

# Strengthening Cold Chain & Logistics (CCL) Systems

Report of Meeting on 1 November 2007, UNICEF House, New York

## Summary

Immunization partners (Gates, JSI, PATH, RotaADIP, PneumoADIP, UNICEF and WHO) met on 1 November 2007 to start a collaboration to strengthen national cold chain and logistics (CCL) systems. National Immunisation Programmes (NIPs) have an ongoing need for strong CCL systems. New vaccines will increase the demands on CCL systems. Developments in technology, global policies, national decisions on new vaccine introduction, and vaccine presentations will all impact on CCL systems.

The participants agreed on the need to work together and developed a consensus on vision, goals, and outcomes for strengthening CCL systems. The vision is to strengthen the capacity of NIPs so that every individual benefits from vaccines of assured quality; delivered in the right amount at the right time through efficient logistics, proper vaccine management, and a well-functioning cold chain system. The goals of the partnership are to develop: (1) a framework for CCL strengthening; (2) indicators to monitor progress; (3) methods and database to share information; (4) country prioritisation; (5) roles for each agency.

The outcomes are to build NIP capacity to (1) define policies and procedures; (2) implement and monitor; (3) inventory cold chain equipment; (4) manage vaccine stock. Consensus was also reached on an initial set of global indicators to monitor progress that covered: Vaccine Arrival Reports; EVSM status; national inventory; forecast accuracy; vaccine wastage; storage capacity; and emergency logistic plan. WHO and UNICEF will use existing data to develop a spreadsheet as the first step towards developing a database.

## Next Steps

- “CCL Taskforce” will continue to work together to strengthen CCL systems. Oz Mansoor will act as coordinator for the group. This taskforce is open to other partners joining, as appropriate.
- WHO and UNICEF to develop an interim database (in spreadsheet format) – initial focus to identify priority countries (with ROs/COs). To be completed by mid-December, for review by wider group.
- Input of the group into the WHO review/mapping of the various tools that can be used for CCL system management and strengthening. Aim to have this undertaken before GIM if possible.
- DCB to follow-up with Patrick Lydon on review of cMYP to look at costs required for CCL and available funding stream at global and country level.
- Plan for side-meeting during Global Immunization Meeting (GIM), 19-21 February 2008, Geneva and also start planning for presentation on CCL at GIM.

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## Background

Cold chain and logistics (CCL) systems are a fundamental cornerstone of all immunization programmes. CCL systems ensure that adequate amounts of vaccine can be procured, stored, and distributed for vaccination sessions in a manner that minimizes waste, avoids stockouts and maintains proper temperature control to prevent damage.

Global support for immunization, catalysed by the formation of the Global Alliance for Vaccines and Immunization (GAVI) in 1999, has been increasing over the years. But without a corresponding attention to strengthening CCL systems, the concentrated effort to accelerate new vaccine introduction will be threatened. Fortunately, their importance for new vaccine introduction has been recognised in the requirement that GAVI-supported countries undertake vaccine management assessments every 2-3 years.

The GAVI support for Hib and hepatitis B vaccines placed increased burdens on CCL systems and highlighted the critical need for effective vaccine management. The use of combination vaccines reduced the additional burdens from these vaccines, but this option may not be available for other new vaccines. The current packaging for pneumococcal and rotavirus vaccines means that, there will be at least a 3-fold increase in storage requirements for each vaccine. Other new vaccines, including a vaccine for pandemic influenza will create additional challenges.

Regular maintenance of existing equipment and replacement of outdated equipment pose additional burden on national programmes. The challenge is not only national vaccine storage but also the transportation and management of vaccines on subnational levels. The high cost of the new vaccines increases the need to reduce wastage without compromising levels of coverage. Improving vaccine management and developing innovative approaches to logistics would reduce the need for additional cold chain equipment. There is also the potential with the vaccine vial monitor (VVM) to go beyond the cold chain.

