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REVIEWS

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Adult pneumococcal vaccination – new opportunities

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Summary Pneumococcal infections (*Streptococcus pneumoniae*) remain a significant epidemiological problem globally. Although an invasive pneumococcal disease (IPD), which includes meningitis, sepsis and pneumonia with bacteremia, is the most severe form of pneumococcal infection, the main burden in terms of morbidity and mortality is associated with community-acquired pneumonia in the elderly. The epidemiology of infections caused by *S. pneumoniae* serotypes can change naturally in time and by universal vaccination implementation. The proportion of infections caused by serotypes not contained in any available vaccines is constantly increasing. These changes stimulate the development of new vaccines and ensure the broadest possible protection against *S. pneumoniae* infections. There is a need to raise awareness of the burden of pneumococcal disease in adults and the vaccines used for prophylaxis for pneumococcal infection.

The article discusses the pneumococcal infection burden in the adult population and the factors that raise the risk of infections. We characterised available vaccines for adults, highlighting the significant differences between the conjugated and unconjugated polysaccharide vaccines. Current epidemiological data on pneumococcal infections in Europe and Poland is presented. The latest 20-valent pneumococcal conjugate vaccine (PCV20) is described, and the most recent Advisory Committee on Immunization Practices (ACIP) recommendations on primary prevention and the current implementation of vaccination against pneumococcal infections in the adult population in Poland are discussed.

Key words: *Streptococcus pneumoniae*, pneumococcal vaccines, adult.

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Pneumococcal infections – a significant health problem for the adult population

Streptococcus pneumoniae bacteria (*S. pneumoniae*) are a significant cause of morbidity and mortality in adults, including one of the leading causes of community-acquired pneumonia (CAP) [1, 2]. Invasive Pneumococcal Disease (IPD) is a severe infection in which bacteria enter sterile areas, such as blood or cerebrospinal fluid (CSF). IPD can take the form of pneumonia with bacteremia, sepsis and meningitis, which still constitute serious health problems with high mortality. According to the European Center for Diseases Prevention and Control (ECDC), in 2019 (before the outbreak of the COVID-19 pandemic), there were 23,000 confirmed cases of IPD in the European Union/European Economic Area countries. Confirmed cases of IPD most often occurred among children under the age of one year (13.5 cases per 100,000) and adults over 65 years (16.7 cases per 100,000) [3].

It is estimated that pneumococcal pneumonia is responsible for approximately 98% of the burden of pneumococcal disease in people ≥ 50 years of age [4]. Pneumonia is a heterogeneous disease with a variable clinical presentation and aetiology. In adults, pneumococcal CAP (pCAP) is a non-invasive infection in most cases (75%) [5]. The remaining 25% of cases are pneumonia with bacteremia, associated with greater severity, longer recovery times and a higher risk of death [6]. Pneumococcal CAP is also the most common and severe complication of viral infections. Pneumococcal infection is detected in approximately 35% of patients hospitalised with pneumonia primarily caused by the influenza virus [7].

Pneumonia in adults is a significant burden on healthcare systems worldwide. It is estimated that, depending on the country, 20% to 50% of adults with CAP require hospitalisation [8]. According to the data of the Polish National Health Fund, in 2019, approximately 374.4 thousand adults were treated on an outpatient basis due to CAP, and 54.9 thousand were hospitalised [9]. However, it is challenging to accurately estimate CAP incidence due to *S. pneumoniae*. Pneumonia is treated right after diagnosis, usually without determining the aetiology of the infection [10]. According to observational studies conducted over the last two decades (1999–2020), the percentage of cases of CAP due to *S. pneumoniae* ranges from 33% to 48% among patients of known aetiology. However, the reported frequency of pneumococcal CAP does not include outpatient cases. Therefore, the burden of pneumococcal CAP in adults is likely to be underestimated. Pneumonia has many health consequences, such as an increased risk of death, exacerbation or decompensation of the underlying disease and deterioration of the overall quality of life [11, 12].

