The Controlled Temperature Chain (CTC)

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A typical day in a vaccination campaign

What is a controlled temperature chain?

- An innovative approach allowing to keep vaccines

outside of the traditional cold chain:

  - above +8° C up to a specified threshold temperature
  - for a limited period of time under monitored and controlled conditions
  - for a duration of a specific number of days

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WHO's Programmatic Criteria for CTC

- The vaccine should be used in a **campaign or special strategy** setting.
- The vaccine must be able to tolerate ambient temperatures of **at least +40° C for a minimum of 3 days** and should be accompanied by:
  - A vaccine vial monitor (VVM) on each vial, and
  - A peak threshold indicator in each vaccine carrier

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Peak Temperature Threshold Indicator

PEAK TEMPERATURE THRESHOLD INDICATOR

INSTRUCTIONS

Check the indicator as follows:

- ☐ When you **load the vaccines into the cold box**
- ☐ As you **remove each vial from the cold box**

When the **last dose of vaccine for the day** is administered

Still Good	Take action!!

If the **INNER CIRCLE IS BLACK,**
DO NOT USE the vaccines and contact your supervisor

Why do we need CTC?

- **Origin of CTC:**
  - recognized benefits of flexible use of the cold chain
  - acknowledgment that countries are generally reluctant to use vaccines off-label
- **Objectives:**
  - to help overcome burdens and constraints associated with delivering vaccines in a traditional cold chain
  - to complement supply chain investments
  - to ensure an on-label vaccine use

The CTC agenda: A two-pronged approach

Existing and new products

1. **UPSTREAM:**

   Development and licensure of more CTC-compatible vaccines

2. **DOWNSTREAM:**

   Scale up country-level experience / boost demand

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CTC licensure to date

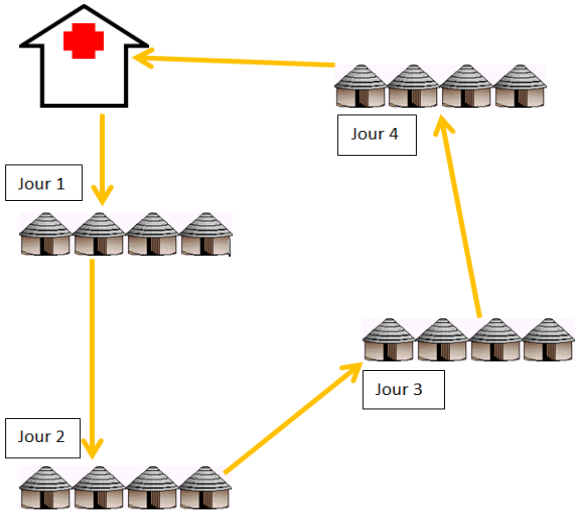
- December 2012: **Meningitis A Vaccine** (MenAfriVac) 4 days / 40° C
  - Scaled up implementation in 6 countries to date
  - ~4 million vaccinated through CTC
  - Planning ongoing, but limited to single introductions
- May 2015: **PCV 13** (Prevnar13) 3 days / 40° C
  - Routine vaccination only / not CTC priority
- June 2016: **Human Papillomavirus Vaccine** 4-valent (Gardasil4) 3 days / 42° C
  - Pilot project under development for 2017

Experience with CTC implementation: MenAfriVac

- Advocacy missions: → country ownership

- Reservations raised by MOH:
  - CTC might undermine cold chain investment already planned – CTC is complementary to cold chain investment; hard to reach populations; limited freezing capacity
  - Fear of confusion at the operational level - health workers are able to distinguish between CTC and non-CTC eligible vaccines
  - Risk of higher levels of closed-vials vaccine wastage – overall not higher wastage, except for South Sudan

How to implement CTC



Field experience: MenAfriVac

	Mauritania	Togo	Côte d'Ivoire	South Sudan	DRC
# of people vaccinated in CTC	83.809	1.014.768	424.376	117.720	2.002.838
CTC coverage	101%	101%	105%	53%**	96%
campaign coverage	102%	101%	107.4%	92%	103.5%
# of vials reaching 4-day limit	421	2	16	102	32
# of vials reaching 40° C	74	0	0	498	0
CTC wastage rate	5.5%	0.002%	-11.6%	17%	0.86%
campaign wastage rate	5%	1%	-3.2%*	12%	0,003%

What are the advantages of CTC ?

- Gaining time: no need to prepare ice packs
- Transportation of vaccines without ice packs:
  → more space for more vaccines;
  → less weight of vaccine carriers
- Possibility to spend more time in the field: carry more vaccines, no need to return to health facility to replace ice packs
- Facilitates the vaccination of isolated and hard to reach populations
- Infrastructure: less worries about cold chain capacities at certain facilities

CTC at global level and next steps

- The need to use more vaccines in a CTC has been endorsed by major global health stakeholders
  - Immunization Practices Advisory Committee: IPAC
    - Working Group on CTC: WHO, UNICEF, Gavi, MSF, PATH, DCVMN, IFPMA
  - Global Vaccine Action Plan
  - Pilot Project for HPV vaccine in a CTC
  - Continued advocacy at country level
  - Continued dialogue with manufacturers

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CTC licensure in the pipeline

- **Oral Cholera vaccine**
- **HepB birth dose**
- **More HPV vaccine products**
- 8 manufacturers currently working on generating data in support of CTC for at least 10 different vaccines.

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Conclusions

- CTC is a promising approach and appreciated by health authorities and health workers
- CTC has gained momentum at global level, manufacturers have shown increased interest
- More country data are needed

For More Information on CTC

Link to CTC information + advocacy film on WHO's web site:
http://www.who.int/immunization/programmes_systems/supply_chain/ctc/en/

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Controlled Temperature Chain versus Out of cold chain

CTC

- Label specifications : 40° or more, minimum of three days
- Tested, Licensed, prequalified – **On label use**
- VVM plus Peak Threshold Temperature Indicator

OCC

- No specificity in terms of temperatures and time
- Not licensed & prequalified – **Off-license use**
- VVM monitoring, but no Peak Threshold Temperature Indicator