C.H.A.I.N. REPORT

Report 2003_3

Validation of Self-Reported Viral Load Levels

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Originally submitted September 24, 2003
Revised October 24, 2003
HRSA Contract H89 HA 0015-12

ACKNOWLEDGMENTS

A Technical Review Team (TRT) provides oversight for the CHAIN Project. In addition to Peter Messeri, PhD, David Abramson, and Angela Aidala, PhD, of Columbia University's Mailman School of Public Health, TRT members include Mary Ann Chiasson, DrPH, MHRA (chair); Susan Forlenza, MD MPH, NYCDOHMH; Robert Cordero, Office of AIDS Policy Coordination; JoAnn Hilger, NYCDOHMH; Julie Lehane, PhD, Westchester County DOH; Jennifer Nelson, MHRA; and Fatima Prioleau, PWA Advisory Group.

This research was supported by grant number H89 HA 0015-12 from the US Health Resources and Services Administration (HRSA), HIV/AIDS Bureau with the supported of the HIV Health and Human Services Planning Council, through the New York City Department of Health and Mental Hygiene and the Medical and Health Research Association of New York City, Inc. Its contents are solely the responsibility of the researchers and do not necessarily represent the official views of the U.S. Health Resources and Services Administration, the City of New York, or the Medical and Health Research Association of New York.

Introduction

This report is the first of a series reports that have as their major objective an understanding of the determinants of successful and failed HAART treatment with a focus on how patient access to the "continuum" of HIV services may best support long-term treatment success. Before we address the main purpose of this sequence of reports, we begin with a technically-oriented report that evaluates the quality of the self reports of viral load test results that CHAIN participants have provided since 1996, in the fourth round of interviews.

Key Findings

- By the sixth round of interviews, initiated in 1998, virtually all CHAIN participated reported having viral load tests

- Completeness of information on test results is reasonably good. For the fifth and subsequent round of interviews and baseline interviews with the new cohort, between 83 and 91 percent of the tested cohort could report results. Over 70 percent of the sample either reported undetectable viral load or could give an exact viral load level. An additional 10 to 17 could report that they were told their viral loads were either good or bad..

- Ability to report test results was relatively uniform across demographic subgroups

- A three-category viral load measure (<400 c/ml/400-9999 / 10000+) was associated in the expected direction with CD4 T Cell counts and opportunistic infections as well as current use and complete adherence to HAART regimen.

- Approximately 60 percent of CHAIN cohorts, who were HAART experienced reported viral loads of 400 c/ml or lower.

Background

The two most proximal measures of HIV-related health status are indicators of immune system functioning, CD4 lymphocyte cell counts, and HIV suppression and replication, viral loads measured as replicates / per milliliter of serum. Consequently CD4 counts and viral loads are important markers of both the natural history of the disease and the efficacy of antiretroviral treatment. Contemporaneous blood drawn (phlebotomy) as part of a research protocol or chart abstraction of the most recent lab test results are preferred methods for obtaining patient information on CD4 cell counts and viral loads (Kalichman et al. 2000). However, phlebotomy and chart abstraction data are prohibitively expensive for studies conducted outside of clinical settings such as the CHAIN study. Therefore the CHAIN study relies upon participant self reports for this information. We have been asking CHAIN participants' for their most recent CD4 test results since the baseline study was initiated in the fall of 1994. We began asking participants for the results of viral loads test with round 4 interviews that were initiated during

1996, soon after this test was introduced to assess the success of combination antiretroviral therapy.

Patient self reports of the results of recent medical diagnostic tests are subject to inaccuracies and biased responses (Kalichman et al. 2000). However HIV positive individuals are very attentive to their test results, which may produce better reporting of HIV-related test results than for other medical tests. Our experience administering the CHAIN interview supports this impression; although the supporting evidence is indirect. CHAIN participants have had little difficulties in reporting results of recent CD4 count tests. Moreover findings involving CD4 counts in numerous CHAIN reports exhibit aggregate trends and association with other health status measures, including mortality consistently associate lower CD4 counts with expedited poorer health outcomes. A few other studies have demonstrated good correspondence between self reports of CD4 counts and chart abstraction data (Kalichman et al.2000).

Because of the much more recent introduction of viral load testing into clinical practice and the large range of values, it is likely that viral loads are less reliably reported than CD4 counts; a situation confirmed in the only known published validation study (Kalichman et al. 2000) of self reports of these two HIV health status indicators.

