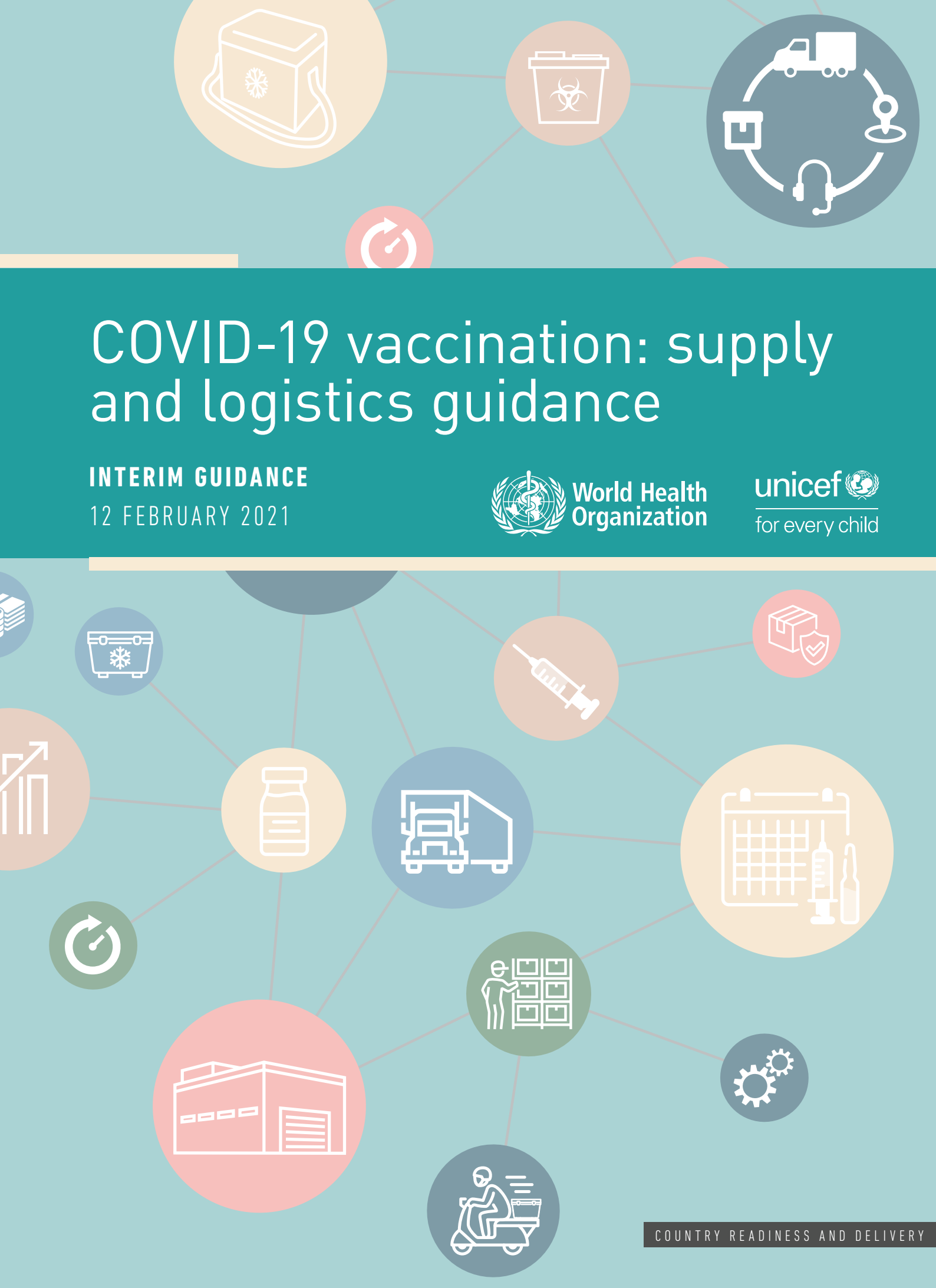

COVID-19 vaccination: supply and logistics guidance

INTERIM GUIDANCE

12 FEBRUARY 2021

World Health Organization

unicef
for every child

COUNTRY READINESS AND DELIVERY

COVID-19 vaccination: supply and logistics guidance

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WHO and UNICEF continue to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO and UNICEF will issue a further update. Otherwise, this interim guidance will expire 5 years after the date of publication.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned.

WHO reference number: WHO/2019-nCoV/vaccine_deployment/logistics/2021.1

Contents

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Gavi, the Vaccine Alliance
John Snow Inc (JSI)
Pan American Health Organization (PAHO)
PATH
United Nations Children's Fund (UNICEF)
VillageReach
World Bank
World Health Organization (WHO).

Abbreviations

ACT	Access to COVID-19 Tools
AEFI	adverse events following immunization
CCE	cold chain equipment
CCEOP	Cold Chain Equipment Optimization Platform
CNCC	COVAX National Coordinating Committee
COVAX	vaccine pillar of the Access to COVID-19 Tools (ACT) Accelerator
COVID-19	novel coronavirus SARS-CoV-2
CTC	controlled temperature chain (during immunization and outreach sessions)
CTWG	COVAX Technical Working Group
EEFO	earliest-expiry-first-out
EMA	European Medicines Agency
EPI	Expanded Programme on Immunization
ESAVI	events supposedly attributable to vaccination
EU	European Union
EUA	emergency use authorization
EUL	WHO Emergency Use Listing
FDA	Food & Drug Administration (United States of America)
FIFO	first-in-first-out
Gavi	Gavi, the Vaccine Alliance
GDP	good distribution practices
GEVIT	Global Ebola Vaccine Implementation Team
GTIN	Global Trade Item Number
ILR	icelined refrigerator
IM	intramuscular
IPC	infection prevention and control
LMIC	low- and middle-income countries
LMIS	logistics management information system
MDVP	multi-dose vial policy
MHRA	Medicines and Healthcare products Regulatory Agency (United Kingdom)
MIS	management information system
MoH	ministry of health
mRNA	messenger ribonucleic acid
NDVP	national deployment and vaccination plan
NITAG	National Immunization Technical Advisory Group
NLWG	National Logistics Working Group
PAHO	Pan American Health Organization
PCM	phase change material
PPE	personal protective equipment

QR	quick read
SB	safety box
SDD	solar direct drive
SmPC	summary of product characteristics (EU)
SOP	standard operating procedure
TOR	terms of reference
UCC	ultra-low temperature cold chain
ULT	ultra-low temperature
UN	United Nations
UNICEF SD	United Nations Children's Fund Supply Division
VAR	vaccine arrival report
VIRAT	Vaccine Introduction Readiness Assessment Tool
VVM	vaccine vial monitor
WHO	World Health Organization
WHO SAGE	Strategic Advisory Group of Experts on Immunization
WICR/FR	walk-in cold room/freezer room
WIRF	walk-in freezer room

1. Context

The COVID-19 pandemic is causing unprecedented human and economic costs in all countries and societies across the world. Collectively, the availability of safe and effective vaccines against the virus, specialized diagnostics technologies and therapeutics, as well as adherence to public health and social measures, and preventing new zoonotic introductions, are instrumental in saving further lives.

The vaccine pillar of the Access to COVID-19 Tools Accelerator (COVAX) Facility aims to accelerate equitable access to appropriate, safe and efficacious vaccines for all countries.

As of January 2021, over 200 novel coronavirus vaccine candidates are under development, of which 64 are in clinical trials. The London School of Hygiene & Tropical Medicine has developed an interactive tool[1] that tracks the progress of the candidate vaccines in real time. It is recommended to access it regularly to verify the status of the vaccines' development progress, profiles and potential controlled temperature chain (CTC).

Given the pandemic context, the vaccines may not be prequalified during their initial periods of use; they will be released under World Health Organization (WHO) Emergency Use Listing (EUL) ( ) 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, the 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 six United Nations (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.

Fig. 1.1 COVID-19 vaccine label information

COVID-19 VACCINE COVAX SUPPLY

[Insert Mode of admin, IM etc.]
[Insert Storage conditions]
[Insert Multidose vial (number of doses × volume)]
[Insert Manufacturing date]
[Insert Lot #]
[Insert Total volume]
[Insert Strength/dosage]
[Insert Manufacturer]
[Insert QR code and/or Website]

[1] COVID-19 vaccine tracker, Vaccine Centre, London School of Hygiene & Tropical Medicine.

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. The priority target groups are identified as:

- **Health workers in health and social care:** It is projected that countries will receive initial doses to vaccinate 3% of their population to cover health workers involved in health and social care in most countries. The International Labour Organization estimates that 234 million health and social care workers make up 3% of the general population, for whom the first tranche of vaccines can be allocated.

- **Older adults (over 65 years old), adults with comorbidities and others, based on local relevant risk factors:** It is projected that countries will 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 guidance

The purpose of this document is to provide guidance for 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;
- assess, design and implement appropriate waste management mechanisms to safely treat and dispose waste while protecting the environment and populations;
- strengthen appropriate cold chain and logistics requirements, including reverse logistics; and
- provide tools to support country readiness activities.