Risk factors for pneumococcal infection

The main risk factor for *S. pneumoniae* infection is advanced age, which, depending on the source, is defined as over 50 or 65 years of age [13]. Changes related to the aging of the immune system and a significantly higher incidence of comorbidities in the elderly contribute to an increased susceptibility to infections [14, 15]. The frequency of pneumococcal pneumonia among healthy people ≥ 65 years of age is nearly five times higher than that observed in adults 18–49 years of age [13]. Chronic disease, regardless of age, increases the risk of pneumococcal infection compared to healthy persons. This is why adults with chronic heart, lung, liver disease and diabetes belong to the group having a moderate risk of pneumococcal infection [16] (Table 1). The coexistence of several moderate risk factors increases the risk of *S. pneumoniae* infection several times compared to adults of the same age [13]. Unhealthy behaviours such as smoking and alcohol abuse also increase the risk of *S. pneumoniae* infection [17]. For example, the risk of IPD among smokers 18 to 64 years of age is more than twice as high as that of non-smokers of the same age [18]. Environmental factors, including previous influenza infection [19] or residing in long-term care facilities [20], are also essential factors increasing the risk of pneumococcal disease.

The highest risk of pneumococcal infection occurs in people with an impaired immune system, i.e. adults with immunosuppression due to congenital or acquired immunodeficiencies, HIV infection, chronic renal failure, nephrotic syndrome, leukaemia, lymphomas, Hodgkin's disease, generalised malignancy and solid organ transplant [21]. Treatment with immunosuppressants (i.e. iatrogenic immunosuppression) is also a high-risk factor for infection [17]. Immunosuppressive medications used in rheumatic or oncological diseases are a diverse group of substances, including oral corticosteroids or rituximab [22]. A high risk of pneumococcal infection is also associated with CSF leakage and cochlear implants [16].

Polysaccharide vaccine and pneumococcal conjugate vaccines

Currently, two types of pneumococcal vaccines are available: pneumococcal polysaccharide vaccine (PPSV or PPV) [23] and pneumococcal conjugate vaccines (PCV) [24–26]. In literature, the names of pneumococcal vaccines are given by the type and valence (i.e. number of pneumococcal polysaccharide serotypes) of a given vaccine. For example, PCV13 is a 13-valent polysaccharide conjugate vaccine (PCV13).

Table 1. Risk factors for pneumococcal infection in adults

Age [13, 20]	Host factors		Environmental factors [19, 20]	Unhealthy behaviours [17]
	Moderate risk factors [13, 16, 17]	High-risk factors [13, 16, 17]		
≥ 65 years	• chronic heart disease • chronic lung disease* • diabetes • chronic liver disease	• HIV infection • hronic renal failure, nephrotic syndrome • cancer (solid, hematologic) • solid organ transplant • autoimmune disease • immunosuppressive therapy, corticosteroid therapy • primary immunodeficiencies • cerebrospinal fluid leak • functional or anatomical asplenia • cochlear implant	• previous respiratory viral infection (e.g. influenza) • frequent contact with children • stay in a care institution (e.g. a nursing home)	• cigarette smoking • alcoholism

* Including chronic obstructive pulmonary disease, emphysema and asthma; HIV – human immunodeficiency virus.

Table 2. Comparison of pneumococcal vaccines: polysaccharide and conjugate		
Feature	**Unconjugated polysaccharide vaccine (PPSV or PPV)**	**Conjugated polysaccharide vaccines (PCV)**
Type of antigens	Pneumococcal polysaccharides [23]	Pneumococcal polysaccharides covalently bound to carrier protein [24–26]
Induction of an immune response	The immune response is **T-cell independent**, only B-cell dependent [31]	**T- and B-cell dependent** immune response [31]
	Stimulates B-cells to produce antibodies and does not induce immune memory [31]	Stimulates T-cells to produce antibodies by B-cells and immunological memory formation [31]
Duration of immune protection	**Short-term** – in some cases, the next dose is required after about 3 years [23]	**Long-term** – no additional doses are required for adults* [24–26]
Dosage in adults	**1 dose,** revaccination is recommended after more than 3 years in case of an increased risk of infection or a decrease in the level of antibodies [23]	**1 dose*** [24–26]
Efficacy and effectiveness in preventing invasive pneumococcal disease in adults	**Efficacy and effectiveness shown** in randomised controlled trials and observational studies [29, 30]	**Efficacy and effectiveness were studied** in a large randomised controlled trial [33, 34] and an observational study [42]‡
Efficacy and effectiveness in the prevention of non-invasive pneumococcal disease in adults	**Inconsistent efficacy and effectiveness** data from individual studies and meta-analyses [29, 30]	**Proven efficacy** in a randomised clinical trial in the prevention of pneumococcal CAP, including non-bacteremic cases [33, 34]‡ **PCV13 effectiveness shown** against vaccine-type CAP in adults ≥ 65 years of age [41]

