

Utilization of the Kentucky AIDS Drug Assistance Program versus Kentucky Medicaid Using Medication Possession Ratio

Policy Implications for a Public Program

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Executive Summary

Uninsured and underinsured people living with Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) are able to utilize federally funded AIDS Drug Assistance Programs (ADAPs) to cover the price of their HIV-related medications. In Kentucky, this program also provides support services through social workers, a dedicated pharmacist, and medications by mail order. With the Affordable Care Act, many patients previously covered by the Kentucky AIDS Drug Assistance Program (KADAP) will be newly eligible for Medicaid and will no longer receive services through KADAP. There is concern that people in this situation will be at a disadvantage without these services and, in turn, be less adherent to their medications. People living with HIV/AIDS should regularly take $\geq 95\%$ of their medications in order to prevent medication resistance and disease-related morbidity and mortality,

The purpose of this study is to determine the average medication adherence of patients in KADAP and Kentucky Medicaid, evaluate whether people enrolled in Medicaid have significantly lower adherence compared to KADAP, and determine if any demographic variables are associated with medication nonadherence in either program through multivariate regression. With this information, recommendations will be made regarding what can be done from programmatic and policy standpoints to increase medication adherence in this population.

Pharmacy claims and demographic data were collected from the Kentucky Clinic Pharmacy and the Bluegrass Care Clinic at the University of Kentucky for all of 2011. Medication adherence was calculated using the medication possession ratio (MPR), which calculates the percentage of time the patient has their medications on hand each month based on pharmacy claims data. The average MPR for KADAP patients is 84.7% (n=2,204; range: 14.9%-100%) and the average MPR for Medicaid patients is 77.3% (n=55; range: 16.4%-100%). When KADAP and Medicaid data were combined, 3 variables were significantly associated with MPR in multivariate regression: age (coef: 0.123, $p < 0.001$), black race (coef: -3.8, $p < 0.001$), and Medicaid enrollment (coef: -6.23, $p < 0.001$). Similar significant was found with KADAP alone, but not with Medicaid.

Younger, black KADAP patients tend to have lower MPRs and Kentucky Medicaid patients have significantly lower MPRs than KADAP patients. In order to increase adherence, the policy regarding Medicaid and KADAP co-enrollment should be changed to allow newly eligible Medicaid patients to continue using KADAP's services without financial need. Additionally, pharmacy call lists could be made, with priority on younger, black KADAP patients, for refill reminders and to open dialogue between the patient and the pharmacist regarding medication concerns.

Background

Section 1: HIV and Medication Adherence

Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS)

Human Immunodeficiency Virus (HIV) is a retrovirus that attacks certain immune system cells (CD4 or T cells) and decreases the body's ability to fight off infections. Once a patient is infected with HIV, he or she is infected for life. The diagnosis of Acquired Immune Deficiency Syndrome (AIDS) is given when an HIV-positive patient's CD4 cell count drops below 200 cells/mL or when a patient with HIV acquires a certain "AIDS-defining" condition, including opportunistic infections and cancers. HIV is transmitted through the blood, semen, genital fluids, or breast milk of an individual infected with the virus and is most commonly transmitted through unprotected sexual contact or sharing needles and syringes.¹

The prognosis of an HIV-infected individual has greatly improved since the initial outbreak of the virus due to the use of highly active antiretroviral therapy (HAART), which is a combination of specific antiretroviral medications usually composed of three medications from varying drug classes.² Due to these medications and increased awareness of the disease, the age-adjusted HIV death rate has dropped by 80 percent since its peak in 1995, including an 11 percent drop between 2007 and 2008.^{3,4} Additionally, antiretroviral treatment (ART) has been shown to significantly reduce the risk of transmission of the disease giving the patient the possibility of having an undetectable viral load (amount of virus in

blood).⁵ However, even with these medications, it has been shown that only one-quarter of the 1.1 million Americans living with HIV have their virus under control, with only 37 percent of HIV patients remaining in regular care.⁶

Section 2: Literature Review

Medication Adherence in HIV-positive Patients

Research has shown that patients typically take a much lower percentage of their medications than is required to successfully suppress viral replication. In a 2006 study by Gross and colleagues, researchers assessed the magnitude of antiretroviral therapy adherence (based on pharmacy refill data) needed to maintain HIV suppression in patients who had already achieved initial viral suppression. The study assessed a population-based cohort of 1,634 patients who had at least 2 consecutive viral loads less than 500 copies/mL and had prescriptions filled at least 3 times during the follow-up period. It was found that patients with less than 95 percent adherence were 1.66 times more likely to experience virological failure (2 consecutive viral loads greater than 1000 copies/mL) than those with greater than 95 percent adherence.⁷ In a 2005 retrospective audit study by Fairley and colleagues, self-reported adherence and pharmacy records were used to determine adherence and compared to the patient's viral load. The study found that the proportion of patients with viral load below 400 copies/mL fell below 60 percent when adherence fell below 95 percent (by pharmacy record) and 97 percent (by self-report). The study also found that adherence increased significantly each year, and adherence was significantly higher for once a day

compared with twice a day treatment.⁸ In a 2000 prospective, observational study by Paterson and colleagues, 81 patients were studied in order to assess the effects of different levels of adherence (measured by the Medication Events Monitoring System) to therapy on virologic, immunologic, and clinical outcomes. The study found that patients with 95 percent or greater adherence had better virologic outcomes, a greater increase in CD4 lymphocyte count, and a lower hospitalization rate than patients with lower levels of adherence.⁹ Prior to this study, 80 percent adherence was typically regarded as the threshold for better outcomes among patients, highlighting the importance of adherence for HIV patients in order to optimize their overall health and survival.

