Vital Surveillances

Surveillance for Adverse Events Following Immunization with Domestic Sabin-Strain Inactivated Poliovirus Vaccine — China, 2015–2022

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ABSTRACT

Introduction: Domestic Sabin-strain inactivated poliovirus vaccine (sIPV) was approved for use in China in 2015 and introduced into the national immunization schedule in a sequential schedule with oral poliovirus vaccine (OPV) in May 2016. However, a comprehensive analysis describing the characteristics, occurrences, and incidences of adverse events following immunization (AEFI) with sIPV in China is lacking.

Methods: Data on sIPV doses administered and AEFI reported from 2015 to 2022 were obtained from the Chinese National Immunization Information System (CNIIS). Descriptive epidemiological methods and statistics were used to analyze and describe the characteristics, occurrences, and incidences of AEFI following sIPV in China from 2015 to 2022.

Results: From 2015 to 2022, over 110,000,000 sIPV doses were administered, and 46,748 sIPV AEFIs were reported, resulting in an AEFI reporting rate of 42.44/100,000. Most AEFIs (46,333, 99.11%) were non-serious. Causality assessment determined 46,061 (98.53%) AEFIs were vaccine product-related reactions, including 44,001 (94.12%) common and 2,060 (4.41%) rare vaccine reactions. Among common vaccine reactions, reporting rates for fever >38.5 °C, local redness and swelling ≥2.6 cm, and local induration ≥2.6 cm were 12.02/100,000, 5.13/100,000, and 1.67/100,000, respectively. Among rare vaccine reactions, reporting rates for anaphylactic rash, thrombocytopenic purpura, and febrile convulsion were 1.56/100,000, 0.09/100,000, and 0.03/100,000, respectively.

Conclusions: Most reported sIPV AEFIs were non-serious, and the reporting rate of rare vaccine reactions has been very low since sIPV was approved for use in China. As sIPV remains in use in China, surveillance of AEFIs associated with this vaccine needs to be maintained.

Poliomyelitis (polio) is an acute, communicable disease caused by poliovirus, which has three serotypes (types 1, 2, and 3) with limited cross-protection. Poliovirus is transmitted person-to-person, and humans are its only reservoir. In the pre-vaccine era, poliovirus was the leading cause of permanent disability in children. There is no effective treatment for polio; vaccination is the most effective preventative measure. Two types of polio vaccines are licensed for use in China: live, attenuated oral poliovirus vaccine (OPV) made with Sabin-strain polioviruses and inactivated poliovirus vaccine (IPV) made with Salk- or Sabin-strain polioviruses (*1*). OPV has been the vaccine of choice for polio eradication since the launch of the eradication effort in 1988. In approximately one in 3,000,000 doses administered, OPV regains neurovirulence through mutation during replication in the vaccinee, causing vaccine-associated paralytic poliomyelitis (VAPP), which can lead to long-term paralysis. OPV can also regain transmissibility and become a circulating vaccine-derived poliovirus (VDPV), causing outbreaks similar to wild-type poliovirus outbreaks (*2*). After the 2015 declaration of global eradication of type 2 poliovirus, the World Health Assembly resolved that all Member States using OPV withdraw the type 2 component of OPV by April 2016, changing to bivalent types 1 and 3 OPV (bOPV) (*3*). Following OPV2 withdrawal, immunity to type 2 polio would come mainly from IPV. In the case of a type 2 VDPV outbreak, monovalent OPV2 vaccines can be used to stop the outbreak upon approval of the WHO Director General.

There are two types of IPV approved for use in China: one made from Sabin strains (sIPV) and the other made from Salk (wild) strains (wIPV). Salk-strain IPV has been available as a private-sector vaccine in China since 2009. The first domestically produced

standalone sIPV was licensed in 2015, followed by the approval of 2 other domestic sIPVs in 2017 and 2021 (*4*). All are Vero-cell-grown sIPVs.

In 2015, 6 provinces conducted IPV pilot studies, introducing one dose of IPV (sIPV or wIPV) into their routine immunization programs (*5*–*6*). On 1 May 2016, China introduced one dose of IPV into the national immunization schedule, administering one dose of IPV followed by three doses of bOPV (IPV at 2 months and bOPV at 3 and 4 months and 4 years). In December 2019, the national schedule changed to IPV at 2 and 3 months and bOPV at 4 months and 4 years (*7*).

