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Estimation of oral poliovirus vaccine effectiveness in Afghanistan, 2010–2020

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Abstract

Background: Afghanistan is one of two countries with endemic wild poliovirus type 1 (WPV1). The oral poliovirus vaccine (OPV) is the predominant vaccine used for polio eradication. Although OPV has been administered in routine childhood immunization and during frequent supplementary immunization activities, WPV1 continues to circulate in Afghanistan and case incidence has been increasing since 2017. We estimated the effectiveness of OPV in Afghanistan during 2010–2020.

Methods: We conducted a matched case-control analysis using acute flaccid paralysis (AFP) surveillance data from 29,370 children < 15 years with AFP onset between January 1, 2010 and December 31, 2020. We matched children with confirmed WPV1 (cases) with children with non-polio AFP (controls) by age at onset of paralysis (+/− 3 months), date of onset of paralysis (+/− 3 months), and province of residence, and compared their reported OPV vaccination history to estimate the effectiveness of OPV in preventing paralysis by WPV1 using conditional logistic regression. To account for changes in OPV formulations provided over the analysis period, we stratified the analysis based on dates of the global switch from trivalent OPV (tOPV) to bivalent OPV (bOPV) in April 2016.

Results: Between January 1, 2010 and December 31, 2020, there were 329 WPV1 cases in Afghanistan. The per-dose estimated effectiveness of OPV against WPV1 was 19% (95% CI: 15%–22%) and of ≥ 7 doses was 94% (95% CI: 90%-97%). Before the global switch from tOPV to bOPV, the per-dose estimated effectiveness of OPV was 14% (95% CI: 11%-18%) and of ≥ 7 doses was 92% (95% CI: 85%-96%). After the switch, the per-dose estimated effectiveness of OPV against WPV1 was 32% (24%-39%) and of ≥ 7 doses was 96% (95% CI: 90%-99%).

Discussion: OPV is highly effective in preventing paralysis by WPV1; these results indicate that continued WPV1 transmission in Afghanistan is due to failure to vaccinate, not failure of the

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2021.09.020.

vaccine. Although difficult to implement in parts of country, improving the administration of OPV in routine immunization and supplementary immunization activities will be critical for achieving polio eradication in Afghanistan.

Keywords

Poliovirus; Vaccine; Oral poliovirus vaccine; Vaccine effectiveness; Afghanistan

1. Introduction

Guided by standardized poliovirus surveillance, systematic use of oral poliovirus vaccine (OPV) in routine immunization programs and in rigorous supplementary immunization activities (SIAs) has led to global eradication of two of the three wild poliovirus (WPV) serotypes: WPV type 2 was declared eradicated in 2015 and WPV type 3 in 2019 [1]. Five of the six World Health Organization (WHO) regions have been certified free of indigenous WPV circulation: the Americas (1994), Western Pacific (2000), European (2002), South-East Asia (2014), and African (2020) [2]. Afghanistan and Pakistan in the Eastern Mediterranean Region are the only countries where WPV type 1 (WPV1) remains endemic.

In Afghanistan, OPV has been included in the routine immunization program since 1978. Per WHO recommendation, OPV is administered through routine immunization as a four-dose schedule at birth, 6 weeks, 10 weeks, and 14 weeks [3]. However, due, in part, to decades of ongoing armed conflict, Afghanistan's routine immunization program has never reached > 75% national OPV coverage by 1 year of age, and OPV coverage has been much lower in areas under control by insurgent groups. To increase population immunity against poliovirus, in 1997 Afghanistan began conducting multiple rounds of SIAs annually; house-to-house vaccination was introduced in 2001. However, inaccessibility due to security challenges, bans on vaccination campaigns, and difficult terrain poses a substantial barrier to reaching every child with OPV. House-to-house vaccination activities have been intermittently banned since 2016; most recently, insurgent groups have banned house-to-house campaigns since 2018. In September 2019, vaccination in areas under insurgency control restarted only at health facilities [4,5].

