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**Predictors of Retention in HIV/AIDS Care at the Yale-New Haven Hospital Nathan Smith
Clinic: Exploratory Analysis Using the Community CAREWare Database**

A Thesis Presented to
The Faculty of the Yale School of Public Health

In Candidacy for the
degree of Master of Public Health

2013

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Abstract

Background: A ‘test-and-treat’ strategy for HIV prevention in the United States is a method that was proposed in an effort to curb and reduce HIV transmission. However, the magnitude of the limitations observed at the various stages in the spectrum of engagement in care can threaten the ‘test-and-treat’ HIV prevention initiative because successful retention remains problematic. Based on the United States’ retention statistics, approximately one fourth to one half of those who were diagnosed with HIV were out-of-care. This figure suggests we need more information about the best ways to retain HIV-infected individuals in care.

Objective: In order to determine the best methods to retain HIV positive patients in care over time, primary predictors driving or influencing HIV positive patients’ retention status must be assessed to better focus intervention strategies that would promote retention in care for those at high risk of falling out of care. This investigation sought to query into how one may employ the CAREWare database, used by Ryan White funded agencies, to study predictors of engagement in care at the Yale-New Haven Hospital Nathan Smith Clinic, which is the largest Ryan White funded clinic in Connecticut. The identification of key barriers influencing retention in care will allow health care providers and public health officials to devise a multidisciplinary team model that would specifically cater to the needs of HIV/AIDS patients at the Clinic, so that interventions may be aimed at optimizing the longitudinal care initiative and improving clinical health outcomes.

Method & Materials: A cross-sectional study was conducted to identify key predictors associated with the retention status of HIV/AIDS patients who attended the Nathan Smith Clinic between October 1, 2011, and October 1, 2012. The timeframe of one year was chosen because the Health Resources and Services Administration (HRSA) definition of retention is, over a given year, an HIV/AIDS patient must have at minimum two primary care visits, with each visit being at least 3 months apart. Clients who failed to meet the HRSA retention definition were designated as out-of-care. The community CAREWare database and Logician (GE Centricity), the Yale-New Haven Hospital’s electronic medical records system, were employed to abstract patient information. The Pearson X^2 and independent samples t-tests were used to assess the unadjusted associations between the patients’ baseline characteristics and retention status. Logistic regression analyses and a backward elimination method of selecting variables were utilized to discover potential contextual factors influencing retention in care.

Results: From October 1, 2011 to October 1, 2012, 696 patients obtained outpatient HIV/AIDS primary care services at the Nathan Smith Clinic and were eligible for the study. Of this total, 134 (19.3%) HIV/AIDS clients were determined to be out-of-care under the HRSA definition for retention in care. The model selection technique yielded three statistically significant predictors of retention that best represented the data. Males were observed to be 1.81 times as likely to fall out-of-care compared to females [adjusted OR 95% CI (1.17, 2.82)]. Patients with no insurance [adjusted OR: 3.30, $p=0.004$], with private insurance [adjusted OR: 1.86, $p=0.040$] or with Medicaid [adjusted OR: 2.47, $p=0.002$] were at an increased risk of falling out-of-care compared to individuals with Medicare. Lastly, HIV/AIDS clients who had received none of the three HIV/AIDS support services (i.e. medical case management, mental health or substance abuse) had a 3.29 increased odds of falling out-of-care compared to individuals who had any one of the three support services [adjusted OR 95% CI (2.05, 5.26)].

Conclusions: These findings suggested that barriers affecting engagement in care at the Nathan Smith Clinic involved gender and insurance differences as well as engagement in HIV/AIDS support services. In order to optimize the longitudinal care initiative and improve clinical health outcomes, an HIV/AIDS multidisciplinary team model should be devised to target these predictors of retention.

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Introduction

HIV/AIDS Background:

According to recent HIV/AIDS prevalence estimates published in the CDC's *Morbidity and Mortality Weekly Report*, 1.2 million adults and adolescents were living with diagnosed or undiagnosed HIV infection in the United States at the end of 2008.¹ Over the years, it is observed that better treatment has contributed to an increased in survival. Despite nearly three decades of HIV/AIDS, the number of incident remains high, with approximately 50,000 Americans becoming infected with HIV each year.²

A 'test-and-treat' strategy for HIV prevention in the United States is a method that was proposed in an effort to curb and reduce HIV transmission. This strategy advocated for the early identification of HIV-infected individuals (through testing) and the initiation of antiretroviral therapy (through treatment) in HIV positive individuals to reduce the incidence of new HIV infections, contributing to the HIV epidemic.^{3 4 5} The 'test-and-treat' strategy to reduce HIV transmission hinges on linking and retaining HIV patients in care; this means that high risk individuals need to know that they are HIV infected, be engaged in regular HIV prevention care and receive and adhere to effective antiretroviral therapy. According to Gardner et al, the magnitude of the limitations observed at the various stages in the spectrum of engagement in care can threaten the 'test-and-treat' HIV prevention initiative.⁶ Using epidemiological data to model the spectrum of engagement, Gardner and colleagues noted that at the end of 2006, about 1.1 million adults and adolescents were living with HIV infection in the United States, yet only about 874,056 individuals were diagnosed with HIV. Out of these, only 655,542 were linked to care within 6-12 months after diagnosis. Of those who were linked to care, only 437,028 were retained in HIV care (i.e. by attending a scheduled medical visit or by having a CD4 count or viral load laboratory test within a given year); of those who were retained in care, 349,622 needed antiretroviral therapy based on a CD4 cell count of <500 cells/ μ L; of those who needed antiretroviral therapy, only 262,217 individuals actually received antiretroviral therapy; and out of those who were on antiretroviral therapy, only 209,773 (or 19% of the HIV-infected population in the U.S.) were adherent to the treatment protocol and so had undetectable viral loads (defined as <50 copies/ μ L).⁶ This model suggested that incomplete engagement in HIV care in the United States accounts for the largest proportion of HIV-infected individuals with detectable viremia.⁶ Therefore, this observation has direct implications for the 'test-and-treat' programs because the majority of HIV-infected individuals have detectable viral loads and are capable of transmitting HIV.⁶

The factors that promote successful retention are multiple, complex and incompletely characterized. Therefore, effective retention remains problematic. Giordano and colleagues found that nearly half of patients attending a clinic intake visit were subsequently lost to follow-up and thus failing to fully establish outpatient treatment after initial linkage to care.¹⁵ In three population-based studies from the United States, about 40%-55% of known HIV-infected individuals fail to receive any HIV primary medical care over a given year.^{7 8 9} In addition, multiple cohort studies have found that 25%-44% of HIV-positive individuals are entirely lost to follow-up, but may

eventually re-establish care.^{10 11 12 13} Moreover, in some communities, approximately one-third of HIV-infected individuals fail to access care for 3 consecutive years.^{9 14} Finally, Gardner and colleagues' model showed that about 50% of known HIV-infected individuals in the U.S. are out of care.⁶ Based on these U.S. retention statistics, approximately one fourth to one half of those who were diagnosed with HIV were out-of-care.⁶⁻¹⁵ This figure implies we need more information about the best ways to retain HIV-infected individuals in care. In order to determine the best methods to retain HIV positive patients in care over time, factors driving or influencing HIV positive patients' retention status must be identified. Primary predictors associated with out-of-care individuals must be assessed to better focus intervention strategies that would promote retention in care for those at high risk of falling out of care.

