

## Review

## Improving cold chain systems: Challenges and solutions



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## ARTICLE INFO

## Article history:

Available online 23 September 2016

## Keywords:

Vaccine cold chain  
Cold chain technology  
Cold chain capacity  
Temperature monitoring  
Cold chain equipment maintenance  
Immunization supply chain

## ABSTRACT

While a number of new vaccines have been rolled out across the developing world (with more vaccines in the pipeline), cold chain systems are struggling to efficiently support national immunization programs in ensuring the availability of safe and potent vaccines. This article reflects on the Clinton Health Access Initiative, Inc. (CHAI) experience working since 2010 with national immunization programs and partners to improve vaccines cold chains in 10 countries—Ethiopia, Nigeria, Kenya, Malawi, Tanzania, Uganda, Cameroon, Mozambique, Lesotho and India—to identify the root causes and solutions for three common issues limiting cold chain performance. Key recommendations include:

## (1) To address cold chain capacity:

- developing an accurate picture of cold chain capacity gaps based on current and future needs;
- resource mobilization, and;
- effective monitoring during implementation.

## (2) To encourage upgrade of cold chain with latest technology suitable in country:

- in-country piloting of new equipment;
- utilization of tools to better understand equipment trade-offs, and;
- guide equipment selection and regular engagement with suppliers.

## (3) To control temperature excursions and equipment breakdowns

- introduction of temperature monitoring and control (TMC) devices and practices;
- improve competence and availability of existing and future technicians, and;
- ensure availability of spare parts.

Collectively, the solutions detailed in this article chart a path to substantially improving the performance of the cold chain. Combined with an enabling global and in-country environment, it is possible to eliminate cold chain issues as a substantial barrier to effective and full immunization coverage over the next few years.

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\* Open Access provided for this article by the Gates Foundation.

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## 1. Introduction: the importance of immunization cold chain performance

Immunization is widely acknowledged as one of the most successful and cost-effective public health interventions in history, saving two to three million lives every year [1]. New vaccines such as pneumococcal conjugate vaccine (PCV) and rotavirus vaccines could save an additional million lives per year [2,3]. However, national immunization programs continue to face delivery challenges in terms of sustainably closing the immunization coverage gap,<sup>1</sup> introducing new vaccines and securing sustainable funding.

Vaccine cold chain and logistics systems are central to addressing some of these challenges [4–7]. While a number of new vaccines have been rolled out across the developing world (with more vaccines in the pipeline), cold chain systems are struggling to support national immunization programs. This has resulted in (a) risks of reduced potency of vaccines administered (e.g. due to poor temperature control, nonfunctional equipment), (b) poor availability of immunization supplies (due to inadequate storage capacity, disrupted service delivery, vaccine stockouts, etc.) and (c) inefficient use of limited financial and human resources (e.g. through losses from vaccine wastage). Improving cold chain systems can therefore, expand effective immunization coverage and further reduce the number of deaths caused by vaccine preventable diseases.

For example, in Ethiopia, the introduction of the pneumococcal, rotavirus and pentavalent vaccines has increased the volume of antigens delivered by more than fivefold (see Fig. 1). In parallel, the value of vaccines delivered has increased ten-fold, meaning that any vaccine wastage due to cold chain weaknesses (e.g. poor temperature control, insufficient storage capacity, etc.) will incur significant costs.<sup>2</sup> As such, ensuring the safety, sufficiency and efficiency of the cold chain is critical.

This article reflects on CHAI's experience working with national immunization programs and partners to improve vaccine cold chains in 10 countries—Ethiopia, Nigeria, Kenya, Malawi, Tanzania, Uganda, Cameroon, Mozambique, Lesotho, and India—since 2010.

While the implications of weak cold chains have been reviewed in several studies, there are fewer publications evaluating interventions to address these performance issues [4–7,9]. To address that, section 2 discusses some structural factors that perpetuate

cold chain challenges, while section 3 deep-dives into three common challenge areas, and the solutions that can help address them.

## 2. Challenges in improving cold chains

In many low-income countries, vaccine delivery systems have remained largely unchanged due to challenging contextual factors that have limited their ability to meet immunization program requirements. Structurally, the scale and geographic spread of cold chain systems have been demanding, given the need to consistently reach the whole population. Kenya, with a yearly birth cohort of nearly 1.5 million children, currently provides immunization services at nearly 6000 facilities equipped with cold chain storage capacity [10].<sup>3</sup>

Furthermore, diverse population settlements (e.g., urban, semi-urban, rural) present unique contextual challenges that test cold chain capabilities and managerial responses. For example, road and mains power access is challenging for over 70% of health facilities in Uganda, with limited road networks further complicating access to 'off-grid' solutions like gas.

