Public health impact of switching from a 13-valent to a 15-valent pneumococcal conjugate vaccine in the Chilean national immunization program

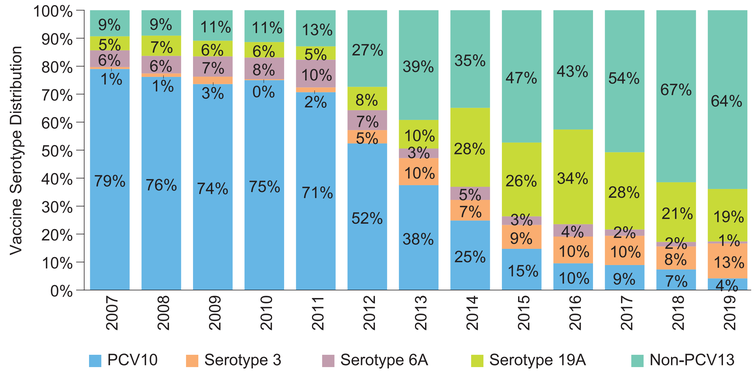
Hirata L[1]; Wong Ticona RR[2]; White M[3]; Huang M[4]; Webster J[3]; Urrego-Reyes J[5]; Chhabra N[6]; Kamboj H[6]; Gotarkar S[6]; Parellada CI[1]

[1]Center for Observational and Real-World Evidence, MSD Brazil, São Paulo, Brazil; [2]Market Access, MSD Chile, Santiago de Chile, Chile; [3]Center for Observational and Real-World Evidence, Merck & Co., Inc., Rahway, NJ, USA; [4]Health Economic and Decision Sciences, Merck & Co., Inc., Rahway, NJ, USA; [5]Center for Observational and Real-World Evidence, MSD Colombia, Bogotá, Colombia; [6]CHEORS, North Wales, PA, USA

Background

- *Streptococcus pneumoniae* represents the main etiology and cause of deaths of lower respiratory diseases worldwide, affecting mainly children under 5 and older adults[1,2]
- In Chile, PCV10 was introduced in the National Immunization Program (NIP) for infants in 2011 and later switched to PCV13 in 2017. Despite the substantial reduction in incidence of pneumococcal disease (PD) following the introduction of PCV, residual disease caused by some serotypes contained in PCV13 (mainly STs 3 and 19) and non-vaccine serotypes have emerged in the last few years (**Figure 1**).[2] To further reduce the burden of PD, a PCV15 was developed containing serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, and 33F

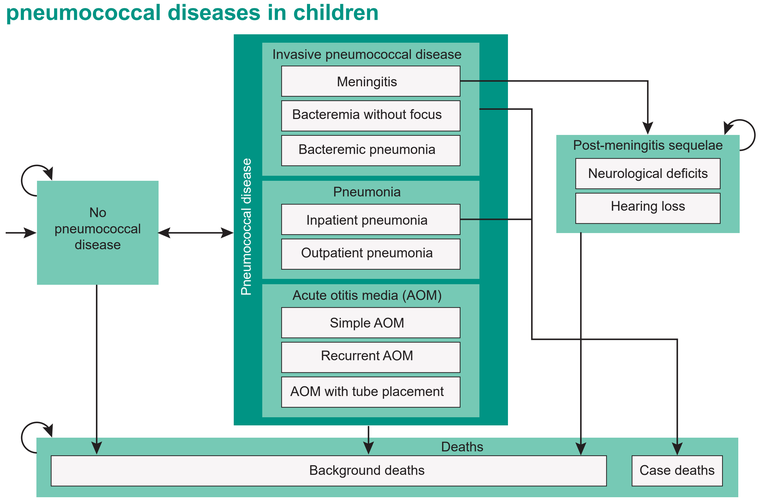
Figure 1. Invasive pneumococcal disease incidence and distribution of vaccine serotypes in Chile, 2007-2019



Objective

- To evaluate the potential public health impact of switching from PCV13 to PCV15 in the NIP for infants in Chile

Figure 2. Schematic of the model showing the natural history of pneumococcal diseases in children



Methods

- A state-transition Markov model was adapted to the Chilean population. The model incorporated three health states – no PD, post-meningitis sequelae (PMS), and death – and tracked the occurrence of acute PD events, including acute otitis media (AOM), non-bacteremic pneumococcal pneumonia (NBPP), and invasive pneumococcal disease (IPD). The clinical inputs and assumptions used in the model are presented in **Table 1** and **Table 2**
- The model started in year 2024 with a birth cohort of 235,715 newborns. The following 100 cohorts were eligible to receive either PCV13 or PCV15. Indirect effects for IPD caused by ST 22F and 33F were included for the first 5 years after the introduction of PCV15 for all age groups

