

INTRODUCING THE PNEUMOCOCCAL CONJUGATE VACCINE (PCV) IN JORDAN

A compilation of relevant information from countries within
the World Health Organization Eastern Mediterranean Region

15 January, 2023



Photo: UNICEF/Rami Nader, 2018

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EXECUTIVE SUMMARY

Pneumonia continues to be the number one infectious killer of children globally. In the World Health Organization (WHO)'s Eastern Mediterranean (EMRO) region, each year an estimated 923,000 children under 5 years of age (U5) die, with pneumonia accounting for over 20% of deaths among this age group (1). The pneumococcal conjugate vaccine (PCV) is a lifesaving vaccine that protects against infections caused by *Streptococcus pneumoniae*, a leading cause of severe pneumonia (2). Numerous global studies have demonstrated the positive impact PCV makes in preventing disease and preserving life. There are three commercially available, WHO pre-qualified PCV products in the global market (2).

As of October 2022, 164 out of 194 WHO member states have introduced PCV into their national immunization programs (3). The WHO EMRO region serves 21 Member States as well as occupied Palestinian territory. In the EMRO region, 16 countries have introduced PCV into the national schedule and an additional country (Iraq) has currently suspended PCV (3) (4). The overall PCV coverage rate in the WHO EMRO region is 54%, according to data from the WHO/UNICEF vaccination coverage reports for 2021 (3) (4). Jordan is one of five EMRO countries (alongside Egypt, Somalia, Syrian Arab Republic, and Islamic Republic of Iran) that has yet to introduce PCV into the national schedule. The following evidence-based brief compendium on PCV use globally and within the EMRO region has been compiled to support discussions by Jordan's National Immunization Technical Advisory Group (NITAG) members with respect to PCV introduction.

Photo: UNICEF/Fahdl, 2022



INTRODUCTION



Photo: UNICEF/Djemidzi, 2022

This document is a collection of information on the pneumococcal conjugate vaccine (PCV) situation globally with a focus on Jordan's neighboring countries in the World Health Organization (WHO) Regional Office for the Eastern Mediterranean (EMRO) region who have introduced PCV. Overall information will be provided for all WHO EMRO countries, with a particular focus on Jordan's neighboring countries.

As Jordan is one of the five countries in the WHO EMRO region that have yet to introduce PCV (alongside Egypt, Somalia, Syrian Arab Republic, and Islamic Republic of Iran), pulling information on the PCV situation in neighboring countries can help equip in-country decision-makers with evidence-based information to inform the decision to introduce PCV. The information from the desk review will be shared with Jordan's National Immunization Technical Advisory Group (NITAG) members to help take steps in the PCV introduction decision.

BURDEN OF PNEUMOCOCCAL DISEASE

Pneumococcal disease, caused by the bacterium *Streptococcus pneumoniae*, (commonly called pneumococcus) is the leading vaccine preventable cause of mortality during infancy and childhood (1) (5). In settings where mortality is high, pneumococcus is responsible for a greater fraction of mortality and morbidity than in lower mortality settings. In countries with a lower burden of child mortality, pneumococcal disease remains a ubiquitous pathogen that causes pneumonia, bloodstream infections and meningitis that require immediate, appropriate treatment, and can result in long-term sequelae among survivors (including neurological impairment in those who had meningitis and compromised lung function among those who had pneumonia) (6). Pneumococcal disease also incurs substantial financial treatment costs to families and to government health care systems. In addition to causing severe morbidity and mortality, pneumococcus also causes mild infections such as acute otitis media (OM) and community-acquired pneumonia which result in productivity and economic losses, much of which can be prevented through use of PCVs (7).

Pneumococcal disease is the leading vaccine preventable cause of mortality of infancy and childhood.

OVERVIEW OF PCV

What is PCV?

Pneumococcal conjugate vaccines (PCV) help protect against infections caused by *Streptococcus pneumoniae* (pneumococcus) (2). Its protection is evident especially among children under age five (U5) who are the most vulnerable age group to pneumococcal infections. The World Health Organization (WHO) recommends that all countries should include PCV in their national immunization program for infants and young children (5). As of 2022, 164 countries out of 194 WHO member states have introduced PCV into their National Immunization Programs (NIPs) either nationally or sub-nationally (8).