Barriers to Retention:

The definition of patient retention can be measured in different ways (i.e. appointments missed, medical visits at regularly defined intervals, evidence of CD4 or viral load laboratory tests within a given period, or a combination of these methods).^{7 15 16} Previous studies have contributed important insights into the evaluation of the contextual factors influencing HIV/AIDS patients' retention in care. Ulett et al proposed a blueprint for HIV treatment success, a framework adapted from Giordano et al¹⁷ and Samet et al,¹⁸ to convey how environmental and patient characteristics influence the processes of linkage and retention.¹⁹ Ulett et al noted that the environmental factors include the contextual environment (i.e. rural vs. urban, neighborhood and dependent care) and the health care environment, which includes clinic factors (i.e. clinic distance, appointment availability and waiting time), system factors (i.e. mental health services, substance abuse services and case management) and provider factors (i.e. trust, experience and concordance).¹⁹ The patient factors include predisposing factors (i.e. age, race/ethnicity, gender, poverty, education, mental health, substance abuse and stigma), enabling factors (i.e. insurance status, transportation, housing, social support and self-efficacy) and perceived need (i.e. symptoms and health beliefs).¹⁷ Other studies have noted that years been HIV positive, laboratory values (i.e. CD4 counts and viral loads) and the type of antiretroviral therapy (ART) regimen also served to influence retention in care.^{20 21 22 23 24 25 26 27 28}

In order to address the diverse characteristics and needs of people living with the HIV infection, a multidisciplinary team model of HIV care is recommended to provide the standard of care for HIV/AIDS patients.²⁹ As the barriers affecting engagement in care varies across primary care sites, regions, neighborhoods and geographic locations, the multidisciplinary team model must be unique to each individual site or location—it must reflect and serve to address the key barriers observed at that particular region or locale. This investigation attempted to present findings in an effort to provide insight into determining key barriers or variables affecting HIV/AIDS patients' retention in care at the Yale-New Haven Hospital Nathan Smith Clinic, which is the largest Ryan White funded clinic in Connecticut. The identification of key barriers influencing retention in care (as defined by the Health Resources and Services Administration (HRSA)) will allow health care providers and public health officials to devise a multidisciplinary team model that would specifically cater to the needs of HIV/AIDS patients at the Clinic,

so that interventions may be aimed at optimizing the longitudinal care initiative and improving clinical health outcomes.

Ryan White/CAREWare database:

The Ryan White CARE Act (RWCA) was passed by Congress and signed into law in 1990.³⁰ The CARE Act was a Federal program (managed by the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB)) that provided financial aid to support the needs of communities that had been greatly affected by the HIV/AIDS epidemic.^{31 32} Since its development, RWCA had been a major part of the network for providing care to individuals with HIV/AIDS in the United States. In December 2006, the CARE Act was replaced by the Ryan White HIV/AIDS Treatment Modernization Act.³⁰ Despite this law replacement, HRSA remained the agency overseeing the Ryan White (RW) funds that are allocated to communities.³¹

The HIV/AIDS Treatment Modernization Act is divided into five parts, Part A, B, C, D and F.^{30 32 33} Under this Act, the mayor or Chief Elected Official, in a city determined by the federal government as an Eligible Metropolitan Area (EMA) with the largest number of AIDS cases, is responsible for the administration of RW Part A funds.³⁴ Before 2009, HIV/AIDS community health agencies, in the five regions of Connecticut (New Haven, Bridgeport, Waterbury, Stamford/Norwalk, Danbury), competed for RW funding.^{35 36} In 2009, a Single Lead Agency per Region model was adopted and one Lead Agency was established at each of the five regions to discourage competitions among agencies.^{35 36} In order to receive RW Part A funding for the fiscal year, each Lead Agency must submit an annual proposal to the Mayor's Planning Council.³⁶ The Council identifies needs within the communities and equitably distributes funds by the percentage of AIDS cases in proportion to the number of HIV cases reported by the five regions.³⁴ The Yale University School of Medicine serves as the Lead Agency representing hospital-based and community organizations that are jointly funded by RW Part A funds in New Haven.^{36 37}

Since 2009, HRSA requires that all grantees and providers who deliver RW HIV/AIDS Program funded services submit a Ryan White HIV/AIDS Program Services Report (RSR) each year.^{38 39} In addition, RW Program grantees must use the free software database, called CAREWare, to manage HIV/AIDS care service and client data.^{40 41} This database allowed grantees and providers to generate specific client reports as well as expedite the process of completing the RSR.³⁹

The CAREWare database is used to capture diverse community trends such as demographics and processes of care as well as temporal trends over time.^{35 36} This database is capable of generating customized performance measure reports, which allow hospital and community agencies to monitor HAB-recommended HIV/AIDS care quality improvement processes within their organizations.^{35 36} CAREWare can also be used to inform healthcare providers and medical case managers the retention status of their clients.^{35 36} Unlike the state departments and Veterans Affairs' surveillance databases, CAREWare is not funded by the federal government (i.e. HRSA);³⁵ therefore, a limitation accompanying this database is that RW funded agencies do not have the financial resources to

maintain an established validation team to cross-verify data entry into the system.³⁵ Nevertheless, this database has the potential to assess the demographics of patients, the quantity and quality of HIV/AIDS primary care service delivery within a given region or healthcare organization; and also to facilitate implementation research. Since there have not been significant publications made using the CAREWare database, this investigation also sought to query into how one may employ the community CAREWare database to study predictors of engagement in care.

Methods & Materials

Study Sample:

A cross-sectional study was conducted to investigate the relations between HIV/AIDS patients' baseline characteristics and engagement in care status. The primary objective of this study was to identify key predictors associated with the retention status of HIV/AIDS clients who attended the Nathan Smith Clinic between October 1, 2011, and October 1, 2012. The established timeframe of one year was chosen because the HRSA definition of retention is, over a given year, an HIV/AIDS patient must have at minimum two primary care visits, with each visit being at least 3 months apart.⁴² Clients who failed to meet the HRSA retention definition were designated as out-of-care.

Ethical Review:

The eligibility of patients for this investigation was contingent on receiving the Yale University Human Investigation Committee approval. Given that the study protocol presented minimal risk to subjects, patient informed consent was waived per federal regulation 45 CFR 46.116(d).

Data Abstraction Procedure:

The Nathan Smith Clinic, as part of the HIV Continuum of Care facility funded by the Ryan White HIV/AIDS Treatment Modernization Act, must report all patient visits in HRSA's Ryan White HIV/AIDS Program Services Report (RSR). This requires that in the first week of each month, the date of patient visits must be reported to the Clinic's CAREWare data manager to be recorded in CAREWare. CAREWare is capable of generating the retention status of clients under the HRSA definition of retention.

