

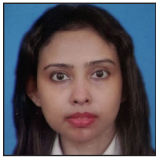


ORIGINAL ARTICLE IMMUNIZATION COVERAGE

Immunization Status, Immunization Coverage, and Factors Associated with Immunization Service Utilization Among HIV-Exposed and HIV-Infected Children in India

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ABSTRACT

Background and Objective: HIV-infected and HIV-exposed children are known to have a lower immunization coverage. However, the current immunization coverage for this group of children in India is unknown. The present study assessed the immunization status, service-utilization issues, and factors associated with immunization status among them.

Methods: A descriptive, cross-sectional, and multisite study was conducted in four districts (Nadia, Murshidabad, South and North 24 Parganas) of West Bengal, a state in the Eastern part of India. Children aged between 12 and 59 months were included in the study. A sample size of 131 was calculated using Cochrane's formula. Onsite data was collected using an interviewer-administered predesigned, pre-tested, face-validated, semi-structured schedule. Immunization status was the outcome variable. The unadjusted association of the outcome variable with other variables was tested by the Chi-square test and the adjusted association was tested by regression analysis.

Results: The mean age of the children was 35.5 months (± 15.7) and 50.4% were male. There were 18 (13.7%) HIV-infected children. Eighty-four percent of children were adequately immunized, but when considered along with the birth dose of the Hepatitis-B (Hep-B) vaccine, this reduced to 58.8%. Murshidabad district had the lowest proportion of fully immunized children (50%), while South 24 Parganas district had the lowest proportion of completely immunized children (60%). More than 95% of vaccinations were done in government facilities. Service utilization issues identified were lack of awareness of vaccine due dates and facing stigma from providers. Immunization status was associated with experience of stigma, mode and place of delivery by Chi-square test, it was only associated with stigma by regression analysis.

Conclusion and Global Health Implications: Relatively lower immunization coverage among children born of HIV-infected women can be attributed to parents' unawareness about vaccination due dates and facing stigma while accessing service. Measures like documenting vaccine due dates and training healthcare providers on non-discriminatory, respectful care may improve vaccination coverage.

Keywords: Human Immunodeficiency Virus, Child, Immunization, Social Stigma, Vaccination Coverage

INTRODUCTION

Background of the Study

Vaccines are critical tools to prevent and control more than 20 communicable diseases and therefore underpin global health security. The Immunization Agenda 2030 of the World Health Organization envisions a global strategy to leave no one behind.^[1] Hence, the cohort of children born to HIV-infected parents should have equal opportunities to complete immunization schedules

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like their peers. In the National Immunization Schedule of India (NIS), primary and most booster doses of vaccines are completed before human immunodeficiency virus (HIV) can be diagnosed, so perinatally exposed children should not be denied vaccines.^[2]

For HIV-infected children, the risk of serious infections and subsequent complications is higher.^[3] Fortunately, the widespread use of antiretroviral therapy (ART) has resulted in improved immunologic status for most HIV-infected children with practically no contraindication to vaccination. Nevertheless, healthcare providers responsible for immunization may miss opportunities for immunizing HIV-exposed and/or infected children because they are unaware of updated recommendations on vaccination. Often providers are concerned about greater risk with the use of vaccines among these children. African and European studies have found lower immunization coverage of HIV-infected children compared to uninfected peers, while a North American study found equally low vaccination coverage, in both groups for some of the vaccines.^[4-9] In a rural South African population, maternal HIV-positive status was independently associated with lower vaccination rates for four vaccines in children 12–23 months of age.^[10] However, an earlier study conducted at Kolkata in India in 2009 reported comparable immunization rates between HIV exposed and the general population.^[11] The current proportion of HIV-exposed children covered by all NIS vaccines is unknown as this information is not routinely collected under the HIV program. The care, support, and treatment (CST) component of the National AIDS Control Program Phase IV (NACP IV) of India spells out the provision of comprehensive care to women and children, infected and affected with HIV.^[12] This model of CST is to be maintained and expanded further under the ongoing fifth phase of NACP.^[13] Children born of HIV-infected parents are expected to be provided with comprehensive care in the broader context of child health strategies, with age-appropriate immunization being an essential component. With data and possible action gaps in the fundamental public health service of immunization, research is necessary to guide integrated actions under ongoing programs to control HIV and vaccine-preventable diseases (VPD).