Overall, a high level of medication adherence is imperative in HIV patients in order to maintain viral suppression and prevent medication resistance, transmission of resistant viruses, AIDS-related morbidity, mortality, and hospitalizations.^{9,10} In a recent study by Montaner and colleagues, the increased use of HAART in British Columbia between 1996 and 2012 was associated with increasing virological suppression and decreasing drug resistance.¹⁰ Additionally, AIDS incidence decreased by 80 percent ($p=0.330$), HIV mortality decreased 80 percent ($p=0.0115$), and new HIV diagnoses decreased by 66 percent ($p=0.0004$). Their models predicted that for every increase of 100 individuals on HAART, the estimated HIV incidence decreased 1.2 percent and for every 1 percent increase in the number of individuals suppressed on HAART, the estimated HIV incidence also decreased by 1 percent.

Risk Factors for Nonadherence in HIV-positive Patients

Several studies have been completed to determine which characteristics put a patient at increased risk of having a low rate of adherence and, therefore, suboptimal health outcomes. In a 2007 prospective, cross-sectional, observational study by Barclay and colleagues, 185 HIV-positive adults were studied to determine age-associated predictors of medication adherence.¹¹ The study found that HIV-infected adults aged 50 and older were twice as likely to achieve a 95 percent adherence rate than were younger HIV-positive participants and that, among the older age group, neurocognitive functioning was the sole significant predictor of medication adherence. Poor adherence among younger HIV-positive participants was associated with current drug abuse/dependence and a lack of independent financial resources. In a 1999 cross-sectional study by Gordillo and colleagues, sociodemographic and psychological factors that influence adherence were assessed by patient self-report and pill count.¹² Based on the multivariate analysis, subjects aged 32-35 years, who were not intravenous drug users, had CD4 cell counts from 200-499 cells/mL at enrollment, were not depressed, and with self-perceived good social support had better adherence to antiretroviral therapy. In the study previously discussed by Gross and colleagues, patients with greater than 95 percent adherence were less likely to be injection drug users, were less likely to have received a protease inhibitor in the first regimen (a specific type of antiretroviral contained in HAART), were slightly older, and were more likely to have received follow-up from physicians with more HIV-1 treatment experience than subjects with less than 95 percent adherence. Additionally, the study found that being an

injection user at any time, younger age, and higher baseline CD4 cell count were significantly associated with the likelihood of virological failure, irrespective of adherence.

A 2011 prospective cohort study done by Godwin and colleagues from the 1917 Infectious Diseases Clinic at the University of Alabama – Birmingham studied medication adherence specifically for patients enrolled in their state’s AIDS Drug Assistance Program using medication possession ratio (a ratio of how often a patient has their medication on-hand calculated by pharmacy claims data).¹³ Using multivariate ordinal logistic regression, the study found that certain patient characteristics, including younger age, nonwhite males, lower CD4 count, and a history of alcohol abuse, were associated with poor medication adherence. The study also found that approximately 25 percent of the patients had a medication possession ratio of less than 69 percent, while the optimal medication possession ratio is greater than 95 percent.

Section 3: Public Programs for Patients with HIV/AIDS

Ryan White Program

The Ryan White Program is the largest federal program designed specifically for individuals living with HIV in the United States and is estimated to reach approximately half a million people each year.¹⁴ The namesake of the program was diagnosed with AIDS at age 13 from his hemophilia treatment and was then ostracized from his school due to a lack of education about the disease among school officials and the community.¹⁵ Subsequently, he and his mother championed for

HIV/AIDS research and public education about the disease, which led to the formation and passing of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. The program provides care and support services to individuals and families affected by the disease and operates as the “payer of last resort” by acting as a financial safety net for patients who have no source of coverage or are otherwise unable to pay.¹⁴

The program is administered by the Health Resources and Services Administration (HRSA) and is the third largest source of federal funding for HIV care in the U.S. after Medicare and Medicaid.¹⁴

AIDS Drug Assistance Programs (ADAPs)

The Ryan White Program consists of several parts and states, cities, and other organizations apply for funding by part. Part B, which provides grants to states and U.S. Territories to improve the quality, availability, and organization of HIV/AIDS health care and support services, has funds earmarked by Congress specifically for ADAPs.^{14,16} ADAPs provide medications for the treatment of HIV and program funds may also be used for services that enhance different aspects of drug treatments, including medication adherence.¹⁶ Each state must establish its own eligibility criteria for ADAP and each state is required to make patients recertify every 6 months¹⁶. It has been reported that ADAP provides care to one-third of people living with HIV and demand is increasing as people with HIV are living longer.^{17,18} In FY2013, ADAP’s budget was \$2.01 billion but the program still required an additional \$75 million of emergency funding, which it also received in FY2012.¹⁸ The emergency funding was given to the states to help eliminate some of the cost-

containment measures that had been put into place, including waiting lists and restricted formularies.¹⁸ However, many states still have these cost-containment measures in place due to funding issues. Although funding for the program has increased over time, when adjusted for inflation, FY2012 funding is at the same level as it was last decade, despite an increase in the number of people living with HIV.¹⁹

Kentucky AIDS Drug Assistance Program (KADAP)

In Kentucky, in order to participate in ADAP, residents must have documented HIV/AIDS, have an income less than 300 percent of the Federal Poverty level, and not be 100 percent by another third party payer. The Kentucky Clinic Pharmacy at the University of Kentucky is the contract pharmacy for KADAP and all KADAP enrollees must have their KADAP-covered medications filled exclusively at this pharmacy. The Kentucky Clinic Pharmacy provides several services to these patients, including preparation and dispensing of KADAP formulary medications, counseling and education services, compliance counseling and tracking, and mail order service for medication delivery.²⁰ The pharmacy employs one pharmacist and one technician who are dedicated to providing these services to KADAP patients. Patients are limited to receiving a quantity of medication to last 30 days at a time, and any patients not having any medication refilled for 90 days have their accounts placed on hold. Although the pharmacy does refill prescription automatically, a reorder reminder notice is provided with each filled prescription.

