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ESTIMATING THE IMPACT OF MEDICAL INNOVATION: A CASE STUDY OF HIV ANTIRETROVIRAL TREATMENTS

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ABSTRACT

As health care consumes a growing share of national income in the U.S., the demand for better estimates regarding both the benefits and the costs of new health care treatments is likely to increase. Estimating these effects with observational data is difficult given the endogeneity of treatment decisions. But because the random assignment clinical trials (RACTs) used in the FDA's approval process do not consider costs, there is often no good alternative. In this study we use administrative data from the Medicaid program to estimate the impact of a particular category of new treatments - HIV antiretroviral drugs - on health care spending and health outcomes. We use the detailed information on health care utilization to proxy for health status and exploit the differential take-up of ARVs following their FDA approval. Our estimate of a 70 percent reduction in mortality is in line with the results from RACTs and with studies that had more detailed clinical data. We also find that the ARVs lowered short-term health care spending by reducing expenditures on other categories of medical care. Combining these two effects we estimate the cost per life year saved at $22,000. Our results suggest that the administrative data that is readily available from programs like Medicaid, used with a properly specified econometric model that allows for heterogeneity in take-up rates and in effectiveness based on initial health conditions, can produce reliable estimates of the impact of new health care treatments on both spending and health.

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I. Introduction

During the 2004 calendar year, health care expenditures accounted for 16 percent of GDP in the U.S., with this share substantially greater than in any other industrialized country and more than twice as large as the corresponding value in 1970. The Centers for Medicare and Medicaid Services predict that this rapid growth will continue with health spending expected to account for 19 percent of GDP by 2014. Much of the past and projected growth in health care spending has been fueled by the Medicaid and Medicare programs, which provided health insurance to nearly 90 million individuals in 2005 at a cost of more than $650 billion. According to estimates from the Congressional Budget Office, the share of federal spending accounted for by these two programs will increase from 22 to 35 percent during the coming decade (CBO, 2006).

Previous research has suggested that an important contributor to rising health care costs in the U.S. and in other industrialized countries is the introduction and diffusion of new and more expensive treatments (Newhouse, 1992; Cutler, 2004). The pace at which these changes occur is likely to be affected by health insurance, which reduces or even eliminates a patient's incentive to consider price when choosing between alternative treatments. To date, most private and public insurers base coverage decisions for new treatments solely on safety and efficacy grounds. However, budgetary pressures may soon lead insurers to require that coverage also be based on cost effectiveness by considering whether the increment to health from a new treatment is sufficiently large to justify its cost (Garber, 2004). Recent evidence for this can be found in the Medicare Modernization Act (MMA), which allows the private drug plans that provide Medicare recipients with coverage for prescription drug expenses to use cost-effectiveness as one criterion for excluding treatments from their list of covered prescription drugs.

Unfortunately, research evaluating the cost effectiveness of new treatments lags behind what patients, physicians, insurers, and policymakers need to make well-informed decisions. Part of the problem is that the dominant method for determining causal relationships in medicine is the random assignment clinical trial (RACT). For example, the U.S. Food and Drug Administration uses RACTs in deciding whether to approve new health care treatments. While these trials make important contributions

to knowledge, they have a number of important limitations. Perhaps most importantly, they rarely consider the effect of a new treatment on expenditures but instead focus only on health.[1] Additionally, results from RACTs may not apply to real-world settings, where adherence to a treatment regimen may be different from in the controlled environment of an RACT.

Researchers must therefore use alternative methods and sources of data to measure the benefits of new medical innovations in real world settings. One possible strategy is to use administrative data on health care utilization generated by government programs such as Medicaid and Medicare. These claims data sets have the advantage of large sample sizes and of capturing treatment patterns in the real world. But they also have limitations. The two most important are that treatments are not randomly assigned and that there is limited clinical information that can be used to measure health status. Despite these and other limitations, claims data has been used in previous work to estimate the impact of alternative treatments and of changes in policy. For example, McClellan, McNeil and Newhouse (1994) use Medicare claims data merged with mortality records to study the impact of heart attack treatments.

In this paper, we use similar data but take a different approach from these authors and from most previous work by using approval by the U.S. Food and Drug Administration (FDA) of new health care treatments as a plausibly exogenous source of variation in treatment options. We focus on the effect of pharmaceutical innovations for a particular condition – HIV/AIDS - that has been the focus of much previous work and for which treatment patterns have changed dramatically in recent years. We exploit the fact that there were sharp changes in the treatment of this illness following the FDA's approval of certain antiretroviral drugs (ARVs). The most striking changes occurred after the approvals of Epivir and three protease inhibitors in late 1995 and early 1996, which preceded the sharp reduction in mortality among individuals with HIV/AIDS.[2]

[1] Because the variance of medical spending is typically large in a cross section of patients, sample sizes in RACTs would have to be extremely large to generate precise estimates of the impact of treatment on medical expenditures.
[2] According to data from the Centers for Disease Control (CDC), AIDS deaths increased from 31,538 in 1990 to a peak of 51,670 in 1995, then dropped sharply to 38,296 in 1996, 22,245 in 1997 and to a low of 17,139 in 2000.

To estimate the effect of these and other ARVs on health outcomes and health care expenditures, we use individual-level claims and eligibility data for a large sample of Medicaid patients from the state of California with one or more months of eligibility for the program between 1993 and 2003. Our data includes patient demographic characteristics along with detailed information on each individual's health care utilization during this eleven-year period, which includes the approval dates of 19 of the 22 drugs available to treat HIV/AIDS by the end of 2003. Additionally, the Medicaid data has been linked to individual-level mortality records through the end of 2001.

The key obstacle to obtaining reliable estimates for the effect of ARVs is that treatment is endogenous. The guidelines in effect during our study period recommended that HIV-positive individuals abstain from treatment until their health deteriorated to a certain level. Failing to account for this would therefore lead us to understate the benefits of ARVs. Fortunately, the detailed information on health care utilization in our data allows us to proxy for health status at the time the treatments were approved. Consistent with suggested protocols, we find that sicker patients are significantly more likely to initiate treatment following the approval of Epivir and protease inhibitors (hereafter Epivir/PI).

In investigating the effects of these treatments, we demonstrate that controlling for pre-treatment health status substantially increases our estimate for the effect of the treatments on mortality probabilities. Moreover, we uncover substantial heterogeneity in this effect, with the sickest patients experiencing the largest reductions in mortality. In all, we estimate that Epivir/PI reduced mortality by approximately 70 percent among the patients who took them. This corresponds quite closely with the decline in overall mortality rates for AIDS patients observed during the 1995 to 1998 period, suggesting that these treatments were the driving force behind the decline in mortality for AIDS patients in the U.S. These estimates are similar in magnitude to those from RACTs and from studies that had more detailed clinical data for these same pharmaceutical treatments. However, few of these previous studies have analyzed data for a vulnerable population such as Medicaid recipients. Additionally, our sample sizes are sufficiently large that we can examine impacts for particular subgroups like females and minorities. And most importantly, these previous studies did not also consider the effect on health care spending.

Our findings for the effect of the treatments on expenditures reveal substantial heterogeneity, with large reductions in spending for the sickest patients but statistically significant increases for healthier patients. The mechanism for this is that the use of the new treatments increased pharmaceutical spending but reduced the need for hospitalizations and other types of medical care. Healthier patients had little care to offset and thus the increase in ARV utilization increased total spending on them. We also find that Medicaid spending actually increased for dual eligibles, the one-third of our sample also eligible for Medicare when the new treatments were approved. This is because Medicare realized much of the savings from this offset because it is the primary expected payer for those eligible for both programs.

In the final section of our paper, we investigate the effect of the new treatments on long-term Medicaid spending, life expectancy, and the corresponding cost per life-year saved.[3] The new treatments reduced quarterly Medicaid spending by an average of 10 percent for those not on Medicare but increased life expectancy by more than a factor of three. Combining these two effects leads us to estimate the cost per life year saved of the four treatments introduced in late 1995 and early 1996 at close to $22,000, which is well within the range of what is considered to be cost effective.

Claims data sets from programs such as Medicaid and Medicare are inexpensive and plentiful. Our findings demonstrate that one can use this data - combined with an econometric model that allows for heterogeneous takeup and effectiveness - to reliably estimate the impact of new treatments on health outcomes and health care spending.[4] This suggests that studies using administrative data can be a useful complement to RACTs as patients, physicians, insurers, and policymakers strive to allocate resources optimally in an environment characterized by rapidly expanding choices and costs.[5]

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[3] Of course these treatments may have influenced other outcome variables as well. For example, Lakdawalla et al. (2006) find that ARVs increase risky behavior such as unprotected sex and intravenous drug use. While important, we consider these outcomes to be outside the scope of the current study, though a full welfare calculation would have to include them as well as the gains to pharmaceutical manufacturers.

