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Food Assistance and its effect on the Weight and Antiretroviral Therapy Adherence of HIV Infected Adults: Evidence from Zambia

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Abstract

We evaluate the effects of food assistance on the weight and adherence of HIV patients on Anti-Retroviral Therapy (ART) using survey and administrative data on 314 patients and their households enrolled in a World Food Programme food assistance program in peri-urban Lusaka in Zambia. We find no significant differences in weight change at 6 months between patients receiving food assistance and a comparison group of non-beneficiaries. Cross sectional matching and regression estimates show a significant and positive average effect of food assistance on ART adherence. A sub-population analysis finds that the duration of ART treatment affects the effect size of food assistance on adherence to treatment. The receipt of food assistance has significant and larger positive effect sizes on adherence to treatment for patients who had been on ART for less than the sample median of 995 days, while food assistance has no effect (ordinary least squares regression) or some negative effect (instrumental variable regression) on adherence for patients whose duration of ART was greater than the sample median.

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Introduction

The overlap of a high prevalence of HIV-1 infection, malnutrition, and chronic food insecurity in much of sub-Saharan Africa has highlighted the need for more comprehensive approaches to health care (FAO 2008, UNAIDS 2008). Inadequate caloric intake in the setting of HIV infection has a negative impact on patients; accelerates HIV-associated weight loss, compounds immunosuppression and may accelerate the progression to AIDS, potentiates the side-effects of some antiretroviral therapy (ART) medications, and reduces the capacity for physical activity and decreases labor productivity and negatively impacts the HIV affected household (Schaible and Kaufmann 2007, Bukusuba and Kikafunda 2007, Hardon et al 2007, WHO 2003, Chandra 1991).

Several studies from sub-Saharan Africa found that a low BMI at the time of ART initiation is a powerful and independent predictor of early mortality, and the role of malnutrition in HIV disease progression and poor clinical outcomes is significant and likely under-reported (Johannessen et al 2008, Zachariah et al 2006). Two recent reports drawn from large programmatic cohorts in Zambia, Kenya and Cambodia described a strong association between early weight gain on ART and improved outcomes 3 to 6 months after ART initiation (Madec et al 2009). While these analyses examined patients starting ART (when mortality is highest), they suggest that adequate nutrition promotes beneficial health outcomes. Improving the functional status of HIV-infected individuals, especially adults with dependant relatives or children, through appropriate nutritional interventions may improve the productivity, income and overall welfare of the HIV-affected household. Studies have shown that households with chronically ill

members report yearly income reductions of 30-35%, and in rural areas, HIV-affected families farm less land and have lower agricultural output (Mutangadura et al 1999). Indeed, the anticipation that supplementary feeding can improve medication adherence, patient retention and household welfare has prompted some HIV programs in sub-Saharan Africa to incorporate nutritional programs for malnourished clients (Mamlin et al 2009). Consequently several organizations are integrating micronutrient or macronutrient supplementation with ART programs.

While there has been substantial research on the role of *micro*nutrient supplements (*e.g.,* vitamins or mineral supplements) in delaying HIV disease progression (Fawzi et al 2004, Kaiset et al 2006), there has been limited research to date on the clinical effects of *macro*nutrient supplementation (*i.e.,* caloric supplementation in the form of staple foods or energy-dense specialized nutritional products) for HIV-infected adults in resource-constrained settings. Cantrell *et al.* (2008) reported a significant difference in ART adherence, but no difference in weight gain, CD4+ cell response, or mortality, among HIV-infected adults receiving food assistance rations compared to control patients not receiving rations after 12 months in an observational study in Lusaka, Zambia. A more recent trial in urban Malawi found a significantly greater increase in body mass index (BMI; calculated as weight in kilograms divided by height in meters, squared) after 3.5 months among those receiving food supplements, but no significant differences in survival, HIV viral load, CD4 count change, or quality of life (Ndekha et al 2009). Other existing research, qualitative in nature, found positive impacts in self reported weight gain, recovery of physical strength, improved adherence to treatment (Byron et al 2006, Egger and Strasser 2005).

This study assesses the impact of participation in a World Food Programme (WFP) household food supplementation scheme on weight and ART adherence over a period of 6 months among HIV-infected adults in Lusaka Zambia. The analysis compares food assistance beneficiaries (intervention group) at four participating public-sector ART clinics with similar HIV-infected individuals at four matched non-participating clinics (comparison group). We find that food assistance has no significant effect on weight. However food assistance has a significant positive effect on ART adherence, and the results hint at a likely greater effect of food assistance during the early stages of ART.

The paper is organized as follows. The next section presents the data collection process used for the study. We then present the methodology used in estimating the impact of food assistance followed by a section presenting the results from propensity score matching and regression analysis. The following section then discusses the results and their implications, and the limitations of the study. The final section presents the conclusion of the paper and recommendations for further research.