Affordable Care Act (ACA)

With the implementation of the Patient Protection and Affordable Care Act, it is difficult to determine how the Ryan White Program and, consequently, ADAP will be affected. Since states can opt-in for Medicaid expansion, which will include additional HIV patients who did not previously qualify for Medicaid, it is unknown whether the Ryan White Program and ADAP will continue as they currently function. However, a recent study involving 15 states showed that only 21 percent of Medicaid patients with HIV were linked to appropriate care within one year of their diagnosis.²¹ The National Alliance of State and Territorial AIDS Directors (NASTAD) suggests that the Ryan White program will still be needed to fill gaps in covered services and populations and continue support services even after the full implementation of ACA²². In addition, 70 percent of Ryan White program clients have public or private insurance coverage, indicating that having insurance coverage is not always sufficient enough to aid in the cost of HIV-related care.^{14,23} The Ryan White program would also continue to provide adherence, linkage, and retention services that would not be included in the ACA.¹⁷ Since Medicaid does not provide the same services as ADAP (including additional pharmacy services, access to social workers, and retention services), it is unknown how the Medicaid expansions will affect patients who are newly eligible for Medicaid and no longer eligible for ADAP.

Section 4: Problem Statement

With this information, there are two main problems that need to be addressed. The first problem is that there are many barriers to adherence for HIV patients in either KADAP or Medicaid that can be improved upon in order to increase their medication adherence and program utilization. These barriers are important to consider in order to decrease disease-related morbidity and mortality, decrease transmission of the disease, and prevent medication resistance. Additionally, since many states have waiting lists, it is important for patients who are in the program to be using the program to its fullest potential. While some of these barriers are linked to demographics, as addressed above, some of these barriers are structural or have other causes. A very recent study from the HIV clinic in Alabama invited patients to participate in focus groups to determine barriers to adherence and to find out if any of these barriers are structural/programmatic in nature.²⁴ Patients cited side effects, comorbid depression, pill fatigue, fear of toxicity, medication resistance, stigma, short time enrolled in ADAP, and problems with ADAP recertification as barriers. The clinic also determined that there may be some health literacy concerns that stemmed from the conversations, in which patients thought that side effects from the medication meant that the medication was not working. Although this capstone will only be able to analyze the association between adherence and different demographics, programmatic and policy barrier will be important to consider. The second problem is that Medicaid expansion through the ACA could negatively affect HIV patients who will be newly eligible for Medicaid and no longer eligible for ADAP. Since ADAPs offer additional retention services that should, theoretically,

increase medication adherence, the patients moving to Medicaid may be at a disadvantage. This will be important to consider when determining the future of ADAPs in this changing healthcare environment.

Methods

In order to analyze the medication adherence of patients in KADAP and Kentucky Medicaid and to determine if any demographic factors are associated with medication non adherence, a retrospective, cross-sectional analysis of pharmacy claims data from the Kentucky Clinic Pharmacy as well as patient data from the Bluegrass Care Clinic, both located at the University of Kentucky, from one calendar year will be analyzed. Adherence will be determined by the medication possession ratio (MPR) equation, discussed below. Each patient will have an average MPR calculated from all of their claims data throughout the year. An average MPR will also be calculated for KADAP and Medicaid. In order to determine any demographic factors are associated with MPR, multivariate regression will be run with each demographic factor as an independent variable (age, sex, race, number of medications, income, and program) and MPR as the dependent variable. Dummy variables will be created for program, sex, and race for regression purposes. Separate regressions will be run for KADAP and Medicaid together, KADAP alone, and Medicaid alone.

Data Collection

In this retrospective, cross-sectional analysis, pharmacy claims data from the Kentucky Clinic Pharmacy as well as patient data from the Bluegrass Care Clinic, both located at the University of Kentucky, were collected from January 1, 2011 to December 1, 2011. Four separate sets of data were collected, and are shown below:

Table 1: Values Contained in KADAP Pharmacy Claims	
KADAP ID number	Drug Name and Strength
Date of each fill	Quantity filled
Prescriber	Drug Cost
Age	Race
Gender	

Table 2: Values Contained in Medicaid Pharmacy Claims	
Medical record number	Drug Name and Strength
Dates of first and last fill	Number of refills
Days supply of each fill	Age
Gender	

Table 3: Values Contained in KADAP Clinic Data	
KADAP ID number	Drug Name and Strength
Date of each fill	Quantity filled
Prescriber	Drug Cost
Age	Race
Gender	Income
Insurance	

Table 4: Values Contained in Medicaid Clinic Data	
Medical Record Number	Race

All data except for Medicaid pharmacy claims data had been compiled into excel documents by clinic staff or by the pharmacy claims process. Medicaid pharmacy claims data were manually collected by the author by matching the medical record numbers provided by the clinic with patients in the pharmacy's computer system. KADAP pharmacy claims data were segregated by month, with the exception of demographics (race, age, and sex), which were reported quarterly. The demographic data reported in January were used for the statistical analysis and assumed to be true for the entire year. Data from pharmacy claims and from the Bluegrass Care Clinic were merged. When data overlapped, pharmacy claims data were used. Since a list was not available for which patients were eligible for KADAP or Medicaid for the entire year, patients were assumed eligible based on the list generated by pharmacy claims data and the Bluegrass Care Clinic from the first quarter of the year.

Inclusion and Exclusion Criteria

Pharmacy claims data were included if the patient was at least 18 years old, was included on the KADAP ID number or Medicaid medical record number list provided by the clinic, if the medication was for an antiretroviral, if the medication was for at least a quantity of 15 and assumed to be a 30-day supply, and if the patient filled one or more medications at least two times during the study period (the minimum requirement for the medication possession ratio equation).

Pharmacy claims data were excluded if the number of days of supply could not be determined or if the KADAP ID number or medical record number were missing.

