

## BRIEFING NOTE

# Cooling for All: The role of cold chain in delivering a COVID-19 vaccine

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# 1. Introduction

The SARS-COV-2 (COVID-19) pandemic has had a major impact on international development. Between 71 and 100 million people are likely to be forced into extreme poverty in 2020, the first increase since 1998 and negating gains made since 2017.<sup>1</sup> The effects are multidimensional: 121 million additional people face acute food insecurity due to the pandemic;<sup>2</sup> remote learning remains inaccessible to at least 500 million students;<sup>3</sup> and the incomes of 1.6 billion people employed in the informal sector have dropped an estimated 60 percent.<sup>4</sup> Women have experienced 1.8 times more job insecurity than men during the pandemic<sup>5</sup> despite representing seven in ten jobs in essential occupations, and many have faced a serious increase in domestic violence since stay-at-home measures were implemented.<sup>6</sup>

Among the impacts of the pandemic are critical disruptions to regular vaccine cold chains, which will be essential to the delivery of a COVID-19 vaccine. Up to 80 million children are at risk of missing out on vaccinations against vaccine-preventable diseases due to COVID-19. These interruptions are primarily due to supply chain disruption, reduced healthcare capacity and stay-at-home measures.

Cold chains are likely to play a significant role in the delivery of a COVID-19 vaccine. To reach herd immunity (defined as the indirect protection of individuals from an infectious disease when a high proportion of the population is immune) it is estimated that between 60 and 70 percent of the population will need to obtain immunity either through a vaccination or the development of antibodies following an infection.<sup>7</sup> At present, it is estimated that less than 10 percent of the general population have detectable COVID-19 antibodies,<sup>8</sup> and the longevity of the immune response through infection is unknown. As such it is at minimum a viable possibility that 4.7 to 5.5 billion people (60–70 percent of the global population) will require a vaccination to achieve herd immunity. To put the enormity of the challenge into perspective, GAVI vaccination campaigns have reached 760 million people since the year 2000.

There are additional unknown factors pertaining to the vaccine cold chain. These include the temperature sensitivity of the vaccines that will be distributed. Many of the leading vaccine candidates require cold storage at between 2°C and 8°C, while some candidates in Phase 3 trials require storage in temperatures as low as -70°C and -80°C. This includes the first COVID-19 vaccine to announce efficacy results from mass testing which requires cold storage at -70°C.<sup>9</sup>

Global inequities in terms of vaccine access were already prevalent prior to the pandemic. In 2019, coverage for the vaccine protecting against diphtheria, tetanus, and pertussis (DTP3), which requires storage between 2°C and 8°C, was at 85 percent globally, down slightly from 86 percent in 2018. A total of 85 countries have yet to achieve the targeted vaccination rate of 90 percent for DTP3.<sup>10</sup>

These challenges could be magnified exponentially should a COVID-19 vaccine require consistent cold storage at -70 to -80°C and necessitate a rollout to hundreds of times the population that would typically receive vaccinations in a given year. Most low- and middle-income countries do not have a robust 2°C to 8°C cold chain for existing medical needs or -70 to -80°C cold chains. At minimum a COVID-19 vaccine requiring cold storage will require the most significant build out of cold chains in the developing world ever, and new -70 to -80°C cold chains could be required across low- and middle-income countries. It will be the poor who will face the most significant challenges in accessing a vaccine and delivering sustainable cold chains could become a serious issue of equity that underpins equal and fair access to a COVID-19 vaccine.

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<sup>1</sup> Projected Poverty Impacts of COVID-19, World Bank Group, 8 June 2020. [Link](#)

<sup>2</sup> FAO-WFP Early Warning Analysis of Acute Food Insecurity Hotspots, FAO-WFP, July 2020, [Link](#)

<sup>3</sup> Impact of COVID-19 on SDG Progress: A Statistic Perspective, UN/DESA, August 2020. [Link](#)

<sup>4</sup> UN Report Finds COVID-19 is Reversing Decades of Progress on Poverty, Healthcare, and Education, UN/DESA, July 2020. [Link](#)

<sup>5</sup> COVID-19 and Gender Equality: Countering the Regressive Effects, McKinsey and Company, 15 July 2020. [Link](#)

<sup>6</sup> Will the Pandemic Derail Hard-won Progress on Gender Equality? UN Women-Women Count (2020). [Link](#)

<sup>7</sup> Interview with WHO Chief Scientist, Dr. Soumya Swaminathan, WHO, 28 August 2020. [Link](#)

<sup>8</sup> What We Know About the COVID-19 Immune Response, WHO, 2 August 2020. [Link](#)

<sup>9</sup> Gallagher, James, Covid vaccine: First 'milestone' vaccine offers 90% protection, BBC News, November 10, 2020. [Link](#)

<sup>10</sup> In 2019, an estimated 14 million infants were still not reached by vaccination services, UNICEF, July 2020. [Link](#)

## 2. State of the cold chain medical market

Cold chains consist of several components that usually include at least pre-cooling, cold storage and refrigerated transport. For the medical sector, the cold chain is typically used for the transportation and storage of temperature-sensitive health products that include but are not limited to vaccines, blood products, and a range of medicines that support common health services. These products are usually handled by medical staff logisticians in the cold chain and at the point of delivery but may also involve consumers if and when these products are to be taken home and kept cool for use over time.

The success of immunization efforts depends on maintaining cold chains. Vaccines may lose their integrity if exposed to temperatures outside the recommended ranges for long periods of time. The purpose of the vaccine cold chain is to maintain the quality of vaccines by ensuring they are handled, stored and transported within the prescribed temperature range, typically between 2°C and 8°C, from the time of manufacture until the point of administration.

Different products are also likely to have specific cooling requirements. Blood products, for example, must be kept at a consistent temperature of between 2°C to 6°C.<sup>11</sup> Some vaccines must stay frozen, but for others, accidental freezing can render them dangerous. In 2017, the improper storage of a measles vaccine in South Sudan contaminated 15 children under the age of five, who subsequently died of severe sepsis and toxicity.<sup>12</sup> A few years later, it was discovered that refrigeration equipment distributed globally and manufactured by a reputable company was freezing the vaccines instead of storing them at the correct temperature.