The polio program in Afghanistan has introduced different formulations and presentations of poliovirus vaccines over the years. OPV, when successfully eliciting an immune response, imparts both serologic and intestinal mucosal immunity, which can break community poliovirus transmission. OPV contains live, attenuated Sabin vaccine strains of poliovirus and was given as trivalent OPV (tOPV, containing Sabin-strain types 1, 2, and 3) since the late 1960s until 2016. Multiple doses are needed to reach high proportions of triple seroconversion in children [6]. In a community with low vaccination coverage, prolonged transmission of Sabin-like poliovirus among susceptible children can allow sufficient genetic mutation of the virus into a form that can widely circulate and cause paralysis, known as vaccine-derived poliovirus (VDPV) [7]. The risk of VDPV paralysis can be mitigated by introduction of injectable inactivated poliovirus vaccine (IPV, containing inactive serotypes 1, 2 and 3) into the immunization program [8]; IPV imparts serologic immunity and

prevents paralytic disease after poliovirus infection, but unlike OPV it does not prevent fecal shedding of poliovirus, so further transmission can continue [6]. In 2015, Afghanistan introduced a single dose of IPV into their routine immunization program to increase the immunity base to type 2 poliovirus in advance of the planned global withdrawal of type 2 OPV; one dose of IPV provides seroconversion and protection from paralysis against type 2 poliovirus in 46%-63% of recipients when given at 4 months of age [9]. To reduce the risk of VDPV due to type 2 OPV use after WPV type 2 eradication, in April 2016, type 2 OPV was withdrawn through a globally synchronized switch from tOPV to bivalent OPV (bOPV, containing types 1 and 3) in routine and supplementary immunization [8]. Vaccination with bOPV leads to higher seroconversion for types 1 and 3 than tOPV, dose for dose [10]. Despite the introduction and use of bOPV and IPV and steady OPV coverage since 2016 (73%), WPV1 incidence in Afghanistan has increased each year since 2017. In 2020, Afghanistan reported 56 WPV1 cases, the highest yearly polio incidence reported since 2012 (37 cases).

Though the efficacy of OPV in preventing paralytic poliomyelitis is well established [11], there is evidence of lower OPV efficacy in developing countries than in developed countries. A 1991 review of 32 studies in low-income countries reported that a median of 72% of children had detectible antibodies to poliovirus type 1 after three doses of tOPV [12]. Trials in Canada and the United States reported detectible antibodies among 97% of children after three tOPV doses [13,14]. Previous OPV effectiveness studies in similar outbreak and endemic settings reported per-dose OPV to be 18% in Somalia (OPV type not distinguished) [15], 16% in Nigeria (tOPV) [16], and 12.5% (tOPV) and 23.4% (bOPV) in Afghanistan and Pakistan [17].

Afghanistan remains a conflict-affected, low-income country ranked 169 of 189 in human development in 2019 [18]. Given known challenges with vaccine coverage in Afghanistan, the objective of this study was to verify field effectiveness of OPV in this context as a means to understand whether continued transmission of WPV1 is due to failure to vaccinate or to vaccine failure. To estimate the effectiveness of OPV against paralysis by WPV1, we used acute flaccid paralysis (AFP) surveillance data to conduct a retrospective matched case-control analysis, accounting for changes in OPV types provided over time.

2. Methods

2.1. Data collection

We used AFP surveillance data reported to the WHO Polio Information System (POLIS), a case-based standardized data repository of polio surveillance and immunization activities across each WHO region and member state. AFP surveillance began in Afghanistan in 1997. AFP cases in any child under 15 years of age with AFP or in any person of any age if polio is suspected, are investigated, reported, and the child tested for poliovirus, per WHO standards [19]. Initial case investigation includes an interview with the child's caregiver to document demographic information (e.g. age, sex, district of residence), details of illness, and vaccination history, including the number of OPV doses received through routine immunization and SIAs. Two stool specimens are collected 24–48 h apart and within 14 days of paralysis onset and shipped under a reverse cold chain (4–8 degrees Celsius)

to the WHO reference laboratory in Islamabad, Pakistan where they are tested for wild and vaccine-derived polioviruses. Results of the AFP investigation and laboratory analysis are part of the national program's surveillance data that are reported weekly to WHO and uploaded to POLIS.

