Published in final edited form as:

AIDS Care. 2015 ; 27(7): 829–835. doi:10.1080/09540121.2015.1021745.

Adherence to highly active antiretroviral therapy impact on clinical and economic outcomes for Medicaid enrollees with HIV and hepatitis C co-infection

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Abstract

We examined the impact of antiretroviral treatment adherence among Hepatitis C co-infected HIV patients on survival and clinical outcomes. We analyzed Medicaid claims data from fourteen southern states from 2005-2007, comparing survival and clinical outcomes and cost of treatment for HIV and hepatitis-C co-infected patients (N=4,115) at different levels of adherence to antiretroviral therapy.More than one in five patients (20.5%) showed less than 50% adherence to antiretroviral treatment, but there were no racial-ethnic or gender disparities. Significant survival benefit was demonstrated at each incremental level of adherence to antiretroviral therapy (one-year mortality ranging from 3.5% in the highest adherence group to 26.0% in the lowest). Low adherence patients also had higher rates of hospitalization and emergency department visits. Relative to patients with high (>95%) ART-adherence, those with less than 25% treatment adherence had four-fold greater risk of death (adjusted odds ratio 4.22 [95% CI, 3.03,5.87]). Non-drug Medicaid expenditures were lower for high adherence patients, but cost of medications drove total Medicaid expenditures higher for high-adherence patients. Cost per quality-adjusted life year (QALY) saved (relative to the <25% low-adherence group) ranged from $21,874 for increasing adherence to 25-50% to $37,229 for increasing adherence to 75-95%. Adherence to antiretroviral therapy for patients with HIV and hepatitis C co-infection is associated with lower adverse clinical outcomes at a Medicaid cost per QALY commensurate with other well-accepted treatment and prevention strategies. Further research is needed to identify interventions which can best achieve optimal ART adherence at a population scale.

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Keywords

HIV; antiretroviral therapy; adherence; outcomes; Medicaid; Hepatitis C co-infection

Introduction

Similar routes of transmission result in extremely high rates of hepatitis C (HCV) co-infection among patients with human immunodeficiency virus (HIV) in the United States. The prevalence of HCV among HIV infected people is 25%([CDC, 2013]). Based on treatment guidelines for HIV and HCV co-infection, the benefits of highly active antiretroviral therapy (ART) outweigh concerns regarding drug induced liver injury in HIV + HCV co-infected individuals.

ART adherence is one factor determining treatment success. Unfortunately, adherence to ART is often sub-optimal. In the context of HIV and HCV co-infection, successful treatment requires nearly perfect adherence to ART in order to reduce viral load and prevent the emergence of drug resistant variants ([Moatti et al., 2000]; [Soriano et al., 2002]).

Medicaid is the largest public health insurance program for low-income persons in the United States, and provides health care coverage for nearly half of all people with HIV in the US. Medicaid claims data also provide a detailed longitudinal record of health care utilization and prescription drug usage. Further, Medicaid claim databases are more likely to accurately reflect real-world adherence. The purpose of this study was to quantify the clinical and economic benefits of adherence to ART, with a special focus on the sub-set of Medicaid enrollees with both HIV and HCV co-infection.

Methods

We used a retrospective cohort design to measure adherence rate and assess its clinical and economic benefits for HIV and HCV co-infected patients. We examined the clinical and economic outcomes one year after the initial diagnosis of HCV co-infection in established patients with HIV. The data for this analysis came from 2005-2007 100% of Medicaid paid claims data provided by the Centers for Medicare and Medicaid Services (CMS) as Medicaid Analytic Extract (MAX) files from 14 states: Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Maryland, Missouri, Mississippi, North Carolina, South Carolina, Tennessee, Texas, and Virginia. This project was approved by the Morehouse School of Medicine Institutional Review Board for human subjects research, and our data security and confidentiality protocols were approved by the US/DHHS Center for Medicare and Medicaid Services (CMS) Privacy Board. These studies have been deemed exempt from informed consent requirements, because the protection of the individual's confidentiality would be endangered more by obtaining their name and address to seek informed consent than it is by using the data in a less personally-identifiable format.

