2016

The Impact of an Ambulatory Clinical Intervention on Viral Load Suppression and Retention in Care for Newly Diagnosed HIV Persons

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The Impact of an Ambulatory Clinical Intervention on Viral Load Suppression and Retention in Care for Newly Diagnosed HIV Persons

Submitted to

The College of Public Health

By Latasha R. Jones

In Partial Fulfillment of the Requirements for the Degree

Master of Public Health in Health Management and Policy

August 2016

University of Kentucky

Lexington, KY

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Abstract:

Ambulatory clinical healthcare settings that serve patients infected with the human immunodeficiency virus (HIV) are critical in improving access to quality HIV care and treatment, in part due to their ability to streamline patient care along the HIV care continuum. Barriers to HIV care are significant among newly diagnosed HIV patients and in order to engage and retain these individuals in care and treatment, specific interventions must be in place to link these individuals to care. In this study, the difference in differences method was used for data analysis to measure the impact of an ambulatory clinics intervention on their newly diagnosed HIV patients in an effort to improve their retention in care and HIV viral load suppression. The study participants all received their HIV specific care and treatment solely at the University of Kentucky, Department of Infectious Diseases HIV/AIDS Clinical Program (IMDP) that is a Ryan White HIV/AIDS program funded ambulatory clinic. Of the 1,156 patients enrolled in the IMDP clinic during the study, only 178 met the criteria for inclusion in the study. This retrospective cohort study included data extracted from 178 patients' electronic health records over a 24-month period, with 96 patients in the first 12-month cohort and 82 patients in the second 12-month cohort. The differences in means from the two data sets were analyzed for significance using the Kolmogorov Smirnov two-sample test (KS) and p-value. The length of time between readings of the biomarkers viral load and CD4+ T-lymphocyte cell count at attended provider visits was statistically significant, suggesting that clients exposed to the intervention with these readings less than 90 days apart were more likely to have the recommended number of provider visits in a 12-month period more than 90 days apart. No significant differences in visit spacing means were found when controlling for viral load or CD4+ T-lymphocyte cell count. Additionally, each cohort's mean differences showed a positive trend towards decreased viral load and increased CD4+ T-Lymphocyte cell count. Overall, this study provided empirical evidence for more consideration towards implementing HIV clinical interventions within large ambulatory clinical health systems that improve health outcomes and retention in care for newly diagnosed HIV patients.

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INTRODUCTION

Individuals infected with the human immunodeficiency virus (HIV) are living longer and experiencing improved quality of life due to scientific innovations in antiretroviral therapy, and, as a result, they are achieving viral load suppression sooner, which significantly reduces the risk of transmitting the disease (Doshi, 2015). Despite these scientific advances, over a million individuals in the U.S. are living with HIV and only one in eight know that they are infected (Centers for Disease Control and Prevention, Health Resources and Service Administration, 2014). Data from the Centers for Disease Control and Prevention (CDC), displayed in Figure A, estimates that only 66 percent of individuals living in the US diagnosed with HIV were linked to HIV care, and of those, only 25 percent ever achieved viral load suppression (Centers for Disease Control and Prevention, Health Resources and Service Administration, 2014). These alarming statistics have garnered the attention of national government leaders, healthcare facilities that offer HIV care, and healthcare providers. Consequently, in 2010, President Barack Obama and his administration released the National HIV/AIDS Strategy for the United States. The strategy seeks to reduce the incidence rates of HIV, improve health outcomes for those living with HIV, reduce disparities and inequities in healthcare for HIV care and treatment, and provide healthcare facilities and providers a framework to move patients along the HIV continuum of care (The Office of National AIDS Policy, 2015). The HIV Care Continuum (Figure B) was established through an executive order by President Barack Obama in 2013 and directed federal departments to prioritize increasing

the number of individuals tested, diagnosed, linked and engaged in care, actively on antiretroviral therapy, and achieving viral load suppression while implementing (The White House Office of National AIDS Policy Executive Order, 2013). Evidence suggests that an approach similar to that outlined in the HIV Care Continuum may be an effective means to deliver services related to HIV (Gardner E. M., 2011).

Retention in care, although challenging, is a critical step in the HIV continuum of care and supports the patient achieving the desired outcome of viral load suppression, and initiation of antiretroviral therapy (Mugavero & et.al., 2011). The CDC defines it as the process of assisting persons with HIV to attend scheduled follow-up HIV medical appointments after they have started HIV medical care (Centers for Disease Control and Prevention, Health Resources and Service Administration, 2014). The Institute of Medicine defines clinical recommendations for retention outcomes as the patient attending two HIV medical visits with in one year at least 90 days apart following new HIV diagnosis (Institute of Medicine of the National Academies, 2012).

