Journal of Cardiovascular Disease Research
ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 07, 2021

An Overview about Pneumococcal Conjugate Vaccine Utility in Chronic Kidney Disease Children

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Abstract

Background: Streptococcus pneumoniae is encapsulated gram-positive, catalase-negative coccus that has remained an extremely important human bacterial pathogen since its initial recognition in the late 1800s. The term pneumococcus gained widespread use by the late 1880s, when it was recognized as the most common cause of bacterial lobar pneumonia.To improve the immune response to the capsular polysaccharide in young children, third-generation vaccines in which capsular polysaccharides are conjugated to one of several different proteins were developed. The first such vaccine to be registered by the FDA for use in infants and children in February 2000 was a 7 valent pneumococcal conjugate vaccine (PCV) named Prevnar 7. Following this a 13 valent pneumococcal conjugate vaccine was licensed in March 2010 and now a 13-valent PCV is available. Conjugate vaccines act via stimulation of T cells and consequently tend to have a superior antibody response, maintenance of antibody levels for a longer duration and induction of immunological memory. Pneumococcal vaccination has been recommended for immunocompromised children, including patients with chronic kidney disease.

Keywords: Pneumococcal Conjugate Vaccine

Introduction

CKD is defined as abnormalities of kidney structure or function, present for >3 months **(1).** Childhood CKD registries are usually restricted to small reference populations, The median incidence of RRT (renal replacement therapy) in children < 20 years old is 9 per million of age-related population (pmarp) worldwide, and the prevalence is reported as 65 pmarp the pediatrics incidence of CKD also in Europe is reported to be around 11–12 per million of age-related population for stages 3–5 **(2)**

In special study Showed reviewed the records of 1018 Egyptian children (ages from 1 to 19 years, males 56.7%) suffering from CKD of all stages and followed-up at the pediatric

nephrology units of 11 universities providing tertiary medical care to children from all Egyptian governorates during the year 2012-2013 Children with CKD stage I and stage II comprised 4.4% of the studied group, while those with stage III, IV and V comprised 19.7%, 18.3% and 57.6%, respectively **(3).**

Streptococcus pneumoniae is encapsulated gram-positive, catalase-negative coccus that has remained an extremely important human bacterial pathogen since its initial recognition in the late 1800s. The term pneumococcus gained widespread use by the late 1880s, when it was recognized as the most common cause of bacterial lobar pneumonia **(4).**It is a common member of the bacterial flora colonizing the nose and throat of 5–10% of healthy adults and 20–40% of healthy children **(5).** With childhood conjugate vaccination for Streptococcus pneumoniae, the colonization frequency has decreased **(6).**

The first ever attempt to vaccinate humans against pneumococcus took place in Africa in 1911 using a whole cell vaccine. Advances in understanding germ theory led to typing of pneumococci then the isolation of capsular polysaccharides in 1916. This then paved the way for the creation of the first quadrivalent pneumococcal polysaccharide vaccine (PPV) in 1944–1945 which did show promising results, then a hexavalent vaccine was developed in 1947. However, at this point, clinicians preferred to treat with antibiotics rather than vaccinate until it was recognized that antibiotic resistance was becoming a concern with continued high case fatality rates in spite of treatment; thus, efforts were reintensified to create effective vaccines. This then led to a to 14 valent PPV being licensed in 1977 and this was followed by the 23 valent pneumococcal vaccine which was first introduced in the United States in 1983 (**7**). Polysaccharide vaccines act via a T-cell independent mode of B-cell stimulation which is not able to generate a memory effect; and pneumococcal polysaccharide vaccines are poorly immunogenic in children younger than 2 years of age. This is of concern as 80% of invasive pneumococcal disease occurs in children under the age of 2 (**8**).

To improve the immune response to the capsular polysaccharide in young children, third-generation vaccines in which capsular polysaccharides are conjugated to one of several different proteins were developed. The first such vaccine to be registered by the FDA for use in infants and children in February 2000 was a 7 valent pneumococcal conjugate vaccine (PCV) named Prevnar 7 (**9**). Following this a 13 valent pneumococcal conjugate vaccine was licensed in March 2010 (**10**), and now a 13-valent PCV is available. Conjugate vaccines act via stimulation of T cells and consequently tend to have a superior antibody response, maintenance of antibody levels for a longer duration and induction of immunological memory (**11)**. In addition, conjugate pneumococcal vaccines have been shown to have excellent immunogenicity in children below 2 years of age (**12;13**). **Figure**

II depicts the differences between PPV and PCV in terms of their structure and the immune response.

