

# **Improving the vaccine supply chain in developing countries via increasing freeze protected cold chain equipment**

October, 2014



# CHAI's mission is to save lives by increasing access to health commodities and services in developing countries



When President Clinton established the Clinton Foundation in 2002, fewer than 300,000 people living with HIV/AIDS were receiving life-saving antiretroviral (ARV) medicines.



**Today, more than seven million patients are accessing treatment in the developing world**



# CHAI is an independent nonprofit with in-depth operations in more than 32 countries

## Who we are

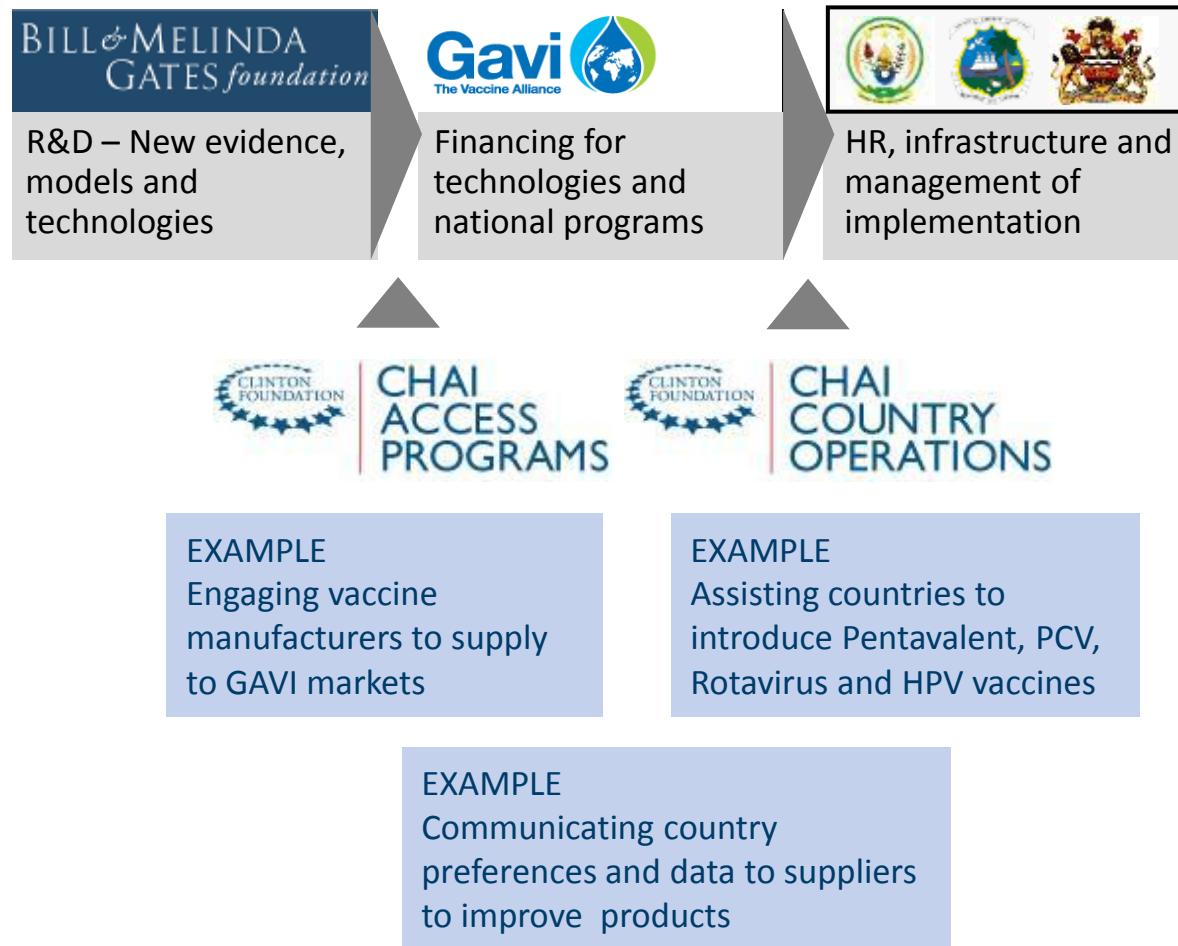
- **Founded** In 2002, as an initiative of the Clinton Foundation
- **Leadership** President Clinton, Chairman of the Board;  
Ira Magaziner, CEO and Vice Chairman of the Board
- **Staff** >1,300 staff
- **Budget** \$110 million in 2013

## Where we work



# CHAI plays a unique role - it is not a donor or implementer by nature, but instead focuses on management and markets

By helping to organize commodity markets and better manage national programs, CHAI has a catalytic impact: governments and donors are able to do more with available resources



# Vaccines and immunization is one of CHAI's strategic areas of focus at both the global and in-country levels

## Vaccines

- Accelerate introduction of new vaccines, reduce prices of vaccines, and improve the efficiency and effectiveness of vaccine delivery systems

## Value for Money

- Increase efficiency of spending on key health commodities and identify and pursue significant structural inefficiencies in global health spending

## Malaria

- Support rapid scale-up of effective treatment and diagnosis, achievement of elimination where feasible, and sustained financing

## Human Resources for Health

- Improve the production, distribution, and quality of health professionals to significantly accelerate closing the human resource gap

## HIV/AIDS and TB

- Improve efficiency and effectiveness of global spending, increase long-term survival for PLWHA & accelerate scale-up of eMTCT & TasP