The HRSA QM001 feature in CAREWare is robust. It allows one to build a custom report to identify patients who had met and who had not met HRSA's retention definition as well as to include patient variables of interest (i.e. DOB, gender, race/ethnicity, etc.). The QM001 feature was used and a filter date of October 1, 2011, to October 1, 2012 was specified as the observational time of interest. The following patient variables of interest were selected from the QM001 Field Selection Directory: DOB, gender, race/ethnicity, HIV risk factor, antiretroviral therapy (ART) medication(s) the patient was on within the specified year and insurance type. Once the QM001 custom report was generated, with the patients' retention status and their corresponding information of interest, it was exported from CAREWare to a Microsoft Excel spreadsheet. Patients who were indicated as being "In the Numerator" were out-of-care clients, while patients who were indicated as being "Not in Numerator" were in-care clients. A filter option was chosen in Excel to group patients with the "In the Numerator" status together and the patients with the "Not in Numerator" status together so that out-of-care and in-care patients, respectively, could be identified.

Logician (GE Centricity), the Yale-New Haven Hospital's electronic medical records system, was also employed to abstract patient information that was missing from or not captured by the CAREWare database. The following variables were obtained from the patient medical charts: education, marital status, residency status, HIV status disclosure, HIV/AIDS support services, insurance type (percentage missing from CAREWare: 38.9%) and ART medication(s) the patient was on within the specified year (percentage missing from CAREWare: 3.9%). Although CAREWare does capture all CD4 and viral load count lab values, we were interested in the first recorded lab values within our given time frame, or else the most recent lab readings prior to October 1, 2011 to serve as our baseline CD4 and viral load measures. Since patients have their CD4 and viral load measured at different dates, there were no program algorithms in CAREWare that could populate a report to identify the baseline lab values of interest. Therefore, the baseline CD4 and viral load values were abstracted from the patients' medical charts.

Defining Baseline Variables of Interests:

Dependent variables

In-care vs. out-of-care patient status: The built-in HRSA QM001 feature in CAREWare was used to populate the list of in-care and out-of-care patients at the Nathan Smith Clinic. To ensure that new patients as well as newly diagnosed patients enrolled at the clinic were not wrongly classified as being out-of-care because they did not have the opportunity to make a second visit during the period of interest, patients newly enrolled in care during the last six months of the year were excluded.⁴¹ In addition, patients who were reported to the Clinic as deceased or had transferred their care to another health care facility were also excluded from the study. At the time of the investigation, two individuals were determined to be deceased, while no records in regards to clients transferring care were noted. Lastly, individuals who were known by the Clinic to have been incarcerated were also excluded contingent on the following criteria: 1) an arrest had prevented them from returning for a second primary care visit within the observation period or 2) due to the arrest, they were not able to make a first primary care visit until April 1, 2012, or after this cut-off date during the observation period. At the time of data abstraction, no delinquent client records were reported to the Clinic.

Independent variables

Variables were selected based upon review of the literature and the framework for successful HIV retention. Contextual factors, such as patient factors (i.e. age, gender, race/ethnicity, HIV risk factor, health insurance, education, marital status, baseline CD4 counts, baseline HIV viral loads, type of ART regimen, housing and status disclosure), as well as environmental system factors (i.e. mental health services, substance abuse services and medical case management) were of interest as they served to influence the process of retention in care.¹⁶⁻²⁶

Abstraction Source: CAREWare Database

Date of birth, gender, race/ethnicity, HIV risk factor: Each year, the patients' medical records are reviewed and relevant patient information is abstracted from the medical charts and updated onto the CAREWare database by March 1st of each year. These baseline variables of interest, abstracted using the QM001 specialized Field Selection feature, reflected the patient information that was updated onto CAREWare on March 1, 2012.

Abstraction Source: Logician (Electronic Medical Records System)

CD4/viral load lab values, education, marital status and residency status: The baseline CD4/viral load lab value, education, marital status and residency status characteristics were abstracted if the given characteristic was the first record captured in the patient's medical chart during the observation period, or else the most recent information recorded prior to October 1, 2011. The CD4 and viral load values were abstracted from the patient's laboratory reports. The education, marital status and residency status information was abstracted from both the social work and registration notes.

HIV/AIDS support services and status disclosure: These baseline variables were abstracted from the patients' social work and office visit notes. The HIV/AIDS support services variables were abstracted if the given support service(s) was the first record captured in the patient's social work or office visit notes within the given period under observation. Similarly, the HIV/AIDS status disclosure information was abstracted if the given disclosure information was the first record captured in the notes, during the observation period. In addition, previous records noting the HIV/AIDS status disclosure of patients were also reviewed and status disclosure information was abstracted if this information was not captured within the given time frame of interest.

Abstraction Source: Logician and CAREWare

Health insurance and ART medication(s): The patient insurance type and ART medication(s) abstracted from CAREWare reflected the patient's information that was updated onto CAREWare on March 1, 2012. The insurance status of patients that were missing from CAREWare was captured using the patient's electronic medical records. Since the registration charts, in the electronic medical records, do not archive past insurance history, the insurance of clients during the specified year of interest could not be obtained. Therefore, missing insurance types were imputed using the most current insurance status as of January 1, 2013. The missing baseline insurance type was replaced given the assumption that a small number of patients would change their insurance status in the time frame between March 1, 2012 (the baseline date for variables

abstracted from CAREWare) and January 1, 2013. The patient's ART medication(s) missing from CAREWare was captured using the patient's medical records. The ART medication(s) that the patient was on, in the given observation period, was abstracted.

Data Analytic Plan:

All statistical analyses were performed using the SAS 9.3 statistical software package (SAS Institute Inc., Cary, NC). The Pearson X^2 and independent samples t-tests were used to assess the unadjusted associations between the patients' baseline characteristics and retention status. Bivariate and multivariate logistic regression analyses were employed in order to determine the significant predictors influencing an HIV/AIDS individual's risk of falling out of care. Variables that were significant at the alpha level of 0.05 in the unadjusted analysis were considered as candidates for the multivariate analysis. A backward elimination method of selecting variables was also utilized. A model selection criterion was established at the significance alpha level of 0.05 to obtain the most parsimonious logit model that best fitted the data.

Results

Sample Characteristics and Unadjusted Associations with Out-of-Care Status:

From October 1, 2011, to October 1, 2012, the Ryan White CAREWare database reported that the Nathan Smith Clinic provided outpatient primary care services to 698 HIV/AIDS patients. Of this total, 696 patients were eligible for the study. From the eligible sample, 134 (19.3%) HIV/AIDS individuals were determined to be out-of-care under the HRSA definition for retention in care. The remaining 562 (80.8%) HIV/AIDS patients met the HRSA definition and were considered to be retained in care.

Tables 1-4 provide demographic, socioeconomic, clinical, HIV/AIDS status disclosure and support services descriptive of patients at the Nathan Smith Clinic and unadjusted associations between patient characteristics and out-of-care status. The majority of clients (51.6%) at the Clinic were 50 years of age or older. There was not a statistically significant association between age group and out-of-care status [$p=0.777$]. More than half of the clients (60.9%) were males. Among those who were males, 22.9% were out-of-care and among those who were females, 13.6% were out-of-care. There was a statistically significant association between retention status and gender [$p=0.003$]. About 41.1% of the patients at the Clinic had Medicaid as their primary source of insurance, while 6.9% of the patients had no insurance. There was a significant association between insurance type and retention status [$p=0.007$]. Educational background was missing for 23.0% ($n=160$) of the clients at the Clinic. For clients whose education information was captured, no statistical difference was observed between education and retention status [$p=0.685$].