We analyzed data from 29,370 AFP cases in Afghanistan with a date of onset of paralysis between January 1, 2010–December 31, 2020 and final laboratory results (as of March 17, 2021) (Fig. 1). Cases for the study were drawn from AFP cases with laboratory virologic confirmation of WPV1 from at least one stool sample (n = 329). Controls were drawn from AFP cases in children from whom WPV1 was not isolated (n = 29,041). Children missing demographic or vaccine history data, children from whom WPV1 was not isolated and without two adequate stool samples (stool specimens collected > 24 h apart, within 14 days of paralysis onset, and with arrival at a WHO-accredited laboratory in good condition [cool and without leakage or desiccation] [19]) or with laboratory virologic confirmation of other poliovirus infection (VDPV of any type) were excluded from the analysis. We also excluded children less than four months old since they had not yet had the opportunity to receive the recommended four doses of OPV through routine immunization (at birth and 6, 10, and 14 weeks of age), as recommended by WHO. Overall, two children with WPV1 and 2,633 children without WPV1 were excluded, leaving 327 potential cases and 26,408 potential controls.

WPV1 cases were each matched with up to four controls using random selection without replacement. Cases and controls were matched by age at onset of paralysis (+/− 3 months), date of onset of paralysis (+/− 3 months), and province of residence [15,17,20,21] using the CALIPMATCH program [22] in Stata Version 16 [23]. Of the 327 eligible WPV1 cases, 284 (87%) were matched to 966 (4%) controls; 43 (13.1%) cases were unmatched, 24 (7.3%) cases were matched to 1 control, 33 (10.1%) cases were matched to 2 controls, 32 (9.8%) cases were matched to 3 controls, and 195 (59.6%) cases were matched to 4 controls.

2.2. Statistical analysis

We used conditional logistic regression models to estimate the log odds of paralysis by WPV1 as a function of OPV status before the onset of paralysis, where log odds were estimated by:

$$\ln(odds) = \beta_{OPV} x_{OPV}$$

OPV status (x_{OPV}) was defined as the sum of OPV doses received through routine immunization and SIAs and was categorized in two ways. First, because the Afghanistan Polio Eradication Initiative (PEI) recommends ≥ 7 doses of OPV between both routine immunization and SIAs in the first year of age, OPV status was categorized as zero doses, 1–3 doses, 4–6 doses, and ≥ 7 doses to demonstrate the effect of any additional doses beyond the WHO recommended 4-dose schedule. Second, to estimate the per-dose protective effectiveness of OPV against WPV1, OPV status was examined as a continuous variable of all OPV doses received.

Effectiveness of OPV against paralytic poliomyelitis due to WPV1 was estimated by [24]:

$$1 - (OR) * 100$$

To account for changes in OPV types provided over the analysis period, we stratified the analysis based on dates of the global switch from tOPV to bOPV (April 17-May 1, 2016). The pre-switch strata included cases and matched controls with reported onset of paralysis prior to April 17, 2016. The post-switch strata included cases and matched controls among children born after May 1, 2016. Cases and controls among children born before but paralyzed after May 1, 2016 were excluded from the stratified analysis given the theoretical opportunity to have been vaccinated both before and after the global switch from tOPV to bOPV. Receipt of IPV is not recorded during AFP case investigation in Afghanistan, therefore we were unable to account for the effect of the introduction of IPV into routine immunization.

All analyses were completed using Stata Version 16 [23].

2.3. Ethics

This study was determined by U.S. Centers for Disease Control and Prevention to be non-research utilizing data already collected for public health monitoring; as such, full ethical review was not required.

3. Results

Characteristics of children among cases and their matched controls are described in Table 1. There were no differences in child's age or sex between cases and controls. Children in the case group received fewer OPV doses than controls; fewer children among cases than controls received ≥ 4 OPV doses through routine immunization or ≥ 7 OPV doses through routine immunization and SIAs combined; and more children among cases than controls did not receive any doses of OPV.

There were no differences in male sex, age, or OPV doses received between matched and unmatched cases. There was no difference in male sex between matched and unmatched controls; matched controls were younger and received fewer OPV doses than unmatched controls (Supplementary Table 1). The mean number of OPV doses received by children were higher in the pre-switch period compared to the post-switch period (mean doses pre-switch = 13.5, mean doses post-switch = 10.6, $p < 0.01$).