Ambulatory clinical settings provide a critical access point to take advantage of the time interval between a patient's HIV diagnosis and the initiation of antiretroviral therapy (Irvine, 2015). This study used data from 178 newly diagnosed HIV patients ages 18-64, enrolled in a Ryan White HIV/AIDS program (RWHAP) funded clinic in a large, urban, academic medical center retrospectively followed over a 24 month period, to examine the impact of an

retention in HIV care intervention on HIV biomarkers and the time periods between HIV medical appointments.

METHODOLOGY

Study Design Overview

In this retrospective cohort study, data was collected from electronic medical records of 178 newly diagnosed HIV patients enrolled in University of Kentucky Department of Infectious Diseases HIV/AIDS Clinical Program (IMDP) which is part of the University of Kentucky Healthcare system in Lexington, KY. Data from the first cohort of patients, labeled Group A, was collected during a 12-month period from June 1, 2013 through May 31, 2014. Data from the second cohort of patients, labeled Group B, was collected from June 1, 2014 through May 31, 2015. In a response to improving their performance measures and attempting to meet the recommended clinical guidelines for HIV Care by the National Health Resources and Services Administration (HRSA), HIV/ AIDS Bureau, the clinic's continuous quality management (CQM) team developed an intervention. The multifaceted intervention for a 12-month period involved linking individuals to other medical and social support services, multiple case management sessions, navigation assistance for enrolling on health insurance, and transportation services to IMDP clinic provider visits. Group B was the only group exposed to the intervention. The CQM team closely monitored every encounter with a patient using an Excel spreadsheet to document each client's date and attendance at IMDP clinic provider visits, frequency of medical case management services provided, and appointment reminders. Each patient from Group B was assigned

to one CQM team clinical social worker (CSW), who managed the case beginning at the patient's initial visit to the IMDP clinic.

Study Population

Patients were referred to the IMDP clinic by an outside agency, hospital inpatient follow-up for HIV specific care, or self-referral resulting from an inconclusive or positive HIV-1 RNA oral antibody test. The IMDP clinic only serves clients who live within its 68 county region, which includes majority of the counties on the eastern half of the state of Kentucky (Figure C). The data included all newly diagnosed HIV patients that were treatment naïve for antiretroviral therapy during the period of June 1, 2013 through May 31, 2015.

Study inclusion criteria were: at least one new patient intake visit at the IMDP clinic, blood serum confirmed HIV infection laboratory test, treatment naïve for antiretroviral therapy, aged 18 to 64 years old, not pregnant and did not become pregnant, die, discharge to palliative care, or become imprisoned during the study period. Data elements included demographic information (Table 1); attendance at all regularly scheduled provider visits at IMDP clinic, and recorded labs results of every blood serum test for HIV viral load and CD4+ T-lymphocyte cell count at each HIV provider visit. The IMDP clinic's intervention included improving the frequency of communication for newly diagnosed HIV patients in an effort to improve their retention rates. The intervention increased the frequency of CSW encounters for case management and in-person contacts for appointment reminders. Criteria for encounters included the CSW's facilitation of any additional medical or support services (Table 5). Criteria for in-person

contacts for appointment reminders included direct contact with the patient through phone, email, or in-person at least one week before any scheduled provider visit and follow-up for missed appointments at the IMDP clinic.

Patients' electronic medical records were individually reviewed if the patient was not retained in care (definition below) due to a self-reported move out of IMDP service area, death, discharge to prison, or discharge to palliative care. If the date of any of these incidents occurred during the study then the patient was excluded from analysis of the data from that date forward.

