Sharing field experiences on new vaccine delivery approaches

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John Snow, Inc. (JSI)

Developing Countries Vaccine Manufacturers Network
VACCINES, OUR SHARED RESPONSIBILITY

15th Annual General Meeting
27-29th October 2014 – New Delhi
Age groups targeted to receive vaccines

- Infants
- Young children (e.g., measles 2\textsuperscript{nd} dose)
- Pre-adolescents (HPV)
- Women of child-bearing age (tetanus toxoid)
- Expanded age groups during campaigns (e.g. polio, measles, meningitis A)
New vaccine introductions

Overview 1991-2013 of introduction status and 2014-2016 projections

Source: WHO/IVB Database as of 18 October 2013
Date of slide: 18 October 2013
New vaccines have brought new challenges

- Increase in number of vaccines (6 → 12-15)
- Age restrictions (Rotavirus vaccine upper age limit)
- New target age groups (HPV: adolescents) requiring new service delivery channels
- New messages (syndromes, partial protection)
- Integrated approaches to disease control
- Cost of new vaccines
- Cold chain/logistics challenges (bulk and waste disposal)

*Most new vaccines require a well-functioning routine immunization program.*
Challenges to the immunization supply chain

Growing volume (cm³) to vaccinate per child

Increasing number of doses

2010

2020

Introduction of more expensive vaccines

Increase in stock keeping units

Note: All figures relate to GAVI-funded vaccines
1. UNICEF Supply 2012 Financial report, WHO data for Pneumo and Rota vaccines, and HPV (only for girls); 2. 2010: GAVI Shipment Data; 2020: GAVI SDF Forecast; Including volume for GAVI future graduated countries; 3. Comparison based on 2013 Price; 2020 Vaccines include: Rota, Pneumo; HPV; 2010' vaccines include: YF, Measles, DPT, OPV (UNICEF SD); 4. GAVI Background SDF Information; 2010": estimates based on 2009 data; 2020: estimates based on 2013 forecast
Immunization challenges: cold chain and logistics management
Examples of impact of increasing vaccine volumes on developing country supply systems, 2007

- **4100 doses**
  - of Polio and Measles Vaccines
  - Rural hospital storage, Mozambique

- **625 doses**
  - of Rotavirus Vaccine
  - District vaccine store, Brazil

- $635.50
- $4,687.50
Cumulative value and volume of vaccines used in routine childhood immunization: Ethiopia

- Measles, Polio Introduced
- DTP, BCG Introduced
- Pentavalent Introduced
- Pneumococcal Introduced*
- Rotavirus Introduced*

* Planned introduction date

What have decision makers mostly focused on before introducing a new vaccine?

- Disease burden (incidence, mortality, morbidity, disability)
- Vaccine efficacy, effectiveness
- Vaccine safety, reactogenicity
- Fits with existing immunization schedule (e.g., timeliness issues)
- Simultaneous administration possible?
- Combination with other antigens into single product possible?
- Current and future price, stability and security of vaccine market
- Trade-offs with other investments
- Immunogenicity
- Expected health gains
- Health care cost savings
- Care-related productivity gains
- Outbreak potential
- Public perception of the disease
- How to communicate about the disease/syndrome
- Willingness to give/accept more than one injection on same visit
But what other things are informed decision makers increasingly concerned about?

Programmatic characteristics of competing products:

- heat stability
- storage temperature
- number of doses per vial
- wastage rate
- storage volume
- volume of waste for disposal
- acceptability by health staff (e.g., # injections on same day)
- ease of use (preparation and administration)
- volume of dose administered
<table>
<thead>
<tr>
<th></th>
<th>Rotarix™ (GSK)</th>
<th>RotaTeq® (Merck)</th>
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</thead>
<tbody>
<tr>
<td>Type of vaccine</td>
<td>Live, liquid vaccine</td>
<td>Live, liquid vaccine</td>
</tr>
<tr>
<td>Method of administration</td>
<td>1.5 ml for Oral use</td>
<td>2 ml for Oral use</td>
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<tr>
<td>Presentation and vial size</td>
<td>Mono-dose, liquid tube</td>
<td>Mono-dose, liquid</td>
</tr>
<tr>
<td>Target age group</td>
<td>Infants &lt;32 weeks of age, first dose no earlier than 15 weeks</td>
<td>Infants &lt;32 weeks of age, first dose no earlier than 15 weeks</td>
</tr>
<tr>
<td>Number of doses</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Schedule</td>
<td>Co-administered with Penta1 and Penta2</td>
<td>Co-administered with Penta 1, Penta 2, Penta 3</td>
</tr>
<tr>
<td>VVM type</td>
<td>14</td>
<td>No Vaccine Vial Monitor (VVM) technology has been validated for use</td>
</tr>
<tr>
<td>Packaged volume per dose</td>
<td>17.1 cm³ in 50 dose carton</td>
<td>46.3 cm³ in 25 dose packaging</td>
</tr>
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### Single dose versus multi-dose trade-offs

<table>
<thead>
<tr>
<th>Comparison of the Major Programmatic and Economic Advantages of Single- Versus Multi-Dose Vaccine Containers&lt;sup&gt;a&lt;/sup&gt;</th>
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<td><strong>Single-dose</strong></td>
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<tr>
<td><strong>Production</strong></td>
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<td><strong>Packaging</strong></td>
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<td><strong>Distribution</strong></td>
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<td><strong>Cold chain</strong></td>
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<td><strong>Safety</strong></td>
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<tr>
<td><strong>Syringe usage (for injectable vaccines)</strong></td>
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<tr>
<td><strong>Vaccine wastage</strong></td>
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<td><strong>Coverage rates</strong></td>
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<tr>
<td><strong>Medical waste</strong></td>
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<sup>b</sup> Compact prefilled autodisable syringes (Uniject) have less waste volume than multi-dose vials with syringes.
Fear of vaccine wastage using some larger multi-dose vials leads to delayed protection

<table>
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<th>Policies/Practices</th>
<th>Consequences</th>
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<tr>
<td>Measles vaccine on specific days to increase session size (weekly or monthly)</td>
<td>Mothers not sure when to come for services</td>
</tr>
<tr>
<td>Minimum number of children required to open a vial</td>
<td>Children are turned away, untimely vaccinated, never vaccinated</td>
</tr>
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Missed opportunities, UNICEF survey, 2012

Countries’ policies on opening measles vial (N=33)

- Open vial for any child: 55%
- Ask Caregiver to come back on scheduled day: 42%
- Other: 3%

Countries indicated that 35% of their demand is for 5-dose vials.
## Practices related to wastage

<table>
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<th>Cambodia (95% MCV1 coverage)</th>
<th>Nigeria (57% MCV1 coverage)</th>
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<tbody>
<tr>
<td>Average measles vaccine wastage rate in health centers</td>
<td>58%</td>
<td>19%</td>
</tr>
<tr>
<td>Average number of children before opening measles vaccine vial</td>
<td>2.2</td>
<td>6.2</td>
</tr>
<tr>
<td>Proportion of parents saying they were turned away for vaccination</td>
<td>4%</td>
<td>30%</td>
</tr>
<tr>
<td>Proportion of turned away who never received vaccine</td>
<td>12%</td>
<td>53%</td>
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<tr>
<td>Vaccines missed among turned away</td>
<td>MCV: 63%</td>
<td>BCG: 33%</td>
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<td>MCV: 26%</td>
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### How to reduce the threshold to open a vaccine vial?

Source: unpublished data, 2011 Nigeria CDC/WHO/NPHCDA study, 2013 Cambodia WHO/CDC/MOH study in nationally representative samples of health facilities
Key Messages

• managers have become more informed
• research your market and learn product preferences directly from prospective clients
• design more programmatically suitable vaccines
• think downstream earlier in deciding formulation, presentation and packaging
• vaccine presentations influences coverage and equity
• lead the pack, be nimble and responsive to developing country needs
Lessons from USAID’s MCHIP on new vaccine introduction


Let’s make sure every child is a VIP…

Vaccinated, Immunized & Protected!

Thank You