

HIV/AIDS CLINICAL CARE QUALITY ASSURANCE PROJECT

**Factors Associated with Retention in Care
Among HIV Positive Patients
In BPHC Sites Funded Through Ryan White Part A Program
1999-2006**



JSI Research & Training Institute, Inc.

Laureen M Kunches PhD
Nancy E. Reinhalter RN, CCRC
Eugenie Coakley
Wendy Chow
Jacqueline Steiner
Joseph Musolino
Lisa R. Hirschhorn MD, MPH

DRAFT 2

**For the Boston Public Health Commission
March 2009**

TABLE OF CONTENTS

I. INTRODUCTION	3
1.1 Background	3
1.2 Participating Sites	4
1.3 Analytic Sample Selection	4
1.4 Terminology	4
1.5 Data Collection Protocol	4
II. METHODOLOGY	6
2.1 Measures	6
2.2 Statistical Methods	6
2.3 Generalizability	7
III. RESULTS	7
3.1 Description of Study Sample	7
3.2 Duration of Follow-Up, Overall Retention-in-Care Rate	10
3.3 Kaplan-Meier Analysis:	
Individual Patient Characteristics Related to Retention	10
3.4 Cox Proportional-Hazards Regression Model of Patient Characteristics	18
3.5 Cox Proportional-Hazards Model of Clinical Characteristics	20
IV. LIMITATIONS	20
V. CONCLUSIONS	21

Funding for this project was provided by the Boston Public Health Commission through Part A of the Ryan White HIV/AIDS Treatment Modernization Act of 2006.

I. INTRODUCTION

1.1 *Background*

Patient retention, or regular engagement in care, is necessary for routine monitoring and management of HIV disease and thus is an essential component to measure in HIV care quality management. Current guidelines recommend a medical visit with an HIV provider every three to four months. In 2007, the Health Resources and Services Administration HIV/AIDS Bureau (HRSA-HAB) released the HIV Core Clinical Performance Measures which defined the medical visit performance measure as being seen at least once every six months or two or more visits in a review year that are at least three months apart.

Engaging and retaining persons with HIV in routine primary medical care has been and continues to be a challenge. Studies have shown that discontinuity in care or sporadic care is associated with negative health outcomes, greater mortality, and higher risk of disease progression to AIDS.¹ Therefore, identifying factors associated with poor retention is important for assisting care providers in targeting outreach interventions and services to promote consistent and equitable access to care.

Since 1999, JSI Research & Training Institute (JSI) has conducted biannual retrospective chart reviews of HIV/AIDS primary outpatient care provided in all nine Boston EMA Ryan White Part A sites. This effort is part of a quality assurance project funded by the Boston Public Health Commission (BPHC) to evaluate clinical performance and to identify opportunities for managing quality and for improving care and health outcomes of people living with HIV/AIDS. Data on provider visits were gathered on all selected patients each year to evaluate care patterns and identify potential gaps in care. The purpose of this report is to determine the retention rate and to describe factors associated with whether or not patients were retained in care, for all nine sites combined. For the purposes of this report, retention is defined as having at least one face-to-face HIV primary medical care visit each year the patient was part of the study cohort.

¹ Backus LI, Mole LA, Morgan RO. Retention in care: a challenge to survival with HIV infection. Clin Infect Dis. 2007 Jun 1;44(11):1493-9.

1.2 Participating Sites

Clinical chart reviews and medical record data abstractions were conducted during 1999-2006 at clinical sites providing HIV care funded by the Boston Public Health Commission through Part A of the Ryan White HIV/AIDS Treatment Modernization Act. These sites included:

- Boston Medical Center
- Fenway Community Health Center
- Great Brook Valley Health Center
- Greater Lawrence Family Health Center
- Lowell Community Health Center
- Lynn Community Health Center
- Martha Eliot Health Center
- Whittier Street Health Center
- Zinberg HIV Clinic (Cambridge Health Alliance)

1.3 Analytic Sample Selection

For this analysis, all study cohort members reviewed from 1999 through 2006 who were fully engaged in care during their initial review year were eligible for inclusion. “Fully engaged” is defined as having at least two medical care visits with an HIV primary care provider (PCP) in the initial review year. This criterion was required so that a complete set of baseline data would be available. It was also required so that a more clearly defined outcome could be studied – *retention* in care among those who were initially *engaged* in care for at least one year. The resulting analytic sample comprised of 1,040 patients.

1.4 Terminology

In this report, the term “retention” is used to describe the outcome of having had at least one face-to-face medical visit with an HIV PCP per calendar year. Its opposite term, “lost-to-care” (or non-retention), is used to describe patients with zero visits in the year. The term “lost-to-follow-up” is used to characterize when a patient died, transferred to another clinic, moved, was incarcerated, or was institutionalized. Each patient was tracked or followed until he/she became either lost-to-care, lost-to-follow-up, or retained in care through 2006, whichever of these events occurred first.

1.5 Data Collection Protocol

Medical chart abstractions were conducted by JSI research nurses and clinical research assistants who received detailed training on the quality assurance project and on standards/processes of HIV outpatient care. JSI staff signed confidentiality agreements assuring complete adherence to patient privacy protection. Nurses and research staff utilized medical records, including process notes, flow sheets, laboratory reports, and other documentation found in patient records to complete elements on the data collection instrument. Secondary data sources, such as case management notes and verification from providers, were used to fill in

gaps (e.g. patient status at the site) or confirm chart information as appropriate. In more recent years, many clinics have converted to electronic medical records and thus both paper and electronic sources were used to ensure the fullest data capture.

During the first review period (1999-2000), JSI created the initial cohort by collecting data on 70 randomly sampled patients at each clinic (all patients were reviewed at sites with fewer than 70 patients). In all subsequent review cycles, JSI collected data on the initial cohort, and added to the cohort a maximum of 30 newly diagnosed patients entering care at each site. For sites with more than 30 new patients during the review cycle, a random sample was selected. For sites with smaller caseloads, all new patients were added to the cohort and reviewed. Starting in the 2005-2006 review cycle, abbreviated chart reviews were conducted on the longer-term cohort members; specifically those who were continuing care and diagnosed before 2003.