[4] A related literature has estimated the benefit to consumers of new products. For example, Petrin (2002) develops a technique for estimating the benefits of the minivan. A key difference between the health care market and other markets is that patients with health insurance typically do not share in the cost of their medical care. In the current setting the price of all ARVs is essentially zero (though California has recently introduced small co-pays).

[5] While we consider here the effect of new medical innovations, a large literature has investigated the determinants of innovation. For recent examples see Acemoglu and Linn (2004), Finkelstein (2004), and Acemoglu et al. (2006).

II. Background and Significance

A. Previous Research Using Claims Data and Replicating RACTs

Insurance claims data bases have large sample sizes, are inexpensive to construct, and contain a wealth of information about patients' treatments in real-world situations. Previous research has used samples from claims data bases to analyze the impact of various treatment options. McClellan, O'Neil and Newhouse (1994) use a sample of Medicare patients to analyze the effectiveness of various heart attack treatments. Cutler (1995) uses data on hospital discharges for Medicare patients to examine whether movement to the Prospective Payment System altered patient outcomes. Cutler et al. (1998) use Medicare claims data to construct medical care price indices for heart attack treatment.

To date however, little research has examined whether analyses using a claims data base can replicate a stylized result generated from a more controlled research environment such as a random assignment clinical trial (RACT). These types of replication exercises have been important in economics in shaping research agendas and fostering the use of new statistical techniques. Lalonde's 1986 paper, which demonstrated that econometric evaluations of job training programs could not replicate results from random assignment trials, led to a long line of research evaluating the statistical methods used in such studies. In contrast, the results in Dehejia and Wahba (1999) which showed that propensity score matching techniques could replicate the results from these same job training experiments, helped launch the use of this technique in economics.

In this paper, we follow the lead of these previous authors and examine whether applying appropriate econometric methods to a claims data base can replicate the results of studies that benefit from randomization. To do this we use administrative data from California's Medicaid program to construct a sample of HIV/AIDS patients. The context within which we are conducting this exercise is interesting in its own right. The Centers for Disease Control report that through 2004, approximately one million people in the U.S. had been diagnosed with AIDS, with more than half of these individuals dying by the end of that same year. Prior to the introduction of Epivir/PI in November of 1995, annual mortality rates of AIDS patients stood at 30 percent. Among HIV/AIDS patients in the U.S., half are

insured through the Medicaid program (Bhattacharya et al., 2003)

The focus on examining the effectiveness of a pharmaceutical intervention in Medicaid is also of interest given the important role that new drugs have played in raising Medicaid expenditures, which exceeded $300 billion during the 2004 fiscal year. Between 1995 and 2004, the fraction of Medicaid costs devoted to prescription drugs nearly doubled, from 7.4 to 13.7 percent. Most of this increase was driven by the introduction of new and more expensive treatments, with the average cost of a Medicaid-reimbursed prescription increasing by 90 percent since 1995. In 2004, 65 percent of prescription drug costs for branded drugs[6] in the Medicaid program were for treatments introduced in or after 1997, while only 6 percent were attributable to drugs introduced in 1990 or earlier.

B. Background on HIV/AIDS and Antiretroviral Treatments

AIDS is a chronic disease that damages, and ultimately destroys, an individual's immune system. AIDS is caused by HIV, an infection that kills the body's "CD4 cells", a type of white blood cell that helps the body fight off infections. When this epidemic first appeared, providers could only treat opportunistic illnesses resulting from the weakened immune system rather than attack the virus itself. This changed with the entry of Retrovir (AZT) to the market in 1987. This drug was the first one approved by the FDA in the therapeutic class known as NRTIs (nucleoside reverse transcriptase inhibitors). Despite the entry of three additional NRTIs from 1991 to 1994, use of these drugs among AIDS patients actually declined from 1992 through 1995. This trend reversed following the approval of Epivir (another NRTI) and three drugs from a new class known as protease inhibitors (PIs) in late 1995 and early 1996. The first NNRTI (non-nucleoside reverse transcriptase inhibitor) was approved in June of 1996. Twelve additional drugs were approved in the seven years from 1997 to 2003 (Table 1).

The release of Epivir/PI spawned the use of highly active antiretroviral therapy (HAART), which is the simultaneous use of two or more ARVs to treat HIV. The optimal time to initiate HAART depends

[6] Brand name drugs accounted for approximately half of Medicaid prescriptions in 2004 but 85 percent of the $39 billion in Medicaid prescription drug spending.

both on the strength of the patient's immune system and on the concentration of HIV in the patient's blood. Current guidelines recommend HAART for all patients with less than 200 CD4 cells per cubic millimeter of blood and suggest that all patients with CD4 cell counts between 200 and 350 be offered treatment (NIH, 2004; Yeni et al., 2002).[7] Thus those HIV-positive individuals who take the drugs will tend to be sicker than their counterparts who do not.[8]

In a short period after the approval of Epivir/PI, HAART became the standard treatment for those infected with HIV.[9] The sharp increase in the use of the drugs coincided with a substantial decline in the mortality rate among AIDS patients. According to data from the U.S. Centers for Disease Control, between 1995 and 1998, the mortality rate for individuals with AIDS fell by 70 percent.

A large number of studies, some using randomized research designs (Hammer et al., 1997; Delta Coordinating Committee, 2001; Floridia et al., 2002) and others using observational data with detailed clinical information (Palella et al., 1998; Detels et al., 1998; CASCADE Collaboration, 2003) investigated the life saving benefits of the new ARVs.[10] All of these studies found that the new treatments generated statistically significant reductions in mortality. For example, in a random assignment trial examining the effectiveness of one protease inhibitor in combination with Retrovir and Epivir, Hammer et al. (1997) found that 48-week mortality rates were 55 percent lower among those taking a protease inhibitor. Palella et al. (1998) used observational data for 1255 patients in eight U.S. cities to examine the impact of ARVs on mortality. Controlling for a variety of socioeconomic factors and CD4 count levels prior to treatment, the authors found that mortality fell by more than 70 percent among those using protease inhibitors with two or more NRTIs.[11]

Demonstrating that we could replicate the results from RACTs or studies with more detailed

[7] The main benefit of starting HAART early is that it can prevent both the degradation of the immune system and the elevation of viral loads. The main costs are that patients often experience severe side effects and they can also develop drug resistance, thereby reducing future treatment options.
[8] Individuals with HIV are defined as having AIDS once their CD4 count falls below 200 or once they are diagnosed with an AIDS-defining illness.
[9] Bozzette et al., (1998 and 2001) found that by the end of 1996, nearly 60 percent of HIV infected patients were using protease inhibitors.
[10] Lichtenberg (2003) uses aggregate, national-level data for the U.S. to estimate the effect of ARV approvals.
[11] There are no RACTs of which we are aware that compare the use of both Epivir and PI with the use of neither, though this Palella study using observational data essentially does.

clinical information within a claims data base offers a potential leap forward in the types of questions that can be addressed with non-clinical data in a real-world setting. We therefore view estimates from these studies as a useful benchmark in our analyses below. If the treatments are similarly effective for those on Medicaid and if these individuals adhere well to the treatment regimens then we should detect a similar effect for them on mortality.[12] One important advantage of our study relative to virtually all previous work is that we simultaneously consider the effect on both spending and health outcomes.[13]

III. Constructing the Analysis Files

A. The California Medicaid Claims and Eligibility Data

We utilize claims and eligibility data[14] for a random 24 percent sample of Medicaid recipients from the state of California to estimate the effect of HIV antiretroviral drugs. In our data there are 4.03 million people who were eligible for the program in at least one month between January of 1993 and December of 2003. The eligibility files contain demographic information for program participants including gender, month and year of birth, race, ethnicity, and zip code of residence. Additionally, there are two variables that allow us to determine whether an individual is dually eligible for health insurance through Medicare in each month. Finally, the eligibility file indicates whether the Medicaid recipient is enrolled in a Medicaid managed care plan in each month and if so, lists the plan number.