Exposures and Outcomes

For the purpose of this study, the Institute of Medicines (IOM) standards for HIV care were indexed to analyze the impact of the intervention on the outcomes for retention in care, viral load suppression, and improved CD4+ T-lymphocyte cell count. IOM defines, retention in care for newly diagnosed HIV patients, as attending an infectious disease provider visit three times, at least 90 days apart, in a 12-month period (Institute of Medicine of the National Academies, 2012). The IMDP clinic's protocol and procedures for clinical HIV care states that for each provider visit ≥90 days apart that the provider order routine HIV labs for HIV viral load and CD4+ T-lymphocyte cell count either the same date as provider visit or one week before scheduled provider visit. A patient's medical record with at least three attended provider visits, ≥90 days apart during the study were considered retained in care. If the patient's medical record reported less than two provider visits, ≥ 90 days apart they were not considered as retained in care. When controlling for viral load and CD4+ T-lymphocyte cell count the duration of

time between attended provider visits was analyzed to illustrate the impact of the intervention on retention in care. Thus supporting how critical the time between attended provider visits may affect retention in care and the patient's progress towards viral load suppression and improved immune system. Viral load suppression and improved CD4+ T-lymphocyte are key biomarkers expressing the impact of the intervention on retention in care (Doshi, 2015).

Viral load suppression as defined by IOM is a blood serum HIV-1 RNA viral load less than or equal to 200 copies/mL each patient-year (Institute of Medicine of the National Academies, 2012). The patient's plasma HIV viral load and CD4+ T-lymphocyte cell count was recorded at each of these, as well as the baseline values ≥90 days from their first IMDP clinic intake visit and when the patient started anti-retroviral therapy. Patients with blood serum HIV viral loads ≤200 copies/mL were characterized as virally suppressed and assigned a value of 200 copies/mL for data analysis (Mugarvero, 2014). HIV viral loads greater than 10,000,000 copies were assigned to upper limit quantification of 10,000,000 copies per/mL. If a no viral load data was available for a patient during each 12-month period, the patient was considered to have a viral load greater than 200 copies/mL and therefore were not considered virally suppressed based on the IOM standards. If the patients' medical records did not report at least two viral load readings during the 12 month period, the patient was defined as not virally suppressed and was recorded to have an HIV viral load greater than 200 copies/mL during the 12-month period.

For further analysis of viral load suppression, the study captured each CD4+ T-lymphocyte cell count test ordered at every IMDP clinic provider visits. The CD4+ T-lymphocyte cell count is a biometric measure to gauge the improvement of the patient's immune system during first 12 months of care following new HIV diagnosis. Patients with CD4+ T-lymphocyte cell count levels ≤200 cell/ mm^3 given a value of 200 cells/mm^3 for data analysis purposes (U.S. Department for Human and Health Services: HIV/AIDS Bureau, 2016). Any Improved CD4+ T-lymphocyte cell count reading greater than initial IMDP visit reading supports viral load suppression and the impact of antiretroviral therapy for patients retained in care (Mugavero M. R., 2012).

Statistical Analysis

Categorical data was analyzed using Kolmogorov Smirnov two-sample test (KS) and p-values were computed. SAS software developed by SAS institute was used to perform statistical computations using the difference in differences method (DiD) to compare the difference in means for Groups A and Group B. The primary outcome variables were viral load suppression, improved CD4+ T-lymphocyte cell count, and time between readings for viral load and CD4+ T-lymphocyte cell count. Multivariate and univariate logistic regression analysis were performed at the end of the 12-month period for each cohort.

Experimental studies can underestimate critical factors that vary across times and geographical statistics in order to identify casual effects of alternative policies or interventions (Stuart, 2014). The DiD method aids in identifying these causal effects by contrasting the change in outcomes pre- and post- exposure to an intervention for a reference group and a comparison group. The method

assumes that without exposure to the intervention the average outcomes of the comparison group and the reference group would result in equivalent trends over time. The difference-in-differences method (DiD) was used to analyze the significance of the IMDP clinic's recent intervention to improve its retention rate. Analysis of both cohorts' differences in means for viral load readings, CD4 T-lymphocyte cell count readings, and duration of time between provider appointments was calculated using the KS two sample test. The p-value generated from this KS analysis was evaluated to determine significance for each outcome and specific period.

RESULTS

The study included 178 newly diagnosed HIV patients ages 18 to 64 who started their HIV care and antiretroviral treatment at the IMDP clinic between June 1, 2013 and May 31, 2015. Gender at birth was 85 percent (n=151) male and 15 percent (n=27) female. Regarding HIV risk factors, 70 percent reported being men having sex with other men, while eighteen percent reported their risk factor as heterosexual exposure. Intravenous drug use (IDU) was, reported as a risk factor by 2.25 percent, while another 2.25 percent reported two risk factors being both as men who have sex with men and engage in IDU. The remaining 7.5 percent of risk factors were unknown or due to exposure to infected blood or blood components. Furthermore, 75 percent of the full sample was white non-Hispanic individuals, 15 percent Black/African American, 6 percent Hispanic or Latino origin, and 4 percent other or unknown race/ethnicity. In addition, at the time of the patient's intake visit, 60 percent of the full sample had income levels

below 100 percent of the federal poverty level, 15 percent had no medical insurance, and 50 percent of the full sample were actively enrolled in the Kentucky Medicaid program as their primary source of medical insurance (Table 1).

