WOŹNIAK, Kinga, DACHOWSKA, Sandra, FAŁCZYŃSKA, Aleksandra, HARAJ, Jan, NAMYSŁ, Maria, MATCZAK, Simon, BIENIEK, Maciej, and SOBKOWIAK, Marcin. Evaluation of the Effectiveness of Pneumococcal Conjugate Vaccines in Children. Journal of Education, Health and Sport. 2026;87:67624. eISSN 2391-8306.
https://dx.doi.org/10.12775/JEHS.2026.87.67624
https://apcz.umk.pl/JEHS/article/view/67624

The journal has had 40 points in Minister of Science and Higher Education of Poland parametric evaluation. Annex to the announcement of the Minister of Education and Science of 05.01.2024 No. 32318. Has a Journal's Unique Identifier: 201159. Scientific disciplines assigned: Physical culture sciences (Field of medical and health sciences); Health Sciences (Field of medical and health sciences).
Punkty Ministerialne 40 punktów. Załącznik do komunikatu Ministra Nauki i Szkolnictwa Wyższego z dnia 05.01.2024 Lp. 32318. Posiada Unikatowy Identyfikator Czasopisma: 201159. Przypisane dyscypliny naukowe: Nauki o kulturze fizycznej (Dziedzina nauk medycznych i nauk o zdrowiu); Nauki o zdrowiu (Dziedzina nauk medycznych i nauk o zdrowiu).
The authors declare that there is no conflict of interests regarding the publication of this paper.
Received: 19.12.2025. Revised: 06.01.2026. Accepted: 10.01.2026. Published: 11.01.2026.

Evaluation of the Effectiveness of Pneumococcal Conjugate Vaccines in Children

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Abstract

Diseases caused by *Streptococcus pneumoniae* are one of the most common infectious causes of death worldwide, making them a major global burden. For this reason, pneumococcal conjugate vaccines (PCVs) are one of the key achievements in preventive medicine. PCVs are not only among the most widely used vaccines in the world but also have high clinical efficacy in preventing pneumococcal diseases, including invasive pneumococcal disease, meningitis, bacteremia, pneumonia, otitis media, and upper respiratory tract infections. In addition, PCVs contribute to herd immunity and reduce respiratory tract colonization with streptococci, particularly in newborns and infants, especially during the pre-vaccination period.

Due to their very good safety profile, including a low risk of serious adverse reactions and high immunogenicity, PCVs are an important part of international and national vaccination programs. Nevertheless, their availability remains limited in low- and middle-income countries.

The high replaceability and persistence of some serotypes, along with multi-drug resistance, keep *Streptococcus pneumoniae* infections as a major epidemiological challenge. This underscores the importance of monitoring variants and updating vaccination schedules. Modern PCVs now include more serotypes to combat these diseases, guiding future clinical research.

Keywords: PCV, children, vaccine, streptococcus pneumoniae, invasive pneumococcal disease

Content

1. Introduction

Streptococcus pneumoniae (S. pneumoniae) is the leading cause of morbidity and mortality among children and adults worldwide, responsible for a wide spectrum of diseases ranging from mild upper respiratory tract infections to potentially fatal invasive pneumococcal disease (IPD) [1]. In 2021, pneumonia killed about 2.2 million people. It was the top infectious killer worldwide. Pneumococci caused over 400,000 of the 1.3 million deaths directly from antimicrobial resistance. They also caused 1.5 million of the 5 million deaths linked to antimicrobial resistance.

Pneumococcal conjugate vaccines (PCV) significantly reduce the incidence of bacterial pneumonia and limit the need for antibiotics. They are therefore one of the key achievements of modern preventive medicine — vaccines are thought to reduce the risk of IPD by 80% [2,3]. The introduction of PCV has also significantly reduced mortality from IPD in the youngest patients [2]. Despite their proven effectiveness, access to PCV vaccines in low- and middle-income countries remains limited. Although Global Alliance for Vaccines and Immunization support has increased vaccination coverage in the poorest countries, many middle-income countries are not eligible for this support [4].