China established a nationwide, online, passive surveillance system for adverse events following immunization (AEFI) — the Chinese National AEFI Information System (CNAEFIS) — which was subsequently integrated into the Chinese National Immunization Information System (CNIIS). Data on sIPV AEFI in China are limited, with only a few clinical trials and subnational surveillance data analyses conducted to date. To gain a more comprehensive understanding of the real-world safety profile of sIPV, this study analyzed sIPV AEFI cases reported in China from 2015 to 2022 and reported the results of its analyses.

METHODS

In China, sIPV AEFIs are reported to the CNIIS from local reporting sites in all 31 provincial-level administrative divisions (PLADs) [excluding Hong Kong Special Administrative Region (SRA); Macau SAR; and Taiwan, China] and Xinjiang Production and Construction Corps (XPCC). This study evaluated AEFI cases reported to the CNIIS from 2015 to 2022 that followed the administration of either of the two domestic, standalone sIPVs. This study excluded standalone wIPV and combination vaccines containing wIPV, as these vaccines are manufactured using a technology different from sIPV.

AEFI Monitoring and Evaluation

An AEFI case is a reaction or event following vaccination suspected to be potentially related to the vaccination, according to national guidelines for AEFI surveillance in China. AEFIs are classified as serious if they meet any of the following criteria: death; life-threatening condition; permanent or significant disability; or damage to organs or body functions (*8*). In 2022, the revised national guidelines redefined a serious AEFI as an event that: results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability or incapacity; or is a congenital anomaly or birth defect. Any medical event that requires intervention to prevent one of these outcomes may also be considered serious. Responsible reporting units and reporters include healthcare facilities, vaccination clinics, CDCs, adverse drug reaction (ADR) monitoring agencies, and vaccine marketing authorization holders (MAH). AEFI reporting follows the principles of localized management. The public, vaccinees, or their families can report AEFIs to any authorized reporter. Vaccination clinics or county CDCs complete AEFI case reporting cards and enter data into the CNIIS. All administrative levels of CDCs and ADR agencies can access AEFI data. All AEFIs should be investigated, except for common vaccine reactions with a clear diagnosis (e.g., fever, redness, injection site swelling, or induration). County CDCs collect relevant data, complete AEFI case investigation forms, and enter results into the CNIIS. County CDCs are also responsible for organizing experts to conduct causality assessments. For certain events suspected to be related to immunization, including death, severe disability, AEFI clusters, and AEFIs of significant public concern, prefectural or provincial CDCs organize AEFI expert panels to conduct causality assessments. If a causality assessment conclusion is disputed, the vaccinee or family, vaccination unit, or MAH may request another causality assessment by the authorized Medical Association.

After causality assessment, AEFIs are classified using the Chinese AEFI classification schema. This schema includes vaccine product-related reactions, coincidental events, immunization anxiety-related reactions, suspected immunization error-related reactions, and suspected vaccine quality defect-related reactions. Vaccine product-related reactions are adverse events believed to be caused by the vaccine and are further classified as common (usually minor) or rare (possibly serious) vaccine reactions.

Statistical Analysis

This study used descriptive epidemiological methods and statistics to analyze sIPV AEFIs. Analyses were conducted using the Pandas package (version 2.1.4) of Python (version 3.11.7) and Microsoft Excel (version

2016, Microsoft Corporation, Redmond, WA, USA).

Ethical Review

Individual-level, case-based AEFI surveillance and analysis is mandatory in China and exempt from ethical review.

RESULTS

From 2015 to 2022, 110,146,524 sIPV doses were administered, with annual increases from 2015 to 2021 followed by a decrease in 2022 (Table 1). A total of 46,748 sIPV AEFI cases were reported, resulting in an overall reporting rate of 42.44 per 100,000 doses. Of these, 415 (0.89%, 0.38/100,000 doses) were classified as serious, and 46,333 (99.11%, 42.06/100,000) were non-serious. Based on cause, 46,061 (98.53%, 41.82/100,000) were classified as vaccine product-related reactions, including 44,001 (94.12%, 39.95/100,000) common and 2,060 (4.41%, 1.87/100,000) rare reactions; 627 (1.34%, 0.57/100,000) were classified as coincidental events, 6 as anxiety-related reactions, 7 as suspected vaccine administration errors, and 47 are pending classification or unclassified.

