Research Square

Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

Level of immune response to polio vaccines among fully vaccinated children aged 1-10 years in Maniema and Ituri provinces, Democratic Republic of Congo : a cross- sectional survey

Bienvenu Kuyangisa Boloko
Mireille Nganga Nkanga
Aurore Beia Mbombo
Clarisse Kwessena
Audace Kilolo
Gabriel Lukusa
Alain Salaboni
Thérèse Katoka
R Apalata
Marcel Mubelo Aspro
bishopmubelo@gmail.com

Benjamin Longo-Mbenza

Research Article

Keywords: vaccine failure rate, immune response, polio vaccines, Democratic Republic of the Congo

Posted Date: November 6th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-11066795/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

Additional Declarations: No competing interests reported.

Abstract

Introduction:

The Democratic Republic of the Congo (DRC) bears a great number of cases of poliovirus. The study aimed to assess the level of immune response to polio vaccines among fully vaccinated children aged 1–10 yeas.

Methods

This cross-sectional study was conducted in two provinces of the DRC and included 348 children.

Results

The mean age was 4.7years ± 2.7 and the median age was 5 years with extremes of 1 to 10 years. The vaccine failure rate was 56.9% for girls and 43.1% for boys. This rate was 59.3% in the Maniema site and 53.5% in the Ituri site. The difference was not statistically significant (p = 0.278). Considering the age groups, the vaccination failure rate was respectively 59.4% in children aged between 5 and 54.5% in those under 5 years of age. There was no statistically significant difference (p = 0.354).

Conclusion

This study showed a significant rate of vaccine failure among fully vaccinated children. This result requires further studies to investigate the factors associated with this failure.

INTRODUCTION

Polio is a highly contagious infection caused by the poliovirus (1). According to the World Health Organization (WHO), the incidence of polio is estimated at 37 cases of wild poliovirus, with a disease that remains endemic with type 1 in Afghanistan and Pakistan (2). However, in recent years there has been a rise in the incidence of polio cases due to circulating poliovirus derived from vaccine strains in the African region (3). Nowadays, the Democratic Republic of the Congo (DRC) is among the most affected countries by polio, with 945 cases reported between 2022–2023 (3).

Strategies to control polio primarily rely on strengthening immunization services through routine vaccination and supplementary immunization activities. These interventions use oral polio vaccines, including bivalent oral polio vaccine (bOPV) and novel oral polio vaccine type 2 (nOPV2), as well as the inactivated polio vaccine (IPV) (4–6). The widespread implementation of these vaccines has proven highly effective and has contributed substantially to the dramatic reduction in poliomyelitis cases worldwide (7–9).

Despite the remarkable success of polio vaccination programs, vaccine-derived poliovirus (VDPV) outbreaks continue to occur in several countries. Research suggests that factors such as intestinal infections, immune deficiencies, malnutrition, and disruptions in health services may compromise vaccine-induced immunity and facilitate the emergence and circulation of VDPVs. These challenges are particularly prevalent in low-resource settings, where political instability and weaknesses in healthcare systems can further hinder the effectiveness of immunization programs and disease control efforts (10, 11).

As a consequence, vaccine-derived polioviruses may continue to circulate even in settings reporting high vaccination coverage. In the DRC, a resurgence of VDPV cases has been documented despite administrative vaccination coverage exceeding 95% and reports that most affected children were fully vaccinated. This resurgence has been particularly evident in the provinces of Maniema, Ituri, Haut-Katanga, Haut-Lomami, and Tanganyika, raising concerns about the adequacy of population immunity and the factors influencing vaccine responsiveness in these settings (3, 12, 13). Therefore, The study aimed to assess the level of immune response to polio vaccines among fully vaccinated children aged 1–10 yeas in the provinces of Maniema and Ituri in 2024.

METHODS

Study design

This was a descriptive cross-sectional study conducted from February 2021 to July 2024.