In other situations, the service delivery type (e.g. static, outreach, mobile) can drive key challenges. Some countries provide more than 50% of services via outreach, which places particular burdens on health care workers (who might have to walk long distances) and impact the ability to deliver frequent immunization sessions [11].

Finally, understanding of cold chain performance is often limited by lack of performance management systems. While glimpses of cold chain performance are available from infrequent, ad hoc cold chain assessments (e.g., inventories or temperature monitoring studies), there are rarely routine systems in place to provide consistent insight into cold chain performance, and enable day-to-day performance management.<sup>4</sup>

## 3. Immunization cold chains: Core challenges and solutions

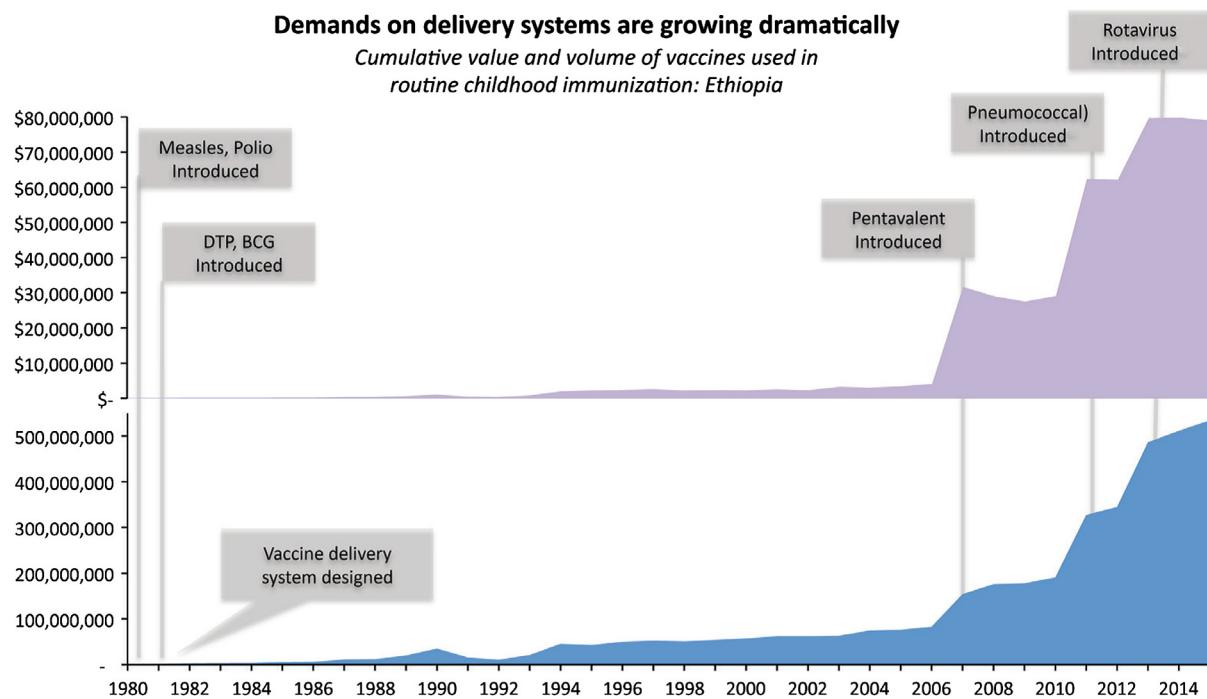
With the support of local governments and development partners, CHAI's work has identified three key issues limiting cold chain performance: (1) Insufficient cold chain capacity. (2) Lack of latest technology or 'optimal' equipment. (3) Inadequate temperature monitoring and maintenance systems.

<sup>1</sup> Each year, an estimated 22 million children are unvaccinated, and 1.5 million children under the age of 5 lose their lives to vaccine-preventable illnesses [29].

<sup>2</sup> WHO-recommended routine immunization schedule has raised the price of a full immunization course from US\$0.67 in 2001 covering six diseases (tuberculosis, measles, diphtheria, tetanus, pertussis and poliomyelitis) to a minimum of US\$32.09–45.59 to immunize a child against 12 diseases (covering additionally rubella, hepatitis B, Haemophilus influenza type b, pneumococcal diseases, rotavirus and, for adolescent girls, human papillomavirus–HPV; assuming 3 doses) in 2014 (based on lowest available prices for UNICEF Supply Division for Gavi eligible countries).

<sup>3</sup> At an even larger scale, India caters to its 26 million large birth cohort [30] by conducting 9 million immunization sessions a year (75% of which are outreach sessions) through 27,000 cold chain points [31].

<sup>4</sup> See CHAI Commentary article in this issue for a more comprehensive review of this issue.



