Use of Newer Antiretroviral Treatments Among HIV-Infected Medicaid Beneficiaries With Serious Mental Illness

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Objectives: The study compares rates of protease inhibitor (PI) use during the 3 years following the introduction of these newer treatments among human immunodeficiency virus (HIV)–infected individuals with and without serious mental illness and examines persistence of use of these therapies across these subgroups.

Method: We used merged autoimmune deficiency syndrome (AIDS)/HIV surveillance and Medicaid claims data to examine use of PIs and non–nucleoside reverse transcriptase inhibitors (NNRTIs) among New Jersey Medicaid beneficiaries with AIDS between 1996 and 1998. Based on the ICD-9-CM diagnoses assigned by a high-credibility source in 1 inpatient or 2 outpatient claims, we identified patients with schizophrenia (ICD-9-CM code 295) and those with severe affective disorder (combining patients with recurrent major depressive disorder [ICD-9-CM code 296.3] or bipolar disorder [296.4, 296.5, 296.6, 296.7, or 296.8]). These groups were compared with those patients with no serious mental illness.

Results: In this sample, patients with schizophrenia (68.3%) and those with severe affective disorder (75.6%) were more likely to have initiated new antiretroviral therapy than were those without serious mental illness (64.3%). Patients with severe affective disorder, but not those with schizophrenia, were significantly less persistent ($p < .01$) in their use of PI/NNRTI therapy than those without serious mental illness.

Conclusions: No evidence was found that the presence of a serious mental illness discourages physicians from initiating new antiretroviral therapy, perhaps reflecting a comparatively high level of integration of these patients into the health care system. Patients with schizophrenia are as persistent in their use of PI/NNRTI therapy as those without a serious mental illness. Lower rates of medication compliance by those with severe affective disorder justify increased efforts to support optimal adherence.

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The care of patients with human immunodeficiency virus (HIV) infection has been transformed by the introduction of newer antiretroviral regimens, which include protease inhibitors (PIs) and non–nucleoside reverse transcriptase inhibitors (NNRTIs), often used in combination with older antiretrovirals (reverse transcriptase inhibitors) in highly active antiretroviral therapy (HAART) regimens. These treatments have been shown to delay the onset of autoimmune deficiency syndrome (AIDS) and reduce mortality,[1–5] and within 2 years of their introduction in 1996, these new treatments had been received by a majority of those in the United States known to be infected with HIV.[6–10]

Despite these gains, the full benefit from these new treatments has been constrained by clinical dilemmas that make it difficult for the prescribing physician to know who is an appropriate candidate for the therapy and how best to initiate and maintain it. Inconsistent use increases viral resistance and treatment failure for the patient[11] and risks producing drug-resistant strains of the virus that can be transmitted into the general population by risky behavior.[12,13] Although increasing adherence is associated with greater HIV suppression,[14] many patients with HIV lead lives that make optimal medication adherence very difficult.[15–17] As in other populations with medical illness, psychological factors such as distress, as well as depressive symptomatology, have also been linked to lower adherence rates among patients with HIV.[18–21] Among HIV-

infected substance abusers, psychiatric problems have been reported to be associated with lower adherence.[22–24] Investigators have also reported delays in initiation of PI therapy for patients with depression.[25]

Little is known regarding antiretroviral use by one of the most challenging patient groups, that with serious mental illness. The spread of HIV in this population has been documented in a number of studies. Seroprevalence studies with U.S. psychiatric patients published in peer-reviewed journals through 1996 found that, of the 2873 psychiatric patients tested in these studies, 223 (7.8%) were HIV positive.[26] Most studies have been conducted in institutional, usually inpatient, settings,[27–37] but 3 recent reports[38–40] indicate that this population can be found in outpatient settings and statewide populations as well.

A physician who must determine a patient's suitability for new antiretroviral therapy is appropriately sensitive to numerous facts about the patient's life that might predict adherence. People with serious mental illness have a reputation as difficult patients in some general medical circles. Their physical illnesses often are not identified and treated.[41] Drug interactions between antiretrovirals and psychotropic medications can lead to subtherapeutic drug concentrations, making clinical management difficult and labor-intensive.[42,43] Infectious-diseases physicians surveyed regarding factors relevant to the decision to initiate HAART regimens indicate that prior history of psychiatric disorder counts against use of HAART.[44] However, few data are available on whether HAART is actually less likely to be initiated among patients with such histories.

