# MAJOR ARTICLE







# Mortality Over Long-term Follow-up for People With HIV Receiving Longitudinal Care and Antiretroviral Therapy in Rural Haiti

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**Background.** Deaths from HIV have fallen dramatically with the increasing availability of fully suppressive antiretroviral therapy (ART), and yet HIV remains the ninth leading cause of death in low-income countries. As more people with HIV enter care and receive ART, the focus will need to shift from expanding ART to including long-term program effectiveness and outcomes for people with HIV already engaged in care.

*Methods.* We evaluated risk factors for mortality among people with HIV on ART receiving longitudinal care in rural Haiti. We assessed baseline characteristics using a household survey and abstracted clinical characteristics from the electronic record. We used multivariable Cox regression models to identify risk factors for mortality.

Results. There were 464 people included in this study with a median follow-up (interquartile range [IQR]) of 69 (44–77) months, during which time 37 (8%) were lost to follow-up and 118 (25%) died (median time to death [IQR], 29 [12–53] months). After adjustment, poverty (adjusted hazard ratio [AHR], 1.12 per 10–percentage point increased probability; 95% CI, 1.01–1.24) and single marital status (AHR, 1.59; 95% CI, 1.08–2.36) were associated with increased mortality. Age (AHR, 0.78 per 10-year increase; 95% CI, 0.64–0.94), role function quality of life (AHR, 0.75 per quintile increase; 95% CI, 0.62–0.90), and CD4 count (AHR, 0.66 per 100 cells/μL; 95% CI, 0.58–0.75) were associated with decreased mortality.

**Conclusions.** Poverty, marital status, and quality of life were associated with mortality. Social protection should be evaluated as a strategy to reduce mortality for people with HIV in concert with increasing access to ART.

**Keywords.** Haiti; HIV; long-term mortality; low-income setting; social determinants of health; social support; structural drivers.

Annual deaths from HIV have decreased by over half since peaking at 1.95 million in 2006 [1]. Much of this improvement has resulted from a progressive expansion of access to antiretroviral therapy (ART) [2], with the percentage of people with HIV receiving ART increasing from 24% in 2010 to 62% in 2018 [3]. Despite this improvement, substantial heterogeneity remains, with HIV still remaining the leading cause of death in Sub-Saharan Africa and the ninth leading cause of death in low-income countries worldwide [1]. The Joint United Nations Programme on HIV/AIDS (UNAIDS) released a Fast Track plan in 2014 with the goal of ending HIV as a public health threat and reducing deaths from HIV by 90% by 2030 [4]. This

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plan emphasizes the rapid scaling up of clinical services, primarily through engagement and retention in care and universal ART access, with targets for HIV diagnosis, treatment, and viral suppression of 90-90-90 by 2020 and 95-95-95 by 2030 [5].

As more people with HIV enter care and initiate ART in the current era of universal treatment, the focus will need to expand beyond engagement in care to ensure long-term program effectiveness for people with HIV receiving ART. While HIV viremia is an essential surrogate marker of risk for adverse outcomes, overall survival remains the most critical indicator of treatment success. Relatively few published studies have evaluated risk factors for mortality over long-term follow-up among people with HIV receiving ART in low- and middle-income countries [6–13]. The majority of these studies have been reported from high-burden, middle-income countries in Sub-Saharan Africa during periods of major expansion in ART access.

Haiti is a low-income country in the Caribbean with a moderate HIV prevalence of 2% [3]. Compared with similar settings, Haiti experienced an early expansion of HIV clinical services and ART. This expansion of access coincided with a fall in the HIV-related death rate in Haiti starting in 2000, 7 years before the global decline in HIV deaths began, with a 70% reduction in

deaths per year from HIV since then [1]. There is thus an opportunity in Haiti to better understand risk factors for adverse outcomes among people with HIV receiving longitudinal care in a low-income setting after ART access has been prioritized. Two studies from a large clinic in Port-au-Prince, the capital of Haiti, evaluated risk factors for mortality over long-term follow-up among people with HIV initiating ART: 1 study followed participants for 10 years after ART initiation in 2003–2004 [10]; the other had a median follow-up time of 3.5 years for participants who had initiated ART in 2003–2011 [8]. In this study, we report risk factors for mortality during long-term follow-up over the most recent decade in a rural Haitian cohort of people with HIV who are in care and receiving ART.