As with any medical chart review project, the validity of findings depends on the clarity, accuracy, and completeness of data maintained in patient records. If patients were lost-to-follow-up and the reasons were not systematically documented, it could result in the misclassification of patients as lost-to-care, and thus overestimate the rate of patient non-retention. To minimize these errors, collaborators at the clinics were asked to verify the status of each patient ever reviewed and identify those who were no longer in care at the site. Furthermore, progress notes were used and providers were consulted as necessary to determine patient status of those with no visits found during the chart review. Where information was available, reasons for lost-to-follow-up (death, move, transfer care, incarceration, and institutionalization) were noted.

Since information about death is so important, additional validation of this outcome was performed. For a sample of patients who entered care in 2002 or later and had fewer than 2 visits in any year during follow-up, we used name codes, date and place of birth, and gender to verify vital status by cross-referencing with the state death registry. Of the patients checked, only 1% was recorded as deceased during the follow-up period, indicating minimal misclassification of deceased patients as not retained.

II. METHODOLOGY

2.1 *Measures*

Patient demographics were measured, including gender (male and female only), age at entry to care at site (categorized as ≤ 39 yrs. / ≥ 40 yrs.), race/ethnicity (Hispanic, non-Hispanic black, non-Hispanic white), and place of birth (born in the United States/born outside the US - “non-U.S. born”). The primary route of HIV transmission was categorized as MSM risk, IDU risk, heterosexual risk, and other. Patients with multiple HIV risk factors were classified according to their greatest transmission risk factor (IDU, then MSM, then heterosexual risk). Patients were also classified as either continuing-care or newly diagnosed and/or new-to-care at the clinic at the time they were enrolled in the study cohort. For each year, the last-measured CD4 count and viral load value were determined. Finally, years during which the medical chart noted active mental illness or active substance abuse were determined.

For each year of follow-up, we determined whether patients had one or more HIV primary medical care provider visits and computed the number of years of retention for each patient. The count of the number of years of retention ended once a patient became lost-to-follow-up or lost-to-care. If a patient had zero primary care visits in a given year *and* had not been lost-to-follow-up, an indicator variable captured the fact that they were “lost-to-care” or not retained. Since the purpose of this study is to examine characteristics associated with patients’ first becoming lost-to-care, it does not track whether there is evidence of re-engagement into care during subsequent chart review cycles.

2.2 *Statistical Methods*

The sample is described using frequencies and cross-tabulations of the various measures. To identify measures related to the amount of time patients were retained in care, we employed a statistical method called “survival analysis”. Survival analysis is a set of techniques for studying the occurrence and timing of events. Originally designed for the study of time-to-death or survival (e.g. from cancer), it is now applicable when modeling the time-to-any type of dichotomous event (event happened or not). In this report, we modeled the amount of time patients were retained in care and identified the time at which they were lost-to-care. These techniques are particularly useful because they account for situations in which events are censored, or in other words, when a competing event occurs prior to the event of interest. In this report, the competing event would be loss-to-follow-up, or the end of the study follow-up time.

The Kaplan-Meier (K-M) technique was used to estimate the fraction of patients remaining in care each year, accounting for loss-to-follow-up. This method allows retention trends to be compared across levels of a categorical variable (such as gender) using a statistical test called the log-rank test; K-M retention curves can also be plotted for easy group-level

comparisons. Two limitations of the method are that it does not quantify the degree of difference across levels of the categorical variable and only one variable can be examined at a time. The K-M method was used to identify individual variables with differential retention rates. Cox proportional hazards models were then used to include all significant variables into one model simultaneously (joint effects). Cox models also provide “hazard ratios” (hazard of being lost-to-care) that are interpreted like odds ratios and help quantify the degree to which subgroups of the sample differ with regards to (non-) retention rates.

2.3 Generalizability

Due to sampling variability across sites, results may or may not be generalizable to each individual site, especially sites with smaller caseloads that contributed only a few patients to the study sample. Findings should be interpreted in the context of all BPHC-funded sites combined.

III. RESULTS

3.1 Description of Study Sample

A total of 1,040 patients were fully engaged (≥ 2 visits) in their initial review year and were included in the analysis. The sample consisted of 61.1% male, 38.9% female, and 64.3% age \leq 39 years at entry to care at site. The cohort included similar proportions of White non-Hispanic (33.5%), Black non-Hispanic (34.1%), and Hispanic (32.4%) patients. About one-third of patients were born outside of the United States. The Black, non-Hispanic racial/ethnic category made up the highest proportion of non-U.S. born members (57.5%). One-third of patients entered care with IDU risk as a transmission risk factor and 22.2% had MSM risk. About half of the cohort was new-to-care when they were enrolled in the cohort. Table 1 describes demographics and health characteristics of the cohort. Table 2 shows that the majority of patients were entered into the study cohort in 1999 & 2000 and in 2002 & 2003.

Table 1. Study Sample Characteristics

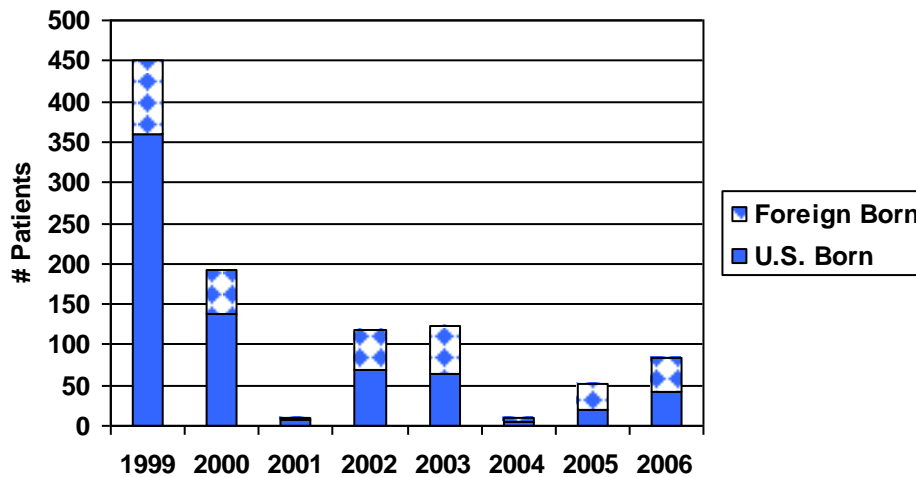
PATIENT CHARACTERISTIC	PERCENTAGES N=1,040
Gender	
Males	61.1%
Females	38.9%
Country of Birth	
Non-US born	32.0%
Born in US Territories	20.5%
Born in US States	47.1%
Race-ethnicity	
White non-Hispanic (12.9% born outside of U.S.)	33.5%
Black non-Hispanic (57.9% born outside of U.S.)	34.1%
Hispanic (24.7% born outside of U.S.)	32.4%
HIV Transmission Risk Factor	
IDU Risk	30.4%
MSM	22.2%
Heterosexual	45.0%
Other	2.4%
Age Group (Age at First Visit to Site)	
0-39	64.3%
40+	35.7%
Relationship to Clinic	
New-to-care	51.3%
Continuing care	48.7%
Last CD4 Count	
≤ 200	21.9%
> 200	78.1%
Last Viral Load	
≤ 400	41.5%
> 400	58.5%
Active Substance Abuse during Initial Year	
Yes	23.0%
No	77.0%
Active Mental Illness during Initial Year	
Yes	42.8%
No	57.2%