Despite the significance of this topic, it appears that the only large published study[45] on initiation and persistence of antiretroviral use among seriously mentally ill patients with HIV dates from the era prior to the new antiretroviral therapies. In this study, the authors found no difference in the frequency with which antiretroviral treatment was initiated by HIV-infected Medicaid beneficiaries with and without schizophrenia, and they found that those with schizophrenia showed higher levels of antiretroviral adherence once therapy was initiated. One recently published study that used both self-report and electronic monitoring to examine adherence over a 2-week period for a small sample (N = 47) of patients with serious mental illness reported average rates (66%) similar to those found in other populations with HIV.[46]

In the present study, data are presented on the use of new antiretroviral therapies with patients with serious mental illness and the persistence of this therapy once initiated. Two general perspectives can be considered. One view predicts that providers will be relatively reluctant to initiate new antiretroviral therapies due to the real or perceived risk of suboptimal adherence. This prediction is consistent with reports indicating that a psychiatric diagnosis counts against initiation of treatment.[44] The alternative view is that prolonged treatment of patients' psychiatric illnesses serves to integrate these patients into the health care system and to socialize them into patient roles. The predicted result is that new antiretroviral therapy will be commonly initiated and that adherence will be good. This prediction is consistent with the finding that patients with schizophrenia showed superior adherence in the era prior to the new therapies.[45]

METHOD

Study Population

This study was based on adult Medicaid participants diagnosed with HIV/AIDS in New Jersey between January 1991 and December 1998. The link between the HIV/AIDS registry and the Medicaid file was generated by the New Jersey Department of Health and Senior Services (DHSS); the New Jersey Department of Human Services, Division of Medical Assistance and Health Services (DMAHS) provided paid Medicaid claims and Medicaid eligibility files for the linked cohort. The Medicaid claims histories contained all processed claims for services and pharmacy prescriptions provided from January 1988 through April 1999. To allow for time lags in the billings and claims payment process, we included services received through December 1998 in the analyses. The nondrug claims file provided information on claim type, diagnosis, category of service, dates of service, and actual amount paid by Medicaid for each of the services. The pharmacy claims file contained information on National Drug Codes (NDC), dispensing dates, and the actual amount paid by Medicaid. The Medicaid eligibility file contained the Medicaid enrollment and termination dates for each individual. Using these dates, we excluded individuals who terminated from Medicaid on or before March 1, 1996, and who had indications of interrupted participation in Medicaid. We combined information on death dates from Medicaid eligibility file and surveillance data to classify respondents as decedents or nondecedents.

The study population was composed of individuals diagnosed with AIDS between January 1991 and March 1996 who participated in the New Jersey Medicaid program between January 1996 and December 1998. We included only those individuals who received Medicaid services in 1996 or later, based on PI availability. To better control for disease stage, we limited our analysis to individuals with registry diagnosis of AIDS and individuals with registry diagnosis of HIV with at least 1 claim for an AIDS-defining opportunistic infection. Additional inclusion criteria were age 18 years or older at the time of AIDS diagnosis and enrollment in Medicaid for at least 90 days during the study period. We excluded individuals with managed-care participation because encounter data for these individuals may not be complete. Some evidence

indicates that patterns of mental health care may differ for Medicaid patients in managed care[47,48]; thus, our findings cannot be generalized to this population. In the final stage, we identified 2459 Medicaid beneficiaries who met the criteria mentioned above.

Measures

Serious mental illness. Our measure of serious mental illness is based on prior work that uses diagnostic codes for medical care episodes contained in Medicaid claims data.[38,39] Each claim provided information on specific health care services utilized, category of service, dates of service, and up to 5 diagnosis codes conforming to the *International Classification of Diseases*, 9th Revision, Clinical Modification (ICD-9-CM). Individuals with at least 1 inpatient claim or 2 outpatient claims with ICD-9-CM codes of 295 were categorized as having schizophrenia. Patients with bipolar affective disorder (ICD-9-CM codes 296.4, 296.5, 296.6, 296.7, or 296.8) or major depressive disorder, recurrent episode (ICD-9-CM code 296.3) were classified as having severe affective disorder. Again, we required either 1 inpatient claim or 2 outpatient claims for bipolar affective disorder or major depressive disorder in order to classify an individual into the severe affective disorder group. Following a hierarchical decision rule used in prior work,[38] individuals with both bipolar affective disorder and schizophrenia were classified under the "schizophrenia" group, as were individuals with both schizophrenia and major depressive disorder, recurrent episode.

Using the above diagnostic categories, we classified individuals into the following hierarchy: (1) schizophrenia, (2) severe affective disorder (either bipolar disorder or recurrent major depressive disorder) without schizophrenia, and (3) none of the above. To avoid false positive classifications, we followed prior work[38] by limiting claims to high-credibility sources, such as physician visits, and did not include claims for other categories of reimbursable services, such as those from home health agencies, case managers, podiatrists, and reimbursable transportation to providers.

