# Comparing the Public Health Impact of a 15- or 20-Valent Pneumococcal Conjugate Vaccine Pediatric National Immunization Program in Spain



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# **BACKGROUND**

- Pneumococcal disease, one of the most common vaccine-preventable diseases worldwide, consists of invasive pneumococcal disease (IPD) and noninvasive disease, such as pneumonia and otitis media (OM).<sup>1</sup>
- The introduction of pneumococcal conjugate vaccines (PCVs) in pediatric national immunization programs (NIPs) have had a substantial impact from widespread use<sup>2</sup>; however, the disease burden remains due to non-PCV serotypes.
- In Spain, where the 13-valent vaccine (PCV13) is part of the infant NIP under a 2+1 schedule, PCV13 serotypes caused 16.1% of residual IPD burden in 2019 in children <2 years old. The 15-valent vaccine (PCV15) serotypes caused 8.5% of residual burden, while the 20-valent vaccine (PCV20) serotypes caused 31.8% of residual burden (Figure 1).3

## **OBJECTIVE**

• To determine the public health impact (cases and deaths) for the entire Spanish population of switching from PCV13 to either PCV15 or PCV20 in the pediatric NIP.

# **METHODS**

- A decision-analytic forecasting model was adapted to compare the health impact of switching infant vaccination from PCV13 to either PCV15 in 2023 or PCV20 in 2024 after the expected licensure over a 5-year time horizon (Figure 2).<sup>4-5</sup>
- The model uses historical age and serotype-specific real-world data in Spain between 2013 and 2019 to project future IPD incidence across the overall population to capture both direct and indirect protection assuming a 97.5% pediatric vaccination coverage rate.<sup>6</sup>
- Clinical and population data were derived or estimated from country-specific published sources (Table 1).
  - Spanish population size was obtained from the Spanish Statistics National Institute.<sup>7</sup>
  - IPD incidence and serotype distribution were sourced from published literature.<sup>3,8</sup>
- The percentage of IPD presenting as meningitis was obtained from recent published literature. We assumed 14.25% for children 0 to 2 years of age, 12% for children 2 to 17 years of age, and 11.40% for children 18 years and older, respectively.9-12
- For all-cause noninvasive disease, we assumed a percentage to be caused by *Streptococcus pneumoniae*. For adults, 28.8% of all-cause disease was assumed to be pneumococcal pneumonia. For children 0 to 17 years of age, 20% of all-cause disease was conservatively assumed to be pneumococcal pneumonia and pneumococcal OM. 4,5
- All-cause mortality rates for all age groups were obtained from the Spanish Statistics National Institute.<sup>8</sup>
- IPD and hospitalized pneumonia-related case fatality rates were sourced from published literature.<sup>10, 12–13</sup>
- Future PCV15-13 and PCV20-13 serotype trends from 2024 to 2028 were forecasted using the overall average historical PCV13-7 serotype trends between 2013 and 2019 in Spain.
- Of note, changes in epidemiology during the COVID-19 era were not considered, and an assumption was made that IPD trends would return to pre–COVID-19 levels at the time of PCV15/PCV20 launch.
- Future noninvasive disease incidence rates were assumed to vary proportionally with IPD.

Table 1: Sources of Clinical and Population Data			
Parameter	Source		
Population	Spanish Statistics National Institute, 2022		
IPD incidence & serotype distribution	De Miguel et al., 2021; Redin et al., 2021		
Percentage of IPD presenting as meningitis	Ruiz-Contreras et al., 2018; Ruiz-Contreras et al., 2017; González-Díaz et al., 2020		
All-cause pneumonia (hospitalized & nonhospitalized)	Spanish Ministry of Health, 2021; Base de Datos Clínicos de Atención Primaria, 2021		
	Torres et al., 2021; Jimenez et al., 2017 for the adult population		
	20% pneumococcal assumed for the pediatric population		
OM incidence	Base de Datos Clínicos de Atención Primaria, 2021		
	20% pneumococcal assumed based on all-cause OM		
All-cause mortality rate	Spanish Statistics National Institute, 2022		
IPD and hospitalized pneumonia case fatality rates	Ladhani et al., 2013; Ruiz-Contreras et al., 2017; De Miguel et al., 2021; Rejas et al., 2022; De-Miguel-Díez et al., 2022		
IPD=invasive pneumococcal disease; OM=otitis media.			

