

Equity approach to cold chain deployment Application in Pakistan





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Background

Access to potent vaccines is a challenge for nearly 20 million under-immunized children around the world.¹ Improving immunization coverage and equity requires a comprehensive approach that addresses many supply- and demand-side challenges, which contribute

to persisting inequities. A crucial aspect of this is ensuring that potent vaccines are available when and where individuals need them. To maintain their potency, vaccines must be kept at specified cold temperatures from manufacture to point of administration, which requires establishing an end-to-end cold chain.

Functioning cold chain equipment (CCE) for vaccine storage is an essential component of an end-to-end cold chain. Low CCE

In this constrained resource environment, countries must make important decisions about where to deploy new equipment, with the aim being to prioritize investments that improve coverage and equity.

coverage and insufficient capacity may contribute to health facilities storing less vaccines than target population needs, which may lead to inequities in immunization access and ultimately coverage. In 2014, it was estimated that 90 per cent of health facilities in several countries eligible for support from Gavi, The Vaccine Alliance (Gavi) were not equipped with adequate CCE.² As populations grow, persisting CCE shortages are only likely to worsen as countries introduce new vaccines and other products that require a cold chain. Sufficient CCE coverage has recently become an important issue as countries work towards introducing a new COVID-19 vaccine in 2021.

To improve vaccine availability and coverage, Gavi and other donors are investing significant resources in helping countries acquire adequate CCE. In 2015, Gavi approved the creation of the Cold Chain Equipment Optimisation Platform (CCEOP) to expand the availability of CCE to store vaccines. The platform was launched in January 2016 with a commitment of \$250 million over a five-year period.³ By the first week of December 2020, 50,000 vaccine refrigerators had been purchased with 35,000 successfully installed in health facilities of 43 countries across Africa and Asia. Even with these investments, the demand for CCE is estimated to be 20–40 per cent higher than originally forecast.⁴ In this constrained resource environment, countries must make important decisions about where to deploy new equipment and appropriately link CCE deployment with other supply chain functions, such as distribution and network, for investments to contribute to improving coverage and equity. For example, countries must decide where to replace or repair existing equipment as well as expand and extend equipment to new areas (see the example Gavi CCEOP operational deployment plan in the <u>resources</u> section).

¹ World Health Organization (WHO) and United Nations Children's Fund (UNICEF), National immunization coverage estimates, 2018 revision; United Nations, Department of Economic and Social Affairs, Population Division. World Population Prospects 2019. <u>https://population.un.org/wpp/Publications</u>

² Gavi, the Vaccine Alliance, Cold Chain Equipment Optimisation Platform, Gavi, December 2020. https://www.gavi.org/sites/default/ files/publications/Cold-chain-equipment-technology-guide.pdf

³ Gavi, the Vaccine Alliance. 'Report to the Board: Review Of Cold Chain Equipment Optimisation Platform'. June 2017. <u>https://www.gavi.org/sites/default/files/board/minutes/2018/14-june/02f%20-%20Consent%20agenda%20-%20Review%20of%20Cold%20</u> Chain%20Equipment%20Optimisation%20Platform.pdf

⁴ Ibid.

As part of its support to the Government of Pakistan in 2017–2018, the United Nations Children's Fund (UNICEF) collaborated with VillageReach to conduct an analysis of the country's immunization supply chain design. At the time, Pakistan was one of the first countries receiving CCE through the CCEOP, and in the first year of deployment. Although the analysis could not inform the first year of deployment (which was designed to meet urgent needs), its equity lens was leveraged to prioritize cold chain deployment in subsequent years. This document describes the equity approach developed during the supply chain re-design process in Pakistan. It informs, as an example, the identification of areas with both insufficient cold chain storage and low immunization coverage and recommends these as highest priority areas to receive CCE. As new threats, such as COVID-19, emerge and new vaccines are developed, analysing CCE needs using an equity lens will be crucial in helping to provide the most people possible with live-saving health products. Detailed steps of the process used in Pakistan are included in <u>appendix 1</u> for other countries to follow.