Protease inhibitor/non–nucleoside reverse transcriptase inhibitor use. As of the end of 1998, 13 antiretrovirals for treatment of HIV disease had been approved by the U.S. Food and Drug Administration.[49] These included 6 nucleoside analogue reverse transcriptase inhibitors: abacavir (Ziagen), didanosine (ddI [Videx]), lamivudine (3TC [Epivir]), stavudine (d4T [Zerit]), zalcitabine (ddC [Hivid]), and zidovudine (ZDV or AZT [Retrovir]); 3 NNRTIs: nevirapine (Viramune), delavirdine (Rescriptor), and efavirenz (Sustiva); and 4 approved PIs: indinavir (Crixivan), ritonavir (Norvir), saquinavir (Fortovase/Invirase), and nelfinavir (Viracept). We used NDCs recorded in pharmacy claims to identify PI or NNRTI use. PIs that were available during the observation period included ritonavir, indinavir, saquinavir, and nelfinavir, and available NNRTI drugs included nevirapine, delavirdine, and efavirenz. For each individual, we constructed an indicator variable with value "0" indicating no PI or NNRTI use and "1" indicating the use of either a PI or an NNRTI. Although there is an assumption that patients taking PIs/NNRTIs have been on combination regimens, this assumption does not hold true in every case. Exclusive use of NNRTIs was found for 39 individuals, totaling less than 2% of the total studied and providing too few cases for subgroup analysis.

Persistence of protease inhibitor/non–nucleoside reverse transcriptase inhibitor use. These analyses were restricted to users of PIs/NNRTIs. We analyzed persistence of treatment by examining the quarterly use of PIs/NNRTIs among users. Under this approach, person-quarter files were created by organizing PI/NNRTI use data into quarters, counting forward from date of first prescription. For each quarter, we constructed a variable indicating the use of PIs/NNRTIs in that quarter. The unit of analysis was quarterly use of PI/NNRTI drugs by an individual. The number of quarterly observations can vary across individuals depending on the time of initiation and end of follow-up. We restricted the analysis to individuals who were observed for at least 2 quarters after initiating the therapy.

Demographic characteristics. Demographic characteristics (i.e., sex, race, county of residence at diagnosis), exposure category, and date of AIDS diagnosis were obtained from the surveillance data. Race/ethnicity was characterized as white, African American, or Latino. In multivariate analyses, "white" was used as the reference group. Exposure category was based on information on injection drug use history from the AIDS registry, and patients were classified as either injection drug users or non–injection drug users. Age at diagnosis was categorized into the following groups: 18–29 years (the reference group in multivariate models), 30–39 years, 40–45 years, and 46 years and older. We also contrasted the treatment rates for residents living in the highest-prevalence counties nearest to New York City and near Philadelphia versus elsewhere.

Illness stage. To better control for disease stage, dummy variables for year of AIDS diagnosis and decedent status were included in the regression as control variables. Based on death dates available from both the AIDS registry and the Medicaid eligibility file, respondents were classified as decedents or nondecedents. Because individuals with AIDS can have a very wide illness severity range, we also included the presence of opportunistic infections including *Pneumocystis carinii* pneumonia, Kaposi's sarcoma, disseminated infection with mycobacterium avium complex, and others as a marker of severity of illness. A complete list of the opportunistic in-

fections included can be obtained upon request. These infections were identified based on diagnostic codes in the claims data conforming to the ICD-9-CM.

Medicare participation. Since Medicare participation may influence access to health care, we included Medicare coverage as a covariate. Medicare coverage was assessed for each year of observation in the study based on claim type recorded in the claims data.

Waiver status. In New Jersey, some of the Medicaid population is enrolled in the AIDS Community Care Alternatives Program (ACCAP), an HIV/AIDS-specific Medicaid home- and community-based care waiver program that offers a variety of home-care services, including mandatory case management with monthly visits by case managers. Access to the home- and community-based services provided by the waiver program has been shown to be associated with differences in patterns of service utilization (S.C., U.S., A. LaSasso, Ph.D., unpublished data, 1998). Therefore, we also used waiver status as a covariate in all our analyses. Participation in the waiver program was determined by using the procedure codes in Medicaid claims for waivered services. Procedure codes for waivered services were provided by DMAHS.

Analytic Procedures

In bivariate analysis, we tested for subgroup differences in the use of PIs/NNRTIs with χ^2 statistics. Logistic regressions were estimated to predict the probability of PI/NNRTI use and to isolate the effects of characteristics such as sex and race. Parameter estimates from logistic regressions were transformed into odds ratios (ORs) (with 95% CIs) associated with each independent variable. Analyses on persistence of PIs/NNRTIs were restricted to users of PI/NNRTI drugs. To analyze persistent use of PIs/NNRTIs, we constructed a binary variable indicating use of PIs/NNRTIs for each quarter after initiating therapy. Thus, a given individual could contribute up to 12 quarters. Because quarterly use of PIs/NNRTIs is based on repeated observations on an individual, our bivariate analysis presents both number of patients for all patient groups and quarters with PI/NNRTI use.

