Introducing a new vaccine into the childhood immunization programme
a South African perspective

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"Immunization remains one of the best buys in health. Nothing on the planet saves children's lives more effectively and inexpensively than vaccines."

Margaret Chan, WHO - Ann Veneman, UNICEF
Graeme Wheeler, World Bank - SOWVI 2009
Principles and considerations for adding a vaccine to a national immunization programme

FROM DECISION TO IMPLEMENTATION AND MONITORING

Purpose

Informed decision making:
Public Health priorities

Programmatic, Financial & Economic feasibility

Impact on immunization programme & overall health system

Guide introduction process

Opportunity to strengthen Immunization & Health systems

http://www.who.int/immunization/documents
From Decision to Implement to Monitoring Introduction of New Vaccine

1. Introduction and background
2. Decision Making
3. Planning & Management
4. Monitoring and Evaluation

Examples of ways & means
Templates for:
New Vaccine Introduction Plan
New Vaccine Introduction Checklist, Activity list & Timeline
Vaccine Introduction may mean

- Target disease not previously covered e.g. malaria, HIV
- New formulation (lyophilized > liquid vaccine)
- New combination vaccine (DTP-HepB-Hib)
Before introducing new vaccine require the following:

- Was this policy decision evidence-based?
- Has there been additional training of health workers?
- Has there been communication & social mobilization?
- What new programme activities are required for widespread delivery?
- Has monitoring been put in place?
### 5 minimum requirements for “Good Donation Practice”
( WHO-UNICEF Joint Statement on Vaccine Donations)

<table>
<thead>
<tr>
<th>Requirement</th>
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<tbody>
<tr>
<td><strong>Suitability:</strong> Epidemiologically &amp; Programmatically appropriate for immunization programme: vaccines are consistent with goals, priorities &amp; practices of immunization programme of country for which it is being donated.</td>
</tr>
<tr>
<td><strong>Sustainability:</strong> Long term cost borne of routine immunization programme of country.</td>
</tr>
<tr>
<td><strong>National officials informed:</strong> Of all donations being considered, prepared, or actually under way. Donation should only be accepted &amp; vaccine shipped upon their confirmation.</td>
</tr>
<tr>
<td><strong>Supply requirements:</strong> Donated vaccine should sufficient shelf life: for routine immunization programmes 12 months or sufficient self life to cover campaigns.</td>
</tr>
<tr>
<td><strong>Safe disposal:</strong> Auto-disable syringes &amp; safety boxes for safe disposal.</td>
</tr>
<tr>
<td><strong>Cost of distribution:</strong> Customs clearance, insurance &amp; delivery to designated sites should be precisely assessed &amp; funding secured before acceptance.</td>
</tr>
<tr>
<td><strong>Licensed vaccine:</strong> Prescribed licensing and/or other control procedures set up by recipient government. Licensed for intended use by National Regulatory Authority of producing country.</td>
</tr>
</tbody>
</table>
**Vaccine Introduction Guidelines**

Adding vaccine to national immunisation programme: decisions & implementation

<table>
<thead>
<tr>
<th>Investors &amp; Manufacturers</th>
<th>Health authorities &amp; Donor organizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Risk = lengthy, complex &amp; expensive process</td>
<td>Evaluate</td>
</tr>
<tr>
<td>• Research &amp; Development</td>
<td>• Efficacy &amp; effectiveness,</td>
</tr>
<tr>
<td>• Clinical trials</td>
<td>• Perceptions &amp; priorities</td>
</tr>
<tr>
<td>• Registration &amp; Marketing</td>
<td>• Capacity of country to deliver &amp; sustain EPI</td>
</tr>
<tr>
<td>• Pricing &amp; competition</td>
<td></td>
</tr>
</tbody>
</table>

Adding vaccine to national immunisation programme: decisions & implementation
Guidelines on Vaccine Introduction

1. Policy issues:
   • Burden of disease
   • Opportunity costs - other public health priorities
   • public perceptions
   • professional opinions
   • vaccine efficacy
   • quality & safety
   • economic & financial issues

2. Programmatic issues:
   • Vaccine presentation
   • Supply issues
   • Programme capacity to handle logistics associated with new vaccine

3. Long term Budget and Sustainability
   WHO-UNICEF guidelines for developing a comprehensive multi-year plan
FIG. 1. Key issues to consider when deciding on the introduction of a vaccine

**THE DISEASE**
- Public health and political priorities, alignment with global and regional recommendations
- Disease burden
- Status of other disease prevention and control measures

**THE VACCINES**
- Performance and characteristics of available vaccines
- Economic and financial issues
- Availability of vaccine supply

**SHOULD THE VACCINE BE INTRODUCED NOW?**

**STRENGTH OF THE IMMUNIZATION PROGRAMME AND HEALTH SYSTEM**
Planning vaccinating population
(or individual)

Vaccine efficacy
Vaccine effectiveness
Severity of disease
Burden of disease
Professional opinions
Risk to contacts
Public concerns
Coverage