With the development of new generations of vaccines that cover a broader spectrum of pneumococcal serotypes, knowledge of their efficacy and safety is continually expanding. The aim of this study is to evaluate the effectiveness of pneumococcal vaccination in children in reducing the incidence of pneumococcal disease based on available clinical trials and epidemiological data.

2. Characteristics of pneumococcal conjugate vaccines

2.1. Structure and mechanism of action of PCV vaccines

PCVs use innovative technology to combine *S. pneumoniae* capsular polysaccharides with carrier proteins [5]. This technology enables the induction of a T-cell-dependent immune response in infants [6]. Unlike older polysaccharide vaccines (PPSV23), which are poorly immunogenic in children under 2 years of age, conjugate vaccines effectively stimulate the production of immune memory even in the youngest patients, as shown in Figure 1 [3,7]. These vaccines elicit high titers of immunoglobulin G (IgG) antibodies specific to individual serotypes [5].

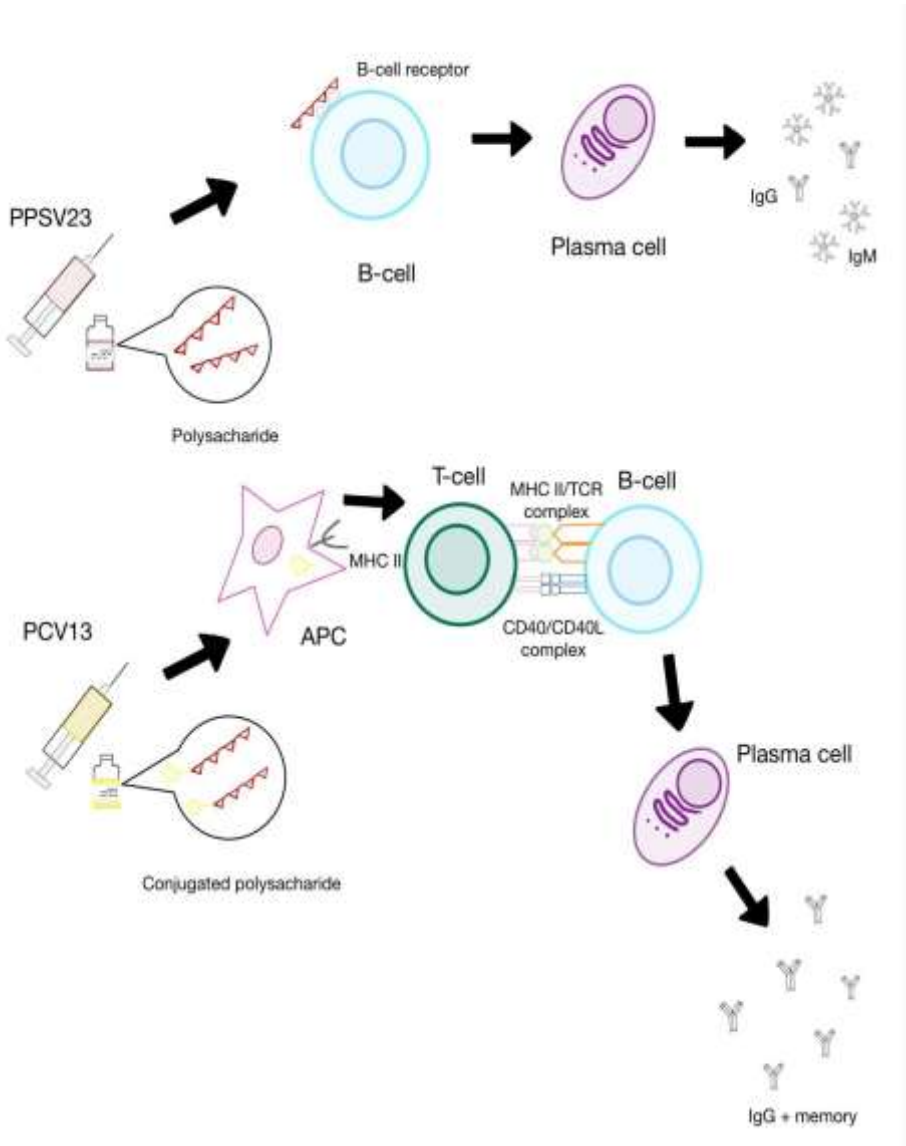

Figure 1: Different mechanisms of induction of immunity, according to PPSV23 vs PCV13. Based on: (6).

