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The effect of Food Assistance on Adherence to Antiretroviral Therapy among HIV/AIDS Patients in Sofala Province, in Mozambique: A Retrospective Study

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Abstract

Background: The availability of Antiretroviral Treatment (ART) has changed the course of HIV/AIDS, by transforming it into a chronic condition. However, important challenges remain in the management of HIV/AIDS. These challenges are exacerbated by the fact that in resource limited settings, food insecurity and HIV/AIDS overlap. The aim of our study was to evaluate the effect of a food assistance program on adherence to ART in Sofala province, Mozambique.

Methods: In order to assess the effect of the food assistance program on adherence we used propensity score matching with difference in differences estimation. We compared food assistance recipients with controls. We measured adherence based on pill pick-up, a pharmacy adherence measure.

Results: During the food assistance programme, the adherence of food assistance recipients who received food assistance for a period of six and 12 months and non-food assistance recipients is not significantly different as the average impact is only 0.4% (p=0.94) and -2.3% (p=0.73) respectively. For the period after food assistance had been terminated, adherence is still not significantly different between the two groups, as the average impact is 5.3% (p=0.44) and 1.9% (p=0.65).

Conclusion: Our study suggests that food assistance provided to HIV/AIDS patients in Sofala province in Mozambique had no effect on their adherence to ART. Our results indicate that although efforts have been put forth to reduce food insecurity among HIV/AIDS patients, more should be done to ensure that these efforts really result in the improvement of adherence to ART.

Keywords: Antiretroviral treatment; Food insecurity; Food assistance; Adherence; Mozambique

Introduction

The availability of antiretroviral treatment (ART) has changed the course of HIV/AIDS, by transforming it into a chronic condition. ART has reduced the number of deaths and increased survival time. For example, in sub-Saharan Africa, the part of the world most impacted by HIV, the number of people dying of AIDS-related causes has declined by 32% between 2005 and 2011 [1]. However, important challenges remain in the management of HIV/AIDS. These include attempts to ensure that people in need of ART get it on time and take it at a regular basis for the rest of their lives. Taking medication at a regular and continuous basis is exhausting in any chronic condition, as it may lead to pill fatigue for example [2-4]. This challenge is exacerbated by the fact that in resource limited settings, food insecurity and HIV/AIDS overlap.

The vicious cycle of food insecurity and HIV/AIDS is well documented. HIV/AIDS reduces the capacity for food production or purchase, and this increases the vulnerability to HIV transmission by compromising the immuno status and by creating conditions for engagement in unprotected sex, involvement in intergenerational sex partners and transactional sex [5-8]. Food insecurity also impedes access to HIV treatment and care services since patients are reluctant to initiate ART because of the anxiety regarding being able to maintain consumption of sufficient food and a balanced diet [9-11]. Food insecurity also worsens clinical outcomes, particularly adherence [12-15] which is a determinant factor for the virological success of ART, [16-19] and consequently of great importance in the prevention of HIV transmission [20].

In order to minimize food insecurity, food assistance interventions are being incorporated into ART programs [21]. Evidence in a range of low and middle income countries shows that this approach is effective as it is associated with improved food security, nutritional status, ART adherence, slow disease progression and probability of survival [22-26]. However, less is known about the impact of food assistance programs in Mozambique, where the prevalence of HIV/AIDS is 11.5% and more than a third of households (35%) are highly vulnerable to food insecurity [27,28]. Therefore, the aim of our study was to evaluate the effect of a food assistance program on adherence to ART in Sofala province, Mozambique.

Methods

Description of the food assistance program

We evaluated the food assistance program as implemented by the

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United Nations World Food Program (WFP), in collaboration with the Health Alliance International (HAI) and the Ministry of Health. HAI is a non-governmental organization that initiated operations in Mozambique in 1987. Its mission is to support the development of policies that foster social and economic equity for all, with a focus on public-sector health systems and a progressive realization of the right to health. In 2003, in partnership with the government of Mozambique, HAI began to support the implementation and expansion of ART for HIV/AIDS patients. It is within this partnership that HAI also collaborates with the WFP in providing food assistance for HIV/AIDS patients in Sofala Province.