Figure 1 demonstrates the typical vaccine flow in routine immunization programmes and the equipment found at different levels along the cold chain, from the point of manufacture down to the health centres and outreach points where the vaccines are administered.

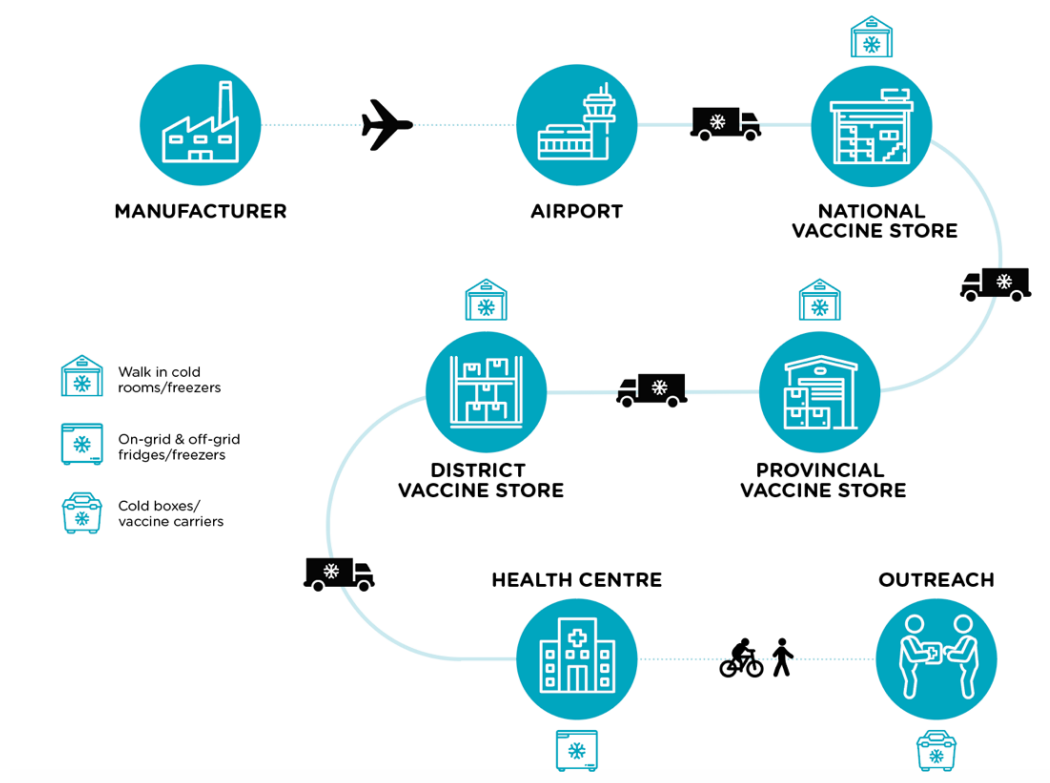


Figure 1: General structure of vaccine cold chain in routine immunization programmes

<sup>11</sup> Cold Chain and Refrigeration, USAID. [Link](#).

<sup>12</sup> Devex.com: Opinion – Why a strong cold chain is more critical than ever to defeat COVID-19 – by Raja Rao, 21 April 2020.

## 2.1 Technology and equipment

According to Efficiency for Access' 2020 Off-Grid Market Survey, vaccine and blood bank refrigerators are ranked as the most important devices for healthcare delivery.<sup>13</sup> In order to deliver the COVID-19 vaccine to adequate percentages of the world's population, massive amounts of cold chain equipment will be necessary.

**Walk-in cold rooms (WICs) and freezer rooms (WIFs)** are often used for bulk storage at national, provincial and district vaccine stores. They require a continuous supply of electricity and standby generators in case of a power outage. Vaccines are stored in specialized areas in the rooms before being moved to lower-level storage facilities.

**Ice-lined refrigerators (ILRs)** run on mains electricity or generators. Many new ILR models can provide safe storage for vaccines at the required temperature range between 2°C and 8°C for long periods of time with only eight hours of power supply in 24 hours.<sup>14</sup> In case of a power outage, the ice lining maintains the required temperatures for vaccines. Some fridges can maintain temperatures for up to 10 days.

**On-grid freezers** also run on mains electricity or generators. They provide better temperature monitoring and safer storage than standard domestic freezers.<sup>14</sup>

**Solar-powered refrigerators and freezers** are designed to maintain vaccines at the prescribed temperature without the need for electricity from the grid. Even though the initial cost of solar-powered systems is higher than electric refrigerators/freezers, they offer significant energy cost savings and reduce emissions. Solar-powered refrigerators and freezers are especially recommended for areas with no access to the national power grid or with limited/intermittent power supply. There are two types of solar powered refrigerators and freezers: solar direct drive (SDD) and battery solar-powered systems. While SDDs are generally more expensive to buy and install than battery-powered systems, they require less maintenance as they do not need batteries to operate. Ice-lined off-grid solar refrigerators use SDD systems.

**Cold boxes** are insulated storage boxes that are used to keep vaccines cold during transportation and/or short-term storage.

**Vaccine carriers** have less capacity than cold boxes, and they are generally used by health workers during outreach immunization sessions. Both cold boxes and vaccine carriers are passive systems<sup>15</sup> that require ice or coolant packs, and therefore freezers, to keep vaccines at required temperature ranges. There is far less ability to ensure correct temperature and usage with boxes left open or the wrong number of ice packs used. Companies such as Sure Chill are developing active cooling (micro-chillers with thermo-electric refrigeration) with data capabilities and WHO is writing a new set of PQS standards for active cold boxes.

**Refrigerated vans** are used for bulk transportation of vaccines between storage points. They are equipped with a refrigeration unit and an insulated cargo compartment.

