SUBJECT:	**COLD CHAIN EQUIPMENT OPTIMISATION PLATFORM**
Report of:	Hind Khatib-Othman, Managing Director, Country Programmes
Authored by:	Lauren Franzel, Alan Brooks, Alex de Jonquières
Agenda item:	12
Category:	For Decision
Strategic goal:	Affects all strategic goals

Section A: Overview

1. Purpose of the report

1.1 The Programme and Policy Committee (PPC) considered the attached paper on the Cold Chain Equipment Optimisation Platform ("the CCE platform") at its meeting on 4-6 May 2015. In this meeting, the PPC confirmed its support for the CCE platform, while highlighting the following themes for consideration in developing the platform:

(a) **Impact of the CCE platform:** The PPC requested further insights into how the platform will contribute to Gavi's strategic goals

(b) **CCE maintenance:** The PPC requested further clarity on ways that the platform can ensure maintenance of cold chain equipment

(c) **Relative prioritisation of unequipped health facilities:** The PPC asked the Secretariat to elaborate on the potential to prioritise extending cold chain equipment into currently unequipped facilities over replacing existing poorly- or non-functioning equipment.

1.2 This cover note describes the PPC's recommendations to the Board and provides insights on these three themes.

2. Recommendations

2.1 The PPC recommends to the Gavi Board that it:

(a) **Approve** the creation of an innovative mechanism to strengthen country cold chain systems and advance the Alliance's Supply Chain Strategy and, ultimately, its coverage and equity goals (the "CCE platform"), the design of which is set out in Section 8 of Doc 15 to the PPC and includes a funding model tiered by country GNI level; and

(b) **Note** that an amount of US$ 50 million (to be reassessed and potentially increased based on initial applications to the CCE platform) will be allocated from the resources pledged for 2016-2020 (which envisage funding for strategic initiatives to realise Gavi's new strategy) to launch the implementation of the CCE platform and fund the initial applications in 2016-2017 and **request** the Secretariat to report back to the PPC and to the Board in 2017 on the implementation of the CCE platform.

Section B: Content

3. Impact of the CCE platform

3.1 The CCE platform has direct and significant impact on all four of the Alliance's strategic goals. The CCE platform will:

(a) Increase coverage and equity (SG 1) by addressing multiple underlying problems limiting vaccine availability and potency. It will do so by increasing the number of facilities equipped with CCE (contributing to improved equity), and improving the performance of CCE devices (contributing to the availability, potency, and safety of vaccines in order to improve coverage;

(b) Incentivise stronger CCE management, maintenance, and functioning thereby contributing to improvements in the effectiveness and efficiency of immunisation and wider health systems (SG2);

(c) Accelerate development and deployment of higher-performing technologies with lower operating costs and total cost of ownership. These technologies will increase the sustainability of the intervention and the efficiency of the immunisation delivery system (SG2 and SG3); and

(d) Correct CCE market failures in both supply and demand, stimulating the development of more appropriate technologies at lower prices. This market shaping will serve as the first application of SG4 beyond vaccines.

3.2 In addition to this impact, the CCE platform will help mitigate risk related to wastage/quality of vaccines and increase Gavi's value for money. In the 55 eligible countries, the Alliance is providing vaccine investments of approximately US$ 1 bn per year in 2016 and 2017. It will also increase value for money by decreasing the prices of cold chain equipment. Current equipment prices reflect the limited transparency and relatively inefficiency of today's market.

3.3 Rigorous monitoring and evaluation (M&E) will allow the Alliance to measure the progress of the platform. As well as globally-collected data it will include components of country performance frameworks, such as:

(a) The number of facilities that replace the old CCE with new, higher-performing CCE purchased with support from the platform

(b) The number of previously-unequipped facilities that are newly equipped (where appropriate) with the higher performing CCE

(c) Weighted average purchase price by device category

(d) The percentage of equipment that is functioning

(e) In the medium term, additional metrics such as frequency and duration of temperature excursions may be added as temperature-monitoring capabilities, including remote/wireless data collection, improve and health facility data becomes more available.

3.4 Regular and rigorous measurement of the CCE platform's impact will enable the Alliance (and countries receiving platform support) to estimate the increased efficiency of supply chains and cost savings, and continuously strengthen the impact of this intervention. The Secretariat, as requested by the PPC, will report back on the CCE platform's implementation in 2017.

4. Ensuring CCE maintenance

4.1 Effective maintenance of next-generation, more-reliable and -sustainable CCE devices, consists of two primary activities:

(a) **Preventative maintenance:** This begins with correct installation of devices. For example, for solar direct drive refrigerators, proper installation is the single biggest determinant of functionality. Following correct installation, preventing failure requires basic device care by the health center staff, such as wiping out or cleaning the fridge and cleaning accumulated dust off solar panels each month. Although not universally recommended by manufacturers, it may be reasonable to anticipate a technician visiting each facility to confirm appropriate equipment functioning within 3-6 months of installation and annually thereafter.

(b) **Corrective maintenance:** Corrective maintenance requires technical interventions to repair broken devices. Examples of corrective maintenance include replacing failed compressors or repairing a broken door lining. This maintenance is conducted by skilled mechanics and often requires available spare parts that correspond to the failed device type. The most common causes of failure requiring corrective maintenance in widely-used equipment today can be addressed through equipment design and procurement requirements.

4.2 The PPC has asked for further elaboration of the potential options for addressing maintenance requirements of cold chain equipment. Extensive consultations were conducted prior to and since the PPC with CCE users, maintenance experts, and manufacturers to develop perspectives on how the CCE platform could address the most pressing maintenance problems.

These were supported by a review of lessons learned from different in-country maintenance models.

4.3 A set of targeted interventions will provide critical assurance that the most common maintenance issues will be addressed. These will address the majority of the root causes that lead to temperature excursions and device failures today. They will be complemented by additional innovative approaches towards sustainable maintenance solutions. A number of options beyond those below, such as leasing equipment, were considered and de-prioritised (Annex D of the PPC paper presents further details on options).

4.4 The targeted interventions to address the primary causes of fridge failure include:

(a) Incentivise manufacturers to build **features** into their devices **to mitigate the most common causes of device failure**. For example, for fridges on the electrical grid this means requiring that they have built in or bundled voltage regulators to mitigate the damaging effects of voltage spikes; for solar, this means requiring a “direct drive” design that no longer requires batteries to store energy. The platform will also incentivise features that support preventative maintenance, such as simple pictures on the equipment illustrating maintenance activities to be performed by health workers. This effort will leverage target product profiles (TPPs) developed as part of the implementation of the Supply Chain Strategy.

(b) **Bundle device delivery, installation, end-user training and spares** into device contracts, making manufacturers accountable for these services and goods. This requirement will mitigate some of the most common causes of device failure, namely improper installation, insufficient spare parts for corrective maintenance, and inadequate end-user skills to provide preventative maintenance. Alongside this bundle, manufacturers will continue to provide two-year warranties guaranteeing repairs for major device malfunctions.

(c) **Monitor device performance** and potentially offer positive incentives for appropriate functionality (e.g., share of time device is operating between 2-8 degrees).

(d) Require countries to prepare and submit a **maintenance plan** for scrutiny by the Independent Review Committee that specifies the provider, processes and protocols, as well as a budget and funding source, as part of their application to the platform. This requirement emphasises country accountability and ensures that the government has the essentials in place for an effective maintenance system. Technical partners will support countries that do not have such plans and budgets to develop them prior to application, in line with the broader national immunisation supply chain plans and continuous improvement process. Innovative approaches for such maintenance plans are further elaborated below.

4.5 Typically the maintenance plan noted above would reflect the Ministry of Health committing its human and financial resources to provide preventative and corrective maintenance. The Alliance has an opportunity to explore whether additional interventions might further ensure functionality of equipment. In the platform's operational planning phase and potentially in the scale up year, several of these additional interventions will be considered in terms of their potential effectiveness, efficiency, sustainability, and feasibility. These interventions include:

(a) Requiring manufacturers to bundle the full spectrum of maintenance services into their device contracts. This would extend the scope of the currently-proposed bundled installation described above. In this intervention, the manufacturer would be accountable for the maintenance of the device, and could elect to provide this maintenance itself or through local third parties. The country government, manufacturer and local provider would jointly set the performance metrics and measure delivery against them.

(b) Requiring governments to establish maintenance contracts with rigorous performance metrics and consequence management with sub-national levels or private maintenance companies. Such contracts could provide greater assurance that maintenance systems are in place to support basic preventative activities and corrective repairs.

(c) Exploring the creation of a marketplace for maintenance providers and users. A mechanism could be created to aggregate maintenance providers, connect them with users, and provide a forum for users to share experiences with providers. This could create a more robust "maintenance market" that matches maintenance demand and supply while also creating more visibility and competition in the maintenance provision market. Such an approach could be considered on a country-specific or regional basis.

5. Relative prioritisation of unequipped health facilities

5.1 The question of whether the CCE platform should prioritise unequipped facilities, as a means to accelerating coverage and equity, was considered in the early design work of the platform.

5.2 It is proposed that the platform not prioritise at the global level between currently equipped facilities and non-equipped facilities, but instead defer to national plans and relative prioritisation of the current and planned supply chain design for increasing coverage and equity. For example, evidence suggests that approximately 20% of facilities across Gavi countries have non-functional cold chain devices at the health facility level. It may be that it is more efficient, impactful and rapid to replace broken equipment before extending equipment to new facilities. Introducing CCE into a facility often requires other health system inputs (e.g. human resources) and modifications to immunisation delivery (e.g. vaccine delivery models, immunisation session frequency).

5.3 Requiring countries to prioritise extending equipment into new facilities could be challenging for countries to implement and Gavi to monitor. The platform should be scaled to have sufficient resources to support both cold chain expansion and upgrading, as both of these activities are required to achieve the Alliance's coverage and equity goals.

Section D: Annexes

Annex A: Paper on Cold Chain Equipment Optimisation Platform submitted to Programme and Policy Committee for meeting on 4-6 May 2015

Report to the Programme and Policy Committee
4-6 May 2015

SUBJECT:	**COLD CHAIN EQUIPMENT OPTIMISATION PLATFORM**
Report of:	Hind Khatib-Othman, Managing Director, Country Programmes
Authored by:	Lauren Franzel, Alan Brooks, Alex de Jonquières
Agenda item:	15
Category:	For Decision
Strategic goal:	Affects all strategic goals

Section A: Overview

1. Purpose of the report

1.1 This report presents an investment case for a Cold Chain Equipment (CCE) Optimisation Platform (hereafter referred to as the CCE platform). The platform supports the Alliance Supply Chain Strategy approved by the Gavi Board in June 2014. It sets out the rationale for the platform, recommendations on the design and implementation, and initial estimates of its impact and financial requirements. The attached annexes summarise the full set of considerations and evidence informing the recommendations set forth.

2. Recommendations

2.1 The PPC is requested to recommend to the Board that it:

(a) **Approve** the creation of an innovative mechanism to strengthen country cold chain systems and advance the Alliance's Supply Chain Strategy and, ultimately, coverage and equity goals (the "CCE platform"), the design of which is set out in Section 8 of Doc 15 and includes a funding model tiered by country GNI level.

(b) **Note** that an amount of US$ 50 million (to be reassessed and potentially increased based on initial applications to the CCE platform) will be allocated from the resources pledged for 2016-2020 (which envisage funding for strategic initiatives to realise Gavi's new strategy) to launch the implementation of the CCE Platform and fund the initial applications during approximately 2016-2017 and **requests** the Secretariat to identify resources for the remaining financial requirements for the period 2018-2020.

2.2 Subject to the PPC's recommendation and the Board's approval, the Secretariat and its partners will start operational planning, targeting the platform's launch as early as January 2016.

3. Executive summary

3.1 The Alliance Supply Chain Strategy recognises the cold chain as a pre-requisite to achieving the Alliance's coverage and equity goals. Sufficiently deployed, high-performing and well-maintained cold chain equipment is a critical component of the supply chain, and vital to ensure that vaccines are available and potent to protect all children reliably, efficiently and sustainably. Non-availability of cold chain points in remote, hard to reach geographies is a key barrier in reaching the excluded populations. Overcoming this bottleneck will be an important driver of success for Gavi's 2016-2020 strategy.

3.2 The Alliance aspires for the platform to impact the total CCE need – estimated at 105,000-135,000 health facilities and devices[1][2]. This assumes replacement of all the existing old devices with new ones and extension of the cold chain into unequipped facilities.[3] Approximately a third of these facilities will be small, remote health posts that do not have appropriate cold chain solutions today. Equipping these facilities will extend the reach of immunisation services to periphery communities and advance progress towards full coverage and equity.

3.3 Achieving this ambition calls for dramatic improvements in the scale and performance of current cold chains systems. Across Gavi countries, 20% of targeted health facilities are unequipped with CCE; 20% of installed devices are broken; and over 50% of the equipment is poor-performing, older generation devices that increase the risk of exposing vaccines to temperature excursions. These devices not only limit vaccine availability (especially at unequipped facilities) but also compromise potency and safety. They also often impose high operating and wastage costs e.g. by requiring regular kerosene refills and battery replacements. This situation will become all the more pressing as countries continue introducing vaccines that are physically larger, more expensive and freeze-sensitive into their cold chain systems. Simply put, strengthening country cold chains is necessary to efficiently and sustainably protect and maximise the impact of the Alliance's >US$ 1 billion per year investments in life saving vaccines, and to get those vaccines to reach every community.

[1] This covers fifty five Gavi countries. India is excluded as covered by the India strategy and not by the CCE platform. Adding India increases the number of health facilities to 140,000-180,000. Ranges from base case based on country plans vs. higher ambitions in equipping unequipped facilities.

[2] At this stage, consultations with manufacturers suggest that they have sufficient capacity to meet these projected needs, although they will require annual demand visibility to plan their production cycles.

[3] Over a full replacement cycle, typically of seven years

3.4 In recent years, manufacturers have increased the pace of development and commercialisation of improved cold chain technologies. These new technologies address some cold chain challenges – for example, they protect vaccines from freezing and can operate on solar power, making them more reliable and less expensive to operate in remote facilities that lack electricity. However, uptake of these new technologies by countries is slow, for three primary reasons:

(a) As articulated in the Alliance Supply Chain Strategy, cold chain funding is insufficient to meet the needs. Indeed, the funding gap for CCE device purchases currently stands at approximately U$ 50 million a year. In addition to being limited, this funding is fragmented, often unpredictable and irregular from one year to the next.

(b) Even though lifetime costs of improved cold chain technologies are lower and more sustainable due to decreases in operating costs, their up-front capital costs are often higher. This creates a financial barrier for countries to purchase new technologies, especially in a context of funding constraints.

(c) The cold chain market has several market failures including limited demand visibility, fragmented procurement, in-transparent pricing, and insufficient information exchange between manufacturers and buyers. As a result, buyers' choices are often insufficiently informed, manufacturers' production planning and inventory management are complex, and costs and prices are higher than they would be under more favourable market conditions. In many ways, these market challenges resemble those faced in the vaccines market previous to the Alliance's interventions since the year 2000.

3.5 As a continuation of the Supply Chain Strategy, the Secretariat has been working with partners to develop an investment case for a CCE platform to address these acute problems. The main objective of the platform is to get more equipment that is more efficient and sustainable, and better performing, deployed to every health facility where it is required at an affordable price, as a means to make progress towards Gavi's strategic goals. With this platform, the Alliance will pool and increase resources for CCE and directly address the current CCE market failures, in line with the Board's endorsement to extend Gavi's market-shaping beyond vaccines.

3.6 The CCE platform will create incentives to stimulate both the supply and demand for CCE, engaging with both manufacturers and countries:

(a) Manufacturers: Through the platform, the Alliance will accelerate the time to market of technology improvements by co-investing in purchases of CCE. Further, the Alliance will reduce funding fragmentation by providing a mechanism for existing donors to channel their funding through the platform, thereby creating a larger, more predictable market for manufacturers. This predictability will enable manufacturers to better plan their production and capture scale economies.

(b) Countries: Building on country supply chain improvement plans, the Alliance, through the platform, will stimulate country demand for more reliable and efficient equipment. It will do so directly by offering financial incentives and funding to countries choosing higher performing technologies. The additional and more predictable funding will also incentivise countries to equip currently unequipped health facilities. The Alliance will rely on technical assistance partners to support countries to conduct rigorous cold chain planning, to consider supply chain design options and to select the best-available technologies to meet their needs. The Alliance would not only influence CCE management including maintenance through conditions to funding, but also in the medium term, seek to incentivise countries to maintain their devices by offering performance incentives for countries that keep their devices functional. This aspect of the design would be further detailed following PPC and Board approval.

3.7 Using similar market interventions and tools, the Alliance aims at having a comparable impact on the CCE market dynamics as it had on the vaccines market. It will achieve this by deploying a set of proven market-shaping tools e.g. strategic demand forecasting, manufacturer engagement, and pooled procurement, that will have a long-term impact on the CCE market, improving the efficiency and sustainability of supply chains.

4. Risk implication and mitigation

4.1 There are four major risks associated with the platform, most related to implementation in-country.

4.2 First, there is a risk that countries lack sufficient information to purchase the appropriate devices. Evidence suggests that few countries have reliable, up-to-date, detailed data on health facility needs including vaccine storage and electrification requirements across their systems. The platform's design would mitigate this by requiring countries to provide cold-chain inventories and health facility surveys as part of their funding applications. Most countries may require technical assistance to get this evidence in place, select the right equipment and redesign the broader immunisation service system to maximise coverage and equity. Alliance technical assistance partners would provide this support through the Partnership Engagement Framework.

4.3 Second, there is a risk that even if countries do select fit-for-purpose equipment, they may not be able to adequately nor rapidly deploy it to the targeted health facilities and appropriately maintain the new devices. This could be due to poor planning, limited transportation and/or insufficient installation capacities. The new technologies will have lower maintenance requirements (e.g. the electric fridges will have voltage regulators to prevent damage from voltage spikes), but this still poses a risk of failure, especially given limited field experience with new technologies. To mitigate this risk, the platform would require countries to submit detailed deployment and maintenance plans and budgets with their funding

requests. Additionally, the platform would require manufacturers to bundle delivery, installation, training, and spare parts as part of the device purchase contracts.[4] Manufacturers with limited or no in-country presence would be expected to fulfill this requirement by partnering with local distributors and/or other third parties or by training local Ministry of Health (MOH) technicians. This requirement would have the added benefit of potentially stimulating demand for local private sector partners and contribute to a growing cadre of trained CCE technicians. Lastly, the Alliance will establish active feedback loops on equipment performance to manufacturers and WHO Performance Quality and Safety (PQS) to inform future device developments and purchase decisions.

4.4 Third, there is a risk that the Alliance through the CCE platform crowds out other sources of cold-chain financing, especially from bilateral donors and Gavi country governments. This risk is mitigated by the platform's funding model. The funding model, described in Section 8, is designed to amplify current available funds by co-investing with countries. In addition, the Secretariat will conduct clear and targeted advocacy with CCE donors to articulate how this platform will complement (and not replace) their current funding.

4.5 Fourth, establishing a specific funding mechanism for cold chain risks creating additional complexity for countries and undermining their ownership. The integration and alignment of the platform with HSS, including application requirements and windows, mitigates this risk. In addition, the platform design reinforces country ownership by holding countries responsible for securing base investments for the purchased devices, and requiring them to cover operating and recurring costs.