KEY MESSAGES

- **Supply chain readiness is key to efficiently deploying COVID-19 vaccines to the target populations in line with defined vaccination strategies.**
- **Due to potential variations in the 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 government agencies and the 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 an ultra-low temperature cold chain (UCC) profile pose several challenges for many low- and middle-income countries (LMIC) because of the lack of existing UCC within their health/immunization systems. Countries that will receive COVID-19 vaccine requiring ultra-low temperature (ULT) storage temperatures (e.g. -70 °C +/-10 °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.**
- **Initial batches of COVID-19 vaccines may be scarce and 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 mechanisms will need to be particularly rigorous and efficient.**

KEY MESSAGES continued

- **A robust mechanism to ensure the traceability of COVID-19 vaccines, should be in place to avoid the 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 campaigns.**
- **Ensure safety plans to safeguard stock at national and subnational 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 facilities and for products in transit in a situation of high demand but limited stocks.**
- **COVID-19 vaccination campaigns are expected to generate unusually large amounts of health care waste. Countries should ensure that a 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.**

Document structure

Section	Goal	Key guidance
1. Context	Introduce country teams to the COVAX Facility. It provides information on the characteristics of the candidate vaccines and how these might affect 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	Inform country teams on challenges that the candidate vaccines will pose in terms of supply and logistics.	• Vaccine development scenarios • Challenges specific vaccines might bring • Characteristics • Tools for use in selecting vaccines
4. Cold chain and supply strategies	Orient country teams on how to organize a COVAX Technical Working Group (CTWG). Provide supply and logistics guidance in preparation for COVID-19 vaccination. Inform country teams on security and budget activities to support the campaign.	CTWG guidance on: • 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. Vaccine store infrastructure and power requirements	Guide country teams on understanding the challenges that candidate COVID-19 vaccines might bring in terms of cold chain and dry storage requirement.	• Store infrastructure • Ultra-low temperature cold chain (UCC) equipment system • Power requirement • Dry storage

Document structure continued

Section	Goal	Key guidance
6. Health care waste management	Orient country teams on best practices to manage hazardous and medical waste during the COVID-19 vaccination campaign.	• Practical steps described on how to prepare a waste management plan • Guidance on how to dispose of syringes, vials and other COVID-19 waste
7. Human resources	Provide guidance on how to ensure staff availability, safety and security.	• Strategy on staffing • Capacity building
8. Country preparedness activities	Inform country teams on key activities suggested through the COVAX country vaccine readiness assessment. Provide 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 function: • Overview and scope of the supply chain • Analyse readiness and identify supply 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
Annexes	Provide tools, procedures and templates that could be useful to country teams.	• Tools decision matrix • Guidance on UCC • Country readiness self-assessment checklist • Vaccine accountability monitoring reporting form (reverse logistics) • Reported immunization waste form

3. Vaccine profiles

More than 200 COVID-19 vaccine candidates are in the research and development pipeline and some of them may require storage at ultra-low temperature (ULT) to maintain potency, especially the messenger ribonucleic acid (mRNA) vaccine types. This poses additional challenges to cold chain storage and transport, especially in remote areas, away from major transport links and refrigeration facilities, and places with unstable power supply.

On 31 December 2020, WHO listed the COVID-19 mRNA vaccine BNT162b2 for emergency use, making the Pfizer-BioNTech vaccine the first to receive emergency validation from WHO since the outbreak began a year earlier. To maintain potency, this vaccine has to be stored at ULT but once thawed, undiluted vaccine can be stored for 5 days at 2 ºC to 8ºC or up to 2 hours up to 30 ºC prior to use. Depending on stability data, other vaccines in the same category may require different management procedures once taken out of UCC storage. Therefore, attention must be given to vaccine-specific recommendations when handling and delivering the different types of COVID-19 vaccine.

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 volumes required, which means, initially, countries may not have a wide variety of vaccine types 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 3.1 are provided to inform decision-makers on planning and delivering vaccines.

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 °C to 8 °C; -20 °C; or -70 °C +/-10 °C (UCC), the level of preparedness and the country's readiness will be critical in selecting and accepting any vaccine.

Key supply and logistics drivers for readiness will depend on:

- priority target groups to be vaccinated;
- vaccine characteristics (availability, storage temperature, shelf life, dose regimen etc.);
- timeline and strategy to vaccinate target groups;
- availability of adequate cold chain storage and transportation capacities; and
- human and financial resources required to adequately handle the vaccine deployment.

To help countries select and accept donations of vaccines, refer to the following general guidance:

- *WHO Principles and considerations for adding a vaccine to a national immunization programme* ().
- *WHO-UNICEF Joint Statement on vaccine donations* ().
- *WHO Vaccination in humanitarian emergencies* ().

Table 3.1 Candidate COVID-19 vaccine profiles (as of 14 January 2021)

Characteristics	COVID vaccine A mRNA (liquid)	COVID vaccine B mRNA (liquid)	COVID vaccine C viral vector (liquid)	COVID vaccine D viral vector lyophilized	COVID vaccine E protein subunit (liquid)
Vaccine manufacturer	**Pfizer-BioNTech**	**ModernaTx**	**Oxford-AstraZeneca**	**tbc**	**tbc**
Approval status	Approved under WHO EUL: https://extranet.who.int/pqweb/vaccines/who-recommendation-covid-19-mrna-vaccine-nucleoside-modified-comirnaty%C2%AE ()	US Food and Drug Administration (FDA) approved under emergency use authorization (EUA): https://www.modernatx.com/covid19vaccine-eua/fda-letter-eua.pdf ()	Medicines and Healthcare products Regulatory Agency (UK) temporary authorization for emergency supply from 24/09/2020 to 29/12/2020: https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/conditions-of-authorisation-for-covid-19-vaccine-astrazeneca ()	NA	NA
Efficacy	95%	94.1%	70.4% (2 full doses at 28-day interval); 90% (with initial low primer dose – requires further study)	tbc	tbc
Safety	Refer to: https://www.cvdvaccine.com/ ()	Refer to: https://www.fda.gov/media/144638/download, or https://www.modernatx.com/covid19vaccine-eua/ ()	Refer to: https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca ()	tbc	tbc
Dosage and dose regimen	0.3 mL, 2 doses	0.5 mL, 2 doses	0.5 mL, 2 doses	2	2
Duration between doses	21– 28 days	28 days	4–12 weeks	4 weeks (tbc)	4 weeks (tbc)

Table 3.1 Candidate COVID-19 vaccine profiles (as of 14 January 2021) continued

Characteristics	COVID vaccine A mRNA (liquid)	COVID vaccine B mRNA (liquid)	COVID vaccine C viral vector (liquid)	COVID vaccine D viral vector lyophilized	COVID vaccine E protein subunit (liquid)
Vaccine manufacturer	**Pfizer-BioNTech**	**ModernaTx**	**Oxford-AstraZeneca**	**tbc**	**tbc**
Cold chain requirements	-80 °C to -60 °C in ULT freezer. -90 °C to -60 °C in thermal shipper as temporary storage for up to 30 days from delivery (should be re-iced every 5 days if opened up to 2 times a day, less than 3 minutes at a time).	-25 °C to -15 °C. Do not store on dry ice or below -40 °C. Prior to administration, thaw one vial at a time.	+2 °C to 8 °C. Do not freeze.	+2 °C to 8 °C (tbc)	+2 °C to 8 °C (tbc)
Stability at 2 °C to 8 °C	5 days	30 days	6 months	Yes	Yes
Shelf life	**Undiluted vaccine at storage temperature** -90 °C to -60 °C: 6 months after date of manufacture. **Undiluted thawed vaccine** at +2 °C to +8 °C: up to 120 hours (5 days) prior to dilution. **Undiluted thawed vaccine** at temperatures up to +30 °C: up to 2 hours. **Diluted vaccine** at +2 °C to +30 °C: 6 hours after dilution.	**Unopened vials** can be stored refrigerated between 2 °C to 8 °C for up to 30 days prior to first use. **Unpunctured vials** may be stored between 2 °C to 8°C for up to 30 days or between 8 °C to 25 °C for up to 12 hours. **After the first dose has been withdrawn**, the vial should be held between 2 °C to 25°C. Discard vial after 6 hours.	**Unopened vials** can be stored at 2 °C to 8 °C for 6 months or up to 25 °C for 2 hours. Opened vials can be stored at 2 °C to 25 °C for use within 6 hours.	Refer to manufacturer's instructions via QR/barcode or manufacturer's website.	Refer to manufacturer's instructions via QR/barcode or manufacturer's website.
Vaccine presentation/vial size	Frozen, sterile, preservative-free, multi-dose concentrate for dilution before administration. One vial (0.45 mL) contains 6 doses of vaccine after dilution.	Liquid suspension, one vial (0.45 mL) contains 10 doses of vaccine.	Liquid ready to use; preservative free. One vial (5 mL) contains 10 doses of vaccine or one vial (4 mL) contains 8 doses of vaccine. Not all pack sizes may be marketed.	10 and 20 (tbc)	10 and 20 (tbc)
Mode of administration	Intramuscular (IM) injection on deltoid muscle.	Intramuscular (IM) injection on deltoid muscle.	Intramuscular (IM) injection on deltoid muscle.	Intramuscular (IM) injection.	Intramuscular (IM) injection.
Packed volume per dose (secondary package)	Single tray/carton holding 195 vials (1170 doses). Dimensions: 22.9 x 22.9 x 4.0 cm = **1.79 cm^3/dose**	A carton of contains 10 multiple-dose vials. Each vial contains 10 doses. **4.63 cm^3/dose**	18.5 x 9.5 x 6 cm = **2.10 cm^3/dose**	4.63 cm^3/dose (tbc) 1.20 cm^3/dose (tbc)	4.63 cm^3/dose (tbc) 1.20 cm^3/dose (tbc)
Packed volume per dose (tertiary package)	Insulated box containing 5 secondary cartons with a total of 975 vials (5850 doses). External dimensions: 40 × 40 × 56 cm = **15.31 cm^3/dose**. Insulated box is capable of maintaining UCC for max. 15 days, conditional on dry ice reloading.	A case includes 12 cartons, or a total of 120 vials providing 1200 doses. A shipping pallet may include up to 192 cases. Dimensions of carton of vaccine: 13.97 × 5.59 × 6.35 cm = **4.96 cm^3/dose**.	31 × 19 × 13.3 cm = **2.61 cm^3/dose**	tbc	tbc

