

ULTRA-LOW TEMPERATURE FREEZERS: KEY CONSIDERATIONS FOR COVID-19 VACCINES: **SUPPLEMENT**

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Many cold chain issues occur in the “last mile/kilometre” of vaccine distribution, with samples lost due to improperly handled freezers. ISBER, the International Society for Biological and Environmental Repositories, offers our shared expertise in cold chain management to educate new users of ultralow temperature (ULT) -70°C freezers as part of COVID-19 vaccine distribution programs.

For more information on the Best Practices referenced here visit
(or scan QR Code): isber.org/page/BPR



PURPOSE

This document is intended to provide guidance managing the deployment of frozen COVID-19 vaccines. It is not designed to be a comprehensive series of instructions on cold chain management. Rather this is designed to be a guide to the considerations that need to be addressed by managers wishing to set up a robust system for the SARS-CoV-2 vaccine deployment.

BACKGROUND

With the urgent global need for SARS-CoV-2 vaccines, pharmaceutical manufacturers, third-party logistics providers and healthcare systems are addressing significant challenges that threaten widespread vaccine distribution and availability. Whilst the vaccine developers and public health authorities are seeking the rapid deployment of as many doses throughout a population as possible, the logistics of distribution are, in many cases, not well defined, nor do they appear to be a requirement for vaccine use approval.¹

The UK's NHS (National Health Service) SOP for COVID19 vaccine deployment in community settings, dated December 18 2020 (p7, 38, 39) states;

"Vaccines must be transported only in approved and validated cool boxes, and the temperature of the cool box and contents must be monitored and reviewed before use. Means of detecting when a temperature excursion has occurred are required and that any 'out of specification' recordings are addressed promptly and appropriately, and that a full audit trail is maintained."

The following documents detail examples of cold chain actions from the point of receipt of vaccines at the deployment centers.

- The NHS Specialist Pharmacy Services exemplar document for vaccine cold chain management.²
- Delivering Pandemic Resilience: How to secure stable supply chains for vaccines and medical goods during the COVID-19 crisis and future health emergencies³

According to the World Health Organization, more than 50% of vaccines may be wasted every year because of

temperature control, logistics and shipment-related issues. Loss of cold chain security through mismanagement of freezers leading to breaks in the cold chain create short term chaos⁴ reduction in clinical efficacy and public health benefit as well as long term financial losses⁵. ULT cold chain logistics requirements cause considerable issues for health authorities to negotiate, especially the use of ULT freezers. These issues may be even greater for the local family doctor or remote clinic outpost.

Distribution of vaccines in the current situation requires a different viewpoint from the normal (prior) considerations when examining ideal storage modality. Under normal circumstances we consider temperature requirements, availability of refrigerant or power for refrigeration, long term storage capacity requirements, transaction types and quality criteria. In a simple single delivery with a well defined cold chain, many of these requirements are less significant. The extent of the current global deployment required has placed additional consideration of cold chain logistics that are only now becoming apparent. The necessary requirements at multiple smaller and often remote locations that must be deployable rapidly must occur without the need for complex installation of special freezer storage or local infrastructure.

With the leading SARS-CoV-2 vaccines requiring storage in -80°C and -20°C temperature conditions, "last mile"⁶ vaccine distribution gets even more daunting as regional/local levels of government, healthcare and pharmacy systems are responsible for planning. The ability to replenish refrigerants like dry ice and liquid nitrogen during vaccine transport by courier or a transport company in an efficient manner may not be feasible in local and remote settings, becoming a rate-limiting step in the successful deployment of the vaccine, especially as supply and demand needs increase over time. Those that warehouse the vaccines will need to either maintain multiple models of freezers to accommodate the current and potential future vaccine requirements or find a solution that will provide safe storage

1 <https://www1.racgp.org.au/newsgp/clinical/tip-of-the-cold-chain-iceberg-vaccines-worth-26-mi>

2 <https://www.sps.nhs.uk/home/covid-19-vaccines/pfizer-biontech-vaccine/pfizer-biontech-handling-in-trusts>

3 <https://www.dhl.com/au-en/home/insights-and-innovation/thought-leadership/white-papers/delivering-pandemic-resilience.html>

4 <https://www.cnn.com/2021/01/06/us/california-broken-freezer-vaccines-trnd/index.html>

5 <https://www.abc.net.au/news/health/2020-12-04/uk-coronavirus-rollout:-what-does-it-mean-for-australia/12946414>

6 "Last mile" is a general term used within the cold chain space to indicate the connection from a regional repository to the end patient recipient.

