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Cost-effectiveness of a 13-valent pneumococcal conjugate vaccine compared with currently available pneumococcal conjugate vaccines in Indian children.

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INTRODUCTION

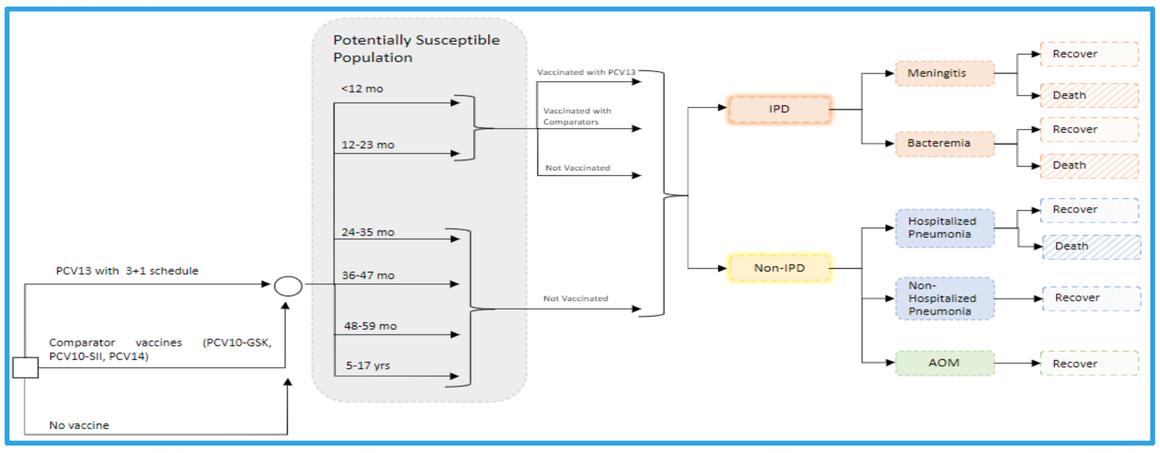
- Although PCVs have greatly reduced the burden and costs of pneumococcal disease (PD) in many countries, a significant burden remains.[1]
- In India, PD accounted for almost a quarter (23.4%) of all deaths in children under the age of 5 in 2015.[2]
- In India, an estimated 10.60 million and 12.65 million annual PD cases are attributable to serotypes contained in the pneumococcal conjugate vaccines (PCVs) PCV10-GSK and PCV13-Pfizer, respectively, resulting in an estimated 43,161 and 51,508 deaths.[3]
- One 13-valent (PCV13-Pfizer), two 10-valent (PCV10-GSK, PCV10-SII), and one 14-valent (PCV14-BioE) PCVs are currently available for infant immunization in India's private healthcare setting. PCV10-SII has been part of India's pediatric National Immunization Program (NIP) since 2021.[4,5]

OBJECTIVE

- To compare the clinical and economic impacts of different PCVs and the cost-effectiveness of PCV13-Pfizer versus currently available PCVs in the Indian pediatric population under 18 years of age from an out-of-pocket payer perspective.

METHODS

- A multicohort decision-analytic Markov model was developed to quantify the health and economic impact and cost-effectiveness of PCV13-Pfizer (3+1 schedule) versus currently available PCVs (PCV10-GSK [3+1], PCV10-SII [3+0], and PCV14-BioE [3+0]) from the Indian private healthcare payer perspective (Figure 1).



Abbreviations: AOM, acute otitis media; IPD, invasive pneumococcal disease; mo, months; PCV, pneumococcal conjugate vaccine; PCV13, PCV13-Pfizer; PCV14, PCV14-BioE

Figure 1. Model structure.

- Key model outcomes were PD cases, including invasive pneumococcal disease (IPD), which can manifest as meningitis or bacteremia, all-cause hospitalized and non-hospitalized pneumonia, and acute otitis media (AOM), and deaths due to IPD and hospitalized pneumonia, total costs, life-years (LYs), quality-adjusted life years (QALYs), and incremental cost-effectiveness ratio (ICER)
- Epidemiological and economic inputs for each age group were informed by Indian-specific data, model assumptions, and published literature. All model inputs are shown in Table 1.
- Direct vaccine effect (VE, i.e. the expected reduction in PD incidence attributable to serotypes covered by the vaccine among vaccinated children aged <2 years) was based on a real-world PCV13-Pfizer effectiveness study[6] and PCV7 clinical studies.[7-9] VE of PCV10-SII and PCV14-BioE were estimated based on the comparison of immunogenicity data between PCV13-Pfizer and PCV10-SII and PCV14-BioE with adjusting factors of 0.56 and 0.71, respectively. Table 2 shows VE estimates for post primary dose and post booster dose. The model did not consider indirect VE.
- The time horizon was 10 years with an annual discount rate of 3% applied to health and economic outcomes.
- The study assumed a vaccine coverage of 65.52% for primary and booster doses, and a willingness-to-pay (WTP) threshold of 3X India's GDP per capita in 2023 (INR 590,949)
- Vaccine cost per dose was assumed to be 2,495 INR, 2,599 INR, 3,991 INR, and 3,195 INR for PCV10-SII, PCV10-GSK, PCV13-Pfizer, and PCV14-BioE, respectively.[10]
- Deterministic sensitivity analysis (DSA) and scenario analysis using VE estimates based on opsonophagocytic assay (OPA) geometric mean titers (GMTs) for PCV10-SII and PCV14-BioE were conducted to examine model parameter uncertainties.