Study area

This study was conducted in two provinces of the DRC, including Maniema and Ituri. The Maniema province is located in the central part of the Democratic Republic of the Congo (DRC) and covers an area of 132,250 km², representing 5.6% of the country's total surface. This study focuses on the Kindu and Alunguli health zones, specifically targeting the following health areas: Brazza, RVA, Ngezi, and Lumbulumbu.

The Ituri province, located in the northeastern part of the country, and covers an area of 65,688 km². The province faces a highly fragile security situation, characterized by incursions from foreign armed groups into several border villages. This ongoing instability has led to significant internal displacement. Due to high reported cases of polio, four health zones were selected in the Ituri province: Bora Uzima, Bigo, Kindia, and Lembao, corresponding to Health Zones 1 and 2 of Bunia.

Study Population

The study focused on children aged 1-10 years who had been fully vaccinated against polio, using both oral and injectable vaccines, and who resided in the selected health zones and whose mothers showed vaccination cards. Children were excluded from the study if they lacked a vaccination card or if parental consent was not obtained.

Sample size

A sample size of 408 was estimated assuming a presumed failure rate of 10%, a precision of 5%, and a Confidence Interval of 95%, and a design effect of 1.2 using the following formula:

$$n = [DEFF*Np(1-p)]/ [(d2/Z21-\alpha/2*(N-1) +p*(1-p)]$$

Sampling method

Four health zones spread across the two provinces (Maniema and Ituri) were selected, taking into account reports of cases of VDPV and good performance in terms of vaccination coverage for OPV3 and IPV. In each health zone, 2 health areas were selected. Within these health areas, the villages housing the health facilities (FOSA) were selected, and then using the cluster method, the households were selected to take the samples. In the households, children aged between 6 months and 10 years who had been correctly vaccinated with OPV and IPV with proof of card and consent obtained from their parents or guardians were selected and subjected to surveys to collect demographic, anthropometric, and clinical data on the child and to collect samples of biological data.

Data collection

Data were collected by a team composed of trained interviewers, specialists in medical biology, and field supervisors. Prior to data collection, all field staff underwent a three-day training workshop covering the study objectives, participant recruitment procedures, informed consent process, administration of questionnaires, anthropometric measurements, blood sample collection, specimen handling, and ethical considerations. Following the training, a pilot test of the data collection tools and procedures was conducted in a health area not included in the study. The pretest enabled the research team to assess the clarity, relevance, and consistency of the questionnaire and to make the necessary adjustments before the start of the survey.

A structured questionnaire was administered face-to-face to mothers of eligible children. Information collected included sociodemographic characteristics (child's age and sex, parental education, and household characteristics), vaccination history verified using vaccination cards, recent medical history, and other factors potentially associated with immune response. Anthropometric measurements were also obtained following standard procedures to assess the nutritional status of participating children. Field supervisors reviewed completed questionnaires daily to ensure completeness and accuracy and provided immediate feedback to data collectors when necessary.

For biological analyses, eight milliliters of blood were collected from the children in dry tubes (3.5 ml for hematology and 5 ml for biochemical analysis). Once the samples had been taken, they were placed in isothermal containers and then sent to the storage laboratories for conservation at +2 and +8 degrees Celsius. The hematological analyses were immediately carried out using the Mindray BC-5150 automated blood analyzer. For biochemistry and serology analyses, samples were transferred to the Kinshasa university clinics laboratory to be stored at -20 degrees Celsius in a PR-5V360 freezer and then

processed using the Mindray BS-240 automated system. Serological tests for antibodies were carried out at the Lomo University Research Lomo-Medical laboratory using a branded Elisa COBAS C 311 (ROCHE: HITACHI) with the human poliovirus IgG (PV-IgG) ELISA KIT reagent, and social-demographic data (sex, age in completed years).