Patient selection

Data covered paid claims for activities occurring from 01/01/2005 to 12/31/2007. We identified 102,782 HIV patients in these 14 states, and 13,129 of these HIV-infected individuals had claims consistent with HCV co-infection. We excluded 3,102 patients whose initial diagnosis of co-infection occurred after 01/01/2007 in order to assure that we had a full 365 days for follow-up tracking. Among those eligible enrollees, only 4,115 patients left.

Five types of Food and Drug Administration(FDA) approved ARV drugs were recommended or available in Medicaid during the observation period:

- nucleoside reverse transcriptase inhibitors (NRTIs), which include zidovudine, didanosine, stavudine, lamivudine, abacavir, emtricitabine,andtenofovir;
- non-nucleoside reverse transcriptase inhibitor (NNRTIs) which include efavirenz, nevirapine, delavirdine, and etravirine;
- protease inhibitor (PIs) which include atazainavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir, and lopinavir;
- entry inhibitors which include maraviroc fusion inhibitors enfuvirtide
- integrase inhibitor (raltegravir).

As with ART-naive, HIV-infected persons, a combination ART regimen with at least two nucleoside reverse transcriptase inhibitors plus one non-nucleoside reverse transcriptase inhibitors or one ritonavir-boosted protease inhibitor, or one integrase inhibitor was recommended.

Adherence to ART

Adherence to ART was determined by examining the proportion of prescribed days covered (PPDC) by ART regimens. PPDC was defined as total ART days' supply divided by the 365 days follow-up period. For example, a person who received a total of 240 days' supply of ART would have a PPDC of 0.66 (240/365).We stratified person-years adherence to ART on an ordinal scale of five levels (<25%, 25-50%, 50-75%, 75-95%, and >95%).

Clinical Outcomes

One year mortality

Presence of either Medicaid or Medicare date of death in personal summary file was used to flag mortality.

Hospitalization

Hospital admissions were captured in inpatient files and categorized as dichotomous (yes/no). All hospitalization claims were captured from the 365 days after initial diagnosis of HCV co-infection in established HIV patients.

Emergency department (ED) services within the 1 year period after initial diagnosis of HIV-HCV co-infection were identified in inpatient and outpatient files. We categorized ED visit as dichotomous (yes/no) for use in multivariate models.

Quality adjusted life years (QALYs)

QALY is an outcome measure that considers both the quality and the quantity of life lived. Each year in perfect health is assigned the value of 1.0. Each year of less than perfect health is assigned a value less than 1.0 down to a value of 0.0 for death. Studies commonly report a pooled estimated of utility of 0.70 for patients who have AIDS related syndromes and 0.82 for other co-infections(M. A. Chesney et al., 2000). Average QALYs were reported for different adherence groups.

Other covariates

HCV treatment

Any peginterferonalfa or ribavirin claims during the one year tracking period were used as the indicator to define HCV treatment status. We then dichotomized this variable as Yes/No.

AIDS conditions

We captured the presence of AIDS-defining clinical conditions as defined by CDC(Schneider et al., 2008) by searching for corresponding ICD-9-CM codes in the primary or secondary diagnosis fields of each co-infection patient.

Cost Measures

Direct costs paid by Medicaid were obtained from MAX files. ART treatment cost was calculated by the summation of one year of ART related prescription drug costs after the initial co-infection diagnosis. We aggregated outpatient costs, inpatient costs and all prescription costs, and then deducted the ART-associated cost to estimate the total cost excluding drug costs.

Cost effectiveness analysis

Incremental cost-effectiveness ratio (ICER), a standard measure used in cost-effectiveness analysis, was reported in our study. ICER is represented as the ratio of the difference in expected antiretroviral regimen costs among different adherence groups compared with the difference in QALY outcomes among those same adherence groups.

