

Factors Associated with the Use of Highly Active Antiretroviral Therapy in Patients Newly Entering Care in an Urban Clinic

*†Thomas P. Giordano, *A. Clinton White, Jr, *Prasuna Sajja, *‡Edward A. Graviss, §Roberto C. Arduino, ||Ahmed Adu-Oppong, *||Christopher J. Lahart, and *Fehmida Visnegarwala

*Sections of *Infectious Diseases and †Health Services Research, Department of Medicine, and ‡Department of Pathology, Baylor College of Medicine, Houston, Texas; §Section of Infectious Diseases, Department of Medicine, University of Texas Health Science Center at Houston School of Medicine, Houston, Texas; and ||Thomas Street Clinic, Harris County Hospital District, Houston, Texas, U.S.A.*

Summary: Ethnic minority, female, and drug-using patients may be less likely to receive highly active antiretroviral therapy (HAART), despite its proven benefits. We reviewed the medical records of a consecutive population of 354 patients entering care in 1998 at the Thomas Street Clinic, an academically affiliated, public, HIV-specialty clinic in Houston, to determine the factors associated with not receiving HAART as recorded in pharmacy records. Ninety-two patients (26.0%) did not receive HAART during at least 6 months of follow-up. Patients who did not receive HAART were more likely to be women and to have missed more than two physician appointments and were less likely to have a CD4 count <200 cells/ μ L or a viral load $\geq 10^5$ copies/mL. In multivariate logistic analysis, missed appointments (OR = 5.85, $p < .0001$), female sex (OR = 2.53, $p = .001$), and CD4 count ≥ 200 cells/ μ L (OR = 2.50, $p = .001$) were independent predictors of not receiving HAART. More than half the patients who never received HAART never returned to the clinic after their first appointment. Among patients new to care, women and those with poor appointment adherence were less likely to receive HAART. Efforts to improve clinic retention and further study of the barriers to HAART use in women are needed. **Key Words:** Highly active antiretroviral therapy—Women—Adherence—Naive patients—Appointments—HIV.

Highly active antiretroviral therapy (HAART) has dramatically improved the survival of patients infected with HIV who have access to the medications (1–3). Not all patients with a clinical indication for HAART receive treatment, however. In various studies, injection drug users (IDUs) (2,4–10), racial/ethnic minorities (8,10–12), and women (13–15) have been found to be less

likely to receive HAART, although there are conflicting data (2,4–9,11,12,16–20). Some of these studies are cross-sectional and are subject to bias by underrepresenting persons who receive less frequent care or who are lost to follow-up (4,6,16,17,20). Cohort and population-based studies that have examined access to HAART are less subject to bias but have been accomplished in unique groups relative to the HIV-infected population in the United States, including patients in countries with free medical care (5,13,14,21), predominantly white men who have sex with men (MSM) (2,8), women (10), IDUs (19), or patients in care early in the HAART era (11,12, 18). Furthermore, the majority of the patients in these studies were poised to receive HAART because they were already established in care when it became available. Therefore, available studies may not accurately re-

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Address correspondence and reprint requests to Fehmida Visnegarwala, Thomas Street Clinic, Room 424, 2015 Thomas Street, Houston, TX 77009 U.S.A.; e-mail: fehmidav@bcm.tmc.edu

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flect who is receiving HAART among patients newly presenting for care in the HAART era. In addition, few studies assessed the impact of physician experience on receipt of HAART (9,13), although it has been related to use of HAART and mortality (22–26).

We undertook a study to assess the factors associated with not receiving HAART in persons newly presenting for care in the HAART era at the Thomas Street Clinic, an HIV clinic in Houston affiliated with Baylor College of Medicine and the University of Texas Houston School of Medicine. The clinic annually serves about 4000 primarily uninsured urban patients. We performed a retrospective chart review of consecutive patients entering care to determine the factors associated with not receiving HAART as recorded in pharmacy records.

METHODS

Patient Population

The Thomas Street Clinic serves low-income HIV-infected persons who reside in Harris County, Texas. Fees for services are on a sliding scale and range from no out-of-pocket costs for those whose employment income is below the US poverty level (the vast majority of patients) to self-pay for those whose income is >250% of the poverty level. Residency and income are periodically verified. At the first clinic visit, a nurse and social worker obtain a medical history, assess a patient's needs, and obtain baseline laboratory tests, including a urine toxicology screen. Patients are scheduled to see a physician provider, usually within 2 to 4 weeks, who is either an attending physician or a supervised fellow or resident. Staff attempt to reschedule patients who miss an appointment by telephone and then by mail. This study includes all new patients who kept at least one physician appointment between April 20, 1998 and December 31, 1998.

