The Promise of New Vaccine Delivery Technologies

Next-Generation Vaccine Delivery Technology Meeting
Geneva, Switzerland

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February 18, 2014

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A catalyst for global health

Photo: PATH

New and alternative delivery technologies

- Many new technologies are needlefree.
- Some are compatible with existing vaccine formats (e.g., vials or ampoules).
- Others are integrated with formulation (e.g., vaccines or adjuvants).
- There is the potential for improved thermostability out of the cold chain.
- Improved ease of vaccine delivery and safety for health care workers and the public is a key focus.
- This is through a combination of industry, academic, and nonprofit research projects.

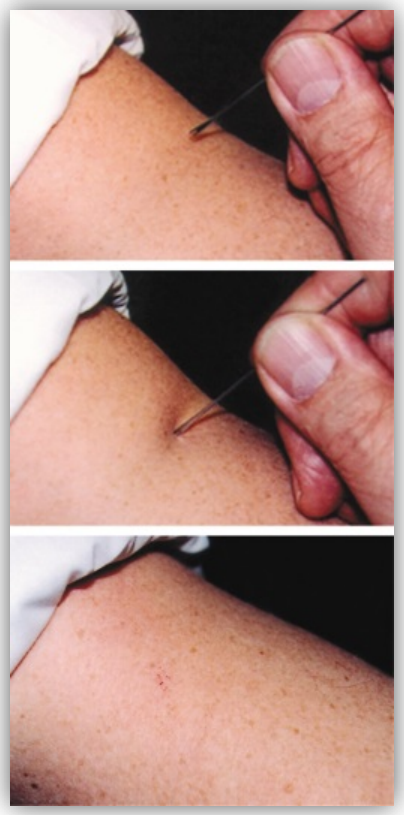
Photo: Georgia Tech

Photo: The Hindu

Photos: PATH

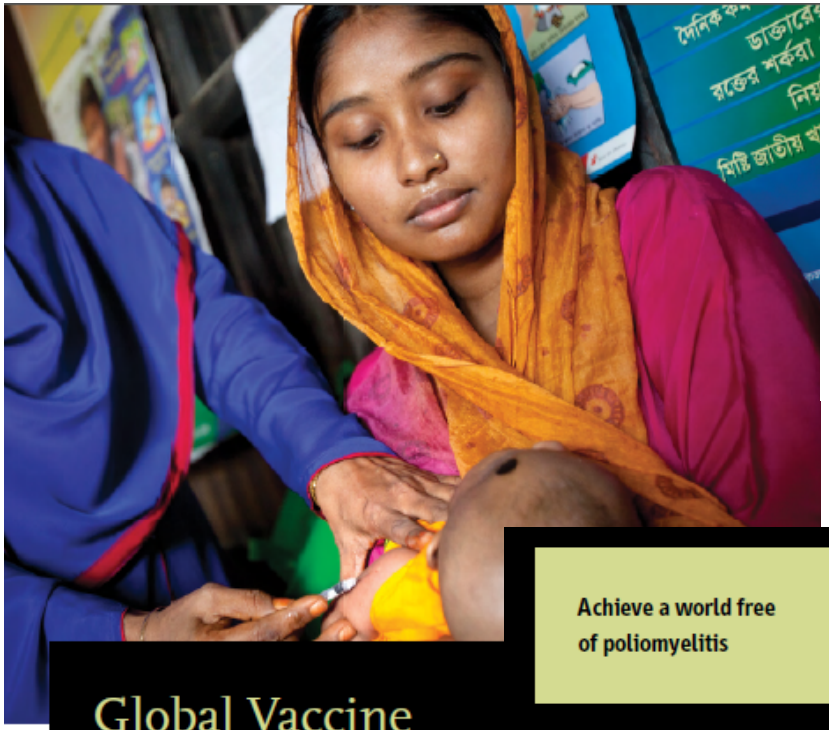
Innovative delivery technologies of the past—smallpox

- The first half of the smallpox eradication program used high-speed jet injectors with intradermal nozzles, delivering tens of millions of doses.
- Bifurcated needles replaced jet injectors for the later half of eradication.
- Alternative delivery technologies were critical in the success of smallpox eradication.



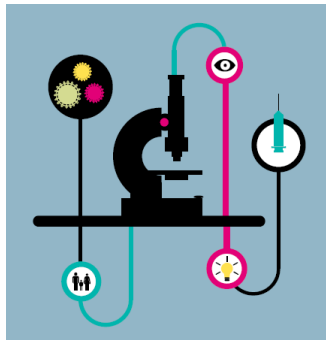
Photos: Bruce Weniger

Global Vaccine Action Plan



Strategic objective 6

Country, regional and global research and development innovations maximize the benefits of immunization.



Global Vaccine Action Plan
2011–2020

- Achieve a world free of poliomyelitis
- Meet global and regional elimination targets
- Meet vaccination coverage targets in every region, country and community
- Develop and introduce new and improved vaccines and technologies
- Exceed the Millennium Development Goal 4 target for reducing child mortality

Source: World Health Organization (WHO). *Global Vaccine Action Plan, 2011–2020*. Geneva: WHO; 2013. Available at: http://www.dovcollaboration.org/action-plan/

