Case Study: The UniJect™ Injection System

Global Vaccine and Immunization Research Forum

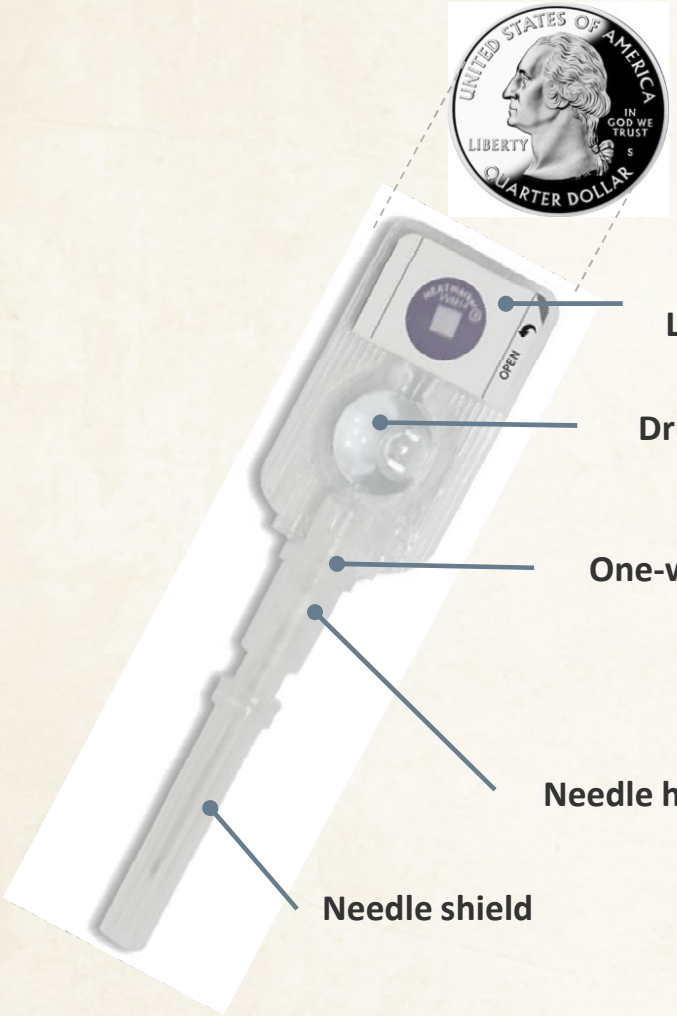
March 5, 2014

Debra Kristensen

Group Leader,
Vaccine and
Pharmaceutical
Technologies

PATH
A catalyst for global health

Uniject™* injection system



Uniject is a compact prefilled autodisable device.**

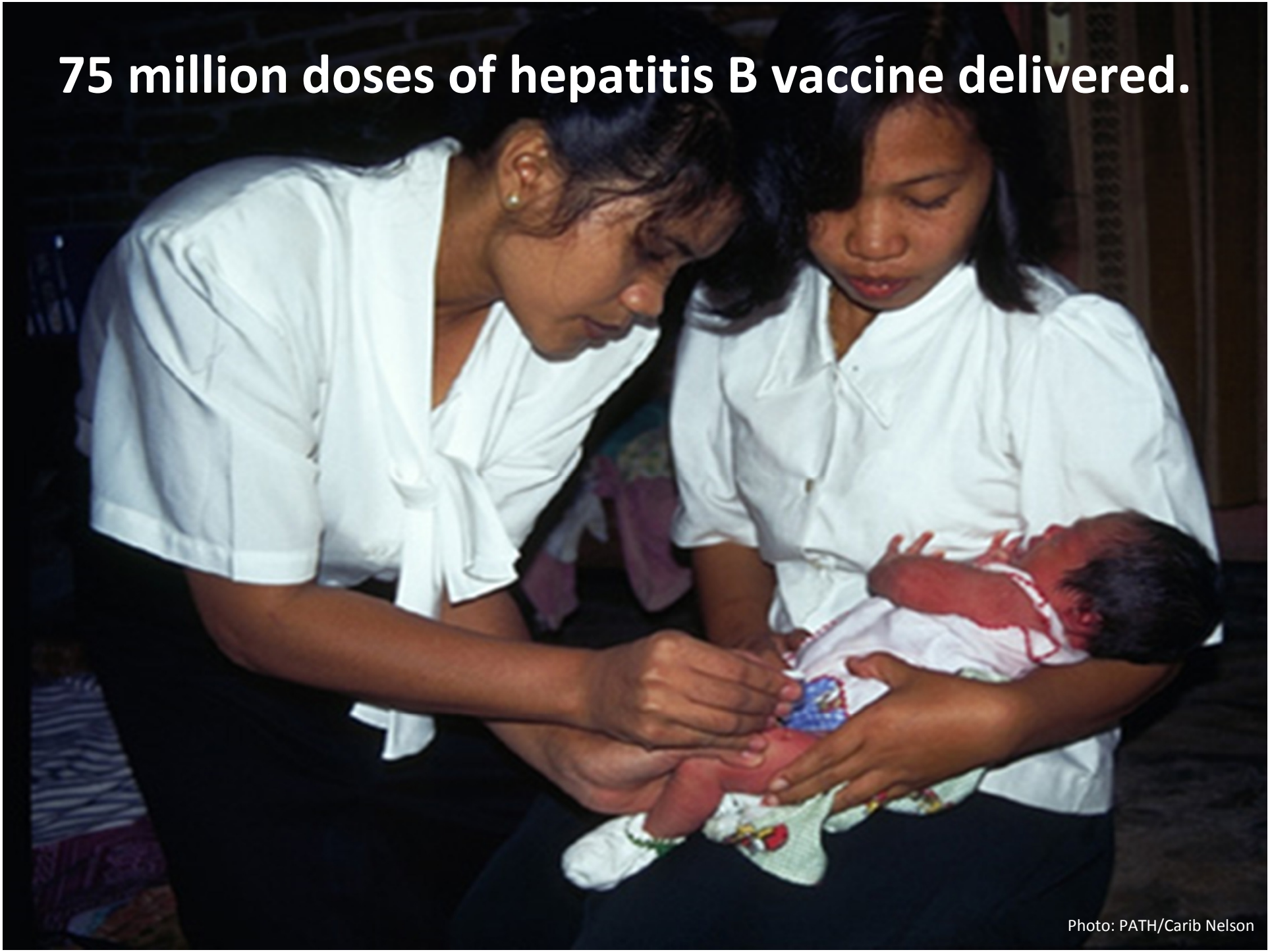
*Uniject is a trademark of BD. **PATH website. Available at: http://www.path.org/our-work/uniject.php. Accessed January 7, 2014.

Benefits of vaccines in Uniject

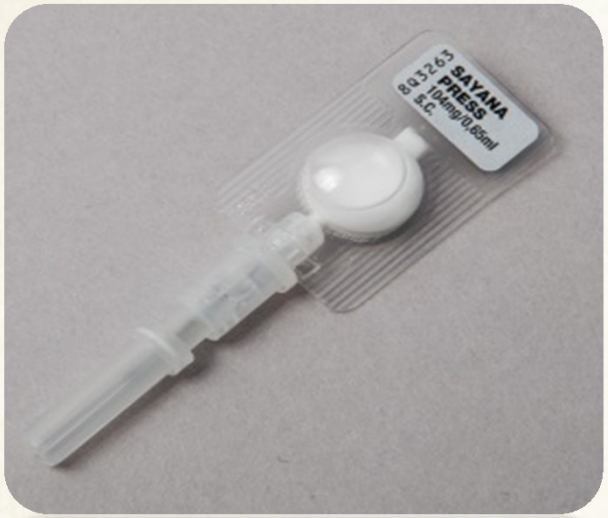
FEATURES	BENEFITS
Non-reusable (autodisable)	Reduces risk of contamination
Prefilled and single dose	Accurate dose, less buffer stock required, improves logistics (no need for separate auto-disable syringe), minimizes vaccine wastage, decreases missed opportunities, facilitates outreach
Transparent container	Easy to examine vaccine contents
Less solid waste and no toxic by-products upon incineration	Environmentally friendly
Compact	Less overall volume for transport, storage, and disposal
Few steps required to use	Simplifies training, saves health worker time, can be used by lesser-trained health workers, improves immunization experience for all

Photo: PATH/Carib Nelson


9 million doses of tetanus toxoid vaccine delivered. Potential procurement of 35 million more.
Photo: BD (used with permission)


75 million doses of hepatitis B vaccine delivered.
Photo: PATH/Carib Nelson

Up to 12 million doses of Sayana Press* will be delivered in the next three years



Photos: Pfizer

- 104 mg Depo-Provera (*depot medroxyprogesterone acetate).*
- Delivered every three months.
- Prefilled in Uniject.
- Subcutaneous injection.
- 3/8” needle.