The current report examines the quality of viral load reports in two ways. First we examine whether there are differences in the health status and demographics of individuals who are and are not able to report the results of their viral load tests. There is some evidence that education level is associated with the knowledge of test results (Kalichman et al. 2000). Here we extent the range individual correlates to factors such as housing, mental health functioning and drug use. We also investigate the quality of reports by examining the association of viral loads with other HIV-related health status measures, self reports of CD4 counts and occurrence of Opportunistic Infections (O.I.'s) as well as its association with current use of HAART. We conclude this data with trends in our proposed measure of HAART treatment success and failure based upon the viral load self reported data.

METHODS

Data Sources

The purpose and general methodological strategy of the CHAIN project is well described in numerous other CHAIN reports. Study data are taken from the fourth through eighth rounds of the original CHAIN cohort. We also report comparable findings for the first 444 interviews with the new CHAIN cohort. Recruitment for the new cohort was initiated in 2002 and will continue through the fall of 2003.

Viral load questions

CHAIN participants were first asked for the results of viral load tests with round four

interviews. The initial wording of the question was:

> "Have you ever had a test for viral load?
> Yes / No
> " IF YES, what was your recent viral load test?

The interviewer would right down a numeric value or "don't know" if the respondent could not give a numeric value.

Since a large percentage of individuals reported they did not know their viral load test results we modified the wording of the above question in round five to include a "good" and "bad" results categories as well as an undetectable category. If the respondent could not give a numerical response, the interviewers could probe for one of the above qualitative responses before coding a "don't know." The expanded response format sharply reduced the number of "don't know" test results from 39% in round 4 to 12% in round 5. Because the change in wording had a substantial impact on responses, the current analysis is restricted to data collected in rounds 5 and onward. Beginning in round 5, CHAIN participants were also asked the date of the most recent test result.

To assess the overall quality of reporting, responses to the viral load questions were grouped into one of three categories: 1) reported results of viral load test, 2) tested but did not report results, 3) Never tested. For test results reports, exact and qualitative responses were combined into a three-point interval scale. Level 1 combined reports of undetectable viral loads, numerical values <= 400 c/ml (copies per milliliter), or being told viral level was "good". Level 2 grouped numeric reports between 401 c/ml and 9999 c/ml. Level 3 group all numerical reports of 10,000 c/mL and larger with being told viral level was "bad." Level 2 was included to capture an intermediate stage of partial suppression with possible health benefits. Assignments of "good" and "bad" test results to level 1 and level 3 categories was based on intuitive appeal. Supplemental analysis, included in the appendix of this report, suggests that reports of bad viral load have an HIV health status profile similar to individuals with viral loads above 10000 c/ml.. The HIV health status profile of those with "good" viral loads best approximate the middle viral load category, although in this report we choose to combine those with "good" viral levels with vira;l loads below 400 c/ml..

As a further refinement of our analysis we often compare all reported test results with those for tests reported to be completed within a half year of the interview. Unless otherwise indicated presentations of findings are restricted to test results done within six months of the intervals (186 days to be precise). Although we often conducted additional runs that included all test results.

Data on HAART and other study variables follow coding procedures used in previous CHAIN studies.

Findings

Completeness of response

The response to the viral load questions over five rounds of interviews with the original CHAIN cohort combined with initial interviews with the new cohort as summarized in Table 1 give reason for optimism that the quality of self reports are improving as patients become more familiar with this test procedure. Indicative of the fact that viral load testing had become routine clinical practice, 96% of the cohort interviewed during round 6 interviews reported "ever having" a viral load tests.

A large majority of CHAIN participants, who were tested, were able to report their test results. Six in 10 of CHAIN participants were able to report a viral load value when we first introduced the question at round 4, the number who could report test results increased to between 83 and 91 percent in subsequent rounds of interviews. The large increase in those reporting test results in round 5 and subsequent interviews is attributable to the addition of qualitative categories/ . Among participants who every had a viral load test, between 10 to 17 percent at each round of interviews reported that they were told that their viral loads were "good" or "bad" rather than reporting an exact count or reporting "undetectable" viral loads.

Characteristics of individuals who know their test results.