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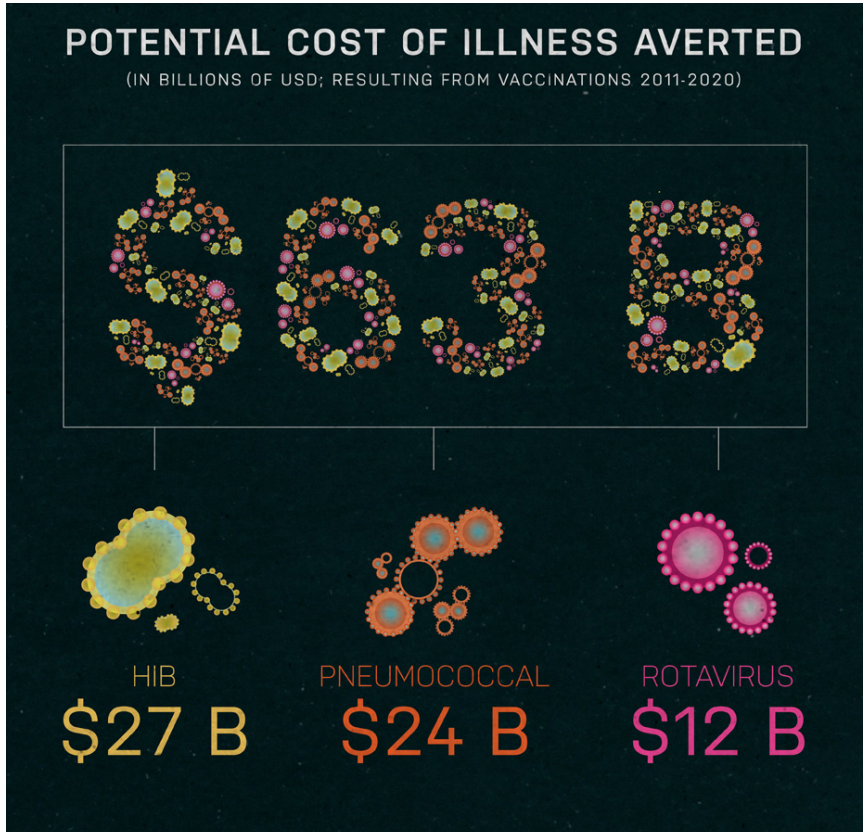
Projected benefits of vaccines worldwide: 2010 to 2020

Bill & Melinda Gates Foundation: Vaccines Work



Source: Bill & Melinda Gates Foundation. *Vaccines Work*. Seattle: Bill & Melinda Gates Foundation; 2013. Available at: http://www.gatesfoundation.org/What-We-Do/Global-Development/Vaccine-Delivery/Infographics#.

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Vaccine delivery technologies:
Potential public health benefits

- **Vaccine safety and efficacy:**
  - Improve existing vaccines.
  - Enable new vaccines to reach clinical targets.
  - Realize new routes of administration.
  - Increase efficacy in different populations.
- **Economics and vaccine availability:**
  - Drive efficiencies in immunization programs.
  - Promote schedule reduction.
  - Increase the availability of high-cost or supply-constrained vaccines.

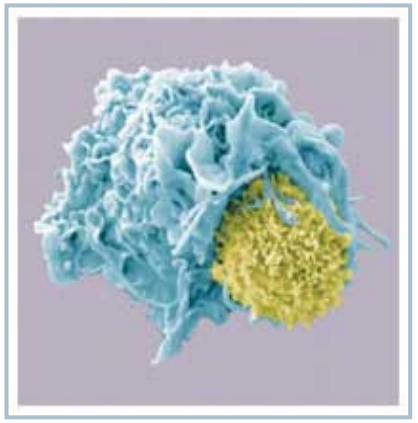
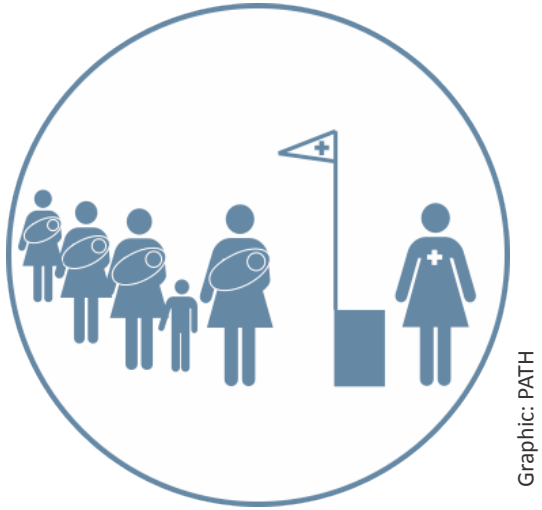