More than half of the patients (56.4%) had CD4 counts greater than or equal to 500 cell/mm^3 , while only 9.9% of the patients had CD4 counts less than 200 cell/mm^3 or clinically defined AIDS. There was no statistically significant association observed between CD4 count and retention status [$p=0.379$]. Clients at the Clinic predominately had undetectable viral load levels (66.2%). Individuals with high viral loads composed only 3.0% of the client population. However, among those with high viral loads, more than a quarter of the patients (33.3%) were out-of-care. Moreover, among those with unsuppressed viral loads, almost one fourth of the patients (24.3%) were out-of-care. A significant association was observed between viral load levels and retention status [$p=0.041$]. Greater than half of the patients (69.1%) at the Clinic were on a multiple pills ART regimen, while only a little more than one fourth of the patients (27.0%) were on a fixed, single pill ART regimen. A statistical difference was observed between type of ART regimen and retention status [$p=0.017$].

Status disclosure information was missing for 132 patients at the Clinic, with 26 or 19.7% of those with missing information being out-of-care. Of the status disclosure information that was available, no statistical difference was observed between HIV/AIDS status disclosure and retention status [$p=0.925$]. Of the clients who sought primary care at the Clinic, greater than three quarters of the patients had no HIV/AIDS support services such as medical case management (75.4%), mental health services (77.9%) and substance abuse services (92.8%).

Retention status was significantly associated with whether clients had medical case management [$p=0.001$] as well as mental health services [$p<0.001$]. However, the association between retention status and substance abuse services did not reach statistical significance [$p=0.177$]. Nonetheless, the use of any of the three services was significantly associated with retention status [$p<0.001$].

Bivariate and Multivariate Descriptive:

Table 5 presented the bivariate and reduced multivariate logistic regression models predicting characteristics associated with the risk of falling out-of-care. A bivariate logistic regression model was performed for each variable of interest. The following characteristics were determined to have an unadjusted statistically significant association with retention status at the alpha level of 0.05: gender, health insurance, viral load, type of ART regimen and HIV/AIDS support services. Males were observed to be 1.88 times as likely to fall out-of-care compared with females [unadjusted OR 95% CI (1.25, 2.85)]. Patients with no insurance [unadjusted OR: 3.23, $p=0.003$], with private insurance [unadjusted OR: 2.38, $p=0.003$] or with Medicaid [unadjusted OR: 1.95, $p=0.017$] were at an increased risk of falling out-of-care compared to individuals with Medicare. HIV/AIDS patients with unsuppressed viral loads had a 1.65-fold increased odds of falling out-of-care compared to HIV/AIDS patients who had undetectable viral loads [unadjusted OR 95% CI (1.06, 2.58)]. Although patients with high viral loads were observed to be 2.57 times as likely to fall out-of-care compared to patients with undetectable viral loads [unadjusted OR 95% CI (1.00, 6.57)], this association was marginal and statistically non-significant at the alpha level of 0.05. There was a statistically significant unadjusted association between no ART regimen and out-of-care status. Clients on no ART regimen were 2.86 times more likely to fall out-of-care compared to individuals on a multiple pills ART regimen [unadjusted OR 95% CI (1.27, 6.48)]. An unadjusted statistically significant association was observed between medical case management services and retention status as well as mental health services and retention status. Clients who had no case management were 2.41 times as likely to fall out-of-care compared to clients who had case management [unadjusted OR 95% CI (1.42, 4.10)]. The odds of falling out-of-care for individuals who did not receive mental health services were 3.82-fold higher compared to individuals who had mental health services [unadjusted OR 95% CI (2.00, 7.28)]. Lastly, HIV/AIDS clients who had none of the three services (i.e. medical case management, mental health or substance abuse) had a 3.46-fold increased odds of falling out-of-care compared to individuals who had any one of the three services [unadjusted OR 95% CI (2.20, 5.45)].

When the predictors that had statistically significant unadjusted associations with retention status were incorporated into a multivariate logistic regression model, the following variables were non-significant or marginally non-significant at the alpha level of 0.05: private health insurance [$p=0.084$], suppressed viral load [$p=0.191$], unsuppressed viral load [$p=0.050$], no ART medication [$p=0.054$] and fixed, single pill ART medication [$p=0.256$] (see Table 6). In order to discover the most parsimonious model that would best fit the data, a backward elimination method was employed. The model selection technique yielded three statistically significant predictors (i.e. gender,

health insurance and having any of the three services) of retention that best represented the data. When the type of insurance and having any of the three services were taken into account, the odds of falling out-of-care for males (compared to females) were attenuated [adjusted OR: 1.81]. After adjusting for the other covariates (i.e. gender and having any of the three services), the odds that individuals with Medicaid [adjusted OR: 2.47] or no insurance [adjusted OR: 3.30] would fall out-of-care (when compared to individuals with Medicare) were increased. Lastly, when adjusting for gender and the type of insurance, the likelihood that HIV/AIDS clients who had none of the three services would fall out-of-care (when compared to HIV/AIDS clients who had any one of the three services) was reduced [adjusted OR: 3.29].

Discussion

Results and Implications:

The chief purpose of this study was to characterize HIV/AIDS patients to discover key barriers or predictors that may affect HIV/AIDS patients' retention in care at the Yale-New Haven Hospital Nathan Smith Clinic. Gender was found to be an important predictor as it was highly significant in both the bivariate and reduced multivariate analyses (see Table 5). Once the complexity of the model was addressed, three categories of variables were determined to be associated with retention status. Females were less likely to fall out of care (see Table 5). Individuals with Medicare were the least likely to fall out of care (see Table 5). Patients who did not have any of the three HIV/AIDS support services (e.g. medical case management, mental health, or substance abuse) were highly at risk of falling out of care (see Table 5). In aggregate, these findings suggested that barriers affecting engagement in care at the Nathan Smith Clinic involved gender and insurance differences as well as engagement in support services.

In order to optimize longitudinal care and improve clinical health outcomes, an HIV/AIDS multidisciplinary team model should be devised to target these three predictors of retention. Outreach initiatives designed to better engage male patients as well as patients with Medicaid, no insurance and private insurance could help to ensure regular primary care follow-up with health care providers. Beyond primary care services, HIV/AIDS support services such as medical case management, mental health services and substance abuse services are also crucial in the continuum of HIV care. Medical case managers along with mental health and substance abuse providers are an added source of contact for HIV/AIDS clients. In addition to providing counseling, mental health and substance abuse providers should take on the role of a medical case manager to identify and address other personal and/or physical barriers that may prevent their clients from making the necessary appointments at their primary care center, as well as to follow-up on whether their clients were able to make their appointments. Lastly, an increase in medical case manager capacity will ensure that all patients at the Clinic are assigned to a medical case manager. This will guarantee that individuals who do not need a mental health and substance abuse counselor would have a health care contact beyond that given through their primary care provider. Therefore, better engagement may require additional resources to be allocated to these services to support interventions aimed at augmenting retention in care.