## Maternal, Newborn, and Child Health

- Accelerate scale-up of essential child treatment with a focus on zinc/ORS and improve systems to reduce maternal/neonatal mortality in key countries

## Applied Analytics

- Generate evidence needed to improve healthcare through expertise in epidemiology, economics, program measurements, and evaluation methods

## Access to Medicines

- Accelerate patient access to healthcare by coordinated and intensive engagement on supply and demand side of the market

# In-country CHAI teams have supported governments to introduce new vaccines and improve immunization delivery in eight focus countries

## Nigeria

- Supporting development of Penta, PCV and IPV introduction plans
- Supported improvement of vaccine supply chain
- Provide ongoing budgeting and financing assistance to the MOH

## Uganda

- Supporting IPV and HPV introductions
- Supporting immunization supply chain strengthening

## Ethiopia

- Supported MOH and GAVI to minimize delays in PCV introduction amidst global supply shortage
- Supporting MOH to improve vaccine supply chain

## Kenya

- Provided broad management support and detailed planning for PCV introduction
- Supported development of robust proposal to GAVI for rotavirus

## Cameroon

- Supporting planning for the introduction of rotavirus and IPV vaccines
- Improving vaccine supply chains

## Tanzania

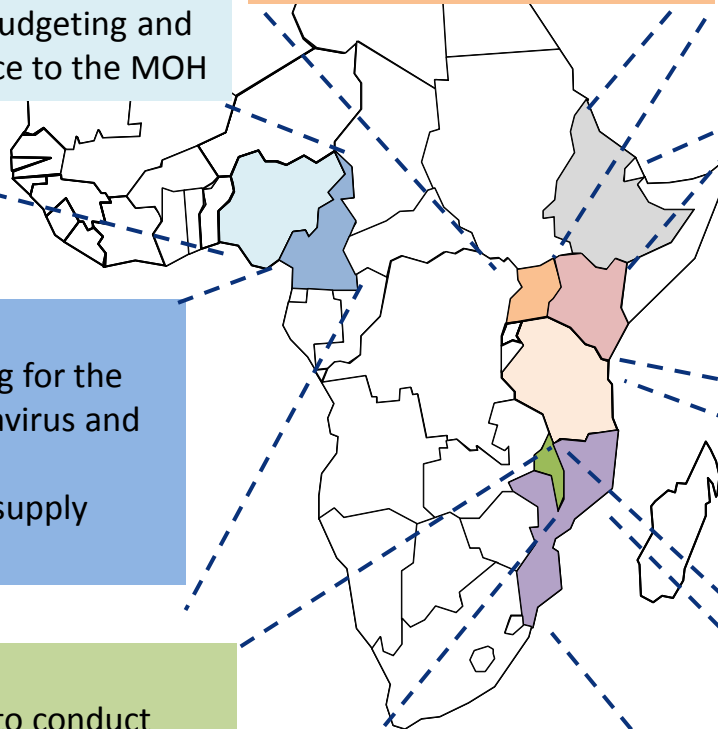
- Supported introduction of concurrent PCV and rotavirus introductions
- Working with MOH to improve vaccine supply chain and service delivery

## Malawi

- Assisted the MOH to conduct cold chain expansion
- Supported the introduction of PCV vaccine

## Mozambique

- Supporting the government to improve immunization supply chain and delivery systems



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2. Understanding the **urgency** for introducing freeze protection standards
3. Mitigating the risk with freeze **protection standards and technology**

## **Need**

Freeze Protection  
Standards



## **Urgency**

Significant CCE  
demand in 2014-18



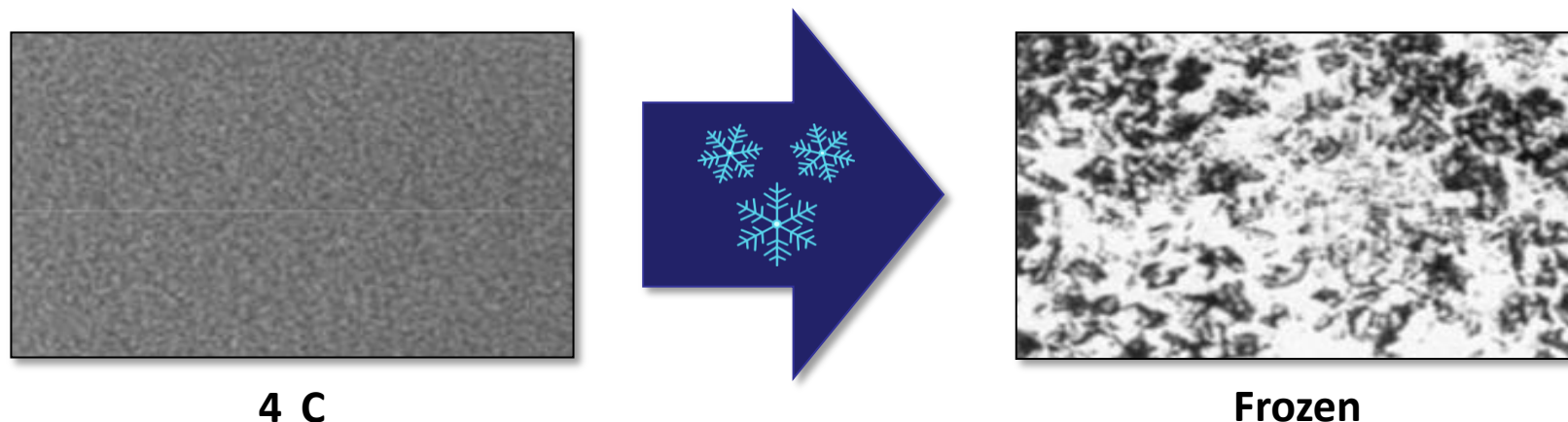
# **1. Background on vaccine freezing risks in the cold chain**