Photo: WHO



Graphic: PATH

Vaccine delivery technologies:
Potential public health benefits

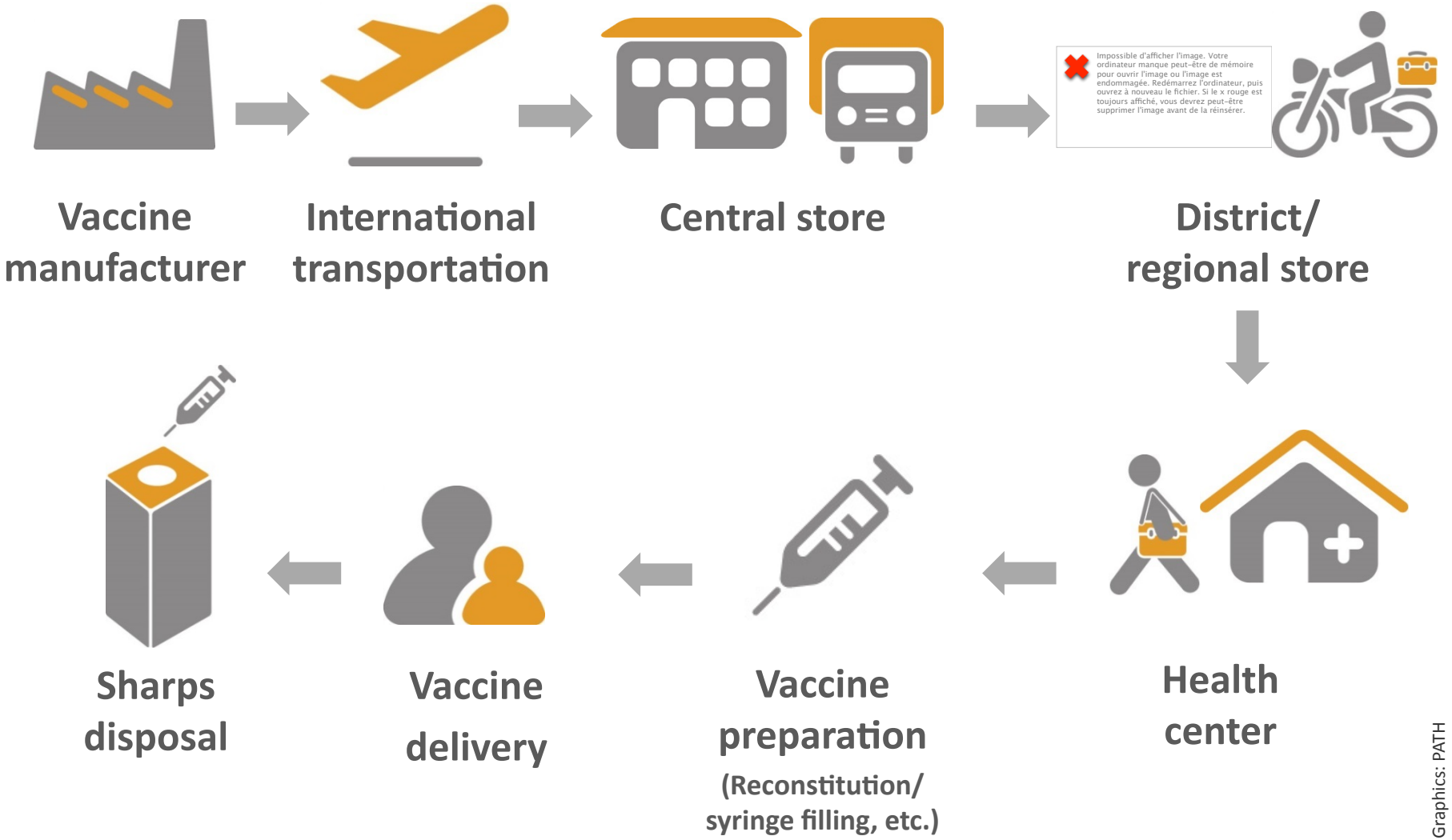
- **Vaccine logistics:**
  - Increase efficiency in the vaccine supply chain.
  - Eliminate the need for the cold chain.
  - Enable more rapid outbreak response.
- **Vaccine delivery:**
  - Eliminate sharps waste.
  - Reduce number of steps for vaccine preparation and delivery.
  - Increase vaccination coverage and public acceptance.

