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Vertical transmission of HIV to neonates in a reference hospital in Northeastern Brazil from 2013 to 2017

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ABSTRACT

The aim of this study was to estimate the rate of Mother-to-child Transmission (MTCT) of HIV to neonates in a reference university hospital in Sao Luis city, the capital of Maranhao State (MA), evaluating MTCT-associated factors. A retrospective cohort study based on data from the Notifiable Diseases Data System (SINAN) was carried out and included all HIV-exposed neonates notified from 2013 to 2017 by the university hospital. The study population comprised 725 HIV-exposed neonates, of whom 672 neonates were exposed and uninfected, and 53 were exposed and infected. The estimated rate of MTCT in the period of 2013 to 2017 was 7.3%. Most pregnant women were ≥ 20 years old (86.9%), reported ≥ 8 years of schooling (53.2%), reported full-time or independent paid work (46.9%) and were residents in other cities of the state (61.7%). Regarding healthcare, 86.3% received prenatal care, 74.6% received Antiretroviral Therapy (ART) as prophylaxis during pregnancy, 81.8% received ART prophylaxis during childbirth and 78.1% underwent cesarean section. Among the neonates, 92.8% received ART prophylaxis and 94.3% were not breastfed. Despite these variables, the 7.3% MTCT rate found in this study makes it clear that the interventions recommended by the Ministry of Health were not fully adopted.

KEYWORDS: Vertical transmission of infectious diseases. Infectious complications in pregnancy. HIV infections. Incidence.

INTRODUCTION

In 2019, there were approximately 38 million persons living with HIV worldwide, of which 1.8 million were children from 0 to 14 years old[1]. In Brazil, in 2019, there were 43,312 new HIV cases notified on the Notifiable Diseases Data System (SINAN), of which 11,879 were females and 8,268 were pregnant women[2]. At the United Nations General Assembly, world leaders committed to ending HIV epidemics by 2030, being essential to concentrate efforts on the reduction of Vertical Transmission (VT) of HIV[3,4] because it is the main mode by which infants worldwide acquire HIV-1 infection[3,5,6].

The dynamics of HIV/AIDS has changed over the decades. Presently, HIV/AIDS epidemics are characterized by the increase of cases among the heterosexual population, with rising incidence rates in females, especially among women of reproductive age, resulting in the growing risk of mother-to-child transmission of HIV[7-10]. In Brazil, in the period from June 2000 to June 2021, there were 141,025 notifications of pregnant women infected with HIV. When comparing a period of 10 years, there was an increase of 30.3% in the rate of HIV detection

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among pregnant women, rising from 2.1 cases/thousand live births in 2010 to 2.7 cases/thousand live births in 2020. In Maranhao State, the rate of HIV detection among pregnant women in the same period rose from 1.0 case/thousand live births to 2.1 cases/thousand live births[2].

The first case of vertical transmission of HIV was described in 1982 in the United States of America (USA) by the Centers for Disease Control and Prevention (CDC); in Brazil, it was diagnosed in 1983, in the same period when two cases of AIDS in women were registered[4,9]. Several studies show that the vertical transmission of HIV can occur during pregnancy in 35% of cases and during labor and childbirth in 65% of cases; breastfeeding increases the risk of transmission between 7% and 22%; and in planned pregnancies with interventions adequately conducted during prenatal, birth and breastfeeding, the risk of vertical transmission of HIV is reduced to less than 2%[9,11,12].

In Brazil, the vertical transmission rates described in studies vary widely from 1.8% to 27.8%, presenting significant reductions through the years, although with differences between the country's regions and still demonstrating gaps in health care services regarding prevention[3]. The monitoring of mother-to-child transmission (MTCT) of HIV is based on the indicator of AIDS detection rate in children who are ≤ 5 years old. In the past decade, this rate presented a reduction from 4.0 cases/one hundred thousand inhabitants in 2010 to 1.2 cases/one hundred thousand inhabitants in 2020, corresponding to a decrease of 69.7%[2]. Much of this decrease is due to protocols and directives instituted by the Ministry of Health for the reduction of vertical transmission[12-14].

