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Maternal Adherence to the Zidovudine Regimen for HIV-Exposed Infants to Prevent HIV Infection: A Preliminary Study

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Abstract

Objective—To describe the extent of adherence to the recommended neonatal zidovudine (ZDV) regimen administered to infants who have been exposed to the human immunodeficiency virus (HIV) to prevent mother-to-child transmission of HIV and to determine which maternal factors are associated with compliance.

Methods—HIV-infected women (n = 87) who were participating in a larger study of perinatal transmission at 3 inner-city New York City hospitals were interviewed 2 to 6 weeks' postpartum to assess adherence to neonatal prophylaxis, social support, social network factors, and depression. In addition, plasma samples of 45 of their infants were assayed for ZDV levels.

Results—A majority of women (71%) administered all of the prescribed 4 daily doses in the previous week, as measured by interview; self-reported adherence was not associated with any maternal characteristics. In contrast, poor adherence, as measured by lower infant ZDV plasma levels, was associated with asymptomatic HIV illness in the mother and having 2 or more other children; good adherence, as indicated by higher ZDV levels, was associated with the presence of a maternal social support network, disclosure of HIV infection, and mothers' adherence to their own ZDV regimens during pregnancy. In multivariate regression analyses, maternal asymptomatic status ($\beta = -0.40$) was associated with lower infant ZDV levels, and maternal adherence during pregnancy ($\beta = 0.37$) was associated with higher levels.

Conclusions—Women who are HIV asymptomatic and lack a social support network are more likely not to comply with the recommended neonatal prophylactic regimen of antiretroviral therapy. Future studies should address the prenatal period and social network factors, such as disclosure of serostatus, and the custody of other children.

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In 1994, AIDS Clinical Trial Group (ACTG) Protocol 076 demonstrated that zidovudine (ZDV) could reduce mother-to-child transmission (MTC) of human immunodeficiency virus (HIV) by 68%.¹ Prophylactic treatment of all infected pregnant women and their infants with the 076 regimen was subsequently recommended by the US Public Health Service² and rapidly became the standard of care. A later study indicated reduced transmission rates in infants who were treated with ZDV within 48 hours of birth, even in the absence of maternal treatment.³ The current prophylaxis for full-term HIV-exposed infants includes a 6-week course of oral ZDV 4 times daily in doses of 2 mg/kg body weight, initiated as soon as possible, and within 12 to 24 hours of delivery.²

Understanding factors that are associated with adherence to neonatal prophylaxis has become increasingly important as greater proportions of HIV-exposed infants are being identified and treated as a result of more aggressive prenatal HIV testing policies⁴ and recent advances in rapid HIV testing technology that could expedite the initiation of treatment for exposed neonates.⁵ In August 1999, New York became the first state to legislate universal testing of women with undocumented HIV status or their newborn infants at delivery.⁶ Although this offers the opportunity for the timely initiation of prophylactic treatment during labor and to the newborn immediately at birth, it does not ensure that the 6-week regimen will be continued or administered correctly to the neonate by the parents or other caregivers after discharge.

Little is known about adherence to the prophylactic regimen for HIV-exposed neonates after they are discharged from the hospital, although recent studies have addressed adherence rates, efficacy, and correlates among HIV-infected children.^{7,8} Adherence to the neonatal regimen may be especially problematic for several reasons. The mothers of HIV-exposed infants face multiple stressors,⁹ including scarce social support and resources, stigma of HIV, and fear of disclosure of their HIV status to family members and their sexual partners in particular. They may also experience anxiety, self-blame, or other emotional distress as a result of their infants' exposure to HIV and potential infection. The ability of new mothers to adhere to the 6-week neonatal regimen may also be compromised by their own symptomatic or acquired immunodeficiency syndrome (AIDS) stage and sequela of antiretroviral therapy, including medication side effects. Other possible barriers include caring for other children and the practical difficulties of giving oral medication to infants 4 times daily.

The goal of the current analysis was to describe patterns of maternal adherence to the neonatal regimen as assessed by maternal report and infant ZDV plasma assays. In addition, we sought to determine the relationship of adherence with maternal factors such as demographics, depression, clinical and social network factors (including social support, disclosure of HIV status, custody, and care of other children), and previous adherence to ZDV prophylaxis during pregnancy.

Methods

Participants and Procedure

The participants in this report were 87 HIV-infected women who enrolled in a longitudinal study, the Perinatal AIDS Collaborative Transmission Study (PACTS), sponsored by the

Centers for Disease Control and Prevention (CDC).¹⁰ From among women who were participating in PACTS at 3 New York City sites, all women who were notified of HIV infection before delivery, were fluent in English or Spanish, and signed informed consent were eligible. Enrollment occurred from April 1997 through June 1998 at Bronx-Lebanon, Montefiore, and Metropolitan Hospital Centers. Approval was obtained from the institutional review boards affiliated with the 3 sites and with the Medical and Health Research Association of New York City, Inc, the grantee agency.