PPSV 13 is a polysaccharide vaccine. After administration, viral antigen epitopes bind directly to B lymphocyte receptors. This activation causes B lymphocytes to become plasma cells. These cells begin producing mainly M-class antibodies. This process usually does not lead to the development of immunological memory.

PCV13 is a conjugate vaccine that has the CRM197 protein attached to a polysaccharide chain. After administration, antigen-presenting cells phagocytose or capture the viral antigen. They then present it to T lymphocytes via MHC II and activate them. These T lymphocytes present the antigen to B lymphocytes via the MHC II/TCR complex. When the B lymphocyte recognizes the antigen, the T cell activates expression of CD40L. CD40L binds to CD40 on the B cell. This step fully activates B cells. B cells then differentiate into plasma cells and produce Ig antibodies and memory cells.

Abbreviations:

PCV13 - 13-valent Pneumococcal Conjugate Vaccine, PPSV23 - 23-valent pneumococcal polysaccharide vaccine, IgG - antibodies G-class, IgM - antibodies M-class, CD40 - Cluster of Differentiation 40, MHC II - Major Histocompatibility Complex Class II, TCR - T-Cell Receptor, B-cell - B lymphocyte, T-cell - T lymphocyte, APC - Antigen-Presenting Cell.

Currently available vaccines include preparations with different valencies. The first conjugate vaccine introduced into clinical use was the 7-valent vaccine (PCV7) in 2000. Its introduction was accompanied not only by a decline in invasive pneumococcal disease caused by vaccine serotypes [8]. Pneumococcal conjugated vaccine 10-valent (PCV10) contains 10 pneumococcal serotypes conjugated to *Haemophilus influenzae* protein D and tetanus and diphtheria toxoids. PCV13 protects against 13 serotypes using the CRM197 carrier protein (a non-toxic mutant of diphtheria toxin) [9]. Pneumococcal conjugate vaccine 15-valent (PCV15) and pneumococcal conjugate vaccine, 20-valent (PCV20) vaccines provide protection against 15 and 20 pneumococcal serotypes, respectively [10,11]. The latest vaccine is the 21-valent conjugate vaccine (PCV21) for adults aged ≥18 years, approved by the Food and Drug Administration in 2024. However, it has not yet been approved for use in children [12].

The broader serotype coverage of these newer preparations is intended to counteract the phenomenon of serotype replacement observed after the introduction of earlier-generation vaccines [10].

2.2. Immunogenicity of vaccines in infants

Studies of the immunogenicity of PCV vaccines in infants have demonstrated their ability to elicit a strong humoral response against all serotypes contained in the vaccine [11]. In a phase III clinical trial evaluating PCV13, all infants achieved IgG antibody concentrations ≥0.35 microgram per milliliter for most vaccine serotypes after the primary series. The anamnestic response after a booster dose was particularly strong, indicating the development of immune memory [7].

A meta-analysis of studies on PCV15 in infants (number of participants (N) ranged from 5104 to 5128) showed IgG responses that were noninferior to those with PCV13 for 12 common serotypes. For the unique serotypes 22F and 33F, responses were significantly higher in the PCV15 group [10]. Studies of PCV20 in a 3 prime + 1 booster (3p+1) schedule in healthy infants (N=1991) confirmed that the vaccine elicits strong serological responses for all 20 serotypes. PCV20 met criteria that were no worse than PCV13 in terms of geometric mean IgG concentrations after the third and fourth doses. The vaccine also demonstrated the ability to induce functional opsonophagocytic antibodies [13].