The overall per-dose estimated effectiveness of OPV against paralytic poliomyelitis due to WPV1 between 2010 and 2020 was 19% (95% CI: 15%–22%). Before the switch from tOPV to bOPV (cases = 163, controls = 517), per-dose estimated effectiveness of OPV was 14% (95% CI: 11%-18%). After the switch (cases = 86, controls = 300), per-dose estimated effectiveness was 32% (24%-39%) (Table 2). Estimated average predicted probabilities of WPV1 infection at each level of OPV dosage overall, pre-switch, and post-switch are shown in Fig. 2; post-switch, the probability of WPV1 infection approached 0 at a lower number of doses compared to overall and pre-switch.

OPV effectiveness increased by number of doses received, overall and when stratified by the switch (Table 2), though in the post-switch strata, effectiveness of 1–3 OPV doses was not significantly different from 0 doses. Overall estimated effectiveness of the recommended ≥ 7 OPV doses was 94% (95% CI: 90%-97%); before the switch, effectiveness of ≥ 7 doses was 92% (95% CI: 85–96%); after the switch, effectiveness of ≥ 7 OPV doses was 96% (95% CI: 90%-99%).

4. Discussion

Results from this analysis indicate that in Afghanistan during 2010–2020, OPV was 94% effective at preventing WPV1 among children vaccinated with ≥ 7 doses through routine immunization and SIAs, as recommended by the Afghanistan PEI; per-dose effectiveness was 19%. To our knowledge, this analysis provides the first estimates of type 1 OPV effectiveness after the 2016 global switch from tOPV to bOPV; the effectiveness of ≥ 7 doses of OPV was higher after the switch (96% effective) compared to before the switch (92% effective). The clearly distinct per-dose estimates pre- and post-switch with a lack of overlapping confidence intervals provide strong evidence for the superior effectiveness of type 1 OPV after the switch from tOPV to bOPV. Overall, these results indicate that OPV is highly effective in Afghanistan, and that failure to vaccinate, not vaccine failure is the overwhelming contributor to continued WPV1 transmission.

In the current study, most children with WPV1 (95%) had not received 4 doses of OPV through routine immunization, 68% had not received ≥ 7 OPV doses through routine immunization and SIAs combined, and 27% had not received any OPV. Reaching and vaccinating every last child is a longstanding challenge in Afghanistan. High coverage (≥80%) of immunization with at least four doses of OPV through routine immunization is a key component of the polio eradication strategy. In Afghanistan, however, coverage of OPV received through routine immunization services has always been sub-optimal [25]. During 2010–2019, the WHO-UNICEF estimates of national coverage with the complete OPV series among children aged < 12 months ranged from a low of 62% (2014) to a high of 73% (2016–2019) [25]; sub-national estimates vary considerably and coverage is much lower in areas with continued poliovirus transmission [26]. Low immunization coverage could in itself lower overall OPV effectiveness, as seen by reduced effectiveness point estimates in the lower dose strata. One of many advantages of OPV as the vaccine of choice for polio eradication is that individuals excrete the vaccine virus for several weeks after administration; close contacts of vaccinated children could be exposed secondarily to the vaccine virus, leading to indirect immunization [6]. Therefore, in addition to reduced individual protection among incompletely vaccinated individuals, individuals in communities with low immunization coverage might also experience fewer benefits from indirect immunization. Low community OPV coverage also increases the risk of VDPV emergence and spread [27].

We found that OPV was more effective at preventing WPV1 among children with ≥ 7 OPV doses compared with 4–6 OPV doses (72% effective overall, 65% pre-switch, and 79% post-switch). Children in high- and middle-income countries are well protected against poliovirus after four doses of OPV. In conditions that favor both poliovirus transmission and a high

