

Vital Surveillances

Post-Marketing Surveillance of Adverse Events Following 23-Valent Pneumococcal Polysaccharide Vaccination — China, 2021–2024

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ABSTRACT

Introduction: This study assesses the adverse events following vaccination with the 23-valent pneumococcal polysaccharide vaccine (PPV23) in China from 2021 to 2024.

Methods: We obtained reports of adverse events following immunization (AEFI) with PPV23 and the number of PPV23 doses administered during the study period from the Chinese National Immunization Information System (CNIIS). We descriptively analyzed the AEFI characteristics and reported incidences per 100,000 doses administered.

Results: During the study period, 26.65 million doses of PPV23 were administered and 22,221 PPV23 AEFI were reported, i.e., a reported incidence of 83.37 AEFI per 100,000 doses administered. The incidence per 100,000 doses of common vaccine reactions was 80.51, and the incidences of rare vaccine reactions and serious AEFI were 1.70 and 0.43, respectively. The incidences of AEFI, common vaccine reactions, and rare vaccine reactions decreased with age. The most frequently reported common vaccine reactions were fever (54.07/100,000 doses) and local redness and swelling (41.61/100,000 doses), and the most frequent rare vaccine reaction was allergic rash (0.92/100,000 doses). 99.15% of adverse vaccine reactions occurred within 3 days after vaccination.

Conclusion: PPV23 had a good safety profile during 2021 to 2024. The findings support the use of PPV23 as recommended from a safety perspective.

Pneumococcal diseases are caused by *Streptococcus pneumoniae* bacterial infection and include invasive diseases, such as meningitis and bacteremia, and non-invasive diseases, such as otitis media, sinusitis, and non-bacteremic pneumonia. The 23-valent

pneumococcal polysaccharide vaccine (PPV23) was introduced in China in 1996 to prevent diseases caused by pneumococcal infections.

In 2008, China established a nationwide online monitoring system for adverse events following immunization (AEFI). The system was integrated into the Chinese National Immunization Information System (CNIIS), which provides nationwide AEFI and dose-administered data. Since 2021, data regarding PPV23 vaccination doses administered across different dimensions, such as sex, age, and dose number, were available. This provided a more comprehensive overview of PPV23 post-marketing safety. Therefore, we analyzed PPV23 adverse event data reported to the CNIIS during 2021–2024 in China to assess post-marketing PPV23 AEFI characteristics and per-dose incidences.

METHODS

Data Sources

We obtained from CNIIS all PPV23 doses administered and PPV23 AEFI reports with vaccinations administered during the study period from January 1, 2021, to December 31, 2024, and downloaded them on March 18, 2025.

Vaccines for Surveillance

PPV23 protects against 23 pneumococcal serotypes (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F) and is indicated for individuals who are ≥ 2 years old and are at an increased risk of pneumococcal infection or pneumococcal disease. These include the elderly, patients with chronic diseases, immunocompromised individuals, and people living with human immunodeficiency virus.

PPV23 is a non-national immunization program vaccine, and in most regions of China, this vaccination

is voluntary and self-paid. PPV23 is administered as a single dose; if revaccination is necessary, the inter-dose interval is 3–5 years.

AEFI Definitions and Investigation

An AEFI is a reaction or event that occurs after vaccine administration and is suspected to be related to vaccination. AEFIs are reported and investigated according to the *National AEFI Surveillance Guidelines*, released in 2010 and revised in 2022, jointly issued by the National Health Commission of the People's Republic of China and the National Medical Products Administration of China.

AEFI Classification

Based on their seriousness, AEFIs are categorized as serious or non-serious. According to the national AEFI surveillance guidelines in 2022, serious AEFIs are adverse events that result in death, are life-threatening, cause permanent or significant disability/incapacity, lead to hospitalization or prolonged hospitalization, or are congenital abnormalities or birth defects suspected to be caused by maternal vaccination during pregnancy.

