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

https://tinyurl.com/WhyCTC

CONTROLLED TEMPERATURE CHAIN (CTC)

FUTURE DEVELOPMENT

Reaching more people, saving more lives

Episode 3 of 3

World Health Organization
**Programmatic definition of CTC**

**DEFINITION:** A specific set of conditions allowing for a vaccine to be stored and transported outside of the traditional 2°C 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?

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

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
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

Risks

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

Benefits

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

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