

CHAIN REPORT 2008-2



# Predictors of Antiretroviral Treatment Effectiveness

Peter Messeri  
Dan Weglein  
Sara Berk  
Angela Aidala  
María Cabán  
Mary Ann Chiasson  
Fabienne Laraque

Columbia University  
Mailman School of Public Health  
In collaboration with the NYC Department of Health and  
Mental Hygiene, the Westchester Department of Health,  
NY Health & Human Services IV Planning Council, and  
Public Health Solutions

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**C.H.A.I.N. REPORT**

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## Introduction

Since the introduction of highly active antiretroviral therapy (HAART) in 1996, life expectancy of persons living with HIV has dramatically increased,<sup>1</sup> with a corresponding reduction in excess mortality.<sup>2</sup> In the U.S., life expectancy has increased from 10.5 years for a person diagnosed with HIV in the U.S. in 1996 to 22.5 years for a person diagnosed in 2006.<sup>1</sup> Although the benefits of HAART treatment are widely shared, substantial differences in life expectancy remain across major segments of the HIV infected population. Whereas life expectancy in 1996 was similar across major U.S. ethnic groups, by 2006 a newly diagnosed white male was expected to live 5.6 years longer than a newly diagnosed black male and 3.7 years longer than a newly diagnosed Hispanic male.<sup>1</sup> During the decade following the introduction of HAART, HIV infected IDU showed substantially smaller gains in life expectancy<sup>1</sup> and reduction in excess mortality when compared with persons in other HIV risk factor categories.<sup>2</sup> Finally, although the number of years of life lost has been greatly reduced, persons living with HIV 15 years into the HAART era continue to have shorter life expectancy<sup>1</sup> and excess mortality<sup>2</sup> compared with their age, gender and racial peers in the general population.

Although group differences in improved life expectancy are in part attributable to behaviors and co-morbidities, they also point to possible uneven quality of or access to HIV medical care. In contrast to the extensive research literature that has thoroughly documented the link between HAART and reduced mortality, much less is known about the determinants of what might be regarded as the more proximal measures of treatment effectiveness: the time to viral suppression after initiation of antiretroviral (ARV) treatment<sup>3-5</sup>, viral load rebound after initial suppression<sup>4,6,7</sup> or early discontinuation of medications.<sup>8</sup> The small body of research suggests the following provisional predictors. Treatment success is most consistently associated with medication adherence<sup>7</sup> as well as keeping scheduled appointments.<sup>6,7</sup> Evidence is less conclusive when it comes to patient characteristics. Older age was associated with treatment success in four studies<sup>3,6,8,9</sup> but not in a fifth.<sup>5</sup> Women experienced viral suppression more rapidly in one study, but two other studies found no gender differences in treatment success.<sup>5,6,10</sup> Substance use and nonwhite racial status<sup>6</sup> were also associated with treatment failure. Housing status has been identified as a contextual factor independently associated with treatment outcomes, controlling

for demographics and substance use.<sup>11,12,13</sup>

The current study extends existing research on antiretroviral treatment effectiveness in the following ways. First, the study sample reflects experiences of care provided in a broad spectrum of medical care settings in which HIV patients are treated in urban, suburban and rural communities, rather than the findings from a single clinic. Second, this study investigates treatment effectiveness over a longer time frame--up to six years--than is typical of previous studies. Third, the study draws upon information collected through repeated personal interviews that permit examination of a much broader array of patient characteristics, life situations and medical care factors than can be abstracted from patient records.

For this study, we draw upon personal interview data collected for the Community Health Advisory & Information Network (CHAIN) Project, a longitudinal study of people living with HIV/AIDS (PLWHA) in New York City and the Tri-County region, to the north of the City. Treatment effectiveness is measured in two ways: (1) timely achievement of viral suppression among cohort members with detectable viral loads, and (2) persistence of viral suppression, defined as the number of follow-up interviews for which viral suppression is maintained following initial suppression. We investigate the association of these two outcomes with adherence to HAART, quality of medical care, residential location, age, ethnicity, education, immigrant status, housing stability, mental health status and substance use.

### **Key Findings**

1. Among CHAIN cohort members for whom ARV use was clinically indicated, 46% reported suppressed viral load in the interview following report of detectable viral load.
2. Once viral suppression was achieved, 63% of the study sample maintained viral suppression through two or more follow-up interviews.
3. Superior ARV treatment outcomes were associated with complete adherence to HAART regimen and older age.
4. Inferior ARV treatment outcomes were associated with current substance use and unstable housing.
5. There appeared to be regional variation in ARV treatment effectiveness.

6. Quality of medical care measures used in this study had minimal association with treatment effectiveness.

## Methodology

### Cohort Recruitment and Study Samples

Study samples were drawn from participants in the Community Health Advisory & Information Network (CHAIN) Project, a prospective cohort study of persons living with HIV and AIDS in New York City and the Tri-County region to the north of the City. Tri-County is a heterogeneous region covering the lower Hudson River Valley. It encompasses Rockland County on the west side of the Hudson River and Westchester and Putnam Counties to the east. The Tri-County region encompasses urban communities, bordering New York City, affluent and working class suburbs dispersed throughout the region, and exurban and rural areas in the north.

*Cohort recruitment* CHAIN cohorts in New York City and Tri-County were recruited following similar two-stage sampling procedures. First, a sample frame of agency recruitment sites was formed from medical care and social service agencies that provide specialized HIV services. Private medical providers, including large group practices, were excluded from the agency sample frame.<sup>i</sup> In New York City, agencies were randomly selected from this list, stratified by type of agency (medical versus social service agency) and by borough. The sampled agencies were then invited to serve as recruitment sites. All listed Tri-County providers were invited to participate as recruitment sites because of the small size of the HIV care network serving this region.

