



Keeping the Cold Chain Cold

Vaccine Supply Chains:
Reaching the Final 20 Policy Paper Series
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VILLAGE REACH[®]
X STARTING AT THE LAST MILE...

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Policy Series Overview

We are mid-way through the *Decade of Vaccines*, marking a period of significant activity to prevent millions of deaths through a more equitable access to vaccines. Today, more than 80% of children around the world receive a complete routine of life-saving vaccines during their first year of life. The *Decade of Vaccines* was established to bring attention to the importance of reaching that final 20% of children without access to these life-saving vaccines. This decade is bearing witness to many exciting efforts to strengthen routine immunization, accelerate control of vaccine-preventable diseases, and introduce new and improved vaccines.

To a large extent, the evaluation of this decade's success will be based on the degree to which vaccines reach the people who need them. A strong end-to-end supply chain should adapt to the resource constraints of these communities to ensure that delivery is complete: from the point of production of the vaccine at the manufacturing unit to the point of immunization. This policy series considers the different components of the supply chain, addresses the challenges faced at the last mile for distribution, and presents examples of innovative approaches to address those challenges. This first paper in the series covers the equipment component, with a focus on the cold chain.

VillageReach Overview

VillageReach, headquartered in Seattle, Washington, has worked for more than a decade to develop, test, and refine system innovations to improve the performance of different components of in-country vaccine supply chains. Working closely with the Ministry of Health in Mozambique and with support from the Bill & Melinda Gates Foundation, the *Final 20 Project* is building a sustainable model of innovative supply chain design, enhanced data collection and reporting, and public-private partnerships to improve the underlying infrastructure which the health system requires.

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In Mozambique, as in many low-income countries, the government vaccine supply chain typically follows administrative structures of the health system, distributing commodities from the national, to the provincial, and then to the district levels. The districts are then responsible for ensuring commodities are delivered to the health centers. Many of these health centers are located in rural, hard-to-reach geographies, with little available transport, limited telecommunications infrastructure, and sporadic electricity supply, if at all. Fulfilling delivery to achieve immunization requires a focus on the unique complexities of distributing to health centers in such remote, challenging environments. This 'last mile' delivery is typically the weakest link in the supply chain due to lack of infrastructure, overburdened personnel and inadequate technical capacity.

In addressing the unique challenges of last mile distribution, VillageReach is engaged in a multi-year program in Mozambique to improve the performance of the country's health system, focusing on rural communities that represent over 50% of the country's population. The approach – *the Dedicated Logistics System (DLS)* – was developed in collaboration with provincial governments and the Mozambican organization *Fundação para Desenvolvimento da Comunidade* (FDC). The DLS uses task shifting, level jumping, and dedicated resources to improve vaccine supply chain effectiveness and efficiency.

Requirements at the Last Mile

The Importance of Keeping the Cold Chain Cold

To ensure the optimal viability of vaccines, their storage and handling need careful attention.

Vaccines are highly thermo-sensitive biological substances which have a fixed shelf-life and lose viability over time. The loss of viability is irreversible and accelerated if proper storage and temperature conditions are not maintained. A vaccine vial must remain between 2 and 8 degrees Celsius throughout the entire cold chain system – when it is transported, when it is stored in a refrigerator or cold store, and when it is used at an immunization session. In addition to maintaining adequate refrigeration needs, proper handling practices need to be understood and practiced by all personnel along the supply chain. ^{1,2}

Monitoring and maintaining the viability of vaccines is important for several reasons:

1. *Product efficacy*: Vaccine failures caused by administration of compromised vaccines may result in child mortality and the re-emergence or occurrence of preventable infectious diseases.
2. *Resource management*: Vaccines are expensive and are often in short supply in rural communities with challenging transportation environments.
3. *Lost opportunities*: Loss of vaccines may result in lost opportunities to immunize on a large-scale, especially in hard-to-reach areas and resource-poor settings.
4. *Confidence in public health*: Re-vaccination for those who have received an ineffective vaccine compromises public confidence in the health system.