The claims data includes all fee-for-service payments made from January of 1993 until June of 2004, though because there is often a lag in processing the claims, we consider utilization through just December of 2003. There are three types of claims in our data. Inpatient claims are generated for admissions to hospitals and long-term care facilities and include information about the patient's primary and secondary diagnosis, the dates of service, the amount paid by Medicaid, and the procedures performed. Outpatient claims have similar data about payments to physicians, clinics, hospital outpatient

[12] According to the results from previous research, Medicaid patients typically had lower use rates for the new drugs (Bozzette et al., 2001; Shapiro et al., 1999).
[13] Other studies have used individual-level data to consider the effect of ARVs on health care utilization and expenditures. See for example Gebo et al. (1999).
[14] See Duggan (2005) for a detailed description of this Medicaid data.

facilities, laboratories, and other health care providers. Finally, prescription drug claims provide data on payments made to pharmacies for drugs covered by Medicaid. Each pharmacy claim includes an eleven-digit National Drug Code that allows us to determine the drug and the dosage amount. All three types of claims include the patient's Medicaid identifier, which can then be matched to the eligibility files. Finally, we reached an agreement with the California Center for Health Statistics and the Medical Care Statistics Section that allowed us to merge death records for the 1993 through 2001 period to the Medicaid data. These records identify date and cause of death for all residents of the state of California.[15]

B. Defining the HIV/AIDS Sample

A number of previous researchers have used Medicaid claims data to construct samples of HIV/AIDS patients (Eichner and Kahn, 2001; Kahn et al., 2002; Morin et al., 2002). Following this research, we use ICD-9 diagnosis codes on the Medicaid inpatient and outpatient claims to determine whether individuals are diagnosed with this illness. To reduce the possibility of false positives, we restrict attention to patients with two or more non-prescription HIV/AIDS claims.[16] This algorithm yields a sample of 12,932 individuals who have one or more HIV/AIDS claims, are eligible for Medicaid at some point during our study period, have a valid social security number, and have consistent age and gender information across years in the eligibility files.[17]

Although our Medicaid claims data contain a rich set of information, it does have some important limitations. First, our data is for just one state and thus our results may not generalize to Medicaid recipients elsewhere in the U.S. Second, we lose patients who temporarily or permanently exit because

[15] This match could only be performed for the 92 percent of our sample with a valid social security number.
[16] False negatives are also a possible concern though we can use external data to gauge the importance of this. Using our mortality data, we identify 4,371 individuals in the 24 percent sample who died with HIV/AIDS as the primary cause. Our algorithm captures 3,617 of these individuals (almost 83 percent). The patients missed by our algorithm have fewer eligible months (11.6 versus 22.6) and a much large fraction of months in Medicaid managed care (49.1 percent versus 9.7 percent). This latter difference reflects the fact that utilization data for those in MMC will typically be incomplete (Duggan, 2004) and we therefore exclude MMC recipients in constructing our sample. If we also include individuals who take any ARVs we increase the number from 3,617 to 3,723.
[17] Previous research using Medicaid claims data has found that this algorithm captures the vast majority of recipients diagnosed with HIV/AIDS. For example, Rosenblum et al., (1993) matched Medicaid claims data to medical records of patients known to be infected with HIV and found that they successfully identified 91 percent of the patients.

they become ineligible for Medicaid.[18] Third, we do not know when patients were first diagnosed with HIV or AIDS but instead only the date of their first Medicaid HIV/AIDS claim during our study period. Fourth, claims data do not contain diagnostic information about patients such as CD4 cell counts or HIV viral loads. This information is important because it indicates who is recommended to receive ARVs. Fifth, we do not have Medicare expenditure data for people also eligible for that program. Medicare will typically cover most of the hospitalization costs of dual eligibles. Thus while we can accurately measure utilization, we will understate health care expenditures by the government for this group.[19] Finally, we have incomplete utilization data for patients enrolled in a Medicaid managed care plan and thus exclude them from our analyses.

Even with these limitations, our data has a number of important benefits over the data sets used in all previous research. First, it is the largest sample of HIV/AIDS patients generated from one consistent source.[20] Second, our period of analysis covers an important time including three full years before and nearly eight years after the introduction of Epivir/PI, allowing us to investigate the effect of the treatments on both short and long-term health and spending. Third, because of the rich set of information in our claims data we can proxy for individual's pre-treatment health status and thus try to account for endogenous treatment decisions. Finally, we can estimate not just the average effect of antiretroviral treatments but also the extent to which this varies across individuals.

C. Sample Characteristics

On the left-hand axis in Figure 1, we plot the number of Medicaid recipients in our sample who were alive at the beginning of half-year periods starting in January of 1994. The patients in each half-

[18]Less than 2 percent of the sample exits the sample per quarter and this actually declines during our study period. For example it falls from 1.96% in the last quarter of 1995 to 1.42% in the first quarter of 1998.
[19] Medicare did not cover prescription drugs for dual eligibles during our study period.
[20] The HIV Cost and Services Utilization Consortium (Shapiro et al., 1999) followed a cohort of 2,864 HIV patients for January of 1996 through January of 1998. The CASCADE Collaboration (2003) pooled data from 22 cohorts of HIV patients from European, Canadian and Australian studies to construct a sample of 7740 HIV patients covering the pre-1997 through 2001 period. The ART Cohort Collaboration (Egger at al., 2002) pooled data from 13 cohort studies of patients starting HAART from Europe and North America to generate a sample of 12,574 patients.

year cell had their first HIV/AIDS claim by the end of that period although they may have been enrolled in Medicaid for some time before that date. Roughly one-fourth of the sample appears in the first half-year of the time period and the sample grows steadily after that date. On the right-hand axis of the figure, we graph the total number of people living with AIDS in California[21] at the end of each six month period as reported by the CDC in their publication *HIV/AIDS Surveillance Report.* These two surveys track one another quite closely (ρ=0.98). Our numbers suggest that roughly 52 percent of people living with AIDS in California are on Medicaid,[22] a number close to the national average (Bhattacharya et al., 2003). Similarly the number of individuals in our sample grows at an almost identical rate to the statewide total (58 percent for both from 1994 to 2001). Given the possible limitations with using claims data outlined above, our algorithm for identifying Medicaid recipients with HIV/AIDS appears to work quite well.[23]

In Figure 2, we graph half-year mortality rates for the Medicaid recipients in our sample of 12,932 patients during the 1994-2001 period. On the second vertical axis of the table, we graph the half-year mortality rate among all California AIDS patients. Death rates in our sample are 1.5 – 2.5 percentage points higher than deaths rates for all AIDS patients in California, indicating that our sample is substantially sicker than the typical AIDS patient. The timing and magnitude of the change in mortality in our sample is similar to the changes found for California AIDS patients. Between the first half of 1995 and the second half of 1997, six month mortality rates fell by 69 percent in our sample and 79 percent

[21] We should note that our sample includes not only patients with AIDS but also some who are just HIV-positive. Unfortunately, in most years California only reported to the CDC the number of people living with AIDS, not the number with HIV. Thus in one respect it is plausible that the patients in our sample would be healthier than the typical AIDS patient in California. However, most of the individuals in our sample qualify for Medicaid through the means-tested Supplemental Security Income (SSI) program. Thus they must be in relatively poor health to meet SSI's medical eligibility criteria. As we document below, the death rates for our sample are substantially higher than for non-Medicaid AIDS patients in California. Therefore, comparing trends in the number of HIV/AIDS patients on Medicaid to overall trends of AIDS patients seems a reasonable compromise given the available data.

[22] Consider the first half of 1994 when there are 3,237 individuals in our sample. To estimate the number on Medicaid with HIV/AIDS one must multiply this by (1/.24). Additionally we must multiply by 1.058 to account for the exclusion of those with an invalid SSN. This yields 14,270, which is 52.0% of the statewide total of 27,454. The actual fraction may be even higher given that we exclude individuals with just one HIV/AIDS claim or with prescription drug claims only during the study period. On the other hand, some of the individuals in our sample have not yet progressed to AIDS and thus our estimate will to some extent overstate the Medicaid fraction.

[23] One possible concern with focusing just on Medicaid recipients is that the incentive to enroll in the program will change after new treatments become available (Goldman et al., 2001), raising the possibility of composition bias. The fact that our series tracks closely with the total number in the state suggests this is not too problematic.

among all California AIDS patients.

In Table 2, we report descriptive information about our Medicaid HIV/AIDS sample at four points in time: 1994, 1997, 2000 and 2003. In constructing this sample we drop the 1,063 individuals who live in one of the eight counties that moved its Medicaid recipients into a county-organized health system during our study period because our claims data would often be incomplete for them. We also drop the 1,802 individuals with one or more months in a Medicaid managed care plan during our eleven-year study period.[24] This leaves us with a final sample of 10,067 HIV/AIDS patients. As the table shows, the annual mortality rate in the sample fell from 23.0 percent in 1994 to 5.2 percent in 2000, contributing to a large increase in the average age of the sample. The fraction of the population under 40 fell from 50 percent in 1994 to 28 percent nine years later. During our study period the fraction of the sample that is black and female increased by 47 and 19 percent, respectively.

