	tbc
Shelf Life	Refer to manufacturer's instructions via QR/barcode or manufacturer's website			
Vaccine presentation / Vial size	5 (Pfizer) & 10 (tbc)	10 & 20 (tbc)	10 & 20 (tbc)	10 & 20 (tbc)
Mode of Administration	IM	IM	IM (tbc)	IM (tbc)
Packed volume per dose (secondary package)	2.5cm3 /dose (Pfizer) 4.63cm3 /dose (tbc)	4.63cm3 /dose (tbc) 1.2cm3 /dose (tbc)	4.63cm3 /dose (tbc) 1.2cm3 /dose (tbc)	4.63cm3 /dose (tbc) 1.2cm3 /dose (tbc)
Open vials wastage	15% (tbc)	15% (tbc)	15% (tbc)	15% (tbc)
Multi-Dose Vial Policy (MDVP)	No reuse	No reuse	No reuse	No reuse
Freeze sensitivity	Refer to Product Information leaflet (PIL)	Refer to PIL	Refer to PIL	Refer to PIL
Freeze/Thaw cycle	Refer to PIL	Refer to PIL	Refer to PIL	Refer to PIL
Light sensitivity	Refer to manufacturer's instructions via QR/barcode or manufacturer's website			
VVM	tbc	tbc	tbc	tbc
Barcode	Yes (tbc)	Yes (tbc)	Yes (tbc)	Yes (tbc)

[2] COVID-19 vaccine tracker, Vaccine Center, London School of Hygiene & Tropical Medicine: link

QR code	Yes (tbc)	Yes (tbc)	Yes (tbc)	Yes (tbc)
Diluents	Yes (Pfizer) & others tbc	tbc	tbc	tbc

- Some manufacturers are exploring the possibility of producing vaccines that could be delivered under controlled temperature chain (CTC) conditions.

Note that whether the vaccine requires cold chain at 2 to 8°C, -20°C or -70°C +/- 10 (ultra-low temperature cold chain), the level of preparedness and the country's readiness will be critical in selecting and accepting any vaccine. Key supply & logistics drivers for readiness will depend on:

- Priority target groups to be vaccinated
- Vaccine characteristics (availability, storage temperature, shelf life, # dose regimen…)
- Timeline and strategy to vaccinate target groups
- Availability of adequate cold chain storage & transportation capacities
- Human and financial resources required to adequately handle the vaccine deployment

To help countries select and accept donations of vaccines, the general guidance to introduce are:
- Principles and considerations for adding a vaccine to a national immunization programme (Link).
- WHO-UNICEF Joint Statement on Vaccine Donations (Link).
- Vaccination in humanitarian emergencies (Link).

4. COLD CHAIN and SUPPLY STRATEGIES

4.1 COVAX Supply Chain Technical Working Group (CTWG) and National Logistics Working Group (NLWG)

Strong supply chain management team is critical for the vaccine introduction. Countries should build on existing committees and working groups already in place to define the COVAX teams but keeping in mind that the target groups will be different than the usual new vaccine introduction activities. It will therefore be necessary to widen the committees to other relevant stakeholders

Under the guidance of the COVAX National Coordinating Committee (CNCC), the CTWG and NLWG should activate the following activities:
- Assign receiving and acceptance responsibilities to the right entities, such as:
  - the regulatory authority bodies within a country, or existing mechanism for importing vaccines; and
  - customs agents or national custom authorities.
- Secure the system design with the support of the national logistics teams to ensure:
  - temporary customs storage;
  - transportation from the airport to the national stores;
  - adequate cold chain equipment capacity;
  - vehicles to transport vaccines safely to all regions and districts with different loading capacities; and
  - system design team to distribute vaccines within the country.

The composition and guidance on how to establish a NLWG can be found here: NLWG Guide.

4.2 Coordination Mechanism

The CNCC, CTWG and/or NLWG need to meet frequently to coordinate and monitor the implementation of the core functions of the activities listed below. There should be regular weekly and bi-weekly coordination meetings between all stakeholders.

The CTWG and/or the NLWG are responsible for developing and monitoring the key activities listed on Table 4, in preparation of the distribution plans up to the last mile, in line with the national deployment and vaccination plan in place in the country.

4.3 Pre-planning: core functions & logistics

Countries should already be analyzing the information available to them that relates to the COVID-19 vaccination campaigns. Table 4 below identifies the core supply and logistics functions that countries should discussed when developing their National Deployment and Vaccination Plan (NDVP) within their committees to strengthen their COVID-19 vaccination campaign.

Table 4: Core supply & logistics functions at each supply chain levels

Core Functions	Description of the activity	National	Sub national	District	Proposed Timeline
Background	Explain, the scope of the vaccination campaigns in term of: ➢ target population, ➢ vaccines that will be used, ➢ delivery sites.	X	X	X	3-6 months prior
Coordination and monitoring	Build the structures for coordination and Vaccine Management (CTWG / NLWG) at all levels of the health services. Monitor progress using methods such as dashboard with key indicators, readiness assessment tools, etc.	X	X	X	3-6 months prior
Logistics structure	Explain the distribution and collection pattern and how campaign logistics will be different from the routine structure, and reasons for difference.	X	X	X	3-6 months prior
Cold chain	Give details on cold chain capacities with a gap analysis and plans to fill the gaps.	X	X	X	3-6 months prior
Transport	Give details on transportation capacities and plans for the distribution.	X	X	X	3-6 months prior
Waste management	Explain the national policy in term of COVID vaccine waste management and give details on practical ways (routes, methods, disposal sites.) to safely collect, treat/dispose the waste.	X	X	X	3-6 months prior
Risk mitigation	Detail the strengths, weaknesses, opportunities and threats related to all components of vaccine management for this vaccination: human resources, information management, cold chain management, waste management,	X	X	X	3-6 months prior

	recalls and others related to country context.				
Accountability framework Before/during/after	Give information on the activities that must be conducted with person in charge, timetable and expected deliverables. Discuss procedures related to reverse distributions.	X	X	X	3-6 months prior
Human resources	Give details on the people in charge with their roles and responsibilities.	X	X	X	3-6 months prior
Training	Detail the training plan, schedule, audience, duration and content.	X	X	X	3-6 months prior
Procurement & distribution	Give a summary of the forecast and distribution plan.				3-6 months prior
Reverse logistics	Explain how and when the usable and unusable vials will be collected from the vaccination teams.	X	X	X	3-6 months prior
Information management	Identify and explain tools and forms from the routine Logistics Management Information System or tools designed specifically for this response.	X	X	X	3-6 months prior
Chronogram of the supply and logistics activities	Give details on the timeline of the supply and logistics activities.	X	X	X	3-6 months prior
Budget	Estimate the costs of all activities and identify funding sources.	X	X	X	3-6 months prior

To guide countries in listing different activities that must take place prior to the vaccine deployment, a COVAX Vaccine Introduction Readiness Assessment Framework / Tool (VIRAF/T) (refer to section 9, tool #2) has been prepared by the global subject-matters experts. The National Deployment and Vaccination Plan (NDVP) is another guide to help countries prepare the vaccination sessions. While completing these activities, it's important to keep in mind the following considerations:

Planning steps

1. **Assess your country readiness using the VIRAF/T (Refer to section 9, Tool #2)**
2. **Forecast vaccine and logistics needs using the immunization supply chain sizing tool link (Refer to section 9, Tool#3)**
3. **Develop the COVID-19 strategies using the National Deployment and Vaccination Plan for COVID-19**

- Early planning with regular monitoring and adjustments is key for success.
- The development of different plans and their implementation should be a team effort under the coordination of the COVAX Technical Working Group and/or NLWG under the COVAX National Coordinating Committee.
- Countries should test their supply chain's ability to receive, store and distribute COVID-19 vaccines and relevant ancillary products to identify and address any bottlenecks, and to inform their deployment plan.

- The country-led deployment plan should be in line with the selected vaccination strategy and be initiated several weeks before vaccination begins.
- The volumes of incoming shipments for both COVID-19 vaccines and ancillary products and their delivery frequencies should be aligned to existing storage and distribution capacity at the initial and final delivery points destination.
- Whenever applicable, countries are encouraged to seek additional storage and distribution capacity from their partners including outsourcing from private sector.
- Countries should adapt their supply and logistics SOPs specific to their own context.
- Countries need to develop or adapt their logistics management information systems to track, trace and report the vaccine and logistics stocks and utilisation on a regular basis.
- Countries should invest in closely monitoring the quality of COVID-19 vaccines and ancillary products for patient safety. A reporting system should be in place together with other mitigation measures to limit any risks.

4.4 Deployment Operations

Vaccine delivery will not be a one-time event but rather a continuous effort for the duration of the COVID-19 pandemic. Most countries may receive large quantities of vaccines in multiple shipments from the manufacturer over a period of time. The CNCC, in partnership with local health authorities, will provide the priority sequence by which their populations are to be vaccinated as vaccines arrive in countries.

The deployment operations are:

1. Reception of products and ancillary products
2. Storage
3. Repackaging
4. Coolant packs
5. Transportation
6. Reverse Logistics
7. Information
8. Tracking vaccines

4.4.1 Reception of vaccines, PPE and ancillary products

The guidance is presented by health services stores' level:

- Central level and port of entry
- Sub national level

CENTRAL LEVEL AND PORT OF ENTRY

At the port of entry, ensure that customs clearance arrangements have been established and that transportation or storage arrangements are in place. The "COVAX ARRIVAL SOP" below can inform you on the tasks to complete for successfully receive the vaccines and the ancillary products.

Countries procuring vaccines through UNICEF and PAHO Revolving Funds (RF) may utilize the SOP below for incoming COVID-19 vaccine shipments. Note that the SOP may need to be adjusted where VVMs on vaccines are not available and/or expiry dates are only available on QR/barcodes.

Table 5: COVAX ARRIVAL SOP

Task	National Cold Store Responsibilities	EPI Responsibilities	UNICEF/WHO/ PAHO/CO Responsibilities	UNICEF SD/PAHO

Pre-arrival	1. Review of pre-alert documentation & prepare to receive vaccine 2. Ensure sufficient storage is available & appropriate transport arrangements 3. Notify MoH procurement to assign a clearing agent & inform CO 4. Confirm with airline readiness to receive consignment	Assign clearing agent & share shipping documentation	Share pre-advice (copies to MoH, Cold Store, Prog)	Release of pre-advice & shipping documentation
Customs clearance & transport to national store	Confirm clearance & transport vaccines to national store immediately	Clear customs	Arrange for clearing when consignee is CO	Provision of appropriate documentation
Inspection of shipment (to be completed as soon as the shipment arrives at national store)	1. Check for physical damage or missing items 2. Open each container & stop VaxAlert/Qtags 3. Mark the VaxAlert/Qtags to link with each container/batch 4. Check for the following documents: invoice, packing list, release certificate, VAR 5. Check shipping indicators & VVM status of vaccines (if no VVM, check QR code) 6. Complete the VAR for each antigen shipment & forward to CO	Inform NRA of vaccine arrival & facilitate batch testing process	Verify VAR & forward to SD/PAHO	Acknowledge receipt of VAR & review as appropriate
Stocking of shipment	**Vaccines accepted:** 1. Unpack vaccines & place in WICR/FR. Place diluents in dry store 2. Record in stock management system & file documentation 3. If available, track barcode and register data on a central repository **Vaccines rejected:** 1. Do not unpack the vaccine until problem is resolved or an interim decision has been made 2. Alert CO of problem immediately (within 2 hours of detecting problem) 3. Quarantine vaccines & do not move from cold store (store in WICR/FR and mark with an "X") 4. Collect VaxAlert/Qtags data & make copies of the device screen 5. Each vial VVM to be checked (if no VVM, check QR code)			
Reporting of problems	1. Start collecting information for investigation (pictures, all documentation, timelines) 2. Ensure WHO/UNICEF CO/ PAHO are involved in the investigation 3. Complete VAR and supply copy of VaxAlert/Qtags screens (link to shipment & vaccine batch), serial numbers and condition of VVMs.	Call a NLWG within 24 hours of receipt of vaccine & send official response to UNICE CO/ PAHO indicating rejection of shipment	Share complaint letter with UNICEF CO/ PAHO & together with WHO guide the MoH in investigation	Guidance of CO on investigation in collaboration with WHO
Follow-up actions	1. Follow-up with SD/PAHO on recourse action 2. Based on recourse action, NLWG to develop response on management of vaccines	Through the NLWG, provide feedback to UNICEF CO/ PAHO on investigation	Follow up with SD/ PAHO on recourse	Follow up with freight forwarder, manufacturer & WHO

