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Determinants of suboptimal adherence and elevated HIV viral load in pregnant women already on antiretroviral therapy when entering antenatal care in Cape Town, South Africa

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Abstract

Across sub-Saharan Africa, prevention of mother-to-child transmission services are encountering increasing numbers of women already established on antiretroviral therapy (ART) when entering antenatal care. However, there are few data examining ART adherence and HIV viral load in this group. We used multivariable logistic regression models to examine self-reported suboptimal adherence (defined as missed ART doses on ≥ 2 days during the preceding 30 days), elevated viral load (> 1000 copies/mL), and factors associated with each among women entering antenatal care on ART. Participants were recruited from one primary care clinic in Gugulethu, Cape Town, as part of a larger study of HIV-positive pregnant and postpartum women. Among 482 pregnant women established on ART and enrolled between May 2013 and June 2014 (median age: 31 years; median duration of ART use: 3 years), 15% reported suboptimal adherence and 12% had elevated viral load. After adjustment for age, suboptimal adherence was significantly more common among women who were not married/cohabiting and women who reported a higher level of concern about taking ART; a higher level of adherence self-efficacy was associated with a reduced odds of suboptimal adherence. In a multivariable model, elevated viral load was significantly associated with previous discontinuation of ART, a higher level of concern about taking ART, and report of an unintended pregnancy. Suboptimal adherence and elevated viral load are common among women entering antenatal care already on ART. Our findings highlight specific beliefs and concerns about ART use during pregnancy that should be addressed in counselling messaging, and

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Disclosure statement

The authors have no potential conflicts of interest to declare.

suggest that family planning should be more effectively integrated into HIV care. Including adherence and viral load monitoring as part of pregnancy planning for women on ART may be important to achieve safer conception and promote healthy pregnancies.

Keywords

Adherence; HIV viral load; antiretroviral therapy; pregnancy; South Africa

Introduction

Across sub-Saharan Africa, services for the prevention of mother-to-child HIV transmission (PMTCT) are encountering increasing numbers of women already established on antiretroviral therapy (ART) when entering antenatal care. Among women who initiate ART prior to conception and maintain suppression of HIV viral load, mother-to-child transmission (MTCT) rates close to zero have been documented (Mandelbrot et al., 2015). The incidence of pregnancy following ART initiation is high (Westreich et al., 2012), but sexual and reproductive health and HIV services remain siloed in many countries (Kendall, Bärnighausen, Fawzi, & Langer, 2014). PMTCT services and research have typically focussed on women who are newly initiating ART or short-course antiretroviral prophylaxis, and there are few data examining ART adherence and viral load among women who are already on ART when entering antenatal care.

Although already established on ART, the factors that affect adherence in this population may differ from those among adults accessing general HIV care. Pregnant women may be at increased risk of poor mental health outcomes, especially in low- and middle-income countries (LMICs) (Walker et al., 2007; Walker et al., 2011), and pregnancy may place additional demands on adherence. In general HIV-positive populations, factors such as HIV knowledge (Jones, Cook, Rodriguez, & Waldrop-Valverde, 2013; Wawrzyniak, Ownby, McCoy, & Waldrop-Valverde, 2013), adherence self-efficacy (Langebeek et al., 2014; Nel & Kagee, 2011), and beliefs and concerns about medications (Gonzalez et al., 2007; Kalichman, Kalichman, & Cherry, 2016) have been shown to be significantly associated with adherence, and similar determinants have been documented among HIV-positive pregnant and postpartum women (Hodgson et al., 2014). However, it is unclear to what extent these factors are associated with adherence among pregnant women who are already on ART when entering antenatal care. We thus examined self-reported suboptimal adherence, elevated viral load, and the factors associated with each among HIV-positive pregnant women already on ART when entering PMTCT services in Cape Town, South Africa.

Materials and methods

This cross-sectional analysis includes enrolment data from a larger study of HIV-positive pregnant and postpartum women in the former township of Gugulethu in Cape Town, South Africa (<https://clinicaltrials.gov/ct2/show/NCT01933477>) (Myer et al., 2016). The study was conducted at a primary care clinic which provides services including antenatal care to the

surrounding low socioeconomic community, where the antenatal HIV prevalence is approximately 30% (Myer, Phillips, Manuelli, et al., 2015).