PCV has been around since 2000, when the vaccine was first introduced in the U.S. national immunization programs to provide infants with protection against the most prevalent and pathogenic pneumococcal serotypes (9). The 7-valent PCV (PCV7) was the first PCV to be licensed, which was replaced by two higher valent vaccines covering 10 and 13 serotypes, namely PCV10 (Synflorix) and PCV13 (Prevenar) in 2009 (5). Additionally, another 10-valent PCV (Pneumosil manufactured by the Serum Institute of India) has been licensed in some markets since receiving World Health Organization (WHO) pre-qualification in December 2019 (10).

Why is it important to introduce PCV?

The WHO estimates that pneumonia causes more deaths among children than any other infectious disease, claiming the lives of more than 800,000 children U5 every year, which is around 2,000 every day. Globally, there are over 1,400 cases of pneumonia per 100,000 children every year, with the greatest incidence and deaths occurring in developing countries. (1) A large proportion of these deaths are preventable. Countries that introduced PCV have observed large reductions in severe and invasive pneumococcal disease and pneumonia deaths. Multiple studies published recently have estimated that over 54.6 million pneumonia disease cases and 399,000 deaths could be averted annually in children U5 with the global use of PCV (9).



What is the impact of PCV?

There have been numerous studies globally that have documented reductions in invasive pneumococcal disease (IPD), pneumonia, otitis media and antibiotic resistance from the use of PCVs (9). These vaccines not only prevent infections in children, but also help to prevent infections from spreading to others. An analysis of data from a population-based surveillance in Gambia, which introduced PCV7 in 2009 and PCV13 in 2011, showed 80% incidence reduction in IPD and a 27% decline in pneumonia hospitalizations among children aged 2-59 months who had received the primary 3-dose PCV regime (11). In Turkey, where PCV13 was introduced in the national immunization program in April 2011, mean annual incidence of acute otitis media among children ≤ 5 years of age, decreased by 54% in 2017 (12). A multi-country analysis of PCV impact in Asian countries reported that in the 12 countries that had PCV13 in their national immunization programs, 19.2 million infants had received PCV13 which averted 12.9 million pneumococcal disease cases and almost 16,000 deaths (13).

Indirect benefits of PCV introduction in childhood immunization among adults has also been reported. In the United States after four years of PCV7 introduction in the infant schedule, hospitalization rates for pneumonia among adults aged 18 to 39 years significantly reduced by 26%. Studies with an extended follow-up period recorded annual pneumonia hospitalization reductions of 1,301 hospitalizations per 100,000 population among adults > 85 years in 2007-2009 compared to pre-PCV era of 1997-1999 (14).

There have been numerous studies globally that have documented reductions in invasive pneumococcal disease, pneumonia, otitis media, and antibiotic resistance from the use of PCVs.

How cost effective are PCVs?

Since cost of PCV has been an often-cited concern for its introduction, it is valuable to note that twenty-two cost-effectiveness studies in Asia found PCV to be a cost-effective intervention. Four studies found PCV7 to be a cost-effective intervention compared to no intervention at all, one study found PCV7 to be cost saving, and six studies found PCV13 to be cost-effective. Seventeen of these twenty-two studies used WHO criteria to assess cost-effectiveness, which compares the incremental cost-effectiveness ratio (ICER) to GDP per capita to ascertain the cost-effectiveness of a product. ICER measures the economic value of an intervention compared to an alternative and is calculated as the ratio of the difference in cost of two interventions to the difference in their effect. According to the WHO criteria, a vaccine would be considered cost-effective if the ICER was not more than three-times the GDP per capita. On the other hand, a vaccine would be considered cost-savings if the ICER was not more than the GDP per capita. The other five studies used a more conservative approach where cost-effective was defined as the ICER not exceeding the GDP per capita (15).

The WHO recommends that surveillance of pneumonia and pneumococcal disease, and where possible, serotype surveillance of invasive disease and nasopharyngeal carriage from sentinel sites be conducted to monitor changes in disease and to assess the impact of PCV after introduction (5).