2.3. Indirect protection mechanism

PCV vaccines also have a strong herd effect by reducing pneumococcal transmission in the community [14,15]. Following the introduction of PCV vaccination in infants, a decline in vaccine-type IPD has been observed in older children and adults due to indirect effects [16]. In the United States, a 60% reduction in the overall incidence of IPD in people over 65 years of age was observed between 1998 and 2018, even though adults were not routinely vaccinated with PCV13 [17]. The effectiveness of indirect protection depends on vaccination coverage, the time since vaccination was introduced, and the vaccination schedule used [14,15]. Countries with high vaccination rates (>80%) achieve a stronger herd effect [15].

3. Pneumococcal vaccination in Poland and worldwide

3.1. Vaccination programs in Poland

Free and mandatory vaccination against *S. pneumoniae* was introduced in 2017. The current program assumes a 2 prime + 1 booster (2p+1) schedule in the 1st–2nd year of life (two doses in the 1st year and a third in the 2nd year). A 3p+1 vaccination schedule is recommended for premature babies and children at risk (three doses administered in the first year of life, followed by a fourth dose in the second year of life) [18]. The introduction of reimbursement and mandatory vaccinations

led to an increase in the percentage of children who completed the full vaccination schedule after 2017, from approximately 60% to over 85% [19].

All the vaccines used in vaccination programs has been shown in Table 1.

Table 1: Pneumococcal vaccines. Based on: (9,12,44).

Pneumococcal vaccine	Vaccine information
PCV7 (7-valent Pneumococcal Conjugate Vaccine)	Vaccine containing 7 pneumococcal serotypes (4, 6B, 9V, 14, 18C, 19F, 23F) – introduced in 2000 Vaccine containing 10 serotypes (PCV7 + serotypes 1, 5, 7F) – introduced in 2009.
PCV10 (10-valent Pneumococcal Conjugate Vaccine)	Vaccine containing 10 serotypes (PCV7 + serotypes 1, 5, 7F) – introduced in 2009.
PCV13 (13-valent Pneumococcal Conjugate Vaccine)	Vaccine containing 13 serotypes (PCV7 + serotypes 1, 3, 5, 6A, 7F, 19A) - introduced in 2010, most commonly used.
PCV15 (15-valent Pneumococcal Conjugate Vaccine)	Vaccine containing 15 serotypes (PCV13 + serotypes 22F, 33F) - approved in 2021.
PCV20 (20-valent Pneumococcal Conjugate Vaccine_	Vaccine containing 20 serotypes (PCV13 + serotypes 8, 10A, 11A, 12F, 15B, 22F, 33F) - approved in 2021

3.2 The World Health Organisation (WHO) international recommendations

The WHO including PCV vaccines in the national immunisation programmes of all countries. The WHO advises using either a 2p+1 or 3 prime + 0 booster schedule, based on local epidemiology, and notes that neither schedule is clearly superior. Vaccination is also recommended in countries with limited epidemiological surveillance systems. Catch-up vaccinations are recommended for children who have not received all vaccinations by age 5. For children aged ≥2 years, one dose of

PCV is recommended. For those aged 12–23 months, the dosing is either 1 or 2 doses, with the specific number determined by local guidance and the need for monitoring vaccine efficacy [20].

3.3 Premature babies and children with immune deficiencies

Many countries, including Poland, have introduced mandatory PCV vaccination in a 3p+1 schedule for all premature babies born before 37 weeks of pregnancy, a group particularly vulnerable to severe pneumococcal infections [21]. Studies of PCV7 immunogenicity in very low birth weight preterm infants (≤1000 grams) have shown that these infants achieve antibody concentrations similar to those of full-term infants for most serotypes. However, the response to serotypes 6B and 23F may be weaker in the smallest preterm infants [22].

For immunocompromised children, a 3p+1 regimen also is recommended [23]. Primary or secondary immunodeficiency, including human immmunodeficiency virus (HIV) infection, carries a significantly increased risk of IPD. The efficacy of the pneumococcal conjugate vaccine 9-valent against IPD in HIV-infected children was only 32%. This is much lower compared to 78% in immunocompetent children. Nevertheless, vaccination remains recommended for this group, as even partial protection can prevent severe infection [24].