Several studies point as main risk factors of vertical transmission: maternal variables, such as high Viral Load (VL), no Antiretroviral Therapy (ART) received as prophylaxis during pregnancy, and smoking; obstetrical variables, such as not conducting cesarean section when VL is > 1,000 copies/mL after 34 weeks and membrane rupture > 4 h; and neonatal variables, such as low birthweight, breastfeeding, and preterm birth[5,9,12,15]. The main prophylactic measures adopted by the Ministry of Health for the prevention of vertical transmission of HIV, according to Protocol 076 (PACT 076) of the AIDS Clinical Trials Group, World Health Organization (WHO), were: use of ART during pregnancy; use of injectable ART during childbirth; conducting cesarean section when indicated; use of oral ART in the exposed neonate; and inhibition of lactation associated with the use of infant formula[2,16-20].

Despite the advances in the prevention of vertical transmission, data point out that, in 2019, there were 1.8 million children worldwide living with HIV and over 150,000 were recently infected[1,3]. In Brazil, in 2015, in all regions of the country, there were 7,901 cases notified of infected pregnant women and 62 cases of infection with HIV in children who were ≤ 5 years old, and it is estimated that vertical transmission on a national level is currently between 15% and 24%[3,21]. Even with all available prophylactic measures, the prevention of vertical transmission of HIV remains a public health problem and a great challenge in Brazil, especially in the Northeastern region, where there is a lack of resources and favorable socioeconomic conditions for the population's health. Therefore, the aim of this study was to estimate the rate of vertical transmission of HIV in a reference university hospital in Sao Luis city and evaluate the factors related to MTCT in the period from 2013 to 2017.

MATERIALS AND METHODS

Study design and population

This is a prospective cohort study based on the analysis of SINAN notification and investigation data. The analysis included all HIV-exposed neonates notified from 2013 to 2017 by the University Hospital of Maranhao, in Sao Luis city, the capital of Maranhao State. It is a public reference hospital for specialized high-risk mother-child care. The study population comprised 725 notification records of neonates exposed to HIV and medical records of pregnant women infected with HIV and their exposed neonates.

The specialized prenatal ambulatory care receives seropositive pregnant women already being followed up at the hospital or who were referred by the regulation system. The pregnant women infected with HIV who are admitted to the hospital for delivery may or may not have received prenatal care at the hospital; they may have had the obstetric reception as their entry door. After birth, the neonates are followed up in a specialized pediatric ambulatory care for HIV-exposed children.

This study comprised all records of HIV-exposed children notified by and investigated at the University Hospital of the Federal University of Maranhao in the period from 2013 to 2017. The records of HIV-exposed children with blank or ignored form fields that are essential epidemiological variables, besides duplicity, were excluded from this study.

This study considered as infected the HIV-exposed neonates with two detectable viral loads and an indirect immunofluorescence confirmatory test or Western Blot at the age of 18 months[12]. The rate of vertical transmission of HIV was calculated using the number of neonates infected at birth to women infected with HIV as the numerator and the total number of neonates born to women infected with HIV as the denominator, multiplied by 100.

Data collection and analysis

A database was organized in an Excel spreadsheet to collect data of pregnant women infected with HIV (schooling, ethnicity, occupation, age, prenatal care, antiretroviral prophylaxis during pregnancy and birth, mode of delivery) and of their exposed babies (antiretroviral prophylaxis, weeks of prophylaxis, breastfeeding). These epidemiological data were obtained from the notification and investigation records of children exposed to HIV.

The variables of this study were described as proximal, intermediary and distal, according to the weight of the outcome variable found in the literature. The distal block variables were: maternal age, maternal schooling, maternal occupation, maternal ethnicity, and municipality of residence. The intermediary variables were: received prenatal care and received ART prophylaxis during prenatal care. The proximal variables were: mode of delivery, ART prophylaxis during childbirth, ART prophylaxis in the neonate, total duration of use of oral ART in the neonate, and maternal breastfeeding. Figure 1 shows the blocks of variables.

