The UniJect™ Injection System: Lessons Learned

Next-Generation Vaccine Delivery Technology Meeting
18 February 2014

Debra Kristensen
Group Leader
Vaccine and Pharmaceutical Technologies Group

PATH
A catalyst for global health

Photo: PATH/Patrick McKern
Uniject™ injection system

Uniject is a compact pre-filled autodisable device**

## Benefits of vaccines in Uniject™

<table>
<thead>
<tr>
<th>FEATURES</th>
<th>BENEFITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-reusable (auto-disable)</td>
<td>Reduces risk of contamination</td>
</tr>
<tr>
<td>Prefilled and single-dose</td>
<td>Accurate dose, less buffer stock required, improves logistics (no need for separate AD syringe), minimizes vaccine wastage, decreases missed opportunities, facilitates outreach</td>
</tr>
<tr>
<td>Transparent container</td>
<td>Easy to examine vaccine contents</td>
</tr>
<tr>
<td>Less solid waste and no toxic by-products upon incineration</td>
<td>Environmentally friendly</td>
</tr>
<tr>
<td>Compact</td>
<td>Less overall volume for transport, storage, and disposal</td>
</tr>
<tr>
<td>Few steps required to use</td>
<td>Simplifies training, saves health worker time, can be used by lesser trained health workers, improves immunization experience for all</td>
</tr>
</tbody>
</table>
9 million doses of tetanus toxoid vaccine
75 million doses of hepatitis B vaccine
Up to 12 million doses of Sayana Press* will be delivered in the next three years

- 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 (NRA) in January 2014
- WHO prequalification submission expected in Q2 2014
Lessons Learned
Lesson 1.
The technical hurdles are high for new vaccine containers. For public-sector-focused technologies, sustained financial support from both the public and private sector is needed.
Lesson 2.
Do not underestimate the regulatory approval side of vaccine introduction.

<table>
<thead>
<tr>
<th>Example</th>
<th>NRA (Korea)</th>
<th>WHO</th>
<th>Importing Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uniject™</td>
<td>Device registration required (6 months)</td>
<td>Only the finished product (with vaccine) requires registration</td>
<td>Depends on country’s local requirements (3-12 months)</td>
</tr>
<tr>
<td>Pentavelent vaccine in Uniject™</td>
<td>New registration (9-12 months)</td>
<td>New presentation (3-6 months)</td>
<td></td>
</tr>
</tbody>
</table>

The best case scenario approval time period: 21 months
The worst case scenario approval time period: 36 months
Lesson 3.
A more costly technology is more easily adopted as part of a higher-priced vaccine. However, price is a moving target.
Lesson 4.
This 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.
Lesson 5.
Industry can create and implement innovative solutions if they have clarity about the need and estimates of demand.

Re-sealable packaging has been developed to attain cold chain volumes comparable to single-dose vials.

• 20 devices per tray
• Unit volume (per device): 14.055 cm³
Thank you
Vaccine Vial Monitors: Lessons Learned

Next-Generation Vaccine Delivery Technology Meeting
18 February 2014

Debra Kristensen
Group Leader
Vaccine and Pharmaceutical Technologies Group

© PATH/Patrick McKern
Vaccine vial monitors (VVMs) are labels for vaccine vials that register cumulative heat exposure over time.
More than 5 billion VVMs have been used to date.
LESSONS 
LEARNED

Photo: Umit karioğlu
Lesson 1. Perseverance is required!

1979
- WHO idea; R&D begins at PATH

1988
- PATH identifies a new core technology from LifeLines

1990
- WHO/PATH meet with vaccine producers

1992
- TECHNET requests VVMs on all vaccines starting with OPV

1994
- UNICEF includes VVMs in 1994 tender for OPV
- Tanzania and Vietnam pilot production

1995
- TECHNET urges introduction

1996
- UNICEF includes clause in 1992-1994 tender

1998
- TECHNET urges introduction

1999
- 5 other manufacturers work on VVM development

2000
- UNICEF includes VVMs in 2000 tender for ALL vaccines
- Only 3 new vaccine producers include VVMs

2001
- 45/71 UN pre-qualified products include VVMs

2002
- Technical Review VVM implementation

2006
- 45/71 UN pre-qualified products include VVMs

1990
- WHO/PATH meet with vaccine producers

1992
- TECHNET requests VVMs on all vaccines starting with OPV

1994
- UNICEF includes VVMs in 1994 tender for OPV
- Tanzania and Vietnam pilot production

1995
- TECHNET urges introduction

1996
- UNICEF includes clause in 1992-1994 tender

1998
- TECHNET urges introduction

1999
- 5 other manufacturers work on VVM development

2000
- UNICEF includes VVMs in 2000 tender for ALL vaccines
- Only 3 new vaccine producers include VVMs

2001
- 45/71 UN pre-qualified products include VVMs

2002
- Technical Review VVM implementation

2006
- 45/71 UN pre-qualified products include VVMs
Lesson 2. Implementing a technology on all vaccine products is no small undertaking.
Lesson 3. Global effort and long-term financial support are required.

Organizations involved included:

**Public-Sector Agencies:**
Alberta AID, Basic Support for Institutionalizing Child Survival Project, Canadian Public Health Association, Canadian International Development Agency, Centers for Disease Control and Prevention, Department for International Development, Edna McConnell Clark Foundation, GAVI, International Development Research Centre of Canada, London School of Hygiene and Tropical Medicine, OXFAM, Pan American Health Organization, PATH, United Nations Children’s Fund, United States Agency for International Development (greatest financial contribution), and World Health Organization.

**Ministries of Health:**
Argentina, Bangladesh, Bhutan, Bolivia, Brazil, Cameroon, Egypt, India, Indonesia, Kenya, Mexico, Nepal, Pakistan, Peru, Philippines, Sierra Leone, South Africa, Tanzania, Thailand, Turkey, Vietnam, Yemen, Zambia, and Zimbabwe.

**Private Sector:**
Albert Browne Ltd., CCL Label, 3M, Rexam (formerly Bowater), TEMPTIME (formerly LifeLines).
Lesson 4. Champions are required.
Lesson 5. Policy development can be an essential first step.
Lesson 6. A strong supplier was essential.

TEMPTIME
Strong and proactive supplier; transparent pricing and good customer service record.
Production capacity easily meets the needs for the projected global vaccine market in 2025.

TEMPTIME headquarters in Morris Plains, NJ
How do good health technologies get to poor people in poor countries?

Laura J. Frost & Michael R. Reich
Thank you