Pneumococcal Vaccine Project

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PATH
A catalyst for global health
PATH’s Mission

To improve the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors.
PATH’s Vaccine Work

- Vaccines and immunization make up over 50% of PATH’s work
- Our work spans the range of vaccine-related activities from research and development to advocacy, financing, distribution, administration, and uptake
Pneumococcal Vaccine Project

• Goal: Accelerate development of safe, effective, and affordable vaccines against *S. pneumoniae* in order to reduce childhood acute lower respiratory infections and mortality in Africa and other low income regions

• Resources: ~US$84 million (2 grants)

• Timeframe: 2004 – 2011
PVP Objectives

1. Support development of low cost conjugate vaccines
2. Genome analysis to define vaccine targets
3. Advance protein vaccine candidates
4. Validate immune mechanism of protection against carriage
5. Pursue other strategies arising from a review of technologies
Global Access

Global access provisions are critical to all PATH partnerships in order to ensure availability of the vaccines to those who need them most

- Affordability/pricing: e.g., public sector preferred pricing
- Manufacturing capacity: e.g., dedicated level or duration of production
- Quality: WHO prequalification requirements
Currently Funded Projects

- Intercell – common protein vaccine
- Children’s Hospital Boston – whole cell vaccine

Completed Projects

- TIGR (JCVI) – genome sequencing
- Serum Institute of India (SII) – virtual conjugate (pilot funding)
- Oliver Wyman (Mercer) – economic driver and cost profile analysis of vaccine candidates
Intercell

- Austrian-based biotechnology company
- Developed Antigen Identification Technology and applied to several candidate products including *S. aureus* and *S. pneumoniae*
- Candidate *S. pneumoniae* vaccine consists of 3 distinct proteins
Antigen discovery at Intercell

Learn from individuals who’s immune system has encountered the pathogen

Antibodies
Genomic peptide libraries
Vaccine
Protection

Serum from exposed and diseased humans
Bacterial surface display (10 to 150 amino acids)
Defined peptides/proteins
Defined adjuvant
Animal models
Clinical trials
Intercell: results of 3 component protein vaccine

- Two adjuvants, 2 experiments each

PROTECTION RESULTS – COMBINATION RESULTS

- d7
- d14

![](chart)
Children’s Hospital Boston

- Development of an inactivated whole cell vaccine for Phase 1 clinical trials
- Would require no refrigeration and could be given through the nasal passage
- CHB established partnership with Butantan Institute in Brazil for developing-world manufacture
CHB: WCV protection against sepsis

P = 0.017

Percent survival vs. days since infection

WCV+CT

CT
Genome Sequencing

TIGR/JCVI

• Sequence 5 pneumococcal strains
• Potentially identify new vaccine targets/sequence information on existing candidates
• Data is publicly available
  • http://strepneumo-sybil.igs.umaryland.edu/cgi-bin/sybil/shared/index.cgi?site=pneumo
Request for Letters of Inquiry (LOI)

- LOI requested for 2 distinct categories of research
  - Vaccine discovery and development
  - Research activities in support of vaccine development
- 45 proposals received, over $208 million requested
## Pneumococcal vaccine portfolio

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<th>Research</th>
<th>Pre-clinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
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<td>1. Protein vaccine</td>
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Research Activities in Support of Vaccine Development

- Establish collections and characterization of pneumococcal strains from diverse geographic sources
- Establish protocols and reference laboratory for standardized animal models to help select vaccine candidates for further development
- Define burden of illness and age specific attack rates to facilitate preparation of Phase 3 field sites
Research Activities in Support of Vaccine Development

• Develop new diagnostics to improve accuracy and specificity of the diagnosis of pneumococcal disease
• Characterize the natural human immune response to candidate vaccine antigens
• Assess the ability of novel adjuvants to enhance the immunogenicity and protective capacity of pneumococcal vaccines
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