In the bottom half of the table, we report some basic information about health care utilization in our sample. Patients have high medical care use but some measures are improving over time. Almost 48 percent of patients in the sample had an inpatient stay in 1994 and this number fell to 28 percent during the next nine years. Annual inpatient spending fell by an even larger percentage from $7125 to $3510.[25] In contrast, annual outpatient spending increased slightly while spending on prescription drugs tripled, driven primarily by the increased use of antiretroviral drugs and their high cost. Although average annual spending on prescription drugs increased by $8,000 over the period, total spending increased by just $4,800. The fraction of HIV/AIDS patients who are also eligible for Medicare increased from 28 to 45 percent, with this change likely contributing to the fall in average Medicaid spending on inpatient care given that Medicare covers most inpatient costs for dual eligibles.

[24] The lack of data for patients in managed care could be problematic if it leads to changes in the composition of our sample over time. The fraction of all Medicaid recipients in a managed care plan does increase substantially during our study period, though as Duggan (2004) notes, these changes differentially affected AFDC/TANF recipients who account for a small share of our sample. SSI recipients, who account for nearly 70% of the patients in our sample, were not required to enroll in managed care in any counties except those moving to a county-organized health system and it is for this reason that we drop these counties. The fact that the number of individuals in our sample tracks the number statewide with AIDS quite closely (Figure 1) suggests that this issue is not too problematic.

[25] Expenditure data cited here and elsewhere in the paper are adjusted to December, 2001 dollars using the Bureau of Labor Statistics' Consumer Price Index for Urban consumers (CPI-U).

IV. The Impact of HIV Antiretroviral Treatments: A Graphical Presentation

The FDA's approval of Epivir in November of 1995 and of three protease inhibitors during the next four months coincided with a sharp decline in the mortality rate among the Medicaid recipients in our sample. As Figure 2 demonstrates, from the latter half of 1995 to the same period in 1997, the six-month mortality rate among California Medicaid recipients diagnosed with HIV/AIDS fell by 70 percent, from 11.3 to 3.4 percent. This decline was quite similar to the corresponding decline reported by the CDC for all California residents diagnosed with AIDS, though the figure demonstrates that the individuals in our sample appear to be in worse health than the average California AIDS patient. During the next four years the mortality rate in our sample declined gradually and was equal to 2.8 percent in the second half of 2001. Figure 3 depicts the fraction of individuals in the sample filling at least one prescription for an ARV in the quarter. From the third quarter of 1995 to the second quarter of 1997, this fraction more than doubled, increasing from 28.7 to 59.0 percent. This growth was entirely driven by an increase in the use of Epivir/PI, with no one taking these drugs in the third quarter of 1995 and 56.0 percent taking one or more of these treatments in the second quarter of 1997 (Figure 4). There were no significant changes in utilization for other ARVs. Taken together, the series depicted in Figures 2, 3, and 4 strongly suggest that Epivir/PI were the primary cause of the significant decline in mortality rates observed during our study period.

This is more easily represented in Figure 5, where on the left vertical axis, we report the fraction of patients that are using either Epivir or protease inhibitors, and on the right vertical axis, we report the patient quarterly mortality rate. There are three things to highlight in this graph. First, notice that prior to the first quarter of 1996, quarterly mortality rates had been falling (though this trend had leveled off early in 1995). This suggests that there might have been some decline in AIDS mortality rates from 1995 to 1997 even if Epivir/PI had not been introduced. Second, as Epivir/PI use increased from zero to 56 percent between the fourth quarter of 1995 and the second quarter of 1997, quarterly mortality rates fell by 72 percent, from 6.7 percent to just under 2 percent. As Epivir/PI use stabilized in mid-1997, so did

mortality rates. Between mid 1997 and the end of our sample, quarterly mortality rates were originally 1.8 percent, fell as low as 1.4 percent, and ended at 1.6 percent.

The potential importance of Epivir/PI as an explanation for the decline in mortality is most easily illustrated with a simple time series model in which we regressed the first-difference in quarterly HIV/AIDS mortality rates on the first difference in quarterly Epivir/PI use among HIV/AIDS patients in the California Medicaid sample during the 1994-2001 period. The coefficient on the first-difference in Epivir/PI use is -0.0789 (with a standard error of 0.0148). Epivir/PI use peaked at 56 percent in mid 1997, and therefore this simple time series regression suggests that the introduction of these drugs can explain 4.4 percentage points of the 4.7 percentage point drop in quarterly mortality.[26]

V. The Impact of HIV Antiretroviral Treatments: Individual-Level Evidence

In this section we estimate the impact of Epivir/PI use on medical and cost outcomes with individual-level data. There are two key factors we must consider when constructing an econometric model. First, individuals who are in worse health are both more likely to die and more likely to use these treatments. Failing to account for this would likely lead us to underestimate the benefits of the treatments and overestimate their effect on Medicaid expenditures. Second, the effect of the treatment is likely to vary substantially across individuals. If patients and their physicians accurately forecast the effects of the treatments and are trying to maximize their health, then one would expect to see a relatively small health benefit for the marginal patient. If the effect does vary substantially across individuals, the effect for the marginal patient would shed little light on the effect for all other patients.

A. Estimating Health Status from Claims Data

In an effort to address these identification issues, we begin by exploiting the longitudinal nature of the Medicaid claims data to construct a proxy for the severity of a person's HIV/AIDS diagnosis before

[26] It is worth noting that many taking Epivir and/or a protease inhibitor were also taking one or more other ARVs. A very common combination soon after the release of the new treatments was AZT, Epivir, and one protease inhibitor. Thus our estimates are to some extent capturing an interaction of new and existing treatments.

use of ARVs. We start with a simple approach and count the quarterly number of inpatient and outpatient claims for each patient with a primary or secondary diagnosis of HIV/AIDS. Because treatment patterns may change over time, the average health of an individual with N claims in one quarter may differ from their counterpart with N claims in a subsequent quarter. To account for this possibility, we calculate the percentile in which each patient is located in each quarter. A person with a value of 0.75 for our severity index would therefore have more HIV claims than 75 percent of the other individuals in the sample in that quarter. Of course the distribution of health may change over time. Thus to reduce the possibility of composition bias we focus on the period immediately before and after the release of Epivir/PI when estimating the effect of these treatments.

While this measure is no doubt an imperfect proxy for health status, it is a powerful predictor of mortality during the first three quarters of 1995, just prior to the approval of Epivir and the first protease inhibitors. The first two columns of Table 3 summarize regression results from models that have the outcome of interest as an indicator variable $M_{j,t+1}$ that equals one if person j dies in the next quarter and is otherwise equal to zero. The model we estimate is of the form

$$(1) \qquad M_{j,t+1} = \alpha_t + \mu * H_{jt} + \Theta * X_{jt} + \varepsilon_{jt}$$

where H_{jt} is individual j's percentile in the severity index distribution in period t. The vector X_{jt} includes a set of control variables for the person's age, gender, race, and Medicare eligibility and α_t is a full set of year*quarter indicator variables. The equations are estimated as linear probability models, though the results are qualitatively similar if we instead estimate them as probits. For a person-quarter observation to be included in the sample, he/she must be alive at the end of quarter t and must have an HIV/AIDS claim in the current quarter or a previous one.

The results summarized in the first column of Table 3 do not include our measure of health status. The statistically significant estimate of -.0305 for the FEMALE variable implies that women were three percentage points less likely than men to die in the next quarter. Given an average quarterly mortality rate of approximately 7 percent among the men during this period, this represents a substantial difference.

Younger patients were also less likely to die as were individuals who were enrolled in the Medicare program. This latter relationship could reflect an effect of Medicare on health status, or it may simply reflect the fact that non-elderly individuals typically qualify for Medicare through the Social Security Disability Insurance (DI) program. To be eligible for DI, a person must have worked in at least five of the ten most recent years.[27] Thus Medicare enrollment may be proxying for income or some other factor that is also related with health status.

The second specification includes our HIV severity measure. As expected, the sign of the coefficient is positive and it is precisely estimated. The point estimate implies that a 10 percentage point increase in the severity distribution is associated with a 1.6 percentage point increase in the quarterly mortality rate. Interestingly, the inclusion of this variable reduces the magnitude of all of the coefficients that were statistically significant in column one. For example, the estimate for the FEMALE coefficient falls by more than half to -0.0152, though it remains statistically significant. This suggests that the lower mortality rates of women are due in part to the fact they have less severe cases of HIV/AIDS. The same holds true for younger individuals in the sample and those enrolled in the Medicare program.

As mentioned above, the guidelines for the use of ARVs recommended that patients initiate treatment only once their health had declined to a certain level. We would therefore expect to observe a positive relationship between our severity index and the use of ARVs even prior to the introduction of Epivir/PI in late 1995. The results summarized in column 4 indicate this is the case. The point estimate of 0.2617 implies that a ten percentage point increase in the severity index is associated with a 2.6 percent increase in the utilization of ARVs. In the first three quarters of 1995, women were significantly less likely than men to use ARVs, but the differences by race were small and statistically insignificant.