Data

Setting

The Zambian national program for HIV care and treatment was implemented in April 2004 and has expanded rapidly (Stringer et al 2006). By May 2009, 198,000 patients were enrolled in HIV care at 67 sites, and 127,000 had started ART. The WFP country programme in Zambia aims to improve the nutritional status and health of vulnerable populations through targeted assistance

programs for people living with HIV/AIDS, among others (*e.g.,* pregnant and lactating women and orphaned children). In 2009, over 10,000 HIV-infected individuals received WFP supported food assistance in Zambia.

The WFP food assistance program studied here has been implemented in the capital-city, Lusaka, since February 2009. Four public-sector ART clinics distributed a standardized household food assistance ration containing the local staple food (*i.e.*, maize meal), cooking oil, lentils and/or fortified blended flour. The targeting criteria for food assistance was based on a screening questionnaire to evaluate household food insecurity and vulnerability to undernutrition. Anthropometric measurements or other clinical nutritional assessments were not utilized. Responses to the screening questionnaire were tallied into a composite socioeconomic score. Patients were deemed vulnerable and eligible for food assistance when their socioeconomic score equaled or exceeded a numerical threshold.

Sampling strategy

This study is retrospective and obtained baseline, comparative data using the programmatic ART database in conjunction with a household survey carried out in August 2009. Random sampling was used to select 50 participants from eight public-sector health clinics providing ART in Lusaka; 200 patients at four clinics participating in the food distribution program (Mtendere, Chawama, Kanyama, George), and 200 patients at 4 control clinics not included in food program (Bauleni, Chipata, Matero Reference, and Chilenje). To provide a rough equivalence between study groups, control clinics were selected and paired with study clinics according to three criteria: active patient population, duration of operation, and historical survival at 12 and 18 months post-ART initiation (as of 1st August 2009). Individuals in the comparison group were

screened for study inclusion using the same food security and vulnerability screening tool and the same numerical score threshold applied to the intervention group.

Data Sources

We carried out a household survey on the sampled 400 patients using a structured questionnaire capturing household demographic, consumption, employment and asset data. Weight and ART adherence data was obtained from the *SmartCare* electronic medical record system (http://www.smartcare.org.zm) developed by the Zambian Ministry of Health, the Centers for Disease Control and Prevention, and the Centre for Infectious Disease Research in Zambia

