

COLD CHAIN SOLUTIONS FOR VACCINE TRANSPORT: PLANNING AND IMPLEMENTING SOLUTIONS TO ADDRESS FREEZING IN TRANSPORT

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Objectives and Audience



Objective:

- 1) Share country guidance on how to plan and implement appropriate freeze-preventive transport solutions

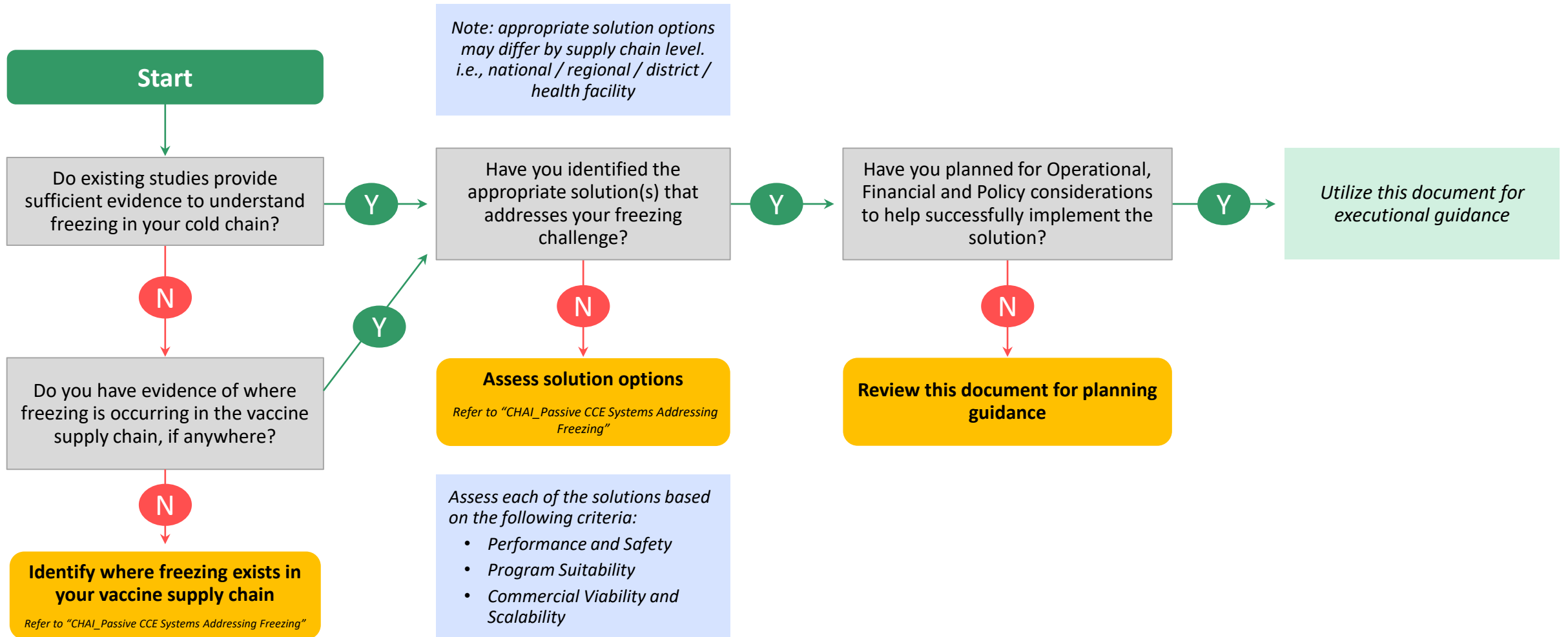


Audience:

- Expanded Programme on Immunization (EPI) decision-makers
- Personnel involved with:
 - Country immunization strategy development
 - Cold chain equipment selection, procurement and deployment
 - Development partners organizations supporting immunization supply chain programs

Note: This document focuses on transport of freeze-sensitive routine immunization vaccines, and does not aim to address transport of non-freeze-sensitive vaccines (such as some of the new COVID-19 vaccines)

Implementation Process Overview



- 1. Executive Summary**
2. Planning for Implementation
3. Executing Implementation

Executive Summary: Overview of Current State



Problem Statement

Vaccine transport systems using fully-frozen ice packs without freeze-preventative devices are demonstrated to expose ~20% of vaccines to freezing¹.