5. Financial implications: Partners' Engagement Framework and budgets

5.1 To support all 55 Gavi-eligible[5] and graduating countries[6] (excluding India[7]) potentially qualifying for funding, the platform will require approximately US$ 240-310 million over the first 5 years (2016-2020)[8] for equipment

[4] This addresses common causes of device failure, e.g. damages during transportation, improper installation, and facilitates required maintenance activities by training end-users on regular upkeep and ensuring spare parts are available for replacement.
[5] Includes Gavi "Low-income" and "Intermediate countries" (annual GNI per capita <US$1,045); full list in Annex A
[6] Includes Ghana, Nicaragua, Nigeria, Papau New Guinea, Solomon Islands, Uzbekistan and Vietnam who are graduating (annual GNI per capital > US$ 1,045) but meet the criteria of having access to HSS funds for at least three years (2016-2018)
[7] Support to India will be determined by the Board's decision on the Gavi India Strategy. If India is included, this would add between 30,000 to 50,000 health facilities to be equipped and the overall financial need for the CCE platform from 2016-2020 would increase to US$ 310-390 million (US$ 60-80 million per year).
[8] Estimates were calculated based on a usual 7 year replacement cycle. In order to align with the 2020 timeline, all estimates were scaled proportionately to 5 years. This will be reevaluated based on demand forecast including yearly fluctuations in volumes.

purchases (US$ 50-60 million per year). These costs include device purchase, delivery, installation and spare parts as well as prices adjustments (e.g. expected price reduction). The Alliance can expect a price reduction in the range of 10-20% on current CCE prices[9] in the medium term resulting from more and better coordinated purchases. Further decreases might be targeted in the following years. This needs-based estimate assumes that the currently installed CCE will be progressively and entirely replaced over seven years and cold chain will be extended into currently unequipped facilities[10]. Annex A further details the demand assumptions and Annexes C and D further detail funding and financial assumptions.

5.2 These estimates are believed to be in the right order of magnitude based on current available information, but actual amounts might be different if key assumptions change. The biggest swing factors for demand and financial requirements are:

(a) The pace at which countries demand the equipment. The pace will depend on how rapidly countries want to replace their current devices and extend their cold chain systems. Extending country cold chains successfully has implications on other elements of the supply chain strategy as well as broader supply chain and health systems (e.g. human resources, transportation, maintenance systems, etc.).

(b) Availability of co-investment from Gavi country governments and bilateral donors. Insufficient funding from other sources will potentially dampen demand for the CCE platform.

(c) Device prices. The financial estimate assumes that prices can be reduced by up to 20% below the PQS minimum price.[11] This is based on initial estimates of the net cost implications of the additional performance requirements and services (increasing cost) and impact of economies of scale from higher volumes, demand visibility, and pooling of purchases (decreasing cost). The expected net effect of these drivers would continue to be refined during further operational planning for the platform.

5.3 UNICEF Supply Division (SD) is currently developing, with other in-country partners, a CCE demand forecast that will provide further confirmation and precision on how demand might evolve over the next five to seven years. This forecast, expected by mid-2015, will further inform the platform's impact and near-term financial requirements. In addition, the Alliance will

[9] Based on current PQS minimum prices

[10] Numbers of unequipped health facilities to equip are based on facilities targeted in country expansion plans (lower range) and a stretch scenario where countries extend their cold chains even beyond current plans (higher range). See annex for details.

[11] The achieved price reduction will ramp up over seven years as manufacturers and volumes scale up. An average of 15% price reduction potential has been factored in for the purpose of sizing the CCE platform.

monitor on a yearly basis how needs-based estimates translate into actual demand and potentially begin conducting strategic demand forecasts for CCE, in a similar fashion as done with vaccines.

5.4 Beyond equipment co-investment, additional resourcing for manufacturer agreements and market shaping, financial management, monitoring, and other functions in partners and the Secretariat will also be required. These costs would be considered under the Partners' Engagement Framework (PEF) and Secretariat budgets that are approved by the Board on a regular basis.

Sources of funding

5.5 To meet this funding need, the Alliance will mobilise US$ 50 million (to be reassessed and potentially increased after year one depending on speed of platform scale-up) from the allocation to Gavi's Strategic Initiatives to fund initial applications to the platform in 2016-2017. This enables the Alliance to test further the demand and draw lessons from the initial implementation period before seeking additional funding from external sources.

5.6 The Alliance partners will work together to ensure that the Partners' Engagement Framework reflects the needs for in-country technical assistance for CCE management. These assistance activities would be coordinated among partners, including WHO and UNICF, via existing mechanisms. Additional resources required by UNICEF SD to facilitate procurement at higher scale will be addressed through existing agreement mechanisms.

Section B: Content

6. Background

6.1 In its 2016-2020 strategy, the Alliance sets out to immunise a further 300 million children, substantially raising coverage of the full range of Gavi-supported vaccines, and increasing equity by reaching the hardest-to-reach communities. A strong and far-reaching supply chain is a pre-requisite to deliver immunisation reliably, efficiently, and sustainably. However, many of supply chain systems were designed up to forty years ago and, as a result, are complex and outdated.

6.2 Recognising the importance of supply chain, the Board approved the Alliance Supply Chain Strategy in June 2014. This strategy sets out interventions to strengthen five components of the supply chain: planning and funding, system design, human resources, data for management and CCE. Within this scope of the strategy, cold chain equipment plays a critical role and in fact has implications on each of the other strategy components.

7. The case for a CCE Optimisation Platform

7.1 Available evidence suggests that country cold chain systems are currently insufficient in scale, performance, and resourcing. Across Gavi-eligible countries, an estimated 20% of health facilities that need CCE in order to more efficiently and effectively reach their target populations are still unequipped. In the facilities that do have equipment, over 50% of devices are older technologies that carry a higher risk of exposing vaccines to temperature excursions, and 20% of devices are broken. Inaction in the current state puts the Alliance's investments into vaccines at risk, limits successful new vaccine introduction, and decreases its ability to reach all children reliably and efficiently.

7.2 In recent years, manufacturers have increased development and commercialisation of improved cold chain technologies to meet target product profiles set by WHO-PQS. These new technologies better protect vaccines from temperature excursions and better meet the needs of small and remote facilities that may lack reliable electrical-grid access. This next generation of devices includes "ice-lined" refrigerators ("ILRs")[12] with user-independent freeze protection, solar-direct drive refrigerators ("SDDs") that operate with just solar power, and thermos-like devices that keep vaccines cool up to a month with just ice ("passive devices").

7.3 These new technologies are also more cost-efficient for health facilities. For example, the operating cost of an SDD is US$ 400 compared to US$ 3,600 for a traditional gas fridge over the device lifetime. The lower operating cost results in a lower total cost of ownership (TCO)[13] than the current generation of devices deployed. For example, at current price levels solar fridges have roughly 60-80% of the TCO of kerosene refrigerators that serve the same set of off-grid facilities. The reduced TCO supports greater sustainability and indirectly reduces downtime, as these operational costs tend to be financed – often with difficulty – by health facilities or districts.

7.4 Countries have started to purchase and deploy such new technologies. However, both the pace of technology development and uptake need to be more rapid to achieve greater impact. For example SDD systems only represented 17% of the volumes procured through UNICEF SD in 2014.

7.5 Achieving this acceleration in cold chain improvements will require three broad components to be in place:

[12] Requiring external electricity sources

[13] TCO refers to total cost of ownership, i.e. costs over the lifetime of the device including capital expenses referring to prices according to the PQS catalogue and UNICEF SD plus operating expenses including maintenance and energy costs. The lower operating costs largely off-set higher upfront costs (U$ 2,450 for an SDD compared to US$ 1,340 for a gas fridge for <25L devices)

(a) More dedicated resources for CCE: As articulated in the Supply Chain Strategy, current funds for CCE are insufficient; a CCE funding gap of ~US$ 50 million a year persists. Replacing all current devices with new technologies (accounting for 65-80%)[14] and extending cold chain into new facilities to reach under-served communities (20-35%) will cost, on aggregate [15], an estimated US$ 360-440 million over 5 years (approximately US$ 70-90 million per year). This implies an approximate doubling of current global CCE funding levels.

(b) Stronger incentives and interventions to create a healthier market dynamic: Although suppliers currently receive guidance from WHO PQS [16] on desired technology improvements, there is potential to accelerate the innovations to market and improve the feedback loop bridging country CCE experience to WHO PQS and manufacturers through financial incentives as Gavi does for vaccines. Supply availability and pricing should also be improved through stronger demand forecasting and market transparency. Countries also need incentives to shift their purchasing selections from last-generation technologies to the new improved devices. Barriers to uptake are not only higher upfront costs, but also lack of knowledge about new technologies, and switching costs (e.g. for spare parts, training of technicians).

(c) Extended support to countries to strengthen their supply chain management within their wider health system: The platform will mainly require critical components of cold chain management as a condition for funding including CCE inventory, rehabilitation, deployment and maintenance plans as well as temperature monitoring. The broader Supply Chain Strategy is working through partners on a full package of support spanning the full set of CCE management activities, including developing CCE inventories and facility segmentations, supply chain network design, planning, procurements, deployments, performance monitoring, and maintenance.

7.6 Several alternative interventions could be considered to help address the CCE problems identified above and the three broad considerations:

(a) To increase funding, the Alliance could advocate to country governments and donors to increase their CCE-dedicated contributions.

(b) To stimulate healthier market dynamics, the Alliance could apply tested market shaping tools and capabilities to complement the policy-setting role of WHO PQS.

[14] Ranges from base case based on country plans vs. higher ambitions in equipping unequipped facilities

[15] Refers to total cost (excluding India), of which the CCE platform will provide a portion of funding in addition to base funding from countries, HSS, VIG and bilateral donors

[16] PQS (Performance, Quality and Safety) are device performance standards set by the WHO Department of Immunization, Vaccines and Biologicals Quality, Safety and Standards Team

(c) To improve country CCE management, the Gavi Partners' Engagement Framework (formerly Gavi Business Plan) could provide more funding to technical partners.

7.7 Each of these interventions would fix a portion of the problem, but even taken together, they are unlikely to achieve impact at the pace and with the degree of confidence needed to achieve the Alliance's 2020 goals. In a fragmented financing and procurement landscape these interventions are challenging. Gavi's supply chain strategy calls for a step change at country level to improve the entire cold chain system and its management and shift investment and technology choices.

7.8 The platform is proposed because it provides a unique instrument from which the Alliance can bring all of these components in place to generate impact that is greater than the sum of its individual parts. For example, the Alliance would use the platform's financial power to incentivise both manufacturers (to accelerate technology developments) and country governments (to engage in rigorous cold chain selection, planning and management). There is also opportunity to improve information flow - e.g. by establishing better demand visibility and strengthening feedback processes from countries to manufacturers. In leveraging these multiple interventions, the Alliance will more effectively and durably correct CCE market failures, and do so with rapid speed and broad scope, as it did for the vaccines market.

Illustration: Market shaping objectives

	From…	To…
Demand	• Small market size of approximately $40-50M / year of CCE purchases	• Larger volumes, more than doubling current spend levels
	• Unpredictable due to limited reliability of forecasts and volatility due to irregular purchases	• Reliable forecasts and stable demand planned over the long run
	• Fragmented procurement, partly driven by fragmented funding	• Consolidated procurement through UNICEF, with majority of funding flowing through the platform
	• Limited optimal technologies selected by countries, partly due to lack of knowledge and variable level of planning	• Careful evaluation of optimal technologies and rigorous multi-year CCE strategies and planning
	• Unreliable CCE maintenance, driven by lack of planning, capabilities and funding	• Robust maintenance plans with secured funding to maximise uptime of devices
Supply	• Limited incentives to develop and commercialise new technologies, mainly driven by lack of certainty on demand	• Incentives encouraging continuous technology improvements through future demand visibility
	• Lack of feedback on device field performance to guide technology improvements	• Visibility into device performance through creation of feedback mechanisms
	• Higher costs and production complexity, due to volatile demand and limited scale	• Potential cost reduction due to higher and more predictable volumes
	• Variable prices across countries, with limited transparency	• Transparency through price publishing

7.9 The proposed CCE platform has three main objectives:

(a) **Accelerate deployment of existing, appropriate, innovative CCE devices to health facilities.** To do so, the Alliance will use the platform to incentivise supply and demand for new improved technologies. In utilising tested market-shaping strategies, the Alliance wants to accelerate deployment of technologies that maintain more stable temperatures and mitigate common causes of device failures (e.g. voltage spikes), reduce operating costs and reliance on unreliable fuel supplies and provide more appropriate technologies for health facilities with no or unreliable electric mains. As successfully done in the vaccines market, the Alliance will also make use of strategic demand forecasts (SDFs) to send clear market signals to industry partners on the level of demand for CCE.

(b) **Facilitate and accelerate extension of country cold chain systems.** To meet this objective the Alliance will employ the platform to make funding more predictable and consistent and enable countries to better plan their cold chain purchases. Part of this financing support will be directed at creating a market for devices that serve the remote, hardest-to-reach facilities - many of which do not have appropriate cold chain solutions today. This will make potent vaccines more available at the last mile.

(c) **Ensure that devices are continuously maintained to keep vaccines potent.** The Alliance will do this by requiring manufacturers to bundle installation and delivery, training, and spare parts for any devices purchased with platform support. The Alliance will in turn require countries to demonstrate inventory management and a maintenance plan with service provider, budget and secured funding as a condition for funding. In the future, the Alliance would periodically monitor device performance and offer countries associated performance incentives.

7.10 The Alliance through the platform directly supports all four strategic goals of the Alliance's 2016-2020 strategy in the following way:

(a) Strategic Goal 1: Having functioning CCE in the right places and accelerating the extension of the cold chain into currently unequipped health facilities is critical to achieve coverage and equity goals.

(b) Strategic Goal 2: Continuously maintained and well-functioning CCE, as well as strengthened in-country capabilities, increases the efficiency and effectiveness of immunisation and wider health systems.

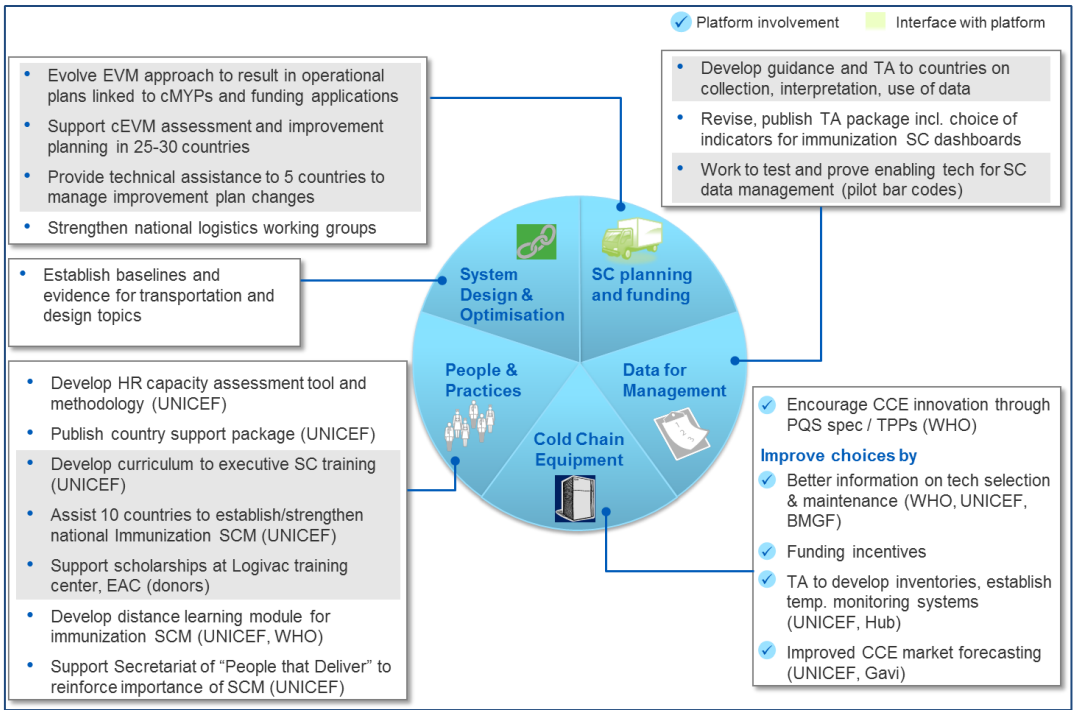
(c) Strategic Goal 3: Moving to more reliable technologies with lower operating costs is critical to ensuring sustainability.

(d) Strategic Goal 4: Introducing a platform dedicated to CCE is the first application of expanded SG4 which includes market shaping for immunisation commodities.

7.11 The CCE platform will interlink with other elements such as the broader Supply Chain Strategy, the 2016-2020 Alliance strategy activities, and the Partners' Engagement Framework. The platform will build upon and amplify (rather than replicate) existing cold chain efforts, including WHO-PQS efforts to incentivise manufacturers to align to updated target product profiles (TPPs) and improve equipment quality, and UNICEF SD's goal to strengthen CCE strategic demand forecasting.

7.12 A key interdependency is WHO & UNICEF commitment to strengthen in-country CCE management and maintenance. Several partners (including UNICEF, WHO, PATH, and CHAI) are already providing dedicated in-country CCE management support, and more work is needed to ensure that all countries receive the assistance they need, and that the support reflects the best available evidence and approaches. In addition to assistance in executing CCE management activities, strengthening of human resources and building in-country capacities will be a key activity that enables sustainable CCE management. This will include developing leadership capabilities and CCE specific competencies for immunisation supply chain managers and health system workers as well as improved workforce planning and retention. Human resources strengthening will fall under the Human Resource pillar of the Supply Chain Strategy.

Illustration of interlinks between CCE platform and Supply Chain Strategy



8. Recommendation on how the platform will work

8.1 Key design considerations are proposed to shape the platform and affect its scope of investment as well as scale and mode of impact. More details on each of the design dimensions, range of options explored and supporting analytics can be found in the technical annexes.

8.2 The recommendations were formed by a team of Alliance partners and are based on findings from extensive consultations with a broad set of stakeholders and constituencies including EPI Managers and Supply Chain Logisticians from Gavi country governments; in-country supply chain experts from partners; and CCE manufacturers. Annex G provides further details on the process to develop this report.

8.3 Overall, the design recommendations offered below are guided by six principles: the CCE platform should be country driven; sustainable; equitable and scaled; catalytic and integrated; simple in accessibility and operations; and transparent and evidence based. Additionally, where possible, the platform will make use of existing processes and reporting requirements. Annex G provides further details.

What technologies and device types will be supported to promote innovation and accelerate deployment across health facilities

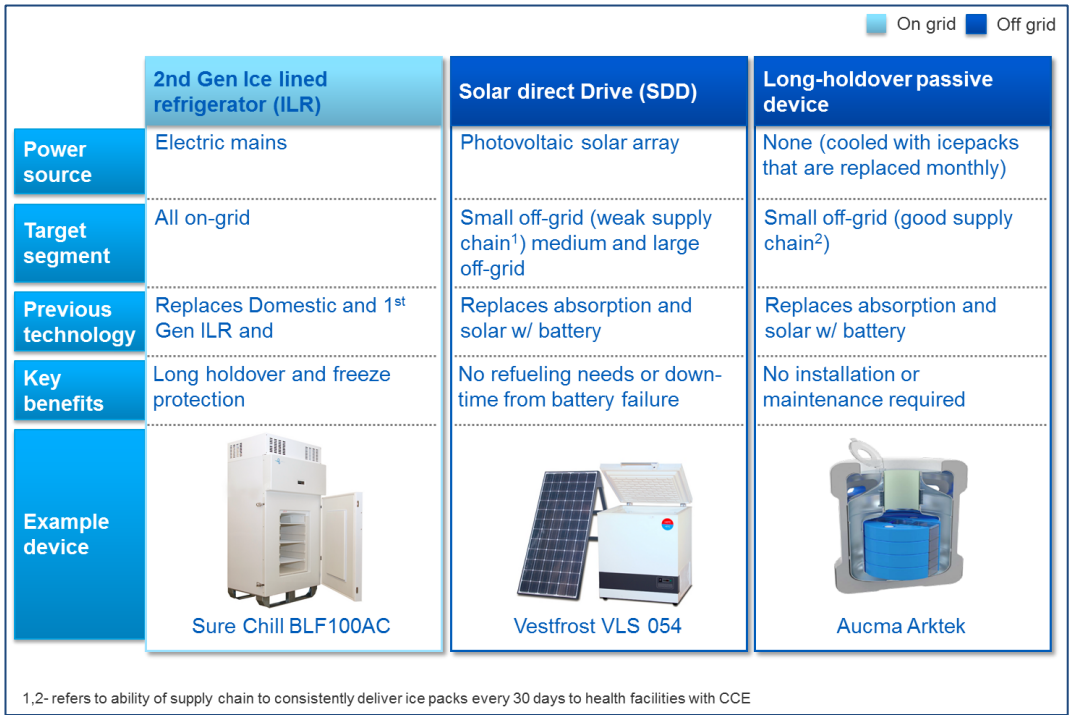
8.4 The CCE platform will support the purchase and deployment of devices in appropriate PQS categories that meet target product profile specifications for improved performance, quality and safety.

