LINKING VACCINE DEVELOPMENT AND DELIVERY

Orin Levine
Director, Vaccine Delivery

DCVMN meeting
New Delhi, India
October 28, 2014
1974: EPI LAUNCH

- **Initial Vaccination**
  Only *5 percent* of children protected from *6 diseases* targeted by *4 vaccines* *(OPV, BCG, DTP, Measles)*

- WHO launched **Expanded Program on Immunization (EPI)** on heels of smallpox in May 1974

- EPI in every country by 1980s
MEASURING PROGRESS

% DTP3 coverage

…today four out of five children are immunized

Source: UNICEF Immunization Summary: A statistical reference containing data through 2011 (2013 ed.)
WHERE WE’VE IMPROVED

Vaccine Introduction by Income Group

Note: Limited projections are available for PCV introduction in High Income Countries

RECORD NUMBERS OF NEW VACCINE INTRODUCTIONS

Source: GAVI Alliance Strategic Demand Forecast version 8, as of November 2013.
Note: Only the first phase of introductions and campaigns is included. IPV projections are only partially based on country input.
Implied in this slide is the idea that the systems have progressed as coverage has progressed.

But has it? Has innovation improved delivery?

Source: UNICEF Immunization Summary: A statistical reference containing data through 2011 (2013 ed.)
LET’S TAKE AN IMMUNIZATION SAFARI AND SEE
This clinic is staffed by a motivated, trained nurse named Ben.
When the vaccine arrives, it goes into this refrigerator where the vaccine needs to be kept between 2-8 degrees, even if the power goes out.
Vaccine refrigerator temperatures are recorded daily in a notebook.

Useful for supervisory visits but doesn’t continuously monitor the temperature.

Instead, Ben leaves a light on in his house. The fridge and his light bulb share the same power source.
Ben diligently tracks his vaccine stocks. The lines in red are the vaccines that arrived.

The daily log indicates how many he took to the clinic to deliver and how many were returned to the fridge later, a figure he then reconciles with the figures from the start of the day.
But the current “system” doesn’t provide real-time data back to the central levels. So Ben sends a text message with stock info every Friday.

You can see the hand-written message on top of the refrigerator here..
Next, consider how Ben knows where to look for the children in his community.

Ben depends on a hand-drawn cartoon map like this one (and local knowledge, of course).
Finally, when Ben has successfully vaccinated a child, he records it twice.

Once on the child’s immunization and health card, and also on a logbook register like this one.
But the reporting back to his supervisors is based on a simple tally sheet like this and gets rolled up on a weekly or monthly basis.

These sheets become national coverage estimates.
Globally, ~25M children are immunized outside fixed facilities each year, representing 40-50% of routine immunizations.

**SOURCE:** Expert interviews, World Bank indicators, McKinsey analysis
The ANM faces difficulties in carrying all her paraphernalia to the immunization site even when she has a mode of conveyance. The register used for recording details of the immunized recipients does not fit in the handbags of ANMs owing to its large size.
Immunization session conducted outside a recipient’s house

ANM sitting on a brick pavement while conducting the session
No proper provision for storing equipment leads to unhygienic practices.

Melted ice pack

Materiality issues

Lid is not airtight which creates temperature control issues.
Few changes are obvious from the EPI system created in 1970s
Cold chain equipment, hand drawn maps, registers and tally sheets virtually unchanged
Name-based data remains at lowest levels only
Innovations? Real-time temperature monitoring by light bulb?!
“By 2020, prevent 11 million deaths, 3.8 million disabilities, and 230 million illnesses, through high, equitable, sustainable vaccine coverage and supporting polio eradication”

- BMGF Vaccine Delivery Impact Goal
## OUR TOP PRIORITIES

### Vaccines
- Inactivated Polio
- Pneumococcus
- Rotavirus
- HPV
- Measles-Rubella
- MenAfriVac™
- Cholera
- Pentavalent
- Japanese Encephalitis
- Malaria
- Dengue
- Typhoid Fever

