



# **CONTROLLED TEMPERATURE CHAIN: Myths & Truths**

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**Anna-Lea Kahn – WHO/IVB, Switzerland**

**Joe Woodring – WHO/WPRO, Philippines**

**Ruth Coulibaly - Ministry of Health, Côte d'Ivoire**

# The Controlled Temperature Chain (CTC) :

## DEFINITION

*A specific set of conditions allowing for a vaccine to be stored and transported outside of the traditional 2° to 8°C cold chain...*

- ✓ **One** excursion, just prior to administration
- ✓ Specifically **limited duration** (at least 3 days)
- ✓ Ambient temperatures up to **40°C+**
- ✓ According to the demonstrated stability and **approved labelling** of the product
- ✓ Key temperature monitoring tools =  
Vaccine Vial Monitor (**VVM**) +  
Peak Threshold Temperature Indicator (**PTTI**)

# The Controlled Temperature Chain (CTC) :

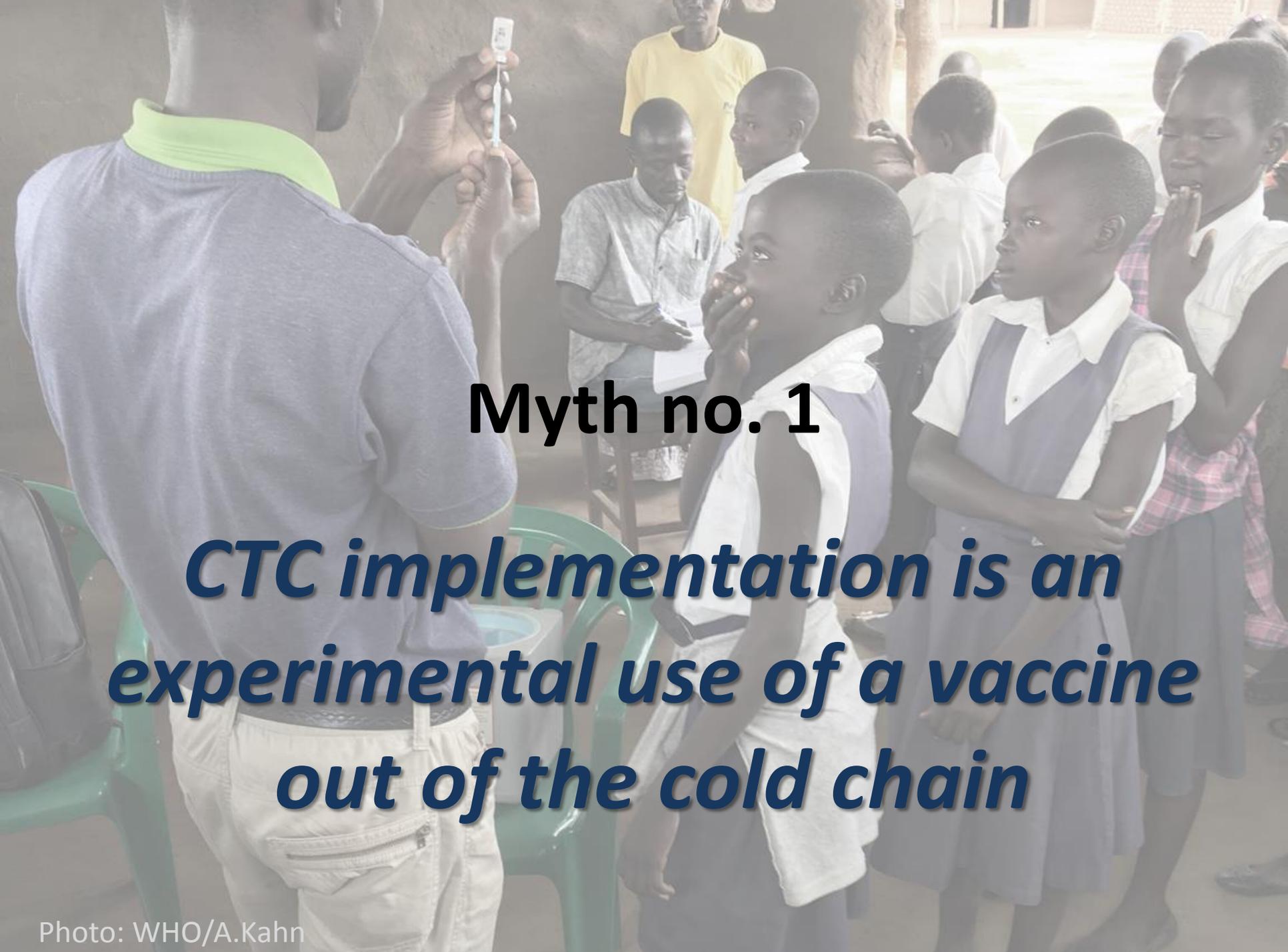
## AGENDA

### FOCUS:

- **UPSTREAM:** Development and licensure of more CTC-compatible vaccines (as per GVAP indicator)
- **DOWNSTREAM:** Scale up country-level experience

### PRIORITIES:

- Vaccines with best CTC potential for use in **campaigns & special strategies**
- prioritized by the **CTC Working Group** under the Immunization Practices Advisory Committee (IPAC)



## Myth no. 1

***CTC implementation is an experimental use of a vaccine out of the cold chain***

# Truth no. 1

- CTC is a vaccine DELIVERY STRATEGY based on fully validated data on the thermostability of a given product.
- CTC only can be implemented when the product it is being applied to is labelled for use in this way.
- CTC implies **scientific validation** by the manufacturer + **regulatory validation** by the relevant NRAs + **WHO validation** through the prequalification process + **programmatic validation** by the respective Ministry of Health adopting this strategy.