Table 3.1 Candidate COVID-19 vaccine profiles (as of 14 January 2021) continued

Characteristics	COVID vaccine A mRNA (liquid)	COVID vaccine B mRNA (liquid)	COVID vaccine C viral vector (liquid)	COVID vaccine D viral vector lyophilized	COVID vaccine E protein subunit (liquid)
Vaccine manufacturer	**Pfizer-BioNTech**	**ModernaTx**	**Oxford-AstraZeneca**	**tbc**	**tbc**
Open vials wastage	tbc	tbc	tbc If a full 0.5 mL dose cannot be extracted, discard remaining volume.	15% (tbc)	15% (tbc)
Multi-dose vial policy (MDVP)	Max. 6 hours from the time of dilution.	Discard vial 6 hours after opening.	Discard vial 6 hours after uncapping and withdrawing first dose.	No reuse	No reuse
Freeze/thaw cycle and light sensitivity	Do not refreeze thawed vials. Do not freeze diluted. Do not shake the vial. Minimize exposure to room light. Avoid exposure to direct sunlight and ultraviolet light. Do not shake the thawed vial.	Do not refreeze. Keep the vials in their original package to protect them from light.	Do not freeze. Keep vials in outer carton to protect from light. Do not shake the vial.	Refer to manufacturer's instructions via QR/barcode or manufacturer's website.	Refer to manufacturer's instructions via QR/barcode or manufacturer's website.
VVM	None – initial pandemic supply will not include a VVM.	None – initial pandemic supply will not include a VVM.	None – initial pandemic supply will not include a VVM.	tbc	tbc
Labelling information on vial label (QR code, DataMatrix, barcode) and type of information embedded on them	***Not final – subject to European Medicines Agency (EMA) review and approval*** (Unit of use – 1 vial) Lot number and expiry printed on label.	No	Human readable Global Trade Item Number (GTIN) as per GS1 standard printed on the vial label.	tbc	tbc
Labelling information on secondary packaging (QR code, DataMatrix, barcode) and type of information embedded on them	***Not final – subject to EMA review and approval*** (Unit of sale – tray of 195 vials) QR code: link to patient information leaflet and EU summary of product characteristics (SmPC) 2-D barcode: • GTIN • lot number • expiry date.	Yes, QR code.	2-D DataMatrix barcode on secondary packaging with following embedded: • GTIN • batch number • expiry date • serial number.	tbc	tbc
Diluents	Yes (bundling: tbc)	No	No	tbc	tbc

4. Cold chain and supply strategies

4.1 COVAX Supply Chain Technical Working Group and National Logistics Working Group

A 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 keep in mind that the target groups will be different to those in usual new vaccine introduction activities. It will therefore be necessary to widen the committees to include other relevant stakeholders.

Under the guidance of the COVAX National Coordinating Committee (CNCC), the COVAX Technical Working Group (CTWG) and National Logistics Working Group (NLWG) should initiate 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 CCE 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 of and guidance on how to establish a NLWG can be found at: 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 or twice weekly coordination meetings between all stakeholders.

The CTWG and/or the NLWG are responsible for developing and monitoring the key activities listed in Table 4.1, in preparation for distribution plans up to the last mile, in line with the national deployment and vaccination plan (NDVP)[1] in place in the country.

[1] The COVID-19 Partners Platform will host the country readiness for delivery of vaccine introduction coordination providing two main functions serving as a repository of NDVPs and mapping vaccine technical assistance and resources allocated.

4.3 Preplanning: core functions and logistics

Countries should already be analysing the information available to them that relates to COVID-19 vaccination campaigns. Table 4.1 identifies the core supply and logistics functions that countries should discuss when developing their NDVP through their committees to strengthen their COVID-19 vaccination campaign.

Table 4.1 Core supply and logistics functions at each supply chain level

Core functions	Description of the activity	National	Subnational	District	Proposed timeline
Background	Explain, the scope of the vaccination campaigns in term of: • target population • vaccines that will be used • delivery sites.	●	●	●	3–6 months prior
Coordination and monitoring	Build the structures for coordination and vaccine management (CTWG/NLWG) at all levels of the health service. Monitor progress using methods such as a dashboard with key indicators, readiness assessment tools, etc.	●	●	●	3–6 months prior
Logistics structure	Explain the distribution and collection pattern and how campaign logistics will be different from the routine structure, and the reasons for the difference.	●	●	●	3–6 months prior
Cold chain	Give details on cold chain capacities with a gap analysis and plans to fill the gaps.	●	●	●	3–6 months prior
Transport	Give details on transportation capacities and plans for the distribution.	●	●	●	3–6 months prior
Waste management	Explain the national policy in term of COVID-19 vaccine waste management and give details on practical ways (routes, methods, disposal sites) to safely collect, treat/dispose the waste.	●	●	●	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, recalls and others related to country context.	●	●	●	3–6 months prior
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.	●	●	●	3–6 months prior
Human resources	Give details on the people in charge, with their roles and responsibilities.	●	●	●	3–6 months prior
Training	Detail the training plan, schedule, audience, duration and content.	●	●	●	3–6 months prior
Procurement and 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.	●	●	●	3–6 months prior
Information management	Identify and explain tools and forms from the routine logistics management information system (LMIS) or tools designed specifically for this response.	●	●	●	3–6 months prior
Chronogram of the supply and logistics activities	Give details on the timeline of the supply and logistics activities.	●	●	●	3–6 months prior
Budget	Estimate the costs of all activities and identify funding sources.	●	●	●	3–6 months prior

- To guide countries in listing different activities that must take place prior to vaccine deployment, a COVAX Vaccine Introduction Readiness Assessment Tool (VIRAT) (refer to Section 9, Tool 2) has been prepared. The NDVP is another guide to help countries prepare their vaccination strategies to reach the target populations. The identification of the target populations (e.g. health workers, older people and those with underlying health conditions) should be guided by the WHO Strategic Advisory Group of Experts on Immunization (SAGE) values framework and prioritization roadmap[1] (☝) and the fair allocation mechanism for COVID-19 vaccines through the COVAX Facility (☝), as well as the available vaccine supply, national context and epidemiologic setting. The country-led decision-making process for identifying target populations should be done in consultation with the National Immunization Technical Advisory Group (NITAG) or technical advisory group and wide consultation with stakeholders.

- Personnel (e.g. vaccination teams, supervisors, campaign monitors and logisticians) directly implementing the deployment and vaccination operation are at risk of exposure to COVID-19 infection. They are key to successfully implementing the vaccination and deployment operations, therefore their health and safety must be ensured throughout the campaign period. The aide memoire on infection prevention and control (IPC) for vaccination (☝) provides guidance on the safe conduct of COVID-19 vaccination.

While completing these activities, it is important to keep in mind the following considerations:

PLANNING STEPS

1. **Assess your country readiness using the VIRAT (refer to Section 9, Tool 2).**
2. **Forecast vaccine and logistics needs using the Immunization Supply Chain Sizing Tool (☝) (refer to Section 9, Tool 3).**
3. **Develop COVID-19 strategies using the NDVP for COVID-19.**

- Early planning, with regular monitoring and adjustments, is key for success.

- Obtain accurate estimates of the target subpopulations from reliable sources to facilitate vaccine procurement, allocation of supply and resources, and deployment planning.

- The development of different plans and their implementation should be a team effort under the coordination of the CTWG and/or NLWG under the CNCC.

- The country-led deployment plan should be in line with the selected vaccination strategy to equitably reach the identified target populations and be initiated several weeks before vaccinations begin.

- The national deployment plan should include strategies to ensure health workers and logisticians directly implementing the vaccination and deployment operations will have adequate and timely access to personal protective equipment (PPE) and vaccines. The plan should clearly define when these personnel should receive the COVID-19 vaccine to ensure protection during the campaign, with consideration to the number of doses and interval between doses required to develop immunity.

[1] WHO (2020). WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination, 14 September 2020. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/334299).

- The logistical implication of the vaccination strategy – whether facility- or community-based – must be carefully assessed to ensure that both health workers and vaccines will have safe access to the vaccine and risk of disease transmission is minimized. 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 the deployment plan.

- 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 point destinations, and in consideration with the strategy to reach target populations. Whenever applicable, countries are encouraged to seek additional storage and distribution capacity from their partners, including outsourcing from the private sector.

- Countries should adapt their supply and logistics SOPs specific to their own context.

- Countries need to develop or adapt their LMIS to track, trace and report vaccine and logistics stocks and utilization 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 manufacturers 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, PPE and ancillary products

2. storage of vaccines and ancillary products

3. repackaging vaccines and ancillary items

4. production or purchase of coolant packs

5. transportation of vaccines

6. reverse logistics

7. managing recalls

8. management of supply chain information.

4.4.1 Reception of vaccines, PPE and ancillary products

The guidance is presented by health services store level:

- port of entry
- central level
- subnational level.

Port of entry and central level: 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" list (Table 4.2) outlines the tasks to complete to successfully receive the vaccines and the ancillary products.

Countries procuring vaccines through the UNICEF Supply Division (SD) and the Pan American Health Organization (PAHO) revolving funds 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 quick read (QR) codes or barcodes.

