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Title: Examining Survival of People Diagnosed with HIV in Florida Between 2015-2021 Following a Late, Delayed, or Timely Diagnosis

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Declarations

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Abstract

Introduction: Late HIV diagnosis is a global concern linked to poor health outcomes and is a barrier to ending the HIV epidemic. However, differences in survival outcomes between late and

delayed diagnoses remain unclear in the era of effective treatments. This study examined all-cause mortality among individuals with late (CD4 <200 cells/μL), delayed (200≤CD4<350 cells/μL), or timely (CD4≥350 cells/μL) HIV diagnoses in Florida from 2015–2021.

Setting: Using data from the Florida Enhanced HIV/AIDS Reporting System (eHARS), we included 24,374 individuals with at least three CD4 tests. Mortality data were linked through the National Death Index and Social Security Death Index.

Methods: Cox proportional hazards models and Kaplan-Meier curves assessed mortality risk, adjusting for age, year of diagnosis, race/ethnicity, and sex.

Results: Among participants (mean age 37.1 years; 20% female; 39% non-Hispanic Black; 34% Hispanic; 25% non-Hispanic White), 895 deaths (4%) occurred. Late and delayed diagnoses accounted for 23% and 18% of cases, respectively. Compared to timely diagnosis, the hazard of death was significantly higher for late (HR=2.18, 95% CI: 1.89–2.52) and delayed (HR=1.25, 95% CI: 1.03–1.52) diagnoses. Female sex and older age were associated with increased mortality, while Hispanic and non-Hispanic Black individuals had lower mortality risks.

Conclusion: Late and delayed HIV diagnoses were associated with elevated mortality risk, with late diagnosis posing the greatest risk. These findings underscore the need for earlier HIV detection and intervention to improve survival outcomes.

Introduction

Late HIV diagnosis is a perennial barrier to the ending the HIV Epidemic (EHE) initiative[1] and is associated with worse health, increased morbidity, and opportunistic infections.[2–7] There is also a higher risk for other poor outcomes following a late HIV diagnosis, such as a longer time to achieve suppressed viral load,[8] worse viral load trajectories,[9,10] higher

cost of medical care, poor response to treatment, and mortality.[3,11–18] Additionally, those with a late HIV diagnosis have been living with untreated HIV for a prolonged period of time, up to years, potentially unknowingly transmitting HIV.[2,19] Late diagnosis is defined as meeting AIDS case criteria (CD4<200 cells/μL or AIDS-defining event) at the time of diagnosis or within three months of initial HIV diagnosis according to the Centers for Disease Control and Prevention (CDC) and other public health organizations.[20] Internationally, both the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO) Regional Office for Europe define late diagnosis as entering HIV care with a CD4 count below 350 cells/μL.[21]

It is unclear whether there is clinical significance to these differing late diagnosis criteria; however, evaluating outcomes following a late diagnosis may offer valuable insight into this issue. As an example, if those with a CD4 <350 cells/μL at diagnosis experienced morbidity and mortality at a rate similar to those diagnosed at CD4 <200 cells/μL, it could be prudent to broaden the definition of late HIV diagnosis used in the United States to more accurately capture those at risk and enhance public health strategies and clinical care. Florida, like many areas of the Southern United States,[24] experiences a high HIV burden.[1,25] Though Florida ranks among the highest states in the number of HIV tests conducted,[26] in 2022, 22% of new HIV diagnoses in Florida were late.[27] Gaining insight into outcomes following a late HIV diagnosis could help public health officials and clinicians in high-incidence and high-prevalence areas better allocate resources and develop targeted policies to support affected populations.

This study aimed to assess both all-cause and HIV-associated mortality among individuals who had had a late (CD4<200 cells/μL), delayed (200 cells/μL≤CD4<350 cells/μL), or timely (≥350 cells/μL) HIV diagnosis between 2015-2021 in Florida. We also considered the

effect of factors that could be associated with mortality risk, i.e. age, race/ethnicity, sex, and calendar year of diagnosis. We hypothesized that (1) individuals with delayed or late HIV diagnoses would have a higher risk of all-cause and HIV-associated mortality compared to those with timely diagnoses; and (2) the mortality risks associated with late and delayed diagnoses would be comparable.