Standardized interviews were administered between 2 and 6 weeks' postpartum by trained staff members to assess maternal reports of ZDV administration, depression, social support, and social network factors. Demographic, clinical, and substance abuse variables were obtained from the NYC PACTS database. AIDS status was defined according to the classification criteria of the CDC.¹¹ Maternal symptomatic status was assigned for histories of constitutional symptoms (eg, fever, weight loss) or comorbid infectious disease (eg, tuberculosis, oral thrush). A subset of women had also been assessed during pregnancy for adherence to the prenatal ZDV regimen with the physiologic markers of urine assay (n = 54) and mean corpuscular volume (MCV; n = 72; unpublished data). Short-term adherence during pregnancy was defined by the presence of ZDV or its metabolite in urine assay, and long-term adherence was determined by elevated MCV indicating erythrocyte macrocytosis, a known manifestation of chronic ZDV use.^{12,13}

Maternal Reports of Adherence to the Neonatal Regimen

Participants were asked the number and the amount (in milliliters) of neonatal doses prescribed daily and the number of doses given and missed the day and the week before the interview. The expected ZDV dose size prescribed was calculated for comparison with maternal reports of prescribed dose size according to the current pediatric guidelines of 4 daily doses of 2 mg/kg body weight.² Supervising physicians at the pediatric clinics that cared for the infants verified that all prescriptions were for every 6 hours.

Laboratory Assays of Infant Plasma ZDV Levels

Frozen specimens of infant blood collected at routine postpartum visits for the PACT study were assayed for ZDV plasma levels when the specimen was drawn within 1 week before the mothers' interview (n = 45). The specimens were analyzed by the Pediatric Pharmacology Assay Laboratory at the University of California, San Diego, using a standard commercially available enzyme-linked immunosorbent assay (Immuno-Diagnostic Reagents, Vista, CA). According to the manufacturer's specifications, the assay has a sensitivity of 5 ng/mL. Pharmacokinetic studies¹⁴ have determined that the half-life of ZDV in plasma is 1.9 hours and total body clearance is 19.0 mL/min/kg for infants >14 days of age. This indicates that nearly all ZDV is cleared from the systemic circulation within 12 hours after administration. Therefore, we conclude for the purposes of this analysis that if ZDV is undetectable in the plasma, then it is unlikely that a dose has been administered within the 12 hours before sampling. The Pediatric Pharmacology Assay Laboratory, a participant in the Pediatric ACTG, has been certified in the performance of such assays by the ACTG Pharmacology Committee Quality Assurance program, which included standardization through analysis of blinded samples.

Social Support and Network

Perceived availability of social support was assessed with an 8-item scale to determine the probability that people in the participants' social network could be depended on for emotional, financial, and instrumental support (eg, "get a ride to the doctor"). This scale was originally developed with 7 items^{15,16}; a large cohort study (N = 319) of HIV-infected pregnant women added an item to determine whether child care would be available if the respondent were ill.¹⁷ The response scale ranged from 1 (definitely not) to 5 (definitely yes). In addition, detailed questions were asked regarding living arrangements for the women themselves and their children, custody status of children, and whether their serostatus was known to the infants' father and their own parents.

Depression

The Center for Epidemiologic Studies-Depression Scale is a 20-item self-report measure widely used in survey research with excellent reliability and validity.¹⁸ Depressive symptoms are rated on a 0 to 3 scale for the previous week, with a maximum possible score of 60. Scores 16 are indicative of high depressive symptomology.

Statistical Analysis

Square root transformations were applied to the primary outcome variables, maternal reports of neonatal adherence, and infant plasma levels to correct for skewed distributions.¹⁹ Two categorical variables for infant plasma levels were generated: one a dichotomy at the median and the other comparing the lowest quartile to the upper 75%. Bivariate analyses of the relationship of the outcomes with demographic, clinical, depression, and social support and network variables were conducted with Fisher exact test, *t* tests, and nonparametric tests (Spearman's rho, Mann-Whitney-Wilcoxon rank-sum test, Wilcoxon signed-rank test) as appropriate. Variables associated in the bivariate analyses at P < .10 were tested in multiple linear regression models; the significance level for all other analyses was set at .05. All analyses were conducted with SPSS for Windows Version 8.0 (SPSS, Inc, Chicago, IL).