Table 4.2 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 and prepare to receive vaccine. 2. Ensure sufficient storage is available and appropriate transport arrangements. 3. Notify ministry of health (MoH) procurement to assign a clearing agent and inform country office. 4. Confirm with airline readiness to receive consignment.	Assign clearing agent and share shipping documentation	Share pre-advice (copies to MoH, cold store, programme)	Release of pre-advice and shipping documentation
Customs clearance and transport to national store	1. Confirm clearance and transport vaccines to national store immediately.	Clear customs	Arrange for clearing when consignee is country office	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 and 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, vaccine arrival report (VAR). 5. Check shipping indicators and VVM status of vaccines (if no VVM, check QR code). 6. Complete the VAR for each antigen shipment and forward to country office.	Inform NRA of vaccine arrival and facilitate batch testing process	Verify VAR and forward to UNICEF SD/PAHO	Acknowledge receipt of VAR and review as appropriate

Table 4.2 COVAX arrival SOP continued

Task	National cold store responsibilities	EPI responsibilities	UNICEF/WHO/PAHO co-responsibilities	UNICEF SD/PAHO
Stocking of shipment	**Vaccines accepted:** 1. Unpack vaccines and place in walk-in cold room/freezer room (WICR/FR). Place diluents in dry store. 2. Record in stock management system and 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 country office of problem immediately (within 2 hours of detecting problem). 3. Quarantine vaccines and do not move from cold store (store in WICR/FR and mark with an "X"). 4. Collect VaxAlert/Qtags data and 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 (photos, all documentation, timelines). 2. Ensure WHO/UNICEF country office/PAHO are involved in the investigation. 3. Complete VAR and supply copy of VaxAlert/ Qtags screens (link to shipment and vaccine batch), serial numbers and condition of VVMs.	Call a NLWG within 24 hours of receipt of vaccine and send official response to UNICEF country office/ PAHO, indicating rejection of shipment	Share complaint letter with UNICEF country office/PAHO and together with WHO guide the MoH in investigation	Country office guidance on investigation of problems collaboration with WHO
Follow-up actions	1. Follow up with UNICEF 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 country office/ PAHO on investigation	Follow up with UNICEF SD/PAHO on recourse	Follow up with freight forwarder, manufacturer and WHO

Table 4.3 Track and trace activities (refer to Section 9, Tools 13 and 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 LMIS. • Prepare central repository system for tracking barcodes. • 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 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 (MIS) 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 barcodes 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 received the vaccine store. Avoid storing the vaccine for a long period of time.

The potential COVID-19 vaccine candidates currently being developed can be categorized by three storage requirements (as of January 2021):

- **vaccines required to be stored at 2 °C to 8 °C:** where the WHO guidance for managing vaccines applies ();
- **vaccines required to be stored at -20 °C:** where the same WHO guidance applies; and
- **vaccines required to be stored at -70 °C +/-10 °C:** where significant investment in UCC storage capacity and training in handling vaccines and ULT equipment 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. Analysing this dataset will:

- support decision-making in the choice and quantity of vaccines to procure;
- 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, options include (see Section 9, Tools 14–16 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 6-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 is important to determine for which products and where this should be done in the country (segmentation). This option may be very favourable, particularly in economies where the market is mature and high-quality storage options exist. The UNICEF guidance on *Supporting private sector engagement with governments for supply chains* () provides further information.

3. Split shipments and increase frequency of distribution

UNICEF 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 level. 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 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 Immunization Supply Chain Sizing Tool (Section 9, Tool 3), to determine your net storage capacity requirements:

- **Calculate the cold chain capacity at the national and subnational levels of your supply chain.**
- **Analyse your inventory data against the requirements.**

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 4.4 Central level cold chain planning steps (refer to Section 9, Tools 13–15 for supply chain systems redesign)

Vaccine storage temperatures	Central level
2 °C to 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, Tools 3 and 8). • If storage capacity requirements are insufficient, consider the options below: – procurement of WICR (cold storage room), refrigerated container or additional refrigerators – leasing of a refrigerated container or private facility – split shipments and increase distribution frequency – 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: – procurement of WICR or refrigerated container – leasing of a refrigerated container or private facility – split shipments and increase distribution frequency – staggered vaccination campaigns.
-70 °C +/-10 °C	As countries are not familiar with vaccines managed at this temperature range, a specialized strategy has been developed for UCC (see Annex 2).

Subnational level: The subnational 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 °C to 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 subnational stores in Gavi eligible countries. Thus, the impact of increasing storage capacity requirements at this level will not be as high.

Table 4.5 Subnational planning (refer to Section 9, Tools 14–16 for supply chain systems redesign)

Vaccine storage temperatures	Subnational level
2 °C to 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, Tools 3 and 8). • If storage capacity requirements are insufficient, consider the options below: – procurement of WICR, refrigerators or refrigerated container – leasing of a refrigerated container or private facility – split shipments and increase distribution frequency – staggered 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 walk-in freezer room (WIFR) or refrigerated container – leasing of a refrigerated container or private facility – split shipments and increase distribution frequency – staggered vaccination campaigns.
-70 °C +/-10 °C	As countries are not familiar with vaccines managed at this temperature range, a specialized strategy has been developed for UCC (see Annex 2).

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 Vaccine Volume, Forecasting and Cold Chain Gap Analysis Tool (Section 9, Tool 8) and ensure they have sufficient storage capacity (using the Immunization Supply Chain Sizing Tool, Section 9, Tool 3) within the health facilities.

Table 4.6 Health facility cold chain capacity planning (refer to Section 9, Tools 14–16 for supply chain systems redesign)

Vaccine storage temperatures	Health facility level
2 °C to 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, Tools 3 and 8). • If storage capacity requirements are insufficient, consider the options below: – procurement of solar direct drive (SDD) or icelined refrigerators (ILR) and/or cold boxes and vaccine carriers – leasing of a private facility – split shipments and increase distribution frequency – staggered 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 and vaccine carriers – leasing of a private facility – split shipments and increase distribution frequency – staggered campaigns.
-70 °C +/-10 °C	As countries are not familiar with vaccines managed at this temperature range, a specialized strategy has been developed for UCC (see Annex 2).

Table 4.7 Warehouses storage (refer to Section 9 for 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 Expanded Programme on Immunization (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.	• 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. • 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 receiving warehouses can verify if there were any cold chain excursions. • Inspect the physical integrity of the cold boxes and replace as needed.

4.4.3 Repackaging vaccines and ancillary items

Most COVID vaccines will necessitate cold chain transport at 2 °C to 8 °C. Refrigerated vehicles from the national level are recommended but if these are not available in your country, other standard WHO performance, quality and safety prequalified 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[1] + phase change material (PCM)[2] or thermal shipper + dry ice should be used.

Table 4.8 Repackaging vaccines (refer to Section 9 for 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 to keep 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. • 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 as needed. • Ensure that sufficient trained staff are available. • Determine the need for staff training for those who will receive, store, repack and ship the vaccines.	• 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. • 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 receiving warehouses can verify if there were any cold chain excursions. • Inspect the physical integrity of the cold boxes and replace 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 above +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.

[1] Arktek model YBC-5 is a modified version of the **Arktek Passive Vaccine Storage Device** that uses PCMs rather than ice packs 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).

[2] 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).

- **If the required storage temperature is below -70 °C +/-10 °C, refer to Annex 2 for guidance on UCC use.**
- **Some UCC vaccine may require special handling during repackaging. Always check the manufacturer's information for additional guidance.**
- **Logisticians have to strengthen their existing SOPs on repackaging vaccines with particular attention to COVID-19 vaccine profiles.**

Reminder

☐ Avoid using non-insulated containers for storing or transporting vaccine.

☐ Vaccine temperature needs to be monitored before transport and upon receipt of delivery. Most vaccines in the pipeline are heat sensitive, therefore refrain from frequently opening the transport box to check for temperature.

☐ Record vaccine type, lot numbers, brand names, quantity, date, delivery or arrival time and originating facility on a packing slip.

☐ When transporting vaccine stored at 2 °C to 8 °C, coolant packs should be conditioned at room temperature for 1–2 hours until the edges have defrosted and the packs look like they are sweating. Refer to WHO SOP *How to use passive containers and coolant packs for vaccine transport and outreach operations* (☞).

☐ Diluents that are stored at room temperature must be refrigerated at least 24 hours if placed in an insulated cooler with vaccines. If not cooled in a refrigerator, they must be transported separately from vaccines. Room temperature diluents placed in insulated coolers with vaccines may raise the temperature of the cooler. Never freeze diluents.

☐ Before accepting the vaccines, the recipient should make sure that the temperature limits have not been exceeded by reading the temperature monitoring devices and analysing the VVM, if available.

4.4.4 Production or purchase of coolant packs

For vaccines requiring storage and transportation between 2 °C to 8 °C:

☐ **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 1– 2 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 (☞).

Table 4.9 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 on a continuous basis to detect and resolve any problems that can affect deployment.

For vaccines requiring storage and transportation at -20 °C:

- ☐ **Frozen ice or gel packs:**
  - must be stored in a 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):
Refer to Section 5.2 and Annex 2 for guidance on UCC.

4.4.5 Transportation of vaccines

Data loggers are the preferred option for monitoring the temperature during transportation as they monitor the vial temperature throughout transportation. The temperature of the vaccine should be duly documented:

- ☐ for data loggers inside the container – check the temperature at the beginning and end of the trip (avoid exposing vaccines through frequent openings);

- ☐ for data loggers with an outside reader – check the temperature at least twice during the trip.

Table 4.10 Transportation of products (refer to Section 9, Tools 3 and 8, for cold chain gap analysis, and Tools 14–16 for supply chain 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. • 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 fuel supply and repair sites. • Calculate the transportation costs, including per diem expenses for the transport operators. The 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 procurement of fuel.	• Monitor availability of all transport resources and operators. • Ensure the availability of 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 and other supplies either to dispose or reuse. For example, reverse logistics was applied on recalling trivalent oral polio vaccine for final disposal during the "trivalent oral polio vaccine to bivalent oral polio vaccine switch" in 2016.

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

- 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.

See Annex 4 for the vaccine accountability monitoring reporting form – used for accurately tracking and reporting 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;
- the 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 authority. However, during storage, recalled products must be labelled "quarantined" and separated 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 all 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 to ensure their appropriate usage (Tools 13 and 16); and

- ensuring sufficient distribution capacity (vehicles, transport boxes, carriers) to deliver the COVID-19 and routine vaccines on schedule (Tools 15–17).

As the target groups for COVID-19 vaccines are different from the EPI target population, countries will need to adapt their current MIS 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.

Table 4.11 summarizes areas where data collected and recorded will need to be analysed.