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for a large range of temperature requirements. Meanwhile the demand for stand-alone ULT freezers has significantly increased lead times from an average 4 weeks to as long as 16-18 weeks, which creates issues for many local areas in gaining the necessary equipment to do the job. The ideal solution for storing vaccines at the local areas may not be available because of long lead times.

Consistency in storage is key. One of the key drivers associated with ULT freezer logistics and distribution will be related to the recently released ISO-21973 (*Biotechnology — General requirements for transportation of cells for therapeutic use*). It includes recommendations around management of equipment being utilized for the SARS-CoV-2 vaccine distribution. Vaccine preparedness teams across the globe are now finding themselves urgently planning the provision of ULT equipment and dry ice services, sometimes with limited experience and guidance to support their efforts.

The **International Society for Biological and Environmental Repositories (ISBER)**, represents professional experts in the distribution of biological material. ISBER is dedicated to the creation and promulgation of international best practices and standards in biobanking, including establishing cold chain security for biospecimens and therapeutics. This document just released draws on accepted practices known to ensure robust ULT product storage and distribution that are routinely used by biorepositories. The document represents a consensus view from the biobanking community. The organization drew on the expertise of biorepository managers and industry vendors to draft a position statement intends to supplement guidance from national and local health agencies on managing the cold chain deployment of frozen COVID-19 vaccines.

The Best Practices below are only selected examples relevant to the consideration being described. At no point is this considered a comprehensive list but merely an extraction from our more thorough **ISBER Best Practices: Recommendation for Repositories 4th Edition** which should be considered the source material ⁷.



STAFF TRAINING IS CRITICAL

❄️ Provide all vaccination staff with proper training in cold chain supply, freezer operations and frozen sample handling.

According to the CDC's Vaccine Storage and Handling Toolkit⁸;

"Vaccine storage and handling practices are only as effective as the staff that implements them. Staff that is well-trained in general storage and handling principles and organization-specific storage and handling standard operating procedures (SOPs) is critical to ensuring vaccine supply potency and patient safety."

It needs to be recognized that large hubs will have more capable and trained staff. Yet, the further from resourceful hubs, into regional, local and even more remote areas, it will be less likely that administrators will have access to trained, experienced specialists who understand cold chain management. Furthermore, knowledge of the science behind vaccine storage requirements (i.e., cryobiology) will strengthen practices at all levels. Hence, consistent messaging through education and training must be made available. The most effective manner for this may be through online education and on demand webinars. ISBER, as experts in cold chain logistics for biospecimens and therapeutics has such educational resources available.

7 <https://www.isber.org/page/BPR>

8 <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

ISBER Best Practices: C12.3 Equipment Maintenance and Repair; G. Training

Properly trained personnel with expertise in monitoring and repairing repository equipment (especially freezers and refrigerators) should be used for regular and emergency repairs.

These trained technicians may be on the repository staff, may be on staff within the larger organization within the institution in which the repository resides, may be available through a “fee for service” arrangement with a commercial entity with this expertise, or repair services may be obtained from a similar entity on a retainer basis.

*Training Resources available at:
isber.org/page/webinars-on-demand*

facilities and pharmacies are choosing to choose non-traditional ULT freezer appliances with highly compact designs for remote, portable and even mobile use. Larger freezer units take longer to recover temperature after door openings.

Portability: Can it be repurposed after the vaccination program is complete. Can the system be easily relocated? Is it mobile?

Suppliers and Support: Is the system/supplier/service provider dependable? What is the currency, frequency of delivery and installation time? Can regular maintenance be easily performed in order to maintain the system’s peak performance? What happens if there is a problem with the system? How easy is the system of use and does it require minimal staff training.

Monitoring: Are 24/7 monitoring and alarm systems available? Will trained personnel be available to respond at all times? Can the monitoring system be tampered with? How simple is it to create an audit trail of freezer stocks (e.g. biospecimens, vaccine doses)? Are service agreements available for both freezer and monitoring system and do they provide immediate coverage.

- ❄️ **Choose freezers with the widest temperature range to accommodate multiple vaccine candidates and choose the smallest freezer required.**

Consider preparing for the range of temperatures at which multiple COVID-19 vaccine candidates must be stored. Not being able to meet the storage requirements of any one of the approved vaccines will limit vaccine administration options at the point of patient care, especially considering multi-dose patient requirements. Aim to cover all the options by choosing ULT freezers with the widest temperature set-point range to optimize ultra cold storage for all vaccine candidates.