* Only in the particular group of patients, i.e. in individuals with a haematopoietic stem cell transplant, the recommended immunisation series consists of 4 doses of PCV13 [24]; ‡ Based on 13-valent pneumococcal conjugate vaccine; CAP – community-acquired pneumonia.

The unconjugated pneumococcal polysaccharide vaccine has been on the market for approximately 40 years [27]. In the context of adult vaccination, it has some limitations compared to conjugate vaccines. The most important of these are the lack of stimulation of immune memory, the relatively short duration of protection and the need for revaccination (Table 2). The immune response to the polysaccharide vaccine in elderly persons with certain chronic diseases or immunodeficiency is lower than in healthy people [28]. While the effectiveness of the polysaccharide vaccine in preventing invasive pneumococcal disease in adults has been confirmed [29], the effectiveness in preventing non-invasive infections is inconclusive [30]. The combination of pneumococcal polysaccharide antigen with a carrier protein in conjugated vaccines (PCV) creates a robust immune response by B and T lymphocytes, resulting in the generation of long-term immune memory [31]. Consequently, the conjugate vaccine shows comparable (typically not worse) immunogenicity in adults with chronic, pharmacologically well-controlled diseases to that of healthy individuals [32]. The efficacy of the 13-valent conjugate vaccine (PCV13) in people ≥ 65 years of age in the prevention of IPD and pneumococcal CAP, including non-bacteremic cases, was confirmed in a randomised clinical trial [33, 34]. As standard, one dose of the conjugate vaccine effectively protects adults against pneumococcal infection, including patients with risk factors. The administration of another dose of conjugate vaccine is necessary only in particular patient populations, i.e. after the transplantation of haematopoietic bone marrow cells [24].

Pneumococcal national vaccination programmes with conjugate vaccines positively impact public health, while the effects of unconjugated vaccines have not been confirmed. In the United States, the unconjugated polysaccharide vaccine (PPSV) has been indicated for children over two years of age and adults and has been available since the 1980s. Interestingly, a decrease in IPD incidence in the adult population was observed only after the introduction of vaccination with the conjugate vaccine, as part of the universal vaccination of children with the PCV7 vaccine (since 2000), and after the recommendation to vaccinate adults with PCV13 (since 2012) [35]. The reduction in the incidence of IPD in the population is due to the documented effect of the conjugate vaccine on the decrease in nasopharyngeal carriage of vaccine serotypes in vaccinated subjects [36, 37]. However, the impact of the unconjugated vaccine on pneumococcal carriage is unclear [38].

Pneumococcal conjugate vaccines in adults

By the end of 2021, the only conjugate vaccine available to prevent pneumococcal infections in adults was PCV13. Initially, PCV13 was only approved for use in the paediatric population [39]. However, due to some limitations of the polysaccharide vaccine (including unclear efficacy in preventing pneumococcal pneumonia without bacteremia), a series of PCV13 clinical trials was initiated in the adult population. The efficacy of the PCV13 vaccine was assessed in a large randomised, controlled clinical trial under the acronym CAPiTA (Community-Acquired Pneumonia Immunization Trial in Adults), which enrolled over 84,000 patients ≥ 65 years of age. PCV13 efficacy in preventing vaccine-type (VT) pneumococcal IPD was shown to be 75%, and in preventing VT pneumococcal CAP and VT pneumococcal non-bacteremic CAP, it was 46% and 45%, respectively. Moreover, it has been proven that the vaccine's efficacy does not decrease significantly over 4–5 years [33]. The PCV13 vaccine was well tolerated, and the most common adverse events were reactions at the injection site (redness, pain, limited arm movement) and generalised adverse events (fatigue, muscle pain, fever) [33]. PCV13 effectiveness was similar in the subgroup with comorbidities such as heart disease, diabetes and lung disease [40]. The results of the CAPiTA clinical trial were confirmed in a study conducted in real clinical practice [41, 42]. Vaccination of adults over 65 with PCV13 reduced the risk of any VT pneumococcal CAP requiring hospitalisation by 73% and non-bacteremic pneumococcal CAP by 70%. In this study, 88% of patients had ≥ 1 comorbid disease increasing the risk of pneumococcal infection [41].