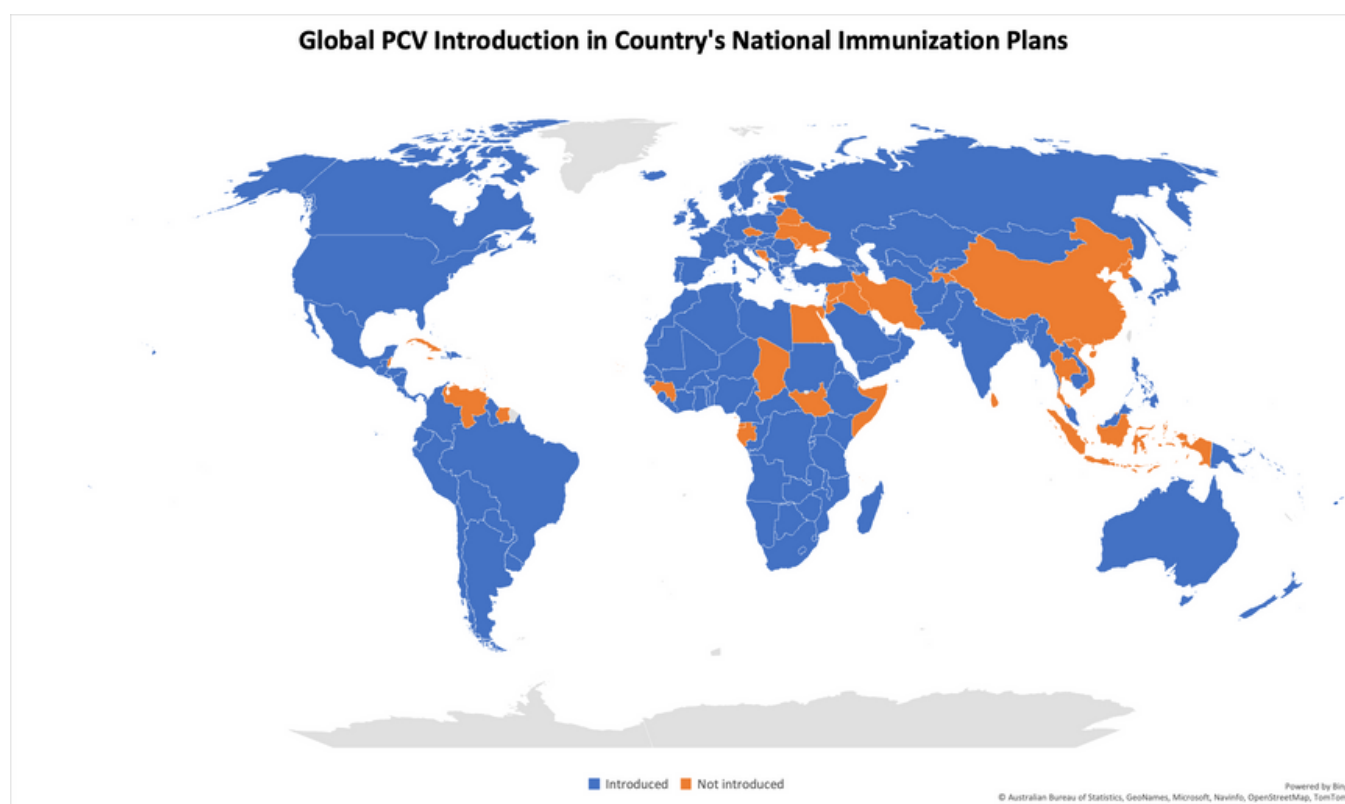


Photo: UNICEF/Dalia Younis, 2021

What countries have introduced PCV?

As of December 2022, forty-two countries have yet to introduce PCV into their national immunization plans (3). Among these countries, nine have introduced PCV however either to risk groups only and/or to certain regions of the country. As the PCV is not administered in the national schedule, they are considered as non-PCV countries. The map below provides a visual of which countries have and have not yet nationally introduced PCV.

Figure 1: Map showcasing countries that have and have not yet nationally introduced PCV.



