Disclosure Slide

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Please place an ‘X’ in the boxes as appropriate
Pneumococcal vaccines

1911: Clinical trials of whole-cell pneumococcal vaccine conducted in South Africa

1938: Injection with purified capsular polysaccharides provide clinical protection against type-specific disease

1983: 23-valent pneumococcal vaccine licensed

2000: 7-valent pneumococcal conjugate vaccine (PCV) licensed in U.S.

2009: 10-valent PCV vaccine

2010: 13-valent PCV introduced
Pneumococcal Polysaccharide Vaccine (PPSV)

- Polysaccharide antigen from 23 serotypes
  - Effective in preventing the invasive pneumococcal disease (IPD)
- Safe vaccine; occasional local side effects
- Does not reduce nasopharyngeal carriage
- Does not provide herd immunity
- Recommended for persons aged ≥65 years and people in certain high-risk groups aged 2 to 64 years
Pneumococcal Conjugate Vaccines (PCV)

- **PCV$_{10}$** serotypes:
  - 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F & 23F

- **PCV$_{13}$** serotypes:
  - 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F
PCV Efficacy

Cochrane Systematic Review of seven studies\(^1\)

Invasive pneumococcal disease (IPD):

Pooled vaccine efficacy (VE)

- For Vaccine Serotypes-
  \[80\% \ (95\% \text{ CI} \ 58\% \text{ to } 90\%, \ P \text{ < 0.0001})\]

- For All Serotypes-
  \[58\% \ (95\% \text{ CI} \ 29\% \text{ to } 75\%, \ P = 0.001)\]

\(^1\)Lucero MG, \ et al. \ Pneumococcal conjugate vaccines for preventing vaccine-type invasive pneumococcal disease and X-ray defined pneumonia in children less than two years of age. Cochrane Database Syst Rev 2009;(4):CD004977.
PCV Efficacy

Radiologically defined pneumonia

- Most studies report radiologically defined pneumonia (standardized WHO definition)
  - Pooled VE:
    - 27% (95%CI 15% to 36%, P < 0.0001)
  - Reduction in pneumonia even in studies that did not follow WHO definition

PCV Efficacy

Clinically defined pneumonia

• Pooled PE: 6% (2% - 9%, P 0.0006)

• PCV vaccination reduces hospitalization in virus-associated pneumonia; where disease severity is increased by co-infection with pneumococcus

PCV Efficacy

Otitis media

- Efficacy of 10-50% against recurrent otitis media or for prevention of tympanostomy tube placement\(^1\)
- Pneumococcal isolates fell by 39% - 66% among severe otitis media cases or from 'otitis-prone' children\(^2,3\)

\(^3\)Block SL, et al.. Community-wide vaccination with the heptavalent pneumococcal conjugate significantly alters the microbiology of acute otitis media. Pediatr Infect Dis J 2004;23(9):829-33.
PCV Efficacy

Nasopharyngeal carriage

• Most of the available data are on PCV$_7$

• Marked fall in vaccine-type pneumococcal carriage in all age groups (23.7% to 26.8% at baseline to 7.1% to 8.5% post-vaccination)$^1$

• Recent studies have reported effectiveness of PCV$_{13}$$^2$


Safety of PCV

• PCVs have a well tolerated and acceptable safety profile\textsuperscript{1-3}

• Main adverse events are injection-site reactions, rash, headache, fatigue, joint pain, fever, decreased appetite

• Serious rare events include bronchiolitis, pneumonia, gastroenteritis in infants/toddlers

\textsuperscript{1} Dicko A, \textit{et al.} Primary vaccination with the 10-valent pneumococcal non-typable Haemophilus Influenzae protein D conjugate vaccine (PHiD-CV) in infants in Mali and Nigeria: a randomized controlled trial. BMC Public Health 2011;11:882.


PCV: Efficacy vs Effectiveness

- Clinically relevant outcomes of public health significance include: mortality, IPD, pneumonia, adverse effects/events

- Reduces the odds/risk of developing pneumonia, IPD by vaccine serotypes and all-cause mortality (efficacy)

- Absolute risk reduction is much lower (effectiveness)

- No major adverse event except a small increase risk of asthma

Indian Scenario

• High case fatality (25-30%) of invasive pneumococcal disease in all age groups\(^1\)

• Pneumococcus is a predominant pathogen in community acquired acute bacterial meningitis (61.8%)\(^2\)

• High nasopharyngeal colonization (28%), and

• High rates of resistance to antibiotics in unvaccinated HIV infected children\(^3\)

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Indian Scenario

- Efficacy trials on PCV\textsubscript{10}, PCV\textsubscript{13} not conducted but studies report immunogenicity of these vaccines
- PCV13 and PCV7: similar safety & tolerability profiles\textsuperscript{1}
- PCV\textsubscript{10}, PCV\textsubscript{13} have been licensed and are available in the private sector
- Pneumococcal vaccination not included in the Indian National Immunization Schedule

Way Forward

• Introduction of PCV in National Immunization Schedule
• Surveillance of pneumococcal serotypes
• Better diagnostic tools needed to monitor burden of disease
Thanks