The WFP is responsible for the provision of food while health centres are responsible for the identification of eligible patients and HAI is responsible for the distribution of food to patients. This intervention is provided to HIV/AIDS patients of all ages, including children, tuberculosis patients and pregnant and breast-feeding women enrolled in prevention of mother-to-child transmission (PMTCT) programs. The objective is to ensure patient nutritional recovery and treatment success.

The inclusion criteria in the food assistance program were body mass index (BMI) below 18.5 kg/m^2, earning no income or with income less than the monthly national minimum income and many dependents. Patients were identified before or after they started ART. They were first identified by a social worker, and their eligibility was later confirmed by a clinician. After being identified, patients received an identification card that entitled them to collect food at the distribution site, usually a warehouse or health facility. They received food assistance once per month for a period of three months, after which they were reassessed to determine whether their nutritional status had improved. If improved, patients were discharged from the program; otherwise, the patients remained in the program for an additional period of three to six months. Food assistance consisted of 10 kg of soya, 5 kg of cowpeas and 25 kg of maize.

Study design

This is a retrospective study where we extracted data from clinic and pharmacy records of HIV/AIDS patients for a period of 3 years (September 2007 to December 2010). From these records we collected information on the dates patients were scheduled to pick-up medication and the dates that they actually picked-up medication. In addition to that, we also collected their demographic information namely age, gender, occupation, educational level, marital status, number of household members, along with health information on CD4 counts, BMI, haemoglobin, opportunistic infections and WHO staging. We only collected, data of HIV/AIDS adult patients (18 years or older in September 2007) and excluded children, pregnant and breast-feeding women enrolled in PMTCT.

In order to assess the effect of the food assistance program on adherence, we compared patients who have received food assistance (food assistance recipients) from five districts in Sofala province (Beira, Dondo, Nhamatanda, Caia and Muanza) with similar patients, who did not receive food assistance (controls) from four districts in Zambezia province (Quelimane, Namacurra, Nicoadala and Mopeia). We choose Zambezia province, because this province like Sofala province, is also located in Mozambique central region and there was no food assistance program during that period. The food assistance recipients were selected by simple random sampling from a list of patients who had received food assistance between September 2008 to August 2010. The controls were randomly selected from the health facilities database based on the inclusion criteria used to select food assistance recipients. This study was approved by the Mozambican National Bioethics Committee.

Variable description

The main treatment variable was receipt of food assistance in the form of a food basket ration. Adherence was the primary outcome variable.

We measured adherence based on pill pick-up, a pharmacy adherence measure (PAM), which measures whether an individual picks-up all or a majority of their prescribed ART. PAMs are ideally suited to monitoring adherence because they are objective and can be easily derived from data routinely collected for other purposes, such as clinical care or drug supply management [29]. The underlying premise of this method is that if patients do not receive timely refills from the pharmacy, they are either missing doses (as measured by prolonged periods between refills) or not taking the medication at all. Adherence rates from pharmacy refill records are determined either by comparing actual to scheduled refill dates or by identifying "medication gaps," defined as periods of time during which the patient's supply of medication is assumed to have been exhausted [30]. The pharmacy refill approach has been validated as a measure of adherence since it has been shown to correlate significantly with clinical and virological outcomes [31-37].

We compared actual to scheduled refill dates and calculated medication gaps in terms of quantity and length. If a patient failed to pick-up medication on a scheduled date, we considered it a gap in pick-up and therefore a gap in medication for a certain number of days. Since most ART programs give additional pills for three days after the scheduled date, we only considered a gap in pick-up when the gap had a length greater than or equal to 3 days. If a patient picked-up ART on or before the scheduled refill date, we considered them to be on time. In Mozambique patients usually pick-up ART once every month. They may pick-up more than once in a month if for example; there are not enough pills at the health facility on the scheduled date.