8.5 For primary vaccine storage and refrigeration, the Alliance will mainly support new technologies that offer clear market shaping opportunities. These new technologies include second generation ice-lined refrigerators (ILRs) for the on-grid facilities and solar direct drive refrigerators (SDDs) for off-grid. A recent innovation is long-term passive technology (thermos-like devices that keep vaccines cool with ice for up to 35 days). These technology advances create new opportunities for the off-grid facilities. Additionally, vaccine carriers and cold boxes will also be eligible for platform support as outreach is one of the primary means to reach under-served communities and increase coverage. Important technological improvements such as freeze protection are also expected in this category by 2016. Altogether refrigerators, passives and outreach devices account for ~60%[17] of the platform's costs.[18]

[17] Does not include delivery and installation and spare parts which represent ~25% of total platform costs

[18] Walk-in cold rooms and walk-in freezers as well as refrigerated vehicles will not be supported by the CCE platform, at least initially. The supporting rationale for this recommendation is found in Annex B.

Illustration of refrigeration technologies



8.6 In addition to enabling higher performance and improved uptime, other devices that are important to cold chain effectiveness will be eligible for platform support. These devices are included as they are critical for coverage and equity goals; however they have limited initial market shaping potential. First, freezer devices for both on and off-grid facilities will be included to support outreach activities. Critical accessories including voltage regulators and temperature monitors/loggers[19] will also be bundled with the device purchase. Altogether these supporting devices account for 15% of the platform's costs.

8.7 In the medium term, the Alliance could use the platform to introduce new innovations that leverage the scale of deployment of devices by the platform. For example, solar refrigerators could generate excess power to support ancillary devices and services in health facilities. The Bill & Melinda Gates Foundation is currently working with the Solar Electric Light Fund (SELF) to pilot such a technology, and WHO is about to launch a programme on electrification of health facilities. The Alliance may also, over time, extend the reach of remote temperature monitors into more health facilities, to give health system leaders much greater visibility into cold chain performance and needs.

8.8 The scope of the CCE platform and prioritisation of devices will be reviewed regularly (e.g. on an annual basis). The Alliance will coordinate yearly engagement with manufacturers, supply chain leaders and partners

[19] At this stage temperature monitors/loggers have been planned for the devices purchased by the CCE platform, i.e. no standalone procurement allowed. The scope of the platform might be extended after its launch.

providing technical assistance to countries on cold chain equipment management to solicit formal feedback and discuss how the CCE platform might evolve its design and operating model to better meet its objectives. This engagement will also review if and how new innovations can be leveraged and how experiences with new technologies may inform future TPPs.

How will the CCE platform support countries for purchasing and deploying eligible devices

8.9 The decision on the appropriate funding model for devices is driven by the choice of which of the CCE platform's objectives should be prioritised. As such, a set of options with principal trade-offs around simplicity, country ownership, sustainability, attractiveness and speed of uptake is presented in Annex D.

8.10 Co-investment by country governments is crucial to ensure high country ownership and "skin in the game". A co-investment funding model also ensures higher and faster uptake of new technologies and stimulation of demand at scale by attracting countries to the CCE platform while mitigating (at least partially) the risk of crowding out existing funding sources by acting as an amplifier of existing funding.

8.11 The proposal is to implement a tiered model based on GNI groups – similar to the model for supporting vaccines. Countries will use as base investment the current funds used to procure equipment (e.g. drawing on HSS, VIG, country national budget or bilateral donor funds). The intention is that the CCE platform will be complementary and amplify these funds (not replace) to purchase more efficient and reliable technologies. Low-income countries would qualify for 80% platform co-investment for device purchase price, intermediate countries and graduating countries with at least three years of HSS support (2016-2018)[20] receive 50% platform co-investment. Other graduating and graduated countries would not be eligible for funding; however they would have access to the platform's negotiated prices, and procurement services offered by the procurement agency. The treatment of graduated countries should be aligned with the pending decision on Access to Appropriate Pricing (ATAP).

8.12 In order to encourage countries to choose improved technologies, the price differential between older generation devices and new technologies must be covered and ideally exceeded, to provide the additional incentives needed to overcome previous brand familiarity. In general, 50% will consistently off-set the higher price, especially for SDDs and is expected to drive the objective of incentivising the shift. Based on consultations and analysis of countries' funding ability, the 50% platform co-investment was considered insufficient to fill the current funding gap and ensure uptake by low income countries that are often constrained by funding. The platform

[20] Rationale is that the CCE platform will facilitate a step change in CCE management over a longer time period requiring a minimum number of years for support.

co-investment level for low income countries was thus set at 80% to support countries in equipping all targeted health facilities.

8.13 It is suggested that the platform's co-investment comes as a multi-year grant. This provides increased predictability and the required transparency for countries and manufacturers to enable effective longer term planning. Two other options, loaning and leasing, were also considered but were not selected, primarily due to significant concerns around uptake and complexity to manage. The duration of commitments and disbursement process would be further detailed during the operational planning phase based on the procurement forecast and financial resourcing outlook.

8.14 Countries eligible for platform co-investment would be required to meet several important conditions. These conditions are intended to ensure that funds are spent for highest impact and that countries make improved technology choices. Countries need to have basic fundamentals in place to understand their current and future needs, and have a plan to manage their cold chain systems within the wider supply chain and health system. To reduce burden on countries the proposed conditions strongly build on existing cEVM[21], HSS and cMYP[22] processes - for example comprehensive EVM improvement plans, rehabilitation plans, activities of WHO and UNICEF to support countries in conducting and updating facility segmentation and CCE inventories. Primary additional requirements will be around deployment, maintenance and decommissioning of replaced equipment[23]. Details will be developed during operational planning.

8.15 Most countries already have some of related evidence and planning in place. For those with gaps, the countries will rely on technical partners' support to get these components into place. It is important that this support be initiated as soon as possible following a Board decision, if the Alliance is to launch the platform in early 2016.

How will these devices be managed and maintained to ensure continued device functionality

8.16 To ensure that the devices are functional, the Alliance will take three actions. First, it will incentivise manufacturers through the CCE platform to build in features that mitigate common causes of device failure. The Alliance will do this by supporting devices that meet PQS specifications and selected TPPs features set out or being developed by WHO (e.g.

[21] cEVM or "comprehensive EVM" refers to an updated EVM (Effective Vaccine Management) program currently offered by WHO. Key additions in the cEVM include increased pre-assessment preparation and advocacy, an expanded post-assessment country support in the fom of workshops (previously recommendation lists) and increased support from the Hub in terms of tools and financing

[22] cMYP or "comprehensive multi-year plan" refers to a national plan for immunization created by countries, using the Gloal Vaccine Action Plan as a guiing framework. The cEVM seeks to align with the cMYP and HSS applications

[23] Technical assistance and condition around decommissioning of replaced devices is critical from an environmental and sustainability perspective.

voltage regulation, etc.). Second, the Alliance will require countries to submit with their funding requests CCE inventories and health facility segmentation, deployment and maintenance plans including service provider, budgets and secured funding. The Independent Review Committee would then consider the suitability of these plans and the alignment between the funding request and these plans as one of several criteria for grant approval. Third, the Alliance will require manufacturers to bundle critical goods and services as a package - including device delivery, installation, user training and spare parts - into their equipment purchase contracts. In doing so, the Alliance will mitigate common challenges leading to equipment failure. The Alliance will not intervene directly into country maintenance systems or fund maintenance plans through the CCE platform to avoid fragmentation of maintenance interventions between platform-procured and other devices.

What is the relationship between the CCE platform and HSS and what are sources of funding to ensure uptake by countries

8.17 Ease of access to the CCE platform as well as facilitation of medium term CCE planning within the broader context of health system interventions will be critical to achieve high uptake and impact. The CCE platform will therefore use the HSS application mechanism and be available through the current twice-yearly HSS window. The Independent Review Committee will make platform co-investment recommendations to the CEO for approval through the budget envelope. This approach will leverage existing processes, follow the programme funding envelope model used for other forms of support and avoid the creation of a bespoke process for the CCE platform. Aligning with the HSS window and application processes will minimise the additional administrative burden on countries. Monitoring would be done through Gavi's usual joint appraisal and high level review panel mechanisms. Following device deployment, the Alliance would require countries to report periodically on key performance metrics and device performance as part of their overall Gavi Performance Framework. To increase uptake in the first two years and enable access to countries midway through existing HSS grant cycles, exceptional opportunities would be made to permit countries to apply to the CCE platform on a standalone basis with applications addressing the incremental requirements of the platform.

8.18 2016 will be considered a "scale up year" to learn, refine approach and tools and capture quick wins before reaching steady state of the CCE platform. Thus, technical assistance might initially be focused on high priority countries with a decent level of advancement in terms of fulfilling the application requirements to engage them and support them in their applications to the platform. There is a clear need to involve specific

countries as soon as possible as they are already preparing for large upcoming CCE procurements.[24]

8.19 The proposed monitoring and evaluation framework of the platform includes input metrics such as number of countries with supply chain and CCE plans reflecting coverage and equity objectives; process metrics such as number of grants recommended for approval, time from disbursement to commissioning; outputs with number of optimal equipment purchased, average purchase price; and outcomes such as number of facilities replacing their equipment or being equipped with optimal technology, percent of functioning equipment and frequency of temperature excursions. Some of the proposed metrics are new and might take time to develop and implement. For example, the uptime metric would require the use of temperature monitoring (e.g. through 30 day temperature recorders or remote temperature monitors where available[25]) or potentially site visits and would need further development. The monitoring & evaluation framework will be further refined during the operationalisation phase to reduce as much as possible the additional burden on countries and align with national systems. Details on monitoring and metrics can be found in Annex F.

Section C: Implications

9. Market impact:

9.1 The Alliance through the CCE platform will promote the availability of more efficient and sustainable technologies at the best possible price. Market interventions will include four aspects:

(a) Balance supply & demand by increasing demand visibility and quality of procurement forecasts as well as stimulating demand to accelerate deployment of improved technologies through technical assistance.

[24] UNICEF SD forecasts over 9,000 SDDs and over 6,500 compression refrigerators and freezers to be procured in 2015. This demand is expected to increase further if the CCE platform and new funds were to be announced.

[25] The introduction of remote temperature monitors requires four key components: connectivity infrastructure (consistent access to GPRS or other cellular networks), funding for the technology and its operational costs, clear process and protocol on usage of data (particularly for alarms) and training on usage and reporting. Current pilots show some challenges in implementing these components below district level.

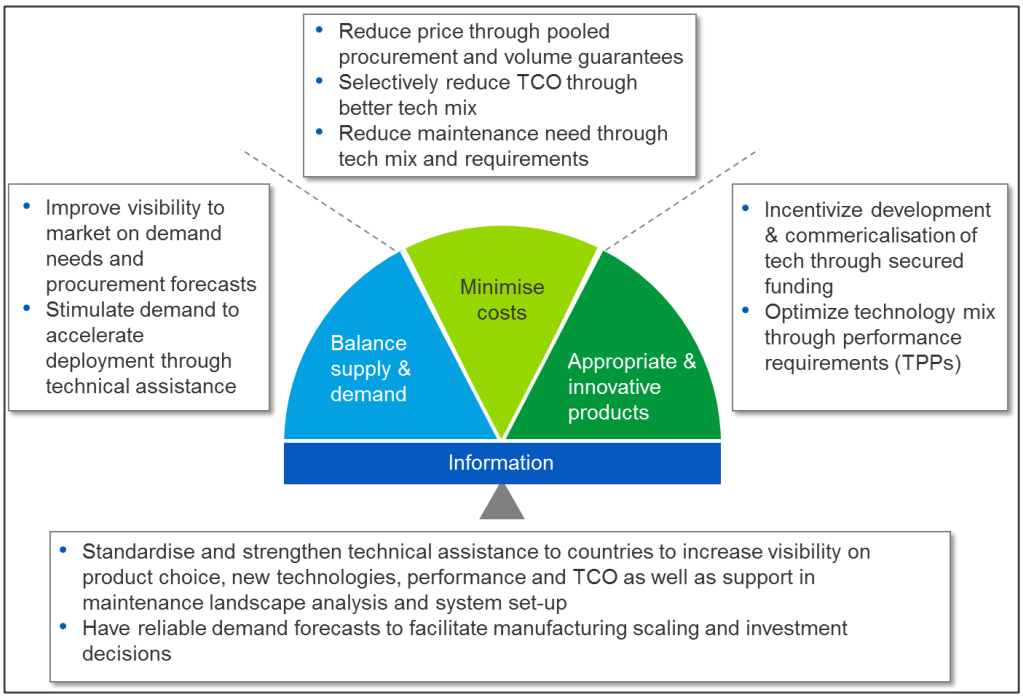
(b) Minimise costs by implementing appropriate procurement mechanisms such as pooled procurement and volumes guarantees. Such mechanisms are an important step towards reducing transaction costs for manufacturers, and reducing total cost of ownership and recurring operational costs through a better technology mix. In addition, higher demand and pooled procurement might enable price reduction over time. These savings would be partially off-set by manufacturer costs to integrate new features and to bundle after-sales services (e.g. installation and end-user training). The steady-state net potential for price reduction is initially estimated at ~20% which represents a cost saving of ~US$ 30 million over five years.[26] This potential price reduction will be further analysed during the operational planning phase.

(c) Have appropriate and innovative products by incentivising manufacturers to develop and commercialise new technologies due to more predictable funding and demand, and off-setting the higher upfront costs for countries.

(d) Improve information flow by strengthening technical assistance to countries through partners to increase visibility on product choice, performance and costs, by facilitating manufacturer scaling and investment decision through more reliable demand forecasts and supporting strong feedback loop to improve the flow of CCE performance information to inform the needs of next generation of CCE.

[26] The achieved price reduction will ramp up over seven years as manufacturers and volumes scale up. An average of 15% price reduction potential has been factored in for the purpose of sizing the platform.

Illustration on market shaping interventions



10. Impact on countries

10.1 The Alliance will fill a critical financing gap for CCE through the platform, enabling countries to replace unrepairable devices and extend their cold chain systems to more facilities. The CCE platform provides a crucial foundation for strengthening supply chains and driving improvements in coverage and equity. Country supply chain leaders consulted to date have unanimously expressed support for such a platform.

10.2 Countries have also expressed both excitement and reservations about new technologies. While many countries believe the new generation of devices could strengthen their cold chain performance, many stakeholders felt that they had limited knowledge of the full breadth of performance and TCO trade-offs. It will therefore be critical for the CCE platform to collaborate with relevant global and in-country partners, including WHO and UNICEF to generate this information and share transparently and systematically to country decision-makers and stakeholders.

10.3 For their part, countries will be expected to further strengthen their commitments to cold chain management to ensure that the devices funded are deployed to the right places and well-maintained. This could be reinforced by performance incentives in the medium term. Countries may be additionally burdened, especially in the first years, by these requirements. However, by leveraging existing processes the Alliance can reduce this burden, and the impact of strong CCE planning and management would seem to outweigh the burden. Country governments will also be responsible for securing base investments for the device purchases, on aggregate at the same levels that they are mobilising from various sources (HSS, VIG, government budgets, bilateral donors) today.

Over time countries may be required to take up a larger percentage of the country co-investment costs. In addition to further increase country ownership and sustainability countries could be requested to reprogram savings from shifting to new technologies - for example the kerosene costs - to the maintenance, future purchases of the devices or other immunisation related interventions. Countries are also responsible for funding all operating and recurring costs including maintenance (as they do today). This is critical to ensure sustainability of the system.

10.4 In the medium term the CCE platform offers an opportunity for countries to consider integrating other health products and services beyond immunization into the supply chain. For example, although the CCE platform would not co-invest in equipment for other commodities, countries may leverage the experience and innovations of the EPI cold chain to support other temperature sensitive pharmaceuticals. This integration is in line with the Alliance's mandate under SG2.

11. Impact on Gavi stakeholders

11.1 Successful set up and administration of such a platform will require intensive and concerted effort and active engagement from multiple Alliance partners, particularly those working on supply chain. Support would be provided through existing mechanisms, including additional partner resources where necessary.

11.2 Using the Gavi Joint Appraisal process under the Alliance's 2016-2020 strategy, technical assistance will be planned and programmed in a coordinated manner with Alliance partners. For example, the Alliance could leverage the WHO & UNICEF immunisation supply chain Hub to support countries with guidelines and other guidance documents, tools, sharing of best practices and strengthening quality of support.

11.3 The Alliance will continue to rely on WHO for leadership on setting CCE performance standards, and use these standards as a basis for incentivising manufacturers through the CCE platform.

11.4 UNICEF Supply Division, in collaboration with other Alliance members, will play a central role in helping to convert the needs-based estimates into a global strategic demand forecast and defining strategic roadmaps and procurement strategies for the platform-supported devices. These forecasts and roadmaps will be broadly communicated to the market, improving visibility for suppliers and purchasers. Additionally, UNICEF SD will use available procurement tools which might include volume guarantees to further stabilise current market volatility. To execute procurements and get the most competitive prices and contracting terms from manufacturers UNICEF SD will reissue new tenders and long-term agreements with manufacturers. Finally, UNICEF SD will also work with WHO to strengthen the feedback loop for equipment performance. Additional resources required for UNICEF SD to perform this full set of actions will be covered by their procurement fees.

12. Impact on Secretariat

12.1 The Secretariat will have to align and formalise the platform's processes and governance, as done with other new mechanisms for supporting countries. Secretariat teams - e.g. Country Support and M&E teams - will work together with partners in the design and implementation process.

12.2 Significant supply chain and market shaping expertise have been built which can support this effort. However, in order to implement the CCE platform from January 2016, several Secretariat departments may require additional human resources. These costs would be built into the Secretariat's budget and presented to the Board through existing mechanisms.

12.3 As part of the eventual steady state, Senior Country Managers will be expected to engage country stakeholders regularly to share information about the CCE platform, provide relevant support, track progress, and to solicit feedback for future iterations of the CCE platform.

13. Legal and governance implications

13.1 The Alliance will enter into agreements with contributing donors, and partners related to platform operations.

14. Gender implications

14.1 The recommended investment case is not expected to bring unique benefits to one gender. Current Gavi gender policies apply.

Section D: Annexes

Annex A: Cold chain equipment needs estimate

Annex B: Input for technologies supported

Annex C: Inputs for estimating Cold Chain Equipment platform financial need

Annex D: Funding level

Annex E: CCE management including installation and maintenance

Annex F: M&E Framework

Annex G: Process and Consultations

Annex A: Cold chain equipment needs estimate

A1.1 Purpose of CCE needs estimation

The needs estimate for cold chain equipment serves as a basis for informing overall CCE demand and the subsequent potential size of the CCE optimisation platform.