Adverse events
Price – opportunity costs
BOX 3. Tools for economic analyses for new vaccines*

- Estimating costs of introducing new vaccines
- Immunization costing & financing: Multi-Year Planning
- Standardisation of economic evaluations of immunization programmes
- Cervical Cancer Prevention and Control Costing (C4P) Tool
- Models for calculating cost-effectiveness of new vaccines (PAHO)
- Economic analyses to support decisions about HPV vaccines in low- and middle-income countries
- Appraisal of existing cost-effectiveness tools for new vaccines
- Making choices in health: guide to cost-effectiveness analysis
- Identifying the economic consequences of disease and injury

* Many of these & other tools are available at http://www.who.int/immunization/programmes_systems/financing/en
Economies of scale

FIG. 3. Change in the UNICEF DTP-HepB-Hib pentavalent vaccine market over time: Volume of sales, number of suppliers and average price per dose, 2001 – 2011

Source: UNICEF Supply Division. Note: Data based on year purchase order was placed
Measuring the impact of a new vaccine

• Estimate of the burden of disease,
• Effectiveness of the vaccine,
• Programme Logistics,
• Coverage achieved
• thoroughness of the monitoring and evaluation.
Monitoring & evaluation
Monitoring

• Rotavirus vaccine introduced in W Cape in 2009
Cause of death <5 yrs (excl neonates)

Children 1-59 mths, Western Cape

Diarrhoea down, HIV down, septicaemia down,
Pneumonia up, malnutrition sl up
Less ill defined – but still increase pneumonia
Is it due to vaccine?

- HIV?
- PMTCT?
- Putting HIV infected children onto ARVs?
- Better water & sanitation?
Impact of Immunization upon Under-Five Child Mortality

Source: 2005 World Health Report

IMMUNIZATION POTENTIAL:
~25% CHILD MORTALITY REDUCTION BY 2015
Other issues
Other issues:

Disinhibition:
HIV –
vaccine 50% effective
New vaccine
Herd immunity
Innovations in Financing

• **International Financing Facility for Immunization (IFFIm)**
  development financing institution accelerate the availability of funds for immunization and related health programs.
  >US $2 billion for GAVI’s immunization programs

• **Advance Market Commitments**
  Provides capital to vaccine manufacturers to invest in R &D
  AMC funding helped piloted conjugated pneumococcal vaccine

• **Buy-downs**
  are where donor resources are used to lower the costs of credits and loans for priority health interventions.
  Funding is dependent on performance.
**SA EPI Schedule: since April 2009**

- **Birth:** Oral Polio, BCG
- **6 weeks:** (DTaP-IPV/Hib), Hep B, Oral Polio, Rotavirus Vaccine, PCV
- **10 weeks** (DTaP-IPV/Hib), Hep B
- **14 weeks** (DTaP-IPV/Hib), Hep B, Rotavirus Vaccine, PCV
- **9 Months:** Measles, PCV
- **18 Months:** (DTaP-IPV/Hib), Measles
- **6 Years:** Td
- **12 years Td**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>Bacillus Calmette Guerin</td>
</tr>
<tr>
<td>OPV</td>
<td>Oral Polio Vaccine (drops by mouth)</td>
</tr>
<tr>
<td>DTaP-IPV//Hib</td>
<td>Combined Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio, Haemophilus influenzae type b</td>
</tr>
<tr>
<td>RV</td>
<td>Rotavirus Vaccine (drops by mouth)</td>
</tr>
<tr>
<td>PCV&lt;sub&gt;7&lt;/sub&gt;</td>
<td>7 valent Pneumococcal Conjugated</td>
</tr>
<tr>
<td>Hep B</td>
<td>Hepatitis B Vaccine</td>
</tr>
<tr>
<td>Measles</td>
<td>Vaccine</td>
</tr>
<tr>
<td>Td</td>
<td>Vaccine Tetanus &amp; reduced strength diphtheria</td>
</tr>
</tbody>
</table>
Vaccine cost of a fully immunized child in South Africa 2009

R 1 338 in the public sector
R 4103 in the private sector

1 254 707 births registered in South Africa.