In order to assess the effect of food assistance on adherence, we divided the whole period of analysis in three: before, during and after food assistance. For the control group, since they did not receive the food assistance, we divided the three periods based on the average length of each period of the food assistance recipients. As a measure of adherence, we calculated a score by dividing the number of medication gaps (times patients failed to pick-up ART) by the number of months in each period. By doing this, we standardized the periods since patients have different timing for each period. Accordingly, the higher the adherence score, the less adherent in the patient.

We also collected data on CD4, BMI, and haemoglobin for each period but did not include them in the analysis because there was not enough information for every month since they were not measured systematically at all health facilities included in the study.

Data analysis

We estimated the impact of food assistance using propensity score matching (PSM) with 'difference in differences' estimation. PSM allows us to match each food assistance recipient to a sample of similar non-food assistance recipient based on similar values of propensity scores. We used the available data to match the samples. We used the following characteristics, which we hypothesised to be associated with an increased propensity to receive food assistance and that satisfied the balancing condition of propensity score matching: gender, marital

status, household size, ART initiation date and education level. We used the kernel estimator to match food assistance recipients to non-recipient with the nearest estimated propensity score using the method of Leuven and Sianesi [38].

In order to analyse the change in adherence over time we combined PSM with difference in differences estimation to minimize selection bias and remove the effect of any unobserved time invariant differences between the treatment and comparison groups [22]. The difference in differences estimation compares the change on adherence over time for the food assistance recipients with the change on adherence over time for the control group by estimating the overall difference from the baseline and post differences between the two groups. We also categorized the patients based on the duration of receiving food assistance. In this case, the time periods were six and twelve months duration of receiving food assistance. In this study we estimated the difference between the period before food assistance (pre) and during the food assistance program (during) for both those on six and twelve months duration. We also estimated the difference between the period before (pre) and after food assistance was terminated (post).

Results

Table 1 shows that food assistance recipients (172) and controls (185) did significantly differ by gender, age, marital status (unmarried and widow categories), educational level and occupation ($p<0.05$ for all of these comparisons) and not by household size and marital status (the married category). Food assistance recipients received food assistance for 7 months on average. Based on simple cross-section analysis, the mean adherence score of the food assistance recipients is significantly higher than the control group in the during and post period ($p=0.029$ and $p<0.001$ respectively) (Table 2). This result suggests that food assistance recipients were less adherent to ART than the control group for the two periods. As for the mean adherence score by socio-demographic characteristics, it is significantly higher for the food assistance recipients with the following characteristics: female, less than 30 and 30-39 years old categories, unmarried and married categories, no formal education and secondary education categories, not at work and household size ($p<0.05$ for all of these comparisons, Table 2). Otherwise, the adherence score for patients with other characteristics is reasonably similar for the two groups.

Using PSM, we generated a sample of matched food assistance recipients and controls. The total sample comprised 283 cases where

Variables	FA recipients (N=172)	Controls (N=185)	P-value
Gender n (%)			
Male	38 (22.09%)	60 (32.43%)	0.029
Female	134 (77.91%)	125(67.57%)	
Age in years, mean (SD)	38.52 (9.06)	36.61 (10.20)	0.014
Marital status n (%)			
Unmarried	32 (18.60%)	67 (36.22%)	0.000
Married	86 (50%)	96 (51.89%)	0.721
Widow	50 (29.07%)	14 (7.57%)	0.000
Education levels n (%)			
No formal education	82 (47.67%)	30 (16.22%)	0.000
Primary education	76 (44.19%)	108 (58.38%)	0.007
Secondary education	14 (8.14%)	47 (25.41%)	0.000
University	0 (0 %)	3 (0.55 %)	
Occupation n (%)			
At work	25 (14.53%)	96 (51.89%)	0.000
Not at work	147 (85.47%)	89 (48.11%)	
Household size n (%)			
≤ 4 members	74 (43.02%)	75 (40.54%)	0.635
> 4 members	98 (56.98%)	110 (59.46%)	
Missing	13.63 %	8.94 %	
Months per period *, mean (SD)			
Pre	12.65 (6.85)	8.62 (3.34)	
During	7.27 (6.05)	8.55 (3.42)	
Post	10.15 (5.85)	8.50 (3.51)	
Gaps per period **, mean			
Pre	2.14	1.06	0.201
During	1.2	1.1	0.03
Post	1.8	1.05	0.001