incidence of diarrheal diseases, such as in areas with tropical climates and poor hygiene and sanitation, additional doses might be necessary to fully protect a child [12,28]. Our results support the Afghanistan PEI target that children receive ≥ 7 OPV doses cumulative between routine immunization and SIAs in the first year of life and the Afghanistan PEI's strategy of frequent SIAs every year targeted to children < 5 years of age to increase population immunity to a level sufficient to interrupt WPV1 transmission. However, our results also indicate that after approximately 10 OPV doses (post-switch), the additional reduction in probability of WPV1 infection was minimal. In Afghanistan, SIAs are typically conducted between 7 and 8 times each year in accessible areas, and between 3 and 6 times each year in geographically or politically hard to reach areas. However, armed conflict, security concerns, and insurgent group bans on vaccination activities frequently limit vaccinators from accessing children in some high-transmission areas [26,29], posing a major challenge to polio eradication efforts. In addition, sub-optimal campaign coverage in accessible areas, primarily due to poor SIA planning, management, and supervision; inappropriately considered contraindications; vaccine refusals; and polio campaign fatigue contributes to the continued circulation of WPV1 [4,26]. Though SIAs remain essential to the success of polio eradication, our results suggest that rather than increasing the frequency or maintaining high frequency of these events, the Afghanistan PEI should redouble efforts on improving the quality and reach of SIAs in order to find and vaccinate un-immunized and underimmunized children. Enhanced efforts to resume house-to-house vaccination in insurgency-held areas will be critical to reaching inaccessible children and improving OPV coverage. Integrating polio vaccination with other services, such as multi-antigen campaigns, humanitarian relief, and development programs may increase community demand for vaccination and improve accessibility for vaccinators, particularly in hard-to-reach areas.

This analysis is subject to several limitations. First, we are unable to elucidate the added benefit of the introduction of IPV on OPV effectiveness or differences between estimated tOPV and bOPV effectiveness in this study because neither information on IPV doses received nor OPV type received is routinely reported during AFP case investigations in Afghanistan. IPV might improve intestinal immunity to poliovirus among children who previously received OPV [30,31], and bOPV is more effective against WPV1 than tOPV because the Sabin 2 vaccine virus can inhibit uptake of other serotypes [32]. However, we cannot assume all OPV administered pre-switch was tOPV and all OPV administered post-switch was bOPV due to varying products used during SIAs. According to POLIS, approximately 59% of doses administered in SIAs during the pre-switch analysis period were bOPV, 34% were tOPV, and 6% were mOPV1; post-switch, approximately 88% of doses administered in SIAs were bOPV, 4% were mOPV1, 3% were mOPV2, and 4% were tOPV The higher effectiveness of OPV after April 2016 is likely attributed to both the introduction of IPV and the switch from tOPV to bOPV. Recording IPV status during AFP case investigations could aid future analyses and facilitate IPV coverage estimates. Second, matching might lead to selection bias because not all cases and controls were matched and included in the analysis. We evaluated this bias through sensitivity analyses that compared matched cases with all eligible cases and matched controls with all eligible controls (Supplementary Table 1). Paralytic polio typically affects children < 2 years, but AFP is reportable for children up to 15 years, therefore the age imbalance between

matched and unmatched controls was expected; because matched controls were younger than unmatched controls, they had fewer opportunities to take OPV, and therefore received fewer OPV doses. Last, our predictor, OPV doses received, was based largely on caregiver report and is therefore subject to recall bias. Since this information is reported during the AFP investigation prior to knowing the laboratory results, differential reporting of OPV status between cases and controls is unlikely, though recall bias could limit the precision of OPV effectiveness estimates.