Based on causality assessment, AEFIs are categorized into adverse vaccine reactions, vaccine quality defect-related reactions, program error-related reactions, coincidental events, and psychogenic reactions. Adverse vaccine reactions refer to reactions caused by the characteristics of the vaccine itself and are not related to the purpose or action of the vaccination. These can be further categorized into common vaccine reactions (usually minor), which are transient or mild, and rare vaccine reactions (possibly serious) that result in organ damage.

In China, all AEFIs following PPV23 must be categorized. Except for common vaccine reactions, all AEFIs are investigated. Serious AEFIs are classified by expert groups organized by the CDCs. If there is an objection to the conclusion of an expert group, a local medical association is requested to resolve the classification. Non-serious AEFIs requiring investigation and diagnosis are classified by an expert group organized by the CDCs, while others are classified by the CDCs or vaccination units.

Data Analysis

Data were analyzed using Microsoft Excel (version 2016, Microsoft Corporation, Redmond, WA, USA) and the SAS software (SAS version 9.4, SAS Institute

Inc., Cary, NC, USA). We determined distributions of sex, age, dose numbers, and clinical diagnoses, and calculated the AEFI reporting rates per 100,000 doses administered.

PPV23 AEFI reporting rates = (PPV23 AEFI cases / PPV23 doses administered) × 100,000 doses

RESULTS

AEFI Reporting Incidences by Classification

During 2021–2024, 26.65 million doses of PPV23 were administered, and 22,221 PPV23 AEFIs were reported, with a reporting incidence of 83.37 per 100,000 doses. Among these AEFIs, 21,459 (96.57%), 452 (2.03%), 275 (1.24%), and 26 (0.12%) were common vaccine reactions, rare vaccine reactions, coincidental events, and psychogenic reactions, respectively. Incidences per 100,000 doses administered were 80.51, 1.70, 1.03, and 0.10, respectively. The other 9 (0.04%) cases were unclassified AEFIs. There were 115 serious AEFIs reported (0.52% of reports; incidence 0.43 per 100,000 doses) and 63 serious AEFIs were rare vaccine reactions (0.24 per 100,000 doses administered).

Annual numbers of doses administered were 7.16, 7.82, 7.40, and 4.27 million doses by study year. Annual AEFI incidences were 71.46, 70.68, 90.21, and 114.74 per 100,000 doses administered. Annual incidences of common vaccine reactions were 68.72, 68.22, 87.37, and 110.93 per 100,000 doses. Annual incidences of rare vaccine reactions were 1.73, 1.51, 1.57, and 2.20 per 100,000 doses (Table 1).

AEFI Characteristics

Table 2 shows AEFI characteristics by sex. PPV23 AEFI reports represented 10,592 male and 11,629 female vaccinees, with a male:female ratio of 0.92:1. Incidences per 100,000 doses of AEFI, common vaccine reactions, rare vaccine reactions, and serious cases were 79.67, 76.78, 1.75, and 0.49 for males and 86.52, 83.72, 1.64, and 0.37 for females, respectively.

By age group, proportions of AEFI reports for 2–5-, 6–17-, 18–59-, and ≥60-year-olds were 65.61%, 14.73%, 4.98%, and 14.68% with incidences of 106.88, 89.81, 43.43, and 47.96 per 100,000 doses administered, respectively. The incidences per 100,000 doses by age group were 103.16, 87.21, 41.74, and 46.26, respectively, for common vaccine reactions; 2.35, 1.40, 0.98, and 0.81, respectively, for rare

TABLE 1. AEFI reporting incidence per 100,000 doses administered by AEFI classification in China, 2021–2024.