Data Collection and Definitions

A trained reviewer abstracted the data from the medical record into a computerized database beginning July 1999; thus, all patients had at least 6 months of follow-up. Data abstracted included age, sex, race/ethnicity, HIV risk factor (MSM, IDU, heterosexual contact, or other/unknown), insurance status (insured or uninsured), diagnosis of AIDS, prior antiretroviral therapy, medication use during follow-up, drug or alcohol use (defined as a positive toxicology screen or identified as a problem by the screening nurse, social worker, or health care provider), incarceration in the past or during follow-up, baseline CD4 count, baseline viral load (assayed by reverse transcriptase [RT]-PCR, range of detection: 400–750,000 copies/mL), adherence to appointments, and level of training of physician provider (attending physician or supervised fellow or resident). Patients were considered new to the clinic if they had never been seen there before or had not been seen in at least 1 year. HAART was defined as a protease inhibitor plus two nucleoside reverse transcriptase inhibitors (NRTIs), a non-NRTI plus two NRTIs, or abacavir plus two other NRTIs. Receipt of HAART was assessed by documentation in computerized on-site pharmacy records that a HAART regimen was dispensed at least once. Medications obtained through research and expanded access protocols were recorded. Failure to receive HAART could be due to patient refusal, failure of the

physician to prescribe HAART, or failure of the patient to fill prescriptions. If the medical record clearly indicated why a person did not receive HAART, that information was recorded. "Missed appointments" was defined as missing more than two primary physician appointments in 6 months.

Data Analysis

The outcome variable for this study was receipt of HAART at any time during the follow-up period. Explanatory variables of interest included age, sex, race/ethnicity, HIV risk factor, insurance status, diagnosis of AIDS, prior antiretroviral use, drug or alcohol use, incarceration, baseline CD4 count, baseline viral load, missed appointments, and level of training of physician provider. Categorical data were analyzed with the χ^2 test or Fisher exact test if an expected cell value was <5. Stepwise multivariate logistic regression was performed by including all biologically plausible explanatory variables and those with $p < .20$ and then eliminating variables with $p > .10$ from the final model. Goodness of fit was assessed with the Hosmer-Lemeshow statistic, and no model was determined to have "poor fit." Statistics were analyzed with SAS version 8.2 (SAS Institute, Cary, NC, U.S.A.).

RESULTS

There were 354 patients in the study after removing the single Asian patient and 11 patients without a baseline viral load (Table 1). The median age was 38 years (interquartile range [IQR]: 32–44 years). Slightly more than half the patients were African American (54.5%), 21.2% were Hispanic, and 28.5% were women. The risk factor for HIV was MSM for 39.3%, heterosexual sex for 42.1%, IDU for 12.2%, and other/unknown for 6.5%. Two thirds of the patients (63.6%) were antiretroviral naive. Median CD4 count was 188 cells/ μ L (IQR: 66–434), and median \log_{10} viral load was 4.71 copies/mL (IQR: 3.50–5.39). Two hundred sixty-two patients received HAART, and 92 (26.0%) did not (Table 2). These patients did not differ in age, race/ethnicity, HIV risk factor, insurance status, or history of incarceration compared with patients who received HAART. Those who did not receive it were more likely to be female (45.7% vs. 22.5%, $p < .0001$), had missed appointments (79.4% vs. 32.1%, $p < .0001$), had a CD4 count ≥ 200 cells/ μ L (70.6% vs. 40.8%, $p < .0001$), and had a viral load $< 10^5$ copies/mL (73.9% vs. 55.0%, $p = .001$). Only 10.9% of patients who did not receive HAART and 17.2% of those who did were cared for by a fellow or resident ($p = .15$). In multivariate analysis, missed appointments (OR = 5.85, 95% CI: 3.46–9.90, $p < .0001$), female sex (OR = 2.53, 95% CI: 1.46–4.39, $p = .001$), and CD4 count ≥ 200 cells/ μ L (OR = 2.50, 95% CI: 1.49–4.19, $p = .001$) were independently associated with not receiving HAART (Table 3).