Table 6: Track and trace activities
(Refer to section 9, Tools #13 & #19)

Tracking vaccines and other supplies received and stored in the warehouses	
Before vaccination campaign	**During vaccination campaign**
• Create map with sites of the warehouses and record each site in the country information system, ex: LMIS • Prepare central repository system for tracking bar codes • Establish procedures to read QR codes with smart phones for potential real-time expiry dates and vaccine information on secondary or tertiary packages • Review temperature monitoring procedures in case there are no VVM on vaccines vials • Establish procedures to apply for reverse logistics activities	• Record the arrival of vaccines and supplies by signing for reception in the management information system registry (e.g., number of doses, batch numbers and expiration dates) • Issue reports on vaccine reception at the destination sites immediately to confirm shipment arrivals and keep a record of the items stored at each distribution site • Collect and analyse the vaccine accountability monitoring reporting forms at each round • Scan bar codes with a barcode scanner at each step of the supply chain, if available to track location of vaccines

4.4.2 Storage of vaccines and ancillary products

Guidance on COVID-19 vaccines storage and temperature monitoring is dependent on:

- country's supply chain infrastructure
- government's cold chain storage and equipment capacity
- availability of cold chain storage in the private market for leasing
- the key characteristics and thermostability requirements of the new vaccines

The COVID-19 vaccines must be administered promptly once stored. Avoid storing the vaccine for a long period of time.

The potential COVID-19 vaccines candidates currently being developed can be categorized by three storage requirements (as of November 2020):

1. vaccines required to be stored at 2-8°C, where the WHO guidance for managing vaccines will apply (refer to this link) ;
2. vaccines required to be stored at -20°C, where the same WHO guidance applies; and
3. vaccines required to be stored at -70°C +/- 10, where significant investment in ultra-low temperature cold chain (UCC) storage capacity and training in handling vaccines will be necessary.

Countries will need to calculate their cold chain capacity to determine their net capacity and help support decision-making in the choice of vaccines. In section 9, Tools #3 and 8, can help determine the country's net capacity requirements. Analyzing this data set will:

- support decision-making in the choice and quantity of vaccines to procure; and
- help determine if the country will have sufficient storage capacity; and
- identify changes needed to the supply chain design to accommodate constraints.

If storage capacity is insufficient in the country, here are some options (see section 9, Tools #14 to #16 for supply chain system redesign tools' recommendation):

1. **Procure additional storage capacity**

   This option will increase the flexibility and robustness of the supply chain in the long term. However, a minimum of six-month lead time is required to procure and install equipment.

2. **Engage with the private sector to store and distribute products**

   Another option is to pay another party to store and/or manage the temporary distribution of products. It's important to determine which products and where it should be done in the country (segmentation). This option may be very favorable, particularly in economies where the market is mature and high-quality storage options exist. The Guidance on "Supporting Private Sector Engagement with Governments for Supply Chains (link) will help meet your objective.

3. **Split shipments and increase frequency of distribution**

   UNICEF Supply Division (SD) and PAHO have been appointed as the COVAX Procurement Coordinators. They can be requested to split vaccine shipments, to ease the pressure on vaccine storage facilities, particularly at national levels. Countries can also increase the frequency of distribution to storage sites, if lower tiers of the supply chain do not have sufficient storage capacity. It should be noted that this may result in higher operational costs and needs to be planned and budgeted for accordingly.

4. **Stagger vaccination efforts and service delivery models**

   Careful planning of vaccination efforts can ease the pressure on the cold chain systems. Staggering campaigns and/or target groups may be a more feasible option to ensure sufficient storage capacity.

WHAT CAN YOU DO NOW AT COUNTRY LEVEL?

Use the Supply Chain Sizing tool (section 9, Tool #3), to determine your net storage capacity requirements.

- Calculate the cold chain capacity at national and sub national levels of your supply chain

The following cold chain storage planning is recommended.

Central level

The central level stores will have to manage high volumes of vaccines and ancillary products during the COVID-19 vaccination campaigns. An increase in storage capacity requirements is to be expected.

Table 7: Central level cold chain planning steps
(Refer to section 9, Tools #13 to #15 for supply chain systems redesign)

Vaccine Storage Temperatures	Central level
2-8°C	• Map all cold chain storage points (public and private) at this temperature range • Conduct a gap analysis to determine cold chain storage needs (see section 9, Tool #3 & 8)

	• If storage capacity requirements are insufficient, consider the options below: o Procurement of WICR (cold storage room), reefer (refrigerated container) or additional refrigerators o Leasing of a reefer or private facility o Split shipments & increase distribution frequency o Staggered vaccination efforts
-20°C	• Map all cold chain storage points (public and private) at this temperature range • Conduct a gap analysis to determine cold chain storage needs • If storage capacity requirements are insufficient, consider the options below: o Procurement of WIFR or reefer o Leasing of a reefer or private facility o Split shipments & increase distribution frequency o Staggered vaccination campaigns
-70°C +/- 10	• As countries are not familiar with vaccines managed at this temperature range, a specialized strategy has been developed for ultra-low temperature cold chain. • This can be found in Annex B

Sub national level

The sub national stores will have to manage higher than usual volumes of vaccines and ancillary products during the COVID-19 vaccination campaigns. A need to increase storage capacity requirements is to be expected.

It is suggested that district meetings are leveraged to target health workers who are part of the target group for vaccination. This will affect district storage points, however significant capacity at -20°C and 2-8°C exists at this level and has recently been reinforced with the Cold Chain Equipment Optimization Platform (CCEOP) in Gavi eligible countries.

The recent CCEOP and other funded projects reinforced the CCE capacity of the -20°C and 2°C to 8°C sub-national stores in Gavi eligible countries. Thus, the impact to increase storage capacity requirements at this level will not be as high. Suggested planning as follows:

Table 8: Sub National Planning
(Refer to section 9, Tools #14 to #16 for supply chain systems redesign)

Vaccine Storage Temperatures	Subnational Level
2-8°C	• Map all cold chain storage points (public and private) at this temperature range • Conduct a gap analysis to determine cold chain storage needs (see section 9, Tool #3 and 8) • If storage capacity requirements are insufficient, consider the options below: o Procurement of WICR, refrigerators or reefer o Leasing of a reefer or private facility o Split shipments & increase distribution frequency o Stagger vaccination campaigns

-20°C	• Map all cold chain storage points (public and private) at this temperature range leveraging all polio infrastructure
	• Conduct a gap analysis to determine cold chain storage needs
	• If storage capacity requirements are insufficient, consider the options below:
	  ○ Procurement of WIFR or reefer
	  ○ Leasing of a reefer or private facility
	  ○ Split shipments & increase distribution frequency
	  ○ Stagger vaccination campaigns

-70°C +/- 10	As countries are not familiar with vaccines managed at this temperature range, a specialised strategy has been developed for ultra-low temperature cold chain and can be found in Annex B

Health facility level

During the COVID-19 vaccination campaigns, the over-65 years old target group will be accessed through a combined fixed-posts and outreach strategy. The CTWG will need to calculate vaccine requirements (using the tool "Vaccine & Gap Forecasting tool", found in section 9, Tool #8) and ensure they have sufficient storage capacity (using the "Cold chain sizing tool", section 9, Tool #3) within the health facilities.

Table 9: Health facility cold chain capacity planning
(Refer to section 9, Tools #14 to #16 for supply chain systems redesign)

Vaccine Storage Temperatures	Health Facility Level

2-8°C	• Map all cold chain storage points (public and private) at this temperature range
	• Conduct a gap analysis to determine cold chain storage needs (see section 9, Tool #3 & 8)
	• If storage capacity requirements are insufficient, consider the options below:
	  ○ Procurement of SDDs, ILRs and/or cold boxes and vaccine carriers
	  ○ Leasing of a private facility
	  ○ Split shipments & increase distribution frequency
	  ○ Stagger campaigns

-20°C	• Map all cold chain storage points (public and private) at this temperature range leveraging all polio infrastructure
	• Conduct a gap analysis to determine cold chain storage needs
	• If storage capacity requirements are insufficient, consider the options below:
	  ○ Procurement of freezers, cold boxes & vaccine carriers
	  ○ Leasing of a private facility
	  ○ Split shipments & increase distribution frequency
	  ○ Stagger campaigns

-70°C +/- 10	As countries are not familiar with vaccines managed at this temperature range, a specialised strategy has been developed for ultra-low temperature cold chain and can be found in Annex B.

Table 10: Warehouses storage
(Refer to section 9, Tools that support different supply chain functions)

Storage in the different warehouses

Before vaccination campaign	During vaccination campaign
• Assess currently available cold chain capacity within the EPI and adjacent MoH systems; • Decide whether to procure or seek alternative storage capacity in the private sector; • Keep signed copies of the contracts and ensure that they are valid at the time of vaccination • According to EPI standards, evaluate in each establishment: ➢ Operation of the cold rooms to ensure correct temperature range ➢ Procedures to detect and report temperatures outside the appropriate range ➢ Train staff on vaccine storage, packing, and shipment ➢ Security system to prevent supply losses ➢ Continuous temperature recording device and auxiliary generators to ensure electricity supply if there is a power outage • Define the data for monitoring cold chain temperatures and establish an accountability process for storage of vaccines and other supplies.	• Record the arrival of vaccines and supplies by signing for reception in the management information system registry (e.g., number of doses, batch numbers and expiration dates) • Identify the person responsible for vaccine reception, repacking and shipment • Issue reports on vaccine reception at the destination sites immediately to confirm shipment arrivals and keep a record of the items stored at each distribution site • Fill out the Reverse Logistics form called: "Vaccines accountability monitoring reporting form" and send it to the designated focal point after each round

4.4.3 Repackaging vaccines and ancillary items

Most COVID vaccines will necessitate cold chain transport at 2-8°C. Refrigerated vehicles from the national level are recommended but if these are not available in your country, other standard WHO pre-qualified (PQS) containers can be used.

For vaccines requiring UCC, the vaccination strategy recommended is fixed posts, which should not require the need for repackaging. If internal transport is required, specialized containers, such as Arktek[3] + Phase Change Material (PCM)[4] or Dry + Dry Ice boxes should be used.