This lack of infrastructure and inadequate monitoring of uptime and its resulting impact on the cold chain is illustrated in the following statement from Dr. K.O. Antwi Agyei, head of the Expanded Program on Immunizations in Ghana: “We have good coverage rates in Ghana including in the North, but recently we had a measles outbreak because vaccine potency [viability] was compromised when the cold chain failed. We then had to organize a special campaign and this cost us additional resources.” ³

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Challenges to Maintaining the Cold Chain

The World Health Organization reports that the Effective Vaccine Management assessment (carried out in more than 70 countries between 2010 and 2012) found that only 29% of countries met its minimum recommended standards for temperature control.

Many challenges and complexities exist in ensuring the effective management of cold chain monitoring and maintenance at each level of distribution, as highlighted below:

Insufficient equipment and infrastructure

- Underdeveloped infrastructure in low-resource settings often results in an unreliable power supply with sporadic and frequent power cuts. This situation leads to an ineffective cold chain with greater reliance on human supervision and regulation and can result in inadequate and ad-hoc approaches to resolving cold chain problems.

¹ Milstien J, Kartoglu U, Zaffran M. Temperature sensitivity of vaccines. Geneva: World Health Organization; 2006. [WHO/IVB/06.10].

² WHO. Ensuring the quality of vaccines at country level. Geneva: World Health Organization; 2002. [WHO/V&B/02.16].

³ Sarley, David. [When RED meets RED: How Coca Cola and the Health Systems in Ghana are learning from each other](#), 2013.

- Unreliable communication networks limit data flow, the ability for the health system to coordinate resources, and increase response times to failures in the cold chain.
- Investment in the cold chain has not kept up with investments in vaccine development and deployment (see Figure 1). WHO estimates that about \$200 million US dollars is needed per year to address the cold chain needs in low-income countries.⁴