All PLADs reported sIPV AEFIs from 2015 to 2022. The number of cases reported per PLAD ranged from 37 to 6,709; 29 PLADs reported rare vaccine reactions, ranging from 3 to 511 rare reactions per PLAD. Table 2 shows the 44,001 common and 2,060 rare vaccine reactions by gender, age group, region, quarter of the year, and dose number. In total, 55.12% of reports were for males; 2 months of age was the most frequently reported age group (33.43%); the eastern region was the highest reporting region (42.83%); the second quarter had more reports (31.22%) than any other quarter; and the first dose was the most frequently reported dose when sIPV was given as a multi-dose series (56.48%).

Table 3 shows clinical descriptions and diagnoses of the vaccine product-related reactions. Among 44,001 common vaccine reactions, reporting rates for fever >38.5 °C, local redness and swelling ≥2.6 cm, and local induration ≥2.6 cm were 12.02/100,000, 5.13/100,000, and 1.67/100,000, respectively. Among 2,060 rare vaccine reactions, the most reported diagnosis was allergic rash (*n*=1,713, 1.56/100,000), followed by thrombocytopenic purpura (*n*=103, 0.09/100,000). Among acute serious allergic reactions, 22 (0.02/100,000) were anaphylactic shock, and 1 (0.001/100,000) was laryngeal edema. Among nervous

TABLE 1. Number and reporting rate (per 100,000 doses) of sIPV AEFI cases by severity and reaction classification — China,2015–2022.

Year	Doses	Severity				Reaction classification												Total	
		Serious		Non-serious		Common vaccine reactions		Rare vaccine reactions		Coincidental events		Results pending		Immunization anxiety-related reactions		Suspected immunization error-related reaction			
		No.	Reporting rate*	No.	Reporting rate*	No.	Reporting rate*	No.	Reporting rate*	No.	Reporting rate*	No.	Reporting rate*	No.	Reporting rate*	No.	Reporting rate*	No.	Reporting rate*
2015	508,391	0	0	109	21.44	102	20.06	6	1.18	1	0.20	0	0	0	0	0	0	109	21.44
2016	3,991,505	26	0.65	1,755	43.97	1,621	40.61	131	3.28	26	0.65	2	0.05	0	0	1	0.03	1,781	44.62
2017	6,804,364	29	0.43	2,526	37.12	2,360	34.68	152	2.23	41	0.60	2	0.03	0	0	0	0	2,555	37.55
2018	10,026,944	67	0.67	6,894	68.75	6,482	64.65	358	3.57	103	1.03	17	0.17	0	0	1	0.01	6,961	69.42
2019	12,580,249	60	0.48	6,081	48.34	5,690	45.23	348	2.77	90	0.72	10	0.08	1	0.01	2	0.02	6,141	48.81
2020	24,525,933	116	0.47	11,961	48.77	11,349	46.27	536	2.19	178	0.73	7	0.03	4	0.02	3	0.01	12,077	49.24
2021	28,671,801	72	0.25	9,492	33.11	9,101	31.74	336	1.17	122	0.43	4	0.01	1	0.00	0	0	9,564	33.36
2022	23,037,337	45	0.20	7,515	32.62	7,296	31.67	193	0.84	66	0.29	5	0.02	0	0	0	0	7,560	32.82
Total	110,146,524	415	0.38	46,333	42.06	44,001	39.95	2,060	1.87	627	0.57	47	0.04	6	0.01	7	0.01	46,748	42.44

* Reporting rate per 100,000 doses administered.

TABLE 2. Distribution of sIPV vaccine product-related reactions by gender, age (months), region, quarter of year, and dose sequence number — China, 2015–2022.