Table 11: Repackaging vaccines
(Refer to section 9, Tools that support different supply chain functions)

Divide shipments into smaller shipments, repack in cold boxes or refrigerated trucks and send to the designated sites	
Before vaccination campaign	**During vaccination campaign**
• Plan repacking operations to a minimum • Define the size of the shipments according to the needs of the population at each destination and ship the vaccines through the smallest possible number of distribution sites required to reach their destination	• Indicate the number of vials per pack and the expiration date on the outer part of the transport containers and cold boxes. At first, expiry dates might not be indicated. Ensure to read frequently the QR code to find the latest information from the manufacturer. • Adhere to the cold chain management protocols

[3] A modified version of the **Arktek Passive Vaccine Storage Device** that uses phase-change materials rather than ice to maintain a cold environment; only device capable of keeping Ebola vaccines at -80°C without power in remote areas for up to 6 days. https://www.intellectualventures.com/buzz/insights/ivs-global-good-fund-a-legacy-of-impact-invention

[4] Phase change materials (PCMs) are substances which absorb or release large amounts of so-called "latent" heat when they go through a change in their physical state, which helps improve thermal performance when applied to a cold chain product. https://path.azureedge.net/media/documents/DT_pcm_summary_rpt1.pdf

• Plan the supply of sufficient cold boxes of different sizes to ship different amounts of vaccines according to the requirements of the local populations • Inspect the physical integrity of the containers on a regular basis and replace them as needed • Ensure that sufficient trained staff is available • Determine the need for staff training that will receive, store, repack, and ship the vaccines	• Use procedures and devices to prevent improper handling • Insert temperature control devices (freeze tags, data loggers or others) in each cold box so that the warehouses that receive can verify if there were any cold chain excursions • Inspect the physical integrity of the cold boxes and replace them as needed

The container used for vaccine transport should maintain the required temperature throughout its journey.

- Prior to packaging, the vaccines should be kept within the recommended storage temperature.
- The vaccine must be packed inside an insulated package to ensure that the temperature does not rise about +8°C.
- Insulated containers must demonstrate the ability to maintain the appropriate temperature and must be large enough to store vaccines and packing materials.
- External surfaces must be intact, strong, durable, clean, and the lid tight fitting.
- The container must be clearly identified as containing valuable, fragile and temperature sensitive vaccines.

- If the required storage temperature is below -70°C +/- 10, refer to Annex B for "Guidance on UCC use for deployment of COVID-19 vaccines"
- Logisticians have to strengthen their existing SOPs on repackaging vaccines with a focus on COVID-19 vaccine profiles
- Keep vaccines in their original secondary packaging throughout storage and transport to protect the QR and bar codes.

REMINDER:

- Avoid using non-insulated containers for storing or transporting vaccine
- Vaccine temperature needs to be monitored during transport:
- Record vaccine type, lot numbers, brand names, quantity, date, delivery or arrival time and originating facility on a packing slip.
- Coolant packs should be conditioned at room temperature for one to two hours until the edges have defrosted and the packs look like they are sweating. Refer to WHO SOP on "How to use passive containers and coolant-packs for vaccine transport and outreach operations (link).
- Diluents that are stored at room temperature must be refrigerated at least 24 hours if placed in insulated cooler with vaccines. If not cooled in refrigerator, they must be transported separately from vaccines. Room temperature diluents placed in insulated coolers with vaccines may raise the temperature of the cooler.
- Before accepting the vaccines, the recipient should make sure that the temperature limits have not been exceeded by reading the temperature monitoring devices and analyzing the vaccine vial monitors (VVM), if available.

4.4.4 Production or purchase of coolant packs

For vaccines requiring storage and transportation between 2^0C to 8^0C:
Refrigerated water packs:

- must be stored between 2°C to 8°C; and
- must be stored in refrigerator a minimum of 24 hours prior to use

Conditioned ice packs

- Coolant packs should be conditioned at room temperature for one to two hours or until the edges have defrosted and the packs look like they are sweating. Refer to WHO SOP on "How to use passive containers and coolant-packs for vaccine transport and outreach operations (link)".

Table 12: Repacking small shipments

Divide shipments into smaller shipments, repack in cold boxes or refrigerated trucks and send to the designated sites	
Before vaccination campaign	**During vaccination campaign**
• Calculate the amount of coolant that should be available for the shipments • Evaluate the capacity of the public and private facilities and equipment available to provide coolant packs • Contact private companies if the production of coolant packs is insufficient.	• Monitor the production of coolant or on a continuous basis to detect and resolve any problems that can affect deployment

For vaccines requiring storage and transportation at -20^0C:
Frozen ice or gel packs:

- must be stored in freezer a minimum of 24 hours and be completely frozen prior to use; and
- use of bagged or loose ice is NOT acceptable.

For vaccine requiring ultra-low temperature cold chain (UCC), please refer to section 5.2 on UCC strategies.

4.4.5 Transportation of vaccines

Data loggers are the preferred option to monitor the temperature during transportation as it monitors the vial temperature throughout the transportation. The temperature of the vaccine should be duly documented:

- for datalogger inside the container - check the Temp at beginning and the end of the trip (avoid exposing vaccines through frequent openings)
- for dataloggers with outside reader - check temperature at least 2 times during the trip

Table 13: Transportation of products
(Refer to section 9: Tool #3 & 8 for CC gap analysis and #14-16 for SC redesign)

Transport vaccines and ancillary products to all sites by land, air or sea	
Before vaccination campaign	**During vaccination campaign**
• Determine how to transport the vaccines and ancillary products to the predetermined distribution sites and then classify them by type of route and means of transport required	• Monitor availability of all transport resources and operators • Ensure the availability of fuel

• Determine the routes that are high risk due to geographical or security conditions in order to identify resources that guarantee protection of personnel and products • Establish delivery and shipment calendars for each level • Determine the number and location of trucks, ships, airplanes, motorcycles and other available means of transport; transport operators (e.g., drivers, pilots, ship operators) and the location of the fuel supply and repair sites • Calculate the transportation costs, including the per diem expenses for the transport operators. Private sector can also be contracted, if necessary. • Update the contact information of the transport operators on a regular basis • Organize simulations of the transport operations and resupplying fuel.	• Monitor the establishment of timetables and procedures for shipment of remittances • Monitor the progress of the shipments to detect security problems, climate conditions and road conditions that could affect the delivery periods • Work with the law enforcement agencies to provide security • Ensure that the peripheral warehouses and health services promptly report the arrival and condition of the shipments • Guarantee sufficient inventory of appropriate containers for vaccine shipment if refrigerated vehicles are not used

4.4.6 Reverse Logistics

Reverse logistics refers to the process of retrieving unused vaccines either to dispose or reuse. For example, reverse logistics was applied on recalling tOPV for final disposal during the "tOPV-bOPV Switch" in 2016.

In the context of COVID vaccination, most COVID-19 vaccines will be initially used under EUL recommendation; some vaccines may come first without VVM. Most vaccines only come with manufacturing date instead of expiry date.

For safety and accountability reasons, it is critical to ensure all vaccine vials are duly accounted in every health facility and any unused vials must be returned to the higher-level store. Strict stock management practices, vaccine inventory, accurate storage and transaction recording at all supply chain levels, especially at the service points is a critical requirement.

These practices are absolutely required:

- during the vaccination campaigns (e.g. need to re-allocate vaccines to higher risk areas based on latest epidemiological information);
- after the vaccination campaigns (return of unused vaccine to higher level store at the end of vaccination campaigns);
- during a possible temporary pause (temporary pause of vaccination campaign for any reason); and
- to recall the vaccine for any reason.

You will find a "Vaccine accountability monitoring reporting form", in Annex D to accurately track and report on all vials.

4.4.7 Managing recalls

Countries should review their current procedure to recall vaccine products known or suspected to be defective or counterfeit, ensuring that:

- a designated person(s) is responsible for recalls;

- national drugs regulatory authority and the original manufacturer and/or marketing authorization holder are informed in the event of a recall;
- recalled vaccine products are segregated during transit and clearly labelled as recalled products;
- storage conditions are maintained during storage and transit until a decision has been made regarding the product in question by the national drugs regulatory agency. However, during storage recalled products must be labeled « Quarantined » and separate from other products in the cold chain to avoid accidental dispatch or use;
- all stakeholders should be promptly informed of any intention to recall the product because it is, or is suspected to be, defective or counterfeit;
- the progress of a recall process is recorded and a final report issued;
- upon confirmation of the product being counterfeit a formal decision should be taken on its disposal; and
- both distributors and recipients should be accountable for administering their returns process and ensuring that the aspects of their operation are secure and do not permit the entry of counterfeit products.

4.4.8 Management of supply chain information

Close management of supply chain information will be essential for successful deployment of the COVID-19 vaccine. This includes:

- Monitoring cold chain capacity and performance for safe storage space availability at target sites / distribution points (Tool #14);
- Monitoring stock distribution and consumption to ensure the right quantity of vaccines are distributed to every site and ensure their appropriate usage (Tool #13 & 16);
- Ensuring sufficient distribution capacity (vehicles, transport boxes, carriers) to deliver the COVID-19 and routine vaccines on schedule (Tool #15 to #17).

As the target groups for COVID-19 vaccines are different from the EPI target population, countries will need to adapt their current management information systems accordingly to include:

- Storage/transport requirements (if different storage/ transportation conditions are required);
- GS1 standards and barcodes (GS1);
- supply chain/distribution routes;
- supplies volumes;
- target populations; and
- any other according to the country's context.

The following table summarizes areas where data collected and recorded will need to be analysed:

Table 14: Data requirements

Area	Key Data for review
Cold Chain Storage Capacity	✓ Current available CCE storage capacity at target sites ✓ Forecasted storage need for COVID vaccine and current available capacity
Cold Chain Performance	✓ Temperature monitoring log (including excursions) for any CCE storing COVID-19 and EPI vaccines ✓ Functionality of CCE required for vaccines: o If non-functional, time (days, weeks) since failure was reported ✓ Performance / functionality of generators supporting CCE (if applicable for UCC equipment)

Supply Chain	✓ Performance of delivery timeliness ✓ Proportion of planned target deliveries confirmed as delivered ✓ Stocks and consumption rate of COVID-19 vaccine ✓ Location of stocks
Reverse Logistics	✓ Tracking of all vials (open, unopened and used) ✓ Report to collect and record after each round of vaccination

Table 15: Strategic solutions for data management in different contexts

Challenges	Potential Solution(s)
Stock and distribution data are currently handled through a digital platform, but it cannot be updated to meet COVID-19 needs in time.	For the first round of COVID-19 vaccination, consider establishing a fit-for-purpose tool while the broader system is updated. Examples: ➢ Adapt an Excel tool used for campaigns, creating a module with DHIS2 (or similar), or potentially some paper-based approaches. ➢ Consider adapting the management information system, or if that is better invested, develop a strong fit-for-purpose system. The best-fit system will depend on local context, including how easy the existing MIS is to adapt. Several countries have already found success in adapting existing MIS platforms and products to meet COVID product needs (e.g., PPE, diagnostics).
The country has received a UCC vaccine along with specialized equipment but has no tools or existing standards for reporting on performance.	• For storage hubs, establish an online reporting tool or call-in number for hubs to regularly report performance data to the central EPI. • For transport and outreach delivery, develop a specific vaccine delivery / outreach report form that includes UCC performance indicators.
There are concerns about the diversion of vaccines at lower levels of the supply chain	• Refer to the "Tracking vaccine & related items" (section 4.5) and "Security" (section 4.6) in this document. • To track all vaccine vials during the campaign, record and report the vaccines vials movement using the "Vaccine accountability monitoring reporting form", found in annex D.
Diversion and falsification of vaccines	• The implementation of GS1 standards through barcoding on secondary vaccine packaging will ensure traceability of the vaccine and can further help with product recalls
The country does not have onsite data on COVID-19 vaccine at service delivery at facility or campaign sites.	• Refer to section 9 – Table 23 – Tools #18 • COVID-19 vaccines may come with a QR codes on their secondary and/or tertiary package. Scanning this code with a mobile phone or scanner will help find crucial information in real-time.
At first, the COVID-19 vaccines might only have a manufacturing date without the expiry date	• A designated country focal point will scan the QR codes to verify real-time expiry on the secondary packages, as the information will be available on the manufacturer's web site. Then, this information will be disseminated and acknowledged by managers and HW at all • A "Vaccine Accountability Monitoring Reporting Form" (found in Annex D) needs to be collected and analysed during and after each round to decrease risks of losing expired vials during the campaign