TABLE 1. Baseline characteristics of new patients seen at the Thomas Street Clinic between April and December, 1998

	All new patients (n = 354)		Antiretroviral-naive patients meeting 1998 DHHS criteria (n = 203)	
	n	Percent	n	Percent
Sex				
Male	253	71.5	145	71.4
Female	101	28.5	58	28.6
Race/ethnicity				
White	86	24.3	38	18.7
African American	193	54.5	115	56.7
Hispanic	75	21.2	50	24.6
HIV risk factor				
MSM	139	39.3	74	36.5
Heterosexual sex	149	42.1	99	48.8
Injection drug use	43	12.2	18	8.9
Other/unknown	23	6.5	12	5.9
No insurance	331	93.5	191	94.1
Antiretroviral-naive	225	63.6	— ^a	— ^a
Age, years, median (IQR)	38	(32–44)	38	(32–44)
CD4 count, cells/ μ L, median (IQR)	188	(66–434)	120	(43–339)
VL, copies/mL, log ₁₀ , median (IQR)	4.71	(3.50–5.39)	5.06	(4.43–5.57)

^a All patients naive by definition.

DHHS, US Department of Health and Human Services; IQR, interquartile range; MSM, men who have sex with men; VL, viral load. Patients meeting 1998 DHHS criteria have AIDS, a CD4 count \leq 500 cells/ μ L, or a VL \geq 20,000 copies/mL (27).

Antiretroviral-Naive Patients Meeting Criteria for the Initiation of HAART

To minimize the potential effect of prior antiretroviral therapy and severity of HIV disease on results, we analyzed the subgroup of antiretroviral-naive patients who met the 1998 US Department of Health and Human Services (DHHS) recommended criteria for HAART (AIDS, CD4 count \leq 500 cells/ μ L, or viral load \geq 20,000 copies/mL), the recommended criteria when these patients were being seen (27). Of 203 patients in this subgroup, 153 received HAART and 50 (24.6%) did not (see Table 2). These patients did not differ in age, race/ethnicity, insurance, diagnosis of AIDS, or drug or alcohol use. Compared with patients who received HAART, patients who did not receive HAART were more likely to be female (44.0% vs. 23.5%, $p = .005$), had IDU as a risk factor for HIV (20.0% vs. 5.2%, $p = .01$), had missed appointments (82.0% vs. 28.8%, $p < .0001$), had a CD4 count \geq 200 cells/ μ L (64.0% vs. 30.7%, $p < .0001$), and had a viral load $< 10^5$ copies/mL (66.0% vs. 43.1%, $p = .005$). Ten percent of patients who did not receive HAART and 18.4% who did were cared for by a fellow or resident ($p = .16$). In multivariate analysis, missed appointments (OR = 7.87, 95% CI: 3.80–16.4, $p < .0001$), female sex (OR = 2.55, 95% CI: 1.18–5.50, $p = .02$), and CD4 count \geq 200 cells/ μ L (OR = 2.71, 95% CI: 1.34–5.45, $p = .005$) were the independent factors associated with not receiving HAART (see Table 3).

Why Patients Did Not Receive HAART

Forty-eight of the 92 patients (52.2%) who did not receive HAART never returned to the clinic after their first physician appointment, likely explaining why they did not receive HAART. These patients did not differ from those not lost to follow-up in age, race/ethnicity, HIV risk factor, insurance status, prior antiretroviral treatment, diagnosis of AIDS, drug or alcohol use, level of training of physician, history of incarceration, or viral load (data not shown). More women were lost to follow-up than men (19.8% vs. 11.1%, $p = .03$), and more of those lost to follow-up had a CD4 count \geq 200 cells/ μ L (64.6% vs. 46.1%, $p = .02$). When patients lost to follow-up were excluded from the analysis, the effect of missed appointments (OR = 2.70, 95% CI: 1.43–5.07, $p = .002$), CD4 count \geq 200 cells/ μ L (OR = 4.10, 95% CI: 2.06–8.15, $p < .0001$), and female sex (OR = 3.62, 95% CI: 1.90–6.91, $p < .0001$) remained, both in the whole population and when the DHHS criteria were applied (data not shown).

The remaining 44 patients who did not receive HAART were not lost to follow-up. Four of these patients refused HAART, 4 had advanced comorbid conditions, 5 did not maintain clinic eligibility, 12 were drug or alcohol users, and 8 additional patients had missed appointments. Eleven patients without any of these characteristics did not receive HAART; their median CD4 count was 593 cells/ μ L. In total, 6 patients did not receive HAART because they had terminal conditions, including cirrhosis, renal and cardiac disease, and cancer.

