WHAT IS A CONTROLLED TEMPERATURE CHAIN (CTC)?



APPROVED FOR CTC

A controlled temperature chain is an optional method of transporting and storing vaccines in carriers

WITHOUT ICE PACKS up to a specific number of days before the vaccines are administered. It is only recommended for vaccines

OFFICIALLY LABELED FOR THIS USE where a pronounced need is apparent and

TRAINING AND SUPERVISION are provided.

Vaccines carried in a CTC must be monitored using a vaccine vial monitor (VVM) and peak temperature threshold indicator (PTTI)

to indicate exposure to heat.



Not all vaccines can be used in a CTC. To be used in a CTC, four conditions should be met:

LAB

The vaccine must undergo and pass stability testing.

NATIONAL REGULATORY AUTHORITY Appropriate regulatory authorities must license the vaccine for CTC use with a label that specifies the conditions of use.



WHO

The vaccine must be prequalified by the World Health Organization.



COUNTRY The government of the country where must give its consent













HOW DOES A CTC COMPARE TO A TRADITIONAL COLD CHAIN?

TRADITIONAL COLD CHAIN



Vaccine label indicates +2°C to +8°C for **all** storage and transport.



Vaccine vial monitors protect potency and quality by monitoring cumulative exposure to heat.



Conditioned ice packs or cool water packs are required in



No need for additional training, monitoring or supervision.



When implemented correctly, preserves the safety and potency of the vaccine.



Requires cooling equipment, transport, and human resources at all levels to maintain cold chain.

CONTROLLED TEMPERATURE CHAIN (CTC)

Vaccine label indicates +2°C to +8°C for **initial** storage and transport.



and permits up to **40°C** for at least 3 days prior to use

APPROVED



Vaccine vial monitors and peak temperature threshold indicators protect potency and quality by monitoring cumulative and peak exposure to heat.



No ice packs or cool water packs are required in vaccine carriers. Reduced risk of freezing

additional training, monitoring



and supervision. When implemented correctly,

Health workers need



preserves the safety and

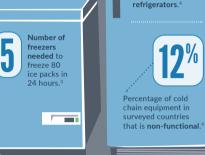


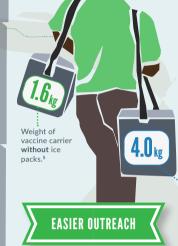
Half the cost.1 Fewer freezers, fewer journeys and less staff time are needed to manage and maintain cold chain requirements.

- Lydon P, et al. Economic benefits of keeping vaccines at ambient temperature during mass vaccination: the case of meningitis A in Chad. WHO Bulletin. 2014;92:86-92.
- WHO EVM Database: data from the most recent EVM assessments in 64 countries across 6 WHO regions, 2010-2014.
- Assuming each vaccination team requires 8 ice packs per day to vaccinate 100 people. Need 10 teams to vaccinate 1,000 people. Translates to 80 ice packs to vaccinate 1,000 people in a day.

 A commonly-used WHO pre-qualified freezer can freeze around 7.2 kg of ice packs in 24 hours. Five of these freezers are required to freeze 80 ice packs in 24 hours.

WHY IS CTC USEFUL? INCREASED COVERAGE Number of days that health workers to reach more remote FEWER RESOURCES antigen er of ice packs ed daily to vacci Percentage of health facilities Percentage of vaccinators in Benin who agreed that CTC was

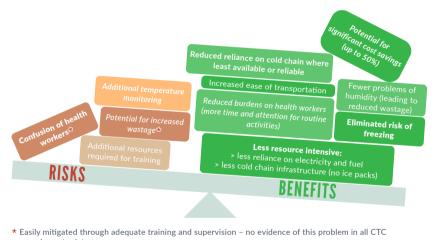




them to vaccinate more persons.6

Weight of loaded with conditioned ice packs.5

CONSIDERATIONS FOR CTC UPTAKE



experience to date



Shanchol™ was licensed and WHO-Prequalified in 2018 for use in a CIC: permitting a single removal from the cold chain into ambient temperatures not exceeding 40°C for up to 14 days prior to

administration.

Numerous countries have already successfully delivered OCV through a CTC approach, including Bangladesh, Cameroon, Mozambique, and

Immunization programmes should contact the GIFCC for potential technical and financial support, should a CTC approach be of interest.

#ENDCHOLERA #CTC_VACCINES



Want to know more about CTC? Email <u>vaccines@who.int</u> or visit: $\underline{www.who.int/immunization/programmes_systems/supply_chain/}$

- A commonly-used WHO pre-qualified vaccine carrier with a capacity of 1.7 L weighs 1.6 kg when empty and 4.0 kg when fully loaded with ice packs.
- Zipursky S, et al. Benefits of using vaccines out of the cold chain: Delivering Meningitis A vaccine in a controlled temperature chain during the mass immunization campaign in Benin. 2014. Vaccine;32:1431-1435
- Vaccines for different antigens may allow for excursions of an even higher number of days.