The variables were defined as: 1) Response variable: vertical transmission of HIV infection; 2) Explanatory variable: sociodemographic data (age, schooling, occupation, ethnicity and municipality of residence), data related to prenatal care (received prenatal care and received ART prophylaxis during prenatal care), data related to care during childbirth and to the neonate (mode of delivery, ART prophylaxis during childbirth, ART prophylaxis in the neonate, total duration of ART prophylaxis in the neonate).

The adequate prophylactic measures adopted were divided into: Stage 1 – during pregnancy (ART during pregnancy); Stage 2 – during childbirth (intravenous ART and definition of mode of delivery according to VL); and Stage 3 – in puerperium (oral ART in the neonate associated or not with Nevirapine, and inhibition of breastfeeding associated with infant formula until the age of six months[12]).

The Chi-square test was used for the univariate analysis of the association between HIV infection and maternal age, schooling, occupation, ethnicity, municipality of residence, use of ART during prenatal care and childbirth, mode of delivery, weeks of ART prophylaxis in the exposed baby, and breastfeeding. An analysis using Poisson's logistic regression was conducted to evaluate the association between the presence or absence of infection and the other explanatory variables. The variables are categorized and described on tables containing the absolute and relative frequencies. The factors associated with vertical transmission were evaluated using Chi-Square, and the net and adjusted prevalence ratios were obtained using Poisson's regression, with robust adjustment for variance, and with the calculation of p-value for heterogeneity or

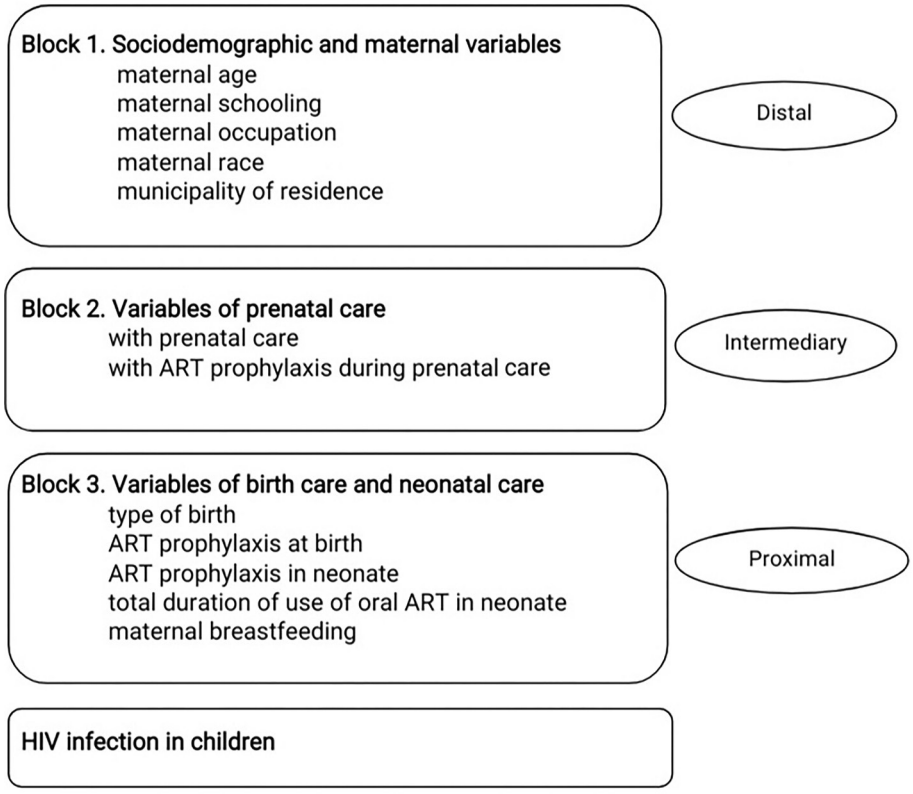

Figure 1 - Hierarchical model for HIV infection in children

linear tendency for ordinal variables. All analyses were performed using statistics and data science software Stata (version 14, StataCorp LLC, College Station, Texas, USA).