TABLE 2. Characteristics of patients who did and did not receive HAART, among new patients seen at the Thomas Street Clinic between April and December, 1998

	All new patients (n = 354)			Antiretroviral-naive patients meeting 1998 DHHS criteria (n = 203)		
	Received HAART?		p value	Received HAART?		p value
	Yes (n = 262)	No (n = 92)		Yes (n = 153)	No (n = 50)	
Age <35 years	34.4	42.4	.17	34.6	38.0	.67
Sex			<.0001			.005
Male	77.5	54.4		76.5	56.0	
Female	22.5	45.7		23.5	44.0	
Race/ethnicity			.15			.33
White	23.3	27.2		17.0	24.0	
African American	53.1	58.7		56.2	58.0	
Hispanic	23.7	14.1		26.8	18.0	
HIV risk factor			.28			.01
MSM	41.2	33.7		39.9	26.0	
Heterosexual sex	42.0	42.4		49.0	48.0	
Injection drug use	10.3	17.4		5.2	20.0	
Other/unknown	6.5	6.5		5.9	6.0	
No insurance	92.8	95.7	.33	92.8	98.0	.30
Antiretroviral-naive	61.8	68.5	.25	— ^a	— ^a	
AIDS	41.2	30.4	.07	47.1	42.0	.53
PCP	20.2	14.1	.20	22.9	12.0	.10
Drug or alcohol use	29.8	39.1	.10	32.0	40.0	.30
Ever incarcerated	22.1	28.3	.23	10.5	20.0	.08
Missed appointments	32.1	79.4	<.0001	28.8	82.0	<.0001
Resident or fellow physician	17.2	10.9	.15	18.4	10.0	.16
CD4 count \geq 200 cells/ μ L	40.8	70.6	<.0001	30.7	64.0	<.0001
VL $<10^5$ copies/mL	55.0	73.9	.001	43.1	66.0	.005

^a All patients naive by definition.

Patients meeting 1998 DHHS criteria have AIDS, a CD4 count \leq 500 cells/ μ L, or a VL \geq 20,000 copies/mL (27). P values are from chi-square test or Fisher exact test if an expected cell count is <5 .

All data are percent unless noted. HAART, highly active antiretroviral treatment; DHHS, US Department of Health and Human Services; MSM, men who have sex with men; PCP, *Pneumocystis carinii* pneumonia; VL, viral load.

Excluding these 6 patients from the analysis did not appreciably change the results (data not shown).

DISCUSSION

Despite its proven benefits, about 25% of new patients with an indication for HAART did not receive treatment,

even in this academic HIV clinic. Various studies from the United States (7,18) and Europe (4–6,21) corroborate this finding. Patients with higher CD4 counts were less likely to receive HAART in every analysis, suggesting that physicians relied heavily on this marker of immune function in deciding when to start therapy. In contrast, viral load did not independently predict HAART use.

TABLE 3. Multivariate analysis of factors associated with not receiving HAART among new patients seen at the Thomas Street Clinic between April and December, 1998

	All new patients (n = 354)			Antiretroviral-naive patients meeting 1998 DHHS criteria (n = 203)		
	OR	95% CI	p value	OR	95% CI	p value
Missed appointments	5.85	3.46–9.90	<.0001	7.87	3.80–16.4	<.0001
Female sex	2.53	1.46–4.39	.001	2.55	1.18–5.50	.02
CD4 count \geq 200 cells/ μ L	2.50	1.49–4.19	.001	2.71	1.34–5.45	.005

Patients meeting 1998 DHHS criteria have AIDS, a CD4 count \geq 500 cells/ μ L, or a viral load \leq 20,000 copies/mL (27). P values are Wald p-values. In addition to the above variables, the following variables were considered for the model, but were not retained due to a lack of significance at the .10 level: age <35 years, race/ethnicity, HIV risk factor, insurance status, prior antiretroviral therapy, AIDS, *Pneumocystis carinii* pneumonia, drug or alcohol use, history of incarceration, physician experience, and viral load $>10^5$ copies/mL.

HAART, highly active antiretroviral treatment; DHHS, US Department of Health and Human Services; OR, adjusted odds ratio; 95% CI, estimated Wald 95% confidence interval for odds ratio.

HAART has the most clinical benefit in patients with lower CD4 counts, and current guidelines suggest delaying therapy later than previously recommended (28,29). Thus, some patients may not have received HAART due to limited anticipated benefits.

