Preplanned Studies

Post-Marketing Surveillance of Adverse Events Following Meningococcal Vaccination — China, 2013–2021

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Summary

What is already known about this topic?

From 2010 to 2012, the incidence of adverse vaccine reactions from meningococcal vaccine (MenV) in China ranged from 8.46 to 56.30 per 100,000 doses.

What is added by this report?

From 2013 to 2021, the overall reported rate of adverse events following immunization (AEFI) of five types of market-authorized MenV-containing vaccines in China was 37.87 per 100,000 doses administered, with a reported incidence of adverse vaccine reactions of 37.39 per 100,000 doses. The reported incidence of adverse vaccine reactions was comparable to that from 2010 to 2012 and perceived to be within an acceptable range. Most rare vaccine reactions were allergic rashes, and most of these cases were transient and non-serious.

What are the implications for public health practice?

In China, the incidence of AEFI was very low, and serious abnormal reactions were extremely rare. We should continue to carry out technical training for vaccinators and on-site treatment capabilities to improve emergency treatment for anaphylactic shock and other serious events and ensure the continued safety of vaccination.

Epidemic meningococcal meningitis is a severe acute infectious disease caused by *Neisseria meningitis* (*Nm*) infection, which spreads through respiratory secretions. Based on *Nm*-specific surface polysaccharide antigens, there are 13 serogroups (A, B, C, D, E, X, Y, Z, W135, H, I, K, and L) (*1*). The incidence of invasive meningococcal disease in China has declined since 1985, when large-scale vaccination with group A meningococcal vaccine (MenV) began (*2*). MenV vaccination programs align with broad healthcare principles, including generally accepted benefit-risk approaches to vaccination and the World Health Organization's goal of defeating meningitis by 2030 (*3*). The current MenV-containing vaccines marketed in China are group A meningococcal polysaccharide vaccine (MPV-A), group A and C meningococcal polysaccharide vaccine (MPV-AC), group A and C meningococcal polysaccharide conjugated vaccine (MPCV-AC), group A, C, Y, and W135 meningococcal polysaccharide vaccine (MPV-ACYW135), and group A and group C meningococcal polysaccharide conjugated vaccine in combination with *Haemophilus influenzae* type b vaccine (MPCV-AC/Hib). With the increasing number and diversity of MenV-containing vaccines in use, adverse events following immunization (AEFI) with these vaccines have also increased (*2*). AEFI is reported through the Chinese National Immunization Information System (CNIIS). Our analysis of AEFI reports found that from 2013 to 2021, the total incidence of reported AEFI for five MenV-containing vaccines was 37.87/100,000 doses administered, which falls within an acceptable range (*4*). Rare vaccine reactions were reported, mainly allergic rash, with incidences between 0.81 and 3.19 per 100,000 doses; most cases were transient and non-serious. Post-marketing surveillance of MenV AEFI in China should be strengthened, especially for serious allergic reactions.

We obtained the number of MenV-containing vaccine doses administered and AEFI cases reported from 2013 to 2021 from the CNIIS. The system includes basic case information (e.g., gender, age), vaccination status (e.g., vaccine type, vaccination time), and other important information (e.g., reaction onset time, event diagnosis). According to national AEFI surveillance guidelines, standard practice in China is that following verification and causality assessment by relevant professionals, AEFIs are classified as vaccine product-related reactions, coincidental events, immunization anxiety-related reactions, suspected immunization error-related reactions, or suspected vaccine quality defect-related reactions. Vaccine product-related reactions are further classified as common (usually minor) or rare (possibly serious) vaccine reactions. According to national AEFI surveillance guidelines, AEFIs that are required to be reported include fever (≥38.6 °C), local redness (>2.5

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cm), induration (>2.5 cm), anaphylactic shock, allergic rash, allergic purpura, thrombocytopenic purpura, angioedema, laryngeal edema, local allergic necrosis reaction (Arthus reaction), febrile convulsions, epilepsy and ADEM, GBS, encephalitis and meningitis, polyneuritis, encephalopathy, and any other serious disease. A serious AEFI is an AEFI that is life-threatening, results in permanent or significant disability, results in organ function impairment, or leads to death.