The type of refrigerants used in equipment in the medical cold chain typically relies on the temperature control requirements of the vaccines/medicine. For instance, most of the deep-frozen systems (up to -80°C) are at the upstream of the medical chain. Deep-frozen systems can be based on synthetic HFC refrigerants, natural refrigerants such as ammonia (R-717) and carbon dioxide (R-744), and also cascade systems that use both natural and synthetic refrigerants. The refrigeration applications for storage and transport in the downstream that typically require positive temperature ranges (2°C to 8°C) are mostly synthetic HFC-based systems such as R-134a, R-404A, etc.. Some hydrocarbon-based natural refrigerant systems are also increasing in the global market.

The COVID-19 related response may require additional cold chains or the strengthening of existing ones. Countries that are importing vaccines would need to assess this requirement and ensure that their technology choices are not detrimental to their Montreal Protocol commitments and have the lowest impact on energy and climate possible.

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<sup>13</sup> Efficiency for Access, Off-grid Appliance Market Survey, October 2020. [Link](#).

<sup>14</sup> GAVI Cold chain Equipment Optimisation Platform, [https://www.gavi.org/sites/default/files/publications/Cold\\_chain-equipment-technology-guide.pdf](https://www.gavi.org/sites/default/files/publications/Cold_chain-equipment-technology-guide.pdf) [Accessed on 18 October 2020]

<sup>15</sup> Passive cooling systems use no energy, as opposed to active cooling systems that use energy for cooling.

## 2.2 Environmental impacts

While the cold chain is an integral part of achieving immunization targets, it comes with an environmental cost. Including both energy emissions (i.e. indirect emissions) and leaks of highly potent HFC refrigerant gases (i.e. direct emissions), one estimate suggests that cold chains are responsible for approximately 1 percent of global GHG emissions and can represent 3–3.5 percent GHG emissions in developed economies.<sup>16</sup> Recent estimates also indicate that the healthcare sector is responsible for approximately 5 percent of global emissions, including refrigerants.<sup>17</sup>

On-grid refrigerators and freezers indirectly contribute to emissions from cooling through energy consumption. Replacing old equipment with energy-efficient technologies reduces energy costs and emission contributions, especially if the on-grid supply is generated from non-renewable resources. Moreover, many health facilities and communities in developing countries suffer from a lack of grid electricity. As a result, these facilities often rely on polluting diesel systems. Likewise, refrigerated vans in the cold chain run on diesel contribute to emissions, and sub-optimized routes, delays on roads due to congestion or poor road infrastructure further worsen the impact.

Emissions are also caused by refrigerant leakages. Outdated cold chain equipment with environmentally damaging high-GWP fluorinated refrigerants should be replaced with new equipment with natural or synthetic refrigerants with minimal GWP/ climate impact. WHO's effective vaccine management (EVM) assessment revealed that chlorofluorocarbon (CFC) refrigerants are still in use in 81 countries across all WHO regions.<sup>18</sup> The national compliance and monitoring mechanisms of the Montreal Protocol need to ensure that such CFC inventories do not promote illegal trade and incentives are in place to replace such systems with equipment that meets relevant environmental safeguards. The challenge is also significant from a Kigali Amendment perspective; in its PQS catalogue of approved equipment for vaccine cold-chain,<sup>19</sup> WHO lists equipment using R-404A, which has a GWP of 3922, the highest of all the commonly-used refrigerants that has been banned in Europe (recovered or reclaimed R-404A can be used until 2030).

## 2.3 Challenges

### Cold chain equipment replacement

Efficient and reliable cold chain equipment is vital to reach target immunization coverage effectively and equitably. Some outdated equipment used in cold chains results in high operating costs with energy and environmental impacts. Such equipment may lack temperature control capabilities, leading to temperature fluctuations and the administration of ineffective vaccines and avoidable wastage. In 2014, Gavi estimated that up to 90 percent of health facilities were not equipped with adequate cold chain equipment in several Gavi-eligible countries.<sup>20</sup>

### Temperature monitoring

The cost of vaccine wastage due to exposure to temperatures outside the recommended range is estimated at USD 34.1 billion annually, a figure that does not include the physical and financial cost of avoidable illnesses with on-time delivery of effective vaccines.<sup>21</sup> One estimate from 2019 suggests that 25 percent of vaccines are degraded by the time they arrive at their destination from the manufacturer due to a lack of compliance, standardization, accountability and transparency across the air transport supply chain.<sup>22</sup>

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<sup>16</sup> B.R. Heard, S.A. Miller "Potential changes in greenhouse gas emissions from refrigerated supply chain introduction in a developing food system" *Environ. Sci. Technol.*, 53 (2019), pp. 251-260

<sup>17</sup> *Climate-Smart Healthcare: Low-Carbon and Resilience Strategies for the Healthcare Sector*. World Bank Group, 2017. [Link](#).

<sup>18</sup> *Effective Vaccine Management (EVM) Global Data Analysis 2009-2018*.

[https://www.who.int/immunization/programmes\\_systems/supply\\_chain/EVM-Global-Data-Analysis-2010-2018-EN.pdf?ua=1](https://www.who.int/immunization/programmes_systems/supply_chain/EVM-Global-Data-Analysis-2010-2018-EN.pdf?ua=1) [Accessed on 19 October 2020]

<sup>19</sup> [https://apps.who.int/immunization\\_standards/vaccine\\_quality/pqs\\_catalogue/](https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/) [Accessed on 26 October 2020]

<sup>20</sup> *Cold Chain Equipment Optimisation Platform*, GAVI: The Vaccine Alliance. October, 2019. [Link](#).

<sup>21</sup> Keeping coronavirus vaccines at subzero temperatures during distribution will be hard, but likely key to ending pandemic.

<https://theconversation.com/keeping-coronavirus-vaccines-at-subzero-temperatures-during-distribution-will-be-hard-but-likely-key-to-ending-pandemic-146071> [Accessed on 19 October 2020]

<sup>22</sup> How to become CEIV Pharma Certified.