Objectives of the Study

The objectives of the study were to assess the immunization status of HIV-exposed and HIV-infected children, service-utilization issues, and factors associated with immunization status among the study participants.

Specific Aims

The aim of the study was to find out if a considerable proportion of HIV-exposed and HIV-infected children

remain incompletely immunized and what service level factors can be changed to improve their immunization coverage.

METHODS

This study was a descriptive study of cross-sectional design and the study report follows the strengthening the reporting of observational studies in epidemiology (STROBE) guideline for reporting of observational studies.^[14]

Study Setting and Variables

This study was conducted in West Bengal, an eastern state of India with a population of 10,112,599. It is the fourth most populated state in India and is divided into 23 districts.^[15] The adult HIV prevalence in West Bengal is 0.08% with 2730 new infections in 2022.^[16] In India, based on high district-level HIV burden, districts are categorized as high (adult prevalence of $\geq 1\%$ or people living with HIV – PLHIV size of ≥ 5000) or moderate priority (adult prevalence of 0.4% to $\leq 1\%$ or PLHIV size of 2500 to ≤ 5000). West Bengal has 13 such districts (6 high and 7 moderate priority districts) contributing to 84% of PLHIV and 85% of new HIV infections.^[17] Each of these districts had community-based organizations (CBO) operated by PLHIVs and supported by the National AIDS Control Organization (NACO) of India. These CBOs run care support centers (CSC) with a mission to expand access to essential services and improve the quality of life of PLHIVs.^[18] CSCs provide a safe and acceptable space to PLHIVs, so district-level data was collected from CSCs. After feasibility assessment, two high (South and North 24 Parganas) and two moderate (Murshidabad and Nadia) priority districts were purposively selected for the study.

The National Immunization Schedule (NIS) of India mandates every child should complete a primary series of vaccines by 11 months of age. These include one dose of Bacillus Calmette Guerin (BCG), three doses of Oral Polio vaccine (OPV), Inactivated polio vaccine, Rotavirus vaccine (RVV), Pneumococcal Conjugate vaccine (PCV-10), Pentavalent vaccine, and one dose of Measles-Rubella (MR) vaccine. Additionally, the Hepatitis-B (Hep-B) vaccine, OPV-0 is given at birth for institutional deliveries, and the Japanese encephalitis (JE) vaccine is given along with MR in endemic areas. The booster or second doses of vaccines to be completed by 23 months include a second dose of MR (also JE in endemic areas), booster for diphtheria-pertussis-tetanus (DPT), and OPV. Dates of taking the vaccines and the due date for the next dose are to be documented in the immunization card; the variant used in the government health sector is known as the mother and child protection card (MCPC).^[19]

The study population was 12 to 59-month-old children whose one or both parents were HIV infected. Children living in any

of the four study districts of West Bengal whose caregivers could have been contacted by the CBOs working in the district and who were willing to participate were included in the study. Sick children, children lacking documents of immunization (MCPC or similar immunization card), and those who did not turn up at the study sites for data collection were excluded. Considering a priori immunization coverage proportion of 0.73 among HIV-exposed children,^[11] a relative error of 7.5% and α of 0.05, 95% confidence limit, the finite population of 5000, the calculated sample size was 131. A sample of 30–40 children was drawn purposively from each district.

The dependent variable in this study was the child's immunization status. Explanatory variables were demographic (age, sex, mothers' HIV status, parents' survival status), birth-related (mothers' ART during pregnancy, birth weight, type of delivery, place of delivery), service-related (place of vaccination, completeness of MCPC recording, experience of stigma, communication of immunization related key messages, immunization cards being ever checked at ART clinic).

