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Proper Vaccine Storage & Handling Practices

for COVID-19 Vaccines

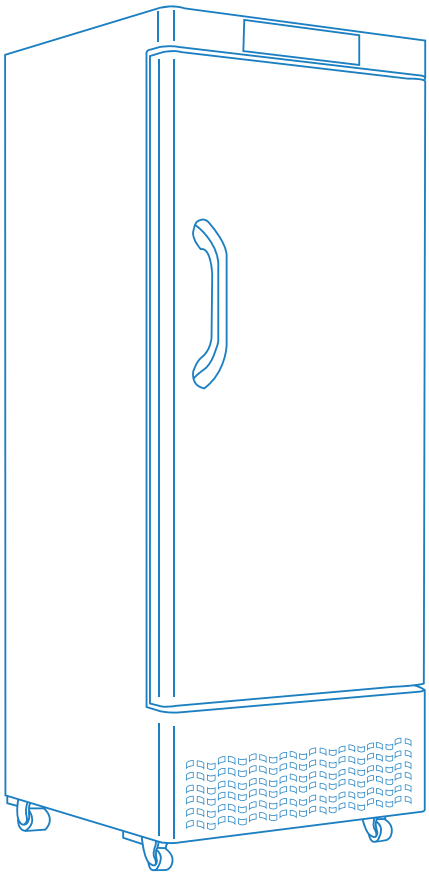
ISO 9001 Registered

Content

Temperature range for the vaccines

Maintaining cold-chain integrity

Being refrigeration solution



Temperature Range for the vaccine

THE RIGHT COLD

A vaccine's required storage conditions include the temperature and other features. Moreover, creating the right cold conditions for vaccines depends on using pharmaceutical-grade refrigerators and freezers. As noted in Excellence in Cold Chain Storage: "Use of non-compliant household or domestic refrigerators for pharmaceutical storage is unsafe and costly." The cold chain for a COVID-19 vaccine demands more equipment. On September 9, 2020, The Wall Street Journal reported: **"Hospitals, pharmacies and physicians' offices are expected to be vaccination sites, but they have few such specialized freezers." The Journal added: "That is prompting a mad dash by logistics, public health and drug-industry officials to cobble together a cold storage supply chain that can deliver vaccines around the country without letting them become warm and ineffective."**[5] Various companies can play a role in expanding the vaccine cold chain. For example, shipping company UPS is building freezer farms around the world. But it will be difficult to serve some regions fast enough. According to the Asia-Pacific Cold Chain Logistics Market - Growth, Trends, and Forecasts (2020–2025), for example: **"The Asia-Pacific cold chain market is highly fragmented." The report notes that the key challenges in the region include "large energy and space consumptions along with huge setup and modification costs."**[6]

With the right cold storage equipment and trained teams, though, currently available and new vaccines can be kept safe and effective. That can only be accomplished when the equipment and personnel provide the required conditions from raw materials through vaccine administration at a clinical site. Doing that requires preparation, following updated guidelines, and ensuring proper management across facilities around the world. Meeting all of those criteria remains crucial for existing vaccines that fight disease and grows increasingly vital as the world battles the COVID-19 pandemics—today and tomorrow.

Cold chain challenges loom ahead for a safe and effective vaccine for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes COVID-19. On September 4, 2020, The Wall Street Journal reported: **"The race to distribute Covid-19 vaccines to hundreds of millions of Americans could come down to one question: Do we have enough freezers?" With some of the vaccines in development requiring some storage steps at –80° C, the Journal adds: "To address concerns about equipment and storage capacity, hospitals are considering plans to buy special freezers."**[5] Stretching that challenge around the world quickly adds up to lots of cold storage equipment.

The precise equipment required will depend on vaccine, because the leading ones in development require different handling.