Agencies that agreed to participate followed a rigorous recruitment protocol that was designed to assemble a representative sample of PLWHA with some connection to the HIV care system in the New York City region. With the assistance of agency staff, clients were randomly selected from agency client rosters or through an onsite sequential recruitment procedure. To protect

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<sup>i</sup> Although not included in the agency sampling frame, private physicians' offices were reported by 7.4% of individuals recruited into the CHAIN cohort as their source of HIV medical care. Our best estimate is that 15% to 24% of New York PLWHA receive HIV medical care from solo or small group office-based practices (Ellen Weiwel, personal communication).

client privacy, staff from the recruitment site made the initial contact. When a client gave provisional assent to participate, identifying information was turned over to CHAIN staff to complete enrollment, obtain informed consent and schedule an interview.

In New York City, recruitment was conducted at 34 of 55 sampled agencies between July 2002 and December 2003. Baseline interviews were completed with 684 clients. In addition to the agency-based recruitment, we searched for HIV-positive individuals unconnected to medical care through outreach activities. Nine of the unconnected to care completed the full interview and are retained in the longitudinal cohort<sup>ii</sup>. The sociodemographic composition of the cohort closely mirrored that of the population using Ryan White CARE Act services at time of recruitment in 2002. Compared with the general population of persons living with HIV/AIDS, the CHAIN cohort under represents white men and over represents black and Hispanic men.

Tri-County recruitment occurred at 28 agencies, dispersed throughout the region. Baseline surveys were completed by 398 individuals between November 2001 and November 2002<sup>iii</sup>. Compared to the sociodemographic composition of surviving AIDS cases in Tri-County at time of recruitment, the CHAIN cohort over represented females. However, the cohort's ethnic composition within gender closely approximated the AIDS case data.

For this study, we followed treatment outcomes for up to five rounds of interviews, a period of time that may span seven or eight years (through the middle of 2009). Successive rounds of interviews were completed with more than 80% of eligible participants.<sup>iv</sup> The median interval between successive rounds of interviewing ranged from 15 to 17 months.

*Study Samples* The two overlapping samples created for this study correspond to the two outcome measures: achievement of viral suppression (AVS) and persistence of viral suppression (PVS) once achieved.

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<sup>ii</sup> A detailed description of the recruitment of the 2002 NYC cohort, CHAIN Report 2004- 4: Field Notes: Recruiting a Longitudinal Cohort<sup>14</sup> and the unmet needs of the unconnected<sup>15</sup> is available on request.

<sup>iii</sup> A detailed description of the recruitment of the Tri-County cohort, Tri-county CHAIN Report 2002-4b: Field Notes: Recruiting a Longitudinal Cohort<sup>16</sup>, is available on request.

<sup>iv</sup> CHAIN Cohort members eligible for follow-up interviews were those not know to have died, moved outside of the study region, or who had not withdrawn from the study at an earlier interview and were not either in jail or physically unable to complete an interview.

*AVS Sample* CHAIN participants eligible for the AVS analysis met initial ARV use criteria and reported a *detectable viral load* at one interview followed by valid viral load information at follow-up interview. Nine hundred and eighty-five (985) CHAIN participants (NYC = 630 and Tri-County = 355) met the ARV use criteria: they reported either currently taking ARV medications or a CD4 T-cell count below 200. From this initial pool, 431 individuals were excluded because they always reported an *undetectable* viral load (see below for operational definition of undetectable viral load) upon meeting the ARV use criteria. Among the 554 individuals who met the ARV use criteria with one or more reports of a detectable viral load, 121 were excluded because they were not re-interviewed following the interview in which they reported a detectable viral load. Another 72 with follow-up interviews were excluded because they did not report viral load information at the follow-up interview. The final AVS study sample consisted of 361 CHAIN participants; 246 were from the NYC cohort and 115 were from the Tri-County cohort.

*PVS Sample* CHAIN participants eligible for the PVS analysis reported ARV use and *undetectable* viral load by the third round of interviews and at least one interview with valid viral load information following initial suppression. Among an initial pool of 924 participants (NYC = 583 and Tri-County = 341) reported taking ARV by the third round of interviews, 706 also achieved viral suppression by the third round of interviews. Among those who met initial eligibility criteria, 130 were dropped from the study sample due to absence of interview following the initial report of undetectable viral load. Seventeen (17) cohort members were excluded because viral load information was missing at follow-up interview and 14 were excluded because of unreliable viral load reports. The final PVS study sample consisted of 545 CHAIN participants: 359 were from the NYC cohort and 186 were from the Tri-County cohort.

## **Study Variables**

*Treatment Effectiveness* The two study outcomes entailed tracking changes in viral load status across interviews. CHAIN participants were asked at each interview to recall the results of their most recent viral load test. The cut point between undetectable and detectable at each interview was set at 400 copies/ml. If participants could not recall a numeric value, they were asked whether their doctor told them that their viral load was “undetectable,” “good,” or “bad.” Categorical responses of “undetectable” or “good” were coded as undetectable, and “bad” was coded as

detectable. A small validation study was completed, comparing self-reported clinical markers and medical regimens with medical records review. Consistent with similar studies, there was very high agreement between self-reports and information in medical charts for clinically important categories of viral load (undetectable vs. detectable) and CD4 (e.g. less than 200, greater than 500).<sup>17,18</sup>

For the PVS analysis, we imputed viral load status for 31 participants missing viral load information at a middle interview, when viral load was reported at both the preceding and subsequent interviews<sup>v</sup>. Based upon the modal pattern of viral load status for participants who reported viral loads at three successive rounds of interviews, the missing middle value was always imputed to be undetectable. Thus a missing value pattern of U\_U was imputed as UUU; a missing value pattern of U\_D was imputed as UUD.

*Achievement of viral suppression (AVS)* was assessed based upon the viral load status at first follow-up interview following a report of a detectable viral load: 1=undetectable viral load, 0=detectable viral load. More than one observation per individual was possible when an individual experienced a second spell of detectable viral load followed by at least one further interview.