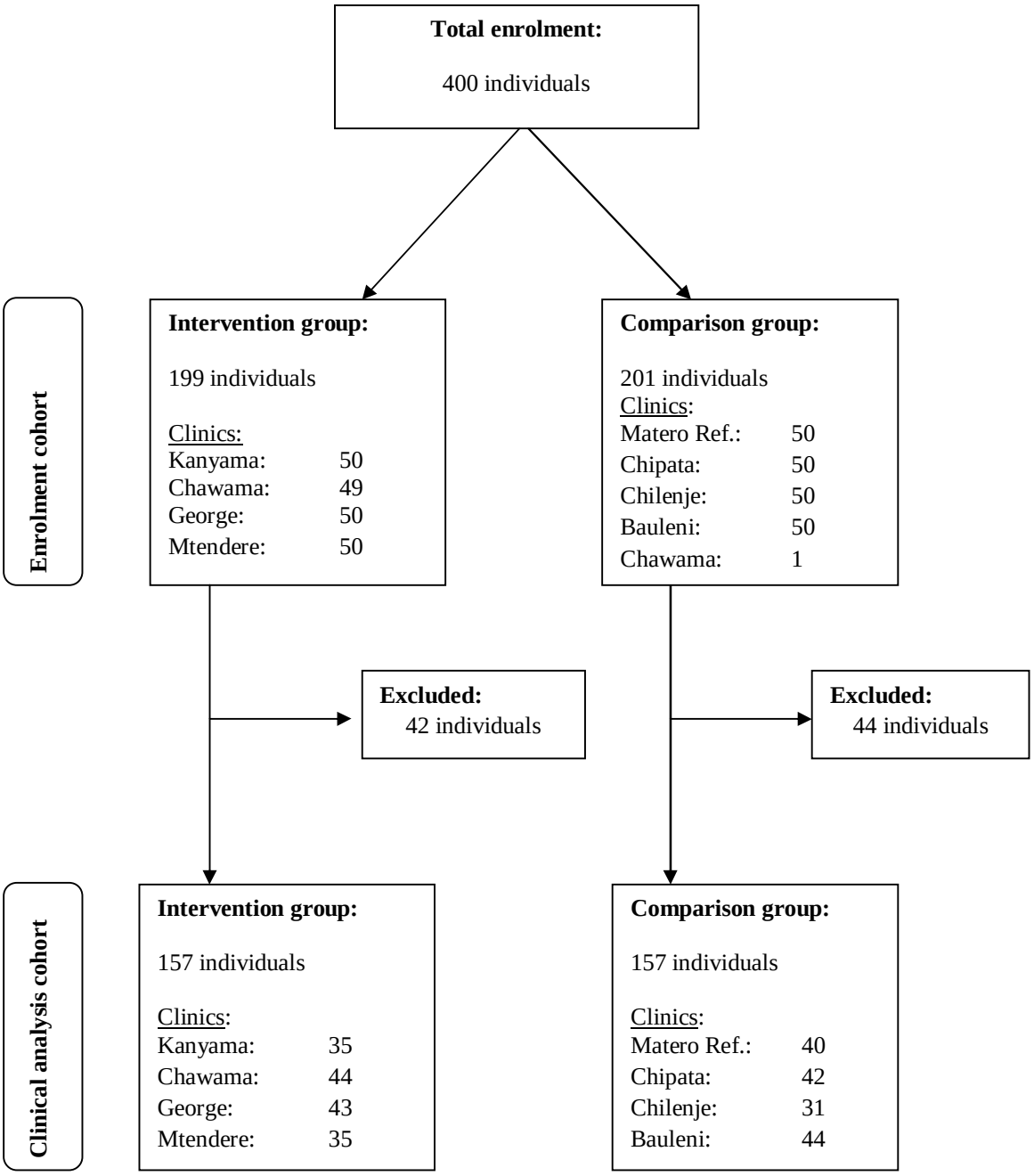
Analytic Sample

The analytic sample is based on an extract of socio-economic variables from the household survey and clinical variables from the electronic medical records over a 6 month period from January 2009 to August 2009. Participants were enrolled at the clinic site and the medical record number provided was checked against the programmatic database to confirm eligibility prior to inclusion in the analysis. Participants were excluded from the analysis if the documented medical record number could not be located in the database, or if the individual was registered in the database but was <18 years of age, was registered as a patient at a different clinical site, had no recorded clinical visits after 1st January, 2009, did not have a recorded clinic visit during the study initiation period (1st January to 1st March, 2009), or was not on ART Retrospective, baseline weight and pharmacy refill data (used to calculate adherence) were obtained from the SmartCare electronic medical record system using a window period of 60 days before or after 1st January, 2009. This approach has been used by similar studies (Thirumurthy et al 2008, Wools-

Kaloustian et al 2005).[1]The final cohort for analysis had 157 patients in the intervention group and 157 patients in the comparison group. The selection process is illustrated in figure 1.

[1] For inclusion in the calculations of CD4+ lymphocyte count, haemoglobin, and weight change, patients required the necessary values recorded in the Smart Care database within predefined window periods. For inclusion in the calculation of ART adherence (defined as the medication possession ratio [see below]), patients had to have a pharmacy visit within the window periods[1] We use HIV prevalence rates for pregnant women as a proxy for actual HIV prevalence using statistics calculated by Stringer et al 2008

Figure 1 Participant enrolment and final clinical analysis cohort



Methodology

The statistical analysis comprises three stages. The first stage comprises descriptive statistical analysis and independent sample tests for the unmatched sample. Median values, as opposed to mean values, are calculated for weight and BMI to limit the effect of potentially erroneous outlier values in the unmatched sample. Statistical significance for median values is assessed using a Wilcoxon mann whitney test. The medication possession ratio (MPR a measure derived from pharmacy refill data which describes the proportion of days a patient on a treatment regimen is known to have medication available) is used to assess adherence to ARV therapy (Goldman et al 2008). A two independent sample t-test with unequal variances is used to test for statistical significance of mean difference in MPR. However this analysis does not account for selection bias, hence we proceed to carry out further analysis to correct for any selection bias.

We then estimate the average treatment effect of food assistance using propensity score matching combined with difference in difference matching. We are interested in the average treatment effect on the treated (ATT) which may be written as follows:

$$ATT = E\left(Y^1_t - Y^0_t \mid X,\ D=1\right) = E\left(Y^1_t \mid X,\ D=1\right) - E\left(Y^1_t \mid X,\ D=1\right) \qquad (1)$$

We also combine difference in differences estimation with matching for panel data to remove any potential bias from unobservable heterogeneity and from all time-invariant unmeasured factors between the treatment and comparison group (Heckman et al 1997, 1998). The DID estimator maybe written as follows (Gilligan and Hoddinott 2006):

$$\text{ATT} = \text{E}\left(\left(\text{Y}^1_t - \text{Y}^0_t\right) - \left(\text{Y}^1_\tau - \text{Y}^0_\tau\right) \mid \text{X}_\tau, \text{D}=1\right) = \text{E}\left(\text{Y}^1_t - \text{Y}^1_\tau \mid \text{X}_\tau, \text{D}=1\right) - \text{E}\left(\text{Y}^0_t - \text{Y}^0_\tau \mid \text{X}_\tau, \text{D}=1\right)$$

(2)

Since we do not observe the counterfactual and intend to solve our problem of causal inference we use propensity score matching. The propensity score is defined as P(*X)* = Pr (*D* = 1| *X)*. Propensity score matching enables us to statistically construct a comparison group by matching observed characteristics of food assistance beneficiaries to non-beneficiaries based on similar values of *P(X)*. Unbiased inference from propensity score matching is based on the assumptions that; the treatment and potential outcomes are independent conditional on a set of pre-program characteristics *X* (Heckman et al 1998) and that there exists common support for individuals in both groups (overlap) (Rosenbaum and Rubin 1983).