A group of children, mostly boys, are standing in a line on a dirt path in front of a traditional mud-brick building with a thatched roof. The children are wearing various colorful clothing. The scene is set in a rural, open area with some trees in the background.

## Myth no. 2

***There is minimal demand expressed by countries for CTC and so the associated investment with a label variation is not worthwhile.***

## Truth No. 2

- Countries all too often lack awareness on CTC and would like more evidence on the potential benefits and optimal methodology.
- **72 %** of countries who participated in a recent survey conducted in the WPRO & AFRO regions suggested that CTC would facilitate the provision of Hepatitis B birth dose.
  - Countries which have not introduced birth dose are not comfortable using a product off-label, but would welcome the option for CTC with the appropriate guidance and technical support.
  - Strong interest in CTC in countries with universal hep B birth dose but low coverage

## Myth no. 3

***Vaccine Vial Monitors (VVMs) monitor use of vaccines out of the cold chain and suffice when CTC practices are adopted***

## Truth no. 3

- VVMs are not meant for monitoring intentional cold chain excursions, but rather designed to capture heat exposure due to accidental breaks in the cold chain.
- VVMs are designed to tolerate temperatures only up to a maximum of 37°C, while ambient temperatures can often exceed that.
- VVMs respond gradually to accumulated exposure to heat and will not reflect any sudden peaks in heat exposure which can damage a vaccine.
- CTC temperature monitoring relies on VVMs and the use of Peak Temperature Threshold Indicators designed to instantly respond when exposed to 40°C or above.



**Myth no. 4**

***CTC is not needed in countries with adequate cold chain capacity***

## Truth No. 4

- CTC doesn't only overcome cold chain constraints, it also facilitates access to remote communities or in the case of Heb-B BD, mothers who have home-births.
  - ✓ Six countries in the WP region increased birth dose coverage through successful OCC pilots
- CTC can significantly reduce the risk of damaging vaccines due to freezing.
- CTC reduces the time burden placed on health workers and can diminish supply chain costs by up to **50%**.

## Myth no. 5

***CTC could lead to health workers taking the wrong vaccine out of the cold chain due to confusion.***

## Truth no. 5

- CTC has been successfully applied in 7 different countries across the African continent, for the vaccination of over 2 million persons.
  - Thanks to effective training and supervision, there have yet to be any accounts of health worker confusion linked to CTC.
  - CTC has not been shown to have any impact on AEFIs.
  - CTC has not been shown to have a negative impact on wastage rates.

## Myth no. 6

***Using a vaccine in a “Controlled Temperature Chain (CTC)” and use of vaccines “Out of the Cold Chain (OCC)” amount to the same thing.***

## Truth No. 6

- ✓ **CTC** = ON-label use  
**OCC** = OFF-label use
- ✓ **CTC** = Liability lies with manufacturer  
**OCC** = Liability lies with country
- ✓ **CTC** = specific monitored conditions and criteria  
**OCC** = no specifications per se, but VVMs and monitoring considered minimal standards
- ✓ **CTC** = favoured approach by SAGE  
**OCC** = sanctioned only when CTC not available and with guidance from IPAC

# Thank You

Link to CTC  
information +  
advocacy film on  
WHO's web site:

[http://tinyurl.com/](http://tinyurl.com/WHOCTC)

[WHOCTC](http://www.who.int/immunization/programmes_systems/supply_chain/ctc/en/) or

[http://www.who.int/immunization/  
programmes\\_systems/supply\\_chain  
/ctc/en/](http://www.who.int/immunization/programmes_systems/supply_chain/ctc/en/)



Don't miss the CTC poster in the TechNet Conference Project Gallery...  
+ Interactive "Potency in Motion" session in Sala VI today at 11am

Photo: WHO/A.Kahn

# Viet Nam AEFIs (in cold chain)

- 3 deaths due to program error in 2013
- Drop in birth dose coverage from 76% to 56%
- Estimated impact: 90,000 chronic infections and 17,000 excess deaths



ELSEVIER

Contents lists available at [ScienceDirect](#)

Vaccine

journal homepage: [www.elsevier.com/locate/vaccine](http://www.elsevier.com/locate/vaccine)

Impact of Adverse Events Following Immunization in Viet Nam in 2013 on chronic hepatitis B infection

Xi Li<sup>a</sup>, Eric Wiesen<sup>b,\*</sup>, Sergey Diorditsa<sup>b</sup>, Kohei Toda<sup>c</sup>, Duong Thi Hong<sup>d</sup>,  
Nguyen Lien Huong<sup>d</sup>, Nguyen Van Cuong<sup>d</sup>, Nguyen Tran Hien<sup>d</sup>