Table 1. Model inputs.

Parameter/Age	<12 mo	12-23 mo	24-35 mo	36-47 mo	48-59 mo	5-17 y
Population[11,12]	949,000	945,000	953,000	970,000	979,000	13,456,000
Annual incidence rate (per 100,000)						
IPD[13]	49.90	17.80	17.80	17.80	17.80	17.80
All-cause Hospitalized pneumonia[1]	1,011	1,011	1,011	1,011	1,011	1,011
All-cause Non-hospitalized pneumonia[1]	1,564	1,564	1,564	1,564	1,564	1,564
-All-cause AOM[14]	9,200	9,200	9,200	9,200	9,200	9,200
Percentage of IPD due to meningitis[15] (%)	20.00	20.00	20.00	20.00	20.00	20.00
All-cause mortality per 100,000[12]	33,404.80	1,134.00	1,143.60	1,164.00	1,174.80	7,682.90
Case fatality rates (%)						
Meningitis[16]	34.00	34.00	34.00	34.00	34.00	34.00
Bacteremia[16]	21.00	21.00	21.00	21.00	21.00	21.00
All-cause Hospitalized pneumonia[17,18]	17.20	17.20	17.20	17.20	17.20	19.30
	Female			**Male**		
Baseline utility[19]	0.99			0.94		
	Meningitis	**Bacteremia**	**Hospitalised pneumonia**	**Non-hospitalised pneumonia**		**AOM**
Direct medical cost per disease episode (INR)	276,201	230,156	339,025	6,650		2,300
Disutility[20-23]	0.023	0.008	0.006	0.004		0.005

Table 2. Vaccine effect estimates post primary doses and post booster dose.

	PCV13-Pfizer/PCV10-GSK 3+1 Dose		Base Case (based on IgG GMC)		Scenario analysis (based on OPA GMT)	
			PCV10-SII	PCV14-BioE	PCV10-SII	PCV14-BioE
Vaccine effect (%)	**Post-primary***	**Post booster dose**	**Post-Primary Dose (3+0)**	**Post-Primary Dose (3+0)**	**Post-Primary Dose (3+0)**	**Post-Primary Dose (3+0)**
IPD[6]	67.1	88.7	37.3	47.5	47.6	55.8
All-cause Outpatient Pneumonia[9]	19.3	25.5	10.7	13.6	13.7	16.0
All-cause Inpatient Pneumonia[7]	4.5	6.0	2.5	3.2	3.2	3.8
All-Cause AOM[8]	5.9	7.8	3.3	4.2	4.2	4.9

Abbreviations: AOM, acute otitis media; GMC, geometric mean concentration; GMT, geometric mean titer; IgG, immunoglobulin G; INR, Indian Rupees; IPD, invasive pneumococcal disease; mo, months; OPA, opsonophagocytic assay; PCV, pneumococcal conjugate vaccine; y, years

RESULTS

Base case analyses

- Over 10 years, PCV13-Pfizer was estimated to prevent an additional 255,060, 40,336, and 247,750 cases of PD, resulting in over 534,000, 86,500, and 520,200 QALY gains compared with PCV10-SII, PCV10-GSK, and PCV14-BioE, respectively (Table 3).
- Compared to PCV10-SII, PCV10-GSK, and PCV14-BioE, PCV13-Pfizer was estimated to result in additional cost savings of INR 22.5, INR 3.63, and INR 21.9 billion, respectively, from PD cases prevented.
- Given the greater disease prevention and higher PD-associated cost savings, PCV13-Pfizer was cost-effective versus the two 10-valent PCVs and was dominant over PCV14-BioE under the Indian WTP threshold.

Table 3. Incremental base case results over a 10-year period.