Approach

A three-part process was developed to identify priority areas for CCE deployment and thus reduce inequities in immunization coverage. This approach involves analysing the relationship between available cold chain storage capacity, the required cold chain capacity to immunize target populations and current programme performance (such as coverage and equity).

The three-step approach taken was to:

- 1.
- **Determine the cold chain storage volume required to fully immunize the target individual.**⁵ Using the country's Expanded Programme on Immunization (EPI) schedule, vaccine presentation, delivery frequency and wastage rates to determine the cold chain storage volume needed to fully immunize each target individual.
- 2.

Determine the available cold chain storage volume per target individual The available cold chain volume per target individual calculated based on the actual population.

3.

Compare required and available cold chain storage with immunization coverage to guide cold chain deployment.

Sufficient CCE is most essential at health facilities where services are delivered. This approach should therefore ideally be applied at the health facility level. Health facilities with a combination of (1) cold chain coverage/capacity below what was required and (2) low immunization coverage should be identified using this approach. These facilities should then be prioritized for CCE deployment. The following illustrates the application of this approach in Pakistan for analysis at the district level.

For this approach, the Effective Vaccine Management (EVM) Assistant Tool v2.0⁶ (October 2018) was used.

⁵ The "target individual" was adapted from the terminology of "fully immunized child" to include vaccines not specific to children, e.g. tetanus, HPV, COVID-19. This can be scaled for target populations as well.

⁶ Please note that this is different from the EVM Assessment Tool.

Other documents consulted include:

- 1. the EPI schedule for routine immunizations and campaigns
- 2. the buffer stock policy
- **3.** the resupply frequency
- 4. the most recent cold chain inventory
- 5. immunization coverage data

Pakistan: application of the equity approach

An equity approach was used in the system design analysis carried out in Pakistan to recommend CCE deployment for districts with insufficient CCE and low coverage. Since countries do not often make significant investments in CCE (Pakistan included), this approach anticipated growing CCE capacity needs over the next few years to accommodate planned new vaccine introductions and increasing populations and ultimately ensure vaccine availability.

Given the often-limited availability of and access to subnational data, this approach was extremely helpful in assessing the 156 districts in Pakistan receiving \$50 million worth of CCE over five years. However, this level of analysis may still hide inequities that exist within districts regarding the distribution of CCE across health facilities. Others looking to use this approach could apply it to different administrative levels, ideally using the health facility as the unit of analysis. Other factors that were not assessed as part of this exercise are also important to consider when making deployment decisions, such as the distribution network, the frequency of vaccine distribution, the reach and state of CCE management/maintenance and site readiness for new equipment.

Part 1: Determine the cold chain storage volume required to fully immunize a target individual

In this first part, the cold chain storage volume required to store the vaccines needed to fully immunize a target individual was determined using the **EVM Assistant Tool** v2.0 and Pakistan's EPI schedule.⁷



Vaccines over an individual's life course, starting with those required to fully immunize a child in their first year of life, and then beyond their first year (including the second dose of measles and tetanus vaccines), were considered, as well as Pakistan's resupply frequency and buffer stock policy. Vaccines that were not yet part of Pakistan's EPI schedule but expected to be introduced in the next three years (such as human papillomavirus (HPV) and typhoid vaccines) were also considered.

7 The EVM Assistant Tool is a Microsoft Excel tool used to assist in EVM Assessments.

Since countries do not often make significant investments in CCE (Pakistan included), this approach anticipated growing CCE capacity needs over the next few years to accommodate planned new vaccine introductions and increasing populations in order to ensure vaccine availability.

Required polio vaccines for monthly campaigns were considered but not one-off outbreak or response campaigns on the assumption that buffer cold chain capacity would accommodate these.