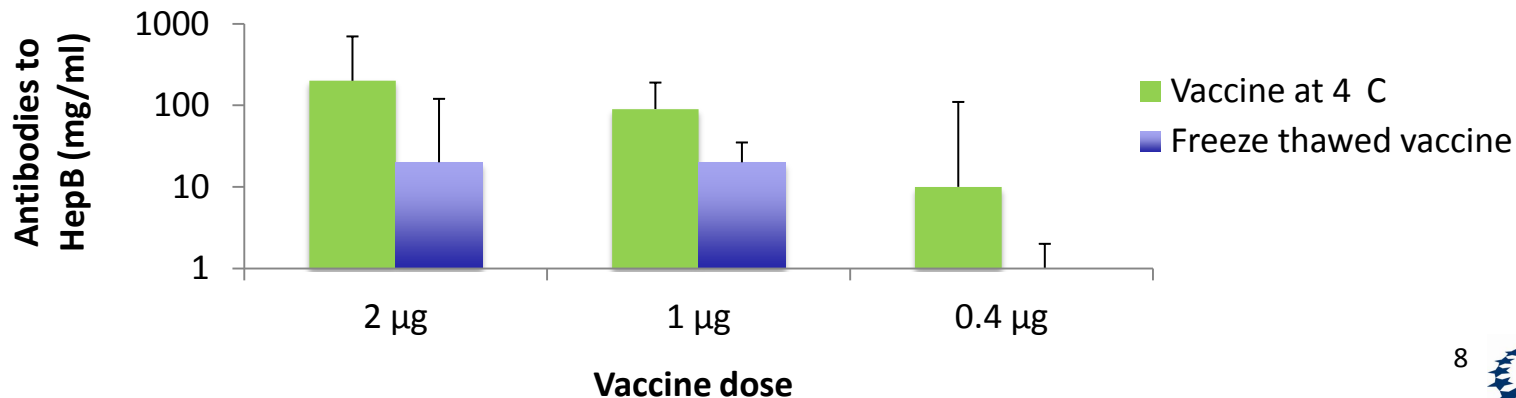
# Freezing causes serious damage to many vaccines, reducing potency and thus having a negative impact on immunization outcomes and public health

*Freezing damages the protein structure of many vaccines*



**Freeze damage to vaccine proteins reduces the potency of many vaccines**

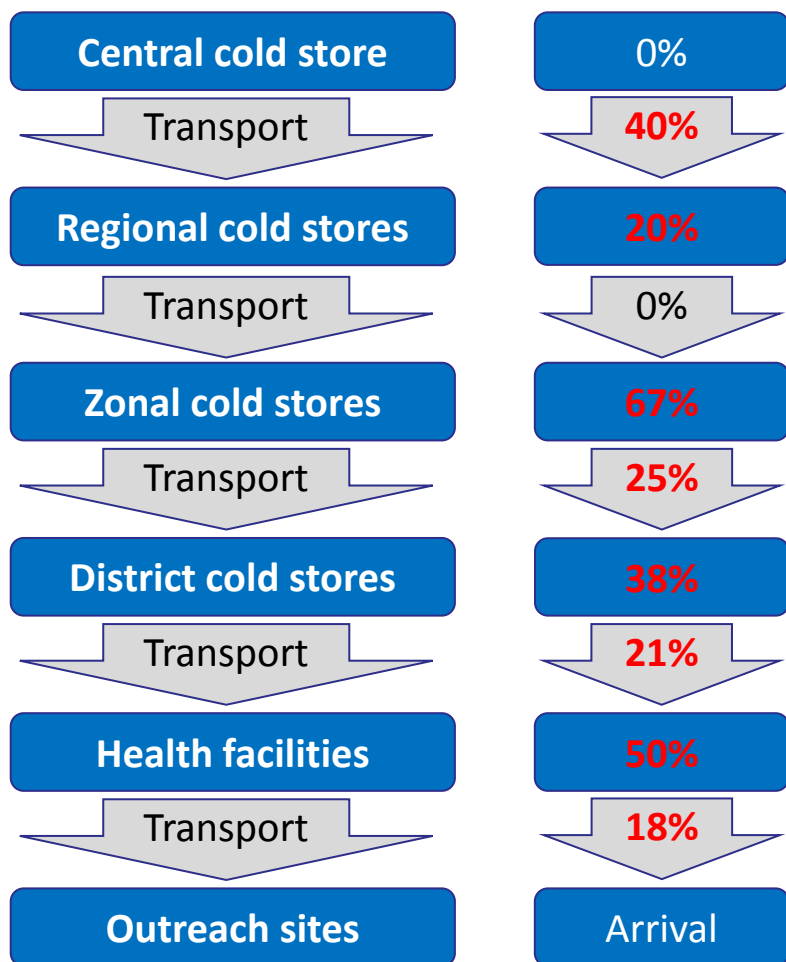
*Antibodies generated by properly stored Hep B vaccine vs frozen-thawed vaccine*



# Evidence shows that vaccine freezing occurs through-out the vaccine supply chain, during both transport and storage at all types of facilities