Pneumococci are divided about 90 distinct pneumococcal serotypes based on differences in the polysaccharide composition of the capsule. The spectrum of prevailing capsular types varies with age, time and geographical region, although common serotypes are consistently identified throughout the world. Globally, about 20 serotypes are associated with >80% of invasive pneumococcal disease occurring in all age groups, the 13 most common serotypes cause at least 70–75% of invasive disease **(14).**

The vaccines have always targeted the most prevalent strains causing invasive disease and since their introduction, there have been tremendous reductions in invasive pneumococcal disease due to strains included in the vaccines **(15**). A Cochrane review of conjugate pneumococcal vaccines reported that the pooled vaccine efficacy was 80% (95% CI 58–90%) against vaccine-type disease and 58% (95% CI 29–75%) against all serotype invasive disease in children under 2 year (**16).** However, the rates of infection due to strains not included in the vaccines has risen (**15**). Aiming to prevent pneumococcal infection is of paramount importance especially in this era of ever increasing pneumococcal resistance to penicillins and cephalosporins.

The conjugate vaccine provides long-lasting B-lymphocyte memory responses **(17)** and the PCV reduced the overall incidence of severe pneumococcal disease in young children, as well as pneumonia in elderly people and other high-risk patients, presumably through herd immunity **(18).**

Current Recommendations for Pneumococcal Vaccination:

In Healthy Children

WHO strongly recommended that pneumococcal vaccination be included in national childhood immunization programme **(14**). To reduce morbidity and mortality from invasive pneumococcal disease by vaccinating all infants and children who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).**CDC, (19)** and **CDC and ACIP, (10)** As of 2018, 142 countries had introduced the pneumococcal vaccination as part of their national immunization program (**20**).

For PCV administration to infants, WHO recommends 3 primary doses (the 3p+0 schedule); or 2 primary doses plus a booster (the 2p+1 schedule). If the 3p+0 schedule is used, vaccination can be initiated as early as 6 weeks of age with an interval between doses of 4–8 weeks, with doses given at 6, 10, and 14 weeks or at 2, 4, and 6 months, depending on programmatic convenience. If the 2p+1 schedule is selected, the 2 primary doses should be given during infancy as early as 6 weeks of age at an interval preferably of 8 weeks or more for the youngest infants and 4–8 weeks or more between primary doses for infants

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 07, 2021

aged ≥7 months. One booster dose should be given between 9 and 15 months of age. In choosing between the 3p+0 and 2p+1 schedules, countries should consider locally relevant factors including the epidemiology of pneumococcal disease, the likely coverage, and the timeliness of the **Recommendations for Immunocompromised Children**

It is recommended that immunocompromised children aged 2–18 who have completed the immunization with PCV 7 or PCV 13 should receive additional dose of PPV 23 in view of the increased spectrum of coverage against more serotypes (**21,22**).

ACIP guidelines for immunocompromised children between the ages of 6 and 18 are that PPV naïve children receive a first dose of PCV 13 followed at least 8 weeks later by a dose of PPV 23 and then another dose of PPV23 at least 5 years later. Those vaccinated with PPV23 should receive a single dose of PCV 13 at least 8 weeks after the last PPV23 dose, even if they had previously received PCV7**(14;23).**

Valent Pneumococcal Conjugate Vaccine:

Vaccine Composition:

PCV13 (Prevnar13) contains polysaccharides of the capsular antigens of S. pneumonia serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, individually conjugated to a nontoxic diphtheria cross-reactive material (CRM) carrier protein (CRM197). A 0.5-mL PCV13 dose contains approximately 2.2 μ g of polysaccharide from each of 12 serotypes and approximately 4.4 μ g of polysaccharide from serotype 6B; the otal concentration of CRM197 is approximately 34 μ g. The vaccine contains 0.02% polysorbate 80 (P80), 0.125 mg of aluminum as aluminum phosphate (AlPO4) adjuvant, 5mL of succinate buffer, and no thimerosal preservative **(23)**. Except for the addition of six serotypes, P80, and succinate buffer, the formulation of PCV13 is the same as that of PCV7 **(24;25;26).**

Administration: PCV13 is supplied as a prefilled single-dose 0.5-mL syringe for intramuscular injection in the anterolateral aspect of the thigh in infants and in the deltoid muscle of the upper arm in infants, children, and adults to all healthy children as well as children with a medical condition or other risk factor **(25**).

Side effect: The most common side effects reported include irritability, injection site reactions, decreased appetite and sleep, fever, fatigue, headache, muscle and joint pain, chills, or rash moderate or severe acute illness with or without fever, or change in sleep. Severe allergies are very rare **(25;26**).

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 07, 2021

Contraindications:

Do not give PCV13 to a child who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components (including to any diphtheria toxoid-containing vaccine) **(25**).