Year	Classification by cause										Classification by seriousness										AEFI									
	Common vaccine reactions					Coincidental events					Psychogenic reactions					Unclassified							Non-serious					Serious		
	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence			
2021	4,921	96.17	68.72	124	2.42	1.73	68	1.33	0.95	3	0.06	0.04	1	0.02	0.01	5,086	99.39	71.03	31	0.61	0.43	5,117	100.00	71.46						
2022	5,337	96.51	68.22	118	2.13	1.51	69	1.25	0.88	5	0.09	0.06	1	0.02	0.01	5,505	99.55	70.36	25	0.45	0.32	5,530	100.00	70.88						
2023	6,463	96.85	87.37	116	1.74	1.57	84	1.26	1.14	9	0.13	0.12	1	0.01	0.01	6,639	99.49	89.75	34	0.51	0.46	6,673	100.00	90.21						
2024	4,738	96.67	110.93	94	1.92	2.20	54	1.10	1.26	9	0.18	0.21	6	0.12	0.14	4,876	99.49	114.16	25	0.51	0.59	4,901	100.00	114.74						
Total	21,459	96.57	80.51	452	2.03	1.70	275	1.24	1.03	26	0.12	0.10	9	0.04	0.03	22,106	99.48	82.94	115	0.52	0.43	22,221	100.00	83.37						

Abbreviation: AEFI=adverse events following immunization.

TABLE 2. Characteristics of PPV23 AEFIs in China, 2021–2024 (incidence per 100,000 doses).

Variables	Doses administered	Common vaccine reactions					Rare vaccine reactions					Non-serious					Serious					AEFI	
		Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)		
Sex																							
Male	13,294,436	10,207	47.57	76.78	232	51.33	1.75	10,527	47.62	79.18	65	56.52	0.49	10,592	47.67	79.67							
Female	13,440,408	11,252	52.43	83.72	220	48.67	1.64	11,579	52.38	86.15	50	43.48	0.37	11,629	52.33	86.52							
Age (year) [†]																							
2–5	13,641,076	14,072	65.58	103.16	321	71.02	2.35	14,504	65.61	106.33	76	66.09	0.56	14,580	65.61	106.88							
6–17	3,644,199	3,178	14.81	87.21	51	11.28	1.40	3,255	14.72	89.32	18	15.65	0.49	3,273	14.73	89.81							
18–59	2,546,815	1,063	4.95	41.74	25	5.53	0.98	1,103	4.99	43.31	3	2.61	0.12	1,106	4.98	43.43							
≥60	6,801,265	3,146	14.66	46.26	55	12.17	0.81	3,244	14.67	47.70	18	15.65	0.26	3,262	14.68	47.96							
Dose number																							
1	24,477,014	19,937	92.91	81.45	442	97.79	1.81	20,571	93.06	84.04	112	97.39	0.46	20,683	93.08	84.50							
≥2	2,175,472	1,522	7.09	69.96	10	2.21	0.46	1,535	6.94	70.56	3	2.61	0.14	1,538	6.92	70.70							
Region*																							
Eastern	10,753,803	7,163	33.38	66.61	192	42.48	1.79	7,475	33.81	69.51	46	40.00	0.43	7,521	33.85	69.94							
Middle	7,949,057	8,086	37.68	101.72	118	26.11	1.48	8,212	37.15	103.31	30	26.09	0.38	8,242	37.09	103.69							
Western	7,989,028	6,210	28.94	77.73	142	31.42	1.78	6,419	29.04	80.35	39	33.91	0.49	6,458	29.06	80.84							
Total	26,652,486	21,459	100.00	80.51	452	100.00	1.70	22,106	100.00	82.94	115	100.00	0.43	22,221	100.00	83.37							

Note: Minor changes may exist in vaccination data downloaded on different dates.
Abbreviation: AEFI=adverse events following immunization; PPV23=23-valent pneumococcal polysaccharide vaccine.
* Region divisions are given in reference 2.
[†] Doses administered to individuals <2 years old are not included.

reactions; and 0.56, 0.49, 0.12, and 0.26, respectively, for serious cases.

According to the dose number, 93.08% of AEFIs occurred after the first dose, with an incidence of 84.50 reports per 100,000 doses, of which incidences for common vaccine reactions, rare vaccine reactions, and serious cases were 81.45, 1.81, and 0.46 per 100,000 doses, respectively. Incidences after revaccination were 70.70, 69.96, 0.46, and 0.14 per 100,000 doses, respectively.