## A CHAI study in one developing country found freezing across the vaccine supply chain

*% of vaccine shipments exposed to freezing at each level of the supply chain*



### Global research suggests that:

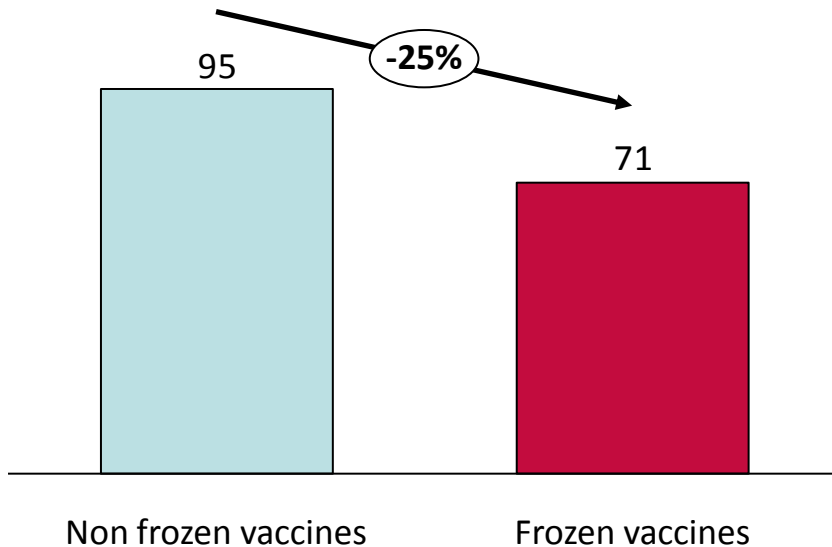
- Over **75% of vaccine shipments are exposed to freezing** at some point in the supply chain
- At least **21% of refrigerators** used in developing countries for vaccine storage **expose vaccines to freezing**

**Therefore, preventing vaccine freezing will increase “effective immunization rates”**

# Freezing of vaccines has a negative impact on public health outcomes for children in many developing countries

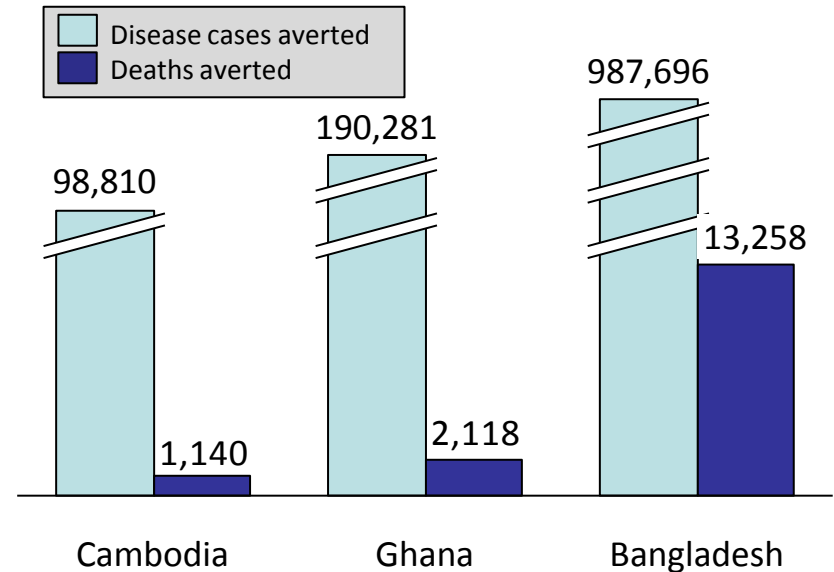
**25% fewer children who had been given frozen Hep B vaccine showed an adequate antibody response to the vaccine, likely due to freeze damage**

*% of children with adequate Hep B antibodies following immunization*



**Eliminating vaccine temperature damage in 3 countries could avert over a million cases of disease and thousands cases of child mortality**

*Estimated health outcomes of future thermostable vaccines in Cambodia, Ghana, Bangladesh*



**“Potency loss does occur when freeze-sensitive vaccines undergo the phase change to a frozen state.** Many epidemiological studies have also pointed to vaccine freezing as a possible contributor to low immune response in vaccinated individuals and the existing literature relating freeze exposure to potency loss is compelling enough to suggest some degree of impact on immune response.” – PATH, 2006

Note: In this analysis, thermostable vaccines can act as a proxy for normal vaccines with no temperature damage

Sources: Levin, A. et al “An economic evaluation of thermostable vaccines in Cambodia, Ghana and Bangladesh” in Vaccines (2007); Chen, D