In assessing the quality of the viral load self-reports it is important to determine the completeness of reporting across the full cohort, but whether recall of results is associated with patient attributes or health status. Table 2 presents rates of reporting test results among all observations in which individuals report ever having a viral load test. Data are pooled for round 6 and subsequent interviews. Although there are significant differences in reporting test results related to gender ethnicity, drug use and education, none of the differences are of a substantial magnitude. The validity of self reported data may also be weakened, if failure to report viral load results is associated with health status. It appears from Table 3 that those not reporting viral loads have more compromised immune system functioning than those reporting results. This is most evidence in the difference in percentage in individuals with CD4 counts above 500. Among individuals who knew their test results, 36 percent reported CD4 counts above 500. Whereas among those who didn't recall their viral test results only 20% reported a CD4 count above 500. In contrast rates of OI do not differ with respect to viral load reporting status. Use of HAART and HAART adherence is also unrelated to knowledge of viral test results.

Dating of most recent test results

Another source of invalidity is the time that has elapsed between the viral test and the time of interview. Most analyses employing viral load as an outcome presume that the report corresponds to a time not far removed from the interview. A total of 1,973 test result were reported when baseline interviews with the new cohort are combined with observations for the original cohort for the fifth through 8th rounds of interviews. The great majority of reported test

results, 1,435 or 73%, were performed within a half year of the interview. Among the remaining tests results, a relatively small number, 122, were for tests done a half-year or more prior to the interview. Results were missing for 420 observations in which individuals reported every having a test.. Virtually all the test results with missing dates are from rounds 5 and 6 interviews. A more detailed examination of the dates of test results indicates that more than half the viral load data are for tests done within two months of the interview and 90 percent are within six months of the interviews.

Correspondence between viral load testing and health status

A more direct assessment of the quality of the viral load data was performed by examining the association between viral load levels and other measures of HIV-related health status. For this analysis observations with viral results for tests performed within 6 months of interviews were pooled for rounds 5 through 8 for the original cohort the baseline interviews for the new cohorts. Similar results were obtained when observations were included for test results obtained more than six months prior to the interview. Gammas statistics reported in these tables are measures of association between two variables with ordered categories rather than numeric values. Table 4 indicates that viral loads has the expected association with both CD4 counts and O.I's. Lower viral loads are significantly associated with both increasing CD4 counts and lower rates of O.I.'s. Observe that the distribution of CD4 counts for the partially suppressed viral load level, is that for the undetectable grouping than for the "high" load level. This middle viral load category occupies a middle ground between the low rates of O.I. for the lower load category and the higher incidence of O.I.s for the high viral load category. Among individuals who were tested but did not report recent test results, the distribution of their CD4 count were most similar to the high viral load category but had O.I. rates that were virtually identical to that for the low viral load category.

Table 5 shows the distribution of viral load categories by HAART status. Use of HAART and adherence to HAART are associated with large increases in the percentage of participants with undetectable viral loads or viral loads below 400 c/ml. . The percent of individuals with undetectable/low viral loads increases from 50 to 60 percent when comparing individuals not on HAART with those who are partially adhering to HAART regimens. The percentage with undetectable/low viral loads increases to 70% for individuals completely adhering to their HAART regimens.

Tables 6 , 7 and 8 display trends in the association between viral load levels and other HIV-related health status measures starting with round 5 interviews. Although not entirely consistent, the general pattern of association is similar across rounds of interviews and between the original and new CHAIN cohorts. The cross sectional association between viral loads and CD4 t-cell is relatively stable across inteviews. With the exception of round 7 interviews the gammas fall within a very narrow range betwen .29 and .34 (Table 6). A relative stable pattern of association across rounds of interviews is evident as well for viral load levels (Table 7).

Table 8 shows that using HAART and HAART adherence are usually but not always

associated with increased percentages of individuals with low and undetectable viral loads and reduced percentages of people with undetectable viral loads. Complete adherence is almost always associated with improved viral load outcome when compared to partial adherent use of HAART.

Trends in treatment success

To conclude the analysis for this report, we illustrate how the self-reported viral load data may be used to monitor trends in HAART treatment success. A provisional definition of succeeding on HAART a viral load test within six months of the interview that was undetectable, below 400 c/ml or "good". Table 9 indicates that the number of individuals who are HAART naive has been reduced by a third between the sixth and 8th round of interviews while those currently on HAART has remained at just over half the sample interviewed. The third column of table 9 indicates that the percentage of all cohort members "succeeding" on HAART increased between the 6th and the 7th and 8th rounds of interviews. Among those who have every been on HAART approximately two-thirds have low to undetectable viral loads. In concert with the sustained benefits the cohort continues to enjoy from HAART, note that the number of individuals who are able to maintain low and undetectable viral loads without HAART is becoming an increasingly smaller percentage of the cohort with each successive round of interviews. The final column prevents the reverse side.. At each round of interview a stable 25% to 30% of the cohort is experiencing HAART failure. That is to say they have or were on HAART but have recent viral load levels > 400 c/ml.