[https://www.iata.org/contentassets/494bc14afd934b0193735e9a47091d72/iata\\_ceivpharma\\_how20to20become20ceiv20pharma20certified.pdf](https://www.iata.org/contentassets/494bc14afd934b0193735e9a47091d72/iata_ceivpharma_how20to20become20ceiv20pharma20certified.pdf) [Accessed on 19 October 2020]

## Energy access and energy efficiency

Resilient energy access is critical for maintaining cold chains and preserving vaccines. However, estimations suggest that tens of thousands of health centres across low- and middle-income countries are not connected to the grid, and a similar number of hospitals suffer from an unreliable energy supply.<sup>23</sup> Estimations from 2013 suggest that 46 percent of health facilities in India and more than 30 percent of healthcare facilities in Sub-Saharan Africa do not have access to electricity.<sup>24</sup> Further data available from WHO's EVM assessment reveal that many facilities across the vaccine cold chains, especially the service points, suffer from an unreliable energy supply (See Figure 2).

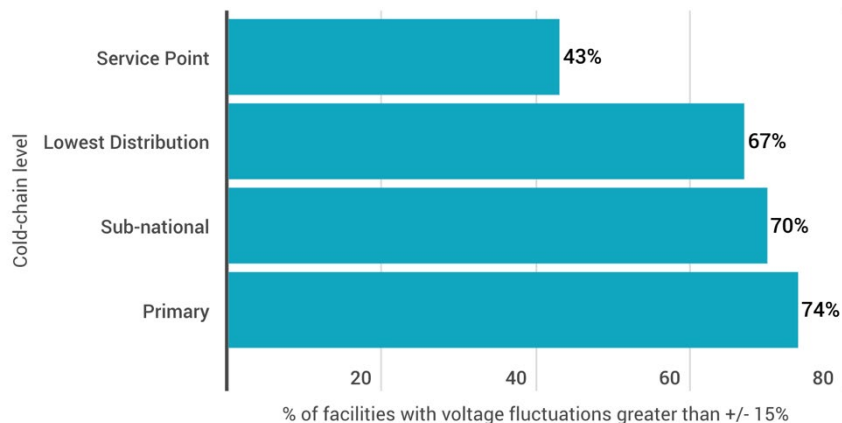


Figure 2: Facilities with voltage fluctuations greater than +/- 15% (%). (The data were collected between 2009 and 2017 in 81 countries across all 6 WHO regions). [Adapted from EVM Global Data Analysis 2009-2018].

In many countries, procurement processes do not consider the energy cost of the vaccine cold chain. The lack of application-specific energy efficiency standards and policies also leads to inefficient systems being added into the cold chain. Energy efficiency needs to be an important criterion in procurement guidelines for countries to ensure that the energy requirement from the cold chain is kept to a minimum.

### Limited outreach

In low- and middle-income countries, a large proportion of the population live in rural, remote areas<sup>25</sup> with geographical barriers, poor infrastructure — such as lack of transportation and bad road conditions — and where access to health and immunization services is generally limited. These countries may also have nomadic or seasonally mobile populations that make no contact with routine immunization services and usually are not registered at the place where they are temporarily residing, creating issues in ensuring timely and complete immunization as well as proper recording and reporting of information.<sup>26</sup>

### Financing and market barriers

The cost of fully vaccinating a child has been estimated to be USD 25–45, not including other non-vaccine costs such as cold chain equipment, staff, training, operation and maintenance.<sup>27</sup> At the same time however, besides saving 2 to 3 million lives each year, immunization is very cost effective considering the medical cost savings as well as productivity gains that come with it. UNICEF estimates that every dollar spent on child immunization provides USD 44 worth of economic benefits.<sup>28</sup> However, exploiting this cost efficiency requires strengthening the weakest links of cold chains to improve access to vaccines. Achieving this sustainably with minimal environmental footprint requires significant investments in clean and energy-efficient cold chain solutions. For developing countries, international development assistance alone will not be enough to meet such investments. Much of this finance will need to be

<sup>23</sup> WHO, <https://www.who.int/news/item/18-06-2020-call-for-expression-of-interest-electricity-access-in-healthcare-facilities> [Accessed on 19 October 2020]

<sup>24</sup> Practical Action, 2013 <https://infohub.practicalaction.org/bitstream/handle/11283/556928/PPEO%202013.pdf;jsessionid=122A58661E972DD6B8643C6E1DAC343C?sequence=1> [Accessed on 19 October 2020]

<sup>25</sup> WHO, Rural Population, [https://data.worldbank.org/indicator/SP.RUR.TOTL?end=2019&most\\_recent\\_year\\_desc=false&start=1960&type=shaded&view=map](https://data.worldbank.org/indicator/SP.RUR.TOTL?end=2019&most_recent_year_desc=false&start=1960&type=shaded&view=map). [Accessed on 19 October 2020]

<sup>26</sup> Mihigo et al., 'Global Vaccine Action Plan: Regional Vaccine Action Plans 2016 Progress Reports'.

<sup>27</sup> Mihigo, R. M., Okeibunor, J. C., O'malley, H., et al. (2016). Investing in life saving vaccines to guarantee life of future generations in Africa. *Vaccine*, 34, 5827–5832.

<sup>28</sup> UNICEF, <https://www.unicef.org/immunization#:~:text=Immunization%20is%20the%20most%20cost,because%20they%20weren't%20vaccinated.> [Accessed on 19 October 2020]



mobilized locally, and from private sources. Innovative financing mechanisms, incentives, business models, and financial supporting mechanisms can spur new investments in energy-efficient cold chain solutions.

For most cooling technologies, the main components contributing to the life cycle cost of the equipment are energy consumption and maintenance. The initial investment is in fact only a small fraction of the overall cost. In other words, the total cost of ownership of cooling systems is most effectively reduced by installing the most energy-efficient systems, by optimizing preventive maintenance, and by applying systemic thinking to minimize active cooling needs, such as through passive and behavioural solutions, and to further optimize energy use, such as through thermal energy storage systems.