Table 2. Number of Patients Entering Care or Newly Reviewed in Each Year 1999-2006

<i>Year of Entry to Care or First Review</i>	<i>Number of Patients</i>	<i>Percentage of Total Sample (N=1040)</i>
1999	452	43.5%
2000	193	18.6%
2001	10	1.0%
2002	118	11.4%
2003	123	11.8%
2004	9	0.9%
2005	51	4.9%
2006	84	8.1%
Total	1040	100%

The mix of non-U.S. born persons enrolled in the study changed over time. Starting in 2002, more non-U.S. born persons joined the cohort, representing a greater proportion of all new cohort members (Figure 1). Also, due to the sampling design, patients were more likely to be new-to-care in later years of the study. From 1999-2001, patients were randomly selected for review without regard to the duration of their relationship to the clinic. From 2002 and onwards, patients added to the cohort were both newly diagnosed and new-to-care at the site.

Figure 1: Number of Non-U.S. Born & U.S. Born Patients in each Review Year



3.2 Duration of Follow-Up, Overall Retention-in-Care Rate

On average, patients were followed for 4.5 years in this analysis. Seventy-five percent of the cohort was followed for two or more years. A total of 261 patients, or 25.1%, had a year in which they did not have at least one face-to-face medical primary care visit with an HIV provider. Thus, the overall retention rate was 75%. It is interesting to note that using the more stringent criteria for retention of two or more such visits per year, 37.4% were lost-to-care over the review period; thus the retention rate was 62.4%. Returning to our primary measure of care retention (≥ 1 visit), patients were more likely to drop out of care within the first two years of care (about 60% of all those who were lost-to-care).

Table 3. Percentage of Patients who became Lost-to-Care in each year during the 8-Year Follow-Up Period

<i>Number of Years Followed</i>	<i>Number of Patients who became Lost-to-Care</i>	<i>Percentage of Total Patients who became Lost-to-Care (n=261)</i>
1 year	0	0.0%
2 years	95	36.4%
3 years	60	23.0%
4 years	39	14.9%
5 years	32	12.3%
6 years	18	6.9%
7 years	15	5.8%
8 years	2	0.8%
Total	261	100%

3.3 Kaplan-Meier Analysis: Individual Patient Characteristics Related to Retention

Males, those born in the United States, and intravenous drug users (as HIV transmission risk factor) were significantly more likely to be retained for shorter periods of time than females, older adults, non-U.S. born persons, and non-intravenous drug users. In the original models, age was classified into two groups, based on a cut-point of 50 years. With this split, age was significantly related to retention, with older men more likely to be retained in care. With the current categorization into ages ≤ 39 years and ≥ 40 years, the association is in the same direction, but much attenuated. This implies many of those in the 40-49 age range had retention probabilities more similar to the younger age group. The original age classification is shown in the Kaplan-Meier Curve, Figure 2.