Of the forty-two remaining countries that have not yet introduced PCV into their national immunization plans, thirty-five are low- and middle-income countries (LMICs). Facilitating PCV introduction in these countries requires effort to improve logistical and financial planning activities as well as sustained commitment between donors, technical agencies, and respective countries' Ministries of Health (MOH) (16). Barriers to PCV introduction are specific to individual country contexts. Thus devising strategic and context specific methods to address these barriers is critical for accelerated and equitable PCV introduction in the remaining non-PCV countries.

What PCV products are available?

Currently, there are three PCVs on the market that are WHO qualified (17):

- PCV13 (Pneumovax – Pfizer)
- PCV10 (Synflorix – Glaxo-Smith-Kline [GSK])
- PCV10 (Pneumosil – Serum Institute)

Pneumococcal serotypes that are the most likely ones to be associated with severe human disease are included in the vaccines. The epidemiologic and biologic evidence as well as the programmatic considerations surrounding performance, effectiveness, and impact for PCV products have been extensively studied by groups at the International Vaccine Access Center at Johns Hopkins Bloomberg School of Public Health, as well as by the WHO and Gavi (18). The serotype distribution of the different PCV products varies slightly, but the overlap of the significant serotypes is substantial. (Table 1)

Table 1: Serotype distribution of PCV products

		Serotypes												
		1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F
PCV13 (Pfizer)	Pneumovax	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F
PCV10 (GSK)	Synflorix	1	-	4	5	-	6B	7F	9V	14	18C	-	19F	23F
PCV10 (SII)	Pneumosil	1	-	-	5	6A	6B	7F	9V	14	-	19A	19F	23F

The consensus from WHO is that PCV 10 and PCV 13 have been shown to have substantial impacts against pneumonia, pneumococcal disease and nasopharyngeal carriage, and immunogenicity studies among the vaccine products are comparable. The choice of product to be used in a country should be based on programmatic characteristics, vaccine supply, vaccine price, the local and regional prevalence of vaccine serotypes and antimicrobial resistance patterns (10).

A fourth product, PCV15, by Merck has been recently approved by the US FDA in June 2022 for use in children 6 weeks and older (19).

Main characteristics of PCVs pre-qualified by the WHO

Table 2: Current PCV products pre-qualified by the WHO (20)

Vaccine name	Prevenar 13		Synflorix			PNEUMOSIL	
Manufacturer	Pfizer Europe MA EEIG		GlaxoSmithKline (GSK) Biologicals SA			Serum Institute of India Pvt. Ltd.	
Vaccine type	Pneumococcal conjugate vaccine, 13 valent		Pneumococcal conjugate vaccine, 10 valent			Pneumococcal conjugate vaccine, 10 valent	
Composition / Pneumococcal Serotypes	1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F		1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F			1, 5, 6A, 6B, 7F, 9V, 14, 19A, 19F, 23F	
Conjugated protein	Non-toxic diphtheria CRM197 protein		Haemophilus influenzae protein D			Non-toxic diphtheria CRM197 protein	
Country of manufacture	UK		Belgium			India	
Responsible National Regulatory Authorities (NRA)	European Medicines Agency (EMA)		European Medicines Agency (EMA)			Central Drugs Standard Control Organization (India)	
Presentation (doses per container, primary container type, pharmaceutical form)	PCV13, 1 dose/vial, liquid	PCV13, 4 doses/vial, liquid	PCV10, 1 dose/vial, liquid	PCV10, 2 doses/vial, liquid	PCV10, 4 doses/vial, liquid	PCV10, 1 dose/vial, liquid	PCV10, 5 doses/vial, liquid
Year WHO pre-qualified	20 August 2010	14 July 2016	30 October 2009	19 March 2010	16 October 2017	18 December 2019	18 December 2019
WHO recommended vaccine schedule	3 doses	3 doses	3 doses	3 doses	3 doses	3 doses	3 doses
Route of administration	Intramuscular	Intramuscular	Intramuscular	Intramuscular	Intramuscular	Intramuscular	Intramuscular
Pharmaceutical form	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use
Secondary packaging	Carton of 50 vials (50 doses)	Carton of 50 vials (200 doses); Carton of 25 vials (100 doses)	i) Carton of 1 vial (1 dose); ii) Carton of 10 vials (10 doses); iii) Carton of 100 vials (100 doses)	Carton of 100 vials (200 doses)	Carton of 100 vials (400 doses)	Carton of 50 vials (50 doses)	Carton of 50 vials (250 doses)
Shelf life	36 months at 2 - 8 °C	36 months at 2 - 8 °C	48 months at 2 - 8 °C	48 months at 2 - 8 °C	36 months at 2 - 8 °C	36 months at 2 - 8 °C	36 months at 2 - 8 °C
Vaccine vial monitor (VVM)	Type 30*	Type 30	Type 30	Type 30	Type 30	Type 30	Type 30
Cold chain volume per dose (cm ³)	12 cm ³	3.5 cm ³	i) 58 cm ³ ii) 11.5 cm ³ ; iii) 10 cm ³	4.8 cm ³	2.4 cm ³	14.06 cm ³	3.515 cm ³
2023 price per dose (USD)**	\$3.30	\$2.75	N/A	N/A	\$2.90	\$2.90	\$2.00***

