

AN UPDATE ON WORK IN SUPPORT OF THE CONTROLLED TEMPERATURE CHAIN (CTC)



**World Health
Organization**

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DCVMN Annual General Meeting – September 2017
PATH /UNICEF/WHO workshop on Innovative Solutions for
Vaccine Supply and Distribution

Why CTC ?

<https://tinyurl.com/WhyCTC>

CONTROLLED TEMPERATURE CHAIN (CTC) FUTURE DEVELOPMENT

Reaching more people, saving more lives

Episode 3 of 3



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Programmatic definition of CTC

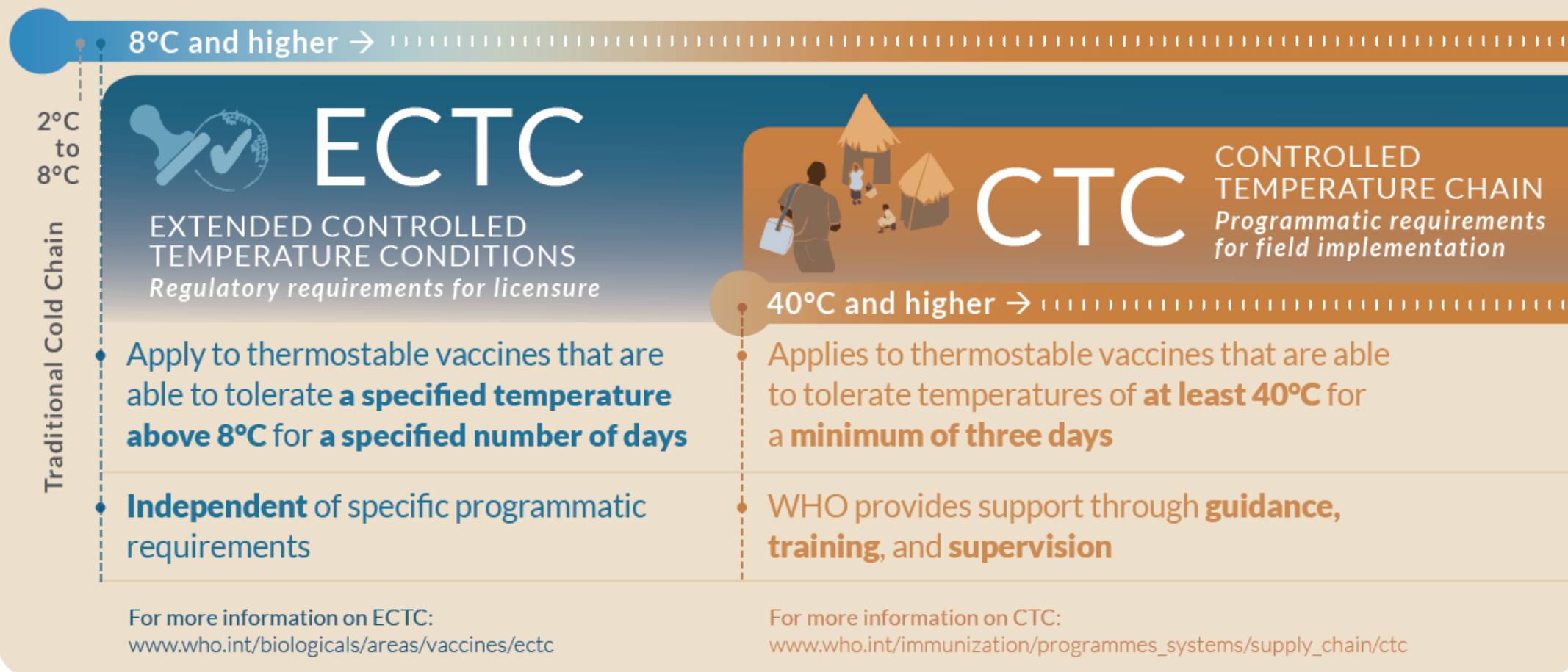
- **DEFINITION:** A specific set of conditions allowing for a vaccine to be stored and transported outside of the traditional 2° to 8°C cold chain
 - 1) One excursion, just prior to administration
 - 2) Specifically limited duration (at least 3 days)
 - 3) Ambient temperatures up to 40°C+
 - 4) Full validation =
 - ✓ Tested (for safety & stability)
 - ✓ Licensed
 - ✓ Prequalified
 - 5) Key tools = VVM + Peak Threshold Temperature Indicator
- **PRIORITIES:** Current focus → campaigns and special strategies