Analyses and Model Limitations:

The results obtained from the analyses should be interpreted with respect to the limitations of the study. First, due to the restricted availability of certain patient information, not all variables influencing retention status were investigated. Therefore, the final model may exclude other significant predictors of retention. In addition, missing client information (i.e. education and status disclosure) and imputed information (i.e. insurance type) may have compromised the analyses and the results obtained from them. Although the goal of model selection was to produce a predictive model that was parsimonious and accurate as it excluded variables that do not contribute to explaining

differences in the dependent variable, the accuracy of the available data may influence the quality of the results produced by the reduced model. Lastly, as with all observational studies, one was able to identify associations but cannot attribute causality.

CAREWare Database and Logician (GE Centricity) Limitations:

The secondary purpose of this study was to investigate the use of the community CAREWare database to study predictors of engagement in care. The database had the potential to assess the demographics of patients and to populate reports identifying in-care and out-of-care clients. However, two elements influenced the accuracy, precision and availability of the data. Heterogeneous data entry may result due to imprecise or incorrect data entry by personnel. Since HRSA does not provide funds to support data coordinators, certain patient information became unavailable as priorities were made to capture only what was required for HRSA's RSR reports. Although variables such as date of birth, gender, race/ethnicity and HIV risk factors were readily obtainable through CAREWare, other predictors of interest, captured by CAREWare, had missing patient information or were not captured by the database. It was noted that 38.9% of the patients' insurance status and 3.9% of the patients' ART medication information were missing from the database. In this event, each patient's medical charts were reviewed to obtain the necessary value(s) for analyses. Additionally, variables such as education, marital status, residency status, HIV/AIDS support services and status disclosure were obtained through medical chart reviews because these variables were limited or not captured by CAREWare. Although CAREWare does record all CD4 and viral load count lab values, we were interested in the first recorded lab values within our given time frame, or else the most recent lab readings prior to October 1, 2011, to serve as the baseline CD4 and viral load measures. It was difficult to isolate these measurements in CAREWare because there were no program algorithms that could populate a report to identify the baseline lab values of interest. Therefore, it was most efficient and practical to abstract baseline CD4 and viral load lab values from the patients' medical charts.

Like CAREWare, Logician (GE), the Yale-New Haven Hospital Nathan Smith Clinic's electronic medical record system, is a dynamic medical database—in that it captures the most up-to-date patient information. Unlike CAREWare, specific baseline measurements can be easily obtained, in Logician, as dates are denoted along with the given patient information. Nonetheless, a limitation was noted in Logician pertaining to insurance status. Since the electronic patient registration charts do not keep records of past insurance history, the insurance of clients during the specified year of interest could not be obtained. Therefore, missing insurance types were imputed using the most current insurance status as of January 1, 2013. Replacement of the missing baseline insurance type with the current information was a limitation; a strong assumption was made in regards to the fact that a small number of patients would change their insurance status in the time frame between March 1, 2012 (the baseline date of variables abstracted from CAREWare) and January 1, 2013. Additionally, health care providers and social workers are not required to document patients' educational level, whether patients are utilizing support services or have disclosed

their HIV/AIDS status, and the patients may not have voluntarily disclosed this information. It is therefore possible that the social work and office visit notes used to abstract the education, status disclosure and HIV/AIDS support services variables were missing relevant details.

There was also a concern as to the accuracy of the list of in-care and out-of-care patients generated by CAREWare. Although it was possible for one to exclude newly diagnosed or new patients who may be wrongly classified as being out-of-care, it was not possible for one to guarantee that patients who were deceased, who had transferred their primary care needs to another health care facility, and who were incarcerated and were not able to return for a second visit or make a first visit until April 1, 2012 (the cut-off date) were not wrongly classified as out-of-care. While active CAREWare data management is continuously carried-out to ensure that the lists of in-care and out-of-care patients are as accurate as possible, if a patient's death was not reported to the Clinic, then the individual would be classified in CAREWare as out-of-care. Likewise, if no notifications were received by the Clinic in regards to a patient receiving primary care at a different health care facility, then the patient would also be considered, in CAREWare, as out-of-care. Moreover, if incarceration status was not made known to the Clinic and, due to the arrest, clients were not able to return for their second primary care visit or make an initial primary care visit until April 1, 2012, then these patients would be improperly categorized as out-of-care, by CAREWare.

Lastly, given that the CAREWare database only captures patients who are clients at Ryan White funded agencies, the statistical findings cannot be generalized to the population of HIV/AIDS individuals at other sites. Our analysis may only contribute insights applicable to the Clinic and to similar settings.

Future Directions:

In summary, the limitations of this investigation bring awareness to the challenges that must be overcome for health care professionals and public health officials to conduct sound epidemiological research, as well as to develop an HIV multidisciplinary team model to enhance retention and improve health outcomes. In order for the CAREWare database to be a promising implementation research tool, HRSA should consider the allocation of Ryan White funds to support a greater capacity of full-time data coordinators and Information Technology (IT) personnel at agencies. Providing organizations with the financial means to hire full-time or more data managers would result in improved data maintenance (i.e. less missing patient information) and the capture of more patient information (i.e. socioeconomic factors). The ability to support IT personnel would allow new program algorithms to be built into CAREWare that would expedite data collection through the generation of specific custom reports for implementation research. Moreover, IT personnel may be able to develop a computer program interface which would allow patient information entered into the Clinic's electronic medical charts to be automatically captured in the CAREWare database. This program interface will be useful, as it would limit the potential errors that may be associated with the manual entry of patient information into CAREWare. Lastly, with enhanced data integrity, IT personnel can also facilitate the connection of Ryan White CAREWare databases among various agencies so that they are accessible by

other agencies; this will enable health care providers as well as researchers to share, track and note a patient's in-care status.

Nonetheless, the push for Federal fund considerations is a difficult and challenging issue. Therefore, in order to refine and validate our findings, the next research step would be to conduct a prospective cohort study to reconfirm and discover new risk factors associated with retention. A prospective cohort design would allow the research group to have better control over patient enrollment eligibility, the collection of more variables of interest and less reliance on medical charts and databases for data abstraction. An additional advantage of a prospective cohort study lies in the fact that it is a longitudinal observational study, where data collection is recorded at regular time intervals over time. This means that recall, data entry and reporting errors will be minimized. The reduction of these potential biases would strengthen the findings obtained through analyses.

List of Tables

Table 1. Demographic Descriptive of Patients at the Nathan Smith Clinic and Unadjusted Associations between Patient Characteristics and Out-of-Care Status^a

Characteristic	Overall N = 696 (100%) ^b	Out-of-care ¹ N= 134 (19.3%) ^b	p ^c
Age (yrs.) ^d			0.777
18-33	74 (10.6)	12 (16.2)	
34-49	263 (37.8)	51 (19.4)	
50+	359 (51.6)	71 (19.8)	
Gender			0.003
Male	424 (60.9)	97 (22.9)	
Female	272 (39.1)	37 (13.6)	
Race/ethnicity			0.477
Non-Hispanic white	221 (31.8)	49 (22.2)	
Non-Hispanic black	323 (46.4)	59 (18.3)	
Hispanic	126 (18.1)	23 (18.3)	
Asian/Other	26 (3.7)	3 (11.5)	
Marital status			0.734
Single	378 (54.3)	73 (19.3)	
Married/partnership	123 (17.7)	22 (17.9)	
Separated/divorced	159 (22.8)	34 (21.4)	
Widowed	36 (5.2)	5 (13.9)	
HIV risk factor			0.635
Heterosexual	296 (42.6*)	54 (18.2)	
MSM or MSM/IDU	189 (27.2*)	41 (21.7)	
IDU	173 (24.9*)	33 (19.1)	
Other	37 (5.3*)	5 (13.5)	
Missing	1 (0.1**)	1 (100.0)	

^a Table values are n (column %) to describe categorical variables for the overall sample and n (row %) to describe categorical variables for the out-of-care outcome.