Multivariate data analysis of CD4+ T-lymphocyte cell count and HIV viral load using the difference in differences method found no significant difference between Group A and Group B (Tables 2, 3). However, analysis of the duration of time between readings of viral load and CD4+ T-lymphocyte cell count combined found a significant difference between the Group A and Group B for the first reading to the second reading (diff. 2.6, $p < .0425$) and from the first to the third reading (diff. 10.4, $p < .0019$) (Table 4). Group A and Group B both demonstrated trends for improved CD4+ T-lymphocyte cell counts, initiation of antiretroviral therapy within 90 days of first reading, and progress towards viral load suppression. Group A showed decreased mean viral load only in the first and second readings (Table 2). Group B had significantly higher mean CD4+ T-lymphocyte counts and higher mean viral loads at the time of their initial intake visit at IMDP clinic compared to Group A.

DISCUSSION

Retention in care and viral load suppression are key determinants in mortality and morbidity for newly diagnosed HIV patients within the first 12 months following diagnosis (Mugavero M. L., 2009). Ambulatory care clinics are the front line of access to medical care for newly diagnosed HIV patients and critical points of access to antiretroviral therapy (Irvine, 2015). Providing the

needed infrastructure to equip ambulatory care clinics to move newly diagnosed HIV clients through the HIV continuum of care in the first 12 months of diagnosis and then long-term is a critical factor in reaching the goals and objectives of the U.S. HIV /AIDS strategy and HIV/AIDS prevention efforts (Mayer, 2011). The difference in differences analysis provided a methodology for analysis of one ambulatory clinic's intervention to improve health outcomes for their newly diagnosed HIV patients. The analysis did not find significance differences between means for viral load suppression and CD4+ T-lymphocyte cell count, but there was a positive trend for both cohorts towards expected outcomes of decreased viral load and improved CD4+ cell T-lymphocyte cell count, suggesting that other variables may be impacting the results. Another method to evaluate significance, such as a McNemar comparison with logistic regression analysis, might have different results. Because of the complexity of the HIV disease, it is often difficult to evaluate interventions using randomized controlled trials (Gardner, 2014). The difference-in-differences method allowed for before-and-after analysis of the differences in means for this intervention in an ambulatory setting, similar to those often found in large urban or academic medical campus healthcare systems. Although for this study, the method may not have been as effective in identifying significant differences between the means from Group A and Group B, the desired outcomes for decreased viral load and improved CD4+ T-lymphocyte cell count showed positive trends over each 12-month period.

A poor retention in care rate is an important indicator that the patient is not progressing along the HIV continuum of care (Giordano, 2007). Although challenging, retention in care for newly diagnosed HIV patients improves quality of life, CD4+ T-lymphocyte cell count, the likelihood the patient will receive the maximum benefits of antiretroviral therapy, and the patient's progress towards achieving viral load suppression (Centers for Disease Control and Prevention, Health Resources and Service Administration, 2014).

It is imperative to find more interventions that fill the gaps in HIV delivery of care and support ambulatory clinics with evidence-based practices that progress newly diagnosed HIV patients along the HIV continuum of care within the first 12 months of diagnosis.

Limitations of the study

This study has several limitations. First, it is a retrospective cohort study of a single ambulatory clinic, which limits the generalizability of its findings to other HIV populations. The IMDP clinic is one of six RWHAP-funded ambulatory clinics in Kentucky, and further research on retention in care and viral load suppression for newly diagnosed clients from other ambulatory clinics in Kentucky and other states could add to the study's findings. A second limitation is that the study could have missed patients that moved out of the IMDP service area during the study. Thirdly, missing viral load data during each 12-month period was recorded as not being virally suppressed when in fact the patient could have achieved viral load suppression during the study. Fourth, because the clinic receives patients on a referral basis for Kentuckians who live in its region, the clients who were self-referred or had a partner who

receives HIV care at the clinic may have been more motivated to stay engaged in care at the IMDP clinic. This limitation could influence the results for retention in care, viral load, and CD4+ T-lymphocyte cell count. Finally, the lack of control for data from the CSW encounters and personal contacts provided to Group B may have given rise to an undetected correlation between specific types of encounters and their impact on retention in care and viral load suppression.