For Pakistan, the calculated **cold chain volume needed to fully immunize a target individual was 0.06 litres**. See <u>appendix 1</u> for the detailed step-by-step description of how the EVM Assistant Tool was used to calculate the cold chain volume needed for districts in Pakistan.

Part 2: Determine the available cold chain storage volume per target individual

Next, the available cold chain storage volume required to fully immunize each target individual was determined at the district level.

In this analysis, the cold chain storage volume was calculated per surviving infant or the number of children that reach their first birthday in a given year. Although 'surviving infant' does not fully capture the target population for all vaccines (as the term also includes children older than 1 year, adolescents and pregnant women for some vaccines), most of the vaccines target surviving infants making this readily available figure a good proxy. As new vaccines and health products requiring cold chain storage are introduced, the approach should be adapted to include different target populations.

The analysis carried out in Pakistan was at the district level, so the following steps were calculated for districts. See <u>appendix 2</u> for calculations.

1. Determine current cold chain storage.

2.

Determine the number of surviving infants in districts.

3.

Determine the volume of cold chain per surviving infant for each district.

Part 3: Compare required and available cold chain storage with immunization coverage to guide cold chain deployment

The last part compared the required volume of cold chain storage for a fully immunized individual (part 1), available cold chain storage for each surviving infant (part 2), and immunization coverage. If the amount of cold chain storage available was less than the target, and there was not sufficient storage, it was assumed that the facility would not be able to keep enough vaccines potent and would experience stockouts. It was recommended that health facilities or districts with low immunization coverage and insufficient cold chain storage receive CCE.

The results from the analysis in Pakistan were presented to the national and provincial EPI representatives. A subset of the anonymized results is provided in Figure 1 and shows the cold chain volume per surviving infant and immunization coverage, as measured by third dose of diphtheria-tetanus-pertussis (DTP3). There are several districts with a cold chain close to or below the target for Pakistan. Based on the analysis, it was recommended that subsequent cold chain deployment should be prioritized in districts with both low cold chain coverage and low immunization coverage. For Pakistan this meant that, from an equity lens, districts A, B and D should be prioritized.

Figure 1. Results for cold chain and immunization coverage from select districts in Pakistan

| District | Cold chain / surviving infant (litres) | DTP3 cover- age (%) | Urban-rural gap | in DTP3 coverage | (%) |
|----------|--|------------------------|-----------------|------------------|-----|
| Α | 0.04 | 24 | - | - | 24 |
| В | 0.06 | 30 | 25 | - | 30 |
| С | 0.07 | 100 | 100 | - | 100 |
| D | 0.07 | 49 | 65 | - | 49 |
| E | 0.08 | 92 | 87 | - | 93 |
| F | 0.12 | 96 | 93 | - | 96 |
| G | 0.12 | 95 | 100 | - | 94 |
| Н | 0.47 | 100 | 100 | - | 100 |
| 1 | 0.58 | 98 | 95 | - | 99 |

Red – Indicator is below the target

Yellow – Indicator is at or near the target Green – Indicator is above the target

The relationship between cold chain coverage and immunization coverage from the overall analysis for Pakistan varied based on the province. Several districts had low immunization rates despite

Increasing the volume of cold chain storage in areas with insufficient CCE capacity helps ensure that sufficient vaccines can be stored and kept potent to reach individuals, thereby helping to improve immunization coverage. adequate cold chain coverage, which was an expected result as several factors impact immunization rates, such as demand and service delivery. No district with inadequate cold chain coverage had high immunization rates, as the cold chain is necessary to ensuring that vaccines are available and potent for service delivery.

Increasing the volume of cold chain storage in areas with insufficient CCE capacity helps ensure that sufficient vaccines can be stored and kept potent to reach individuals, thereby helping to improve immunization coverage. Changing resupply frequencies could also help improve vaccine availability, depending on road infrastructure, transport availability and the impact on service delivery. When planning CCE deployment, decision makers should consider these factors alongside others such as site readiness, appropriate type of CCE and overall CCE maintenance capacity.