### **METHODS**

### **Setting and Participants**

We conducted a secondary analysis of data from a randomized controlled trial comparing 2 types of food supplements (ready-to-use supplementary food [RUSF] and corn soy blend [CSB]) for people with HIV receiving care at 1 of 3 rural health centers in the Artibonite Department of Haiti—St Marc, Petite Rivière de l'Artibonite, and Verrettes [14]. These health centers provide comprehensive medical care free of charge to patients and are managed by the nongovernmental organization Partners in Health/Zanmi Lasante in collaboration with the Haitian Ministry of Health. Participants were recruited beginning in June 2010 and were eligible for the trial if they were 18 years of age or older, confirmed to have HIV infection, had initiated ART within the prior 24 months, and were still currently receiving ART at the time of enrollment.

## Data

The study included structured survey assessments of the participants and their households at baseline and at 6- and 12-month follow-up. This secondary analysis was restricted to participants who completed the baseline survey. Through the survey, we collected information on the participants' age, sex, marital status, literacy, education, whether they had any incomegenerating activity, household size, and whether they were assigned a community health worker. We used a previously validated, Haiti-specific poverty scorecard based on 10 indicators to estimate the predicted probability that a participant's household had a total consumption below the national poverty line (~\$1 per day) [15]. We assessed for household food insecurity using the Household Hunger Scale, a subset of 3 items from the Household Food Insecurity Access Scale that has been validated across a variety of cultures [16]. The Household Hunger Scale classifies households into 1 of 3 categories: no hunger in the household, moderate hunger in the household, or severe hunger in the household. We adapted 3 quality-of-life measures for local use based on subscales of the Medical Outcomes

Study HIV Health Survey—health perception, role function, and physical function [17]. These quality-of-life measures are reported from 0 to 100, with a higher score indicating better quality of life. We defined suboptimal adherence as self-report of missing any doses of ART in the prior 30 days. Using the electronic medical record, we abstracted date of ART initiation, CD4 count, hematocrit, height, and weight at study enrollment, as well as current clinical status (actively followed and receiving ART, actively followed but not receiving ART, transferred, lost to follow-up, or deceased). The baseline time point data were collected in June 2010, and clinical status was collected in November 2017.

# **Statistical Analysis**

We reported baseline characteristics and outcomes using No. (%) for categorical variables and median (interquartile range [IQR]) for continuous variables.

We fitted a multivariable Cox proportional hazards model to identify risk factors for mortality, our primary outcome of interest. Missingness was <10% for all variables except hematocrit (14%). To account for missing data, we performed multiple imputation (n = 20) by covariate and outcome data using the fully conditional specification method and generated pooled hazard ratios (HRs) with 95% confidence intervals across data sets. We used univariable models to identify which baseline variables were associated with mortality at the P < .2 significance level and then included all such variables in a multivariable model. All included variables were considered biologically plausible risk factors for our outcome. We tested the proportional hazards assumption by inspecting Schoenfeld residuals and hazard ratio plots. We calculated the variance inflation factor to assess for multicollinearity among model covariates and conservatively considered an inflation factor >2.50 to be indicative of potential multicollinearity, sequentially dropping variables with the highest VIFs from the regression model until none of the remaining variables had a VIF >2.5.

We also estimated risk factors for loss to follow-up as a secondary outcome, again using a multivariable Cox proportional hazards model. We estimated cause-specific HR for loss to follow-up, with death considered to be a competing risk. We used a similar process as above to identify candidate variables to include in the multivariable model, except that we used a *P* value cutoff of <.05 rather than <.2 because there were relatively few loss to follow-up events, and a more parsimonious model was necessary to achieve convergence.

We performed statistical analysis using SAS, version 9.4 (SAS Institute, Cary, NC, USA).

# **Patient Consent Statement**

Ethical approval was granted by the Institutional Review Boards of Partners HealthCare (Boston, MA, USA; protocol numbers 2008P002017 and 2019P002866) and Zanmi Lasante (Cange,

Haiti). All participants provided written informed consent, or if unable to write, verbal consent was witnessed.

### **RESULTS**

Of the 524 people with HIV who participated in the trial, 464 completed the baseline survey and are included in this study (Table 1). Most were women, with a median age (IQR) of 38 (31–46). The median predicted probability (IQR), based on the poverty scorecard data, of living in a household below the poverty line (<\$1 per day) was 61% (51%–83%). Nearly all (497 [89%]) reported having moderate or severe hunger in the household. Participants reported moderate quality-of-life impairments, with a median health perception score (IQR) of 42 (33–58), role function score of 50 (50–100), and physical function score of 63 (50–88).