The odds of use of PIs/NNRTIs by a person in a given quarter were modeled with robust logistic regressions. By pooling multiple quarters of the data, we created repeated observations on an individual; the observations are not independent but are clustered within individuals. Therefore, to analyze persistent use, we applied robust covariance methods.[50] This model is an extension of the general linear model with a complex error structure and was estimated with the generalized estimating equation technique for binary outcome variables using Stata's xtgee procedure. Since multiple tests can pose some risk of spurious findings of significance, our tables include significant findings at both the 5% and 1% levels. We considered findings to be robust if they were significant at the 1% level.

Table 1. Description of HIV-Infected Individuals on Medicaid by Serious Mental Illness (SMI)[a]

	SMI				
	Schizophrenia (N = 199)	Severe Affective Disorder[b] (N = 209)	No SMI (N = 2051)	Total (N = 2459)	
Characteristic	%	%	%	N	%
All	8.1	8.5	83.4	2459	100.0
Sex[c]					
Male	7.1	6.9	86.0	1526	62.1
Female	9.6	11.1	79.2	933	37.9
Race/ethnicity[c,d]					
White	6.6	13.9	79.5	560	22.8
African American	9.3	5.5	85.2	1433	58.3
Latino	6.2	11.3	82.5	452	18.4
Risk group[c]					
IDU	8.8	8.7	82.4	1486	60.4
Non-IDU	6.1	9.6	84.3	668	27.2
Age at diagnosis, y[c]					
18–29	11.1	7.4	81.4	350	14.2
30–39	8.9	9.4	81.7	1208	49.1
40–45	6.2	7.9	86.0	585	23.8
46 and older	5.1	7.6	87.3	316	12.9
County of residence[c]					
High prevalence	6.4	10.3	83.3	1730	70.4
Elsewhere	8.8	7.7	83.5	729	29.6
Year of diagnosis					
1991–1992	9.9	8.7	81.5	588	23.9
1993–1994	8.1	7.8	84.2	1288	52.4
1995–1996	6.3	9.9	83.7	583	23.7
Waiver participation[c,e]					
ACCAP	3.8	10.8	85.5	502	20.4
Non-ACCAP	9.2	7.9	82.9	1957	79.6
Medicare enrollment[c,e]					
No Medicare	8.6	7.3	84.1	1552	63.1
Medicare	7.3	10.5	82.2	907	36.9
Severity of illness[c]					
No OI	5.1	7.3	87.6	509	20.7
OI	8.9	8.8	82.3	1950	79.3
Vital status as of 1998[c]					
Decedent	5.3	7.4	87.4	720	29.3
Nondecedent	9.3	9.0	81.8	1739	70.7

[a]Based on continuously eligible fee for service Medicaid participants with AIDS, age 18 years or older. Utilization was observed between January 1996 and December 1998.
[b]Severe affective disorder = bipolar affective disorder or major depressive disorder, recurrent episode.
[c]χ^2 Test for statistical significance: $p < .05$.
[d]Subgroup Ns do not sum to total N due to missing values.
[e]Participation anytime between 1996 and 1998.
Abbreviations: ACCAP = AIDS Community Care Alternatives Program, IDU = injection drug user, OI = opportunistic infection.

RESULTS

Table 1 describes the study population and characteristics of the study population by serious mental illness groups. Among 2459 Medicaid beneficiaries, 62% were male, 58% were African American, 70% lived in the high-prevalence counties, and 63% were under 40 years of age at diagnosis. We found significant differences between serious mental illness categories by sex ($p < .0001$), race/

Table 2. Serious Mental Illness (SMI) and Rates of Any PI/NNRTI Use Among New Jersey Medicaid Beneficiaries[a]

Variable	SMI: Schizophrenia %	SMI: Severe Affective Disorder[b] %	No SMI %
All[c]	68.3	75.6	64.3
Calendar year			
1996	31.7	51.2	42.9
1997	60.7	72.2	62.0
1998	65.3	65.1	62.7
Sex			
Male	70.6	69.5[c]	63.8
Female	65.6	81.7	65.1
Race/ethnicity			
White	75.7	79.5	73.0[c]
African American	68.4	72.2	61.4
Latino	57.1	74.5	63.0
Risk group			
IDU	61.8[c]	71.5	65.0
Non-IDU	78.0	81.3	65.0
Age at diagnosis, y			
18–29	64.1	69.2	61.1
30–39	70.4	77.9	65.7
40–45	77.8	69.6	64.2
46 and older	43.8	83.3	62.7
County of residence			
High prevalence	69.7	76.9	64.8
Elsewhere	63.8	73.3	62.9
Year of diagnosis			
1991–1992	63.8	78.4	66.0
1993–1994	68.3	77.0	63.7
1995–1996	75.7	70.7	63.9
Waiver participation[d]			
ACCAP	52.6	81.5	68.1
Non-ACCAP	70.0	73.5	63.3
Medicare enrollment[d]			
No Medicare	61.7[c]	71.9	58.7[c]
Medicare	81.8	80.0	74.0
Severity of illness			
No OI	61.5	62.2[c]	57.0[c]
OI	69.4	78.5	66.3
Vital status as of 1998			
Decedent	60.5	60.4[c]	47.1[c]
Nondecedent	70.2	80.8	71.9