- Exposure to freezing temperatures during transport can cause vaccines to be less effective.
- Such exposure is often due to non-compliance in pre-conditioning frozen ice packs prior to packing cold boxes and vaccine carriers.



Solution Evaluation

To address freezing, this document proposes EPI implement one of two solutions per system²:

- Freeze-preventative carriers and cold boxes + fully-frozen ice packs
- Conventional carriers and cold boxes + cool water packs



Plan and Implement

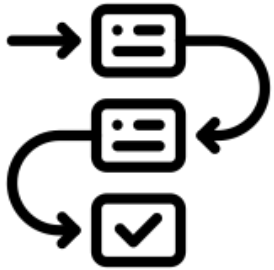
Once a solution is chosen, this document offers guidance for:

- 1) Planning for implementation
- 2) Executing implementation

1) Hanson et al. Is freezing in the vaccine cold chain an ongoing issue? A literature review. *Vaccine*. 2017 Apr 19.

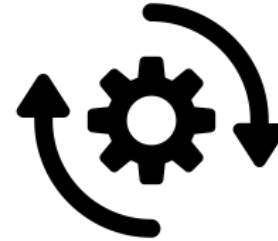
2) "System" is defined as an operational zone within which one of the recommended solutions can be fully executed, i.e., mixing solutions is not desired

Executive Summary: Overview of Document Approach



Plan for implementation

- Evaluate key solution implementation considerations: operational, financial, current equipment status, and policy planning
- **For FP devices + fully-frozen ice packs:** purchase appropriate freeze-preventative devices, train HCWs, remove conventional devices from the field, ensure attendant freezer-maintenance plan is in place
- **For conventional devices + CWPs:** transition to cool water packs, train HCWs, ensure plans are in place to monitor heat excursions, ensure attendant non-vaccine refrigerator purchase and maintenance plan is in place
- Understand responsibilities of key stakeholders involved in the implementation planning and utilize a process that aligns with these responsibilities

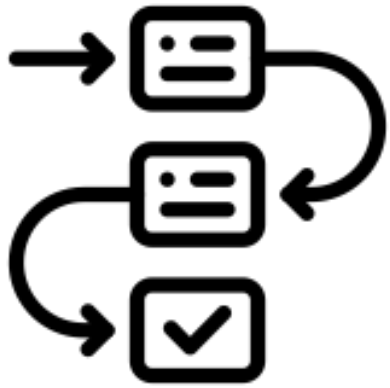


Execute implementation

- Provide useful resources and guidance for monitoring and evaluation post implementation
- Outline the responsibilities of key stakeholders involved in the implementation
- Demonstrate how to monitor and evaluate the effectiveness of the solution; in particular, systems utilizing cool water packs in conventional carriers require follow-up to ensure packs are not too cold or too warm, and associated vaccine temperature excursions are not occurring

For guidance on problem statement, device solutions, and selection, please refer to
See “CHAI_Passive CCE Systems Addressing Freezing” for details

1. Executive Summary
- 2. Planning for Implementation**
3. Executing Implementation



What will this section cover?