5. Conclusion

OPV is highly effective in preventing paralysis against WPV1 among children with ≥ 7 OPV doses in Afghanistan. In the past decade, WPV1 transmission has been interrupted for short periods in the historic reservoirs of the Southern and Eastern regions at least twice [33]. In order to achieve eradication, improving vaccination coverage, especially in high-transmission, security-compromised areas, will be essential. Providing additional benefits through expanded integration with other health services, such as nutrition, water, sanitation, and hygiene, could improve poliovirus vaccine coverage through increased community demand and additional opportunities to access hard-to-reach areas.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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All authors attest they meet the ICMJE criteria for authorship. The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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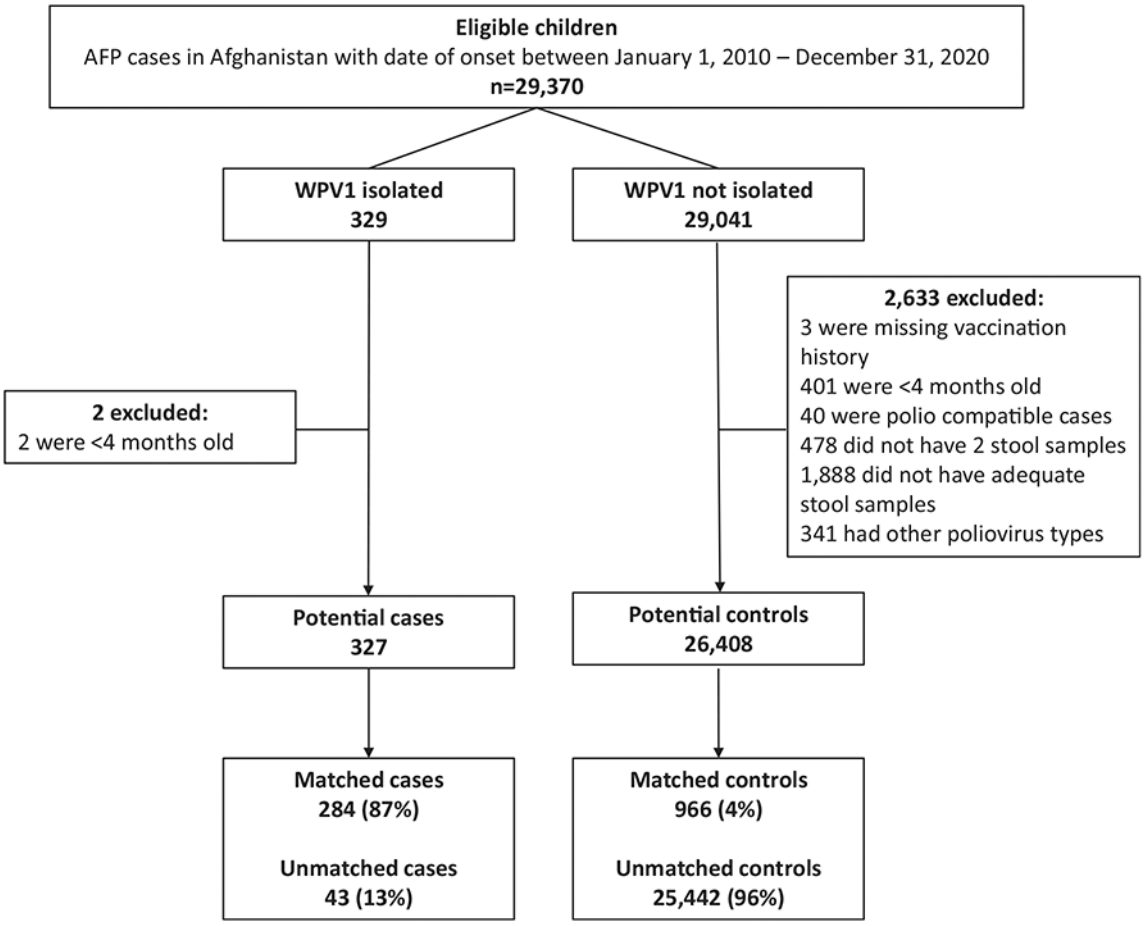

Fig. 1.
Selection of study population.