A1.2 Country scope

Scope of estimated CCE needs and demand includes a total of fifty-six Gavi countries, of which forty-nine are currently Gavi-eligible countries and seven are Gavi-graduating countries[27].

Table A1: Included countries

Gavi-eligible countries (49)		
Afghanistan	Guinea Bissau	Pakistan
Bangladesh	Haiti	Rwanda
Benin	India[28]	São Tomé e Príncipe
Burkina Faso	Kenya	Senegal
Burundi	Korea, DPR	Sierra Leone
Cambodia	Kyrgyz Republic	Somalia
Cameroon	Lao PDR	South Sudan
Central African Republic	Lesotho	Sudan
Chad	Liberia	Tajikistan
Comoros	Madagascar	Tanzania
Côte d'Ivoire	Malawi	Togo
Djibouti	Mali	Uganda
DRC	Mauritania	Yemen
Eritrea	Mozambique	Zambia
Ethiopia	Myanmar	Zimbabwe
Gambia	Nepal	
Guinea	Niger	
Gavi-graduating countries (7)		
Ghana	Papua New Guinea	Vietnam
Nicaragua	Solomon Islands	
Nigeria	Uzbekistan	

[27] With at least three years of HSS support (2016-2018). Rationale is that the CCE platform wants to support countries during graduating process but also seeks to facilitate a step change in CCE management over a longer time period requiring a minimum number of years for support.

[28] India currently classified as Gavi-eligible based on GNI; however support to India will be determined by the Gavi Board's forthcoming decision on the Gavi India Strategy

A1.3 Needs estimate methodology

Step 1: Mapping of current baseline (2013)

Estimates of the current number of equipped facilities below district level derive from two sources, CCEM data (available for seven countries: Kenya, India, Malawi, Nigeria, Tanzania, Uganda and Zimbabwe) and cMYP data (used for remaning fifty countries).

Table A2: Current installed base – number of health facilities with CCE

Country	Currently equipped facilities (2013)	Country	Currently equipped facilities (2013)
India	27,597	Togo	830
Pakistan	10,000	Malawi	821
Ethiopia	8,670	Lao PDR	775
Nigeria	6,240	Chad	680
Tanzania	5,000	Benin	679
Bangladesh	5,000	Somalia	598
Kenya	3,976	Niger	583
DRC	3,000	Burundi	525
Yemen	3,000	South Sudan	502
Ghana	3,000	Tajikistan	455
Madagascar	2,800	Papua New Guinea	445
Cameroon	2,500	Rwanda	426
Uganda	2,290	Guinea	407
Vietnam	1,900	Eritrea	406
Zimbabwe	1,862	Korea, DPR	364
Cambodia	1,830	Kyrgyz Republic	364
Sudan	1,719	Liberia	342
Zambia	1,500	Central African Republic	330
Côte d'Ivoire	1,406	Nicaragua	306
Burkina Faso	1,400	Mauritania	288
Uzbekistan	1,393	Guinea Bissau	122
Mozambique	1,277	Lesotho	70
Afghanistan	1,250	Gambia	61
Myanmar	1,200	Djibouti	56
Nepal	1,125	Solomon Islands	50
Senegal	1,075	São Tomé e Príncipe	35
Mali	1,050	Comoros	29
Sierra Leone	1,050		
Haiti	931	**Total:**	**115,590**

Step 2: Planned country CCE expansion and segmentation

Country consultations and CCE plan reviews in twelve countries (Bangladesh, DRC, Ethiopia, India, Kenya, Malawi, Nigeria, Pakistan, Tanzania, Uganda, Vietnam and Zimbabwe) allowed an estimate of each country's individual CCE expansion plans, i.e., equipping currently-unequipped facilities over the next ~7 years (full replacement cycle[29]). The average expansion percentage of these twelve countries (~18%, excluding Nigeria as an outlier) was then applied to remaining Gavi countries. Using this methodology, country expansion plans estimate a total of 26,000 additional facilities to be equipped across the full fifty-seven country set. Adding this to the existing base of 112,000 facilities results in a total of 139,000 facilities to be equipped with CCE.

To help determine the appropriate type of cold chain equipment for each facility, facilities were categorised along the two dimensions of cold chain volume requirement and electrification status to form an overall facility "segmentation" by country. CCEM facility-level data provided the most robust basis for segmentation, and was used to create country-specific CCE volume and electrification matrices for the seven countries where CCEM data was available. For these seven countires, required CCE volumes were estimated using catchment infant populations and applying a standard assumption of 400cc of CCE storage volume per immunised child[30]; electrification groupings were determined by number of hours of reliable electricity at each facility per day. The results of this segmentation were tested for sensitivities around CCE volume per immunised child and took into account the needs for ice vs. chilled water in outreach activities. An example segmentation matrix is shown below.

Table A3: Illustrative segmentation matrix (number of facilities below district level)

Zimbabwe base segmentation		Electrification					
		Off-Grid	Minimal Mains	Very Unreliable	Unreliable	Reliable	Total
Volume (litres)	250+	0	0	0	4	13	17
	50-250	0	7	0	85	12	104
	30-50	4	3	0	48	7	62
	15-30	14	11	0	64	11	100
	8-15	29	18	0	88	17	152
	0-8	607	122	0	540	158	1,427
	Total	**654**	**161**	**0**	**829**	**218**	**1,862**

Facilities in Gavi countries without robust bottom-up CCEM data were segmented either through country consultations or by extrapolation. Consultations with

[29] 7 year estimate of device replacement cycle based on averages of equipment ages in CCEM data and confirmed through consultations with UNICEF SD and WHO; new generation devices could be expected to have longer lifespans but there is no evidence to prove this yet.

[30] Assuming monthly vaccine deliveries. 400cc volume per fully immunised child a result of analysis considering vaccine volume, non-vaccine commodities, buffer stock, campaigns, demand asymmetry and wastage and based on extensive expert interviews and EPI schedules.

country-level officials provided segmentation matrices for Bangladesh, Ghana, Nepal, Nicaragua, Pakistan, Sudan, and Vietnam. For the remaining forty-three countries, an archetype methodology was used to extrapolate facility segmentation: individual countries were matched with one of the seven CCEM bottom-up segmentation profiles based on observed similarities in facility density between countries. Then, relative percentages for each segment from the CCEM archetype segmentation were applied to a country's total facility base to produce each country's extrapolated segmentation.

To account for increasing electrical grid access over the next replacement cycle in select countries, segmentation matrices for six countries (Ethiopia, Ghana, Kenya, Liberia, Nigeria and Tanzania) were adjusted in line with trends from Power Africa. The effect on the overall fifty-seven countries of this adjustment was to increase average on-grid percentage by 5-10% across the full country set. In order to simplify overall segmentation, five electrification categories[31] were combined to form two main electrification segments: effectively "on-grid" (facilities with an average >8 hrs of electricity per day and without power cuts of >48 hours) and "off-grid" (all others). Additionally, volume segments were combined/modified for a more natural split according to volumes of available devices. The final segmentation groups and corresponding allocation of the 139,000 facilities is shown below.

Table A4: Overall segmentation for country expansion plans (number of facilities)

Off-Grid <15L	Off-Grid 15-50L	Off-Grid 50-100L	Off-Grid 100L+	On-Grid <15L	On-Grid 15-50L	On-Grid 50-100L	On-Grid 100L+	Total
38,379	19,186	3,560	1,241	32,691	24,254	14,390	5,253	138,954

Step 3: Upper bound and segmentation

In 2015 an additional round of consultations with 10 "focus" countries (shown in table A5 below) informed a bottom-up analysis of country health structures and an assessment of additional CCE expansion opportunities beyond current country plans.

With the intention of pushing the aspiration of further equipping unequipped facilities and expanding cold chain into previously unreached areas, the number of targeted facilities increased from 139,000 to between 182,000 and 204,000. This extended range is based on different assumptions for India and Nigeria: the lower case (182,000) assumes India expands CCE into 10% of the sub-centers (i.e., 14,812 sub-centers) and Nigeria equips one facility per ward (as in the country plan); while in the higher scenario India equips 20% of the sub-centers (i.e., 29,625 sub-centers) and Nigeria equips an additional 10,000 facilities, roughly equating to 2 facilities per ward. "Non-focus" countries were assumed to increase equipped facilities by 15-18%, based on the average increase needed to get all facilities below the mean facility-to-infant cohort ratio up to the mean.

[31] Off-grid, Minimal Mains, Very unreliable, Unreliable and reliable

Table A5: Country plan & upper-bound scenarios for "focus" countries (number of facilities)

	India	Nigeria	Bangl-adesh	Ethio-pia	Tan-zania	Pakis-tan	DRC	Kenya	Nepal	Benin
Equipped facilities	27,597	6,240	5,000	8,670	5,000	10,000	3,000	3,976	1,125	679
To be equipped in country plans	5,000	3,504	-	3,290	3,000	-	1,000	-	197	119
Country plans total	**32,597**	**9,740**	**5,000**	**11,960**	**8,000**	**10,000**	**4,000**	**3,976**	**1,322**	**798**
Incremental upper bound	14,812-29,625	2,200 - 9,744	-	7,340	-	-	5,345	2,024	1,600	-
Upper bound total	**47,409-62,222**	**11,944-19,488**	**5,000**	**19,300**	**8,000**	**10,000**	**9,345**	**6,000**	**2,922**	**798**

Incremental health facilities beyond country plans were allocated to on- and off-grid categories using rural electrification rates, except for Kenya, which used CCEM electrification rates. Additionally, 80% of incremental facilities were assumed to require less than 15L capacity, with the remaining 20% allocated to the 15L-50L segment; this assumption rests on the expectation that newly-equipped facilities in the upper bound would be concentrated in the smaller and more remote health facilities.

This results in a final split across device categories as follows. he two ranges follow the assumptions described previously surrounding India and Nigeria equipment choices.

Table A6: Segmentation in upper bound scenario (number of facilities)

	Off- Grid <15L	Off-Grid 15-50L	Off-Grid 50-100L	Off- Grid 100L+	On-Grid <15L	On-Grid 15-50L	On-Grid 50-100L	On-Grid 100L+	Total
Upper bound (lower range)	58,004	23,919	3,560	1,241	47,463	27,817	14,390	5,253	**181,647**
Upper bound (higher range)	66,854	26,054	3,560	1,241	56,625	30,027	14,390	5,253	**204,003**

A1.4 Summary of needs estimate results

Using the methodology detailed in section 1.3, initial needs estimates for CCE fall into the range of 139,000 to 182,000 facilities, with a possible extension up to 204,000 total equipped facilities across the full set of fifty-seven Gavi countries. Due to its size and special status India is separated below for visibility.

Table A7: Total CCE need estimates by volume and electrification segment (facilities)

	Current installed base	Country plans	Upper bound 1	Upper bound 2
Total without-India	**91,283**	**106,357**	**134,237**	**141,781**
India	27,597	32,597	47,410	62,222
Total including India	**118,880**	**138,954**	**181,647**	**204,003**

A1.5 Translation of equipped facilities to device need

To translate equipped facilities into devices, a typical CCE package was constructed and applied to each facility. This package includes: 1 vaccine refrigerator[32] (type and volume vary according to facility segmentation – Ice-lined refrigerator [ILR] , Solar direct drive [SDD] or long-holdover passive device), 1 freezer, 1 temperature monitor (1 per fridge) and 1 cold box[33]. Additionally, on-grid facilities were allocated 2 voltage regulators[34] (1 per fridge and 1 per freezer). Finally, vaccine carriers were included in packages based on outreach levels: facilities in countries where outreach constitutes more than 30% of all immunisations were allocated 10 vaccine carriers per facility while all other facilities received 5 vaccine carriers.[35] Total devices estimated using this package for country-plan and upper-bound scenarios are shown below, assuming a full replacement cycle.

Table A8: Estimated refrigerator and other device needs (excluding India)

Refrigerator device	Country Plan	Upper Bound
Passives[36]	12,093	18,891
SDD 15L	24,553	38,354
SDD 50L	13,525	18,494
SDD 100L (for 100L and 250L segments)	4,666	4,666
ILR 20L	31,691	39,633
ILR 50L	15,244	17,159
ILR 100L (for 100L and 250L segments)	6,896	6,896
Other devices and accessories	**Country Plan**	**Upper Bound**
Freezers (off-grid)	53,779	73,250

[32] One exception applies to the 1 vaccine refrigerator per facility allocation: for facilities segmented into the 100-250L category, 2 100L refrigerators are allocated (due to lack of existing 2nd generation devices of this size). This applies for both ILRs and SDDs in that volume segment.

[33] Not generally for use in facilities but serve as transport devices to facilities.

[34] In certain large facilities, 3 voltage regulators allocated for facilities in the on-grid 100-250L category due to assumption that 2 100L refrigerators are purchased.

[35] This estimate may be conservative; other models have predicted higher numbers of vaccine carriers. An underlying source of difference originates from an assumption that cold chain expansion implies a shift towards fixed immunization and away from outreach.

[36] Passives are allocated for off-grid facilities needing <15L of storage capacity and with supply chain systems expected to be able to effectively deliver ice packs on a monthly basis (out of total <15L segment this assumed to be roughly one third of facilities).

Freezers (on-grid)	52,578	60,988
Temperature monitors	96,613	134,237
Voltage regulators	99,958	124,482
Vaccine carriers	650,809	890,310
Cold boxes	96,613	134,237

Table A9: Estimated refrigerator and other device needs (including India)

Refrigerator device	Country Plan	Upper Bound
Passives	12,665	22,062
SDD 15L	25,714	44,792
SDD 50L	19,186	26,054
SDD 100L (for 100L and 250L segments)	6,041	6,041
ILR 20L	32,691	56,625
ILR 50L	24,254	30,027
ILR 100L (for 100L and 250L segments)	24,896	24,896

Other devices and accessories	Country Plan	Upper Bound
Freezers (off-grid)	62,365	86,724
Freezers (on-grid)	76,589	94,923
Temperature monitors	138,954	181,647
Voltage regulators	163,683	200,352
Vaccine carriers	1,025,500	1,364,405
Cold boxes	138,954	181,647

It should be noted that certain accessories such as temperature monitors and voltage regulators may need to be replaced over the lifetime of a refrigerator. These replacement costs are expected to be covered by countries as part of their ongoing CCE planning and programs.

A1.6 Triangulation of methodologies:

Need estimations were triangulated with other approaches from PATH and CHAI (UNICEF-SD is currently engaged in developing a multi-year CCE forecast with expected completion in April of 2015). Results across available methodologies are comparable, in a rough range of 130,000 to 180,000 facilities and a similar number of devices.

Table A10: Demand estimate comparison (number of facilities, includes India)

Gavi country plan (7 year)	Gavi upper bound (7 year)	PATH
139,000	182,000-204,000	131,000-139,000

Table A11: Demand estimate comparison (number of vaccine refrigerators, includes India)

Gavi country plan (7 year)	Gavi upper bound (7 year)	CHAI (5 year)	CHAI (scaled to 7 years)
145,000	188,000-211,000	130,000	113,000 -182,000

Included below are descriptions of the different methodologies across organisations.

CHAI methodology

The CHAI vaccine refrigerator demand forecast, released in July 2014, forecasts procurements from the 53 countries eligible for Gavi support between 2014 and 2018. The forecast aggregates known budgeted procurements; it also estimates need, based on in-country plans (NVI schedule, cold chain expansion and rehabilitation assumptions, etc.) and assumes a percentage of the remaining need forecasted will translate into procurements, with a base case of 80% and ranging from 50% to 100%. A combination of primary data collection and extrapolation methods were used to estimate this demand:

1. For the countries CHAI works in (Nigeria, Ethiopia, Tanzania, Mozambique, Kenya, Uganda & Malawi), primary data collection, including cold chain inventories, in-country cold chain plans and country consultations were utilised. These countries represent 25% of CHAI's forecast of total Gavi market demand.
2. India, Pakistan, Bangladesh, DRC, Republic of Sudan and Afghanistan were chosen for detailed extrapolation, based on representing an additional 45% of the Gavi market demand. Extrapolation was based on NVI-related needs only as per public data sources and/or external party analysis.
3. The remaining 30% of the CHAI forecasted Gavi market demand is assumed to be attributable to the remaining 40 Gavi-eligible countries.

According to CHAI analysis, an estimated total of 110,000 vaccine refrigerator units are expected to be procured between 2014 and 2018, split 55% for ILRs and 45% for SDDs. Passive devices are not included in this forecast and solar battery refrigerators were excluded given lack of in-country consideration. An average of 22,000 vaccine refrigerators are expected to be procured per year, with steady annual demand in the range of 20,000 to 32,000 units from 2015 to 2018. ~50% of this requirement is expected to be from high volume African countries (Nigeria, Ethiopia) and India. Dependent on timing of NVIs in country, existing inventory replacement rate, availability of funding and the delays between planned vs. actual procurement, total forecasted demand could range between 80,800 to 129,500 units between 2014 and 2018. The scaled comparison of the CHAI demand compared to the Gavi demand can be found in table A10. CHAI is currently updating the demand forecast inputs from the countries it works in for 2015-2019 and expects to share with partners in April 2015.

PATH methodology

The PATH CCE installed base and forecast model includes 56 Gavi eligible and graduating countries. Current installed base estimates originate from country reported data on current CCE and are categorised by distribution level and technology type. Forecasts are based on estimated capacity needs by distribution level for storage, transport and outreach. Estimated needs are driven by current and new vaccine introductions.

Total vaccine administrative structures (used to represent CCE sites across distribution levels) are estimated to be ~140k by 2020. Of these, ~130k will sit at the lowest (sub district) distribution level.

In terms of device needs, the estimate for 2020 is for ~145k refrigerators. Current data on installed base indicates ~40k existing devices, implying an opportunity to equip an additional ~100k facilities. Data availability and quality may limit the accuracy of the current estimate for installed CCE base; uncaptured data on existing CCE would result in a lower opportunity for CCE expansion across the country set.

A1.7 Limitations of needs-based demand estimate

There are a number of possible limitations to the needs approach:

- A “needs” approach does not directly determine procurement volumes: country decision-making and execution will affect the degree to which need-based plans are realised. This might result in actual demand being lower than estimated needs.
- Country plans may change significantly over the course of an equipment replacement cycle: recent large tenders, as seen in Ethiopia and India, provide examples of unexpected CCE procurements that directly alter demand and extend beyond original estimates.
- There are limits to the precision of using extrapolations to predict CCE expansion in non-consulted countries. The “non-focus” countries may differ in significant ways from the 10 “focus” countries, although there is no clear or consistent direction of bias. This risk is mitigated by the large proportion of total CCE contained within the 10 focus countries (~60%) and the inclusion of a varied set of characteristics within focus countries (population, region, wealth structure etc.).

A1.8 Procurement forecast:

Consultations with CHAI, PATH and UNICEF SD will allow needs estimates to be converted into a procurement forecast, taking into consideration a time lag between the needs identification and the procurement. UNICEF SD is currently working on a procurement forecast, expected to be completed by mid 2015.