The next two columns describe the results from linear probability models in which we examine the determinants of Epivir/PI use after their entry in late 1995. The pattern of results is similar to what we found for older ARVs, though in this case the relationship between severity and ARV use is even

[27] Most individuals in our sample qualify for Medicaid through the means-tested Supplemental Security Income (SSI) program. This program pays benefits to low-income aged, blind, and disabled individuals and individuals do not need work experience to be eligible. Many of those on SSI are also eligible for DI.

stronger. The estimate of 0.5704 for the severity coefficient is more than twice as large as the corresponding one from specification 4. Thus takeup of the drug was greatest among patients with the lowest level of health as measured by medical care usage.[28] As before, there are large differences in use by gender, with women less likely to take the new treatments. But in this case, statistically significant differences also emerge by race. Usage rates among African-Americans were more than ten percentage points lower than among other individuals in the sample. The last two columns show an almost identical set of results when the dependent variable is the use of any ARV. The similarity in the results is not surprising given that the vast majority of patients taking an ARV during this period were taking either Epivir or a protease inhibitor.

B. Estimating the Impact of ARVs on Mortality and Medicaid Expenditures

In this section we estimate the effect of Epivir/PI on mortality and health care spending for the individuals in our sample. We focus on the two year period from the first quarter of 1995 to the final quarter of 1996. This gives us essentially four quarters of information prior to the introduction of Epivir/PI and four quarters when the new treatments were rapidly diffusing. There are three main reasons for focusing on this two year period even though we have eleven years of data. First, it is clear from the trends in mortality that this two year period is the most important one, with mortality rates falling by more than 60 percent during a one-year period. Second, there were no other treatments released in 1995 and 1996, except for one drug in another category that had very low utilization (1.0 and 3.3 percent in the third and fourth quarters, respectively, of 1996). This reduces the possibility that changes in other treatment patterns might bias our results. The third and most important reason is that, once the new treatments were released, the distribution of health in our Medicaid sample begins to change rapidly. By choosing a smaller time period we reduce (but do not eliminate) the possibility of changes in the composition of the sample that could bias our estimates of the impact of the new treatments.

[28] If we estimate this regression separately by quarter the coefficient increases. For example, in the fourth quarter of 1995 our estimate is a statistically significant .127, but one year later it is .669. The constants in these specifications (controlling for age, race, and Medicare enrollment) are .002 and .197, respectively.

Mortality rates for individual j in the next quarter (t+1) are estimated to be a function of treatment in the previous period (t) for Epivir or PI, denoted as E_PI_{jt} plus the same covaiates that appeared in equation (1). The equation we estimate is of the form

$$(2)\ M_{j,t+1} = \alpha + \beta_{jt} * E\_PI_{jt} + \mu * H_{jt} + \Theta * X_{jt} + \varepsilon_{jt}$$

In this equation, β_{jt} captures the effect of the treatment, which is allowed to vary both across individuals and within an individual over time. The health index H_{jt} and demographic covariates X_{jt} control for health status and other characteristics (e.g. age and gender) that are plausibly related to an individual's baseline mortality probability.[29]

In considering whether to take the treatment, a forward-looking individual might be interested not only in the effect on mortality in the current period but also the effect in future periods. Put simply, an individual could rationally decide to delay treatment even if the magnitude of β_{jt} was high because by doing so he/she would increase the likely effect of the treatment in the future. But even considering this dynamic effect, one would expect individuals who take the treatment in period t to have significantly higher values of β_{jt} in (1) above. Thus the magnitude of the average effect on the treated (ATT) would likely exceed the average treatment effect (ATE) for all individuals with HIV/AIDS.

The empirical results summarized in Table 4 examine the relationship between mortality and the use of Epivir or a protease inhibitor. The sample is constructed from the sample of 10,067 HIV/AIDS patients described in section 3, though because we are considering a two-year period rather than the full eleven-year period the number of individuals considered here is lower. The outcome of interest is $M_{j,t+1}$, which is equal to one if individual j dies in the next quarter and zero otherwise. There are 20,235 quarterly observations for 4152 individuals, with the number of observations for each person ranging from one to eight. All specifications are estimated as linear probability models and include eight year*quarter indicators. Standard errors are clustered by person.

[29] Of course the treatments may also influence health status, which could lead us to understate their impact on mortality. But to the extent that individuals' position in the severity distribution (measured in H_{jt}) does not change, failing to account for this indirect effect will not bias our estimates for the effects of interest. We obtained very similar results if we held H fixed after the introduction of the treatments, though the estimated effects for mortality were slightly larger (76 percent rather than 70 percent reduction).

The results of various mortality equation specifications are reported in Table 4. In the first column, we report results that include only the time effects and the dummy indicating whether the patient takes Epivir/PI in the current quarter. Because sicker patients were likely to take these treatments, the magnitude of this estimate is likely to be biased down. The point estimate of -.0101 suggests that the treatments reduce mortality rates by approximately one percentage point. Recall that the quarterly mortality rate in the period just prior to the introduction of Epivir/PI was about 7 percent. This is much lower than the time series estimates presented above or than the estimates from random assignment clinical trials mentioned in section two. The inclusion of demographic variables and the fraction of months in which the person was enrolled in Medicare lead to a modest increase in this coefficient estimate to -.0126. In both cases the estimate of interest is statistically significant at the one percent level.

Neither of these first two specifications control for health status. In the third specification we add the HIV severity measure defined above to the set of explanatory variables. The inclusion of this variable leads to more than a threefold increase in the magnitude of the estimate for the impact of Epivir/PI to -.0394. This estimate increases still further to -.0461 in the fourth specification, which adds controls for utilization of other types of medical care in the previous quarter. This should to some extent capture the severity of other conditions afflicting individuals with HIV/AIDS. Dividing this point estimate by the average mortality rate just prior to the introduction of these treatments, this suggests a 66 percent reduction in mortality rates. Of course, given that sicker patients with higher baseline mortality probabilities were the ones taking the drugs, the implied effect would be somewhat lower.

In the fifth specification we allow the effect of the treatments to vary with severity by interacting the treatment indicator with our measure of HIV severity. This assumes that the effect of the treatment increases linearly with this severity measure.[30] The results suggest that the effect of the treatment is increasing in severity, with an implied reduction of 8.57 (0.0952-0.0102) percentage points in the quarterly mortality rate for the sickest patients. The point estimate for the Epivir/PI coefficient is slightly

[30] This is analogous to an assumption of a linear demand curve, with the health benefits corresponding to the consumer's willingness to pay. As mentioned above, Medicaid-insured patients do not share in the cost of their care and thus the financial cost for all patients is equal to zero.

positive, which likely reflects the fact that the treatments deliver little benefit to relatively healthy patients. In the final specification we constrain this main effect coefficient to equal zero, implying that the healthiest HIV/AIDS patients would derive no benefit. The point estimate of -.0825 implies that the sickest patient experienced an 8.3 percentage point decline in mortality as a result of taking the treatments. Dividing this estimate by the corresponding one for the severity coefficient, our results suggest that taking Epivir/PI reduced individuals' mortality rates by 70 percent. This is similar to the results reported above for the RACTs[31] and for studies that had detailed clinical information on patients. It therefore appears that our estimates do a good job of replicating the results from studies with superior data or with the benefits of randomization.

Given the apparent impact of Epivir/PI on mortality rates among Medicaid recipients with HIV/AIDS, it is plausible that the treatments would also influence health care expenditures. Both the sign and the magnitude of this effect are theoretically ambiguous. These treatments were substantially more expensive than their predecessors and it is therefore possible that overall spending increased. Alternatively, the improvements in health resulting from their use could have reduced the demand for other types of medical care, such as emergency room and hospital visits.[32] Although a large number of RACTs have considered the impact of ARVs on health, none have looked at their impact on medical care use or health care expenditures.

Suggestive evidence of the impact of Epivir/PI on medical care use is presented in Figure 6, which shows that while average Medicaid spending on prescription drugs began increasing in the final quarter of 1995, average Medicaid spending on all other categories of medical care started to decline at that same time. The net effect of this in the quarters right after the introduction of Epivir/PI was a small decline in quarterly Medicaid spending, from $5,172 in the last quarter of 1995 to $4,995 in the first quarter of 1997.

[31] It is not strictly comparable to the RACT results because most of these studies considered the effect of just protease inhibitors when combined with AZT and Epivir. Other RACT research suggests that Epivir produced significant health improvements even with no protease inhibitor (Gulick et al. 1997).

[32] See Lichtenberg (1996) for an exploration of the effect of pharmaceutical treatments on the utilization of other types of medical care.