The CTC agenda: a 2 pronged approach

1. **UPSTREAM:** Development and licensure of more CTC-compatible vaccines
 - Regular dialogue with manufacturers and regulators to promote awareness and interest in CTC
 - Development of WHO Guidelines on the Regulatory pathway for ECTC licensure (approved by ECBS in 2015)



HOW DO CTC AND ECTC RELATE TO EACH OTHER?



The CTC agenda: a 2 pronged approach

- 1. UPSTREAM:** Development and licensure of more CTC-compatible vaccines
 - Regular dialogue with manufacturers and regulators to promote awareness and interest in CTC
 - Development of WHO Guidelines on the Regulatory pathway for ECTC licensure (approved by ECBS in 2015)
 - Clarify barriers and challenges / identifying solutions
- 2. DOWNSTREAM:** Scale up country-level experience
 - Support CTC implementation where and when feasible
 - Generate more data to articulate the CTC value proposition
 - Advocate for CTC with national stakeholders at multiple levels

Existing
and new
products

Progress to date

- December 2012 – **Meningitis A Vaccine** (MenAfriVac) licensed, prequalified and pilot tested for CTC
 - 4 days / 40°C
 - Scaled up implementation in 6 countries to date
 - Close to 4 Million vaccinated already through CTC
 - Planning ongoing, but limited to single introductions
- June 2016 – **Human Papillomavirus Vaccine** 4-valent (Gardasil4) licensed and prequalified for CTC, guidance to be developed
 - 3 days / 42°C
 - Pilot study under development for October 2017 implementation
- Next in pipeline – an **Oral Cholera vaccine** and **HepB birthdose**

Upstream barriers

- **2015 Evaluation of Manufacturers perceptions of CTC** led to the following action by WHO:
 1. Definition of overall and vaccine specific strategies
 2. Increased focus on clarifying the CTC value proposition
 3. Provision of technical assistance and guidance on the regulatory pathways (especially re. PQ)
 4. Improved communications and dialogue with industry on CTC
 - inclusion of vaccine manufacturers on the IPAC CTC WG