Although KADAP requires that only 30 days of medication are given at a time, it was determined during analysis that there may have been cases when more than 30 days were given. The author manually analyzed each claim and excluded the claims where the

number of days of supply was indeterminable. For example, if a medication was written for a quantity of 15, the author looked at the refills to determine if they were refilled in 15-day intervals or 30-day intervals. If they were refilled in 15-day intervals, the data were excluded since calculations assumed each medication was filled for a 30-day supply. Several antiretrovirals rotate between once a day and twice a day dosing (a quantity of 30 for 30 days versus a quantity of 60 for 30 days). For these medications, the author manually assessed these claims to ensure that the medications found to rotate between a quantity of 30 and 60 are medications that are commonly prescribed this way (e.g. Norvir) before assuming that they were written for a 30-day supply.

Medication Possession Ratio

Adherence was determined based on the medication possession ratio, which was calculated using the following equation:

$$\frac{\text{Entire length of prescription} - \text{length of last fill}}{\text{Number of days between first and last fill}} \times 100$$

A medication possession ratio was calculated for each individual medication, and an average medication possession ratio was calculated for each patient by adding the percentage for each medication and dividing by the number of medications. For KADAP pharmacy claims data, the days supply was assumed to be 30 days for each medication, but claims were excluded if this information was indeterminable. For Medicaid data, the days supply were readily available.

For the numerator of the equation, the entire length of the prescription was assumed to be 30 (the days supply) multiplied by the number of refills. Therefore, if a patient refilled a prescription 3 times, the entire length of the prescription would be 90 days. The length of

the last fill is always 30 days. The medication possession ratio was calculated in Microsoft Excel.

Statistical Analysis

Once the average MPR was calculated in Excel, the data was transferred to Stata (version 11). Initially, descriptive statistics were calculated for the KADAP and Medicaid patients to determine baseline demographics.

KADAP Demographics

As shown in the table below, the majority of KADAP patients are white males and the total population consists of 2,024 patients.

Race	Frequency: Number of patients (% of total)	Gender	Frequency: Number of patients (% of total)
White	1,233 (61%)	Male	1,624 (80%)
Black	633 (31%)	Female	397 (19%)
Hispanic	116 (6%)	Unknown	3 (<1%)
Other	42 (2%)		
Total	2,024	Total	2,024

Looking further into the demographics of these KADAP patients (Table 6), the average salary of these patients is just under \$7,000 per year, the average age is 45 years, and the

average number of antiretrovirals they take is three. Of these patients, their average medication possession ratio is 84.7 percent, with a range from 14.9 to 100 percent.

Table 6: Mean Demographics of All KADAP Patients with Ranges	
MPR	84.7% (14.9%-100%)
Age	45 (21-79)
Annual Income	\$6,770 (\$0-\$71,623)
# of Meds	2.7 (1-9)

Medicaid Demographics

Listed in the below table are the baseline demographics of the Medicaid patients. The majority of the eligible patients are black males, but the total number of patients in this group (n=55) is much smaller than that of the KADAP group.

Table 7: Demographics of Included Medicaid Patients			
Race	Frequency: Number of patients (% of total)	Gender	Frequency: Number of patients (% of total)
White	23 (42%)	Male	33 (60%)
Black	31 (56%)	Female	22 (40%)
Amer. Indian	1 (2%)		
Total	55	Total	55

KADAP Regression Analysis

Multivariate regression analysis was done for the KADAP data to determine if patient demographic factors, including age, race, sex, annual income, and number of antiretrovirals taken influence the average medication possession ratio. The regression output is shown in the table below.

Table 8: Multivariate Regression for KADAP MPR					
Variable	Coefficient	Standard Error	t	P> t	95% Confidence Interval
Age	0.12128	0.03896	3.11	0.002	[0.04487-0.1976955]
Income	0.00002	0.00004	0.54	0.59	[-0.00006-0.000102]
Count	-0.43416	0.30195	-1.44	0.151	[-1.02634-0.158006]
Black Race	-3.7394	0.88369	-4.23	0.000	[-5.47247- -2.00638]
Male Sex	1.6702	1.03005	1.62	0.105	[-0.34984-3.69032]
					R ² =0.0189; n=2,024

Medicaid Regression Analysis

Multivariate regression analysis was done for the Medicaid data to determine if patient demographic factors, including age, race, sex, and number of antiretrovirals taken (count) influence the average medication possession ratio. The regression output is shown in the table below.

Table 9: Medicaid Regression Output			
Variable	Coefficient	P-value	95% Confidence Interval
Age	0.106	0.740	[-0.5315-0.7431]
Male Sex	11.055	0.114	[-2.7336-24.8427]
Black Race	3.014	0.963	[-9.1561-15.1841]
Count	-0.1573	0.963	[-6.866-6.5515]

Medicaid and KADAP Regression Analysis

Multivariate regression analysis was done for Medicaid and KADAP combined data to determine if patient demographic factors, including age, race, sex, program, and number of antiretrovirals taken (count) influence the average medication possession ratio. The regression output is shown in the table below.

