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ORIGINAL RESEARCH

Medication Adherence and Health Outcomes of People Living with HIV Who Are Food Insecure and Prescribed Antiretrovirals That Should Be Taken with Food

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ABSTRACT

Introduction: Food insecurity is a well-established predictor of poor health outcomes. Antiretroviral therapies (ARTs) that should be taken with food to increase bioavailability may further challenge food insecure patients. This study examined factors associated with antiretroviral adherence and HIV viral suppression among people living with HIV who are food insecure and prescribed medications that require food.

Methods: A community sample of 313 men and 105 women who experienced food insecurity in the previous month and were currently taking ART completed computerized interviews, urine screening for drug use, prospective biweekly unannounced pill count adherence assessments, and obtained their HIV viral load and CD4 cell counts from medical records.

Results: Individuals taking ART regimens that should be taken with food were significantly more likely to be unemployed, were living longer with an HIV diagnosis, had lower CD4 cell counts, poorer HIV suppression, and endorsed more beliefs that taking medications was necessary for their health. Multivariable regression models controlling for potential confounding factors showed that receiving ART that requires food was significantly related to poorer ART adherence and unsuppressed HIV in this food insecure sample.

Conclusion: People living with HIV who are food insecure likely experience multiple facets of poverty that challenge their medication adherence, but food insecurity is the only such factor that is directly related to the pharmacokinetics of some antiretroviral medications. Achieving optimal treatment outcomes for HIV infection will require routine assessment of access to food when determining patient-tailored ART regimens.

Keywords: Adherence; Antiretroviral therapy; Food insecurity; HIV treatment

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INTRODUCTION

Food insecurity is a significant barrier to long-term antiretroviral therapy (ART) in resource-rich as well as resource-limited settings [1–3]. In urban centers with abundant but inequitable access to food, including in the United States (US) and Canada, people living with HIV who experience food insecurity are less likely to be adherent to treatment, achieve poorer HIV viral suppression, and have greater mortality than their food secure counterparts [4–7]. Food insecurity itself can interfere with medication adherence by disrupting daily routines, impairing memory and attention, impeding adherence strategies, and reducing motivation [8]. In essence, the immediacy of accessing food to meet survival needs can understandably take priority over adhering to medication schedules. Patients may forego taking medications at times when food is unavailable if they have been instructed that their medicines should always be taken with food. In addition to the direct effects of food insecurity on antiretroviral adherence, lacking food will further challenge the clinical efficacy of ART when required to be taken with food for maximum absorption and clinical benefit [9].

Food is required for processing, absorption, and optimal clinical benefits for certain ART regimens, with pharmacokinetic studies showing as much as a 38% increase in the availability of some antiretrovirals when taken with food [10, 11]. The protease inhibitor darunavir, for example, is rapidly absorbed and systemic exposure is increased by 30% when taken with a meal [12, 13]. Similarly, administration of atazanavir with a light meal results in a 70% increase in drug plasma concentration [14]. The bioavailability of ritonavir, which itself is used to boost the bioavailability of other protease inhibitors, is also suboptimal when taken without food [15]. Similarly, taking tenofovir and rilpivirine with a meal can mean as much as a 36% increase in drug bioavailability [16, 17]. People who are food insecure must therefore periodically choose to either take their medications knowing they are not following directed use or miss their medications altogether when food is unavailable. People living with HIV who experience food insecurity may therefore have poorer clinical outcomes as a result of both non-adherence and insufficient absorption. In a previous study, we found that a significant number of people living with HIV who are food insecure are prescribed ART that should be taken with food and these individuals had more HIV symptoms, lower CD4 cell counts, and poorer HIV suppression than their counterparts who were not prescribed ART that requires food [18]. Given that our previous study was the first to investigate antiretrovirals that require food prescribed to people with HIV who are also food insecure, the current study sought to extend those findings in an independent sample.