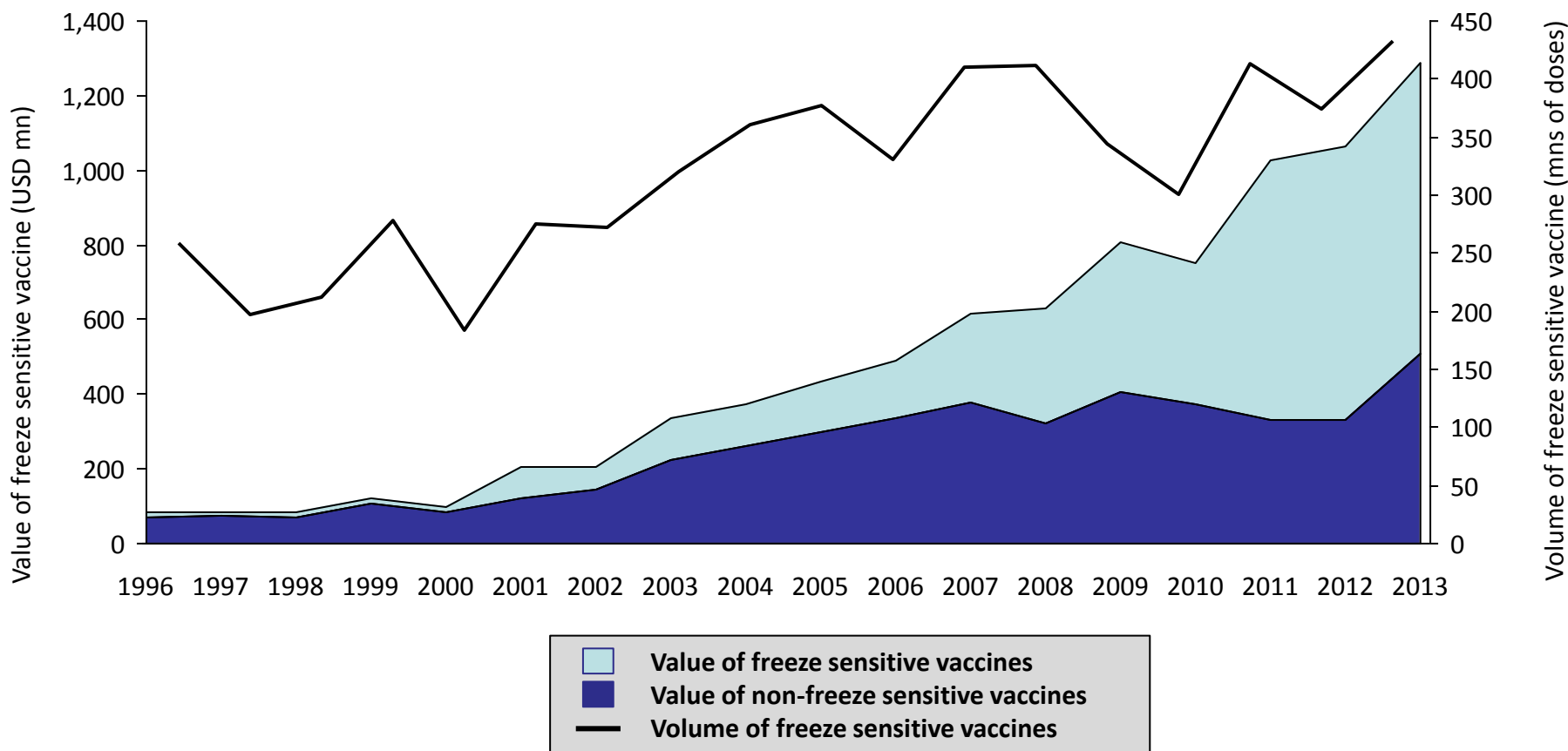
“Opportunities and challenges of developing thermostable vaccines” in Expert Rev. Vaccines (2009)

## **2. Understanding the urgency for introducing freeze protection standards**



# The volume and value of freeze-sensitive vaccines being procured is increasing, raising the public health benefits of “freeze protection”

*Value (in millions of USD) and volume (millions of doses) of vaccines procured by UNICEF SD, 1996 to 2014*



Sources: UNICEF SD vaccine procurement data available online at:

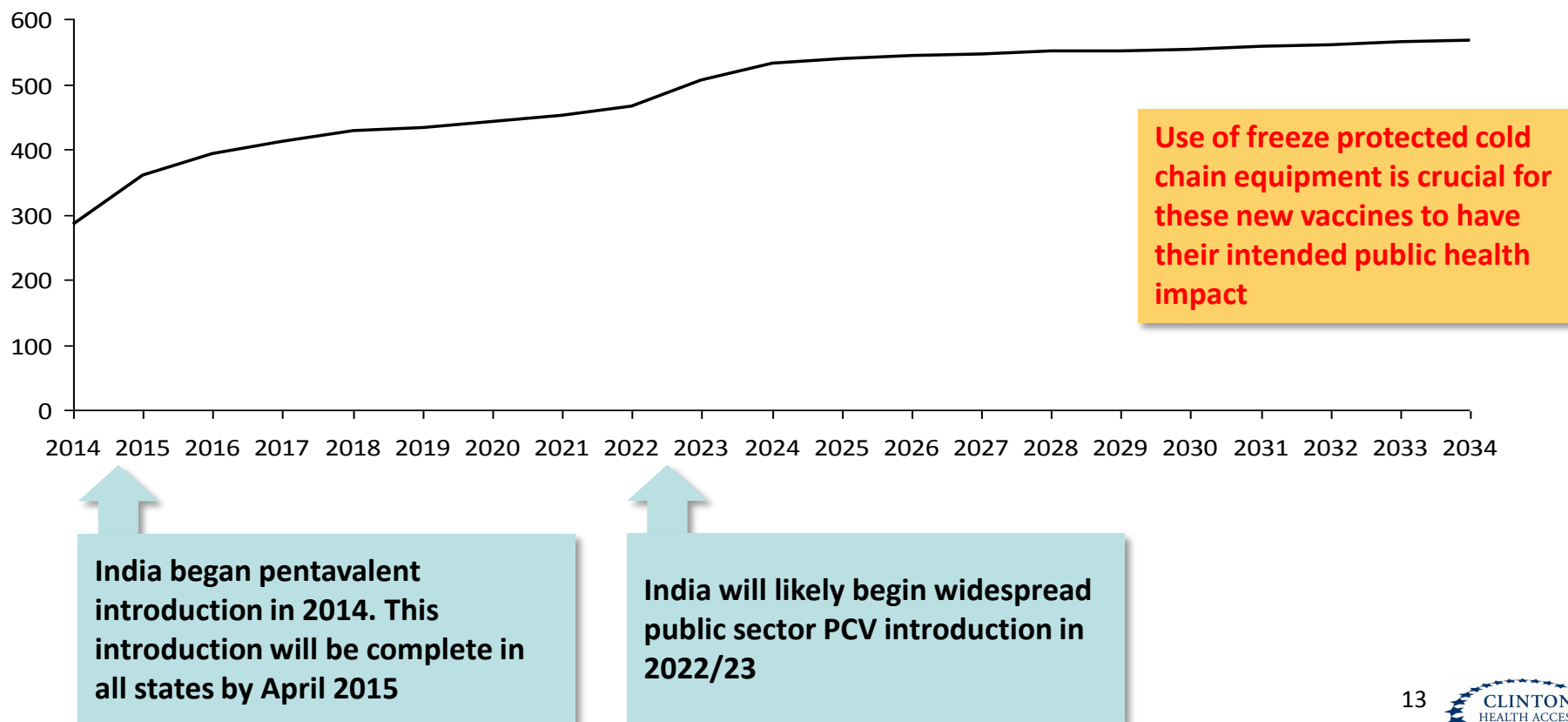
[http://www.unicef.org/supply/files/Table\\_of\\_vaccine\\_procurement\\_1996\\_2013\\_volume.pdf](http://www.unicef.org/supply/files/Table_of_vaccine_procurement_1996_2013_volume.pdf)