Methods

Study Design and Sample

This study employed a retrospective observational epidemiologic design using surveillance data from the Enhanced HIV/AIDS Reporting System (eHARS), a tool was developed by the CDC to support state and local health departments in managing and analyzing HIV surveillance data.[28] Inclusion criteria were receiving a new HIV diagnosis[29] in Florida between January 1, 2015-December 31, 2021 with CD4 test results and other laboratory data from the time of their diagnosis. All participants needed to have laboratory CD4 tests from at least three timepoints, regardless of time between points, to be included in this analysis. This criterion was chosen to better assess disease progression and reduce misclassification of diagnosis timing. Of 30,411 individuals[30] newly diagnosed with HIV in Florida between 2015 and 2021, 6,037 (20%) were excluded due to having fewer than three CD4 measurements, resulting in a final sample of 24,374.

Of the 24,374 individuals in the sample, the mean age was 37.1 years (standard deviation [SD]=13.0, median age=34.0 years), 20% were assigned female at birth, 39% were non-Hispanic Black, 34% were Hispanic, 25% non-Hispanic White, and 2% non-Hispanic other race. Of new diagnoses during the study period, 17% occurred in 2015, 18% in 2016, 17% in 2017, 17% in 2018, 15% in 2019, 10% in 2020, and 6% in 2021.

[Table 1]

This study was determined to be non-human research and given authorization by the Florida Department of Health (FDOH) IRB and by the University of Florida IRB.

Definitions of Late and Delayed HIV Diagnosis

Late diagnosis was defined as CD4<200 cells/μL, delayed diagnosis as CD4≥ 200 and <350 cells/μL, and timely diagnosis as CD4≥350 cells/μL. This determination was made using the first laboratory test available in eHARS for each individual.

Variables

The eHARS dataset included information mandated by the state to be reported from clinical encounters between people with HIV (PWH) and their healthcare providers. This analysis focused on adults; individuals were eligible if they were at least 18 years old at the time of diagnosis. Death data in eHARS were matched weekly by the Florida Department of Health Death against the Bureau of Vital Statistics and matched at least annually against the National Death Index (NDI) and the United States Social Security Death Index (SSDI), with more frequent matching conducted as necessary. Matching with both NDI and SSDI improves completeness and accuracy of death ascertainment, particularly for deaths that occur out of the state.

Analysis

We examined the absolute number and proportion of all-cause and HIV-associated (i.e., HIV is listed as a cause of death on the death certificate) deaths by timely, delayed, and late diagnosis across the study period. Differences in sociodemographic characteristics (age at diagnosis, sex, race/ethnicity, and year of diagnosis) were determined with chi-square tests for

categorical variables and Kruskal-Wallis for the continuous age variable. Unadjusted restricted mean survival was used to assess differences in time before mortality occurred during the study period between the diagnosis groups, with significance tested via Wald chi-square testing. To account for potential confounding, continuous age, race/ethnicity, sex, and year of diagnosis were included in the adjusted Cox proportional hazards models and Kaplan-Meier survival curves for both all-cause and HIV-associated mortality. A significant hazard ratio was one in which the 95% confidence interval (CI) did not include 1.0. R 4.4.0 was used for all analyses.[31]

Results

Sample Characteristics

Approximately 23% (n=5,687) of the sample had a late diagnosis, 18% (n=4,333) had a delayed diagnosis, and 59% (n=14,354) had a timely diagnosis. Those who had a late diagnosis had a significantly ($p<0.001$) older average age compared to those who had a timely diagnosis. Female individuals were overrepresented among those with a late diagnosis ($p < 0.001$), but not among those with a delayed diagnosis. Non-Hispanic Black and non-Hispanic individuals of other races were ($p<0.001$) overrepresented among those with delayed or late diagnoses, while Hispanic individuals were overrepresented only among those with delayed diagnoses. Non-Hispanic White individuals had a significantly higher ($p<0.001$) median age of 38.0 years (mean=39.8 years) than non-Hispanic Black (median=32.0 years, mean=36.0 years), Hispanic (median=34.0 years, mean age=36.5 years), or non-Hispanic other race (median=33.0 years, mean=35.6 years) individuals.

Survival Time and Life Tables

Between 2015 and 2021, there were 895 deaths, representing 4% of the study sample. The average follow-up time after diagnosis was 37.7 months (SD = 21.5). Among individuals

with a timely diagnosis (n=14,354), there were 367 (2.6%) deaths, while 13,987 were censored before the study period ended. In the delayed diagnosis group (n=4,333), there were 138 deaths (3.2%) and 4,195 censored individuals. For those with a late diagnosis (n=5,687), there were 390 deaths (6.7%), with 5,297 censored individuals. Cumulative survival probabilities were 93.6% for timely diagnoses, 93.5% for delayed diagnoses, and 85.8% for late diagnoses. For additional information, see the life tables (Tables 2a-c).