4. Clinical efficacy of vaccines against pneumococcal diseases

4.1. The effectiveness of vaccines against IPD in clinical trials

The effectiveness of PCV vaccines against IPD has been confirmed in numerous clinical and observational studies worldwide. For example, in 2025, a global surveillance analysis was conducted following the introduction of PCV10 and PCV13 vaccines. This analysis, covering a 6-year period since their implementation in 2010, showed a significant decrease in the incidence of all serotypes by 58–74% among children under 5 years of age [16].

Similarly, the introduction of PCV7 in the United States in 2000 led to a 97% reduction in vaccine-serotype cases among children under 5 years of age. Following the introduction of PCV13 in 2010, a further reduction in IPD of 89-98% was observed for vaccine serotypes in children [17]. In European countries, the effectiveness of PCV13 against IPD was 73% in the United Kingdom and 82% in Germany for the serotypes included in the vaccine [25]. By 2024, 159 of the 194 WHO member states had introduced PCV vaccines into their national programs, contributing to the saving of more than 1.6 million lives since 2000 [16].

4.2 Protection against meningitis and bacteremia

Pneumococcal meningitis is the most severe form of IDP, characterised by high mortality and the risk of permanent neurological sequelae [26,27]. Notably, epidemiological studies following the introduction of PCV have shown a significant reduction in meningitis cases in children [28]. Building on these findings, an analysis of Australian data covering 377 cases of IChP in children showed that meningitis accounted for 8% of cases, bacteremia for 17%, and complicated pneumonia for 67%. Importantly, 90% of patients received ≥3 doses of PCV, and most cases of meningitis were caused by serotypes not covered by PCV13 [28,29], highlighting ongoing challenges despite vaccine coverage.

4.3 Efficacy against pneumonia

Pneumonia is the most common serious manifestation of pneumococcal infection in children. In 2019, pneumococcal diseases (infections caused by the bacterium S. pneumoniae) were responsible for over 300,000 deaths in children under 5 years of age, mainly in developing countries [16,30]. Vaccination with PCV13 (pneumococcal conjugate vaccine covering 13 types) in a 2p+1 schedule (two primary doses plus a booster) has been shown in a meta-analysis of observational studies to reduce the incidence of radiologically confirmed pneumonia by 27% (95% CI: 15-36%) [3,31], and all clinical episodes of pneumonia by 6% (95% CI: 2-9%) [3]. Furthermore, post-marketing studies indicate a significant reduction in hospitalizations for pneumonia among vaccinated children, with rates ranging from 26% to 47% across different countries and vaccination schedules [31,32]. Supporting these findings, a study from southern Israel evaluating PCV efficacy against alveolar pneumonia (pneumonia affecting the tiny sacs in the lungs) showed 87% protection in children aged 12-35 months and approximately 67% protection in those aged 36-59 months [33]. However, the effectiveness of vaccines against pneumonia is generally lower than against IPD, potentially due to challenges in confirming pneumococcal etiology [32].

4.4. The impact of PVC on non-invasive diseases: sinusitis, non-bacterial pneumonia, and acute otitis media (AOM)

PCV vaccines are not very effective at preventing less serious diseases caused by S. *pneumoniae*, such as sinus infections, some types of pneumonia, and ear infections in children.

Most scientific data concern AOM. For example, a systematic review with meta-analysis reported a 43% reduction in the risk of pneumococcal AOM. However, it should be emphasised that the vaccine has little effect on AOM caused by other pathogens, amounting to only about 7% [34]. In addition, another systematic review with meta-analysis showed a 10% reduction in the risk of

recurrent AOM (95% CI: 7.46–12.65) and a 22.2% reduction in the incidence of tympanostomy tube insertion (95% CI: 14.6–29.8), while also highlighting the limited effect on mild forms [35].

Furthermore, the introduction of PCV7 and PCV13 vaccination was also associated with a 66% reduction in the risk of hospitalization due to sinusitis in children [36]. The lack of literature confirming a reduction in the overall incidence of non-invasive clinical forms is due to the fact that these diseases are most often caused by viruses and a wide range of other pathogens on which PCV vaccines have no direct effect.