Table 16: Activities related to reporting information
(Refer to section 9, Tools #12 and #18)

Collect and report reliable and timely information required to handle supply chain activities	
Before vaccination campaign	**During vaccination campaign**
• Analyse the information management system and adjust or if necessary, create a new system for supply chain operations • Collect and report information on transport, stocks and human resources • Ensure that managers and personnel have access to data on transport, such as: ➢ details of the network, type of transportation available (e.g., trucks, ships and airplanes); ➢ location and operational condition of transport; ➢ public and private institutions that provide the vehicles; ➢ time calculated to travel each route; ➢ amount of fuel and oil required and location of fuel and repair providers • Record movement of supply at all levels: ➢ stock balance; ➢ expiration date and batch number of the vaccines and other supplies; ➢ wastage of vaccines and other supplies; ➢ requisition and delivery forms; ➢ conditions of reception; condition of the warehouses • Human resources: a list that shows the type and number of human resources required by function at each level; condition of human resources (availability and health) • With civil authorities, disseminate information protocols on the condition of the vaccines and other supplies • Use the data from the information system to confirm and document the existing resources for transportation, supplies and human resources, according to: ➢ capacity and availability. ➢ mobilization of resources; and ➢ additional capacity required for deployment within 7 days • Test the management information system before a pandemic • Train personnel on use of the management information system	Use the information system to: • Contact the warehouses and mobilize their personnel • Monitor the delivery of vaccines in order to identify delays due to traffic, climate, threats, or other factors to be resolved by the head of logistics and the security agencies • Track and trace vaccines, bar codes, if available • Dispatch the vehicles and operators • Inform on withdrawal activities of vaccine lots at the request of the Ministry of Health due to adverse event following immunization (AEFI/ ESAVI) or damaged • Report if there are insufficient personnel at the distribution sites • Contact the transport companies and locate additional human resources • Report on the status of the operations to the supervisors • Update the information system in order to record reception, shipment of vaccines and other supplies, the condition of the shipments and the transportation resources, when required

4.5 Traceability and vaccines rapid information

(Refer to section 9, Tools #13 and #19)

To protect against falsification, fraud and diversion, countries should consider putting in place viable track and trace systems that leverage GS1 standards to enable tracking and tracing of COVID-19 vaccines and therapeutics. The WHO's traceability guidelines provide information on benefits and approach to track and trace medical products, including vaccines.

Some COVID-19 vaccines will come with QR code on the secondary and tertiary packaging containers. When scanning the QR code, you may find information on:

- real-time shelf life
- heat stability
- new information on vaccines' profiles

When scanning the bar code, you will find information on:

- manufacturer information
- lot/batch numbers
- expiry date

Countries should consider the possibility of:

- → updating their data repository system to record data
- → develop or strengthen current guidance,
- → conducting training,
- → and strengthening their supply chain information management systems.

QR codes:
Are intended to provide rapid access to important vaccines' information to health workers. Barcodes are symbols that can be scanned electronically using laser or camera-based systems. The barcode enables ability to receive and track critical information (e.g. "master data") on products released to national markets, including serialization, which accommodates validation by unique serial numbers.

Barcodes:
Can help monitoring the movement of the vaccines. The first batches of COVID-19 vaccines may not have VVM, so CCE temperature monitoring, vaccines distribution and inventory management will need to be particularly rigorous and efficient through the supply chain.

The vaccination programs will need to track the movement of vaccines to protect themselves against fraud or diversion. The COVAX facility will offer guidance to suppliers on how to use bar codes on their secondary packaging or serialization on vials. This will facilitate the tracking of the vaccines at arrival and distribution points by countries. It is recommended that programs or in country logistics operators use this functionality, it will likely be enabled by bar code scanners or through scanners in mobile phones. This information, once scanned, would be shared to a central repository that can verify if the vaccine is in its expected destination. Features include:

Challenges Feature	Global Trade Item Number (GTIN)	GTIN + Batch/Lot	GTIN + Serial Number
Low-precision identification	X		
Medium-precision identification		X	
High-precision identification			X
Item exists in multiple locations at the same time	X	X	
Item exists in only one location at the same time			X
Enables inventory control		X	X

Enables anti-substandard and falsified measures			X
Enables product recall	All units of a given GTIN	All units of a given GTIN + batch/lot	Specific unit with a matching GTIN + serial number

4.5.1 Traceability and fight against counterfeit vaccines

Evidence shows that counterfeit medicines pose a growing threat to public health around the world. Vaccines, as other lifesaving drugs are not exempt from the risk of counterfeit, in particular in a situation of high demand and limited supply.

Building public and government awareness as well as cooperation between stakeholders and national enforcement agencies represents the foundation. You must include governments, customs agencies, law enforcement agencies, regulatory authorities, manufacturers, distributors, immunization programmes and entities responsible for the supply of vaccines for tackling counterfeiters and preventing them entering the national supply chains.

To avoid introduction of counterfeits products into the immunization supply chain countries should consider the following good distribution practices (GDP):

- WHO GDP for pharmaceutical preparations to be included in the national legislation and guidelines for the distribution of vaccines; this applies to:
  - vaccine products moving forward in the supply chain;
  - products moving backwards in the chain as a result of the return or recall;
  - vaccines donation;

- Documentation and authorization of actors involved in the different aspects of the distribution process within the supply chain should be in place (including the manufacturers of finished products, vaccine wholesalers as well as other parties such as brokers, suppliers, distributors, logistics providers, transport companies);

- Requirements and procedures or receipt and dispatch of vaccines (i.e. authorized distributors should receive and/or supply vaccine products to/from authorized entities; completion of vaccine product arrival reports etc.) should be established;

- Managing outsourced services:
  - some duties and responsibilities may be delegated or contracted out to suitably designated persons or entities as authorized and as necessary;
  - duties and responsibilities may only be delegated to entities which are suitably authorized in line with the national legislation; and
  - duties and responsibilities should be documented in a written agreement and there should be audit in place to monitor compliance to agreement provisions.

- Ensuring product traceability from the manufacturer to the immunization service delivery sites. Manufacturers of the COVID-19 vaccines are requested to place a QR/barcode on each secondary package. Once this code is scanned it will inform if the product is not a falsified vaccine and give the real-time expiry information.

Table 17: Protection against counterfeit

➢ Protect the immunization supply chain from counterfeit vaccines	
Before vaccination campaign	**During vaccination campaign**
• Install centralised software to collect and report products bar codes, if not possible, ensure that the existing systems are leveraged to record and report. Health workers can also check lot numbers at central level when receiving the vaccines • Organise "WhatsApp" group per district that includes healthcare workers involved in the vaccination campaigns	• Collect bar coding information upon arrival of the product within the country • Scan and collect bar codes during internal movement, from central level to the district levels • Share daily with your "WhatsApp" group the product information that manufacturers updated on their websites • Using software, trace the products' movements • If falsified products are found, put the vials in quarantine and apply the national recall procedure

4.6 Securing the Supply chain

A potential high demand and limited quantity of COVID-19 vaccines may lead to insecure situations or conflicts in some areas. These circumstances should be foreseen, and activities should be planned to ensure the safety of the people, facilities, equipment, and vaccines.

Table 18: Protection of personnel, equipment and infrastructure
(Refer to section 9, Tool #19)

➢ Protect the deployment and logistics personnel, equipment, facilities	
Before vaccination campaign	**During vaccination campaign**
• Determine the high-risk areas where there could be civil disturbances • Coordinate the preparation of a plan to protect deployment of: personnel, equipment, facilities, and vaccines with the appropriate agencies and local authorities • Consider the security requirements in high-risk areas with community leaders and request their assistance to provide security • Determine the degree and location of the security components that can be supplied by the government offices and obtain their consent to provide them • If necessary, hire private security companies to provide the additional services required for the deployment operations • Perform risk assessments on a regular basis, particularly in high-risk areas, and use the results to improve the security of fixed facilities and routes.	• Ensure that supervisors report on the security situation in their respective areas on a regular basis • Ensure that the transport operators have communication devices to report any security problem and request assistance in transit • Monitor the climate conditions, construction activity, and other factors to determine the delivery routes that should be avoided

➢ Duties and responsibilities should be documented in a written agreement and there should be audit in place to monitor compliance to agreement provisions.

➢ Ensuring product traceability from the manufacturer to the immunization service delivery sites. Manufacturers of the COVID-19 vaccines are requested to place a QR/barcode on each secondary package. Countries should use this code to confirm that the product is not a falsified one.

4.7 Budgeting and Financial Management

Estimating budgetary requirement for the supply chain is an important part of the country's preparedness and deployment plan. The costed plan will be presented to the Ministry of Finance and partners to seek resource mobilization and political commitment.

In the context of a health emergency, allow enough lead time (e.g.at least 6 months lead time) prior to implementation. The budget plan should include:

- details to justify financial requirements and facilitate approval;
- national and sub-national needs for successful implementation;
- costs to procure additional cold chain equipment, if there is a gap;
  - not to forget tax, duty fees, customs brokerage and shipment cost; and
  - if a walk-in cold room or freezer is procured, add costs for preparing the site.
- a contingency fund, between 5% to 10% of the total operational costs:
  - used to provide unplanned core and support activities; and
  - unpredictable circumstances during implementation and others.

Planning and financing of the deployment operations should consider:

- the government's budget cycle;
- turn-around time for clearances, approvals and processing, especially if no emergency fund disbursement policy is in place; and
- application deadlines and the processing time needed by donors to approve and release funding.

To assist countries with forecasting and cold-chain requirements, tools for vaccine management and logistics support have been developed
(see section 9)

Once financial support is secured, a precise detailed budget should be prepared based on national, district and local-level micro-plan. District planning follows a schedule of activities similar and complementary to national level planning but with greater operational detail.

Remember to include these into your logistics' budget:

- Custom clearance activities
- Cold chain equipment repairs and maintenance costs
- Fuel and vehicle's maintenance
- Mechanism to release and distribute funds to lowest level of operations
- Contractual agreements for waste management, additional storage & transport
- Security services at vaccination sites or during transport
- Any other country context activities related to supply and logistics

At the end of the deployment and vaccination operations, countries should document the lessons learned for future emergencies.

KEY CONSIDERATIONS

- ✓ Who is in charge of budgeting and financial management?
- ✓ Is there an existing policy for fund allocation, disbursement, monitoring, liquidation and financial reporting in the context of a health emergency?
  - If not, should it be developed or are people expected to follow the usual procedures?
- ✓ Is the supply chain plan aligned with the preparedness and deployment plan?
- ✓ What are the critical budget line items that require secured funding?
- ✓ Are there less critical but essential items for successful deployment?
- ✓ What funding sources are available?
- ✓ If multiple fund sources, how much (%) can be covered by each?
- ✓ Is funding secured?
- ✓ When will the funds become accessible?
- ✓ What is the requirement and mechanism to access these funds?
- ✓ Is there a funding gap?
- ✓ Are the costed plan, policies and guidelines clearly communicated to all levels?
- ✓ How unexpected expenses will be dealt with?
- ✓ Can a contingency fund be developed to complement and strengthen the regular supply chain system?

Table 19: Procedures to develop a budget[5]

➢ Establish a budget to support the supply chain operations with clear guidelines for disbursement and the reporting requirements	
Before vaccination campaign	**During vaccination campaign**
• Establish procedures to transfer funds to each location so that deployment operations are not halted due to lack of resources • Understand and document the accounting procedures required to ensure appropriate follow-up of financial obligations and expenditures • Agree on the requirements and expenditures report format • Define and document how and when supervisors will report the information, administrative and financing actions • Record the expenditure in the management information system	• Assign a person responsibility for financial management to ensure compliance with administrative regulations, appropriate disbursal and transfer of funds, so that deployment operations are conducted without delay • Organize emergency procedures to transfer additional funds when required to prevent interruption of deployment activities, if, for example, funds are required to resolve an unexpected event • Monitor implementation

[5] Reference made from PAHO – Technical Guidelines for Vaccination against the Pandemic Influenza Virus, 2009

• Inform and train personnel of their fiduciary responsibilities, financial rules and regulations • Organize tests to verify knowledge of the financial and information procedures • Monitor fund transfers	

5. Vaccines' store infrastructure and power requirement

The potential COVID-19 vaccines types have varying storage temperature requirement 2-8°C, -20°C and -70°C +/- 10.