Restricted mean survival time, the average time for mortality to occur following diagnosis during the study period, was 77.1 months (95% CI: 76.6-77.7) for those with a late diagnosis, 80.2 months (95% CI: 79.3-80.7) for those with a delayed diagnosis, and 80.7 months (95% CI: 80.4-80.9) for those with a timely diagnosis. Compared to those who had a timely diagnosis, those who had a late diagnosis had a significantly shorter (p=0.032) adjusted survival time of approximately 2.51 months during the study period. The adjusted between-group contrast between the delayed and timely diagnosis groups was not significant (p=0.568).

[Table 2a-c]

Of the total deaths, 299 (33% of all deaths) were HIV-associated deaths. Of these, 193 (65%) were among those with a late diagnosis, 35 (12%) were among those with a delayed diagnosis, and 71 (24%) were among those with a timely diagnosis. Compared to those with a timely diagnosis, those with a delayed (1.58 [95% CI: 1.05-2.37]), or late (5.52 [95% CI: 4.19-7.27]) diagnosis had a greater hazard of experiencing an HIV-associated death in Cox proportional hazards models.

Examining all-cause mortality, among non-Hispanic White individuals, there were 331 deaths (5.5%), 385 deaths (4.1%) among non-Hispanic Black individuals, 164 deaths (2.0%) among Hispanic individuals, and 15 deaths (2.6%) among non-Hispanic other race individuals.

In the adjusted survival analysis, the hazard of death compared to those with a timely diagnosis was 2.18 (95% CI: 1.89-2.52) for late diagnosis and 1.25 (95% CI: 1.03-1.52) for delayed diagnosis. Moreover, the hazard of mortality among those with a late diagnosis compared to those with a delayed diagnosis was 1.77 (95% CI: 1.45, 2.15). Female sex (1.41 [95% CI: 1.21-1.63]) and age (1.04 [95% CI: 1.03-1.04]) were significantly associated with increased all-cause mortality in the survival analysis while non-Hispanic Black (0.75 [95% CI: 0.64-0.87]), Hispanic (0.43 [95% CI: 0.36-0.52]), and non-Hispanic other race (0.49 [95% CI: 0.29-0.83]), were associated with reduced all-cause mortality, as compared to non-Hispanic White race. Compared to the year 2015, only the years 2019 (1.37 [95% CI: 1.06-1.76]) and 2020 (1.57 [95% CI: 1.10-2.23]) were significantly associated with all-cause mortality. No other years (2016, 2017, 2018, 2021) had a significant association.

[Figure 1]

Discussion

Relative to those with a timely diagnosis, PWH with a delayed or late diagnosis had a significantly higher hazard of all-cause mortality. Those with a late diagnosis had a 2.18 times higher all-cause mortality rate and those with a delayed diagnosis had a 1.25 times higher all-cause mortality rate. Approximately 70% of HIV-associated deaths occurred among individuals with a late HIV diagnosis, and both delayed and late diagnoses were linked to an increased hazard of HIV-related mortality.

Though those with a late diagnosis had a 1.77 times higher all-cause mortality rate than those with a delayed diagnosis, both late and delayed diagnosis were significantly associated with all-cause mortality when compared to a timely diagnosis. Moreover, those with a delayed or a late diagnosis make up approximately 40% of all new HIV diagnoses. At the population level,

this could lead to thousands of excess deaths nationally. These findings highlight the importance of early diagnosis and treatment initiation, consistent with current clinical and public health recommendations aimed at improving survival outcomes. Additionally, they suggest that individuals with a delayed or late diagnosis may benefit from targeted support and resources once they enter care, given their elevated risk of mortality.

Several factors were found to be associated with an increased risk for mortality among people newly diagnosed with HIV. We found that, compared to non-Hispanic White individuals, non-Hispanic Black, Hispanic, and non-Hispanic other race individuals had reduced likelihood of mortality during the study period. This finding seems at odds with what has been found in the literature regarding mortality among people with HIV, particularly among non-Hispanic Black individuals.[32,33] We did find that non-Hispanic White individuals had more deaths during the study period and had a higher mean age, which could contribute to the differences in mortality by race/ethnicity that we observed, but further research is needed to understand the mechanisms behind this finding. The reasons for increased mortality in 2019 and 2020 are also unclear. These trends could be related to disruptions in healthcare access due to a public health emergency during that period,[34–36] though this remains uncertain. The higher mortality among females may be influenced by differences in healthcare access, comorbidities, or social determinants of health, which require further investigation.

