Vital Surveillances

Cases of Residual Paralysis in an Acute Flaccid Paralysis Surveillance System — China, 2001–2010

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ABSTRACT

Background: China has been polio-free since 2000 and maintains an acute flaccid paralysis (AFP) surveillance system. Residual paralysis (RP) in children with acute flaccid paralysis can be caused by Sabin-strain poliovirus (PV) and non-polio enteroviruses (NPEV).

Methods: The national AFP surveillance data was analyzed to describe AFP cases with RP in the mainland of China during 2001 to 2010. Epidemiological patterns and virus detection of AFP cases with RP were described.

Results: Annual incidence of AFP with RP among children aged <15 years old ranged between 0.22–0.35 cases per 100,000. The peak age for AFP with RP and PV was 2 to 4 months. Among cases with viral Sabin-strain viral isolates, types II and III were the most common. A summer season peak in RP cases was similar to cases with NPEV isolated.

Conclusions and Implications for Public Health Practice: The first ten years after polio eradication of AFP surveillance data for the occurrence of RP can serve as a baseline rate for poliovirus vaccine changes in the routine immunization system to help detect vaccine safety signals in a timely manner and to support the routine polio immunization program switch in China.

INTRODUCTION

Residual paralysis (RP) in children with acute flaccid paralysis (AFP) is a severe clinical condition that can be caused by infectious and non-infectious factors. Enteroviruses causing RP include polioviruses and non-polioviruses. Historically, wild poliovirus types I, II, and III were the most common causes of AFP. Approximately 1% of polio infections led to infection of motor neurons. Vaccine-associated paralytic poliomyelitis (VAPP), caused by Sabin poliovirus, is a rare adverse event following the administration of oral poliovirus vaccine (OPV), which can also cause persistent paralysis. Non-polio enteroviruses (NPEV), including Coxsackie virus, echovirus, and newly discovered enteroviruses, are also major causes of AFP and can occasionally cause RP.

In 2000, China was certified polio-free by the World Health Organization (WHO). AFP surveillance was established in 1991 and has been operating in all provincial-level administrative divisions (PLADs) since 1993. The system can promptly detect and identify wild polioviruses (WPV) and vaccine-derived polioviruses (VDPV). This surveillance is a nationwide source of data about the occurrence of RP, including virus isolation and virus identification. This study analyzed national AFP surveillance data to describe AFP cases with RP in the mainland of China during 2001–2010 to provide insight into the epidemiological patterns of AFP cases with RP and detection of virus.

METHODS

AFP was defined as any case of acute onset flaccid paralysis in a child <15 years of age, and any case, regardless of age, in whom poliomyelitis was suspected. When an AFP case was identified and reported to the surveillance system, epidemiological and clinical information was collected in both an initial investigation and 60 days after onset of paralysis. Afterwards, 2 stool specimens were collected within 14 days of onset of paralysis for virological testing in accordance with WHO recommendations. Isolates were reported as negative or positive for poliovirus and/or NPEV. The percentages of AFP cases with adequate stool samples (2 stools with more than 5 g each collected within 14 days after onset, at least 24 hours apart, arriving at the laboratory in good condition and kept cold with ice) ranged from 88%–91% (*1*) during 2001–2010.

AFP cases that occurred during the period of

2001–2010, were aged less than 15 years, and that had available enterovirus isolation results and reports of 60-day follow-up clinical examination, were reviewed for this study. For cases with no virus isolated, we only included cases with stool samples that satisfied the "adequate stool" criteria.

AFP cases were classified into 4 categories depending on results of 60-day follow-up examinations and stool isolates identification: 1) AFP with RP with isolated Sabin-strain poliovirus (PV); 2) AFP with RP with isolated NPEV; 3) AFP without RP but with isolated PV; and 4) AFP without RP but with isolated NPEV. AFP in which both PV and NPEV were isolated, were classified in both categories, so the total number of AFP-isolated PV and NPEV was larger than the number of AFP cases.