Developments in technology, global policies, national decisions on new vaccine introduction, and the presentations in vaccines will all impact on CCL systems. Therefore, it is important for partners to work together on strengthening national CCL systems. To help develop collaborative workplans for each agency, UNICEF hosted a meeting with partners on 1 November 2007.

### Meeting purpose

To strengthen CCL support by developing a global consensus between partners on:

- Global vision, goals, objectives/outcomes and challenges
- Activities and responsibility for these
- Indicators for monitoring status and progress
- Global database of indicators and other data
- Selection of priority countries for the initial work, for each partner

### Participants

B&M Gates Foundation: Vio Mitchell (Apologies: Steve Landry)  
JSI (IMMbasics): Michel Othepa (Apologies: Robert Steinglass)  
PATH/ RotaADIP: Sophie Newland / Robin Biellik (Apologies: John Lloyd)  
PneumoADIP: Angeline Nanni  
UNICEF: Ahmed Magan, Annika Salovaara, Basil Rodrigues, Gaby Mallapaty,  
Oz Mansoor (Apologies: Gregory Kiluva); Alan Court (opening remarks)  
WHO: Patrick Zuber, Solo Kone, Diana Chang-Blanc (Apologies: Michel Zaffran)

GAVI: (Rosamund Lewis & Raj Kumar) and CDC (Carla Lee) will remain involved in the project, but were not able to attend the meeting.

## Global Vision, Goals and Outcomes for CCL strengthening

Specific activities to strengthen cold chain and logistics systems need to be included under the umbrella of the Global Immunization Vision and Strategies (GIVS) and support the vision and goals for the year 2015.

There are five relevant strategies in GIVS covering all four strategic areas:

GIVS Strategy	GIVS Strategic Area	Relevant CCL Activities (abbreviated)
Strategy 6: Improve and strengthen vaccine-management systems	Protecting more people in a changing world	-Demand forecasting -Effective vaccine management -Increase access with "safe chain", incl. 'beyond the cold chain' -Coordinated finance/ management for transport and communications.
Strategy 9: Ensure effective and sustainable introduction of new vaccines and technologies	Introducing new vaccines and technologies	-Train health workers and managers -Prepare the logistics system
Strategy 18: Strengthen the management, analysis, interpretation, use and exchange of data at all levels	Integrating immunization, other health interventions and surveillance in the health systems context	-Better tools (e.g., computer software) for vaccine and logistics management to better support data entry, analysis, feedback, and utilization for programme management.
Strategy 23: Define and recognize the roles, responsibilities and accountability of partners	Immunizing in the context of global inter-dependence	-Define roles of immunization partners at global level to ensure both accountability and efficient coordination -Set global immunization goals jointly
Strategy 24: Include vaccines in global epidemic preparedness plans and measures		-Develop global and country-specific epidemic preparedness and prevention plans relevant to specific diseases.

### Vision

The capacity of National Immunization Programmes (NIPs) is strengthened so that every individual can benefit from vaccines of assured quality delivered in the right amount at the right time through efficient logistics, proper vaccine management, and a well-functioning cold chain system.

### Goals

Partners work together to develop (1) a framework for CCL strengthening; (2) indicators to monitor progress at global, national, and sub-national levels; (3) methods and database for sharing information; (4) list of priority countries for support; and (5) well-defined roles for each agency.

### Outcomes

National Immunization Programmes in all countries, starting with priority countries, are able to:

- Define CCL policies and procedures
- Implement and monitor policies and procedures with appropriately trained staff
- Establish, maintain, and monitor a functional and operational inventory of cold chain equipment
- Manage vaccine stock levels and distribution to fully support programme operations; minimize wastage; and prevent temperature damage

The CCL needs to cover (i) population/coverage growth to 2015 (ii) new vaccines (penta, pneumo, rota at a minimum) and (iii) pandemic influenza vaccine or other campaigns.