Operational definitions were used for the assessment of variables. For early diagnosis of HIV-1 infection among HIV-exposed infants, NACO recommends total nucleic acid-polymerase chain reaction (TNA-PCR) test on dried blood spot (DBS) between 6 weeks to 6 months. Between 6 months to 18 months, both DBS and HIV serological tests are done. Infant and young children testing follows the National HIV Testing Algorithm 2015.^[20] Thus, *HIV-exposed* was defined as a child of unknown or negative serostatus with either or both seropositive parents, while *HIV-infected* was a child tested positive for HIV by early infant diagnosis (EID) before, at, or after 18 months. *Fully Immunized* (FI) child was one, who received primary doses of all vaccines according to the NIS schedule within 11 months of age (birth doses of the Hep-B vaccine and OPV-0 were not considered as per standard definition).^[19] *Completely Immunized* (CI) was a child who has received first boosters of all vaccines according to the NIS schedule within 23 months of age. *Dropout* was a child who has started the immunization schedule but has not completed all the primary and/or booster doses of vaccines within cut-off age limits (11 months or 23 months), while *left out* was a child who has not started the immunization schedule at all. *Adequate immunization status* (AI) was a child who was completely and/or fully immunized, all other children were considered as inadequate immunization status (InI). AI children who also received Hep-B birth dose were considered as *AI +Hep-B birth dose*.

A predesigned, pretested, semi-structured interview schedule and checklist were used for data collection. The CBOs working in the study districts were contacted and trained to

line list and mobilize caregivers of children eligible for this study. Fieldwork for data collection was conducted between November 2022 and February 2023. Researchers collected data onsite by interviewing caregivers for demographic details and by checking MCPC for immunization. Data collection was done by consecutive respondent interviews at the CSC on pre-fixed dates.

Statistical Analysis

For descriptive measures, frequencies and percentages were calculated for categorical variables and measures of central tendency and dispersion for continuous variables. Primary outcome measures were immunization status reported as fully/completely and adequately immunized. Bivariate analysis was conducted to find an association of demographic, birth-related, and service-related factors with adequate immunization by the Chi-square test. Multivariable logistic regression was conducted to find out adjusted measures for the explanatory variables. Missing data was deleted from the adjusted analysis. The statistical package for social sciences version 22 was used for analysis.^[21]

Ethical Approval

The study involved minimal risk as per the National Ethical guidelines for biomedical research involving children. There was likely benefit to children, in general, this study provides an opportunity for catch-up vaccination. As study participants were children less than 7 years of age, informed consent was taken from one or both parents. A reasonable participation allowance to compensate for traveling and wage loss was provided. Article 6.2 of the National Ethical Guidelines for Biomedical Research involving children developed by the Indian Council of Medical Research (ICMR), guides research on HIV-positive children, which was strictly adhered to by the present study.^[22] Data collection was anonymous. Serostatus and the identity of respondents were kept confidential.

The study protocol was approved by the independent ethics committee of Medical College Kolkata with approval number MC/KOL/IEC/NON-SPON/1299/04/22 dated 05/04/2022.

RESULTS

The final enrollment was 131 children, and all the caregivers completed their interviews.

Sociodemographic Characteristics

The mean age of the participants was 35.5 months with a standard deviation of 15.7 months. The demographic characteristics, birth history, and HIV serostatus of the participants along with their immunization status are shown

Table 1: Serostatus, demographic characteristics, birth history, and immunization status of participants (n = 131).

Variable categories	Number	Percentage
Serostatus		
Exposed	113	86.3
Infected	18	13.7
Sex		
Male	66	50.4
Female	65	49.6
Age group		
12–23 months	37	28.2
24–59 months	94	71.8
Respondent caregiver		
Mother	67	51.2
Father	56	42.7
Grandmother	8	6.1
Place of delivery		
Government	108	82.4
Private	16	12.2
Home	7	5.3
Type of delivery		
Vaginal	90	68.7
LUCS	41	31.3
Birth weight (n = 121)		
<2 kg	11	9.1
2–2.4 kg	22	18.2
≥2.5 kg	88	72.7
Mother on ART (antenatal)		
Yes	93	70.9
No	38	29.1
Living arrangement		
Lives with both parents	113	86.3
Otherwise [†]	18	13.7
Immunization status		
Fully immunized (12–23 months)	29/37	78.4
Completely immunized * (24–59 months)	72/94	76.6
Adequately immunized**	110	84.0
Drop out	19	14.5
Left out	02	01.5
Received Hep-B at birth	90	68.7
AI +Hep-B birth dose	77	58.7
Place of vaccination		
Government	125	95.4
Private	4	3.1

(Continued...)