*Type 30 VVM refers to vaccines that have high stability and are the least heat sensitive

**Price in USD per individual vaccine dose based on available data. This price is an indicative vaccine price prepared by the Gavi Secretariat to be used by countries for planning purposes. Price exclusively covers the vaccine dose and does not cover associated expenses including but not limited to freight, cold-chain costs, administrative costs and wastage. In cases in which there are multiple suppliers of the same presentation of the vaccine, or when there is a range of prices offered by the same supplier of the vaccine, a weighted average price (WAP) is utilized. (24)

***An exceptional discount of USD 0.50 is available for a limited volume of doses procured between 2022 and 2024.

PCV INTRODUCTION JOURNEY IN THE EMRO COUNTRIES

Every year, an estimated 923,000 children U5 die in the EMRO region, with pneumonia as a major cause of death accounting for over 20% of deaths among this age group (1).

Table 2 on the next page describes all the WHO Eastern Mediterranean region (EMRO) countries and their PCV introduction status, products being used (formulation), and dosing schedule. Of the EMRO countries, five have yet to introduce PCV nationally and one has currently suspended PCV. Among the sixteen countries in the region that have introduced PCV in the national schedule, thirteen are currently using Prevnar (PCV13), three are using Synflorix (PCV10) (21).



Photo: UNICEF/Hasan Belal, 2021

Table 2: PCV in the EMRO countries

No.	Country	Current vaccine national introduction status	PCV introduction date	PCV product used in NIP	Current dosing schedule
1	Afghanistan	Introduced	December 7, 2013	Pevnar (PCV13)	3+0
2	Bahrain	Introduced	June 1, 2008	Pevnar (PCV13)	3+1
3	Djibouti	Introduced	December 6, 2021	Pevnar (PCV13)	3+0
4	Egypt	Not introduced	-	-	N/A
5	Iran, Islamic Republic Of	Not introduced*	-	-	-
6	Iraq	Suspended**	March 1, 2017	Pevnar (PCV13)	3+0
7	Jordan	Not introduced	-	-	N/A
8	Kuwait	Introduced	January 1, 2007	Pevnar (PCV13)	3+1
9	Lebanon	Introduced	June 1, 2015	Pevnar (PCV13)	2+1
10	Libya	Introduced	October 1, 2013	Pevnar (PCV13)	2+1
11	Morocco	Introduced	October 20, 2010	Synflorix (PCV10)	2+1
12	Oman	Introduced	January 1, 2008	Pevnar (PCV13)	2+1
13	Pakistan	Introduced	October 9, 2012	Synflorix (PCV10)	3+0
14	Palestine	Introduced	2011	PCV10	2+1
15	Qatar	Introduced	January 1, 2005	Pevnar (PCV13)	3+1
16	Saudi Arabia	Introduced	March 1, 2009	Pevnar (PCV13)	3+1
17	Somalia	Not introduced	-	-	N/A
18	Sudan	Introduced	August 1, 2013	Pevnar (PCV13)	3+0
19	Syrian Arab Republic	Not introduced	-	-	N/A
20	Tunisia	Introduced	April 1, 2019	Synflorix (PCV10)	N/A
21	United Arab Emirates	Introduced		Pevnar (PCV13)	3+1
22	Yemen	Introduced	January 29, 2011	Pevnar (PCV13)	3+0