In most countries, the available CCE used for storing vaccines has temperature range of 2°C to 8°C. In most cases, CCE with -20°C storage temperature is available in the higher-level facilities that are storing OPV and freeze-dried vaccine for a relatively longer period.

Challenges that may occur to increase the capacity may include:

- potential long lead-times to deploy large-format cold storage (e.g., WICRs);
- difficulty preparing sites to install large-format cold storage (e.g., power access, sufficient floor space / enclosure availability); and
- lack of long-term utility for large-format cold storage (i.e., repurposing post-COVID).

Very few low middle-income countries (LMIC) have ultra-cold temperature range (-70C) CCE within their health /immunization systems.

- The experience of ultra-low temperature cold chain (UCC) equipment for vaccination campaigns is limited to countries that conducted Ebola outbreak response immunization.
- Some national vaccine-preventable disease reference laboratories may have UCC equipment, but care must be taken on mobilizing this resource for vaccine storage due to risk of contamination.
- Private companies dealing with temperature-sensitive products may also have UCC infrastructure and countries may consider engaging them either through partnership or formalized contract agreement to ensure vaccine can be safely stored.

Global vaccine deployment is being planned to ensure COVID-19 vaccines are equitably distributed. To guide the decisions for vaccine allocation and deployment process, countries need to assess existing cold chain infrastructure available in the national immunization programme, in other relevant government agencies as well as in the private sector and communicate this information by completing the "COVAX Vaccine Introduction Readiness Assessment Tool" found in section 9 (Tool #2).

Given these challenges and as a quick alternative, countries should explore the capacity of logistic service providers (national, regional and global) if they are to take this route.

Highly potential solutions are those that:

- can be readily implemented with short lead-times (3-4 months);
- are cost competitive with the best vaccination alternatives; and
- demonstrate strong responsiveness to government accountability and service delivery needs.

5.1 Store Infrastructure

CCE inventory, including information on functionality and latest preventive maintenance, needs to be updated or completed prior to the COVID-19 vaccines delivery. Repairs and maintenance work should be performed ahead of the vaccine arrival to ensure that every equipment is in good condition to store the COVID-19 vaccines.

Pharmaceutical warehouses, including cold chain facilities, need to be efficiently laid out and should contain all the necessary storage areas, goods assembly, packing, receiving, dispatch bays, offices and ancillary accommodation needed for the effective operation of the store. Pharmacies and health facilities should be laid out so as to minimize dispensing errors and should provide a safe and comfortable environment for staff and patients. Facilities of all sizes and types must be able to store and protect temperature sensitive products against damage during storage.

Countries that are planning additional cold chain facility to accommodate the surge capacity needed to store COVID-19 vaccines and relevant temperature-sensitive products can refer to the WHO guidance on the "Design and Procurement of storage facilities (link)". Some minimum building infrastructures norms of the cold chain and logistics country hubs can be found in the "Global Ebola Vaccine Implementation Team - Annex J", for reference.

5.2 Ultra-low temperature cold chain equipment system

Ultra-low temperature cold chain (UCC) equipment encompasses ***active equipment*** (ULT freezers), that store vaccines at very low temperature (-60/-80C) and ***passive equipment*** that are used to store or distribute low temperature vaccines. Refer to Annex B for UCC guidance.

5.3 Dry storage

Diluents, syringes, safety boxes, spare parts and other immunization supplies must be stored correctly in the dry stores. Refer to EVM SOP on storing goods in the dry stores.

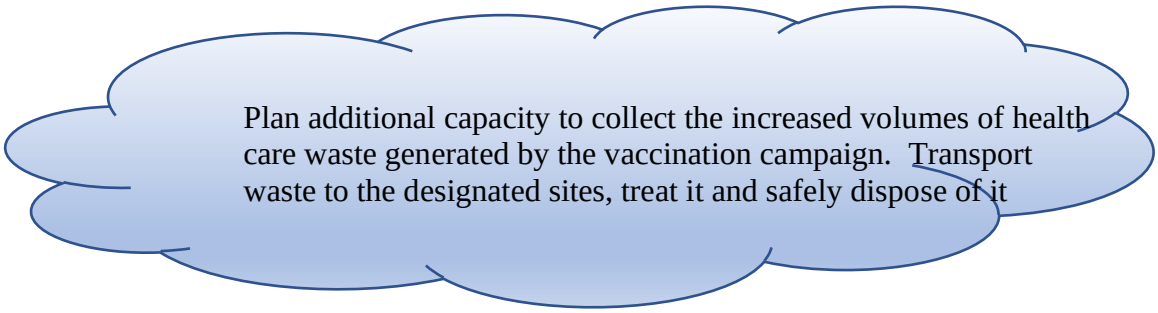
Correct storage practices are:

- All products are safely stored within the temperature and humidity levels specified for the product type.
- Diluents, syringes and other products with a limited shelf life, such as electronic 30-day refrigerator temperature logger devices and electronic freeze indicators with non-replaceable batteries, can easily be located and distributed in Earliest-Expiry-First-Out order or earliest manufacturing date.
- Products without an expiry date, such as safety boxes, can easily be located and distributed in First-In-First-Out order.
- Expired or damaged products marked for disposal are kept separate from useable stock.

6. Health Care Waste Management

(Refer to section 9, Tool #20)

Health care waste management is the process of collection, treatment and disposal of the health care waste produced by vaccination. Management of waste related to COVID-19 vaccination requires special attention, due to the infectious nature of the virus the usage of personal protection equipment (PPE), it will generate large volume of immunization wastes. Safe collection and final disposal of health care waste will eliminate the potential risk to the health of health workers, the public and protect the environment. WHO/UNICEF have published global guidance on health care waste technologies (Technologies Overview).



Hazardous or medical waste disposal, during the COVID-19 vaccination, should be managed through national or local laws in each country. If campaigns are done through facilities, and facilities already have a good treatment and disposal system in place, strengthen the current waste management system and planned for the extra quantity expected. WHO/UNICEF have published global guidance on health care waste technologies.[6]

The head of logistics should establish:

- direct coordination with the municipal offices responsible for safe collection and disposal of medical and hazardous waste;
- mobilize resources and additional capacities during deployment for collection, transport, and disposal of hazardous waste;
- a plan to minimize risks as the vaccination campaign will generate a large amount of waste (e.g., vaccine, vials, needles, syringes and PPE); and
- report detailed information on the activities to the CNCC.

6.1 Three Steps to preparation of a hazardous solid waste management plan[7][8][9]

Step 1: Evaluate the current capacity

- Prepare a list of national regulations and codes related to collection and disposal of hazardous waste, especially waste from injections.
- Use the technical experience and abilities of other departments and sectors, including those responsible for environmental issues.
- Locate and map the current waste disposal facilities that can be used for disposal of hazardous waste and record their data in the information system.
- Calculate the estimated total daily amount of waste that each vaccination site will generate based on the size of the population to be vaccinated and determine the capacity and cost of waste collection and disposal.
- Select routes for collection and transport of waste to the disposal sites.
- Estimate the required waste to be collected for determining the types of transportation for each route. Due to the risk of pollution when transporting waste from the health services to the final disposal site, use dedicated and closed vehicles.
- Calculate the estimated time that each vehicle (including boats) will take to travel to the assigned collection routes.
- Document the locations without waste disposal service, the distance to the closest location with capacity, or the lack of means to transport waste.[10]

[6] Overview of technologies for the treatment of infectious and sharp waste from health care facilities. Technologies Overview
[7] Pan American Health Organization, *Technical Guidelines for Vaccination against the Pandemic Influenza Virus, (*2009).
[8] World Health Organization, *Management of injection waste activities at district level. Guidelines for district health managers (2006).*
[9] UNICEF – Appropriate Disposal of Immunization Waste platform, 2020. Waste Platform
[10] If the collection is from a remote area and safe transport is not feasible; the head of logistics and the authorities should provide alternative methods for safe disposal of injection waste from these remote areas. The supervisors should document the final method of disposal used to ensure that the injection materials are not reused and the method applied does not present a risk to the local community.

- Inspect the current waste treatment sites to ensure that they comply with the recommended practices:
    - Examine the quality and integrity of the waste facility equipment;
    - Ensure that the personnel or company responsible use acceptable methods and comply with technical specifications for disposal of hazardous waste;
    - Ensure that the treatment/disposal equipment meets the correct technical specifications (e.g for incineration temperatures);
    - Ensure that the budget includes funds for coverage of additional waste disposal services provided by public or private companies; and
    - Establish contracts with private or public companies if necessary and update the current contracts as needed.

Step 2: Select the methods used for health care waste collection, transport, treatment, and disposal
Based on the national codes and laws, the country should decide which methods will be used for waste collection, transport, treatment, and disposal. This decision should be communicated to all staff members responsible for waste management during the pandemic. Staff should always be discouraged from recapping needles after injection. A sufficient supply of biohazard and sharp containers should be secured at all vaccination sites based on the estimated population to be vaccinated daily.

The head of logistics and his/her counterparts at all levels should perform the following activities:

- Determine whether waste collection practices have been evaluated recently. If so, examine the results and confirm implementation of the recommendations. If not, or if the recommendations have not been implemented, determine the reason and adopt corrective measures.
- Determine the number of syringes and biohazard containers required at each vaccination site and record this information in the inventory and information systems.
- Ensure shipment of the correct number of biohazard and sharp containers to each site with the vaccines and syringes.
- Record the disposal sites and contact data in the information system.
- Coordinate with environmental, sanitary, and municipal authorities the collection practices and services that have worked well in the past, as well as the factors that have prevented improvement of these practices.
- Coordinate with health care providers, health managers at municipal/district/canton and department/state/provincial level and the civil authorities at these levels to define the most appropriate waste management methods that will be adopted given local conditions; this may be a combination of public and private capacities available locally

Step 3: Definition of a hazardous health care waste management strategy
Based on step 1, evaluation of current capacities, countries should define strategies for mobilization of resources and additional capacities. The authorities at the different levels, with the technical assistance of environmental authorities and the vaccination program, should review the current systems, determine the strategy for mobilization of resources, and specify the additional capacity for treatment of the volumes of waste expected.

Countries should formulate a detailed plan for waste collection, transport, and disposal during the pandemic and use the plan to obtain financing and other resources for implementation of the plan.

A variety of disposal methods can be chosen, depending on the amount of waste, the location (rural or urban) and the availability of local disposal facilities. The method should be safe, respect the environment, comply with the national laws and codes on health and safety.
Open-air incineration is not recommended due to the environmental risks.

An effective waste management strategy includes the following activities:

- Verifying the regulations on transportation of sanitary waste.
- Training supervisors and personnel to comply with the laws, codes, standards, and practices that govern safe disposal of vaccination waste. In order to support this training, the authorities should:
  - prepare a "code of safe practices" for waste management – Job Aids are very useful and very inexpensive to produce in the required languages;
  - distribute documents on waste management; and
  - notify all authorities, supervisors, and health workers of the practices and methods agreed on with significant advance notice prior to vaccination (a good method for completing this step is to use a work aid).
  - Using simple indicators to monitor the quality of waste management and disposal.
- Designating a trained supervisor at each level to ensure compliance with waste management procedures.
- Providing technical assistance to improve waste management practices.
- Guaranteeing trained supervision for compliance with waste management practices by public or private companies. Effective supervision is essential for successful implementation of the waste management plan.