*If communication and accountability is good, the local health department may supply vaccines free of charge to doctors in private practice.*
<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Tender Price per dose</th>
<th>Number of doses</th>
<th>Total Public Sector</th>
<th>Private Price per dose</th>
<th>Total Private Sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>1.3</td>
<td>1</td>
<td>1.3</td>
<td>3.23</td>
<td>3.23</td>
</tr>
<tr>
<td>OPV</td>
<td>2.61</td>
<td>2</td>
<td>5.22</td>
<td>2.82</td>
<td>5.64</td>
</tr>
<tr>
<td>DTaP-IPV/Hib (Penta)</td>
<td>91.92</td>
<td>4</td>
<td>367.68</td>
<td>295.75</td>
<td>1183</td>
</tr>
<tr>
<td>Hep B (10 dose vial)</td>
<td>5.68</td>
<td>3</td>
<td>17.04</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hep B (1 dose vial)</td>
<td></td>
<td>3</td>
<td></td>
<td></td>
<td>53.49</td>
</tr>
<tr>
<td>RV</td>
<td>85.95</td>
<td>2</td>
<td>171.9</td>
<td>274.87</td>
<td>549.74</td>
</tr>
<tr>
<td>PCV7</td>
<td>253.08</td>
<td>3</td>
<td>759.24</td>
<td>542.48</td>
<td>1627.44</td>
</tr>
<tr>
<td>Measles (10 d vial) MMR (1 d vial)</td>
<td>3.88</td>
<td>2</td>
<td>7.76</td>
<td>134.84</td>
<td>269.68</td>
</tr>
<tr>
<td>Td (10 d vial)</td>
<td></td>
<td>2</td>
<td>7.76</td>
<td>151.76</td>
<td>303.52</td>
</tr>
<tr>
<td>Td polio (1 d vial)</td>
<td></td>
<td>2</td>
<td>7.76</td>
<td></td>
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<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td><strong>1337.9</strong></td>
<td></td>
<td><strong>4102.72</strong></td>
</tr>
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</table>
three ethical principles

1. Benefits and Harms - Fairly & justly distributed

2. Reasonable access to information, including the risk side effects

3. Participation should be voluntary* to ensure public trust in the programme.

Introducing a new vaccine also means

- Revision of the practice guidelines
- Revision of Road-to-Health charts
- Training
- Cold chain Logistics and Manuals,
- Computer Information Systems,
- Information, Education and Communication,
- Monitoring of Adverse Events
- Surveillance of the disease in question.
- Ongoing Support, Supervision & Problem Solving
See: “Principles and Considerations for Introducing a New Vaccine”
The questions establish the status of key programmatic requirements prior to introduction, to clarify gaps and identify the activities that need to be carried forward into the second worksheet of the Excel file “NVI Activity List & Timeline”.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Timeline (months)</th>
<th>Issue</th>
<th>Lead Agency</th>
<th>Activity/Action to be taken</th>
<th>Is Funding Available</th>
<th>Importance (High, Medium, Low)</th>
<th>Lead Agency</th>
<th>Deadline</th>
<th>Status/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programme objectives/targets</td>
<td>12</td>
<td>Setting short, intermediate and long-term goals of the introduction has not been set to contribute to global, regional and national health goals. What actions need to be taken to ensure this?</td>
<td></td>
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<tr>
<td>Target population and delivery strategy</td>
<td></td>
<td>Establishing the target population. If the new vaccine is for older age groups, or for age groups outside the traditional infant target population, and the size and location of the target population has not been established, what steps need to be taken to establish this information? (including identifying actors not traditionally involved in GIP, e.g. Ministry of Education)</td>
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<tr>
<td></td>
<td></td>
<td>Establishing the target population. If target population is “new”, what steps need to be taken to identify this population and to cost delivery strategy options?</td>
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<td></td>
<td></td>
<td>Delivery Strategy. If the identification of ways of reaching children not located at the primary vaccine delivery site has not been completed, what steps need to be taken to complete this preparation?</td>
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“NVI Activity List & Timeline”

Activities are easily monitored on one sheet by the National Steering Committee, or Technical Sub-Committees established to oversee the introduction of the new vaccine.

Timeline should be regularly reviewed and updated in line with changing plans and priorities.
Decision making process in South Africa

1. National Advisory Group on Immunisation (NAGI),
2. Director General - National Department of Health
3. Inter-departmental and inter-ministerial consultation with, at least the Department of Treasury.
4. National Health Council (NHC), the Minister of Health Provincial Ministers and Heads of Health Departments have to agree to the proposal and budget implications and commit themselves effective delivery and budgeting.

SA: new vaccines are introduced with extra budgetary funding, but following years - funding is allocated as part of the general provincial health budget and the vaccine had to compete uncomfortably with other important commitments and pressures.
Other influences on decision making

- WHO recommendations

- Vaccine introduced into the private sector

- Vaccine introduced other non-aligned countries such as India, Brazil, Cuba and other counties in Africa.

- Professional & Public opinion
Local studies make a difference:


Something to think about

• The ultimate impact can often be markedly enhanced through a catch-up campaign for all under fives.

• Introducing a new vaccine without a clear understanding of the epidemiology may have a negative impact if it increases the susceptibility to disease in certain vulnerable groups.

• Introduction of an immunization schedule for adults, especially for health care staff.
case studies from SA

Hep B vaccine 1996
• Wait 30 years for the impact
• A catch-up campaign for all under fives?
  = a missed opportunity
Rubella in EPI Schedule?
• Incomplete coverage => CRS increase
• What about MMR in private sector?
Flu vaccine for health workers?
conclusions

• The cost and complexity of introducing new vaccines are increasing dramatically.

• It is increasingly important for health professionals, academics, reporters, parents, teachers and learners develop to have good understanding of the benefits, risks and the costs of vaccines.

• For a significant proportion of the public and the professions become active supporters for effective immunization programmes and the introduction of new cost-effective and efficacious vaccines.