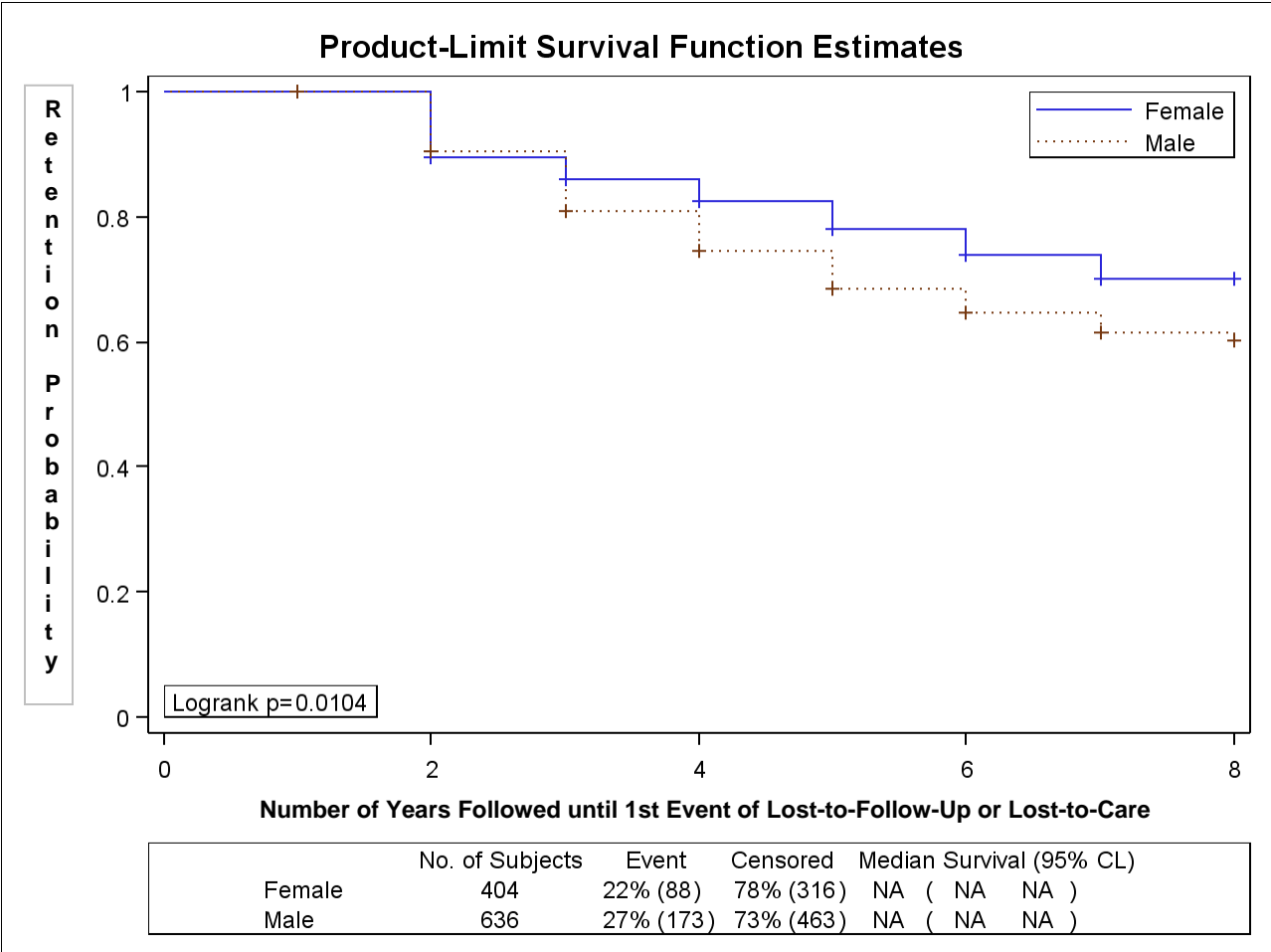
The three racial-ethnic groups did not differ significantly in duration of retention in care. When place of birth was cross-classified by race/ethnicity, the interaction was of borderline significance ($p=0.0667$). Also, when we further stratified place of birth by US-born in the 50 states versus US-born in US territories, there was no difference in retention rates between these two subgroups.² Patients who were new to care when they were enrolled in the study cohort were just as likely to be retained in care (or equivalently, lost-to-care) as continuing care patients. Patients who entered the study during the earlier years of follow-up (1999-2001) were more likely to be lost-to-care, or retained for shorter periods of time, than those who entered the study in later time periods. This difference may either be due to improvements in retention over time or related to the greater number of U.S. born patients who were enrolled earlier into the study cohort. Figures 2–8 provide the K-M curves which trace out the probability of retention in care over time. All of the lines that are traced out decline over time, since once patients are lost-to-follow-up or lost-to-care, they do not re-enter the analysis at a later time. Each graph displays the retention rates over time for levels of each patient characteristic. Table 4 summarizes the results, as well.

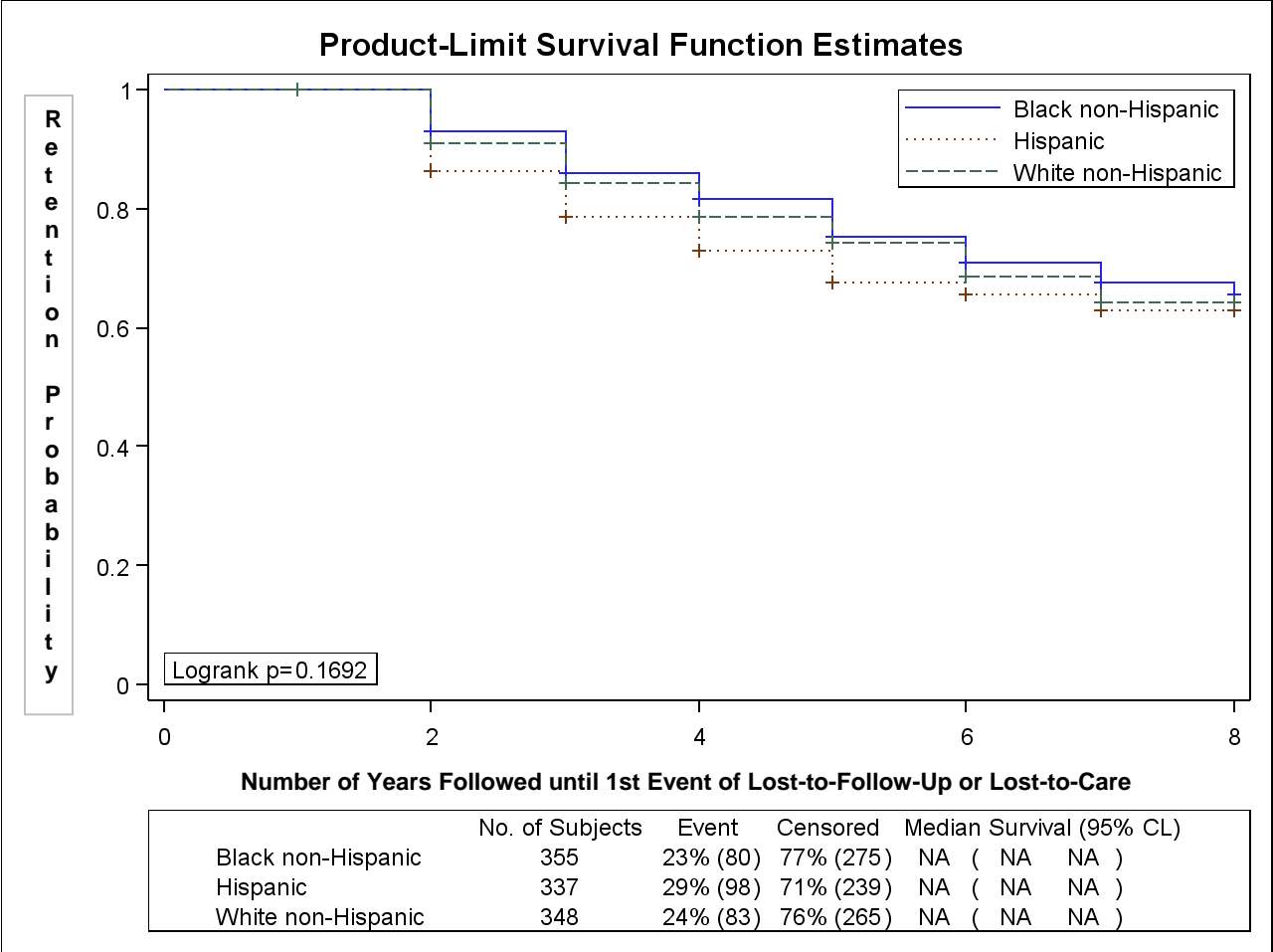
Table 4. Percentage of Patients Lost-to-Care, by Patient Characteristic