**Fig. 1.** Rising demands on cold chain systems. Adapted from [8].

### 3.1. Insufficient cold chain capacity

#### 3.1.1. Scale of the problem

While routine immunization needs, campaigns, and population growth contribute to rising storage capacity requirements, new vaccine introductions have been the major driver of capacity expansion requirements [4,5,12,13]. When such capacity is absent, there are serious consequences:

- New vaccines introductions can be delayed, or – if not delayed – may overwhelm existing capacity leading to exposed vaccines and/or stockouts.
- Coping strategies for insufficient capacity amplify delivery challenges. When higher levels of the supply chain increase delivery frequency, space is created, but delivery costs increase. This may also jeopardize vaccine stock availability and coverage if vaccines are diverted to sites based on capacity rather than consumption/need [13,14].
- Breakdowns in equipment at any level pose an even higher risk to vaccines, as there is less ‘flexible’ capacity in the system. This can disrupt stock and vaccine management principles, resulting in higher levels of damaged or expired vaccine stock [7].
- Inadequate capacity can disrupt service delivery. Unequipped facilities<sup>5</sup> are serviced through outreach activities, which may struggle to ensure sufficient and safe vaccines throughout the session.

#### 3.1.2. Causes of insufficient capacity

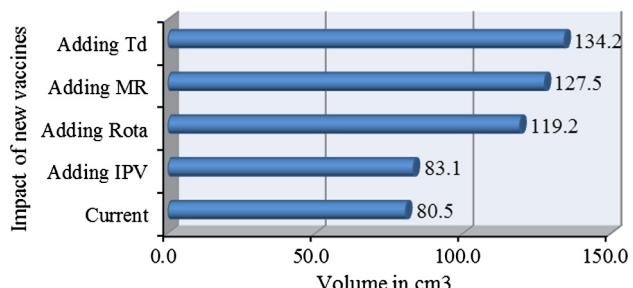
3.1.2.1. Poor visibility/understanding of current cold chain equipment status. Most cold chain inventories do not have systems for routine data collection, which limits the existence of accountability structures and inhibits accurate and regular inventory updates. In response, programs resort to mobilizing resources for expensive

site level inventories, as these provide the reliability to comprehensively update the database. However, in the interim period, immunization programs lack the visibility to identify and prioritize the capacity gaps, or take targeted action to fill them.

3.1.2.2. Insufficient forecasting of future capacity requirements. Anticipating future needs is essential, particularly given the lead times for procurement and installation of cold chain equipment (~1.5 to 2 years). Capacity needs also evolve over time with new vaccine introductions, campaigns, and population growth. For example, with the introduction of IPV, Rotavirus, Td and MR in Uganda over the next few years, positive storage volume requirements for all vaccines will increase by 67% (see Fig. 2).

3.1.2.3. Inadequate implementation systems. Even when sufficiency gaps are identified, immunization programs often lack the systems and resources to fill them. For example, when countries review their cold chain inventories, they usually discover that daunting quantities of equipment need to be procured, which can be hindered by:

#### Estimating Vaccine Storage Volume Requirement



**Fig. 2.** Volume impact (cm<sup>3</sup>) of new vaccine introductions in Uganda. Source: Uganda Cold Chain Expansion and Rehabilitation Plan 2016–2020.

<sup>5</sup> Equipped with either active cold chain capacity like an appropriate vaccines fridge or a very long-holdover passive storage device.

- **Inadequate financing:** Inability to raise sufficient funding forces countries to fill sufficiency gaps in a piecemeal fashion including CCE donations or purchasing through existing GAVI HSS grants.
- **Limited delivery and installation capabilities:** Many countries face bottlenecks in their capacity to store, test and transport new equipment, leading to deployment delays. Limited technician availability further slows deployment, and poor quality installation can result in early breakdown and reduced equipment lifespan.
- **Inadequate implementation monitoring and management:** Without strong systems to track progress, countries will lose track of the capacity gaps that have been filled. This leads to a breakdown in the planning and allocation process, which becomes ad-hoc and detached from evidence.

### 3.1.3. Solutions to address sufficiency gaps

**3.1.3.1. Develop an accurate picture of cold chain capacity gaps based on current and future needs to create a robust action plan.** To achieve the required visibility into the cold chain, data is needed to profile the following:

- **Equipment** available at every storage site (e.g., functional status, type and age).
- **Sites** (e.g., target population they serve, power availability and weather conditions, etc.).

Ensuring regular visibility requires fixed structures for reporting, including accountability, responsibility for data reporting, collection and analysis of both current and future (3–5 year) capacity needs.

Countries may also wish to modify their cold chain network align with efficient immunization approaches. For example, Nigeria's 'SDD for every ward' policy was designed to improve access to stable storage and ease pickup of vaccines [15]. Similarly, Ethiopia recently decided to expand its network to include a large segment of facilities located in pastoralist areas,<sup>6</sup> in order to address inequities in immunization coverage [16].