The current study investigated ART adherence and viral suppression among people living with HIV who are food insecure in relation to receiving ART that should be taken with food. We extend past research that has examined food insecurity in relation to ART adherence by focusing on ART regimens that require food. In addition, the current study incudes potential confounding factors that may account for the previously observed associations between non-adherence and medication requirements including side effects and medication adherence motivational beliefs. We hypothesized that ART adherence and HIV viral suppression would be poorer among people living with HIV who are food insecure and are prescribed antiretroviral regimens that require food compared to individuals who are food

insecure and prescribed ART regimens that do not require food.

METHODS

Participants

Participants were men and women taking antiretrovirals to treat their HIV infection and had experienced food insecurity in the previous month. The site of the study was Atlanta, Georgia with an annual incidence of 30.3 per 100,000, exceeding the 19.6 per 100,000 population rate of HIV in major US cities. Eligible participants were aged 18 years or older, HIV positive, and currently taking ART.

Procedures

The study was conducted between January 2013 and March 2014. A total of 1,101 people living with HIV were recruited through targeted community sampling with both venue recruitment and snowball sampling techniques. Venue recruitment relied on responses to brochures placed in waiting rooms of HIV service providers and infectious disease clinics throughout Atlanta, GA. Participants were also encouraged to use the project brochures to refer their HIV-positive friends to the study. Individuals provided informed consent prior to completing any study activities.

Participants completed four sources of data: audio computer-assisted self-interviews (ACASI) to assess demographic and behavioral characteristics at the start of the study [19, 20]; HIV RNA (viral load) and CD4 cell counts obtained from medical records; a urine specimen for drug screening; and unannounced pill counts to prospectively assess ART regimens and adherence. The specific measures are described below. The University of Connecticut Institutional Review Board approved all procedures.

Measures

Computerized Interviews

Participants were asked their gender, age, years of education, income, ethnicity, and employment status. We also collected the year that participants first tested HIV positive, a measure of 14 HIV-related symptoms of 2-weeks duration (indicated as having or not having experienced each symptom, summed to a composite score) [21], and experience of 11 common ART side effects (ranged between 0 = "not experiencing" to 3 = "severely experiencing", summed to composite score) [22]. To assess alcohol use, we administered the Alcohol Use Disorders Identification Test (AUDIT), a 10-item scale designed to measure alcohol consumption and identify risks for alcohol abuse and dependence [23]. Scores on the AUDIT range from 0–40 and the AUDIT has demonstrated acceptable reliability and validity [24]. The first item on the AUDIT was used to index frequency of alcohol use over the previous week.

To assess food insecurity, we used items adapted from the US Food Security Scale that have been validated in past research and used by the US Census Bureau [25]. The specific items are reported in the results section. We also included an item asking participants if they had to decide whether to buy food or medications. Food insecurity indicators were collected with respect to experiences in the past month, dichotomized (experienced/not experienced), and summed to create a food insecurity index.

We used the Beliefs about Medicine Questionnaire to assess participant's

motivations for adhering to medications [26, 27]. The medication necessity scale consists of five items reflecting the perceived benefits of medications in direct relation to health; example items include "My health, at present, depends on my medicine", "My life would be impossible without my medicine", and "My medicines protect me from becoming worse". The five-item medication concerns scale reflects the potential adverse effects and costs of medication; example items include "Having to take my medicines worries me", "My medicines disrupt my life", and "I sometimes worry about the long-term effects of my medicines". Items are responded to on a 5-point scale, 1 = "strongly agree", 5 = "strongly disagree". The medication necessity and concerns scales were both internally consistent, alphas = 0.78 and 0.81, respectively.

Urine Screening for Drug Use

To objectively screen for illicit drug use, we conducted a multi-panel urine dip test to detect common illicit drug use. This test strip uses a lateral flow chromatographic immunoassay for qualitative detection of 12 drugs and drug metabolites. These tests are Food and Drug Administration (FDA) approved and are reliable and valid for initial drug screening (Reditest®-12; Redwood Toxicology Laboratory, Santa Rosa, CA, USA).

