Validity of Self-reported CD4 Cell Count and HIV Viral Load among HIV-infected Patients in Houston/Harris County

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Background

- The CD4 T-cell count and plasma HIV RNA (viral load) are two surrogate markers that are routinely used to determine indications for treatment and monitoring the efficacy of therapy in HIV-infected persons.
- The most recent information on these two biomarkers is the strongest predictor of subsequent disease progression and survival among infected persons.
- The objective of this evaluation was to determine the level of validity of self-reported CD4 Cell count and HIV viral load among HIV-infected patients compared to documentation in the medical record.

Figure 1: HIV virus and CD4$^+$ levels over the course of an untreated infection

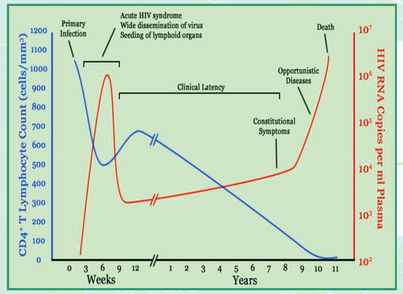

Table 1: Interview questions and response options used

	"What was the most recent CD4 count you've had during the past 12 months?"	"What was the most recent viral load you've had in the past 12 months?"
1	≤ 49 cells/mm3	Below the level of detection, Undetectable
2	50 to 99 cells/mm3	Detectable but less than 5,000 viral copies/ml
3	100 to 199 cells/mm3	5,000 to 100,000 viral copies/ml
4	200 to 349 cells/mm3	Greater than 100,000 viral copies/ml
5	350 to 499 cells/mm3	Don't know
6	≥ 500 cells/mm3	Decline to answer

Material and Methods

- Pilot data collected between December 2005 and March 2006 were used for this study.
- Study was a population-based behavioral and clinical outcome cohort surveillance project.
- In-person interviews and medical record abstractions were conducted for 46 patients (18 years and over), infected with HIV and receiving out-patient care in Houston/Harris County.
- Most recent CD4 count and viral load of patients during the last 12 months obtained from both interviews and medical record abstractions (MRA) were used (Table 1).
- The CD4 and viral loads from MRAs during the same surveillance period were classified according to the options used in the interview instrument.
- The validity and measure of agreement between self-reported and documented information from patients medical records were determined using Kappa Statistics.

Results

Figure 2: Demographic Characteristics of Study Population (N=46)

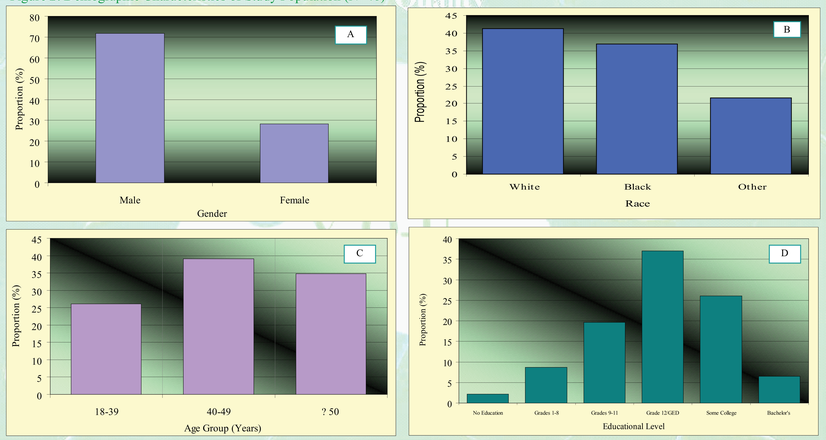

Table 2: Measure of agreement between CD4 count and HIV viral load (VL) obtained through Interviews and Medical records abstractions by demographic characteristics

	Most recent CD4 Count		Most Recent HIV Viral Load	
Characteristics	N	Measure of Agreement (Kappa ± SE)	N	Measure of Agreement (Kappa ± SE)
Overall	28	0.04 ± 0.08 ns	27	0.48 ± 0.15**
Gender				
Male	19	0.06 ± 0.09 ns	19	0.56 ± 0.19**
Female	8	a	8	0.33 ± 0.23 ns
Education				
≤ Grade 12	21	a	21	0.54 ± 0.16***
> Grade 12	6	a	6	0.25 ± 0.41 ns

Table 3: Measure of agreement between CD4 count and HIV viral load (VL) obtained through interviews and medical records abstractions by time since last test, ART and Insurance Status

	Most recent CD4 Count		Most Recent HIV Viral Load	
Characteristics	N	Measure of Agreement (Kappa ± SE)	N	Measure of Agreement (Kappa ± SE)
Overall	28	0.04 ± 0.08 ns	27	0.48 ± 0.15**
Time Since Last HIV CD4/VL Test				
<= 6 months	9	a	8	a
> 6 months	19	a	19	0.37.00 ± 0.19*
Currently on Antiretrovirals				
Yes	23	a	23	0.54 ± 0.17***
No	5	a	4	a
Insurance				
Have Insurance (All types)	18	a	5	0.30 ± 0.19 ns
Have No Insurance	10	a	12	a

[a] Kappa statistics could not be computed because the data did not give an symmetric 2-way table in which the values of the first variable match the values of the second variable. That is, CD4 or VL given during interview and/or obtained through medical record abstractions are constants

** = Significant @ P<0.01; *** = Significant @ P<0.001; ns = Not Significant (P>0.05).

- The overall measure of agreement between self-reported and medical record abstraction record gave a significant (P<0.001) Kappa value of 0.48 for Viral load.
- A non-significant (P>0.05) and poor Kappa value of 0.043 was observed for CD4 counts.
- Fair to moderate agreement levels were obtained when the biomarkers were evaluated against some demographics and behavioral characteristics.

Limitations

- Small sample size (N=46) may not be representative of the population. Improved sample size may reveal a different level of agreement between the two sources of data within the characteristics.
- The design assumed MRA data was accurate (Gold Standard).
- Interview responses consisted of categorized responses while MRA data were abstraction of actual value.
- MRA HIV VLs less than 400 copies/ml was categorized as undetectable although lower undetectable levels exist.

Conclusion

- The results indicate that some significant measure of agreements exist between Viral Load obtained from interviews and medical record abstraction data.
- Choice of data source, medical records or self-reports, will in many instances provide significantly different results and it is likely that this may also be true for other variables of interest to researchers.
- Thus, in the case where no gold standards are available, researchers need to consider carefully the implication of choice of data source on their results.
- These results can serve as a useful guide to researchers contemplating the use of surveys as an alternative to medical record abstraction to ascertain treatment for HIV patient outcomes.
- Findings of this pilot study supports other validation studies with other diseases in which low to moderate agreement between the two data sources were found, depending on the data being collected and the study setting [1-3].

References

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