[a]Based on continuously eligible fee for service Medicaid participants with AIDS, age 18 years or older. Utilization was observed between January 1996 and December 1998.
[b]Severe affective disorder = bipolar affective disorder or major depressive disorder, recurrent episode.
[c]χ^2 Test for statistical significance: $p < .05$.
[d]Participation anytime between 1996 and 1998.
Abbreviations: ACCAP = AIDS Community Care Alternatives Program, IDU = injection drug user, OI = opportunistic infection, PI/NNRTI = protease inhibitor/non–nucleoside reverse transcriptase inhibitor.

ethnicity ($p < .0001$), geographic location ($p < .03$), waiver status ($p < .0001$), Medicare enrollment ($p < .02$), illness severity ($p < .01$), and vital status ($p < .001$) as of 1998.

Differences in Protease Inhibitor/Non–Nucleoside Reverse Transcriptase Inhibitor Treatment

We examined patient characteristics associated with PI/NNRTI treatment. Table 2 displays the sample characteristics of patients with AIDS who were treated with PIs/NNRTIs among the subgroups of serious mental illness. Rates differed significantly ($p = .003$); rates of use of PIs/NNRTIs were higher for HIV-infected patients with schizophrenia (68.3%) and those with severe affective disorder (75.6%) than for those without these diagnoses (64.3%).

Some differences were detected in the influence of various sociodemographic and clinical variables across groups. However, in general, there were few differences in the likelihood of any use among those in each of the 2 defined psychiatric subgroups. For example, logistic regression on any use indicated that, for those with schizophrenia, initiation of treatment was less likely for injection drug users than for non–injection drug users (OR = 0.40, 95% CI = 0.16 to 0.99) and for those not on Medicare than for those on Medicare (OR = 2.79, 95% CI = 1.26 to 6.15). Among those with severe affective disorder, treatment initiation was more likely for women than for men (OR = 2.36; 95% CI = 1.14 to 4.88) and for those responders classified as nondecedents.

Persistence of Protease Inhibitor/Non–Nucleoside Reverse Transcriptase Inhibitor Treatment

As shown in Table 3, among those initiating PI/NNRTI use, rates of persistence differed across subgroups. In bivariate analyses, persistence for those with severe affective disorder (75.2%) was modestly, but significantly, lower ($p < .02$) than for those with schizophrenia (77.3%) or those with no serious mental illness (78.5%).

An examination of follow-up quarters by individual characteristics revealed some significant subgroup differences ($p < .05$) in number of quarters followed after initiation of PI/NNRTI across all categories of mental illness (data not shown). Therefore, to allow for such differential contribution of follow-up quarters, our multivariate analyses on persistence of PI/NNRTI included number of quarters as one of the control variables.

Table 4 describes the odds of PI/NNRTI use in any given quarter after initiation of therapy. In the pooled regression, which combined all groups of mental illness, controlling for demographics, risk group, opportunistic infection, and vital status in a given quarter, PI/NNRTI use was less likely for those in the severe affective disorder group (OR = 0.73, 95% CI = 0.57 to 0.94) than for those with no serious mental illness. The log odds of persistent use did not differ between those with no serious mental illness and those with schizophrenia. Separate robust regression indicated significant subgroup differences ($p < .05$) in the no–serious mental illness category compared with the group with schizophrenia or the group with severe affective disorder. For example, in the no–serious mental illness group, African Americans and Latinos were less likely than whites to use a PI/NNRTI in a given quarter, controlling for other factors. However, there were no significant differences in adherence associated with race/

Table 3. Percent of PI/NNRTI Use (in quarters) Among PI/NNRTI Users (N = 12,131)[a]