**Sayana Press and Depo-Provera are registered trademarks of Pfizer, Inc.*

Crucell is launching pentavalent vaccine in Uniject

- Approved by Korean National Regulatory Authority in January 2014.
- WHO prequalification submission expected in Q2 2014.

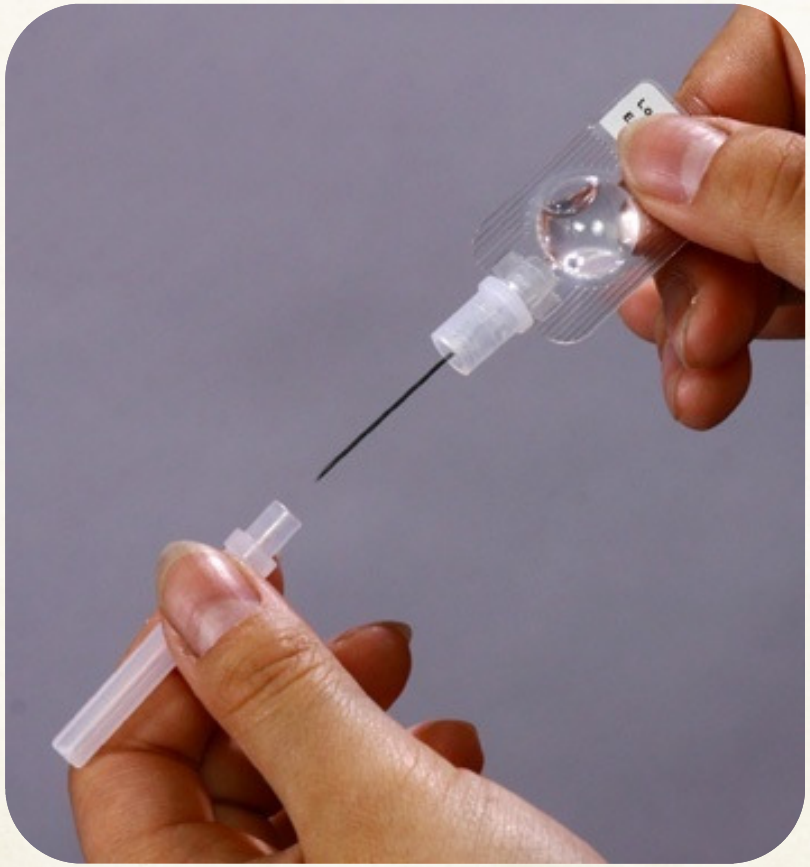


Photo: Crucell

Uniject delivery system features for pentavalent vaccine

Peel-off label* with integrated vaccine vial monitor

Vaccine reservoir

part of the system that encloses vaccine

(max V = 0.63 ml, filled V = 0.60 ml)

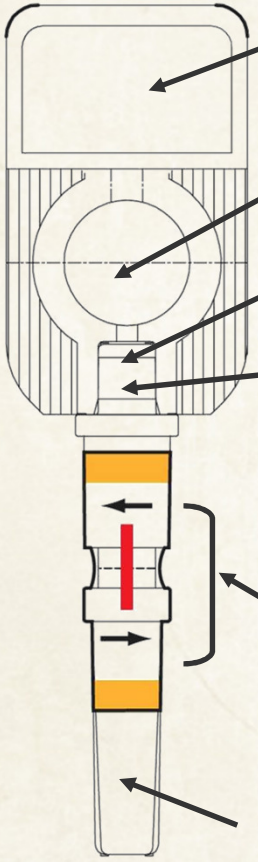
Disc valve discourages attempts to refill the reservoir

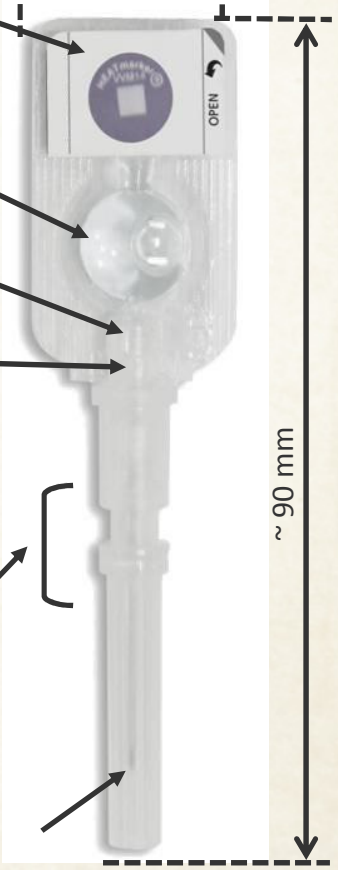
Isolation barrier in the port maintains sterility of the vaccine