*Persistence of viral suppression (PVS)* was measured as the number of successive follow-up interviews – none, one, two, three or four – at which an undetectable viral load was maintained following the first eligible interview. For descriptive analysis, we created a three-category viral suppression variable: (1) failure to maintain suppressed viral load at first follow-up, (2) suppression through first follow-up interview, and (3) suppression at two or more successive interviews. We also from a discrete-time event history variable, a sequence of dichotomous outcomes-- 0=suppressed viral load, 1=detectable viral load--at each interview following initial suppression that we fit to a proportional hazard model as described below in the analysis section.

*Predictor Variables* Table 1 lists the predictor variables for this study. Participant sociodemographic characteristics included age, gender education, country of origin, region of

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<sup>v</sup> This could occur either as an item missing for a completed interview, or when an interview was not completed for a particular round. A small number of participants missing viral load information at two or more interviews were dropped from the PVS analysis.

residence, and residence in a New York City low income neighborhood served by a DOHMH district public health office (DPHO).

We measured three time-varying conditions often linked to disruption in medical care<sup>19,20</sup> and consequently poorer clinical outcomes: low mental health functioning, current substance use and unstable housing. Low mental health functioning was derived from the Medical Outcomes Study (MOS) SF-12 mental health composite scale (MCS).<sup>21</sup> Following MOS empirically based guidelines, a score below 37 on the 100-point scale indicated low or poor mental health status corresponding to a high likelihood of a diagnosed mental illness. Substance use was measured as a binary variable (recent use in the six months preceding the interview versus former/no history). Substance use was indicated by heroin use, cocaine use, crack use or problem drinking. For housing stability, CHAIN participants were placed into one of three groups: stable, unstable or homeless. Individuals in stable housing always reported residing in permanent housing. Unstable housing situations covered the occurrence during the preceding six months of any of the following: residence in a transitional housing program, drug treatment housing with no other address, or temporarily doubling up with friends or family. Homelessness included any episode in the preceding six months of sleeping on the street, living in a shelter or living in an SRO or welfare hotel lacking onsite supportive services.

The set of predictor variables was completed with three quality-of-care measures: ARV use, access to comprehensive primary medical care and receipt of HIV/AIDS standard of care. A three-category ARV treatment variable was created from participant reports of their ARV medications and medication adherence: adherent HAART use, non-adherent HAART use or not taking a HAART combination. Current HAART use was based upon participant reports of HIV medications they were taking at the time of the interview<sup>vi</sup>. Participants were classified as taking HAART if they reported an ARV combination that conformed to the national guidelines for adolescent and adult antiretroviral treatment regimens current at the time the interview was conducted. Two questions were asked regarding medication adherence: (1) number of pills missed in the two days prior to the

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<sup>vi</sup> Study participants were presented with photographs of all forms of approved HIV medications to assist with accurate recall of specific medications. In many instances, interviews were conducted in respondents' homes and information was recorded from medication bottles. Classification into HAART regimens using these techniques was highly reliable.

interview and (2) participants' general experiences in taking HIV medications during the previous six months. Responses to this question could range from "exactly as prescribed" to "rarely take my pills as prescribed". To be considered completely adherent, a participant had to report taking all pills as prescribed in the last two days and taking ARV medications exactly as prescribed during the past six months. Other combination of responses to these two questions indicated non-adherent use. The category for not taking HAART combined individuals currently taking a non-HAART ARV combination and those not taking any ARV medication.

A second quality of care measure was access to medical care that approximated the ideal of comprehensive primary care.<sup>22</sup> Cohort members were considered to have access to comprehensive primary care if they responded positively to all three of the following questions: During the last six months has there always been someone (1) to go to for routine check-ups, vaccinations and medical tests, (2) to go to for health related information or advice, and (3) to call 24 hours a day for a medical emergency. Cohort members were classified as receiving HIV/AIDS standard of care, if in the six months prior to the interview, they had a physical examination and blood work and at least one (1) HIV medical visit (for individuals with CD4 counts greater than 500) or at least two (2) HIV medical visits (for individuals with lower CD4 counts or who were taking ARVs).

## **Analysis Plan**

For the AVS analysis, 361 eligible CHAIN cohort members contributed 576 self-reports of viral load, following an interview at which they had reported a detectable viral load. Values of all predictor variables were measured as of the interview in which a detectable viral load was reported. A sequence of logistic regression equations estimated the odds of viral suppression for each predictor variable and the potential mediation of quality of medical care between patient characteristics and viral suppression. The base model included sociodemographic and time varying conditions. We next added the comprehensive primary care and appropriate HIV medical care predictors. A final model also included the HAART variable. Since addition of the quality of care variables had only modest impact on the size of coefficients for other variables, we report only the

regression equation that included all predictor variables. To adjust standard errors for the presence of multiple observations for some individuals, we estimated the logistic regression models using the population average option available in the Stata 11 implementation of GEE. We also present descriptive findings that complement the logistic regression analysis by cross-tabulating each predictor variable with the viral suppression variable for all observations.

For the PVS analysis, we first conducted a descriptive analysis that examines the observed association between each predictor and the three-category ordinal variable. In Table 4 the values of the ordinal variable are re-grouped to report the percentages of the sample that maintained suppression through at least a single follow-up interview and then through two or more follow-up interviews. Values of the predictor variables are measured at time of initial viral suppression. Significance tests of the association between each predictor variable and duration of suppression were based on chi-square tests of independence. For this analysis, we restricted the analytical sample to the 458 individuals who reported viral load information at two or more successive interviews following an initial report of an undetectable viral load<sup>vii</sup>.