Variable categories	Number	Percentage
Unvaccinated	2	1.5
Immunization according to district		
<i>Fully immunized</i>		
Nadia	8/9	88.9
Murshidabad	5/10	50.0
SPG	11/11	100.0
NPG	5/7	71.4
<i>Completely Immunized</i>		
Nadia	13/16	81.3
Murshidabad	24/30	80.0
SPG	15/25	60.0
NPG	20/23	86.9
<i>AI+ Hep-B birth dose</i>		
Nadia	17/25	68.0
Murshidabad	23/40	57.5
SPG	22/36	61.1
NPG	15/30	50.0
Participation in Intensive Pulse Polio Immunization (IPPI) rounds		
Yes	116	88.5
No	15	11.5
Reported stigmatization by healthcare providers		
Yes	20	15.3
No	111	84.7

† Living with a single parent, grandparents, other relatives, or foster care. * There were nine children between 12 and 23 months who were completely immunized. ** 1 child did not complete primary doses before 12 months, but completed booster within 23 months. LUCS: Lower uterine cesarean section, ART: Anti-retroviral therapy, AI: Adequately immunized, SPG: South 24 parganas district, NPG: North 24 parganas district, Sig: Significance, IPPI: Intensive pulse polio immunization.

in Table 1. Most mothers were respondents (51.2%). There were 18 (13.7%) children who were HIV infected. Most children (108, 82.4%) were born in government institutes but 5.3% of the mothers delivered at their homes. All respondents lived in rural areas and within 5 km of any level of government health facility. The higher proportion of participants was in the 24–59 months age group.

Childhood Immunization Status

The distribution of children according to their immunization status and healthcare-seeking behavior is also shown in Table 1. There were 110 (84%) adequately immunized children, with nearly equal proportions of fully and completely immunized children. There were 90 (68.7%) children who received Hep-B vaccination at birth. The majority of participants (95.4%)

received vaccines from government facilities. There were only two MCPCs that had properly documented due dates for the next immunization visit. There were two more MCPCs where HIV status was written. Stigma experienced while seeking immunization service was reported by 20 (15.3%) respondents.

The overall proportion of complete immunization coverage was almost similar at around 77% but adequate immunization (AI, either FI/CI as per age criteria) and also receipt of Hep-B birth dose was much lower at 58.8%. This low level of AI+Hep-B coverage was seen across all districts with a range of 50%–68%. The proportion of FI was lower compared to CI in Murshidabad and North 24 Parganas (NPG) while the opposite pattern was seen at Nadia and South 24 Parganas (SPG). At SPG, there was a large gap of 40% between FI and CI children. Murshidabad was found to have a low value for FI children. Left-outs were also recorded for this district. The main reasons cited by caregivers of 21 left-out or dropout children for missing vaccines were being unaware of due dates followed by experience of stigma due to provider's discrimination.

Predictors of Adequate Immunization

The associations of adequate immunization status by Chi-square test and multivariable regression analysis are shown

Table 2: Factors associated with adequate immunization status by bivariate and multivariable regression analysis.

Variable	AI Number (%)	Chi-square (df; p)	Exp (B)	Sig
Age				
12–23 months	28 (75.7)	2.63 (1, 0.10)	0.32	0.15
24–59 months ^a	82 (87.2)			
Sex				
Male	58 (87.9)	1.51 (1, 0.22)	2.08	0.31
Female ^a	52 (80.0)			
Serostatus				
HIV infected	16 (88.9)	0.37 (1, 0.54)	0.38	0.49
HIV exposed ^a	94 (83.2)			
Study district				
Nadia	23 (92.0)	4.40 (3, 0.22)	3.35	0.33
Murshidabad	30 (75.0)		0.57	0.61
SPG	30 (83.3)		1.43	0.74
NPG ^a	27 (90.0)			

(Continued...)