The epidemiological profiles of AFP cases with RP were described and compared with AFP without RP in the four categories of AFP cases. Incidence rates were calculated by year and season, described by demographic characteristics (gender and age), and described by OPV vaccination history and final diagnosis. The rates of isolation of the three types of PV in groups with RP or without RP were determined with respect to OPV vaccination history. Median, interquartile range, minimum, and maximum values were used to describe the monthly distribution of AFP with or without RP. Statistical analysis were carried out in SAS (version 9.2; SAS Institute; Cary, NC).

RESULTS

During 2001 to 2010, 52,644 cases were reported into the national AFP surveillance system, among which, 76 AFP cases were 15 years and older; 2,581 did not have 60 day follow-up examination information; 3,609 had negative stool isolation results but did not have qualified stool samples; 8 had stool samples collected but which were not sent for laboratory analysis; and 649 did not have stool samples. A total of 4,266 cases were excluded from analysis. Among the remaining 45,721 AFP cases were 68 cases of AFP with RP and 100 cases of AFP without RP from which both PV and NPEV were isolated.

The overall annual incidence of AFP with RP ranged from 0.22 to 0.35 per 100,000 children <15 years of age and from 0.02 to 0.05 per 100,000 and 0.02 to 0.08 per 100,000 for AFP with RP from which PV and NPEV were isolated, respectively. Table 1 and Figure 1A–1C show this information on an annual basis. AFP with RP decreased over time, as did the PV isolation rate.

NPEV isolation rates did not decrease during this time. The PV isolation rate was higher in AFP with RP (15.7%) than in AFP without RP (3.6%). In AFP with RP, the number of cases with PV isolates was slightly larger than cases with NPEV isolates (1,269∶989). In contrast, the number of cases of AFP without RP and with PV isolates was much smaller than the number of

TABLE 1. AFP with/without RP and with PV/NPEV isolates by year.

Year	AFP cases with RP			AFP cases without RP			Total AFP cases	Incidence of AFP cases having RP (per 100,000)[*]		
	N (% in AFP cases)	Identification of isolates (isolated rate %)		N (% in AFP cases)	Identification of isolates (isolated rate %)			Total	With PV isolate	With NPEV isolate
		PV	NPEV		PV	NPEV				
2001	1,017 (21.5)	182 (17.9)	94 (9.2)	3,718 (78.5)	182 (4.9)	379 (10.2)	4,735	0.35	0.03	0.06
2002	999 (21.0)	218 (21.8)	97 (9.7)	3,761 (79.0)	211 (5.6)	382 (10.2)	4,760	0.35	0.03	0.08
2003	918 (20.8)	153 (16.7)	101 (11.0)	3,498 (79.2)	193 (5.5)	356 (10.2)	4,416	0.32	0.04	0.05
2004	831 (18.5)	143 (17.2)	95 (11.4)	3,672 (81.5)	156 (4.2)	415 (11.3)	4,503	0.29	0.03	0.05
2005	832 (17.7)	146 (17.5)	93 (11.2)	3,863 (82.3)	134 (3.5)	453 (11.7)	4,695	0.30	0.03	0.05
2006	782 (16.0)	113 (14.5)	101 (12.9)	4,097 (84.0)	130 (3.2)	503 (12.3)	4,879	0.28	0.04	0.04
2007	666 (15.6)	84 (12.6)	69 (10.4)	3,613 (84.4)	103 (2.9)	377 (10.4)	4,279	0.24	0.02	0.03
2008	718 (16.1)	86 (12.0)	101 (14.1)	3,735 (83.9)	90 (2.4)	456 (12.2)	4,453	0.26	0.04	0.03
2009	621 (14.2)	80 (12.9)	94 (15.1)	3,750 (85.8)	72 (1.9)	496 (13.2)	4,371	0.22	0.03	0.03
2010	701 (15.1)	64 (9.1)	144 (20.5)	3,929 (84.9)	75 (1.9)	510 (13.0)	4,630	0.25	0.05	0.02
Total	8,085 (17.7)	1,269 (15.7)	989 (12.2)	37,636 (82.3)	1,346 (3.6)	4,327 (11.5)	45,721	—[†]	—[†]	—[†]