Ethical aspects

This research received the approval of the Human Research Ethics Committee of the University Hospital of the Federal University of Maranhao, through the Substantiated Opinion Nº 2.959.231. The Free and Informed Consent Form was not applied to this research due to the use of secondary data.

RESULTS

In the period from 2013 to 2017, there were notifications/investigations of 774 cases of HIV-exposed children, of which 49 were excluded because there was no definition of serological status due to loss of follow-up; thus, the researched population comprised 725 cases of HIV-exposed children. From the total number of HIV-exposed children, 672 were non-infected and 53 were infected. Therefore, the general estimated rate of MTCT in the period was 7.3%, while the absolute number of infection cases per year was 7 in 2013, 12 in 2014, 10 in 2015, 14 in 2016, and 10 in 2017, as shown in Figure 2. The highest estimated rate during this period occurred in 2016 (10.4%).

The age of seropositive pregnant women varied from 14 to 44 years old, and most of them were ≥ 20 years old (86.9%); reported ≥ 8 years of schooling (53.2%); self-identified as black (92.7%); reported full-time or independent paid work (46.9%); are residents in other municipalities of Maranhao State (61.7%); received prenatal care (86.3%); received ART prophylaxis during pregnancy (74.6%); underwent cesarean section (78.1%); received ART prophylaxis during childbirth (81.8%); had ART prophylaxis performed in the neonate (92.8%); had the adequate duration of ART prophylaxis in the neonate (93.1%); and had the suppression of lactation (94.3%). No association was found between vertical transmission of HIV and the characteristics of age, occupation, and municipality of maternal residence. All intermediary and distal variables of the hierarchical model had association with vertical transmission, as presented in Table 1.

In the unadjusted and adjusted analysis of distal factors of the hierarchical model, the schooling and ethnicity of the seropositive mother had an association with the vertical transmission of HIV, with p-value in the adjusted analysis of 0.048 and 0.017, respectively, as shown in Table 2.

In the unadjusted and adjusted analysis of intermediary factors of the hierarchical model, the variables of prenatal care and ART prophylaxis during prenatal care had an association with the vertical transmission of HIV, with a p-value in both the unadjusted and adjusted analysis of < 0.001, as presented on Table 3.

In the unadjusted and adjusted analysis of proximal factors of the hierarchical model, all variables had an association with the vertical transmission of HIV, with a p-value in the unadjusted analysis of < 0.001; however, in the adjusted analysis, the mode of delivery and the suppression of lactation did not have association with vertical transmission, as presented in Table 4.

DISCUSSION

The estimated vertical transmission rate in the period

Figure 2 - Number of infected and non-infected children, based on SINAN investigation records by a reference university hospital in Sao Luis city, Maranhao State, Brazil, 2013 to 2017 (n = 725).

Table 1 - Sociodemographic and clinical characteristics of seropositive pregnant women and children exposed to HIV, based on SINAN notification and investigation records by a university hospital in Sao Luis city, Maranhao State, Brazil, 2013 to 2017 (n = 725).