Participants initiated ART a median (IQR) of 11 (6–17) months before study enrollment. They had a median CD count of 336 (206–476) cells/ $\mu$ L at enrollment. Three quarters reported 100% adherence to ART, and nearly 90% had a community health worker.

The participants had a median follow-up (IQR) of 69 (44–77) months after enrollment, for a total of 2234 person-years of follow-up. At the end of follow-up, there were 296 (64%) still actively followed on ART, 4 (1%) actively followed not on ART, 9

Table 1. Characteristics of Participants at Study Enrollment ( $n = 464^{\circ}$ )

	202 (61)		
	283 (61)		
	38 (31–46)		
Petite Riviere de l'Artibonite	168 (36)		
St Marc	203 (44)		
Verrettes	93 (20)		
	238 (51)		
Able to read and write (n = 463)			
	166 (36)		
Number of people in household			
	136 (29)		
Likelihood of poverty, median (IQR) (n = 456)			
No hunger	49 (11)		
Moderate hunger	171 (38)		
Severe hunger	236 (52)		
Health perception score, median (IQR) (n = 452)			
Role function score, median (IQR) (n = 460)			
Physical function score, median (IQR) (n = 458)			
	36 (33–39)		
Body mass index, median (IQR) (n = 425), kg/m <sup>2</sup>			
CD4 count, median (IQR) (n = 453)			
Months on ART, median (IQR) (n = 460)			
Community health worker			
Suboptimal adherence			
Assigned to RUSF group			
	St Marc Verrettes  IQR) (n = 456)  No hunger Moderate hunger Severe hunger an (IQR) (n = 452)  QR) (n = 460) n (IQR) (n = 458)  I (IQR) (n = 458)		

Data are presented as No. (%) unless otherwise specified.

Abbreviations: ART, antiretroviral therapy; IQR, interquartile range; RUSF, ready-to-use therapeutic food.

<sup>a</sup>Unless otherwise noted.

(2%) who had been transferred to another clinic, 37 (8%) who had been lost to follow-up, and 118 (25%) who were deceased. The death rate was 5.3 per 100 person-years, with heterogeneity across sites: 3.0 per 100 person-years at St Marc, 4.1 per 100 person-years at Verrettes, and 9.3 per 100 person-years at Petite Riviere de l'Artibonite (Figure 1). Among the 118 participants who died, death occurred a median (IQR) of 29 (12–53) months after enrollment.

For the primary outcome of mortality, the following were associated with mortality with P < .2 in univariable analyses: age, sex, single marital status, health center, income-generating activity, likelihood of poverty, severe household food insecurity, role function score, CD4 count, having a community health worker, assignment to the RUSF group, body mass index, and hematocrit (Table 2). Income-generating activity and food insecurity showed evidence of multicollinearity and were removed from the multivariable model. After adjustment, mortality was associated with single marital status (adjusted HR [AHR], 1.59; 95% CI, 1.08-2.36), poverty (AHR, 1.12 per 10-percentage point probability of living under the poverty line; 95% CI, 1.01-1.24), age (AHR, 0.98 per year; 95% CI, 0.96-0.99), role function quality of life (AHR, 0.75 per quintile increase; 95% CI, 0.62-0.90), and baseline CD4 count (AHR, 0.66 per 100 cells/ μL; 95% CI, 0.58-0.75). Participants attending Petite Riviere de l'Artibonite had an increased hazard of death relative to those at St Marc (AHR, 3.02; 95% CI, 1.89-4.81).

For the secondary outcome of loss to follow-up, due to the need for model parsimony, we used a more stringent cutoff for inclusion of the following variables in the multivariable regression model (P < .05 on univariate analysis): age, income-generating activity, role function score, and having a community health worker (Table 3). After adjustment, only having an income-generating activity was associated with loss to follow-up (AHR, 2.16; 95% CI, 1.10–4.24).