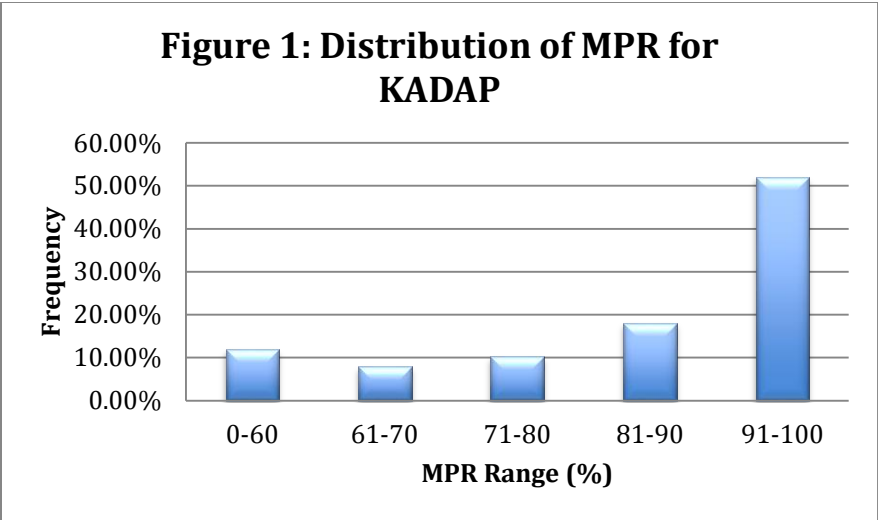
Table 10: Multivariate Regression for KADAP and Medicaid MPR					
Variable	Coefficient	Standard Error	t	P> t	[95% Confidence Interval]
Age	0.127	0.03819	3.33	0.001	[0.052189-0.201986]
Count	-0.4334	0.30192	-1.44	0.151	[-1.05507-0.158682]
Black Race	-3.8368	0.87273	-4.40	0.000	[(-5.54832)-(-2.125297)]
Male Sex	2.0242	1.01655	1.99	0.047	[0.030617-4.017748]
Medicaid	-6.1956	2.5043	-2.47	0.000	[(-11.10686)-(-1.284331)]
R ² =0.0241; n=2,079					

Results

Kentucky AIDS Drug Assistance Program

MPR

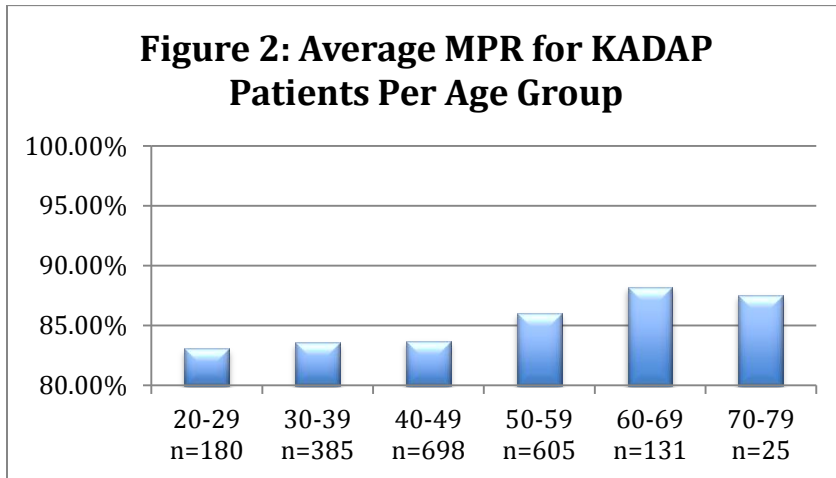
The average MPR for KADAP patients is 84.7 percent. As depicted in Figure 1, over half of the patients in KADAP had medication possession ratios between 91-100 percent. The rest of the patients are distributed throughout other ranges, with 11.9 percent of patients having an MPR of 0-60 percent, 7.9 percent of patients having an MPR of 61-70 percent, 10.2 percent of patients having an MPR of 71-80 percent, and 18 percent of patients having an MPR of 81-90 percent.



Age

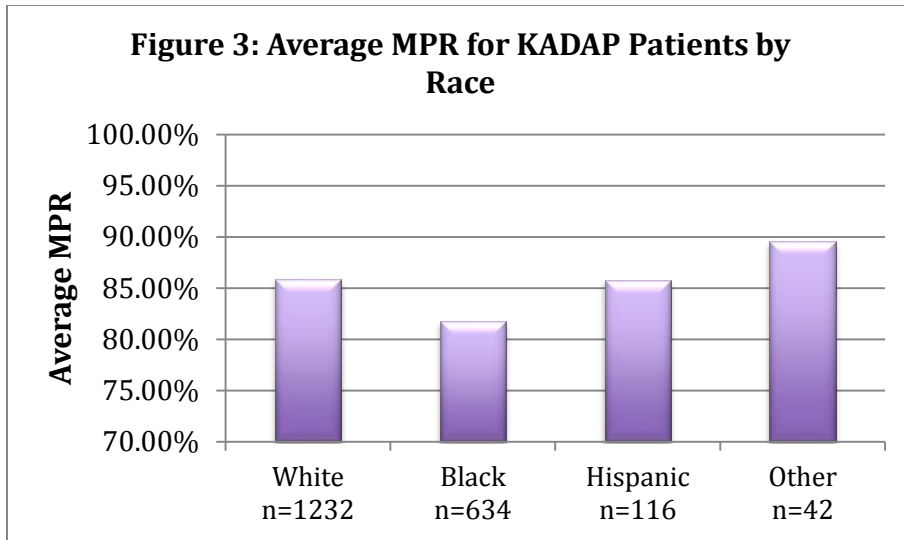
As shown in Table 8, the medication possession ratio was significantly associated with age in regression analysis ($p=0.002$) in which every 1-year increase in age was associated with 0.121 percent increase in MPR. When age is broken into age groups, starting with the youngest group within the patient population, the increased average medication

possession ratio seen with the older decade ranges (50-59, 60-69, and 70-79 years) is visible graphically (Figure 2). The average MPR decreases slightly with the oldest age range, but this is most likely related to the small number of patients depicted in this decade (n=25).



Race

When stratified by race (Figure 3), the average medication possession ratio is 85.9 percent for white patients, 81.8 percent for black patients, 85.8 percent for Hispanic patients, and 89.6 percent for other patients, which includes mixed-race patients. In multivariate analysis, race and medication possession ratio are associated in a statistically significant manner ($p < 0.0001$) with black patients having average MPR's 3.739 percent lower than other races (dummy variables 0=non-black, 1=black).



Sex

Although sex was not statistically significant in multivariate analysis ($p=0.105$; dummy variables 0=non-male, 1=male), it was significant in univariate analysis with male gender having a 2.83 percent increase in average MPR ($p=0.011$).