[*] Population aged <15 years nationwide were used as denominator to calculate the incidences.
[†] not calculate.
Abbreviations: AFP=acute flaccid paralysis; PV=Sabin-poliovirus; NPEV=Non-Polio Enterovirus; RP=residual paralysis.
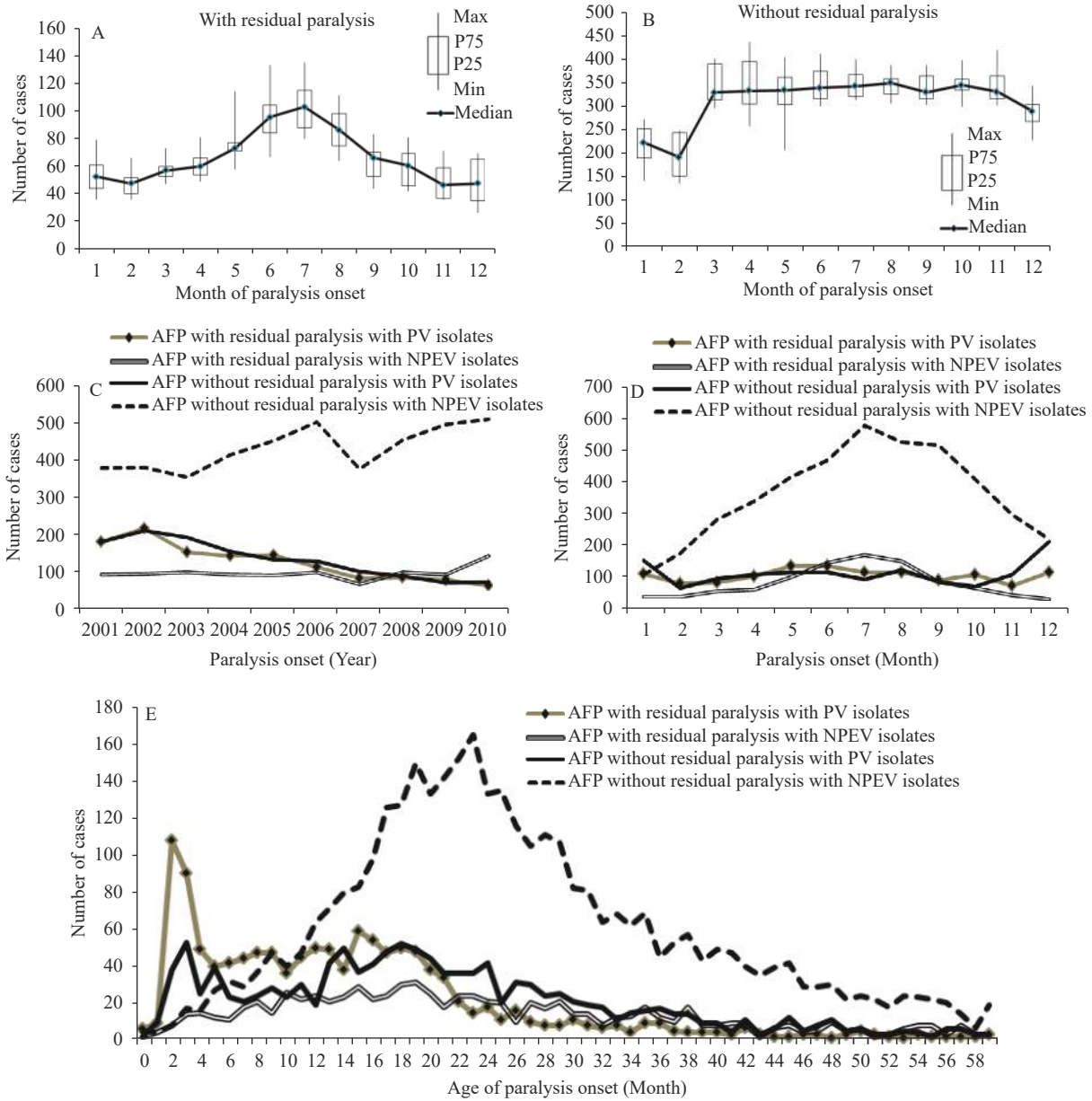
FIGURE 1. Distribution of paralysis onset in AFP cases with/without residual paralysis during 2001–2010. (A) Monthly distribution of paralysis onset in AFP cases with RP during 2001–2010. (B) Monthly distribution of paralysis onset in AFP cases without RP during 2001–2010. (C) Yearly distribution of paralysis onset in AFP case, with/without RP and with PV/NPEV isolates during 2001–2010. (D) Monthly distribution of paralysis onset in AFP case, with/without RP and with PV/NPEV isolates during 2001–2010. (E) Age distribution of <5 year old AFP case with/without residual paralysis and with PV/NPEV isolates during 2001–2010. Abbreviations: AFP=acute flaccid paralysis; RP=residual paralysis; PV=Sabin-poliovirus; NPEV=Non-Polio Enteroviruse.