- Describe key solution implementation considerations: operational, financial, and policy planning
- Focus on considerations for the programmatic adoption of Freeze-preventive devices OR transition to Cool Water Pack policy
- Outline the responsibilities of key stakeholders involved in the implementation planning

Operational, financial and policy planning are key components for successful solution implementation

Critical considerations for solution implementation

A. OPERATIONAL PLANNING

1. **Procurement planning:** Identify procurement needs, quantities and constraints
2. **Deployment planning:** Identify team leads, roles and responsibilities, and timelines
3. **Change management planning:** Training and communication for implementation aligned across operational, financial, and policy timelines

B. FINANCIAL/RESOURCE PLANNING

1. **Cost of solution implementation:** Identify cost drivers for solution execution
2. **Cost of sustaining solution:** Outline the current and future budget to allocate to freeze-preventive solutions considering capital expenditure (CAPEX) and operating expenditures (OPEX)

C. POLICY PLANNING

1. Understand if **policy change will be required** to accommodate new solution and **to what extent policy will need to be changed** to adopt freeze-preventive solutions
2. **Evaluate all protocols and SOPs that need to be adapted for new solution**

SOLUTION PHASING

If the immunization program is likely to face financial or operational constraints in implementing the solution at scale, **consider implementation in a phased manner for the three solution implementation components.**

(Refer to Slide 14 for phasing options and considerations)

Procurement and deployment planning are fundamental components of operational planning to mitigate delay or cost escalation risks

Procurement planning to understand products and quantities to procure

Key questions to be addressed

- What products or corresponding accessories need to be procured for preparation?
- How many units of the product are needed?
- How much funding is available for procurement?
- What is fixed storage capacity?

Key requirements to address the question

- **Visibility into passive cold chain inventory** across target facilities and needs for outreach service delivery, inter-facility transport
- Understanding of **procurement constraints** limiting the number of units to procured. This could include - *budget for solution, storage and distribution bottlenecks*.

Deployment planning to ensure clarity on roles and responsibilities as well as coordination for timely distribution

- Which facilities will require deployment of solution?
- Who will be conducting distribution/ deployment of solution?
- What is the timeline for implementation of solution?

- **Clarity on roles and responsibilities** in the deployment process
- **A project distribution plan** in place with visibility and coordination to ensure stakeholders understand when a facility is receiving the solution, who will be distributing, and how to use it.

Seek potential tools to leverage, such as CCI for procurement planning and ODP for deployment planning

A practical change management plan is an important component of operational planning to equip stakeholders to effectively implement the solution

Change management planning to ensure readiness among stakeholders to implement solution

Key questions to be addressed

- What are the messages to be communicated to staff and what are the materials to be prepared?
- Who are the main stakeholders to be informed about the new SOPs and processes?
- Which channels of communication are most appropriate to ensure effective communication?



Communication

- Easily digestible messages for effective change management
- Structure for continuing knowledge sharing



Training

- Structure of learning sessions
- Schedule and frequency of training
- Location and required attendees



Materials

- Content for user-friendly learning materials
- Short and concise instructions for continuous use
- Multiple languages

Note: there is potential for training issues if choosing to have two different sets of solutions in a country. Risks of confusion in this case would be high and would require attention to training and communication programs

When determining how to estimate the costs of the new solution, account for all the different types of costs i.e., CAPEX and OPEX in order to conduct full financial and resource planning

Cost of solution implementation



CAPEX



1. Cost of solution (per unit) & number of units
2. Cost of procurement and shipping (include procurement agent fees if applicable)
3. Cost of in-country distribution and logistics
4. Cost of accessory items required (e.g., new CCE for CWP)

Cost of sustaining solution



OPEX



1. Ongoing training costs
2. Maintenance costs (↑Actives; ↓Passives)
3. Cost of phasing out of old units
4. Miscellaneous costs

- Align the procurement timeline to budget availability
- Anticipate ongoing operational costs and payment schedules
- Leverage existing tools available, such as the CCEOP budget template for CAPEX for shipping inclusion, the UNICEF fee and 'installation' costs (i.e., in-country logistics and distribution)

Understand whether transition towards a new solution requires an enabling policy change

Identify current policy on cold chain transport and whether a change is needed to enable implementation of freeze-preventive solution

Policy may need to change to adopt new solutions. Consider three key questions for this logistical component:

- What is current policy on freeze-preventive or CWP solutions?
- When and how does policy need to change?
- To what extent does policy need to be changed to adopt new freeze-preventive solutions?