Table 4.11 Data requirements

Area	Key data for review
Cold chain storage capacity	• Current available cold chain storage capacity at target sites. • Forecasted storage need for COVID-19 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: – 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 4.12 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, paper-based approaches. • Consider adapting the MIS or develop a strong fit-for-purpose system. The best-fit system will depend on the 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-19 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 traceability (Section 4.5) and security (Section 4.6) information 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 (Annex 4).
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, Tool 18. • COVID-19 vaccines may come with a QR code 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, i.e. no 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 website. This information will then be disseminated and acknowledged by managers and health workers at all levels of the supply chain. • A vaccine accountability monitoring reporting form (Annex 4) needs to be collected and analysed during and after each vaccination session to decrease risks of losing vials during the campaign.

Table 4.13 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 MIS 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; and – 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; and – condition of the warehouses. • Human resources: list the type and number of human resources required by function at each level; and the condition of the 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 MIS to confirm and document 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 MIS before a pandemic. • Train personnel on use of the MIS.	Use the MIS to: • Contact the warehouses and mobilize 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, using barcodes, if available. • Dispatch the vehicles and operators. • Inform on withdrawal activities of vaccine lots at the request of the MoH due to adverse events following immunization (AEFI) or events supposedly attributable to vaccination (ESAVI) or damage. • 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 MIS 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 traceability guidelines (🕸) provide further information.

QR codes: These are intended to provide rapid access to important vaccine information to health workers. The QR codes are symbols that can be scanned electronically using laser or camera-based systems. The QR codes provide the 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: Barcodes can help in monitoring the movement of vaccines. The first batches of COVID-19 vaccines may not have VVMs, so CCE temperature monitoring, vaccine distribution and inventory management will need to be particularly rigorous and efficient throughout the supply chain.

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

- **real-time shelf life**
- **heat stability**
- **new information on vaccine profiles.**

When scanning the barcode, you will find:

- **manufacturer's information**
- **lot/batch numbers**
- **expiry date.**

Countries should consider the possibility of:

- **updating their data repository system to record data**
- **developing or strengthening current guidance**
- **conducting training**
- **strengthening their supply chain information management systems.**

The vaccination programmes will need to track the movement of vaccines to protect against fraud or diversion. The COVAX Facility will offer guidance to suppliers on how to use barcodes on their secondary packaging or serialization on vials. This will facilitate countries to track the vaccines at arrival and distribution points. It is recommended that programmes or in-country logistics operators use this functionality; it will likely be enabled by barcode 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:

Table 4.14 Barcode features

Features	Global Trade Item Number (GTIN)	GTIN + batch/lot	GTIN + serial number
Low-precision identification	●		
Medium-precision identification		●	
High-precision identification			●
Item exists in multiple locations at the same time	●	●	
Item exists in only one location at the same time			●
Enables inventory control		●	●
Enables anti-substandard and falsified measures			●
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 the 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 this risk, 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 to tackle counterfeiters and prevent them from entering national supply chains.

To avoid the introduction of counterfeit 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 return or recall; and
  - vaccine donations.

- ☐ 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 on 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 national legislation; and
  - duties and responsibilities should be documented in a written agreement and audits established to monitor compliance with 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 that the product is not a falsified vaccine and give the real-time expiry information.

Table 4.15 Protection against counterfeit

Protect the immunization supply chain from counterfeit vaccines	
Before vaccination campaign	**During vaccination campaign**
• Install centralized software to collect and report product barcodes. If this is 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. • Organize communication groups per district that include health care workers involved in the vaccination campaigns.	• Collect barcoding information upon arrival of the product within the country. • Scan and collect barcodes during internal movement, from central level to district levels. • Share daily with your group the product information that manufacturers updated on their websites. • Using software, trace the product movements. • If falsified products are found, put the vials in quarantine and apply the national recall procedure.

4.6 Securing the supply chain

Potential high demand and limited quantity of COVID-19 vaccines may lead to insecure situations or conflict 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 4.16 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 government offices and obtain their agreement 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 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.

4.7 Budgeting and financial management

Estimating budgetary requirements 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) prior to implementation. The budget plan should include:

- ☐ details to justify financial requirements and facilitate approval;
- ☐ national and subnational needs for successful implementation;

- costs to procure additional CCE, if there is a gap:
  - do not forget tax, duty fees, customs brokerage and shipment costs; and
  - if a WICR or freezer is procured, add costs for preparing the site.

- a contingency fund, between 5% to 10% of total operational costs, for:
  - unplanned core and support activities;
  - unpredictable circumstances during implementation; and
  - other unforeseen costs.

Planning and financing of the deployment operations should consider:

- the government's budget cycle;

- turnaround 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 microplans. District planning follows a schedule of activities similar and complementary to national-level planning but with greater operational detail.

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

Remember to include these activities/items in the logistics budget:

- **custom clearance activities**
- **cold chain equipment repairs and maintenance costs**
- **fuel and vehicle maintenance**
- **mechanism to release and distribute funds to the lowest level of operations**
- **contractual agreements for waste management, additional storage and transport**
- **security services at vaccination sites or during transport**
- **any other country context activities related to supply and logistics.**

KEY CONSIDERATIONS IN BUDGETING AND FINANCIAL MANAGEMENT

- ✔ Who oversees 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 there are 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 plans, policies and guidelines clearly communicated to all levels?
- ✔ How will unexpected expenses be dealt with?
- ✔ What safety net is in place to prevent loss or inefficient use of resources resulting from fraud and diversion of vaccine supply and logistics?
- ✔ Can a contingency fund be developed to complement and strengthen the regular supply chain system?

Table 4.17 Procedures to develop a budget

Establish a budget to support supply chain operations with clear guidelines for disbursement and 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 MIS. • Inform and train personnel on their fiduciary responsibilities, financial rules and regulations. • Organize tests to verify knowledge of the financial and information procedures. • Monitor fund transfers.	• Assign a person with responsibility for financial management to ensure compliance with administrative regulations, and appropriate disbursal and transfer of funds authority, 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.

Source: Technical guidelines for vaccination against the pandemic influenza virus (PAHO, 2009).

5. Vaccine store infrastructure and power requirements

The potential COVID-19 vaccines types have varying storage temperature requirements:

- 2 °C to 8 °C
- -20 °C
- -70 °C +/-10 °C.

In most countries, the available CCE used for storing vaccines has a 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 oral polio vaccine and freeze-dried vaccine for a relatively long 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-19).

Very few LMIC have ULT capacity (-70 °C +/-10 °C) CCE within their health/immunization systems.

- The experience of 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 the 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 agreements 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 processes, 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 (see 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

The 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 vaccine arrival to ensure that all 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 – *Design and procurement of storage facilities* (). For reference, some minimum building infrastructure norms for cold chain and logistics country hubs can be found in the *Global Ebola Vaccine Implementation Team (GEVIT) – Practical guidance on the use of Ebola vaccine in an outbreak response (Annex J)*.

5.2 Ultra-low temperature cold chain equipment system

The UCC equipment encompasses **active equipment** (ULT freezers), that store vaccines at very low temperature (-80 °C/-60 °C) and **passive equipment** (ULT insulated containers) that are used to store or distribute low temperature vaccines. Refer to Annex 2 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 the WHO Effective Vaccine Management Initiative SOP (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 (EEFO) 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 (FIFO) order.

- ☐ Expired or damaged products marked for disposal are kept separate from usable stock.

6. Health care waste management

Health care waste management is the process of collection, treatment and disposal of the health care waste produced by vaccination (refer to Section 9, Tool 20). Management of waste related to COVID-19 vaccination requires special attention. Due to the infectious nature of the virus and usage of PPE, large volumes of immunization waste will be generated. Safe collection and final disposal of health care waste will eliminate the potential risk to health workers, the public and protect the environment.

Plan additional capacity to collect the increased volumes of health care waste generated by the vaccination campaign. Transport waste to the designated sites, treat it and safely dispose of it.

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 plan for the extra quantities expected. WHO and UNICEF have published global guidance on health care waste technologies ( ).

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;
- ☐ develop 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

Refer to the following resources:

- ☐ *Technical guidelines for vaccination against the pandemic influenza virus* ( ) (PAHO, 2009).
- ☐ *Management of injection waste activities at the district level: guidelines for district health managers* ( ) (WHO, 2006).
- ☐ Appropriate Disposal of Immunization Waste Platform (ADIW Platform) (UNICEF, 2020) ( ).

Step 1: Evaluate 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.[1]
- ☐ 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.

[1] If 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. 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.

The head of logistics and their 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 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 programme, 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 and comply with 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;

  - 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 job aid); and
  - use 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, supervisors will measure compliance with the standards. The following performance indicators are 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.[1,2]

- ☐ 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.

RECOMMENDATIONS FOR COUNTRIES

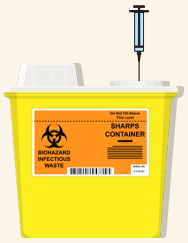
- **Review waste management plans often during the campaign.**
- **Update plans based on changes in vaccine delivery systems or waste management technology.**
- **Stress test plans to verify their effectiveness.**
- **Adapt plans when operational gaps are observed, ensuring safe and rapid collection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

[1] 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.

[2] 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, refer to *Management of injection waste activities at the district level: guidelines for district health managers* (WHO, 2006).

Fig. 6.1 Disposal of syringes, vials and PPE

Disposal of syringes



- Without re-capping the needle, discard the contaminated 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.
- Seal the safety box before transporting it to the disposal site.
- Follow the national guidelines and local government code for final disposal.