cases with NPEV isolates (1,346∶4,327).

AFP cases with RP peaked in the summer season from May to August, compared with AFP cases without RP which was relatively constant throughout the year (Figure 1A–1B). For AFP with PV isolates, the number of cases increased at the end and beginning of the years (Figure 1D).

AFP cases below 5 years of age accounted for 94.7% of AFP cases in which RP and PV were isolated, 76.6% in which AFP with RP and NPEV were isolated, 88.1% in which AFP without RP with PV were isolated, and 81.6% in which AFP without RP but with NPEV were isolated. In AFP with RP and PV isolates, the sharp peak of onset occurred in children

aged 2–4 months old. The age distribution of AFP without RP with PV isolated did not show a peak (Figure 1E).

The sex distribution showed that 61.5%–67.4% of cases were male in all 4 categories.

In AFP with PV isolated, the number of cases of AFP with RP was similar to that of AFP without RP (1,266∶1,346), infants <6 months old constituted 23% of AFP cases with RP, about 2 times the number of AFP without RP. For AFP with RP and PV isolates, 81.3% had fever before paralysis onset, a percent that was greater than in the other 3 categories (52.1%–56.3%). Among the 3 types of PV, type II, followed by type III, had the highest isolation rates of AFP with RP, especially among cases with a 0-dose OPV history (19.0%) (Tables 2–3).

Approximately one-third of AFP cases with RP had diagnoses as "other," which was the most common diagnostic category. Among these cases, PV was isolated in 39.3% and NPEV was isolated in 29.0%. Another 15.8% and 8.8% had no final diagnosis information for PV and NPEV isolates, respectively. GBS constituted the second largest diagnostic category (Table 3).

DISCUSSION

In this study, the annual incidence of AFP with RP among children aged <15 years ranged from 0.22–0.35/100,000 during the years 2001 to 2010. The incidences of AFP with RP in which PV or NPEV was isolated comprised approximately one-tenth of the overall incidence of cases of AFP with RP. The PV isolation rate was greater in cases of AFP with RP than in cases of AFP without RP. Children aged 2–4 months old comprised the peak age of AFP with RP and PV isolation. AFP without RP from which PV was isolated can be regarded as Sabin PV infection. AFP with RP that had PV isolated, may be VAPP. The larger proportion of type-II and type-III PV isolates is consistent with VAPP (2–3).

The summer season peak of RP from which NPEV was isolated was consistent with studies outside of China (4–5). The different age distributions of RP with PV isolated and RP with NPEV isolated may be explained by the different risk age groups and paralytic pathogenicity in PV and NPEVs.

The decreasing numbers of cases of AFP with PV during 2001–2010 were likely associated with the decreased usage of OPV in supplementary immunization activities (SIA) during these years. For AFP with PV isolates, the increase at the end and beginning of years may be related to the subnational SIAs implemented in many PLADs at that time.

China's National AEFI Reporting System was established in 2006 and required VAPP to be reported to the national level. Previously the AFP surveillance system did not collect enough clinical information to diagnose VAPP (6), and AFP surveillance did not make a differential diagnosis of VAPP. To increase the timeliness of AFP surveillance after the outbreak of type I WPV in Xinjiang in year 2011(7), China included AFP case reporting into a nationwide real-time web-based "China Information System for Disease Control and Prevention." AFP surveillance cases from which PV was isolated were fed into the vaccine safety system, linking the two systems together to improve the sensitivity to find VAPP. The 10-year surveillance data on RP occurrence can be used as a baseline prior to period for bivalent OPV (bOPV) and inactivated polio vaccine (IPV) usage in routine immunization system, to take advantage of the real-time direct reporting system to timely detect abnormal signals of AFP, RP, and isolation of PV.