Results

Participant Characteristics

A majority of the participants were black (45 [52.3%] of 86) or Hispanic (39 [45.3%] of 86). The median age was 28.9 years (range: 15.8–41.0 years), and only one third had completed high school (29 [34.5%] of 84). The median time since HIV notification was 13.1 months (range: <1 month–12.9 years). Fewer than half (36 [42.4%] of 85) reported a history before the index pregnancy of substance abuse (cocaine, heroin, or illicit methadone), and 11.5% (10 of 87) reported substance abuse during the pregnancy. Seven women (8%) reported previous intravenous drug use. A majority (49 [63.6%] of 87) had CD4 cell counts 500 cells/mm³ or were asymptomatic (47 [57.3%] of 82) for HIV illness; 29.3% (24 of 82) were classified as having AIDS.

Most of the fathers of the index infants were aware (58 [82.9%] of 70) of the women's HIV status, as were more than half (54.6%) of the women's mothers and 28.8% of their fathers. Of the subjects who were also assessed for adherence to their own ZDV prophylaxis during

pregnancy with physiologic markers, 63.0% (34 of 54) were considered short-term adherent according to urine assay for ZDV, and 62.5% (45 of 72) were considered long-term adherent on the basis of MCV blood level. High depressive symptomology was common in this sample: 63.2% (55 of 87) had Center for Epidemiologic Studies-Depression Scale scores at or above the cutoff score of 16; the median score was 19.

Siblings of the Index Infants

A majority of the women (66 [75.9%] of 87) reported having at least 1 older child (range: 1– 6; median: 2); of these, 10.6% (7 of 66) reported having a living child infected with HIV or a child's death from AIDS or other causes. Problems with both legal custody and maintaining consistent living arrangements for their older children were frequently reported by this sample. One third (22 [33.3%] of 66) said that they had been previously reported to or investigated by the New York City agency responsible for monitoring child abuse and neglect cases. Half of the 168 minor children were not living with their mothers; 28.8% of the mothers (19 of 66) reported that none of their other children were currently living with them. The high prevalence of minor children living apart was at least partially attributable to custody problems; 15 women (22.7%) reported that they did not have legal custody of at least 1 child as a result of adoption or court-mandated foster care.

Rates of Adherence: Maternal Interview Data and Infant Plasma Assay

All participants except 1 had accepted a prescription for ZDV and started the neonatal regimen. At the time of interview, 3 had not given any ZDV to the infant in the previous week. The majority reported having given all 4 daily doses on the day (65 [78.3%] of 83) and week (59 [71.1%] of 83) before the interview. Assay of infant plasma samples did not detect any ZDV in 17.8% of the infants tested (8 of 45). The mothers of 5 of these infants reported that they had given all prescribed doses in the previous week, and 2 reported that they had missed 1 to 2 doses.

Comparison of Maternal Report With the Standard Regimen: Dose Size and Frequency

The standard dose schedule for the neonatal ZDV prophylaxis is 4 doses per day; 15.7% (13 of 83) of women, however, reported that only 1 to 3 doses had been prescribed by the pediatrician. These women did not differ on adherence during pregnancy to maternal ZDV prophylaxis, clinical factors, or sociodemographic factors such as educational level from women who reported the correct number of prescribed doses. The dose size recalled by mothers (mean: 0.66 mL) did not significantly differ from the expected dose (mean: 0.62 mL).

Factors Associated With Infant Plasma Levels and Maternal Report of Adherence

The infants of women with asymptomatic disease status had lower plasma ZDV levels (P = .011) than infants of women with symptomatic HIV disease or AIDS. The infants of women with 2 or more older children also had lower plasma ZDV levels (P = .033). Infants had significantly higher plasma ZDV levels when their mothers had been adherent to their own ZDV regimen during pregnancy according to urine assay (P = .022). Infant plasma levels were more likely to be above the median when the infants' maternal grandmothers knew of

the mothers' HIV infection status (P = .038). Women whose infants had ZDV plasma levels in the lowest quartile reported having lower social support (P = .044). Other maternal demographics or clinical factors and depression were unrelated to infant plasma levels. Maternal self-report of adherence was not related to any study variables.

Multivariate Analyses

Multiple linear regression analyses were conducted by testing variables with significant bivariate associations with infant plasma levels of ZDV. Maternal-reported adherence to the neonatal regimen was not analyzed because no independent variables were associated at P < .10. The best predictive model for infant plasma levels of ZDV ($r^2 = 0.349$; P = .011) is summarized in Table 1. Asymptomatic maternal disease status was associated with lower levels of infant ZDV and maternal adherence during pregnancy with higher levels.