Disposal of vials

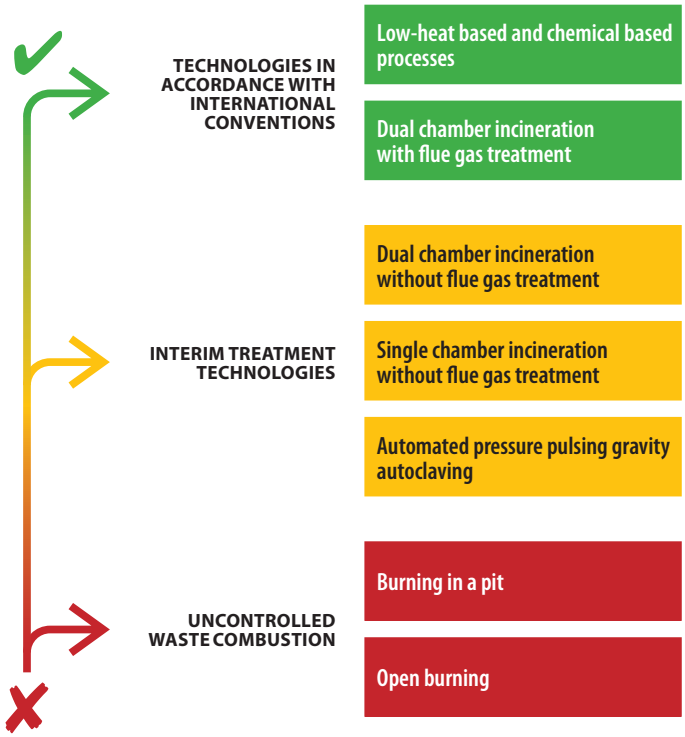
- Used vials of vaccine and unopened vaccine vials, which have expired or suffered heat exposure, should be put into a red bag or biohazard container.
- The containers should be sealed before transporting them to the final disposal site.
- Follow the national guidelines and local government code for final disposal.

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 away from the vaccination room to remove all used PPE.
- There are special procedures for removing PPE; consult MoH guidelines. After safely removing used PPE it should be put into a special waste container or bag.
- Follow the national guidelines and local government code for final disposal.
- Remember to wash your hands after taking off all PPE.

6.2 Overview of treatment options for infectious and sharp waste

- ☐ Plan for treatment and disposal of waste generated during the vaccine campaign at the beginning of the campaign planning.
- ☐ Consider the possibility of reverse logistics 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, such as decontamination of waste by autoclaving or similar procedures or high-temperature incineration.
  - In low-resource or emergency settings, transitional methods such as pit burning or open burning can be used BUT efforts should be made to incrementally improve health care waste management and engage in multisectoral efforts to strengthen systems change.



Further information:

- *Safe management of wastes from health-care activities* (WHO, 2014).
- *Overview of technologies for the treatment of infectious and sharp waste from health care facilities* (WHO, 2019).
- *Waste management during the COVID-19 pandemic: from response to recovery* (UNEP, 2020).

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;
- how the quantities removed from each vaccination site and transported to a treatment/disposal site are documented; and
- how quantities received and disposed at all treatment/disposal sites are validated and reported (see Annex 5 for examples of reported immunization waste forms).

7. Human resources

Refer to Section 9, Tools 10–12.

7.1 Goal and objectives

Due to high volumes of vaccines and ancillary products during COVID-19 vaccine 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 the availability of skilled and trained personal for the coming campaign activities; and
- ensure the health, 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 service;
- 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/aids 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 campaigns, warehousing, management of 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 supply and 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 and their administration; and**
- **handling and 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.

In planning 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 understanding and confidence; and
- keep training sessions short.

Training for managers should focus on:

- working within the country's CTWG to detect problems and resolve them quickly, and 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 MIS and making best decisions with the available information and time.

8. Country preparedness activities

Eight activities are defined, for which, indicators are proposed to measure country preparedness. The "G" numbering system refers to the COVID-19 Vaccine Introduction Readiness Assessment Tool (VIRAT) ().

Table 8.1 Preparedness indicators for vaccine cold chain and logistics

Number	Activity	Proposed timeline
G.1	Establish/strengthen the NLWG with appropriate terms of reference (TOR) and SOPs to coordinate COVID-19 vaccines and ancillary products deployment: a. There is a NLWG. b. The NLWG is functional, having appropriate TOR 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 human resource needs in supply chain management for the COVID-19 response are mapped out based on strategy, and roles and responsibilities are defined. c. Assessment needs are conducted for COVID-19 activities including human resource 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 °C to 8 °C, -20 °C, -70 °C +/-10 °C) and transportation capacity for vaccines and ancillary products: a. Landscape analysis completed, mapping out the existing government and private infrastructure regarding port of entry, primary and secondary storage facilities and transportation services. b. Clearly outlined strategy available for the COVID-19 response regarding port of entry, primary and secondary storage points and transport.	6–3 months prior to receiving vaccines
G.4	Assess storage and cold chain capacity at all levels with regard to the COVID-19 vaccine 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. Cold chain capacity expansion proposal submitted in response to gaps identified. d. Cold chain capacity expanded in response to the gaps identified. e. Functional equipment (%).	6–3 months prior to receiving vaccines
G.5	Establish contractual agreements to prepare for vaccine introduction, if appropriate: a. vaccine warehousing b. transport c. waste management d. cold chain capacity.	3 months prior to receiving vaccines
G.6	Provide SOPs for collection and disposal of medical waste to the relevant stakeholders: a. There is a plan to handle the waste generated by the COVID-19 vaccine response focusing on syringes, vials and PPE. b. There are SOPs for collection and disposal of the COVID-19 response wastes. c. The human resource needs for the COVID-19 response in the area of supply chain management are mapped out based on the strategy, and roles and responsibilities are defined. d. Assessment needs conducted for COVID-19 activities including human resource 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 has incorporated the new COVID-19 vaccines and their characteristics. b. All relevant SOPs 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 SOPs are available to ensure the safety and integrity of COVID-19 vaccines in the existing supply chain.	3 months prior to receiving vaccines

9. Country readiness tools

National and subnational 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 looks at: four critical functions (Section 9.1); country-focused decision/selection criteria (Section 9.2); and outlines recommended supply chain tools (Section 9.3).

For additional country and technical guidance relevant to COVID-19 activities, please go the WHO website on COVID-19 resources and guidance ().

9.1 Tools: critical functions

Available tools can provide benefits in the following areas:

1. **Overview and scope of the supply chain:** Broadly assess existing supply chains, understand national and subnational contexts and identify (at a high level) existing capacities and capabilities.

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

3. **Support effective vaccine deployment:** Facilitate vaccine storage, distribution and delivery "up to the last mile".

4. **Monitor and evaluate supply chain operations and performance:** 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 in recommending available tools for country use (see Annex 1: Tools decision matrix). Identify and analyse if the 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 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 the intended purpose.

3. **Uses readily available data:** 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

Tables 9.1–9.4 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 three or four (of four) decision criteria; and
- not recommended if it only meets one or two (of four) suggested criteria.

Annex 1 provides a comprehensive decision analysis matrix.

Table 9.1 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 Tool (VIRAT)	High-level readiness checklist for vaccine introduction, across different critical thematic areas.
	3. Immunization 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. Effective Vaccine Management [EVM])	Supply chain assessments (previous e.g. EVM) 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 9.2 Readiness analysis and needs identification tools

Tool functional area	Tools	Overview
Cold chain	8. Vaccine Volume, Forecasting and Cold Chain Gap Analysis Tool	Assessing vaccine volumes and corresponding CCE requirements per catchment area.
	3. Immunization Supply Chain Sizing Tool 2020	Assessing cold chain capacity, gaps 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 human resource 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) Toolkit	The Training Needs Assessment Toolkit provides a set of resources for country-driven and low-cost supply chain management training mapping, analysis and planning. It provides a systematic way to identify training needs based on defined supply chain management competencies within the public health system.
	12. Workforce Optimization Tool	Creating staffing scenarios (including optimization) using storage locations, demand data and distribution processes of products across the supply chain network.

Table 9.2 Readiness analysis and needs identification tools continued

Tool functional area	Tools	Overview
Data	13. Supply Chain Reporting in LMIS – DHIS	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 subnational stakeholders with understanding of trade-offs between different supply chain scenarios.
	15. Rapid Supply Chain Modelling 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/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 9.3 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	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 9.4 Supply chain operations monitoring and evaluation 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	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 1: Tools decision matrix

Overview and scoping

Scope	Tools	Decision criteria			
		Leverages (existing)	Non-duplicative use case	Data easy to collect	Simple to use/ deploy
Cold chain	1. Cold Chain Inventory	✔	✔	✔	✗
	2. Vaccine Introduction Readiness Assessment Tool (VIRAT)	✔	✔	✔	✔
	3. Immunization Supply Chain Sizing Tool 2020	✔	✔	✔	✔
Cross-cutting	4. Supply Chain Assessment Report (previous e.g. EVM)	✔	✔	✔	✔
	5. Supply Chain Maturity Model (adapted)	✔	✔	✔	✔
	6. Supply Chain Mapping Tools	✔	✔	✔	✔
	Prioritization of Supply Chain Performance Dimensions	✗	✔	✔	✗
	7. Pre-Service Delivery Checklist	✔	✔	✔	✔

Analyse readiness and identify needs

Scope	Tools	Decision criteria			
		Leverages (existing)	Non-duplicative use case	Data easy to collect	Simple to use/ deploy
Cold chain	8. Vaccine Volume, Forecasting and Cold Chain Gap Analysis Tool	✔	✔	✔	✗
	9. Cold Chain Deployment Plan	✔	✔	✔	✗
Human resources	10. Human Resources for Supply Chain Management Diagnostics	✔	✔	✔	✔
	11. Training Needs Assessment (TNA) Toolkit	✔	✔	✔	✔
	12. Workforce Optimization Tool	✔	✔	✔	✗
Data	13. Supply Chain Reporting in LMIS – DHIS	✔	✔	✔	✗
Distribution/ network	Last Mile Delivery Strategy	✗	✗	✔	✔
	14. Supply Chain Analysis and Intelligence Tool (SCANIT)	✔	✔	✔	✗
	15. Rapid Supply Chain Modelling Tool	✔	✔	✔	✗
	16. Route Optimization Tool (RoOT)	✔	✔	✔	✗
Cross-cutting	17. Outsourcing Toolkit/Private Sector Needs Assessment Tool	✔	✔	✔	✗
	18. Vaccine Management and Logistics Support Tool	✔	✔	✔	✗