Annex B: ANNEX B Input for technologies supported

B1.1 Technologies supported by the platform

A key aspect of meeting the platform's objectives of accelerating deployment of high-performing technologies and expanding the cold chain is the set of technologies that the platform will support. Proposed technologies for support include the following:

Table B1: Proposed technology categories supported by the platform

Technology category	Device category	Rationale
Refrigerator: on-grid	Ice-lined refrigerators (ILRs)	• Highest-performing widely-deployed solution for on-grid with clear advantages over domestic fridges • Key technology innovations available but not adopted at scale – i.e. uptake of 2nd generation ILRs (with features such as user-independent freeze-protection) which can be accelerated through market incentives
Refrigerator: off-grid	Solar direct drives (SDDs)	• Highest-performing solar solution (preferred to solar with battery) with clear advantages in uptime and costs, including lower maintenance needs and fewer replacement parts. • High potential for accelerated adoption through incentives for purchasers
	Long-term passives	• Key emerging solution for low capacity off-grid facilities[37] • Minimal maintenance requirements, reducing challenges encountered in the field • High potential for accelerated adoption through incentives for purchasers
Other	Freezers	• Required to support outreach activities (50% of routine immunization) • Complements fridges without freezer compartments and passives
Transport and outreach devices	Cold boxes Vaccine carriers	• Key technology innovations near market introduction (freeze-free) • Cold boxes necessary to enable transport of vaccines to facility level delivery sites • Vaccine carriers required to support outreach activities (50% of routine immunization)
Accesories[38]	Temperature monitors[39]	• Important for detecting temperature excursions in the field

[37] Passives provide benefits such as zero expected maintenance but will require consistent monthly supply of recharged ice packs. The total cost of ownership and feasibility of passives will need to be evaluated in the context of specific countries and localities.
[38] In some cases these accessories may be integrated into devices; as frequency of integration increases, the need for inclusion and support by the platform may decrease and these devices could be phased out of platform support.
[39] Default type of temperature monitor is continuous temperature monitor device (TMD) such as a FridgeTag 30 day TMD; certain countries may opt for more advanced but operationally complex

Technology category	Device category	Rationale
		and logging equipment performance monitoring
	Voltage regulators	• Key accessory for preventing damage due to common voltage fluctuations in the grid • Included in proposed on-grid fridge/freezer features (may be bundled or integrated)

Conversely, certain technology types were identified as either undesirable for support by the platform due to poor performance profiles or de-prioritised for support in the initial version of the platform but possibly eligible for inclusion at a later date.

Table B2: Proposed technology categories not supported by the platform

Technology category	Device category	Rationale
Refrigerator: on-grid	Domestic refrigerators	• Not PQS pre-qualified and thus not qualifying as technology to be supported by the platform • Significant performance downside due to poor temperature control, common freezing temperatures and severely limited holdover
Refrigerator: off-grid	Absorption	• No devices currently PQS pre-qualified • Significant performance downside due to high operating/fuel costs, high risk of freezing, significant downtime risks due to gas shortages
	Solar w/battery	• Large performance gap to SDD as more expensive, high risk of failure due to battery, higher maintenance needs
	Thermoelectric	• No technology in PQS process • Potentially revisit/include later (in future iterations of the platform)
Other	Walk-in cold rooms and walk-in freezers*	• Lack of recent technology innovation – no clear optimal technology for platform to incentivise or accelerate at this time, especially given complexity of customisation, elements of infrastructure, etc. • Heavily concentrated at higher levels of health structures which have fewer cold chain challenges (as seen in EVM data) • Limited funding gap, especially in comparison with standalone CCE • Potentially revisit/include later; require in country planning but do not fund for time being
	Refrigerated vehicles	• Lack of recent technology innovation • Concentrated above district levels and are used beyond vaccine cold chain

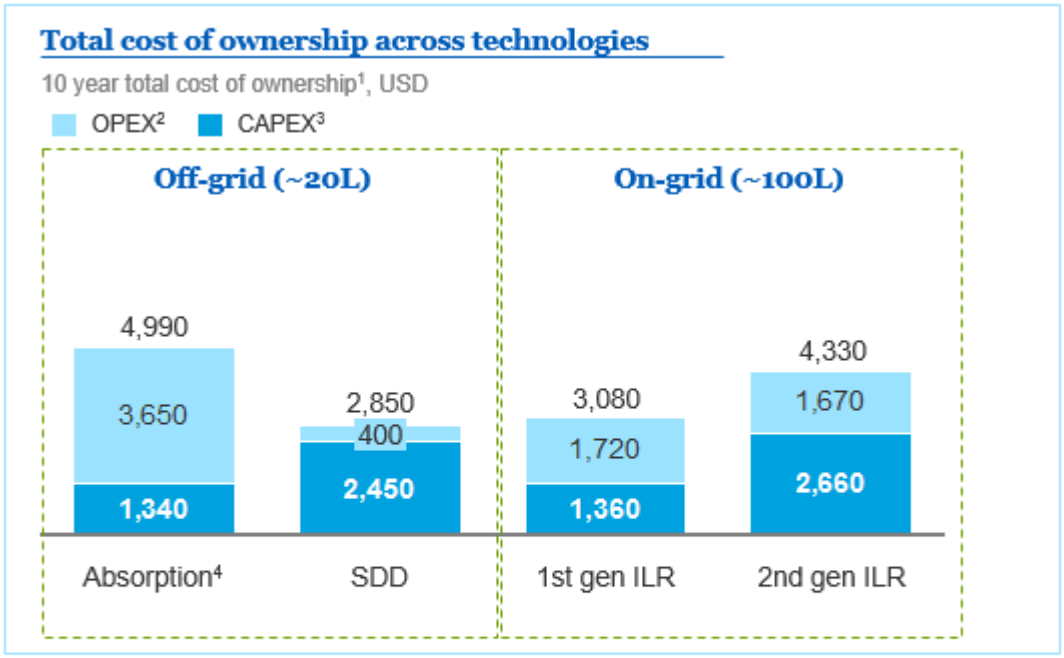
remote temperature monitoring devices (RTMDs) See Annex F, section 1.3 for more details on RTMD technology/requirements and selected initial pilot experiences.

Technology category	Device category	Rationale
*		*Assessed arguments in favor of inclusion, e.g., given the strategy in some countries to replace current fridges with walk-in-cold rooms especially at large district centers, not including them could carry a risk of creating a perverse incentive to purchase large fridges instead of WICRs. Also considered the risk of fragmenting procurement and the ease of communication to countries if included in package.*

B1.2 Implications of technology evolution: TCO and vaccine protection

The shift to higher-performing technologies has implications for both vaccine protection and cold chain costs. Encouraging adoption of SDDs in the off-grid segment (away from absorption fridges) is expected to result in significant savings in operating costs (fuel and maintenance) that outweigh the initial higher purchase price of SDDs; as a result the total cost of ownership (TCO) is expected to decrease for off-grid devices. Within the on-grid segment, 2nd generation ILRs have similar operating costs to 1st generation ILR but higher purchase costs. Despite this, significant advantages in vaccine protection (especially from freezing) underlie the recommended shift from 1st to 2nd generation ILRs. (It is expected that purchase prices for 2nd generation ILRs will decrease in the near future to become more equitable to 1st generation ILRs as suppliers ramp up manufacturing scale.) These points are illustrated in the figure below.

Figure B1: TCO for on-grid and off-grid devices



1 Absorption fridges represented by Dometic RCW 50EG (24L). Comparable SDD model included is BFRV15 (15L). 1st gen ILRs represented by average of four models (MK304, HBC-200, TWC2000AC and VLS300, each ~100L). Comparable 2nd gen ILRs represented by average of four models (ZLF100AC, BLF100AC, GVR100AC, ZLF150AC, each ~100L)
2 Operating expenses estimated from PATH TCO calculation model, assumes 10 year lifetime of equipment
3 Capital expenses refer to full prices in PQS Catalogue
4 the RCW 50EG model is a gas absorption fridge. For the corresponding kerosene absorption fridge purchase cost is $1510 and operating cost $2620

Source: PATH TCO calculation model, team analysis

B1.3 Additional technology requirements

To help achieve the platform's objective of accelerating deployment of high-performing technologies that meet user requirements across health facility types, the Secretariat must specify a minimum standard of quality for technology purchased with its support. Through its choice of technology standards, the Secretariat has a unique opportunity to encourage the development and adoption of innovations that improve device performance.

Currently, WHO has defined an extensive list of quality standards and specifications by device type for CCE through its Performance, Quality and Safety (PQS) programme. PQS effectively serves as an industry standard and is widely recognised by manufacturers, procurement organisations and country recipients. Additionally, through its related Target Product Profiles (TPP) programme, the WHO has created a signalling mechanism that informs manufacturers of desired product improvement features and encourages development of these features through incorporation into PQS over time.

It is strongly recommended that the platform aligns as much as possible with and reinforces the existing standards of PQS and TPPs. Doing so will effectively leverage a) the technical expertise of the PQS and TPP working groups in identifying end user needs/requirements and subsequent key product improvements, b) WHO PQS's existing relationships with manufacturers and c) the associated signalling infrastructure and evolution cycle. It also would avoid creating confusion of a parallel system.

With that in mind, the proposed technology requirements for the initial platform include all current PQS requirements across all platform-supported technology categories. Additionally, specific technology requirements based on WHO PQS TPPs are specified for on-and-off grid refrigerators. These are detailed below.

Table B2: Selected TPPs for inclusion as tech requirements

Technology feature	Description	Tech category	Year for PQS inclusion
1. Freeze protection	• User-independent freeze protection in Vx storage compartment	Fridge, cold box/vaccine carrier	2015
2. Extended ambient temperature range	• Cooling function rated to ambient temperatures from 10 to 43 degrees C	Fridge	2015
3. Temperature monitor & log	• Temperature log with 30 days transferrable data for maintenance analysis	Fridge	2015
4. Maintenance and installation kits	• Inclusion of basic installation and maintenance tools and parts, etc.	Fridge, freezer	2015
5. ID, operating and maintenance stickers	• Inclusion of model info and operating/ maintenance pictograms for clear user instruction	Fridge, freezer	2015

6. PV cable length (SDD only)	• Minimum 20m cable connector to PV array	SDD only	2015
7. Packaging robustness	• Packaging (e.g. wood crates or other) capable of withstanding conditions of transport (physical damage)	Fridge, freezer	2019

It should be noted that two proposed technology requirements are not currently in published TPPs.

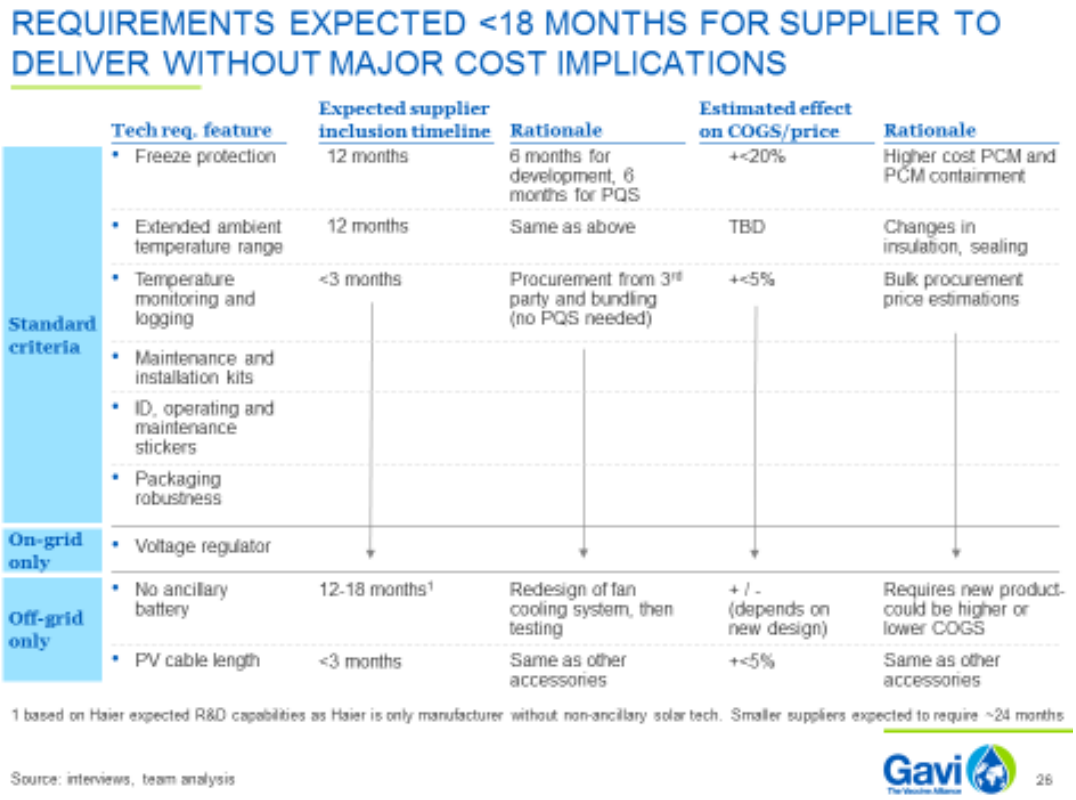
Technology feature	Description	Tech category	Year for PQS inclusion
8. Voltage regulator (ILR only)	• Voltage regulator included in device purchase or integrated into design	ILR fridge and freezer	TBD
9. No ancillary battery for cooling distribution (SDD only)	• Exclusion of ancillary battery in device design	SDD only	N/A

The current expectation is that voltage regulators for ILR (either bundled or integrated) will be addressed in the formulation of ILR TPPs, forthcoming in 2015. Additionally, the requirement of no ancillary battery within SDDs is already in line with broad market movements, to the extent that WHO PQS has de-prioritised its inclusion within TPPs due to lack of observed need. Thus neither feature is believed to conflict with WHO PQS plans and intentions.

A further aspiration is that as existing TPPs evolve and additional TPPs are added for more CCE technology categories, the platform will also reinforce these signals by updating its technology requirements accordingly in parallel with the TPP changes.

Finally, it is important to recognise additional technical requirements beyond PQS may have associated risks of market disruption due to integration challenges for manufacturers. These risks have been tested with select manufacturers and appear to be low, as manufacturers are already integrating most of these features or have them in their R&D plans. The most costly and technically difficult requirement – user-independent freeze protection – is under development by multiple leading manufacturers and additional devices with this feature beyond current SureChill technology are expected to come to market by end of year. Extended ambient temperature range is also widely developed and less difficult to integrate. The remainder of tech requirements involve the bundling of accessories and other non-core components and are not expected to create major barriers. Taken together, all of these technology features are expected to be feasible for supplier integration in less than 18 months and without drastic increases in cost. A summary of expected implications on development and cost are included below.

Figure B2: Expected tech requirement timelines and high level cost impacts



REQUIREMENTS EXPECTED <18 MONTHS FOR SUPPLIER TO DELIVER WITHOUT MAJOR COST IMPLICATIONS

	Tech req. feature	Expected supplier inclusion timeline	Rationale	Estimated effect on COGS/price	Rationale
Standard criteria	• Freeze protection	12 months	6 months for development, 6 months for PQS	+<20%	Higher cost PCM and PCM containment
	• Extended ambient temperature range	12 months	Same as above	TBD	Changes in insulation, sealing
	• Temperature monitoring and logging	<3 months	Procurement from 3rd party and bundling (no PQS needed)	+<5%	Bulk procurement price estimations
	• Maintenance and installation kits				
	• ID, operating and maintenance stickers				
	• Packaging robustness				
On-grid only	• Voltage regulator				
Off-grid only	• No ancillary battery	12-18 months[1]	Redesign of fan cooling system, then testing	+ / - (depends on new design)	Requires new product- could be higher or lower COGS
	• PV cable length	<3 months	Same as other accessories	+<5%	Same as other accessories

1 based on Haier expected R&D capabilities as Haier is only manufacturer without non-ancillary solar tech. Smaller suppliers expected to require ~24 months

Source: interviews, team analysis

26

Annex C: Inputs for estimating Cold Chain Equipment platform financial need

C1.1 Summary

The financial need of the platform depends on six main inputs:

- Volumes: based on needs estimates in terms of optimal equipment for each facility
- Purchase price
- Delivery and installation and costs
- Spare parts
- Level of funding/co-investment

C1.2 Volumes

Estimated volumes are detailed in Annex A: *Cold Chain Equipment Need Estimate*

C1.3 Device prices

To estimate capital expenditure need, the following representative prices were taken for each device category:

Table C1: Fridge and freezer price per device ($)

Segment	Refrigerator device	Price	Freezer device price*
Off-grid <15L	Passives	2,147	685
Off-grid <15L	SDD 15L	2,399	
Off-grid 15-50L	SDD 50L	3,816	
Off-grid 50-100L	SDD 100L	5,980	
Off-grid >100L	SDD 250L	11,961	
On-grid <15L	ILR 20L	1,469	392
On-grid 15-50L	ILR 50L	1,469	
On-grid 50-100L	ILR 100L	2,349	
On-grid >100L	ILR 250L	4,697	

** Freezer device costs are inclusive of delivery and installation costs; for other devices, delivery and installation costs have been specifically estimated and are detailed in section 1.4*

As a general rule, prices for segments above are average minimum listed prices in the PQS catalogue (assuming purchase of over 100 or 200 devices depending on model) for 2nd generation technologies, adjusted for inflation over the 7 year replacement period.[40] For example, the 100L SDD price is the average of the minimum PQS catalogue prices for the three 2nd generation (including freeze protection, extended ambient temperature range, etc.) SDD models in that volume band[41] with relevant adjustments for inflation and price discounts.

[40] Assumed yearly inflation rate of ~4%.

[41] Included models are BLF100DC (Surechill), ZLF100DC (Zero), VC150 (Dulas), and includes cost of solar panels (if not already included in price).

A couple of exceptions to the above rule should be noted, and are driven by a lack of existing 2nd generation equipment (and market prices) in those specific volume bands. For SDD 250L and ILR 250L devices, the price assumption taken is double the price of existing 100L models (assuming purchase of two 100L models to satisfy storage needs). Additionally, the ILR 20L price was assumed for now to be the same as the ILR50L price. These prices may be revised as new 2nd generation equipment is developed and pre-qualified within those volume segments, with particularly large price reductions expected if a ~200L SDD or ILR is developed.

In addition to fridges and freezers, the following representative prices, also inflation adjusted, were applied when estimating capital expenditures for remaining technologies supported by the platform.

Table C2: Other technology price per unit (USD)

Device	Price
Cold box	137
Vaccine carrier	43
Temperature monitor	59
Voltage regulator	64

Vaccine carriers are based on latest estimates for the price of forthcoming carriers with freeze free technology.[42]

All prices shown above for devices reflect an assumed average adjustment from current PQS minimum list prices, based on current expectations of evolving price effects following platform launch. In one direction, the bundling of aftersales services (installation, training) and spare parts into purchases is expected to increase prices, as may the addition of new technology features[43]. However, these potential price increases are believed to be more than offset over the course of the replacement cycle by price decreases due to increased and more predictable volumes and resulting significant manufacturer economies of scale. Currently, the net effect of prices is estimated in the range of up to ~20% off of current PQS minimum pricing. It is the expectation that this price reduction will ramp up over the medium term as volumes scale. Price effects will be one important factor to explore more deeply during the following operationalisation phase, subject to Board decision.

C1.4 Additional cost elements covered by the platform

In addition to capex, the platform is intended to support additional equipment-related expenses. These include delivery and installation costs. Delivery refers to

[42] Assumed starting price of $50 with relevant adjustments for price discounts.

[43] Current delivery, installation and spare parts costs are explicitly accounted for in additional costs described in sections 1.4 and 1.5. However manufacturers may put a premium on these above current levels as part of an bundled/integrated offering in the form of additional manufacturer margins. New technology features include those in the TPPs that are specified as technology requirements for platform-supported devices.

both freight costs (for shipping to ports, customs) and in-country transportation costs to end sites. Installation includes physical installation of device and end-user training (health worker training on monitoring, basic upkeep). For simplicity, delivery and installation costs are added directly to capex prices as a one-time cost, as these costs will be bundled into purchase and are intended to be coordinated by manufacturers. A summary of delivery and installation costs is provided below. These are based on CHAI estimates[44] and are adjusted for inflation. A 20% margin was assumed for manufacturers in bundling these traditionally aftersales services.

