

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

Global Vaccine and Immunization Research Forum
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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.



Photo: Georgia Tech



Photo: The Hindu



Photos: PATH

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.

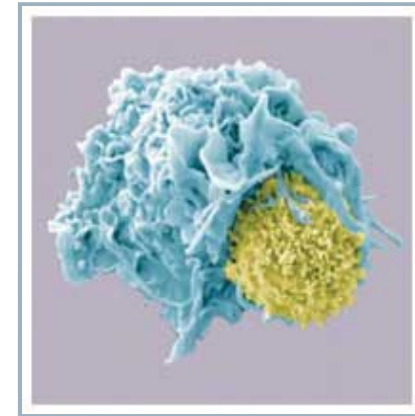


Photo: WHO



Graphic: PATH

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).



Photo: PATH\Ümit Kartoglu



Photo: PATH/Debra Kristensen



Photo: PATH/Debra Kristensen

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



All photos: WHO

- **Technology developers** (multiple industry, academia – representing 9 universities).
- **Vaccine manufacturers** (BioFarma, Crucell, GlaxoSmithKline [GSK], Serum Institute of India, Ltd. [SII], 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

Photo: Georgia Institute of Technology

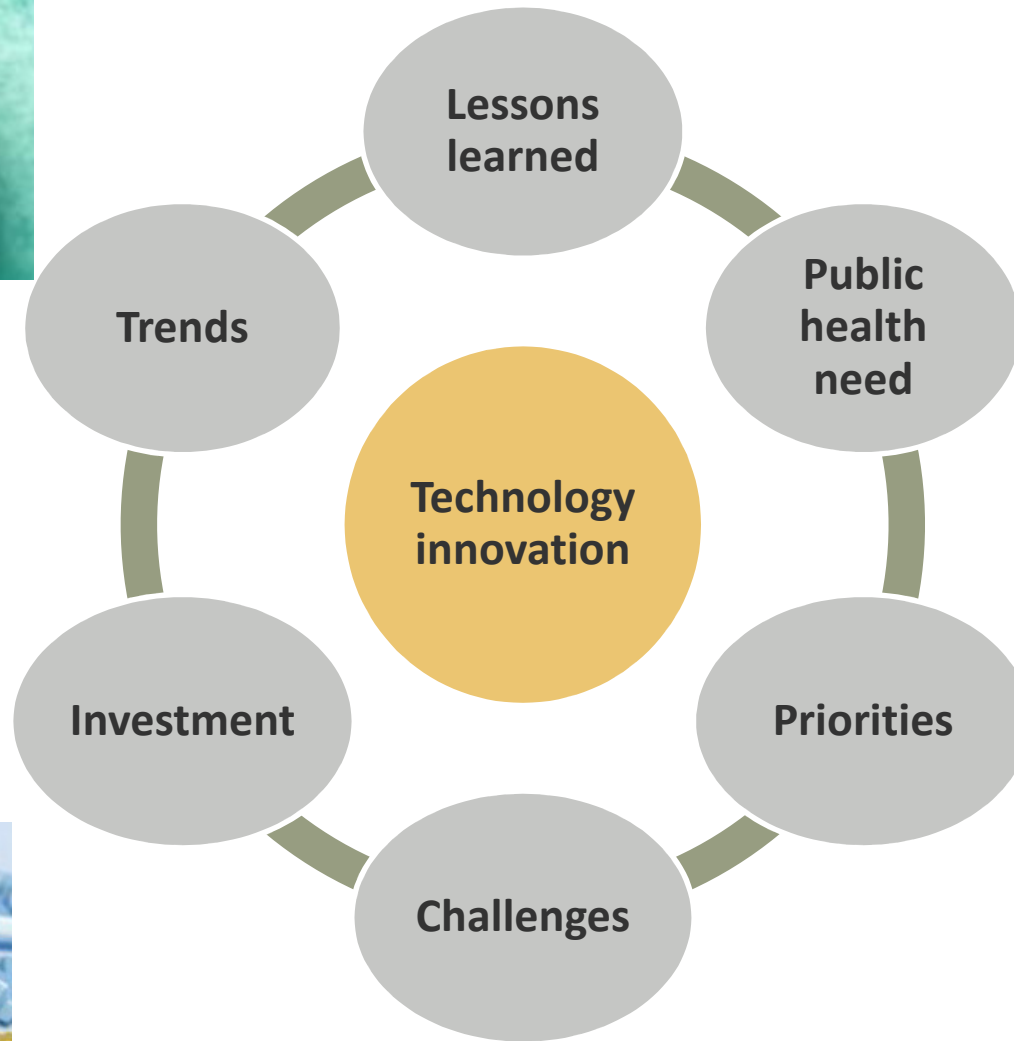
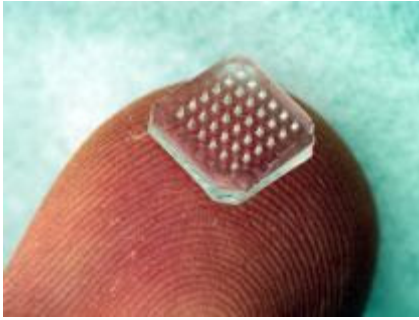


