EE520

Cost-Effectiveness Analysis of the Use of the 20-Valent Anti-Pneumococcal Vaccine (PCV20) in the Spanish Pediatric Population

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INTRODUCTION

- Pneumococcal conjugate vaccine (PCV) use in Spain's pediatric population varied by region until 2016, when 13-valent PCV (PCV13) was introduced into the childhood national immunization program.[1]
- Despite the demonstrated impact of PCVs in the reduction of pneumococcal disease in Spain, a clinical and economic burden persists, partly due to the emergence of non-vaccine serotypes.[2]
- Higher-valent vaccines, 15-/20-valent PCV (PCV15/PCV20), have been approved for pediatric use in Europe, with the potential to further reduce pneumococcal disease burden.[3,4]
- A recent survey study of European countries including Spain demonstrated that healthcare professionals and caregivers see broader serotype coverage against pneumococcal disease as an important unmet need among pediatrics.[5]

OBJECTIVE

- A cost-effectiveness analysis was conducted to assess the impact of implementing PCV20 in the Spanish pediatric population compared with PCV13 and PCV15 for the prevention of invasive pneumococcal disease (IPD), pneumonia, and otitis media (OM).

METHODS

- A decision-analytic multi-cohort Markov model was developed to compare PCV20 (3+1 schedule) with PCV13 or PCV15 (2+1 schedules) in the pediatric population (ages 0–17 years) over 10 years from the Spanish National Healthcare System perspective.
- The model depicted pneumococcal disease outcomes for vaccinated and unvaccinated children, with annual transitions to pneumococcal disease states (IPD, pneumonia, and OM), no pneumococcal disease, and death.
- Epidemiologic, serotype coverage, utility, cost, and clinical model inputs associated with pneumococcal disease data were extracted from published literature and Spanish official databases (**Tables 1–3**).[2,6-27]
- Direct vaccine effects were applied to infants aged <2 years, while the population aged 2–17 years would benefit from indirect effects throughout the time horizon, with inputs informed by PCV13 effectiveness and impact studies, and 7-valent PCV trials (**Table 3**).[14-21]
- Indirect (herd) effects for PCV15- and PCV20-specific serotypes accrued gradually, while PCV13 serotypes (also covered by PCV15 and PCV20) were assumed to have reached a steady state.
- Vaccines ex-factory prices from the Spanish National Pharmacology database were discounted by 7.5% per RDL8/2010 decree, and an administration cost of €6.21/dose was considered.[28-30]
- Clinical and economic (2024 Euros, €) outcomes related to IPD, hospitalized, and non-hospitalized pneumonia, and OM were reported, with incremental outcomes calculated for each vaccine strategy to derive incremental cost-utility ratios (ICUR). A willingness-to-pay threshold of 25.000(E)/QALY was considered for results interpretation[31].
- Sensitivity analyses and additional scenarios examined the robustness of the results.

Table 1. Epidemiologic inputs

Age group, years	Disease incidence per 100,000 individuals				Case fatality rate, %[2,9,10]			Proportion of IPD cases: meningitis, %†[11,12]
	IPD[6]	Hospitalized pneumonia[7]	Non-hospitalized pneumonia[8]	OM[8]	Meningitis	Bacteremia	Hospitalized pneumonia	
<1	21.08	556.00	128.60	24,289.98	3.23	4.62	0.30	17.00
1	21.08	556.00	128.60	24,289.98	2.27	8.24	0.30	11.36
2–4	5.68	293.00	128.60	24,289.98	2.27	8.24	0.20	11.36
5–17	5.68	54.50	31.40	17,294.30	1.67	7.60	0.85	11.36

†IPD cases are either meningitis or bacteremia/sepsis. Abbreviations: IPD, invasive pneumococcal disease; OM, otitis media.

Table 2. Serotype coverage by vaccine and age group

Age, years	ST coverage, %[13]														
	PCV7	PCV10			PCV13			PCV15		PCV20					NVT
	STs	1	5	7F	3	6A	19A	22F	33F	8	10A	11A	12F	15B	
<1	4.7	0.0	0.0	0.0	14.1	0.0	3.5	6.5	4.7	7.6	6.5	2.4	1.2	7.1	42
1–4	3.9	1.9	0.0	0.0	22.3	0.0	7.8	8.7	1.9	3.9	1.9	1.9	0.0	2.9	43
5–17	7.1	2.0	0.0	0.0	18.4	0.0	5.1	6.1	0.0	25.5	3.1	2.0	2.0	1.0	28

Abbreviations: NVT, non-vaccine type; PCV, pneumococcal conjugate vaccine; ST, serotype.