Future Direction and Research

HIV is a complex long-term illness that requires innovative and effective strategies to improve access to care, linkage, retention in care, long-term engagement in care, and initiation and continued use of antiretroviral therapy in order to produce positive health outcomes in persons living with the disease (Marks, 2010). This study presented one organization's strategies to improve retention in care for their newly diagnosed patients. Future research on this data could assess the impact of confounding variables such as patient wait times, provider availability, demographic statistic, time between scheduled and re-scheduled appointments, smaller or larger healthcare systems, and the time between initiation of antiretroviral therapy and viral load suppression. When the third readings were recorded for both groups, there was a declining trend in the number of patients with recorded provider visits ≥240 days from initial IMDP clinic visit and viral load results. This suggests that several clients might have fallen out of care, a finding that deserves further exploratory research in longitudinal studies and cross-sectional studies. Longitudinal studies could further research by exploring interventions that impact retention in care rates and viral load

suppression at 24, 36, 48, or 60 months. Finally, it would be beneficial to study interventions that work in different healthcare settings and vulnerable populations to address patient-specific barriers to care such as transportation assistance, access to medical insurance, HIV stigma, travel distance to clinic, voucher incentives, and access to behavioral health services.

Acknowledgements

I would like to give a special thank you to my faculty committee members for all your time and support. I would also like to thank Dr. Cezar Mamaril for all your efforts and support with this study.

This study has been reviewed and approved by the University of Kentucky Internal Review Board. IRB Exemption Certification for Protocol No. 15-0876-X6B.

There are no conflicts of interest for this project. No financial support was given for this project. Individual conformed consent was not required for this study.

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APPENDIX: Tables and Figures

Table 1. Descriptive Statistics

VARIABLE		Full Sample	Group A	Group B
Number of individuals in sample		178	96	82
Age at Intake (mean)		34.4	35.2	33.5
	sd	*15.6*	*10.7*	*19.9*
Race/Ethnicity				
	white NH	130	69	61
	african american NH	28	14	14
	asian pacific island NH	5	3	2
	hispanic	15	10	5
Gender at Birth				
	female	27	19	8
	male	151	77	74
Risk Factor				
	heterosexual	33	18	15
	IDU	5	4	1
	MSM	125	68	57
	MSM+IDU	4	1	3
	unknown/undetermined	11	5	6
Percent Federal Poverty Level				
	100% FPL	111	58	53
	133% FPL	3	1	2
	150% FPL	5	4	1
	185% FPL	5	5	0
	200% FPL	10	4	6
	300% FPL	9	3	6
	400% FPL	5	4	1
	>400% FPL	3	2	1
Insurance Coverage				
	no insurance	27	15	12
	Medicaid	89	50	39
	BCBS	31	16	15
	other types	31	15	16

Table 2. Method Results for CD4+ T-lymphocyte cell count (uL)					
CD4 Levels (mean uL)	Full Sample	Group A	Group B	Difference	p-value
First Reading	**509**	**505**	**513**	**8**	**0.8735**
std.dev	*324*	*333*	*316*		
non-missing obs	*155*	*81*	*74*		
Second Reading	**518**	**496**	**541**	**44**	**0.3633**
std.dev	*297*	*284*	*310*		
non-missing obs	*149*	*76*	*73*		
Third Reading	**561**	**562**	**559**	**-3**	**0.9592**
std.dev	*329*	*361*	*299*		
non-missing obs	*123*	*60*	*63*		
Change from 1st to 3rd Reading	**102**	**110**	**94**	**-16**	**0.6309**
sd	*117*	*175*	*183*		
non-missing obs	*117*	*57*	*60*		

Table 3. Method Results for HIV-RNA 1 Viral Load (copies/mL)					
Viral Load (mean copies/mL)	Full Sample	Group A	Group B	Difference	p-value
First Reading	**32,615**	**25,653**	**41,043**	**15,390**	**0.6214**
std.dev	*188,881*	*123,932*	*246,315*		
non-missing obs	*168*	*92*	*76*		
Second Reading	**7,584**	**6,457**	**8,820**	**2,364**	**0.6666**
std.dev	*33,026*	*27,684*	*38,202*		
non-missing obs	*151*	*79*	*72*		
Third Reading	**3,216**	**3,251**	**3,182**	**-69**	**0.9827**
std.dev	*17,520*	*15,749*	*19,208*		
non-missing obs	*122*	*60*	*62*		
Change from 1st-3rd Reading	**40,118**	**34,590**	**45,556**	**10,967**	**0.7861**
std.dev	*221,765*	*153,091*	*274,322*		
non-missing obs	*121*	*60*	*61*		