It has been proven that propensity score matching results are best comparable to results from experimental estimators and that propensity score matching also provides reliable and low-bias estimates of program effects (Heckman et al 1997, 1998). We conduct probit regression analyses to predict participation in the food assistance program, and use the model results to estimate propensity scores for the matching algorithms. Conditioning variables used in the model to predict participation in the food assistance program and hence create propensity scores for the matching algorithm are obtained from household survey data. Age, gender and education level of patient, employment status, household size, and asset ownership are included as conditioning variables based on theoretical and empirical grounds of association with participation in the food assistance program (Gilligan and Hoddinott 2007). We also include additional variables based on our knowledge on how the food assistance program targeting criteria was actually implemented.

The vulnerability screening tool includes demographic and socio-economic variables, and unique indicators of vulnerability in HIV affected households (*e.g.,* the number of HIV positive household members or number of disabled household members). We also include variables which may have affected the degree of patient contact with clinic staff and, by extension, the likelihood of being screened for enrolment in the assistance program. These include the distance from the patient's residence to the clinic, the severity of illness of patient at the time of enrolment (*i.e.,* WHO stage 3 or 4), and concurrent enrolment in a community home based care program. The balancing property is satisfied after testing for the equality of means for each characteristic included in the probit model. Difference in difference analysis is carried out for weight and BMI using panel data, while cross sectional estimates are only computed for adherence to ART. Since weight and BMI are continuous variables, we employ the difference-in-differences method with local linear regression (also called lowess) and a tricube kernel. Additional matching methods include nearest neighbour (1 to 1), kernel (bandwith at 0.01) and calliper matching. Confidence intervals are calculated using the bias corrected method. We also conduct sensitivity analysis thorough trimming 10% of treated cases. The matching estimator is implemented using Leuven and Sianesi's method (Leuven and Sianesi 2003).

The third and final stage of analysis is regression. We carry out ordinary least squares (OLS) regression analysis on the effect of food assistance on adherence using cross sectional data (after 6 months of the food assistance program). Regression is based on the following equation:

$$MPR_i = \alpha_0 + \beta_i \, Foodtransfer_i + X_i \gamma + \varepsilon_i \qquad (3)$$

Where MPR_i is the Medication possession ratio (an indicator of adherence) for individual i; $Foodtransfer_i$ is a dummy for receipt food transfers to household *i*; γ is a vector that summarizes observed household characteristics. They include locality, patient characteristics such as marital status of patient, gender, education, age, age squared; household characteristics such as total number of household productive and durable assets, household size, dependency ratio, sex and age of household head; and ε_i is the unobserved idiosyncratic household error

We also correct for the potential endogeneity of participating in the food assistance program, by instrumenting food assistance receipt with variables based on the targeted clinics and rationale behind eligibility into the programme (vulnerability to food insecurity). Hence we use clinic HIV sero-prevalence rates2 (characteristics that influenced selection of the beneficiary clinics), baseline per capita expenditure as a proxy for income and past receipt of food aid to reflect any inertia effects from food aid targeting[3] (Jayne et. al.2002) . We test for the validity of our instruments using the Cragg- Donald wald F test based on the critical values for maximal IV relative bias of 10% (Stock and Yogo 2005) and Sargan test (Sargan 1988) respectively. All statistical analyses are carried out using the procedures for analysis in Stata versions 9.3 and 10.

Results

Descriptive analysis

Baseline characteristics of participants in January 2009 (within a 60 day window for laboratory variables) are presented in table 1. The mean age for both groups is approximately 40 years. Both

[3] Jayne et al 2002 show that inertial effects significantly influence food aid targeting i.e. whether a locality or individual receives food aid is dependent on having received it in previous years.

the intervention and comparison groups are overwhelmingly female (80% for intervention group and 71% for comparison group). The baseline median body mass index is above 20 kg/m^2 for both groups (20.1 kg/m^2 for the intervention group versus 20.9 kg/m^2 for the comparison group). The baseline median weight for the comparison group is significantly higher than the median weight for the comparison group (55.5 kg for comparison group versus 53 kg for intervention group). A significantly higher proportion of the intervention group had WHO stage 3 or 4 of illness compared to the comparison group (41% for intervention group versus 18% for comparison group). A significantly higher proportion of the intervention group lived near a public sector/government clinic (95% for intervention group versus 83% for comparison group) and overwhelmingly received support from community home based care volunteers (61% for intervention group versus 28% for comparison group). Community home based volunteers are usually fellow patients or community support groups for people living with HIV/AIDS.