Table C3: Delivery and installation costs for fridges per unit ($)

	Device	Delivery & install cost (one-time)
Off-grid <15L	Passives	436
Off-grid 15-50L	SDD 15L	1,250
Off-grid 50-100L	SDD 50L	1,458
Off-grid 100L-250L	SDD 100L	1,665
Off-grid 250L+	SDD250L	3,330
On-grid <15L	ILR 20L	436
On-grid 15-50L	ILR 50L	436
On-grid 50-100L	ILR 100L	1,125
On-grid >100L	ILR 250L	2,251

Currently, no installation or delivery costs are allocated for vaccine carriers and cold boxes as well as accessories (voltage regulators and temperature monitors), on the assumption that these are bundled with refrigerator delivery. Delivery and install costs for freezers are included in the purchase price.

All estimates for delivery and install represent a top-down and average estimate. Costs may vary greatly depending on country and local conditions. As a refinement, delivery and installation costs could be revisited at a more granular level during operationalisation.

C1.5 Spare parts

Spare parts will be required to be bundled into device purchases. PATH estimated annual costs for spare parts for SDDs and ILRs were used as a basis for estimating these costs for on and off grid devices. These annual costs were scaled up to a 7 year replacement cycle. It should be noted that these cost estimates are limited to latest generation technology set and do not cover older

[44] Same set of representative 2nd generation device models used for estimating delivery and installation per volume segment as used in device purchase price assumptions. Exception is that MK074 used to approximate for both On-grid <15L, On-grid 15-50L and Off-grid <15L (Passive) due to unavailability of delivery and installation estimates for GVR50AC and Aucma Arktek

technologies such as absorption fridges or solar-with-battery. Passive devices are assumed to require no spare parts.[45]

Table C4: Spare parts cost per year per device (USD)

Device	Spare parts annual cost per device, USD
SDD	30
ILR	27
Freezer[46]	27-30
Passive	0

C1.6 Level of funding support:

Details of funding support considerations can be found in Annex D.

C1.7 Total funding needs and cost to platform

A summary of projected total CCE funding needs is shown below, drawing upon the inputs detailed in sections 1.1 to 1.6 of this annex. Values shown below assume a full replacement cycle of 7 years unless specifically specified otherwise. For a five year period these costs would be scaled proportionately, pending the completion of a consolidated demand forecast and more detailed analysis of volume demand by year.

Table C5: Total CCE funding needs

55 Gavi countries (excluding India)	Base case, USD M	Upper bound, USD M
Capex		
Fridge	249	313
Freezer	57	74
Outreach (vaccine carriers, cold boxes)	44	56
Accessories (temp monitors, voltage regulators)	13	16
Spare parts	40	49
Delivery & Installation	92	116
7 year grand total	**500**	**620**
5 year grand total	**360**	**440**
Annual (rounded)	**70**	**90**

55 Gavi countries (including India)	Base case, USD M	Upper bound, USD M
Capex		
Fridge	340	431
Freezer	73	97

[45] Possible exception exists for purchase of extra custom ice packs; these would be for rotation purposes or replacement of lost ice packs rather than break-down as ice packs are designed to last for the duration of device lifetime. Cost of these icepacks are not available but may be explored in next phase.

[46] Freezer spare parts were approximated using estimated replacement costs for corresponding fridges (ILR spare costs applied for on-grid freezers), as freezers are expected to have similar failure modes in the field.

55 Gavi countries (including India)	Base case, USD M	Upper bound, USD M
Outreach (vaccine carriers, cold boxes)	63	83
Accessories (temp monitors, voltage regulators)	19	23
Spare parts	52	65
Delivery & Installation	129	163
7 year grand total	**680**	**860**
5 year grand total	**480**	**620**
Annual (rounded)	**100**	**120**

With specified tiered funding support levels, the estimated funding needed to cover grants by the platform is shown below, again including and excluding India.

Table C6: Estimated funding to cover platform grants

55 Gavi countries (excluding India)	Base case, USD M	Upper bound, USD M
Capex		
Fridge	170	216
Freezer	39	52
Outreach (vaccine carriers, cold boxes)	30	39
Accessories (temp monitors, voltage regulators)	9	11
Spare parts	27	33
Delivery & Installation	63	81
7 year grand total	**340**	**430**
5 year grand total	**240**	**310**
Annual (rounded)	**50**	**60**

55 Gavi countries (including India)	Base case, USD M	Upper bound, USD M
Capex		
Fridge	215	275
Freezer	47	63
Outreach (vaccine carriers, cold boxes)	39	52
Accessories (temp monitors, voltage regulators)	11	14
Spare parts	33	42
Delivery & Installation	81	104
7 year grand total	**430**	**550**
5 year grand total	**310**	**390**
Annual (rounded)	**60**	**80**

Annex D: Funding level

Considerations for co-investment model

D1.1 Co-investment level overview

The CCE optimisation platform seeks to amplify current funding for CCE from bilateral donors, country national budgets and/or Gavi HSS or VIG by co-investing in CCE device purchases.

A number of options for the co-investment level were explored, and three primary options were evaluated in detail. A summary description of these three primary options follows.

a) *Full funding:* The platform provides 100% of device purchase price[47] for all equipment with no variation across Gavi countries
b) *Partial funding (flat):* The platform co-invests 50% of device purchase price for all equipment with no variation across Gavi countries
c) *Partial funding (tiered by income / GNI groups – similar to the model for supporting vaccines):* Countries will use as base investment current funds used to procure CCE. The platform co-invests either 50% or 80% of device purchase price, depending on country gross national income (GNI) level (Low-income, Intermediate and Graduating countries[48]). All Low-income countries are eligible to receive co-investment of 80% of device purchase price, all Intermediate countries and Graduating countries with at least three years of HSS support (2016-2018) receive co-investment of 50% of purchase price. All other Graduating and Graduated countries platform are not eligible for funding, but have access to the platform's negotiated prices and procurement services offered by the procurement agent. This method of tiered support is reflective of conventions within the current Gavi vaccine co-financing approach.

Partial funding tiered by income / GNI groups is the currently proposed option for the platform. Details of the considerations and tradeoffs supporting this proposal can be found later in this annex in sections 3.2 to 3.4.

Three variants of the tiered funding were considered but not evaluated in detail as they did not align with existing vaccine co-financing conventions. Additionally, these options presented further operational complexities that limited feasibility as the platform's co-investment model. These variants are described below for reference.

- Tiered funding based on income and coverage level: Countries were grouped by Gavi income / GNI groups (Low-income, Intermediate and Graduating) and DTP3 coverage[49] (<70%, 70-90%, >90%). Low-income

[47] Includes one-time bundled costs of delivery and installation and spare parts
[48] Low income countries have annual GNI < $1,045 (Atlas method); Intermediate countries have annual GNI between $1,045 and $1,580; Graduating countries have annual GNI >$1,580.
[49] All references to DPT3 coverage use a 3 year rolling average of DPT3 coverage (2011-2013)

countries with coverage <90% coverage and Intermediate countries with coverage <70% are eligible for 80% funding of device purchase price; all other countries are eligible for 50% funding of device purchase price.

- Tiered funding based on equity and coverage level: Countries are grouped by Low/High wealth inequity (DTP3 coverage in lowest wealth quintile >20% lower than in highest quintile) and DTP3 coverage[50] (<70%, 70-90%, >90%). High-inequality countries with <90% coverage and low-inequality with <70% coverage are eligible for 80% funding of device purchase price; all other countries are eligible for 50% funding of device purchase price.

- Tiered based on replacement vs. newly equipped facilities: All countries are eligible for 50% funding of device purchase price for devices purchased to replace existing CCE and 80% funding of device purchase price for CCE going into previously-unequipped facilities.

  This final tiering method was heavily considered due to its ability to specifically incentivise cold chain expansion. However, it was deemed very difficult to implement operationally in terms of ensuring compliance with stated intentions for CCE following fund disbursement. Perhaps more importantly, major concerns exist with the platform funding levels directly incentivising expansion over replacement; expansion for some countries may not align with broader immunization strategies or goals. (e.g., countries where outreach is used effectively)

D1.2 Evaluation of co-investment level against platform objectives

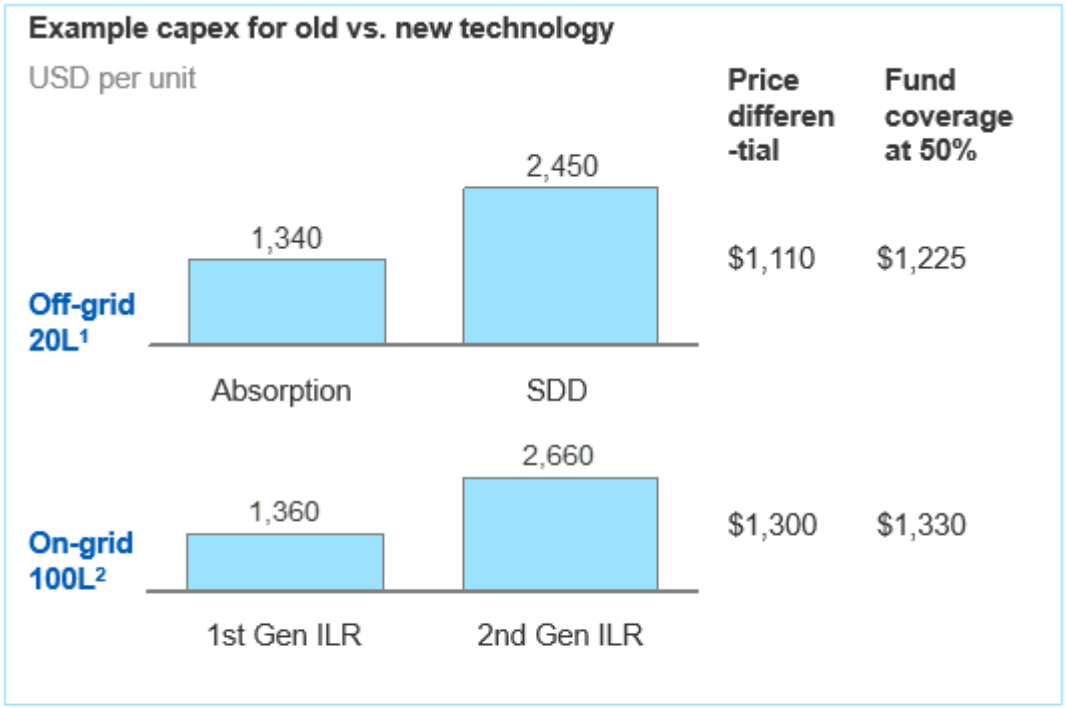
The three primary co-investment options were evaluated first on their ability to drive the CCE Optimisation platform's main objectives, specifically around their ability to incentivise the adoption of new technologies and to extend the current cold chain into currently unequipped facilities.

To incentivise the adoption of new technologies, the key hurdle to overcome currently is the purchase price differential between old and new technologies. In terms of old technologies, absorption devices (for off-electrical grid) and domestic fridges (for on-electrical grid) are currently available as relatively inexpensive options. However, these technologies suffer from significant performance barriers such as frequent downtime occurrences (due to fuel shortages, power outages) and short holdover times. New technologies such as solar direct drives (SDDs) and 2nd generation ice lined refrigerators can offer significantly improved performance, such as extended holdover and freeze protection. However, they have a consistently higher average purchase price; the price differential tends to be 50% or less in most segments[51]. An illustrative comparison is shown in figure D1 below.

[50] See footnote 10

[51] Certain specific segments may have a price differential slightly higher than 50%, particularly in smaller on-grid segments (for which the number of options for 2nd generation ILRs is currently limited) and with passives. However, 50% funding is expected to cover gaps in general across the CCE portfolio

Figure D1: Example capital expenditure for old vs. new CCE technologies



1 Prices for devices within 15L of 25L storage capacity. Absorption model shown is Dometic RCW 50EG, a gas absorption fridge (Comparable kerosene absorption fridge has purchase price of $1,510). SDD model shown is BFRV15

2 Average prices taken from PQS catalogue for devices within between 90-110L storage capacity. 1st Gen ILR models included were TCW2000AC, HBC-200, VLS300, MK304 and 2nd Gen models included were ZLF100AC, BLF100AC, GVR100AC, ZLF150AC

Source: PQS catalogue, PATH TCO model, team analysis

In order to incentivise purchasers to choose new technologies, this price differential must be covered and ideally exceeded, to provide the additional incentives needed to overcome previous brand familiarity. Given that 50% funding broadly covers and exceeds the purchase price differential between old and new technologies and that all three co-investment options provide at least 50% funding, all three options are expected to drive the objective of incentivising adoption of or shift to new technologies.

The second objective of the platform is to extend the current cold chain into previously unequipped facilities. Meeting this objective relies on countries purchasing CCE in volumes exceeding that needed for the replacement of existing equipment. By fully funding CCE, the Alliance would expect the most rapid uptake of the platform by countries and could expect the highest magnitude and speed of cold chain extension. Partial funding has the risk of a slower and potentially lower uptake of platform support. With that in mind, partial funding (flat) at 50% results in the lowest expected impact on the CCE extension objective amongst the three options. Partial funding based on income tiering will have larger impact than 50% flat funding on CCE extension as the poorest Gavi countries will be eligible for a higher level of funding support (80% vs. 50%) which is more in line with their ability to pay.

D1.3 Evaluation of co-investment level against additional considerations

Beyond the fund objectives, the three primary co-investment options were also evaluated against five additional considerations: risk of displacing existing funds,

effect on country ownership, sustainability, simplicity of operation, and attractiveness to countries.

- *Risk of displacing existing funds*: this refers to the degree to which the platform, as a new funding source, may disrupt existing funding for CCE purchases. The fully fund option is expected to have a high potential for displacement. As the platform would cover 100% of the purchase price, countries and bilateral donors might divert funds previously intended for CCE assuming that financing CCE would fully become the responsibility of the platform. Partial funding is expected to reduce this risk as it is clear that countries will need to continue to contribute resources towards CCE and that the platform exists to amplify rather than replace existing CCE investment. 50% funding level will have the lowest anticipated risk of displacing existing funding. There is potential increased risk of fund displacement for low-income countries in the tiered model due to an 80% co-investment contribution from the platform.

- *Country ownership:* this refers to the degree to which the platform encourages a sense of responsibility for the equipment purchased by the platform from a country perspective. Full funding would be expected to have the lowest degree of country ownership as countries would not be contributing any of their own financial resources. This might result in lower incentives to properly maintain equipment towards longer device lifetimes. In contrast, partial funding encourages and rewards country-led actions to invest in CCE. Tiering by income group within the partial funding model is not expected to strongly affect country-ownership; countries will still be responsible for contributing their own resources towards CCE but at an amount that is more in line with income and ability to pay.

- *Sustainability:* this refers to the ability of countries to continue financing adequate CCE purchases once co-investment support from the platform ends. The fully fund option would be expected to encourage the lowest degree of sustainability as it would effectively replace existing CCE funding mechanisms which would need to be built up again following the platform's termination. Partial funding, on the other hand necessitates the continued existence of other CCE funding sources at country level. Naturally, lower sustainability is expected with the tiered partial funding model for low-income countries platform due to higher co-investment from the platform. An option exists to evolve co-investment support over time, either with a specific yearly evolution or through countries' natural progression across income groups. These options may be explored at greater detail during operational design of the platform.

- *Simplicity of operation*: this refers to the degree of simplicity of the procedures involved in administering the fund, including communication. The fully fund option has the highest degree of simplicity; it offers all countries the same level of support and consolidates funding into one flow to the procurement agency. Partial fund (flat) would have the simplicity of offering the same co-investment level to all eligible countries, but would add the

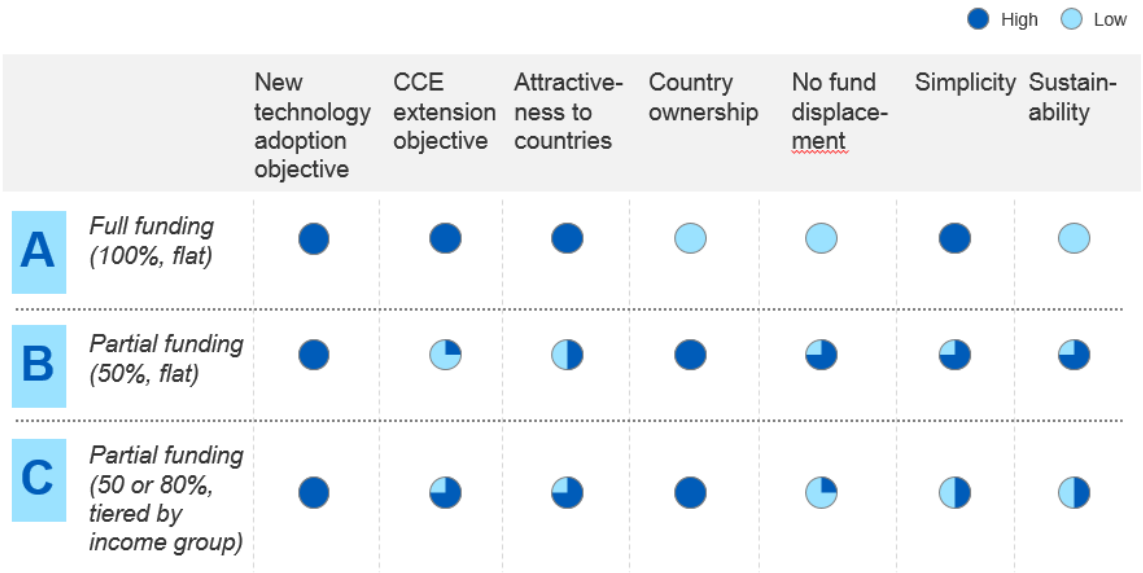
complexity of managing multiple funding sources. This complexity could be mitigated through a co-procurement versus a co-financing operational design.[52] The partially fund (tiered by income/GNI) model would have the lowest degree of simplicity as categorization of countries into two funding level groups requires a methodology to execute and more complex messaging to communicate to countries. These burdens have been mitigated by aligning with existing Gavi principles for tiering support to countries for vaccines. Additionally, the partial tiered model (like the partial flat model) would require countries to manage multiple funding sources, and will likely also use co-procurement rather than co-financing as the mechanism.

- *Attractiveness to countries:* this refers to the degree to which the level of co-investment is sufficient to attract countries to apply to the platform. This is especially relevant considering that a) the platform will put in place conditions and requirements for funding that may not have previously existed for countries when purchasing CCE equipment (including updated CCE inventories, maintenance plans, etc.) and b) current bilateral donor funding generally covers the full cost of devices without contribution from countries. With these factors in mind, the fully fund option would be clearly the most attractive option as it provides the greatest level of funding support to balance out platform application requirements. Partial funding is naturally less attractive to countries and initial consultations have revealed that some low-income countries believe a 50% level of co-investment would prevent or at least delay participation in the platform due to the initial country contribution required. The partial funding model tiered by income group helps alleviate some of this challenge for low-income countries, but stops short of the attractiveness of full funding.

D1.4 Summary of funding level evaluation

A graphical representation summarising the evaluation of the three primary funding level options is shown below. In general, full funding would allow maximum impact in terms of new technology adoption and CCE expansion but would displace current funding sources and reduces country ownership toward a low level of sustainability. In contrast, partial funding at 50% would facilitate country ownership and limit disruption to current CCE financing, but with the result of reduced attractiveness and lower impact on fund objectives and uptake. The partial funding tiered by income group model improves attractiveness to countries compared to partial funding at 50% while maintaining some level of country ownership. It is more complex to implement than both flat funding models, but at the same time aligns with existing conventions for funding support for vaccines.