We next estimated regression models that related the joint independent effects of predictor variables to duration of viral suppression using a discrete-time proportional hazard model.<sup>23</sup> The hazard model estimates changes in rates of failure for different values of the predictor variables. For this study a failure is the first occurrence of a detectable viral load following initial suppression. The rate of failure is the inverse of the duration of suppression, which was operationally defined as the number of successive interviews, following initial suppression, in which an undetectable viral load was reported. The duration of viral suppression ended either with the first interview in which a detectable viral load was reported (the time to failure) or the last completed interview for an individual who always reported undetectable viral loads (a censored observation).

A virtue of the hazard model is that it incorporates variables that change values over time. Six predictors are time varying variables. To establish a strict temporal ordering between predictors and outcome, predictor variables are often lagged by one interview, that is the time varying variable is

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<sup>vii</sup> We included individuals that reported *detectable viral load* at first follow-up interview, even when they lacked viral load information at a second follow-up interview.

measured at the interview preceding the measurement of the outcome. We lagged two time-varying predictors, current HAART use and mental health status, as they were assessed at the time of interview, almost certainly after the date that the viral load was assessed. The other time varying predictors, substance use, housing status, access to comprehensive primary care and appropriate HIV medical care, were not lagged. Measurement of these variables involved recall of episodic activities that occurred during the period between interviews. Were these variables lagged by one interview, the value of these predictors could represent a time-varying state a year or more prior to viral load assessment. Time lags of this length may greatly diminish capacity to detect possible causal effects on viral load. Measuring these predictors contemporaneously with viral load status does come at the cost of some ambiguity in temporal ordering between predictor and outcome, since most recent viral load reports based could have been completed, as well, at anytime between interviews.

To adjusted for possible confounding influence of duration dependence on the rate of viral rebound with longer viral suppression, we included with the predictor variables three binary variables that indicated if a viral observation was from the second, third or fourth follow-up interview.<sup>24</sup> We estimated model coefficients using a complementary log-log regression model implemented in Stata 11.0, which is appropriate when, as in this case, failure time data are grouped into a small number of discrete time periods. The exponentiated regression coefficients for a log-log complementary model have a relative risk interpretation. Exponentiated coefficients greater than "1" indicate the proportionate increase in the risk of reverting to detectable viral load for a unit increase in the predictor variable, or a shortening of the expected duration of viral suppression. Exponentiated coefficients less than "1" indicate the proportionate decline in risk of reverting or increased duration of viral suppression. Standard errors are adjusted for clustering associated with multiple observations for each individual. To investigate the potential mediating role of medical care variables we estimated a sequence of regression models similar to those for the AVS analysis. As we found only minimal differences in the coefficients for patient demographic and behavioral variables, with and without adjustment for the medicalcare variables, we only report coefficients for the full model. All 545 PVS eligible CHAIN participants were included in the hazard analysis. They contributed 1,156 observations (based upon one to four consecutive observations per person) following first report of an undetectable viral load

**Findings**

Table 1 presents characteristics of the AVS and PVS samples. Despite differences in eligibility criteria and the moderate overlap in sample membership, baseline characteristics for the AVS and PVS samples are generally similar.

Table 2 displays clinical markers for HIV disease and treatment for the combined sample of CHAIN participants eligible for either or both the AVS and PVS analyses. The general trend was toward improved HIV health during the course of the study. Both the percentage of study sample members with detectable viral loads and average viral load steadily declined across successive rounds of interviews. CD4 counts showed a corresponding increase during this period. Eligible CHAIN participants with CD4 counts above 500 increased slightly from 30% at initial interview to 46% at fifth-round interview. A sharper drop is evident, as well, in the proportion individuals with CD4 counts below 200, which declined from 29% at baseline interview to 18% at fifth round interview. In contrast, ARV use remained relatively stable during the study period. HAART use varied only slightly between 75% and 79% during the course of the study. The improved health across rounds of interviews should be interpreted with caution. Clearly some of the apparent improvement in HIV clinical outcomes may be due to higher rates of sample attrition among the least healthy members of the CHAIN cohort.

**Table 1: Characteristics for Study Samples\***

<b>Sample</b>	<b>Achievement of Viral Suppression (AVS)</b>	<b>Persistence of Viral Suppression (PVS)</b>
<i>N of Eligible CHAIN participants</i>	<i>361</i>	<i>545</i>
Age		
20-34	22%	22%
35-49	48%	43%
50+	30%	35%
Sex		
Male	59%	54%
Female	41%	46%
Education		
Less Than H.S.	35%	34%
H.S.+	65%	66%
Ethnicity		
White	14%	16%
Black	49%	52%
Hispanic	37%	32%
Country of Origin		
USA	78%	76%
Puerto Rico	9%	10%
Other Country	12%	14%
Cohort		
New York City	68%	66%
Tri-County	32%	34%
Residence in a DOH Health District		
No	72%	73%
Yes	28%	27%
Low Mental Health		
No	66%	72%
Yes	34%	28%
Housing Status		
Stable	82%	83%
Unstable	7%	6%
Homeless	11%	11%
Recent Substance Use		
No	73%	82%
Yes	27%	18%
<u>Quality of Medical Care</u>		
Access to Comprehensive Primary Care		
No	29%	25%
Yes	71%	75%
Receipt of HIV/AIDS Standard of Care		
No	24%	23%
Yes	76%	77%
HAART Use		
Not taking HAART	29%	17%
On HAART, not adherent	27%	25%
On HAART, adherent	43%	58%