When visibility of cold chain is at the site- and model-level, it enables plans to incorporate:

- **Informed decision-making on equipment selection** tailored to the context and needs of individual sites.
- **Costing** of cold chain rehabilitation and expansion requirements.
- **Prioritization** that focuses on equipping the largest and most urgent needs first.
- **Alignment of equipment procured with implementation capabilities** leveraging ability to procure, store, test, transport and install equipment in a phased manner and allocating equipment to sites appropriately.
- **Informed advocacy by governments to donors and partners** that empowers governments to proactively request donations of specific types and quantities of equipment.

**3.1.3.2. Develop a resource mobilization plan to implement actions.** Once cold chain sufficiency funding needs are known, a resource mobilization strategy is critical. Globally, there are an increasing number of funding sources for cold chain equipment, including Gavi's Health Systems Strengthening (HSS) and the Cold Chain

Equipment Optimization Platform (CCEOP) grants. These can also be used to complement one another, as illustrated by countries that are using HSS funds to meet CCEOP co-pay requirements.

However, to fully and sustainably meet their needs, governments must mobilize funding internally and incorporate equipment purchases (which make up relatively small share of overall immunization costs) into their budgets. Utilizing these funds efficiently requires implementation planning that ensures resources are available when needed and that equipment deployment timelines are aligned with deployment capacity.<sup>7</sup>

**3.1.3.3. Monitor plan implementation.** Monitoring progress against cold chain insufficiency should be a central element of national and sub-national logistics reviews. Routinely assessing indicators such as equipment procurement and installation progress allows coordinated corrective action where needed, and maintains timelines.

In line with this, some countries are adopting 'live inventory systems' that flag sites with under-capacity, absent or non-functional equipment. This can be used to trigger re-procurement and maintenance/replacement actions respectively. Such systems must account for country contexts – this means determining an update method that is a) sufficiently regular (real-time, quarterly, bi-annual) for tracking, b) sufficiently accurate to base major decisions on, and c) feasible within operational and budgetary constraints.

### 3.2. Unsafe technology and slow adoption of better equipment

#### 3.2.1. Scale of the problem

The performance of cold chains has been hampered by large quantities of outdated equipment, which fails to provide the protective benefit of more recent designs. These previous-generation units often have poor temperature control, shorter holdover times and lack freeze protection, putting new vaccines at risk and limiting the efficiency of cold chains. Temperature damage to vaccines is a known problem in many countries, and is often driven by failures in equipment [9,17–23]. This poses major risks to national programs—in Ethiopia alone, a 1% increase in vaccine wastage due to poor temperature control would result in losses of over US\$8 million of vaccines per annum.<sup>8</sup>

In CHAI's experience, the cold chain mix in many countries is characterized by:

- **Old and obsolete technologies:** Between 15% and 50% of equipment are older than the recommended 10 years, after which they are more susceptible to breakdown and poor temperature control.
- **"Domestic fridges":** Household refrigerators are cheaper, widely available and easily purchased. However, they are not safe for vaccine storage, as they do not reliably maintain optimal temperature ranges [24]. Despite this, some countries meet 45% of their CCE need with such fridges.
- **Absorption-type fridges:** Fridges fueled by kerosene or bottled liquid petroleum gas are widely used (60–80% of CCE in some countries), but are no longer approved by the World Health Organization (WHO) Product, Quality and Safety (PQS) system<sup>9</sup>

<sup>7</sup> Implementation capacity consists of human resources (e.g., technicians for installation, testing, transport) and physical resources (e.g., trucks for transporting equipment; storage space to safely keep equipment, etc.).

<sup>8</sup> Based on the total value of vaccines to Ethiopia being US\$83 million annually based on the assumption of a 2014 cost of vaccine per fully immunized child of US \$26.7 (CHAI calculations that includes BCG, Pentavalent vaccine, OPV, PCV, rotavirus vaccine, TT and measles) and a birth cohort of 3.1 million in 2014 (<http://www.gavi.org/country/ethiopia/>).

<sup>9</sup> Due to environmental concerns, low efficiency and poor temperature control.

<sup>6</sup> Not all countries focus on expanding storage capacity in the same way. Some countries try to address immunization gaps by having more regular outreach sessions. For example Bangladesh serves a population of 150 million with about 700 cold chain points, operating about 8 outreach sessions per day from fixed facilities.

[24]. They pose a risk to stable service delivery and storage, as fuel availability can easily be disrupted by gaps in funding, procuring and/or canister distribution [25].

### 3.2.2. Causes for weak adoption of better technologies

#### 3.2.2.1. Insufficient awareness and recognition of the benefits of these new features.

Lack of awareness regarding relevance of new features and benefits of upgrading equipment in individual countries is among the most significant barriers to adoption of new technology.