Participants

The larger study from which these data were drawn enrolled consecutive HIV-positive pregnant women who were entering PMTCT services. Women were eligible to participate if they were aged 18 years or older; confirmed HIV-positive using two rapid antibody tests or documentation of HIV status; and entering antenatal care at the study site; women who had initiated ART or prophylaxis at another facility during the current pregnancy were excluded. Enrolment for the larger study was conducted between March 2013 and June 2014. The present analysis was restricted to pregnant women who were already established on ART (self-reported ART use for 4 months) when entering antenatal care at the study site and for whom questionnaire and viral load measures were available. Clinical characteristics and viraemia of the larger sample ($n=1,554$) have been previously described (Myer, Phillips, Hsiao, et al., 2015). All women provided written informed consent prior to enrolment, and the study was approved by the University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee and by the Institutional Review Board of the Columbia University Medical Center.

Measures

This cross-sectional analysis includes self-report measures administered at the time of participants' first routine antenatal visit. Measures were administered in isiXhosa, the predominant local language, by trained interviewers. Demographic and socioeconomic characteristics were assessed and included factors such as marital status, pregnancy intention and educational attainment. Knowledge inventories were used to assess HIV (Kalichman & Simbayi, 2003) and HIV treatment knowledge (Wagner, Kanouse, Koegel, & Sullivan, 2004; Wagner, Remien, Carballo-Diéguez, & Dolezal, 2002). For each inventory, general and PMTCT-specific knowledge scores were created by summing the number of correct responses to items pertaining to each. Beliefs about medications were assessed using a questionnaire adapted from previous published work (Horne, Weinman, & Hankins, 1999). Beliefs about the necessity of ART (Cronbach's alpha (α): 0.78) and concerns about taking ART during the perinatal period (α : 0.77) were assessed separately, as has been widely used elsewhere (Gonzalez et al., 2007; Kalichman et al., 2016). Each item was scored on a Likert scale between 1 ("strongly disagree") and 5 ("strongly agree"), and a mean score was calculated for each subscale such that higher scores indicated higher levels of belief in the necessity of ART and higher levels of concern about taking ART, respectively. Adherence self-efficacy (α : 0.93) was assessed using a 15-item scale assessing confidence to adhere to medications under different circumstances, and which was adapted from previous published research (Chesney et al., 2000). Each item was assessed on a Likert scale between 1 ("not confident at all") and 5 ("very confident"). A mean score was calculated across all 15 items, with higher scores indicating greater self-efficacy. Self-reported ART adherence was assessed based on the number of days on which participants missed dose(s) during the previous 30 days.

In addition to completing self-report measures, participants underwent phlebotomy at their first antenatal visit, and HIV viral load testing (Abbott RealTime HIV-1) and CD4 enumeration via flow cytometry (Beckman Coulter) were conducted by the South African National Health Laboratory Services.

Data analysis

Data were analysed using Stata 12 (StataCorp Inc, College Station, Texas, USA). In order to explore factors associated with suboptimal adherence, variables significantly associated with report of missed ART doses on 2 days during the previous 30 days were identified using χ^2 tests for categorical and Wilcoxon rank sum (Mann-Whitney) tests for non-normally distributed continuous variables. A multivariable logistic regression model was then built in order to identify variables independently associated with suboptimal adherence. When exploring elevated viral load at the start of antenatal care, variables significantly associated with viral load 1000 copies/mL were similarly identified using χ^2 and Wilcoxon rank sum tests. Multivariable logistic regression was then used in order to explore the associations between these variables, potential confounders, and viral load 1000 copies/mL. In sensitivity analyses, suboptimal adherence was defined as report of missed ART doses on 1 day during the previous 30 days, and elevated viral load as 50 copies/mL.

Results

A total of 482 women (median age: 31 years), enrolled between May 2013 and June 2014, were included. Table 1 presents detailed characteristics of this sample. Most women reported a previous pregnancy, and just under half (44%) of the current pregnancies were planned. Intended pregnancy was more likely among married/cohabiting women [odds ratio (OR): 2.53; 95% confidence interval (CI): 1.75–3.66] and women who had been on ART for a longer duration (OR for a one-year increase in duration on ART: 1.13; 95% CI: 1.05–1.22). The median duration of ART use was 2.6 years, and 34 women (7%) reported that they had previously discontinued ART. When entering antenatal care, 20%, 12% and 6% of women had viral load 50, 1000 and 10,000 copies/mL, respectively.