Characteristic	SMI: Schizophrenia (N = 968)	SMI: Severe Affective Disorder[b] (N = 1294)	No SMI (N = 9869)
Rate of persistence	77.3	75.2	78.5
Sex			
Male	76.6	74.6	78.5
Female	78.4	75.7	78.6
Race/ethnicity			
White	80.9	80.2	82.7[c]
African American	75.8	71.4	77.0
Latino	81.4	72.8	77.0
Age at diagnosis, y			
18–29	69.9	69.3	75.3
30–39	80.0	76.8	78.3
40–45	77.2	72.1	78.9
46 and older	72.7	78.4	81.4
Risk group			
IDU	77.5	73.7	78.1
Non-IDU	81.2	75.1	80.3
County of residence			
High prevalence	79.7	76.1	78.5
Elsewhere	69.0	73.6	78.5
Year of diagnosis			
1991–1992	79.7	73.9	78.0[c]
1993–1994	75.0	72.8	80.5
1995–1996	80.1	80.5	74.7
Waiver participation			
ACCAP	83.0	82.6[c]	85.3[c]
Non-ACCAP	77.0	72.6	77.1
Medicare enrollment			
No Medicare	75.3	70.7[c]	74.7[c]
Medicare	81.7	82.5	85.9
Severity of illness			
No OI	77.1	78.8	78.9
OI	77.4	73.0	78.1
Vital status			
Decedent	50.0[c]	20.8[c]	34.9[c]
Nondecedent	77.9	76.2	79.4

[a]The study population is based on continuously eligible fee for service Medicaid participants with AIDS, age 18 years or older, who used PIs/NNRTIs between January 1996 and December 1998.
[b]Severe affective disorder = bipolar affective disorder or major depressive disorder, recurrent episode.
[c]Significant differences ($p < .05$) within diagnostic categories. Estimated effects based on χ^2 test. Statistical test controls for clustering caused by repeated observations of individuals.
Abbreviations: ACCAP = AIDS Community Care Alternatives Program, IDU = injection drug user, OI = opportunistic infection, PI/NNRTI = protease inhibitor/non–nucleoside reverse transcriptase inhibitor, SMI = serious mental illness.

ethnicity among those with schizophrenia or severe affective disorder.

DISCUSSION

This article estimates crude and adjusted rates of PI/NNRTI use among HIV-infected Medicaid recipients with serious mental illness in New Jersey and estimates their persistence of use based on filled prescriptions by those who have initiated therapy. Two findings of practical significance stand out. First, in this sample, patients with schizophrenia (68.3%) and patients with severe affective disorder (75.6%) were more likely to have initiated new antiretroviral therapy than were those without serious mental illness (64.3%). Thus, these data provide no support for the prediction that a patient's serious mental illness discourages prescription of new antiretroviral therapy.

Second, patients with schizophrenia are not significantly less persistent in their use of PI/NNRTI therapy than are those without serious mental illness, but patients with severe affective disorders are less persistent than those with no serious mental illness. Our finding that patients with schizophrenia are no less adherent than patients without serious mental illness provides additional grounds for optimism regarding the adherence of hard-to-treat populations. Other reports indicate that indigent populations may be capable of high levels of adherence to PI therapy.[51]

Electronically monitored adherence over a 2-week period of a small group with serious mental illness found the proportion of taken prescribed doses to be 66%.[46] Direct comparison with our findings is difficult; the much smaller sample size and shorter observation period may play a role. Concern that study participation not disrupt care led these authors[46] to exclude patients who said they relied on a pillbox to remember to take medications because, if the patients used the pillboxes and did well, adherence could be raised; if patients did poorly even with the help of the boxes, adherence could be lowered. Although their outcome measure and the one used in this study ought in principle to be related, the outcome measures may bear on different aspects of adherence. One clinical challenge is to maximize a patient's willingness and ability to take every dose as prescribed, since the effectiveness of HAART is compromised by poor adherence. (Wagner and colleagues[46] note that 40% of their group demonstrated at least 90% adherence.) A further challenge is longitudinal, tailoring a treatment regimen and psychosocial support system to help impaired patients with the long-term commitment and lifestyle changes entailed by HAART. We note that Wagner and colleagues[46] also interpreted their findings as providing evidence of the potential for adherence of this group.

It may be that people with HIV who have long experience with the health care system may enjoy some advantages in adherence to treatment regimens compared with others with HIV. Psychologically, they may have been socialized into patient roles. Belief in one's physician and rejection of the view that health is related to fate or chance increase the likelihood that a patient will initiate PI therapy.[52] HIV-infected patients with schizophrenia may also be more integrated into the care system—for example, through more frequent contact with health care. Their psychiatric care may provide multiple opportunities for referral, support, and advocacy for optimal HIV-patient care, communication with infectious disease phy-

Table 4. Logistic Regression on Any Use of PI/NNRTI (N = 2459) and Robust Logistic Regression on Quarterly Use of PI/NNRTI Among Users (N = 12,131) by Serious Mental Illness (SMI)[a]