CTC criteria in-country

1. Confirmed need:

- Clear cold chain constraints
- Challenging outreach conditions

2. Sufficient resources & time

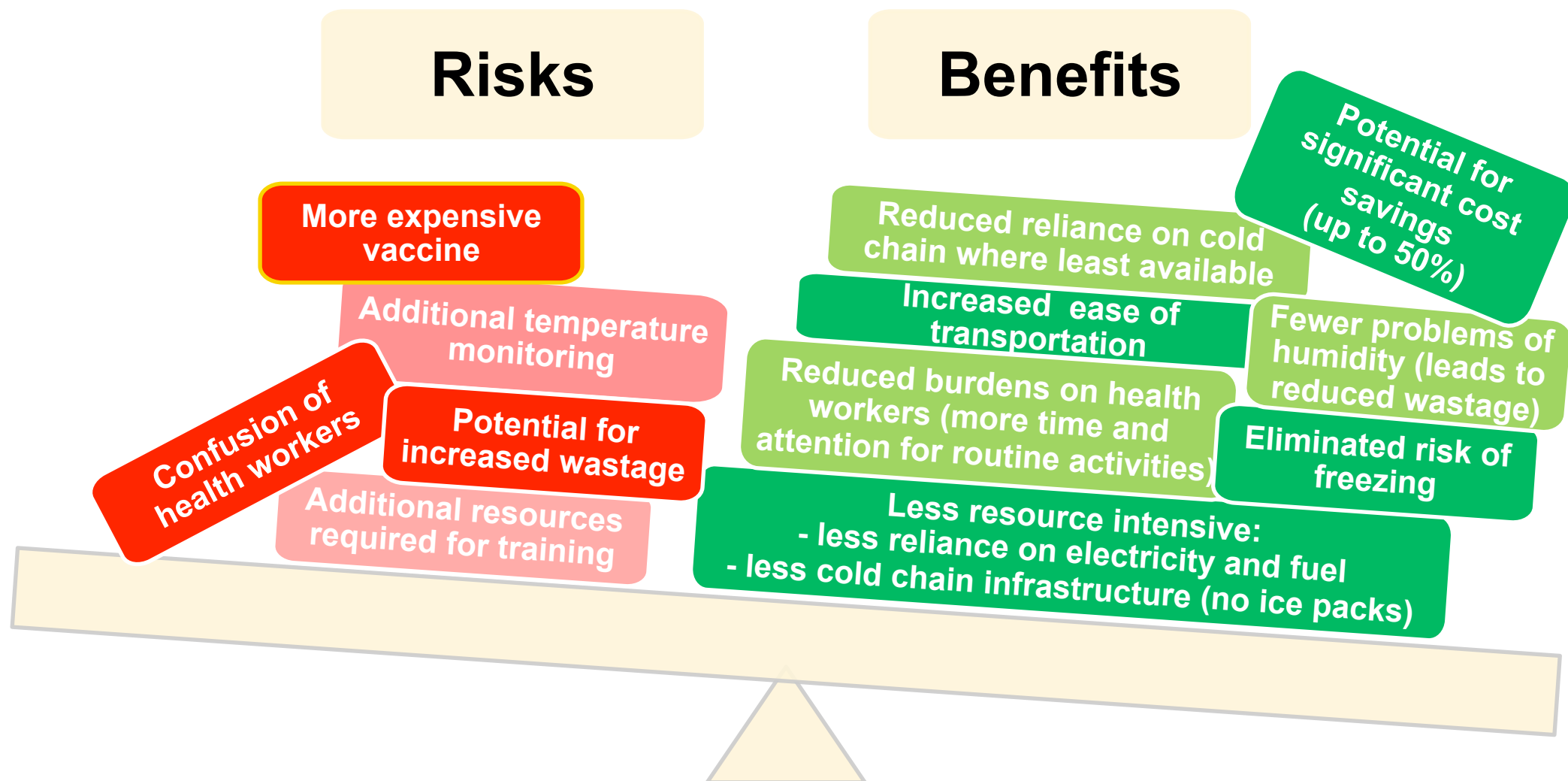
- Proper planning (2 months)
- Training
- Supervision

3. MoH & WHO approval

- Technical support
- Targeted districts (selected by MoH)



Downstream challenges



CTC Working Group

- Established in July 2016, as a subgroup to the Immunization Practices Advisory Committee (IPAC)
- Includes industry representation (DCVMN & IFPMA)
- Open teleconferences every 2 months
- Key outputs to date:
 1. CTC-OCC Position Paper for IPAC
 2. CTC Strategic Roadmap for Priority Vaccines



CTC Strategic Roadmap for Priority Vaccines

- 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)



**Downstream/
programme
level focus**



**Upstream/
industry
level focus**

- 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.



Conclusions

- More occasions to implement CTC are required
 - Generate more data on impact (cost and coverage)
 - Document successes and lessons learned
 - Improve training and monitoring
- More advocacy with stakeholders required
 - More manufacturers need to be aware and willing to consider CTC
 - More partner engagement
 - Shared vision + strategy required
 - Participation in CTC Working Group
 - Increased resource mobilization/funding required
 - More country input on priority vaccines and ownership of implementation



Thank You

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

<http://tinyurl.com/WHOCTC>

or

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