Since 2021, two new pneumococcal conjugate vaccines with wider serotype coverage than PCV13 have been registered: the 15-valent vaccine (PCV15) and the 20-valent vaccine (PCV20). The PCV15 vaccine, in comparison to PCV13, covers two addi-

Table 3. Pneumococcal vaccines indicated for adults available in Poland

Vaccine	Date of first registration in Europe	Indication	Type of antigens
Conjugate polysaccharide vaccines			
PCV13 [24]	XII 2009	Active immunisation for the prevention of **invasive disease, pneumonia and acute otitis media** caused by *Streptococcus pneumoniae* in infants, **children and adolescents from 6 weeks to 17 years of age**. Active immunisation for the prevention of **invasive disease and pneumonia** caused by *S. pneumoniae* in adults ≥ 18 years of age and the elderly*	Pneumococcal polysaccharides conjugated to a carrier protein
PCV15 [26]	XII 2021	Active immunisation for the prevention of **invasive disease and pneumonia** caused by *S. pneumoniae* in individuals **18 years of age and older**	
PCV20 [25]	II 2022	Active immunisation for the prevention of **invasive disease and pneumonia** caused by *S. pneumoniae* in individuals **18 years of age and older**	
Polysaccharide vaccine, unconjugated			
PPSV23 [23]	XII 1996**	Active immunisation against **pneumococcal infections** in **children from 2 years of age, adolescents and adults**	Pneumococcal polysaccharides, unconjugated

* The first recommendation for pneumococcal prophylaxis in adults ≥ 50 years of age in Poland was in 2013 [61]; ** Date of the first marketing authorisation in Poland [23].

Table 4. *Streptococcus pneumoniae* serotype antigens included in pneumococcal vaccines for adult patients

Vaccine	*Streptococcus pneumoniae* serotypes antigen designation																							
	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F	22F	33F	8	10A	11A	12F	15B	2	9N	17F	20
Conjugate polysaccharide vaccines																								
PCV13 [24]	●	●	●	●	●	●	●	●	●	●	●	●	●											
PCV15 [26]	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●									
PCV20 [25]	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●				
Polysaccharide vaccine, unconjugated																								
PPSV23 [23]	●	●	●	●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

tional serotypes (22F and 33F), while PCV20 has seven additional serotypes (8, 10A, 11A, 12F, 15B, 22F, 33F). Both new vaccines have been approved for active immunisation of the adult population to prevent invasive disease and pneumonia caused by *S. pneumoniae* bacteria (Table 3, Table 4) [25, 26].

PCV20 vaccine and the epidemiology of pneumococcal infections in adults

The introduction of universal vaccination of children against pneumococci reduces the overall incidence of IPD in the population, with a simultaneous gradual increase of infections caused by serotypes that are not covered by the vaccines [43]. The phenomenon of serotype substitution was first noted after the introduction of vaccination of children with the 7-valent pneumococcal conjugate vaccine (PCV7), followed by the 13-valent and 10-valent vaccines [44]. According to ECDC data, in 2018, the most frequently identified serotypes causing IPD in all age groups were: 8, 3, 19A, 22F, 12F, 9N, 15A, 10A, 23B and 6C, respectively (Figure 1). These serotypes accounted for approximately 70% of IPD cases [45]. The National Reference Center for Bacterial Meningitis (KOROUN) provides similar data on the epidemiology of pneumococcal infections in Poland. According to KOROUN, in Poland in 2021, the most frequently identified pneumococcal serotypes responsible for invasive infections in people over 20 years of age were: 3, 4, 8, 9N, 19A, 22F, 6C and 14. In turn, the five serotypes most often responsible for deaths were serotypes 3, 4, 14, 11A and 9N [46].