Furthermore, the higher upfront capital cost of sustainable cold chain equipment compared to conventional cooling systems often results in being a major barrier to switch to such systems. The cost savings that result from energy-efficient equipment are realized over a number of years and customers do not typically see the financial benefits of energy-efficient equipment immediately, which can discourage investment. This is particularly important in countries that have high capital costs. Other market barriers relevant to the cold chain industry include a lack of trust in new technology and competing investment priorities. Innovative financial mechanisms and business models can help to overcome these.

*The COVAX Initiative is directed by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi the Vaccine Alliance, and the World Health Organization (WHO). The COVAX Facility aims to purchase 2 billion doses by the end of 2021 through collaboration with vaccine developers. Through COVAX, lower-income countries receive financial support and access to a vaccine once available.<sup>29</sup> The vaccines will be provided to all participating countries in an equitable manner based on their populations, prioritizing healthcare workers first, then expanding to cover the vulnerable. Additional vaccines will then be offered based on “country need, vulnerability and COVID-19 threat.”<sup>30</sup> Furthermore, under COVAX, GAVI has approved USD 150 million in initial funding to help 92 low- and middle-income countries to prepare for the delivery of COVID-19 vaccines.<sup>31</sup>*

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<sup>29</sup> WHO, <https://www.who.int/initiatives/act-accelerator/covax>. [Accessed on 22 October 2020]



<sup>30</sup> WHO, <https://www.who.int/news/item/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility>. [Accessed on 24 October 2020]

<sup>31</sup> GAVI, <https://www.gavi.org/news/media-room/gavi-provide-us-150-million-support-low-and-middle-income-countries-readiness>. [Accessed on 25 October 2020]

### 3. COVID-19 and the medical cold chain

As of 25 October 2020, there were a total of 248 COVID-19 vaccine candidates in development,<sup>32</sup> with 49 of these being tried on humans in clinical trials around the world. 10 vaccine candidates are currently in the final stage of testing (one in Phase 2/3, the rest in Phase 3), which could demonstrate if these vaccines are successful or not before the end of 2020. Table 1 summarizes the leading vaccine candidates that are in their late development stages, and their specifications. While research on vaccines is moving with unprecedented speed, some of them already have significant implications for the cold chain with sub-zero temperature requirements and multiple doses.

Vaccine developer/manufacturer	Vaccine platform	Number of doses	Timing of doses	Phase	Anticipated temperature requirement for shipment and long-term storage	Anticipated duration of storage possible at 2-8 °C
BioNTech/Fosun Pharma/Pfizer	RNA		0, 28 days		-70 °C	5 days*
Moderna/NIAID	RNA		0, 28 days		-20 °C	10 days**
University of Oxford/AstraZeneca	Non-replicating viral vector		-		2-8 °C	N/A
CanSino Biological Inc./Beijing Institute of Biotechnology	Non-replicating viral vector		-		2-8 °C	N/A
Gamaleya Research Institute	Non-replicating viral vector		0, 21 days		2-8 °C	N/A
Johnson & Johnson/Janssen	Non-replicating viral vector		0, 56 days		2-8 °C	N/A
Beijing Institute of Biological Products/Sinopharm	Inactivated		0, 21 days		2-8 °C	N/A
Sinovac	Inactivated		0, 14 days		2-8 °C	N/A
Wuhan Institute of Biological Products/Sinopharm	Inactivated		0, 21 days		2-8 °C	N/A
Novavax	Protein Subunit		0, 21 days		2-8 °C	N/A

 PHASE 2/3       PHASE 3

\* Pfizer Covid Vaccine Trial Reports No Major Safety Issues, <https://www.bloomberg.com/news/articles/2020-09-15/pfizer-covid-vaccine-trial-free-of-major-safety-issues-so-far>. [Accessed on 21/10/2020]

\*\* Moderna COVID-19 vaccine appears to work as well in older adults in early study, <https://uk.reuters.com/article/us-health-coronavirus-cdc-moderna/moderna-covid-19-vaccine-appears-to-work-as-well-in-older-adults-in-early-study-idUSKBN25M1Y0>. [Accessed on 21/10/2020]

Table 1: Leading vaccine candidates and their specifications as of 25 October 2020 [N/A: Anticipated temperature requirement for shipment and long-term storage is already 2–8 °C]

<sup>32</sup> COVID-19 vaccine development pipeline. [https://vac-lshtm.shinyapps.io/ncov\\_vaccine\\_landscape/](https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/). [Accessed on 25 October 2020]



## Potential roadblocks

### *Production capacity*

Once a vaccine is approved it must be produced quickly and on a massive scale, and international cooperation is essential to provide equitable access. Given that vaccination efforts rely on the idea of herd immunity, current production capacities are not large enough to meet the global demand for COVID-19 vaccines while providing the vaccines under routine immunization programmes. Estimates on global production capacity suggest that just 2 billion doses could be produced in 2021,<sup>33</sup> corresponding to only around 25 percent of the world's population. Given that eight of the ten vaccine candidates in late stages of clinical trials require two doses, this number may even go down to ~12 percent.

To cope with the demand, many vaccine producers have already begun production of their vaccine candidates at risk in order to start distribution upon approval. These risks are justified by the urgent need to restart economies, which depends heavily upon the delivery of an effective vaccine on a massive scale. However, UNICEF market assessment suggests that investments to support this production challenge will be “highly dependent on among other things, whether clinical trials are successful, advance purchase agreements are put in place, funding is confirmed, and regulatory and registration pathways are streamlined”.<sup>34</sup>

### *Storage and distribution*

Routine immunization programmes typically target only babies, children and pregnant women. The COVID-19 vaccination however needs to cover a substantial portion of the population at speed for a country to form herd immunity. To put things into perspective, India's administrative coverage data, for example, show that the total number of doses administered under the Universal Immunisation Programme (UIP) in 2019 was around 400 million.<sup>35</sup> India's Ministry of Health plans to immunize 200–250 million people (around 16 percent of the population significantly lower than the herd immunity threshold) against COVID-19 by the first two quarters of 2021.<sup>36</sup> Numbers translate into 400–500 million vaccine doses, considering the high chance that the vaccine will require two doses to be effective (See Table 1). That means the number of COVID-19 vaccines to be delivered is double the number of vaccinations currently given under UIP to achieve the initial COVID-19 immunization target. Taking the calculations further, assuming a packed vaccine volume per dose of 5.2ml,<sup>37</sup> the storage volume required for 400 million doses equates to around 2 million litres. If India were to achieve herd immunity, assuming a herd immunity threshold of 65 per cent, then the required vaccine volume is around 9.5 million litres. Apart from the volume required for the COVID-19 vaccines, the storage needed for medical supplies as well as the reverse logistics required for waste and additional human resources should be considered and addressed, keeping in mind the need to continue with the existing routine immunization programmes. These are all just estimations but provide insights into the scale of the problem.