Photo: PATH\Ümit Kartoglu

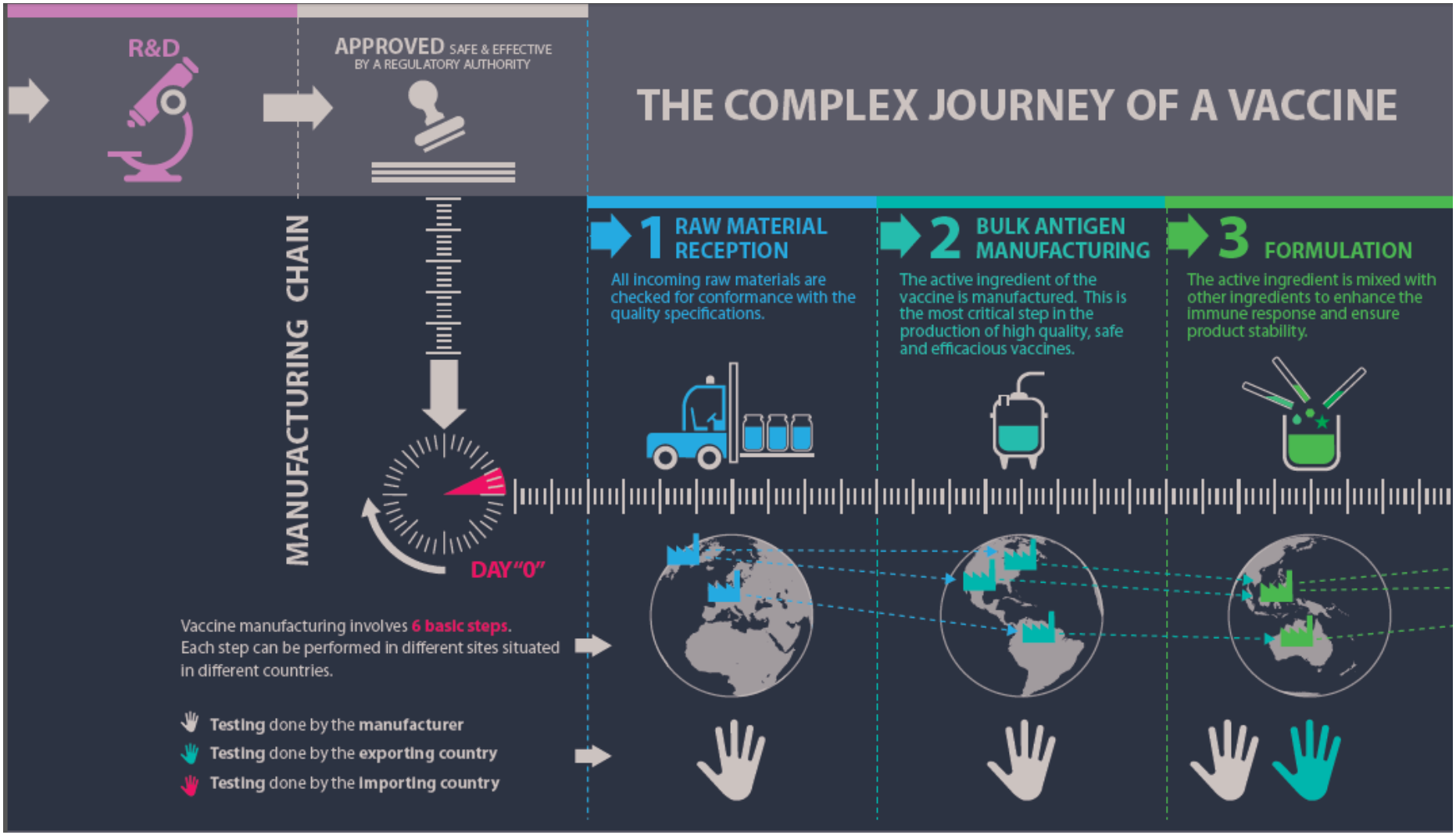
Photo: PATH/Debra Kristensen

Photo: PATH/Debra Kristensen

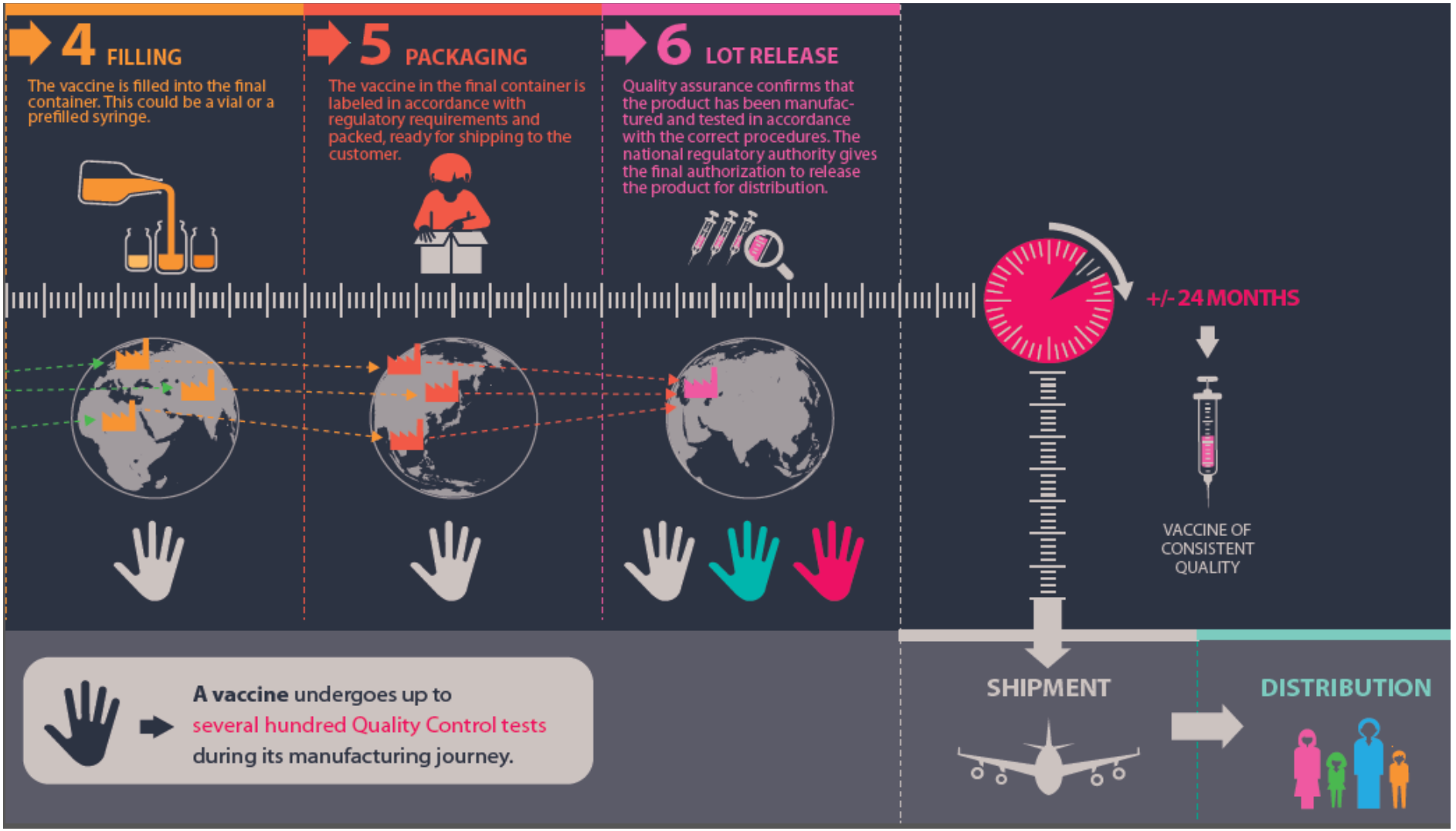
Vaccine delivery—where can innovation occur?