Operational definition of key variables

Children with an IgG antibody titer of **8 IU/L or greater** were considered to have an adequate immune response and were classified as **seroprotected.** Conversely, children with an IgG antibody titer of **less than 8 IU/L** were considered to have an inadequate immune response and were classified as experiencing **vaccine failure.**

Statistical analysis

Data were entered on the computer using Excel version 2013 and analyzed using STATA version 18. Pearson's Chi-square test was used to compare proportions between categorical variables, the Student's T-test to compare means of continuous variables, and Pearson's correlation to determine the correlation coefficient between variables of interest (dependent and independent). A p-value of less than 0.05 was considered the threshold of statistical significance.

RESULTS

Sociodemographics of participants

Overall, 408 children were included in this study. More than half of children (54.2%) were aged 5 years old or younger. The distribution of children was nearly equal between the two provinces, with 50.5% from Ituri and 49.5% from Maniema. Four out of ten (40.2%) mothers of participating children had no formal education (Table 1).

Table 1. Sociodemographic characteristics of participating children and their mothers' education

Variables	n	%
Age		
<5 years	221	54.2
≥5 years	187	45.8
Sex		
Girls	211	51.8
Boys	196	48.2
Province		
Ituri	206	50.5
Maniema	202	49.5
Mother's education		
No formal education	164	40.2
Primary education	85	20.8
Secondary education	139	34.1
University education	20	4.9

Serology among participating children

Figure 1 shows the distribution of serology among children. Overall, the mean IgG titer was 8.98 IU/L (SD = 5.05). Most observations are concentrated between approximately 5 and 15 IU/L, with fewer participants exhibiting values above 20 IU/L (Figure 1).

Level of immune response to polio vaccines

Figure 2 shows a slightly higher proportion of participating children with polio vaccine failure (**55.9%**).

DISCUSSION

This study assessed the immune response to polio vaccination among fully vaccinated children aged 1-10 years from the provinces of Ituri and Maniema in the DRC. More than half of the participating children were younger than five years, the sex distribution was nearly balanced, and a substantial proportion of mothers had no formal education. The mean anti-polio IgG titer was 8.98 IU/L, with most children exhibiting antibody concentrations between 5 and 15 IU/L. Most importantly, more than half of the children (55.9%) were classified as experiencing vaccine failure, indicating inadequate immune protection despite vaccination efforts.

The predominance of children younger than five years is consistent with the epidemiology of polio infection and with global immunization strategies, which prioritize this age group because of its heightened susceptibility to poliovirus infection and paralysis (14,15). Similar age distributions have been reported in post-vaccination serological surveys conducted in other LMICs, reflecting the focus of routine immunization and supplementary immunization activities on younger children (16,17).

A notable finding was that approximately 40% of mothers had no formal education. Maternal education has consistently been identified as a key determinant of childhood vaccination uptake and completion of immunization schedules (18,19). Studies from several Sub-Saharan African countries have demonstrated that children born to mothers with higher educational attainment are more likely to receive all recommended vaccine doses and to access preventive health services (20,21). Educated mothers may possess greater awareness of vaccination benefits, better health-seeking behaviors, and improved ability to navigate healthcare systems. Therefore, the low educational level observed among many mothers in this study may have contributed indirectly to inadequate vaccine-induced immunity through reduced adherence to vaccination schedules or missed opportunities for immunization (18,20).

The distribution of anti-polio IgG titers revealed considerable variability among participants. Although most children demonstrated measurable antibody concentrations, the relatively wide dispersion of titers suggests heterogeneous immune responses. Such variability has been documented in previous studies and may be explained by differences in vaccine exposure, timing of vaccination, nutritional status, concurrent infections, genetic factors, and environmental conditions (22–24). The mean IgG concentration observed in this study indicates that many children mounted an immune response; however, antibody levels alone may not guarantee adequate protection if seroconversion thresholds are not achieved (25).