THE TOP TRIO

At the time of writing this article, the top candidates for a COVID-19 vaccine take three different approaches: DNA; messenger RNA (mRNA); or recombinant viral vectors. These techniques—known as next-generation vaccines—offer a crucial advantage: They **"can be developed based on sequence information alone,"** [7] as reported by Debby van Riel of Erasmus MC in the Netherlands and Emmie de Wit of the U.S. National Institute of Allergy and Infectious Diseases. **"This makes these platforms highly adaptable and speeds up vaccine development considerably, as is clear from the fact that the majority of COVID-19 vaccine clinical trials currently ongoing involve a next-generation platform."** [7]

Some differences distinguish these next-generation approaches to COVID-19 vaccines. For example, DNA is very stable at room temperature, and RNA is not, because it contains a hydroxyl group that can be disrupted by hydrolysis, which makes RNA less stable. So, an unstable mRNA-based vaccine requires very stable storage conditions, including –80° C

Even among the mRNA-based vaccines in development, some similarities and differences exist. In two mRNA-based vaccines being developed, a lipid nanoparticle delivers genetic information for SARS-CoV-2's spike protein. A DNA-based vaccine can also deliver spike protein information but via a viral vector. **Actual viral vector vaccines, as described by van Riel and de Wit, "consist of a recombinant virus (that is, the viral vector), often attenuated to reduce its pathogenicity** [8], in which genes encoding viral antigen(s) have been cloned using recombinant DNA techniques."

COLD CHAIN CRITERIA

The different approaches to making COVID-19 vaccines spawn varying cold chain criteria. The specific conditions required will depend on the vaccine and its point in the overall supply chain.

Among the leading mRNA-based vaccines for COVID-19, distribution and storage require extremely cold conditions. Scientists have known for some time that RNA degrades at room temperature and can even degrade some when frozen at temperatures of –20° C and lower. The stability can be further improved through delivery

via a lipid nanoparticle, which protects the mRNA from nuclease degradation.

Upon delivery to a clinical site, the vaccines will be thawed, but then a vaccine will only be good for a short period of time. The mRNA-based COVID-19 vaccine being developed by BioNTech/Pfizer can be kept at 2–8° C for as many as five days where it will be administered. Conversely, a DNA-based vaccine in development for COVID-19 could be effective for a year at 2–8° C.

The specific conditions will evolve as vaccines move through development and approval. Plus, different conditions will be required from procuring raw materials to giving a vaccine

THE GLOBAL CHALLENGE

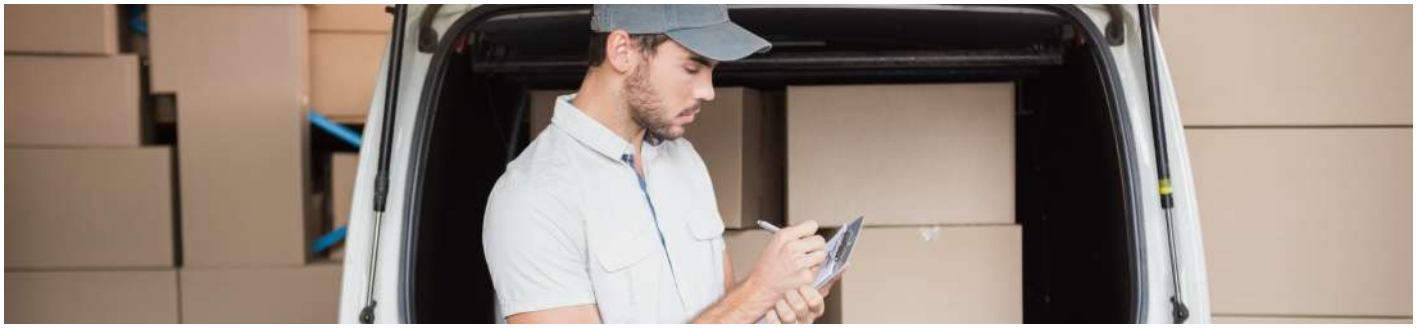
With COVID-19 infecting people around the world, vaccines must be available globally—from urban to rural areas, some of them more accessible than others. Some countries started quickly to improve their cold chains. Singapore, for instance, runs a hub for storing and shipping pharmaceuticals, and it's preparing the facility to handle COVID-19 vaccines. Emirates SkyCargo, an airline based in Dubai, developed a facility just for COVID-19 vaccines, but it can't accommodate the –70 to –80° C needed by some of the existing vaccines. To help countries make the most of existing facilities, **UNICEF and the World Health Organization are "mapping out existing cold chain equipment and storage capacity in the private as well as public sector—and preparing necessary guidance for countries to receive vaccines."**[9] As the air hubs in Singapore and Dubai demonstrate, dedicated facilities could be needed for distributing COVID-19 vaccines. DHL, an expert in global logistics, envisions various approaches to vaccine distribution, including direct shipment to point of use and local warehousing. "The benefits of a centralized approach include more efficient processes, increased transparency, and minimizing the redundancies and fragmentation associated with traditional procurement processes," states the company's Pandemic Resilience-whitepaper. "It also brings a scale advantage, which is critical in widespread health emergencies."