Table 3. Vaccine effectiveness, cost, and utility inputs

	Year				
	1	2	3	4	5–10
Indirect effect – ramp-up (PCV15/PCV20), %[14,15]	37.5	52.8	67.7	82.7	100.0
	IPD	Hospitalized pneumonia	Non-hospitalized pneumonia	OM	
Indirect effect – max. reduction, %[14-18]	83.0	30.5†	25.5†	20.0†	
Direct effects, %[19-21]					
3+1 schedule	89.7	25.5§	6.0§	7.8§	
2+1 schedule	78.2				
	Meningitis	Bateremia	Hospitalized pneumonia	Non-hospitalized pneumonia	OM
Medical cost (per episode), €[22,23]					
All ages	12,342.91	5,503.32	4,637.64	528.51	147.90
Utility values					
QALY decrement[24-26]	0.023	0.008	0.006	0.004	0.005
Baseline utility[27]	0.98 (applied to both sexes and across all ages, 0–17 years)				

†Indirect effect: for pneumonia, data from Levy et al. 2017[16] were adjusted for IPD serotype distribution from Janoir et al. 2016[17] (70% for age 0–59 months and 86% for age 5–17 years); for OM, data from Lau et al. 2015[18] were adjusted for IPD serotype distribution by Ladhani et al. 2018[15] at PCV13 introduction in 2009. §Direct effect data were adjusted using serotype coverage pre-PCV7 to pre-era for higher-valent vaccines. PCV7 all-cause efficacy data were adjusted for pre-PCV7 era (80.6% PCV7 serotype coverage), to pre-PCV20 era for PCV20 (47.5%), PCV15 (17.8%), and PCV13 (12.8%); Pfizer data on file. Abbreviations: IPD, invasive pneumococcal disease; OM, otitis media; PCV, pneumococcal conjugate vaccine; QALY, quality-adjusted life year.

RESULTS

Table 4. Incremental base-case results

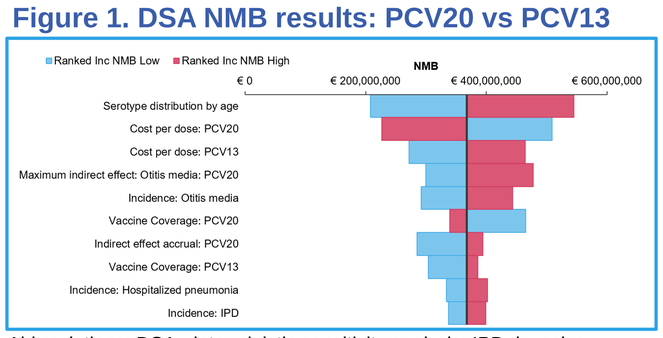
Model outcomes	PCV20 vs PCV13	PCV20 vs PCV15
Total cases of pneumococcal disease	-1,435,912	-1,120,731
Cases of IPD	-1,890	-1,461
Cases of hospitalized pneumonia	-17,157	-11,807
Cases of non-hospitalized pneumonia	-3,521	-2,546
Cases of OM	-1,413,344	-1,104,917
Disease-related deaths	-193	-148
QALYs	15,203	11,712
LYs	4,845	3,700
Total costs	-€63,888,966	-€87,695,935
Vaccination program costs	€197,270,882	€109,879,715
Direct cost of disease	-€261,159,849	-€197,575,650
ICUR per QALY	Dominant	Dominant

Abbreviations: ICUR, incremental cost-utility ratio; IPD, invasive pneumococcal disease; LY, life-year; OM, otitis media; PCV, pneumococcal conjugate vaccine; QALY, quality-adjusted life year.