Needle shield and port maintain sterility of the needle through tortuous path closure principle

Tamper-evident seal* makes it easy to recognize if system has been previously activated and/or needle shield was removed

23 gauge × 1” needle - optimal size for intramuscular injection

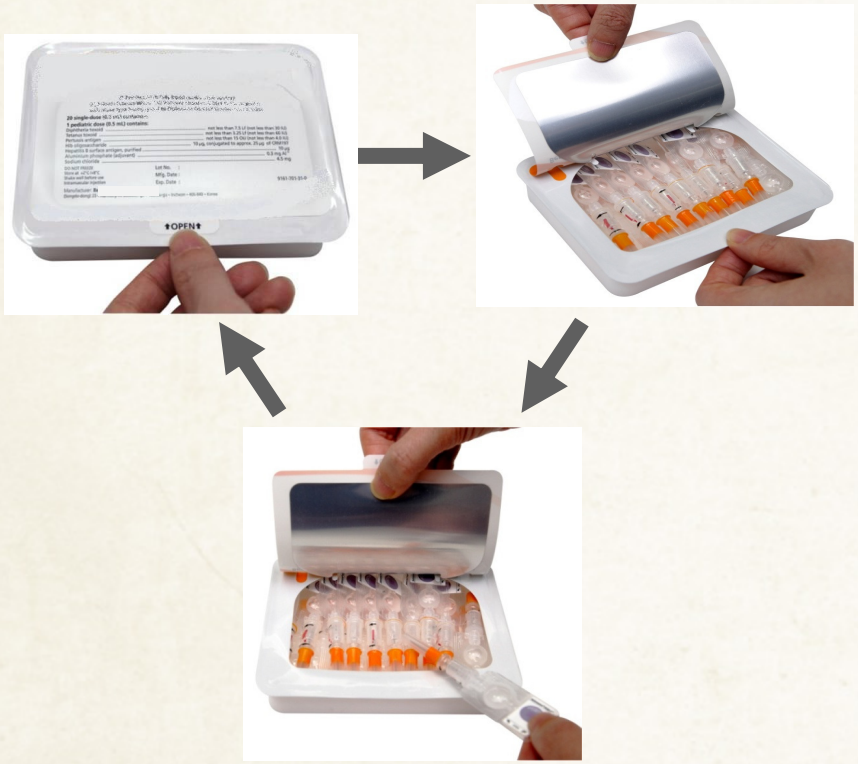




* New Feature added by Crucell

New packaging developed by Crucell to protect single Uniject devices and minimize cold chain volume

Resealable packaging has been developed to attain cold chain volume comparable to single-dose vials



- The current design is the result of extensive discussions with key stakeholders on programmatic needs and challenges.
- Several research projects are completed or ongoing to assess the new design and acceptability at all levels.
- Design is also tested on its “integrity”; 20-dose tray has been included in:
  - Stability studies (opened and closed).
  - Packaging validation studies.
  - Shipping validation studies.

Barriers to Adoption for Vaccines

Technical hurdles are high for new vaccine containers.

Photo: PATH

Regulatory approvals should not be underestimated.

Example	National Regulatory Authority (Korea)	WHO	Importing Countries
Uniject	Device registration required (6 months)	Only the finished product (with vaccine) requires registration	Depends on country's local requirements (3 to 12 months)
Pentavelent vaccine in Uniject	New registration (9 to 12 months)	New presentation (3 to 6 months)	

The best-case scenario approval time period: 21 months

The worst-case scenario approval time period: 36 months

A more costly technology is more easily adopted as part of a higher-priced vaccine. However, price is a moving target.

Photo: BD

The developing-country vaccine market lacks sufficient pull mechanisms for vaccine technologies.

Ease of use, health care worker time savings, impact on coverage, and safety have not been considered in purchase decisions in the past.

Photo: PATH/Simona Zipursky


Thank you
Photo: PATH/Siri Wood