By province, 33.85%, 37.09%, and 29.06% of AEFIs were reported in the eastern, middle, and western provinces, respectively, with incidences of 69.94, 103.69, and 80.84 per 100,000 doses, respectively. Incidences per 100,000 doses administered were 66.61, 101.72, and 77.73, respectively, for common vaccine reactions; 1.79, 1.48, and 1.78, respectively, for rare vaccine reactions; and 0.43, 0.38, and 0.49, respectively, for serious cases.

Among the AEFI reports, 31.49% were associated with PPV23 co-administered with another vaccine. The top three co-administered vaccines were the influenza vaccine (2,900 cases, 41.45% of co-administered AEFI), the live attenuated Japanese encephalitis vaccine (1,995 cases, 28.51%), and the inactivated poliomyelitis vaccine (313 cases, 4.47%).

ADVERSE REACTION DIAGNOSES

Common Vaccine Reactions

Fever (14,411 cases; 67.16% of common reactions) and local redness and swelling (11,090 cases; 51.68%) were the most frequently reported common vaccine reactions, with incidences of 54.07 and 41.61 per 100,000 doses, respectively. Incidences of fever ≥ 38.6 °C, and redness and swelling with diameters >2.5 cm were 33.57 and 31.39 per 100,000 doses, respectively (Table 3).

Incidences of fever ≥ 38.6 °C for 2–5-, 6–17-, 18–59-, and ≥ 60 -year-olds were 53.39, 34.08, 6.24, and 3.87 per 100,000 doses; incidences of redness and swelling with diameters >2.5 cm were 30.16, 44.98, 22.06, and 30.16 per 100,000 doses, respectively.

Rare Vaccine Reactions

Among the rare vaccine reactions, none of the clinical diagnoses had an incidence rate >1 per 100,000 doses. The most frequently reported one was allergic rash (54.20% of rare reactions; incidence 0.92 per 100,000 doses). By age group, incidences of allergic

rash for 2–5-, 6–17-, 18–59-, and ≥ 60 -year-olds were 1.30, 0.47, 0.63, and 0.50 per 100,000 doses, respectively (Table 3).

As for serious cases, 63 were classified as rare vaccine reactions; the top five diagnoses were febrile seizures (17 cases), Henoch-Schonlein purpura (HSP) (8 cases), allergic shock (7 cases), thrombocytopenia (TP) (6 cases), and other allergic reactions (5 cases).

Interval Between PPV23 Vaccination and Adverse Reactions

Table 4 shows that 99.15% of adverse reactions, 99.21% of common vaccine reactions, and 95.80% of rare vaccine reactions occurred within 3 days (d) after vaccination, whereas 78.22% of common vaccine reactions and 81.42% of rare vaccine reactions occurred within 24 hours (h). Among rare vaccine reactions, 97.55% of allergic rash occurred within 3 d and 80.41% occurred within 24 h. All cases of angioedema and febrile seizures occurred within 3 d, and 80% of allergic shock and laryngeal edema occurred within 30 minutes. As for HSP, 88.89% of the cases occurred within 3 d and 66.67% of TP occurred >3 d after vaccination.

DISCUSSION

During 2021–2024, most AEFIs with PPV23 were common, non-serious vaccine reactions. Incidences of rare vaccine reactions and serious cases were extremely low. The incidences of AEFI, common vaccine reactions, rare vaccine reactions, and serious cases in our study were lower than the ones reported from 2016 to 2020 (1). Incidences of AEFI, common vaccine reactions, and non-serious cases have increased annually, consistent with AEFI surveillance of all vaccines in China (2–3). This is likely associated with increasing reporting sensitivity. The incidences of rare vaccine reactions and serious cases remained stable.

There were more AEFI reports for females, which was different from results reported from 2016 to 2020 (1), likely because more women received PPV23 during the present study period. The per-dose incidences of AEFI and common vaccine reactions were higher in females than males, possibly due to reporting sensitivity. Most AEFI reports were from middle provinces, which is different from reports of other vaccines, including influenza and recombinant zoster vaccines (2–5). This is probably due to the increase in use and higher reporting sensitivity for 2–5-

TABLE 3. Clinical diagnoses of adverse vaccine reactions after PPV23 vaccination in China, 2021–2024 (incidence per 100,000 doses).