In Table 5, we report results similar to those in Table 4 but use as the dependent variable different measures of quarterly Medicaid expenditures. In the first three models, the dependent variables are total Medicaid spending, prescription drug spending, and non-prescription drug spending, respectively. Because Medicare will cover a substantial share of the non-prescription drug costs for dual eligibles, and this will have a larger effect on Medicaid spending for the sicker patients, we interact our MEDICARE variable with the severity index. The first three specifications include essentially the same sample of individuals as in Table 4.[33] In this case we do not constrain the main effect to be zero given that taking the treatment could have an effect on spending even for relatively healthy patients.

The statistically significant point estimate of $967 for the Epivir/PI dummy in the first column suggests that the new treatments substantially increased spending for relatively healthy patients. But the estimate for the interaction of this variable with the HIV severity measure demonstrates that this effect declines with severity. For the sickest patients, the point estimate implies a $320 ($967-$1,287) reduction in quarterly Medicaid spending. This variation with health status is driven by an effect on other categories of Medicaid spending. The results listed in column 3 show that Epivir/PI reduced spending on other health care and that this effect was largest for the patients with the most severe cases of HIV.

One limitation with this set of results is that we are unable to observe all health care spending for the one-third of the patients who are also eligible for Medicare in our sample. Thus in the next panel of results, we exclude those who were dually eligible for this other program. We would expect to estimate a larger reduction in spending for the group remaining in the sample and this is what we find. The estimates in column 4 suggest that for the vast majority of HIV/AIDS patients on Medicaid but not on Medicare, the new treatments reduced spending. This was apparently driven by a much larger offset of spending on inpatient and outpatient care, as the estimates in Table 6 show. According to our estimates, the treatments reduced quarterly spending for the median patient by $504 and for the sickest patients by

[33] The sample is not identical because if a person is not enrolled in Medicaid then we do not observe their spending in the next quarter. We would, however, be able to observe whether they had died. Thus we have slightly more individuals and observations in the mortality specifications.

$1,389. Thus the introduction of these treatments reduced Medicaid spending and would have lowered it by even more had it not been for the one-third of the sample also on Medicare.[34]

Taken together, the results presented in Tables 4 and 5 strongly suggest that the impact of the treatments varied substantially across individuals. Our estimates in Table 4 suggest a 70 percent reduction in mortality rates, which corresponds quite closely to the estimates from earlier studies with the benefit of randomization or with more detailed clinical information. Sicker patients benefited more because they had higher baseline mortality rates. The effect on Medicaid spending also varied across recipients, with modest increases for healthy patients or those on Medicare and large reductions for the sickest patients only on Medicaid.

C. Variation by Gender and Race in ARV Use, Expenditures, and Mortality

Given the significant differences across groups in the takeup of Epivir/PI, it is plausible that there were corresponding differences across groups in the evolution of Medicaid spending and mortality following the introduction of these treatments. Figure 7 shows that the use of Epivir/PI was much greater among men after these treatments became available and that this remained true throughout our study period. An examination of mortality rates for the two groups summarized in Figure 8 suggests that differential use of the drugs may partially explain the observed changes. In the last half of 1995, male half-year mortality rates were 13.3 percent, versus just 7.2 percent for women. If anything these rates were diverging just prior to the introduction of Epivir/PI. But just one year later in the last half of 1996, these rates were very close at 6.8 and 6.1 percent, respectively.

If the average effect of the drug on those taking it (ATT) was similar for men and women, then one could estimate this parameter using the commonly employed differences-in-differences strategy. But it seems likely that this average effect would differ between the two groups, in which case an identifying

[34] An examination of trends in Medicaid spending for duals and all others supports this finding. Average quarterly Medicaid spending for those not also on Medicare declined from $6,242 in the third quarter of 1995 to $5,149 two years later. But during that same period, average Medicaid spending for dual eligibles increased significantly, from $3,037 to $4,373. This latter change presumably occurred because there was much less non-prescription drug spending to offset for this group.

assumption of this method would be violated. Recognizing this possibility, in Table 6 we summarize the results from specifications that examine whether there were differential changes by gender and race following the approval of the new treatments:

$$(3)\, Y_{j,t+1} = \theta_0 \mathrm{POST}_t + \theta_1 \mathrm{FEMALE}_j + \theta_2 \mathrm{BLACK}_j + \theta_3 \mathrm{FEMALE}_j * \mathrm{POST}_t + \theta_4 \mathrm{BLACK}_j * \mathrm{POST}_t + \varepsilon_{jt}$$

In this equation, Y is an outcome variable such as mortality or Medicaid expenditures for individual j in quarter t+1. To be included in the analysis sample an individual must still be alive at the end of the quarter. We use just eight quarters of data from the first quarter of 1995 through the final quarter of 1996, thus focusing on the period just prior to and following the introduction of the new treatments. We do this to reduce the possibility that other changes which could differentially affect the two groups would bias our results and to reduce the possibility of composition bias. The variable POST is set equal to zero in the period prior to the approval of Epivir/PI and rises in increments of 0.2 from the last quarter of 1995 to the last quarter of 1996.[35] We do this to capture the fact that the treatments did not diffuse instantaneously but had come close to their equilibrium rate in the final quarter that we consider. All regressions are clustered by individual given that we have multiple observations for most individuals in the sample.

The estimates summarized in the first two columns demonstrate that, consistent with the earlier results, the takeup of the new treatments was significantly lower among women and African-Americans. Despite this, there is little evidence of differential changes for overall Medicaid spending, as shown by the small and statistically insignificant point estimates for FEMALE*POST and BLACK*POST in column three. This total spending masks differential changes by spending category, as columns four and five reveal. The point estimates there suggest that Medicaid spending on prescription drugs rose by less for women and blacks, but that their spending on other categories of care fell by less as well (though these latter estimates are not significant). This provides some suggestive evidence of offset, with spending on prescription drugs leading to declines in the utilization of other categories of medical care.

[35] Our results are very similar if we do not include the POST variable but instead have five year*quarter indicators.

In the final column we investigate whether there were differential changes in quarterly mortality rates by race and gender as well. The statistically significant point estimate of .032 for the FEMALE*POST coefficient implies that the gender gap of more than three percentage points in mortality rates was almost eliminated after the new treatments hit the market. No corresponding differences in mortality rate changes were observed for blacks. This could be because the average effect of the treatment was larger for blacks and this made up for their lower utilization rates. Taken together, our results provide some evidence that the differential takeup of the new treatments by race and gender influenced both health and spending on other categories of medical care.

VI. The Impact on Long-Term Medicaid Spending and the Cost per Life-Year Saved

In this section we investigate the impact of Epivir/PI on long-term health care spending in the Medicaid program. There are two factors that diverge when calculating these costs. First, although Epivir/PI is an expensive treatment, the results in Table 5 suggest that these higher costs are more than offset by lower inpatient expenditures. In contrast, the large reduction in mortality generated by Epivir/PI use increased life expectancy, and hence the amount of time that individuals were eligible for Medicaid.[36] In this section, we build an illustrative model that allows us to capture these two opposing factors in a simple calculation.

Consider an HIV positive patient that has progressed in their illness to the point that physicians would recommend Epivur/PI use, which we label as quarter 0. Suppose in the absence of ARVs, a patient will have medical expenditures of M_0 in period 0, and for simplicity, assume this amount grows at a real rate of (p) per quarter. Patients are assumed to die at a rate of δ in each quarter and this rate is assumed to be constant over time. If r is the quarterly interest rate, the discounted expected lifetime costs for this patient in the absence of antiretroviral treatments are

[36] As Meltzer (1997) outlines, there is some controversy about whether future medical costs should be considered in medical cost-effectiveness studies. Meltzer argues that for cost-effectiveness studies to be consistent with utility maximization, they must include all future lifetime costs, including non-medical expenses. At the other extreme, others argue that only future medical costs directly related to the illness should be included in these calculations. Given available data, we examine all future medical costs but do not include non-medical expenses.

$$(3)\ LT_{wo} = \sum_{t=0}^{\infty} M_0[(1+\rho)/(1+r)]^t\ (1-\delta)^t$$

For simplicity, assume that ρ is equal to r[37] and therefore, that discounted lifetime costs equal M_0/δ. When Epivir/PI were introduced, assume baseline costs and the mortality rates changed to M_0^a and δ^a respectively, and therefore, lifetime costs would then be M_0^a/δ^a. The increase in life expectancy in quarters is simply $[1/\delta^a - 1/\delta]$ and the corresponding change in lifetime costs is $[M_0^a/\delta_a - M_0/\delta]$. Dividing this number by $4[1/\delta^a - 1/\delta]$ produces the cost per life year saved.