## Indicators for Global monitoring

Globally agreed upon CCL indicators will be the foundation of a small but comprehensive data set to monitor national CCL performance and provide:

1. Global level status of CCL and demonstrate the impact of our coordinated work in the area
2. National level monitoring of the country's CCL systems and operations

Global indicators would be a subset of those used at national level, with all data kept in global and national databases, respectively. Ideally, the global data would be uploaded routinely from a national database, supplemented by information from other sources such as the WHO-UNICEF Joint Reporting Form (JRF), special surveys/reports (eg, EVSM) and routine data from UNICEF Supply Division (SD).

### Principles of a proposed Global CCL Database

The development and implementation of a global database is likely to be quite challenging. At this stage, the following principles were agreed:

- Internet-based platform with data publicly viewable; potential to also have restricted data
- Single overall manager, but all partners (including national EPI) can enter data - password-protected and auditable data entry, perhaps using 'wiki' approach
- Process for automatically uploading data from national databases, agency databases, and reports such as EVSM and JRF and surveys
- Reporting function for standard and customisable reports
- Build on experience of similar databases (eg, for immunization coverage and IFS)
- Include country status information including CCL work done/planned; campaigns; and new vaccine application/introduction status for GAVI approved vaccines (penta, pneumo, rota)

It was also agreed that the best way to proceed would be for WHO and UNICEF to develop an interim spreadsheet with the available data. And in this way slowly build it up.

### Proposed Global Indicator Set

Indicator	Data	Source	Aspect	Comment
Vaccine Arrival Reports	% receive by SD % of these <7d	SD	Procedural efficiency	Data already available with UNICEF SD
EVSM status	Year assessment Scores	Report	Quality assessment	Data with WHO
National functional CCL inventory system in place	Year of national survey Av. age of equipment	ND*	Monitoring	
Vaccine forecast accuracy over past year	Order/Forecast (as %) for past year, by vaccine	SD JRF (?PAHO)	Planning quality	Routinely available for countries procuring through UNICEF (& PAHO)
National vaccine wastage monitored	Wastage data, by vaccine	JRF ND*	Monitoring	
National storage capacity	Gross storage capacity Capacity per birth % adequacy -now % adequacy - future	ND*	Planning/Implement	Calculated from storage space required per child – need to develop standard assumptions for current and future need
Emergency logistic plan for vaccine distribution (including < 7days for pandemic)	Yes/No	Review	Planning	Assume 1 dose of 60ml vaccine to every child under-5 years

\* ND = Data to be obtained from National Database; require special survey if ND not able to provide

## Agency activities, issues and plans for CCL

**B&M Gates Foundation:** Based on a recent realization of need for systems to deliver new vaccines, the foundation is finalising the details of a five-year \$34m project. The Foundation will fund PATH and WHO to: (1) finish the unfinished agenda in CCL – especially VVM and EVSM (2) understanding the strengths, weaknesses and issues to develop a mathematical model of the system constraints and the technologies that can address the future (2025) (3) demonstrate the impact of the additional support in six countries (4) develop global policies and profiles needed to make best use of new technologies such as thermostable vaccines. The project aims to look more broadly at logistics for other commodities, and to build on private sector models. There is also the intention to engage “Intellectual Ventures” to come up with future solutions.

**JSI (IMMbasics):** At the global level, JSI has been and continues to be active in CCL. At country level, it continues to be active in several countries in Africa and Asia to support strengthening of CCL. Recent work in Nigeria and DR Congo identified a range of issues around CCL. However, JSI is less active than it was in the 1990's, when it worked extensively in Africa and the NIS to support strengthening of CCL and developed learning materials for global and regional use. As the five-year project has about 18 months before its completion, there are no plans for intensively increasing its involvement in new countries or within its existing countries of operation. JSI will continue to be engaged at the global level.

**PATH:** PATH is involved in a range of policy and technology development activities that impact cold chain and logistics. In addition to raising awareness of the widespread occurrence of vaccine freezing and developing procedures to reduce inadvertent freezing, PATH developed the vaccine vial monitor (VVM) and Uniject™ device, both of which extend the potential use of vaccines beyond the cold chain, as demonstrated for the HepB birth dose in Indonesia. The VVM is now a requirement for UNICEF-procured vaccines and provides flexibility that has not yet been fully explored.