[http://www.unicef.org/supply/files/Table\\_of\\_Vaccine\\_Procurement\\_1996\\_2013\\_Value.pdf](http://www.unicef.org/supply/files/Table_of_Vaccine_Procurement_1996_2013_Value.pdf)

# Demand for freeze sensitive pentavalent, the core of most routine immunization programs, and pneumococcal vaccines will increase

**Demand for two major freeze sensitive vaccines is expected to increase, driven in part by Indian introduction of these vaccines**

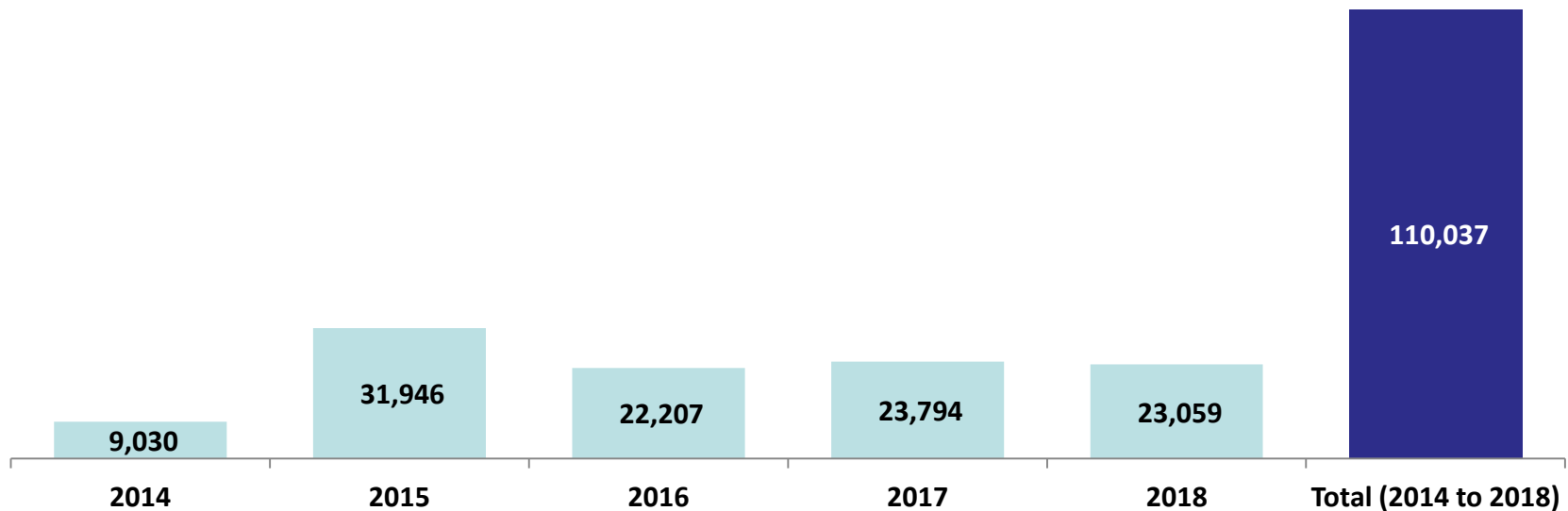
*Low and middle income country (including India) forecast demand for PCV and pentavalent vaccine from 2014 to 2034, in millions of doses*



# Vaccine CCE procurement is expected to be steady and constant over the next few years; now is a good time to install the right technology

**Freeze protection standards are critical to implement now as significant CCE demand is expected over the next five years**