Count and Income

Neither the number of antiretrovirals the patient takes nor their income was significantly associated with MPR ($p=0.151$ and $p=0.59$, respectively).

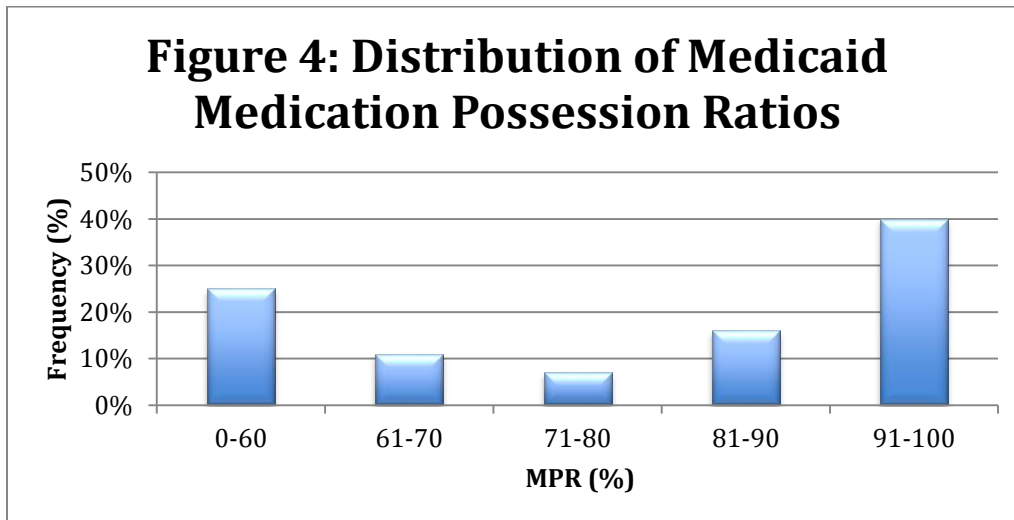
Location

Since patients who do not live in Lexington have their medications mailed to them, the average medication possession ratio of Bluegrass Care Clinic patients (Lexington) were compared to patients outside of the Bluegrass Care Clinic (assumed to be non-Lexington). There was not a statistically significant difference between the two sets of patients (85.9 percent Lexington, 84.4 percent non-Lexington; $p=0.128$).

Medicaid

MPR

The average MPR for Medicaid patients was 77.3 percent. When the medication possession ratios are distributed among groups (0-60 percent, 61-70 percent, 71-80 percent, 81-90 percent, 91-100 percent), 40 percent of patients have a medication possession ratio of 91 percent to 100 percent and one quarter of patients have an MPR of 0-60 percent (Figure 4). However, similar to the KADAP patients, most patients fell into the 91-100 percent MPR category.



Other Variables

Unlike with the KADAP patient variables, none of the Medicaid variables were statistically significantly associated with MPR in regression analysis (Table 9). However, this may be due to the very small number of patients in this category.

Kentucky AIDS Drug Assistance Program and Medicaid

Program

When data from Medicaid and KADAP are combined for regression (Table 10), program status is a statistically significant variable ($p=0.000$; dummy variable 0=KADAP, 1=Medicaid) in which Medicaid is associated with a 6.2 percent decrease in average MPR.

Sex

Unlike with KADAP alone, in this analysis, sex is also statistically significant ($p<0.047$) with the male sex being associated with a 2.02 percent increase in average MPR compared to non-male.

Age

Similar to the KADAP regression analysis, age is statistically significant ($p<0.001$) with each additional year increasing the average MPR by 0.13 percent.

Race

Similar to the KADAP regression analysis, age is statistically significant ($p=0.000$) with black race being associated with a 3.84 percent decrease in average MPR.

Count

Similar to the previous analyses, the number of antiretrovirals the patient took was not statistically significant ($p<0.151$).

Discussion

Kentucky AIDS Drug Assistance Program

As shown above, age and race were significantly correlated with a lower average MPR, with younger, black patients having lower average MPRs than their counterparts. This is consistent with a study from a similar ADAP in Alabama¹³ as well as with other adherence studies that focused specifically on HIV patients. However, with an average MPR of 85 percent, many patients within the program still fall below the optimal adherence level of 95 percent for viral load suppression, putting them at greater risk of developing medication resistance, transmitting the disease, contracting opportunistic infections, and becoming hospitalized. Additionally, Alabama found that 23 percent of the medications did not reach the intended ADAP enrollees¹³. Although the administrative costs of filling these medications has not been quantified, time and money from pharmacists, pharmacy technicians, social workers, and various ADAP administrators were wasted without getting the medication to the intended patient.

Medicaid

There were no significant relationships between age, race, sex, or medication count and MPR for Medicaid patients. Due to the small sample, this study should be repeated with a larger sample size, possibly through Medicaid third-party claims data, to insure adequate power to detect a statistically significant relationship. However, when Medicaid and KADAP data were combined for regression, Medicaid was associated with a statistically significant 6 percent decrease in MPR. Although a larger sample size is needed to make

significant recommendations, this could show that Medicaid patients as a whole are at a disadvantage for adherence and program utilization when compared to KADAP patients. This is due to the increased amount of support given to KADAP patients – a dedicated pharmacist, pharmacy technician, and in house care coordinators/social workers – as well as the requirement to stay involved with the program as eligibility criteria. Medicaid patients do not have the same access to these support services or incentives to become and remain adherent.

Recommendations

Programmatic and Policy Implications

Programmatic Barriers to Adherence

To ensure that patients are fully utilizing these public programs and being adherent to their HIV medications, it is necessary to make changes within each program that will promote medication adherence. Since the analysis shows that younger, black patients are more likely to be nonadherent, initial programmatic changes should be focused on these patients. For KADAP, an easy change that could increase adherence is to make refill reminder calls with call lists stratified by age and race so that the patients more likely to be nonadherent (younger, black patients) will be the focus. Refill reminder call lists are a practice that is already done by some chain retail pharmacies, in which a daily list of patients who are due for a refill is generated. A pharmacy technician calls all patients on the list to remind them that they are due for a refill. Although this may not help patients who simply forget to take their medications or have other reasons for being nonadherent, it could help patients who forget to get their medications refilled. This could also increase

the conversation between pharmacy personnel and the patient, helping to determine the root cause of the patient's nonadherence. While this would take time away from a pharmacy personnel's daily duties, this could be easily done by an unpaid intern pharmacist and would take minimal time if a call list could be generated by the computer system.