^b Numbers may not sum to total due to missing data, and percentages may not sum to 100% due to rounding.

^c P-value is from the χ^2 test for categorical variables.

^d Age at the exclusion date for new to Nathan Smith Clinic care/newly diagnosed HIV patients (April 1, 2012).

¹ Under the HRSA definition for retention in care, HIV/AIDS patients are considered “retained” if, over a 12 months period, they have \geq two primary care visits, with each visit being at least 3 months apart.

*Denominator: N=695 **Denominator: N=696

Table 2. Socioeconomic Descriptive of Patients at the Nathan Smith Clinic and Unadjusted Associations between Patient Characteristics and Out-of-Care Status^a

Characteristic	Overall N = 696 (100%) ^b	Out-of-care ¹ N= 134 (19.3%) ^b	p ^c
Health insurance			0.007
Medicaid	286 (41.1)	57 (19.9)	
Medicare	177 (25.4)	20 (11.3)	
Private	185 (26.6)	43 (23.2)	
No insurance	48 (6.9)	14 (29.2)	
Education			0.685
Less than high school	95 (17.7*)	16 (16.8)	
High school graduate/GED	228 (42.5*)	39 (17.1)	
College/post graduate	197 (36.8*)	42 (21.3)	
Other	16 (3.0*)	3 (18.8)	
Missing	160 (23.0**)	34 (21.3)	
Residency status			0.744
Stable/permanent ^d	654 (94.0)	126 (19.3)	
Institution ^e	16 (2.3)	4 (25.0)	
Non-permanently housed/homeless ^f	26 (3.7)	4 (15.4)	

^a Table values are n (column %) to describe categorical variables for the overall sample and n (row %) to describe categorical variables for the out-of-care outcome.

^b Numbers may not sum to total due to missing data, and percentages may not sum to 100% due to rounding.

^c P-value is from the χ^2 test for categorical variables.

^d Stable/permanent residency status encompassed patients who resided at a permanent address, senior housing or were under supervised assisted living.

^e Institution residency status encompassed patients who resided in nursing homes (i.e. Leeway), HIV/AIDS supportive community establishments (i.e. Liberty House) and recovery/rehabilitation institutions (i.e. the CT Mental Health Center, sober house, or Sierra House).

^f Non-permanently housed/homeless residency status encompassed patients who resided in a shelter (i.e. Columbus House), with friends, at a motel or were transient.

¹ Under the HRSA definition for retention in care, HIV/AIDS patients are considered "retained" if, over a 12 months period, they have \geq two primary care visits, with each visit being at least 3 months apart.

*Denominator: N=536 **Denominator: N=696

Table 3. Clinical Descriptive of Patients at the Nathan Smith Clinic and Unadjusted Associations between Patient Characteristics and Out-of-Care Status^a

Characteristic	Overall N = 696 (100%) ^b	Out-of-care ¹ N= 134 (19.3%) ^b	p ^c
CD4 count (cell/mm ³) ^{e,f}			0.379
<200	69 (9.9*)	14 (20.3)	
200-499	234 (33.7*)	51 (21.8)	
\geq 500	392 (56.4*)	68 (17.3)	
Missing	1 (0.1**)	1 (100.0)	
Viral load (copies/mL) ^{e,g}			0.041
High viral load	21 (3.0*)	7 (33.3)	
Not suppressed	152 (21.9*)	37 (24.3)	
Suppressed	62 (8.9*)	14 (22.6)	
Undetectable	460 (66.2*)	75 (16.3)	
Missing	1 (0.1**)	1 (100.0)	
Type of ART regimen ^h			0.017
None	27 (3.9)	10 (37.0)	
Fixed, single pill	188 (27.0)	42 (22.3)	
Multiple pills	481 (69.1)	82 (17.0)	

^a Table values are n (column %) to describe categorical variables for the overall sample and n (row %) to describe categorical variables for the out-of-care outcome.

^b Numbers may not sum to total due to missing data, and percentages may not sum to 100% due to rounding.

^c P-value is from the χ^2 test for categorical variables.

^e The first lab value captured within the specified year under observation (October 1, 2011 to October 1, 2012) or the lab value most recent prior to October 1, 2011.

^f The CD4 count classification is based on the CDC's surveillance case definition for HIV infection among adults and adolescents (age \geq 13 years) in the United States, 2008.⁴³

^g The viral load classification is based on the CDC's standardized categorical measures used to assess the quality of HIV care and the possible transmission potential for the HIV-infected population that is receiving care.⁴⁴

^h The current single pill, antiretroviral therapy (ART), prescribed at the Nathan Smith Clinic is either Complera or Atripla.

¹ Under the HRSA definition for retention in care, HIV/AIDS patients are considered "retained" if, over a 12 months period, they have \geq two primary care visits, with each visit being at least 3 months apart.

*Denominator: N=695 **Denominator: N=696

Table 4. HIV/AIDS Status Disclosure and Support Services Descriptive of Patients at the Nathan Smith Clinic and Unadjusted Associations between Patient Characteristics and Out-of-Care Status^a

Characteristic	Overall N = 696 (100%) ^b	Out-of-care ¹ N= 134 (19.3%) ^b	p ^c
HIV/AIDS status disclosure			0.925
Yes	521 (92.4*)	100 (19.2)	
No	43 (7.6*)	8 (18.6)	
Missing	132 (19.0**)	26 (19.7)	
HIV/AIDS support services			
Medical case management ^d			0.001
Yes	171 (24.6)	18 (10.5)	
No	525 (75.4)	116 (22.1)	
Mental health service ^e			<0.001
Yes	154 (22.1)	11 (7.1)	
No	542 (77.9)	123 (22.7)	
Substance abuse service ^f			0.177
Yes	50 (7.2)	6 (12.0)	
No	646 (92.8)	128 (19.8)	
Any of the 3 services			<0.001
Yes	289 (41.5)	27 (9.3)	
No	407 (58.5)	107 (26.3)	

^a Table values are n (column %) to describe categorical variables for the overall sample and n (row %) to describe categorical variables for the out-of-care outcome.

^b Numbers may not sum to total due to missing data, and percentages may not sum to 100% due to rounding.

^c P-value is from the χ^2 test for categorical variables.

^d Patients with medical case management were those who, according to the social work notes, had seen or communicated with a medical case manager.

^e Patients with mental health services were those who, according to the social work or office visit notes, had a psychiatrist or attended psychotherapy (individual or group) sessions.