The changing epidemiology of pneumococcal infections and the need to protect adults against them are driving the development of pneumococcal conjugate vaccines. The seven additional pneumococcal serotypes in PCV20 (8, 10A, 11A, 12F, 15B, 22F, 33F) were selected for their steadily increasing importance in the epidemiology of IPD, both in Europe and globally [45, 47]. As shown in Table 4, PCV20 currently has the broadest possible serotype coverage of any available conjugate vaccine used in adults. PCV20 is the only conjugate vaccine indicated for active immunisation against IPD and pneumonia caused by serotypes 8, 12F and 10A – a few of the pneumococcal serotypes most frequently responsible for invasive infections in Europe (Figure 1) [45]. Based on 2018 data from the ECDC-funded *Streptococcus pneumoniae* Invasive Disease network (SpIDnet), it is estimated that the PCV20 coverage rate in Europe in the population over 65 years of age is around 75%, while PCV13 and PCV15 is 45% and 57%, respectively [44]. Based on the KOROUN data from 2021, it can be estimated that the theoretical serotype coverage of PCV20 in the population ≥ 20 years of age in Poland is about 74%, and that of PCV13 and PCV15 stood at 58% and 62% [46].

Each of the additional serotypes in PCV20 is important since these serotypes are now a common cause of IPD from a global perspective. These serotypes are associated with antibiotic resistance (serotype 11A, 15B, 22F, 33F) [48, 49], the cause of meningitis (10A, 15B, 22F, 33F) [50], a higher mortality rate (all serotypes except 12F) [21, 51] and outbreaks (8 and 12F) [52].

Characteristics of PCV20

The 20-valent pneumococcal conjugate vaccine (PCV20) is a next-generation vaccine with additional epidemiologically relevant serotypes compared to other available conjugate vac-

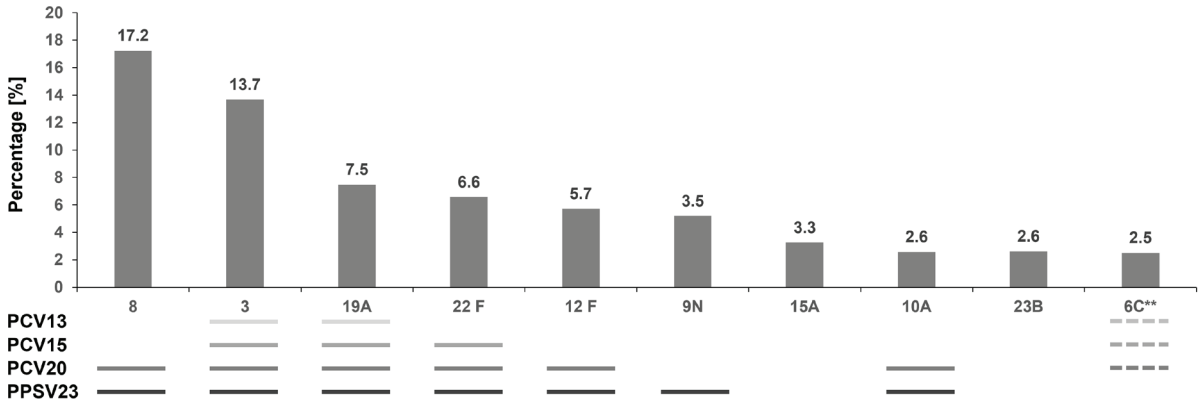

Figure 1. Pneumococcal serotypes most frequently causing IPD across all age groups in Europe* in 2018 [45] and serotypes included in individual pneumococcal vaccines [23–26]

* Austria, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Portugal, Slovakia, Slovenia, Spain, Sweden and the UK; ** cross-reactive serotype.

cines. Aside from the seven additional pneumococcal polysaccharide antigens conjugated to a carrier protein, PCV20 contains the same excipients as PCV13. As the clinical efficacy of PCV13 in the adult population has already been confirmed, ongoing studies with newer-generation vaccines evaluate only safety and immunogenicity. So far, clinical trials have compared the immunogenicity of PCV20 with that of PCV13 for thirteen common serotypes and with PPSV23 for seven additional serotypes (common with PPSV23 but not included in PCV13) [25].

