



# 14th TechNet Conference

Immunization Supply Chain and Logistics:  
Current Challenges, Innovations,  
Future Prospects

**MAY 11-15, 2015  
BANGKOK, THAILAND**

**CTC innovation  
13 May. O.Popova**

# CTC has been on the agenda since ~2008

- Debates: all EPI vs selected / targeted vaccines (campaigns, special groups)
- Policy and regulatory considerations
- Intense dialogue, consultation of manufacturers
- Adaptation of existing vaccines vs new developments
- Inherent ability of antigens to be heat-stable
- WHO regulatory guidelines on adapted & acceptable protocols: this week for public consultation!
- Inherent tension: vaccines price pressure vs product improvements in the same markets
- BMGF effort on incentives and targeted funding for development, as well as “revising procurement mechanisms so that countries can select products that best meet their needs”
- MenAfrivac success story
- *BMGF analysis 2013*: «Overall cost savings from 1-2 CTC vaccines would represent <1% for countries»
- GAVI & partners new supply chain strategy, investment in CCE

# Our case of HepB vaccine birth dose

- Preferred presentation: single (cPAD?) / multi-dose (programmatic advantage for home birth vs cost)? Already very low-priced vaccine
- Thiomersal-free for birth dose (strong recommendations in some countries)?
- What would be the clinical study needed to support SPC change and how can the study cost get amortised?
- Which t<sup>o</sup> and for how many days should be tested and what about VVM30 use? Another CTC t<sup>o</sup> card indicator in vaccine carrier?
- Accelerate WHO PQ? Still out-of-label use of different products?
- Viable / reliable market projections? Competition. Existing / upcoming recommendations for HepB birth-dose?
- Potential funding sources: GAVI? Other donors? National?

# Where we stand today on CTC: opportunities

- We can make better vaccines, subject to scientific feasibility!
- Several research-based vaccine manufacturers are applying extensive resources, especially for PCV, HPV, Hep B, rotavirus, polio and cholera, on testing the temperature robustness of current formulations during few days without refrigeration
- Developing longer term new technologies and formulations. Partners' roles
- Genuine desire to address needs of resource-limited settings – but need for a positive business case and resolving issue of high price pressure: incentives to choose cheaper vaccine presentations. Added CTC value unlikely to be accepted for price premiums; currently no procurement mechanisms in place
- Need strong signals on recommendations for use and consistency of guidance by global health stakeholders vs improvements in cold chain capacity. Reliable and clear product demand and vaccination targets (eg. campaigns)
- Welcome long-awaited WHO regulatory guidelines!

# Where we stand today on CTC: concerns

- Responsibility to assure that a CTC-administered vaccine is safe and potent; avoid any potential mis-use
- Need for clear label guidelines. How to treat one vaccine used in both industrialised (standard label) and developing (CTC label) countries?
- What is the place of CTC versus / alongside Temperature Excursion studies which are now becoming a regulatory requirement in an increasing number of countries? “Temperature Excursion Allowance” over product life-cycle
- Incorporating CTC in early development:
  - Viable market, positive business case, incentives to invest
  - Higher probability of failure / delay to market
- Need to resolve VVM issues (*currently little flexibility to accommodate CTC*):
  - Limited discrete values of current VVMs and the kinetic behavior of the degradation (colour change) are not well adapted to the variety of behaviors that can be observed across the different types of vaccines (*eg. some vaccines can support 40° C for 3 days, but not 42° C for 1 hour, or only one day at 40° C. This is not visible with the current VVMs*)
  - Basically there is a need to better monitor temperatures for specific vaccine

# DoV GVAP conclusion on CTC: 2014 report

“Manufacturers are... showing interest in the idea that some vaccines might safely be transported and stored at a somewhat higher temperature, at least for the last part of their journey.

This “controlled temperature chain” could be cost-saving, helpfully reducing the requirement for refrigeration, which can be a challenge in remote areas with unreliable electricity. ...

Countries are not yet jumping at the idea of CTC-licensed vaccines, though. In particular, they are concerned about causing confusion amongst vaccination staff who have, for decades, been trained on the importance of maintaining the cold chain...

Manufacturers will only continue to have vaccines re-licensed for CTC use if countries show interest in using them.”