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Administration of medications for children born exposed to human immune deficiency virus

Administração de medicamentos para crianças nascidas expostas ao vírus da imunodeficiência humana

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Keywords

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Abstract

Objective: To evaluate HIV-positive mothers' ability to administer zidovudine and trimethoprim-sulfamethoxazole (SMZ/TMP) prophylaxis for HIV-exposed infants.

Methods: This cross-sectional and quantitative study was carried out at a reference hospital for HIV/AIDS patients in Fortaleza (CE), Brazil. A total of 60 mothers responded to the ability assessment scale for the care of HIV-exposed children.

Results: The level of ability to administer zidovudine varied from moderate to high. Maternal variables did not show significant differences ($p > 0.05$). TMP/SMZ administration varied from low, moderate, and high. The variable "parity" was related to a high level of care ($p = 0.051$).

Conclusion: The level of ability of mothers to administer AZT syrup (factor I) varied from moderate to high; with SMZ-TMP administration (factor IV), no difference among low, moderate, and high was seen.

Resumo

Objetivo: Avaliar a capacidade de mães com HIV/Aids de administrar a zidovudina e a profilaxia com sulfametoxazol-trimetoprima aos filhos nascidos expostos ao HIV.

Métodos: Estudo transversal e quantitativo, realizado em hospital de referência no atendimento a casos de HIV/Aids em Fortaleza (CE), Brasil. Utilizou-se a Escala de Avaliação da Capacidade para Cuidar de Crianças Expostas ao HIV, que foi respondida por 60 mães.

Resultados: O nível de capacidade de administrar a zidovudina variou de moderado a alto, sem diferenças significantes em relação às variáveis maternas ($p > 0,05$). Em relação à administração do sulfametoxazol-trimetoprima, o nível de capacidade variou entre baixo, moderado e alto. A variável materna "paridade" apresentou relação com o nível de cuidado alto ($p = 0,051$).

Conclusão: O nível de capacidade das mães para administrar o AZT xarope (Fator I) variou de moderado a alto e para administrar e SMZ-TMP (Fator IV), o nível de capacidade de administração distribuiu-se sem diferença entre baixo, moderado e alto.

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Introduction

AIDS is a disease that has been considered a pandemic and major public issue for decades.⁽¹⁾ The AIDS epidemic in Brazil is complex and dynamic because it was first found to occur among homosexual men and, later, among people who received blood transfusions and those who used injection-type drugs. Nowadays, this disease is more prevalent among heterosexual men and women, with percentages of 43.4% and 96.3%, respectively. In addition, AIDS has been affecting more individuals at reproductive age.^(2,3)

The increase of HIV-infected women during the reproductive years has determined the occurrence of infants exposed to the virus during delivery. Vertical transmission (VT) is the main cause of HIV infection in children.⁽⁴⁾ Pediatric AIDS clinical trials group protocol 076 has been shown to reduce VT of HIV by use of zidovudine (AZT), which was given from 14 weeks' gestation, intravenously until delivery, and until umbilical cord clamping.⁽⁵⁾

In newborns exposed to HIV, breastfeeding should be replaced by artificial milk and other foods, depending on the infant's age. Administration of AZT syrup (10 mg/mL) should be performed until the second hour postpartum for six weeks. After the fourth and sixth weeks of life, until a definitive diagnosis of HIV-positive or HIV-negative infection is given, the child must receive chemoprophylaxis against *Pneumocystis jiroveci* pneumonia (previously called *Pneumocystis carinii*), with trimethoprim-sulfamethoxazole (TMP/SMZ) (SMZ 25-40 mg/kg per day and TMP 5-10 mg/kg per day) in two divided doses per day, three times per week, or on alternate days.^(5,6)

Rates of VT of HIV without any intervention during gestation are between 25% and 30%. Children whose mothers are HIV-positive have a lower risk of becoming infected with the virus if VT is adequately prevented.^(5,6) It is important to emphasize that if all proper protocols were followed during the prenatal and at delivery period, then mothers must be responsible for the care of their children in the postpartum period involving the administration of AZT syrup and TMP/SMZ prophylaxis. Admin-

istration of these medicines is essential to protect infants against HIV and pneumonia, which usually affects children infected with HIV during the first year of life.⁽⁶⁾ However, studies have demonstrated nonadherence to such drug therapy. As a result, the numbers of infected children, cases of pneumonia, and cases of other comorbidities have grown.^(1,7,8)

AZT and TMP-SMZ administration for HIV-exposed children is a challenge because it is done at home and depends on the mother or other caregiver, who must be advised about the therapeutic regimen. Considering the relevance of this topic, this study evaluated the ability of HIV-positive mothers to administer AZT syrup and TMP-SMZ prophylaxis to their newborns exposed to maternal HIV infection.