The most concerning finding was the high prevalence of vaccine failure, affecting nearly six in ten children. This proportion is substantially higher than the seronegativity levels reported in many countries that have achieved high routine immunization coverage (26,27). Studies conducted in India and Nigeria have generally documented seroconversion rates exceeding 80–90% following complete vaccination schedules, although lower rates have occasionally been reported in settings characterized by malnutrition, poor sanitation, and high enteric disease burdens (28,29). Similarly, investigations in Pakistan and parts of Sub-Saharan Africa have shown that vaccine effectiveness may be reduced in populations exposed to chronic infections, environmental enteropathy, and socioeconomic deprivation (30,31). The high prevalence of inadequate immune response observed in the present study therefore raises concerns regarding the effectiveness of vaccination delivery and the persistence of immunity gaps in eastern DRC.

Several factors may explain the observed vaccine failure. First, incomplete vaccination schedules remain a common challenge in resource-limited settings. Children who miss one or more recommended doses may fail to develop adequate protective immunity (32). Second, vaccine potency may be compromised by weaknesses in cold-chain management, particularly in remote areas where transportation

infrastructure and electricity supply are limited. Maintaining the integrity of the cold chain remains challenging in many parts of the DRC and may contribute to reduced vaccine effectiveness (33,34). Third, nutritional status may play a critical role in shaping vaccine responses. Malnutrition remains a major public health problem in the DRC, particularly in eastern provinces affected by poverty, food insecurity, and recurrent humanitarian crises. Protein-energy malnutrition and micronutrient deficiencies have been associated with impaired immune function and reduced responses to several childhood vaccines (35,36). Evidence suggests that undernourished children may exhibit lower antibody production following vaccination than their well-nourished counterparts (37). Consequently, nutritional deficiencies may have contributed to the inadequate immune responses observed in this study.

Study strengths and limitations

This is the first study to quantitatively assess the anti-polio immune response of apparently healthy children fully vaccinated with b OPV, nOPV2, and IPV vaccines in Maniema and Ituri provinces. The study provided relevant data to guide vaccination strategies in areas at high risk of polio transmission in the DRC. Unlike studies that have relied exclusively on vaccination records, this study directly assessed immune response through serological measurements, providing a more objective evaluation of protection against poliovirus. Furthermore, the inclusion of children from two provinces enhances the relevance of the findings for eastern DRC.

However, this study had some limitations. The descriptive cross-sectional design does not enable us to investigate associations and draw causal inference. In-depth information on vaccination history, nutritional status, socioeconomic conditions, and exposure to conflict-related disruptions was not available, limiting the ability to identify the specific mechanisms underlying inadequate immune responses. Also, the contextual realities of Ituri and Maniema should also be considered when interpreting these findings. Both provinces have experienced prolonged periods of insecurity, population displacement, and disruption of health services. In Ituri in particular, armed conflict and recurrent humanitarian emergencies have affected healthcare infrastructure and reduced access to routine immunization services. Population movements may increase the number of missed vaccinations, while insecurity can limit outreach activities and the ability of healthcare workers to reach vulnerable communities. Such conditions have been recognized as major obstacles to achieving and maintaining high vaccination coverage in fragile settings. Finally, the required sample size was not reached. This could have introduced the selection bias and limited the generalizability of the results.

Implications for public health, policy and interventions

The findings have important implications for polio eradication efforts. The presence of a large proportion of children lacking adequate immunity creates conditions favorable for the circulation of poliovirus, including vaccine-derived polioviruses, especially in areas with suboptimal sanitation and vaccination coverage. Achieving and sustaining herd immunity requires not only high vaccination coverage but also effective vaccine delivery capable of inducing protective immune responses. Consequently, strengthening routine immunization systems, ensuring uninterrupted cold-chain maintenance,

conducting periodic supplementary immunization activities, and integrating nutritional interventions into child health programs may help improve vaccine effectiveness and population immunity.

Conclusion

This study reveals a high prevalence of poor response of polio vaccines among fully vaccinated children aged 1–10 years in Maniema and Ituri provinces. Despite measurable antibody levels in many participants, more than half failed to achieve adequate immune protection. This study highlights persistent immunity gaps that may threaten polio control and eradication efforts in the DRC. Further studies are needed to investigate associations between polio vaccine failure and specific exposures. Strengthening routine immunization services, improving cold-chain systems, addressing childhood malnutrition, and ensuring access to vaccination in conflict-affected communities are essential to enhance vaccine-induced immunity and reduce the risk of future poliovirus transmission.