\*At interview of initial eligibility

**Table 2: Viral Load and Treatment Histories for CHAIN Participants Eligible for Either Analysis**

Round of Interview	Round of Interview				
	1	2	3	4	5
Eligible N*	877	768	665	554	261
Detectable VL	32%	32%	29%	17%	16%
Undetectable VL	55%	56%	64%	67%	80%
Missing	12%	12%	6%	6%	4%
Mean of log VL Count	3.9	3.6	3.2	2.7	1.7
Standard Deviation	4.6	4.5	4.3	4.1	3.6
VL Range**					
0-400	62%	66%	70%	73%	85%
401-9,999	20%	19%	16%	15%	7%
10,000-99,999	12%	9%	9%	9%	5%
100,000+	6%	6%	5%	3%	3%
CD4 Count					
0-200	29%	23%	21%	20%	18%
201-349	20%	20%	22%	18%	14%
350-499	21%	24%	25%	26%	22%
500+	30%	33%	33%	36%	46%
Taking ARV					
No	5%	11%	12%	14%	11%
Non-HAART ARV	19%	15%	10%	7%	8%
HAART	75%	74%	79%	79%	81%
Median Days Since Last Interview	---	457	501	509	430

\*Number of CHAIN Participants taking ARV or for whom ARV treatment was indicated based on CD4 count <200

\*\*Sample limited to CHAIN participants reporting a VL count or a “good” or an “undetectable” VL

### *Timely Achievement of Viral Suppression*

Table 3 summarizes the association between the predictor variables and timely viral suppression.<sup>viii</sup>

For the entire AVS sample, CHAIN participants with detectable viral loads achieved viral suppression by follow-up interview 46% of the time. Complete adherence with HAART medication was the strongest predictor of timely viral suppression. Among individuals with detectable viral loads, 52% of those completely adherent to HAART achieved viral suppression at first follow-up

<sup>viii</sup>Borough and county of residence were not significantly related to either outcome measure and were not included in the final multiple regression model. To conserve space, the results for this variable can be found in the Appendix, Tables 3a and 4a.

**Table 3: Timely Achievement of Viral Suppression**

	N	% Achieving viral load suppression by first follow-up interview	Odds Ratio of achieving viral suppression by first follow-up interview	
			Unadjusted (N=361)	Adjusted (N=359)
<b>All</b>	576	46%		
<i>Age (p=.000)^</i>				
20-34	104	42%	1.00	1.00
35-49	302	39%	.93 (.58, 1.47)	.91 (.56, 1.50)
50+	170	60%	2.06** (1.24, 3.43)	1.98* (1.14, 3.41)
<i>Sex (p=.684)</i>				
Male	328	45%	.91 (.64, 1.29)	0.89 (.60, 1.30)
Female	245	47%	1.00	1.00
<i>Education (p=.785)</i>				
Less than HS	193	47%	1.05 (.73, 1.52)	1.03 (.68, 1.54)
High School+	383	45%	1.00	1.00
<i>Ethnicity (p=.135)</i>				
White	91	36%	1.00	1.00
Black	287	47%	1.61+ (.96, 2.69)	1.42 (.82, 2.48)
Hispanic	198	48%	1.69+ (.98, 2.90)	1.24 (.68, 2.26)
<i>Country of Origin (p=.040)</i>				
US	464	44%	1.00	1.00
Puerto Rico	42	64%	2.22* (1.12, 4.37)	2.03+ (.90, 4.57)
Other Country	70	47%	1.18 (.69, 2.01)	.99 (.55, 1.78)
<i>Residence in an Urban Area (p=.037)</i>				
Suburb/Rural Tri-County	70	31%	1.00	1.00
Urban Tri-County	106	47%	2.00* (1.03, 3.86)	1.60 (.81, 3.19)
New York City	399	48%	2.05* (1.17, 3.60)	2.04* (1.09, 3.83)

+p&lt;.1, \*p&lt;0.05, \*\*p&lt;0.01, \*\*\*p&lt;0.001

^Significance for test of independence between variable and Achievement of Viral Suppression

	N	% Achieving viral load suppression by first follow-up interview	Odds Ratio of achieving viral suppression by first follow-up interview	
			Unadjusted (N=361)	Adjusted (N=359)
<i>Residence in a DOH District (p=.785)^</i>				
No	417	46%	1.00	1.00
Yes	163	45%	.96 (.66, 1.40)	.84 (.53, 1.32)
<i>Low Mental Health (p=.835)</i>				
Yes	188	45%	0.97 (.69, 1.38)	1.15 (.79, 1.69)
No	384	46%	1.00	1.00
<i>Housing Status (p=.063)</i>				
Stable	479	48%	1.00	
Unstable	38	37%	0.60 (.30, 1.18)	0.54+ (.29, 1.01)
Homeless	59	34%	0.54* (.31, .96)	.51+ (.24, 1.08)
<i>Recent Substance Use (p=.058)</i>				
Yes	155	39%	0.67* (.46, .99)	.67+ (.44, 1.03)
No	421	48%	1.00	1.00
<i>Access to Comprehensive Primary Care (p=.195)</i>				
Yes	390	48%	1.22 (.86, 1.74)	1.20 (.82, 1.75)
No	186	42%	1.00	1.00
<i>Receipt of HIV/AIDS standard of care (p=.529)</i>				
Yes	439	45%	0.89 (.61, 1.30)	0.83 (.55, 1.26)
No	137	48%	1.00	1.00
<i>Current HAART Adherence (p=.021)</i>				
Not on HAART	183	39%	1.00	1.00
On HAART, not Adherent	164	45%	1.24 (.81, 1.90)	1.27 (.81, 2.00)
On HAART, Adherent	229	52%	1.68** (1.14, 2.50)	1.90** (1.25, 2.90)

+p<.1, \*p<0.05, \*\*p<0.01, \*\*\*p<0.001

^Significance for test of independence between variable and Achievement of Viral Suppression

interview compared to 45% who were taking HAART but were not completely adherent and 39% who were not taking a HAART regimen. Based upon estimates from the logistic regression model, adherent HAART use almost doubles the odds of achieving viral suppression when compared to individuals not taking HAART. In contrast, non-adherent use of HAART did not significantly improve the likelihood of achieving viral suppression by the next interview compared to not taking HAART.