5. Additional effect of vaccination on reduction of nasopharyngeal pneumococcal colonization

Infants and young children are particularly vulnerable to IPD due to the immaturity of their immune systems and the high frequency of nasopharyngeal colonisation by *S. pneumoniae*. Nasopharyngeal colonisation with pneumococci can occur in the first months of life and is a stage preceding the development of disease. In some populations, the rate of pneumococcal colonisation in children can reach as high as 23-25% in the pre-vaccination period [3,11,37,38]. One of the key mechanisms of action of PCV vaccines is the reduction of nasopharyngeal transmission of pneumococci [20,39]. This also leads to indirect protection for unvaccinated individuals [14]. In Germany, four years after the introduction of universal PCV13 vaccination, PCV10 serotypes completely disappeared from the nasopharyngeal flora of children [39].

Similarly, in Poland, three years after the introduction of PCV10 into the mandatory vaccination program, vaccine serotypes accounted for only 4.9% (PCV10) and 17.1% (PCV13) of all pneumococcal isolates [20].

6. Safety of pneumococcal vaccines

6.1 Safety profiles in clinical trials

PCV vaccines have an excellent safety profile [10,40,41]. A meta-analysis of nine randomized controlled trials involving 9,445 healthy infants vaccinated with PCV15 or PCV13 showed a comparable risk of adverse events within 14 days after each vaccine dose, with an incidence of 94.6% in both groups (relative risk (RR): 1.00; 95% CI: 0.99-1.01).

Similarly, the risk of serious adverse events up to 6 months after the last dose was identical in both groups—8.3% vs. 8.4% (RR: 0.99; 95% CI: 0.86-1.14) [10]. The most common adverse events after administration of both PCV13 and PCV20 included mild to moderate local reactions, systemic symptoms as fever, and gastrointestinal symptoms [10,40]. Furthermore, studies on PCV20 have

confirmed a safety profile similar to that of PCV13 [41]. Common adverse events after administration of some PCVs has been shown in Table 2.

Table 2: Common adverse events in children after immunization. Based on: (10,40,41,44).

Vaccine	Adverse events
PCV13	Infants and toddlers: Irritability, injection site tenderness, decreased appetite, sleep alterations, fever, injection site redness, injection site swelling.
	Children age 5 to 17: Injection site tenderness, redness, and swelling, irritability, decreased appetite, sleep alterations, fever.
PCV15	Children age 2 months to 15 months: Injection-site erythema, induration, and swelling, irritability, somnolence, fever, decreased appetite.
	Children and adolescents age 2 through 17: Injection-site pain, erythema, swelling, and induration, myalgia, fatigue, headache, fever.
PCV20	Pain, swelling and reddedness at the injection site, fatigue, irritability, drowsiness, headache, muscle pain, arthralgia.
PPSV23	Injection site pain/soreness/tenderness, injection site induration/swelling, headache, injection site erythema, fatigue/weakness, myalgia.

Abbreviations: PCV15 - 15-valent pneumococcal conjugate vaccine, PCV20 - 20-valent pneumococcal conjugate vaccine, PCV13 - 13-valent pneumococcal conjugate vaccine, PPSV23 - 23- valent pneumococcal polysaccharide vaccine.

6.2 Co-administration with other vaccines

PCV vaccines can be safely administered simultaneously with other vaccines from the infant vaccination schedule. This includes vaccines against diphtheria, tetanus, pertussis, polio, hepatitis B, and Haemophilus influenzae type b, measles, mumps, and rubella, chickenpox, meningococcal type C (conjugated with CRM197 and TT), meningococcal types A, C, W-135, and Y (TT conjugate), and oral rotavirus vaccine [26,42]. Studies have shown that co-administration does not adversely affect the immune response [26]. The only exception is the recommendation to maintain an interval of at least 8 weeks between administration of the PCV and PPSV23 [23].