Methods

This cross-sectional and quantitative study was carried out at Hospital São José de Doenças Infecciosas (HSJDI) which is specialized in the care of HIV/AIDS-positive individuals in Fortaleza (CE), Brazil. This ambulatory service for adult and pediatric infection provides antiretroviral drugs, laboratory and radiological tests, internships, and psychosocial and nutritional support.

The study population was composed of HIV/AIDS-infected mothers whose children (up to age 12 months) were exposed to HIV at delivery. On the basis of the number of deliveries by HIV-positive pregnant women in Fortaleza between 2009 and 2010 (n=122), a convenient sample of 60 biological mothers was included. This population represented 49.2% of births of HIV-exposed children. The convenient sample was gathered in the ambulatory service when mothers took their children to the first medical follow-up visit when this study was performed.

The inclusion criterion was mothers who were able to care for their children by themselves, and exclusion criteria were individuals with mental disease, those who were in the advanced stage of AIDS, and women who had other conditions that kept them from properly caring for their children.

We collected data using the following forms: (1) sociodemographic and clinical-epidemiological featuring for the mothers; (2) clinical-epidemiological featuring for the child and prophylactic measures to reduce VT; and (3) a ability assessment scale regarding the care of HIV-exposed children (EACCC-HIV, acronym in Portuguese), which was developed and validated in Brazil.⁽⁹⁾ Interviews were conducted in an office at the hospital. For validation of these instruments, three pilot interviews, not included in the sample, were conducted to train researchers in data collection.

The EACCC-HIV assessed health care delivered to HIV-exposed children from birth to age 12 months using five factors: factor I – ability to administer AZT syrup for children until the age 42 days; factor II – ability to prepare and feed children until age one year with dry milk; factor III – ability to prepare and introduce complementary food to children older than four months; factor IV – ability to administer TMP-SMZ prophylaxis for children with older than age 42 days until age one year; factor V – ability to guarantee adherence to clinical follow-up and vaccination. Each factor could be assessed separately, which indicated the mother's performance in each aspect.

To achieve the aim of this study, we used factors I and IV related to administration of medicines. Each factor covered four questions. Questions for factor I consisted of the following: (1) I prepared AZT syrup following medical prescription; (2) I administered AZT syrup every six hours; (3) I forgot to give AZT syrup to my baby; (4) I'm aware of treatment duration with AZT syrup that my baby will need. Factor IV included the following questions: (1) I prepared AZT syrup following medical prescription; (2) I gave my baby TMP-SMZ three times a week on alternate days; (3) I forgot to give AZT syrup to my baby; and (4) I administered to my child medicines for pain, fever, or diarrhea not prescribed by the doctor.

On the basis of the EACCC-HIV, participants must indicate only one answer related to how often children received care. A scale resembling the Likert scale, varying from one to five

points, was used. Answers were never, hardly ever, sometimes, many times, and always. Classification of care level ability occurred based on points: low (four to nine points), moderate (ten to 15 points), and high (16 to 20 points).

Data collected were entered into Excel 97 and were exported to the Stata statistical package, version 11, to treat and generate results. Nominal and ordinal categorical variables were described using univariate and bivariate frequency distributions. For evaluation of continuous variables, mean, standard deviation, and median were obtained. Bivariate analyses were performed to describe and verify proportional differences between care level ability expressed by EACCC-HIV dimensions. The Fisher exact test was used to establish maternal characteristics.

The significance level used in all analyses was 5% ($p \leq 0.05$). We used the Cronbach alpha coefficient, which measures the degree of correlation among items of the scale; values varied from zero to one. The value more close to number one had a stronger correlation among items. The classification of correlation among answers was between 0.70 and 0.90 (good internal consistency), less than 0.70 (weak internal consistency), and more than 0.90 (high concordance).⁽⁹⁾

This study followed the national and international ethical and legal aspects of research on human subjects.

Results

This study was composed of 60 HIV-positive biological mothers in different stages of the disease. Participants provided care information on 62 children; two mothers had twin pregnancies.