Among patient characteristics, age, region of residence, place of birth, housing status and recent substance use were all associated with timely achievement of viral suppression. Individuals over the age of 50 achieved viral load suppression 60% of the time following an interview with detectable viral load as compared to 39% and 42% for middle aged (35 to 49) and younger cohort members, under 35. Individuals living in the suburban or rural regions of Tri-County were less likely to achieve viral suppression than individuals residing in the urbanized portion of Westchester and New York City. Cohort members born in Puerto Rico were more likely to achieve timely suppression of viral loads (64%) than either those born in the U.S. (44%) or those born in other countries (47%). Housing instability and recent substance use reduced timely achievement of viral suppression, as well. For instance, recent substance users achieved timely viral suppression 39% of time compared to 48% for a combined grouping of individuals with and without a history of substance abuse.

### *Persistence of Viral Suppression*

Table 4 presents findings for the association between the predictor variables and persistence of viral suppression. The columns on the left side of the table present the cumulative percentages of the PVS sample that sustained undetectable viral load through the first and second follow-up interviews. Thus 76% of the PVS sample sustained viral load suppression through at least one follow-up interview and 63% of the PVS sample sustained viral suppression for two or more interviews.

Substance use, and HAART use were the most important predictors of duration of viral suppression. Substance use between interviews was associated with a doubling of the risk of viral load reverting to detectable levels. Adherent HAART use relative to non HAART use, reduced the risk of viral load rebound by approximately 30%. As was the case for AVS, nonadherent use of HAART did not have a statistically significant effect on risk of reverting to detectable viral load.

**Table 4: Persistence of Viral Suppression**

	N	Cumulative % of cohort for which viral suppression persists through 1 <sup>st</sup> and 2 <sup>nd</sup> follow-up interviews		Relative Risk of Reverting to Detectable Viral Load (N of Respondents=545, N of obs=1,156)	
		1	2	Unadjusted	Adjusted
<b>All</b>	464	76%	63%		
<i>Age (p=.101)<sup>^^</sup></i>					
20-34	106	70%	54%	1.00	1.00
35-49	199	73%	62%	0.86	0.88
<i>Sex (p=.029)</i>					
Male <sup>50+</sup>	159	77%	79%	0.64*	0.71
Female	247	70%	63%	1.08	1.09
<i>Education (p=.110)</i>					
Less than HS	215	78%	63%	1.00	1.00
High School	162	71%	57%	1.28	1.14
<i>Ethnicity (p=.001)</i>					
White	302	75%	66%	1.00	1.00
Black	69	81%	77%	1.00	1.00
Hispanic	241	78%	63%	1.63	1.25
<i>Country of Origin (p=.143)</i>					
US	154	64%	56%	(.79, 3.38)	(.76, 2.05)
Puerto Rico	351	76%	63%	2.74*	1.62+
Other Country	50	62%	56%	(1.06, 7.11)	(.93, 2.84)
<i>Residence in an Urban Area (p=.016)<sup>^^</sup></i>					
Suburb/Rural Tri-County	63	71%	65%	1.00	1.00
Urban Tri-County	92	72%	53%	2.49+	1.11
New York City	311	73%	63%	(.87, 7.11)	(.65, 1.88)
<i>Residence in a DOH District (p=.680)</i>					
No	63	71%	65%	.97	0.90
Yes	134	71%	60%	(.44, 2.12)	(.56, 1.46)
<i>Low Mental Health Score (p=.749)</i>					
No	330	75%	64%	1.00	1.00
Yes	134	71%	60%	1.56	1.24
§					

+p&lt;.1, \* p&lt;0.05, \*\*p&lt;0.01, \*\*\*p&lt;0.001

<sup>^^</sup>Significance level for test of independence between variable and Persistence of Viral Suppression

§ For the hazard analysis, this variable is lagged by one interview.

	N	Cumulative % of cohort for which viral suppression persists through 1 <sup>st</sup> and 2 <sup>nd</sup> follow-up interviews		Relative Risk of Reverting to Detectable Viral Load (N of Respondents=545, N of obs=1,156)	
		1	2	Unadjusted	Adjusted
Yes	139	73%	63%	1.05 (.77, 1.43)	.97 (.70, 1.34)
No	325	74%	62%	1.00	1.00
<i>Current Housing Status (p=.375)</i>					
Stable	385	75%	64%	1.00	1.00
Unstable	29	76%	62%	.83 (.39, 1.77)	0.87 (.49, 1.54)
Homeless	50	64%	50%	1.56* (1.02, 2.45)	1.38 (.79, 2.40)
<i>Recent Substance Use (p=.098)</i>					
Yes	89	66%	53%	2.15*** (1.58, 2.92)	2.00*** (1.44, 2.76)
No	375	74%	65%	1.00	1.00
<i>Access to Comprehensive Primary Care (p=.435)</i>					
Yes	343	74%	64%	0.72* (.54, .96)	0.79 (.58, 1.06)
No	121	74%	60%	1.00	1.00
<i>Receipt of HIV/AIDS standard of care (p=.783)</i>					
Yes	359	72%	64%	0.94 (.67, 1.31)	0.94 (.68, 1.33)
No	105	74%	60%	1.00	1.00
<i>HAART Use (p=.191)</i>					
Not on HAART	77	77%	58%	1.00	1.00
On HAART, not Adherent	120	76%	64%	.92 (.60, 1.40)	0.89 (.57, 1.37)
On HAART, Adherent	267	72%	63%	0.72+ (.49, 1.06)	0.73 (.49, 1.08)

Hispanic and to a lesser extent African American CHAIN members experienced shorter periods of suppression than whites. Only 56% of Hispanics compared to 77% whites maintained viral suppression over two or more interviews. We also found that CHAIN participants residing in the urbanized portion of southern Westchester adjacent to New York City sustained viral suppression

+p<.1, \* p<0.05, \*\*p<0.01, \*\*\*p<0.001

^Significance level for test of independence between variable and Persistence of Viral Suppression

§ For the hazard analysis, this variable is lagged by one interview.

for shorter periods of time than either New York City residents or cohort members living in the rest of Tri-County. Fifty-three percent (53%) of urban Tri-County residents sustained viral suppression for two or more interviews, compared to 77% of the rest of the Tri-County cohort and 63% of New York City residents.