PATH is part of an international partnership, including UNEP, WHO, UNICEF, DTI, and GTZ Proklima, to develop and introduce a battery-free, solar-powered refrigerator (SolarChill). PATH is also providing assistance to Twinbird of Japan with collection of user feedback and the process of achieving WHO Performance Quality Safety (PQS) pre-qualification for an affordable 25L vaccine refrigerator with freeze-prevention features such as a non-adjustable thermostat.

A Cold Chain Equipment Management (CCEM) software tool was developed and piloted by PATH, UNICEF, and WHO. CCEM is a MS-Access tool for national EPI managers to establish and maintain a national cold chain equipment inventory. CCEM provides decision makers with the ability to analyze existing cold chain capacity in relation to current and forecasted vaccine needs and assists with strategic retirement and replacement of equipment. Based on the recently completed successful field trial in Uganda, PATH will finalize the CCEM by January 2008, at which time it will be made freely available.

The impact of new single-dose vaccine presentations and large volume packaging on CCL was demonstrated during the development of the Rotavirus Accelerated Development and Introduction Plan (ADIP). PATH currently serves as a technical lead on GAVI's Vaccine Presentation and Packaging Advisory Group (VPPAG) and supports the development of innovative vaccine preservatives and new multi-dose vaccine products that will be critical to minimizing the impact of new vaccines on CCL.

**UNICEF:** UNICEF is the largest supplier of vaccines to developing countries. Its Supply Division (SD) procures vaccines for 80-100 countries. It also procures cold chain equipment and provides technical guidance on appropriate equipment to use in specific settings. SD also supported implementation of equipment (eg, for national cold rooms in Bangladesh and Mongolia in 2007).

UNICEF is supporting efforts to ‘green’ the cold chain through increased support of cold chain equipment powered by renewable energy sources, including the SolarChill. This includes some planned field assessments of solar equipment in Uganda, and piloting the approach in Mongolia. .

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™ Uniject is a trademark of BD.

In 2006, the Government of Japan provided UNICEF funds to address the pandemic threat, that are being used to meet priority needs for CCL to help potential distribution of vaccine in a pandemic (Annex 1). The work is still in progress, but from this a priority needs template has been developed, as well as identification of the main need for CCL strengthening: human capacity in government systems.

The role of UNICEF county offices (COs) in CCL needs to be further explored and developed in supporting national programmes, including linkages with logistics for other essential child health commodities from antibiotics to zinc.

**WHO:** Country support, especially through the regional offices (ROs) and COs, is a key ongoing activity. This includes facilitation of trainings (GTN/VM, intercountry logistics and MLM workshops); support for implementation, analysis and feed-back of monitoring systems (availability of stocks and bundling, vaccine utilization and wastage, cold chain availability and quality); and undertaking assessments (inventories, VM and/or EVSM assessments, programme reviews)

WHO promotes coordination of efforts in vaccine management at global level through sharing information on vaccines and cold chain; the Vaccine Product Menu (VPM) and developing reference documents to provide norms and guidelines including MLM training modules. WHO maintains a database of EVSM results, and is planning to further analyse the CCL indicators that are reported in the UNICEF/WHO Joint Reporting Form (JRF) and other studies. WHO facilitates experience sharing through the TechNet e-forum, meetings and WHO Logistics meetings and other meetings.

WHO has developed a range of tools to support CCL, including the Vaccine Volume Calculator (VVC), Cold Chain Capacity Planning Tool, Cold Chain Inventory and Replacement Tool, EPI Logistics Forecasting Tool, District Vaccine Data Management Tool, and paper or computerised stock management tools. There is a need to review and map these out, as well as other relevant tools such as CCEM, to provide guidance on which tools are best suited for different uses.

## Challenges and solutions

Data collection and data quality are challenging. Each organization has its own source and method of obtaining country data, which sometimes leads to conflicting information. One example of this is the data on the anticipated dates for countries to introduce new vaccines. There is a need to better share data and to reach a consensus when data are in conflict.