Clinical diagnosis	2–5 years			6–17 years			18–59 years			≥60 years			Total	
	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Cases	Proportion (%)	Incidence	Proportion (%)	Incidence
Common vaccine reactions*	14,072	100.00	103.16	3,178	100.00	87.21	1,063	100.00	41.74	3,146	100.00	46.26	21,459	100.00
Fever	11,348	80.64	83.19	2,004	63.06	54.99	386	36.31	15.16	673	21.39	9.90	14,411	67.16
≥38.6 °C	7,283	51.76	53.39	1,242	39.08	34.08	159	14.96	6.24	263	8.36	3.87	8,947	41.69
Redness and swelling	5,946	42.25	43.59	2,068	65.07	56.75	737	69.33	28.94	2,339	74.35	34.39	11,090	51.68
2.6–5.0 cm	2,995	21.28	21.96	1,049	33.01	28.79	347	32.64	13.62	1,392	44.25	20.47	5,783	26.95
>5.0 cm	1,119	7.95	8.20	590	18.57	16.19	215	20.23	8.44	659	20.95	9.69	2,583	12.04
Induration	3,229	22.95	23.67	1,212	38.14	33.26	437	41.11	17.16	895	28.45	13.16	5,773	26.90
2.6–5.0 cm	1,364	9.69	10.00	534	16.80	14.65	202	19.00	7.93	452	14.37	6.65	2,552	11.89
>5.0 cm	460	3.27	3.37	277	8.72	7.60	96	9.03	3.77	241	7.66	3.54	1,074	5.00
Rare vaccine reactions	321	100.00	2.35	51	100.00	1.40	25	100.00	0.98	55	100.00	0.81	452	100.00
Allergic rash	178	55.45	1.30	17	33.33	0.47	16	64.00	0.63	34	61.82	0.50	245	54.20
Angioedema	18	5.61	0.13	5	9.80	0.14	1	4.00	0.04	5	9.09	0.07	28	6.19
Allergic shock	4	1.25	0.03	1	1.96	0.03	0	0.00	0.00	3	5.45	0.04	8	1.77
Laryngeal edema	2	0.62	0.01	0	0.00	0.00	0	0.00	0.00	0	0.00	0.00	2	0.44
Other allergic reactions	32	9.97	0.23	4	7.84	0.11	4	16.00	0.16	1	1.82	0.01	41	9.07
HSP	8	2.49	0.06	0	0.00	0.00	0	0.00	0.00	1	1.82	0.01	9	1.99
TP	3	0.93	0.02	1	1.96	0.03	0	0.00	0.00	2	3.64	0.03	6	1.33
Febrile seizure	28	8.72	0.21	0	0.00	0.00	0	0.00	0.00	0	0.00	0.00	28	6.19
Sterile abscess	3	0.93	0.02	2	3.92	0.05	0	0.00	0.00	0	0.00	0.00	5	1.11
Phlegmonous inflammation	23	7.17	0.17	12	23.53	0.33	1	4.00	0.04	1	1.82	0.01	37	8.19
Other diseases	22	6.85	0.16	9	17.65	0.25	3	12.00	0.12	8	14.55	0.12	43	9.51
Adverse vaccine reactions	14,393	-	105.51	3,229	-	88.61	1,088	-	42.72	3,201	-	47.06	21,911	-
														82.21

Abbreviation: PPV23=23-valent pneumococcal polysaccharide vaccine; HSP=Henoch-Schonlein purpura; TP=thrombocytopenia.

* In common vaccine reactions, a case may have multiple diagnoses.

TABLE 4. Interval between PPV23 vaccination and adverse reactions.