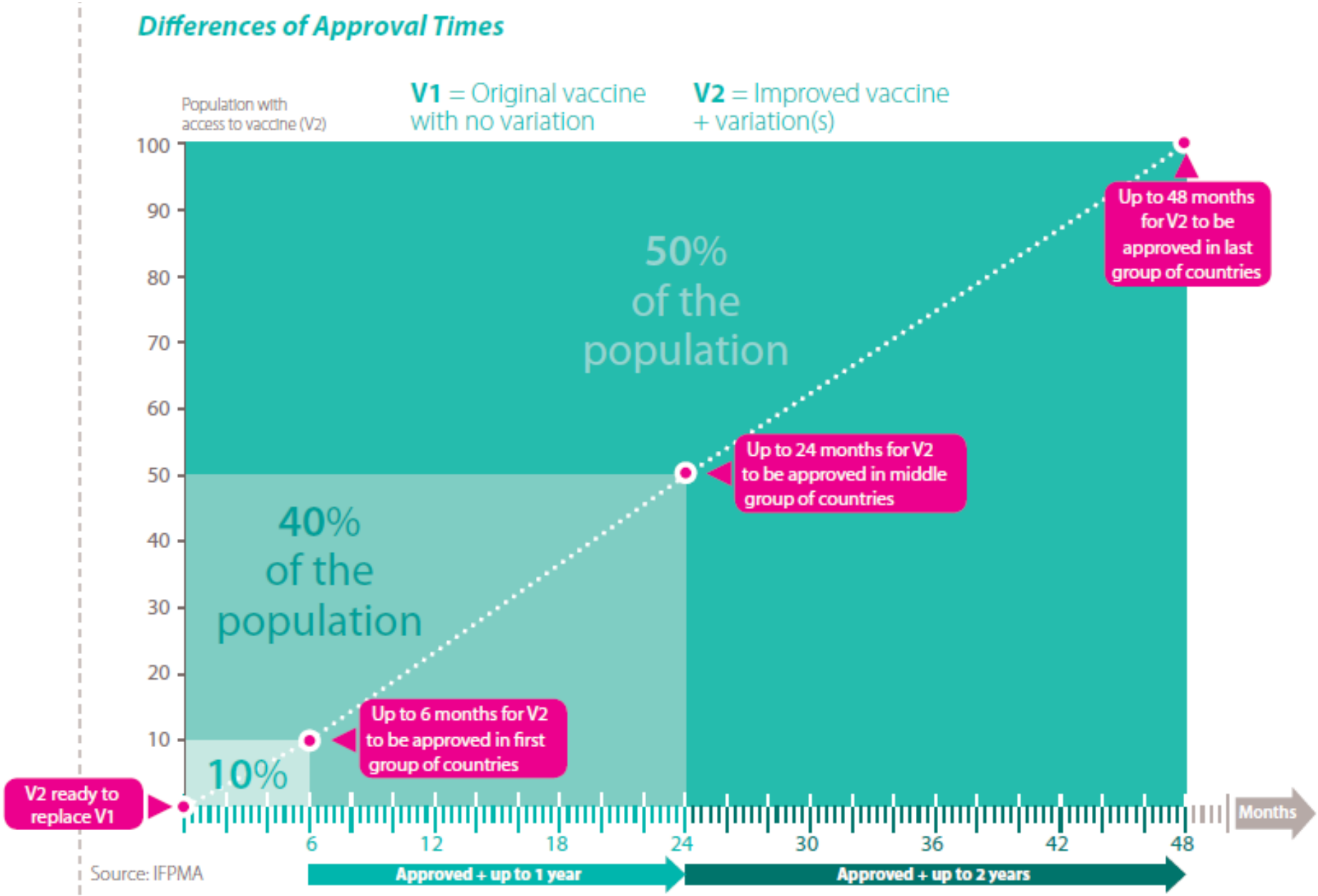
Graphics: PATH



Source: International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). *The Complex Journey of a Vaccine*. Geneva: IFPMA; 2014. Available at: http://www.ifpma.org/fileadmin/content/Publication/2014/IFPMA_Complex_Journey_Vaccine_Publication_2014.pdf.



Source: International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). *The Complex Journey of a Vaccine*. Geneva: IFPMA; 2014. Available at: http://www.ifpma.org/fileadmin/content/Publication/2014/IFPMA_Complex_Journey_Vaccine_Publication_2014.pdf.



Source: International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). *The Complex Journey of a Vaccine*. Geneva: IFPMA; 2014. Available at: http://www.ifpma.org/fileadmin/content/Publication/2014/IFPMA_Complex_Journey_Vaccine_Publication_2014.pdf.

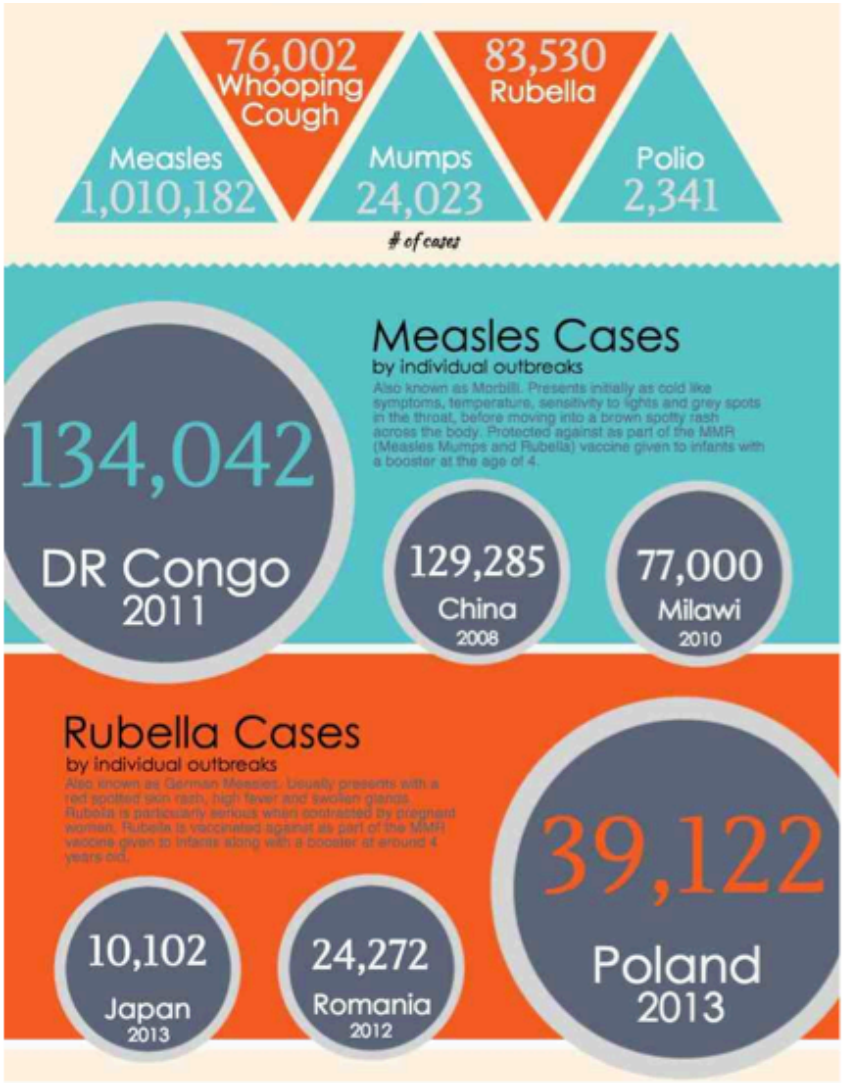
Autodisable and reuse-prevention syringe pricing—baseline technologies