Support vaccine deployment

Scope	Tools	Decision criteria			
		Leverages (existing)	Non-duplicative use case	Data easy to collect	Simple to use/ deploy
Cross-cutting	21. Service Delivery Checklist	✔	✔	✔	✔
	18. Vaccine Management and Logistics Support Tool	✔	✔	✔	✗
Data	19. Track and Trace Tool	✔	✔	✔	✗
	13. Supply Chain Reporting in LMIS – DHIS	✔	✔	✔	✗
Waste management	20. Appropriate Disposal of Immunization Waste	✔	✔	✗	✔

Monitor and evaluate supply chain operations and performance

Scope	Tools	Decision criteria			
		Leverages (existing)	Non-duplicative use case	Data easy to collect	Simple to use/ deploy
Cross-cutting	22. Post-Service Delivery Checklist	✔	✔	✔	✔
Data	19. Track and Trace Tool	✔	✔	✔	✗
	13. Supply Chain Reporting in LMIS – DHIS	✔	✔	✗	✗
Waste management	20. Appropriate Disposal of Immunization Waste	✔	✔	✗	✔

Annex 2: Guidance on UCC use for deployment of COVID-19 vaccines

Countries receiving vaccines requiring UCC should adjust their plan to ensure vaccines are safely stored and transported. The deployment of UCC equipment will require the following:

- installation of ULT freezers with robust and reliable electric power source for storing vaccine and producing phase change material (PCM) packs or dry ice supply;
- specialized technical assistance to manage UCC, with development of relevant SOPs and adequate training of responsible staff; and
- provision and management of PPE (e.g. cryogenic/insulated gloves and eye shield/goggles) for staff responsible for managing UCC system.

Brief description of the technology

There are two categories of ULT cold chain equipment:

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

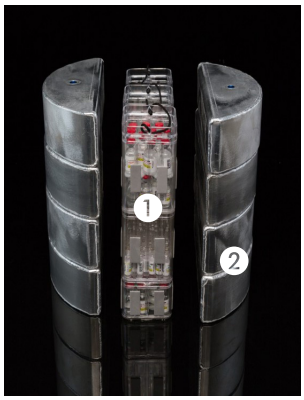
Fig. A2.1 ULT freezer

- Two ULT freezers would be necessary: one to store vaccines and another to freeze and store the PCM at -80ºC.
- 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 equipment (ULT insulated containers)
There are two types of passive equipment recommended for transporting and storing ULT vaccines at facility level. When selecting which passive container to use, consider the storage temperature and duration of storage.

Arktek: The Arktek (YBC-5) is a super-insulated, double-walled large bottle-like container that uses multi-layer insulation technology and eight PCM packs (1 L each) to keep vaccines at ULTs (-80 ºC to -60 ºC) in remote storage and vaccination sites for up to 5 days without any powered refrigeration or extra coolant. It comes with a vial rack system and has a storage capacity of 7.9 L. Each unit is built to withstand a lot of use in the field; and each one is equipped with a built-in temperature data logger capable of monitoring and reporting ULTs. The special PCM used as coolant for the Arktek has to go through a process of conditioning to be able to maintain ULT.

Fig. A2.2 Arktek

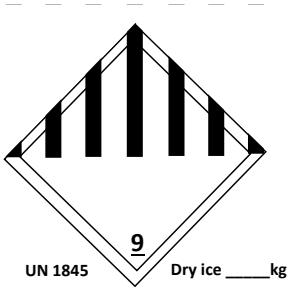


Arktek parts:

1. Vaccine rack
2. ULT PCM metal packs

Thermal shippers: Thermal shippers are used by manufacturers to ship vaccines. Like the Arktek, they do not need an external power supply but instead use a combination of insulation technology and coolants (for example, dry ice) to keep vaccines at ULTs (-80 °C to -60 °C) over the short term. They also typically have an impact-resistant outer layer for durability in the field. Thermal shippers come in a range of sizes: the manufacturer's information will give the precise storage capacity of any individual product.

Fig. A2.3 United Nations identifier for dry ice (UN 1845)



Use only thermal shipper labelled for dangerous goods/dry ice use, e.g. with "UN 1845" marking.

When fully loaded with dry ice and opened only twice a day for less than 5 minutes per opening, the thermal shipper can maintain ULT conditions for at least 5 days, depending on the ambient temperature. With frequent opening, this cold life will drop to a few hours. Thermal shippers should never be depleted of dry ice when used as vaccine storage. This means checking the level of dry ice regularly and refilling as necessary. Note that you will need to secure a consistent supply of dry ice when using thermal shippers, for example, through advance orders from a reliable local supplier.

Thermal shippers can also be reused for longer than 5 days if the dry ice is regularly replenished and there are no signs of wear and tear.

Fig. A2.4 Thermal shippers[1] for dry ice

Coolant/freezing materials for UCC

There are two primary coolant materials that can be used with the passive containers to maintain the vaccine at ULT.

Special ULT PCM: Special PCMs are used for passive freezing when transporting and temporarily storing vaccines in ULT 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 ULT 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 -80 °C to -60 °C.

Fig. A2.5 Liquid ULT PCM and PCM container for Arktek

The PCM liquid should be checked prior to filling the PCM accumulator. PCM liquid should be of appropriate quality, such as PlusICE E-78.

PlusICE E-78 contains solid nucleating agent, without which the liquid will supercool substantially and will not freeze even when cooled below -90 °C. If transferring from this container into multiple smaller containers, ensure that nucleating agent is present in all containers and is evenly distributed.

[1] WHO PQS E003/POW 01.0, provides detailed specifications for ULT freezers' freezing system.

Dry ice: Dry ice or frozen carbon dioxide (CO_2) has a phase change temperature of -78 °C and can also maintain vaccine storage temperature less than -60 °C. Dry ice can either be produced with a dry ice machine or procured from local suppliers. Dry ice is recommended for use with thermal shippers since its phase change takes longer than PCM.

Dry ice and special ULT PCMs are used for UCC equipment as coolant/freezing packs.

Fig. A2.6 Dry ice

Table A2.1 Characteristics of different coolants

Characteristics	Coolant	
	Special ULT PCMs	Dry ice
Phase change temperature	-78 °C to -65 °C	-78.5 °C
Latent heat of phase change	172-115 kJ/kg (e.g. for PlusICE E-60 to E-78)	571 kJ/kg
Personal protective equipment	Eye shield/goggles, cryogenic/insulated gloves	Eye shield/goggles, cryogenic/insulated gloves
Method of preparation	Fill cooling packs, pre-freeze (at -20 °C) then complete freezing (at -80 °C) for at least 24 hours	Produce it using small units; or procure it from local sources
Uses	Packing vaccines for transport and temporary storage	Packing vaccines for transport and temporary storage
Relevant container	Arktek	Thermal shipper/Arktek
Safety consideration	Avoid direct contact with eyes/skin to prevent irritation	Work in open, well-ventilated area to prevent risk of suffocation from carbon dioxide emission

The instructions for using dry ice with thermal shippers and ULT PCM with Arktek can be found here ( ).

Types of ULT equipment based on store level

Central storage:

- large ULT -86 °C freezers (500–1000 L, up to 30 000 vials loading capacity), used as main storage; and
- small ULT -86 °C freezers (70–200 L, up to 9000 vials loading capacity), used as backup and for freezing and storing PCM packs at -80 °C.

Subnational storage:

- small ULT -86 °C freezers.

Remote storage:

- Arktek with ULT PCM or dry ice
- thermal shipper with dry ice (e.g. normally used by manufacturers for international vaccine shipment).

For the purpose of sizing, keep in mind that when using ULT freezers, only about 50% of the storage capacity is used. Therefore, for a ULT freezer of 700 L, only about 350 L would be used.

Options for packing, transporting and storing vaccines

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.

From storage to vaccination site:

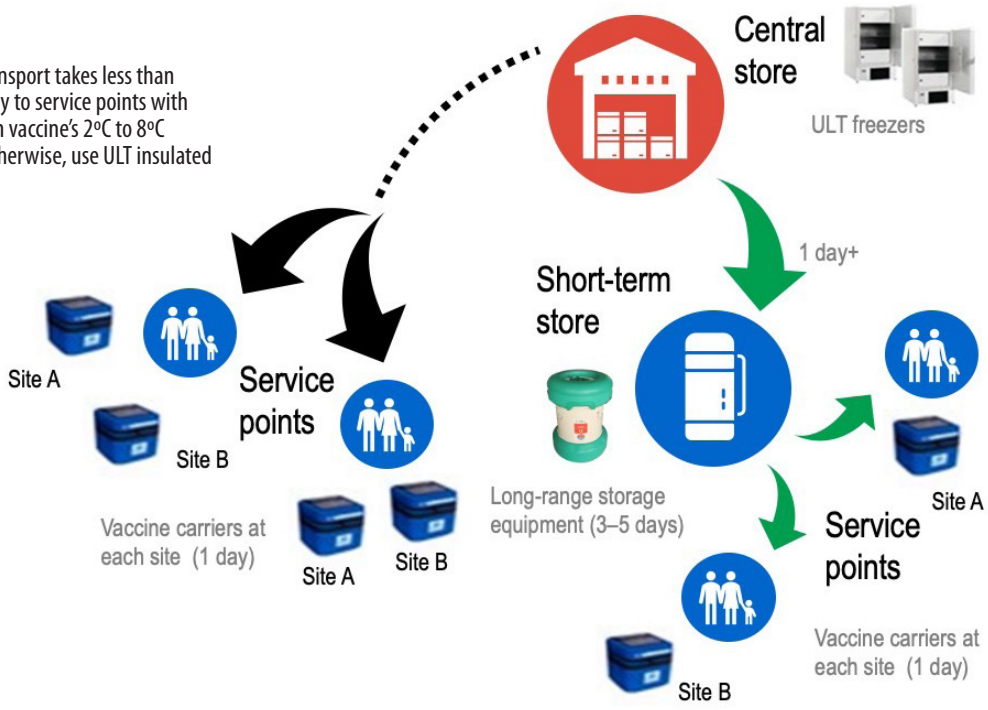
- using high-density vaccine carriers with water/ice packs to transport unfrozen vaccine at 2 °C to 8 °C for immediate use at session;
- using special long-range cold storage device (Arktek) with frozen PCM (-80 °C);
- packs or dry ice or thermal shipper packed with dry ice to transport and store frozen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

UCC equipment deployment options based on travel distance from central store

Option 1: Districts ≤ 1-day travel distance from central store

If central to district transport takes less than 1 day, transport directly to service points with vaccine carriers (within vaccine's 2ºC to 8ºC storage time limit). Otherwise, use ULT insulated containers.