Declarations

Authors contributions:

Participated in design: BKB, BLM, MNN

Collected the data: LMG, ASM, MMA, GLM, ASM, AK, TKM, CK, RA

Involved in analysis: BKB, AB, MNN, BLM

Writers: BKB, MNN, MMA

All authors have read and approved the final frame.

Ethics: The protocol of the present study had obtained approval from the National Ethics Committee under number No. 0318/CNES/BN/PMMF/2021 of 9/12/2021. All methods and procedures were conducted in accordance with applicable guidelines and regulations

Conflict of interest: No conflict of interest was declared by the authors.

Datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Grants

This research did not receive grant funding from any donor. Almost all of this research was funded by the principal investigator, amounting to 80% of the total planned budget, with the remaining 20% provided by the WHO Representative Office in the DRC.

Acknowledgments

We would like to sincerely thank the WHO office in the DRC for funding in terms of 20% of the total cost of this research and the School of Public Health of Kinshasa for providing administrative support. We also thank the health authorities of two provinces as well as all the actors at the level of health zones, health areas without forgetting the community relays and the community for having agreed to participate in this study.

Ethical considerations

The protocol of the present study received ethical approval from the National Health Ethics Committee of the DRC (Approval No. 0318/CNES/BN/PMMF/2021, dated 9 December 2021). Authorization to conduct the study was also obtained from the provincial health authorities and the management teams of the selected health zones before field activities commenced. Written informed consent was obtained from the parents or legal guardians of all participating children after providing detailed information about the study objectives, procedures, potential benefits, and risks. Participation was entirely voluntary, and pa48rents or guardians were informed of their right to withdraw their child from the study at any stage without any consequences. To ensure confidentiality, all collected data were anonymized, stored securely, and used exclusively for research purposes. All methods and procedures were conducted in accordance with relevant ethical guidelines and regulations, including the principles outlined in the Declaration of Helsinki.

References

1. Kew OM, Sutter RW, de Gourville EM, Dowdle WR, Pallansch MA. Vaccine-derived polioviruses and the endgame strategy for global polio eradication. Annu Rev Microbiol. 2005;59:587–635.
2. World Health Organization. Polio eradication strategy 2022–2026: Delivering on a promise. Geneva: WHO; 2021.
3. World Health Organization Regional Office for Africa. Circulating vaccine-derived poliovirus (cVDPV) outbreaks in the African Region: Weekly Bulletin, 2023. Brazzaville: WHO AFRO; 2023.
4. World Health Organization. Polio vaccines: WHO position paper – June 2022. Wkly Epidemiol Rec. 2022;97(25):277–300.
5. Macklin GR, O'Reilly KM, Grassly NC, Edmunds WJ, Mach O, Santhana Gopala Krishnan R, et al. Evolving epidemiology of poliovirus serotype 2 following withdrawal of the type 2 oral poliovirus vaccine. Science. 2020;368(6489):401–5.
6. Konopka-Anstadt JL, Campagnoli R, Vincent A, Shaw J, Wei L, Wynn NT, et al. Development of novel oral poliovirus vaccine type 2 (nOPV2) for the global eradication of poliomyelitis. Expert Rev Vaccines. 2021;20(5):575–85.
7. Sutter RW, Kew OM, Cochi SL, Aylward RB. Poliovirus vaccine—live. In: Plotkin SA, Orenstein WA, Offit PA, Edwards KM, editors. Plotkin's Vaccines. 8th ed. Philadelphia: Elsevier; 2024.
8. Global Polio Eradication Initiative. Polio eradication strategy 2022–2026 implementation report. Geneva: GPEI; 2024.

