

PCV vaccines indicator

Safety of the intervention

Type, including severity, consequences and frequency of short- and long-term adverse events following vaccination

Safety profiles of PCV10 and PCV13 have been reviewed by the WHO GACVS. The GSK and Pfizer products have accrued extensive post-marketing safety surveillance data and are assessed as having excellent safety profiles [1, 2, 3, 4, 5](#) . In the clinical trials of the newer PCVs, PCV10-SII had a similar safety profile compared to PCV10-GSK and PCV13-PFZ [6, 7](#)), and the extended-valency PCVs (i.e., PCV14-BE, PCV15 and PCV20) have a similar safety profile to PCV13-PFZ. [8](#) [9](#) [10, 11](#)

Children with impaired immune responsiveness may exhibit reduced antibody response to PCV10-GSK, PCV13-PFZ and PCV15, which were the only PCVs evaluated in this population. Safety studies suggest that PCV15 and PCV13 have comparable safety profiles in high-risk groups, including among children with HIV infection and sickle cell disease, and among healthy children. [12, 13](#)

Sources

1.

Artama M, Rinta Kokko H, Nohynek H, Jokinen J, Palmu AA et al. (2018). Register based ecologic evaluation of safety signals related to pneumococcal conjugate vaccine in children. *Curr Drug Saf.* 13(2):107-112. doi: 10.2174/1574886313666180219123253.

2.

Feikin DR, Kagucia EW, Loo JD, Link Gelles R, Puhon MA et al. (2013). Serotype specific changes in invasive pneumococcal disease after pneumococcal conjugate vaccine introduction: a pooled analysis of multiple surveillance sites. *PLoS Med.* 10(9):e1001517. doi: 10.1371/journal.pmed.1001517.

3.

World Health Organization (n.d.). Pneumosil® – prequalification dossier and related information. World Health Organization. Available at: <https://extranet.who.int/pqweb/content/pneumosil%C2%AE> 0 (accessed 4 August 2025).

4.

Løchen A, Croucher NJ, Anderson RM et al. (2020). Divergent serotype replacement trends and increasing diversity in pneumococcal disease in high-income settings reduce the benefit of expanding vaccine valency. *Sci. Rep.* 10, 18977. doi: 10.1038/s41598-020-75691-5.

5.

World Health Organization (n.d.). Pneumococcal vaccines and vaccine safety reviews. Global Advisory Committee on Vaccine Safety (GACVS). World Health Organization. Available at: <https://www.who.int/groups/global-advisory-committee-on-vaccine-safety/topics/pneumococcal> (accessed 4 August 2025).

6.

Clarke E, Bashorun A, Adigweme I, Badjie Hydara M, Umesi A, Futa A et al. Immunogenicity and safety of a novel ten-valent pneumococcal conjugate vaccine in healthy infants in The Gambia: a phase 3, randomised, double-blind, non-inferiority trial. *Lancet Infect Dis.* 2021;21:834-46. doi: 10.1016/S1473-3099(20)30735-0.

7.

Adigweme I, Futa A, Saidy-Jah E, Edem B, Akpalu E, Dibbasey T et al. Immunogenicity and safety of a 10-valent pneumococcal conjugate vaccine administered as a 2 + 1 schedule to healthy

infants in The Gambia: a single-centre, double-blind, active-controlled, randomised, phase 3 trial. *Lancet Infect Dis.* 2023;23:609-20. doi: 10.1016/S1473-3099(22)00734-4.

8.

Matur RV, Thuluva S, Gunneri S, Yerroju V, Reddy Mogulla R, Thammireddy K et al. Immunogenicity and safety of a 14-valent pneumococcal polysaccharide conjugate vaccine (PNEUBEVAX 14) administered to 6-8 weeks old healthy Indian Infants: A single blind, randomized, active-controlled, Phase-III study. *Vaccine.* 2024;42:3157-65. doi: 10.1016/j.vaccine.2024.03.056.

9.

Wagner G, Gartlehner G, Thaler K, Ledingger D, Feyertag J, Klerings I et al. Immunogenicity and safety of the 15-valent pneumococcal conjugate vaccine, a systematic review and meta-analysis. *NPJ Vaccines.* 2024;9:257. doi: 10.1038/s41541-024-01048-y.

10.

Senders S, Klein NP, Tamimi N, Thompson A, Baugher G, Trammel J et al. A Phase Three Study of the Safety and Immunogenicity of a Four-dose Series of 20-Valent Pneumococcal Conjugate Vaccine in Healthy Infants. *Pediatr Infect Dis J.* 2024;43:596-603. doi: 10.1097/INF.0000000000004334.

11.

Korbal P, Wysocki J, Jackowska T, Kline M, Tamimi N, Drozd J et al. Phase 3 Safety and Immunogenicity Study of a Three-dose Series of Twenty-valent Pneumococcal Conjugate Vaccine in Healthy Infants and Toddlers. *Pediatr Infect Dis J.* 2024;43:587-95. doi: 10.1097/INF.0000000000004300.

12.

Wilck M, Barnabas S, Chokephaibulkit K, Violari A, Kosalaraksa P, Yesypenko S et al. A phase 3 study of safety and immunogenicity of V114, a 15-valent pneumococcal conjugate vaccine, followed by 23-valent pneumococcal polysaccharide vaccine, in children with HIV. *AIDS.* 2023;37:1227-37. doi: 10.1097/QAD.0000000000003551.

13.

Quinn, C.T., Wiedmann, R.T., Jarovsky, D., Lopez Medina, E., Rodriguez, H.M. et al. (2023) 'Safety and immunogenicity of V114, a 15 valent pneumococcal conjugate vaccine, in children with SCD:

a V114 023 (PNEU SICKLE) study', Blood Advances, 7(3), pp.414-421.
doi:10.1182/bloodadvances.2022008037.