CHARACTERISTICS	General		HIV vertical transmission				p-value*
			Negative (n = 672)		Positive (n = 53)		
	n	(%)	n	(%)	n	(%)	
Maternal age group							0.385
< 20 years	95	13.10	86	12.80	9	16.98	
≥ 20 years	630	86.90	586	87.20	44	83.02	
Maternal schooling							**0.039**
< 8 years	339	46.76	307	45.68	32	60.38	
≥ 8 years	386	53.24	365	54.32	21	39.62	
Maternal ethnicity							**0.024**
Black**	672	92.69	627	93.30	45	84.91	
Non-black**	53	7.31	45	6.70	8	15.09	
Maternal occupation							0.863
Works (full-time or independent paid work)	340	46.90	317	47.17	23	43.40	
Does not work	318	43.86	293	43.60	25	47.17	
Student	67	9.24	62	9.23	5	9.43	
Municipality of residence							0.118
Sao Luis	278	38.34	263	39.14	15	28.30	
Other municipalities	447	61.66	409	60.86	38	71.70	
Prenatal care							**< 0.001**
Yes	626	86.34	606	90.18	20	37.74	
No	99	13.66	66	9.82	33	62.26	
Prenatal prophylaxis							**< 0.001**
Yes	541	74.62	530	78.87	11	20.75	
No	184	25.38	142	21.13	42	79.25	
Mode of delivery							**< 0.001**
Cesarean	566	78.07	540	80.36	26	49.06	
Vaginal	159	21.93	132	19.64	27	50.94	
Prophylaxis at childbirth							**< 0.001**
Yes	593	81.79	572	85,12	21	39.62	
No	132	18.21	100	14,88	32	60.38	
Prophylaxis in the neonate							**< 0.001**
Yes	673	92.83	646	96.13	27	50.94	
No	52	7.17	26	3.87	26	49.06	
Prophylaxis duration in the neonate							**< 0.001**
Adequate	675	93.10	649	96.58	26	49.06	
Inadequate	50	6.90	23	3.42	27	50.94	
Maternal breastfeeding							**< 0.001**
No	684	94.34	650	96.73	34	64.15	
Yes	41	5.66	22	3.27	19	35.85	

*Chi-Square; **Black: includes brown and black; Non-black: includes white, Asian and indigenous.

from 2013 to 2017 was 7.3%. It is considered high, almost four times higher, in relation to the rate of HIV/AIDS in children aged ≤ 5 years in 2017 – 2.0% in Brazil and 2.6% in Maranhao State. It is noteworthy that in 2014 and 2016, in Maranhao State, this rate was 3.0% and 5.1%, respectively[2]. It should be stressed that most of the study population lives

Table 2 - Unadjusted and adjusted analysis of sociodemographic and maternal variables associated with vertical transmission of HIV, based on SINAN notification and investigation records by a university hospital in Sao Luis city, Maranhao State, Brazil, 2013 to 2017 (n = 725).

VARIABLES	Unadjusted		p-value	Adjusted		p-value
	PR*	CI ∞ (95%)		PR*	CI*** (95%)	
Maternal age group			0.383			0.796
> 20 years		1			1	
≤ 20 years	0.73	0.37 – 1.46		0.90	0.43 – 1.90	
Maternal schooling			0.042			0.048
< 8 years		1			1	
≥ 8 years	1.73	1.02 – 2.95		1.72	1.00 – 2.96	
Maternal occupation			0.863			
Works (full-time or independent paid work)		1			1	0.679
Does not work	1.16	0.67 – 2.00		1.27	0.73 – 2.22	
Student	1.10	0.43 – 2.80		1.23	0.43 – 3.51	
Maternal ethnicity			0.023			0.017
Non-black**		1			1	
Black**	0.44	0.22 – 0.89		0.42	0.21 – 0.86	
Municipality of residence			0.124			0.159
Sao Luis		1			1	
Other municipalities	1.57	0.88 – 2.81		1.53	0.84 – 2.77	

*PR = Prevalence ratio > Poisson regression, with robust adjust for variance; **Black: includes brown and black; Non-black: includes white, Asian and indigenous; ***CI = Confidence Interval.

Table 3 - Unadjusted and adjusted analysis of prenatal care variables associated with vertical transmission of HIV, based on SINAN notification and investigation records by a university hospital in Sao Luis city, Maranhao State, Brazil, 2013 to 2017 (n = 725).

VARIABLES	Unadjusted		p-value	Adjusted		p-value
	PR*	CI ∞ (95%)		PR*	CI** (95%)	
Prenatal care			**< 0.001**			**< 0.001**
Yes		1			1	
No	10.43	6.24 – 17.43		4.00	2.35 – 6.81	
Prenatal prophylaxis			**< 0.001**			**< 0.001**
Yes		1			1	
No	11.22	5.90 – 21.35		5.44	2.74 – 10.79	

*PR = Prevalence ratio > Poisson regression, with robust adjust for variance; **CI = Confidence Interval.

in other municipalities of the state and not in the capital. Thus, the vertical transmission rate found is far from that recommended by the Ministry of Health, which is 2%[12]. It is also higher than the rate of 6.3% found in Itajai city[22], the municipality in Brazil with the highest rate of HIV detection in children aged ≤ 5 years[19,23].