Statistical Analysis

Descriptive analyses comparing sample characteristics, demographics, and socioeconomic status of patients with HCV/HIV co-infection were examined using the Mantel-Haenszel test for categorical variables and ANOVA-test for continuous variables. We used the Kaplan-Meier method to estimate the cumulative probability of mortality for different adherence groups. Participants were censored on the date of death or the end of one year observation if they did not die during this time. We then built a Cox proportional hazard model to estimate

hazard ratio for death, with adjustment for covariate effects to obtain adjusted risk ratios. Data were analyzed using SAS 9.2 (Cary,NC).

Results

Table 1 provides descriptive statistics for HIV and HCV co-infected Medicaid enrollees from 14 southern states who had prescription drug claims in 2005-2007 for optimal ART. Based on PPDC levels, 5.9% of patients had low adherence (<25%), 14.6% had 25-50% adherence, 11.5% had 50-75% adherence, 7.9% had 75-95% adherence, and nearly 60% of Medicaid-enrolled HIV and HCV patients had more than 95% ART adherence. More than one in five patients (20.5%) had prescription refill claims indicating less than 50% adherence to antiretroviral treatment. There were no gender, racial/ethnic, or rural/urban differences in adherence.

Table 2 shows the distribution of clinical outcomes including hospitalization, emergency department visit, one year mortality rates, and quality adjusted life years (QALY) by level of adherence to ART. Descriptive statistics also show Medicaid expenditures specific to hospitalization and to ART drug costs, as well as total Medicaid expenditures at different levels of adherence. There was significant survival benefit demonstrated at each incremental level of adherence to antiretroviral therapy (one-year mortality ranging from 3.5% in the highest adherence group to 26.0% in the lowest). Low adherence patients also had higher rates of hospitalization and emergency department visits.

Table 3 shows the crude and adjusted hazard ratio of mortality among different ART groups. After adjusting for age, gender, race/ethnicity, metro/rural residential status, AIDS-related conditions, and HCV treatment status, the association of mortality with lower ART adherence was attenuated, but still significant. Relative to patients with high (>95%) ART-adherence, those with less than 25% treatment adherence still had a greater than four-fold risk of death (adjusted odds ratio 4.22 (95% CI, 3.03, 5.87). Even those with only mild non-adherence (75-95% adherence) had a 1.58 times higher adjusted relative risk (95%CI, 1.02, 2.46) of death (Figure 1).

Incremental cost-effectiveness ratios (ICERs) for different adherence groups are presented in table 4. Non-drug Medicaid expenditures were lower for high adherence patients, but the cost of medications drove total Medicaid expenditures higher for the high-adherence patients. Cost per quality-adjusted life year (QALY) saved (relative to the <25% low-adherence group ranged from $21,874 for increasing adherence to 25-50% to 37,229 for increasing adherence to 75-95%. The highest level of adherence (>95%) was associated with a cost of $66,455 per QALY.

Discussion

This study demonstrates first that high adherence to ART among Medicaid-enrolled patients with HIV and HCV co-infection is achievable – over 60% of such patients in this dataset had over 95% adherence to their ART. The absence of any significant racial-ethnic or gender disparities also suggests an important role for Medicaid in eliminating disparities and

achieving more equitable care and outcomes. Adherence was also associated with significant clinical benefits.

The problem of inadequate adherence to ART can be attributed to both provider and patient behaviors. Hepatotoxicity of ART adds greater complexity to medical decision making. However, barriers to adherence include regimen complexity, side effects, psychological issue, patient belief system, and the patient-provider relationship(M. Chesney, 2003).

Non-adherence also prolongs contagion and increases the risk for AIDS related opportunistic diseases, and death(Kiertiburanakul & Sungkanuparph, 2009; Schneider et al., 2008). The most well-known reason for non-adherence is forgetting(M. A. Chesney et al., 2000; Simoni et al., 2006)which becomes more common as individuals return to work or resume other activities. Confusion over pill schedules and obstacles to medication refills are additional factors in non-adherence(Buchanan et al., 2012; Wolfe, Carrieri, & Shepard, 2010). Personal psychological issues, such as substance abuse, depression, and stress may also contribute(Mellins et al., 2009), as can pain, fatigue, and medication side effects.