Freezer should be capable of storing multiple types of packaging formats. Note that whilst typical reference size for storage boxes are 10X10 cryoboxes, the Pfizer vaccines come



ULT FREEZER SELECTION MUST MEET LOCAL REQUIREMENTS

- ❄️ **DO NOT use frost-free freezers as they use a warming cycle and lead to regular temperature excursions.**

When selecting an ultra-low temperature (ULT) storage system, it’s important to consider the following:

Temperature Settings: Most mechanical cold chain equipment can handle one temperature only. Is the internal storage temperature flexible? Hold time at designated temperature especially during peak times when open and closure may be more frequent.

Freezer Size: What is the system’s capacity and throughput? Is the system modular? Can it be expanded if necessary? What is the system footprint considering peripherals? For this vaccine deployment health care

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in “pizza boxes” which is preferred but will limit the cold chain equipment. Minimum freezer opening (neck size) is estimated as 24” for storage of these large delivery boxes which is estimated to comfortably store 5-7 of the Pfizer shipment boxes.

Confirm the power configuration available in your lab prior to purchase, especially in areas with low-grade power supply.

What are the voltage (e.g., 120v or 220/208v) and amperage (e.g., 10, 15, 20amps) requirements? ULT freezers typically plug into high-voltage power outlets with multiple power supply requirements when deploying units in various regions of the world. Organizations can avoid building power modification delays and careful planning of ULT freezer power options to meet regional standards, by installing ULTs with a wide voltage range and universal power built in.

To address environmental concerns, energy-star rated ULT freezers are available and recommended. ULT freezers utilizing natural, eco-friendly refrigerants are available and recommended.

Have a dedicated backup power system in place in case of power outage.

Ensure ULT freezer outlets are on an emergency circuit powered by a generator preferably with an uninterrupted power supply (UPS) to provide short term power during the power correction that would occur in the event of a power interruption. Emergency backup systems that automatically cool their contents with LN₂ or liquid CO₂ should be considered.

Install an independent internal thermometer sensor to log/alert against temperature fluctuations. Ensure internet or Wi-Fi access and send alerts to multiple staff.

Temperature monitoring and data logging must be recordable and/or transmittable quality so as to be able to regularly report data to ensure compliance with required conditions and thus efficacy of vaccine.

It is strongly recommended to install an independent alarm

monitoring system on any ULT unit. This is additional to the freezer’s original system and acts as an independent monitoring system that can be programmed to alert staff with enough time to resolve the problem and protect the integrity of the stored product. The optimal number, type and location of temperature probes used for freezer monitoring should be considered and should come with a Certificate of Calibration.

ISBER Best Practices: C.1 Storage and Processing Equipment; C.3. Mechanical Freezers; B.5. Backup Power

Temperature mapping should be performed to document and control the temperature distribution within a storage area upon installation and periodically at defined intervals.

Adequate airflow around freezers and refrigerators will decrease the risk of overheating of compressors, shortening compressor life, and decrease growth of mold and other harmful microbial contamination situations.

Heating, Ventilation, Air Conditioning (HVAC) systems are more efficient than simple ventilation systems at maintaining temperatures and humidity.

Repositories should be aware of the location of their building generators and confirm that they are on the backup system. Repositories should be aware of the location of their building generators and confirm that they are on the backup system.



**ULT FREEZER INSTALLATION
REQUIRES A SPECIFIC STORAGE
AREA**

Be aware of facility infrastructure obstacles such as floor space constraints, high energy draws, power distribution, and limited Heating Ventilation and Air Conditioning (HVAC)

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capacity when quickly ramping up ultra-low freezer capacity. This can be mitigated by selecting ULT models with higher storage density that require less space, energy and infrastructure to operate over a wider range of ambient conditions and voltages.

- ❄️ **Each freezer requires an independent circuit. Ensure outlets are on an emergency circuit with built-in redundancy.**

If two units are plugged into the same outlet it is likely you could trip the breaker and impact both units. While not an issue in many regions, local facilities within rural and developing economies may contend with low-grade power. In this scenario, special power conditioners may be required for ULT operation.

- ❄️ **Ensure room where freezer will be housed can handle additional heat load. ULT units will increase humidity and temperature.**

All ULT units, even the more energy efficient units, have significant heat rejection. Many ULT models produce excessive heat as a by-product of ULT production. The more ULTs running in a facility, such as a biobank in a central warehouse, the more heat that builds up within the building interior. These rising ambient temperatures can have significant impact on ULT performance, reliability and efficiency. This may cause HVAC systems to work harder, especially in warmer climates and seasons, leading to increased strain on building systems, higher energy costs and can even lead to freezer failures. If the HVAC of the room was already at capacity, adding a new ULT unit may overload the system. ULT freezers need to have a low ambient environment, preferably around 22°C. A warmer room will negatively affect the recovery rate of the unit and potentially cause restriction or oil logging issues.

