Evolving Care of HIV-infected Pregnant Women in Jamaica

From Nevirapine to HAART

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ABSTRACT

Background: *The Ministry of Health, Jamaica, is scaling-up programmes to improve the health of HIV-positive pregnant women according to the modified WHO recommended preventative mother to child transmission (pMTCT) regimens of therapy based upon the mother's clinical and immunological status. Highly-active antiretroviral drugs (HAART) can result in successful pMTCT to < 1%. We report the clinical and immunological characteristics of HIV/AIDS in an era of evolving treatment and care of HIV-infected pregnant Jamaican women.*

Subjects and Method: *Clinical records were reviewed of patients registered in antenatal clinics in Greater Kingston and St Catherine, Jamaica (annual birth cohort – 20 000) between September 2002 and August 2006. Disease status was determined using the Centers for Disease Control and Prevention (CDC) classification system for adult HIV/AIDS. Demographic, clinical and laboratory data were documented and analyzed.*

Results: *During the four-year period, 571 HIV-infected women were enrolled; 62% from Victoria Jubilee Hospital, 25% from Spanish Town Hospital and 13% from the University Hospital of the West Indies. Mean age was 27–29 (range 15–41) years, median parity was 2 (range 0–9) and 68–70% were unemployed. Ninety-five per cent had live births. CDC categories of illnesses were A - mild disease in 82% (n = 473), B - moderate disease in 4.4% (n = 24) and C - severe disease in 1.4% (n = 8) while 12% (n = 66) had insufficient data. During the first three years, $CD4^+$ cell counts were evaluated in only 2.5% (10 of 406) of patients with median of 344 cells/uL, compared to CD4 evaluation in 50% (83 of 165 women) in the last year with median of 573 cells/uL. Antiretroviral (ARV) medications primarily for pMTCT were given to 89% (n = 506) of women. Of these, uptake of HAART increased during years 1–3 from 2–3% to 62% in year four. Within two years post-partum, 24 women died, 92% (n = 22) from the direct complications of HIV/AIDS.*

Conclusion: *A comprehensive system of care of HIV in the peripartum period has been developed in Jamaica. Detailed medical evaluation during pregnancy is performed with modern guidelines and increasing laboratory availability of $CD4^+$ cell counts and viral loads. We believe declining HIV infection rates in Jamaican infants and healthier mothers are a direct consequence of increased testing in pregnancy with early diagnosis and initiation of HAART-based pMTCT regimens in pregnant women.*

Evolución del Cuidado de las Mujeres Jamaicanas Infectadas por el VIH

– Desde la Nevirapina a la TARAA

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RESUMEN

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Antecedentes: *En la actualidad el Ministerio de Salud de Jamaica se halla en plena campaña por aumentar los programas de salud para mujeres embarazadas por el VIH positivo, sobre la base de regímenes terapéuticos para prevenir la transmisión de madre a hijo (PTMAH), de acuerdo con recomendaciones modificadas de la OMS, a partir del estatus inmunológico y clínico de la madre. Los medicamentos antiretrovirales altamente activos (TARAA) pueden traer como resultado un exitoso PTMAH a < 1%. Reportamos las características clínicas e inmunológicas del VIH/SIDA en una etapa en la que el tratamiento y cuidado de las mujeres embarazadas infectadas con VIH en Jamaica, se halla en evolución.*

Sujetos y Métodos: *Se revisaron las historias clínicas de pacientes registrados en las clínicas prenatales en Greater Kingston y Saint Catherine (cohorte de nacimiento anual – 20 000), entre septiembre de 2002 y agosto de 2006. El estatus de la enfermedad fue determinado usando el sistema de clasificación para el VIH/SIDA en adultos, según los Centros para el Control y Prevención de las Enfermedades (CCPE). Se documentario y analizaron datos demográficos, clínicos y de laboratorio.*