We used descriptive epidemiological methods to analyze the characteristics of reported AEFI associated with meningococcal vaccines. Data were exported from the CNIIS into Microsoft Excel 2020 for descriptive and statistical analyses. The incidence of reported AEFI per 100,000 doses of meningococcal vaccines was calculated as the number of AEFI cases reported in a given period divided by the number of meningococcal vaccine doses administered in the corresponding period ×100,000.

From 2013 to 2021, over 65,000,000 doses of MenV-containing vaccines were administered in China. There were 248,675 MenV-containing vaccine AEFI cases reported, with an overall reporting rate of 37.87 per 100,000 doses. Of the reported AEFIs, 98.74% were classified as vaccine product-related reactions (94.85% common vaccine reactions and 5.15% rare vaccine reactions); 1.14% were coincidental events; 0.06% were immunization anxiety-related reactions; and 0.05% were other reactions, including unclassified reactions, with respective incidences of 37.39, 35.47, 1.93, 0.43, 0.02, and 0.02 per 100,000 doses (Table 1). Incidences for MPV-A, MPV-AC, MPCV-AC, MPSV-ACWY135, and MPCV-AC/Hib were 45.82/100,000 doses, 22.98/100,000 doses, 77.43/100,000 doses, 31.09/100,000 doses, and 42.95/100,000 doses, respectively. The incidences of reported common vaccine reactions and rare vaccine reactions per 100,000 doses were 45.61 and 0.20 for MPV-A; 21.59 and 1.39 for MPV-AC; 72.97 and 4.46 for MPCV-AC; 27.67 and 3.42 for MPSV-ACWY135; and 40.45 and 2.50 for MPCV-AC/Hib.

The male-to-female ratio among reports of vaccine product-related reactions was 1.22:1. Of these reports, 68.01% involved infants, and 64.19% were for the first MenV-containing vaccine dose. Non-serious AEFIs accounted for 99.64% of reports, and 99.57% of reports documented resolution or improvement. Regarding the timing of reactions, 69.86% of common reactions and 76.05% of rare reactions occurred on the day of vaccination. Furthermore, 28.85% of common reactions and 20.75% of rare reactions occurred from days 1–3, while 1.08% and 2.49% occurred from days 4–14. Finally, 0.21% of common reactions and 0.71% of rare reactions occurred more than 15 days after vaccination (Table 2).

The reported incidence of severe fever (≥38.6 °C) after MenV vaccination was 14.52/100,000 doses. The highest incidence was after the MPCV-AC vaccination

TABLE 1. Number of MenV-containing vaccine AEFI and incidence per 100,000 doses administered reported in China from 2013 to 2021 by classification category.

Year	Serious AEFI		Classification by cause											
			Adverse vaccine reaction				Coincidental events		Immunization anxiety-related reactions		Others		Total	
			Common vaccine reaction		Rare vaccine reaction									
	No. of cases	Reporting rate	No. of cases	Reporting rate	No. of cases	Reporting rate	No. of cases	Reporting rate	No. of cases	Reporting rate	No.of Cases	Reporting Rate	No. of cases	Reporting rate
2013	127	0.18	15,975	22.33	945	1.32	235	0.33	10	0.01	8	0.01	17,174	24.01
2014	148	0.21	20,650	29.18	1,139	1.61	296	0.42	6	0.01	12	0.02	22,104	31.23
2015	149	0.20	22,806	30.06	1,279	1.69	290	0.39	13	0.02	11	0.01	24,400	32.16
2016	245	0.36	29,551	43.93	1,544	2.30	375	0.56	13	0.02	18	0.03	31,504	46.83
2017	197	0.25	34,239	42.87	1,675	2.10	363	0.45	18	0.02	15	0.02	36,315	45.47
2018	206	0.26	34,539	44.09	1,786	2.28	392	0.50	25	0.03	38	0.05	36,784	46.96
2019	211	0.28	33,602	44.76	1,991	2.66	405	0.54	21	0.03	10	0.01	36,032	47.99
2020	152	0.21	24,900	34.39	1,450	2.01	301	0.42	28	0.04	9	0.01	26,692	36.86
2021	110	0.17	16,631	25.39	832	1.27	182	0.28	12	0.02	10	0.02	17,670	26.97
Total	1,545	0.24	232,893	35.47	12,641	1.93	2,839	0.43	146	0.02	131	0.02	248,675	37.87