#### Figure 1. Serotype Coverage of Licensed and Investigational PCVs in 2019 in Spanish Children <2 Years of Age

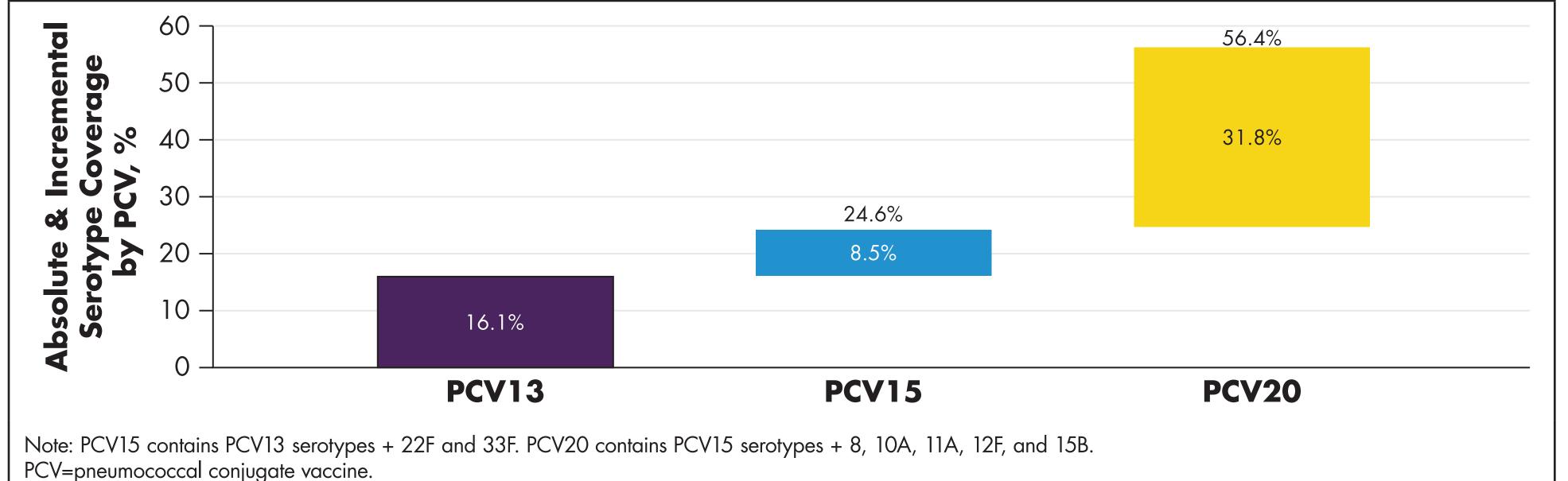
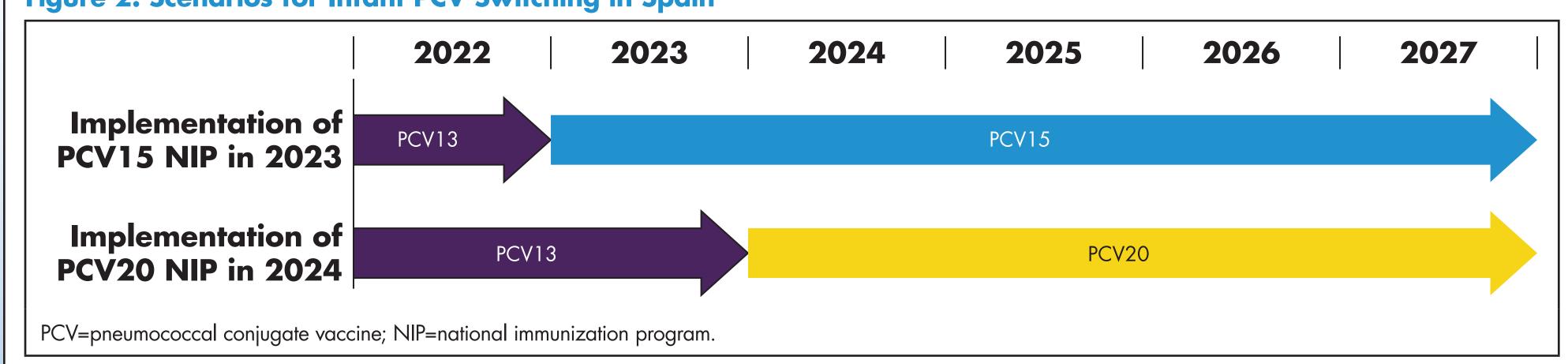


Figure 2. Scenarios for Infant PCV Switching in Spain



## RESULTS

- Compared with PCV15, switching to PCV20 is estimated to prevent an additional 1784 IPD cases, 38,835 pneumonia cases, and 22,934 OM cases, amounting to a total of 63,552 pneumococcal disease cases averted over 5 years across all ages (**Table 2**).
- The additional disease cases averted from PCV20 compared with PCV15 amounts to 761 additional lives saved in the Spanish population (**Table 2**).

Table 2: Results From Public Health Impact Analysis in the Overall Population

Overall		Incremental	
PCV20 in 2024*	PCV15 in 2023**	(PCV20- PCV15)	
2,448,281	2,511,834	-63,552	
11,322	13,106	-1784	
1,523,419	1,546,353	-22,934	
913,540	952,375	-38,834	
6182	6944	-761	
1383	1587	-204	
4799	5357	-558	
	PCV20 in 2024*  2,448,281  11,322 1,523,419  913,540  6182 1383	PCV20 in 2024*         PCV15 in 2023**           2,448,281         2,511,834           11,322         13,106           1,523,419         1,546,353           913,540         952,375           6182         6944           1383         1587	

- \*Infant vaccination with PCV13 from years 2022–2023 and PCV20 from years 2024–2028.
- years 2024–2028.

  \*\*Infant vaccination with PCV13 from years 2022–2022 and PCV20 from years 2023–2028.
- IPD=invasive pneumococcal disease; PCV=pneumococcal conjugate vaccine.

# CONCLUSIONS

- The clinical burden of pneumococcal disease is largely driven by serotypes not covered by the PCV currently included in Spain's NIP.
- Given the incremental protection against serotypes provided by PCV20, replacing PCV13 with PCV20 in 2024 is estimated to provide a greater public health impact compared with PCV15 in 2023 on the pediatric NIP over a 5-year time horizon in Spain.
- PCV20 has the potential to reduce the pneumococcal disease burden for the Spanish population overall by protecting against additional serotypes that are not covered by lower-valent vaccines.
- Depending on adult higher-valent PCV program uptake and implementation, disease burden in the adult population may change before the introduction of these vaccines in the infant NIP.

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## DISCLOSURES

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