Table 1. Model parameters and assumptions

Model parameters	
Vaccination strategies	PCV13: 2+1 schedule at 2, 4, and 12 months PCV15: 2+1 schedule at 2, 4, and 12 months
Perspective	Payer
Time horizon	Until death or 100 years of age
Cycle length	1 year with half-cycle corrections
Discount rate for LYs	0% and 3% per year
Data sources	Chilean-specific data from official sources/literature were used, with data from other Latin American countries as proxy, when unavailable
Vaccine efficacy (VE)	Vaccine efficacy was assumed to be the same for the shared 13 serotypes and the average overall VE of PCV13 was applied to the additional serotypes in PCV15[3,4]
Coverage rate	Primary series – 96.30% Booster dose – 90.50%
Indirect effect	7.8% per year for the first 5 years only for IPD caused by 22F and 33F[5]
Vaccine waning	VE was assumed as 100% during the first 5 years and gradually decreased linearly to 0% over the next 10 years[6]
Health outcomes	Incremental avoided cases of IPD, pneumonia, and AOM compared to PCV13 and incremental gains in L-Ys compared to PCV13

LYs, life-years.

Table 2. Epidemiological inputs for pneumococcal disease

Inputs	<1	1	2-4	5-17	18-34	35-49	50-64	≥65
IPD incidence per 100,000	16.5	21.0	7.9	1.1	1.2	2.6	6.3	11.0-16.1
Case fatality rate	7.3%	4.8%	1.9%	6.4%	2.6%	7.8%	10.7%	13.0%-19.9%
NBPP incidence per 100,000 (inpatient)	136.0	136.0	136.0	9.0	7.0	7.0	13.0	21.0-39.0
Case fatality rate	0.3%	0.3%	0.3%	0.5%	1.7%-2.4%	3.5%	5.5%	6.7%-15.4%
NBPP incidence per 100,000 (outpatient)	153.0	153.0	153.0	42.0	26.0	26.0	43.0	69.0-72.0
AOM[a] incidence per 100,000	12,900	12,900	8,040	1,999				

[a]Due to *S. pneumoniae*. IPD, invasive pneumococcal disease; AOM, acute otitis media.

Results

- PCV15 was estimated to prevent an additional 4,953 IPD cases, 21,339 NBPP cases, 736,547 AOM cases, and 52 PMS cases compared to PCV13 over a 100-year time horizon (**Table 3**)
- Moreover, PCV15 would avert additional 451 IPD deaths and 29 pneumonia deaths compared to PCV13, leading to incremental gains of 11,051 LYs undiscounted) and 2,034 LYs (discounted) over the 100-year time horizon (**Table 3**)

Table 3. Clinical outcomes of pneumococcal disease

Clinical outcomes	PCV15	PCV13	Incremental cases/deaths
IPD cases	207,678	212,631	-4,953
NBPP cases	1,392,614	1,413,953	-21,339
AOM[a] cases	19,577,683	20,314,230	-736,547
PMS cases	5,507	5,559	-52
IPD deaths	23,061	23,511	-451
Pneumonia deaths	17,431	17,460	-29
Life-years	**PCV15**	**PCV13**	**Life-years saved**
Total life-years (discounted)	686,868,127	686,865,824	2,304
Total life-years (undiscounted)	2,160,133,333	2,160,122,282	11,051

Limitations

- Although Markov models are not considered ideal for assessing the impact of an intervention on infectious diseases due to their inability to capture the transmission dynamics, a crude approach was used to incorporate herd effects in this analysis. However, these effects were only applied to IPD and did not consider the potential for serotype replacement
- For simplification and due to lack of reliable data, several assumptions were made about the natural history of pneumococcal disease as well as the attributable serotypes. As an example, serotype distribution was assumed to be constant over time
- This analysis took a conservative approach by assuming the same VE for shared serotypes, including serotype 3. However, PCV15 may potentially avert more cases due to its higher immunogenicity for serotype 3[1]

Conclusions

- Switching from PCV13 to PCV15 is projected to have a substantial impact on health benefits, reducing cases and deaths related to PD in Chile
- PCV15 would prevent an additional 762,839 cases of PD and avert 480 deaths compared to PCV13, resulting in incremental gains of 11,051 life-years over a 100-year time horizon
- The results highlight the positive public health impact of PCV15 in preventing PD mortality and morbidity in Chile for both vaccinated and unvaccinated cohorts

References

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