*GAVI-eligible market demand for SDDs and ILRs from 2014-2018, in units*



- **From 2014 to 2018, total demand of vaccine refrigerators is expected to reach 110,000 units** from the 53 GAVI-eligible countries, as new vaccine introductions and replacement needs in-country require large CCE procurement
- **Implementing freeze protection standards in 2014 is critical** to accelerating the uptake of freeze protected units in this high period of demand



### **3. Mitigating the risk with freeze protection standards and technology**



# Proposed standard to categorize freeze protection capabilities

## User Dependent Freeze Protection (DFP)

User interventions required to mitigate freezing risk

## User Independent Freeze Protection (IFP)

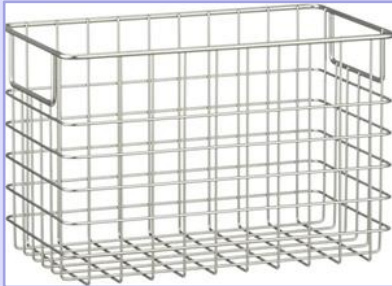
No user interventions required to mitigate freezing risk

- ✓ Proposed standard describes technologies based on the **necessary interventions required** for users to prevent freeze exposure
- ✓ **Codifies WHO PQS guidance** on operating CCE
- ✓ Nomenclature **aligns with existing messaging** from suppliers on proper use of equipment
- ✓ **Unbiased** standard with respect to technology and supplier

# User-Dependent Freeze Protection (DFP) is dependent on the user to prevent freezing

**Definition:** Freeze protection is **DEPENDENT** on proper healthcare worker use and operation

- **Freezing temperatures exist** within refrigerator compartment
- **Interventions must be observed** to mitigate risks

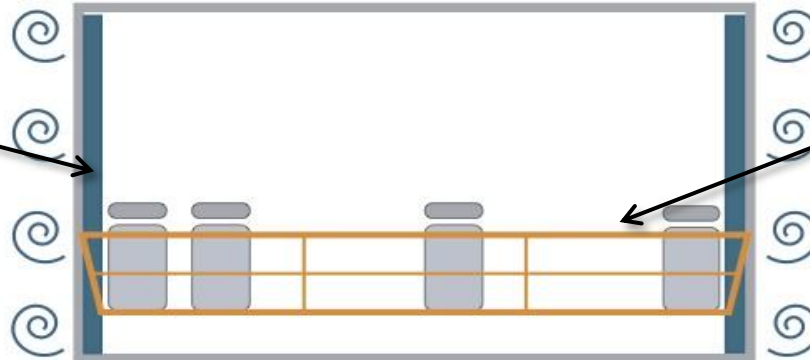


✓ Always store vaccines in **baskets**, away from sidewalls



✓ Regular **defrosting**

Compartment surface area where freezing temperatures can exist

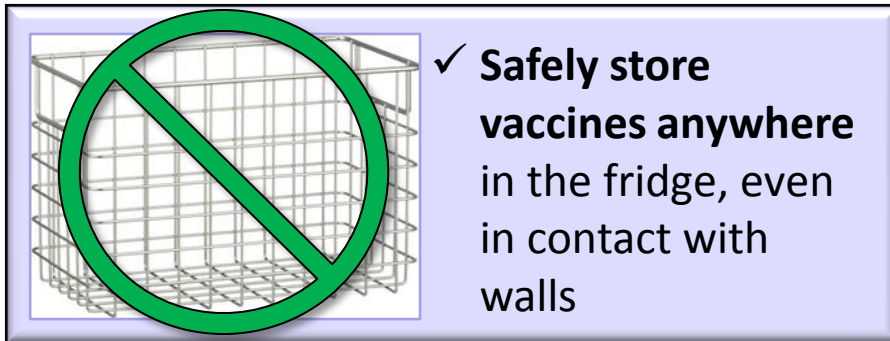


Baskets used to store vaccines away from walls

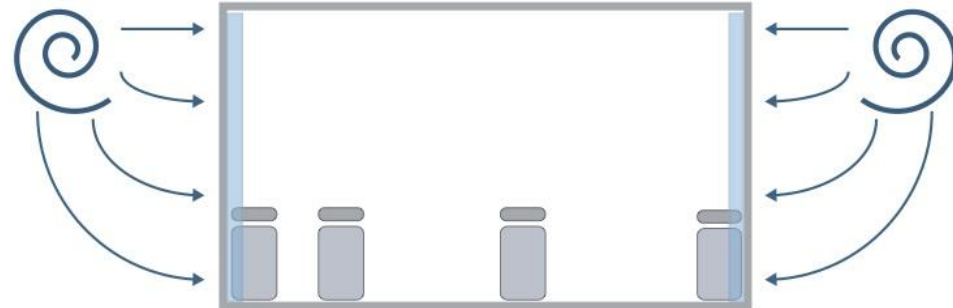
# User-Independent Freeze Protection (IFP) technology prevents vaccine freezing independent of user operation

**Definition:** Freeze protection is **INDEPENDENT** of healthcare worker's use and operation

- Protection is intrinsic to the refrigerator design in that compartment **sidewall surfaces never reach vaccine freezing temperatures.**



*Phase Change Material (PCM)*



*Patented Sure Chill technology*

# Answering the freezing problem through introduction of WHO PQS freeze protection standards

## Market challenges:

- **No accepted standard** for categorizing freeze protection in WHO PQS
- **Lack of IFP options** in capacity and technology segments
- **Significant demand** over next 5 years