PCV20 vaccine immunogenicity

The registration of PCV20 for use in the active prophylaxis of pneumococcal infections in adults was preceded, inter alia, by three Phase 3 clinical trials, which enrolled a total of approximately 6,500 adults in centres in the United States and Sweden: studies by Essink et al. [53], Cannon et al. [54] and Klein et al. [55]. A pivotal clinical trial by Essink et al. included adults over 18 years of age who had not received any pneumococcal vaccine in the past. The primary study cohort was adults 60 years of age and older. An additional two younger cohorts (18–49 years and 50–59 years) were included to evaluate the immune response to PCV20 in comparison to the group ≥ 60 years of age. The percentage of patients with at least one risk factor for pneumococcal infection in the cohort ≥ 60 years of age was 27%. The most common comorbidities were type 2 diabetes, asthma and chronic cardiovascular disease [56]. In a cohort of patients ≥ 60 years of age, the non-inferiority criterion was met for 19 of the 20 PCV20 serotypes assessed by the immune response as measured by the opsonophagocytic assay (OPA) test. Only the immune response of serotype 8 narrowly missed the statistical non-inferiority criterion [53]. However, the clinical relevance of this observation is presently unknown. Interestingly, the response to serotype 8 after vaccination with PCV20 was robust when taking additional analyses of the immune response into consideration [53]. Moreover, given the characteristics of the conjugate vaccine (the ability to induce long-term immune memory and a more robust immune response upon re-exposure to a given serotype [31]), the response to serotype 8 is expected to provide similar protection to the other 19 serotypes which meet the criterion of non-inferiority. In the younger cohorts, the *non-inferiority* criterion was met for all 20 serotypes compared to the cohort ≥ 60 years of age. The safety profile of PCV20 was similar to that observed in PCV13 adult studies [33, 53]. Most frequently, the PCV20 vaccination was associated with systemic reactions (muscle pain) and reactions at the injection site (pain at the injection site), the vast majority of which were mild to moderate in severity [53].

Study by Cannon et al. demonstrated the robust immunogenicity of PCV20 in subjects ≥ 65 years of age who previously received PPSV23, PCV13 or the two-dose regimen of PCV13 and PPSV23 (one dose of PCV13, one dose of PPSV23). In addition, the numerically highest OPA geometric mean titres (GMTs) after PCV20 vaccination were observed in patients previously vaccinated with PCV13 [54]. In turn, a study by Klein et al. demonstrated the consistency of the immune response to the PCV20 vaccine from three different production lots in subjects 18–49 years of age [55].

Latest recommendations for pneumococcal vaccination in the adult population

The PCV20 vaccine was approved in the United States in mid-2021. At the beginning of 2022, the American Advisory Committee on Immunization Practices (ACIP) updated its recommendations concerning the prevention of pneumococcal infections in the adult population [17]. ACIP provides vaccination recommendations for adults ≥ 19 years of age with chronic diseases, those addicted to alcohol or tobacco, with cochlear implants, CSF leakage and immunocompromised individuals (Table 5). At the same time, it concerns all adults ≥ 65 years of age, regardless of any additional factors that increase the risk of *S. pneumoniae* infection. Routine administration of PPSV23 after PCV20 is not recommended, probably due to the uncertain efficacy of PPSV23 in preventing non-bacteremic pneumococcal pneumonia. Furthermore, it is estimated that vaccination with PPSV23 after PCV20 vaccination would generate high costs with minimal health gains [57, 58]. The Committee recommends an alternative sequential vaccination composed of one dose of PCV15 followed by one dose of PPSV23 at an appropriate interval (Table 5). For immunocompromised individuals, or those with cochlear implants or CSF leakage, a shorter interval to PPSV23 administration (i.e. at least 8 weeks) is recommended, and at least 12 months in all other cases. Therefore, the risk of infection could be minimised with the pneumococcal serotypes covered only by the PPSV23 vaccine in people at high risk of disease.