NPEV can cause a broad spectrum of clinical

TABLE 2. Three types of Sabin-like poliovirus isolates in AFP case with/without RP and with different OPV history during 2001–2010.

OPV history	RP No. of cases (isolated rate %) by serotype			Non-RP No. of cases (isolated rate %) by serotype		
	I	II	III	I	II	III
0 dose	34 (2.8)	230 (19.0)	95 (7.9)	9 (0.7)	103 (8.5)	35 (2.9)
1 dose	89 (5.4)	236 (14.3)	172 (10.4)	52 (3.1)	123 (7.4)	83 (5)
2 doses	46 (2.6)	79 (4.4)	70 (3.9)	47 (2.6)	73 (4.1)	59 (3.3)
≥3 doses	100 (0.3)	183 (0.5)	137 (0.4)	348 (0.9)	392 (1)	344 (0.9)
Unknown	13 (0.4)	44 (1.3)	29 (0.9)	19 (0.6)	35 (1.1)	20 (0.6)
Vacancy	0 (0.0)	6 (1.4)	2 (0.5)	6 (1.4)	6 (1.4)	5 (1.1)

Abbreviations: AFP=acute flaccid paralysis; RP=residual paralysis; OPV=oral poliovirus vaccine.

TABLE 3. Demographic features of AFP case with/without RP and with PV/NPEV isolates during 2001–2010.

Item	RP(%)		No* RP(%)		Item	RP(%)		No RP(%)	
	PV	NPEV	PV	NPEV		PV	NPEV	PV	NPEV
Gender†					**OPV history**				
Male	855(67.4)	608(61.5)	892(66.3)	2,893(66.9)	0 dose	318(25.1)	50(5.1)	127(9.4)	100(2.3)
Female	414(32.6)	381(38.5)	454(33.7)	1,433(33.1)	1 dose	369(29.1)	51(5.2)	187(13.9)	95(2.2)
Age group (month)					2 doses	150(11.8)	77(7.8)	140(10.4)	179(4.1)
0–5	296(23.3)	49(5.0)	161(12)	71(1.6)	≥3 doses	350(27.6)	728(73.6)	817(60.7)	3,723(86.0)
6–11	255(20.1)	107(10.8)	143(10.6)	226(5.2)	Unknown	75(5.9)	74(7.5)	63(4.7)	202(4.7)
12–47	634(50.0)	547(55.3)	838(62.3)	2,996(69.2)	Vacancy	7(0.6)	9(0.9)	12(0.9)	28(0.6)
48–	81(6.4)	285(28.8)	204(15.2)	1,031(23.8)	**Interval¶**				
Wrongly filled§	3(0.2)	1(0.1)	0(0.0)	3(0.1)	6–40D	347(27.3)	51(5.2)	243(18.1)	186(4.3)
Fever history					<6D	340(26.8)	342(34.6)	517(38.4)	1,055(24.4)
Fever	1,032(81.3)	557(56.3)	753(55.9)	2,255(52.1)	>40D	264(20.8)	546(55.2)	459(34.1)	2,986(69)
No-fever	225(17.7)	420(42.5)	587(43.6)	2,048(47.3)	No/Unknown**	318(25.1)	50(5.1)	127(9.4)	100(2.3)
Unknown	11(0.9)	12(1.2)	6(0.4)	23(0.5)	**PV isolates**				
Vacancy	1(0.1)	0(0.0)	0(0.0)	1(0.0)	I	140(11.0)	11(1.1)	243(18.1)	19(0.4)
Final diagnosis					II	559(44.1)	30(3.0)	474(35.2)	40(0.9)
GBS	274(21.6)	337(34.1)	247(18.4)	834(19.3)	III	310(24.4)	16(1.6)	293(21.8)	22(0.5)
NPEV	47(3.7)	120(12.1)	71(5.3)	595(13.8)	I + II	65(5.1)	2(0.2)	83(6.2)	5(0.1)
Transverse myelitis	51(4.0)	43(4.3)	32(2.4)	114(2.6)	I + III	41(3.2)	4(0.4)	78(5.8)	5(0.1)
Traumatic neuritis	197(15.5)	115(11.6)	244(18.1)	653(15.1)	II + III	118(9.3)	3(0.3)	98(7.3)	5(0.1)
Other	499(39.3)	287(29.0)	543(40.3)	1,468(33.9)	I + II + III	36(2.8)	2(0.2)	77(5.7)	4(0.1)
Vacancy	201(15.8)	87(8.8)	209(15.5)	663(15.3)	**NPEV isolates**				
					NPEV	68(5.4)	989(100)	100(7.4)	4,327(100)
					Negative	1,201(94.6)	0(0.0)	1,246(92.6)	0(0)