Considerations:

- Current policy likely does not include new freeze-protected solution
- No strong policy changes likely needed, just updates to guidance to procure WHO pre-qualified
- Policy change cycles in some countries can be long; countries are encouraged to explore other mechanisms of adopting solutions (NLWG, ICC, etc) while waiting for upcoming revisions to national policy

If policy change is needed, understand key factors required to implement change

- Who needs to be engaged and informed on the need to change policy?
- What information/materials would be needed to enable them to approve the decision?
- What would the next steps after policy change be?

Considerations:

- Ensure alignment to global best practices
- Update SOPs to match new solutions in lieu of policy changes (no longer a need to pre-condition frozen ice packs)

Focus the procurement on adopting the most appropriate phasing strategy

Financial and operational constraints may require consideration of a phased implementation¹ approach. The following are various options to consider:

Phasing approach	Description	When is the approach suitable?	Pros	Cons
BY SUPPLY CHAIN LEVEL*	Targeting solution to solve freezing in most impacted tier of the supply chain	<ul style="list-style-type: none"> ✓ Temperature studies demonstrate disproportionate levels of freeze excursions in a specific tier of the supply chain² 	<ul style="list-style-type: none"> ✓ Easy to identify which facilities and stakeholders are to be involved in implementation ✓ Relatively quick to implement and observe impact on higher SC levels due to ease of training and monitoring small number of staff 	<ul style="list-style-type: none"> ✗ Complex if focusing on lower levels of supply chain given scale and diversity across country.
BY REGION/AREA*	Targeting solution in certain provinces or districts prior to national level scale-up	<ul style="list-style-type: none"> ✓ Temperature studies demonstrate disproportionate freeze excursions in specific regions² ✓ Interest expressed by sub-national administrations to pilot the solution 	<ul style="list-style-type: none"> ✓ Gradual scale up enables learning from early piloting in focal provinces/districts. ✓ Clarity of ownership and responsibility at sub-national level to manage transition and monitor implementation performance 	<ul style="list-style-type: none"> ✗ Variability across regions may discourage scale-up and uptake in other regions as it may be perceived as not generating lessons. ✗ A phased-switch approach could take much longer to implement and could end up being cost-prohibitive (i.e. multiple rounds of deployment)
BY NEED	Target solution when there is need to replace current solutions, or when there is need for additional capacity, such as with campaigns	<ul style="list-style-type: none"> ✓ Suitable only if we can avoid stakeholders using multiple solutions in parallel due to potential confusion. ✓ Hence if there is a need for entire region/supply chain tier) 	<ul style="list-style-type: none"> ✓ Cost conservative approach to only buy new solutions upon the expiry of old equipment. 	<ul style="list-style-type: none"> ✗ Potential for confusion and misalignment of SOPs across health workers in different facilities

1) Note potential to combine supply chain and regional phasing approaches, e.g., focus on last mile in a region. This could be useful in large regions where individual supply chain tiers are already of considerable scale.

2) As there is existing evidence of a prevalent risk of freezing excursions, it may be reasonable to assume the issue should be addressed by moving to a recommended system rather than investing cost and time in individual studies.

CASE: There are specific solution implementation considerations for the adoption of Freeze-Preventive Devices (FP-VC and FP-CB)

A. OPERATIONAL PLANNING

Procurement and deployment planning	<ol style="list-style-type: none"> 1. Plan a deployment strategy to introduce the solution <ul style="list-style-type: none"> • Switch and replace all of the existing devices OR • Gradually phase in the devices by region or SC level 2. Determine the quantity of devices to be procured <ul style="list-style-type: none"> • Appropriate number of units allocated per health facility (e.g., 2 FP-VCs each) 3. Develop distribution plan for delivery of the devices <ul style="list-style-type: none"> • Devices can either be directly delivered to each site • Health workers can pick up the devices during central training 4. Consider synchronizing the training and deployment timelines 	Change Management	<ol style="list-style-type: none"> 5. Transition requires healthcare workers to adapt and adhere to a new operating practices including: <ul style="list-style-type: none"> • New passive device loading and unloading process • Shifting from pre-conditioning of frozen ice packs to placing frozen ice packs directly into freeze-preventive devices
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B. FINANCIAL/RESOURCE PLANNING