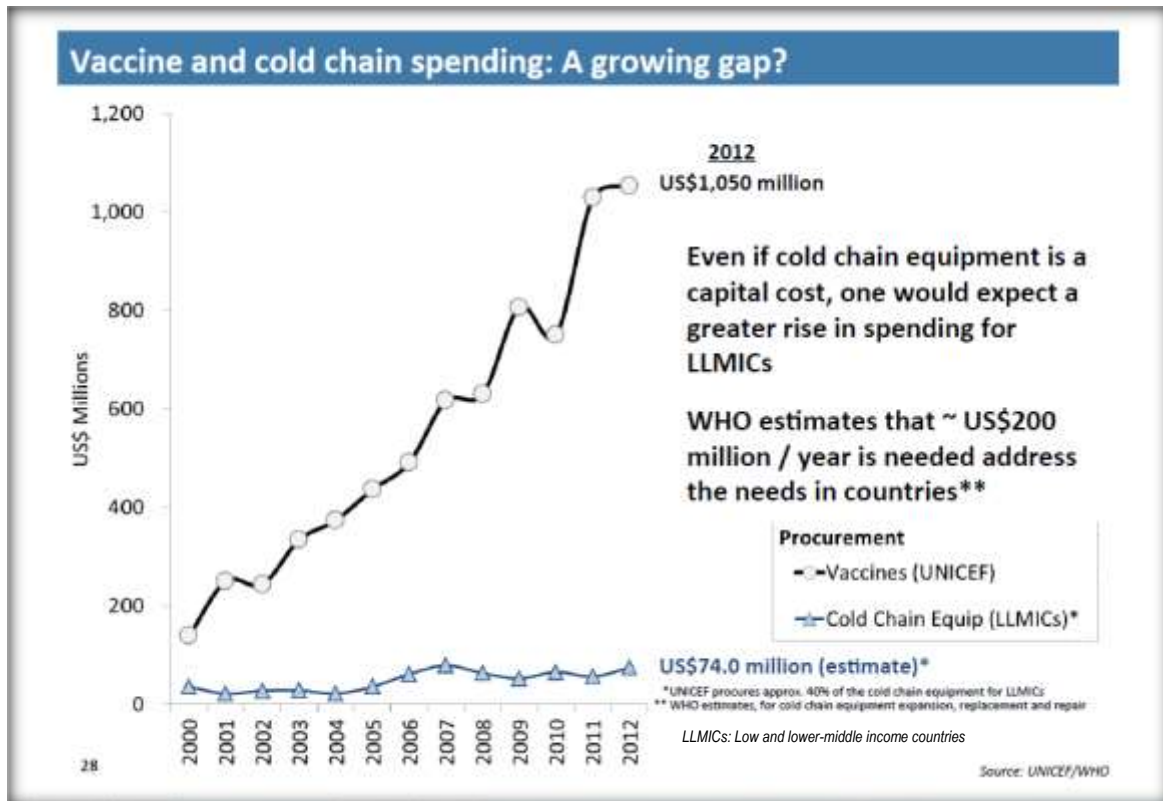


Figure 1: The Growing Gap between Vaccine Spending and Cold Chain Investments

- The use of solar refrigerators has been proven to compensate for power supply reliability but has several challenges of its own. Provincial staff lack sufficient technical knowledge needed for installation and maintenance. Further, batteries must be replaced every five years, requiring robust maintenance plans and budgets for equipment maintenance, neither of which exist uniformly in Mozambique. Additionally, solar panels must be securely installed to prevent theft, raising the cost of installation.
- In Mozambique, more than 10 different brands and types of refrigerators are installed in rural health centers across the country. With such diversity in equipment, the Ministry of Health is challenged to store all of the spare parts necessary and to ensure there is requisite technical knowledge to conduct maintenance and repairs.
- The vaccine vial monitor (VVM), which changes color as it is exposed to heat, informs health workers at a glance if the viability of a vaccine has been compromised. However, no equivalent detection method exists for freezing exposure, which can be more common and more damaging to the vaccines than heat exposure. One review article of 35 temperature

⁴ WHO, [November 2013 Meeting Presentation from the Strategic Advisory Group of Experts on Immunization](#). Geneva: World Health Organization; 2013.

studies found that 34 of the studies cited freezing temperatures in the cold chain, and 14 of those found more than 50 percent occurrence of freezing among recorded temperatures.⁵

- In Mozambique, the Ministry of Health uses mobile brigades (teams of traveling health personnel) to extend the reach of the vaccination program to rural areas. In addition to the challenges of ensuring the availability of transport, fuel and personnel to ensure routine outreach services, mobile cold chain equipment must guarantee the viability of vaccines during these sessions.

Adherence to appropriate vaccine stock management practices

- Over-stocking of vaccines in cold storage and poor shelving of packages leads to restricted air flow, which can present freezing risks or increased exposure to heat. Additionally, over-stocked or poorly stored vaccines can complicate adherence to the earliest-expiry-first-out (EEFO) principle, running the risk of excessive discarding of expired vaccines.
- High staff turnover, particularly in rural settings, impedes knowledge on and adherence to stock management and cold chain maintenance. Trained health workers will often be transferred to other geographic areas and health departments; new personnel coming into the immunization department do not receive proper training in these areas. This turnover exacerbates issues with stock management and other poor practices, such as using the refrigerators for personal food or beverage items. Additionally, there is a common misconception that as long as vaccines are kept cold, their viability cannot be compromised, resulting in misinformed health center staff setting vaccine refrigerators at lower than optimal temperatures.
- The temperature monitoring form should be manually completed twice a day by the health workers recording refrigerator temperature. These forms are often improperly completed. There is anecdotal information of the forms being filled out at the end of the week or just before a supervisor's visit.

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Insufficient technical personnel

- Each province in Mozambique has only one technician employed by the Provincial Directorate of Health (*Direcção Provincial de Saúde* - DPS), responsible for maintenance and repair of the cold chain for typically more than 100 health centers, 10-15 district-level refrigerators, and the provincial-level cold storage facilities.

The lack of availability of sufficient vehicles and poor roads can make it impossible for the sole technician working in each province to reach all health centers on a regular basis and in a timely manner.

New vaccine introduction

- Within this *Decade of Vaccines*, Mozambique will be introducing two new vaccines, Rotarix and HPV. These introductions present a great opportunity for the country but also increases its cold chain needs dramatically. For example, compared with the DTP vaccine, the packed

⁵ Matthias DM, Robertson J, Garrison MM, Newland S, Nelson C. Freezing temperatures in the vaccine cold chain: a systematic literature review. *Vaccine*. 2007; 25(20): 3980-3986.

volume of Rotarix is seven times greater, requiring much larger cold chain space at each level of distribution.

