Vaccine Presentation and Packaging Advisory Group (VPPAG)

Progress on the Controlled Temperature Chain (CTC)

Update for UNICEF Vaccine Industry Consultation
27 October 2015, Copenhagen

Anna-Lea Kahn, Technical Officer
WHO/IVB/EPI
Part 1: VPPAG Update

- Mission + Structure + Process
- Membership
- Major areas of work
VPPAG Mission

To provide a platform for industry and the public sector to engage in constructive dialogue on the presentation, packaging, and delivery of vaccine products in order to harness new innovation and maximize the appropriateness of immunization products for public-sector use.
Sensitize industry to developing-country programmatic preferences and operational realities, and sensitize the public sector to industry constraints and economic realities.
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<th>Organization</th>
<th>VPPAG Members</th>
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<tr>
<td>Bill &amp; Melinda Gates Foundation</td>
<td>Tina Lorenson</td>
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<td>Developing Countries Vaccine Manufacturers Network (DCVMN)</td>
<td>Fernando Lobos (Sinergium Biotech), Sai Prasad (Bharat Biotech), Inderjit Sharma (Serum Institute of India, Ltd.)</td>
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<td>Gavi, The Vaccine Alliance</td>
<td>Edward Baker, Lauren Franzel</td>
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<td>International Federation of Pharmaceutical Manufacturers &amp; Associations (IFPMA)</td>
<td>Andrea Arancibia (Sanofi Pasteur), Sy Gebrekidan (Merck)</td>
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<td>John Snow, Inc.</td>
<td>Ousmane Dia, Robert Steinglass</td>
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<td>Médecins Sans Frontières</td>
<td>Florence Fermon</td>
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<td>PATH</td>
<td>Debra Kristensen (VPPAG Chair), Darin Zehrung</td>
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<td>US Centers for Disease Control and Prevention</td>
<td>Carla Lee, Hardeep Sandhu</td>
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<td>World Health Organization (WHO) / Expanded Programme on Immunization (EPI)</td>
<td>Anna-Lea Kahn (VPPAG Convener)</td>
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<td>WHO / Initiative for Vaccine Research (IVR)</td>
<td>Birgitte Giersing</td>
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<tr>
<td>WHO / Prequalification Team (PQT)</td>
<td>Isaac Gobina, Drew Meek</td>
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VPPAG Mechanisms of Action

- Generating generic preferred product profile recommendations* for vaccines.
- Responding to industry requests for guidance on specific product presentation issues.
- Serving as a standing subcommittee of the WHO Immunization Practices Advisory Committee (IPAC).
- Topic specific-working groups to generate/review evidence and advance consensus recommendations

*http://www.who.int/immunization/policy/committees/VPPAG_Generic_PPP_and_Workplan.pdf?ua=1
VPPAG 2015 Working Groups

PACKAGING – Led by Denis Maire, WHO QSS

BAR CODING – Led by Kaleb Brownlow, Gavi + Rich Hollander, Pfizer

DELIVERY TECHNOLOGY – Led by Birgitte Giersing, WHO IVR + Darin Zehrung, PATH

Photo: Serge Ganivet

Photo: PATH/Patrick McKern
For More Information on VPPAG

- **Secretariat:** Dmitri Davydov, UNICEF
davydov@unicef.org

- **Chair:** Debbie Kristensen, PATH
dkristensen@path.org

- **Link to VPPAG information** on WHO’s web site:
http://tinyurl.com/vppag
Part 2: CTC Update

- What is CTC? Why do we need it?
- Upstream vs Downstream efforts
- 2014 and 2015 progress
- Program priorities and partners
Programmatic definition of 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°
  - Specifically limited duration (at least 3 days)
CTC Workplan – Programmatic incentives

**CHALLENGE:** The logistics for campaigns— from surge cold chain capacity to ice pack freezing are extremely complex and time consuming

**BENEFITS:** Allowing more cost-effective & efficient immunisation programmes, particularly in the last mile of outreach efforts.

**OBJECTIVES:** Increase number of CTC-compatible vaccines on market and ensure a clear and appropriate CTC implementation strategy.
Developing 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 (via Evaluation conducted by Steve Jarrett)
- Development of WHO Guidelines on the Regulatory pathway for ECTC licensure
WHO Guidelines on Stability Evaluation of Vaccines under Extended Controlled Temperature Conditions (ECTC)

- Term ECTC developed to distinguish **Regulatory requirements** from Programmatic requirements (CTC)
- ECTC is independent of specific programmatic needs
- Developed with wide consultation
- Describe stability evaluation of a specific vaccine when exposed to a single short term temperature change immediately prior to administration
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 (Prevnar13) licensed and prequalified for CTC, guidance to be developed
  - 3 days / 40°C

- Next in pipeline— an **Oral Cholera vaccine** and **HPV** product are expected to be licensed and submitted for prequalification within next 6 months

- 8 manufacturers currently working on generating data in support of CTC for at least 10 different vaccines.
Global-level priority

- The need to use more vaccines in a CTC has been endorsed by major global health stakeholders
  - IPAC
  - VPPAG
  - GVAP
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
- Planning pilot implementation efforts for vaccines in CTC pipeline
Where is CTC used?
Last Mile Challenges at 2-8°C

- Carrying vaccines, cold water packs and supplies
- Getting out and back in one day
- Conditioning ice packs to avoid freezing
- Navigating rough roads and trails (and maintaining a vehicle)
- Reaching an active population
- Refreshing cooling supplies mid-day
- Estimating the correct quantify of vaccine required
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Last Mile Challenges in a CTC

Carrying vaccines, cold water packs and supplies

Navigating rough roads and trails (and maintaining a vehicle)

Reaching an active population

Estimating the correct quantity of vaccine required
CTC Demand/Implementation Momentum

To date, MenAfrivac has been the only vaccine licensed for CTC use. More vaccines are expected to be licensed for CTC in the near future.
CTC: EPI Strategic priorities

- Single-antigen vaccines
- Campaigns and special strategies
- Minimum 3 days
- Can tolerate up to at least 40°C
- VVM & Peak Threshold Temperature Indicator

Tested (for safety & stability), Licensed & Prequalified
Partners

PATH / WHO: (via Project Optimize, completed in 2013 and additional collaboration in 2014)
- MenAfriVac CTC license obtained – 2012.
- CTC pilot implementation, Benin – 2012.
- MenAfriVac CTC country implementation guidelines – 2012.
- Studies: CTC Cost Effectiveness Study/Chad (2012) and Togo (2014), CTC feasibility/Mali, CTC potency/Chad
- MenAfriVac implementation in DRC – 2015/2016

AMP: AEFI Study on MenAfriVac used in a CTC, Benin – 2012.

MSF: Tetanus Toxoid CTC study, Chad – 2013 + Advocate for CTC.

BMGF and GAVI: Funding + advocacy support.
For More Information on CTC

- **WHO Focal Point:** Anna-Lea Kahn, EPI/IVB
  kahna@who.int

- **Link to CTC information + advocacy film** on WHO’s website: [http://tinyurl.com/WHOCTC](http://tinyurl.com/WHOCTC)
Thank You