Abbreviation: MenV=meningococcal vaccine; AEFI=adverse events following immunization.

TABLE 2. Characteristics of MenV-containing vaccine adverse vaccine reactions reported in China from 2013 to 2021 by vaccine type.

Characteristics	MPV-A		MPV-AC		MPCV-AC		MPV-ACWY135		MPCV-AC/Hib		Total	
	No. of cases	Percentage (%)	No. of cases	Percentage (%)	No. of cases	Percentage (%)	No. of cases	Percentage (%)	No. of cases	Percentage (%)	No. of cases	Percentage (%)
Gender												
Male	75,675	54.22	37,263	55.90	13,611	54.90	4,979	57.34	3,216	55.10	134,744	54.88
Female	63,886	45.78	29,399	44.10	11,180	45.10	3,704	42.66	2,621	44.90	110,790	45.12
Age (years)												
≤1	138,174	99.01	456	0.68	22,863	92.22	73	0.84	5,422	92.89	166,988	68.01
2–6	1,344	0.96	64,172	96.26	1,747	7.05	8,079	93.04	412	7.06	75,754	30.85
≥7	43	0.03	2,034	3.06	181	0.73	531	6.12	3	0.05	2,792	1.14
Region*												
Eastern	67,242	48.18	26,884	40.33	12,964	52.29	5,187	59.74	2,189	37.51	114,466	46.62
Central	42,305	30.31	25,028	37.54	9,680	39.05	2,638	30.38	2,966	50.81	82,617	33.65
Western	30,014	21.51	14,750	22.13	2,147	8.66	858	9.88	682	11.68	48,451	19.73
Year												
2013	8,560	6.13	4,843	7.27	2,993	12.07	524	6.03	0	0	16,920	6.89
2014	12,874	9.22	5,380	8.07	2,822	11.38	713	8.21	0	0	21,789	8.87
2015	13,662	9.79	6,273	9.41	3,231	13.03	763	8.79	156	2.67	24,085	9.81
2016	19,884	14.25	7,962	11.94	2,146	8.66	672	7.74	431	7.38	31,095	12.66
2017	23,583	16.90	8,053	12.08	2,390	9.64	852	9.82	1,036	17.75	35,914	14.63
2018	21,891	15.69	9,235	13.85	2,606	10.51	1,028	11.84	1,565	26.81	36,325	14.79
2019	18,689	13.39	11,320	16.98	2,653	10.70	1,299	14.96	1,632	27.96	35,593	14.51
2020	12,635	9.05	7,782	11.67	3,549	14.32	1,374	15.82	1,010	17.31	26,350	10.73
2021	7,783	5.58	5,814	8.73	2,401	9.69	1,458	16.79	7	0.12	17,463	7.11
Quarter												
1	26,599	19.06	13,225	19.84	4,773	19.25	1,838	21.16	1,094	18.74	47,529	19.36
2	44,085	31.59	18,568	27.86	7,849	31.66	2,556	29.44	2,062	35.33	75,120	30.59
3	41,032	29.40	17,475	26.21	7,508	30.29	2,365	27.24	1,737	29.76	70,117	28.56
4	27,845	19.95	17,394	26.09	4,661	18.80	1,924	22.16	944	16.17	52,768	21.49
Doses												
1	86,815	62.21	45,609	68.42	14,588	58.84	7,136	82.18	3,448	59.07	157,596	64.19
2	52,700	37.75	20,661	30.99	9,563	38.58	1,242	14.31	1,552	26.59	85,718	34.91
3	36	0.03	207	0.31	593	2.39	181	2.08	826	14.15	1,843	0.75
4	10	0.01	185	0.28	47	0.19	124	1.43	11	0.19	377	0.15
Reaction interval time (day)†												
<1	102,948	73.77	42,634	63.96	16,642	67.13	6,270	72.21	3,814	65.34	172,308	70.18
1–3	34,906	25.01	23,007	34.51	7,784	31.40	2,336	26.90	1,777	30.45	69,810	28.43
4–14	1,441	1.03	845	1.27	283	1.14	57	0.66	202	3.46	2,828	1.15
≥15	266	0.19	176	0.26	82	0.33	20	0.23	44	0.75	588	0.24
Serious AEFI												
Yes	363	0.26	341	0.51	85	0.34	68	0.78	29	0.50	886	0.36
No	139,198	99.74	66,321	99.49	24,706	99.66	8,615	99.22	5,808	99.50	244,648	99.64
Total	139,561	100	66,662	100	24,791	100	8,683	100	5,837	100	245,534	100