- ❄️ **ULT freezers need to pull air in and exhaust without restriction. Check clearance requirements outlined by each manufacturer before purchase.**

Confirm the placement of the unit meets the clearance requirements outlined by each manufacturer in the operator's manual. This is especially important on the front and back

of units. ULT freezers need to pull air in and exhaust without restriction. A ULT freezer placed directly against a wall cannot exhaust and will recirculate on itself and cause the unit to overheat. Care should be taken to ensure the ULT freezer is not placed directly under an HVAC supply register as it would blow air into the unit during door openings. Do not place the unit in direct sunlight, especially afternoon sun.

ISBER Best Practices B. Facilities

An efficient repository has many particular location and design elements to ensure the safe-keeping of the material stored, support the equipment employed, and provide a safe and effective working environment for the repository staff.

In planning the design of a repository, it is necessary to know the types of material being stored, the required storage and handling conditions, the projected retention periods, projected growth of the specimen numbers, and the projected use of the materials.

The design should include sufficient space to accommodate the material planned for initial, future, and backup storage and also provide for the safe movement of people, equipment, and specimens, as needed, or as required by law and/or other regulatory agencies.



**ULT FREEZER OPERATION
AND MAINTENANCE MUST BE
COORDINATED**

- ❄️ **Access to vaccines needs a strict procedure for how staff will manage door openings. Aim for few and short door openings to avoid freezer temperature fluctuations. Allow the freezer to return to set temperature.**

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Limit door openings and minimize the length of time for each opening. ULT units are not designed for continuous door openings and need time to recover after each opening. Utilize the interior doors/sub doors for the ULT freezer. This will allow for greater temperature control for the products stored behind the closed inner doors. The use of small portable ultra low temperature containers for transient storage of vaccine doses may also need to be considered in the daily work flow.

When loading a ULT unit it is recommended by most manufacturers to load one shelf at a time. Load the top shelf then close the door and allow the temperature to recover. Then continue with the subsequent shelves.

❄️ Avoid an empty unit. If you do not have product to fill the unit, consider adding empty aluminum racks to fill it.

Create a digitized audit trail of content entry and withdrawal.

❄️ Regularly clean the condenser and gaskets to prevent ice formation, especially around doors.

The condenser is how the unit removes the heat from the cabinet. If condenser is dirty or blocked it can cause the refrigeration to run warm and cause a restriction or oil logging and shorten the life of the compressor.

Given the extreme temperature of ULT freezers they often form ice on the gasket and around doors. If not regularly cleared it can prohibit the door from closing properly and allow outside air to infiltrate into the cabinet. Ice can also lead to damage to the door latch and door alignment. It is inevitable that the walls inside of a ULT freezer will accumulate ice/frost over time. Some manufacturers recommend defrosting a ULT freezer yearly, although this is not always feasible in most applications. However, if a unit has excessive ice buildup on the interior walls beyond ½" it will directly affect temperature uniformity throughout the unit. In some cases, this can create a 10°C difference between the top and the bottom of the ULT freezer.

❄️ Ensure ULT freezers are calibrated for accuracy of temperature display.

It is not uncommon for the temperature sensor and electronics to drift over time.

ULT units are designed to maintain temperature. They are not intended to cool material down to -80°C. It is preferable that material placed inside a ULT unit is already at -80°C.

To ensure accurate temperature monitoring, test audible and visual alarm functionality regularly. Alarm battery should be checked regularly and replaced approximately every 2 years.

Compressor amp draw should be checked during each preventive maintenance inspection. The amp draw can provide insight as to how hard a compressor is working and can indicate the potential for unit failure.

ISBER Best Practices: C.12 Equipment Maintenance

A system for preventative maintenance and repair of storage equipment, supporting systems, and facilities should be in place. System maintenance should be performed at regular, established intervals per manufacturer's recommendation and as determined as fit for purpose aligned with the repository's practices.

Freezer and refrigerator units should be qualified prior to and periodically during use by performing temperature mapping with multiple thermocouples placed throughout the storage unit to evaluate consistency of temperature.

This temperature profile should be performed prior to its initial use so that warm and cold spots that could be problematic for material storage can be identified.



ULT FREEZER EMERGENCY PLANNING

❄️ Draft an emergency plan in case of freezer failure, power outage, natural disaster, and other common hazards.

Emergencies can cover a wide range of natural and man-made disasters, all of which may have varying effects on the facility and on the ability of the repository to carry out its essential functions. The type and duration of disasters may depend on the geographic location at which the repository is located. Emergency plans should consider scenarios including alternative storage facilities if the primary freezer fails, building access for out-of-hours emergencies, packing of vaccine for rapid transfer to new storage unit and how a freezer temperature will be monitored during a power outage.