Resultados: *Durante el período de cuatro años, se reclutaron 571 mujeres infectadas con el VIH, 62% del Hospital Victoria Jubilee, 25% del Hospital de Spanish Town, y 13% del Hospital Universitario de West Indies. La edad promedio fue de 27-29 años (rango 15-41), la paridad mediana fue 2 (rango 0–9), y el 68–70% eran desempleadas. El noventa y cinco por ciento tuvo nacimientos vivos. Las categorías de enfermedades de CCPE fueron la enfermedad leve A- en 82% (n = 473), la enfermedad moderada B - en 4.4% (n = 24) y la enfermedad severa C - en 1.4% (n = 8) mientras que para el 12% (n = 66) los datos fueron insuficientes. Durante los primeros tres años, los conteos CD4+ fueron evaluados en sólo 2.5% (10 de 406) de los pacientes con la mediana de 344 células/uL, en comparación con la evaluación CD4 en 50% (83 de 165 mujeres) en el último año con una mediana de 573 células/uL. Los medicamentos antiretrovirales (ARV) fundamentalmente para PTMAH fueron dados al 89% (n = 506) de las mujeres. Entre éstas, el consumo de TARAA aumentó durante los años 1–3 de 2–3% a 62% en el cuarto año. En los dos años posteriores al parto, murieron 24 mujeres, 92% (n = 22) de complicaciones directas del VIH/SIDA,*

Conclusión: *Un sistema integral de atención al VIH en el período de periparto ha sido desarrollado en Jamaica. Durante el embarazo, se lleva a cabo una evaluación médica detallada con normas modernas y con aumento de la disponibilidad en los laboratorios del conteo CD4+ y cargas virales. Creemos que la disminución de las tasas de infección por VIH en los infantes jamaicanos y el número de madres más saludables, son consecuencia directa del aumento de las pruebas durante el embarazo con diagnóstico precoz y regímenes de PTMAH basados en TARAA en las mujeres embarazadas.*

BACKGROUND

The Caribbean remains second to Sub-Saharan Africa in world HIV prevalence (1). The Caribbean HIV epidemic is heterosexual and seroprevalence among pregnant women appears to be declining in several nations. In Haiti, the HIV rate among pregnant women declined from 6.0% in 1996 and 5.1% in 2000 to 3.4% in 2004 (2). In the Dominican Republic, HIV prevalence among antenatal clinic attendees aged 15–24 years was 0.5% in 1992, peaked at nearly 3% in 1995 and declined to 1.5% in 1998 and 0.5% in 2000 (2). In contrast, Jamaica has maintained a stable HIV seroprevalence rate of 1.5% in pregnant women (3).

In response to a growing urban paediatric HIV epidemic in Greater Kingston and St Catherine, Jamaica, in the early 21st century, the Kingston Paediatric and Perinatal HIV/AIDS Programme (KPAIDS) was configured in September 2002, as a joint collaborative initiative between the University of the West Indies, the Jamaican Ministry of Health and international partners (4). Its perinatal mandates were (and continute to be): early identification of HIV positive pregnant women, reduction of mother-to-child transmission (MTCT) through provision of antenatal care and antiretroviral therapy and close follow-up of HIV-exposed neonates. Since initiation of the programme, MTCT rates between September 2002 and December 2004 showed significant reduction from prior rates of 31.5% to < 2%, with the use of HAART-based regimens (5). The KPAIDS serosurvey of the antenatal population in Greater Kingston and St Catherine, performed from September 2002 to September 2003, reported a HIV prevalence of 2.1% (6).

While the course of pregnancy is not altered by HIV infection alone, the complications of chronic immunosuppression can be devastating in pregnant women. Natural history studies of HIV infection show a range from asymptomatic infection to life-threatening conditions characterized by severe immunodeficiency, opportunistic infections and cancers. Physicians and nurse-midwives must remember that with improving access to appropriate therapies, caring for HIV-infected pregnant women involves not only prevention of MTCT (pMTCT) but also provision of optimal care to the mother which should result in a much improved prognosis.(7) This can only be achieved by determination of

HIV status in pregnancy as early as possible. The initial assessment should ideally include clinical evaluation of HIV disease status, evaluation of the degree of existing immunodeficiency determined by $CD4^+$ cell count and per cent, assessment of the need for opportunistic infection prophylaxis and risk of disease progression as determined by plasma HIV RNA copy number. This evaluation guides the clinician in choosing when to initiate therapy and in deciding whether to use regimens directed solely at transmission interruption or more comprehensive drug regimens that will simultaneously treat the mother's infection.