CDC recommendations for Administering Pneumococcal Polysaccharide Vaccine to Children and Teens

Purpose

To reduce morbidity and mortality from pneumococcal disease by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices **(10).**

Assess Children and Teens in Need of Vaccination age 2 years and older and lacking documentation of at least 1 dose of pneumococcal polysaccharide vaccine (PPSV23) based on having any of the following conditions:

Contraindications: Do not give PPSV23 to a child or teen that has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components

Side effect: Moderate or severe acute illness with or without fever

Administration of PPSV 23: 0.5 mL for patients age 2 years and older, may be via either the intramuscular (IM) or subcutaneous (Subcut) route. If vaccine is to be administered by the intramuscular route, choose the needle gauge, needle length, and injection site

Pneumococcal Immunizations in children with chronic kidney disease:

Patients with ESRD and on dialysis have altered immunity, which increases the risk of severe infections. The burden of pneumococcal disease in patients with ESRD is high, with S. pneumonia being the cause of more than half of the reported cases of pneumonia in dialysis patients . CKD patients who do not mount an adequate response to Pneumococcal vaccine are more likely to develop pneumococcal infections than patients who respond to the vaccine **(27;28;29).**

ESRD is associated with disorders of the adaptive immune system, which result in decreases in antigen presenting function, the T-cell-mediated immune response, and immunological memory. These patients are thus at risk of vaccine hypo responsiveness. There is evidence of a decreased immunologic response to the PPSV23 in patients undergoing dialysis compared to that in the general population. Moreover, a rapid decline in anti-pneumococcal IgG levels is observed in patients with ESRD within 1 year after vaccination with PPSV23 **(30).**

CKD are at increased risk for vaccine-preventable diseases. These patients may have a reduced response to and/or reduced duration of antibody after immunization and therefore

monitoring of antibody levels or titers is indicated for some vaccines. In addition, pediatric CKD patients require immunizations not routinely provided to healthy children. Unfortunately, studies in pediatric CKD patients, including those on dialysis and awaiting kidney transplantation, have demonstrated sub-optimal immunization rates. In order to minimize the risk for vaccine-preventable disease in pediatric CKD patients, it is imperative that all who care for these patients remain abreast of the recommended childhood immunization schedule, as well as alterations to this schedule required for children with CKD, including end-stage kidney disease (**31)**.

Pneumococcal vaccination has been recommended for immunocompromised children, including patients with chronic kidney disease **(14;20;32).**

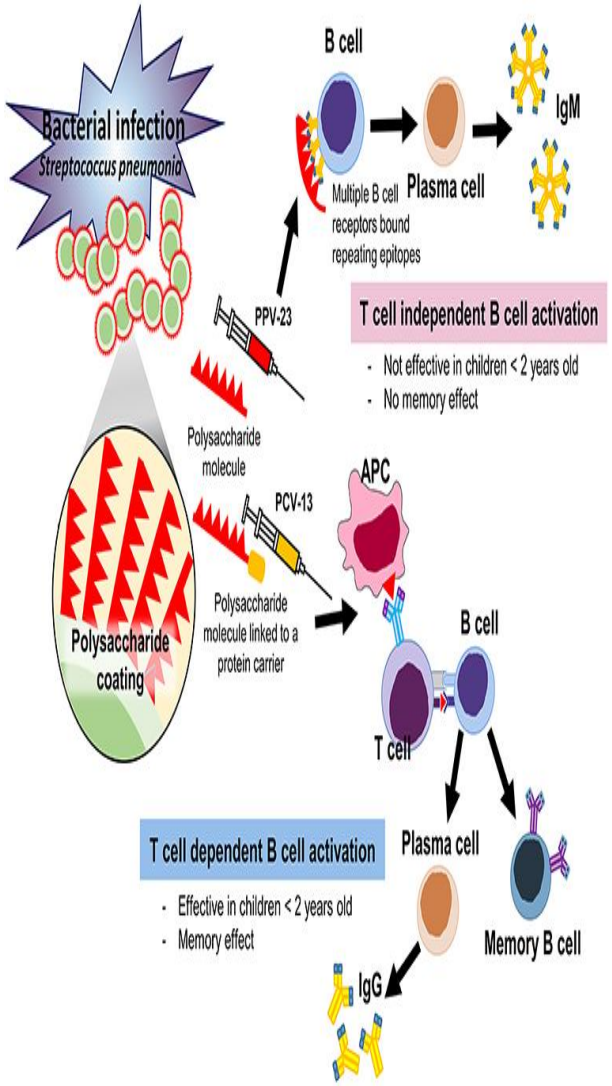

Figure (1): Mechanisms of immunogenicity of PPV vs. PCV

Table 1: Summary of WHO recommended pneumococcal vaccination schedules with PCV 13 for all children <2 years of age

Pneumococcal vaccine regimen	Dose 1	Dose 2	Dose 3	Booster
2 + 1	Within 6 months, at least 8 weeks apart; starting as early as 6 weeks		NA	Between 9–18 months
3 + 0	Within 9 months, at least 4 weeks between doses; starting as early as 6 weeks; to be completed by age 2 years			NA
3 + 1	2 months	4 months	6 months	12–15 months

In developed countries, 3 + 1 is recommended but countries are advised to choose the regimen best suited to their region and accessibility to healthcare.