Model outcomes	Incremental Outcomes		
	PCV13-Pfizer vs. PCV10-SII	PCV13-Pfizer vs. PCV10-GSK	PCV13-Pfzier vs. PCV14-BioE
Clinical Outcomes			
Cases of IPD	-4,305	-758	-4,052
Cases of all-cause hospitalized pneumonia	-73,609	-11,837	-71,860
Cases of all-cause non-hospitalized pneumonia	-26,220	-4,213	-25,589
Cases of all-cause AOM	-150,926	-23,528	-146,249
Total PD cases	-255,060	-40,336	-247,750
Number of deaths due to PD	-12,815	-2,075	-12,498
Total QALYs	534,395	86,558	520,262
Economic Outcomes			
Total vaccination cost (INR)	32,206,300,589	29,965,551,362	17,137,463,787
Vaccine cost (INR)	32,206,300,589	29,965,551,362	17,137,463,787
Total direct cost of disease (INR)	-22,511,181,084	-3,631,694,115	-21,923,187,897
Net costs (INR)	9,695,119,505	26,333,857,247	-4,785,724,110
Incremental Cost-Effectiveness Ratios (ICERs)			
ICER Per QALY (INR /QALY)	18,142 (Cost Effective)	304,234 (Cost Effective)	PCV13 dominant

Abbreviations: AOM, acute otitis media; ICER, incremental cost-effectiveness ratio; INR, Indian Rupees; IPD, invasive pneumococcal disease; LY, life year; PCV, pneumococcal conjugate vaccine; QALY, quality-adjusted life year.

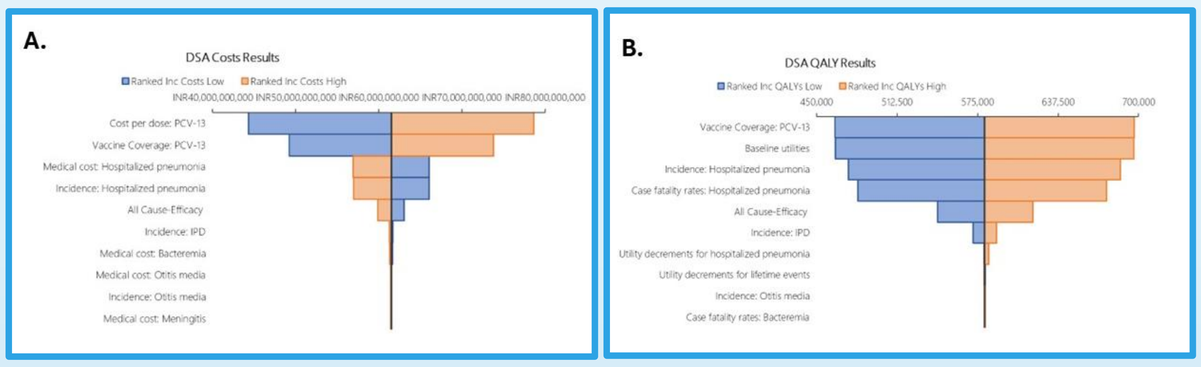
Sensitivity and scenario analyses

- In the DSA, the most influential factors for cost outcomes were the cost per dose of PCV13-Pfizer, vaccine coverage of PCV13-Pfizer, and medical cost of hospitalized pneumonia (Figure 2). The key drivers of QALY outcomes were vaccine coverage of PCV13, baseline utilities, and incidence of hospitalized pneumonia.
- Scenario analysis using different VE estimates suggested that PCV13-Pfizer remained cost-effective versus PCV10-SII and cost-saving versus PCV14-BioE (Table 4).

Table 4. Scenario analysis results for VE.

Scenario	Outcomes	PCV10-SII	PCV14-BioE	PCV13-Pfizer
VE for PCV10-SII and PCV14-BioE: estimation based on OPA GMTs	Total QALY	1,313,349,729	1,313,361,655	1,313,871,312
	Total cost	610,387,678,499	624,960,409,344	620,614,863,400
	ICER	19,608 (Cost Effective)	PCV13 Dominant	Ref

Abbreviations: GMT, geometric mean titer; OPA, opsonophagocytic assay; PCV, pneumococcal conjugate vaccine; QALY, quality-adjusted life year; Ref, reference; VE, vaccine effect



Abbreviations: IPD, invasive pneumococcal disease; PCV, pneumococcal conjugate vaccine; QALY, quality-adjusted life year; PCV13, PCV13-Pfizer

Figure 2. Deterministic sensitivity analysis (DSA) results. A. DSA costs results; B. DSA QALY results.

CONCLUSIONS

- **Vaccinating children in India with PCV13-Pfzier could prevent more PD cases and save more PD-associated medical costs than PCV10 and PCV14-BioE vaccines over 10 years.**
- **From the Indian private market perspective, PCV13-Pfizer was cost-effective compared with the two 10-valent PCVs and dominant over PCV14-BioE.**

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