### *Sub-zero temperatures*

Currently most vaccines under routine immunization programmes are required to be stored between 2–8°C across all cold chain levels, except for the oral polio vaccine (OPV) and Rotavirus. OPV and Rotavirus vaccines are stored at -15°–25°C at national and provincial facilities and are recommended to be stored at 2–8°C at district health facility levels.<sup>38</sup> However, vaccine candidates requiring storage at -20°C and -70°C respectively represent a massive challenge.

Even if we aim for -20°C, many service points, such as hospitals, clinics and pharmacies, will not have the freezers required for storage. It is evident from WHO's EVM assessment that equipment for -20°C storage is not present at the district level and service points across 81 countries assessed (See Figure 3);<sup>18</sup> let alone at the volume required for

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<sup>33</sup> Coronavirus: Only one in 10 to be protected from COVID-19 in first year of vaccine use, <https://news.sky.com/story/coronavirus-only-one-in-10-to-be-protected-from-covid-19-in-first-year-of-vaccine-use-12072473> [Accessed on 20 October 2020]

<sup>34</sup> UNICEF, <https://www.unicef.org.uk/press-releases/unicef-to-lead-procurement-and-supply-of-coronavirus-vaccines/> . [Accessed on 20 October 2020]

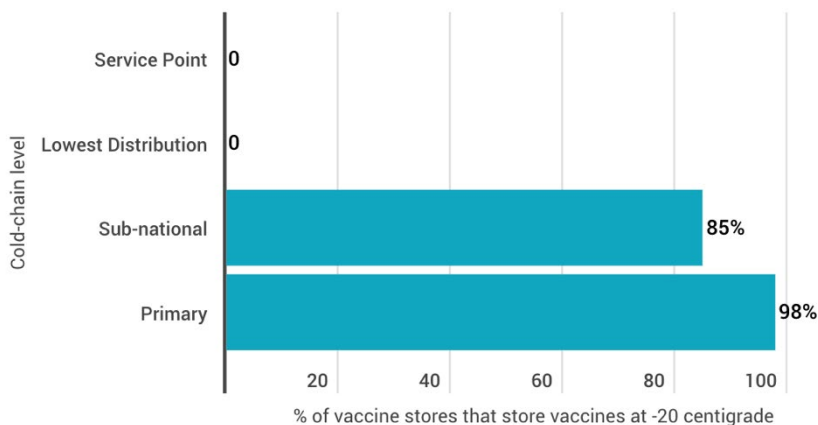
<sup>35</sup> WHO, Country-reported administrative data [https://www.who.int/immunization/monitoring\\_surveillance/data/en/](https://www.who.int/immunization/monitoring_surveillance/data/en/). [Accessed on 20 October 2020]

<sup>36</sup> A COVID-19 Vaccine Is Part 1 – Part 2 Will Be India's Mighty Logistics Challenge, <https://science.thewire.in/health/a-covid-19-vaccine-is-part-1-part-2-will-be-indias-mighty-logistics-challenge/>. [Accessed on 20 October 2020]

<sup>37</sup> Packed vaccine volume per dose of influenza vaccines in multi-dose vials (10 doses per vial). No details have yet been provided on storage volumes of vaccines.

<sup>38</sup> Effective Vaccine Management (EVM) Global Data Analysis 2009-2018. [https://www.who.int/immunization/programmes\\_systems/supply\\_chain/EVM-Global-Data-Analysis-2010-2018-EN.pdf?ua=1](https://www.who.int/immunization/programmes_systems/supply_chain/EVM-Global-Data-Analysis-2010-2018-EN.pdf?ua=1) [Accessed on 19 October 2020]

COVID-19 vaccines. Considering the difficulty of reaching rural populations in developing countries, these low temperature requirements will pose even greater storage and transport challenges. Since these vaccine candidates can only be stored at regular 2–8°C refrigeration temperatures for a very limited amount of time, vaccines may lose their potency during immunization sessions due to prolonged exposure to temperatures outside the recommended range. Regarding the ultra-low -70°C, the number of medical freezers that can handle these temperatures is limited, even in developed countries. Building a cold chain that can handle ultra-low temperatures, therefore, would require significantly higher financial support and funding for developing countries not only for building storage and transport capacity at the required temperature range, but also for training staff who are not used to working with these temperatures.



A recent study by DHL highlights the issues around equitable access. According to its estimations, the current vaccine cold chain can only deliver the vaccine at freezing temperatures to 2.5 billion people in around 25 developed countries. The number doubles to 5 billion if the vaccine requires the conventional temperature range of 2–8°C. Due to a lack of cold chain capacity, Africa, Asia and South America cannot be readily supplied at scale. Furthermore, the vaccine is unlikely to reach the majority of Africa due to high ambient temperatures and lack of cold chain infrastructure.<sup>39</sup>

Figure 3: Vaccine stores that store vaccines at -20°C (%). (The data were collected between 2009 and 2017 in 81 countries across all six WHO regions). [Adapted from EVM Global Data Analysis 2009–2018].

<sup>39</sup> DHL White Paper, Delivering Pandemic Resilience. <https://www.dhl.com/content/dam/dhl/global/core/documents/pdf/glo-core-delivering-pandemic-resilience-2020.pdf> [Accessed on 20 October 2020].