	Logistic Regression on Any Use						Robust Logistic Regression on Quarterly Use Among Users[b]					
	SMI						SMI					
	Schizophrenia		Severe Affective Disorder[c]		No SMI		Schizophrenia		Severe Affective Disorder[c]		No SMI	
Variable	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI
Pooled model[d]	1.04	0.75 to 1.45	1.38	0.97 to 1.96			1.04	0.78 to 1.38	0.73[e]	0.57 to 0.94		
Sex												
Female	0.70	0.34 to 1.41	2.36*	1.15 to 4.97	1.17	0.95 to 1.44	1.24	0.72 to 2.13	0.95	0.59 to 1.54	1.20	1.00 to 1.44
Male												
Race/ethnicity												
White												
African American	0.58	0.21 to 1.45	0.59	0.25 to 1.37	0.56[e]	0.43 to 0.73	0.70	0.35 to 1.43	0.57	0.32 to 1.01	0.68[e]	0.54 to 0.85
Latino	0.30	0.09 to 0.99	0.65	0.24 to 1.75	0.60[e]	0.44 to 0.83	0.86	0.31 to 2.38	0.61	0.31 to 1.19	0.74*	0.56 to 0.98
Age at diagnosis, y												
18–29												
30–39	1.56	0.65 to 3.75	1.89	0.63 to 5.47	1.20	0.90 to 1.62	1.75	0.85 to 3.60	1.58	0.74 to 3.40	1.20	0.92 to 1.58
40–45	3.00	0.94 to 9.58	1.81	0.52 to 6.30	1.16	0.83 to 1.63	2.01	0.80 to 5.07	1.07	0.44 to 2.61	1.32	0.97 to 1.79
46 and older	0.43	0.11 to 1.62	3.48	0.79 to 17.60	1.13	0.78 to 1.65	1.25	0.34 to 4.62	1.23	0.48 to 3.13	1.49*	1.05 to 2.12
Mode of transmission												
IDU	0.40*	0.15 to 0.96	0.53	0.22 to 1.22	1.07	0.85 to 1.35	1.22	0.70 to 2.12	0.85	0.51 to 1.43	1.08	0.90 to 1.33
Non-IDU												
County of residence												
High prevalence	1.52	0.67 to 3.45	1.60	0.75 to 3.43	1.41[e]	1.13 to 1.77	2.01*	1.06 to 3.79	1.29	0.76 to 2.18	1.28*	1.04 to 1.56
Elsewhere												
Waiver participation												
ACCAP	0.53	0.15 to 1.87	1.55	0.66 to 3.93	1.51[e]	1.15 to 1.99	1.35	0.49 to 3.68	1.56	0.93 to 2.62	1.62[e]	1.30 to 2.03
Non-ACCAP												
Medicare enrollment												
No Medicare												
Medicare	2.79*	1.29 to 6.37	1.84	0.89 to 3.94	1.96[e]	1.58 to 2.44	2.22[e]	1.32 to 3.72	1.96[e]	1.30 to 2.96	2.77[e]	2.36 to 3.24
Year of diagnosis												
1991–1992												
1993–1994	1.41	0.64 to 3.09	0.95	0.38 to 2.38	1.03	0.81 to 1.31	0.62	0.32 to 1.21	0.95	0.52 to 1.71	1.25*	1.00 to 1.55
1995–1996	1.93	0.68 to 5.47	0.60	0.22 to 1.64	1.10	0.82 to 1.46	0.97	0.42 to 2.26	1.37	0.69 to 2.73	0.91	0.71 to 1.16
Severity of illness												
No OI												
OI	1.92	0.68 to 5.43	2.06	0.88 to 4.86	1.90[e]	1.50 to 2.40	1.11	0.63 to 1.94	0.56*	0.33 to 0.96	0.74[e]	0.61 to 0.89
Vital status as of 1998												
Decedent	0.74	0.31 to 1.79	0.32[e]	0.15 to 0.67	0.28[e]	0.23 to 0.35	0.30[e]	0.12 to 0.73	0.12[e]	0.05 to 0.29	0.16[e]	0.12 to 0.21
Nondecedent												
Follow-up												
Quarters, N							0.85[e]	0.80 to 0.89	0.85[e]	0.81 to 0.88	0.86[e]	0.85 to 0.87

[a]The study population is based on continuously eligible fee for service Medicaid participants with AIDS, age 18 years or older, who used PI/NNRTI between January 1996 and December 1998.
[b]Robust logistic regressions are based on use of PI/NNRTI in each quarter after initiation. Statistical test controls for clustering caused by repeated observations of individuals. Robust logistic regressions include time (not shown) as a control variable.
[c]Severe affective disorder = bipolar affective disorder or major depressive disorder, recurrent episode.
[d]Effect of diagnostic category in pooled data with no severe illness as the reference group, controlling for sex, race, age, mode of transmission, geographic location, insurance type, and severity of illness.
[e]Statistical significance ($p \leq .01$) of estimated effects, based on χ^2 test.
*$.01 < p < .05$.
Abbreviations: ACCAP = AIDS Community Care Alternatives Program, IDU = injection drug user, OI = opportunistic infection, OR = odds ratio, PI/NNRTI = protease inhibitor/non–nucleoside reverse transcriptase inhibitor.

sicians, and surveillance of adherence. Direct evidence for this interpretation requires collection of more detailed data on care provision for this population and their relationships with providers.