[52] Co-procurement generally separates out contributions into different purchase orders (rather than partial funding of the same devices) and may avoid issues related to the timing of funding and ability to move forward with procurement.



D1.5 Funding type

The preferred type of funding under the partial tiered model is a grant. Two other options, loan and lease, were also considered but were not selected.

Partial leases are not an operationally feasible option. Additionally, leases (even in full form) are not currently offered by manufacturers for CCE.

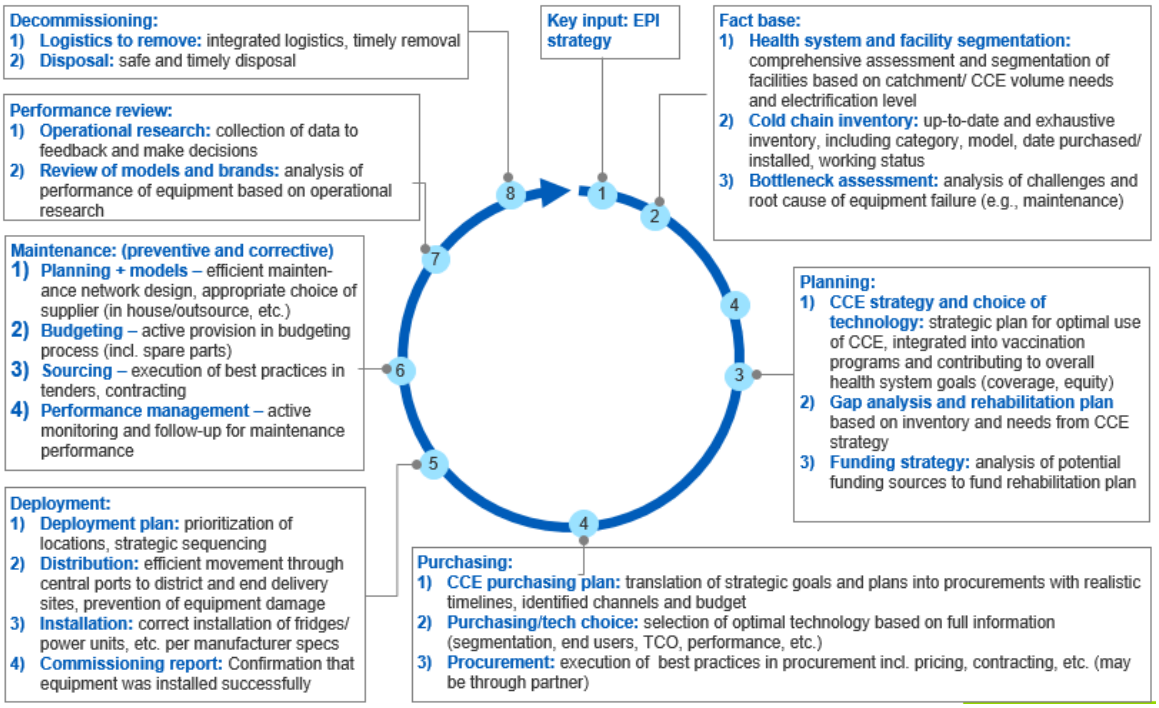
Partial loans are likely to be insufficiently attractive to countries and are expected to significantly decrease participation in the platform. This is supported by evidence provided during consultation with some countries expressing concerns with participation even with grants at a partial funding level. This belief is further supported by current practices around CCE funding which use grants as the prevailing form of funding assistance. Additionally, loans would be expected to add operational complexities in terms of managing repayments, an area which Gavi has had little experience or precedent.

Annex E: CCE management including installation and maintenance

E1.1 The CCE management cycle

Effective CCE management includes an extensive set of activities, beginning with the overall EPI strategy and spanning the range of CCE fact base establishment, planning, purchasing, deployment, maintenance, performance review and decommissioning. Figure E1 illustrates the full cycle of CCE management activities and components with high-level descriptions.

Figure E1: CCE management activities



The many and often complex activities of CCE management present a significant challenge to countries and a key risk for the CCE optimisation platform in realizing its objectives. In particular, the platform's third objective of keeping devices functioning depends heavily on countries' abilities to execute certain CCE management activities (including equipment selection, installation, maintenance and performance monitoring) which are often limited across Gavi countries today. The platform's second objective of CCE extension also heavily relies on CCE management activities such as segmentation and inventories.

An extensive network of in-country partners, including UNICEF PD, WHO, CHAI, PATH, VillageReach and AMP, currently exists to assist countries with various aspects of CCE management. These partners offer a range of technical assistance (TA) services including but not limited to assistance in developing CCE inventories, preparing rehabilitation plans, providing procurement guidance or services, identifying and contracting with maintenance service providers and collecting data on device performance. Some of these partners (WHO and UNICEF PD) are – at least partially – funded through the Gavi Supply Chain Business Plan; others are funded from various external donors. Despite this, a lack of available funding, insufficient supply and weak demand from countries

remain a major hurdle to countries receiving the right degree of technical assistance on CCE management.

Additionally, while the CCE technical assistance network is extensive, it suffers on the whole from a high degree of fragmentation and lack of coordination between partners. The result is that technical assistance packages are often inconsistent in quality, incomplete, and not available in some geographies. In addition, technical assistance efforts broadly struggle with sustainability (e.g. inventories are conducted with the help of TA partners but are not updated by countries following the end of in-country support) and long-term capability building remains a key challenge.

The optimisation platform has the opportunity to directly address some of these challenges. By instituting requirements for certain CCE management inputs (such as CCE segmentation and inventories, rehabilitation and extension plans, deployment plans, maintenance plans, etc.) as a prerequisite for funding, the platform can incentivise countries to engage in key CCE management activities and increase country demand for technical assistance. Additionally, the platform can shift some responsibilities away from countries and towards manufacturers, e.g. requiring manufacturers to be responsible (either directly or through local partners or distributors) for delivery and installation. These mechanisms are described in more detail in section 1.6 of this annex.

Finally, it should be clearly expressed that the platform is not intended to directly provide technical assistance but will rely on existing in-country partners through the Hub to coordinate and execute on-the-ground support. Alliance partners will work together to reflect technical assistance needs into Partners' Engagement Framework.

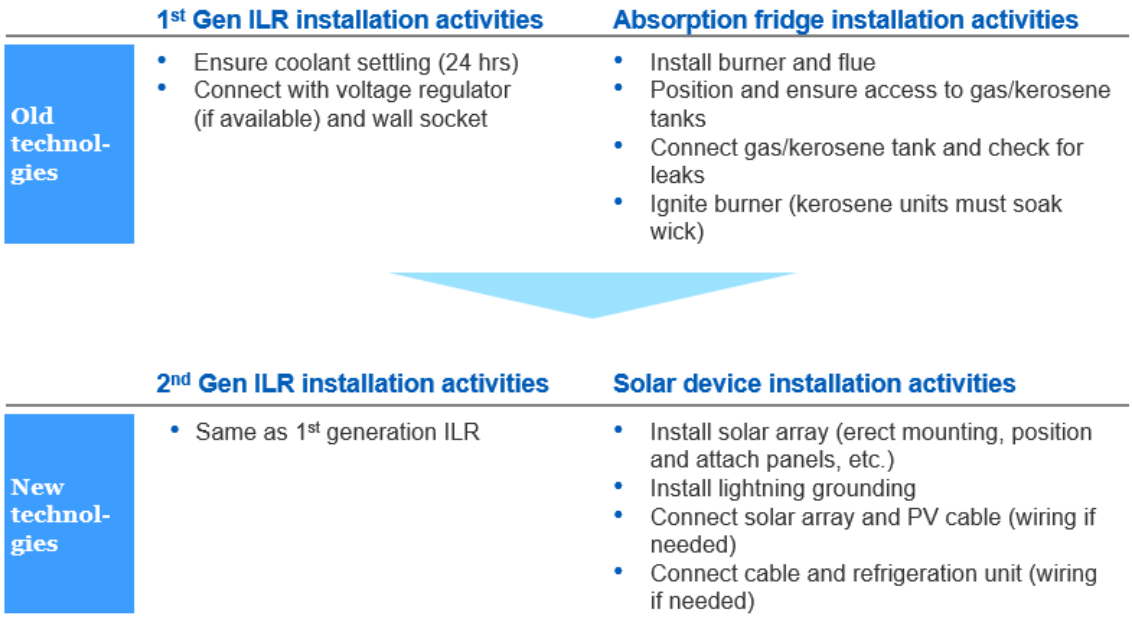
E1.2 Background on CCE installation and maintenance activities

Through numerous consultations with countries and technical cold chain experts, two key activities within the CCE management cycle emerged as strong barriers to device functionality: proper installation and appropriate maintenance. The following sections describe the typical requirements related to installation and maintenance and their evolution between old and new technologies.

Installation

While manufacturers currently provide installation manuals, capabilities in countries around installation are nascent and often underdeveloped, especially for newer technologies (i.e. SDDs). To give a sense of the specific steps required, a list of typical installation activities for fridges is shown below.

Figure E2: Typical required device installation activities (old and new technologies)



In general, installation is much simpler for on-grid devices, whereas off-grid devices (particularly solar) require a number of installation steps that require the skills of a trained technician. Over time, installation complexity has remained the same for ILRs going from 1st generation to 2nd generation devices; in contrast, installation complexity has increased with the shift from absorption to solar devices (as solar array mounting, positioning and wiring tend to be more complex than installation of burner systems).

Currently, the bulk of CCE installation is carried out by in-country technicians that are coordinated by country governments. In some specific cases, manufacturers may also have in-country distributors or partners who take on the responsibility of installation or training for installation, although this practice is still relatively uncommon. One recent example of this a purchase contract between Nigeria and Dometic in 2014.

Maintenance

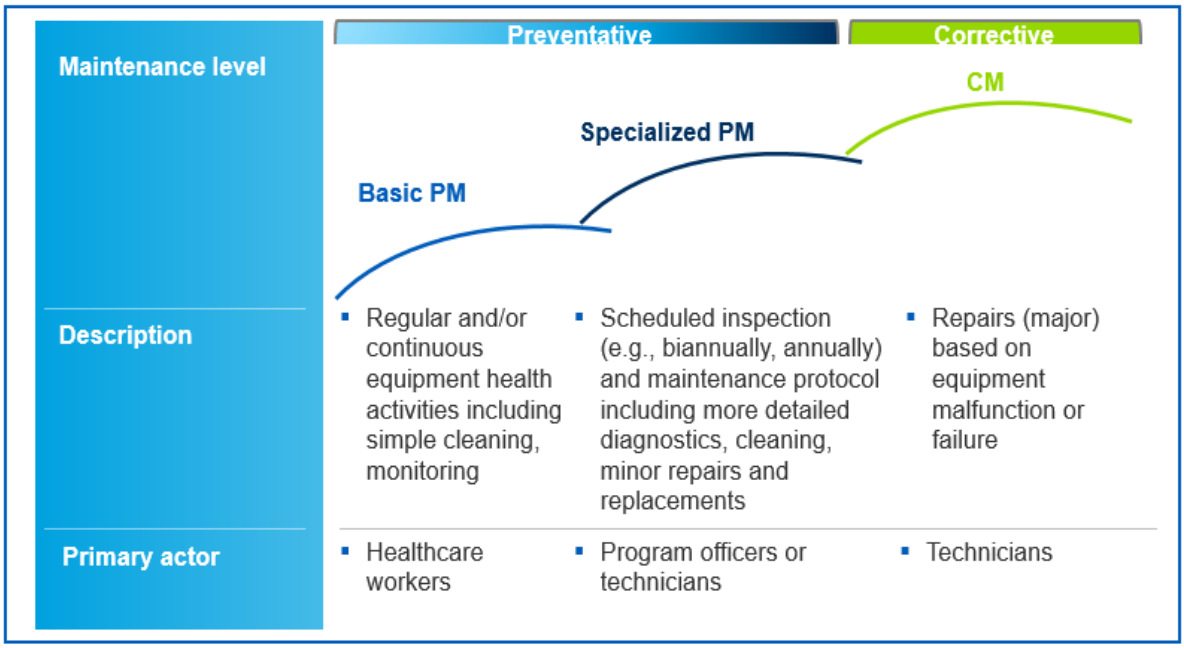
Categories of maintenance

CCE maintenance includes both preventative maintenance (PM) and corrective maintenance (CM). Preventative maintenance refers to regular/periodic maintenance activities performed to reduce the frequency of device failure, and can be further categorised into basic PM (largely the responsibility of CCE end-users/health care workers) and specialised PM (requiring services of a technician or another third party with a greater level of technical skills[53] and usually executed

[53] Due to the potential of replacing and repairing components (door seals, PV cables etc.)

every 6 to 12 months). Corrective maintenance refers to unplanned repair activities following device failure, almost always requiring a trained technician[54].

Figure F3: Maintenance categories



A summary of typical preventative maintenance activities is shown below for on-grid and off-grid fridges and freezers, as recommended by WHO. Corrective maintenance activities will be entirely dependent on specific component failures or damages.

Figure E4: Old generation preventative maintenance activities

	1ST Gen ILR and absorption activities	Additional absorption-specific activities
Daily PM	• Monitor temperature, adjustments if necessary	• Check flame, clean burner and adjust flame control setting if not blue (for kerosene only, wick may also need to be trimmed) • Check for sufficient fuel in bottle, refill
Monthly PM	• Clean (outside, lid/door gasket, condenser/cooling unit) • Defrost • Level (small fall to rear)	• Check for week supply of fuel, refill if necessary • Check for gas leaks, call for repair if found • Trim wick (kerosene only)
Annual PM	• Replace door/lid gasket if damaged • Remove rust from exterior, repair • Repair interior shelves/wire baskets • Restock spare parts	• Clean flue • Clean burner and gas jet • Clean and flush tank (kerosene only) • Replace wick

[54] Due to necessity of diagnosing specific failure root causes and instituting appropriate repairs or replacements

Figure E5: New generation preventative maintenance activities

	2nd Gen ILR and solar activities	Additional solar-specific activities
Daily PM	• Monitor temperature, adjustments if necessary	• Inspect solar panel display (specific actions according to manuals) • Battery charge status inspection (Solar battery only)
Monthly PM	• Clean (outside, lid/door gasket, condenser/cooling unit) • Defrost • Level (small fall to rear)	• Top-up electrolyte if necessary (Solar battery only) • Clean/dust solar array (frequency will vary by local conditions)
Annual PM	• Replace door/lid gasket if damaged • Remove rust from exterior, repair • Repair interior shelves/wire baskets • Restock spare parts	• Check array shading and de-shade • Replace damaged cables

In general, ILRs (1st and 2nd generation) and SDDs have relatively few upkeep and preventative maintenance needs beyond cleaning and defrosting (for ILRs). Absorption fridges, however, require a high degree of upkeep in the form of refueling and maintenance of burner components.

E1.3 Background on device failures

The failure modes of devices vary by technology and local conditions. Unfortunately, data on root causes of failure and frequencies in the field are not widely available. Some feedback collection mechanisms (such as through UNICEF SD) exist but rely on countries to actively report device failures, thus resulting in sporadic data that covers only a limited number of devices and time period (mainly during warranty period) and mostly big problems only. However, based on technical understanding of device functionality, it is possible to identify primary expected failure modes by technology category. These are detailed below for both old and new technologies.

Figure E6: Old technology major failure modes

Key failure

Device type	Downtime cause	Stage	Probability	Downtime effect
Absorp-tion	Physical damage from transport	Transport	◔	◑
	Refrigerant leak (insufficient settling[1]) during installation	Installation	○	◕
	Improper fuel line connection	Installation	○	●
	Fuel shortage	Operation	●	●
	Improper temperature adjustment	Operation	●	●
	Gas leaks	Operation	◔	●
	Burner failure (often wick-related)	Operation	◔	●
1st gen ILR	Physical damage from transport	Transport	◔	◑
	Compressor failure, improper installation	Installation	◔	●
	Compressor failure. voltage spikes	Operation	●	●

1 Recommended 24 hour waiting period between delivery and installation to allow refrigerant to settle (WHO)
Source: Consultation interviews

Figure E7: New technology major failure modes

Key failure

Device type	Downtime cause	Stage	Probability	Downtime effect
Solar	Physical damage from transport	Transport	◔	◑
	Refrigerant leak (insufficient settling[1]) during installation	Installation	○	◕
	Improper wiring (circuit damage)	Installation	◔	●
	Improper panel positioning	Installation	◑	◑
	Compressor failure, improper installation	Installation	◔	●
	Improper lightning ground	Installation	○	●
	Failure to clean panels	Operation	◔	◑
	Controller failure	Operation	◔	●
	Battery failure (does not apply to SDDs)	Operation	◑	●
	Solar panel theft	Operation	◔	●
2nd gen ILR	Physical damage from transport	Transport	◔	◑
	Compressor failure, improper installation	Installation	○	●
	Compressor failure. voltage spikes	Operation	◕	●
Passives	Ice shortage	Operation	◑	●

1 Recommended 24 hour waiting period between delivery and installation to allow refrigerant to settle (WHO)
Source: Consultation interviews

As seen above, major failure modes have evolved in very different ways between on-grid and off-grid technologies, and between different types of technologies. Within on-grid, major ILR failure modes have remained effectively the same between 1st generation and 2nd generation devices; the primary failure mode remains compressor failure caused by voltage spikes. The frequency of these failures is believed to have decreased due to the inclusion of more robust internal components (stronger electronic control units, addition of internal voltage regulators in some models, etc.) but remain a very real threat to device functionality for 2nd generation ILRs not protected by effective voltage regulators. In contrast, major failure modes have shifted significantly in the off-grid segment as technologies move from absorption to solar devices (particularly SDDs). While previous absorption devices are easier to install but require a large amount of upkeep in the form of refueling and maintenance, solar devices are much more vulnerable to issues during installation and do not require significant upkeep and maintenance to remain functional once properly installed.

Taken as a whole, these failure mode trends have two major implications. The first is that installation for solar direct drive devices will become an increasingly important activity within CCE management. The second is that the needs for maintenance, both specialised preventative maintenance and corrective maintenance, are expected to decrease as ILRs continue to become more robust and absorption fridges are replaced by SDDs.

E1.4 Background on maintenance network models

Maintenance models

While technology evolution is expected to decrease the need for maintenance over time, fridge failures cannot be entirely eliminated and CCE functionality will still rely on specialised preventative and corrective maintenance activities. To execute these activities, countries today employ three broad types of maintenance network models.

- **Ministry of Health (MoH) in-house technicians**: a country government hires, trains and employs its own cadre of technicians who are responsible for CCE maintenance. In general, each MoH technician is responsible for all CCE within a particular area (district, province, etc.). Often, technicians are part of a larger maintenance network beyond CCE and are also engaged for maintenance of other health sector equipment such as hospital and lab equipment. Note: a variation of this model exists where manufacturer provide training to MoH technicians.
  Main advantages: High level of government ownership; high degree of integration into cold chain and overall health system infrastructure
  Main drawbacks: Strong dependence on government funding (risk of insufficient funding and technician workforce), government training (risk of insufficiently skilled technicians), and government management capabilities (risk of poor performance management, weak technician retention)
  Example(s): Tanzania, Bangladesh, Nigeria, India

- **Independent third-party vendor:** a country government outsources maintenance to private third party providers who are responsible for hiring,

training and managing technicians. These third parties may be regional or local companies or even individuals. Contracts can be flat fee or fee-for-service.
Main advantages: Higher specialisation, leaner processes and tighter cost management characteristic of private providers; ability to execute performance management through contracts
Main drawbacks: Limited availability of appropriate third-party providers in certain regions; limited skills of local providers, especially across full set of technologies/models; additional burden on countries to identify, source, contract and manage services
Example(s): Northern Nigeria, Vietnam[55]

- **Manufacturer bundling:** Manufacturers provide maintenance through local distributor or partner networks and bundle cost of services into purchase contracts and price. Typical maintenance provision windows are 1-5 years. This type of model is uncommonly seen in the field.
  Main advantages: Reduced complexity for local government; guaranteed maintenance provision at point of sale; increased expertise through manufacturer personnel and training
  Main drawbacks: Potential creation of manufacturer entry barriers due to investment needed to develop in-country presence; creation of duplicate maintenance networks for different device brands; potential displacement of local maintenance infrastructure by setting up a maintenance networks for CCE not integrated into overall maintenance systems (for countries using in-house technicians); limited potential at scale.
  Example(s): Mozambique

E1.5 Background on causes of CCE maintenance challenges

Causes of installation and maintenance challenges:
Across Gavi countries, poor CCE installation and maintenance stems from a wide range of underlying causes. As mentioned previously, the dynamics are highly localised and depend on a specific country or region's maintenance markets and management capabilities. However, some common themes in terms of root causes emerge across countries.