Discussion

This report is a first in a series that is investigating the long-term success of HAART in reducing viral loads. Given concerns about the accuracy and reliability of self reports, this first report explored the quality of viral load data reported by CHAIN cohort members. The general completeness of viral reports and their consistent association with other HIV-related health status measures offer evidence that self reported viral load are acceptable indicators for statistical analysis of treatment success and failure. Our results suggest some guidelines for using these data.

1. Viral load analysis is best restricted to observations collected in rounds six and later. From round six onward, virtually the entire cohort reports having had a viral load test.

2. Even in the latter interviews, useful viral load data is not universal. Roughly one quarter and perhaps less of those interviews either can't recall their viral load value or report a test result that is not very recent. Respondents with missing or unusable viral load do not appear to be very different that those reporting viral load except that those not reporting viral loads have lower CD4 counts. Furthermore the exclusion of viral loads from tests done more than 6 months prior to the interview does not change the level of associations between viral loads and other

HIV-related health status measures. Taken together these suggest that dropping cases that don't provide useful viral load data will not seriously distort generality of findings. Nonetheless imputation of missing viral load data may be considered that takes advantage of known correlations between viral loads and other information.

3. Our presentation indicates that breaking out people with partially suppressed viral loads (between 400 and 1000) may be a useful middle category. It appears that partial suppression may confer some benefits, although this hypothesis requires further exploration.

4. In this report we have defined treatment failure as evidence by viral loads above 400.c/ml This is consistent with clinical guidance in the 2003 edition of John's Hopkins Medical Management of HIV Infection. However this report suggest that there may be value in exploring the impact of raising the level of "success" to under 10,000 c/ml.

In conclusion we believe that the large majority of CHAIN participants can reliably report viral loads given the relatively coarse categorization proposed for future study. It would still be desirable to obtain viral load data from some of the CHAIN participants to provide a stronger validation of self reports. CHAIN staff is in the process of arranging such an analysis.

References

Kalichman, Seth, Rompa David, Cage, Marjorie. 2000 Reliablity and validity of self-reported CD4 lymphocyte count and viral losd test results in people living with HIV/AIDS. International Journal of STD & AIDS. 11: 579-585

Table 1: Summary of Response to Viral Load Questions

Round of Interview	4	5	6	7	8	New Cohort
Sample N=	**420**	**651**	**508**	**444**	**388**	**444**
Ever Viral Load Test						
YES	65%	89%	96%	97%	97%	98%
No	33%	11%	4%	3%	3%	2%
Don't Know / Missing	2%	<0%	<0%	0%	0%	0%
Among Who Have Ever Had a Test (N=)	**(274)**	**(576)**	**(489)**	**(432)**	**(374)**	**(427)**
Undetectable	13%	30%	35%	39%	41%	36%
Know Exact Score: Good (<= 400)	5%	4%	3%	5%	3%	7%
Know Exact Score: Bad (> 400)	42%	39%	34%	21%	30%	38%
Don't know, but has been told "Good"	<0%	10%	8%	12%	7%	7%
Don't know, but has been told "Bad"	0%	4%	3%	5%	3%	3%
Don't know the score	39%	12%	17%	17%	16%	9%
Refuse to answer or Missing Value	0%	0%	<0%	<0%	0%	0%
Range of Viral Score						
Minimum Score	50	23	50	8	50	25
Maximum Score	3400000	1000000	688288	500020	600000	5000000

Table 2: Percent who reported test results among those tested by demographic characteristics (*analysis restricted to round 6 through 8 interviews and new cohort*)

	% Knows Test Results	P-value
Gender		
Male (N=952)	87%	.03
Females (N=766)	83%	
Race/Ethnicity		
Black (N=765)	81%	.03
White (N=171)	86%	
Latino(N=347)	86%	
Drug Use		.01
Never Used (N=305)	83%	
Past User (N=1,061)	87%	
Current user (N=358)	81%	
Housing Status		NS
Stable (N=1,400)	84%	
Doubled Up (N=89)	90%	
Unstable (N=235)	88%	
Mental health Functioning		NS
Normal (N=950)	84%	
Low (N=346)	82%	
Age		
Mean Age Know results	44	NS
Mean Age Don't know Results	43	
Education		
Mean grades completed know Results	11.7	.004
Mean grades comploeted don't know results	11.2	