Stakeholders can use this approach to guide decision-making and advocacy in several ways:

- Provinces or districts can use this information to advocate among higher levels of government or donors for additional CCE capacity at specific health facilities, especially those with low immunization coverage.
- 2.

2.

1.

Governments can use this information to prioritize specific health facilities or districts and to adjust CCE capacity in future deployments.

 When new CCE deployment is not planned, governments can evaluate alternate measures that can be taken to optimize available CCE. For example, resupply frequencies could be increased or decreased to ensure that the vaccines received are not beyond the available storage volume and that there is adequate vaccine supply for each level of the health system.

Resources

Available resources include:

How to calculate vaccine volumes and cold chain capacity requirements

- Gavi CCEOP guidelines and templates
- **EVM Assistant Tool**

Acknowledgements

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Appendix 1. Calculate the cold chain storage volume required to fully immunize a target individual

This section details the approach used to calculate litres of cold chain storage needed to fully immunize a target individual according to Pakistan's existing and proposed EPI schedule, using the EVM Assistant Tool v2.0. Since the EVM Assistant Tool uses the term 'fully immunized child' (FIC),⁸ it is used at times in this calculation, though it should be noted that the calculation also includes all vaccines over an individual's life course as per Pakistan's EPI schedule.

Step 1: Open and prepare the EVM Assistant Tool.

Click on the 'Cover' worksheet tab and enter the country name (in this case Pakistan – see Figure 2).

Figure 2. Entering the country name, language choice and date on the 'Cover' worksheet tab



Step 2: Click on the 'Vaccine_select' worksheet tab and clear the default entries in the first row.

- a. Select the relevant vaccine database filter (average, minimum or maximum) [cell E4]. Given that vaccine presentations' packed volumes can vary depending on the manufacturer, the drop-down list in cell E4 was used to select the average packed volumes from the 'Vaccine_database' worksheet tab for use as the default figures in column F (as opposed to minimum or maximum) (see Figure 3). These were then replaced with autopopulated values by entering the actual country volume figures for Pakistan into columns D and E.
- b. **Select 'FIC' or 'fully immunized child'** as the type of recipient group to be used to estimate vaccine demand [cell E7] (see Figure 3).

⁸ An FIC is a child that has survived to their first birthday and received all recommended vaccine doses in that time.

Figure 3. Choosing the vaccine filter and selecting 'FIC' as the recipient group in the 'Vaccine_select' worksheet tab

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Step 3: Enter all the vaccines in the country's current and anticipated immunization schedule [column B] and specify the vaccine presentations [column C].

Pakistan was used for each vaccine using the pre-filled drop-down lists. Vaccines not included in the drop-down list (such as typhoid), were entered manually (see Figure 4), as were vaccines that were not yet part of Pakistan's immunization schedule (for example, HPV vaccines) to understand the effect that adding these may have on required cold chain storage volume. Considering new vaccines helped anticipate future CCE needs.

In this step, bivalent oral poliovirus vaccine types 1 and 3 (bOPV1+3) were included twice: once for routine immunization and a second time to account for regular polio campaigns.

Figure 4. Entering all vaccines in the current immunization schedule and specifying presentations



Step 4: Enter country-specific volume and wastage rates.

Once columns B and C were completed, columns F, G, J and K populated automatically. Where available, Pakistan-specific volume and wastage rates were used, which were entered into columns D, E and I (as specified in points (a) and (b) of this step) to override the default figures (see Figure 5).

- a. Average, minimum, or maximum packed volume for each vaccine and any diluent [columns F and G] automatically populate from the Vaccine_database tab in the EVM Assistant Tool, according to what we selected in step 2(a). We were able to override these auto-populated values by entering actual country volume figures into columns D and E.
- b. Standard wastage rates and wastage factors from the database automatically populate [columns J and K]. These auto-populated values were replaced by entering available Pakistan-specific vaccine wastage rates into column I.