9. Patel M, Zipursky S, Orenstein W, Garon J, Zaffran M. Polio endgame: The global switch from trivalent to bivalent oral poliovirus vaccine. Expert Rev Vaccines. 2018;17(4):283–95.
10. Grassly NC. The final stages of the global eradication of poliomyelitis. Philos Trans R Soc Lond B Biol Sci. 2013;368(1623):20120140.
11. Famulare M, Chang S, Iber J, Zhao K, Adeniji JA, Bukbuk D, et al. Sabin vaccine reversion and the risk of circulating vaccine-derived poliovirus outbreaks. PLoS Pathog. 2016;12(12):e1006214.
12. Democratic Republic of the Congo Ministry of Public Health. Expanded Programme on Immunization (EPI): Annual Report on Poliomyelitis Surveillance and Vaccination Coverage, 2023. Kinshasa: Ministry of Health; 2024.
13. Global Polio Eradication Initiative. Democratic Republic of the Congo: Polio outbreak situation reports, 2023–2024. Geneva: GPEI; 2024.
14. World Health Organization. Polio vaccines: WHO position paper – June 2022. Wkly Epidemiol Rec. 2022;97(25):277–300.
15. Sutter RW, Kew OM, Cochi SL. Poliovirus vaccine-live. In: Plotkin SA, Orenstein WA, Offit PA, Edwards KM, editors. Plotkin's Vaccines. 8th ed. Philadelphia: Elsevier; 2024.
16. Estívariz CF, Molodecky NA, Jafari H, et al. Immunogenicity of supplemental doses of poliovirus vaccine for children in low-income settings. Vaccine. 2015;33(37):4827–32.
17. Ahmad N, Akbar MS, Khan AA, et al. Seroprevalence against poliovirus among children in high-risk areas of Pakistan. Vaccine. 2015;33(36):4314–9.
18. Restrepo-Méndez MC, Barros AJD, Wong KLM, et al. Inequalities in full immunization coverage: trends in low- and middle-income countries. Bull World Health Organ. 2016;94(11):794–B805.
19. Arsenault C, Johri M, Nandi A, et al. Country-level predictors of vaccination coverage and inequalities in Gavi-supported countries. Vaccine. 2017;35(18):2479–88.
20. Lakew Y, Bekele A, Biadgilign S. Factors influencing full immunization coverage among 12–23 months of age children in Ethiopia. BMC Public Health. 2015;15:728.
21. Wiysonge CS, Uthman OA, Ndumbe PM, Hussey GD. Individual and contextual factors associated with low childhood immunization coverage in Sub-Saharan Africa. PLoS ONE. 2012;7(5):e37905.
22. Grassly NC, Fraser C. The immunological basis for variable responses to oral poliovirus vaccine. Lancet Infect Dis. 2006;6(10):611–9.
23. Parker EPK, Kampmann B, Kang G, Grassly NC. Influence of enteric infections on oral vaccine responses. Vaccine. 2018;36(23):3419–24.
24. John TJ. The biological challenges of polio eradication. Indian Pediatr. 2006;43(11):955–63.
25. Weldon WC, Oberste MS, Pallansch MA. Standardized methods for detecting and interpreting poliovirus neutralizing antibodies. Clin Vaccine Immunol. 2016;23(5):388–94.
26. Morales M, Tangermann RH, Wassilak SGF. Progress toward polio eradication worldwide. MMWR Morb Mortal Wkly Rep. 2022;71(19):650–5.
27. Global Polio Eradication Initiative. Polio Annual Report 2023. Geneva: GPEI; 2024.