Table 1 Baseline characteristics of patients, unmatched sample (January, 2009)

		Intervention Group (N=157)	Comparison Group (N=157)	Significance
Age, mean (CI)		41 (39.6,43)	40 (38.7,41.6)	
Sex	Female	80%	71%	*
	Male	20%	29%	
WHO Stage‡	I or II	59%	82%	***
III		35%	16%	
IV		6%	2%	
Weight, median kg (IQR)		53(48,59)	55.5(50,61)	**
Female		52.5(46,59)	55(49.7,61)	
Male		54.5(50.5,59)	58(52,64)	*
Body Mass Index, median kg/m^2 (IQR)		20.1 (18.3, 23.1)	20.9 (19.0, 23.6)	**
Female		20.6 (18.6, 23.4)	21.5 (19.1, 23.9)	*
Male		18.9 (18.1, 21.1)	19.9 (19.0, 21.7)	*
Education				
No education		14%	12%	
Primary education		48%	41%	
Secondary education		30%	40%	*
College education		2%	3%	
Marital Status				
Married		43%	47%	
Divorced or separated		14%	15%	
Widowed		38%	34%	
Never married		5%	3%	
Other				
Time to reach public sector clinic is less than 1 hr		95%	83%	***
Patient is unemployed		76%	66%	**
Receives support from community home based care volunteers		61%	28%	***
Disabled household members		8%	5%	
Number of HIV positive household members, mean (CI)		1.5(1.4, 1.7)	1.5(1.4, 1.7)	
Household size, mean (CI)		4.8(4.5, 5)	4.8(4.6,5.1)	
Number of durable assets owned, mean (CI)		1.8(1.4, 2.2)	2.2(1.8, 2.5)	

* = p<0.10; ** = p<0.05; *** = p<0.01. Abbreviations: CI, confidence interval; IQR, interquartile range; WHO, World Health Organization; Sample size limited by available data (sampling period +/- 60 days from 1st January, 2009). Sample sizes (intervention/comparison); ‡ 100/102 as of 1st January, 2009

We examine the association between food assistance and the 6 month change in weight, BMI and the difference in the MPR (a proxy measure of adherence) using the unmatched sample. Results are presented in table 2.

Table 2 Median differences in weight, BMI and adherence (unmatched sample)

	Summary Statistic
Weight (6 month change) in kg	
Intervention Group (n=128)	0
Comparison group (n=106)	1
Median difference	-1*
Body Mass Index (6 month change) in kg/m^2	
Intervention Group (n=122)	0
Comparison group (n=100)	0.38
Median difference	-0.38*
Medication Possession Ratio (at 6 months)	
Intervention Group (n=146)	97.1%
Comparison group (n=157)	96.3%
Mean difference	0.8%

Notes. Mann Whitney tests conducted for significance for weight and BMI. Independent samples t-test conducted for medication possesstion ration * = p<0.10; ** = p<0.05; *** = p<0.01.

One hundred twenty-eight patients in the food assistance and 106 in the comparison group had their weight measurement recorded during the pre-defined sampling periods and were included in the analysis. The median change in weight at 6 months is zero and 1.0 kg in the food assistance and comparison groups, respectively. A Wilcoxon mann whitney test yielded a p-value of 0.06, indicating that the difference in median 6 month weight change is statistically significant at 10% level. One hundred twenty-two patients in the food assistance and 100 in the comparison group had a BMI measurement recorded. The Wilcoxon mann whitney test for BMI

yields a p-value of 0.07, indicating a trend towards a greater gain in BMI in the comparison group. We calculate the mean MPR over 6 months for patients in the food assistance and comparison groups. One hundred forty-six patients in the food assistance and 157 in the comparison group are included in the analysis. The mean MPR over 6 months is 97.1% and 96.3% in the food assistance and comparison groups, respectively. Thresholds for interpreting adherence results are based on previously published conventions for adherence by MPR: optimal (>95%), suboptimal (80–94.9%), and poor (<80%). A two independent sample t-test with unequal variances yielded a p-value of 0.44, indicating the difference in mean MPR is not statistically significant. Hence after analysis of the unmatched sample food beneficiaries appear to have the same adherence to treatment as the comparison group.

Propensity score matching estimates on program effect on weight and adherence

The propensity score for participating in the food assistance program from the probit model in Table 3 is used to generate new samples of matched beneficiaries and non-beneficiaries for the food assistance program.