An examination of our data reveals that the median patient on ARVs in 1997 had a severity index of 0.61. Using the results from Table 3, quarterly Medicaid expenditures for this person before the release of Epivir/PI are estimated to be $6,636 ($M_0$) and quarterly mortality in late 1995 for someone at this severity level is 8.27 percent. Use of Epivir/PI is estimated to reduce quarterly spending to $5,920 and quarterly mortality rates by 62 percent to 3.15 percent. These numbers indicate that the discounted lifetime costs of treating an HIV/AIDS patient on Medicaid increased from $80,242 to $187,937 following the introduction of Epivir/PI. The resulting drop in mortality increased expected life expectancy by 4.91 years so Epivir/PI use is estimated to cost a total of $21,918 per life year saved.[38] So, although the use of Epivir/PI increased the lifetime costs of treating HIV/AIDS patients on Medicaid by over $100,000, the cost per life year saved is actually somewhat modest.

We should note that we make a number of strong assumptions; including a constant mortality rate and that the discount rate is equal to the growth in quarterly Medicaid expenditures. The marginal cost per life year saved calculation is not particularly sensitive to the assumed values of M_0 and M^a_0. If we assume there is no change in spending associated with ARVs then the cost per life year saved increases to roughly $26,544. Likewise, the results are not very sensitive to the precise drop in mortality produced by

[37] This assumption seems reasonable given that our estimate of the average growth rate in individual-specific quarterly Medicaid spending in both the pre and post periods was between 0 and 1 percent.

[38] This estimate is similar to estimates presented by Freedberg et al (2001). Those authors use estimates from RACTs to simulate the cost-effectiveness of three-drug anti-retroviral regimens. The authors estimate that such a regimen costs $13,000 to $23,000 per quality adjusted life year in real 1998 dollars.

ARVs. Notice that the numerator and denominator in the marginal cost calculation both contain $1/\delta^a$ so the rise in lifetime costs associated with living longer is functionally proportional to additional life expectancy costs. If quarterly prices are assumed to increase twice as fast as the quarterly discount rate, the cost per life saved increases to about $37,000 per year. But it is clear that even if we relax one or more of our assumptions, the four ARVs studied here and released more than a decade ago are well within the range of what is considered to be cost effective.[39]

It is worth noting that the estimates for this treatment do not generalize to other ARVs or to other new health care treatments. Indeed since the utilization of Epivir/PI settled to its new equilibrium in early 1997, there has been little further decline in mortality rates among Medicaid patients with HIV/AIDS. This has been true despite a consistent increase in pharmaceutical spending in the last several years of our sample, which increased from $2,385 in the second quarter of 1997 to almost $3,900 per quarter in 2001. Of course it could be that mortality rates would have started to rise again had it not been for the new treatments. But the contrast between the drugs released one decade ago and those released since strongly suggest that the cost-effectiveness of the more recent ARVs is much lower.

VII. Discussion

The steady increase in health care spending in recent years and that is projected for the coming decades suggests that greater scrutiny may be given to the benefits of new and more expensive health care treatments. Potential sources of data for these analyses are the claims data sets from insurers such as Medicare, Medicaid, the Veterans Health Administration, or private insurance companies. These data sets have large sample sizes, have detailed information on individuals' treatments, and have very accurate data on expenditures. It is, however, difficult to reliably estimate the effects of interest with this data because of the absence of clinical information that would allow one to control for baseline health status and because treatment decisions are endogenous.

[39] Recent estimates of the value of a life-year lie between $75000 and $150000 (Cutler and Richardson, 1998).

In this study we investigate whether claims data can shed light on the impact of new health care treatments by utilizing a sample of claims and eligibility data for more than 4 million individuals with one or more months of eligibility for California's Medicaid program during an eleven-year period from 1993 to 2003. This large sample size is especially important for our purposes given that AIDS is a relatively rare disease that currently afflicts just 0.14 percent of U.S. residents. We argue that given drug protocols, an econometric model must allow for heterogeneity in both take-up rates and effectiveness based on the initial health of patients. We show that by exploiting the longitudinal nature of the data it is possible to construct proxies for health status. We focus primarily on four drugs released in late 1995 and early 1996, as these are the ones that appear to have generated the largest improvements in health.

Our findings are in line with those from previous studies of the effect of these treatments that use randomized research designs or that have the benefit of more detailed clinical information. Specifically our results suggest that the treatments led to a seventy percent reduction in mortality rates among the individuals who took them. In contrast to these earlier studies, we can investigate the extent to which the use of the treatments in real-world settings varies across individuals and how the effects of the treatments do as well. Additionally, we can consider the effect on health care expenditures. For a variety of reasons – imperfect information, provider financial incentives, and the moral hazard effects of health insurance – current treatment patterns could substantially deviate from what is optimal. This possibility is not limited to HIV/AIDS treatments.

In recent years, a number of authors have developed econometric methods to estimate heterogeneity in the effect of education, job training, and welfare programs.[40] While few would expect any treatment to have uniform effects across all subjects, in many situations, there is often no definitive prediction about how the treatment effect should vary across these people. In the case we consider, the receipt of treatment and the benefits of treatment should both vary monotonically with patient severity, which is exactly what we find.

[40] For three recent examples see Heckman, Smith, and Clements (1997), Abadie, Angrist, and Imbens (2002), and Bitler, Gelbach, and Hoynes (forthcoming).

The methods utilized in this paper could also potentially be applied to evaluate the impact of other health care treatments. The need for this type of information is high already. From 2000 to 2004 Medicaid prescription drug spending almost doubled, increasing from $20.0 billion to $39.2 billion. Government involvement in this sector is set to increase even further as a result of the recently enacted Medicare Modernization Act. As of January of 2006, the federal government has begun to subsidize prescription drug coverage for many of the 45 million beneficiaries of the Medicare program, with the projected costs of this averaging $70 billion per year through 2015. The private insurance plans that provide this coverage will be allowed to consider cost-effectiveness when deciding which drugs to include on their lists of covered drugs, which is a first for the Medicare program.

Although random assignment clinical trials are considered the gold standard for determining the effect of health care treatments, not all questions can be analyzed through experiments because of cost considerations or other factors. For example, Raffi et al. (2001) notes that in the case of AIDS, ARVS have reduced the probability of death to such levels that samples sizes would have to be exceedingly large for mortality to be a clinical outcome in a drug trial of a new ARV. Likewise, because the variance of health care spending in a cross section of patients is typically very large, samples sizes would be prohibitively large to obtain precise estimates of the impact of treatment on this outcome.

Researchers must therefore increasingly rely on non-experimental econometric methods to evaluate the effects of new health care treatments. The methods utilized here suggest that one can use observational data from a real-world setting to estimate the effects of health care treatments on both expenditures and health outcomes, even without detailed clinical data. This is especially true if one has detailed information for the period both before and after the introduction of the new treatments. Analyses that provide reliable estimates of the effect of alternative treatments on health and on health care spending could be an important input to efforts to increase the efficiency of the U.S. health care system.

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Figure 1: HIV/AIDS Cases in the 24% Medicaid Sample and # Living with AIDS in CA