^f Patients with substance abuse services were those who, according to the social work or office visit notes, attended sober recovery/rehabilitation (individual or group) meetings or addiction support services/counseling.

¹ Under the HRSA definition for retention in care, HIV/AIDS patients are considered "retained" if, over a 12 months period, they have \geq two primary care visits, with each visit being at least 3 months apart.

*Denominator: N=564 **Denominator: N=696

Table 5. Bivariate and Reduced Multivariate Logistic Regression Models Predicting Characteristics Associated with the Risk of Falling Out of Care

Characteristic	Unadjusted OR Model (95% CI)	p	Reduced OR Model (95% CI) ^a	p
Age (yrs.)				
18-33	1.00	---		
34-49	1.24 (0.62, 2.48)	0.537		
50+	1.27 (0.65, 2.49)	0.480		
Gender				
Male	1.88 (1.25, 2.85)	0.003	1.81 (1.17, 2.82)	0.008
Female	1.00	---	1.00	---
Race/ethnicity				
Non-Hispanic white	2.18 (0.63, 7.58)	0.219		
Non-Hispanic black	1.71 (0.50, 5.90)	0.393		
Hispanic	1.71 (0.47, 6.19)	0.412		
Asian/Other	1.00	---		
Marital status				
Single	1.48 (0.56, 3.94)	0.430		
Married/partnership	1.35 (0.47, 3.86)	0.576		
Separated/divorced	1.69 (0.61, 4.66)	0.315		
Widowed	1.00	---		
HIV risk factor				
Heterosexual	1.43 (0.53, 3.83)	0.479		
MSM or MSM/IDU	1.77 (0.65, 4.84)	0.264		
IDU	1.51 (0.55, 4.17)	0.428		
Other	1.00	---		
Health insurance				
Medicaid	1.95 (1.23, 3.38)	0.017	2.47 (1.39, 4.38)	0.002
Medicare	1.00	---	1.00	---
Private	2.38 (1.34, 4.23)	0.003	1.86 (1.03, 3.36)	0.040
No insurance	3.23 (1.49, 7.03)	0.003	3.30 (1.48, 7.38)	0.004
Education				
Less than high school	1.00	---		
High school graduate/GED	1.02 (0.54, 1.93)	0.954		
College/post graduate	1.34 (0.71, 2.53)	0.370		
Other	1.14 (0.29, 4.46)	0.851		
Residency status				
Stable/permanent	1.31 (0.44, 3.88)	0.623		
Institution	1.83 (0.39, 8.67)	0.445		
Non-permanently housed/homeless	1.00	---		
CD4 count (cell/mm ³)				
<200	1.21 (0.64, 2.31)	0.556		
200-499	1.33 (0.89, 1.99)	0.171		
≥500	1.00	---		
Viral load (copies/mL)				
High viral load	2.57 (1.00, 6.57)	0.050		
Not suppressed	1.65 (1.06, 2.58)	0.027		
Suppressed	1.50 (0.79, 2.85)	0.220		
Undetectable	1.00	---		
Type of ART regimen				
None	2.86 (1.27, 6.48)	0.012		
Fixed, single pill	1.40 (0.92, 2.13)	0.114		
Multiple pills	1.00	---		
HIV/AIDS status disclosure				
Yes	1.04 (0.47, 2.31)	0.926		
No	1.00	---		
HIV/AIDS support services				
Medical case management				
Yes	1.00	---		
No	2.41 (1.42, 4.10)	0.001		
Mental health				
Yes	1.00	---		
No	3.82 (2.00, 7.28)	<0.001		
Substance abuse				
Yes	1.00	---		
No	1.81 (0.76, 4.35)	0.183		
Any of the 3 services				
Yes	1.00	---	1.00	---
No	3.46 (2.20, 5.45)	<0.001	3.29 (2.05, 5.26)	<0.001

^a For the reduced parsimonious OR model, N =696.

Table 6. Multivariate Logistic Regression Model Predicting Characteristics Associated with the Risk of Falling Out of Care ^a

Characteristic	Adjusted OR (95% CI) ^b	p
Gender		
Male	1.95 (1.24, 3.07)	0.004
Female	1.00	---
Health insurance		
Medicaid	2.28 (1.26, 4.11)	0.006
Medicare	1.00	---
Private	1.71 (0.93, 3.14)	0.084
No insurance	2.69 (1.17, 6.19)	0.020
Viral load (copies/mL)		
High viral load	3.69 (1.27, 10.69)	0.016
Not suppressed	1.65 (1.00, 2.71)	0.050
Suppressed	1.58 (0.80, 3.12)	0.191
Undetectable	1.00	---
Type of ART regimen		
None	2.47 (0.98, 6.18)	0.054
Fixed, single pill	1.30 (0.83, 2.04)	0.256
Multiple pills	1.00	---
Any of the 3 HIV/AIDS support services ^c		
Yes	1.00	---
No	3.46 (2.14, 5.59)	<0.001

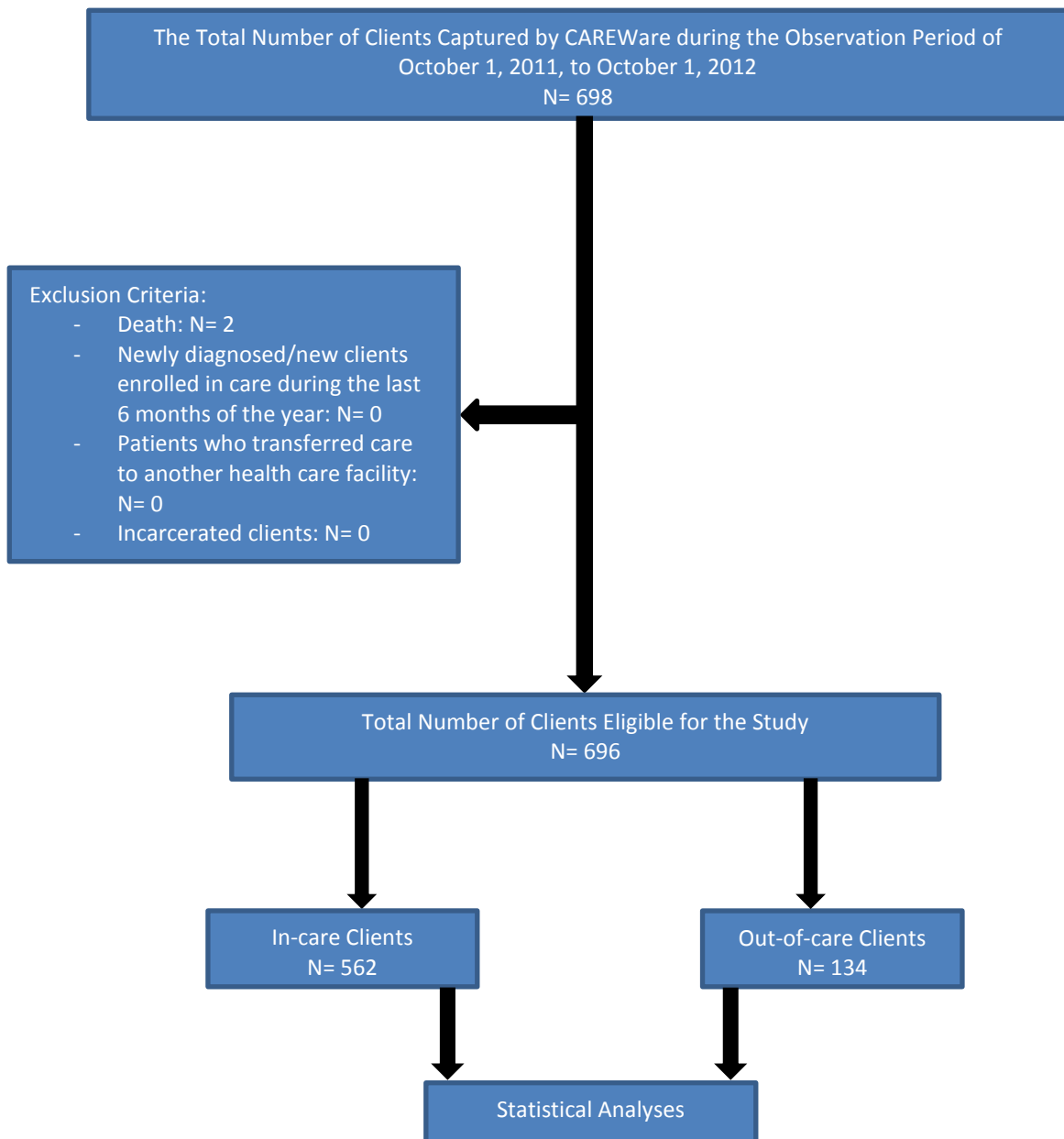
^a Patient characteristics observed to have statistically significant unadjusted association (at the alpha level of 0.05) with retention status were employed for this model. Although individual HIV/AIDS support services such as medical case management and mental health services were statistically significant, they were left out of the model as the variable 'Any of the 3 HIV/AIDS support services' was used.