### Immunization Systems
- GAVI
- Data quality
- Supply chain
- Vaccination outside infant schedules
- Demand generation
- Vaccine financing

### Countries
- Nigeria
- India
- Ethiopia
- Pakistan
- Polio risk countries
OUR INVESTMENTS REFLECT OUR STRATEGIC PRIORITIES

- ~70% to GAVI
- Additional funds add to GAVI impact
- Focused on immunization systems, market dynamics, and new vaccine introduction
Our goal is to ensure that vaccine markets meet the needs of the world’s poorest countries

Vaccine Market Dynamics Priorities:

**Priority 1: Vaccine supply**
Ensure uninterrupted supply and sustainable, affordable pricing of suitable vaccines for GAVI.

**Priority 2: Cross-cutting initiatives**
Improve market dynamics information and expertise and integrate innovative approaches to solve complex vaccine access challenges.

**Priority 3: Partnerships**
Strengthen global health and manufacturer partnerships to enable better alignment and execution of market goals.
How BMGF, GAVI and UNICEF Work Together

BMGF, GAVI and UNICEF SD work in close cooperation across the vaccine market dynamics lifecycle, but with different mandates and toolsets

<table>
<thead>
<tr>
<th>BMGF</th>
<th>Pre-tender</th>
<th>Incentives</th>
<th>Procurement</th>
<th>Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Innovation</td>
<td>Market Analytics</td>
<td>Balance Sheet Incentives</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GAVI</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Roadmap Process</td>
<td>Other Market Incentives</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UNICEF SD</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplier Briefings</td>
<td>Tender Process</td>
</tr>
</tbody>
</table>
Role of Vaccine Delivery Market Dynamics Team

Market Dynamics supports PST needs by leading vaccine investment teams and collaborating with internal and external partners.
Foundation Investment Tools

BMGF tools span upstream and incentives opportunities and include grants, contract management and program-related investments.

- **Upstream Tools** (Product Development)
  - Product Development Funding, including PDPs
  - Early Stage Equity Stakes
  - Technical Assistance Grants
- **Incentives Tools** (Product Delivery)
  - Capacity Scale-up Loans
  - Capacity Scale-up Contracts
  - Supply Volume Guarantees
  - Purchase Pre-payments

**Key:**
- Grants
- PRIs
- Contracts

Not Exhaustive
Linking Development and Delivery

- Vaccine Thermostability
- Cold Chain Equipment
- System Design
Getting vaccines to all children remains a challenge

**Barriers:**

- Heat Sensitivity
- Transport and Stock Management
Vaccine Thermostability Requirements

<table>
<thead>
<tr>
<th>Campaigns</th>
<th>Routine Immunization</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Campaigns rarely last more than 3-5 days</td>
<td>• Vaccines require stabilization for long periods, often for 6 months or longer</td>
</tr>
<tr>
<td>• Usually only 1 or 2 vaccines given</td>
<td>• A broad range of vaccines and vaccine platforms need to be stabilized</td>
</tr>
</tbody>
</table>

Thermostability requirements differ by use case
Can requirements for development be altered by delivery?
How long do vaccines need to be thermostable?

**Months from vaccine entering national store to use**

- **12+**
  - Example 5-level country (7 countries)

- **6+**
  - Example 4-level country (33 countries)

- **4-5**
  - Example 3-level country (17 countries)

Months from vaccine entering national store to use:

- **0**
- **0.5**
- **1.0**
- **1.5**
- **2.0**
- **2.5**


Example categories:

- **12+**
- **6+**
- **4-5**
Projected breakdown of total system cost, 2020
(total = $3,673M)
Cold Chain Equipment: Innovations

- Passive devices
- Solar direct drives
- Thermo-electric devices
- Next generation ice-lined refrigerators
Many vaccines have up to 1 week or more of stability at 40C.

Most labels do NOT reflect this inherent heat tolerance.

Relabeling for Controlled Temperature Chain (CTC) use.

Lower cost, higher probability of success and utility for campaigns.
“It takes a village to raise a child.”

- African proverb
Improving understanding:
Let’s develop a vaccine workshop