Many countries are not aware of the risks in their cold chain until studies are done to reveal the degree of exposure that occurs during storage and/or transport. For example, a study in India found that up to two-thirds of vaccines were damaged by freeze exposure in the cold chain between state stores and administration sites across ten States [22]. In Eastern Nigeria, another study found 42% of yellow fever vaccines available in the private sector had been compromised by freeze damage [23].

**3.2.2.2. Switching costs.** Concerns about the performance and reliability of latest generation units can also inhibit uptake of newer technology. Without evidence on how new units perform in-country, immunization programs may be reticent to make a sudden shift away from models that are perceived to work well. These concerns around new technologies are understandable given the global experience with solar battery technology. A large proportion of these units—first recommended as an alternative to gas and kerosene absorption refrigerators—were abandoned after they failed to function for >3–5 years and did not adequately maintain temperatures [26].

**3.2.2.3. Expensive product offerings.** Countries have favored older technologies as optimal units are initially more expensive; although newer technologies are cost-competitive when evaluated on a 'Total cost of ownership' (TCO) basis [25].

However, changing market dynamics—through regulatory and commercial incentives—are fostering greater competition and enabling 'optimal' technologies to become more cost competitive. New guidelines and standards from WHO—e.g., including freeze protection grades in the PQS catalog [24]—have incentivized suppliers to introduce better products, increasing the competitiveness of the optimal equipment market. Commercially, efforts to supply market intelligence have provided greater certainty to suppliers, enabling them to lower profit margins.

### 3.2.3. Solutions to encourage adoption of better equipment

#### 3.2.3.1. In-country piloting of new equipment, to identify the best performing and most cost-effective models of a given type.

Piloting technologies enables evidence-gathering on performance, cost-effectiveness and usability.

This enables governments to gradually move towards wider adoption, based on observed performance at a smaller scale – thus minimizing risks to the program while leveraging the features of the latest technology. From suppliers' perspective, piloting is a good mechanism to test products and solicit feedback from users on how products could be improved. For example, pilot studies – conducted by CHAI with the support of the local government and partners – in Nigeria of long holdover ice-lined refrigerators helped determine the power supply thresholds required by such models, and their level of performance under 'real world' conditions.

Note, however, that the purpose of piloting new technologies is to evaluate performance and suitability within a country's health system and not necessarily to fill cold chain gaps. Despite the need to fill capacity needs, governments must be prepared to reallocate or remove pilot equipment if they are found to be unsuitable.

**3.2.3.2. Utilize tools to better understand and inform equipment trade-offs and guide equipment selection.** As of 2016, CHAI has supported WHO PQS with updating a number of standards and descriptions in the PQS catalog such as freeze protection capabilities, holdover time and power requirements [24]. These should be considered by immunization programs during equipment selection, and governments can call on partners and UNICEF SD to provide clarification and support where needed.

Equipment selection decisions should be driven by TCO, and not just initial procurement cost [27]. This helps ensure the government gets the best value over the lifetime of the equipment (including costs of maintenance, repair and energy). In Uganda, the government discovered the benefits of using solar direct drive refrigerators at off-grid facilities over absorption equipment by calculating total cost of ownership, with the phasing out absorption equipment (>50% of all equipment in-country) potentially saving US\$3.45 million in energy costs over five years.

**3.2.3.3. Constant engagement with suppliers.** In addition to providing feedback during piloting, countries can benefit by engaging regularly with suppliers to provide feedback or encourage product innovations. This communication to suppliers, when complemented by product design and economic guidance and relevant market intelligence (e.g., demand forecasts), can help introduce products that are higher-performing and better suited for the usage contexts without being over-designed, while also being more affordable and cost-effective in terms of TCO.

### 3.3. Inadequate temperature control and maintenance systems

#### 3.3.1. Scale of the problem

Evidence from cold chain inventories show that many countries are struggling to maintain required storage temperatures, with 17–33% of CCE across four countries<sup>10</sup> found to be inactive at time of assessment. Temperature monitoring studies (TMS) have found that active CCE are often not functioning properly, with significant temperature control problems. Malfunctions are common at the facility level, where CHAI and partner-supported TMS have found that between 10% and 46% (mean, 29%) of CCE are exposing vaccines to freeze risk.<sup>11</sup>

There is strong evidence that functionality issues are not rare exceptions, but represent chronic gaps in CCE management. In Nigeria, the average time to repair a fridge at the lower government area (LGA) level ranged from two months to two years.<sup>12</sup> Furthermore, excursions – extended deviations from the safe 2–8 °C range – are failing to be detected and resolved, even accounting for deviations in monitoring practice. For example, CHAI and partner-supported TMS have found extended excursions at the facility level<sup>13</sup>

- 9–20% of CCE in study facilities maintain sub-zero conditions for longer than 24 hours.
- 12–13% of CCE in study facilities maintain greater than 8 °C conditions for longer than five days.