Interestingly, individuals with a timely diagnosis made up a higher proportion of HIV-associated deaths (24%) than those with a delayed diagnosis (12%), though those with delayed and late diagnoses had a greater hazard of experiencing an HIV-associated death compared to those who had a timely diagnosis. This may reflect severe comorbid conditions or delayed ART initiation among those with a timely diagnosis, which we were unable to assess in our dataset.

This study contributes to the literature and supports prior findings that late HIV diagnosis is associated with poor outcomes. Among these poor outcomes are high medical care costs, poor treatment response, morbidity, and mortality.[3,11–17] In light of this, perhaps enhanced intervention for those who diagnosed at an advanced stage of HIV infection is warranted, including but not limited to rapid antiretroviral treatment initiation, improved linkage to peer educators and other support systems, increased numbers of follow-up appointments, and communications that can remind patients to adhere to medication and attend appointments. Research has found a higher prevalence of comorbidities among older PWH compared to older adults without HIV,[37,38] which could also contribute to mortality, so interventions to improve outcomes after a late HIV diagnosis could include improving access to treatment for comorbid conditions as well.

Increasing HIV testing is one of the best ways to prevent delayed or late diagnosis generally, and to increase testing it is critical that testing accessibility is improved in a variety of settings. The CDC recommends all individuals between that ages of 13-64 receive at least one HIV test during their lifetime as part of their routine care. Providers could offer tests when people are at the primary care or other relevant appointments to avoid missed opportunities for testing.[39] Providers could also recommend more frequent testing for populations at higher risk for HIV acquisition. A significant barrier to HIV testing is HIV stigma, which has been shown to impact behavior and outcomes at every stage of the HIV continuum of care and overall healthcare engagement.[40–43] Reducing stigma requires educational efforts targeting not only the broader community, but also healthcare providers and patients. Beyond stigma, there may be limited awareness among providers and community members about the elevated risks of poor outcomes associated with delayed or late HIV diagnoses. Increasing education around these risks

and the potential benefits of earlier intervention could help inform more effective public health and clinical strategies.

This study has several limitations. First, the study period was 83 months (January 2015-December 2021), and most participants were diagnosed after 2015. If the follow-up period was longer, it is likely that more mortality events would have been observed and influenced our findings. Second, we are unable to draw conclusions on the severity of HIV or account for other co-occurring conditions that could have contributed or could have been the primary reason for the individual's mortality given the data were for surveillance rather than clincal purposes. Third, due to the limitations of working with surveillance data, it is possible that people who died during the study period were not captured in the dataset. To combat this, the FDOH performs a weekly match with the Bureau of Vital Statistics to update the mortality data in eHARS. FDOH also matches eHARS data against NDI and SSDI. However, it is possible for some individuals to not have their death correctly captured in the dataset, particularly if the individual moved to another state or country. Fourth, due to the retrospective nature of the data, our findings may not fully reflect current trends or practices and therefore may have limited generalizability to present-day populations. Finally, excluding individuals with fewer than three CD4 measurements may introduce selection bias, as those with incomplete data may differ from those with more complete records. For example, they may have less consistent care or higher mortality risk, which could lead to underestimating mortality associated with delayed or late diagnosis.

Conclusion

Those with a delayed or late diagnosis HIV in Florida between 2015-2021 had a significantly higher hazard of all-cause and HIV-associated death compared with those who had a timely diagnosis. This highlights that delayed and late diagnoses are significant risk factors for

mortality compared to a timely diagnosis, although late diagnosis has a greater risk for future mortality than delayed diagnosis. Individuals who enter the HIV care continuum with a delayed or late diagnosis may benefit from enhanced interventions. Future research and policy efforts should aim to ensure that the unique needs of these populations are adequately addressed to reduce poor outcomes.

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Figure 1 Legend. Adjusted survival analysis by HIV diagnosis status, considering all-cause mortality from 2015 to 2021. Diagnosis status was categorized as late (CD4 <200 cells/μL), delayed (200 ≤ CD4 <350 cells/μL), or timely (CD4 ≥350 cells/μL) based on the first CD4 test following diagnosis.

