CONTROLLED TEMPERATURE CHAIN: Myths & Truths

Innovative Solutions & Approaches

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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**)
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

Photo: WHO/A.Kahn
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.
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.

Photo: WHO/A.Kahn
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

Photo: CIV-MOH/R.Coulibaly
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 AEFI.
  – 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:

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 AEFI (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