Table (I) Underlying medical conditions that are indications for pneumococcal vaccination among children ,by risk group (33).

isk group	Condition
Immunocompetent children	**Chronic heart disease* Chronic lung disease Diabetes mellitus Cerebrospinal fluid leaks Cochlear implant**
Children with functional or anatomic asplenia	**Sickle cell disease and other hemoglobinopathies Congenital or acquired asplenia, or splenic dysfunction**
Children with immune-compromising conditions	**HIV infection Chronic renal failure and nephrotic syndrome Diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas and Hodgkin disease; or solid organ transplantation Congenital immunodeficiency**

(10)

Table (2) Choose the needle gauge, needle length, and injection site according to the following chart.

Age of infant/child	Needle gauge	Needle length	Injection site
Younger than 12 months	22 – 25	1	Anterolateral thigh muscle
12 through 35 months	22 – 25	$1 – 1^{1/4}$	Anterolateral thigh muscle
		5/8 – 1	Deltoid muscle of arm
3 through 10 years	22 – 25	5/8 – 1	Deltoid muscle of arm
		$1 – 1^{1/4}$	Anterolateral thigh muscle
11 through 18 years	22 – 25	5/8 – 1	Deltoid muscle of arm
		$1 – 1^{1/2}$	Anterolateral thigh muscle

*** preferred site (24;25;26).**

Table (3) Recommended schedule for Administering Pneumococcal conjugate Vaccine (PCV13)

Child's age now	Vaccination history of PCV13	Recommended PCV13 Schedule (For minimum interval guidance for catch up vaccination, see below)
Through 6 months 2	O doses	3 doses, 8weeks apart, 4th dose at age 12-15 months-

	1 dose	**2 doses, 8weeks apart; 4th dose at age 12-15 months**
	2 Dose	**1 dose, 8 weeks* after the most recent dose, 4th dose at age 12-15 months**
7 through 11 months	**0 Dose**	**2 doses, 8weeks apart and a 3rd dose at age 12-15 months**
	1 or 2 doses before age 7 months	**1 dose at age 7-11 months and a 2nd dose at age 12-15 months, at least 8 weeks after the most recent dose .**
	dose at age 7-11 months1	**2 doses: 1 dose at age 7-11 months and a 2nd dose at age 12-15 months, at least 8 weeks after the most recent dose**
	doses at age 7-11 months 2	**1 dose at age 12-15 months**
12 through 23 months	**O doses**	**2 doses, at least 8 weeks apart**
	1 dose before age 12 months	**2 doses, at least 8 weeks apart**
	1 or 3 doses before age 12 months	**1 dose, at least 8 weeks after the most recent dose**

	2 doses at or after age 12 months	**1 dose, at least 8 weeks after the most recent dose**
	2 doses at or after 12 months	**0 Doses**
24 through 59 months (healthy children)	**0 doses**	**1 dose**
	Any incomplete schedule	**1 dose, at least 8 weeks after the most recent dose**
24 through 71 months (children with underlying medical condition as described in Table 3 below)	**Unvaccinated or any incomplete schedule of less than 3 doses**	**2 doses: 1st dose at least 8 weeks after most recent dose and a second dose at 8 weeks later**
	Any incomplete schedule t* of 3 doses	**, at least 8 weeks afte ecent dose**
6 through 18 years with immunocompromising condition, functional or anatomic asplenia, cochlear implant or cerebrospinal fluid leak	**No history of PCV13**	

(33)

Table (4): Recommended schedule for Administering Pneumococcal polysaccharide Vaccine (PPSV23)

Risk group	Schedule for PPSV23	Revaccination with PPSV23
Immunocompetent children and teens with underlying medical condition	**Give 1 dose of PPSV23 at age 2 years or older and at least 8 weeks after last dose of PCV13**	**Not indicated**
Children and teens with immunocompromising condition, functional oranatomic asplenia	**Give 1 dose of PPSV23 at age 2 years or older and at least 8 weeks after last dose of PCV13.**	**Give 1 additional dose of PPSV23 at least 5 years following the first PPSV23; the next recommended dose would at age 65 years**
Children and teens age 6 years & older with chronic liver disease, alcoholism	**If no history of PPSV23 give 1 dose of PPSV23 at least 8 weeks after any prior PCV13 dose**	**Not indicated**

(33)

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