## Solution:

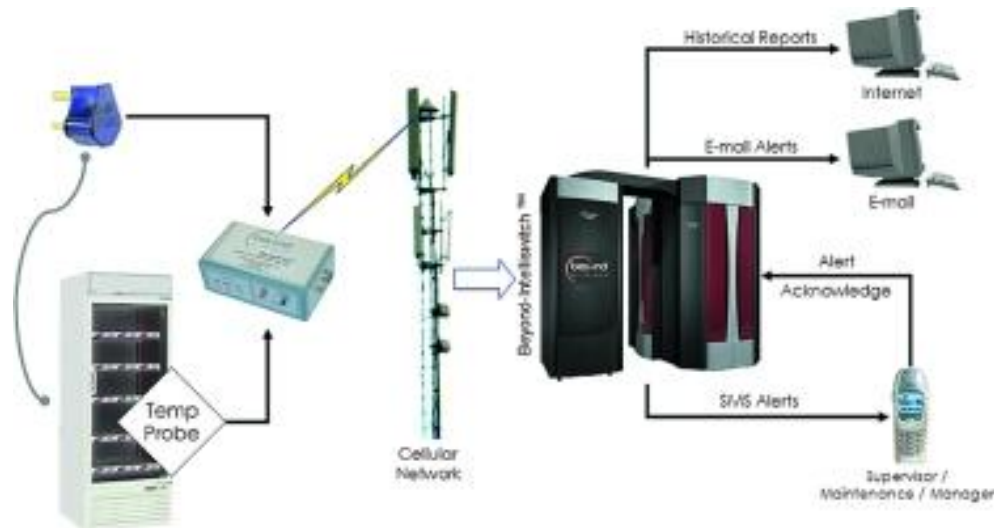
- **Introduce WHO PQS freeze protection standardization to:**
  - ✓ Emphasize to **countries** the importance of procuring and operating FP
  - ✓ Provide market signal to **suppliers** for designing to FP standard
  - ✓ Enable **global partners** to advise appropriate FP procurement and operation
  - ✓ Allow **donors** visibility into vaccine investment protection and insistence on levels of FP in donor-funded country procurements

**ULTIMATE GOAL:** Make an affordable and proven independent freeze-protected fridge option available in every PQS capacity and technology segment of CCE.

# Many stakeholders are working to develop and support the increased adoption of other technologies to prevent freezing, such as RTMDs

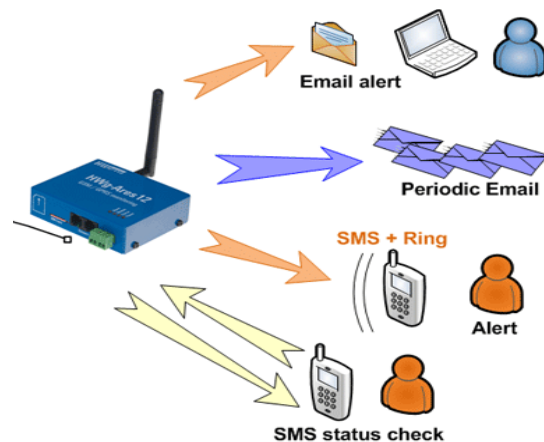
## *How it works:*

An remote temperature monitoring device (RTMD) is placed on a vaccine fridge, and sensors placed inside of the fridge take readings every few minutes, transmitted to cloud via cellular network



When an unsafe temperature is detected, RTMD will transmit an alert via SMS, phone, or email to the appropriate personnel. This enables:

1. Proactive action to prevent vaccine damage due to freezing and heating
2. Awareness of cold chain system in order to better direct maintenance and repair efforts
3. Evidence-based decision-making in future procurements of cold chain equipment



# Appendix

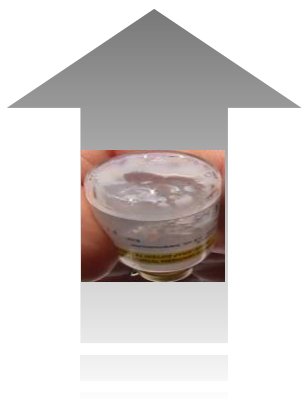


# Sensitivity to freezing of various vaccines

## Freeze sensitivity

## Vaccine

Most sensitive



Least sensitive

DTaP  
DTaP-hepatitis B-Hib-IPV (hexavalent)  
DTwP  
DTwP-hepatitis B-Hib (pentavalent)  
Hepatitis A  
Hepatitis B  
Human papillomavirus  
Meningitis C (polysaccharide-protein conjugate)  
Pneumococcal (polysaccharide-protein conjugate)  
T, DT, dT

Cholera (inactivated)  
Influenza (inactivated, split)  
Hib (liquid)  
Inactivated poliovirus  
Typhoid PS

## Caution:

- ✓ Never expose these vaccines to zero or subzero temperatures.
- ✓ Avoid the use of ice for transport.

**These vaccines are not damaged by freezing.**

**Meningitis A (polysaccharide-protein conjugate)\***  
**Rotavirus (liquid and freeze dried)**  
**Yellow fever**

**Bacillus Calmette-Guérin**  
**Hib (freeze dried)**  
**Japanese encephalitis (live and inactivated)**  
**Measles**  
**Measles, mumps, rubella**  
**Oral poliovirus**  
**Rabies**  
**Rubella**  
**Varicella-zoster virus**

\* The diluent for MenA PS-PCV contains alum adjuvant and is freeze-sensitive.

Note: Bolded vaccines are freeze dried.