AN UPDATE ON WHO WORK IN SUPPORT OF THE
CONTROLLED TEMPERATURE CHAIN (CTC)
Programmatic definition of 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

1) One excursion, just prior to administration
2) Specifically limited duration (at least 3 days)
3) Ambient temperatures up to 40°C+
4) Full validation =
   - Tested (for safety & stability)
   - Licensed
   - Prequalified
5) Key tools = VVM + Peak Threshold Temperature Indicator

**PRIORITIES:** Current focus → campaigns and special strategies
Objectives for current CTC agenda

1. Improving stakeholder involvement, advocacy and alignment on CTC work streams;

2. Increasing the base of evidence in support of CTC and characterizing the value proposition of CTC with respect to improving immunization coverage and equity;

3. Developing operational guidance and communication tools in support of CTC practices; and

4. Supporting efforts towards the licensure and prequalification of appropriate vaccines for CTC.
CTC Working Group

- Established in July 2016, as a subgroup to the Immunization Practices Advisory Committee (IPAC)
- **Objective:** To promote the development and uptake of thermostable vaccines
- Includes industry representation (DCVMN & IFPMA) + partner participation (GAVI, UNICEF, PATH)
- Key outputs to date:
  1. CTC-OCC Position Paper for IPAC
  2. CTC Strategic Roadmap for Priority Vaccines
  3. * Landscape document on HepB Birthdose for CTC
  4. * Guidance on integrating CTC into HPV delivery
- Next meeting: 3-4 December 2019 (Maputo, Mozambique)
4 priority CTC vaccines:
1. Human Papilloma Virus (HPV) vaccine
2. Oral Cholera Vaccine (OCV)
3. Hepatitis B birth dose (HepB-BD)
4. Tetanus toxoid containing vaccines (TT-CV)

selected based on three criteria:

i. potential in terms of adequate heat stability;
ii. a delivery strategy that would benefit from CTC use / expressed country need; and
iii. the technical feasibility of CTC licensure.
Key Lessons learned to date: UPSTREAM (industry level)

1. CTC labelling easier to achieve with new vaccines, than with existing vaccines.

2. Early dialogue with regulatory and PQ authorities is advised.

3. Excursion duration is more important than threshold temperature.

4. ECTC Guidelines only cover regulatory requirements for CTC (not programmatic criteria.)
HOW DO **CTC** AND **ECTC** RELATE TO EACH OTHER?

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**ECTC**

EXTENDED CONTROLLED TEMPERATURE CONDITIONS
Regulatory requirements for licensure

- **Apply to** thermostable vaccines that are able to tolerate **a specified temperature** above 8°C for **a specified number of days**
- **Independent** of specific programmatic requirements

For more information on ECTC:
www.who.int/biologicals/areas/vaccines/ectc

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**CTC**

CONTROLLED TEMPERATURE CHAIN
Programmatic requirements for field implementation

- **Applies to** thermostable vaccines that are able to tolerate temperatures of **at least 40°C** for **a minimum of three days**
- **WHO provides** support through **guidance, training, and supervision**

For more information on CTC:
www.who.int/immunization/programmes_systems/supply_chain/ctc
Key Lessons learned to date:
UPSTREAM (industry level)
– continued

5. CTC programmatic definition may need to be modified to allow more vaccines to qualify.

6. Market for CTC-labelled vaccines is hard to predict.

7. Value proposition for CTC needs to be clarified.
   – Total System Effectiveness (TSE) evaluations

8. Need for signal of support / endorsement from procuring agencies.
   – Vaccine Innovation Prioritization Strategy (VIPS)
Key Lessons learned to date: DOWNSTREAM (national program level)

1. Barriers to immunization need to be clarified for value of CTC to be fully recognized.

2. Technical assistance to ensure proper planning, training, implementation and supervision is currently critical to any CTC field activity.

3. Reduced burden on HCW and reduced risk of vaccine damage considered more compelling than cost savings.

4. Countries want evidence is support of uptake, clarifying trade offs and risk/benefit balance.
CTC programmatic challenges

Risks

- More expensive vaccine
- Additional temperature monitoring
- Confusion of health workers
- Potential for increased wastage
- Additional resources required for training

Benefits

- Potential for significant cost savings (up to 50%)
- Reduced reliance on cold chain where least available
- Increased ease of transportation
- Fewer problems of humidity (leads to reduced wastage)
- Reduced burdens on health workers (more time and attention for routine activities)
- Eliminated risk of freezing
- Less resource intensive:
  - less reliance on electricity and fuel
  - less cold chain infrastructure (no ice packs)
Conclusions

- More occasions to implement CTC are required
  - Generate more data on impact (cost and coverage)
  - Document successes and lessons learned
  - More countries need to be aware and willing to consider CTC

- More advocacy with R&D stakeholders required
  - More manufacturers need to be aware and willing to consider CTC
    - Facilitated dialogue with WHO PQ
  - More partner engagement (GAVI, UNICEF SD, BMGF)
    - Shared vision + strategy required
    - Increased resource mobilization/funding required
  - More country input on priority vaccines, use case and ownership of implementation rationale
Thank You

Link to CTC information on WHO's web site:
http://tinyurl.com/WHOCTC
or

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