* "None" only calculate the result from stools regarded as "adequate";
† The information of gender in 1 AFP belonged to "Non-residual paralysis" and no enterovirus isolates cases was "unknown";
§ Wrongly filled: the filled date of illness onset was prior to birth date;
¶ Interval: Time interval between vaccination and paralysis onset in days;
** No/Unknown: with no OPV vaccination history or unknown OPV vaccination status;
Abbreviations: AFP=acute flaccid paralysis; PV=Sabin-poliovirus; NPEV=Non-Polio Enterovirus; RP= residual paralysis; OPV=oral poliovirus vaccine.

conditions, most of which are mild, asymptomatic, or subclinical. However, NPEV infection can also result in serious or even fatal outcomes such as persistent flaccid paralysis (8). AFP due to WPV infection is rapidly decreasing due to the tremendous efforts made by the polio eradication initiative. It is becoming increasingly important to know the burden of AFP and RP due to non-polio causes. In the past, there were several studies that found at least 20 NPEV serotypes associated with AFP (9–10). Studies of outbreaks of VDPVs in polio-free countries found that VDPVs were recombinations between PV with circulating NPEVs. In order to achieve global eradication of poliomyelitis, it is also important to concurrently understand the circulation pattern of NPEVs. Our

study found 12.2% cases with RP-isolated NPEV, smaller than a study in Pakistan that found 39% (11). The difference may be explained by different sensitivity of AFP surveillance systems.

Current laboratory procedures used in AFP surveillance could only identify a limited number of NPEVs (12). Although NPEV detection is only a "partial-outcome" of AFP surveillance, a significant number of AFP cases with RP from which NPEVs was isolated, along with the epidemiological features of NPEV demonstrated in this study made future studies necessary to be based on serological identification of isolated viruses. This will help understand patterns of circulation and clinical RP occurrence rate associated with each serotype, which may help establish specific

control measures.

The April 2016 replacement of trivalent OPV (tOPV) with bOPV and introduction of IPV affected the dynamics of population immunity, the circulation patterns of PV in communities, and the proportion of VAPP caused by different serotypes of Sabin PVs. IPV does not carry the extremely rare risk of VAPP, but it may leave the newly vaccinated population susceptible to gastrointestinal infection with polioviruses and the risk of circulation of the wild-type virus (*13*). The introduction of insufficient levels of IPV at the time of type-2 OPV cessation may leave countries vulnerable to the emergence of circulating VDPV-2 strains (cVDPV2s). Past occurrence and even outbreaks of VDPV in China demonstrated immunity gaps in some areas and populations. Continued surveillance of cases of AFP to detect polioviruses is essential until poliovirus is completely eradicated.

This study was subject to at least some limitations. First, the isolated enteroviruses from AFP with RP may have coincidental infections, transiently localized in the gastrointestinal tract and shed in stools. Little is known about the casual relation contribution of PV or NPEV to overall AFP and RP. Second, studies have already found that some AFP cases, especially those caused by NPEV, can recover after several months or years. This raised the possibility of misclassification in the follow-up examination existing in this study. Future studies can use a longer follow-up period to correctly classify the outcomes as RP or not.

This study was an overview in China of RP cases with PV/NPEV isolation from the AFP surveillance system. This study provides 10 years of data on RP occurrence that can be used as a baseline prior to the time of IPV introduction and bOPV usage in the routine immunization system. Data generated from this study can help future studies on circulating NPEV serotypes and to support withdrawing type-2 vaccine strain from tOPV to bOPV and introducing IPV into national immunization program.

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