#### 3.3.2. Causes of poor temperature regulation

##### 3.3.2.1. Awareness and monitoring of functionality status.

Acute CCE breakdowns are evident to health workers on site, but freeze and heat exposures are harder to detect. While the WHO mandates

<sup>10</sup> Cameroon, Tanzania, Ethiopia and Uganda.

<sup>11</sup> Results of CHAI-executed temperature monitoring studies conducted across 5 Gavi countries.

<sup>12</sup> Based on baseline data collected as part of Canadian Department of Foreign Affairs Trade and Development grant across 4 states.

<sup>13</sup> Based on TMS data from two countries. Note that due to limited sample size TMS are not statistically representative although they are indicative of a wider issue.

all vaccine CCE to have continuous temperature monitoring devices (CTMDs) to monitor for any excursions, many cold chain sites rely on stem thermometers, which cannot detect such exposures.<sup>14</sup> CTMD deployments can also be problematic, as the most common devices expire after 3 years. This can lead to gaps in coverage, and CHAI studies in countries where CTMDs have been fully deployed found that 54–56% of facilities had CTMDs absent, non-functional, or near expiry.<sup>15</sup>

Where a proper CTMD is present, resources are often lacking to ensure utilization and corrective actions (e.g., requesting repair). Post-rollout studies in three CHAI countries have found knowledge of alarm interpretation and response was between 30% and 66%—despite at-scale distributions and trainings in the preceding two years.<sup>16</sup> Furthermore, managers rarely review device records, which lead to issues going unreported and unaddressed.

**3.3.2.2. Availability of services and resources.** While awareness of functionality is critical, alarms must be tied to corrective actions by a trained and equipped cold chain officer and/or technician. Across many countries, a consistent set of barriers to this have been identified:

- Technician cohorts are underskilled and understaffed, with few sources for replacing retiring/departing staff with appropriately-certified hires.
- Spare parts are unavailable due to absent or inconsistent procurement, and difficult to access when present (e.g., exclusively stored at central level).
- Existing resources—such as Ministry of Works technicians—are difficult to access due to weak inter-departmental agreements and procedures.

### 3.3.3. Solutions to control temperature excursions

**3.3.3.1. Introduce temperature monitoring and control (TMC) devices and practices.** For many countries, a critical first step to improving temperature control practices is the replacement of stem thermometers with CTMDs. These provide visibility into fridge performance that allows staff to take substantive actions. Higher-level sites may also be appropriate for remote TMDs, which provide additional security through SMS and email alarms. In all cases, TMD procurement and deployment should be part of budget planning processes (e.g., cMYPs), to ensure there are no gaps in device coverage.<sup>17</sup>

To ensure CTMD alarms drive meaningful action, health workers should know the procedures to resolve alarms, and all sites should have wall-mounted job aids that clearly define core processes. To support this, countries can integrate TMC practices into pre-service and routine vaccine management training. Additionally, clearly defined accountability measures are crucial where appropriate officers (commonly, district officers) routinely review CTMD alarms and are held responsible for coordinating fridge trouble-shooting and/or repair in the event of severe freeze and heat events. Mandated district- or region-level reviews of fridge performance can help institutionalize this process.

**3.3.3.2. Improve the competence and availability of existing and future technicians.** Proper installation, preventive maintenance and repair

of CCE requires a competent and sufficiently large cohort of technicians. For countries using a public sector model, there is often a need to build both immediate and long-term technician capacity.

To address the near-term gap, countries can leverage maintenance campaigns to provide on-the-job training to existing staff. This hands-on training with real CCE has proved highly successful in driving maintenance outcomes. For example, in Ethiopia, such an approach resulted in 516 mid-level technicians being trained on CCE repair and led to the restoration of over 100,000 L of CCE capacity.<sup>18</sup>

To address long-term needs, a stable intake and staffing approach is needed. In CHAI's operational countries, the immunization programs have found the following efforts promising:

- In Tanzania and Ethiopia, CCE maintenance and repair is being integrated into the curriculum of major technical colleges. This produces graduates already trained to enter cold chain roles.
- In Kenya and Tanzania, the country is looking to existing technical service providers (e.g., MoH and Ministry of Works), and adding cold chain to their competencies. This shares the financial burden across the government system, while still allowing access to maintenance.