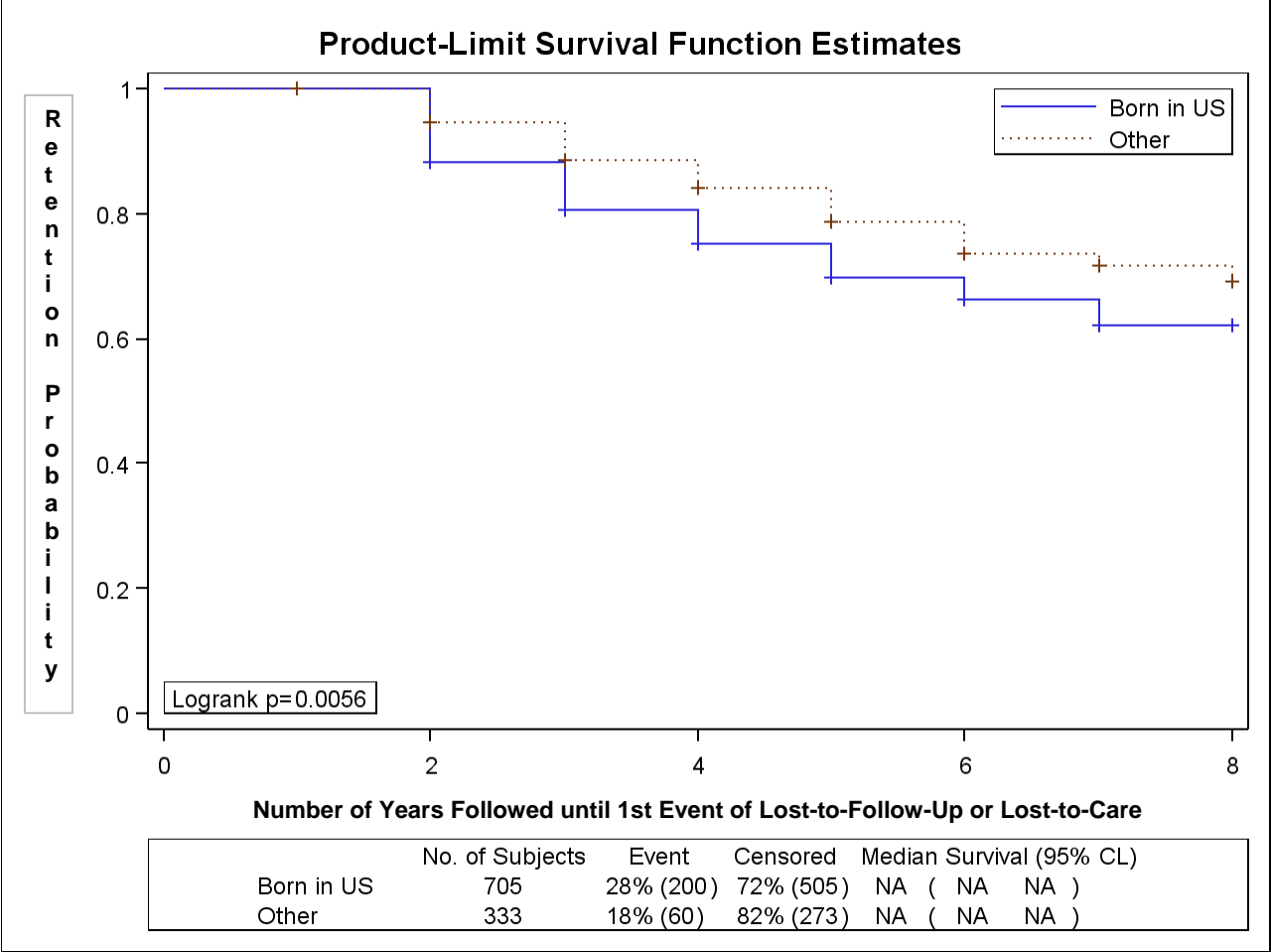
Patient Characteristic	** Group with lower retention rate over time (percent lost-to-care)	Log-rank test for significant differences in Retention rates, p-value
Gender	** Males (27.2%) Females (21.8%)	$p<0.05$
Age	** Age \leq 39 (26.9%) Age \geq 40 (21.8%)	ns ($p<0.18$)
Race/ethnicity	Black, non-Hispanic (22.5%) Hispanic (29.1%) White, non-Hispanic (23.9%)	ns
Place of Birth	** Born in US (28.4%) Non U.S. born (18.0%)	$p<0.01$
HIV Risk Transmission Category	** IDU (34.2%) MSM (20.4%) Heterosexual (20.9%)	$p<0.01$
Year Entered Study	** 1999-2001 (32.4%) 2002-2006 (12.7%)	$p<0.05$
Relationship to Clinic	New-to-care (21.2%) Continuing care (29.2%)	ns