ACIP recommends vaccination schedules according to the patient's vaccination history. Adults who have only received PPSV23 in the past may be vaccinated with a PCV conjugate vaccine (PCV20 or PCV15) at least one year after the last dose of PPSV23. For adults who have received PCV13 but have not completed the recommended series with PPSV23 vaccines, a single dose of PCV20 can be used if the PPSV23 vaccine is not available [17]. No catch-up immunisation is required for individuals who have completed the vaccination schedule with PCV13

Table 5. Current Advisory Committee on Immunization Practices (ACIP) recommendations for the active prophylaxis of pneumococcal infections in adults not vaccinated with pneumococcal conjugate vaccines [17]

Underlying conditions or risk factors	Age group	
	19–64 years	≥ 65 years
None	None	
Alcoholism Chronic heart disease[§] Chronic liver disease Chronic lung disease[¶] Cigarette smoking Diabetes Cochlear implant Cerebrospinal fluid leak Congenital or acquired asplenia Sickle cell disease/other hemoglobinopathies Congenital or acquired immunodeficiencies** Generalised malignancy HIV infection Hodgkin's disease Iatrogenic immunosuppression[††] Leukaemia Lymphoma Multiple myeloma Nephrotic syndrome Solid organ transplant	1 dose of PCV20 **OR** 1 dose of PCV15 followed by one dose of PPSV23 ≥ 1 year later*	1 dose of PCV20 **OR** 1 dose of PCV15 followed by one dose of PPSV23 ≥ 1 year later*

* In adults with underlying conditions that compromise the immune system, cochlear implants or CSF leakage, shorter intervals, e.g. ≥ 8 weeks, may have additional benefits; [§] Includes congestive heart failure and cardiomyopathy; [¶] Includes chronic obstructive pulmonary disease, emphysema and asthma; ** Includes B- or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3 and C4 deficiencies) and phagocytic disorders (excluding chronic granulomatous disease); [††] Treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy.

and PPSV23. The latest ACIP guidelines significantly simplify the principles of pneumococcal vaccination in the adult population. This simplification is expected to increase vaccination coverage among the adult population, which will translate into the effective prevention of pneumococcal diseases [17].

A sequential (two-dose) administration may pose a risk of not completing the vaccination schedule, which should occur after a strictly defined time. In addition, administration of a two-dose regimen may not be possible at an optimal time, due to the specificity of the disease and the current or planned treatment, for example, in patients with systemic connective tissue diseases, such as rheumatoid arthritis, systemic lupus erythematosus or systemic vasculitis, which are treated with immunosuppressive drugs. Recommendations in this group indicate, on the one hand, that vaccination should not be performed during exacerbation of the disease, and on the other hand, the treatment used, such as glucocorticoids, methotrexate or rituximab, may reduce the effectiveness of vaccination [59]. Therefore, the availability of a vaccine that allows its use in a single-dose schedule increases the likelihood of effective prophylaxis for such patients.

Prevention of pneumococcal diseases in adults in Poland

The prophylaxis of pneumococcal infections in the adult population is recommended under Poland's National Immunisation Programme (NIP). Vaccination against *S. pneumoniae* is recommended for adults with various factors increasing the risk of *S. pneumoniae* infection [60]. The first recommendation for pneumococcal prophylaxis with a conjugate vaccine in adults ≥ 50 years of age in Poland was in 2013 [61]. However, it is not financed by the budget of the Polish Ministry of Health (MoH).