When deployment activities have concluded, the supervisors will measure compliance with the standards. The following performance indicators have been proposed:

- Percentage of health services with sufficient biohazard containers for collection of needles and syringes during pandemic vaccination activities.
- Percentage of urban sites with waste collection:
  - 1 week after deployment has concluded;
  - 2 weeks after deployment has concluded; and
  - 3 or more weeks after deployment has concluded.[11] [12]
- Percentage of vehicles that completed their collection routes and delivered the hazardous waste to the treatment and final disposal sites:
  - 1 week after deployment has concluded;
  - 2 weeks after deployment has concluded; and
  - 3 or more weeks after deployment has concluded.
- Percentage of sites that reported waste was not collected.

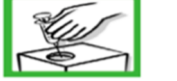
[11] Based on the original national pandemic preparation plan, the reports can be monitored by phone, Internet, or supervision visits in order to identify the sites that have not reported completion of waste collection.

[12] In remote rural areas where transport is difficult or there are no waste disposal services, WHO recommends burying the waste as the best method of disposal. For additional details, see the document *Management of injection waste activities at district level. Guidelines for district health managers.* World Health Organization, Geneva (2006).

It is recommended that countries:

- Review their waste management plans often during the campaign
- Update their plans based on changes in vaccine delivery systems or waste management technology
- Stress test their plans to verify their effectiveness
- Adapt plans when operational gaps are observed, ensuring safe and rapid collection of sanitary waste

Disposal of Syringes



- Used syringes / needles are considered as sharp waste
- Without recapping the needle discard the used syringe into the safety box or safe syringe container.
- Do not fill the safety box more than ¾ of its capacity or up to the red line marked on the container.
- Ensure that box is properly labeled with the infectious substances symbol
- Seal the safety box before transporting it to the treatment site.

Disposal of Vials

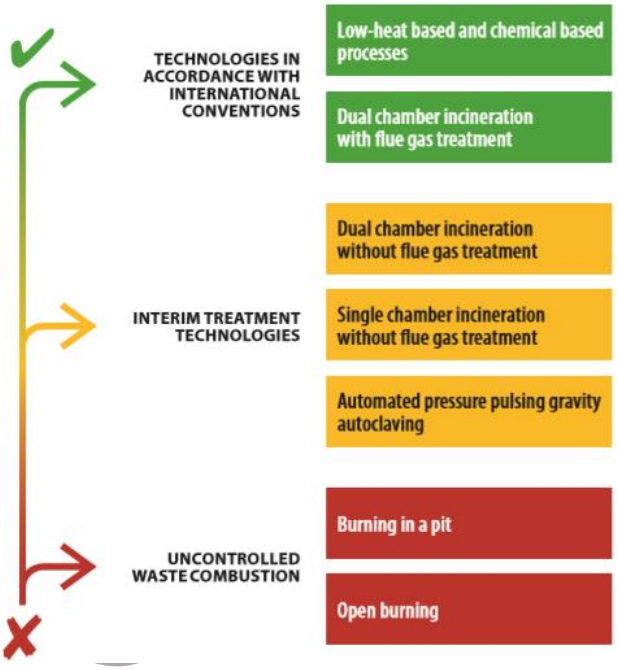
- Used vials of vaccine and unopened vaccine vials which have expired or suffered heat exposure should be put into a red / yellow bag for infectious waste or use biohazard container.
- In case the open vials are posing a risk of cuts it might be classified as sharp waste.
- Ensure that bag / container is properly labeled with the infectious substances symbol
- The containers should be sealed before transporting them to the treatment site.

Disposal of PPE

- PPE includes single-use gloves, aprons and gowns, surgical masks, face protectors in the form of glasses, goggles or face shields.
- Staff should use a room/ place away from the vaccination room to remove all used PPE.
- There are special procedures for removing PPE, consult the national guidelines.
- After safely removing used PPE they should be put into a waste container or bag for infectious waste (color yellow or red).
- Ensure that bag / container is properly labeled with the infectious substances symbol
- The containers should be sealed before transporting them to the treatment site.

6.2 Overview of treatment options for infectious and sharp waste

- Plan for treatment and disposal of waste generated during vaccine campaign at the beginning of the campaign planning.
- Consider the possibility of reverse logistic in case safe onsite treatment and disposal of the vaccine waste is not given.
- Follow the national guidelines and codes for final disposal – if these are not available:
- Preferably use Best Available Technologies in accordance with the Stockholm Convention like decontamination of waste by autoclaving or similar procedures or high temperature incineration.
- In low-resource or emergency settings, transitional methods like pit burning or open burning can be used BUT efforts should be made to incrementally improve Health Care Waste Management and engage in multi-sectoral efforts to strengthen systems change.



Further information can be found here:

- WHO, Safe management of wastes from health-care activities, 2014. (link)
- WHO, Overview of technologies for the treatment of infectious and sharp waste from health care facilities, 2019. (link)
- UNEP, Waste Management during the COVID-19 Pandemic - From Response to Recovery, 2020. (link)

To make sure all the health care waste generated during the campaign is well managed, the waste management plan should clearly define:

- the responsibilities and supervisory roles at all steps of the waste management process; and
- how the quantities removed from each vaccination site and transported to a treatment /disposal site be documented; and
- quantities received and disposed at all treatment/disposal sites be validated and reported.

An example of reporting template is provided in Annex E - Reported Immunization Waste forms.

7. Human Resources

(Refer to section 9, Tool #10-12)

7.1 Goal and objectives

Due to high volume of vaccines and ancillary products during COVID-19 vaccines deployment, staff shortages may occur due to additional workload or staff unavailability due to sickness, injury or having to care for their families. Additional personnel with the right skillset, who are trained, motivated and supported is crucial. Under such scenarios, make sure to:

- identify additional human resources;
- plan hiring and training ahead of time; and
- ensure that health workers are protected and secured to do their jobs.

The goal is to:

- ensure availability of skilled and trained personal for the coming campaign activities; and

- ensure safety and security of personnel, infrastructures, equipment and vaccines.

7.2 Staffing

Effective deployment of COVID-19 vaccines and use of different vaccination strategies will depend on how well the experience and skills of staff members fit the requirements of their respective jobs.

The logistics managers and immunization managers need to establish:

- operational tasks at each level of the health services;
- determine the necessary skill categories;
- identify the profile and quantity of heath personnel available in the private sector;
- outline the roles and responsibilities of staff members and teams; and
- supervise preparation of job descriptions for every function.

Staff and health personnel that are identified should demonstrate:

- experience and skills to fit the need determined by the logistics and immunization managers;
- adequate training to work on their own and as part of a team; and
- ability to coordinate with other teams throughout the chain of command.

7.3 Capacity building

Training for staff and managers should include:

- basic and specific skills to ensure efficient performance;
- skills to ensure teamwork and coordination throughout the chain of command;
- functional areas, such as: information technology and communications, transportation, administration of mass vaccination campaign, warehousing, management of cold chain equipment (CCE), safe injections, post-deployment surveillance; and
- supervision, administrative and technical support, security and safety.

COVID-19 vaccines deployment will be challenging to staff involved in the supply & logistics activities due to:

- the high volume of products that will be distributed;
- the traceability and tracking of all vials to ensure safety and security;
- the tight timelines between the arrival of the vaccines in the country to its administration; and
- handling & management procedures that will need to be strengthened or implemented.

Quality training and surge staff will be necessary to ensure a successful and timely deployment.

To plan training sessions, a manager should:

- develop a simple but comprehensive curriculum;
- develop training materials using simple visual aids providing bibliographic references for those who wish to have more information;
- use role playing to encourage participation and dialogue to impart a sense of ease; and
- keep training sessions short.

Training for managers should focus on:

- working within the country's CCWG to detect problems and resolve them quickly, strengthen and implement new SOPs and procedures related to COVID-19 vaccines;

- guiding staff to meet objectives and deadlines, involving them in needs assessment (i.e. identifying when, by whom, and what tasks have to be performed);
- providing in-field training;
- establishing performance indicators to assess staff performance;
- ensuring staff security and welfare; and
- managing information and data in the management information system (MIS) and making best decisions with given available information and time.

8. Country preparedness – Activities

Eight activities are defined to which indicators are proposed to measure country preparedness. The numbering system refers to the COVAX Vaccine Introduction Readiness Assessment Framework and Tool (VIRAF/T).

Table 20: Preparedness indicators for Vaccine, Cold chain & Logistics

No	Activity	Proposed Timeline
G.1	Establish/strengthen the national logistics working group with appropriate terms of reference and standard operating procedures to coordinate COVID-19 vaccines and ancillary products deployment: a. There is a National Logistics Working group b. The NLWG is functional, having appropriate Terms of References and regular meetings c. The NLWG is mandated and resourced to support the COVID-19 Supply Chain Management	6 months prior to receiving vaccines
G.2	Map key roles and responsibilities needed for vaccine and ancillary products deployment; collect and confirm contact information for key personnel and facilities: a. Key roles and responsibilities are defined in support of COVID-19 vaccines and related commodities deployment b. The HR needs for COVID-19 response in area of SCM is mapped out based on strategy and role and responsibilities defined c. Assessment needs conducted for COVID19 activities including HR needs	6 months prior to receiving vaccines
G.3	Map the potential port(s) of entry, points of storage (stores), and facilities in the country with their respective cold chain storage (2-8°C, -20°C, -70°C +/- 10) and transportation capacity for vaccines and ancillary products: a. Landscape analysis completed mapping out the existing government as well as private infrastructures towards port of entry, primary and secondary storage facilities and transportation services b. Clearly outlined strategy available for COVID-19 response in relation to port of entry, primary and secondary storage points and transport	6 to 3 months prior to receiving vaccines
G.4	Assess storage and cold chain capacity at all levels with regards to the COVID-19 vaccines characteristics and fill the identified supply and logistics gaps: a. The national cold chain inventory data is up to date b. In response to COVID-19, cold chain capacity assessment completed c. CC capacity expansion proposal submitted in response to gaps identified d. CC capacity expanded in response to the gap identified e. Functional equipment (%)	6 to 3 months prior to receiving vaccines
G.5	Establish contractual agreements to prepare for vaccine introduction, if appropriate: a. vaccine warehousing b. transport	3 months prior to

	c. waste management d. cold chain capacity	receiving vaccines
G.6	Provide standard operating procedures for collection and disposal of medical waste to the relevant stakeholders: a. There is a plan to handle the waste generated by COVID-19 vaccine responses focusing on syringes, vials and PPE b. There is a Standard Operating Procedures for collection and disposal of COVID-19 responses wastes c. The HR needs for COVID-19 response in area of SCM is mapped out based on strategy and role and responsibilities defined d. Assessment needs conducted for COVID19 activities including HR needs	3 months prior to receiving vaccines
G.7	Update vaccine stock management tools and operating procedures to reflect the characteristics of COVID-19 vaccines (i.e. vial size or VVM): a. The existing vaccine stock management tool incorporated the new COVID-19 vaccines and its characteristics b. All relevant Standard Operating Procedures and guidance documents are updated in response to COVID-19 vaccines	3 months prior to receiving vaccines
G.8	Establish security arrangements to ensure the integrity of COVID-19 vaccines and ancillary products throughout the supply chain: a. Risk factors are assessed to determine potential harms and propose mitigation strategies b. A guidance document and SOP available to ensure the safety and integrity of COVID-19 vaccine in the existing Supply Chain	3 months prior to receiving vaccines

(the "G" no. comes from the COVAX Vaccine Introduction Readiness Assessment Framework and Tool (VIRAF/T))

9. Country Readiness Tools

National and sub-national stakeholders could benefit from supply chain tools that support preparation, deployment and post-deployment processes for vaccines and other commodities to the points of service delivery. This section outlines recommended supply chain tools (section 9.3) across four critical functions (section 9.1) using a country-focused decision on defined criteria (section 9.2).