^b For the fully-adjusted model, N =695.

^c The 3 HIV/AIDS support services included medical case management, mental health services and substance abuse services.

List of Figures

Figure 1. Schematic Diagram Overviewing HIV/AIDS Patients' Inclusion Eligibility and the Study Sample



Appendix I: Tables

Table 7. Supplementary Description of Continuous Variables and Unadjusted Associations between Patient Characteristics and Retention Status ^a

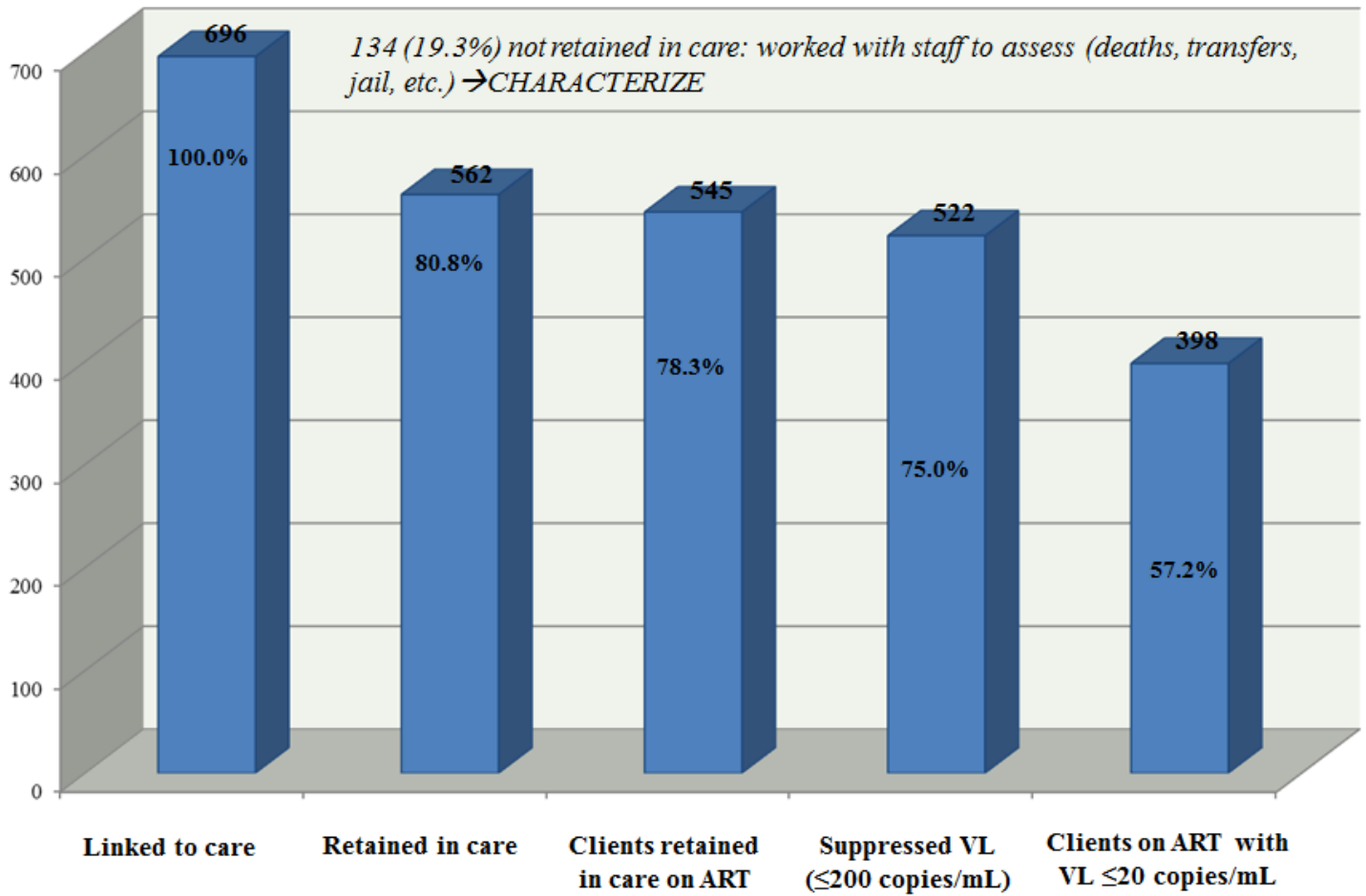
Characteristic	In-care N= 562 (80.75%)	Out-of-care N= 134 (19.25%)	P ^b
Age (yrs.)	(49.13 ± 11.11)	(48.58 ± 9.77)	0.603
Range (min, max)	(19, 82)	(21, 73)	
CD4 count (cell/mm ³)	(601.54 ± 351.14)	(540.86 ± 331.77)	0.071
Range (min, max)	(4, 2206)	(6, 1658)	
Viral load (copies/mL)	(16420.26 ± 98779.26)	(70407.27 ± 644473.61)	0.337
Range (min, max)	(0, 1360422.00)	(0, 7423270.00)	

^a Table values are mean ± SD and minimum and maximum values for continuous variables.

^b P-value is from the t-test for continuous variables.

Appendix II: Figures

Figure 2. Engagement in HIV/AIDS Care at the Nathan Smith Clinic (October 1, 2011 to October 1, 2012)



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