Demand for maintenance

a) Misaligned user mindsets: End users tend to prioritise replacement over maintenance/upkeep ("if it's broken, replace it"), resulting in limited incentive to engage with maintenance. Also, funders are more likely to pay for replacement than repair.
b) Missing data transparency: Insufficient inventories and up-to-date equipment performance data inhibit planning for preventative maintenance and creation of response systems for corrective maintenance

[55] In initial stages of Vietnam's contracts all maintenance was performed by the third party; eventually third party technicians trained government technicians on preventative maintenance and subsequently only performed corrective maintenance

c) Insufficient operational funding: Funding for maintenance activities (e.g., technician per diems, fuel for transportation, etc.) is either not budgeted, or is delayed or repurposed

Supply of maintenance services

a) Insufficient end-user activity: Health care workers do not perform basic preventative maintenance and upkeep activities, (e.g., cleaning, monitoring) due to a lack of awareness, training or capabilities
b) Limited pool of available technicians: Insufficient number of properly-trained technicians for specialised preventative and corrective maintenance, arising from difficulties in hiring/recruitment, improper or insufficient training across many devices and brands, and poor retention. Additional challenges to availability also stem from competing priorities of trained technicians (who may service other CCE or other health equipment).
c) Unavailable spare parts: Spare parts are not accessible locally and have long lead times for delivery from central stores, or may not even be stocked properly at central levels.
d) Transport deficiency: Limited transportation infrastructure prevents timely deployment of technician resources

Performance management

a) Limited managerial expertise: Actors responsible for managing maintenance networks lack skills to oversee maintenance system design, maintenance planning and budgeting, and management of maintenance quality
b) Weak governance: Ineffective performance monitoring systems and accountability measures for maintenance providers leads to delays and variable quality of maintenance services
c) Limited incentive systems: Poor compensation and other incentive packages are unable to offset heavy workloads/travel schedules and result in low technician motivation, substandard performance and high turnover
d) Lack of performance data???

E1.6 Recommended CCE management actions for the CCE optimisation platform

Installation

Installation issues (particularly important for SDDs) will be addressed by requiring and paying for manufacturers to guarantee correct installation of devices through bundling into device purchase contracts. Manufacturers might do so by directly installing devices through their distribution networks, by sub-contracting to local service providers or by providing training (including practical assessments) to local technicians. Initial consultations indicate manufacturer interest in providing such aftersales services contingent upon sufficient financing.

Maintenance

Technology improvements will be the first lever through which the Alliance aims to increase CCE functionality and decrease the need for maintenance. The Alliance through the platform will directly incentivise the adoption of high-performing technologies that are expected to reduce failure modes and require

less maintenance activity (e.g., the replacement of absorption fridges that need regular refueling, and burner/wick maintenance with SDDs that mainly require periodic panel cleaning.) The Alliance will also drive manufacturers to develop further innovations over time that increase device functionality by putting in place technology requirements aligned with WHO TPPs (e.g., inclusion of voltage regulators as expected in forthcoming ILR TPPs). These two actions are expected to decrease the overall current burden of preventative and corrective maintenance.

With regards to basic preventative maintenance, the Alliance through the platform will address challenges in terms of health care worker awareness and capabilities. Specifically, the Alliance will require and pay for manufacturers to bundle end-user training into purchase contracts as part of installation and to conduct thorough training sessions prior to commissioning of new equipment. (The Alliance may require documented evidence of training execution.)

On specialised preventative maintenance and corrective maintenance, the Alliance will institute conditions for access to the platform such as a robust maintenance plan (including an identified service provider and a protected budget, as well as an updated spare parts and accessories inventory). The Alliance will rely on partners in countries to support country governments in preparing and submitting credible maintenance plans. In addition, the CCE platform will address the issue of availability of spare parts for maintenance by bundling spare parts with device purchases as part of a starter kit.

At this point it is proposed that the Alliance does not execute any direct maintenance contracts through the platform, given that a) maintenance network set-up is highly localised and dependent on specific capabilities in country and b) that direct intervention through the platform risks fragmentation of existing maintenance interventions between platform-funded and other devices. In-country partners, in part funded by the Gavi Supply Chain Business Plan, are expected to provide on-the-ground support for maintenance activities as one piece of the overall CCE management technical assistance offering. Technical assistance activities may include maintenance diagnostics, support in identifying and contracting (if appropriate) maintenance providers, helping to set up robust equipment management plans and managing overall performance of maintenance networks. In addition to in-country technical assistance, the Alliance will also leverage existing training for technicians and CCE managers through regional centers of excellence (CoE) such as the one being established by the East African Community (EAC) in Rwanda or Logivac in Benin. These models could be replicated in other regions and manufacturers would be encouraged to contribute their expertise to the curriculum.

Finally, the CCE platform has the opportunity to encourage the development of systems for CCE performance monitoring that will facilitate future improvements to CCE planning, selection, deployment and maintenance by establishing routine data collection and analysis systems. More details on monitoring and metrics can be found in Annex F.

Annex F: M&E Framework

F1.1 Objectives of the platform

As stated previously, the CCE optimisation platform has 3 main objectives:

a) Accelerate deployment of existing, appropriate, innovative CCE devices to health facilities, enabling the achievement of SG3 and SG4.

b) Facilitate and accelerate extension of country cold chain systems (critical to SG1 and SG2).

c) Ensure that devices are continuously maintained to keep vaccines potent (also critical to SG2).

F1.2 Metrics

The success of the platform in meeting these objectives and strengthening cold chain will result in a more effective overall vaccine supply chain across Gavi countries and is expected to support the Alliance's overall coverage and equity goals.

A robust monitoring and evaluation framework will allow the Alliance to determine progress of the platform towards its objectives and also observe broader progress on overall supply chain performance and health impact indicators.

In line with the Alliance M&E conventions and building upon IHP+, the proposed set of key metrics for the platform fall into one of five categories: inputs, processes, outputs, outcomes and health impacts. An overview of these metrics is presented below. These metrics will be further refined and tested, and targets for specific metrics will be established where appropriate during the operationalization phase from June to December of 2015.

Table F1: Supply chain strategy and key metrics for platform

Inputs	Processes	Outputs	Outcomes	Health Impact[56]
• Funds raised by the platform • Funds disbursed by the platform • # of countries with SC and CCE plans reflecting	• # countries applying to the platform • # grants recommended for approval by IRC • Time between IRC approval to disbursement • Time between disbursement	• # of optimal equipment purchased with platform support • # of PQS qualified models available in the CCE market • meeting selected optimal TPPs	• # equipped facilities replacing old tech with optimal tech • # of previously unequipped facilities equipped (where appropriate) with optimal tech • % equipped	• % infants receiving penta3 • Reduction in inequity of coverage (wealth, urban/rural, gender)

[56] These refer to Gavi Alliance overall strategic goal indicators; the CCE platform would be one contributing factor amongst all Alliance activities towards increasing coverage and equity

Inputs	Processes	Outputs	Outcomes	Health Impact[56]
coverage and equity objectives • Biannual demand forecast completed	and comissioning	• Weighted[57] average purchase price	facilities with functioning equipment • *Frequency and duration of temperature excursions at facilities** • Stockout rates • Closed vial wastage rate	
* *Medium to long-term metric; requires well-functioning continuous temperature monitoring equipment and systems to be implemented at scale*				

Inputs

As the platform leverages funding as a primary instrument for meeting its objectives, input metrics focus on the ability of the Alliance to raise necessary funds to cover platform co-investments in CCE and the amount of those funds are disbursed to countries. These resources complement country level plans for improving supply chains including design and location of delivery sites and equipment and rigorous demand forecasts. Metrics on country SC planning and demand forecasts are thus included due to their strong relationship with platform inputs even though the platform will not play a primary role in driving these factors.

Processes

Process metrics fall in two broad groups. The first group focuses on application/adjudication and examines a) the level of uptake and the ability of the platform to attract countries and b) how well countries are meeting requirements and passing adjudication process. The second group of metrics measures the pace of the platform processes, from the time of IRC approval to that of device deployment and commissioning. Time between IRC approval to disbursement will measure the platform's internal disbursement timeliness while time between disbursement and commissioning will be used to measure the timeliness of external partner processes, including procurement, delivery and installation led by procurement agency, technical assistance partners and manufacturers in conjunction with countries.

Outputs

Output metrics focus on platform elements that facilitate or complement the platform's three primary objectives. The total number of equipment purchased with platform support will serve as the foundation for CCE replacement and extension. Additionally, the number of PQS models available in the market that meet selected TPPs will measure the degree to which the platform is helping to accelerate development and commercialisation of innovative and higher performing technologies by manufacturers. Finally, as the platform scales and

[57] Weighted by device volume

overall demand increases and stabilizes, CCE purchase price movements will be tracked to assess the degree to which the platform's market shaping impacts are leading to reduced costs and improved pricing.

Outcomes

Outcome metrics fall into two groups. The first group is intended to directly measure progress against the platform's three primary objectives. On the first objective of accelerating deployment of appropriate, innovative technologies, the platform will ask countries to report the number of facilities that replace old CCE with optimal CCE purchased with support from the platform, as well as the number of previously unequipped facilities that are newly equipped (where appropriate) with optimal CCE. The latter metric will also indicate the platform's progress towards the second objective of specifically accelerating the extension of cold chain systems beyond current status. Finally, to evaluate the platform's performance on its third objective of ensuring devices are maintained and functional, the platform will measure or estimate the % of equipped facilities with functioning equipment. In the medium to longer term, additional metrics focused on uptime, such as frequency and duration of temperature excursions may be added as temperature monitoring capabilities improve and data becomes more available.

Additionally, a second group of outcome metrics will focus on overall supply chain performance, of which the platform's objectives will play a major part[58]. These metrics align with indicators within the draft Alliance Supply Chain Guidance Dashboard as developed through the Supply Chain Strategy. Stock out rate at facilities could serve as an indication of vaccine availability, which could be impacted by non-functioning CCE. Closed vial wastage rate could give indications on supply chain efficiency and wasted vaccines due to potency losses, also which may be impacted by poor performing or non-functioning CCE.

Health impacts

Ultimately, a high-functioning cold chain will contribute towards a stronger supply chain and will help enable the Alliance to further its overall objectives of immunisation coverage and equity. Overall progress on these goals is measured by the Alliance strategic indicators of Penta3 coverage rate and coverage equity, based on the Alliance's three equity formations of wealth, urban/rural and gender. It should be clearly noted that the platform will be only one of many contributing factors towards improvement in these indicators.

F1.3 Data sources and monitoring systems

Reliable data collection to monitor platform's metrics will be important, both across the Alliance partners and within countries.

Input and process metrics will in general be collected as part of the platform's standard operations and routine management. For these metrics, identified as

[58] Beyond the amount of CCE deployed and the functional status/performance of deployed CCE, multiple other factors will affect supply chain outcomes of availability, potency and efficiency.

"platform internal reporting" metrics, no additional monitoring system will be needed.

Output metrics will rely on reporting from partners such as UNICEF and WHO. The Alliance will need to ensure that platform metric requirements are aligned with current collection and reporting by partners (e.g. UNICEF price verification and reporting).

Outcome metrics will rely on close partnership with countries and technical assistance partners to measure and report. Deployment plans and commissioning reports in particular will need to be systematically submitted and reviewed to determine the number of devices going towards replacement versus equipping new facilities, as well as the timing of device installations.

Within outcome metrics, measuring device functionality, stockout rates and closed-vial wastage would potentially present the greatest challenge, as data for these metrics would need to be regularly collected or sampled from individual health facilities across geographies (including many remote sites). The frequency and method of collection for device functionality data will depend on individual country capabilities and systems. At a minimum, equipment functional status will be assessed every ~3 years during CCE inventory updates and EVM assessment sampling. The Alliance through the platform may institute more regular sampling of temperature excursion data to evaluate device performance, either through 30 day temperature loggers (30DTR) or remote temperature monitors (RTM) where appropriate. However, the platform will need to rely heavily on technical assistance partners and countries to implement or strengthen the training, protocols and feedback systems necessary to execute effective temperature monitoring using either method. Lessons learned from these efforts will be critical in developing temperature monitoring capabilities more broadly across Gavi countries. Additionally, the private sector may also help drive advances in monitoring through integration of temperature monitoring capabilities into devices and creating more streamlined user interfaces. It is the hope that in the medium to long-term, temperature monitoring data will become successfully scaled and integrated into cold chains at scale.

Sampling of stock-out rates and closed vial wastage rates will also require coordination of countries and technical partners. Like temperature monitoring, the development of systems and capabilities that track these metrics represents a major opportunity for countries with support from partners to improve their supply chain data visibility and management.

Finally, health impact metrics in the form of coverage and equity will be tracked in accordance with existing conventions and within scope of the overall Gavi 2016-2020 strategy.

F1.4 Remote temperature monitoring

Remote temperature monitors (RTMs) are an innovative solution for the tracking of CCE functionality and temperature excursions. One particular benefit is that these monitors can be configured to report data directly to a country's central

data warehouse and from there may be accessed by the Alliance[59], avoiding the need for manual data readings and cascading reporting mechanisms.

RTMs function by combining temperature probe(s) with a cellular transmitting device and sim cards. Temperature probes continuously monitor temperature within one or multiple devices and data is transmitted from the facility cellular module to a receiving module or server in another location (usually a district or central facility). Here, temperature data can then be aggregated, analyzed and accessed at large through the internet.

An example RTM system is show below:

Figure F2: Temperature @lert temperature monitoring system

Several pilots of remote temperature monitoring systems are currently underway. In Mozambique and India, NexLeaf and VillageReach are helping to roll out a technology (ColdTrace) that sends SMS alerts during departures from optimal temperature ranges while also collecting and storing the data. Additionally, pilots in Albania and Nicaragua started during PATH's Project Optimize are implementing another RTM system that relays data to a central server via SMS. Finally, Nigeria, Tanzania and Ethiopia are also currently piloting different RTM systems with the support from CHAI.

While the benefits in terms of data accessibility are significant with the use of remote temperature monitors, the successful implementation of RTMs requires a number of components to be in place prior to launch. Specifically, the introduction of remote temperature monitors requires four key components: connectivity infrastructure (consistent access to GPRS or other cellular networks), funding for the technology and operational costs, clear processes and protocols on usage of data (particularly for alarms) and training to heath workers and managers on

[59] Data transferred to warehouse via SMS/cellular networks and receiving remote servers; countries can grant access to real-time data to the Alliance through web-based tools

analysis and reporting. Given these implementation pre-requirements (particularly those around processes/protocols and training), it is expected that implementation of RTM will require in-country support from technical assistance partners.

Initial pilots provide evidence of key benefits as well as challenges with RTM rollout. For example, Nigeria with support from CHAI was able to identify non-functioning equipment in cold stores using RTM, leading to decommissioning of broken equipment and successful transfer of vaccines to back-up stores. At the same time, however, Tanzania and Ethiopia have experienced difficulties in RTM rollout, primarily in the form of insufficient cellular connectivity.

Annex G: Process and Consultations

Process, consultations and guiding principles

G1.1 Process to develop recommendations to the PPC

Under the auspices of the Supply Chain Strategy implementation, the Secretariat, with support from and together with colleagues from BMGF, UNICEF and McKinsey and Company, developed an investment case for a CCE fund. The Secretariat led three phases of work to develop the recommendations in this paper:

(a) Phase 1: Fact gathering and analytics to inform the fund design and core business case. This entailed quantitative analytics on demand projections, device prices and current and projected CCE funding flows. These analytics drew on work by UNICEF, PATH, CHAI and McKinsey. This phase also included qualitative analyses on drivers of CCE purchase and funding choices, current CCE management and maintenance systems, and perspectives on how the fund should link with HSS. Extensive consultations were conducted with in-country CCE experts to generate these insights.
(b) Phase 2: Operational set up. In this phase, an initial perspective was developed on how the fund would operate. This perspective was developed based on consultations across Secretariat functions, partners, countries, manufacturers and donors. This initial view would be further refined following PPC decision.
(c) Phase 3: Refine investment case. Following the core design and operational work, technical considerations were further tested and refined with key constituencies, including country supply chain leaders, manufacturers, donors and partners.

Throughout these phases stakeholder groups were consulted for both fact-gathering and design-testing purposes. The consultations included:

(a) More than 30 fact-gathering interviews with in-country supply chain partners and country experts from UNICEF-PD, CHAI, PATH, Village Reach, AMP, Riders for Health, and eHealth.
(b) Consultations with EPI managers and logisticians from 12 focus countries (including Bangladesh, Benin, Côte d'Ivoire, DRC, Ethiopia, Kenya, Nepal, Myanmar, Uganda, Sri Lanka, Tanzania, Zambia) to generate relevant insights, test the emerging design, and understand potential risks and mitigation measures.
(c) Questionnaire input from 9 Immunization Managers[60], including input from Indonesia, Madagascar, Malawi, Myanmar, South Africa, South Sudan, Zambia, Zimbabwe.
(d) Regular engagement with WHO-PQS to discuss device performance and to align the CCE fund's technology requirements with WHO's TPPs.

[60] One anonymous response without provided country affiliation

(e) Discussions with selected donors and the Resource Mobilization team to test the concept and to inform the design. These consultations suggested potential emerging interest in the fund. The Secretariat will conduct more formal donor consultations following Board approval.
(f) Consultations with 4 major manufacturers (Sure Chill, Vestfrost, Dometic, and Haier) to understand their ability to deliver the performance requirements and scale their production to meet expected demand. The emerging fund design was also tested with manufacturers.
(g) Regular engagement with the Gavi Alliance Supply Chain Steering Committee, Task Force and CCE priority working group structures to solicit input and to test the emerging design recommendations.
(h) Engagement with the Alliance's Strategic Goal 2 Management Team to inform the design considerations. The Data for Management and People and Practices Working Groups were also consulted to link the CCE fund with the broader set of supply chain priorities.

Taken together, the recommendations presented in this paper are generated on the basis of input from all of these relevant stakeholder groups.

G1.2 Principles guiding platform design recommendations to PPC
Six principles were chosen to help guide design choices for the platform.

(a) **Country-driven,** addressing gaps and solutions identified by the country governments, in line with governments' own plans
(b) **Sustainable**, generating outcomes that surpass the life of the Fund and by ensuring that countries can sustain financial and technical requirements beyond Gavi's support
(c) **Equitable and scaled**, offering wide access to Gavi-eligible and graduating countries, while also being responsive to each country's unique needs
(d) **Catalytic and integrated**, complementing and amplifying current Alliance members' activities
(e) **Simple in accessibility and operations**, minimizing transaction costs for countries and donors
(f) **Transparent and evidence-based,** adhering to high standards of openness and objectivity in its rules and operations