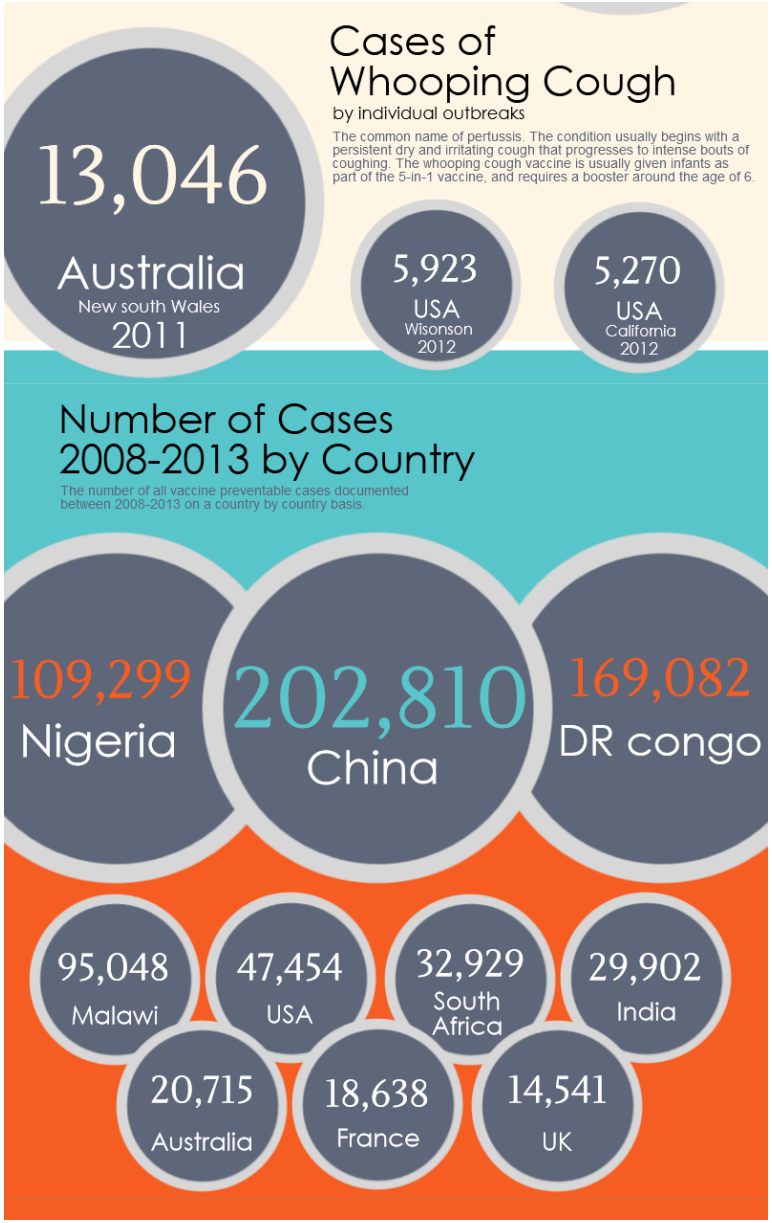
Autodisable (AD) syringes	Type	Total awarded quantity (units)	Weighted average price per unit (USD)
0.5 mL AD syringe	 For immunization injections of all 0.5ml dose vaccines	1,158,000,000	$0.0396
0.1 mL AD syringe	 For immunization injections of BCG vaccine	440,000	$0.0410
0.05 mL AD syringe	 For immunization injections of BCG vaccine	84,000,000	$0.0463

Syringe, re-use prevention (RUP), 2 mL			Long-term arrangement fixed-unit prices based on incoterm FCA port/ airport of origin
Supplier name	Product	Product type	June 2013-May 2015
Helm Medical GmbH		Syringe, RUP, 2 ml, with fixed needle/BOX—100	$4.25

Sources: (1) United Nations Children's Fund (UNICEF). *2014-2015 AD Syringes Projections: Quantities and Pricing*. New York: UNICEF; 2014. Available at: http://www.unicef.org/supply/files/2014-2015_AD_Syringes_Projections.pdf. (2) UNICEF. *Re-Use Prevention Syringes Current LTA's Price Data*. New York: UNICEF; 2011. Available at: http://www.unicef.org/supply/files/Re-Use_Prevention_(RUP)_syringes_current_LTAs_price_data.pdf.