28. Jafari H, Deshpande JM, Sutter RW, et al. Efficacy of inactivated poliovirus vaccine in India. Lancet. 2014;384(9953):1686–97.
29. Baba MM, Haruna BA, Ogunmola OJ, et al. Seroprevalence of poliovirus antibodies among children in northern Nigeria. J Infect Dev Ctries. 2012;6(10):726–31.
30. Habib MA, Soofi S, Ali N, et al. A study of poliovirus vaccine response in Pakistan. Vaccine. 2013;31(13):1718–23.
31. Nnadi C, Damisa E, Esapa L, et al. Continued endemic transmission of poliovirus in areas with socioeconomic deprivation. J Infect Dis. 2017;216(Suppl 1):S368–72.
32. Patel M, Orenstein WA. Classification and causes of vaccine failure. Vaccine. 2016;34(51):6658–64.
33. Zipursky S, Boualam L, Cheikh DO, et al. Assessing the potency of vaccines through cold-chain monitoring in Africa. Vaccine. 2011;29(41):7143–8.
34. Hanson CM, George AM, Sawadogo A, Schreiber B. Is freezing in the vaccine cold chain an ongoing issue? A literature review. Vaccine. 2017;35(17):2127–33.
35. Prendergast AJ. Malnutrition and vaccination in developing countries. Philos Trans R Soc Lond B Biol Sci. 2015;370(1671):20140141.
36. Bourke CD, Berkley JA, Prendergast AJ. Immune dysfunction as a cause and consequence of malnutrition. Trends Immunol. 2016;37(6):386–98.
37. Moore SE, Goldblatt D, Bates CJ, Prentice AM. Impact of nutritional status on vaccine responses in children. Proc Nutr Soc. 2003;62(4):851–9.

Figures

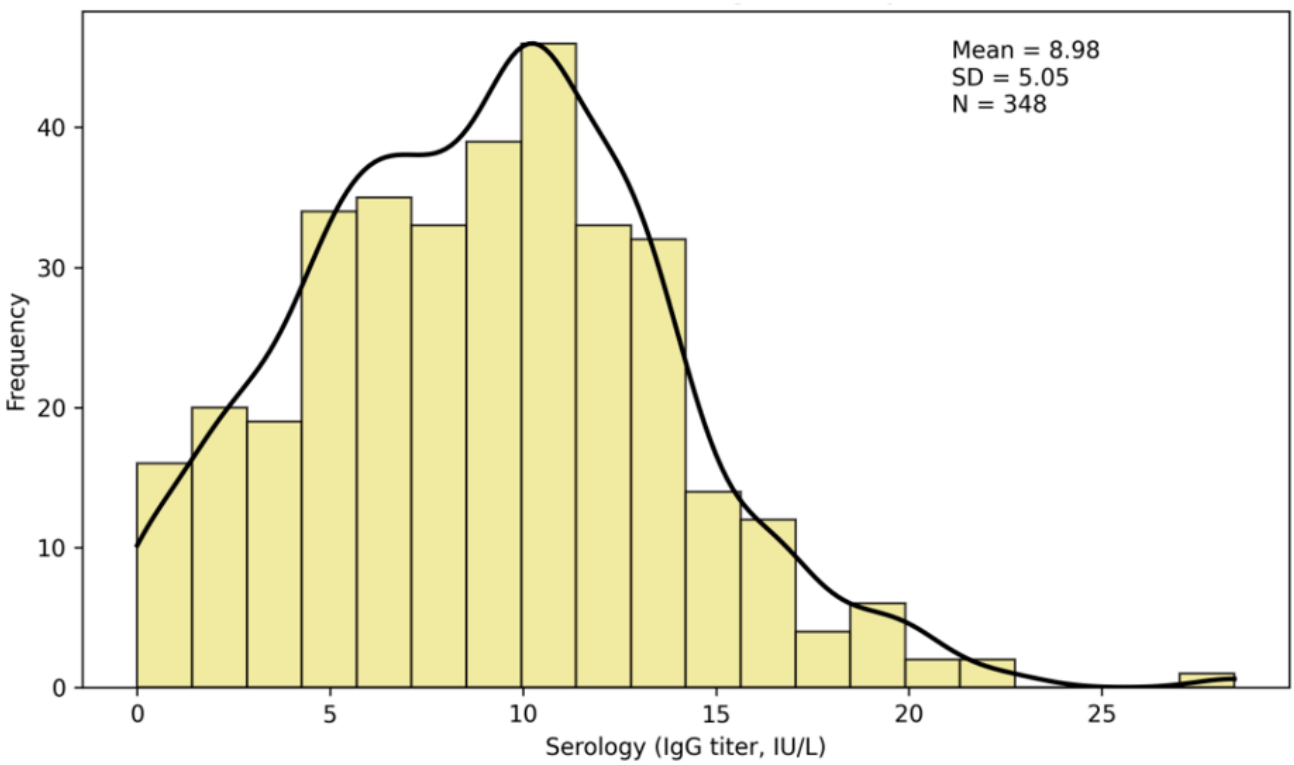


Figure 1

Distribution of Serology (IgG titer, IU/L) among participating children.