Abbreviation: MPV-A=group A meningococcal polysaccharide vaccine; MPV-AC=group A and C meningococcal polysaccharide vaccine; MPCV-AC=group A and C meningococcal polysaccharide conjugated vaccine; MPV-ACWY135=group A, C, Y, and W135 meningococcal polysaccharide vaccine; MPCV-AC/Hib=group A and group C meningococcal polysaccharide conjugated vaccine in combination with Haemophilus influenzae type b vaccine; PLAD=provincial-level administrative division; XPCC=Xinjiang Production and Construction Corps.

* The eastern region includes Beijing, Tianjin, Hebei, Liaoning, Shanghai, Jiangsu, Zhejiang, Fujian, Shandong, Guangdong and Hainan PLADs; the central region includes Shanxi, Jilin, Heilongjiang, Anhui, Jiangxi, Henan, Hubei and Hunan PLADs; the western region includes Inner Mongolia, Guangxi, Chongqing, Sichuan, Guizhou, Yunnan, Xizang, Shanxi, Gansu, Qinghai, Ningxia, and Xinjiang PLADs; and XPCC.

† Reaction interval time: Reaction time-inoculation time.

(27.85/100,000 doses), followed by MPV-A (19.89/100,000 doses), MPCV-AC/Hib (17.12/100,000 doses), MPSV-ACYW135 (11.53/100,000 doses), and MPV-AC (7.78/100,000 doses). The reported incidence of serious redness and swelling (>5.0 cm) after MenV vaccination was 0.60/100,000 doses. The highest incidence was after MPCV-AC vaccination (1.84/100,000 doses), followed by MPV-ACYW135 (0.73/100,000 doses), MPCV-AC/Hib (0.62/100,000 doses), MPV-AC (0.61/100,000 doses), and MPV-A (0.45/100,000 doses). The reported incidence of serious induration (>5.0 cm) after MenV vaccination was 0.21/100,000 doses. The highest incidence was after MPCV-AC vaccination (0.64/100,000 doses), followed by MPV-ACYW135 (0.27/100,000 doses), MPCV-AC/Hib (0.26/100,000 doses), MPV-AC (0.24/100,000 doses), and MPV-A (0.13/100,000 doses).

Allergic reactions and nervous system reactions were the most frequent rare vaccine reactions reported. The most frequently reported allergic reaction was allergic rash (1.23/100,000 doses), followed by angioedema (0.05/100,000 doses), allergic purpura (0.03/100,000 doses), thrombocytopenic purpura (0.02/100,000 doses), and anaphylactic shock (0.01/100,000 doses). Laryngeal edema and Arthus reactions were reported at rates less than 0.005/100,000 doses. The incidence of reported allergic rash was highest for MPCV-AC (3.19/100,000 doses), followed by MPV-ACYW135 (1.87/100,000 doses), MPV-A (1.37/100,000 doses), MPCV-AC/Hib (1.32/100,000 doses), and MPV-AC (0.81/100,000 doses). Febrile convulsion was the most frequent nervous system reaction reported (0.05/100,000 doses). The incidence of reported febrile convulsions was highest for MPCV-AC (0.12/100,000 doses), followed by MPV-A and MPV-ACYW135 (0.06/100,000 doses), and MPV-AC and MPCV-AC/Hib (0.03/100,000 doses). Other nervous system reactions — GBS, ADEM, epilepsy, syncope, polyneuritis, encephalitis, and meningitis — were reported at rates less than 0.005/100,000 doses (Figure 1).