### **DISCUSSION**

This observational study of 464 adults with HIV receiving ART in rural Haiti is one of the few reporting factors associated with mortality over long-term follow-up in a low-income setting. With <10% overall loss to follow-up, one-quarter of the participants died over a median follow-up time of nearly 6 years. The concurrent findings of high mortality and high clinical retention for people with HIV on ART in rural Haiti suggest that regular clinical follow-up and provision of ART are insufficient to prevent poor outcomes in impoverished settings. Using multivariable regression models, we found that poverty, single marital status, younger age, poorer role function quality of life, and lower baseline CD4 count were independently associated with mortality. We also found significant variation in mortality by location.

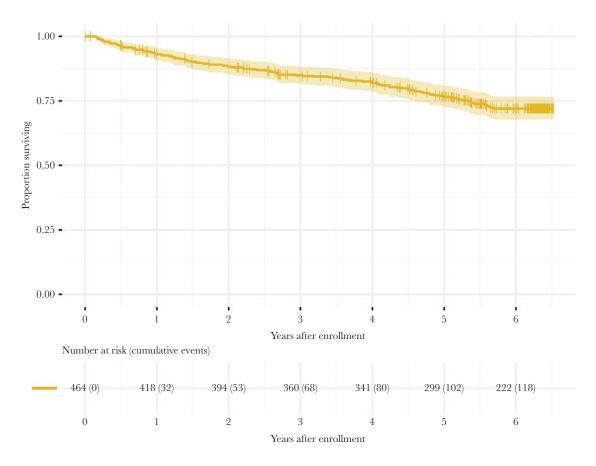


Figure 1. articipant survival over time shown on a Kaplan-Meier curve with a 95% confidence limit band (n = 464). The dashed lines represent censored events.

Rural Haitians face widespread impoverishment and limited public infrastructure, and this study took place during a particularly challenging time in Haiti, shortly after a devastating earthquake and in the midst of a large cholera epidemic. The health centers in this study had prioritized ART access for over a decade at the time of this study and provide some economic assistance as part of routine care for people with HIV (eg, transportation vouchers, school fees for patients' children). Despite these measures and even though economic hardship and food insecurity were pervasive in this community, we still found that relative poverty within our rural study population remained a powerful predictor of death independent of immunologic status and other demographic, clinical, and social factors. This finding is consistent with an earlier study of people with HIV in Haiti, albeit in an urban setting, which found an association between poverty and death over 10 years of follow-up [10].

This finding has several implications. Social protection and poverty reduction programs, particularly those targeting households experiencing the worst levels of deprivation, may be important components of reducing mortality for people with HIV who are on ART. This suggestion is supported by a randomized controlled trial of financial incentives in the United States for people with HIV on ART, which found an improvement in viral suppression rates over 3 years of follow-up [18]. Another

randomized controlled trial of unconditional cash transfers for people with HIV on ART in rural Uganda did not find a significant improvement in CD4 count or ART adherence after 1 year [19]. However, that study was limited by a high baseline CD4 count and a lack of viral load monitoring or poverty assessment. There has also been 1 small cluster randomized trial in which people with HIV on ART in Kenya were provided with a water pump, microfinance loan for farm commodities, and education in sustainable farming practices and financial management [20]. This study found an improvement in food security, CD4 count, and rates of viral suppression after 1 year. Companion qualitative studies suggested additional beneficial impacts on stigma and mental health [21, 22]. In addition to social protection and poverty reduction programs, standardized assessments capable of distinguishing relative impoverishment should be incorporated into routine clinical care for HIV in order to identify patients at highest risk of poor outcomes.

No studies have evaluated the effect of socioeconomic interventions on mortality for people with HIV receiving ART. Other studies of social protection in the context of HIV have primarily focused on cash transfers or microfinance loans for the prevention of HIV in young women [23–26]. High-quality research should be undertaken to better understand the efficacy and effectiveness of various social protection strategies implemented

Table 2. Cox Proportional Hazards Models Showing Unadjusted and Adjusted Risk Factors for Mortality (n = 464)