Variable	AI Number (%)	Chi-square (df; p)	Exp (B)	Sig
Mother on ART				
Yes	76 (81.7)	1.21 (1, 0.27)	0.07	0.07
No ^a	34 (89.5)			
Place of delivery				
Government	91 (84.3)	11.85 (2, 0.003)**	3.03	0.213
Private	16 (100)		594	
Home ^a	3 (42.9)		-	
Type of delivery				
Vaginal	70 (77.7)	8.19 (1, 0.004)**	0.143	0.069
LUCS ^a	40 (97.6)		-	
Birth weight				
<2.5 kg	28 (84.8)	0.04 (1, 0.83)	0.77	0.76
≥2.5 kg ^a	76 (86.4)			
Place of vaccination				
Government	107 (86.3)	0.41 (1, 0.523)	2.6	0.55
Private ^a	3 (75.0)			
IPPI participation				
Yes	99 (85.3)	1.42 (1, 0.23)	8.17	0.07
No ^a	11 (73.3)			
Stigmatized by providers				
Yes	11 (55.0)	14.72 (1, <0.001)**	0.199	0.04*
No ^a	99 (89.2)		-	

^aReference category, *p < 0.05 **p < 0.01. LUCS: Lower uterine cesarean section, ART: Anti-retroviral therapy, AI: Adequately immunized, SPG: South 24 parganas district, NPG: North 24 parganas district, Sig: Significance, IPPI: Intensive pulse polio immunization, Exp (B): Exponential beta, df: Degrees of freedom, p: Probability.

in Table 2. Place and type of delivery and experience of stigma were significantly associated with AI status. However, by multivariable regression, only experience of stigma was significantly associated. Experience of stigma made a child 80% less likely to be adequately immunized.

DISCUSSION

The present study assessed the immunization status, service-utilization issues, and factors associated with immunization status among HIV-exposed and HIV-infected children. The study reports a fair coverage of HIV-exposed children with primary and booster doses of vaccines, with 110 (84%)

children having adequate immunization. Vaccination coverage varied by district with low coverage of the primary series in Murshidabad (40%), and that for the boosters in South 24 Parganas (60%). The only pattern consistent throughout districts was low coverage when adequate immunization status was considered along with the birth dose of the Hep-B vaccine. Immunization did not vary according to sex, serostatus, or living arrangement. Place and type of delivery, facing stigma while accessing service were associated with immunization status in Chi-square test; however, facing stigma was the only association by multivariable analysis.

When district-wise adequately immunized children were compared with the national level survey endorsed by the Government of India, the National Family Health Survey-5th round (NFHS-5) report, it was found that the vaccination coverage among HIV-exposed children for all four districts except Nadia was lower than that reported among the general population in NFHS-5. The lower coverage of the Hep-B vaccine birth dose and consequently lower values of age-appropriate vaccination was consistent with NFHS-5 data. Adequately vaccinated children who also received Hep-B birth dose vaccine were much higher than NFHS-5 data for Nadia [Table 3]. The overall estimate from this study for AI was 84% and AI with Hep-B birth dose was 58.8%, which is lower than the West Bengal state estimate of 87.9% and 63%, respectively.^[23]

There is a decreased immune response to vaccines with increasing age in HIV-infected children, so immunizations should take place early.^[9] Delayed vaccinations and being dropped out or left out are of concern for HIV-infected children. Early immunization is especially important for the Hep-B vaccine because of the higher risk of becoming a chronic carrier among HIV-infected children and adults than for uninfected persons.^[10] Some issues identified in this study that could have resulted in missing immunization appointments

were non-recording of vaccine due dates in the MCPC, lack of understanding and initiative among HIV-outreach workers on the importance of childhood vaccinations, and undesirable attitude of immunization providers while vaccinating HIV-exposed children. There must have been multiple missed opportunities for vaccination as all the children lived within 5 km of a health facility, they had confidence in government health services and largely utilized healthcare from the government sector and came in contact with providers for vaccination as well as HIV care services. An analysis from 92 countries reports lower vaccination uptake among poor and marginalized communities.^[24] Gavi, the vaccine alliance, defines such vulnerable and deprived groups as “missed communities”.^[25] Mother’s social cohesion was associated with childhood immunization in a study from Uttar Pradesh, while another study from Delhi reported lower immunization coverage among recently settled migrants.^[26,27] Both studies indicate social isolation as a possible reason for incomplete immunization. Gurnani reports lower awareness to be the main reason for missing vaccine doses in supplementary rounds (45%) with operational factors contributing a mere 4%. In the present study, however, operational factors were important in missing doses as stigma was associated with lower vaccination coverage.^[28] Gaps identified in the implementation of immunization programs and the stigma faced by parents/guardians need to be addressed to improve immunization coverage among HIV-exposed children. Elimination of VPDs necessitates that no one should be left behind.