CAPEX Implementation costs	<ol style="list-style-type: none"> 1. Unit cost for estimated device quantities <ul style="list-style-type: none"> • Freeze-preventive devices are typically 2-3 times the cost of non-freeze protective passives • CWP-based systems may require purchase of dedicated non-vaccine refrigerators 2. Deployment costs to deliver devices to end-users <ul style="list-style-type: none"> • Freight forwarding and customs clearance • Warehousing and distribution costs • Additional last mile transportation costs 	OPEX Maintenance costs	<ol style="list-style-type: none"> 3. Maintenance cost <ul style="list-style-type: none"> • Freeze-preventive devices require minimal maintenance, though freezers may need additional monitoring and maintenance • CWP-based systems require dedicated refrigerators to be monitored and maintained 4. Personnel training costs [centralized or decentralized] 5. Miscellaneous costs <ul style="list-style-type: none"> • May include the need to purchase a larger fleet of devices if larger vaccine storage capacity is required • Reverse logistics costs to extract and recycle older
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C. POLICY PLANNING

Policy	<ol style="list-style-type: none"> 1. FP-VC/CBs would require different policies to that of other solutions, such as CWP. To avoid confusion, clear policy guidance documents will be necessary 2. When a new device is introduced, there may be transition phases during which EPI staff will need time to get used to new habits, SOPs and policy guidance
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CASE: There are specific solution implementation considerations for Cool Water Packs (CWP)

A. OPERATIONAL PLANNING

Procurement and deployment planning	<ol style="list-style-type: none">1. Inventory available CWP containers/ ice-packs to understand if they are sufficient for service delivery/outreach needs2. Determine if there are existing resources/equipment to designate for cooling of CWP¹	Change Management	<ol style="list-style-type: none">3. Involves a shift from pre-conditioning of frozen ice packs to placing cool water packs (eliminates the requirement for pre-conditioning)4. New protocols need to be developed and distributed to health workers5. Involves additional basic user maintenance activities for CWP refrigerators6. May involve the decommissioning of freezer units to avoid further generation of frozen ice-packs
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B. FINANCIAL/RESOURCE PLANNING




CAPEX Implementation costs	<ol style="list-style-type: none">1. Very little or no procurement cost required (for the water packs)<ul style="list-style-type: none">• Simply involves cooling water-packs instead of freezing them• Potential for added infrastructure cost if procuring a separate refrigerator for cooling the water packs2. Deployment costs to deploy refrigerator units<ul style="list-style-type: none">• Equipment service bundle costs (i.e., logistics, installation, commissioning , CCE training)	OPEX Maintenance costs	<ol style="list-style-type: none">3. Maintenance costs needed for separate CWP refrigerator<ul style="list-style-type: none">• Planned preventive maintenance, curative maintenance and spare parts4. Training costs should be relatively low<ul style="list-style-type: none">• However, there is a potential for confusion between CWP and pre-conditioning of frozen ice packs and may require ongoing training5. Other miscellaneous costs<ul style="list-style-type: none">• There may be a need for the replacement of damaged coolant packs
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C. POLICY PLANNING

Policy	<ol style="list-style-type: none">1. CWPs would require different policies to that of other solutions, such as FP-VC/CBs. To avoid confusion, clear policy guidance documents will be necessary2. When a new device is introduced, there may be transition phases during which EPI staff will need time to get used to new habits, SOPs and policy guidance
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Key stakeholders' roles and responsibilities to plan for solution implementation

The key stakeholders that should be engaged for Step 3 to plan for solution implementation:

Stakeholder	Step 3 (Plan for solution implementation)
 <p>National / Sub-National EPI Managers and Development Partners</p>	<ol style="list-style-type: none"> 1. Conduct inventory need assessment & determine quantity of selected solution required for implementation from visibility into inventory of passive vaccine carriers 2. Develop deployment strategy to introduce the solution 3. Develop procurement and cost plans with a clear source of funding 4. Ensure clarity on roles and responsibilities as well as coordination for timely distribution to all levels 5. Develop new SOPs, policy documents, and change management guidance for the new solution options 6. Coordinate rollout and monitor implementation process to address any bottlenecks 7. Lead implementation planning with key stakeholders and engage lower levels on new solution implementation plans (training, communication etc.)
 <p>District EPI Managers</p>	<ol style="list-style-type: none"> 1. Direct coordination of health facility readiness to solution implementation 2. Collate service delivery level inventory and needs for passive vaccine carriers 3. Participate in preparatory and deployment plans
 <p>Health Workers</p>	<ol style="list-style-type: none"> 1. Participate in preparatory activity 2. Ensure readiness to solution implementation 3. Provide feedback on implementation plans to ensure all concerns are addressed and incorporated

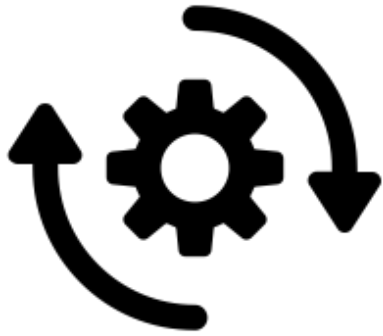
Note: Roles and responsibilities of stakeholders may vary based on country context and policies

Implementation Action Plan At a Glance

3A. Operational Deployment	3A. Change Management	3B. Budget Development	3C. Policy Alignment
Solution Planning			
<ul style="list-style-type: none"> Develop a costed operational plan which considers site selection and inventory, logistics for solution deployment and all other infrastructure requirements etc. 	<ul style="list-style-type: none"> Inform key stakeholders desired to drive solution introduction Assess appetite for adoption and gauge requirements needed for system re-design 	<ul style="list-style-type: none"> Estimate costing needs for the full spectrum of solutions Identify and secure a suitable funding line to implement the preferred solution 	<ul style="list-style-type: none"> Identify policies that currently support solution adoption If non are available, articulate the key policy changes required to enable solution adoption
Solution Development			
<ul style="list-style-type: none"> Work with key stakeholders to manage the end-to-end solution logistics, procurement and eventual deployment to site 	<ul style="list-style-type: none"> Work with EPI staff, health workers and partners to prepare an effective transition strategy (From status-quo to new solution) 	<ul style="list-style-type: none"> Balance budget with preferred solution costs, including full solution costs, with CAPEX and OPEX considerations 	<ul style="list-style-type: none"> Work with key stakeholders to incorporate the FP-solution framework into the national supply chain policy guidelines
Solution Execution			
<ul style="list-style-type: none"> Installation of devices or adoption of new practices Hands on training of Health staff, CCE logisticians and EPI managers 	<ul style="list-style-type: none"> Develop training packages and communication resources to help build HCW capacity and awareness Set up a monitoring and evaluation system to track implementation 	<ul style="list-style-type: none"> Outline long-term budget and payment structures to cover the full timeline of solution adoption 	<ul style="list-style-type: none"> Develop SOPs that describes how solution will be deployed Outline JDs and TORs with clear roles and responsibilities for all staff involved with roll-out



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What will this section cover?

- Demonstrate how to monitor and evaluate the effectiveness of the solution
- Provide useful resources and guidance for monitoring and evaluation post implementation
- Outline the responsibilities of key stakeholders involved in the implementation



Monitor and evaluate the progress of the implemented solution to establish if the intervention has been effective or if it requires improvements to ensure it achieves desired impact

Ongoing Evaluation of Freeze-Preventive Transport Solutions

Some key parameters to evaluate

Monitor the timeliness, quality and cost of the solution deployment to reflect implementation progress (e.g.)