The mothers' profile, main sociodemographic features, and clinical-epidemiological characteristics are presented. More than half of the mothers were 29 years old (55.0%); the mean age was 28.8 ± 6.0 years. The majority of participants were married or had a stable relationship (78.3%). Regarding education, 20 women (33.3%) had five or less years of study, and 51 (85.0%) were unemployed. In general, family income was two minimum wages that

were reported by 45.0% of participants. When this study was conducted, the minimum wage was R\$510.00.

A total of 30 women (50.0%) reported receiving AZT during pregnancy from 14 weeks' gestation. It is important to highlight that eight mothers did not receive AZT during gestation.

One child (1.6%) had an HIV-positive diagnosis, and 32 (51.6%) were not tested for HIV infection. Most of the children were 7 months old (37%) and were delivered at term (69.3%). Regarding breastfeeding, 53 children (85.5%) were not breastfed; however, 3.2% were breastfed and 11.3% had mixed feeding. AZT syrup was administered within 24 hours after birth for 61 newborns (98.4%). During the study, 11 children (17.8%) were receiving AZT prophylaxis. No statistically significant findings were found among variables ($p > 0.05$) (Table 1).

From the total, only ten mothers answers questions related to factor I regarding evaluation function of children up to age 42 days. A total of 50 mothers whose children's ages ranged from 43 days up to 12 months answered factor IV questions. Twin mothers answered each factor, which resulted in 11 children in dimension I and 51 children in dimension IV.

The level of the ability to administer AZT syrup (factor I) varied from moderate to high. We did not find proportional differences regarding participants' characteristics and ability level to administer the medicine. Regarding TMP-SMZ prophylaxis (factor IV), the ability level of administration varied among low, moderate, and high. Parity was represented by the number of children, which consisted of three children with a higher percentage when a high level of care was delivered. Parity had proportional significant differences in borderline level concerning the ability to administer TMP-SMZ prophylaxis ($p = 0.051$).

We did not find significant differences among the mothers; however, participants with more years of education had a higher ability to administer TMP-SMZ prophylaxis (42.1%), which suggests that more educated people tend to act more positively in this dimension. The Cronbach alpha

coefficient had values of 0.96 in dimension I and 0.85 in dimension IV, which indicated meant high internal consistency and good internal consistency, respectively (Table 2 and 3).

Table 1. Clinical-epidemiological characteristics of children and prophylactic measures to reduce vertical transmission

Children's characteristics	Gender		Total n(%)	p-value*
	Male n(%)	Female n(%)		
Anti-HIV serology results				
Positive	1(3.0)	0(0.0)	1(1.6)	0.661 ^a
Negative	6(17.6)	5(17.8)	11(17.7)	
Inconclusive	11(32.4)	6(21.4)	17(27.5)	
Not performed	16(47.0)	17(60.8)	33(53.2)	
Age (months)**				
≤ 1	5(14.7)	3(10.7)	8(13.0)	0.848 ^a
2 - 3	7(20.5)	7(25.0)	14(22.5)	
4 - 6	11(32.4)	7(25.0)	18(29.0)	
≥ 7	11(32.4)	11(39.3)	22(35.5)	
Gestational age at birth				
Preterm	10(29.5)	8(28.5)	18(29.0)	0.789 ^a
At term	24(70.5)	20(71.5)	44(71.0)	
Post-term	0(0.0)	0(0.0)	0(0.0)	
Breastfeeding				
Yes	2(5.8)	0(0.00)	2(3.3)	0.077 ^a
No	26(76.5)	27(96.5)	53(85.5)	
Mixed feeding	6(17.7)	1(3.5)	7(11.2)	
Duration of AZT use*** (syrup)				
Within 24 hours	33(97.0)	28(100.0)	61(98.4)	1.000 ^b
Not used	1(3.0)	0(0.0)	1(1.6)	
Time of prophylaxis initiation (AZT)				
In use	5(14.7)	6(21.5)	11(17.8)	0.942 ^a
3 to 5 weeks	2(5.8)	1(3.5)	3(4.8)	
6 weeks	26(76.5)	21(75.0)	47 (75.8)	
No used	1(3.0)	0(0.0)	1(1.6)	

Legend: n(%) values: n(%) men 34(54.8), n(%) women 28(45.2), n(%) total 62(100); *p-value obtained in chi-square test^a or Fisher exact test^b;

Regarding children's age: mean: 5 months, minimal value: 7 days of life, maximum value: age 12 months; *AZT: zidovudine

Table 2. Maternal variable distribution and ability level to administer zidovudine syrup (SMZ) and sulfamethoxazole (SMZ) prophylaxis associated with trimethoprim (TMP)