High levels of general HIV and general treatment knowledge were observed, but women had lower levels of PMTCT-specific knowledge, with a mean score of 2.4 [standard deviation (SD): 1.1] out of a maximum of 5. High levels of belief in the necessity of ART were reported (mean score: 4.2 (SD: 0.6) out of a maximum of 5), as well as high levels of adherence self-efficacy (mean score: 4.8 (SD: 0.4) out of a maximum of 5); nevertheless, fairly high levels of concern about taking ART during the perinatal period were also reported (mean score: 2.3 (SD: 1.0) out of a maximum of 5). Missed ART doses during the previous 30 days were reported by 22% of participants ($n=104$), and missed doses on 2 days was reported by 15% ($n=70$). Suboptimal self-reported adherence was strongly associated with elevated viral load (OR: 2.68; 95% CI: 1.41–5.11).

Variables associated with suboptimal adherence were examined in logistic regression models. In unadjusted analyses, suboptimal adherence was significantly more common among women who were not married or cohabiting; women reporting an unintended pregnancy; and women reporting higher levels of concern about taking ART during the

perinatal period and lower levels of adherence self-efficacy (Table 2a). After adjustment for age, single marital status (OR: 1.80; 95% CI: 1.03–3.15) and higher levels of concern about taking ART (OR: 1.40; 95% CI: 1.09–1.82) remained significantly associated with suboptimal adherence, while higher levels of adherence self-efficacy remained significantly associated with a reduced odds of suboptimal adherence (OR: 0.47; 95% CI: 0.26–0.82). In addition, suboptimal adherence was more common among women reporting an unintended pregnancy, although this did not reach statistical significance after adjustment (OR: 1.75; 95% CI: 0.99–3.08).

Variables associated with elevated viral load were similarly examined in logistic regression models. Elevated viral load was significantly more common among women reporting previous discontinuation of ART and among women who reported higher levels of concern about taking ART. Women with better general HIV treatment knowledge were less likely to have elevated viral load (Table 2b). In adjusted analyses, elevated viral load remained independently associated with previous discontinuation of ART (OR: 6.59; 95% CI: 2.93–14.79) and with greater levels of concern about taking ART (OR: 1.38; 95% CI: 1.03–1.85). In addition, elevated viral load was significantly associated with report of an unintended pregnancy (OR: 1.92; 95% CI: 1.02–3.64).

In sensitivity analyses, the association between higher levels of medication concerns and report of missed doses on 1 day during the previous 30 days persisted (OR: 1.38; 95% CI: 1.10–1.72), and the associations with unintended pregnancy (OR: 1.57; 95% CI: 0.98–2.52) and higher levels of adherence self-efficacy (OR: 0.62; 95% CI: 0.37–1.03) were borderline. When examining viral load ≥ 50 copies/mL, only the association between previous discontinuation of ART and elevated viral load persisted (OR: 6.45; 95% CI: 3.07–13.57).

Discussion

This research explored suboptimal adherence to ART, elevated viral load, and factors associated with each among pregnant women already on ART when entering PMTCT services. Missed doses on 1 day during the previous 30 days were reported by 1 in 5 women, with similar levels of elevated viral load observed. Levels of PMTCT-specific knowledge were observed to be low and, although high levels of belief in the necessity of ART were reported, many women expressed concerns about taking ART during the perinatal period. Notably, a higher level of concern was significantly associated with both suboptimal adherence to ART and elevated viral load ≥ 1000 copies/mL. Previous discontinuation of ART was reported by 7% of women, and was strongly associated with elevated viral load. Suboptimal adherence and elevated viral load ≥ 1000 copies/mL were more common among women reporting an unintended pregnancy, and the association between unintended pregnancy and elevated viral load was significant when adjusted for other variables independently associated with elevated viral load.

