Eliminating epidemic meningitis as a public health problem in sub-Saharan Africa

Intellectual Property Rights and Vaccines for Developing Countries
Geneva, April 2004

MVP is a partnership between WHO and PATH
Epidemic Meningitis in Africa

Number of cases

Year

92,347 80,743 88,939 188,345

96 92 86 02

90

88,089 45,401

60

50

0

0 20,000 40,000 60,000 80,000 100,000 120,000 140,000 160,000 180,000 200,000

96 92 86 02
# Properties of Meningococcal Vaccines

<table>
<thead>
<tr>
<th>Property</th>
<th>Polysaccharide vaccines</th>
<th>Conjugate vaccines</th>
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<tbody>
<tr>
<td><strong>Immunogenicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 yr olds-adults</td>
<td><strong>High</strong></td>
<td><strong>High</strong></td>
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<tr>
<td>Young children</td>
<td><strong>Poor</strong></td>
<td><strong>High</strong></td>
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<tr>
<td><strong>Response to booster</strong></td>
<td><strong>Poor</strong></td>
<td><strong>High</strong></td>
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<tr>
<td><strong>Quality of antibody in children</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avidity</td>
<td><strong>Low</strong></td>
<td><strong>High</strong></td>
</tr>
<tr>
<td>Bactericidal activity</td>
<td><strong>Low</strong></td>
<td><strong>High</strong></td>
</tr>
<tr>
<td><strong>Induction of memory</strong></td>
<td><strong>No</strong></td>
<td><strong>Yes</strong></td>
</tr>
<tr>
<td><strong>Effect on colonization</strong></td>
<td><strong>No</strong></td>
<td><strong>Yes</strong></td>
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African Trials of Conjugate Meningococcal Vaccines

- Field tests in Niger and Gambia in 1990s
- Projects discontinued in mid- and late 1990s
- Products were not commercially viable with opportunity costs that were too great
Development of MVP

• Renewed interest in conjugate vaccines at WHO after the 1996-1997 epidemic
• EVA (Epidemic Vaccines for Africa) Project established at WHO (Dr. Luis Jodar)
• In-depth discussions with vaccine manufacturers in 1999 and 2000; costing model for conjugate vaccines developed; evolution of a collaboration between WHO and CVP/PATH

Confidential & Proprietary Information
The Meningitis Vaccine Project

• Created in June 2001 by a $US 70 million grant from the Bill & Melinda Gates Foundation as a 10 year partnership between WHO and PATH (Program for Appropriate Technology in Health)

• Mission: to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa through the development, testing, licensure, and widespread use of conjugate meningococcal vaccines
Discussions with African Public Health Officials & WHO/AFRO, Fall 01-Spring 02

• Cost of vaccine was the most important limiting factor to the introduction of new vaccines
• Meningitis belt countries are the poorest in the world
• Success of MVP (widespread use of a conjugate meningococcal vaccine in mass campaigns) would not be possible unless vaccines were priced less than $US 0.50 per dose
Choice of Men A Conjugate Vaccine

- Extensive discussions throughout the Fall of 2001 and a decision was made to pursue the development of a monovalent A vaccine because:
  - Great proportion of meningococcal isolates from Africa still Group A
  - Advantage of simplicity, low risk, and solid public health impact
  - Low price-sustainability of the program
Use of the Monovalent A Conjugate Vaccine

- Used as a single dose in mass vaccination campaigns throughout the meningitis belt for persons between 1 and 29 years of age (target population about 250 million in 18 countries)
- EPI antigen in under ones (2 doses; 14 weeks with DTP3 and at 9 months with measles)
Men A Conjugate Vaccine Development

- Could not reach agreement with major vaccine manufacturers; negotiations ended in March 02
- A triangular model was developed that included:
  - Dutch company to produce A PS
  - Public laboratory in US to develop conjugation method
  - Indian company to provide TT and make vaccine

Target price of 40 cents per dose
MVP Men A Vaccine Development Model

Target price $US 0.40/dose
MVP IP Management

- Confidentiality agreement with FDA/CBER
- Material Transfer Agreement with FDA/CBER
- Licensing agreement with NIH
Transfer of Technology

- CRADA with FDA/CBER
- Training of SII team at FDA in Washington, D.C.
- Training of SII team in Pune-India
Licencing Agreement

- Territory: lower and upper middle income economies (World Bank)
- Right to sublicense
- Patent costs
- Earned royalties
Characteristics of Men A Vaccine Development

- North/South transfer of technology not currently available
- South/South transfer of a vaccine product at an affordable price
- Capacity building for African investigators
- Model for other vaccines/products
Challenges and Opportunities of this Model

**Challenges**
- Higher risks
- Technical and managerial complexity
  - Technology transfer
  - Clinical and regulatory

**Opportunities**
- Low cost of vaccine (0.40 US$) - sustainability
- Acceptable timelines
- No opportunity costs
- Tailor-made for Africa
- Developing-country vaccine capacity strengthened
- Model for other orphan vaccines

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Lessons Learned so Far

- Price is important
- Wanting to “do good” is not enough
- Economic model must make sense
- There are excellent vaccine manufacturers in developing countries (“emerging suppliers”)
- Working with “emerging suppliers” offers a model for providing needed vaccines that have limited market potential
Collaborating Institutions

- Centers for Disease Control and Prevention, Atlanta, USA
- National Institute for Biological Standards and Control, UK
- London School of Hygiene and Tropical Medicine, UK
- Swiss Tropical Institute, Basel, Switzerland
- Médecins sans Frontières, Geneva, Switzerland
- Pasteur Institute and Association pour l’Aide à la Médecine Préventive, Paris, France
- National Institute of Health (NIH) and Fogarty Center, Bethesda, USA
- CBER Laboratories at the Food and Drug Administration (FDA), Bethesda, USA