Since January 2022, PCV13 has been available as a reimbursed vaccine with a 50% co-payment for the population of adults ≥ 65 years of age having an increased (moderate to high) risk of pneumococcal disease development [62]. Adults who meet the age criterion and who have at least one of the following risk factors for infection are eligible for vaccine reimbursement: chronic heart disease, chronic liver disease, chronic lung disease, diabetes, cochlear implant, CSF leakage, congenital or acquired asplenia, sickle cell anaemia, and other haemoglobinopathies, chronic renal failure, congenital or acquired immunodeficiency, generalised neoplastic disease, HIV infection, Hodgkin's disease, iatrogenic immunosuppression, leukaemia, multiple myeloma, solid organ transplant [62]. The wide range of reimbursement conditions for PCV13 increases its availability among the target population.

In Poland, free-of-charge pneumococcal vaccinations are also provided by some local government bodies. From 2016 to June 2022, the Agency for Health Technology Assessment and Tariff System (AOTMiT) assessed 36 health policy prophylaxis programmes, of which the vast majority (82%) are dedicated to the general population ≥ 55 years of age. Even though the reimbursement of PCV13 came into force in 2022, two local government units submitted draft programmes to prevent pneumococcal infections in the general population 65 years of age and older. In the event of high demand, the vaccine will be administered first to individuals with the highest risk of *S. pneumoniae* infection development [63].

Recommendation for the prevention of pneumococcal infections during the COVID-19 pandemic

Due to the outbreak of the COVID-19 pandemic (Coronavirus Disease 2019) in March 2020, the World Health Organization (WHO) issued recommendations on implementing preventive vaccinations. WHO emphasises that implementing vaccination against pneumococci and seasonal influenza in groups of people with an increased risk of infection should be the priority. WHO provides a clear message that implementing preventive vaccinations constitutes a crucial health aim during the COVID-19 pandemic [64]. The Polish MoH and Chief Sanitary Inspectorate, following WHO guidelines, issued similar recommendations

which support the legitimacy of vaccinations. The MoH and Chief Sanitary Inspectorate recommend the dissemination of vaccination against pneumococci and influenza in populations at risk, including adults ≥ 60 years of age with chronic diseases of the lungs, cardiovascular system, cancer, diabetes, kidney failure and immunity disorders. The recommendation indicates that people with these diseases are particularly vulnerable to pneumonia [65]. Notably, the Dutch and Spanish health services have recognised the need to prevent pneumococcal infections in people previously hospitalised for COVID-19 [66, 67].

Conclusions

Pneumococcal infections in adults remain a significant health problem. The risk of *S. pneumoniae* infection in adults increases with age or other contributing factors, such as chronic diseases, immunosuppressive conditions and certain environmental factors. In the adult population, pneumococci are the primary cause of pneumonia, which puts a significant burden on the healthcare system and leads to serious health consequences for patients. Invasive *S. pneumoniae* infections, although not as common as non-bacteremic pneumonia, are associated with severe complications, including death, especially among the elderly.

The changing prevalence of pneumococcal serotypes in the population is the driver for developing the next generation of vaccines. Among the currently available pneumococcal conjugate vaccines, PCV20 provides the broadest possible serotype coverage in both Poland and Europe as a whole. PCV20 immunogenicity is proven to be at a comparable level to the previously registered vaccines (PCV13 and PPSV23). The key advantage of conjugated vaccines (including PCV20) over unconjugated vaccines is the induction of immune memory and a robust response after administering another dose (the so-called booster effect). As described above, the PCV20 vaccine contains antigens of epidemiologically important pneumococcal serotypes. Therefore, it is estimated that PCV20 constitutes a proper response to the current epidemiological situation in Poland, Europe and globally. In the latest ACIP recommendations for preventing pneumococcal infections in adults, a single dose of PCV20 or a two-dose regimen (i.e. PCV15 + PPSV23) is recommended. The introduction of a single-dose schedule with the use of PCV20 seems to be a significant simplification of vaccination practice, which may positively affect vaccination in adults.

Moreover, the introduction of PCV13 pharmacy reimbursement in Poland, with 50% co-payment for people ≥ 65 years of age and with at least moderate risk factors for pneumococcal infection, increased access to vaccinations in the most vulnerable population. At the same time, in light of the constantly changing epidemiology of pneumococcal infections and the latest ACIP recommendations, there remains the need to increase access to modern infection prophylaxis.

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