In an attempt to adopt this approach to therapy, the Ministry of Health of Jamaica revised its policies with regard to prevention of perinatally acquired HIV. Modified WHO recommended pMTCT regimes are being instituted, targeting antiretroviral drug therapy based upon the clinical and immunological status of women. As we move towards provision of care aimed at improving the health of HIV-positive pregnant women, we sought to determine the health status of our current cohort. The 1986 Centers for Disease Control (CDC) classification system for human immunodeficiency virus (HIV) infection among adolescents and adults (8) was used to assess the spectrum of clinical disease seen in the women registered in the programme during the four-year period September 2002 to August 2006.

METHODS

Study population

Between September 2002 and August 2006, attendees of antenatal clinics in Greater Kingston and St Catherine, Jamaica, were offered group voluntary counselling and HIV testing (VCT) as part of a standard antenatal haematological panel at booking (3–5). All patients seen at the University Hospital of the West Indies (UHWI) were booked in the first trimester. At the other two sites *ie* Victoria Jubilee Hospital (VJH) and Spanish Town Hospital (STH), patients presented for booking at various times in the first, second and third trimesters. A few patients presented to the labour ward unbooked and in active labour. Patients were identified as HIV-positive if they had an initial positive ELISA or Determine Rapid test followed by a confirmatory Western blot. These patients were then post-test counselled and referred simultaneously to the high risk pregnancy clinic at UHWI, VJH or STH. Informed consent was obtained for registration with the KPAIDS Programme due to obtaining data for programme evaluation research purposes.

Study design

This was a retrospective review of the medical records of this cohort. Antenatal care was provided by a team composed of obstetricians, midwives and social workers. Assessment of HIV disease status using CDC criteria was made at the first visit to the antenatal clinic after established HIV seropositive diagnosis. Visits were as per a standard antenatal schedule with extra visits as indicated clinically. Where necessary for medical or obstetric indications, the patients were admitted to UHWI, VJH or STH. The primary goal of antiretroviral therapy was prevention of perinatal transmission using the Thailand regime (9), zidovudine 300 mg orally twice daily from 28 weeks antepartum, every three hours during labour and as a suspension postpartum for 6 weeks to the infant. Patients presenting late in pregnancy who did not receive antepartum zidovudine received a single dose of nevirapine antepartum during labour and postpartum to the infant as per the HIVNET 015 trial (10). Highly active antiretroviral therapy (HAART) was continued throughout pregnancy in patients who conceived while on medication. $CD4^+$ counts were initially determined as laboratory availability and patient's finances allowed. Later as the programme evolved, lymphocyte subsets and HAART were commenced through support from the Global Fund to Fight AIDS, Tuberculosis and Malaria (5). HAART initially comprised of zidovudine and lamivudine with either nevirapine, nelfinavir or lopinavir with ritonavir, beginning within the first trimester or as early as possible. For those presenting late in labour, nevirapine was administered. A dedicated nurse manager employed by the programme within each obstetric hospital sought to ensure that patients were compliant with visits and medications and other interventions (11).

A data extraction form was used by the programme nurse to obtain information from the patient's primary hospital records. This included demographic, clinical and laboratory data documented at enrolment and subsequent clinical data recorded at each antenatal visit. Categorization of HIV disease based upon the CDC clinical criteria was assigned retrospectively to each patient after review of the clinical assessment documented by the obstetrician or nurse-midwife. Where this information was not adequately documented, the patients were assigned a category based upon a more thorough review of their clinical records. Data were cross-checked and confirmed or cleaned as indicated prior to statistical analysis. Main outcome measures included: age at pregnancy, parity, employment status, haemoglobin, $CD4^+$ T-lymphocyte count: according to year of pregnancy, CDC stage of disease, antiretroviral therapy, pregnancy outcome (normal delivery, ectopic pregnancy, spontaneous abortion) and maternal death. Bivariate analysis was performed using the statistical package in Microsoft Excel® (Microsoft, WA, USA).