Loss to follow-up and poor adherence to appointments emerged as the most important barriers to HAART. Poor adherence to clinic appointments, which has been related to lower odds of virologic suppression in patients on HAART (30,31), has been associated with lower odds of receiving HAART among IDUs (19). In our broader clinic population as well, patients who missed appointments were less likely to receive HAART. Nearly half the patients in the study (44.4%) missed more than two appointments in 6 months, 46.5% of whom did not receive HAART. In contrast, only 9.6% of patients who did not miss appointments were untreated ($p < .0001$). A patient who missed appointments was about six times more likely to not receive HAART (see Table 3). In a multivariate model, age <35 years (OR = 2.31, 95% CI: 1.45–3.70, $p = .0005$), IDU as an HIV risk factor (OR = 2.58, 95% CI: 1.22–5.43, $p = .01$), and drug or alcohol use (OR = 2.12, 95% CI: 1.31–3.42, $p = .002$) were associated with missed appointments. Thus, substance use is related to missed appointments, which, in turn, are most predictive of not receiving HAART. Because substance use also impairs medication adherence (32), it may be appropriate to refer substance-abusing patients to treatment programs and defer HAART (28, 33,34).

Half the patients who did not receive HAART did not return to the clinic after their first physician appointment. It is unlikely that these patients received HAART elsewhere, because there were no other Ryan White–funded clinics in the county at that time, only 3 patients had Medicaid, and none had private insurance. Overall, 13.6% of the patients were lost to follow-up after their first physician visit, and an additional 30.8% of patients missed more than two appointments in 6 months, indicating that establishing care is a complex and dynamic process whose outcome is by no means determined once a patient accesses care. The current approach to fighting the spread of HIV in the United States is based on getting patients with HIV into care for education and treatment (35). Clearly, intense support of newly diagnosed patients as they attempt to enter and remain in care is needed.

Even after controlling for disease severity, HIV risk factors, race/ethnicity, and missed appointments, women were about three times less likely to receive HAART than men in all analyses. Most previous studies have not found that gender influenced whether patients received

HAART, but these studies were not designed with this intent (2,4,6–9,12,16–20). Mocroft et al. (14) specifically assessed the effect of gender and found that women were less likely to receive HAART. Because those patients were already established in care when HAART became available, many barriers to care that are more likely to affect women, such as transportation problems (36), may have already been solved by the women in that study. Our study now adds concern that women new to care are less likely to both remain in care and receive HAART.

Race/ethnicity was not associated with the receipt of HAART, missed appointments, or being lost to follow-up in this study in contrast to other studies (8,10–12). These results are encouraging, because 73% of new HIV infections in the United States occur in minority patients (37). Similarly, although use of antiretrovirals has been related to provider experience in previous studies (9,13, 22,26), being cared for by a resident or fellow in the present analysis was not associated with lower odds of HAART use. This null finding may be due to attending physician supervision of the trainees or to the small number of patients cared for by the trainees.

This study has a number of limitations. The data for this study were gathered retrospectively, and physicians may have recorded information in a biased manner. To minimize this bias, we relied on data collected prior to physician visits (i.e., at the screening visit) or objective results (e.g., pharmacy records and appointment-keeping behavior) whenever possible. Toxicology screening was only done at a single time point, likely underestimating the number of illicit drug users. Patients may have moved out of the county and received HAART elsewhere. We were unable to consider other potential determinants of HAART utilization such as income (12,16, 36) and education (4,10,16,20,21). Nevertheless, in a multivariate analysis excluding MSM, who might have higher income and education levels than other patients, women and patients who missed appointments were still less likely to receive HAART (data not shown).

This study has a number of advantages over previous studies. Inclusion in the study was not biased by frequency of contact with the clinic. The study population was diverse, with relatively large numbers of female, minority, and non-MSM patients. We studied patients who were new to the clinic and primarily antiretroviral naive. To our knowledge, this is the first study evaluating the factors associated with the receipt of HAART conducted with primarily antiretroviral-naive patients newly entering care. Persons poorly adherent to physician visits and women were less likely to receive HAART. The poor adherence to appointments and high rate of loss to follow-up observed during the period when patients are

newly establishing care suggest that this is a critical phase in patient care that requires further study. Because contact with case managers has been shown to decrease unmet needs for support services, improve clinic retention, and increase utilization of HAART, we have recently implemented an intensive case management program specifically for women entering care in our clinic, and preliminary data suggest improved resource utilization and outcomes (38–40). As the epidemic in the developed world continues to shift to women and socially disadvantaged populations, it is crucial to improve on clinic retention and treatment of patients with intensive case management, social support, and disease-specific education efforts.

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