Some countries may look to the private sector for CCEM services. When considering this route, CHAI's experience points to a few key requirements:

- During selection, a vendor must be able to demonstrate a history of competence with refrigeration equipment, ideally in medical settings.
- A clear contract is needed, including prices, service requirements (e.g., time-to-repair), and consequences for any breach of contract. This allows the government to stop payment and/or terminates the contract in the event of underperformance.
- Stable funding flows are essential. Delays or non-payment will result in vendors denying service. This can result in non-functional CCE, with few (or no) public-sector resources to draw on.

**3.3.3.3. Ensuring availability of spare parts.** With easy and consistent access to spare parts, technicians are able to complete repair requests more rapidly. This requires systematic procurement of spares—for both new and existing equipment. As of now, many manufacturers are bundling a lifetime estimate of spare parts with all new purchases – if these have not been included by default, the procurement agent should request these be included. For existing equipment, an inventory of current spare parts should be performed, with replacements procured for any gaps. CHAI has developed a tool for Kenya that assists in these calculations, which is available upon request.

Once the spares are in-country, they should be stored in such a manner that they are readily accessible to technicians. Similar to other immunization commodities, a stock management system is needed to track the consumption of spares and alert when it is time for procurement and distribution. Spares should be warehoused at or close-to where technicians are located (e.g., regional workshops), preventing delays and costs associated with spare collection.

<sup>14</sup> For more detail on the risks from stem thermometers, see the WHO's 2015 "Vaccine Management Handbook: Monitoring Temperatures in the Cold Chain."

<sup>15</sup> Data taken from sub-scale samples in two East African countries. In latter case, the 56% refers to proportion of FridgeTags at 'Low Batt' status.

<sup>16</sup> Results taken from studies done in three African countries between 2013 and 2015.

<sup>17</sup> For more information on what devices are available, where to allocate them, how to roll them out, the WHO's *Vaccine Management Handbook: Temperature Monitoring in the Cold Chain* provides clear and actionable guidance.

<sup>18</sup> In addition 414 new midlevel technicians received in-service training by using standard training materials by using demonstration and practical exercise methodologies.

## 4. Conclusion

This article summarizes some of the critical performance gaps that have been observed in cold chains and highlights some proven interventions to tackle them. However, these solutions should not be adopted in isolation, but as part of a broader transformation of cold chain performance management. As countries address immediate gaps in their cold chain, stakeholders must look beyond these initial challenges to securing long-term safety, sufficiency and efficiency.

Achieving this will require significant investment of resources, effort and political will – both in-country (as detailed here) as well as at the global levels. Cold chain infrastructure is a small cost compared to the value of vaccines it safeguards, so there is a strong case for Gavi and other stakeholders to ensure timely and sufficient funding to implement cold chain system improvements in order to protect the vaccines that were also procured through their investments<sup>19</sup> [28]. The Gavi CCEOP is a significant move in this direction, reducing barriers to adopting better equipment and other existing mechanisms (e.g., HSS) could also be adapted to better serve system-improvement needs.

Collectively, the solutions detailed in this article – and in the other contribution to this issue – chart a path to substantially improving the performance of the cold chain. Combined with enabling global and in-country environments, it is possible that the next few years will no longer see cold chain issues as a substantial barrier to effective and full immunization coverage.

## Authors' contributions

All authors contributed to the content of this article.

## Role of the funding source

This work was funded in part by a grant from the Bill & Melinda Gates Foundation – United States. The views expressed herein are solely those of the authors and do not necessarily reflect the views of the Foundation.

## Conflict of interests

All authors have no conflict of interests.

## Acknowledgements

The authors of this article wish to thank and acknowledge the efforts of Amy Roberts in editing the text for publication, Katherine Pela DeMarco and her team for providing edits and reviews, and Anita Kishore for contributing to original concept and structure of content.