Chart Abstracted HIV Viral Load and CD4 Cell Counts

We used a participant-assisted method for collecting chart abstracted HIV viral load and CD4 cell counts from participants' medical records. Participants were given a form that asks their physician's office to provide the results of their most recent HIV viral load and CD4 cell counts and dates (not older than 3 months). These data were therefore obtained directly by the participants from their health care providers. The form included a place for the provider's office stamp or signature to assure data authenticity. HIV RNA below detection was defined as less than 200 copies/mL for uniformity across providers.

ART Regimen Determination and Adherence

Participants consented to three unannounced telephone-based pill counts that occurred over a 6-week period. Unannounced pill counts are reliable and valid in assessing medication adherence when conducted in homes [28] and on cell phones [29, 30]. In this study, we conducted unannounced cell-phone-based pill counts. Participants were provided with a free cell phone for use in the study assessments. An office-based interview included a full accounting and recording of all prescription medications, determining ART regimen, and systematic training in the pill counting procedure. Participants were subsequently called at three unscheduled times over 12- to 16-day intervals. Pharmacy information from pill bottles was also collected to verify the number of pills dispensed between calls. Adherence was defined as the ratio of pills counted relative to pills prescribed, taking into account the number of pills dispensed. ART adherence was examined as a continuous variable and as a clinically defined categorical variable with adherence defined as greater than 85% of their medications [3, 4].

Data Analyses

Of the 1,101 individuals recruited, 498 screened positive for experiencing at least one indicator of food insecurity (see below for exact items). Among these participants, 481 (96%) returned with their medical chart abstracted viral loads and 418 (84%) completed unannounced pill

counts for ART adherence. All participants with adherence data also had returned with their viral loads. Therefore, analyses were performed on the 418 food insecure persons with adherence data. Setting $P < 0.05$ significance for an odds ratio of 1 standard deviation increase in exposure and odds ratio of 1.5 for one standard deviation increase in a covariate with a sample size of 418, calculations estimate statistical power of 0.89, indicating sufficient power for our statistical models [31, 32].

Participants were grouped on the basis of the food requirements of their ART regimen. We obtained recommended ART administration instructions from antiretroviral treatment guidelines for adults [33] and recommendations from AIDSmeds [34]. Five protease inhibitors and one non-nucleoside reverse transcriptase inhibitor (NNRTI) were recommended for administration with food; 195 participants were taking ART that did not require food and 223 participants were taking ART that requires food. Descriptive analyses compared participants who were taking ART that did not require food with those who were taking ART that did require food. Comparisons used contingency table Chi-square tests for categorical variables and independent *t* tests for continuous measures. To test the main study hypothesis that participants who are prescribed ART that requires food would have poorer ART adherence and poorer viral suppression, we performed separate multivariable logistic regressions for each outcome, reporting odds ratios with 95% confidence intervals. The regression models controlled for factors that are known to predict adherence (i.e., substance use) and variables found related to ART regimens that require food in the descriptive analyses. All variables were continuous scaled except employment (coded 0 = unemployed, 1 = employed), income (0 = <$10,000/year, 1 = ≥ $10,000/year), drug use (0 = none detected, 1 = detected), and ART regimen requiring food (0 = does not require food, 1 = requires food). All analyses were conducted in SPSS Statistics (version 20; IBM Corporation, Armonk, NY, USA) and statistical significance was defined as $P < 0.05$.

RESULTS

Of the 418 individuals who had experienced food insecurity in the previous month, 223 (53%) were prescribed ART that should be taken with food. The majority of participants were receiving regimens that included nucleoside/nucleotide reverse transcriptase inhibitors (NRTI) and protease inhibitors, the two largest classes of medications. Overall, ART adherence averaged 81% of medications taken over the subsequent month, with considerable variability in adherence across classes of medications (see Table 1). Results showed that most indicators of food insecurity were evenly distributed among people who were not and were prescribed ART that requires food. However, having had to choose between paying for food or obtaining medications occurred significantly more often for individuals prescribed ART that should be taken with food (see Table 2).