Source: VIEW-hub - an online, interactive, map-based platform for visualizing data on vaccine use and impact that was made by the International Vaccine Access Center (IVAC). Available at: <https://view-hub.org/map/>

*Introduced for risk groups only

**Introduced nationally in 2017 but current vaccine administration is suspended as of 2019. (https://immunizationdata.who.int/pages/vaccine-intro-by-antigen/pneumo_conj.html?ISO_3_CODE=IRQ&YEAR=)

When did each of the countries in the EMRO region introduce PCV?

Among the eighteen countries that have introduced PCV, fourteen are using Prevnar-PCV13 while four are using PCV10-Synflorix (21). The first country in the EMRO region to have introduced PCV is Qatar, who introduced PCV in 2005, followed by United Arab Emirates and Kuwait in 2007, Oman and Baharain in 2008, Occupied Palestinian Territory and Saudi Arabia in 2009, Morocco in 2010, Yemen in 2011, Pakistan in 2012, Afghanistan, Libya, and Sudan in 2013, Lebanon in 2015, Iraq in 2017, Tunisia in 2019, and finally Dijibouti in 2021 . Egypt, Jordan, Iran, Somalia, and Syria are the remaining five countries in the EMRO region that have not yet nationally introduced the PCV (3).

Egypt, Iran, Jordan, Somalia, and Syria are the remaining five countries in the EMRO region that have not yet nationally introduced PCV.



Photo: UNICEF/Aldroubi, 2020

How was PCV introduced and scaled up in the EMRO countries?

The next two sections focus on Jordan's geographic neighbors: Palestine, Lebanon, Iraq, and Saudi Arabia that have introduced PCV in the national schedule.



Palestine

In Palestine, access to PCV was limited until 2011. In 2011, PCV10 was introduced through the Palestinian Ministry of Health (MOH) to the pediatric national immunization program in a 2+1 schedule through primary care physicians. The vaccination was provided free of charge to all age-eligible children by the Palestinian MOH (22).



Lebanon

In Lebanon, PCV7 was introduced by the private sector in 2006, followed by PCV10 and PCV13 in 2010. As of January 2016, PCV13 has been added to the expanded program of Immunization using the 2+1 schedule. However, there are no official national recommendations for adult immunization, and PCV for adults is limited to some practitioners following the international guidelines in their private practice (23).



Iraq

In Iraq, there is limited data currently on the country's introduction and rollout of PCV. The WHO data indicates that PCV was introduced in 2017-2019 (3).



Saudi Arabia

In Saudi Arabia, PCV7 was first included in the countries' NIP in March 2009. After receiving PCV13 licensure in 2010, the country transitioned from PCV7 to PCV13. Currently, it is recommended that all children, including those with high-risk conditions, receive PCV13 in a 4-dose series at ages two, four, six, and twelve months. In 2015, the MOH initiated a vaccination campaign of catch-up doses of PCV13 for children between the ages of two to five years. Following this campaign, PCV uptake in Saudi Arabia was around 98.7% (24).

What is the PCV coverage levels in the EMRO countries?*

According to WHO/UNICEF estimates of national immunization coverage (WUENIC data), the overall PCV coverage in the WHO EMRO region is 54% as of data in 2021 for final dose of PCV (4).