The ultra-low temperature requirements of mRNA-based vaccines could enforce centralized distribution. According to Paula Cannon, Distinguished Professor of Molecular Microbiology & Immunology at the Keck School of Medicine of USC, keeping a vaccine at extremely low temperatures all the time **"creates a problem both for transportation, as well as storage in a pharmacy or doctor's office. Initial rollout may well be restricted to large centers that can provide this range of capability."**[10]

PLANNING AHEAD

If COVID-19 taught the world's public health experts anything, it's the need to plan ahead. That includes incorporating the proper cold storage equipment in the needed places—all with a coordinated plan. As DHL stated: "Robust physical infrastructure—including available stock of medical supplies, and access to the required warehousing facilities and logistics capabilities—is key to a successful emergency response." For example, clinical sites will need the right equipment, including gloves, to handle the shipments of super-cold vaccines. Plus, the people in the distribution system and at clinical sites must all be trained to correctly handle the vaccines.

Without this planning, even an effective vaccine cannot slow the COVID-19 pandemic. There's a lot of work to be done. As ABC reported: **"nearly 3 billion of the world's 7.8 billion people live where temperature-controlled storage is insufficient for an immunization campaign to bring COVID-19 under control."**[11] It's time for all hands on deck in vaccine storage and distribution.



Maintaining Cold-Chain Integrity

The cold chain matters more than ever in the battle against COVID-19 because some of the vaccines in development require very low temperatures from production through patient inoculation. From vaccine manufacturing to distribution and administration, actions taken throughout the process determine the efficacy and safety of a vaccine for patients. In each step, the required cold storage must meet several key criteria: accuracy, uniformity, recovery after opening, and ambient tolerance.

STEPS IN THE PROCESS

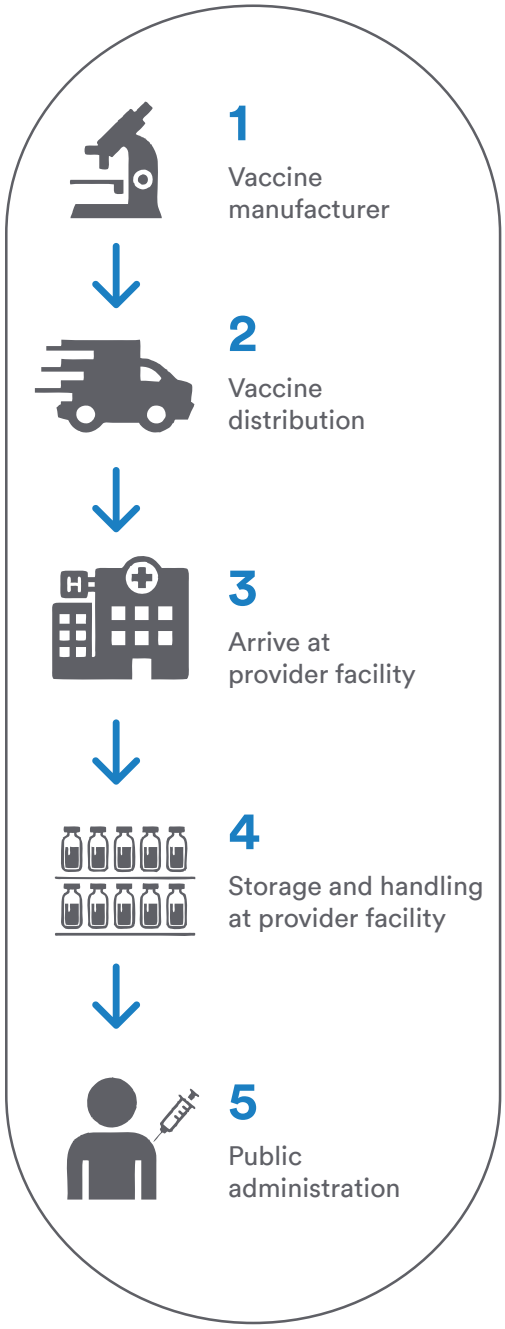
Using devices, such as bioreactors, a drug maker produces a vaccine's ingredients, which might be transported to another location for formulation and shipping. Then, the vaccines will go to distribution centers, often shipped by air. Most vaccines will require precise temperatures throughout—in some cases, as low as −80°C. From a distribution center, vials of vaccine will go to clinics, hospitals, and other sites to vaccinate patients, and the required temperatures will range from −20 to +8°C, depending on the ingredients, formulation, and packaging size & materials.