Factors Associated with Receiving ART that Requires Food

Table 3 shows the characteristics of participants taking ART that does not and does require food. Descriptive analyses found that individuals taking ART that requires food were significantly more likely unemployed, had lower CD4 cell counts, were more likely to have unsuppressed HIV viral loads, were living

Table 1 Antiretroviral medications prescribed to food insecure people living with HIV

Antiretroviral medication		*N*	%	*M*	SD
Generic name	**Brand name**				
NRTI		278	67	81.2	21.5
Zidovudine + lamivudine (AZT + 3TC)	Combivir	9	2		
Emtricitabine (FTC)	Emtriva	6	1		
Lamivudine (3TC)	Epivir	6	1		
Abacavir + lamivudine	Epzicom	55	13		
Zidovudine (AZT)	Retrovir	13	3		
Zidovudine + lamivudine + abacavir	Trizivir	6	1		
Tenofovir + emtricitabine	Truvada	183	44		
Didanosine (ddI)	Videx	5	1		
Tenofovir	Viread	15	4		
Abacavir	Ziagen	10	2		
NNRTI		35	8	60.5	41.0
Etravirine (TMC125)[a]	Intelence[a]	13	3		
Efavirenz	Sustiva	12	3		
Nevirapine	Viramune	10	2		
Dual class					
Efavirenz + tenofovir + emtricitabine	Atripla	84	20	75.8	29.2
Protease inhibitor		243	58	80.4	21.5
Ritonavir[a]	Norvir[a]	206	49		
Darunavir[a]	Prezista[a]	92	22		
Atazanavir[a]	Reyataz[a]	119	29		
Nelfinavir[a]	Viracept[a]	2	<1		
Lopinavir/ritonavir	Kaletra	26	6		
Fosamprenavir	Lexiva	5	1		
Entry inhibitor					
Maraviroc	Selzentry	23	6	32.2	40.0
Integrase inhibitor					
Raltegravir	Isentress	73	18	67.7	35.9

SD standard deviation

[a] Denotes medication that should be taken with food. Medications only shown if at least one participant was prescribed, January 2013 to March, 2014

Table 2 Food insecurity indicators among food insecure people living with HIV prescribed antiretroviral medications that do not and do require food

Food Insecurity (past month)	Food not required with ART ($N = 195$)		Food required with ART ($N = 223$)		X^2	P
	n	%	*n*	%		
Worried if food would run out before having money to buy more	163	84	178	80	1.22	ns
Food did not last and did not have money to get more	153	79	172	77	0.18	ns
Had to choose between paying for medicine or buying food	41	21	69	31	5.53	0.01
Adults in household cut meal size for not having money for food	106	55	117	53	0.20	ns
Ate less than felt like needed to because was not enough money	115	59	125	56	0.44	ns
Hungry without eating for not being able to afford food	72	37	96	43	1.62	ns
Adults in household not eat for a whole day without money for food	49	25	48	21	0.75	ns
Number indicators endorsed					9.1	ns
1	39	20	55	25		
2	33	17	37	17		
3	31	16	23	10		
4	33	17	31	14		
5	26	13	48	22		
6	33	17	29	13		
Mean (SD) indicators	3.3	1.7	3.3	1.8		

ART antiretroviral therapy, *ns* not significant, *SD* standard deviation

with HIV diagnoses longer, and reported significantly more beliefs that their medications are necessary for their health. There were no other differences between individuals taking ART that requires food verses those not taking medications that require food.

Predictors of ART Adherence

We constructed a multivariable logistic regression model to test the independent effects of ART regimens requiring food on medication adherence over the prospective 1-month period. The model included factors that were associated with taking ART regimens that require food including employment, years living with HIV diagnosis, and adherence motivation beliefs. In addition, the model included socio-demographic and behavioral factors that are generally known to be associated with adherence including education, income, substance use, and medication side effects. Results showed that greater alcohol use, fewer beliefs that medications are necessary, and being prescribed an ART regimen that requires food significantly predicted poorer ART adherence over and above the other factors included in the model (see Table 4).