Base-case results

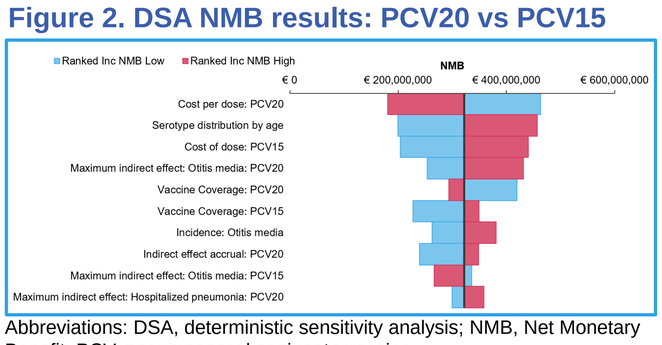
- PCV20 prevented more pneumococcal disease cases and disease-related deaths, as well as providing cost-savings due to considerable savings in medical costs, vs both PCV13 and PCV15, making PCV20 the dominant (more effective and less costly) vaccination strategy in both pairwise comparisons (**Table 4**).

Figure 1. DSA NMB results: PCV20 vs PCV13



Abbreviations: DSA, deterministic sensitivity analysis; IPD, invasive pneumococcal disease; NMB, Net Monetary Benefit; PCV, pneumococcal conjugate vaccine.

Figure 2. DSA NMB results: PCV20 vs PCV15

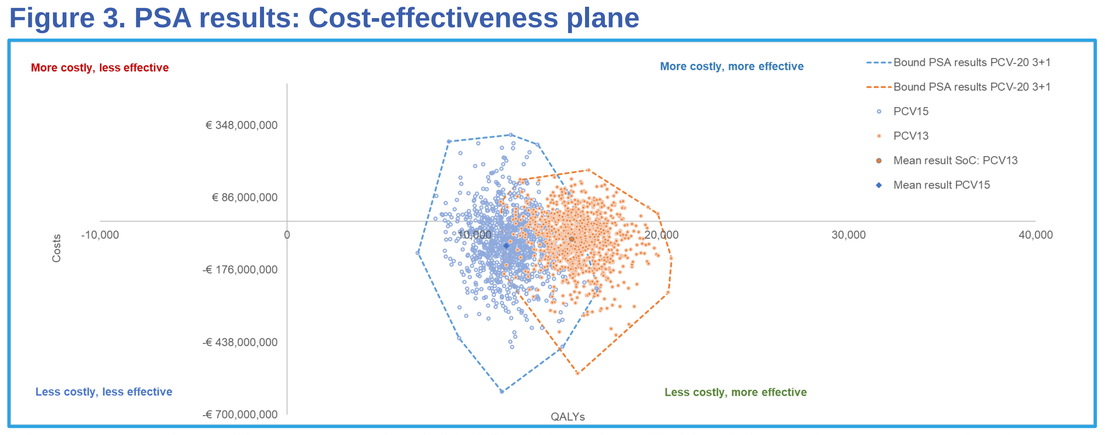


Abbreviations: DSA, deterministic sensitivity analysis; NMB, Net Monetary Benefit; PCV, pneumococcal conjugate vaccine.

Sensitivity and scenario results

- Deterministic sensitivity analyses (DSA) identified similar key drivers of Net Monetary Benefit (NMB) in both comparisons (**Figures 1 and 2**).
- The variation in cost per dose (+25% to PCV20 or -25% to comparator prices) resulted in PCV20 being either cost-effective or dominant vs comparators.
- Probabilistic sensitivity analyses (PSA) with 1,000 simulations identified PCV20 as the dominant strategy vs PCV13 in 74.0% of simulations and vs PCV15 in 78.2% of simulations (**Figure 3**).
- PCV20 was consistently dominant or cost-effective vs PCV13 and PCV15 in all sensitivity analyses.
- In scenario analyses, discount rates of 0% and 5% for both costs and health outcomes resulted in PCV20 remaining dominant vs both PCV13 and PCV15.

Figure 3. PSA results: Cost-effectiveness plane



PSA was assessed at a willingness-to-pay threshold of €25,000 per QALY.[31] Abbreviations: PCV, pneumococcal conjugate vaccine; PSA, probabilistic sensitivity analysis; QALY, quality-adjusted life year; SoC, standard of care.

CONCLUSIONS

- **In this cost-effectiveness analysis of the Spanish pediatric population, the vaccination strategy of PCV20 (3+1) was more effective and less costly (i.e., dominant) compared with both PCV13 (2+1) and PCV15 (2+1) over 10 years.**
- **The implementation of an immunization program for the Spanish pediatric population with PCV20 (3+1) is an efficient measure from the National Healthcare System perspective, due to its broader serotype coverage and increased protection against pneumococcal disease.**

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