* Periods: Pre= before food assistance, during= during food assistance, post = after food assistance,

** Zero included in the mean, zero=37% of all cases in the total sample

-Standard deviations are in the parentheses

- FA- food assistance

Table 1: Summary statistics of food assistance recipients and controls.

	Adherence score*, mean (SE)		
By period	**FA recipients (N=172)**	**Controls (N=185)**	**P-value**
Pre	0.153 (0.012)	0.131 (0.013)	0.201
During	0.182 (0.016)	0.137 (0.013)	0.029
Post	0.199 (0.016)	0.129 (0.012)	0.001
By socio-demographic characteristics**			
Gender			
Male	0.172 (0.021)	0.68 (0.016)	0.882
Female	0.178 (0.001)	0.115 (0.007)	0.000
Age groups			
<30 years old	0.167 (0.022)	0.114 (0.014)	0.033
30-39 years old	0.186 (0.015)	0.129 (0.128)	0.004
>=40 years old	0.175 (0.012)	0.149 (0.012)	0.138
Marital status			
Unmarried	0.204 (0.024)	0.121 (0.012)	0.001
Married	0.176 (0.012)	0.138 (0.010)	0.015
Widow	0.144 (0.014)	0.131 (0.023)	0.641
Education levels			
No formal education	0.192 (0.012)	0.144 (0.018)	0.035
Primary education	0.161 (0.013)	0.148 (0.010)	0.428
Secondary education	0.182 (0.039)	0.087 (0.010)	0.001
University***	-	-	
Occupation			
At work	0.188 (0.026)	0.169 (0.012)	0.470
Not at work	0.176 (0.009)	0.091 (0.008)	0.000
Household size			
<= 4 members	0.178 (0.013)	0.116 (0.011)	0.000
Members >4	0.177 (0.012)	0.143 (0.010)	0.025

* Adherence score=number of gaps/number of months in each period, zero included in the score.

**The adherence score for the socio-demographics is the mean for the three periods.

-Hypothesis tested against mean difference in adherence score between two groups!=0

- *** small number of cases

Table 2: T-test statistics of adherence score.

133 were food assistance recipients and 150 were controls (on common support). To check if our matching was successful and of good quality, we tested for equality of means for each variable used in determining the propensity score and that showed that none of the variables were significantly different between food assistance recipients and controls (Table 3).

Table 4 shows the PSM estimates for adherence (plus difference in differences estimation). During the food assistance programme, the adherence of recipients who participated in the programme for six months is not significantly different from the non-recipients as the average impact is only 0.4% (p=0.94). For those who had been on the programme for 12 months, the average impact is -2.3% and not significantly different from the non-recipients (p=0.73). After food assistance has been terminated, there is some improvement in the average adherence levels, however it remains non-significant. The average impact for those who had been on the food assistance programme for six months is 5.3% (p=0.44), while for those who had been on the programme for 12 months the impact on adherence is 1.9% (p=0.65).

Discussion

Our analysis suggests that food assistance provided to HIV/AIDS patients in Sofala province in Mozambique had no effect on their adherence to ART, measured here as the number of times patients failed to collect medication; whereby patients received food assistance for 7 months on average.