9.1 Tools functions:

Available tools can provide benefits in the following areas:

1. Overview and Scope of the supply chain:
   - to broadly assess existing supply chains, understand national and sub-national contexts and identify (at a high-level) existing capacities and capabilities.

2. Analyze readiness and identify supply chain needs:
   - to analyze supply chain readiness; and
   - analyze gaps and identify needs across different functions that are required to effectively deploy vaccines.

3. Support effective vaccine deployment:
   - to facilitate vaccine storage, distribution and delivery up to the last mile.

4. Monitor and evaluate supply chain operations and performance:

- to monitor and evaluate supply chain functions across operations and enablers, including contributions to programmatic performance.

9.2 Tools selection/decision criteria

Four criteria are considered to recommend available tools for country use. (See Annex A for the "Tools Decision Matrix". Identify and analyze if tool under consideration:

1. Exists or leverages existing data, processes and tools:
   - Identify if the tool already exists or leverages existing tools, data or processes.

2. Has a clear and non-duplicative use case(s) to countries:
   - a previously used case is clearly communicated, and countries do not have an existing tool to achieve intended purpose.

3. Required data is readily available:
   - data requirements for tools must be readily available or easy to collect.

4. Is simple, easy to use and deploy by country stakeholders:
   - due to high turnaround time, tools must be simple, easy to use and deploy. How to guides should be available, clear and informative.

9.3 Recommended Tools

Below tables provide an overview of the recommended tools which can be found on the web platform TechNet-21, under Topics: COVID-19 - Technical Resources. The above decision criteria were used to recommend the right mix of tools, according to country needs:

- a tool is recommended if it meets 3 or 4 (of 4) decision criteria; and
- not recommended if it only meets 1 or 2 (of 4) suggested criteria.

In Annex A, you'll find a comprehensive analysis matrix.

Table 21: Overview and Scoping tools

Tool Functional Area	Tools	Overview
Cold Chain	1. Cold Chain Inventory	Cold chain equipment assets management spreadsheet with details including number per site, functionality, age etc.
	2. Vaccine Introduction Readiness Assessment Framework / Tool (VIRAF/T)	High-level readiness checklist for vaccine introduction, across different critical thematic areas.
	3. Supply Chain Sizing tool 2020	Assessing cold chain capacity, gap and basic costs for the COVID-19 vaccination deployment
Cross-cutting	4. Supply Chain Assessment Report (previous) e.g. EVM	Previous supply chain assessments (e.g. Effective Vaccine Management) report, where performance, gaps and action plans were identified.
	5. Supply Chain Maturity Model	High-level assessment of maturity (capabilities) across supply chain operations and enablers with a resiliency module to measure preparedness to deploy vaccines.
	6. Supply Chain Mapping Tools	Visual representation of in-country supply chain network including storage/warehouse locations, distribution routes, data flow etc.
	7. Pre-Service delivery checklist	Operational checklist for monitoring availability of service delivery needs.

Table 22: Readiness analysis and needs identification tools

Tool Functional Area	Tools	Overview
Cold Chain	8. Vaccine Volume, Forecasting and Cold Chain Gap Analysis	Assessing vaccine volumes and corresponding cold chain equipment requirements per catchment area
	3. Supply Chain Sizing tool 2020	Assessing cold chain capacity, gap and basic costs for the COVID-19 vaccination deployment
	9. Cold Chain Deployment Plan	Identifying planned and pipeline cold chain investments for different supply chain levels
Human Resources/Supply Chain Workforce	10. Human Resources for Supply Chain Management Diagnostics	Rapid assessment tool for estimating HR needs for health supply chain across four pathways. It estimates staff gaps and needs for each supply chain level and function
	11. Training Needs Assessment (TNA)	
	12. Workforce Optimization Tool	Creating staffing scenarios (including optimization) using storage locations, demand data and distribution processes of products across supply chain network
Data	13. Supply Chain Reporting in LMIS – DHIS – other tool	Information management and analytics of supply chain processes and enablers data
Distribution/Network	14. Supply Chain Analysis and Intelligence Tool (SCANIT)	Analysis of in-country supply chains such as storage, distribution and the overall network to provide national and sub-national stakeholders with understanding of tradeoffs between different supply chain scenarios.
	15. Rapid Supply Chain Modeling Tool	Rapid estimation of supply chain costs and service metrics that compares cost of existing system (baseline) with alternate supply chain scenario
	16. Route Optimization Tool (ROOT)	Identify optimal routes for distribution of health products based on transit time and risk to health products due to poor road conditions
Cross-Cutting	17. Outsourcing Toolkit – Other Private Sector Needs Assessment Tool	Assessing and optimizing decision making and implementation opportunities to outsource functions to third parties.
	18. Vaccine Management and Logistics Support Tool	Provides guidance on management and logistics support for deploying vaccines

Table 23: Vaccine Deployment tools

Tool Functional Area	Tools	Overview
Data	19. Track and Trace Tools	Implementing a traceability model that facilitates downstream visibility; track, authenticate, prevent falsification and assure quality of health products; leveraging GS1 standards (vaccines as 'low hanging' fruit).

	13. Supply Chain Reporting in LMIS – DHIS – other tool	Information management and analytics of supply chain processes and enablers data
Waste Management	20. Appropriate Disposal of Immunization Waste	Guides and implements appropriate management of wastes generated by immunization activities
Cross-Cutting	21. Service Delivery Checklist	Operational checklist for monitoring implementation of immunization service delivery objectives
	18. Vaccine Management and Logistics Support Tool	Provides guidance on management and logistics support for deploying vaccines

Table 24: Supply Chain Operations Monitoring and Evaluation

Tool Functional Area	Tools	Overview
Data	19. Track and Trace Tools	Implementing a traceability model that facilitates downstream visibility; track, authenticate, prevent falsification and assure quality of health products; leveraging GS1 standards (vaccines as 'low hanging' fruit)
	13. Supply Chain Reporting in LMIS – DHIS – other tool	Information management and analytics of supply chain processes and enablers data.
Waste Management	20. Appropriate Disposal of Immunization Waste	Guides and implements appropriate management of wastes generated by immunization activities
Cross-Cutting	22. Post-Service Delivery Checklist	Operational checklist for follow-up and next steps, after immunization service delivery

ANNEX A – Tools Decision Matrix

Overview and Scoping

Tools scope	Tools	Decision Criteria			
		(Leverages) Existing	Non-duplicative Use Case	Data easy to collect	Simple to use/deploy
Cold Chain	Cold Chain Inventory	√	√	√	X
	Country Readiness Tool (Covax)	√	√	√	√
Cross-Cutting	(Previous) Supply Chain Assessment Report e.g. EVM	√	√	√	√
	Supply Chain Maturity Model (Adapted)	√	√	√	√
	Supply Chain Mapping	√	√	√	√
	Prioritization of Supply Chain Performance Dimensions	X	√	√	X
	Pre-service delivery checklist	√	√	√	√

Analyze readiness and identify needs

Tools scope	Tools	Decision Criteria			
		(Leverages) Existing	Non-duplicative Use Case	Data easy to collect	Simple to use/deploy
Cold Chain	Vaccine Vol and Cold Chain Gap Analysis	√	√	√	X
	Cold Chain Deployment Plan	√	√	√	X
Human Resources	HR for SCM Diagnostic	√	√	√	√
	Training needs assessment (TNA)	√	√	√	√
	Workforce Optimization Tool	√	√	√	X
Data	SC Reporting in LMIS/DHIS/Other	√	√	√	X
Distribution/Network	Last Mile Delivery Strategy	X	X	√	√
	SC Analysis and Intelligence Tool(SCANIT)	√	√	√	X
	Rapid Supply Chain Modelling Tool	√	√	√	X
	Route Optimization Tool (RoOT)	√	√	√	X
Cross-cutting	Outsourcing/Private Sector Needs Assessment	√	√	√	X
	Vaccine Management and Logistics Support Tool	√	√	√	X

Support vaccine deployment

Tools scope	Tools	Decision Criteria			
		(Leverages) Existing	Non-duplicative Use Case	Data easy to collect	Simple to use/deploy
Cross-cutting	Service delivery checklist	√	√	√	√
	Vaccine Management and Logistics Support Tool	√	√	√	X
Data	Track and Trace	√	√	√	X
	SC Reporting in LMIS/DHIS/Other	√	√	√	X
Waste Management	Appropriate Disposal of Immunization Waste	√	√	X	√

Monitor and Evaluate supply chain operations and performance

Tools scope	Tools	Decision Criteria			
		(Leverages) Existing	Non-duplicative Use Case	Data easy to collect	Simple to use/deploy
Cross-cutting	Post-Service delivery checklist	√	√	√	√
Data	Track and Trace	√	√	√	X
	SC Reporting in LMIS/DHIS/Other	√	√	X	X
Waste Management	Appropriate Disposal of Immunization Waste	√	√	X	√

ANNEX B – Guidance on UCC use for deployment of COVID-19 vaccines

Countries receiving vaccine requiring ultra-low temperature cold storage (UCC) should adjust their plan to ensure vaccine is safely stored and transported.

The deployment of UCC equipment will require the following:

- installation of ultra-low temperature (ULT) freezers with robust and reliable electric power source for storing vaccine and producing phase-change material (PCM) packs and or dry ice supply;
- specialized technical assistance to manage UCC, with development of relevant standard operating procedures (SOPs) and adequate training of responsible staff; and
- provision and management of protective equipment (e.g. cryogenic gloves) for staff responsible for managing UCC system.

A. BRIEF DESCRIPTION OF THE TECHNOLOGY

There are 2 categories of ultra-low temperature cold chain equipment:

1. **Active equipment (ULT freezers)**
   Ultra-low temperature (ULT) freezers produce ultra-low temperatures to store ultra-low temperature vaccines, with temperature requirement ranging from -80°C to -60°C, and to produce the phase change material (PCM) packs needed for keeping the vaccines in ultra-low temperature while stored in a passive equipment.

   Figure 1: ULT Freezer

   - Two ULT freezers would be necessary: one to store vaccines and another to freeze the PCM.
   - ULT freezers should be complemented with deep freezers that start the freezing process of PCM down to -20°C before loading in the ULT freezer.

2. **Passive cooling/freezing equipment**
   There are two types of passive equipment recommended for transporting and storing ultra-low temperature vaccines at facility level. When selecting which passive container to use, consider the storage temperature and duration of storage.

   I. **Arktek plus PCM** - This equipment uses phase change material (PCM) packs that needs to be frozen first at -20°C for packs newly filled with PCM, then complete the freezing at -70°C +/- 10 prior to use. This can keep the vaccine in ultra-low temperature for 4-5 days without requiring power supply or replacement of PCM packs. Each unit is equipped with built-in temperature SMS data logger.

Figure 2: Passive cooling equipment

Thermal shippers – These are specific vaccine carriers that require dry ice, with storage temperature range of -80°C to -60°C and a capacity range from 3.4 to 6.2 litres. They come with vial rack system and built-in temperature data logger. When used only as storage this can keep the vaccine frozen up to 10 days. Cold life with frequent opening is up to 55 hours.

Figure 3: Thermal shippers[13]

II. Coolant/freezing materials for UCC

Special phase change materials (PCM) are used for passive freezing when transporting and temporarily storing vaccines in insulated containers.