RESULTS

The results for the first three years when zidovudine and/or nevirapine were being used were compared with year 4, when a HAART regimen was used primarily for preventing mother-to-child transmission of HIV (pMTCT) or for maternal treatment. During the four-year period, 571 HIV-infected pregnant women were enrolled: 62% at VJH, 25% at STH and 13% at UHWI. Sociodemographic factors are shown for the four-year period (Table 1). Mean maternal age was 27–29 years and 68–70% of the women were unem-

Table 1: Booking clinical and laboratory characteristics of HIV-positive Jamaican women seen in the antenatal clinics

Sociodemographic Factors	**Sept 2002 to Aug 2005**	**Sept 2005 to Aug 2006**
Total women in cohort	369	165
Sociodemographic factors	Sept 2002 to Aug 2005	Sept 2005 to Aug 2006
Maternal mean age in years (range)	27 (15 – 42)	29 (17 – 41)
Parity, mean (range)	2 (0 – 9)	2 (0 – 9)
Employed (%)	112 (30%)	54 (32%)
Partners HIV-tested	Unknown	49 (30%)
Partners HIV-positive	Unknown	16 of 49 (33%)
Partners HIV-negative	Unknown	24 of 49 (49%)
Laboratory Profile		
Haemoglobin in mg/dL	4.6 – 14.20	Range: 6.0 – 14.4 Mean: 11.8
Anaemia, ie haemoglobin < 10 mg/dL (%)	89 (24%)	39 of 134 (29%)
Reactive VDRL (%)	12 (3%)	3 of 139 (2%)
CD4+ cells per µL, mean (range)	611 (5 – 808)	*573 (14 – 1028)

*83 subjects (50%) had CD4 counts performed in this time period

ployed. About 32% of partners were HIV-tested and 33% of them tested HIV-positive. Haemoglobin at booking showed that 24–29% of the women were anaemic and 2–3% had a reactive VDRL. During the first three years, $CD4^+$ cell counts were evaluated in only 2.5% (10 of 406) of patients and ranged from 5 to 808 cells per *u*L (median of 344 cells per *u*L) compared to 50% (83 of 165 women) in the last year with mean CD4 count of 573 cells per *u*L (range 14–1028 cells per *u*L). Viral loads were unavailable due to inability of local laboratories to perform analysis at that time.

For the cumulative four-year period, CDC categories of illnesses were Category A – mild disease 83% (n = 473), Category B – moderate disease 4% (n = 24) and Category C – severe disease 1.4% (n = 8) whereas 12% (n = 66) could not be categorized due to insufficient clinical data (Table 2). Patients who had severe disease had the following conditions (Table 2) *viz*: two women with HIV wasting disease and two with herpes zoster and one each with cryptococcosis outside the lungs, toxoplasmosis of the brain, progressive multifocal leukoencephalopathy, can-didiasis – oesophageal or pulmonary and *Pneumocystis jirovecii* pneumonia. The majority of patients with category A disease had asymptomatic HIV infection while most patients with moderate disease had persistent candidiasis of the vagina. In year one, 28% of patients could not be classified due to insufficient data but this declined to 3% in year four.

Antiretroviral (ARV) medications primarily for prevention of vertical transmission were given to 89% (n = 506)

Table 2: CDC sub-categories of clinical disease seen among HIV-positive antenatal Jamaican women by year registered

Clinical CDC Category **Mild Disease (A)**	Year 1 (n = 106) n %	Year 2 (n = 142) n %	Year 3 (n = 158) n %	Year 4 (n = 165) n %	Total (n = 571) n %
HIV infection (Asymptomatic)	66 (62)	117 (82)	138 (87)	148(90)	469 (82)
Acute (primary) HIV infection	0	1	0	0	1
Persistent generalized lymphadenopathy	0	1	0	2	3 (0.5)
Moderate Disease (B)					
Persistent candidiasis of the vagina	7(6)	3(2)	3	0	13 (2)
Oral candidiasis (thrush)	0	1	0	1	2 (0.4)
Cervical abnormalities	0	0	1	5	6 (1)
Herpes zoster (shingles)	0	1	1	0	2
Idiopathic thrombocytopenia purpura	0	0	0	1	1
Severe Disease (C)					
HIV wasting syndrome	1	1	0	0	2 (0.4)
Cryptococcus outside the lungs	1	0	0	0	1
Toxoplasmosis of the brain	1	0	0	0	1
Progressive multifocal leukoencephalopathy	0	1	0	0	1
Candidiasis – oesophageal or pulmonary	0	1	0	0	1
Pneumocystis jirovecii pneumonia	0	0	1	0	1
Herpes simplex causing prolonged skin problems	0	0	0	1	1
CD4+ counts < 200 and asymptomatic	Unknown	Unknown	2	5	7 (1)
Unknown (O)	30 (28)	15 (11)	14 (9)	7 (4%)	66 (12)

of women during the four-year period ranging from 80% to 93% throughout the period. Among these, use of HAART for pregnant HIV-infected women increased from 2–3% in years one to three to 62% in year four.