Solutions for the Last Mile

The DLS Approach

The DLS approach takes a simple but innovative approach to cold chain maintenance by integrating maintenance activities into vaccine delivery. This approach was created to fit current equipment, infrastructure and transportation conditions, human resource capacity and personnel expertise. It builds on other global experience in cold chain maintenance.⁶ Field coordinators are responsible for distribution of vaccines and data collection. To address the challenges maintaining the cold chain, they are also trained to provide basic maintenance of equipment during distribution visits. This approach broadens the capacity of the system to maintain the cold chain. The field coordinators serve as an extension of the one technician in each province and can provide an extra set of eyes to monitor the cold chain. This method differs from the traditional system of vaccine deliveries by placing a shared responsibility for data collection and cold chain maintenance at the last mile rather than solely at the district and national levels.

The field coordinators have specific tasks for **basic preventive maintenance** during distribution visits:

- Check the refrigerator thermometer to ensure refrigerator temperature is optimal;
- Confirm that the temperature-monitoring form is correctly updated;
- Verify the refrigerator is clean and only being used for vaccines;
- Verify the refrigerator is at a proper distance from walls to prevent overheating;
- Ensure adequate power supply for refrigerators;
- Regulate refrigerator temperature monitors to respond to seasonal weather changes, particularly in hotter months;
- Ensure vaccines in refrigerators are shelved efficiently to provide effective airflow, with older vaccines placed in front to for first use; and
- Provide technical assistance to the health workers at the health centers to ensure they understand basic preventive maintenance techniques.

These field coordinators are the very foundation of the entire cold chain maintenance strategy. Having dedicated personnel with technical capacity who reach every health center each month brings enormous benefits to the cold chain. Preventive maintenance can confirm the equipment is working properly to avoid emergency situations and outages. As normal wear and tear can result in diminishing efficiency, preventive maintenance can conserve the energy and life of the equipment. Additionally, preventive maintenance costs less and takes less time to facilitate than a costly repair or replacement. These simple monthly check-ups help avoid costly breaches in the cold chain.

⁶ [Coca-Cola and Ghana Health Service learning from each other](#). Presented by David Sarley at the Global Health Supply Chain Summit, 2013. Accessed January 15, 2014.

Before the DLS was implemented in these provinces, anecdotal evidence points to recurring problems with the cold chain, with health center staff from the Cabo Delgado province noting that on average, about 40% of the health centers encountered breaches in the cold chain on a regular basis.

The uptime of the cold chain in the four provinces in which the DLS operates is at least 95% or higher, as recorded by field coordinators during monthly distribution visits.

Breaks in the cold chain are inevitable, even with basic preventive maintenance: equipment will fail and batteries will expire. In these situations, **corrective maintenance** is practiced. The health workers at the health centers are required to inform the district officers and field coordinators immediately and arrange for the vaccines to be stored at the district store or a nearby health center to avoid vaccine spoilage. In addition, the field coordinators arrange for corrective maintenance in instances when a simple and immediate repair is not possible. Corrective maintenance includes changing a fuse or replacing a battery for solar refrigerators, for example. In the case of complete equipment failure, the whole device may need to be replaced. Field coordinators collaborate with DPS equipment technicians and VillageReach staff to schedule time and transport to get the technician to these rural areas with the required spare parts.

As a result of this more proactive approach to equipment monitoring and repair, the uptime of the cold chain increases. However, despite these improvements, the DLS approach is not without its own challenges:

- With only one technician per province, the required level of corrective maintenance is difficult to achieve.
- The only verifiable data on refrigerators' uptime at the health centers is when the field coordinators make their monthly visits and check the temperature of the refrigerators. Apart from this single monthly point-in-time check, the uptime of the cold chain is not monitored beyond the staff at the health center. As a result, changes in temperature between field coordinator visits may go unnoticed by health center staff, with no chance for possible follow-up action to test vaccine viability or mal-functioning refrigerators.
- Emphasizing prevention still does not resolve the numerous other issues of transport availability, the need for maintenance plans, and an accessible supply of spare parts (see Box 1).