● Passive devices



Strong central team to:
- manage central store and dispatch;
- manage PCM packs freezing and dispatch.

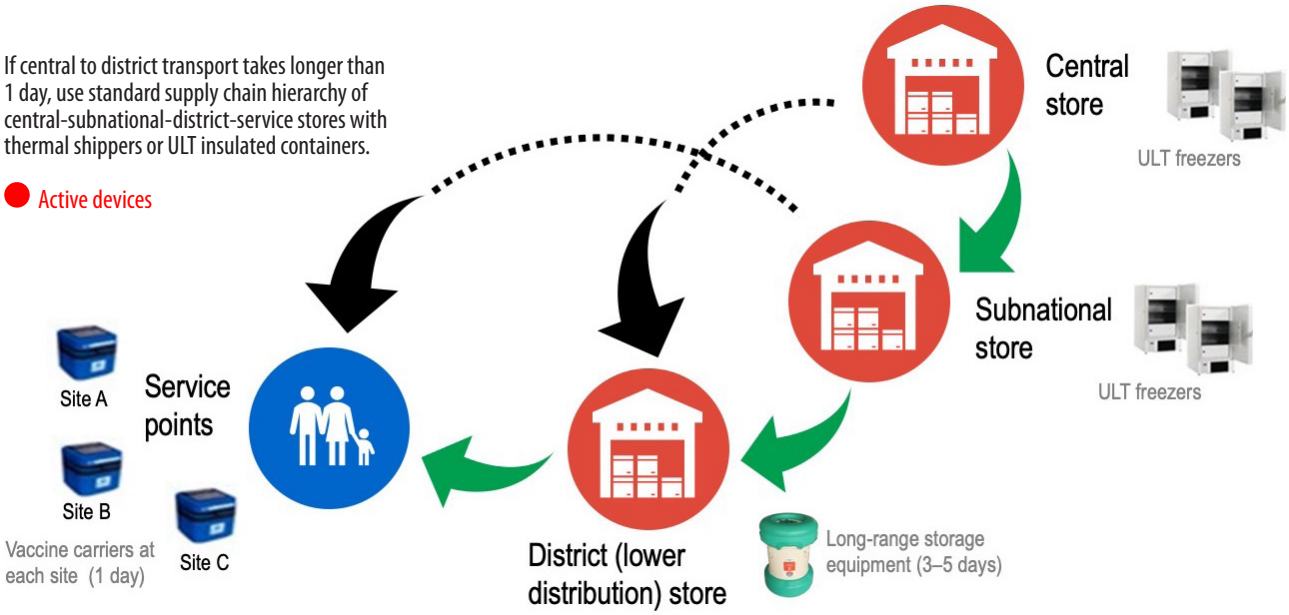
Team composition:
- two assistants (one for vaccines and one for PCM freezing).

UCC estimation:
- two Arktek per district;
- ULT freezers as per vaccine volume;
- standard vaccine carriers to be used.

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

If central to district transport takes longer than 1 day, use standard supply chain hierarchy of central-subnational-district-service stores with thermal shippers or ULT insulated containers.

● Active devices



UCC hub team to:
- manage central store and dispatch;
- manage PCM packs freezing and dispatch.

Team composition:
- cold chain technician;
- two assistants (one for vaccines and one for PCM freezing).

UCC estimation:
- two Arktek per district;
- ULT freezers as per vaccine volume;
- standard vaccine carriers to be used.

Recommended set-up of ULT at vaccine storage hub

- ☐ ULT freezers with large storage capacity for:
  - storing vaccines;
  - freezing PCM packs to be loaded in Arktek for transportation; and
  - holding dry ice stock for repacking vaccine in thermal shipper for transportation to districts.

- ☐ 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 ULT. When cleaning the equipment a face/eye shield is needed as additional PPE.

- ☐ Continuous and quality electricity supply with secured backup generator.

- ☐ Both container devices can be used as backup options for district storage if needed; several thermal shippers should be procured as backup options.

- ☐ Note that dry ice may not be available in all contexts; production can be organized using small dry ice units procured by the programme although their management may require additional training.

Table A2.2 Options for transporting vaccine to district level

Choice of container	Choice of coolant	Description	Requirements
Arktek long-duration passive ultra cooler	Special ULT PCM	• Durable material, with vial rack system. • Arktek is designed for use with PCM packs. • Large capacity range: 7.9 L. • Weight fully loaded: 39.5 kg. • Weight empty: 22 kg. • Number of required PCM accumulators: 8. • Diameter: 52.8 x 74.7 cm. • With built-in temperature SMS data logger. • Cold life: -80° to -60 °C when used with ULT PCM (frozen at -80°C) lasts for 5 days without PCM replacement with multiple opening. • Remaining PCM can be reused.	• Initial high investment cost (US$ 5000 each). • Relatively bulky and not transport ergonomic. • When used with PCM: – each Arktek requires total of 16 metal PCM packs to prepare for ULT storage – two-stage freezing requirement to condition PCM to -80 °C – separate ULT freezer for freezing and storing PCM – PCM for ULT is corrosive to plastic material: only metal/aluminum PCM packs can be used for ULT – training on proper handling and management.
Other commercial thermal shippers	Dry ice only	• Use only thermal shipper labelled for dangerous goods/dry ice use, e.g. with "UN 1845" (dry ice) marking. • Some products may come with built-in temperature data logger and vial rack system. If none, vial rack and data logger should be procured separately and provided per shipper during transport. • Large capacity range: product-specific. • Although the cold life at -80 ° to -60 °C is product-specific, it can be extended with re-icing.	• Ensure enough quantity is available for vaccine storage and transport. • Can be reused with proper care. • Only use this for ULT storage and with dry ice; not to be used for other forms of storage. • Per IATA guidelines, 200 kg is the maximum dry ice load allowed for cargo for UN 1845 (dry ice). • Continuous supply of dry ice: – procuring dry ice machine, or – commissioning a local supplier. • Training on proper handling and management.

Main challenges of ULT cold chain

- Needs SOP and staff training.

- ULT freezers:
  - stringent operating conditions (controlled ambient temperature of < 27 °C and humidity 50%);
  - large consumers of energy (a 700 L ULT freezer consumes as much as a 20 m^3 WICR);
  - reliable power supply;
  - suggested cold life: 48 hours (product-specific).

- Transport at -70 °C +/-10 °C:
  - specific coolant packs using PCM with phase change temperature around -70 °C +/-10 °C and good and stable thermal characteristics (latent and sensible heats);
  - secured and reliable supply of dry ice; and
  - new generation insulated containers (thermal shippers, Arktek).

- Managing the storage at session to minimize wastage.

Annex 3: Country readiness self-assessment checklist

This is a useful checklist to get prepared for your allocation request or to request 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 NLWG.		
2	Summary of procurement and donation mechanisms for vaccine and other ancillary supplies, including PPE 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 fallback facilities (categorized at 2 °C to 8 °C; -20 °C; -70 °C +/-10 °C 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 of the vaccine characteristics.		
6	Description of estimating cold chain and dry store capacity requirements, issues, challenges and solutions.		
7	Summary of requirements to support deployment and vaccination of target groups at different administrative levels prepared.		
8	Cold chain strategy based on the different types of potential vaccines (mapping of in-country 2 °C to 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.		

No.	Activity	Ready Yes or No	Comments
Biohazard and immunization waste management			
15	Description of estimation of volume of waste, including used PPE, according to type and by areas/zones.		
16	Summary of procedures to manage, process and dispose waste 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 4: Vaccine accountability monitoring reporting form

Instruction guide

1. This form should be filled in 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 reported immediately.

4. District supervisors should sample at least 30% of subdistrict 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 no.:	Starting date:	End date: .....
Name of subdistrict level:	District:	
Name of province:	No. of children immunized:	
No. of vial used:	No. of vial unused:	

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

Form 2: Subnational/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 subdistrict sites verified	# of sites visited where any vials were found	# of vials found .....
Remarks						

Annex 5: Reported immunization waste forms

Form 1: Example immunization waste transfer form

TRANSFER SHEET FOR SAFETY BOXES AND VIALS									
1	**ORIGIN**	Number of safety boxes	Number of safety vials	**TRANSPORT**	Number of safety boxes	Number of safety vials	**DESTINATION**	Number of safety boxes	Number of safety vials
	Region:			Means of transport:			Central:		
	District:						Region:		
	Health centre:						District:		
							Health centre:		
	Sending date (day/month/year):			Transportation date (day/month/year):			Date of receipt (day/month/year):		
2	Comments			Comments			Comments		
3	Name, signature of sender			Name, signature of carrier			Name, signature of receiver		

Form 2: Example immunization waste treatment and disposal form

TREATMENT/DISPOSAL REPORT

Date of treatment/disposal (day/month/year)**:** .....

Reference site: .....

TREATMENT AND DISPOSAL METHODS

Treatment	✔	Disposal	✔
Autoclaving		Recycling	
Incineration		Encapsulation	
Chemical sterilization		Burying/landfilling	
Boiling		Other (specify)	
Other (specify)			

NUMBER OF SAFETY BOXES 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 FOR THE TREATMENT AND DISPOSAL

Name	Signature

World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland
www.who.int