Table 3: Health Status and Viral Load Knowledge of Viral Load Results (*analysis restricted to round 6 through 8 interviews and new cohort*)

	Knows Test Results (1,486)	**Tested but did no know results (256)**	**P**
CD4 Count > 500	36%	20%	<..000
CD4 Count <200	20%`	28%	
Reported O..I.	30%	27%	NS
HAART/adherent	34%	28%	NS
HAART/Not Adherent	19%	20%	
Not on HAART	47%	52%	.

Table 4: Distribution of CD4 Counts Occurrence of O.I..'s by Viral Load Levels
(Restricted to viral loads from tests results within a half year of the interview)

Viral Load Levels (N)	10000+* (311)	9999 - 400 (285)	<400** (839)	Unknown*** (256)
CD4 Count (Gamma = 0.30)				
0 - 100	12%	5%	3%	11%
101 - 200	27%	12%	12%	17%
201 - 300	18%	15%	16%	20%
301 - 500	26%	29%	26%	31%
500<	17%	39%	43%	20%
% Reporting Opportunistic Infection (Gamma = -0.29)	44%	35%	26%	27%

*Includes Individuals who said their viral load was "Bad"
** Includes individuals who reported undetectable viral loads or viral loads were good
***Tested but don't know for rounds 6 through 8
N are pooled Observations for rounds 5 through 8 and initial interviews with new cohort

Table 5: Viral Load Levels by HAART Therapy status

Viral Load Levels	HAART/Adherent (N=489)	HAART/Not Adherernt (N=278)	Not on HAART (N=668)
10000*	16%	20%	26%
999-400	14%	19%	24%
<400**	70%	60%	50%

Gamma=.26
*Includes Individuals who said their viral load was "Bad"
** Includes individuals who reported undetectable viral loads or viral loads were good
N are Pooled Observations for rounds 5 through 8 and initial interviews with cohort

Table 6: Association between CD4 Counts and Viral Load by Round of Interviews
(*restricted to individuals reporting date of test within half- year of interview*)

% Reporting CD4<200				
Viral Load Levels:	**10000+***	**9999 - 400**	**< 400****	**Gamma**
Round 5	46%	27%	29%	0.29
Round 6	34%	15%	16%	0.30
Round 7	31%	12%	18%	0.23
Round 8	33%	22%	12%	0.34
New Cohort	63%	39%	34%	0.31

% Reporting CD4>500			
Viral Load Levels:	**10000+***	**9999 - 400**	**< 400****
Round 5	18%	32%	35%
Round 6	9%	47%	43%
Round 7	22%	42%	44%
Round 8	22%	33%	49%
New Cohort	13%	38%	38%

*Includes Individuals who said their viral load was “Bad”
** Includes individuals who reported undetectable viral loads or viral loads were good

Table 7: Association between O.Is And Viral Load by Round of Interviews

	% Reporting O.I.s			
Viral Load Levels:	**10000+***	**9999 - 400**	**<400****	**Gamma**
Round 5	58%	34%	26%	-.45
Round 6	40%	29%	19%	-.37
Round 7	42%	37%	25%	-.31
Round 8	41%	37%	26%	-.25
New Cohort	43%	38%	32%	-.16

*Includes Individuals who said their viral load was “Bad”
** Includes individuals who reported undetectable viral loads or viral loads were good

Table 8: Undetectable Viral Load and HAART Therapy Status by Round of Interviews

% Undetectable Viral Load (<400 c/ml)

	No HAART	Non-Adherent	Adherent	Gamma
Round 5	43%	37%	60%	0.19
Round 6	41%	67%	66%	0.29
Round 7	60%	61%	82%	0.31
Round 8	52%	69%	71%	0.30
New Cohort	49%	60%	63%	0.22

% Viral Load > 10000

	No HAART	Non-Adherent	Adherent
Round 5	33%	32%	22%
Round 6	28%	16%	22%
Round 7	23%	24%	12%
Round 8	26%	12%	14%
New Cohort	26%	19%	15%

Table 9: Trends in HAART Treatment Success (*restricted to observations with viral load test results in last half year***)**

Round of Interviews	HAART naive	Currently on HAART	Succeeding on HAART	Ever on HAART succeeding	Undetected viral load & HAART Naive	Not succeeding on HAART
6 (N=286)	27%	57%	43%	59%	13%	30%
7 (N=333)	20%	57%	57%	69%	11%	25%
8 (N=283)	18%	53%	53%	64%	9%	29%

Except for "every on HAART succeding" values are all percentaged on number participants interviewed and reporting a date of viral load test within a year of interview. For "Ever on HAART succeeding" Values are percentaged on HAART experienced respondents (Current and former users of HAART).