Maternal features	Ability level to administer AZT syrup (factor I)*			p value***	Ability level to administer TMP-SMZ(factorIV)**			p value***
	Low	Moderate	High		Low	Moderate	Alto	
	n(%)	n(%)	n(%)		n(%)	n(%)	n(%)	
Age (years)								
< 29	-	2(66.7)	4(57.1)	1.000 ^a	2(50.0)	6(75.0)	19(50.0)	0.775 ^a
30 - 39	-	1(33.3)	3(42.9)		2(50.0)	2(25.0)	17(44.7)	
40 - 49	-	0(0.00)	0(0.00)		0(0.0)	0(0.0)	2(5.3)	
Parity (number of children)								
1 - 3	-	3(100.0)	7(100.0)	-	3(75.0)	5(62.5)	35(92.1)	0.051 ^b
≥ 4	-	-	-		1(25.0)	3(37.5)	3(7.9)	
Educational level****								
≤ 5	-	0(0.0)	1(14.3)	0.667 ^a	2(50.0)	5(62.5)	11(28.9)	0.119 ^a
6 - 9	-	1(33.3)	4(57.1)		1(25.0)	3(37.5)	11(28.9)	
≥ 10	-	2(66.7)	2(28.6)		1(25.0)	0(0.0)	16(42.2)	
Family income*****								
< 1	-	1(33.3)	2(28.6)	1.000 ^a	3(75.0)	2(25.0)	16(42.1)	0.537 ^a
1 - 2	-	2(66.7)	3(42.9)		1(25.0)	4(50.0)	17(44.7)	
≥ 3	-	0(0.0)	2(28.5)		0(0.0)	2(25.0)	5(13.2)	

Legend: *(Factor I) n = 10; **(Factor IV) n = 50; ***p-value obtained in chi-square test^a or Fisher exact test^b; ****Education: years of study; *****Amount of minimum wage: value of wage in the period of the study: R\$510,00

Table 3. Percentage distribution and descriptive measures of dimensions of care ability

Dimensions (Factors)	Level of ability to care						Cronbach alpha
	Total of mothers	Total of children	Low n(%)	Moderate n(%)	High n(%)	Mean ± SD*	
I	10	11	0(0.0)	3(27.3)	7(72.7)	16.4 ± 3.0	0.96
IV	50	51	4(7.8)	8(15.7)	38(75.5)	16.7 ± 4.1	0.85

Legend: * SD: Standard Deviation

Discussion

A limitation of this study was the seemingly impossible task of following administration of medicines *in loco* in the children's homes. However, a similar approach was used in other analyses on this topic; therefore, this approach renders our findings relevant. Another limitation was the sample size, particularly concerning the number of respondents to factor I. This fact could be justified by the difficulty obtaining this information because it applied only to children up to age 42 days.

Mothers or caregivers must be able to follow recommendations to reduce VT of HIV; it is also

important that people understand the risks involved in nonadherence to treatment.

AIDS is a complex disease that causes changes in biological, social, and psychological aspects of patients' lives, and because of these expressive life changes, several studies are encouraged on this topic.⁽¹⁰⁻¹²⁾ In our study, most of the HIV-infected women were 30 years old or younger, which represents this disease dynamic in Brazil where most of women infected with the HIV virus are of reproductive age.⁽³⁾ In our study, most of HIV-positive women were married or had a stable relationship; this finding is in accordance with a previous study on this topic.^(2,7) Concerning educational

level, few mothers had more than ten years of education. These data corroborate what was shown in similar studies.^(2,7,13) Therefore, such findings suggest a progressive epidemic spread of AIDS among people with low educational levels.

The increase of the number of AIDS cases among people with low educational levels is described as a poverty epidemic, so low family income is a main contributor.^(3,14) In addition, a higher percentage of women in our were unemployed. Considering these facts, we emphasize that financial status interferes in the quality of life of individuals with HIV/AIDS because it renders self-care and specific treatments more difficult⁽⁹⁾ People in poverty live in worse social, environmental, and sanitary conditions. This population also has limited access to general and, mainly, public health services.⁽¹⁵⁾

The majority of women began the AZT regimen from 14 weeks' gestation; however, some of them did not use AZT. The low adherence of HIV-infected pregnant women in health follow-up is common, and because most of them live outside of the urban areas, they report that transportation and financial difficulties are the causes of missed medical visits.⁽¹⁶⁾

