PCV vaccines indicators

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Burden & epidemiology

Number of new cases per year (last 3-5 years)

Disease (incidence) rates are higher in Africa than in Europe or North America, incidence rates in Asia and Latin America range in between. Before widespread PCV introduction in 2006, mean annual incidence of invasive pneumococcal disease in children <2 years was 44/100,000 in Europe, 167/100,000 in the USA, 60 - 797/100,000 in Africa (SA and Mozambique). The reported

incidence in countries in Asia and Latin America falls between these extremes. Some of the differences in disease incidence could be due to differences in surveillance methods. [1], [2], [3], [4], [5]

The introduction of the pneumococcal conjugate vaccine into childhood immunization programmes starting in 2000 led to substantial reductions in the overall IPD incidence in many countries due to reductions in the incidence of vaccine serotype (vaccine-type(s), VT) disease. IPD reductions were also observed in unvaccinated children and adults through herd protection in some countries. Declines in the incidence of VT disease were accompanied by increases in IPD caused by non-vaccine serotypes (NVTs), known as serotype replacement; however, among children, the increase in incidence of IPD due to NVTs was smaller than the decline in VT IPD, resulting in a decline in the overall incidence of IPD. [6]

To note is that the incidence estimates are driven by clinical practices in the country and whether rates are limited to inpatients or also include outpatients. For example, in the US there is a lower threshold than in Europe to do blood cultures, and this impacts incidence rates. Most cases in the US are outpatients with febrile bacteraemia, which can be self-limiting. On the other hand, the cases in Africa may mainly be from inpatients with sepsis or bacteremic pneumonia.

Proportion of the population affected by the disease or infected with the antigen

About 75% of cases of invasive pneumococcal disease and 83% of cases of pneumococcal meningitis occur in children < 2 years of age. It is difficult to determine the proportion of pneumonia due to S. pneumoniae. Cross-sectional point prevalence of nasopharyngeal carriage ranges from 27% to 85%, with higher carriage rates in LMICs and in some indigenous populations in HICs. At least 34% of radiologically confirmed pneumonia could be caused by S. pneumoniae in children < 5 years of age.

Available microbiological, epidemiological and modelled data indicate that there is also a substantial burden of disease attributable to S. pneumoniae in adults ≥50 years of age. [7] [8], [9]

The risk of sequelae is 3 times higher in Africa and Asia than in Europe. [10]

Serogroup or serotype distribution (for serogroup- or serotype-specific vaccines)

There are >100 known serotypes of S. pneumoniae, with some serotypes grouped into serogroups based on similarities in the polysaccharide capsule. Of the numerous pneumococcal serotypes, only a subset is responsible for the majority of cases of invasive pneumococcal disease (IPD). The distribution of serotypes that cause disease varies over time and by age, disease syndrome, disease severity, geographical region and presence of AMR genes.
A 2010 systematic review found that before the introduction of PCV7, 6 to 11 serotypes accounted for ≥70% of global and regional IPD cases, with 7 serotypes (1, 5, 6A, 6B, 14, 19F, 23F) being the most prevalent globally [11]. More recently, the Pneumococcal Serotype Replacement and Distribution Estimation (PSERENADE) project, which compiled data from 45 countries with stable surveillance systems, found that following sustained, high coverage with PCV13 or PCV10, 10 vaccine serotypes (1, 3, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F in all age groups, and serotype 4 in adults) remain among the top 30 serotypes causing IPD. Serotype replacement with other non-vaccine serotypes was also common. [12, 13]
To note that with the introduction of PCV, the more recent availability of new formulations and WHO issuing recommendations about the higher valency vaccines, there is an impact on the circulating serotypes and it is no longer possible to determine the pre-vaccination serotype prevalence.

Number of deaths from the disease per year

In 2015 294,000 deaths of among children < 5 years of age (uncertainty range 192,000–366,000) were estimated to be caused by pneumococcal infections. An additional 23,300 deaths (UR 15,300–40,700) were estimated in children of the same age group co-infected with HIV. Most deaths occur in countries in Africa and Asia. [8] Global estimates of mortality burden are currently being updated using more recent data.