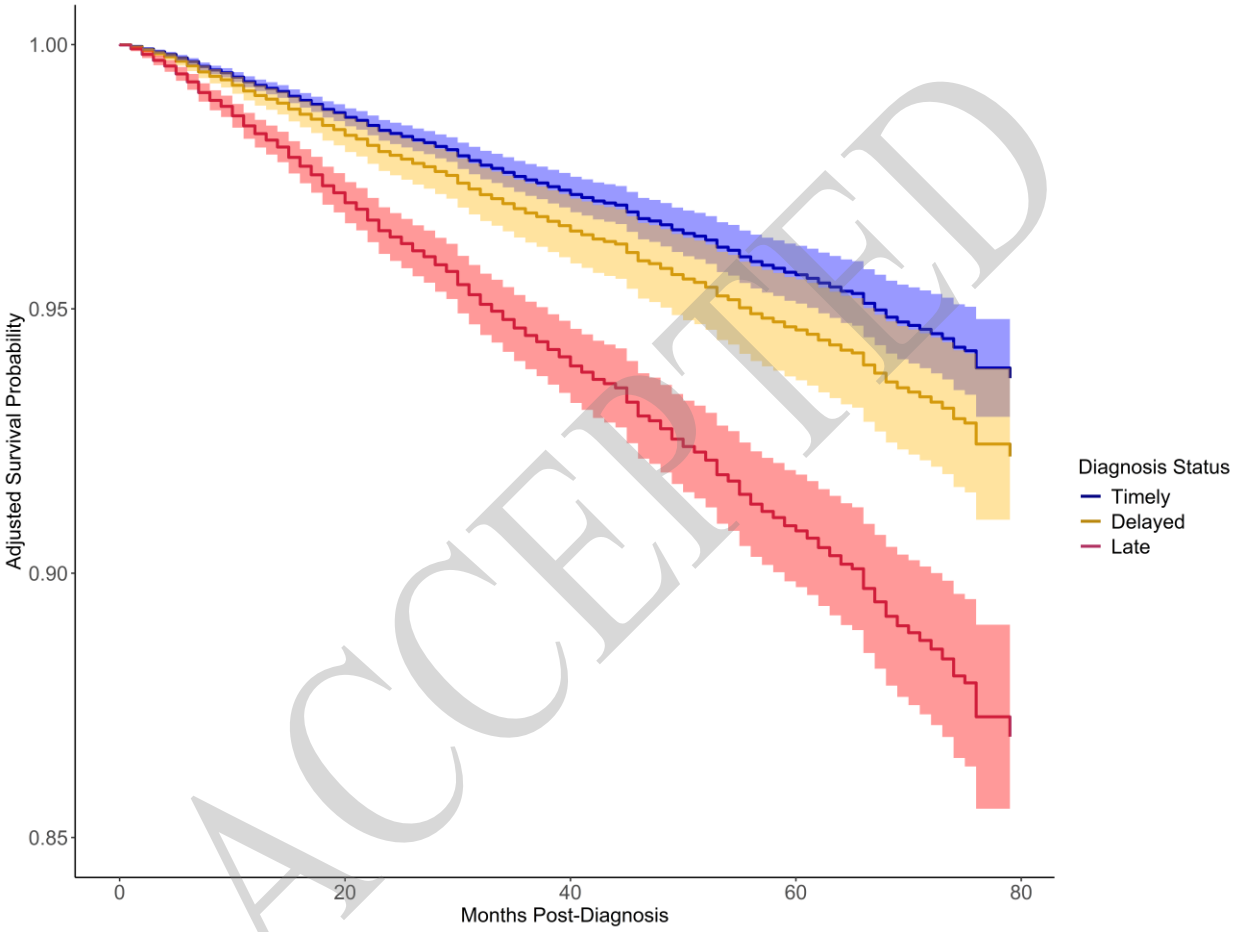

Table 1. Study demographics of people newly diagnosed with HIV in Florida, 2015-2021, by diagnosis status.