The process used to reach a 'best-estimate' for coverage data could be replicated for the CCL data in the JRF or some alternative process of validation used. For example, the wastage figure reported could be compared to the total number of doses vaccines that were shipped to a country and the number of children vaccinated.

An important principle is the need to make sure that value of data/information outweighs the burden on countries. Ideally, global data collection would be of data that countries collected for their own use, as part of their management of the CCL systems. Data that is collected must be used and monitored, at national as well as global levels.

In developing a global database there may be issues about making public the information on a country's performance. This might include the comparison of forecast with actual vaccine orders that UNICEF SD maintains. The advantage of making the information public is that it could encourage improved performance, as well as make the information available to a wider audience. Countries would need to agree before doing so and an approval process would be needed.

Defining the priority countries for enhanced initial support is a complex process that needs to be determined by the ROs and COs. At the global level a potential list of priority countries could be determined from the existing workplans of each agency; assessments such as EVSM that had identified major needs; countries planning measles or tetanus campaigns; and countries that needed to expand their cold chain in order to successfully apply for GAVI support for new vaccine introduction.

The new GAVI policy of providing up to US\$0.30 per infant to support the costs of new vaccine introduction is an important source of funds for the required upgrade to meet the challenges of new vaccines. These funds are given at the time of the GAVI approval, so can be used ahead of the introduction.

## Annex: Japan-funded CCL strengthening

UNICEF and WHO, generously funded by the Government of Japan (GoJ), have been working to strengthen EPI cold chain and logistics (CCL) systems as part of pandemic preparedness. The GoJ grant is time limited, with all funds to be spent by March 2008. The funding of \$8m is to be shared between the 14 countries covered by the grant.

### UNICEF CEE/CIS Region (WHO/EURO)

In the UNICEF CEE/CIS Regional Office, a desk review in late 2006 was followed by field assessments in five countries in 2007 (Bosnia & Herzegovina, Serbia, Ukraine, Turkmenistan, Kyrgyzstan). WHO/EURO collaboration was essential in this process. Below are the main findings:

Forecasting, procurement and licensing: Self-procuring countries usually experience budget limitations, procurement delays and irregular shipments causing vaccine stockouts. All countries can operate fast-track procedures for emergency procurement. Very few countries in the region have a functional National Regulatory Authority (NRA) to ensure vaccine quality.

Cold chain equipment: Most countries have aged equipment which needs renewal. Unreliable power supply and lack of maintenance further limit the equipment life. Substandard domestic equipment is widely used at the service delivery level. Procurement of new equipment usually relies on external funding, using opportunities like campaigns, special projects or GAVI support.

Cold storage space: Considering new vaccines countries may introduce (Hib, pneumococcus, rotavirus, HPV), as well as pandemic needs, increased cold storage - especially at national and subnational levels - are needed in some but not all countries. (May be potential to share capacity).

Transport: Most countries do not have a regular vaccine distribution system and means (vehicle, fuel). This complicates rapid vaccine delivery especially in emergencies like a pandemic. Some countries also have challenges with geographical accessibility.

Alternative delivery systems: Non-health or private sector has also cold storage and transport systems in all countries which can be used to increase surge capacity in emergencies.

Pandemic planning: Although all countries have developed national pandemic preparedness plans, most are lacking the operational planning to deliver pandemic vaccine.

Staff capacity: Health staff is generally adequate in number, dedicated and skillful. Additional training on cold store management and vaccine management is needed. Guidelines and job aids in the local language needs to be developed and distributed on pandemic vaccine delivery. Some countries also need assistance on electronic temperature monitoring and computerized stock management.