Table 4. Method Results for duration of time between readings for viral Load and CD4+ cell count combined

Duration between readings (number of weeks)	Full Sample	Group A	Group B	Difference	p-value
Intake to 1st reading	**14.9**	**13.6**	**16.3**	**2.7**	**0.1113**
sd	*10.6*	*9.2*	*11.9*		
non-missing obs	*160*	*84*	*76*		
1st reading to 2nd reading	**13.1**	**11.8**	**14.4**	**2.6**	**0.0425**
sd	*8.1*	*7.2*	*8.8*		
non-missing obs	*155*	*81*	*74*		
2nd reading to 3rd reading	**17.1**	**16.3**	**17.8**	**1.5**	**0.4354**
sd	*11.0*	*10.7*	*11.2*		
non-missing obs	*126*	*62*	*64*		
Intake to 3rd reading	**41.1**	**35.8**	**46.2**	**10.4**	**0.0019**
sd	*18.8*	*18.0*	*18.4*		
non-missing obs	*123*	*61*	*62*		

Table 5. Encounters Provided by IMDP Clinical Social Workers

Referral for Behavioral Health
Referral for State AIDS Drug Assistance Program
Partner Testing and Counseling
Sexual Education and Condom Use
Risk Reduction counseling
Transportation Assistance
Social Support Services
Food Bank Agency Referrals
Medication Copay Assistance
Assistance for Durable Medical Equipment
Medical Insurance Premium Assistance
Navigation to enroll in state Health benefit exchange program or Medicaid
Tobacco Cessation Counseling
Substance Abuse Treatment Referral
Medication adherence counseling

Figure A: 2011 CDC Analysis: The Continuum of Engagement in HIV Care (Centers for Disease Control and Prevention, 2014)