Our results contradict results from other studies that have found an effect of food assistance in adherence to ART in other resource limited settings. For example, studies in Niger and Zambia [24-26], evaluated the effect of food assistance and found a positive effect on adherence to ART. A study in Haiti [23], found that food assistance improved the timely attendance of monthly clinic visits.

Yet our results should be interpreted with caution. Food insecurity is documented as one of the barriers to adherence to ART [15,39-43] and as such it is unexpected that food supplementation would not improve adherence. We hypothesize that the following factors may explain the unobserved effect of this food program on adherence to ART. First, we did not evaluate the implementation of the food assistance program, and there may be aspects intrinsic to the program that may have affected its ability to produce an effect on patients' adherence to ART. For example, in our evaluation of patient satisfaction with the program, they mentioned that they were not satisfied with the enrolment period in the program. Therefore, future research evaluating the effect of food assistance programs could also assess the role of program design and implementation in order to aid in the interpretation of results.

Second, it may be that the food assistance program may have improved patients nutritional status but not their ability to collect medication. We expect other reasons than food insecurity to have affected access to medication as shown by other studies [44]. Moreover, since food supplies are often housed separately from the health facilities, patients may have faced transport difficulties [10,45-48], especially when timing of food distributions does not match with health facility visits. The placement of food aid at the health facilities and the use of transport vouchers can incentivize pill pick-up [25,26,49].

Finally, since the adherence measure we used is based on pill pick-up, and does not account for medication obtained outside the health facility, it could be that patients got their medication elsewhere, and therefore did not show up at the health facility to collect medication. However, getting medication outside the health facilities where a patient is registered is unlikely in Mozambique.

Our study has several limitations. We used retrospective data, which does face challenges of completeness. Registration is not always accurate and this may have led to an apparent high number of gaps in medication collection, while in reality patients came to collect them. Another consequence related to the limitation in the completeness of data is that we were unable to correlate adherence to ART with other clinical outcomes such as BMI, CD4 and opportunistic infections to better interpret the results as performed in other studies [32-36,50]. Correlating adherence with clinical outcomes is important because there is no guarantee that all ART pills retrieved at the pharmacy are actually taken by patients.

The fact that this was a retrospective study and not prospectively randomised, may have been another limitation. However, we used a quasi-experimental design by performing PSM with difference in differences estimates which allowed us to match each food assistance recipient to a sample of similar non-food assistance recipient and removed the effect of unobserved time invariant differences between both groups. Despite the limitations, by using an objective and not expensive adherence measure easily calculated from information routinely available in medical and pharmacy records, our results could be generalized to other settings.

In conclusion, our study suggests that food assistance provided to HIV/AIDS patients in Sofala province in Mozambique had no effect on their adherence to ART. Our results indicate that although efforts have been put forth to reduce food insecurity among HIV/AIDS patients, more should be done to ensure that these efforts really result in the improvement of adherence to ART.

Variable	Mean		t-statistic	p-value
	FA recipients (N=133)	Controls (N=150)		
Age (in years)	37.90	36.89	0.90	0.37
Female	0.75	0.76	-0.22	0.83
Not married	0.20	0.22	-0.25	0.80
Widow	0.22	0.23	-0.18	0.86
No of household members	4.99	5.16	-0.56	0.58
Date of ARV initiation	20 October 2007	2 December 2007	-1.00	0.32
Primary education	0.49	0.42	1.06	0.29
Secondary education	0.10	0.12	-0.69	0.49

Table 3: Propensity score estimation: mean differences of covariates after matching.

During FA	FA recipients (n)	Controls (n)	Difference in Difference	P-value
Six month duration	0.048 (55)	0.044 (60)	**0.004**	0.94
12 month duration	0.021 (7)	0.044 (81)	**-0.023**	0.73
After FA				
Six month duration	0.071 (56)	0.018 (54)	**0.053**	0.44
12 month duration	0.047 (52)	0.066 (118)	**0.019**	0.65

Table 4: Propensity score matching results on adherence (difference in differences).

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