

The innovation of the Controlled Temperature Chain (CTC) – where do we go from here?



**World Health
Organization**

Anna-Lea Kahn - WHO-HQ/ EPI
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Programmatic definition of a Controlled Temperature Chain (CTC)

- a specific set of conditions allowing for a vaccine to be stored and transported outside of the traditional 2° to 8°C cold chain
 - One excursion, just prior to administration
 - Ambient temperatures up to 40° or more
 - Specifically limited duration/at least 3 days
- Current EPI priorities for CTC:
 - Campaigns & special settings
 - Appropriate tools: VVM, PTTI, Monitoring
 - **Tested** (for safety & stability), **Licensed & Prequalified**



The CTC Agenda : UPSTREAM

- Development and licensure of more CTC-compatible vaccines
 - Clarify definition and programmatic priorities
 - Regular dialogue with manufacturers and regulators
 - ✓ Promoting awareness and interest in CTC
 - ✓ Exploring thermostability of existing vaccines
 - ✓ Encouraging CTC consideration in new product development
 - Generic Preferred Product Profiles (VPPAG)
 - ✓ Clarifying barriers and challenges / identifying solutions
 - Development of WHO Guidelines on the Regulatory pathway for CTC licensure



CTC licensure to date

- December 2012 – **Meningitis A Vaccine** (MenAfriVac) licensed, prequalified and pilot tested for CTC
 - 4 days / 40°C
- May 2015 – **Pneumococcal Conjugate Vaccine** 13-valent (Pevnar13) licensed and prequalified for CTC, guidance to be developed
 - 3 days / 40°C
- End of 2015 – **Oral Cholera vaccine** (Shanchol) expected to be licensed and prequalified for CTC
- 8 manufacturers working on generating data in support of CTC for at least 10 different vaccines.



The CTC agenda: DOWNSTREAM

- Scale up country-level experience / boost demand
 - Integrating CTC into MenAfriVac campaigns
 - Generating more data in support of CTC
 - ✓ Operational Research: KAP, Cost-benefits, Coverage
 - ✓ Wastage, AEFI, Monitoring tools
 - Advocating for CTC with national stakeholders
 - Ensuring appropriate technical support
 - Improving training, supervision, and monitoring tools
 - Documenting and applying lessons learned
 - Developing field implementation guidelines for new vaccines



CTC Demand/Implementation Momentum