Box 1: Notes from the Field: Cold Chain Maintenance in Action

In a recent assessment in one province using the DLS approach, of 160 refrigerators, 37 were not functioning at the time of the assessment. Of those not functioning, 26 (70%) were solar powered, reflecting the enormous challenge of having a constant supply of batteries available to the technician and the DPS for corrective maintenance.

As a result of an emphasis on cold chain preventive maintenance and the provision of extra sets of eyes on the cold chain, VillageReach coordinated efforts among partnering organizations to raise the issue of the need for more batteries for the solar cold chain equipment. A partnering NGO provided several batteries to the DPS, and VillageReach organized transport for the technician to visit these health centers to install them. As a result of these efforts, five more health centers have working refrigerators and can provide vaccines once again.

- It is difficult to incentivize leadership to support this approach, as preventive maintenance activities are not as “high profile” or “high visibility” activities as is fixing a non-functioning refrigerator. This obstacle of placing just as much value or more on the proactive values associated with preventive maintenance is one of the first to be overcome when introducing the DLS.

Global Innovations for the Last Mile

Innovation in Equipment

Much investment is being made in alternative and improved cold chain equipment to respond to existing power sources.⁷ Approximately 50% of health facilities in sub-Saharan Africa are likely to remain functionally off-grid for the foreseeable future. In Mozambique, Ministry of Health surveys of its ten provinces show that 50-80% of the health centers are off-grid.

Technical design and special materials are being used in the manufacture and assembly of insulated vaccine carriers and cold boxes that prevent freezing even when fully frozen ice packs are used. Additionally, new technologies are being used to respond to the need for carriers that can transport larger volumes of vaccines and make more efficient use of transport volumes. Other technologies have been developed to produce highly-insulated containers that maintain a constant temperature for up to a month between ice changes. Examples include:

- [Savsu Nano-Q](#): a stationary passive cooling device designed for long storage times during shipment and for emergency long-term storage in remote areas; and
- Intellectual Venture’s Global Good [Passive Vaccine Storage Device](#): designed to keep vaccines at the appropriate temperatures for one month or more despite repeat opening of the container and with no need for electricity.

As the need for longer-life, larger-capacity cooling technologies becomes necessary, more innovative technologies are expected to be developed.

Innovation in Data Management

Telematics and telemetry, or machine-to-machine communications (M2M), present the global health community with an opportunity to improve the quality of data reported from the field. Using telemetry to digitize paper-logged inventories of vaccines and other medical commodities, to automate performance reporting on equipment found in health centers, or to transmit data collected at remote points to receiving equipment for monitoring all could significantly enhance health systems’ ability to make more cost-efficient, informed decisions and prioritize effectively.

In high-income countries, telemetry is a mature commercial marketplace: the sector has grown to become a \$40 billion industry. Many sectors (banking, food perishables, energy, retail and healthcare) apply telemetry to provide remote monitoring of their cold chain equipment, inventory management, asset tracking and infrastructure assessment. A growing number of application providers, device manufacturers and service providers are participating.

The global health community’s increasing interest in telematics (integrated use of telecommunications and informatics) reflects significant advances in wireless communications and

⁷ [Innovative passive cooling options for vaccines](#). PATH OPTIMIZE: Immunization systems and technologies for tomorrow. Accessed December 10, 2013.

power supply for rural communities. Recent improvements in cell coverage and the provision of alternate power (non-grid) together suggest a growing potential for both telematics and telemetry to enable improved data reporting from the field. In the communications sector in particular, there has been an explosive growth of cell phone usage in Africa, leapfrogging fixed-line deployments (the GSMA estimates Africa wireless connections at 500 million in 2013, with 18% annual growth over the past five years⁸). Today, mobile networks are the primary mode of access to the Internet in the region.

As an example of expanded mobile coverage, in the two most northern provinces of Mozambique (a total population of roughly 3.2 million, with some of the lowest population densities and remote communities) approximately 97% of health centers have 2G wireless access.