	Total New HIV Diagnoses (n=24,374)	Late Diagnosis (n=5,687) (23.3%)	Delayed Diagnosis (n=4,333) (17.8%)	Timely Diagnosis (n=14,354) (58.9%)
Average Age (Standard Deviation)	37.1 (13.0)	41.0 (12.9)	36.2 (13.0)	35.8 (12.6)
Age Category at Diagnosis				
18-24	4,206 (17.3%)	513 (9.0%)	878 (20.3%)	2,815 (19.6%)
25-34	8,143 (33.4%)	1,543 (27.1%)	1,485 (34.3%)	5,115 (35.6%)
35-49	7,173 (29.4%)	2,046 (36.0%)	1,168 (27.0%)	3,959 (27.6%)
50+	4,852 (19.9%)	1,585 (27.9%)	802 (18.5%)	2,465 (17.2%)
Sex				
Male	19,534 (80.1%)	4,442 (78.1%)	3,503 (80.8%)	11,589 (80.7%)
Female	4,840 (19.9%)	1,245 (21.9%)	830 (17.2%)	2,765 (19.3%)
Race/Ethnicity				
Non-Hispanic White	6,022 (24.7%)	1,366 (24.0%)	846 (19.5%)	3,810 (26.5%)
Non-Hispanic Black	9,417 (38.6%)	2,482 (43.6%)	1,844 (42.6%)	5,091 (35.5%)
Hispanic	8,364 (34.3%)	1,681 (29.6%)	1,517 (35.0%)	5,166 (36.0%)
Non-Hispanic Other	571 (2.3%)	158 (2.8%)	126 (2.9%)	287 (2.0%)
Year Diagnosed				
2015	4,255 (17.5%)	1,042 (18.3%)	727 (16.8%)	2,486 (17.3%)
2016	4,270 (17.5%)	985 (17.3%)	782 (18.0%)	2,503 (17.4%)
2017	4,189 (17.2%)	967 (17.0%)	729 (16.8%)	2,493 (17.4%)
2018	4,073 (16.7%)	902 (15.9%)	676 (15.6%)	2,495 (17.4%)
2019	3,715 (15.2%)	838 (14.7%)	681 (15.7%)	2,196 (15.3%)
2020	2,424 (9.9%)	563 (9.9%)	433 (10.0%)	1,428 (9.9%)
2021	1,448 (5.9%)	390 (6.9%)	305 (7.0%)	753 (5.2%)

Column percentages. Percentages consider complete data.

Table 2a. Life table of all-cause mortality among people newly diagnosed with HIV in Florida by diagnosis status, 2015-2021. Timely diagnosis, n=14,354.

Interval (Months Following Diagnosis)	Number Died	Number Censored	Effective Sample Size	Mortality Rate	Survival Probability	Cumulative Survival Probability
0-12	65	1,759	13,474.5	0.005	0.995	0.995
12-24	101	2,466	11,297	0.009	0.991	0.986
24-36	79	2,592	8,667	0.009	0.991	0.977
36-48	51	2,345	6,119.5	0.008	0.992	0.969
48-60	44	2,095	3,848.5	0.011	0.989	0.958
60-72	21	1,720	1,897	0.011	0.989	0.948
72-83	6	1,010	511	0.012	0.988	0.936

Table 2b. Life table of all-cause mortality among people newly diagnosed with HIV in Florida by diagnosis status, 2015-2021. Delayed diagnosis, n=4,333.

Interval (Months Following Diagnosis)	Number Died	Number Censored	Effective Sample Size	Mortality Rate	Survival Probability	Cumulative Survival Probability
0-12	35	599	4,033.5	0.009	0.991	0.991
12-24	40	666	3,366	0.012	0.988	0.980
24-36	25	751	2,617.5	0.010	0.990	0.970
36-48	19	692	1,871	0.010	0.990	0.960
48-60	12	613	1,199.5	0.010	0.990	0.951
60-72	6	575	593.5	0.010	0.990	0.941
72-83	1	299	150.5	0.007	0.993	0.935

Table 2c. Life table of all-cause mortality among people newly diagnosed with HIV in Florida by diagnosis status, 2015-2021. Late diagnosis, n=5,687.

Interval (Months Following Diagnosis)	Number Died	Number Censored	Effective Sample Size	Mortality Rate	Survival Probability	Cumulative Survival Probability
0-12	122	764	5,305	0.023	0.977	0.977
12-24	100	808	4,397	0.023	0.977	0.955
24-36	67	906	3,440	0.020	0.980	0.936
36-48	46	868	2,486	0.019	0.981	0.919
48-60	29	788	1,612	0.018	0.982	0.902
60-72	20	715	831.5	0.024	0.976	0.881
72-83	6	448	230.0	0.026	0.974	0.858