## 4. Ensuring medical cold chain support equitable access to a COVID-19 vaccine

Equitable distribution of the COVID-19 vaccine globally would prevent 61 percent of potential deaths, compared to 33 percent of deaths avoided if it is distributed to high-income countries first.<sup>40</sup> But while significant attention has been paid to the scientific progress made to find a safe COVID-19 vaccine, the medical cold chains needed to transport a vaccine that requires cooling has received considerably less attention despite being a potentially crucial component to an equitable global response. This section lists key pillars of a cold chain strategy to support the equitable, sustainable delivery of a COVID-19 vaccine through medical cold chains.

### *Prioritized immunization strategy*

COVID-19 vaccination programmes should ensure even coverage across all urban and rural regions for it to be successful and for countries to achieve herd immunity. However, as the initial vaccine supply is likely to be limited, many governments are considering some form of a prioritization strategy. It is pragmatic for the most vulnerable in populations to be the first in line to receive the vaccine. Once a vaccine is approved, prioritizing those at higher risk, such as older adults and those with existing health conditions, as well as healthcare workers is justified. Since the vaccines are still under development and full information on their effectiveness across different age groups is not available, this may require developing multiple approaches simultaneously.

In its report published in October 2020,<sup>41</sup> the National Academy of Medicine suggests distributing the vaccine in four phases. The first population group includes healthcare workers, first responders, people with underlying conditions, and older adults living in congregate or overcrowded settings. The prioritization strategy suggested in the report is in line with the one under the COVAX Initiative, which is prioritizing healthcare workers, then expanding to cover the vulnerable. Countries may also use a campaign approach, i.e., immunize 60–70 percent of one geographical location, and move to another location, eventually achieving the herd immunity threshold across the country. This approach could also allow last-mile equipment (cold storage and cold-boxes/vaccine carriers) to be moved to other locations as the vaccination programme progresses.

Any COVID-19 vaccination programme must also consider the routine immunization programmes that have inevitably been disrupted by the pandemic in many countries due to lockdowns, social distancing regulations, and delays of vaccine supplies. Prolonged delays in vaccination programmes may result in outbreaks of vaccine preventable disease (VPD) (measles, diphtheria & Polio-type-2). It is therefore important to allocate resources by considering potential outbreaks, making sure routine immunization programmes continue alongside those of the COVID-19 vaccination.

### *Plan the last mile*

Planning for COVID-19 vaccination programmes should start from the last mile. The key challenge will be ensuring that each vaccination site is equipped with adequate fixed and outreach cooling equipment depending on local needs (such as target population, road conditions, electricity access) to maintain the efficacy of the COVID-19 vaccine. It is also important to consider population densities, travel times, and distance to vaccination sites, where geographic information systems (GIS) data can be particularly helpful.

In many countries, vaccines under routine immunization programmes are delivered through fixed sites (health centres), outreach sessions, and in some cases, mobile activities. Outreach strategies are typically used to increase immunization rates in rural and remote areas where there is no direct access to health centres. With over 44 percent of the global population living in rural settings (for example 63 percent in Bangladesh, 65 percent in India and 83 percent in Rwanda),<sup>25</sup> COVID-19 vaccination programmes will need to be shaped around outreach sessions to reach everyone equitably and for countries to achieve a herd immunity threshold.

Given the need to vaccinate a large percentage of the population efficiently and equitably in a short period of time, taking a campaign-style approach including fixed designated vaccination sites that are easily accessible and supported by public transportation services, and door-to-door immunization could be a viable and effective option.

<sup>40</sup> COVID-19: A Global Perspective, 2020 Goalkeepers Report, Bill and Melinda Gates Foundation, September 2020. [Link](#).

<sup>41</sup> Framework for Equitable Allocation of COVID-19 Vaccine, <https://www.nap.edu/read/25917/chapter/1>. [Accessed on 22 October 2020].

Microplanning may be needed to choose the optimal locations for vaccination sites in order to reach as many people as possible and to aggregate demand, which can reduce costs related to storage, transportation and human resources. Even in urban settings, using hospitals and other health facilities may not be feasible if they are already overwhelmed by the pandemic. Alternative facilities with cold storage, even supermarkets, restaurants, pharmacies, hotels or conference/exhibition centres could be designated as service points in order to cope with the demand.

To ensure uninterrupted delivery of quality vaccines and minimize vaccine wastage due to a lack of reliable electricity, vaccination programmes should be supported by sustainable off-grid cooling equipment along with temperature monitoring systems. Off-grid equipment could then be moved and redeployed in other locations, adding flexibility and accessibility to the vaccination programmes. The critical role of off-grid and high performing appliances in vaccine storage and distribution has been demonstrated by a USD 250 million investment from GAVI to support countries to procure solar appliances. GAVI is currently supporting the procurements of close to 65,000 refrigerators, including solar direct drive refrigerators for nearly 50 countries.

### *Data management and monitoring*

Data management and monitoring technologies will play a vital role in ensuring the timely delivery of quality COVID-19 vaccines to their intended recipients, reducing vaccine wastage and associated costs. Investment in these systems is essential to put all major stakeholders under a common information system that provides real-time information and visibility along the entire cold chain and to identify the strongest and most strategically important links in the existing cold chain. Actions and investments should also make use of existing data sets and processes to ensure planning starts from what is already known. These systems are essential to ensuring vaccine quality from the point of manufacture through to the point of delivery and for minimizing wastage and detecting equipment malfunctions in the cold chain. They are also important to ensure people receive a vital second dose, and to identify and manage risks in real time, such as power outages, weather conditions, and transport delays and disruptions.