Case Fatality ratio (number of deaths / number of new cases, in %)

CFR of invasive pneumococcal disease in children in LMICs range from 20% for septicaemia to 50% for meningitis. There are up to 25% long-term neurological sequelae (hearing loss, mental

retardation, motor abnormalities) in survivors of childhood pneumococcal meningitis. [14] The CFR for bacteremic pneumococcal pneumonia is 5-7% in areas with good access to medical treatment, but can be higher in areas in whic access to care and treatment is more limited. [15]

Outbreak, epidemic or pandemic risk

While pneumococcal disease is typically endemic, outbreaks have been reported in high-risk settings, including daycare centres, shipyards, prisons, homeless shelters and hospitals. [6] Large serotype 1 outbreaks have occurred in the African Meningitis belt. [16] There is limited evidence on the effectiveness of PCV in response to pneumococcal disease outbreaks. Considerations are given to mult-age cohort campaigns and relevant research is ongoing. [6]

Contribution of the vaccine to achievement of the national, regional or global disease goals

WHO recommends the inclusion of PCVs in childhood immunization programmes worldwide. In many countries, the routine use of PCVs has dramatically reduced the incidence of invasive pneumococcal disease with virtual disappearance of disease due to serotypes in the vaccines used. [17]
Between 2000 and 2015, pneumococcal deaths in children aged <5 years declined by an estimated 51%, largely due to the widespread introduction of PCVs. With continued efforts, PCVs are projected to avert approximately 2 million deaths in children aged < 5 years from 2021 through 2030. [18]

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Benefits of the intervention

Serogroup or serotype coverage by vaccines considered (for serogroup- or serotype-specific vaccines)

All vaccines cover >70% of serotypes which were circulating between 1980 and 2007 (before wider PCV use).

10-valent Synflorix ® (GSK) and PCV13-Biomanguinhos covering serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23,
10-valent Pneumosil ® (SII) covering serotypes 1, 5, 6A, 6B, 7F, 9V, 14, 19A, 19F and 23F
13-valent Prevenar-13 ® (Pfizer), PCV13-Sinergium, Weuphoria ® (Walvax), Beijing Minhai and Pneumotex ® (Nanolek) covering serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F
14-valent Pneumobevax ® (Biological E) covering serotypes 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, 33F
15-valent Vaxneuvance ® (Merck/MSD) covering serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, 33F
20-valent Prevenar-20 ® (Pfizer) covering serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, 8, 10A, 11A, 12F, 15B/C, 22F, 33
Cross-protection has been observed against serotype 6A for Synflorix® and against serotype 6C for Prevenar-13 ®. [1]

Efficacy and effectiveness estimates (e.g. against infection, disease, hospitalization, death), including in different populations

The effectiveness of PCV10-GSK and PCV13-PFZP against vaccine serotypes have been demonstrated across multiple schedules, including 3p+0, 2p+1 and 3p+1, with evidence supported by multi-country systematic reviews at global and regional levels. [1, 6, 19, 20] Both vaccines provide direct protection in vaccinated individuals and indirect protection to unvaccinated members of the community through reduced transmission (i.e., herd protection). There is limited protection against serotype 3 in PCV13-PFZP.
PCV10-SII was licensed based on immunobridging studies showing non-inferiority to PCV10-GSK and PCV13-PFZ. [21, 22] Data on the effectiveness and impact of PCV10-SII are limited. PCV10-SII was introduced in Kenya in late 2022, replacing PCV10-GSK, which had been used for 11 years at high coverage, in a 3p+0 schedule. Preliminary results of a study that compared data from the PCV10-GSK period (2012-21) to the PCV10-SII period (2022-23) indicate that overall carriage prevalence remained stable between the two periods. These preliminary results suggest that PCV10-SII has a comparable effect on IPD and nasopharyngeal carriage as PCV10-GSK and PCV13-PFZ. [23]
All three licensed extended valency products, i.e., PCV14, PCV15 and PCV20, were licensed based on immunobridging studies; no real-world clinical data are available on their efficacy or effectiveness against clinical outcomes. [24, 25, 26, 27]

Duration of protection and waning of immunity in general and risk groups

Vaccines provide protection against acquisition of vaccine-serotype pneumococcal carriage for several years with differences across serotypes and PCV schedules. [28] No sustained population-level immunity with 3p+0 schedule was seen in Malawi. [29] A study in the UK that compared the 2p+1 with 1p+1 schedule with PCV13 found no significant difference in breakthrough infections and vaccine failure rates between the schedules. [30] All PCVs result in some degree of serotype replacement, whereby non-vaccine serotypes increase in prevalence in carriage and disease; however, in general among children, reductions in vaccine-type disease are greater than increases in non-vaccine-type disease, resulting in overall reductions in pneumococcal disease.