PCMs are known for their ability to store or release energy in transition between solid (frozen) and liquid (melted) states. The freeze-melt transition temperature varies widely across the range of available PCMs. During phase transition from solid to liquid, a PCM maintains a constant temperature until all the PCM has melted. Typically, the amount of energy required to melt a PCM is large. The combination of the high amount of energy required to melt (latent heat) with the (low) heat leak of the insulated container at a given ambient temperature determines the hold-over times.

For ultra-low temperature passive freezing, special PCM is used in place of water. The suitable PCMs used in this application have melting point of -78°C to -65°C, which is within the required vaccine storage temperatures range of -60°C to -80°C.

The following PCMs are used for UCC equipment as coolant/freezing packs:

- **Liquid CO2/dry ice (-78°C) for UCC**
  - Produce (establishing small units) or procure (from local sources);
  - Store at -80°C using ULT freezer or special container; and

[13] WHO PQS E003/POW 01.0, provides details specification for ULT freezers freezing system.

- Packing vaccines for transport and temporary storage.

- **Special PCM for ULT (-80°C) for UCC**
  - Fill the packs with the PCM liquid and pre-freeze at -20°C;
  - Complete the ULT freezing at -85°C for at least 24 hours; and
  - Packing vaccines for transport and temporary storage.

B. TYPES OF ULTRA-LOW COLD CHAIN EQUIPMENT BASED ON STORE LEVEL

a. *Central storage*:

- Large ULT -85°C freezers (500 to 700 liters, up to 25,000 vials loading capacity); and
- Small ULT -85°C freezers as backup and storing PCM packs at -85°C.

b. *Remote storage* - two options based on travel time from central store:

- Small ULT -85°C freezers (70 liters each), or
- Long range cold storage device (Arktek+PCM) for short term storage at -70°C +/- 10, up to 5 days at remote storage and vaccination sites.

C. OPTIONS FOR PACKING, TRANSPORTING AND STORING VACCINES

a. *From storage to storage*:

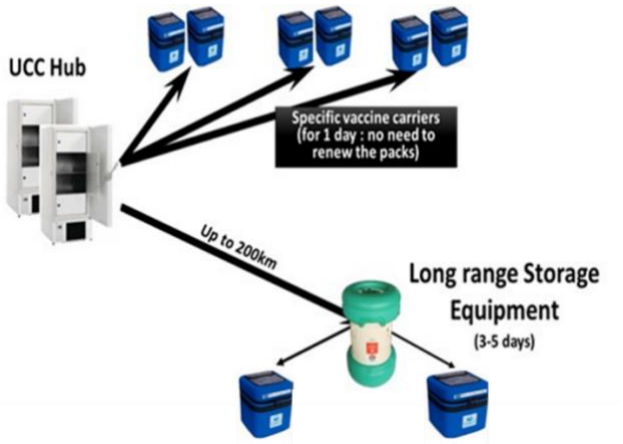
- Using special insulated containers with dry ice (if available).
- Using long term storage devices (Arktek) with PCM packs frozen at -80°C.

b. *From storage to vaccination site*:

- Using high density vaccine-carriers with water/ice packs to transport unfrozen vaccine at +2°C to +8°C for immediate use at session.
- Using special long-range cold storage device (Arktek) with -80°C frozen PCM packs or dry ice to transport and stored frozen vaccine at session for later use to avoid wasting thawed closed vials.

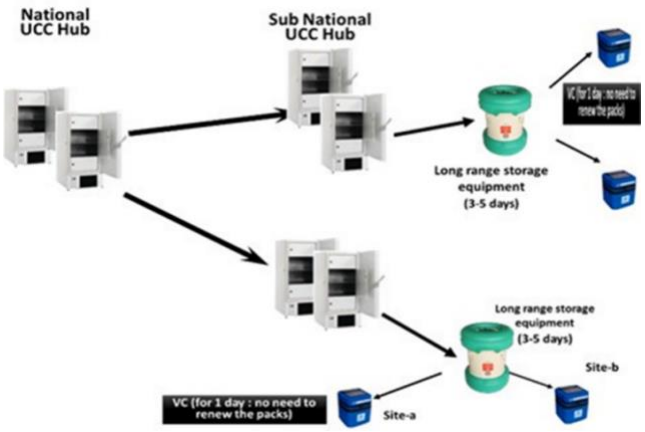
D. UCC EQUIPMENT DEPLOYMNET OPTIONS BASED ON TRAVEL DISTANCE FROM CENTRAL STORE

Option 1: Districts at <= 1-day travel distance central store



- **Strong central team** to:
  - Manage the central storage & dispatch
  - Manage PCM packs freezing & dispatch
- **Team composition**
  - Cold chain technician
  - 2 assistants (1 for vaccine & 1 for PCM freezing)
- **UCC estimation**
  - 2 Arktek per district
  - ULT freezers as per vaccine volume
  - Standard vaccine carriers to be used

Option 2: Districts at >1-day travel distance to central store



- **UCC Hub teams to:**
  - Manage the central storage & dispatch
  - Manage PCM packs freezing & dispatch
- **Teams composition**
  - Cold chain technician
  - 2 assistants (1 vaccine & 1 for PCM freezing)
- **UCC estimation**
  - 2 Arktek per district
  - ULT freezers as per vaccine volume
  - Standard vaccine carriers to be used

E. RECOMMENDED SET-UP OF ULT AT VACCINE STORAGE HUB

- ULT freezers with large storage capacity for:
  - storing vaccines;
  - holding dry ice stock for repacking vaccine for transportation to districts; and
  - freezing PCM packs to be loaded in Arktek for transportation.
- A regular deep freezer (-20°C) to be procured for pre-freezing PCM packs used for transport.
- All ULT freezers to be installed in an air-conditioned room to ensure working ambient temperature <30°C.
- Insulated/cryogenic gloves are required for safe working with ultra-low temperatures. When cleaning the equipment face/eye shield is needed as additional protective equipment.
- Continuous and quality electricity supply with secured backup generator.

F. RECOMMENDATION ON TRANSPORTING VACCINE TO DISTRICT LEVEL

- Both cryogenic passive container and passive cooling device can be used, provided:
  - cold life of long-term storage device (Arktek) has been validated at -80°C with ultra-frozen PCM packs; and
  - cryogenic passive container needs to be adapted for using PCM packs.
- Both container devices can be used as back-up option for district storage if needed, several thermal shippers should be procured as back-up options.
- Note that dry ice may not be available in all context; production can be organized using small dry ice units to be procured by the programme, although the management may require additional training.

G. Main Challenges for ultra-low temperature cold chain

- Ultra-low temperature freezers
  - Stringent operating conditions (controlled ambient temperature - <27°C & humidity – 50%)
  - Big consumers of energy (a 700 litres ultra-low temperature freezer consumes as much as a 20m3 WICR!)
- Transport at -70°C +/- 10
  - Specific cold packs using PCM with phase change temperature around -70°C +/- 10 and good and stable thermal characteristics (latent and sensible heats)
  - New generation insulated containers (thermal shippers, Arktek)
- Keeping at vaccination site
  - Managing the storage at session to minimize wastage

ANNEX C – COUNTRY READINESS SELF-ASSESSMENT

This is a useful checklist to get prepared for your allocation request or for a request for support (e.g. CCE). Summarize and check the level of readiness of your supply chain management.

No.	ACTIVITY	READY Yes or No	COMMENTS
1	Description of supply chain leadership and coordination mechanism, including engagement of national logistic working group		
2	Summary of procurement and donation mechanisms for vaccine and other ancillary supplies, including PPEs and IPC materials		
3	Summary table of potential port(s) of entry, points of storage (stores), transportation capacity and cold chain capacity of in-country fall-back facilities (categorized at 2 to 8°C, -20°C, -70°C +/- 10 storage temperatures)		
4	Description of distribution processes of required volumes, doses, and ancillary items by areas/zones, including identified gaps, challenges and solutions to complete vaccine deployment prior to vaccination start date		
5	Description of supply chain information and vaccine stock management procedures with consideration to the vaccine characteristics		
6	Description of estimating cold chain and dry store capacity requirements, issues, challenges and solutions		
7	Summary of the following requirements to support deployment and vaccination of target groups at different administrative levels prepared		
8	Cold chain strategy based on the different type of potential vaccines (mapping of in-country 2-8°C and UCC, leveraging all national assets)		
9	Strategy for UCC and long-range equipment deployment, including need for joint investment/ external support, when applicable		
10	Investment required to establish UCC hub to reach 3% of the total population capacity for dry ice production at UCC hub		
11	Issues, requirements, and challenges related to transportation of vaccines and supplies		
12	Procedures for contractual agreements to prepare for vaccine introduction (e.g., vaccine warehousing, transport, waste management, cold chain capacity, etc.), where applicable		
13	Description of security arrangements to ensure the integrity of COVID-19 vaccines and ancillary products in terms of warehousing and transportation throughout the supply chain		
14	Summary of required SOPs and trainings to be conducted to ensure proper handling of the novel vaccine and PCM required for managing UCC equipment		
Biohazard and Immunization waste management:			
15	Description of estimation of volume of waste, including used PPEs, according to type and by areas/zones		
16	Summary of procedures to manage, process and dispose waste to be generated from a vaccination campaign, including issues, challenges and solutions		
17	Description of transportation requirements to collect waste identified and collection schedules and disposal methods, including mechanism to commission private waste disposal service as needed		
18	Vaccine vial disposal plan established (Reverse Logistics)		

ANNEX D – Vaccine Accountability Monitoring Reporting Form

INSTRUCTION GUIDE:

1. This form should be filled by the lead vaccinator after each COVID-19 vaccination session.
2. Vaccine quantities should be recorded as vials only in this report.
3. The lead vaccinator should report to the higher level (district EPI manager) within 2 days. If no vials are reported and there is a discrepancy, it should be report immediately.
4. District supervisors should sample at least 30% of the sub-district levels to verify absence of vials and report to the EPI manager.
5. Make sure all opened and unopened vials of COVID-19 vaccines are returned back to a district vaccine store.

FORM 1: Reverse logistics form

Name of lead Vaccinator : _____

Campaign round#: _____ Starting date: _____ End date: _____

Name of sub District level: _____ District: _____

Name of Province: _____ No. of children immunized: _____

No. of vials used: _____ No. of vials unused: _____

6. Track all vials received, distributed and returned at **the end of the round**

Form 2: Sub-national/district form

This portion is filled by the lead vaccinator				This portion is filled by the District Supervisor		
# vials received	# vials distributed	# vials returned opened or unopened	# of vials missing	# of sub-district sites verified	# of sites visited where any vials were found	# of vials found
REMARKS:						

ANNEX E – Reported Immunization Waste forms

Form 3: Example of immunization waste transfer form

TRANSFER SHEET FOR SAFETY BOXES AND VIALS								
1	**ORIGINE**			**TRANSPORT**			**DESTINATION**		
		Nber of SB	Nber of vials		Nber of SB	Nber of vials		Nber of SB	Nber of vials
Region:				Means of transport :			Central:		
District:							Region:		
Health Center							District:		
							Health Center		
Sending date				Transportation date			Date of receipt		
2	Comments			Comments			Comments		
3	Name, signature of sender			Name, signature of carrier			Name, signature of receiver		

Form 4: Example of immunization waste treatment and disposal form

TREATMENT / DISPOSAL REPORT

Date of treatment/disposal:_____/_____/_____

Reference site _____

Treatment & disposal methods

Treatment	stick		Disposal	stick
Autoclaving			Recycling	
Incineration			Encapsulation	
Chemical sterilization			Burying/Landfilling	
Boiling			Other (specify)	
Other (specify)				

Number of SB received and disposed

Health facility where the waste comes from	Quantity received	Quantity disposed	Remaining stock
TOTAL			

Number of vials received and disposed

Health facility where the waste comes from	Quantity received	Quantity disposed	Remaining stock
TOTAL			

Remarks

Responsible of the treatment & disposal

Name		Signature