Photo: Bill & Melinda Gates Foundation



Photo: PATH



Photo: PATH\Gabe Bienczycki

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.



Photo: Umit Kartoglu



Photo: Becton Dickinson (BD)



Photo: Becton Dickinson (BD)

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)

Microneedles



Photo: ©PATH.

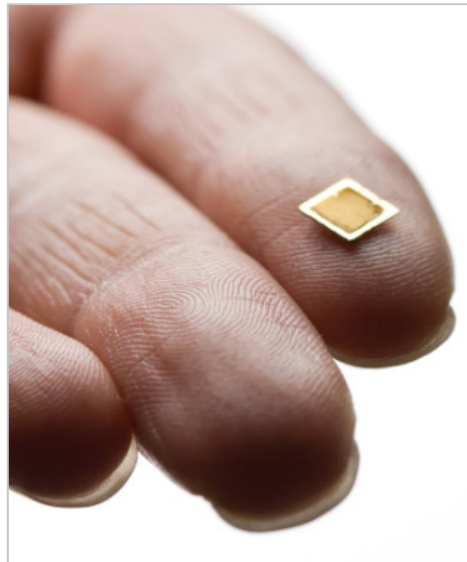


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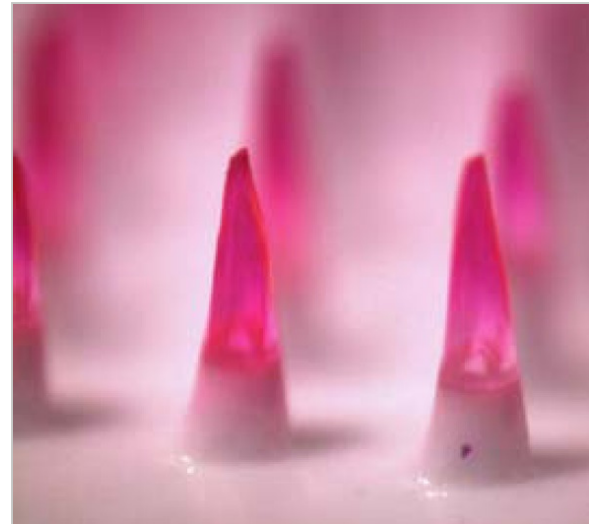


Photo: ©Georgia Tech.

Intradermal delivery



Photos: West Pharmaceutical Services



Photos: Star Syringe

Disposable-syringe jet injectors



Photo: ©PharmaJet.



Photo: ©PATH.



Photo: ©PATH.

Intranasal spray/atomizers

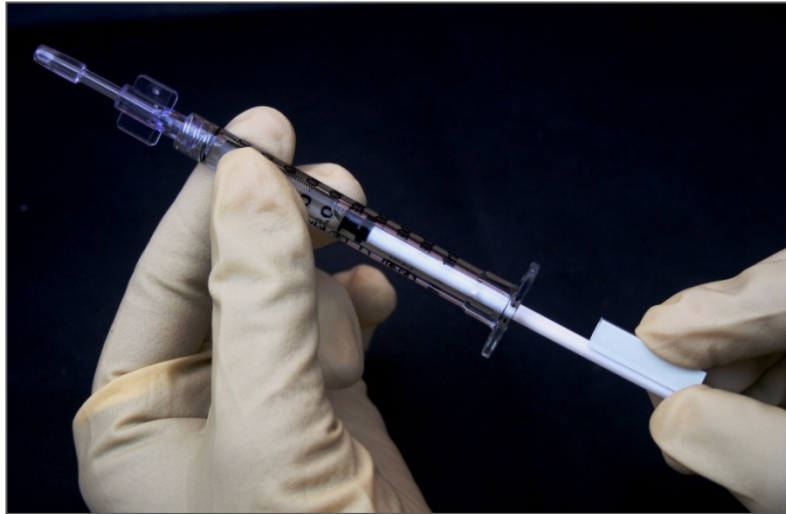


Photo: ©Serum Institute of India, Ltd.