Throughout the four-year period, 95% (n = 542) of the cohort ended in live births. For the four-year period, 3% had stillbirths, 1% had neonatal deaths and 1% had spontaneous abortions (Table 3). For all four years, 24 maternal deaths (4%) occurred; one occurred antepartum and the others within two years of delivery. Four per cent (one of 24 deaths), occurred in the cohort primarily exposed to HAART while 96% (23 of 24) occurred in the cohort exposed to zidovudine/nevirapine. In 92% (22 deaths), the cause of death was directly related to HIV/AIDS or a known complication thereof.

Table 3: Indication for administered antiretroviral therapy and pregnancy outcomes

Antiretroviral Therapy	Year 1 n = 106	Year 2 n = 142	Year 3 n = 158	Year 4 n = 165	Total n = 571
pMTCT (mono, dual and/or HAART)	85 (80%)	125 (88%)	143 (91%)	153 (93%)	506 (89%)
Triple Therapy (subset of pMTCT)	2 (2%)	0	3 (3%)	101 (62%)	105 (21%)
Pregnancy outcome					
Live births	97 (91)	134 (94)	148 (93%)	164 (99%)	542 (95%)
Spontaneous abortions	0	3 (2)	1	1	5
Stillbirths/IUD	3 (3)	3 (2)	9 (5.6%)	1	16 (2.8)%
Neonatal deaths	4 (4)	1 (1)	*1*	0	6 (1%)
Ectopic pregnancies	1	0	0	0	1
Maternal deaths	12	**7**	4	1	24 (4.2%)

NB: Maternal death: the numbers of women who enrolled in the particular year who have subsequently died within two years of giving birth. One maternal death occurred antepartum.

Table 4: Causes of maternal death

	Sept 2002 – Aug 2005	**Sept 2005 – Aug 2006**
HIV/AIDS-related	11	0
Pneumonia	2	0
Meningitis	1	0
Severe anaemia, sepsis	1	0
Kaposi sarcoma	1	0
Left hemiparesis, severe anaemia	1	0
CNS toxoplasmosis	1	0
Pneumocystis jirovecii pneumonitis	1	0
Cancer of vulva	1	0
Suicide	0	1
Gunshot wound (homicide)	1	0
Unknown	1	0
Total	**23**	**1**

DISCUSSION

Clinicians can now offer infected women a very high likelihood of birthing children who will be HIV-uninfected as well as much improved disease prognosis. An important component of the initial evaluation includes joint assessment of the status of the patient's HIV disease by the internist and obstetrician or nurse-midwives. This will guide recommendations about beginning or altering antiretroviral treatment and discussion of interventions to reduce the risk of perinatal HIV transmission. Most of the patients in this cohort were clinically assessed only by the attending obstetrician and nurse midwives. An integrated system of antenatal and postpartum care involving internists and obstetricians is currently being implemented in order to fully address this issue.

In this study, the majority of the maternal cohort had asymptomatic disease. The initial unavailability of $CD4^+$ T-cell testing limited universal use of the 1992 revised classification system which categorizes persons not only on the basis of clinical disease criteria associated with HIV infection but also $CD4^+$ T-lymphocyte counts (12). Studies have shown that as the number or percentage of $CD4^+$ cells decreased, the risk and severity of opportunistic illnesses increased (13). The use of CD4 counts in the revised classification thus more accurately assessed the severity of HIV-related morbidity and immunosuppression. The results as presented could therefore reflect an underestimation of the severity of disease in this cohort. This theory is supported by the finding that only eight patients were found to have severe disease in the first three years, yet 21 of 22 HIV-related maternal deaths occurred within two years of delivery in the cohort exposed primarily to zidovudine and/or nevirapine. The recent island-wide upgrade of laboratory facilities allowing wide availability of $CD4^+$ counts and viral loads as well as the use of HAART has already minimized peripartum deaths in pregnant women with HIV infection. The earlier experience of this group of researchers with postpartum deaths highlights the importance and need for coordinated care beyond pregnancy.