7. Challenges and limitations of vaccination

7.1 The phenomenon of serotype replacement

However, despite reductions in vaccine serotypes, there has been a simultaneous increase in cases caused by serotypes not covered by vaccination [43]. Following the introduction of PCV13, there was an increase in IPD caused by non-vaccine serotypes, particularly 15A, 22F, 23B, 33F, and 35B [16,43]. The dominant non-vaccine serotypes are currently: 22F, 15A, 15B/C, 23B, 33F, 35B, and 24F [16].

After the introduction of PCV7, a significant upward trend in serotype 19A infections was observed, which was reversed in countries that adopted PCV13, where a 61–79% decrease was observed in children <5 years of age. In contrast, in areas using the PCV10 vaccine (which does not contain serotype 19A), the incidence continued to increase by 1.6–2.3 times. Non-PCV13 IPD increased similarly for both vaccines [16].

In summary, these epidemiological changes justify the use of the latest-generation vaccines to further reduce the incidence of IPD.

7.2 Persistence of serotype 3

Serotype 3 poses a particular challenge because, despite its inclusion in PCV13, it exhibits reduced immunogenicity and limited clinical efficacy [25,27]. The pooled efficacy of PCV13 against IPD

caused by serotype 3 was 63.5% (95% CI: 37.3-89.7%) [27]. This is significantly lower than for other vaccine serotypes.

7.3 Resistant pneumococcal strains

In addition to the challenges posed by serotype 3, the growing problem of *S. pneumoniae* antibiotic resistance poses a serious challenge to the treatment of pneumococcal infections. Following the introduction of PCV, resistance has been observed among non-vaccine serotypes. In Australia, 17% of serotype 23B isolates were resistant to ceftriaxone, accounting for 22% of all meningitis cases [28,29]. These observations highlight the importance of including a reserve antibiotic in the treatment of meningitis [28].

8. Conclusions

Conjugate vaccines against pneumococci are among the most effective and safest public health interventions [3,10,40,41]. The introduction of subsequent generations of vaccines with broader serotype coverage (PCV13, PCV15, PCV20) allows for increased protection. Despite their success, vaccination programs face challenges: serotype replacement, monitoring circulating variants, persistence of certain vaccine serotypes, and growing antibiotic resistance [16,29,43]. The continued development of new-generation vaccines, optimisation of vaccination schedules, and expansion of access in developing countries are key to further reducing the global burden of pneumococcal disease. Further research should focus on continued monitoring of emerging serotypes and further development of vaccines that could effectively protect against emerging serotypes.

Dissclosure

Supplementary materials

Not applicable.

Author contributions

Conceptualization, K.W., S.D., S.M.;
writing-original draft preparation, J.H., M.B., M.S., S.M.;
writing-review and editing, A.F., M.N., J.H, M.B., M.S., S.D.;
supervision, A.F., M.N., K.W.
All authors have read and agreed to the published version of the manuscript.

Funding

The study did not receive external funding.

Institutional Review Board Statement

Not applicable.

Informed Consent Statement

Not applicable.

Data Availability Statement

Not applicable.

Acknowledgements

Not applicable.

Conflict of Interest Statement

The authors declare no conflicts of interest.

List of abbreviations

S. pneumoniae - *Streptococcus pneumoniae*

PCV - pneumococcal conjugate vaccine

IPD - invasive pneumococcal disease

CI - Confidence Interval

PCV7 - 7-valent pneumococcal conjugate vaccine

PCV13 - 13-valent pneumococcal conjugate vaccine

PCV21 - 21-valent pneumococcal conjugate vaccine

PPSV23 - 23- valent pneumococcal polysaccharide vaccine

IgG - Immunoglobulin G

PCV10 - 10-valent pneumococcal conjugated vaccine

PCV15 - 15-valent pneumococcal conjugate vaccine

PCV20 - 20-valent pneumococcal conjugate vaccine

N – number of participants

WHO - the World Health Organisation

2p+1 - 2 prime + 1 booster

3p+1 - 3 prime + 1 booster

HIV - human immunodeficiency virus

AOM - acute otitis media

RR - relative risk

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