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| Versine | Presentation | Nationa | el figures | Average par Extracted fro | ked volume on data base | National | figures | WHO/GAVI | Wastage factor | Current | New schedule | Primary sto parame | re supply eters |
| | | | | | Diluent volume | Storage temperatures of typ. | Enter wastage | | Wastage | Enter doses per | Enter doses per | Mari supply | |
| Choose from list | Choose from list | (om/(kise) | (cm/)(kse) | (cm//dose) | (om/dese) | vaccines | nate (%) | westage | factor | recipient | recipient | Interval (months) | (more |
| NON | 20 | | | | 1.5 | | 20 | 20 | 1.05 | 40 | | 10 | 10 |
| Meaning | 40 | | | 24 | 3.0 | | 20 | 40 | 4.25 | 20 | | 10 | 10 |
| DTP HepB Hib | 1 | | | 17.2 | | | 5 | 5 | 1.05 | 30 | | 10 | 10 |
| PCV-10 | 2 | 17.1 | | 4.8 | | | 10 | 15 | 1.11 | 30 | | 10 | 1.0 |
| PV | 10 | | | 25 | | | 20 | 40 | 1.25 | 1.0 | | 10 | 1.0 |
| Rota ing | 1 | | | 51.2 | | | 5 | 5 | 1.05 | 2.0 | | 10 | 1. |
| π | 20 | | | 21 | | | 20 | 25 | 1.25 | 2.0 | | 10 | 1.0 |
| bOPV | 20 | | | 0.8 | | | 20 | 25 | 1.25 | 40.8 | | 10 | 1.0 |
| Typhoid | 5 | 15.0 | | #DIVIOI | #DIVIOI | 1 | 5 | INA. | 1.05 | 3.0 | | 10 | 1.0 |
| HPV | 1 | 29 | | 12.1 | | | 15 | 5 | 1.18 | 10 | | 10 | 10 |
| | - | | | | | | | | | | | | |

Figure 5. Entering country-specific volume and wastage rates

Step 5: Enter the total number of doses per individual for each vaccine [column O] according to the national EPI schedule (see Figure 6).

Doses that would be administered through both routine immunization and regular campaigns were considered in this step.

For example, in Figure 6, four routine doses of bOPV1+3 and 46.8 campaign doses of bOPV1+3 per child were included. Based on Pakistan's vaccine shipment history, the country shipped 11.7 doses of polio vaccines for regular campaigns for every dose of routine polio vaccine, as there are almost monthly polio campaigns. As there are four doses of bOPV in the routine schedule, it was estimated that 11.7 x 4 doses of polio vaccine (bOPV1+3), or 46.8 doses, would be needed per FIC for campaigns.

Figure 6. Entering the total number of doses per individual for each vaccine



Step 6: Enter the maximum supply interval and the safety stock amount for each vaccine [Columns r and s, respectively].

The maximum resupply interval and safety (or buffer) stock in months was entered for districts, which was the level of the analysis in Pakistan. Since districts are supplied monthly and frequency does not vary by vaccine, '1' was entered as the unit for all vaccines. Safety stock refers to the level of buffer stock (in months) that needs to be stored at the level being analysed. For Pakistan, one month for each vaccine was entered into column s (see Figure 7).

The maximum stock volume for each vaccine was then automatically generated [column U] after the maximum supply intervals and months of safety stock were entered