Succeeding on HAART =Viral loads <400 c/ml, undetectable or told "good" & either currently or in the past on HAART

Technical Appendix: Classifying Individuals who were told their viral loads were "good/bad"

A small but nonnegligible number of CHAIN participants reported that their viral load levels were good or bad rather as a substitute for knowing the exact numeric value. On the assumption that these terms were meant to signify viral levels that were consistent with successful or failing treatment, respectively, reports of "good" viral loads were grouped with reports of undetectable viral loads and exact levels less than 400 c/ml. Reports of "bad" viral loads were grouped into the 10,000 + c/ml category. Reported below is a analysis to assess the validity of this classification

The validation analysis was divided into two steps. First an ordered probit model was estimated restricted to observations for which an exact viral load or a report of undetectable was available. The "ordered' dependent variable was the three-level viral load variable (undetected or <=400/ 401-9,999/ <10,000) The independent variables included HIV-health status related measures, CD4 T cell counts, occurrence of one or more opportunistic infections, a HAART status variable (currently on HAART and completely adherent to HAART). The interview round was included as a final independent variable that adjusted for secular improvements in viral load. Coefficients for all independent variables were statistically significant at $p<.05$.

For the second step, the ordered probit equations were used to generate an estimated probit score for both observations in which either an exact or the a qualitative response was available. The probit score is a measure of an assumed underlying continuous distribution of viral load scores from which the ordered viral load variable was derived. The ordered probit also generates cuts points that indicate the interval between the ordered viral load categories. Based upon the cutpoint values and the predicted probit scores, each observation was assigned to one of three predicted viral load categories that correspond to the three ordered categories of exact viral load levels.

The following table summarizes the cross classification of the predicated and actual viral load categories.

Predicted and Actual Viral load Categories

	Actual Viral Load Categories				
Predicted Categories	**Values <=400**	**Told Viral Load "good"**	**401 to 9999**	**>10000**	**Told viral Load Bad**
High viral Load level	2%	3%	4%	11%	13%
Medium Level	23%	35%	35%	48%	56%
Low Level	75%	62%	61%	42%	31%

. The table shows that the probit model produced a predicted classification scheme that does a reasonably good job of distinguishing between the three groupings of actual viral load levels. As one might expect, the set of independent variables selected to generate the predicted levels are good but far from perfect correlates of the actual viral load categories. The distribution across the predicted categories within each of the observed viral load levels shows a consistent and expected shift, such that the proportion of observations that fall into the predicted low-level viral load category decreases as the actual viral load level category shifts from the under <=400 category (75%) to the middle 401-999 category (61%) and the highest exact viral load category (42%.) Correspondingly, the proportion of observations in the predicted high-viral load category increases with increase in the exact viral load grouping.

To assess the validity of the proposed assignment of the "good" and "bad" viral load reports, we examine the similarity in the distribution in the predicted viral categories between each qualitative response category and its assigned exact viral load category. It is clear from an inspection of the table that the predicted distribution of "bad" viral load responses is most similar to its assigned category, above 10,000 c/ml. Contrary to the assignment of the good viral load level to the <=400 c/ml viral load category, the predicted distribution of viral loads most closely approximates that for the middle viral load category. However, the distribution of the lower viral categories are very similar when contrasted with the high viral load categories.

In summary, the profile of t-cell counts, opportunistic infection and HAART status for those with bad viral loads best approximates the profile for those with viral loads over 10,000. c/ml, consistent with our a priori assignment. The profile for those with good viral loads is more similar to those who report intermediate viral load levels than those who report low or undetected viral loads. Given the similarity in distribution of predicted viral loads between the low and intermediate groupings of exact viral loads, we will continue to combine the good viral load responses with exact levels under 400 c/ml. The findings do suggest, that supplemental analysis should be undertaken to determine the sensitivity of findings to classification of "good:" viral load reports.