

Vaccine Conference

Pneumococcal Disease Prevention in Adults: Potential Vaccine Strategies

September 9-10, 2003

Four Points Sheraton in Washington DC (K street)

Draft Agenda

Focus:

Identify gaps and discuss strategies in the effective protection of adults against pneumococcal disease.

Objectives:

To review current knowledge regarding pneumococcal disease in adults and assess potential vaccine strategies for prevention.

To explore biological and clinical trial design considerations for the expanded use of current or future pneumococcal vaccines in adults.

Meeting Day 1:

9:00 a.m. – 6:00 p.m.

Morning session

I. Introduction

- A. Goals of the meeting (15 minutes)
- B. Immunology (90 minutes)

Chair: Ann Arvin (Stanford University)

1. **Richard Insel (Juvenile Diabetes Research Foundation International)**
Basic and clinical immunology of pneumococcal vaccines.
2. **Donna Ambrosino (Dana Farber Cancer Institute)**
Immune responses (to polysaccharides) in immunosuppressed individuals.

Panel Discussion: Richard Insel, Donna Ambrosino, Ann Arvin

What does the basic immunology teach us for design of clinical trials:
Insights with respect to correlates and/or endpoints.

C. Epidemiology (90 minutes)

Chair: Cynthia Whitney (Centers for Disease Control and Prevention, [CDC])

1. **Cynthia Whitney (CDC)**
Pneumococcal disease (invasive) in adults.
2. **Thomas Marrie (University of Alberta)**
Community acquired pneumonia in adults.
3. **Alicia Fry (CDC)**
Data and mathematical modeling of serotype coverage
 - Possible serotype replacement
 - Strengths & limitations of the model
 - Trends in pneumococcal disease as population ages

Panel Discussion: Cynthia Whitney, Thomas Marrie, Alicia Fry
Profile of risk factors for pneumococcal disease.

II. Polysaccharide vaccine (PS): How much protection does a PS vaccine provide against pneumococcal disease at various ages? (90 minutes)

Chair: Daniel Musher (Baylor College of Medicine and Veterans Affairs Medical Center, Houston Texas)

1. **David Fedson (Pasteur Mérieux MSD)**
PS vaccine:
 - Duration of protection
 - Efficacy profile (invasive vs. non-invasive disease)
 - New data
2. **Daniel Musher (Baylor College of Medicine and Veterans Affairs Medical Center, Houston Texas)**
Revaccination:
 - Safety of second doses
 - Immune responses to second doses
3. **Susan Manoff (Merck Vaccine Company)**
Revaccination:
 - Safety of second doses
 - Immune responses to second doses (and how to interpret them)
 - New data

Panel discussion: Daniel Musher, David Fedson, Susan Manoff, George Carlone
Polysaccharide vaccine strengths & weaknesses: revaccination, immune correlates in adults

LUNCH

Afternoon Session

III. Conjugate vaccine: Could a conjugate vaccine of sufficient valency and coverage protect adults against pneumococcal disease? (90 minutes)

Chair: David S. Stephens (Emory University)

1. **Peter Paradiso (Wyeth)**
Conjugate vaccines:
 - Duration of immune response and breadth of immune response.
 - Correlate of immunity in adults: what do we know?
 - Sequential use of PS and conjugate; dose, duration, memory.
2. **Speaker to be named**
Experience with conjugate in adults, immunosuppressed individuals
 - Invasive vs non-invasive disease.
 - Sequential use of PS and conjugate.
 - African conjugate.

Panel Discussion: David Stephens, Peter Paradiso and other speakers
Conjugate vaccine research needs and path forward. Can carriage of pathogen or herd immunity be used as an endpoint? What is known about duration of immunity?

IV. Pneumococcal protein vaccines (90 minutes)

Chair: Mark Steinhoff (Johns Hopkins School of Public Health)

1. **David Briles (University of Alabama at Birmingham)**
Rationale : Why should we have a protein Ag?
2. **GlaxoSmithKline representative**
Development and evaluation of new vaccine candidate
3. **Speaker to be named**
Development and evaluation of new vaccine candidate

Panel Discussion: Mark Steinhoff, David Briles, GSK representative

Meeting Day 2

8:30 a.m. – 12:30 p.m.

V. Trial Designs and Endpoints: What would it take to license a new vaccine? What would it take to recommend a major new use for a licensed vaccine?

Chair: Steve Black (Kaiser Permanente)

1. **Steve Black (Kaiser Permanente)**
Several illustrative scenarios for the conduct of a pneumococcal conjugate efficacy trial in adults.
2. **Speaker to be named**
Defining the trials that might be necessary to move a new or existing pneumococcal vaccine forward to approval.
3. **Carl Frasch (Food and Drug Administration, [FDA])**
FDA research and viewpoint on endpoints for licensure.
4. **Doug Pratt (FDA)**
FDA's viewpoint on design of trials for licensure of new vaccines and establishment of new indications for currently licensed vaccines.
5. **Brian Plikaytis (CDC)**
Statistical considerations, non-inferiority

Panel Discussion: Steve Black, Carl Frasch, Doug Pratt, Brian Plikaytis

VI. Summary and Overview of Issues

Benjamin Schwartz (CDC)