Although established on ART for a relatively long median duration of time, suboptimal adherence and elevated viral load were common in this sample, with potentially dire consequences for both maternal and child health. The finding here that a higher level of concern about taking ART was associated with both suboptimal adherence and elevated viral

load is consistent with work in general HIV-positive populations (Gonzalez et al., 2007; Kalichman et al., 2016), and represents an important aspect that should be addressed in counselling. Strong and persistent associations were observed between previous discontinuation of ART and elevated viral load, suggesting that women who have previously discontinued ART may require more intensive and ongoing management and support, and again representing an important aspect that should be addressed in counselling. Counselling messaging should highlight the benefits of ART and address concerns that women may have about ART use, as well as emphasize the importance of sustained adherence. Further, the low levels of PMTCT-specific knowledge observed in this sample represent an additional area where specific counselling is required at the start of antenatal care.

The finding that unintended pregnancy may be associated with suboptimal adherence and elevated viral load, coupled with the levels of suboptimal adherence and elevated viral load observed, indicates a need for improved family planning in this population. These data highlight a missed opportunity to address family planning among women already engaged in routine care services, and suggest that family planning should be more effectively integrated into HIV care. Further, integrated services should be expanded beyond the provision of contraceptives to include routine assessment of fertility desires (Cooper, Mantell, Moodley, & Mall, 2015; Heffron et al., 2015; Kendall et al., 2014). Effective integration could reduce unintended pregnancies (Cooper et al., 2015; Heffron et al., 2015), and safer conception could be achieved by including adherence and viral load monitoring as part of pregnancy planning for women established on ART.

Several limitations to these findings must be noted. First, many of the data included were self-reported, and are thus subject to social desirability biases. Nevertheless, the variables observed to be associated with self-reported suboptimal adherence and elevated viral load in this group were relatively consistent, suggesting that self-reported missed doses is a reasonable measure of suboptimal adherence in this sample. Also, report of suboptimal adherence was strongly associated with elevated viral load, further demonstrating the utility of this self-reported measure in this context. Other factors known to affect adherence, for example poor mental health and ART side effects, were not investigated in this sample, and their associations with suboptimal adherence and elevated viral load could not be examined. As this study included only cross-sectional measures from participants' first antenatal visit, conclusions cannot be made regarding the specific impact of pregnancy on adherence and viral load, and further exploration using other longitudinal datasets is warranted. Other South African data suggest that suboptimal adherence may be higher during the postpartum period specifically compared to non-pregnant periods among women established on ART (Henegar et al., 2015); here, we were unable to compare reported adherence during pregnancy to that in postpartum or non-pregnant periods. Finally, participants were recruited from one primary care clinic, and while they are likely to be representative of other pregnant women established on ART in this community, the generalizability of these results to other settings should be considered with caution.

Despite these limitations, the findings from this study are notable, given the dearth of data from the growing population of pregnant women already on ART when entering PMTCT services. High rates of incident pregnancy after ART initiation have been observed in South

Africa (Westreich et al., 2012), and understanding the barriers to achieving optimal treatment outcomes in this population will become increasingly important in order to ensure both long-term maternal health as well as reduced risks of MTCT. Given the prevalence of suboptimal adherence and elevated viral load observed here, this information is timely and urgently needed. Our findings suggest that there is a need to address specific beliefs and concerns about ART use during pregnancy, and to effectively integrate family planning into HIV care. Including adherence and viral load monitoring as part of pregnancy planning for women on ART may be important to achieve safer conception and promote healthy pregnancies.

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Table 1

Demographic and clinical characteristics and adherence to antiretroviral therapy (ART)