Table 3 Predicted likelihood of participating in the food assistance program: Probit model estimates

	Coef.	*z-statistic*	
Patient characteristics			
Body mass index at baseline	-0.014	-0.450	
Age	-0.027	-0.310	
Age squared	0.001	0.550	
Female	0.107	0.370	
No education	-0.269	-0.470	
Primary education level	-0.380	-0.770	
Secondary education level	-1.011	-1.960	*
Divorced or separated	0.198	0.530	
Widowed	0.281	0.940	
Never married	0.564	1.090	
Time to reach public sector clinic less than 1 hr	1.072	2.360	**
WHO stage 3 and 4 of HIV disease at baseline	0.667	2.800	***
Receives support from community home based care volunteers	0.588	2.520	**
Patient is unemployed	0.108	0.440	
Household characteristics			
Household does not own a house	0.515	1.970	**
Number of HIV positive household members	0.297	1.890	*
Number of disabled household members	0.114	0.290	
Household size	-0.063	-0.820	
Number of durable assets owned	-0.001	-0.020	
Household uses charcoal as fuel source	0.154	0.540	
Constant	-1.803	-0.900	
Number of observations = 178			
LR chi2 (20) = 49.07			
Prob > chi2 = 0.0003			
Pseudo R2 = 0.2049			

Notes: Dependent variable equals one if household received food assistance in January 2009, and zero otherwise. Patient and household characteristics are from January 2009. * = p<0.10; ** = p<0.05; *** = p<0.01.

Proximity to a public sector clinic and receiving support from community based HIV care volunteers are significant predictors of participating in the program. Other significant predictors include patient diagnosis of being in the latter WHO stages of HIV disease, number of HIV positive members in the household and not owning a house.

Common support is imposed in all the four matching methods using local linear regression matching and nearest neighbour (1 to 1), kernel (bandwith at 0.01) and caliper matching. Accordingly beneficiaries whose estimated propensity score is above the maximum or below the minimum propensity score for the comparison group did not have "common support" in the comparison group and are dropped from the matched sample (Smith and Todd 2005).

We compute the difference-in-differences estimated average treatment effect as the difference in the change in the mean of the outcome variable between January 2009 and July 2009 between the intervention group and the comparison group in the matched sample. We also estimate the average treatment effect on the treated (ATT) for adherence to ART (no baseline). T-testing for the equality of means for each characteristic included in the probit model satisfied the balancing property as none of the baseline characteristics remained significantly different between the two groups after matching (unlike in the unmatched sample).

Difference in difference matching estimates for the ATT for weight and BMI are not statistically significant (table 5). In all the matching methods, results consistently show a negative ATT which is not statistically significant.

Table 4 Difference-in-difference estimates of the impact of food assistance on weight and body mass index

	LLR	***NN***	***Kernel bandwidth (0.01)***	***Caliper (0.01)***	***LLR Trimming 10%***
Weight					
Intervention Group	0.768	0.768	0.267	0.267	0.633
Comparison group	1.81	1.774	1.548	1.528	1.758
Difference in average outcomes ATT	-1.042 (-1.46)	-1.006 (-1.46)	-1.282 (-1.37)	-1.261 (-1.31)	-1.124 (-1.59)
Body Mass Index					
Intervention Group	0.31	0.31	0.129	0.129	0.252
Comparison group	0.686	0.682	0.597	0.592	0.671
Difference in average outcomes ATT	-0.376 (-1.54)	-0.372 (-1.54)	-0.468 (-1.27)	-0.463 (-1.23)	-0.419 (-1.56)

* = p<0.10; ** = p<0.05; *** = p<0.01. N.B . ATT for weight and BMI not significant. t-statisics in parentheses. LLR-Local Linear Regression matching. NN-Nearest Neighbour (one to one) matching.

The results show a significant ATT in adherence. Unlike the earlier results from the unmatched sample, at 6 months of food assistance the intervention group has optimal adherence to ART while the comparison group has suboptimal adherence to ART. The average impact of treatment ranges from 5% (trimming) to 7.4% (local linear regression) depending on the matching method used.

Table 5 Single Difference Estimates of the impact of food assistance on adherence at six months of food assistance

	LLR	***NN***	***Kernel bandwidth (0.01)***	***Caliper (0.01)***	***LLR Trimming 10%***
Medication Possession Ratio					
Intervention Group	0.984	0.984	0.984	0.984	0.983
Comparison group	0.910	0.915	0.934	0.928	0.935
Difference in outcome ATT	0.074 (3.16)***	0.069 (3.16)***	0.050 (2.08)**	0.056 (2.30)**	0.049 (2.46)**

* = p<0.10; ** = p<0.05; *** = p<0.01.t-statistics in parentheses. LLR-Local Linear Regression matching. NN-Nearest Neighbour (one to one) matching.

OLS estimates on the program's effect on adherence and other predictors of adherence

We carryi out further analysis on the association of food assistance and adherence to treatment using OLS and IV regression (instruments: baseline per capita expenditure, past receipt of food aid and local clinic's HIV prevalence rates). It should be noted, however, that the Hausman test for endogeneity is not significant, while tests showed our instruments were strong and valid. We present the results for the effect of food assistance and other significant predictors of adherence in table 6. Excluded variables which did not have a significant effect include age, gender, education level, membership in a HIV support group, receiving support from community based HIV care volunteers, divorce, or widow status of patient, WHO stage 2 and 4 of HIV disease, any perceived stigma by the patient and time taken to reach public sector clinic.