These data corroborate the findings of a study that assessed MTCT reduction in Brazil, in the period of 1994 to 2016, stratified the country's prognostics per region and found that the Northeastern region[5,24-26] had the highest number of states with unfavorable perspective, followed by the Northern[26,27] and the Central-western[19,26] regions.

During the past decades, multicentric studies have found a tendency of reduction of the vertical transmission of HIV in Brazil since 1997[7,28,29]. However, when comparing the results found in this study with the other regions of the country, it was observed that the data are high, similar to those found in other states of the Northeastern, Northern and Central-western regions, where local studies found transmission rates of 6.9% in Acre State[17], 9.2% in Pernambuco State[25], and 8.7% in Mato do Grosso do Sul State[19], respectively. By contrast, other regions were successful in the rate reduction; for example, local studies found evidence of transmission rate of 1.9% in Belo

Table 4 - Unadjusted and adjusted analysis of variables of care at birth and neonatal care associated with vertical transmission of HIV, based on SINAN notification and investigation records by a university hospital in Sao Luis city, Maranhao State, Brazil, 2013 to 2017 (n = 725).

VARIABLES	Unadjusted		p-value	Adjusted		p-value
	PR*	CI ∞ (95 %)		PR*	CI** (95 %)	
Mode of delivery			**< 0.001**			0.798
Cesarean		1			1	
Vaginal	3.69	2.22 – 6.15		0.92	0.48 – 1.73	
Intravenous ART prophylaxis at labor and delivery			**< 0.001**			**0.042**
Yes		1			1	
No	6.84	4.08– 11.48		2.73	1.03 – 7.22	
Prophylaxis in the neonate			**< 0.001**			**0.002**
Yes		1			1	
No	12.46	7.87 – 19.72		0.18	0.06 – 0.53	
Prophylaxis duration in the neonate			**< 0.001**			**< 0.001**
Adequate		1			1	
Inadequate	14.01	8.88 – 22.11		32.65	21.60 – 49.36	
Maternal breastfeeding			**< 0.001**			0.620
No		1			1	
Yes	9.32	5.85 – 14.84		1.22	0.55 – 2.70	

*PR = Prevalence ratio > Poisson regression, with robust adjust for variance; **CI – Confidence Interval

Horizonte city[28] and 2.4% in Santa Maria city[30]. The high estimated rate of this study also corroborates the increasing rates of infection during childhood in Angola, Congo, Equatorial Guinea, Guinea-Bissau, and some regions of Brazil[3,19,31]. A meta-analysis conducted in Ethiopia and India found rates of 11.4% and 8.7%, respectively[32,33].

In relation to sociodemographic variables in the adjusted analysis, the maternal age (p-value = 0.796) did not present an association with vertical transmission. This corroborates studies conducted in Belo Horizonte city[28], Amazonas State[27], Acre State[17] and Ethiopia[34]. However, maternal schooling (p-value = 0.048) and maternal ethnicity (p-value = 0.017) demonstrated an association with vertical transmission, i.e., women with schooling < 8 years and black skin color are more exposed to the risk of vertical transmission. Studies conducted in Acre State[17], Belo Horizonte city[28] and Rio de Janeiro city[9] found that most of the seropositive pregnant women were of black or brown skin color and presented a low level of schooling. According to the Ministry of Health[2,35], in Brazil, women of brown skin color correspond to 49.8% and women of black skin color correspond to 14.2% of pregnant women infected with HIV, which corroborates the findings of this research. In relation to occupation (p-value = 0.863), there was no finding of association with vertical transmission. It was observed that most of the seropositive pregnant women who presented vertical transmission did not have paid work, and this result was also found in studies in Pernambuco State[8] and Rio de Janeiro city[9].