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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 [31, 32, 33, 34, 35] . In the clinical trials of the newer PCVs, PCV10-SII had a similar safety profile compared to PCV10-GSK and PCV13-PFZ [21, 22]), and the extended-valency PCVs (i.e., PCV14-BE, PCV15 and PCV20) have a similar safety profile to PCV13-PFZ. [36] [25] [37, 27]

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. [38, 39]

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Values and preferences

Perception of the target population on the risk of disease

Limited knowledge and awareness of pneumonia symptoms increase the risk of pneumonia in children. [40]
In Bandung, Indonesia, there was poor knowledge of mothers and HWs about PCV, but awareness of high burden and severity of pneumonia enhanced willingness to accept PCV. [40]

Most mothers in Nandi, Kenya knew about pneumonia and were able to mention at least one feature of pneumonia.

Caretakers of children in rural Uganda had relatively adequate knowledge about signs and symptoms of pneumonia, risk factors and treatment measures.

Cultural beliefs including local remedies and healers can significantly impact how caretakers perceive and respond to pneumonia.

The median sensitivity of caregiver recognition of pneumonia was low (37%) in LMICs. [41]

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Acceptability to stakeholders

Acceptability of the vaccine and of vaccination against the disease

Acceptability of the PCV in LMICs is generally high, but varies based on awareness, accessibility, and cultural beliefs.

In China there is a substantial local demand for vaccinating children with PCV13 and partial payment for the vaccine was widely accepted. [42]

In Nairobi, Kenya Income, parity, education level, age and occupation of the caregiver significantly influenced the uptake of PCV. [43]

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Financing & funding

Estimated financial cost of materials per vaccine dose (syringes, needles, safety box) (in USD)

Cost of syringes: UNICEF procurement US$ 0.028 to US$ 0.065 depending on supplier and product / PAHO RF procurement US$ 0.028 to US$ 0.048 depending on supplier and product. [44, 45, 46]

Cost of safety boxes: UNICEF procurement, a box of 25 safety boxes (each with a 5-liter capacity) is about US$ 20.26, resulting in approximately US$ 0.81 per safety box. Each 5-liter safety box can hold around 100 syringes, leading to a disposal cost of approximately US$ 0.008 per syringe. [46, 47]

Estimated vaccine financial cost per dose (in USD)

As of June 2026, the **UNICEF** price per dose for 2026 for countries accessing **Gavi** prices, ranges between US$ 2.00 for PCV10, 5 doses presentation (Serum Institute of India) and US$ 3.30 for PCV13 single dose presentation (Pfizer). Prices are expected to change in 2027 starting from US$ 1.55 for PCV10, 5 doses presentation (Serum Institute of India). For Middle Income Countries (MICs), UNICEF prices per dose for 2026 range between US$ 4.00 and US$ 18.05 depending on country income level, supplier, valency and presentation. Prices for humanitarian use and countries in fragile states range between US$ 2.00 and US$ 7.00 depending on country, supplier, valency and presentation. [48]

UNICEF prices are subject to change. Access to the most up to date price can be found at the following link: Pneumococcal Conjugate Vaccine (PCV) price data | UNICEF Supply Division(1)

Users are encouraged to confirm those prices by contacting UNICEF Supply Division.

As per the 2025 **PAHO** price list, the price per dose for the Revolving Fund for Access to Vaccines ranges between US$ 2.00-2.90 for PCV10, US$ 13.50 for PCV13, and US$ 20.00 for PCV20. [49]

As per the April 2026 **US CDC** pricelist, the cost per dose of pediatric PCV vaccine in the United States ranges between US$184.18 and US$200.13. [50]

As per the 2024 **WHO/UNICEF Joint Reporting Form** reported data, the price per dose for **self-procuring MICs** is on average US$ 19.20 (range US$ 3.03-59.32 depending on country income level, supplier and valency). [51]

Estimated financial cost per person vaccinated (in USD)

Cost of delivery (health facility based): ranges between US$ 0.06 and US$ 3.96 per dose. [52], [53], [54], [55], [56], [57]

Cost-effectiveness ratio

The cost–effectiveness of PCV use depends on many factors, including the burden of disease, vaccine effectiveness, indirect effects, vaccination coverage, vaccine price, delivery costs and schedule. [58], [59] An analysis of data from 22 studies in low- and middle-income countries showed that vaccination with PCV10-GSK and PCV13-PFZ using a 3p+0 or 2p+1 schedule is cost-effective from the perspectives of both the healthcare system and society. [59] The cost-effectiveness according to product choice will depend on country characteristics, including local serotype distribution and coverage rates achieved with different schedules. [58], [59], [60], [61]

Is there a Gavi programme to support the introduction of this vaccine? If a Gavi programme is available, what support is available to countries?