Table 3 Characteristics of food insecure people living with HIV prescribed antiretroviral medications that do not and do require food

Characteristics	Food not required with ART ($N = 194$)		Food required with ART ($N = 223$)		X^2	P
	n	%	*n*	%		
Male	141	72	172	77		
Female	53	27	51	22	1.09	ns
African American	178	91	204	92	3.90	ns
Unemployed	164	84	200	90	9.83	0.05
Income <$10,000	128	66	154	69	0.82	ns
CD4 <200 cell/mL	22	12	60	27	16.45	0.01
Antiretroviral adherence <75%	50	26	70	31	1.68	ns
Antiretroviral adherence <85%	77	40	104	47	2.16	ns
Antiretroviral adherence <95%	123	63	157	70	2.52	ns
Viral load detectable	35	18	62	28	5.89	0.01
Alcohol use	127	65	136	61	2.57	ns
Drug use	117	60	138	62	0.56	ns
Characteristics	***M***	**SD**	***M***	**SD**	***T***	***P***
Age	44.3	11.1	44.7	9.6	0.38	ns
Years of education	12.5	1.7	12.8	1.5	1.57	ns
Years since HIV diagnosis	12.1	7.6	13.9	8.1	2.33	0.05
HIV symptoms	4.0	3.2	4.5	3.6	1.59	ns
Medication side effects	0.51	0.44	0.55	0.49	0.70	ns
Antiretroviral medication adherence	83.3	18.5	80.5	20.1	1.48	ns
CD4 cell count	533.5	273.5	393.3	278.5	5.10	0.01
AUDIT alcohol	13.9	11.5	13.6	11.5	0.30	ns
Medication necessity	20.9	4.0	21.7	3.4	1.98	0.05
Medication concerns	14.5	4.7	14.0	4.5	0.97	ns

ART antiretroviral therapy, *AUDIT* Alcohol Use Disorders Identification Test, *ns* not significant

Predictors of HIV Suppression

A second multivariable logistic regression model tested the independent effects of ART regimens requiring food on chart abstracted HIV viral load. The model included all of the factors described above for the adherence model. Table 5 shows that participant unemployment, greater beliefs about concerns over medications, and being prescribed an ART regimen that requires food significantly predicted having unsuppressed (detectable) HIV viral load, over and above the other factors included in the model.

Table 4 Logistic regression model predicting 85% ART adherence in prospective month

Characteristics	Adjusted OR	*P*	95% CI
Education	0.97	ns	0.86–1.10
Employment	1.05	ns	0.84–1.32
Income	1.19	ns	0.88–1.62
Years since HIV diagnosis	1.01	ns	0.98–1.04
Alcohol use	0.76	0.01	0.63–0.91
Screen positive for drug use	0.73	ns	0.46–1.14
Medication side effects	1.40	ns	0.87–2.27
Medication necessity beliefs	1.08	0.01	1.01–1.14
Medication concerns beliefs	0.96	ns	0.91–1.01
Number of food insecurity indicators	1.02	ns	0.91–1.16
ART requires food	0.65	0.05	0.42–0.99

ART antiretroviral therapy, *CI* confidence interval, *ns* not significant, *OR* odds ratio

Table 5 Logistic regression model predicting most recent HIV viral load

Characteristics	Adjusted OR	*P*	95% CI
Education	0.89	ns	0.76–1.03
Employment	0.72	0.05	0.54–0.95
Income	0.91	ns	0.61–1.36
Years since HIV diagnosis	0.98	ns	0.95–1.01
Alcohol use	1.01	ns	0.80–1.26
Screen positive for drug use	1.65	ns	0.91–2.95
Medication side effects	1.58	ns	0.91–2.71
Medication necessity beliefs	0.99	ns	0.93–1.07
Medication concerns beliefs	1.08	0.01	1.02–1.15
Number of food insecurity indicators	1.08	ns	0.93–1.25
ART requires food	2.34	0.01	1.35–4.04

ART antiretroviral therapy, *CI* confidence interval, *ns* not significant, *OR* odds ratio