Table 6 OLS Estimates of the effect of food assistance on adherence at six months

Dependent Variable: Medication Possession Ratio	***OLS***	***IV***
Food assistance	0.038 **	0.064**
	(0.017)	(0.031)
Other predictors		
Household size	0.01**	0.01**
	(0.005)	(0.005)
Primary education level	-0.052*	-0.053**
Referent: college education	0.027	(0.026)
Secondary education level	-0.046	-0.045*
Referent: college education	(0.028)	(0.027)
Never married	-0.076**	-0.078**
Referent: married	(0.033)	(0.033)
WHO stage 3 of HIV disease	-0.044**	-0.053**
Referent: WHO stage 1 of HIV disease	(0.020)	(0.022)
Constant	1.062***	1.051***
	(0.127)	(0.123)
N	199	198
R-squared	0.136	0.126
Wu-Hausman test for endogeneity	0.369	
Test for weak instruments -Cragg-Donald Wald F test *(Stock and Yogo critical value for 10% IV relative bias is 9.08)*		21.987
Sargan test for overidentifying restrictions		0.357

Notes: * = p<0.10; ** = p<0.05; *** = p<0.01. Standard errors in parentheses. Figures rounded off to 3 d.p. Excluded variables that are not significant include age, gender, education level, membership in a HIV support group, receiving support from community based HIV care volunteers, divorce, or widow status of patient, WHO stage 2 and 4 of HIV disease, any perceived stigma and time taken to reach public sector clinic.

The effect size of food assistance is positive and is similar to the matching estimates. Food assistance effect is nearly 4% in OLS regression and 6% in IV regression (matching estimates with sensitivity analyses ranged from 5% to 7%). It appears food assistance significantly increases adherence to treatment by over 4%. Living arrangements appear to be important in determining the patient's adherence, as shown by the significant and positive effect of household size, and the significantly negative effect of being single (nearly 8%) compared to being married. Lower levels of education have a significant negative effect on adherence to treatment compared to the college level. Stage 3 of HIV disease (WHO) has a significantly negative effect on adherence to treatment when compared to stage 1 of the HIV disease.

OLS estimates on the program's effect on adherence considering duration of ART

We assess the relationship between duration of ART and the effect size associated with food assistance. Ideally we would have preferred to compare patients who began treatment at the same time the food assistance programme began with patients who had already been on treatment before the food assistance programme began. However, due to limited observations (less than 30) and a median period on ART of 995 days, we compare patients below and above the median value. We carry out OLS and IV regressions and again the Hausman test for endogeneity is not significant while tests showed our instruments are strong and valid. The results are presented in table 7. Similar to table 6, excluded variables which did not have a significant effect include age, gender, education level, membership in a HIV support group, receiving support from community based HIV care volunteers, divorce, or widow status of patient, WHO stage 2 and 4 of HIV

disease, education level, any perceived stigma by the patient and time taken to reach public sector clinic.

Table 7 OLS Estimates of the effect of food assistance on adherence considering ART duration

Dependent Variable: Medication Possession Ratio	***ARV duration <median (995 days)***		***ARV duration>median (995 days***	
Significant variables	***OLS***	***IV***	***OLS***	***IV***
Food assistance	0.091***	0.127**	-0.016	-0.032*
	(0.033)	(0.06)	(0.01)	(0.017)
Other predictors				
Household size	0.01**	0.01**	0.007**	0.007**
	(0.005)	(0.005)	(0.003)	(0.003)
Never married	-0.21***	-0.208 ***		
	(0.069)	(0.064)		
WHO stage 3 of HIV disease	-0.056*	-0.066**	0.024*	
Referent: WHO stage 1 of HIV disease	(0.033)	(0.032)	(0.014)	
Constant	1.062***	1.051***		
	(0.127)	(0.123)		
N	105	105	92	92
R-squared	0.262	0.254		
Wu-Hausman test	0.542		0.292	
Test for weak instruments-Cragg-Donald Wald F test *(Stock and Yogo critical value for 10% IV relative bias is 9.08)*		10.84		13.329
Sargan test for overidentifying restrictions		0.802		0.117

Notes: * = p<0.10; ** = p<0.05; *** = p<0.01. Figures rounded off to 3 d.p. Standard errors in parentheses. Excluded variables that are not significant include age, gender, education level, membership in a HIV support group, receiving support from community based HIV care volunteers, marital status of patient, WHO stage 2 and 4 of HIV disease, any perceived stigma and time taken to reach public sector clinic.

Interestingly, food assistance has a larger effect on adherence for patients who had been ART for less than the median (995 days) compared to full sample estimates in table 6. OLS estimates show an effect size of 9% (twice the effect size for the overall sample in table 6) and IV regression estimates of nearly 13%. Household size has an effect size of 1% (like in the overall sample) while being single/never married has a much larger negative effect compared to the full sample estimates (21% reduction in adherence as per OLS and IV estimates). Stage 3 of HIV

disease (WHO) has a significantly negative effect on adherence to treatment when compared to stage 1 of the HIV disease, similar to the full sample estimates.