❄️ Have a written procedure for transferring specimens to alternative storage (e.g. dry ice).

We see the lack of preventative maintenance programs for ULT's and LN2 cold chain equipment as the primary reason for issues/failures. Ensure there is available space for alternative storage. This includes dedicated empty freezer space maintained at operating temperature.

ISBER Best Practices: B.8 Emergency Preparedness

Repositories should have a written procedure for transferring specimens from a failed or malfunctioning unit (one that has exceeded or is on the verge of exceeding its acceptable operating temperature range or become over-filled) and for the return of the specimens to their original location once it is considered safe to do so.

The procedure should include the freezer or refrigerator name or number as well as the location within the freezer where the specimens have been relocated. Repositories should have backup power and/or alternate cooling systems in place, as well as an emergency response plan.

Systems should be equipped with redundant compressors that operate under an electrical alternating control system.

To prepare for the possibility of freezer contamination by blood or other fluids, decontamination equipment and procedures should be available in advance.



SHIPPING & LOGISTICS: DRY ICE AND LIQUID NITROGEN (LN2) LOGISTICS

Regional/local leaders are being challenged to get vaccines from central repositories to remote or immobile communities like extended care facilities, nursing homes, and rural populations, without breaking the ULT cold chain. This is where traditional ULT freezers are too bulky, heavy and generally impractical.

While the use of dry ice cooling may be considered by some to be an option here, it continues to be in short supply and requires PPE and training for safe handling. Also, an average dry ice block has a life span of only 18-24 hours. Especially considering multi-week, multi-dose inoculation requirements, dry ice cannot provide long-term, reliable protection of vaccine dose efficacy.

With the limited availability, life span and temperature control of dry ice cooling methods, best practices for rapid and remote deployment of ULT storage will become increasingly critical for regional/local delivery of safe and effective COVID-19 vaccines to the public.

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❄️ Purpose

Dry ice can be used to keep the vaccines cold longer. Dry ice can have longer hold times if it is saturated in LN₂, done in vapor phase not liquid phase. For expeditious execution of a vaccine program, even large facilities could utilize small liquid nitrogen dewars that could be easily delivered by gas suppliers.

❄️ Supply

Dry ice availability at the Hub site, but also at the delivery site, is very important. Many observers predict a shortage of dry ice world-wide, which is needed to fill/refill the shipping boxes. Fast Couriers like UPS decided to produce dry ice internally and plan to send 42-pounds of dry ice to vaccination points with the shipment of vaccine doses. Experts predict that at vaccinations' peak, the need for dry ice could be 60,000 pounds (27.000 Kg) to 70,000 pounds (32.000 Kg) per day.

However, many local areas do not have dry ice readily available. Also the periodic shortages of CO₂/dry ice in parts of the world can be an issue. Most locals will need to be instructed on safe handling and using of dry ice.

❄️ Handling and Safety

Train all staff on safe handling, use, and disposal of dry ice.

LN₂ freezers, shippers, dewars and laboratory units can be used for storage/distribution of vaccines. It should be done in vapor phase vs liquid.

Shippers with dry ice need to be kept in well ventilated area, with recommended O₂ monitor within the rooms where dry ice is used to protect workers.

ISBER Best Practices: F6.7 Dry Ice Safety

Adequate signage should be used for appropriate storage.

Oxygen monitors/alarms should be used when liquid nitrogen, liquid CO₂, and/or any other oxygen-depriving compressed gases are used.

❄️ Monitoring

Temperature monitoring: all COVID-19 vaccine storage and distribution require temperature monitoring with digital data loggers to verify cold chain trail.

❄️ Shipping Equipment

From a shipping standpoint, double-walled vacuum-insulated containers would have the best possible thermal insulating properties. These units whether typically used at this temperature or at colder temperatures would provide superior hold times compared to other technologies. The lower transmissivity of heat would translate to a lower sublimation rate for dry ice. So, a large aluminum dewar or an ISO framed freezer designed for shipping could hold dry ice for longer durations than other currently proposed systems. This would also allow in-situ storage and reduce dry ice refill requirements easing the administrative burden on vaccine administering facilities. In less developed countries and more remote locations, this could become an important consideration.

ISBER Best Practices: J5. Cold Chain

The management of cold chain should include all measurements, qualifications, validation, and corresponding documentation. All components and operations should be demonstrated to perform reliably.

❄️ Equipment Redundancy and Wastage.

Start-ups and small labs are often interested in refurbished units to control their costs.

Dry ice units and containers requiring disposal will need to be discarded in an environmentally conscious way.