DISCUSSION

Our analysis of MenV-containing vaccine AEFI reported to the CNIIS from 2013 to 2021 found that the incidence of common vaccine reactions ranged from 21.59 to 72.97 per 100,000 doses, while the incidence of rare vaccine reactions ranged from 0.20 to 4.46 per 100,000 doses, depending on the specific MenV-containing vaccine administered. The reported incidence of adverse vaccine reactions was comparable to that observed from 2010 to 2012 and was perceived to be within an acceptable range.

In 2008, China established an online AEFI surveillance system to report suspected vaccine-related reactions or events following immunization, laying the foundation for vaccine post-marketing pharmacovigilance. As the system continuously improved and strengthened, national AEFI reporting

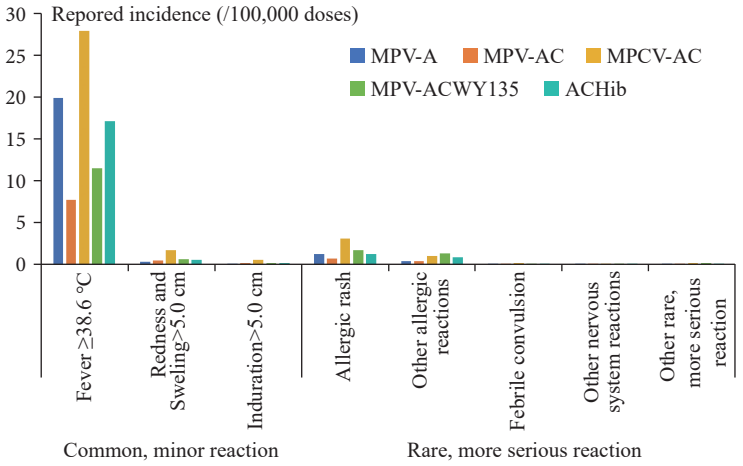

FIGURE 1. Incidence (/100,000 doses) of reported common vaccine reactions and rare vaccine reactions after administration of any of five MenV-containing vaccines.
Abbreviation: MPV-A=group A meningococcal polysaccharide vaccine; MPV-AC=group A and C meningococcal polysaccharide vaccine;MPCV-AC=group A and C meningococcal polysaccharide conjugated vaccine; MPV-CWY135=group A, C, Y, and W135 meningococcal polysaccharide vaccine; MPCV-AC/Hib=group A and group C meningococcal polysaccharide conjugated vaccine in combination with Haemophilus influenzae type b vaccine.

levels increased annually (3–4), consistent with global AEFI monitoring improvements (5). Our study found that the reported incidence of MenV-containing vaccine AEFI reports also increased annually from 2013 to 2019. However, the annual incidence of AEFI with MenV-containing vaccines, as well as the number of vaccination doses and AEFI reports, decreased annually in 2020–2021; this decrease was likely related to the coronavirus disease 2019 (COVID-19) pandemic. In early 2020, vaccination work — other than birth doses of hepatitis B and BCG vaccines and rabies postexposure prophylaxis — was suspended in most of China, and the number of reported AEFIs decreased significantly. The COVID-19 epidemic situation was under strict prevention and control, and the subsequent mass emergency use of COVID-19 vaccines impacted AEFI surveillance. Monitoring in other countries has shown that the sensitivity of AEFI reporting is usually high during the early stages of vaccine introduction or when new recommendations are implemented and will decrease and stabilize as vaccination becomes routine (3–4). In the context of mass vaccination with the new COVID-19 vaccines, patients and healthcare providers may be more concerned about COVID-19 vaccines than other vaccines, increasing reporting sensitivity for COVID-19 vaccination and biasing relative incidences.