The results of the PVS analyses were also suggestive of other possible predictors that had statistically significant bivariate associations with duration of viral suppression. These variables lost statistical significance in the fully specified model, but the regression coefficients for these variables showed only a marginal reduction after adjustment for other model variables. We note with appropriate caution that shorter duration of viral suppression may be associated with spells of homelessness. The data also suggest that being over 50 and having access to comprehensive primary care may be associated with longer viral suppression. Comparison of models in which medical care measures are excluded failed to show strong mediating effects for the quality of medical care or HAART use on patient characteristics.

## Discussion

Study results suggest that timely and persistent suppression of viral load is a realistic but not easily achievable outcome of ARV therapy for a general population of persons living with HIV/AIDS. Within the context of repeated CHAIN interviews completed between one and two year intervals, an ideal ARV treatment outcome trajectory would follow a pattern of uninterrupted reports of undetectable viral loads at successive interviews or sustained viral suppression following an initial report of detectable viral load. Among ARV-experienced CHAIN cohort members with three or more viral load observations (N = 550), about half conform to this ideal outcome pattern: 42% reported undetectable viral load at every round of interviews and another 8% consistently maintained viral suppression after an initial report of detectable viral load. The other half either failed to achieve undetectable viral load at first interview following an initial report of detectable viral load (23%) or reverted to detectable viral load after an initial period of viral suppression (27%). Using study metrics for treatment success, less than half of all AVS eligible CHAIN participants (46%), achieved viral load suppression by the first follow-up interview. Among PVS eligible participants, 63% sustained undetectable viral load through 2 or more interviews, but one-

+p<.1, \* p<0.05, \*\*p<0.01, \*\*\*p<0.001

^Significance level for test of independence between variable and Persistence of Viral Suppression

§ For the hazard analysis, this variable is lagged by one interview.

quarter failed to sustain viral suppression even through the first follow-up interview.

Relatively few of the study predictor variables demonstrated a strong association with treatment effectiveness. Adherent use of HAART and recent substance use were the two most consistent predictors of treatment effectiveness. Adherent HAART use increased timely achievement of viral suppression and lengthened the duration of suppressed viral load once achieved. By contrast, recent substance use reduced the odds of timely achievement of suppression and shortened the duration of viral suppression. Older age and stable housing were associated with timely achievement of viral suppression, and with less certainty, longer duration of viral suppression once achieved. Puerto Rican birth was associated with a higher rate of timely AVS but not PVS. The data also suggested regional variation in treatment effectiveness. New York City residents were more likely than Tri-County residents to report timely AVS. Residents of the southern portion of Tri-County had shorter durations of viral suppression than either NYC residents or individuals residing in the rest of Tri-County. Stronger confirmations of these findings will require large sample sizes or more reliable measures of viral load suppression.

Before commenting on the implications of study findings, we note several methodological limitations. The accuracy of self-reports of viral load status and medication utilization are always a concern. However, skilled interviewers and the use of memory aids during interviews facilitated accurate recall, as the validation study demonstrated.<sup>18,25</sup> Of greater concern is the spacing of viral load observations. Our outcome variables are based on between two and five snapshots of viral load status at widely spaced intervals, typically between a year and 18 months. They are a crude approximation to more continuous measure of time to viral suppression and duration of viral suppression. The widely spaced observations undoubtedly underestimate the extent of movement between detectable and undetectable viral load states that occur between interviews. Therefore, the pattern of viral load status change between interviews should not be interpreted as literal representations of the time to viral suppression or continuity of viral suppression. Nonetheless, we believe that the reports of detectable viral loads at successive rounds of interviews and failure to sustain viral suppression across multiple interviews point to instances of impaired effectiveness of ARV treatment that we believe would correlate with patterns of viral suppression and persistence that would be obtained from more closely spaced measures of viral load.

Aside from dilution of effects of all predictors due to the relatively long interval between interviews,

estimates of the true HAART effect on treatment outcomes are further attenuated because of the imperfect separation of CHAIN cohorts into sharply contrasting treatment conditions. The non-HAART comparison group is not a pure no-treatment condition. Rather, almost all individuals in the study samples were ARV experienced. The non-HAART category is a mixture of individuals who were not taking ARV medications at time of interview (21 %) -- they may have been on a temporary “drug holiday”-- with those who may have gained some therapeutic benefit from taking a non-HAART ARV regimen (6 %). A better way to interpret the HAART findings is to say that the three HAART categories form an imperfect ordering in which individuals, on average, are taking increasingly more effective medication regimens. Thus the non-HAART group was not without some exposure to beneficial therapies, while the adherent HAART group may not all have benefited from a completely optimal regimen.

Although the longitudinal nature of the data strengthen causal interpretation of findings, there remains the problem of how best to sequence measurement of time varying predictor variables and the treatment outcomes. Participant self-reports of viral loads pre-date the interview, often by several months. For a strict causal interpretation of study results, we should lag the measurement of time varying predictors by one interview to ensure that the values of all predictors are unambiguously measured before the viral load observations. We do this for the AVS analysis. All predictors were measured at baseline interview when viral load was detectable, and viral load outcome was measured as of the follow-up interview. Although this ensured a clear temporal sequencing, there may have been a lag of a year or more between the measurement of the predictors and the outcome. The relatively long time interval increased the possibility of intervening changes in time varying predictors such as housing status or substance use, with a corresponding attenuation of estimates of their true causal effects. For the PVS we relaxed a strict temporal ordering for several time varying predictors. We lagged by one interview mental health and HAART use, but all other predictors are measured contemporaneously with viral load reports. In this way, individuals’ recall of substance use and housing status during the six months preceding the interview were more closely aligned with their viral load levels, but at the cost of obscuring the temporal sequence between predictor variable and treatment outcome. There is the possibility that changes in recent substance use and spells of housing instability may have occurred after rather than before the viral load measurement. The predictive strength of the model may have also been limited by the absence in our model of more detailed clinical history, duration of illness, treatment history and drug resistance.

