

Designing Vaccines for Developing Country Populations

Ideal Attributes, Delivery Devices, and Presentation Formats

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OPTIMIZE

Immunization systems and technologies for tomorrow



Presentation outline

Background

- Future vaccine products.
- Project Optimize
- Vaccine Presentation and Packaging Advisory Group (VPPAG).
- Generic preferred product profile (gPPP) for vaccines.

Recommendations and ongoing work

- Formulation.
- Presentation.
- Labeling.
- Packaging.

Roles for vaccine developers

Vaccine products: what will the future bring?

More antigens

- Cholera, H1N1, human papillomavirus (HPV), pneumococcal, rotavirus, rubella, typhoid...

More delivery routes and devices

- Dissolvable tablets, intradermal, jet injectors, nasal, sublingual...

New target-age groups and strategies

- School-age children, newborns at home, epidemics...

New handling instructions

- Low dose without preservative.
- New temperature storage ranges.
- Addition of buffer or diluent with adjuvant.

= More Complexity

How is Optimize involved?

- **Five-year project managed by WHO and PATH.**
- **Thinking ahead to shape the future of technologies and logistic systems for vaccines in low- and middle-income countries.**
- **Scope includes working with stakeholders to optimize future vaccine products.**

Vaccine Presentation and Packaging Advisory Group (VPPAG) :

- **Facilitate improvements in the presentation and packaging of emerging vaccine products to maximize their appropriateness for developing-country markets.**
- **Provide a forum for dialogue between the public sector and industry regarding product-profile decisions.**
- **Provide input to WHO policy development.**

VPPAG history

- **Established by the GAVI Alliance in 2007 to focus on product profiles for pneumococcal and rotavirus vaccines.**
- **Governance transitioned to WHO in 2008.**
- **Also supported by the United Nations Children's Fund (UNICEF) and Optimize.**
- **Now working on generic and specific product profiles for new vaccines.**

Current VPPAG membership

CDC: **Hardeep Sandhu**

DCVMN: **Selwyn Kahanovitz (Biovac/Litha Healthcare)**

GAVI Alliance: **Jon Pearman**

IFPMA: **Christopher Nelson (Merck)**

John Snow, Inc.: **Robert Steinglass**

PATH: **Debra Kristensen; Simona Zipursky, Secretary**

UNICEF Program Division: **Osman Mansoor, Chair**

UNICEF Supply Division: **Ann Ottosen**

WHO, IVB: **Soulemane Kone, Convener; Gill Mayers**

WHO, QSS: **Drew Meek**

Generic preferred product profile for vaccines

- Vetted with constituents from industry and public-sector agencies.
- Consensus reached on existing recommendations.
- Endorsed by many vaccine development programs.
- Includes a work program to add specificity to recommendations.

Vaccine Presentation and Packaging Advisory Group
Generic Preferred Product Profile for Vaccines

Version 2.1

Recommendations and Work Programme



Draft: 25 August 2009

Available on Conference CD and also at :
<http://sites.google.com/site/vppagp/gppp>

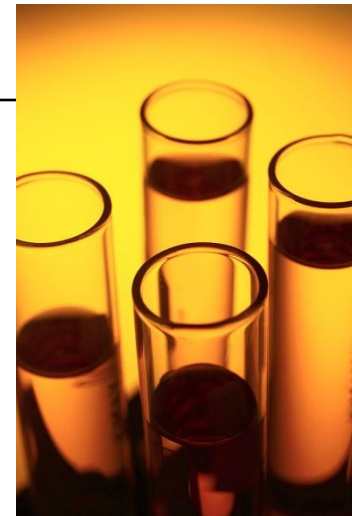
Formulation

Recommendations (from gPPP)

- Ready-to-use presentations preferred.
- Maximize heat- and freeze-stability and license for higher temperature storage.
 - Freeze-protection technology available from PATH—in public domain.
- Multidose vials should contain antimicrobial preservatives, where feasible.

Ongoing work

- Optimize is leading efforts to define desirable higher temperature storage conditions for vaccines using hepatitis B vaccine as a pathfinder.
 - Advisory group established with national regulatory authorities from Germany, South Korea, Thailand, and the United Kingdom.
 - Laboratory study coordinated by WHO/QSS with six brands of hepatitis B vaccine—includes stability testing at 45°C for seven days and correlation of potency with vaccine vial monitor (VVM) readings.



Presentation



Recommendations (from gPPP)

- Format should minimize number of steps and potential for programmatic errors.
- Vaccines in prefilled injection devices should have both space-saving and autodisable features.

Ongoing work

- Vaccine Presentation Assessment Tool developed by MVI* and further advanced by Optimize to help determine optimal doses per container for specific vaccines and use scenarios.
- WHO/IVB gathering data on session sizes to help inform doses per container decisions.
- Optimize and VPPAG investigating barriers/opportunities for introduction of prefilled devices.

Labeling

Recommendations (from gPPP)

- Include VVMs on all vaccines, as recommended by WHO and UNICEF.



Photo: PATH

Ongoing work

- WHO is exploring placement of a visual cue on primary containers to identify when they can be kept for subsequent sessions once opened.
- In response to an industry request, VPPAG plans to develop guidance on the optimal location and number of inserts in secondary or tertiary packaging that will meet regulatory requirements.

Packaging

Recommendations (from gPPP)

- Minimize volume and weight of secondary and tertiary packaging, as well as the need for repackaging for in-country supply chain distribution.
- Use materials that minimize the environmental impact of waste disposal for resource-limited systems.



Photo: Julie Jacobson

Ongoing work (by WHO, Optimize, and VPPAG)

- Proposing new maximum packed volume recommendations for all levels of packaging.
- Investigating the possibility of bundling multiple-component products.

VPPAG can assist with specific product profiles (e.g., current work on 2nd generation HPV vaccines)

Working with countries already introducing HPV vaccine to assess:

- Session sizes and vaccine wastage to determine optimal doses per container.
- Ambient temperatures during outreach to determine potential for controlled ambient temperature storage/transport.
- Immunization program stakeholder views regarding desirable product attributes.



Photo: PATH

Roles for vaccine developers

Consider product profile issues from the beginning of the product development process.

Review the generic Preferred Product Profile and explore applicability to vaccines in development.

Provide feedback to the VPPAG on:

- Recommendations.
- Best ways to disseminate information and engage vaccine developers.

Use the VPPAG as a resource to:

- Develop specific product profiles.
- Obtain feedback on product profile issues from the public sector and/or industry.
 - Confidential bilateral discussions between VPPAG and industry are possible.
- Analyze trade-offs during product development.

Merci! Thank you!

For more information:

www.technet21.org

www.path.org

www.who.int

<http://sites.google.com/site/vppagp/>



Photo: UNICEF