Characteristic	Common vaccine reactions		Rare vaccine reactions		Total	
	No. of cases	Percent	No. of cases	Percent	No. of cases	Percent
Gender						
Male	24,207	55.01	1,182	57.38	25,389	55.12
Female	19,794	44.99	878	42.62	20,672	44.88
Age (months)						
2	14,680	33.36	720	34.95	15,400	33.43
3	8,757	19.90	381	18.50	9,138	19.84
4	4,614	10.49	196	9.51	4,810	10.44
5–11	5,821	13.23	275	13.35	6,096	13.23
≥12	10,129	23.02	488	23.69	10,617	23.05
Region*						
Eastern	18,587	42.24	1,139	55.29	19,726	42.83
Middle	13,747	31.24	400	19.42	14,147	30.71
Western	11,667	26.52	521	25.29	12,188	26.46
Quarter of year						
1	9,085	20.65	464	22.52	9,549	20.73
2	13,761	31.27	620	30.10	14,381	31.22
3	11,541	26.23	524	25.44	12,065	26.19
4	9,614	21.85	452	21.94	10,066	21.85
Dose sequence number						
1st	24,784	56.33	1,231	59.76	26,015	56.48
2nd	12,033	27.35	479	23.25	12,512	27.16
3rd	1,667	3.79	81	3.93	1,748	3.79
4th	5,176	11.76	231	11.21	5,407	11.74
≥5th	341	0.77	38	1.84	379	0.82
Total	44,001	100.00	2,060	100.00	46,061	100.00

Abbreviation: PLAD=provincial-level administrative division; XPCC=Xinjiang production and construction corps.
* Eastern: Beijing, Tianjin, Hebei, Liaoning, Shanghai, Jiangsu, Zhejiang, Fujian, Shandong, Guangdong, and Hainan PLADs. Middle: Shanxi, Jilin, Heilongjiang, Anhui, Jiangxi, Henan, Hubei, Hunan PLADs. Western: Inner Mongolia, Guangxi, Chongqing, Sichuan, Guizhou, Yunnan, Tibet, Shaanxi, Gansu, Qinghai, Ningxia, and Xinjiang PLADs; and XPCC.

system reports, 28 (0.03/100,000) were febrile convulsions, 10 (0.01/100,000) were convulsions, and 2 (0.002/100,000) were epilepsy. Among autoimmune disorders, 3 (0.003/100,000) were Acute Disseminated Encephalomyelitis (ADEM), 1 (0.001/100,000) was neuromyelitis optica, and 1 (0.001/100,000) was Guillain-Barré syndrome (GBS). There was no significant clustering of serious or rare vaccine reactions, including anaphylactic shock, nervous system diseases, and autoimmune disorders.

DISCUSSION

This study evaluated reported AEFIs following the administration of more than 110,000,000 doses of domestic Sabin-strain inactivated poliovirus vaccine. Of the 46,748 AEFI cases reported (42.44/100,000) during the 8-year surveillance period, most were common, non-serious, vaccine product-related reactions, primarily fever (29.46/100,000 doses). Few (1.87/100,000) were rare vaccine reactions, with allergic rash being the most frequently reported. Most allergic rash cases were transient and non-serious. Although anaphylactic shock is rare, it is the most serious life-threatening allergic reaction. Vaccination clinics should be prepared for emergency treatment during the post-vaccination observation period. Other serious and rare vaccine reactions reported, such as

TABLE 3. Reporting rate (per 100,000 doses) of vaccine product-related reactions by diagnosis — China, 2015–2022.

Vaccine reaction	No.	Reporting rate (/100,000 doses)
Common vaccine reactions*		
Fever (axillary temperature, ℃)		
37.1–37.5	4,001	3.63
37.6–38.5	15,204	13.80
≥38.6	13,240	12.02
Subtotal	32,445	29.46
Injection-site redness or swelling (diameter cm)		
≤2.5	4,447	4.04
2.6–5.0	4,387	3.98
>5.0	1,265	1.15
Subtotal	10,099	9.17
Injection-site induration (diameter cm)		
≤2.5	2,614	2.37
2.6–5.0	1,500	1.36
>5.0	344	0.31
Subtotal	4,458	4.05
Rare vaccine reactions		
Anaphylactic rash	1,713	1.56
Thrombocytopenic purpura	103	0.09
Other allergic reactions	54	0.05
Other diseases†	54	0.05
Febrile convulsion	28	0.03
Angioedema	26	0.02
Henoch-schonlein purpura	20	0.02
Anaphylactic shock	22	0.02
Sterile abscess	15	0.01
Convulsion	10	0.01
Acute disseminated encephalomyelitis	3	0.003
Arthus reaction	2	0.002
Epilepsy	2	0.002
Myelitis	2	0.002
Neuromyelitis optica	1	0.001
Guillain-barré syndrome	1	0.001
Syncope	1	0.001
Laryngeal edema	1	0.001
Local abscess	1	0.001
Erythema multiforme	1	0.001
Subtotal	2,060	1.87