| | STEP | STE | P 3 | Default | figures | STEP 6 | STEP 7 | STE | P 8 | Veccines | | Diluen |
|-----------------|------------------|---|---------------|------------|-------------------|---------------------|-----------------|----------------------------------|----------------------------|-------------------------|------|---|
| Vaccine | Presentation | National | figures | WHO/GAVI | Wartage factor | Current schedule | New schedule | Primary sta param | re supply eters | Volume Max ((cm3) | tock | Volume Mar (cm3) |
| Occus from list | Choose from list | Storage temperatures of lys. vaccines | Enter wustage | Indicative | Wastage | Enter doses per | Enter doses per | Maxi supply interval imported | Safety stock Investigal | Current schedule New | - | Correct a |
| CG | * 20 | | 50 | 50 | 2.00 | 1.0 | | 1.0 | 1.0 | 0.4 | | 0.4 |
| OPV | 20 | | 20 | 25 | 1.25 | 40 | | 1.0 | 1.0 | 0.7 | | |
| Neasles | 10 | | 20 | 40 | 1.25 | 2.0 | | 1.0 | 10 | 0.9 | | 1.3 |
| TP-Hep8-Hib | 1 | | 5 | 5 | 1.05 | 3.0 | | 1.0 | 1.0 | 9.0 | | 1. State 1. |
| CV-10 | 2 | | 10 | 15 | 1.11 | 3.0 | | 1.0 | 1.0 | 9.5 | | |
| N. | 10 | | 20 | -40 | 1.25 | 1.0 | | 1.0 | 1.0 | 0.5 | | 1 |
| pil_stoi | 1 | | 5 | 5 | 1.05 | 20 | | 1.0 | 1.0 | 18.0 | | |
| Т | 20 | | 20 | 25 | 1.25 | 2.0 | | 1.0 | 1.0 | 0.9 | | |
| OPV | 20 | | 20 | 25 | 1.25 | 46.8 | | 1.0 | 1.0 | 8.1 | | |
| phoid | 5 | | 5 | #NA | 1.05 | 3.0 | | 1.0 | 1.0 | 7.9 | | |
| PV | 1 | | 15 | 5 | 1.18 | 1.0 | 1 | 1.0 | 1.0 | 0.6 | | |
| | | | | | | | | | | | _ | |
| | | | | | | | | | | | | |

Figure 7. Entering the maximum supply interval and safety stock amount

Step 7: Add the maximum volumes required to store vaccines and diluents per fully immunized individual [Cells U37 and X45].

The volume in cell U37 is the aggregated maximum cold chain capacity that might be needed for vaccines at any given time at the district level of the supply chain (based on the maximum resupply and safety stock entered in columns r and s). Cell X45 is the maximum storage volume that might be needed at any given time for diluents. These two values were added to determine the maximum storage volume needed at any given time for both vaccines and diluents (see Figure 8).

Figure 8. Adding the maximum volumes required to store vaccines and diluents per FIC in cells U37 and X45



Step 8: Convert cubic centimetres to litres, as cold chain volume is often assessed in litres to establish a target for cold chain storage volume per FIC.

To determine the cold storage volume in litres, the cubic centimetres volume was divided by 1,000. The cold chain target will be different for every country depending on the immunization schedule, vaccine volumes, buffer and cycle stock policies, wastage rates and the level of analysis, all of which are used as inputs in this approach. In the case of Pakistan, the cold chain volume target needed per FIC for districts was $56.5 + 1.7 = 58.2 \text{ cm}^3/1,000$, or **0.06 litres**.



Appendix 2. Calculate the available cold chain storage volume per target individual

The analysis carried out in Pakistan was at the district level, so the steps described were calculated for districts.

Step 1: Determine current cold chain storage.

The most recent cold chain inventory was reviewed to determine the available cold chain storage capacity for each district.

Step 2: Determine the number of surviving infants in districts.

In Pakistan's national planning documents, the number of live births is estimated to be equal to 3.5 per cent of district population, with 92.6 per cent of live births estimated to survive to the first year (surviving infants).

| Number of surviving infants in a district in Pakistan = 92.6% x (3.5% | % x district population) |
|---|--------------------------|
| | |
| % surviving infant | ts live births |

Step 3: Determine the volume of cold chain per surviving infant for each district.

To determine the cold chain volume per surviving infant, the results from steps 1 and 2 were used in the following formula:

Litres of cold chain per surviving infant = (aggregate cold chain volume in district)
/ (number of surviving infants)