A number of non-medical determinants have also been found to impact adherence. Factors such as stable housing, secure employment, and social support all positively predict ART adherence(Godin, Cote, Naccache, Lambert, & Trottier, 2005; Moss et al., 2004). Lack of access to reliable transportation is associated with poor access to ART and poor adherence to ART.

Patient self-management is central for medication adherence. At the provider level, increased physician experience with HIV and AIDS is the most important factor associated with the successful treatment of HIV infected patients(Kitahata et al., 1996). At the practice level, lessons learned from successful chronic disease management programs such as nurse care managers, patient navigators, peer support, group visits, open access scheduling, telephone and text-message follow-up, and other panel-based care management strategies can be applied to the complexity of managing HIV and HCV co-infection(Starr & Springer, 2014; Tu et al., 2013).

Limitations of our study are inherent in the use of administrative claims data. Pharmacy claims are limited by their inability to directly assess whether the patient took the medication. Medicaid claims data do not reflect clinical covariates such as HIV viral load, and duration or severity of illness, or measures of impaired renal function such as GFR or creatinine. Medicaid data also do not provide individual-level information on socioeconomic status, education level, country of origin, length of stay in the US, or degree of social support, all of which may contribute to health care utilization. Finally, any healthcare cost paid for by sources other than Medicaid would not be captured in our data.

The prevalence of HCV co-infection in our study may seem low, when compared to prevalence figures generated from population-based or birth-cohort screening(Sherman, Rouster, Chung, & Rajicic, 2002). However, prior to the recent CDC recommendation of birth cohort screening for HCV, the recommendation was to screen for HCV based on risk factors. Most providers screened patients only if they have risk factors such as IV drug use or had liver function abnormalities. Thus the overall prevalence of HCV/HIV co-infection in

our initial study sample (15%) is similar to previously reported risk based screening prevalence measures (16%).

The recent approval of effective directly-acting antiviral treatment for HCV by the FDA is expected to dramatically change the treatment paradigm, reducing the rate of liver complications and providing additional benefits to HIV/HCV co-infected patients who are adherent to treatment. Reducing the cost of ART to state Medicaid programs could substantially lower the cost per QALY associated with increased ART adherence, or even provide absolute cost savings from increasing adherence.

Acknowledgments

Funding sources: Agency for Healthcare Research and Quality (AHRQ) mid-senior Career Development grant # K18HS022444; NIH/NIMHD RCMI Infrastructure for Clinical and Translational Research grant # U54MD007588; NIH/NIMHD Reducing Health Disparities in Vulnerable Populations (P20) grant # 1P20MD006881-02; DHHS Office of Minority Health Cooperative Agreement #5MPCMP121069-02-00.