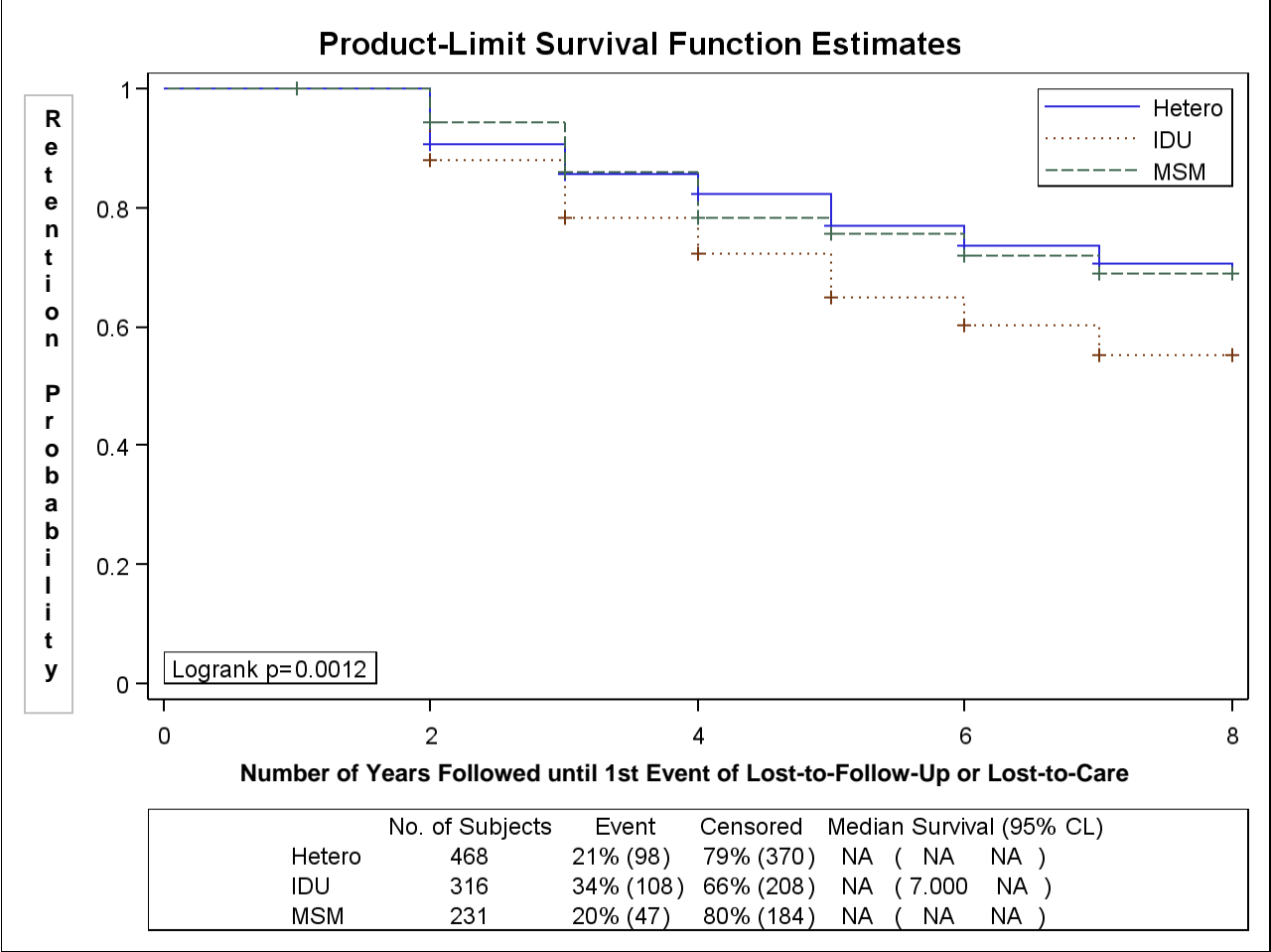
ns = no significance

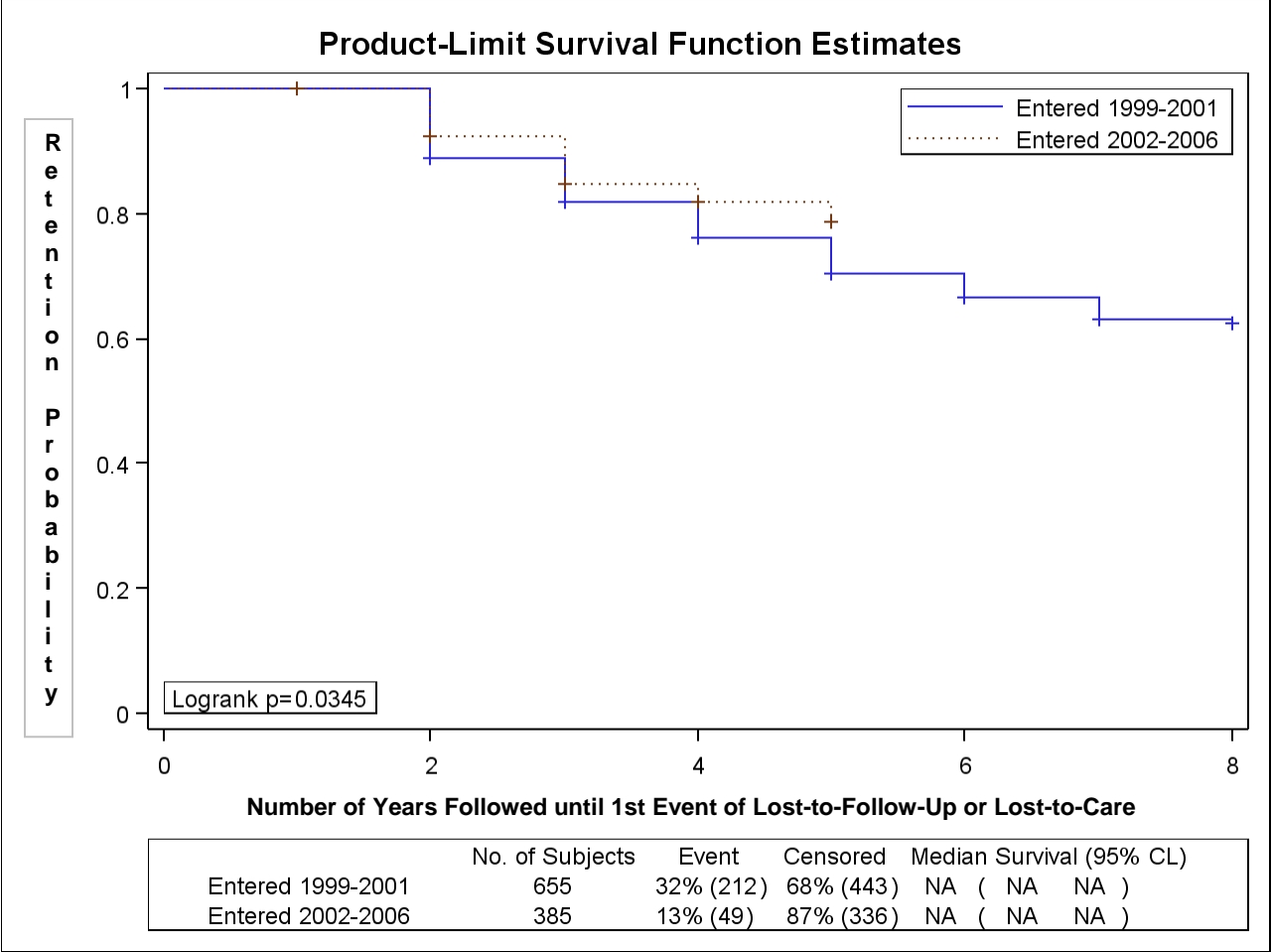
² All patients were born in Puerto Rico, with the exception of one patient born in the Northern Marianas Islands.