Strengths and Limitations of the Study

The strength of the study lies in the geographical coverage and CBO involvement in data collection which allowed us to recruit a representative sample and derive reliable estimates.

The immunization status of children was decided based on MCPC entries, so in the unlikely situation of incorrect MCPC entries would have affected the result. Parents living in remote areas might not have participated. Stigma might require further qualitative exploration and viewpoints of multiple stakeholders. These were a few limitations of the study.

CONCLUSION AND GLOBAL HEALTH IMPLICATIONS

There was lower vaccination coverage among HIV-exposed/infected children. Overall, one out of every five HIV-exposed children had inadequate vaccination. Facing stigma while seeking immunization services, incomplete documentation, lack of sensitization of the manpower involved in HIV control about childhood immunizations, and immunization providers on vaccinating HIV-exposed children are the possible reasons for lower immunization coverage.

Table 3: Comparison of vaccination coverage between the present study and NFHS-5.

District	All basic vaccinations [†] (% of children)		Age-appropriate vaccinations ^{††} (% of children)	
	NFHS-5	Present study	NFHS-5	Present study
SPG	92	83.4	59	61.1
NPG	93	90	63.3	50
Murshidabad	90	75	63	57.5
Nadia	90	92	43.1	68

[†]Comparable with % AI; ^{††}Comparable with % AI+ Hep-B birth dose. NFHS: National family health survey, SPG: South 24 parganas district, NPG: North 24 parganas district.

This study has implications related to government policy, health programs as well as public health practice. The HIV/AIDS (Prevention & Control) Act, 2017 provides non-discriminatory healthcare services to PLHIVs,^[29] however, in practice, there are gaps, as pointed out in this study. Targeted training programs for healthcare providers on NIS and special situation vaccinations, non-discriminatory, respectful care, and community awareness campaigns to minimize stigma are suggested for policy and practice. Supplementary immunization drives known as Intensified Mission Indradhanush (IMI)^[30] are conducted in India but they need to be planned in consultation with CBOs so that immunization dropout HIV-infected and exposed children can be aligned with the immunization schedule. Leaving pockets of unvaccinated or partially vaccinated children has important public health implications as they will contribute to childhood mortality and decelerate the progress toward the elimination of vaccine-preventable diseases. The study findings should alert doctors and other healthcare professionals associated with HIV care to be observant about the immunization status of these children. Missed opportunities during HIV testing and ART refills should be eliminated. Providers should bring in practice to fill due dates for vaccines in MCPCs and communicate with the parents. The CBOs can play a pivotal role in extending healthcare services to PLHIVs, even CSCs can be used as outreach sites for vaccination and similar preventive healthcare services. It cannot be overemphasized, that giving equal chance of vaccination to all children is an issue of global health equity and it must be addressed.

Key Messages

- A variable proportion of HIV-exposed and infected children may remain incompletely immunized
- Communicating and documenting vaccine due dates and training providers on respectful care can improve coverage
- HIV care providers are missing opportunities to align beneficiaries for vaccination catch-up

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COMPLIANCE WITH ETHICAL STANDARDS

Conflicts of Interest

One of the authors (Dr Rahul Biswas) holds the office of West Bengal State AIDS Prevention & Control Society

(WBSAP&CS) as Joint Director of Care, Support & Treatment. Other authors have no conflicts of interest. No objection certificate for publishing the research has been obtained.

Financial Disclosure

Nothing to declare.

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Ethics Approval

The study protocol was reviewed and approved by the independent ethics committee of Medical College Kolkata with approval number MC/KOL/IEC/NON-SPON/1299/04/22 dated 05/04/2022.

Declaration of Participant Consent

The authors certify that they have obtained all appropriate participant consent.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology/LLMs for assisting in the manuscript preparation.

Disclaimer

None.

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