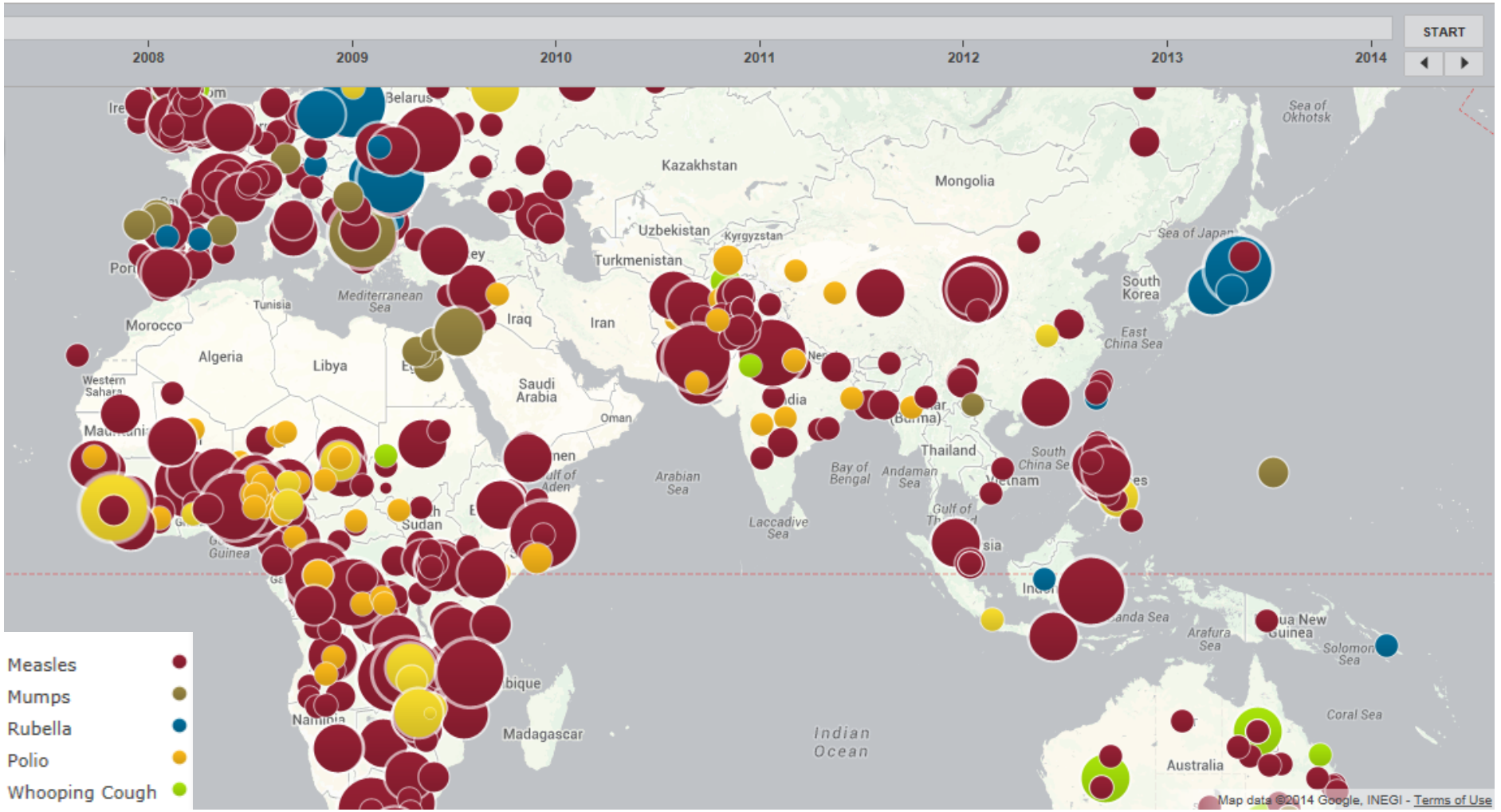
Vaccine preventable outbreaks 2008 – 2013





http://www.vaccinenation.org/2014/01/28/infographic-the-largest-preventable-outbreaks

Vaccine-preventable disease outbreaks
2008 – 2014 (all)



http://www.cfr.org/interactives/GH_Vaccine_Map

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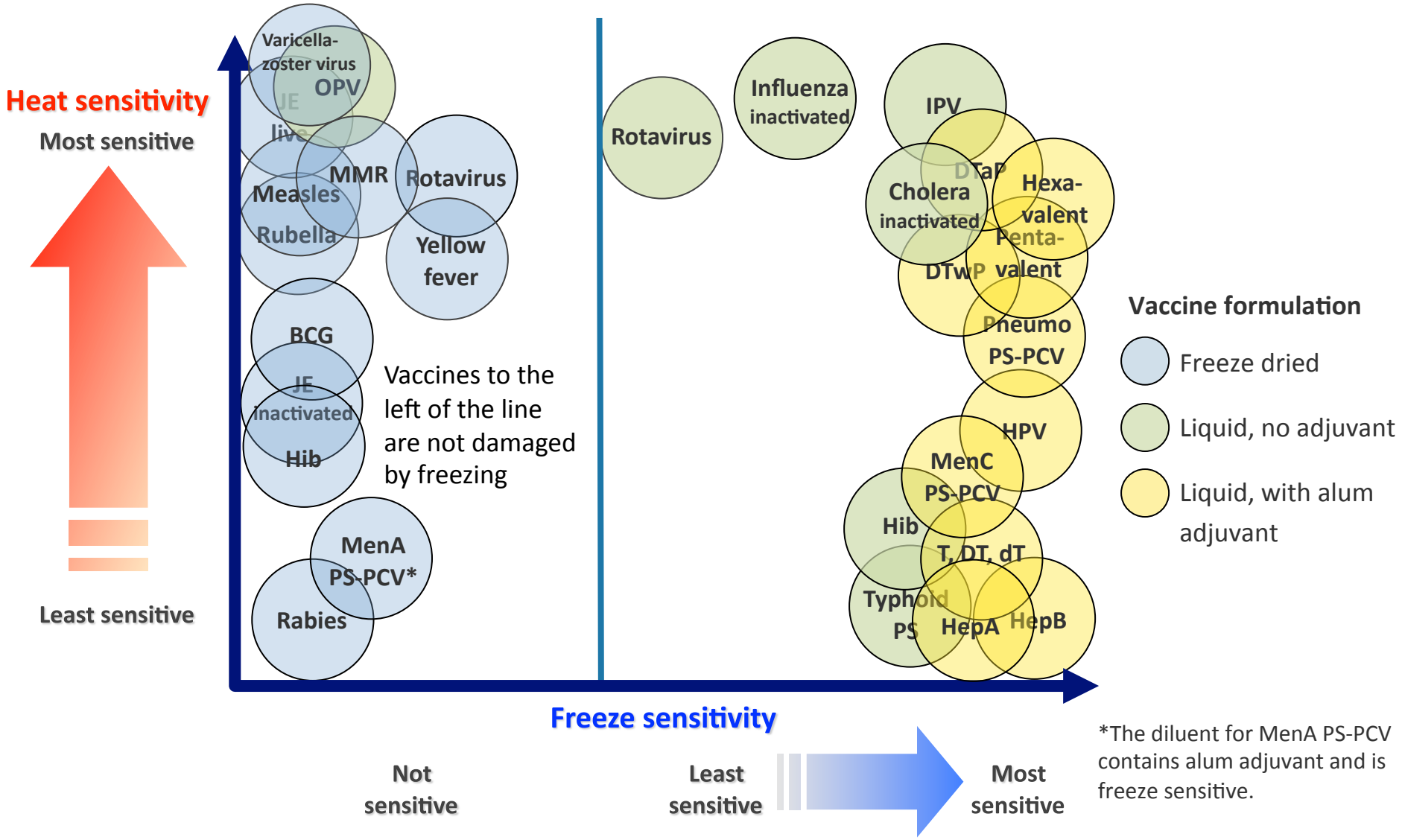
Temperature sensitivity of vaccines