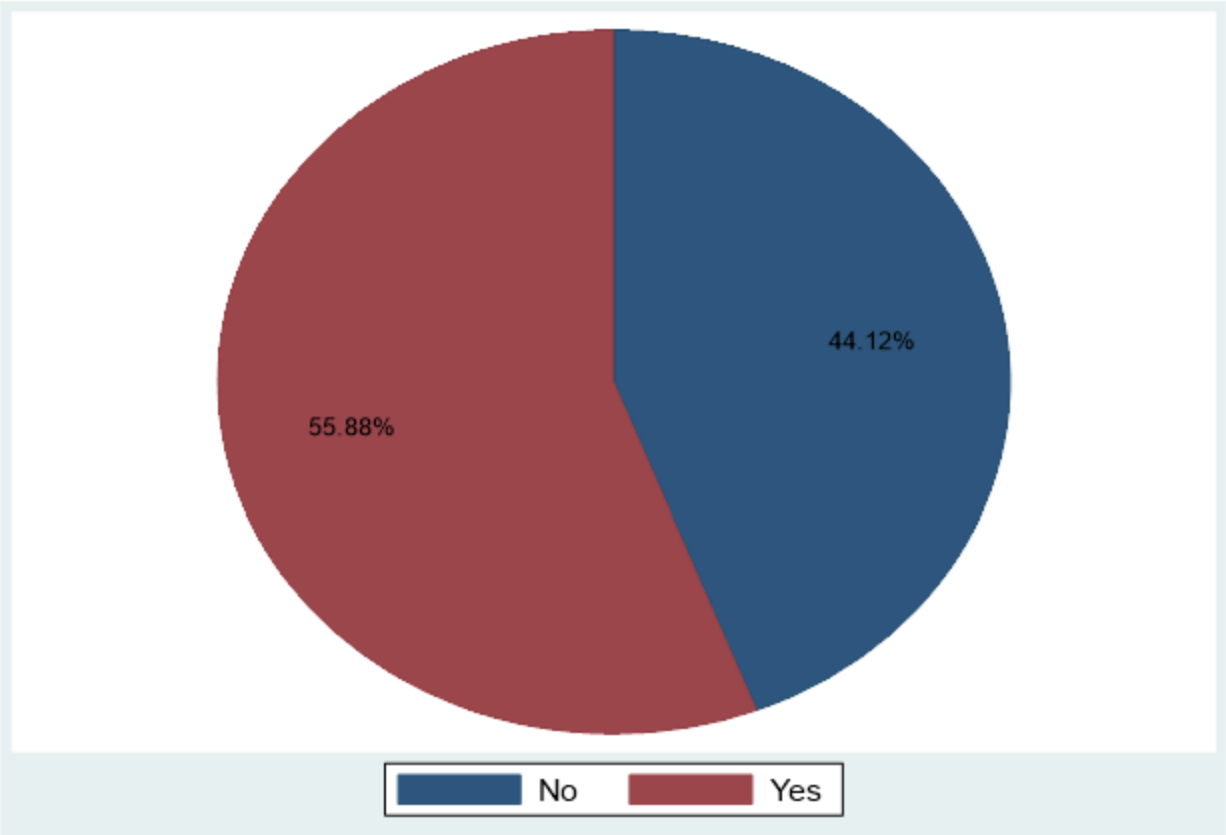


Figure 2

Distribution of participating children according to polio vaccine status