* For common vaccine reactions, only fever, redness, swelling, and induration were included in analyses.
† Other diseases refer to cases with symptoms of discomfort but no definitive diagnosis of the disease.

thrombocytopenia purpura, Henoch-Schönlein purpura, GBS, ADEM, and myelitis, occurred much less frequently. Evidence of a causal link between these rare conditions and IPV has not been found; only anaphylaxis is listed in the vaccine injury table of the US Vaccine Injury Compensation Program (*9*). These findings are consistent with other sIPV surveillance reports and clinical trials (*10*–*14*) and with safety profiles of other routinely used vaccines in China's National Immunization Program（NIP）. This study's findings support the continued, routine use of domestic sIPVs.

This study's sIPV AEFI rate was similar to the rate of 53.02 per 100,000 found by Kang and colleagues in Jiangsu Province (*10*) but lower than the rates found in Jilin Province (169 per 100,000) (*11*) and by Shi and colleagues (2,464 per 100,000) in Ningxia Hui Autonomous Region, identified through active surveillance (*12*). Using passive monitoring, Shi and colleagues found an AEFI rate of 53.35 per 100,000, similar to these findings and those of Kang and colleagues. Sabin-strain IPVs have been evaluated in clinical trials for safety, and no serious safety problems have been observed with any licensed sIPV. The rate of serious AEFIs is comparable to rates for other vaccines routinely used in the NIP. For example, in 2019, serious AEFIs for vaccines primarily used in children ranged from 0.17 per 100,000 (for hepatitis B vaccine) to 0.47 per 100,000 (for inactivated Japanese encephalitis vaccine), similar to the year-by-year rate of serious AEFIs this study found for sIPV (0.2 to 0.67 per 100,000) (*15*).

The Global Commission for Certification of Poliomyelitis Eradication announced in 2015 that wild poliovirus type 2 had been eradicated globally. In 2016, OPV-using countries were required to switch from trivalent OPV (tOPV; types 1, 2, and 3) to bivalent OPV (bOPV; types 1 and 3) and introduce IPV to provide protection from all 3 types of poliovirus. After this adjustment, countries worldwide faced IPV shortages. Shortages in China were alleviated by the approval of a second domestic sIPV in 2017, and by 2019, the supply was fully met (*16*–*17*). In 2020, upon advice from China's National Immunization Advisory Committee, a second IPV dose was added to the routine immunization schedule for stronger protection against type 2 polioviruses. This adjustment explains the significant increase in sIPV doses administered in 2018 and the near doubling of doses in 2020 compared to 2019.

To this study's knowledge, this is the largest sIPV

safety monitoring study, monitoring over 110 million administered doses through China's official AEFI surveillance platform. Reports were received from all PLADs.

This study has limitations associated with passive surveillance, similar to passive AEFI surveillance limitations in other countries. Compared with active safety monitoring, passive monitoring is less sensitive, especially for non-serious AEFIs, for which families may not seek medical attention. Given the limited use of similar inactivated poliovirus vaccines internationally, as well as differences in surveillance systems and definitions, directly and accurately comparing the reported incidences of sIPV AEFIs with the incidences of AEFIs associated with IPV-containing vaccines used abroad is not possible. Causality assessment of rare and serious diseases is complex, and the causal classification of several cases may be controversial.

In conclusion, this study of AEFIs following the administration of over 110 million doses of sIPV found that the vast majority were non-serious, and the rate of serious AEFIs was very low, similar to other routine childhood vaccines. As sIPV remains in use in China, surveillance of AEFIs associated with this vaccine needs to be maintained.

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