Many HIV-exposed children remain undiagnosed. Infants whose mothers are HIV-positive receive anti-HIV IgG antibodies during gestation. All children are HIV-positive at birth; those not infected often seroconvert after ages nine and 12 months; however, the test result could be positive up to age 18 years. Children ≥ 18 months old are considered HIV-negative when the test result for the anti-HIV agent is negative, or one negative sample is shown on two HIV quick tests. If different results are found on the two first assays, a third quick test is done; if this later result is negative, the sample is considered a "HIV-negative sample".^(5,6)

Because of the increase in HIV infection in women of childbearing age, the number of children in this risk group has been increasing. For this reason, the Brazilian Health System (SUS, acronym in Portuguese) implemented a project called "Born-Maternities" that aims to increase the number of early diagnoses of VT. The project

also offer free antiretroviral treatment and formulas to replace natural breastfeeding.⁽¹⁷⁾ AZT administration within the first 24 hours after birth was reported for 98.5% of moms, which optimized health care of HIV-exposed newborns. However, another study in Fortaleza reported that only 64.4% of children received AZT within the first 24 hours after birth.⁽⁹⁾

AZT is a drug approved by the US Food and Drug Administration (FDA) that inhibits reverse transcriptase and is used for the treatment of HIV-infected adults and children and to prevent transmission from the mother to the child. AZT could also be used in combination with other antiretroviral drugs. SMZ is a bacteriostatic agent that disrupts folate synthesis, hence, in nucleotide synthesis by the bacteria. TMP is also a bacteriostatic agent that acts by folate antagonism.⁽¹⁸⁾

According to the EAACCC-HIV the ability level of mothers to administer AZT syrup to their children varied from moderate to high; such information shows that they tried to accomplish the task. Research has shown that HIV-positive mothers are afraid to infect their children and they wish not for their baby to be infected; therefore, they follow the antiretroviral treatment regimen.^(19,20) In general, these women are afraid that their children are HIV-positive and could become frequently ill because of the virus. This fear is felt until they receive a definitive diagnosis, which is why they make many efforts to adequately administer AZT to the child.⁽²⁰⁾

The ability level to administer TMP-SMZ prophylaxis varied from low, moderate, and high. Mothers with more years of education were more able to administer the medicine to their children. Because of the inequality that exists in Brazilian society and the spread of HIV infection throughout the country, the AIDS epidemic has been classified as a women's disease and a heterosexual disease that mostly affects poor people living outside of the urban areas and also those with older age and lower educational level. All of these factors directly influence the quality of life of HIV-infected people and their families and, most of the time, affecting treatment.⁽²¹⁾

We observed that parity, represented in our study by the number of children having been born, tended to be associated with ability level of administering TMP-SMZ. Some studies that evaluated families of HIV/AIDS-positive people showed that families with more children have a higher risk of nonadherence to antiretroviral therapy or to other medicines. Such factors could also interfere in the mother's care during delivery of the child. Therefore, mothers with more children, particularly if they demand more care, could have problems in their routine because they have to care for more children.^(22,23)

For this reason, the benefit of HIV VT prophylaxis with antiretroviral drugs associated with other measures is unquestionable.⁽¹¹⁾ Bonding between the parents or caregivers and the child is critical for care and must be based on differential listening and care directed to the life conditions of each patient.

Although not the aim of our study, we believe it is important to mention that several mothers (11.0%) reported discontinuing TMP-SMZ administration because the medicine had run out and they did not have a medical prescription, which required them to wait until the next visit with a pediatrician. They also mentioned that, because of financial difficulties, they were not able to purchase the medicine and use public transportation to access health care service.

Finally, this study could be used as a guideline for health care professionals who need to give instructions to people who care for HIV-exposed children. It is essential that health units be prepared to adequately assist and guide mothers dealing with such circumstances. If nursing professionals and other members of the health care team received proper training on how to care for families with HIV-exposed children, they could offer support regarding child care to these families, considering each family's social context and characteristics.

In addition, other researchers developing actions contributing to the care of HIV-exposed children are encouraged to improve the quality of life in this population.

Conclusion

The mother's ability level to administer AZT syrup (factor I) varied from moderate to high. We did not find significant differences concerning maternal characteristics and ability level to administer medicines. Regarding TMP-SMZ prophylaxis (factor IV) the ability level to administer this drug had no statistically significant difference among low, moderate, and high. In this study, mothers with higher educational levels were more able to administer the medicines to their child.

Collaborations

Freitas JG, Cunha GH, Barroso LMM, and Galvão MTG contributed to the design of the study; drafted the paper; and analyzed and interpreted the data. They were also solely responsible for critical analysis and final approval of proofs.

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