Discussion

In our analysis of adherence to neonatal ZDV prophylaxis, maternal reports of prescribed dose size were consistent with the standard protocol, whereas dose frequency was discrepant. This suggests that ability to comprehend the regimen may not be problematic but rather that mothers may be unable to follow the prescribed dosing schedule and are embarrassed or otherwise reluctant to admit this. Therefore, it may be crucial to utilize more aggressive approaches to facilitate adherence to the 6-hour dosing schedule. A less frequent dosing schedule may facilitate adherence and alleviate regimen burden as twice-daily and 3-times-daily schedules have for adults and infected older children. Recent international studies²⁰ have shown that a twice-daily schedule combining ZDV with lamivudine is well tolerated and provides ZDV serum exposure comparable to that of the standard 4-times-daily monotherapy regimen.

Several maternal factors were associated with infant plasma levels of ZDV. Asymptomatic HIV disease stage and having 2 or more other children were associated with lower infant ZDV; conversely, adherence to ZDV during pregnancy, social support, and disclosure to the participant's own mother were associated with higher infant ZDV levels. In contrast, neonatal adherence based on maternal self-report was not associated with any study variables.

Our findings for infant plasma ZDV levels, however, should be considered preliminary for several reasons. We used specimens for assay that had not been collected specifically for this analysis but rather for ongoing research on HIV-exposed infants. Therefore, information regarding the time and size of the last ZDV dose necessary to interpret more fully ZDV plasma levels was not obtained from the mothers at the time the blood specimens were collected.

In addition, elimination kinetics of ZDV are slow at birth and develop differentially in term and preterm infants (ie, <37 weeks at birth).²¹ In term infants, ZDV elimination rapidly increases and reaches a plateau approximately equal to adult levels between the fourth and eighth week of life. In premature infants, ZDV elimination is initially lower than in term infants and increases at a considerably slower rate. In the present study, infant ZDV levels

were determined between 2 and 6 weeks of age (median: 32 days). Therefore, this changing elimination constant could have had the effect of overestimating compliance among mothers of younger infants in our sample. The effect would be expected to have been especially strong among the few preterm infants (4 [4.8%] of 42) but may have been somewhat offset by the fact that they were older (33–43 days) than the median.

The relatively small size of our subsample assayed for ZDV (n = 45) limited our statistical power and, hence, our ability to define more precisely the relationship of infant plasma levels with our predictor variables. Although preterm status and infant age both are important covariates to consider in the analysis of infant ZDV levels, we could not control for these factors because of our limited sample size. However, the infants in our sample tended to be older than 4 weeks (80% were >28 days old), the point at which ZDV elimination approaches adult levels in term infants. Because neonatal prophylaxis is administered only in the first 6 weeks of life, it would not be possible to assay infants older than 8 weeks to control effectively for age.

Despite these limitations, we believe that our findings suggest that a significant minority of HIV-exposed infants may receive inadequate, incomplete, or poorly timed doses of the ZDV prophylactic regimen. In 18% of infants tested in our analysis, ZDV was undetectable. therefore indicating that probably no or almost no medication had been administered in the 12 hours before phlebotomy—the equivalent of missing 2 doses of the standard every-6hour schedule. MCT rates and the incidence of pediatric AIDS attributable to MCT²² have dropped dramatically in the United States.²³ This trend is considered to be attributable primarily to the rapid implementation of the successful 076 regimen.^{24,25} However, high MCT rates (10%) considered unacceptable or excessive in light of the efficacy of neonatal regimen²⁶ persist among women who received no or inadequate prenatal care, especially women who are economically disadvantaged, lack legal citizenship documentation, or are drug users.²³ Such women may be especially vulnerable to nonadherence during the neonatal period without intensive interventions.²⁷ Given the likely effectiveness of the neonatal regimen even in the absence of prenatal or intrapartum prophylaxis and the growing feasibility of identifying through rapid testing technology HIV-infected women who present in labor,²⁶ understanding and improving adherence to neonatal prophylaxis remains critical to the elimination of MCT in the United States and other countries.

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Abbreviations

ACTG	AIDS Clinical Trial Group	
ZDV	zidovudine	
МСТ	mother-to-child transmission	
HIV	human immunodeficiency virus	
AIDS	acquired immunodeficiency syndrome	
PACTS	Perinatal AIDS Collaborative Transmission Study	
CDC	Centers for Disease Control and Prevention	
MCV	mean corpuscular volume	

 Table 1

 Multiple Linear Regression: Final Model for Infant Plasma Levels of ZDV

Variable	В	β	Р
Asymptomatic maternal disease status		-0.40	.04
Maternal short-term ZDV adherence during pregnancy		0.37	.05

B indicates unstandardized regression coefficient; β , standardized regression coefficient.