DISCUSSION

In recently published Antiretroviral Treatment of Adult HIV Infection Recommendations, the International AIDS Society (IAS) reviewed the many benefits of HIV treatment and provided guidelines for achieving optimal clinical outcomes [35]. Recommendations are focused on settings where ARTs are available, particularly resource-rich countries. Guidance for ART takes into consideration multiple patient and regimen characteristics including efficacy, toxicity, pill burden, dosing, viral resistance, comorbid conditions, and cost. However, a significant omission from consideration in selecting an ART regimen is the patient's access to sufficient and reliable food sources. In the current study of people living with HIV who experience food insecurity, we found that more than half were prescribed ART that should be taken with food. The prevalence of multiple indicators of food insecurity was evenly distributed among individuals who were prescribed ART that does and does not require food, including more than one-third experiencing hunger in the previous month. However, the one factor that was associated with taking ART that requires food was having had to choose between obtaining medications and paying for food in the previous month. This finding speaks to the complexity of managing scarce resources in meeting the demands of medications that must be taken with food among people who are food insecure. Unlike other challenges to ART adherence among the poor, the dilemma posed by medications with food requirements is resolvable by either prescribing an ART regimen that does not require food, when appropriate and feasible, or assuring that patients are provided food to be taken with their medication.

In many cases, providers will have fewer medication options for patients who have a history of poor adherence and those patients who have been treated longer with ART. These clinical realities may explain the patterns of results in this study. Patients who are food insecure also demonstrate poorer adherence and may therefore develop resistance, leaving fewer treatment options. In addition, not all ART regimens are equally accessible through various drug assistance programs. Thus, even when providers are aware of the conflict between food insecurity and prescribing ART that requires food, their best treatment option may be a regimen that requires food for optimal absorption. In addition, programs that provide nutritional support and meals to patients are scarce in many settings. Again, even when providers are aware of patient food insecurity there are limits to their ability to provide food. These clinical realities, therefore, present clinical dilemmas that can only be resolved with access to more affordable treatment options and increased meal services for patients in need.

These findings should be interpreted in light of the study limitations. First, we relied on a convenient sample that cannot be considered representative of people living with HIV infection. The sample also came from a wide range of providers that likely varied in health services and prescription practices. While we had objective measures of ART regimens, adherence, current substance use, and clinical health status (CD4 count and viral load), our study relied on self-report instruments to assess social and behavioral characteristics, including food insecurity. Although we used reliable and valid measures, self-report data may still be subject to social response biases. In addition, we grouped all medications that require food into one class despite the variable importance of food for the absorption of any single medication. Our data also do not allow precise measurement of whether missed medication doses occurred in relation to times when food was scarce, particularly whether medications that are instructed to be taken with food are missed at those times. Future research may use event/dose level medication monitoring with time-linked measures of food intake to determine more precise associations. With these limitations in mind, we believe that our findings have implications for treatment guidelines, clinical practice and future research.

CONCLUSION

Given that HIV is embedded in a context of poverty, access to food should be formally assessed and explicitly considered when prescribing ART. Patients should not be expected to overcome the shame and stigma of not having food to initiate this conversation. In addition to the obvious necessity of nutrition in health, access to food is known to improve adherence [36–38]. The importance of food in health takes on a new dimension when the bioavailability of medications depends on food. Treatment guidelines cannot address every issue facing providers and patients in selecting treatment regimens. However, requiring food for optimal absorption is the only aspect of poverty directly related to the pharmacokinetics of ART. Failing to address adequate access to food when selecting ART regimens will undermine the clinical care of a significant and growing population of HIV infection patients living in poverty.

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Conflict of interest. Seth C. Kalichman, Christopher Washington, Tamar Grebler, Ginger Hoyt, Brandi Welles, Christopher Kegler, Moira O. Kalichman, and Chauncey Cherry declare no conflict of interest.

Compliance with ethics guidelines. Individuals provided informed consent prior to completing any study activities. The University of Connecticut Institutional Review Board approved all procedures.

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