Clinical diagnosis	Total cases	<24 h		1–3 d		≥4 d	
		Cases	Proportion (%)	Cases	Proportion (%)	Cases	Proportion (%)
Common vaccine reactions	21,459	16,786	78.22	4,505	20.99	168	0.78
Fever	14,411	11,624	80.66	2,697	18.71	90	0.62
≥38.6 °C	8,947	7,286	81.44	1,621	18.12	40	0.45
Redness and swelling	11,090	8,106	73.09	2,898	26.13	86	0.78
2.6–5.0 cm	5,783	4,113	71.12	1,627	28.13	43	0.74
>5.0 cm	2,583	1,967	76.15	599	23.19	17	0.66
Induration	5,773	4,168	72.20	1,540	26.68	65	1.13
2.6–5.0 cm	2,552	1,769	69.32	754	29.55	29	1.14
>5.0 cm	1,074	813	75.70	249	23.18	12	1.12
Rare vaccine reactions	452	368	81.42	65	14.38	19	4.20
Allergic rash	245	197	80.41	42	17.14	6	2.45
Angioedema	28	22	78.57	6	21.43	0	0.00
Allergic shock	8	8	100.00	0	0.00	0	0.00
Laryngeal edema	2	2	100.00	0	0.00	0	0.00
Other allergic reactions	41	40	97.56	0	0.00	1	2.44
HSP	9	7	77.78	1	11.11	1	11.11
TP	6	1	16.67	1	16.67	4	66.67
Febrile seizure	28	25	89.29	3	10.71	0	0.00
Sterile abscess	5	4	80.00	0	0.00	1	20.00
Phlegmonous inflammation	37	28	75.68	8	21.62	1	2.70
Other diseases	43	34	79.07	4	9.30	5	11.63
Adverse vaccine reactions	21,911	17,154	78.29	4,570	20.86	187	0.85

Abbreviation: PPV23=23-valent pneumococcal polysaccharide vaccine; h=hours; d=days; HSP=Henoch-Schonlein purpura; TP=thrombocytopenia.

year-olds. The AEFI incidence was not higher for revaccination, consistent with results from Shanghai (6) and supporting PPV23 revaccination when indicated. The reporting incidences of AEFI, common reactions, and rare reactions decreased with increasing age, similar to findings in Hangzhou (7), and supporting PPV23 vaccination for the elderly from a safety perspective.

Most adverse vaccine reactions were common and minor, usually resolving in 2–3 d, which was consistent with PPV23 clinical trials (8–9) and other post-marketing safety studies (10–12). Incidences of rare vaccine reactions were extremely low, regardless of diagnosis, raising no safety concerns. Rashes and angioedema were the most frequently reported allergic reactions and were unlikely to be consequential. The incidence of anaphylaxis was less than 1 per million doses; however, anaphylaxis can be life-threatening and requires a rapid intervention. Febrile seizure was the most frequently reported neurological disorder; all

reports were for 2–5-year-olds. Febrile seizures frighten parents but do not cause long term harm for the children. Health monitoring is essential after PPV23 vaccination in children aged 2–5 years, and special attention should be paid to the symptomatic management of high fever to prevent the occurrence of febrile seizures. One case of Guillain-Barré syndrome (GBS) and several cases of TP were classified as rare vaccine reactions; however, a self-controlled risk interval study (13) and a self-controlled case series study (14) showed no increased risk of GBS and TP following PPV23. The incidence of HSP was much lower than the background rate (15) with no evidence of a causal association between HSP and PPV23. Phlegmonous inflammation at the vaccination site may be caused by bacterial infections, and currently no evidence indicated that proper vaccination can lead to this condition. It is important to ensure safe vaccination practices and keep the injection site clean after vaccination to prevent infection.

Almost all adverse vaccine reactions occurred within 3d, reminding individuals to monitor their health status within this interval and seek medical attention, if necessary. Of the anaphylaxis cases, 80% occurred within 30 minutes of vaccination, supporting the routine 30-minute observation period.

This study provides the first national-level post-marketing PPV23 AEFI incidence analysis by sex, age, dose number. The limitations are that the AEFI surveillance system in China is passive, which makes it prone to underreporting, and the quality of causality assessment may vary by region, influencing classification accuracy.

In conclusion, our study of post-marketing AEFI reports found that PPV23 had a good safety profile during 2021 to 2024. These findings support the use of PPV23 as recommended from a safety perspective.

Conflicts of interest: No conflicts of interest.

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