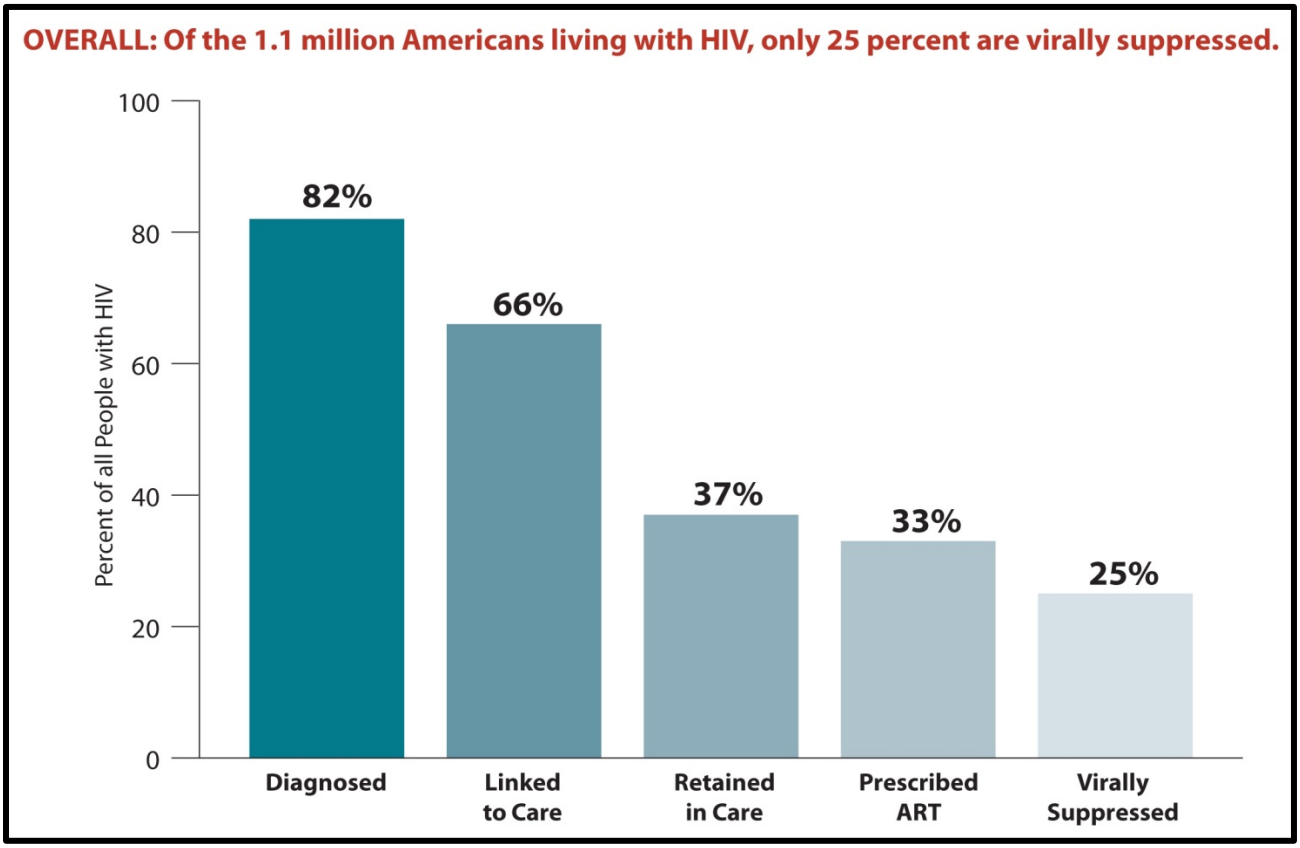

Figure B. The Continuum of Engagement in HIV medical care

(Centers for Disease Control and Prevention, 2014).

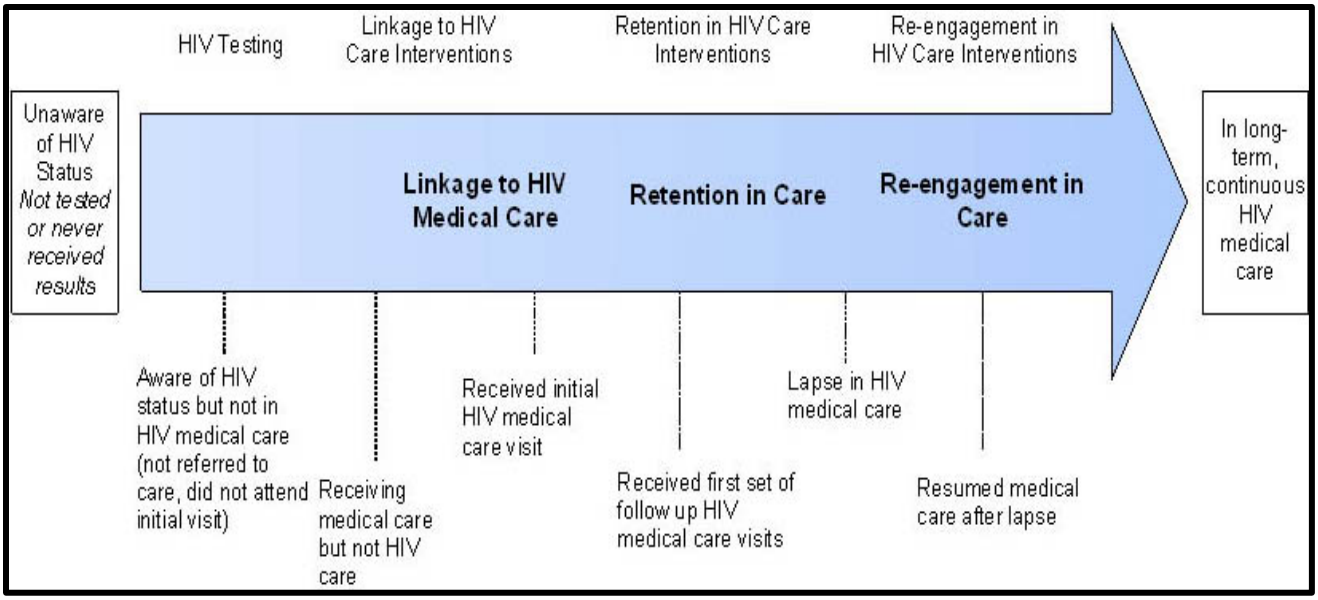

Figure C. University of Kentucky Department of Infectious Diseases HIV/AIDS Clinical Program (IMDP) Service Area Map (University of Kentucky, College of Medicine, 2015)