SUPPLYING THE CHAIN

A complete line of cold-storage devices—such as Being's refrigerators through ultra-low freezers—will be required for protection in every step. All aspects of a specific vaccine and its components and processing will determine the temperature needed along the way. To ensure safety and efficacy, there will be precise temperature specifications for raw materials, R&D, manufacturing, distribution, storage, and handling.

A HEALTHY HEAD START

With various vaccines in development, it's difficult to determine the range of cold-storage platforms that will be needed. As a result, the U.S. Centers for Disease Control and Prevention recommends getting a jump on preparation by installing increased amounts of equipment where needed, from raw-materials producers through clinical sites. Advanced preparation is essential to ensuring that the vaccines currently under development can ultimately make a difference in the fight against COVID-19.



Steps in the process

Refrigerating solutions

Being pharmaceutical refrigerators and freezers satisfy any storage protocol or space requirement. Robust refrigeration systems and cabinet designs assure temperature uniformity, reliability and energy efficiency. All are engineered to maintain required temperatures for product viability and to achieve rapid temperature recovery after multiple door openings.

2°C~20°C Refrigerator

Model	Capacity	Dimension (mm)
BYC-5L310	317L	640 x 582 x 1880
BYC-5L656	662L	1220 x 642 x 1885
BYC-5L1000	997L	1220 x 872 x 1885

-25°C Freezer

Model	Capacity	Dimension (mm)
BDW-25L260	263L	673 x 676 x 1630
BDW-25L320	332L	673 x 676 x 1886

-40°C Freezer

Model	Capacity	Dimension (mm)
BDW-40L260	263L	673 x 676 x 1630
BDW-40L320	332L	673 x 676 x 1886

-86°C Ultra low refrigerator

Model	Capacity	Dimension (mm)
BDW-86L390	390L	909 x 797 x 1990
BDW-86L490	490L	900 x 929 x 1990
BDW-86L650	650L	1091 x 929 x 1990

Credit, citation & source

[6] https://www.prnewswire.com/news-releases/asia-pacific-cold-chain-logistics-market-2020-2025-with-covid-19-impact-analysis-301151111.html

[7] https://www.nature.com/articles/s41563-020-0746-0

[8] https://www.linknovate.com/affiliation/4d-molecular-therapeutics-78874/all/

[9] https://www.pharmacist.com/article/unicef-stockpile-over-half-billion-syringes-year-end

[10] https://pressroom.usc.edu/pfizers-covid-19-vaccine-announcement-sparks-hope-and-questions-about-next-steps-2/

[11] https://abcnews.go.com/Health/wireStory/vaccine-storage-issues-leave-3b-people-access-73815623

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