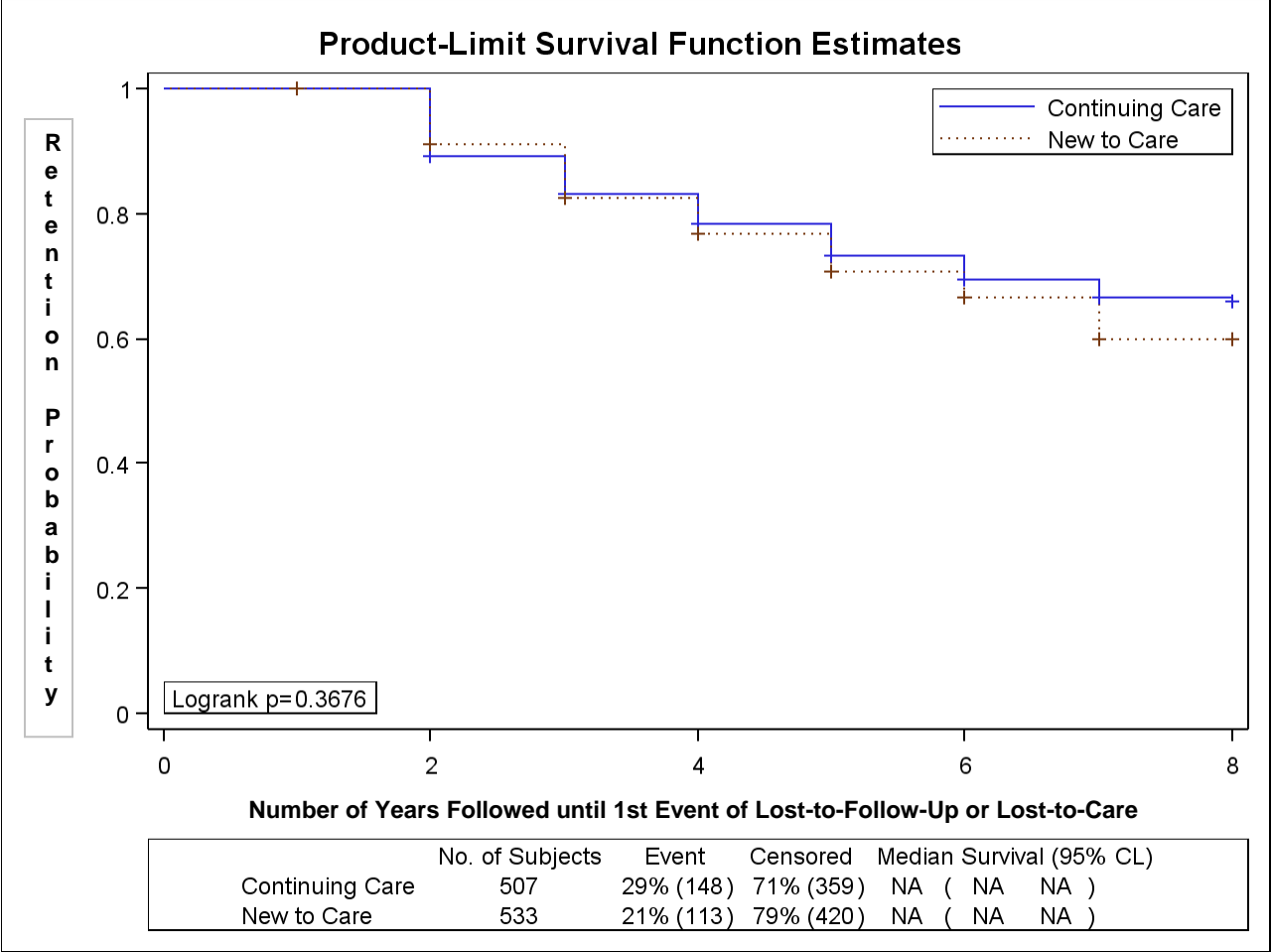












3.4 Cox Proportional-Hazards (CPH) Regression Model of Patient Characteristics

All of the patient characteristics described above were entered into a CPH regression model (Table 5). With all patient characteristics included in the model, younger age and male gender remained significant risk factors for loss-of-retention in care. However, place of birth (U.S. born) was no longer a significant risk factor. Further, relationship to clinic (being new-to-care upon entry to study cohort) became a significant risk factor, and entry into the study (before 2002) was a stronger risk factor than it was an individual factor.

Table 5. Risk of Being Lost-to-Care, by Patient Characteristic

Patient Characteristic	Hazard Ratio
Male	1.34*
Age <= 39 years	1.33*
Hispanic	1.21
Black, non-Hispanic	1.09
Born in U.S.	1.25
New to Care	1.83***
Entered Study Cohort before 2002	1.92**
Intravenous drug use as HIV risk factor	1.41*

Hazard ratio = relative risk of being lost-to-care.

Chi-square test of significance: ns = no significance, *p < 0.05, **p < 0.01, ***p < 0.001

Referent categories: row 1: females; row 2: age >=40 yrs; rows 3 & 4: white, non-Hispanic; row 5: non-U.S. born; row 6: continuing-care; row 7: entered study 2002-2006; row 8: HIV risk from MSM, heterosexual, other.

Intravenous drug use is a key confounder of the relationship between place of birth and retention in care. As can be seen in Table 6, nearly all of the IDUs (as reported at baseline; a measure of “ever using intravenous drugs”) were born in the U.S. Thus, when placed in the model together, IDU explained far more in terms of risk of being lost-to-care than place of birth.