For patients who had been on ART for more than the median of 995 days, food assistance appears to have no significant effect (OLS) or a negative effect of 3% (IV). Household size has a less than 1% effect on adherence among these patients. The only other significant predictor was Stage 3 of HIV disease (WHO), which had a significantly positive effect on adherence to treatment when compared to stage 1 of the HIV disease (2%), contrary to the full sample estimates which showed a negative effect.

Discussion

Our analysis of clinical data from beneficiaries of a WFP food assistance scheme for HIV-infected adults on ART at four public-sector clinics in Lusaka, Zambia, and an equal number of non-beneficiary patients at matched comparison clinics, finds no significant differences in weight and BMI change over a six month period following program implementation in January 2009. The lack of a significant effect on weight may be a reflection of the food assistance program targeting criteria, which emphasized household food insecurity and vulnerability rather than the nutritional status of the HIV-infected individual. Food assistance beneficiaries were on ART for a prolonged period prior to program enrolment and demonstrated strong immune reconstitution, as evidenced by a baseline median CD4+ lymphocyte count above 300 cells/mm^3.

Propensity score matching and regression estimates demonstrate a statistically significant effect of food assistance on the MPR (our metric of ART adherence), supporting recent data on the effect of macronutrient supplementation on adherence to ART (Ndekha et al 2009, Cantrell et al 2008). Matching estimates show that the intervention group has optimal adherence while comparison group has sub-optimal adherence (N.B optimal is ≥95%, suboptimal is 80–94.9%, and poor is <80%). Positive predictors of adherence included household size, while negative predictors include being unmarried, having a lower education level, and having a prior diagnosis of WHO stage 3 disease. The results also demonstrate a significant and positive average effect of food assistance on the adherence (MPR) when patients are stratified by the duration of ART treatment. Among patients on treatment for less than the sample median of 995 days, enrollment in the WFP program has a significant and larger positive effect size compared to full sample estimates. However, food assistance does not appear to increase adherence among patients who had been on ART for more than the median of 995 days. This suggests enrolment in the WFP food assistance program has a greater effect on adherence among patients more recently started on ART. However, caution is warranted in interpreting these results given the small sample size and the unclear clinical significance of small variations in the MPR.

This study had several limitations. We posit that since the study's small sample and limited follow up, it was difficult to ascertain the impact of food assistance separately from ART, since ART is proven to have an effect on weight as well. As it is a retrospective analysis, patient responses to the household survey may have been affected by recall bias. The targeting criteria for enrolment in the food supplementation program emphasized food insecurity and vulnerability for eligibility, but the role of clinic staff in determining which patients would be administered the

screening tool is unknown. Participants in the intervention group were significantly more likely to live within one hour of the clinic, be unemployed, and be enrolled in community home based care, which may indicate a selection bias. To reduce confounding, we include these findings as conditioning variables in the model for predicting participation in the food assistance program and also use instrumental variables. Study clinics were matched according to duration of operation, active patient population, and 18-month mortality rate, but data was not available to match clinics according to economic or social characteristics of the population accessing care. Finally, our clinical data was collected from a programmatic database, as opposed to a research database, which may be more likely to include erroneous values. However, the Zambian national ART database has been the source for multiple prior published analyses of ART outcomes, and widespread errors have not been previously reported.

Our study did not demonstrate an increase in weight from food assistance, in keeping with multiple prior reports from resource-constrained and resource-rich settings. The lack of a consistent, reproducible effect on biomarkers suggests that alternative metrics to evaluate the effect of food assistance in relation to HIV-infection may be necessary. Beyond individual health effects, a high prevalence of HIV infection in a community is a multifaceted phenomena with broad economic, social, and political impact. At the level of the family, the burden of morbidity conferred by HIV disease may have widespread effects on income, labour supply, consumption, stability and the ability to provide and care for dependants. For example, households with chronically ill members report yearly income reductions of 30-35%, and in rural areas, HIV-affected families farm less land and have lower agricultural output (Haddad and Gillespie 2001, Mutangadura et al 1999, Kwaramba 1998). By focusing on the HIV-affected family or

community, it may be possible to identify economic effects of welfare interventions like food assistance.

8. Conclusion

Our analysis did not show any significant effect on weight by the food assistance program. We recommend that if the WFP food assistance program is to have any clear and measurable impact on general health improvement the patients need to be engaged earlier in treatment. Results also indicate food assistance improves adherence to ART. While for this food assistance program, duration of ART and clinical characteristics were not part of the targeting criteria, our results hint at a likely greater impact of food assistance on adherence during earlier days of ART rather than later.

The intersection of malnutrition and HIV infection affects millions of HIV-infected adults in sub-Saharan Africa and represents a critical uncertainty and a major challenge to the success of ART programs. In light of the limitations we faced, we also recommend further analysis through larger, randomized prospective studies with a longer period of follow up to observe the full effect of food assistance on patients to provide further evidence on the need of food assistance in HIV care.

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