- Confirm number of FP-VC/CB deployed to site
- Document number of facilities using CWPs

Assess knowledge management across all staff involved with implementation (e.g.)

- Evaluate whether HCW training was adequate
- Obtain feedback from project management staff to assess implementation effectiveness

Track any adverse events or deviations that arise during field implementation of solutions

- Monitor and evaluate temperature performance during transport post-implementation.
- Set up reporting systems to detect, investigate and manage any potential product or process issues (e.g., broken FP-VCs or ice-packs)

What tools can be used for tracking?

- Baseline, end line and mid-line surveys to evaluate effectiveness of the solution
- Planning, scheduling tools (i.e., Gantt charts) and budget expense sheets
- Periodic passive cold chain inventory assessment updates

- HCW knowledge, attitude and practices questionnaires
- In-depth process interview guides
- Focus group discussions tools and forums

- Freeze-tag or other temperature monitoring device, and appropriate reporting forms
- An incidence log sheet to help identify implementation bottlenecks
- Decision making forums to escalate, and problem solve issues
- Lessons learned checklist to document areas for future improvement

Example of some related resources

- JSI CCEOP evaluation assessments
- Country-led Cold chain inventory analysis
- UNICEF-led PII and WHO-PMM

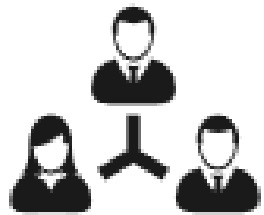
Post implementation surveys evaluating HCW and PMT experiences:

- Nigeria's FP-VC pilot
- Tanzania's transition to Cool Water Packs
- Kenya CCEOP vs World bank evaluation

- Project management review meetings
- CCEOP deviation and incidence reports
- UNICEF Quality assurance report portals

Key Stakeholders' Roles and Responsibilities for Execution of Solution Implementation

The key stakeholders that should be engaged for Step 4 to execute implementation:



**National / Sub-National /
Regional EPI Managers**

1. Secure feedback from users to understand solution performance
2. Monitor adherence to SOPs and take action to ensure sustained
3. Follow up and evaluate solution deployment implementation process
4. Document and report deviations during field implementation of solutions



District EPI Managers

1. Coordinate monitoring and adherence to SOPs at the service delivery
2. Provide supportive supervision during field implementation of solutions
3. Report deviations during field implementation of solutions



Health Workers

1. Attend scheduled training workshops to gain knowledge about the new solution
2. Provide user-experience feedback about the implemented solution to higher level

Potential Risks and Mitigations

Despite following the 4-phased approach for new solution choice and implementation, there are some potential risks regardless of which solution has been chosen:

Challenges

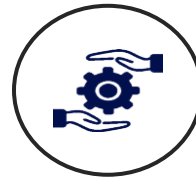
Mitigation Strategies

Coordination: Political environment does not enable implementation of new solutions, possibly hindering proper planning of the eventual introduction



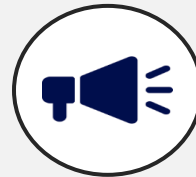
Ensure buy in from global and country stakeholders on the importance of freeze-protective transport strategies

Financing: Lack of sufficient funds to effectively implement and scale up the solution (limited resource allocation to set-up and sustain solution long-term)



Secure internal funds through ministry of finance processes, critical partners, and synergies with other programs and request support via mechanisms or other external funding partners

Communication: New solution introduction can lead to widespread confusion on protocols and proper vaccine transport



Coordinate an effective strategy to communicate changes to protocols, and continue to train health workers to ensure smooth adaptation to the new solution

Cold Chain level: Addressing freezing issues with a new solution may not fully eliminate freezing at all levels of the cold chain



Conduct regular temperature monitoring studies and monitor transport practices to continuously recognize freezing