		Univariable		Multivariable	
		Hazard Ratio	95% CI	Hazard Ratio	95% CI
Age <sup>a</sup>		0.87	0.73-1.03	0.78	0.64-0.94
Female		0.71	0.49-1.02	0.67	0.44-1.01
Single		1.28	0.89-1.85	1.59	1.08-2.36
Health center	St Marc	ref		ref	
	Verrettes	1.40	0.80-2.47	1.27	0.71-2.27
	Petite Riviere de l'Artibonite	3.09	2.01-4.76	3.02	1.89-4.81
Income-generating activity		0.66	0.42-1.02		
Some secondary education		1.16	0.75-1.79		
Number of household members <sup>b</sup>		1.01	0.94-1.08		
Likelihood of poverty <sup>c</sup>		1.13	1.03-1.24	1.12	1.01-1.24
Severe household food insecurity		1.50	1.03-2.19		
Health perception score <sup>d</sup>		1.02	0.85-1.22		
Role function scored		0.80	0.69-0.92	0.75	0.62-0.90
Physical activity scored		0.88	0.78-1.01	1.09	0.92-1.30
CD4 count <sup>e</sup>		0.66	0.58-0.74	0.66	0.58-0.75
Community health worker		0.60	0.37-0.98	1.04	0.62-1.74
Suboptimal adherence		0.91	0.58-1.43		
Assigned to RUSF group		0.76	0.53-1.10	0.80	0.55-1.17
Body mass index <sup>f</sup>		0.95	0.89-1.00	1.00	0.95-1.06
Hematocrit <sup>g</sup>		0.97	0.94-1.01	0.96	0.92-1.00

Abbreviation: RUSF, ready-to-use supplementary food.

with a goal of reducing mortality for people with HIV on ART in low-income settings.

While UNAIDS has released a report in support of social protection in the context of HIV treatment [27], the only socioeconomic support mechanism highlighted in the Fast Track plan is cash transfers for girls in areas with low school enrollment [5]. Funding for social protection through UNAIDS and the President's Emergency Plan for AIDS Relief (PEPFAR) has reduced over time and is currently principally available through the Orphans and Vulnerable Children (OVC) program and the Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe (DREAMS) public/private partnership for adolescent girls and young women [28]. However, this study and the others referenced above suggest that impoverishment itself could be considered a criterion for eligibility for social support for people with HIV and that funding for a broader scope of social support programming should be considered, with the goal of improving long-term outcomes in Haiti and similar settings.

We also found that poorer role function quality of life was independently associated with risk of mortality. The role function quality of life subscale is comprised of 2 questions: (1) "Does your health keep you from working at a job, doing work around the house or going to school?" (2) "Have you been unable to do certain kinds or amounts of work, housework or schoolwork because of your health?" This study suggests that loss of ability to function in a societal role is a major marker for subsequent poor outcomes for people with HIV. In settings of relative scarcity, where loss of livelihood can have especially dire consequences for a household, people may be more likely to continue working at a job or in the home until illness and/or disability is advanced. Questions like those in the role function quality of life subscale may be useful as a quick and straightforward risk assessment to identify people with impending crises who may benefit from more intensive clinical support and social services. Overall health-related quality of life was found to be associated with survival among people with HIV on ART in the Netherlands [29], but this relationship has not previously been explored in low-income settings.

We found an independent association between single marital status and risk of death, suggesting the potential benefits of increased family support for people with HIV in rural Haiti. While this finding is consistent with other observational studies that have found an association between family support and improved HIV outcomes, a systematic review identified no studies evaluating interventions around family support with the goal of improving HIV morbidity or mortality [30].

<sup>&</sup>lt;sup>a</sup>Per increase of 10 years

<sup>&</sup>lt;sup>b</sup>Per 1-member increase.

<sup>°</sup>Per 10% increase.

<sup>&</sup>lt;sup>d</sup>Per quintile decrease

ePer increase of 100 cells/μL

Per increase in 1 m/kg2

<sup>&</sup>lt;sup>g</sup>Per increase in 1%.

Table 3. Cox Proportional Hazards Models Showing Unadjusted and Adjusted Risk Factors for Loss to Follow-up, With Mortality Considered a Competing Risk (n = 464)

		Univariable		Multivariable	
		Hazard Ratio	95% CI	Hazard Ratio	95% CI
Age <sup>a</sup>		0.69	0.49-0.97	0.70	0.49-1.01
Female		0.68	0.36-1.30		
Single		0.76	0.40-1.45		
Health center	St Marc	ref			
	Verrettes	0.93	0.40-2.14		
	Petite Riviere de l'Artibonite	0.86	0.41-1.82		
Income-generating activity		2.57	1.35-4.89	2.16	1.10-4.25
Some secondary education		1.28	0.60-2.71		
Number of household members <sup>b</sup>		0.95	0.83-1.09		
Likelihood of poverty <sup>c</sup>		1.03	0.88-1.19		
Severe household food insecurity		0.82	0.43-1.56		
Health perception score <sup>d</sup>		1.15	0.85-1.56		
Role function score <sup>d</sup>		1.39	1.08-1.79	1.25	0.96-1.63
Physical activity score <sup>d</sup>		0.92	0.72-1.15		
CD4 count <sup>e</sup>		0.87	0.72-1.05		
Community health worker		0.44	0.20-0.97	0.54	0.24-1.22
Suboptimal adherence		0.88	0.41-1.86		
Assigned to RUSF group		1.71	0.86-3.40		
Body mass index <sup>f</sup>		0.94	0.85-1.04		
Hematocrit <sup>g</sup>		1.02	0.95-1.11		