This study found that the percentage of MenV-containing vaccine AEFI was highest in the eastern region and lowest in the western region. The highest incidence was for MPCV-AC, followed by MPV-A, MPCV-AC/Hib, MPV-ACYW135, and MPV-AC. These incidence variations may be related to parental sensitivity to AEFI, with parents expressing more concern about non-NIP vaccines. Additionally, differences may be related to the various ages at vaccination. The starting age for MPCV-AC vaccination is 3 months, earlier than other MenV-containing vaccines. Younger age is associated with a greater probability of reaction. The estimated incidence of total and common vaccine reactions reported for MPV-A was higher than for MPV-AC, while the estimated incidence of rare vaccine reactions was lower for MPV-A than MPV-AC. This incidence difference may be related to the different ages of vaccination. The starting age for MPV-A vaccination is 6 months, while MPV-AC vaccination begins at 3 years. Compared with the WHO's expected incidence of allergic reactions of less than 0.1/100,000 doses (1,6), the incidence findings for both MPV-A and MPV-AC were lower than those expected by the WHO and reported in relevant domestic and international studies. In China, MPCV-AC, MPV-ACYW135, and MPCV-AC/Hib are non-NIP vaccines, meaning families can select these vaccines as substitutes for the program MenV-containing vaccines but must pay for them out-of-pocket. The reported incidence of all AEFI, common vaccine reactions, and rare vaccine reactions for MPCV-AC and the overall incidence found in this study was higher than respective incidences for MPV-ACYW135 and MPCV-AC/Hib but lower than incidences reported in relevant domestic and international studies (7–8).

Of common vaccine reactions, the incidence of fever was the greatest, followed by local redness and local induration. The most common of the rare vaccine reactions was allergic rash, and most cases were transient and non-serious. Febrile convulsion was the most common neurological reaction. Anaphylactic shock, laryngeal edema, GBS, ADEM, and other serious cases were all very rare, with estimated reported incidences of lower than 0.01/100,000 doses. Most reactions followed the first dose of a MenV series, consistent with previous experience (9). Most rare events recovered spontaneously or resolved after treatment. Evidence from our analyses augments clinical trials showing that these five types of MenV-containing vaccine have good immunogenicity and acceptable incidences of AEFI (7–8).

Vaccine antigens, residual animal proteins, antibacterial agents, and preservatives can cause allergic reactions. Allergic rashes are frequent in early childhood and this will make vaccination prone to coincidence with vaccination, necessitating investigation to determine whether the relation between rash and vaccination is causal or coincidental. Febrile convulsion is a relatively frequent event in infants and very young children who have high or rapidly increasing fever, usually from acute viral infections. The reported incidence of high fevers was relatively high, and therefore causal relationships between vaccination and febrile convulsion needs further study (3). Other neurological reactions, including ADEM, GBS, encephalitis, and meningitis, have insufficient evidence of causal association with vaccines (4,10).

In China, the incidence of MenV-containing vaccine AEFI was very low and serious abnormal reactions were extremely rare. We should continue to carry out the technical training of vaccinators and on-site emergency treatment capabilities, focusing on treatment for anaphylactic shock and other serious

events to ensure the safety of vaccination.

Conflicts of interest: No conflicts of interest.

Acknowledgments: We thank the staff of the provincial, prefectural and county CDCs and all vaccination clinics for conducting the adverse event surveillance. We thank Lance Rodewald, senior consultant of China CDC, for his comments and recommendations for editing the manuscript.

Funding: This study was funded by the Emergency Response Mechanism Operation Program of China CDC (102393220020010000017).

doi: 10.46234/ccdcw2024.263

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Submitted: March 04, 2024
Accepted: April 22, 2024
Issued: December 13, 2024

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