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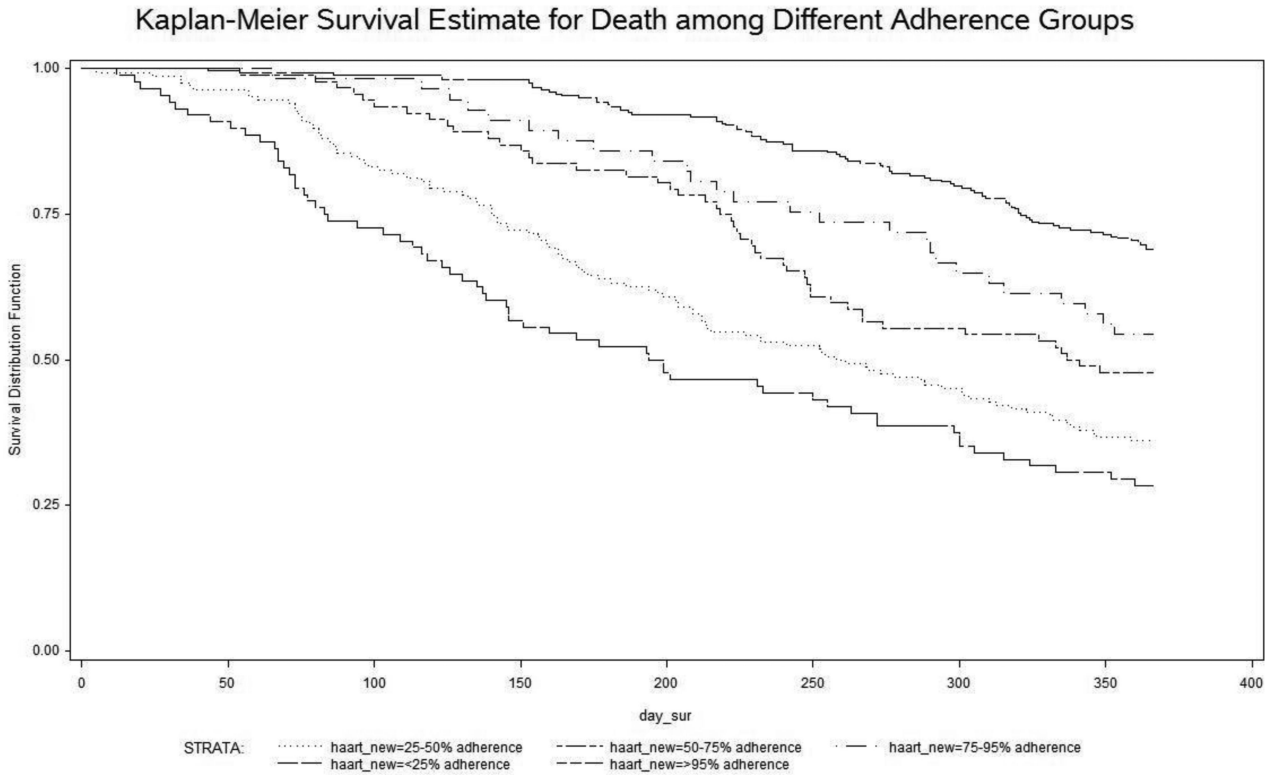

Figure 1.
ART adherence vs survival function

Table 1

Characteristic of patients with HIV& HCV co-infections among different ART adherence treatment groups (N=4,115)

	>95% adherent ART	75-95% adherent ART	50-75% adherent ART	25-50% adherent ART	<25% adherent ART	P
N (%)	2473(60.1%)	324(7.9%)	475(11.5%)	601(14.6%)	242(5.9%)	
Age						
Mean (SD)	46.3(7.7)	46.0(8.0)	45.4(7.4)	44.5(7.8)	46.0(7.7)	<.01 *
Gender						
Female	897(36.6%)	120(37.6%)	179(38.3%)	252(43.0%)	83(35.9%)	.05 ^
Male	1556(63.4%)	199(62.4%)	288(61.7%)	334(57.0%)	148(64.1%)	
Race/Ethnicity						
White	577(23.5%)	73(22.9%)	105(22.5.0%)	151(25.7%)	47(20.4%)	.99 ^
African American	1637(66.7%)	213(66.8%)	315(67.5%)	376(64.0%)	161(69.7%)	
Hispanics	98(4.0%)	15(4.7%)	25(5.4%)	28(4.8%)	11(4.8%)	
Other	142(5.8%)	18(7.9%)	22(4.7%)	33(5.6%)	12(5.2%)	
AIDS	668(27.0%)	112(5.6%)	175(36.8%)	226(37.6%)	100(41.3%)	<.01
HCV treatment **						
Yes	161(6.5%)	14(4.3%)	11(2.3%)	11(1.8%)	1(0.4%)	<.01
Rural/Urban Status						
Large Metro Area	117(4.7%)	12(3.7%)	20(4.2%)	34(5.7%)	5(2.1%)	.25 ^
Small Metro Area	176(7.1%)	15(4.6%)	15(7.4%)	33(5.5%)	15(6.2%)	
Rural Area	2180(88.2°%)	297(91.7%)	420(88.4%)	534(88.9%)	222(91.7%)	
Medicaid Eligible Months per year						
Mean (SD)	10.1(2.8)	9.4(3.2)	8.8(3.3)	8.1(3.7)	6.7(3.9)	<.01 *