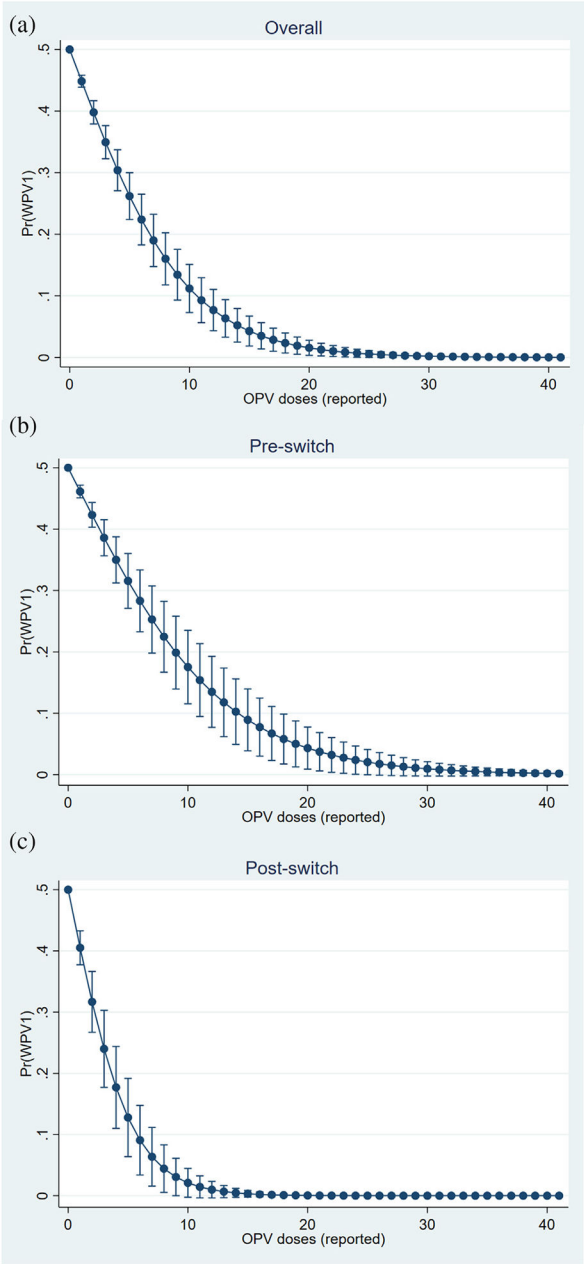

Fig. 2.

a–c. Predicted probabilities of WPV1 infection by OPV doses received, overall (a), pre-switch (b), and post-switch (c).

Table 1

Characteristics of children among study WPV1 cases and matched controls, Afghanistan 2010–2020.

Characteristic of child	Cases (n = 284)	Controls (n = 966)	*p*-value
Male sex, n (%)[1]	162 (57.0%)	540 (55.9%)	0.73
Mean (SD) age in months[2]	27.1 (24.2)	26.0 (22.8)	0.48
Mean (SD) number OPV doses received[2]	5.1 (6.2)	9.3 (6.4)	<0.01
Received ≥ 4 OPV doses through routine immunization, n (%)[1]	15 (5.3%)	227 (23.5%)	<0.01
Received 0 OPV doses, n (%)[1]	76 (26.8%)	67 (6.9%)	<0.01
Received 1–3 OPV doses, n (%)[1]	73 (25.7%)	136 (14.1%)	<0.01
Received 4–6 OPV doses, n (%)[1]	46 (16.2%)	112 (11.6%)	0.04
Received ≥ 7 OPV doses, n (%)[1]	89 (31.3%)	651 (67.4%)	<0.01

WPV1 = wild poliovirus type 1; SD = standard deviation; OPV = oral poliovirus vaccine.

[1] p-value based on chi-square test.

[2] p-value based on two-sample *t*-test.

Table 2

Odds ratio of WPV1 infection and vaccine effectiveness of OPV against WPV1 among WPV1 cases and matched controls, Afghanistan 2010–2020.

	Overall		Pre-OPV Switch		Post-OPV Switch	
	OR (95% CI)	**VE (95% CI)**	**OR (95% CI)**	**VE (95% CI)**	**OR (95% CI)**	**VE (95% CI)**
Number of OPV doses received (continuous)						
	0.81 (0.78, 0.85)	19% (15%, 22%)	0.86 (0.82, 0.89)	14% (11%, 18%)	0.68 (0.61, 0.76)	32% (24%, 39%)
Number of OPV doses received (categorical):						
0 doses	**REF**	**REF**	**REF**	**REF**	**REF**	**REF**
1–3 doses	0.51 (0.3, 0.84)	49% (16%, 70%)	0.43 (0.21, 0.86)	57% (14%, 79%)	0.71 (0.31, 1.62)	29% (−62%, 69%)
4–6 doses	0.28 (0.16, 0.51)	72% (49%, 84%)	0.35 (0.17, 0.75)	65% (25%, 83%)	0.21 (0.07, 0.62)	79% (38%, 93%)
≥7 doses	0.06 (0.03, 0.1)	94% (90%, 97%)	0.08 (0.04, 0.15)	92% (85%, 96%)	0.04 (0.01, 0.1)	96% (90%, 99%)

WPV1 = wild poliovirus type 1; OPV = oral poliovirus vaccine; OR = odds ratio; CI = confidence interval; VE = vaccine effectiveness; REF = reference categoryc