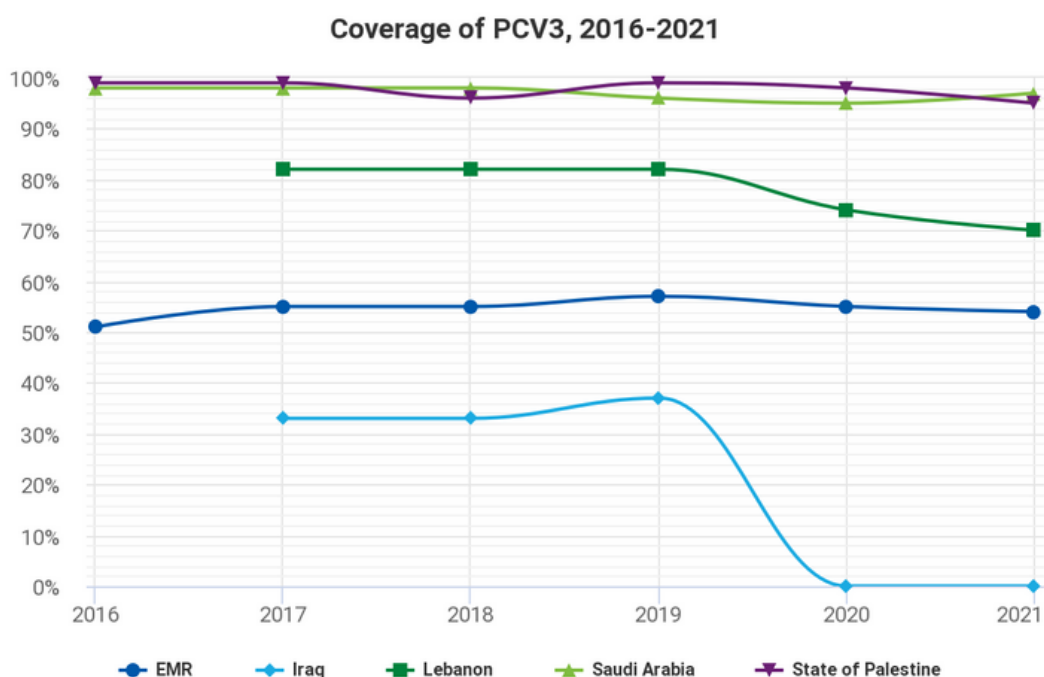
In Palestine, PCV10 was not introduced until late 2011, with a coverage of 25%. In 2012, the coverage rose to 97% and they have consistently have reported high coverage rates. The latest data from 2021 shows Palestine's PCV coverage at 95% (4).

Although PCVs were available in the private sector in Lebanon starting in 2006, it was not introduced at a national level until late 2015 into 2016. As of 2021, the proportion of children under two years of age who received any PCV is 70% in Lebanon (4).

In Iraq, the PCV coverage in 2017 when they nationally introduced the vaccine was 33%. The coverage rose to 37% in 2019, and subsequently dropped to 0% in 2020 and 2021 (4). WHO and UNICEF have reported a global drop in vaccine coverage rates largely due to the COVID-19 pandemic, which provides some insight into the drop in PCV coverage rate for Iraq.

Since its introduction in 2009, Saudi Arabia has one of the highest PCV coverage within the EMRO region. At its peak, Saudia Arabia had a coverage of 98.7% in 2018 (24). The latest data from 2021 shows that Saudi Arabia has a PCV coverage of 97% (4).

Figure 2: Coverage of PCV in select EMRO countries



Source: WHO/UNICEF estimates of national immunization coverage, 2021 revision

What are the lessons learned from PCV use in the EMRO countries?

In many countries, including Kuwait and Saudi Arabia from the EMRO region, there has been a trend showcasing that PCV introduction into national immunization programs has resulted in large decreases in incidence of invasive pneumococcal disease and disappearance of some vaccine serotypes (24). Similarly in Palestine, within the first three years following PCV implementation, dramatic reductions were observed in PCV13 serotypes, thus indicating the effectiveness of PCV in preventing severe disease (22). Studies of PCV in the EMRO region highlight the importance of preventing pneumococcal disease as a primary management approach, and further investigation is recommended from larger sample sets as well as further follow-up for long-term effects.



Countries take various approaches to childhood immunization, and as such, drivers and facilitators as well as barriers and challenges for introducing PCV should be considered when developing guidance for countries.



The information in this document can be used to inform such strategies, tailored to the specific country context, to support the launch of PCV into Jordan's National Immunization Plan.



Introducing PCV in Jordan is a big stride in closing the global PCV introduction gap and preventing the needless suffering of children around the world

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