*The diluent for MenA PS-PCV contains alum adjuvant and is freeze sensitive.

Current challenges to vaccine delivery

- Training and availability for health care workers.
- Routine, supplementary immunization activity, and outbreak response.
- Appropriate vaccine management.
- Supply access (e.g., needles and syringes, safety boxes).
- Needlestick injuries to health care workers.
- Disposal of sharps waste—community needlestick injuries.

Photo: WHO

Photos: WHO

Unsafe injections in developing and transitional countries – 2010*

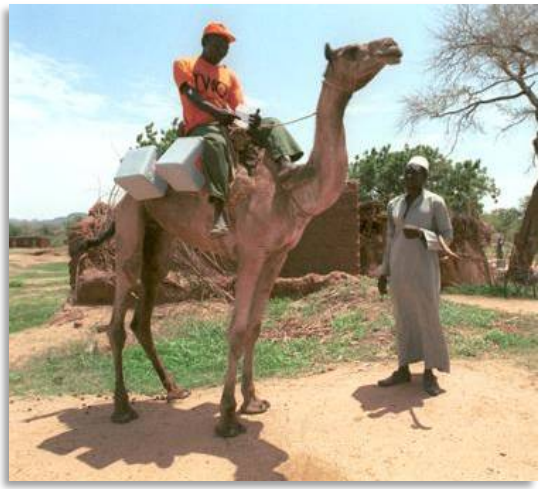
- Total number of injections: 16.3 billion
- Number of injections per person per year: 2.88
- Reuse rate: 5.5%
- Infections resulting from unsafe injections:
  - Hepatitis B: 1.7 million.
    - 2.6 % of all new cases.
  - Hepatitis C: 315,000
    - 6 % of all new cases.
  - Human immunodeficiency virus (HIV): 35,000.
    - 1.3 % of all new cases.

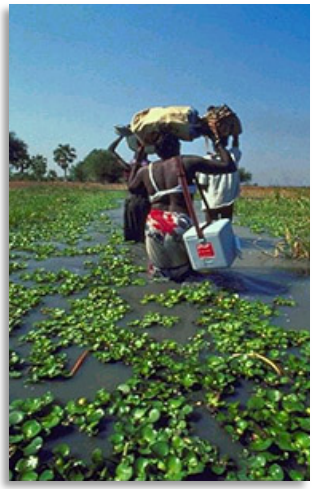
Photo: PATH\Mark Clifford

Photo: PATH

*New data from WHO on the burden of disease from unsafe injections. WHO (Selma Khamassii) personal communication February 2014

Last-mile logistics involve unreliable cold chain





All photos: PATH except where noted

Photo: UNICEF

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Value-added product attributes

- **Enhanced thermostability** (heat and freeze protection) enables supply logistics and distribution at or beyond the cold chain.
- **Compact, low-weight packaging** minimizes product volume and reduces space requirements.
- Increased **potential for fractional dosing** reduces supply and delivery costs.
- **Ease of use** is improved within different delivery scenarios (routine immunization or mass campaign).

Source: World Health Organization (WHO). *Vaccine Presentation and Packaging Advisory Group Generic Preferred Product Profile for Vaccines*. Geneva: WHO; 2009. Available at: http://www.who.int/immunization_delivery/systems_policy/VPPAG_Generic_PPP_and_Workplan.pdf.

Value-added product attributes (continued)

- **Simplified product preparation** reduces the number of steps and requirements, helping to ensure effective delivery.
- **Autodisable features** prevent reuse and potential disease transmission.
- Innovative materials (including primary container, secondary, and tertiary packaging) **minimize environmental impact, the risk of needlestick injury, and unsafe medical waste**.
- **Improved patient/parent acceptance** increases willingness for vaccination.

Source: World Health Organization (WHO). *Vaccine Presentation and Packaging Advisory Group Generic Preferred Product Profile for Vaccines*. Geneva: WHO; 2009. Available at: http://www.who.int/immunization_delivery/systems_policy/VPPAG_Generic_PPP_and_Workplan.pdf.

Questions to consider

- What are the outstanding public health needs?
- What are the biggest challenges in the development of new vaccine technologies?
- How should product attributes be prioritized?
- What are important trends to consider?
- What are the barriers to introduction?
- How should global stakeholders prioritize potential solutions?
- How can industry- and public-sector investment be best focused?

Thank you

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