In Mozambique, VillageReach will be piloting the *ColdTrace* monitoring platform, developed by [Nexleaf](#). This device uses a low-cost wireless sensor to remotely monitor the temperature of cold chain equipment and transfer the monitoring data via telemetry to decision makers. Through this device, any breach in the cold chain can be immediately brought to the attention of the technician and program supervisor for them to respond accordingly.

Conclusion – The Next Step: More Data, Increased Transparency, Knowledge Sharing

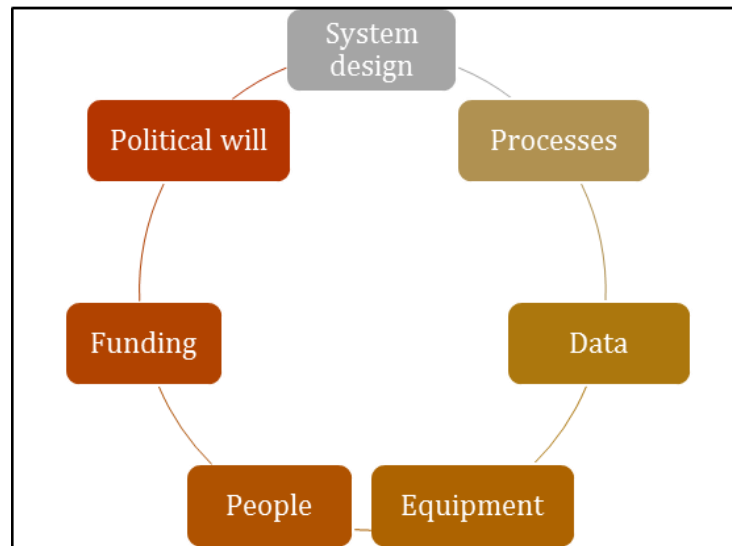
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The many challenges of vaccine distribution systems in low-income countries highlight the need for innovative solutions regarding the cold chain. Knowledge on cold chain uptime is crucial to ensuring vaccine viability. At the time of this writing, little evidence is available on the ways in which low-income country governments and NGOs are recording continuous cold chain uptime. More studies are needed to augment the evidence-base in order to gain a better understanding of the cost-effectiveness of investing in cold chain uptime monitoring. Detailed studies that monitor both time and temperature exposure across the entire length of the cold chain could provide the richest source of information for such purposes.⁹ If cost-effective solutions are in practice, it is vital this information and knowledge is shared and disseminated widely within the global health vaccine community. Further, doubts about data quality and equipment uptime can also be avoided by investing, testing, and introducing new cost-effective technologies that provide continuous temperature monitoring and recording.

⁸ GSMA Intelligence, <https://gsmaintelligence.com/analysis/2011/09/global-mobile-connections-to-surpass-6-billion-by-year-end/299/>.

⁹ Matthias DM, Robertson J, Garrison MM, Newland S, Nelson C. Freezing temperatures in the vaccine cold chain: a systematic literature review. *Vaccine*. 2007; 25(20): 3980-3986.

Policy Series Background



Components of the Vaccine Supply Chain

This paper is the first in a series addressing the components of the vaccine supply chain. The health supply chain is a dynamic ecosystem which can increase access to high quality products by efficiently bringing the different components together to ensure delivery of commodities, as seen in the figure above. *System design* involves the set-up of the components of the supply chain system and how they interface with each other. The *processes* and policies determine how logistics practices get implemented in the field. Information and *data* flow influence forecasting, procurement, and daily management of the system, both at the global and in-country levels. *Equipment* ensures vaccines are delivered and have proper storage at every point of the supply chain. A key component is the *people* who operate and influence the supply chain and their capabilities, expertise, culture and behavior. The availability of *funding*, and particularly the flow of funding for each of the different levels of the system, is vital to ensuring delivery of vaccines. Finally, *political will* and the aspirations of leaders and champions can influence the performance of a supply chain by regulation and creating an enabling environment. Determining how the seven main components of the vaccine supply chain work together ultimately influences the degree of availability of vaccines at the point of immunization.

Future papers in this series will address other components, drawing on the evidence from the last mile of vaccine distribution through the *Final 20 Project* and global experience.

For more information, please visit www.villagereach.org.

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