For the four-year period, 82% of patients had category A disease and 89% received antiretroviral therapy primarily directed at preventing perinatal transmission. These figures

on the surface would be concurrent and appropriate; however, the category of patient who is clinically asymptomatic but whose $CD4^+$ count is less than 200 cells/*u*l and would require HAART therapy urgently remained unidentified and was therefore inappropriately treated. However, current increasing availability of $CD4^+$ counts has addressed this for the present and future. A clear deficiency in therapy was seen in the early years of this study, however, only 1% received the indicated triple antiretroviral therapy despite 8% of patients having been clinically assessed as category C disease. Funding provided by the Elizabeth Glaser Paediatric AIDS Foundation during the first three-year period enabled provision of zidovudine monotherapy and hence increased the proportion of patients that commenced any antiretroviral intervention in pregnancy. Use of mono- or dual-therapy for pMTCT reflected the past problem of triple antiretroviral therapy being largely unaffordable to the population. The Ministry of Health with the aid of the Global Fund has subsidized substantially the cost of medication enabling improved access to triple antiretroviral therapy; therefore access to HAART was increased in year four to 68%, with a substantial decrease in HIV-attributable mortality.

Obi *et al* (14) found that seropositive women were significantly more likely than controls to have recurrent vulvovaginitis and positive syphilis serology. The present cohort also appears to reflect this pattern, as recurrent vulvovaginitis was the most frequent category B disease. Although 3% of the cohort had a positive VDRL which was diagnosed at booking in the antenatal clinic, there was unfortunately no documentation of a confirmatory test for syphilis. A repeat VDRL is also recommended in the third trimester to document seroconversion to a positive VDRL in these vulnerable HIV-infected pregnant women.

Anaemia was documented in over 25% of this cohort. Aggressive diagnosis and treatment of anaemia has to be emphasized as the potential for worsening anaemia in pregnancy with its antecedent antenatal and postpartum complications which coexist with antiretroviral therapy. Despite showing overall improved obstetric outcomes and few maternal toxicities associated with antiretroviral therapy during pregnancy, Tuomola *et al* demonstrated that HAART use in pregnancy was associated with anaemia [OR= 1.6, 95% CI: 1.1, 2.4] (15).

Despite challenges, pregnancy outcomes were relatively good, considering the modest per capita incomes in Jamaica and the low socio-economic status of the patients. The live birth rate was 95% overall. This indicates a low risk of adverse pregnancy outcome in this predominantly CDC class A and B HIV+ cohort, the majority of whom received zidovudine monotherapy. Similar findings of low evidence of adverse pregnancy outcomes were demonstrated by Phanuphak *et al* in a study of HIV-infected pregnant women in Thailand. The women received single dose nevirapine in addition to zidovudine (16).

In 2008, we offer four-drug HAART (*ie* zidovudine, lamivudine, lopinavir with ritonavir) to all HIV-infected women who are diagnosed early in pregnancy, with islandwide uptake consistently approaching 90% regardless of the woman's individual disease stage (15). Lymphocyte subsets and HIV viral loads are also being evaluated consistently. By bringing the patient's viral load to an undetectable level, HAART has minimized the chance of perinatal transmission to < 2% in Kingston and to < 5% islandwide and has also reduced substantially the need for Caesarean delivery for a HIV indication (5). Simultaneously, the mother's prognosis is optimized with minimal maternal toxicity and without significant adverse impact on pregnancy outcome (16).

In summary, a comprehensive system of care of HIV in the peripartum period has been developed in Jamaican nurses and nurse midwives played an important and pivotal role in the execution of the entire KPAIDs programme (11). Detailed medical evaluation during pregnancy in light of the evolution of the guidelines and increasing availability of laboratory facilities to determine $CD4^+$ cell counts and HIV-viral loads, along with opportunistic infection prophylaxis and HAART are now being implemented with comprehensive treatment and care continuing postpartum. The use of HAART-based regimes in pregnant women is now associated with the best outcomes for both the infant who is HIV-negative and the mother with better prognosis evidenced by decreased HIV-attributable morbidity and mortality.

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