* ANOVA

** Any Peginterferon Alfa (PegIFN) and Ribavirin (RBV) during the one year tracking period

^ Mantel-Haenszel test

Table 2

Annual clinical outcomes and cost of treatment in relation to adherence to HHART among HIV & HCV co-infection cohort in Medicaid (N=4,115)

	>95% adherent ART	**75-95% adherent ART**	**50-75% adherent ART**	**25-50% adherent ART**	**<25% adherent ART**	**P**
N (%)	2473(60.1%)	324(7.9%)	475(11.5%)	601(14.6%)	242(5.9%)	
1 year mortality	3.5% (86)	8.0% (26)	10.1% (48)	17.8% (107)	26.0% (63)	<.01^
Hospitalization	56.3% (1393)	63.6% (206)	68.8 (327)	72.6% (436)	76.9% (186)	<.01^
Emergency Dept. Visit	34.9% (34.9%)	38.3% (324)	43.4% (261)	43.4% (261)	46.7% (113)	<.01^
QALY(Quality Adjusted Life Years)*						
mean(sd)	0.78 (0.08)	0.76(0.11)	0.75(0.13)	0.71(0.19)	0.66(0.24)	<.01
Inpatient payment						
Mean (95%CI)	$ 7642 (6944,8340)	$ 9997 (8046,11948)	$ 12314 (10005,14263)	$ 12320 (10573,14066)	$ 15386 (11262,19512)	<.01
ARV treatment payment						
Mean (95%CI)	$ 9164 (8887,9441)	$ 4912 (4576,5249)	$ 3408 (3198,3618)	$ 2283 (2155,2410)	$ 1189 (1092,1287)	<.01
Total Medicaid Payment (exclude ARV payment						
Mean (95%CI)	$ 17407 (15889,18925)	$ 17658 (15046,20269)	$ 18401 (15719,21083)	$ 17368 (15341,19395)	$ 19606 (14878,23735)	.92

*Quality of life estimates for HIV/AIDS, 0.70 for AIDS patients, and 0.82 for other HIV patients.

^Mantel-Haenszel test

Table 3

Relative risk (and 95% CIs) of mortality by different levels adherence of ART treatment in 14 southern states HIV & HCV co-infection Medicaid enrollees

Treatment	Crude relative risk (95%CI)	Adjusted relative risk (95%CI)**
>95% adherent ART	1.00	1.00
75-95% adherent ART	1.65(1.06,2.55)*	1.58(1.02,2.46)*
50-75% adherent ART	2.07(1.45,2.95)*	2.05(1.44,2.94)*
25-50% adherent ART	3.06(2.30,4.07)*	3.21(2.39,4.31)*
<25% adherent ART	4.11(2.97,5.69)*	4.22(3.03,5.87)*

* P<.05

** Cox hazard regression model was adjusted for age, gender, race/ethnicity, metro/rural residential status, AIDS- related conditions, and HCV treatment status.

Table 4

Cost effectiveness as determined by incremental cost-effectiveness ratios

Treatment	Cost	QALY	ΔC	ΔE	ICER
<25% adherent ART	$ 1,189.2	0.66	0	0	0
25-50% adherent ART	$ 2,282.9	0.71	0.05	$ 1093.7	$ 21,874.0/QALY
50-75% adherent ART	$ 3,408.0	0.75	0.09	$ 2218.8	$ 24,653.3/QALY
75-95% adherent ART	$ 4,912.1	0.76	0.10	$ 3722.9	$ 37,229.0/QALY
>95% adherent ART	$ 9,163.8	0.78	0.12	$ 7974.6	$ 66,455.0/QALY

Note: all costs are in US dollars