We found higher rates of treatment initiation among HIV-infected individuals with severe affective disorders than among those with schizophrenia or those with no serious mental illness. However, once treatment was initiated, we found that these patients were less persistent in prescription refills, a finding that adds to the growing literature on the negative consequences of mood disorder symptoms.

Although the negative impact of depression on medication adherence has been widely documented for HIV, its presence ought not to rule out initiation of HAART. HAART regimens themselves can reduce depression,[53–56] numerous opportunities for aggressive treatment of depression have been identified,[57] and treatment of comorbid depression has been found to improve medication adherence with other medical disorders.[58] Prior work indicates that those depressed patients who are treated with antidepressants are more likely to receive antiretroviral therapy.[59] Even when depressive symptoms persist, psychoeducation may be helpful, since patients who attribute depressive symptoms to their medication are more likely to discontinue their antiretrovirals temporarily.[60]

Strengths of this study include its large, statewide sample of community-dwelling patients with serious mental illness, many of whom receive medical care from a broad range of providers. Claims data are able to capture care for more severely ill patients who were most likely missed in many studies that require patient recruitment. Some patients with mental illness cannot participate because they are unable to give consent (and arrangements for proxy consent are difficult), and many such patients may be difficult to interview. Care that is provided in resource-poor settings unlikely to welcome research teams is also captured. Thus, these data include many patients whose care might otherwise be impossible to study.

Reliance on administrative data also has limitations. Diagnoses are assigned based on an algorithm that uses provider diagnoses from high-credibility sites. Congruence between medical record diagnoses and administrative data files is generally high for patients with more serious psychiatric disorders,[61,62] but the quality of the provider diagnosis nevertheless constrains our ability to assign diagnoses. The data presented comes from a population under care for these serious psychiatric illnesses. Our approach emphasizes specificity, even at the cost of some sensitivity. We believe false positives are not common and think the result represents a reasonable lower-bound estimate of serious mental illness conditions. Our belief that false positives are relatively rare is supported by findings in the literature that more serious psychiatric diagnoses are comparatively stable and that, when a change in diagnosis occurs, it is more likely to be a change from a less-serious to a more-serious diagnosis than the reverse.[63–65]

It is of course possible that, in such a disabled patient population, symptom status may have affected access. Study of this issue would require access to data on specific symptoms, which we lack. Tackling this problem is likely to be difficult, even when primary data collection is used, since many of the same symptoms that might affect access may also limit participation (e.g., paranoia, thought disorder).

A further limitation comes from the absence of information on important clinical covariates, such as CD4+ counts, viral load, and health-related functional status. Filled prescriptions are an imperfect measure of actual adherence but must be weighed against the alternatives, each of which has its own problems. For example, provider estimates of adherence have been shown to be problematic[66]; patient recall of medication-taking is often unreliable (as it is even for such major events as hospitalization or emergency room use[67]); and even complex, high-tech methods such as medication caps equipped with computer chips to monitor container opening (MEMS caps) underestimate actual adherence.[68] However, although Wagner and colleagues[46] relied on MEMS technology, they asked the serious mental illness group followed to report any problems using it, and used these data to adjust adherence summary scores.

In studies that use pharmacy claims data, it is possible that some individuals continue to fill prescriptions without actually taking the drugs, leading to a possible underestimation of dropout from treatment. However, although medication possession as a result of filling a prescription is not a sufficient condition for actual receipt of a treatment, it is generally a necessary condition. Some validation of this approach comes from findings that pharmacy records for prescriptions of antiretrovirals have been shown to predict changes in viral load.[69]

Our findings cannot be generalized to Medicaid patients in managed care or to populations with HIV not served by Medicaid. The group with HIV and serious mental illness covered by employer-based or other private insurance is probably not large. Even if those served by Medicaid differ from others, their care is important to study because their poverty, social marginality, and complex care needs make them vulnerable both to adherence problems and to providers' reluctance to prescribe.[70] In addition, because Medicaid finances a basic level of care for all covered patients, attention to this group allows us to examine nonfinancial, systemic barriers to care.

Drug names: abacavir (Ziagen), delavirdine (Rescriptor), didanosine (Videx), efavirenz (Sustiva), indinavir (Crixivan), lamivudine (Epivir), nelfinavir (Viracept), nevirapine (Viramune), ritonavir (Norvir),

saquinavir (Fortovase, Invirase), stavudine (Zerit), zalcitabine (Hivid), zidovudine (Retrovir).

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