Gavi supports PCV introduction since 2009 with use of Pneumococcal Advance Market Commitment up to 2020. Contracts with manufacturers continue through 2029. Gavi provides

support for routine introduction and catch-up introduction funding PCVs and injection supplies and vaccine introduction grants. 62

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Market (feasibility)

Available vaccines, licensing status, prequalification status, presentation, formulation, dosage and route of administration

There are currently 12 vaccines with marketing authorisation with different number of serotypes (10 to 20) and different country reach (some are only authorised in one country, other in many). Of those, four have WHO prequalification (PCV10-GSK, PCV13-PFZ, PCV10-SII, PCV14-BioE). Detailed information on the different products can be found in the comparison table

Once a PCV vaccination programme has been initiated, product switching is not generally recommended unless there are substantial changes in the epidemiological, programmatic, or financial situation that determined the original choice of product, e.g., an increasing burden of serotype 19A. Switching to another WHO-prequalified vaccine demonstrating similar immunogenicity to the currently used PCVs may be acceptable based on cost-saving considerations. If the series cannot be completed with the same vaccine, the available PCV product can be used. Restarting a series with a different PCV is not recommended, even for the primary series.

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Service delivery (feasibility)

Number of doses and timing of administrations

The available evidence does not indicate a clear superiority of either 3-dose schedule (i.e., the 2p+1 or 3p+0) over the other for protection from pneumococcal disease or carriage.

WHO recommends the use of either schedule, depending on the local context.
The choice of schedule may be influenced by other programmatic factors relevant at the country level and epidemiological factors that would make one schedule optimal.

- For either schedule, the first dose may be administered at ≥6 weeks of age.
- If the 2p+1 schedule is selected, an interval of ≥8 weeks is recommended between the 2 primary doses; the interval may be shortened if there is a compelling reason to do so, such as improving timeliness of the second dose and/or achieving higher coverage with a 4-week interval.
- For the 2p+1 schedule, the booster dose should be given at 9–18 months of age, according to programmatic considerations; there is no defined minimum or maximum interval between the primary series and the booster dose.
- If the 3p+0 schedule is used, a minimum interval of 4 weeks should be maintained between doses.
- For unvaccinated children aged 1 to 5 years, catch-up vaccination is recommended. Catch-up vaccination can be done with a single dose of PCV for children ≥24 months. Current data are insufficient for a firm recommendation on the optimal number of doses (1 or 2) required in 12–23-month-olds as part of catch-up vaccination, so countries choosing to use 1 dose should monitor for impact and vaccine failures.

Countries can reduce vaccine costs by using less expensive PCVs in a 3-dose schedule. As another way to reduce costs and possibly reduce programmatic complexity, WHO recommends that alternative PCV strategies could be implemented (1p+1, fractional dose). However, these strategies should only be considered in settings with mature 3-dose PCV programmes and/or well-established population immunity, as described below.
Currently, there is limited real-world evidence for the use of alternative strategies, including in certain high-risk populations (e.g., immunocompromised and malnourished children). The quantity and quality of evidence will improve if these strategies are implemented and evaluated in real-world settings.

WHO recommends that alternate vaccination schedules (2-dose schedules or fractional doses) can be used if certain conditions are met and with a careful consideration of the trade-offs. [1]

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Logistics (feasibility)

Cold chain volume required per vaccine dose (in cm3)

PCV 10 - Synflorix ®: 4-dose vial: 8 cm3.

PCV 13 - Prevenar 13 ®: 1-dose vial: 37.8 cm3; 4-dose vial: 11.7 cm3.

PCV 10 - Pneumosil ®: 1-dose vial: 53 cm3; 5-dose vial 11 cm3. 63

PCVs in multidose vials may be kept for use up to 28 days if stored at 2-8°C.

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