Barriers Created by the Affordable Care Act and Medicaid Expansion

Based on the analysis in which KADAP patients have statistically significantly higher MPRs, it may be necessary to alter the requirements for Medicaid and KADAP co-enrollment in order to ensure medication adherence within Medicaid. Since many KADAP patients will be newly eligible for Medicaid due to Medicaid expansion with the ACA, these patients will lose the added retention and adherence programs afforded to them by KADAP. As shown in the analysis, patients enrolled in Medicaid have lower adherence rates than KADAP patients, and studies have shown that public insurance is associated with two times the mortality rate at one year when compared with private insurance and no insurance HIV populations²⁶. While patients can currently be enrolled in both programs, KADAP typically functions as a "safety net" to cover medication copays. However, copay assistance may not be a main barrier to medication adherence for Medicaid patients. Since these patients benefit from the additional services KADAP offers, a new policy that allows patients to be covered by Medicaid while still receiving services from KADAP regardless of financial need may be warranted. This would also be a more cost-effective and efficient option than implementing these services newly in Medicaid.

Other Programmatic and Policy-Related Barriers to Adherence

As previously discussed, a recent study from the HIV clinic in Alabama²⁴ invited ADAP patients to participate in focus groups to determine barriers to adherence and to find out if any of these barriers are structural/programmatic in nature. Patients cited side effects, comorbid depression, pill fatigue, fear of toxicity, medication resistance, stigma, short time enrolled in ADAP, and problems with ADAP recertification as barriers. The clinic also determined that there may be some health literacy concerns that stemmed from the conversations, in which patients thought that side effects from the medication meant that the medication was not working. Since there appears to be programmatic similarities between the ADAP in Alabama and KADAP, these findings generate ideas for programmatic and policy changes that could be helpful to both programs. From a programmatic standpoint, it could be beneficial to have a mandatory “HIV 101” class for newly enrolled patients. This one-time class could address the basics of HIV, how the medications work, the importance of taking medications appropriately, and complications from medication nonadherence. This class could be run by pharmacy residents and count as part of their mandatory teaching component. Depending on the frequency, this could also be facilitated by clinic pharmacists who have a specific interest in HIV care. A pilot program study would be needed to determine the utility of such a program in HIV patients.

Since many patients cited depression as a barrier to adherence, and depression and HIV/AIDS tend to be comorbid, having dedicated psychiatric support with counselors could aid these patients in becoming adherent and living fulfilled lives. This cost could be significant to the program, as a full-time counselor makes \$40,000 annually on average²⁵. However, depending on the change in medication adherence that could come from

counseling services, this cost may be justified. A pilot program study would be needed to determine this utility.

From a policy standpoint, many patients in the Alabama study stated that the recertification process was a burden and paperwork sometimes got lost within the system, increasing time for recertification. Anecdotally, this is also a problem that has occurred with KADAP. Some patients stated that they had been dropped from the program and did not realize it until they went to pick their medications up from the pharmacy. With increased use of technology in healthcare, computerizing this process could be beneficial for this program. While this would be a costly endeavor, having the capability to upload documents to a website, check ADAP status, and allow patients and social workers to communicate regarding program eligibility questions could make the process more efficient. Patients cited having limited access to transportation, making it difficult to come to the clinic when there were recertification and eligibility problems. Having a website to upload documents and update information could decrease the need for costly transportation for patients.

Limitations

This study has several limitations that require discussion. First, since the days supply of medications in the original data obtained was not always easily determined, errors could have been made in assuming that medications were intended for 30 days. Additionally, many medications were excluded when the days supply could not be determined. These issues typically happened with only a few medications, which could create bias by removing several pieces of data for the same medication. Additionally, it is unknown

whether these patients were enrolled in KADAP for the entire year. Some patients could have gained insurance for part of the year and then re-enrolled in KADAP, making their MPR falsely low.

The MPR calculation itself has limitations. First, it is unknown whether the patient picked up the medication on the day the claim was processed. Medications are not reprocessed unless they have been not picked up for 10 days. Additionally, the patient having the medication on-hand does not mean that they will take it daily as prescribed, so the MPR may not always accurately reflect the patient's adherence.

Additionally, only a small number of Medicaid patients were eligible for the study since they had to both see a prescriber at the Bluegrass Care Clinic and fill their medications at the Kentucky Clinic Pharmacy. For the patients who did fit these criteria, they may have filled their medications at a different pharmacy throughout the year, making their MPR falsely low. Additionally, these patients could have been eligible for KADAP throughout the year, making it difficult to analyze Medicaid as a separate entity from KADAP.

Lastly, there are other factors that are not associated with any of the variables studied that could affect a patient's medication adherence, such as comorbid conditions, level of education, length of time in the program, family support, transportation, housing, and drug/alcohol dependence. Many of these factors have been studied in the literature and could contribute to medication nonadherence.

Conclusions

Most patients enrolled in KADAP do not reach the 95 percent adherence rate necessary for optimal viral suppression. However, on average, the studied Medicaid patients had a

significantly lower MPR than patients enrolled in KADAP. In order to increase adherence in both programs, changes need to be made to decrease barriers to adherence, including refill reminders, HIV classes for new KADAP enrollees, increased access to psychiatric and counseling services, online access, and requirement changes for Medicaid and KADAP co-enrollment.