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Photo: ©LMA.

Aerosolization/nebulizers



Photos: ©World Health Organization

Dry-powder inhalers



Photos: ©AktivDry.

Reconstitution



Photo: ©Eulysis.



Photo: ©Aktivax.



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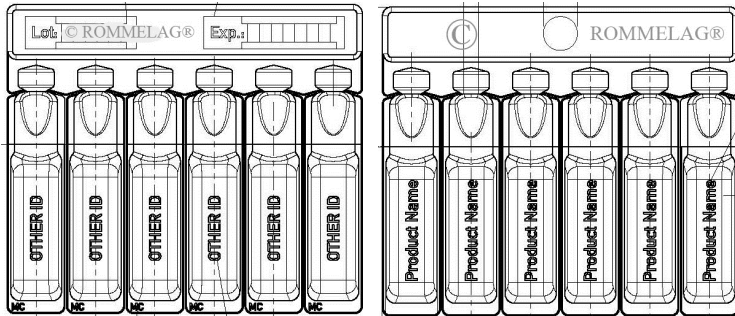


Photo: Duoject



Photo: Lyogo

Blow-fill-seal



Photos/graphics: © Rommelag.

Preservative-free packaging



Photos/graphics: © Medical Instill (MEDInstill)

Electroporation



Photo: ©Ichor Medical Systems, Inc.

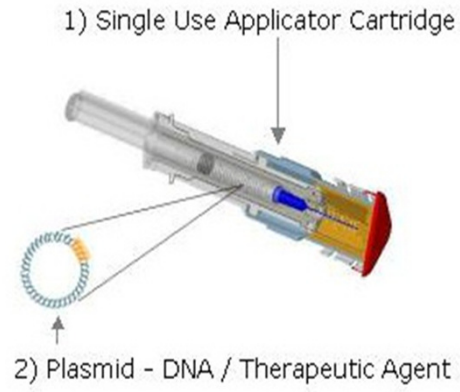


Photo: ©Ichor Medical Systems, Inc.



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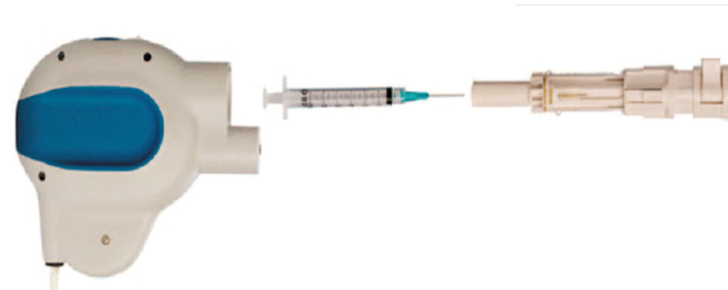


Photo: ©Ichor Medical Systems, Inc.

Solid-dose/dissolvable needles



Photo: ©Glide Pharma

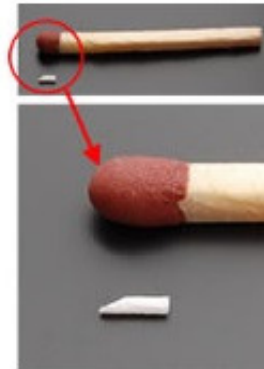


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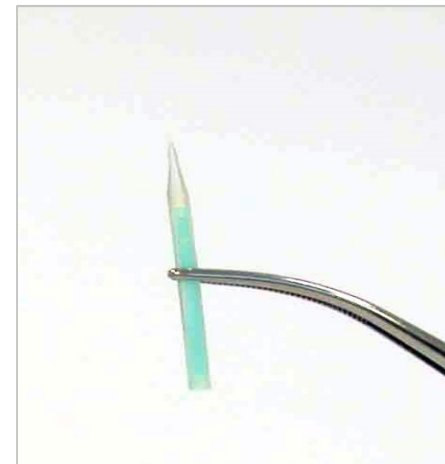


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New vaccine technologies—key input

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?

New vaccine technologies—key input (cont.)

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!

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