## References

- [1] UNICEF website <[http://www.unicef.org/immunization/index\\_2819.html](http://www.unicef.org/immunization/index_2819.html)> [accessed: 04-May-2016].
- [2] WHO. Immunization coverage <<http://www.who.int/mediacentre/factsheets/fs378/en/>> [accessed: 14-May-2016].
- [3] Tried and tested – Gavi, the Vaccine Alliance <<http://www.gavi.org/about/value/tried-and-tested/>> [accessed: 14-May-2016].
- [4] Kaufmann JR, Miller R, Cheyne J. Vaccine supply chains need to be better funded and strengthened, or lives will be at risk. *Health Aff* 2011;30(6):1113–21.
- [5] Humphreys G. Vaccination: rattling the supply chain. *Bull World Health Organ* 2011;89(5):324–5.
- [6] Next-generation immunization supply chains are needed to improve health outcomes. PATH, Gavi: The Vaccine Alliance, Bill & Melinda Gates foundation, John Snow Inc, and Village Reach; 2015.
- [7] Zaffran M, Vandelaer J, Kristensen D, Melgaard B, Yadav P, Antwi-Agyei KO, et al. The imperative for stronger vaccine supply and logistics systems. *Vaccine* 2013;31(suppl. 2).
- [8] Sabot O, Yadav P, Zaffran M. Maximizing every dose and dollar: the imperative of efficiency in vaccine delivery. Seattle (USA); 2011.
- [9] VillageReach. Keeping the cold chain cold vaccine supply chains: reaching the final 20 policy paper series. Seattle (USA); 2014.
- [10] Kenya National Bureau of Statistics and ICF Macro. Kenya demographic and health survey; 2014.
- [11] WHO. In-depth evaluation of the reaching every district approach in the African region; 2007.
- [12] Burchett HED, Mounier-Jack S, Torres-Rueda S, Griffiths UK, Ongolo-Zogo P, Rulisa S, et al. The impact of introducing new vaccines on the health system: case studies from six low- and middle-income countries. *Vaccine* 2014;32(48):6505–12.
- [13] USAID. Bottlenecks and breakthroughs: lessons learned from new vaccine introductions in low-resource countries, 2008–2013; 2014.
- [14] Hyde TB, Dentz H, Wang SA, Burchett HE, Mounier-Jack S, Mantel CF. The impact of new vaccine introduction on immunization and health systems: a review of the published literature. *Vaccine* 2012;30(45):6347–58.
- [15] Government of Nigeria. Nigerian national routine immunization strategic plan (2013–2015); 2015.
- [16] Ethiopian Federal Ministry of Health. Health sector transformation plan (2015/16–2019/20); 2015.
- [17] 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):3980–6.
- [18] Lloyd J, Lydon P, Ouhichi R, Zaffran M. Reducing the loss of vaccines from accidental freezing in the cold chain: the experience of continuous temperature monitoring in Tunisia. *Vaccine* 2015;33(7):902–7.
- [19] Setia S, Mainzer H, Washington ML, Coil G, Snyder R, Weniger BG. Frequency and causes of vaccine wastage. *Vaccine* 2002;20(7–8):1148–56.
- [20] Techathawat S, Varinsathien P, Rasdjarmrearnsook A, Tharmaphornpilas P. Exposure to heat and freezing in the vaccine cold chain in Thailand. *Vaccine* 2007;25(7):1328–33.
- [21] Nelson CM, Wibisono H, Purwanto H, Mansyur I, Moniaga V, Widjaya A. Hepatitis B vaccine freezing in the Indonesian cold chain: evidence and solutions. *Bull World Health Organ* 2004;82(2):99–105.
- [22] Murhekar MV, Dutta S, Kapoor AN, Bitragunta S, Dodum R, Ghosh P, et al. Frequent exposure to suboptimal temperatures in vaccine cold-chain system in India: results of temperature monitoring in 10 states. *Bull World Health Organ* 2013;91(February):906–1013.
- [23] Chukwuma G, Okoye L, Ngwoke K, Esimone C. The potency of yellow fever vaccines sold in open markets in eastern Nigeria. *J Bioanal Biomed* 2013;5(5):133–7.
- [24] WHO. PQS devices catalogue: pre-qualified equipment for the Expanded Programme on Immunization (EPI). Geneva (Switzerland); 2016.
- [25] McCarney S, Robertson J, Arnaud J, Lorenson K, Lloyd J. Using solar-powered refrigeration for vaccine storage where other sources of reliable electricity are inadequate or costly. *Vaccine* 2013;31(51):6050–7.
- [26] PATH and WHO. Direct-drive solar vaccine refrigerators—a new choice for vaccine storage. Seattle (USA); 2013.
- [27] PATH. Total cost of ownership tool for cold chain equipment – PATH <<http://www.path.org/publications/detail.php?i=2576>> [accessed: 20-May-2016].
- [28] Brenzel L. What have we learned on costs and financing of routine immunization from the comprehensive multi-year plans in GAVI eligible countries? *Vaccine* 2015;33(suppl. 1):A93–8.
- [29] Höybråten D. Why global health needs a private sector touch; 2014 <<http://www.gavi.org/library/news/gavi-blogs/>> [accessed: 17-May-2016].
- [30] Ministry of Women & Child Development and UNICEF. Rapid survey on children (RSOC), November 2013; 2014.
- [31] UNICEF. National cold chain assessment India; 2008.

<sup>19</sup> Sometimes global funding also creates perverse incentives that slow efforts to improve cold chain performance. For example, a low-income country that introduces a new vaccine with Gavi support during the initial self-financing phase, has most of the vaccines commodity costs (and thus vaccine wastage cost caused by the cold chain) paid for by Gavi which reduces its incentive to fix its cold chain. Moreover as countries graduate from Gavi funding, these losses in efficiency seriously damage their ability to fulfill program requirements.