The findings of this research show that receiving prophylaxis during prenatal care and birth had association with vertical transmission in the adjusted analysis. Regarding prenatal prophylaxis, VT occurred in 20.7% (11) of pregnant women who underwent ART and in 79.2% (42) of those who did not undergo ART. Regarding childbirth, VT occurred in 39.6% (21) of those who underwent prophylaxis during childbirth and in 60.3% (32) of those who did not undergo ART. Several national and international studies have demonstrated that the association of prophylaxis during prenatal care and during childbirth are effective prophylactic measures for the reduction of vertical transmission[1,9,19,28]. A study conducted in Alagoas State, assessing 76 pairs of mother and child, verified that 19.0% of infected pregnant women did not receive ART prophylaxis during pregnancy and 22% did not receive it during childbirth, resulting in a vertical transmission rate of 6.6%[28]. These studies corroborate the findings that the use of prophylaxis during prenatal care is reduced – it is most commonly used during childbirth and in neonates –, demonstrating the low testing rate for HIV infection during pregnancy.

Regarding the mode of delivery (p-value = 0.798), data of this study did not show association with vertical transmission in the adjusted analysis, which is corroborated by studies conducted in Belo Horizonte city[28], Acre State[17], Rio de Janeiro city[9], Mato Grosso do Sul State[19], Ethiopia[32] and India[33]. Although the clinical protocol is for seropositive pregnant women to have vaginal birth when VL is undetectable or lower than 1,000 copies, this study found that most women had cesarean section; and because data are secondary, retrieved from SINAN records, there is no information about VL after 34 weeks of pregnancy for the indication of mode of delivery, corroborating findings identified in Acre State[17].

The findings regarding the use of ART prophylaxis (p-value = 0.002) in neonates suggest that there is an association with vertical transmission in the adjusted analysis, which is corroborated by studies conducted in Aracaju city[20], Rio de Janeiro city[9], Belo Horizonte city[28] and Acre State[17]. In the same way, a study conducted in Angola showed that the risk of vertical transmission was higher in neonates who did not receive prophylaxis (32%) in relation to those who had received it (7%); and a meta-analysis in Ethiopia revealed that neonates exposed to HIV who did not receive prophylaxis, and whose mothers did not receive ART during pregnancy, had almost six times more chance of being infected with HIV[9].

Regarding breastfeeding inhibition (p-value = 0.620), data of this study did not show an association with vertical transmission in the adjusted analysis; which is corroborated by studies conducted in Belo Horizonte city[28] and Acre State[17]. Currently, the Ministry of Health guides the pharmacological method with the use of cabergoline to inhibit lactation, with breast wrapping being used only when there are no pharmacological inhibitors. It is worth highlighting that, in our institution, the pharmacological method is used to suppress lactation due to the suffering and pain caused by the mechanical method of breast wrapping. In this way, although some mothers refer to sad feelings due to the restriction of lactation, others manage to see such a contraindication as an act of love, because of the prevention of vertical transmission, protecting their child from being infected by HIV[10].

The limitation of this study refers to the source of secondary data, because there might be sub-registration of data on SINAN notification/investigation registers on the Health Information System for Epidemiological Surveillance (SISCEL) data system and on electronic medical records – which might jeopardize the quality of the assessment –, as well as sub-notification of cases on the Ministry of Health's official systems. In addition, the loss of follow-up may have brought some bias to the study. However, despite these hindrances, the research is relevant because it made evident the local reality of vertical transmission of HIV, and enables healthcare managers and professionals in this area to plan, assess and implement more adequate prophylactic measures in order to prevent vertical transmission, drawing on the indicated failures.

CONCLUSION

The outcomes of this research point are that the estimated vertical transmission rate of 7.3% is still very high and prove that the interventions recommended by the guidelines and protocols of the Ministry of Health were not fully adopted. Therefore, healthcare professionals, managers and services must perform the established and effective prophylactic measures in order to reduce and/or eliminate the vertical transmission of HIV and achieve the global alliance's goal to end AIDS in children by 2030.

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