World Health Organization—Next-Generation Vaccine Delivery Technology Meeting Summary

Global Vaccine and Immunization Research Forum
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Darin Zehrung
dzehrung@path.org
Senior Technical Officer and Portfolio Leader, Delivery Technologies
PATH
Vaccine and Pharmaceutical Technologies Group
New and alternative delivery technologies

- Many new technologies are needle-free.
- Some are compatible with existing vaccine formats (e.g., vials or ampoules).
- Others are integrated with formulation (e.g., combination products).
- Improved ease of vaccine delivery, efficacy, cost-effectiveness, and safety are areas of focus.
- Developers include industry, academic, and nonprofit research groups.
Potential public health benefits

- Increase vaccine access and coverage—enable community health workers to deliver vaccines.
- Improve immunogenicity.
- Reduce the need for and the number of injections.
- Reduce risk of infections/cross-contamination.
- Reduce potentially dangerous sharps waste.
Potential public health benefits

- Relieve tensions and fears surrounding immunization.
- Reduce drop-out by optimizing schedules.
- Reduce health worker workload—simplified administration and reconstitution (free up time for other tasks).
- Reduce cold chain dependency through improved thermostability (heat and freeze stability).
Meeting background and objectives

• Follow-on to 2013 NUVI meeting. Theme: Innovation in Immunization.

• Objectives:
  – Review lessons learned of earlier vaccine technologies.
  – Conduct rapid review of existing and future technologies:
    ▪ Delivery devices, packaging, and vaccine formulation.
  – Provide a vision for the future of vaccine delivery technologies:
    ▪ Short-term (within the Decade of Vaccines timeline) and long-term objectives (beyond 2020).
  – Determine strategic next steps to guide and enable the development, introduction and uptake of new technologies, to include industry incentives, with potential for public health impact.
Meeting participants

- **Technology developers** (multiple industry, academia – representing 9 universities).

- **Vaccine manufacturers** (BioFarma, Crucell, GlaxoSmithKline [GSK], Serum Institute of India, Ltd. [SIIL], Sanofi, Merck, Pfizer, Thai Red Cross).

- **Public-sector agencies** (World Health Organization [WHO], United Nations Children's Fund [UNICEF]), United States Centers for Disease Control [CDC]).

- **Nongovernmental organizations** (Bill and Melinda Gates Foundation [BMGF], PATH, Aeras, Doctors Without Borders/Médecins Sans Frontières International [MSF], Clinton Health Access Initiative [CHAI], GAVI Alliance, Global Good, Intravacc).

- **Regulatory authorities** (WHO, Brazil, Nigeria, Tanzania, the Netherlands).
Questions and meeting themes

- Technology innovation
- Trends
- Investment
- Challenges
- Lessons learned
- Public health need
- Priorities

Photo: PATH/Gabe Blenczynski

Photo: Georgia Institute of Technology

Photo: Bill & Melinda Gates Foundation

Photo: PATH
Lessons learned—technologies

- **Autodisable (AD) syringes:**
  - Providing clear direction to developers is critical.
  - Global leadership is essential (WHO, UNICEF).
  - A long-term commitment to the technology is necessary.

- **Vaccine vial monitors (VVMs):**
  - Perseverance is key.
  - Champions are crucial.
  - WHO policies help drive uptake.
  - Global effort and long-term financial support required.

- **Uniject injection system:**
  - Demand drives uptake.
  - Value proposition analysis is important.
  - Regulatory processes must be considered.
  - Incentives are necessary.
Technologies reviewed and represented

**Delivery devices**
- Disposable-syringe jet injectors
- Intradermal delivery devices
- Electroporation
- Intranasal delivery
- Microneedles
- Aerosol/dry powder inhalation

**Packaging**
- Novel primary containers
- Reconstitution
- Improving packaging materials and reducing volumes

**Formulation**
- Mucosal delivery
- Solid-dose implants
- Thermostability (heat/freeze)

All photos: PATH
Microneedles
Intradermal delivery

Photos: West Pharmaceutical Services

Photos: Star Syringe
Disposable-syringe jet injectors
Intranasal spray/atomizers

Photo: ©Serum Institute of India, Ltd.

Photo: ©The Hindu.

Photo: ©LMA.
Aerosolization/nebulizers
Dry-powder inhalers

Photos: ©AktivDry.
Reconstitution
Blow-fill-seal
Preservative-free packaging
Electroporation

1) Single Use Applicator Cartridge

2) Plasmid - DNA / Therapeutic Agent

Photo: ©Ichor Medical Systems, Inc.

Photo: ©Inovio Pharmaceuticals Inc.

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Solid-dose/dissolvable needles
New vaccine technologies—key input

A **bold, transformative** vision must be generated, incorporating technology and industry trends.

Public sector must define needs and objectives—**problem statement**—eliminate conflicting messages.

**Regulatory process and requirements** must be established at global and country level—guidance documents?

**Improved cost benefit analysis** is required to assess new technologies—to include systems costs. Who pays and who benefits?
Lessons learned are critical to capture both successes and challenges.

Developers need **feedback and guidance**—Vaccine Presentation and Packaging Advisory Group (VPPAG) expansion?

**Country input** is critical (design/prioritization/procurement).

**Incentive structures** are needed to push and pull promising ‘game changer’ technologies forward—advance market commitments (AMCs), other mechanisms?
Meeting participant poll results: Vision of the future of immunization

- Integrated combination products available to be used by community health workers (85 percent).
- No more manual reconstitution of vaccines (69 percent).
- Significantly improved thermostability of new EPI vaccines (66 percent).
- No more needles to administer vaccines (53 percent).
- Combining vaccines at the point of delivery (49 percent).
Proposed next steps—strategy and evidence base

- **Develop vision and goals** for the next decade(s).

- **Identify champions** to move the process forward.

- **Develop a forum** for device developers to seek feedback from VPPAG—initiate guidance documents.

- **Establish cost-benefit analysis** criteria and thresholds from a system perspective—vaccine-specific investment cases?
Proposed next steps—strategy and evidence base (cont.)

- **Support the formation of associations** of vaccine device developers, academia, and vaccine manufacturers.
- **Conduct a comprehensive assessment** on the vaccine delivery technology needs of developing countries—the user perspective is key.
- **Set up country sites** (e.g., WHO Collaborating Centers) for new technology field evaluations.
- Prepare for a **future SAGE discussion** on new vaccine delivery technologies.
Proposed next steps—regulatory

**Develop guidance on the regulation** of combinations of devices and vaccines with regulators—enable harmonization and maintain flexibility.

**Hold follow-up meetings**: Device-specific, regulatory (devices and vaccines) meetings to include key stakeholders.

**Consider facilitated country registration procedures** for WHO-prequalified vaccines and recommendation for delivery with specific devices.
Thank you!

Carsten Mantel  
Priority Area Leader  
New Vaccines and Innovations  
Expanded Programme on Immunization (EPI)  
Dept. of Immunization, Vaccines and Biologicals (IVB)  
World Health Organization  
mantelc@who.int

Darin Zehrung  
Senior Technical Officer & Portfolio Leader, Delivery Technologies  
Vaccine and Pharmaceutical Technologies Group  
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dzehrung@path.org