Variable	n (%)
Number of participants	482
<i>Demographic and clinical characteristics</i>	
Median [IQR] age	31 [28, 35]
Ethnicity – Black/African	482 (100)
Completed secondary/some tertiary education	106 (22)
Currently employed	187 (39)
Married/cohabiting	234 (49)
Primigravida	49 (10)
Median [IQR] gestation in weeks when entering antenatal care	20 [14, 28]
Unintended pregnancy	268 (56)
Median [IQR] duration on ART in years	2.6 [1.4, 4.8]
Previously discontinued ART	34 (7)
ART regimen	189 (39)
Does not know names of medications	161 (33)
TDF-3TC-EFV	53 (11)
TDF-3TC-NVP	50 (10)
Other NNRTI-based regimen	27 (6)
PI-based regimen	2 (0.4)
Other second-line regimen	
HIV viral load at start of antenatal care	385 (80)
<50 copies/mL	40 (8)
50–999 copies/mL	28 (6)
1000–9999 copies/mL	29 (6)
10,000 copies/mL	
CD4 cell count at start of antenatal care (n=473)	50 (11)
200 cells/μL	141 (30)
201–350 cells/μL	133 (28)
351–500 cells/μL	149 (32)
>500 cells/μL	
<i>HIV and treatment knowledge, medication beliefs and adherence self-efficacy</i>	
Mean (SD) HIV knowledge scores	3.6 (0.7)
General HIV knowledge score (max=4)	2.4 (1.1)
PMTCT knowledge score (max=5)	
Mean (SD) HIV treatment knowledge scores	5.0 (0.7)
General treatment knowledge score (max=6)	1.9 (0.5)
PMTCT treatment knowledge score (max=2)	
Mean (SD) medication beliefs scores	4.2 (0.6)
Medication necessity score (max=5)	2.3 (1.0)
Medication concerns score (max=5)	
Mean (SD) adherence self-efficacy score (max=5)	4.8 (0.4)
<i>ART adherence</i>	
Report of missed doses on 1 day during previous 30 days	104 (22)
Report of missed doses on 2 days during previous 30 days	70 (15)
Mean (SD) number of days on which doses missed (n=104)	2.9 (4.1)

Table 2

Variables associated with (a) suboptimal adherence to antiretroviral therapy and (b) elevated HIV viral load¹

Variable	(a) Variables associated with suboptimal adherence			(b) Variables associated with elevated viral load		
	Unadjusted odds ratio [95% CI]	P-value	Adjusted odds ratio [95% CI]	Unadjusted odds ratio [95% CI]	P-value	Adjusted odds ratio [95% CI]
Age	0.97 [0.92, 1.02]	0.181	0.98 [0.93, 1.04]	0.97 [0.92, 1.03]	0.305	0.98 [0.92, 1.04]
Educational attainment						
Completed secondary/any tertiary	Reference	0.850		Reference	0.855	
Primary/some secondary	0.94 [0.52, 1.73]			1.06 [0.54, 2.10]		
Employment						
Employed	Reference	0.173		Reference	0.747	
Unemployed	1.46 [0.85, 2.51]			1.10 [0.62, 1.95]		
Relationship status						
Married/cohabiting	Reference	0.005	Reference	Reference	0.062	Reference
Single	2.15 [1.26, 3.66]		1.80 [1.03, 3.15]	1.72 [0.97, 3.05]		1.42 [0.77, 2.63]
Pregnancy intention						
Intended	Reference	0.037	Reference	Reference	0.076	Reference
Unintended	1.77 [1.03, 3.02]		1.75 [0.99, 3.08]	1.70 [0.95, 3.04]		1.92 [1.02, 3.64]
Previously discontinued ART						
Never discontinued	Reference	0.301		Reference	<0.001	Reference
Previously discontinued	1.58 [0.66, 3.79]			5.68 [2.66, 12.14]		6.59 [2.93, 14.79]
General HIV knowledge score						
	0.84 [0.60, 1.17]	0.297		1.12 [0.74, 1.71]	0.583	
PMTCT knowledge score						
	1.06 [0.85, 1.34]	0.601		0.86 [0.67, 1.12]	0.259	
General treatment knowledge score						
	0.90 [0.64, 1.25]	0.519		0.69 [0.49, 0.97]	0.035	0.78 [0.54, 1.11]
PMTCT treatment knowledge score						
	0.85 [0.51, 1.43]	0.544		0.91 [0.51, 1.64]	0.765	
Medication necessity score						
	0.75 [0.51, 1.12]	0.158		0.87 [0.56, 1.34]	0.521	
Medication concerns score						
	1.45 [1.13, 1.85]	0.003	1.40 [1.09, 1.82]	1.32 [1.02, 1.73]	0.038	1.38 [1.03, 1.85]
Adherence self-efficacy score						
	0.40 [0.23, 0.70]	0.001	0.47 [0.26, 0.82]	0.56 [0.30, 1.04]	0.065	0.70 [0.36, 1.36]

¹ Suboptimal adherence defined as missed ART doses on 2 days during preceding 30 days; elevated viral load defined as 1000 copies/mL