UNICEF and WHO support will continue to concentrate on the areas below:

- **Expand the cold chain capacity** in critical points (cold rooms, refrigerators, cold boxes, vaccine carriers, thermo recorders, generators, voltage stabilizers).
- **Improve cold storage and vaccine management** practices by training of key staff, introducing computerized stock control and preparation of central stores for certification (EVSM).
- **Improve vaccine delivery** for regular distribution using innovative approaches to transport.
- **Explore alternative** storage and transport capacity in non-health and/or private and other sector for routine as well as surge capacity.
- **Streamline** vaccine forecasting, procurement and licensing **procedures**.
- **Develop operational plans** for pandemic vaccine delivery including microplans.

UNICEF pandemic vaccination support from the Japanese funds has been very much appreciated at the country level by all partners, being tangible and immediately available. Apart from improving pandemic preparedness, the support is viewed as a valuable contribution to strengthen national immunization programmes.

## UNICEF EAPRO Region (WHO/WPRO)

Assessments have also been undertaken in EAPRO countries, but the work of strengthening only initiated in Mongolia, where the focus has been on expanding the national cold chain storage capacity as well as improved temperature monitoring throughout the system with Fridge-Tags.

The assessment included a cold chain inventory undertaken by WPRO in five countries (Cambodia, Lao PDR, the Philippines, Papua New Guinea, and Viet Nam), that will provide the basis for countries to identify their priority needs.

An assessment was also undertaken in Indonesia (WHO/SEARO), but this assessment did not result in defining the priority needs for support from this grant

### Priority needs template

UNICEF and WHO developed an Excel spreadsheet template for countries to list their priority needs, based on the assessment and a consensus between government, WHO, and UNICEF. The template includes a blank as well as an example sheet:

Area of Support	Level of Support	Activity or Item	Specifications	Lead partner	Timeline	Expected Outcome	Cost (USD)	Funding Source			Status/ comments	
								Govt.	GoJ	Other		
System	Nat	Policy development				Enhanced CCL performance - ideally in measurable terms, eg % reduced wastage, stockouts etc.						
	Nat	Management/ IT/ Comms										
	Nat	Guidelines development										
	Nat	Forecasting/Wastage mgt.										
	Nat	External assessments (eg, EVSM, VMAT, procurement)										
	Subnat	Management/ IT/ Comms										
Storage	Nat	Construction work				Assurance of temperature of storage; % reduction in vaccines temperature damaged						
	Nat	WIC/WIF/Fridge/Freezer										
	Nat	Power source										
	Nat	Back-up power										
	Nat	Voltage stabilizers										
	Nat	Temperature monitoring										
	Subnat 1	WIC/WIF/Fridge/Freezer										
	Subnat 1	Power/ back-up										
	Subnat 1	Voltage stabilizers										
	Subnat 1	Temperature monitoring										
	Subnat 2	Fridge/Freezer										
	Subnat 2	Temperature monitoring										
	H. facility	Fridge										
	H. facility	Temperature monitoring										
H. facility	Vaccine carrier/ Cold box											
Transport	Nat	Refrigerated trucks				Timely vaccine distribution						
	Nat	Other vehicles										
	Nat	Vaccine carrier/ Cold box										
	Subnat 1	Vehicles										
	Subnat 1	Vaccine carrier/ Cold box										
	Subnat 1	Temperature monitoring										
	H. facility	Temperature monitoring										
	H. facility	Vaccine carriers										
Capacity building	All	Training										
	All	Training materials										
	All	On-site technical assistance and practical training										
Other	Nat											
	Subnat											
	H. facility											
TOTAL						\$ -	\$ -	\$ -	\$ -			

### Human capacity

One of the key findings is that human capacity is one of the key needs – both in terms of people dedicated to managing the CCL systems, as well as the training of those who are involved. This has not been able to be very well covered, apart from some limited inputs, by the Japan grant because it is time-limited. In addition, advocacy is needed with governments to provide more dedicated staff for CCL management.

### Pandemic vaccine storage needs

As there is uncertainty about the nature of the vaccine and the target, a simplifying assumption that has been used for calculating the storage needs is to assume every child under age five years would be given Prevnar size (~60 ml per dose). Such a campaign might be an effective response to a pandemic; in addition, this estimate would cover the entire population of a vaccine in a multi-dose vial.