An unexpected study finding was the absence of strong evidence for a mediating role between HAART use and the other predictor variables. When the multi-variable models for AVS and PVS were re-estimated without the HAART status, the estimated coefficients for the remaining predictor variables showed minimal change from the coefficients in Tables 3 and 4. It should not be inferred from the minimal changes in the coefficient estimates that the predictor variables are not associated with HAART use and treatment adherence. On the contrary, several predictor variables had significant associations with HAART use and adherence. When we fit an ordered logistic regression to the three-category HAART use outcome variable, the following variables were associated with increased rates of adherent HAART use: older age, male gender, non-Hispanic white ethnicity, NYC residency, better mental health, birth outside the U.S., abstinence from recent drug use and housing stability. These findings align with other studies that report lower rates of HAART use and adherence associated with substance use, mental illness and unstable housing or homelessness.<sup>26-29</sup> Detecting the mediating effects of HAART use implied by these findings may require a larger sample size or more reliable measures of HAART use and viral load.

The persistence of direct effects, most notably recent substance use, unmediated by adherent HAART use may result from respondent bias in reporting medication adherence. The negative effect of recent substance use on treatment effectiveness, for example, might arise because recent substance users may overstate their level of medication adherence compared to other individuals. A more appealing explanation is that active substance use and possibly other significant predictors capture uneven effectiveness of medications among even adherent users within different subgroups. For example, current use of illicit substances may compromise immune functioning<sup>30</sup> or result in adverse interactions with ARV medications that may reduce the efficacy of HAART medications in substance using populations.<sup>27, 30-32</sup> Prior research suggests that unstable housing conditions may also create a physical and social environment that results in sub-optimal response to HAART. Unstable and chaotic life patterns, stress, social isolation, and increased stigma associated with unstable housing are all known to reduce adherence,<sup>26, 33-37</sup> but further research is necessary to better understand the significance of unstable housing's direct effect on treatment effectiveness. Although active substance use presents special treatment challenges, successful treatment is possible when appropriate supportive and drug treatment services are integrated with medical management.<sup>27,28,38,39</sup>

The substantial proportion of CHAIN cohort members on HAART at each round of interviews and

the absence of strong associations between most of the predictors and treatment effectiveness point to substantial progress in federal, state and local initiatives to reduce socioeconomic disparities in gaining access to ARV medications. Nonetheless, there remains considerable room for improving the quality and delivery of HIV care, as substantial numbers of CHAIN cohort members experience difficulty in achieving undetectable viral load and sustaining viral suppression over extended periods of time. These findings underscore the continuing importance of improving access to and quality of clinical and community-based services that support patient efforts to begin and maintain adherence to HAART regimens. They also point to the need to continue efforts to improve integration of medical care with substance abuse treatment and housing placement in ways that promote sobriety and stable housing, but also offer treatment options most robust to patients lacking secure housing and/or at risk of substance use relapse.

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## Appendix

**Table 3a: Timely Achievement of Viral Suppression: Borough and Residence**

	N	% Achieving viral load suppression by first follow-up interview ^	Odds Ratio of achieving viral suppression by first follow-up interview	
			Unadjusted (N=361)	Adjusted (N=359)
<b>All</b>	576	46%		
<i>Borough/County (p=.214)^</i>				
Bronx	96	49%	1.00	
Brooklyn	117	46%	0.92 (.52, 1.62)	
Manhattan	111	41%	0.71 (.40, 1.26)	
Queens	60	57%	1.36 (.68, 2.69)	
Staten Island	14	71%	2.44 (.69, 8.64)	
Putnam	7	43%	0.77 (.16, 3.69)	
Rockland	21	38%	0.59 (.22, 1.61)	
Westchester	148	41%	0.73 (.42, 1.25)	
<i>Cohort (p=.141)</i>				
New York City	399	48%	1.00	
Tri-County	177	41%	0.76 (.52, 1.10)	

+p&lt;.1, \*p&lt;0.05, \*\*p&lt;0.01, \*\*\*p&lt;0.001

^Significance level for test of independence between variable and Achievement of Viral Suppression by first follow-up

**Table 4a: Persistence of Viral Suppression**

	N	Cumulative % of cohort for which viral suppression persists through 1 <sup>st</sup> and 2 <sup>nd</sup> follow-up interviews <sup>^</sup>		Relative Risk of Reverting to Detectable Viral Load (N of Respondents=545, N of obs=1,156)	
		1	2	Adjusted	Unadjusted
<b>All</b>	464	76%	63%		
<i>Borough/County (p=.218)*</i>					
Bronx	78	69%	60%	1.00	
Brooklyn	87	70%	63%	1.08 (.68, 1.71)	
Manhattan	86	78%	70%	0.81 (.59, 1.34)	
Queens	41	73 %	61%	.97 (.54, 1.74)	
Staten Island	19	74%	42%	1.39 (.68, 2.84)	
Putnam	5	60%	60%	1.26 (.38, 4.14)	
Rockland	22	77%	73%	0.65 (.29, 1.47)	
Westchester	126	76%	61%	1.03 (.66, 1.59)	
<i>Cohort (p=.526)</i>					
New York City	311	73%	63%	1.00	
Tri-County	153	76%	63%	0.98 (.71, 1.35)	

+p&lt;.1, \*p&lt;0.05, \*\*p&lt;0.01, \*\*\*p&lt;0.001

<sup>^</sup>Significance level for test of independence between variable and Achievement of Viral Suppression by first follow-up