Bibliography

1. National Institutes of Health AIDSinfo. (2013, 27 September). HIV Overview: The Basics. Accessed at: http://aidsinfo.nih.gov/contentfiles/HIVAIDS_theBasics.pdf
2. Crum NF, Riffenburgh RH, Wegner S, et al. Comparisons of causes of death and mortality rates among HIV-infected persons: analysis of the pre-, early, and late HAART (highly active antiretroviral therapy) eras. *J Acquir Immune Defic Syndr*. 2006;41(2):194-200.
3. Kaiser Family Foundation. (2014, 7 April). The HIV/AIDS Epidemic in the United States. Accessed at: <http://kff.org/hivaids/fact-sheet/the-hivaids-epidemic-in-the-united-states/#footnote-healthus>
4. Centers for Disease Control. (2013, May). Health, United States, 2012. Accessed at: <http://www.cdc.gov/nchs/data/hus/hus12.pdf>
5. Cohen MS, Chen YQ, Mccauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med*. 2011;365(6):493-505.
6. Centers for Disease Control. (2012, July). HIV in the United States: The Stages of Care. Accessed at: http://www.cdc.gov/hiv/pdf/research_mmp_StagesofCare.pdf
7. Gross, R., B. Yip, V. Lo Re III, E. Wood, C. S. Alexander, P. R. Harrigan, D. R. Bangsberg, J. S. Montaner, and R. S. Hogg. 2006. "A Simple, Dynamic Measure of Antiretroviral Therapy Adherence Predicts Failure to Maintain HIV-1 Suppression." *Journal of Infectious Diseases* 194: 1108-14.
8. Fairley, C. K., A. Permana, and T. R. Read. 2005. "Long-Term Utility of Measuring Adherence by Self-Report Compared with Pharmacy Record in a Routine Clinic Setting." *HIV Medicine* 6: 366-9.
9. Paterson DL, Swindells S, Mohr J, et al. Adherence to protease inhibitor therapy and outcomes in patients with HIV infection. *Ann Intern Med*. 2000;133(1):21-30.

10. Montaner JS, Lima VD, Harrigan PR, et al. Expansion of HAART Coverage Is Associated with Sustained Decreases in HIV/AIDS Morbidity, Mortality and HIV Transmission: The "HIV Treatment as Prevention" Experience in a Canadian Setting. PLoS ONE. 2014;9(2):e87872.
11. Barclay, T. R., C. H. Hinkin, S. A. Castellon, K. I. Mason, M. J. Reinhard, S. D. Marion, A. J. Levine, and R. S. Durvasula. 2007. "Age-Associated Predictors of Medication Adherence in HIV-Positive Adults: Health Beliefs, Self-Efficacy, and Neurocognitive Status." *Health Psychology* 26: 40–9.
12. Gordillo, V. J. del Amo, V. Soriano, and J. Gonzalez-Lahoz. 1999. "Sociodemographic and Psychological Variables Influencing Adherence to Antiretroviral Therapy." *AIDS* 13: 1763–9.
13. Godwin NC, Willig JH, Nevin CR, et al. Underutilization of the AIDS Drug Assistance Program: associated factors and policy implications. *Health Serv Res.* 2011;46(3):982-95.
14. Kaiser Family Foundation. (2013, 05 March). The Ryan White Program. Accessed at: <http://kff.org/hiv aids/fact-sheet/the-ryan-white-program/>
15. Health Resources and Services Administration. About the Ryan White HIV/AIDS Program: About Ryan White. Accessed at: <http://hab.hrsa.gov/about hab/ryanwhite.html>
16. Health Resources and Services Administration. About the Ryan White HIV/AIDS Program: Part B: AIDS Drug Assistance Programs. Accessed at: <http://hab.hrsa.gov/about hab/part bdrug.html>
17. Kaiser Family Foundation. (2012, September). The Affordable Care Act, The Supreme Court, and HIV: What Are the Implications? Accessed at: <http://kaiserfamilyfoundation.files.wordpress.com/2013/03/8363.pdf>
18. Kaiser Family Foundation. (2014, 08 April). AIDS Drug Assistance Programs (ADAPs). Accessed at: <http://kff.org/hiv aids/fact-sheet/aids-drug-assistance-programs/>

19. Kaiser Family Foundation. (2013, April). Updating the Ryan White HIV/AIDS Program for a New Era: Key Issues & Questions for the Future. Accessed at:
<http://kaiserfamilyfoundation.files.wordpress.com/2013/04/8431.pdf>
20. University of Kentucky Hospital. (2012, February). Department of Pharmacy Policy: Kentucky AIDS Drug Assistance Program (KADAP). Accessed at:
<http://www.hosp.uky.edu/pharmacy/departpolicy/PH12-14.pdf>
21. Johnston SS, Juday T, Seekins D, et al. Patterns and correlates of linkage to appropriate HIV care after HIV diagnosis in the US Medicaid population. *Sex Transm Dis.* 2013;40(1):18-25.
22. National Alliance of State & Territorial AIDS Directors. (2012, August). National ADAP Monitoring Project Annual Report. Accessed at:
http://www.nastad.org/Docs/021503_National%20ADAP%20Monitoring%20Project%20Annual%20Report%20-%20August%202012.pdf
23. Health Resources and Services Administration. (2010, July). Ryan White HIV/AIDS Program 2010 State Profiles. Accessed at: <http://hab.hrsa.gov/stateprofiles/index.htm>
24. Olson KM, Godwin NC, Wilkins SA, et al. A Qualitative Study of Underutilization of the AIDS Drug Assistance Program. *J Assoc Nurses AIDS Care.* 2014.
25. U.S. News and World Report. (Copyright 2014). Mental Health Counselor. Accessed at: <http://money.usnews.com/careers/best-jobs/mental-health-counselor>
26. Mugavero MJ, Lin HY, Willig JH, et al. Missed visits and mortality among patients establishing initial outpatient HIV treatment. *Clin Infect Dis.* 2009;48(2):248-56.