Abbreviation: RUSF, ready-to-use supplementary food.

The health centers included in our study have similar staffing, resources, clinical protocols, social service support, and supervision. Despite this, as in other settings [13], we found significant variation in mortality by site. Our study does not allow us to determine the precise reason for this difference, but several potential causes may be contributing. In particular, unmeasured structural barriers to care and patients' social circumstances vary regionally, even within the relatively small geographic area of this study. For example, health workers at Petite Rivere de l'Artibonite report that patients are less likely to agree to visits by a community health worker, that there are more patients who are men who have sex with men, and that there is a higher migrant farmer population than at other sites; these factors may contribute to differential outcomes between health centers. While there may also be unrecognized differences in health service delivery, differences in site-level outcomes should be more deeply explored to better address issues specific to those communities.

There was low loss to follow-up in this study overall, likely due to the clinical model of care, which includes an understanding of the social circumstances for individual patients, a social worker on the clinical care team, and home visits by

community health workers (termed "accompaniment") as part of adherence support. We found that having incomegenerating activity was an independent risk factor for loss to follow-up. We hypothesize that this finding relates to both the difficulty of attending regular clinical follow-up when working (especially if a patient is informally employed, has no days off during the week, and/or has no protections for sick leave) and the link in Haiti between employment and migration, with the inherent challenges of transferring health care in such situations. Nontraditional or flexible clinical follow-up plans with expedited appointments and longer intervals between visits have been associated with low rates of loss to follow-up in urban Haiti [31] and may be specifically useful for patients with regular income-generating activity. Other innovations around delivery of ART by community health workers and adherence clubs may also be helpful for this population [32, 33]. The seemingly contradictory finding that both material impoverishment and income-generating activity are associated with poor outcomes in this study underlines the social complexity of life and illness in rural Haiti and the fact that retention in care may be a poor surrogate for mortality risk in the universal ART era.

<sup>&</sup>lt;sup>a</sup>Per increase of 10 years

<sup>&</sup>lt;sup>b</sup>Per 1-member increase

<sup>&</sup>lt;sup>c</sup>Per 10% increase.

<sup>&</sup>lt;sup>d</sup>Per quintile decrease

<sup>&</sup>lt;sup>e</sup>Per increase of 100 cells/μL.

fPer increase in 1 m/kg2

<sup>&</sup>lt;sup>g</sup>Per increase in 1%.

The strengths of this study include a comprehensive baseline assessment of both clinical and socioeconomic factors, low loss to follow-up, use of the hard end point of mortality, and little missingness of data. This study also has several limitations. Viral load monitoring was not routinely available in Haiti until 2015, so we cannot evaluate the connection between identified risk factors, virologic suppression, and mortality. There may be additional unmeasured factors that confound the relationship between the included variables and mortality. While the relationship between the role function quality of life scale and mortality is meaningful for the reasons listed above, the selected subscale measures reported in this study should be interpreted with caution as they are validated for use as a composite score. While consideration of covariates in a time-dependent manner would allow for understanding of how changes over time impact mortality risk, we considered only characteristics at the initial survey assessment because this assessment occurred after initial clinical stabilization on ART, thus reducing likelihood of bias from return to health phenomena, and because of substantial missingness at later time points.

### CONCLUSIONS

In conclusion, we found that poverty and single marital status were directly and independently associated with mortality and that age, role function quality of life, and CD4 count were inversely and independently associated with mortality in a cohort of people with HIV on ART in rural Haiti. This study also identifies impairment in role function as an important marker of subsequent poor outcomes. Our findings suggest that a standard assessment of a patient's socioeconomic conditions should be included as part of routine HIV care and that social protection should be evaluated as a strategy to further reduce mortality for people with HIV who are on ART in low-income settings.

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