### *Investment and partnerships*

Delivering vaccines to remote places requires substantial investments and technological innovation. International development assistance alone will not be enough to meet the need, and collaboration between the private sector and public resources and locally-mobilized private finance will be necessary. Current government-controlled vaccine cold chains used under routine immunization programmes, especially in developing countries, will not be able to cope with the demand, even if the vaccine requires the conventional temperature range of 2–8°C. To ensure the uninterrupted availability of quality COVID-19 vaccines from the manufacturer to every community, village and settlement in a country, the cold chain capacity needs to be improved in terms of storage, transportation and having in place a skilled workforce for monitoring, maintenance and support. Further, cold chains should be equipped with rigorous temperature and humidity control systems throughout along with waste management and recycling infrastructure.

One solution to the lack of vaccine cold chain may be sharing capacity with the food cold chain. This approach would save time and money, as it would reduce additional storage and transportation requirements. Private cold chain operators may allocate specific resources in their network to meet the challenge. As the private sector makes aggressive investments in technology and innovation, their capacity to achieve cold chain success is likely to exceed what is possible within the public sector. In anticipation of the COVID-19 vaccine requiring sub-zero temperatures, UPS is constructing two facilities for safe storage of millions of doses of COVID-19 vaccines at -70°C.<sup>42</sup> Additionally, to ease distribution, Pfizer has announced that it will provide a “dry ice pack” container for its vaccines that is able to maintain the required temperature of -70°C up to 10 days before requiring re-icing.<sup>43</sup>

### *Sustainable technology and innovative finance*

Cleaner and more efficient cold chain technologies exist, but they face major barriers to financing and deployment at scale. The upfront costs of equipment and installation, lack of expertise to maintain these systems, perceived technology risks, and poor stakeholder incentives to pursue efficiency make it hard for developing countries to invest in cold chain equipment.

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<sup>42</sup> UPS Readies Freezer Farms to Ship Virus Vaccine — If We Get One, <https://www.bloomberg.com/news/articles/2020-08-03/ups-readies-freezer-farms-to-ship-virus-vaccine-if-we-get-one>. [Accessed on 21 October 2020]

<sup>43</sup> Pfizer Sets Up Its ‘Biggest Ever’ Vaccination Distribution Campaign, <https://www.wsj.com/articles/pfizer-sets-up-its-biggest-ever-vaccination-distribution-campaign-11603272614>. [Accessed on 21 October 2020]

Out of the box thinking is needed to deliver sustainable and inclusive cooling quickly and at scale while mitigating the impact on climate change. Sustainable cold chains for medical products require more than state of the art equipment; they require a holistic, market-based approach addressing issues on both supply and demand side. Business models can play a key role to achieve this. Innovative business models should set in place market mechanisms that align incentives between the key stakeholders to implement and operate the cleanest and most efficient technologies available.

A model that has been able to make use of existing structures and networks to deliver vaccines in Africa's most remote areas is Project Last Mile. Project Last Mile is a public-private partnership that makes use of Coca-Cola's supply chain management and expertise to support African governments in reaching the "last mile" to deliver vaccines. Coca-Cola has penetrated even the most remote areas of the African market and it would take years for governments to achieve such a robust cold chain structure. As distribution is not the end of the problem for successfully delivering vaccines, in some countries, Coca-Cola has trained the procurers of the refrigerators on how to use, distribute and maintain them.

An example of a successful business model for vaccine distribution can be seen in Cooling as a Service (CaaS). CaaS is a pay-per-use model based on the servitization strategy, in which the service of cooling is provided without selling the equipment. By maintaining ownership of the equipment as well as the responsibility to operate and maintain it, several key causes of cold chain failure could be addressed along with market barriers limiting the investments. CaaS could also allow repurposing of technology to address a multitude of cooling needs. This characteristic of the model to enable asset utilization optimization is highly relevant due to the sudden but temporary need for massive deployment of cooling systems for COVID-19 vaccine distribution, and the long lifespan of the equipment versus the timeline for vaccine needs.

Innovative business models like CaaS are also effective vehicles to involve the private sector to complement the supply chain and leverage private capital towards sustainable cold chain solutions. Innovative recapitalization mechanisms based on commercial or blended finance through project finance, asset-backed finance or securitization can help create portfolios of green projects for private and institutional investors.

### *Waste management*

Syringes, broken or discarded vials containing leftover vaccines and packaging materials as well as PPE will need to be disposed of properly. While packaging materials can be considered as municipal solid waste (but still of considerable volume to be disposed of sustainably), syringes, and leftover vaccines (bio-medical waste) will need to be treated through autoclaving/microwaving.<sup>44</sup> However, as we are mainly talking about outreach/mobile sessions, generated bio-medical waste will need to be carried to proper treatment facilities. A robust reverse logistics plan therefore should be in place.

### *Human resources*

As a substantial portion of the population will need to be vaccinated, additional staff will likely be required. If the vaccine is delivered at a rate of 84 doses per day by each member of medical staff (assuming that medical personnel work seven hours a day, and delivering each dose takes five minutes), then a single medical worker could deliver 1,680 doses per month (assuming 20 working days per month and seven working hours per day). Following the India example, to deliver the initial target of 400 million doses by June 2021, in a period of six months, around 39,683 medical staff will be needed. If India aims to achieve herd immunity in one year, then it will need around 90,278 medical staff to deliver the vaccine.<sup>45</sup> The introduction of new cold equipment will also require investment in the knowledge and skills of technicians and maintenance personnel across Africa and Asia. Close partnership with the Centres of Excellence around the world could support systematic investment in these human resources for COVID-19 cold chain management.

***If a COVID-19 vaccine requires cold storage, a significant and potentially dramatic expansion of sustainable cold chains across low- and middle-income countries must be treated as an urgent issue of equity. Without them, fair access to the vaccine is not guaranteed and it will be the poor who suffer the consequences.***

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<sup>44</sup> Guidelines for Disposal of Bio-medical Waste Generated during Universal Immunisation Programme (UIP) [https://www.mpcb.gov.in/sites/default/files/biomedical-waste/BMW\\_Generated\\_during\\_UIP03032020.pdf](https://www.mpcb.gov.in/sites/default/files/biomedical-waste/BMW_Generated_during_UIP03032020.pdf). [Accessed on 22 October 2020].

<sup>45</sup> Assuming the vaccine will require two doses to be effective.