Table 6. Relationship between Race, Place of Birth, and Intravenous Drug Use

<i>Percent (n) of Intravenous Drug Users who are...</i>	<i>Race</i>	<i>Place of Birth</i>
96.2% (253)	Hispanic	U.S. Born
3.8% (84)	Hispanic	Non-U.S. Born
94.4% (149)	Black, non-Hispanic	U.S. Born
5.6% (206)	Black, non-Hispanic	Non-U.S. Born
93.8% (303)	White, non-Hispanic	U.S. Born
6.3% (45)	White, non-Hispanic	Non-U.S. Born

Table 7 presents the CPH regression models stratified by IDU. Among those who have ever used intravenous drugs, age, gender, race, and place of birth were not significant predictors of being lost-to-care (not being retained in care with at least 1 medical PC visit with an HIV PCP). In other words, regardless of “who” the patient is, IDU places him or her at elevated risk of not being retained in care. Furthermore, if the intravenous drug using patient was also new to care at the clinic, he or she was at additional risk of loss of retention. This was particularly true for those who enrolled earlier in the study (before 2002). Among non-IDUs, the more familiar pattern of male patients being at higher risk of loss-to care is noted. The role of place of birth was not significant, further showing that IDU was the mediating variable in the relationship between birth of place and retention. Being new-to-care or entering the cohort earlier in the study was each borderline significantly related to retention among non-IDUs.

Table 7. Risk of becoming Lost-to-Care, by Patient Characteristics, IDU and non-IDU

<i>Patient Characteristic</i>	<i>IDU Hazard Ratio</i>	<i>Non-IDU Hazard Ratio</i>
Male	1.10	1.63**
Age <= 39 Years	1.25	1.36
Hispanic	1.12	1.44
Black, non-Hispanic	0.69	1.54
Born in U.S.	2.04	1.28
New-to-Care	2.50***	1.48
Entered Study Cohort before 2002	2.49*	1.67*

Hazard ratio = relative risk of being lost-to-care. Significance levels: ns = no significance, *p< 0.05, **p <0.01, ***p < 0.00. Referent categories: row 1: females; row 2: age >=40 yrs; rows 3 & 4: white, non-Hispanic; row 5: non-U.S. born; row 6: continuing-care; row 7: entered study 2002-2006.

We also ran a model using active substance abuse rather than baseline report of IDU as a predictor of retention. Although findings were quite similar, we report the results of the IDU variable instead because there were significant missing data for the active substance abuse variable. Thus, both “ever” IDU and active substance abuse increased the risk of being lost-to-care.

3.5 **Cox Proportional-Hazards Model of Clinical Characteristics**

Data on viral load and CD4 count were collected each review year. Multiple values may be collected in a given year; in this analysis, we report on the last calendar-year value for each measure. In order to predict subsequent loss of retention for each patient, we modeled the prior year’s viral load and CD4 count on the next year’s retention, continuing for however long follow-up lasts. Because the values of these clinical characteristics change and are updated over time, they are referred to as “time varying covariates” in the CPH model.

Patients with a viral load of less than 400 copies/ml, or have viral suppression, had a lower hazard of being lost-to-care (e.g. more likely to be retained in care). Viral load suppression can be interpreted as a marker for adherence to ARV medication, and patients who adhere to medications are more likely to be adherent to medical visits. CD4 count is a marker of severity of illness; those who are sicker or have a CD4 < 200 were more likely to be retained in care (lower hazard of being lost-to-care), though the trend was not significant.

Table 8. Risk of Being Lost-to-Care by Clinical Characteristics

<i>Clinical Characteristic</i>	<i>Hazard Ratio</i>
CD4 < 200	0.69
Viral Load < 400	0.60**

Hazard ratio = relative risk of being lost-to-care.

Significance levels: ns = no significance, *p< 0.05, **p <0.01, ***p < 0.001

IV. LIMITATIONS

This study has some limitations in terms of the conclusions that can be drawn. Due to the nature of medical chart data, our ability to examine time-varying covariates was limited. Explanatory variables collected in the year prior to the year the patient became lost-to-were used in this analysis because limited chart data were available in the year patients became lost. It is likely that a stronger relationship would have been found, for example, between active substance use and loss-to-care if substance use were actually measurable during the year of dropout. The modeling technique we employed explained factors related to loss-to-care, but not potential

subsequent re-engagement in care. Finally, there are multiple ways to define loss-to-care, such as having no visits at all versus having less than two visits in a calendar year. The clinical implications of results may vary based on this definition. Thus, our results may not be directly comparable to studies that use a different definition although we would expect overall findings to be similar.

V. CONCLUSIONS

Retention rates do vary by a variety of patient and clinical characteristics. The relationship is complex because the characteristics are inter-related in intricate ways. Intravenous drug use, and likely substance abuse in general, is a very strong predictor of shorter duration of retention (in other words, predictive of loss-to-care), regardless of race, gender, place of birth, or age. This risk was particularly great among patients who were new-to-care; thus, early identification and treatment of substance abuse may well improve retention rates. When drug use is not apparent, younger persons and males have a somewhat higher risk of shorter duration of retention over time. CD4 count, a marker of severity of illness, was not significantly related to retention. However, patients with viral suppression were more likely to be retained in care than patients with detectable viral loads. Viral suppression is a marker of ARV medication adherence and patients who are adherent to medications are also more likely to be adherent to medical visits.

Retention in care is critical for ensuring delivery of quality HIV medical services for all persons living with HIV. Clinicians and providers should pay particular attention to patients at highest risk of non-retention, specifically those with documented substance use or IDU history. Also, efforts at creating good provider-patient relationships and reducing barriers to coming to clinic are important since patients were more likely to become lost-to-care or lost-to-follow-up during initial engagement in care. Effective treatment requires providers to not only focus on patients' HIV-care related services, but also to address concurrent medical conditions that may interfere with management of HIV disease. Collaboration with other providers and utilization of interdisciplinary teams may be necessary to improve retention. Furthermore, clinics should employ outreach efforts to promote retention in care and should continually assess and adapt these interventions as appropriate to meet patient needs.