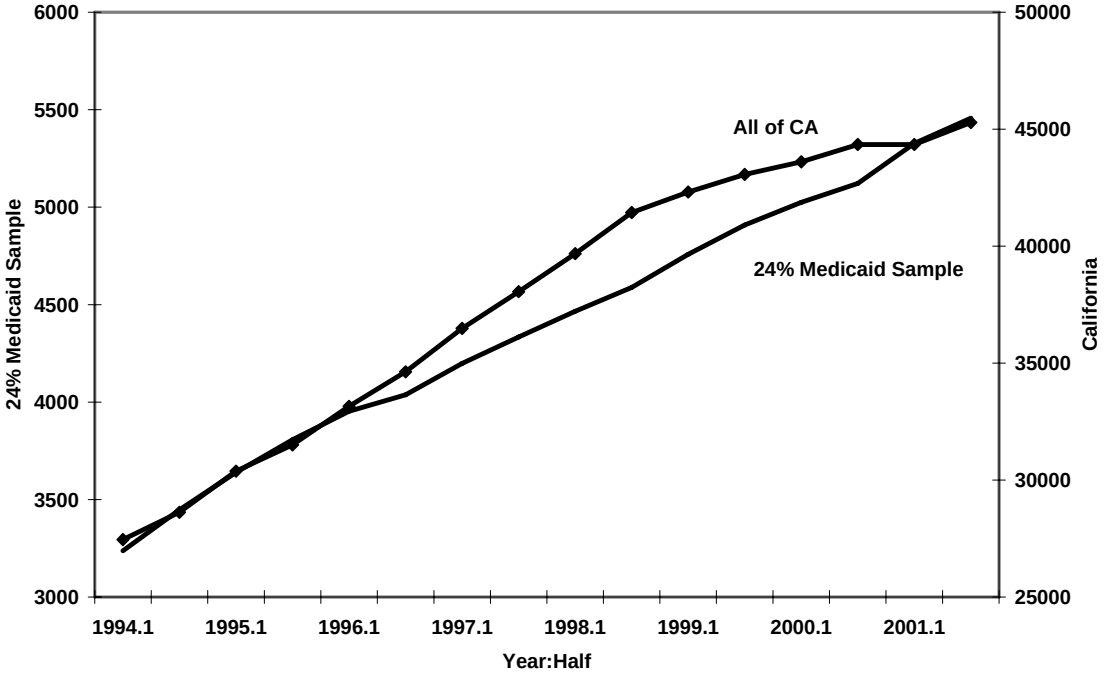

Figure 2: Half-Year Mortality Rate for AIDS Patients

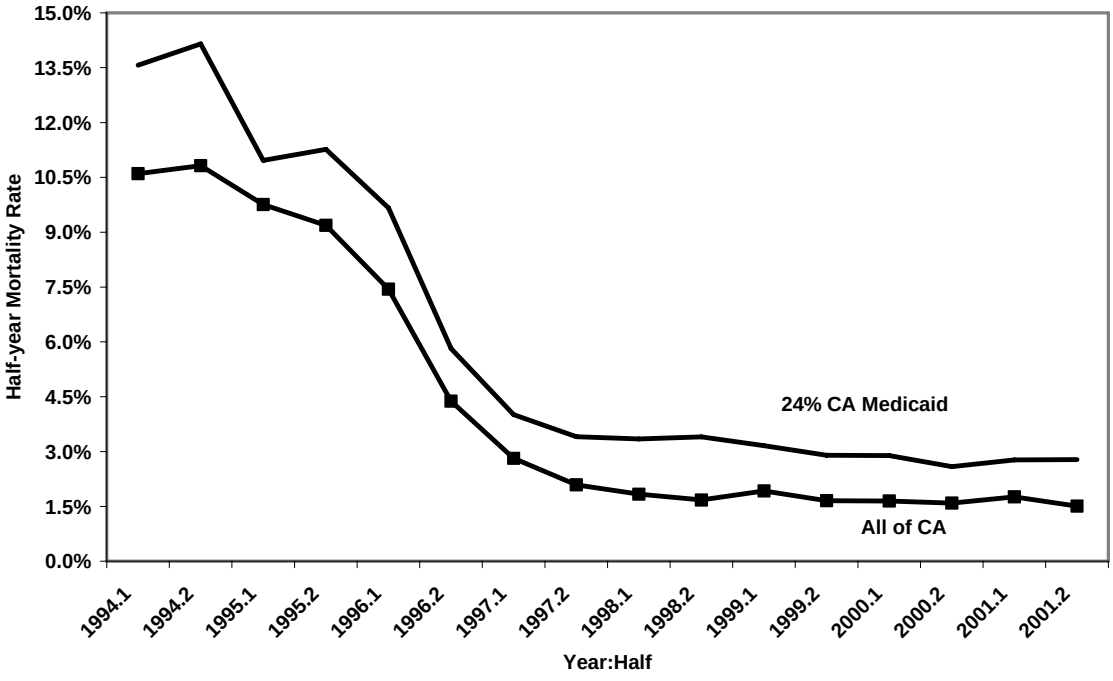

Figure 3: Fraction of CA Medicaid Sample Taking 1+ HIV Drugs in Each Quarter

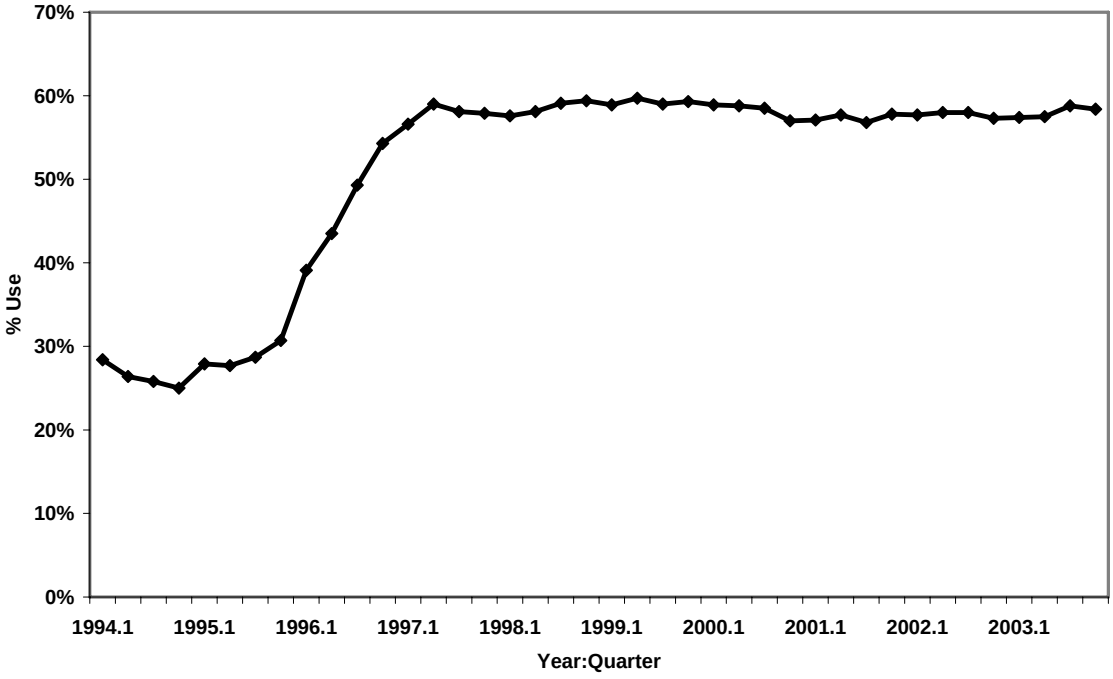

Figure 4: Diffusion of Epivir and Protease Inhibitors: 1994Q1 - 2003Q4

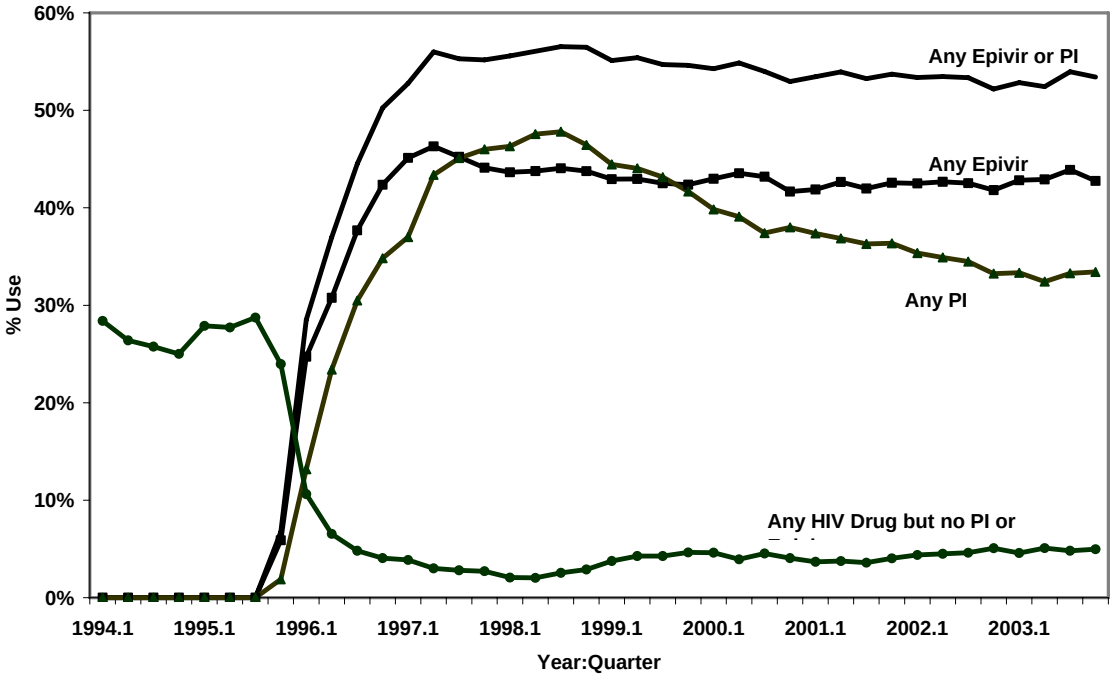

Figure 5: Quarterly Mortality Rate and Use of PI/Epivir

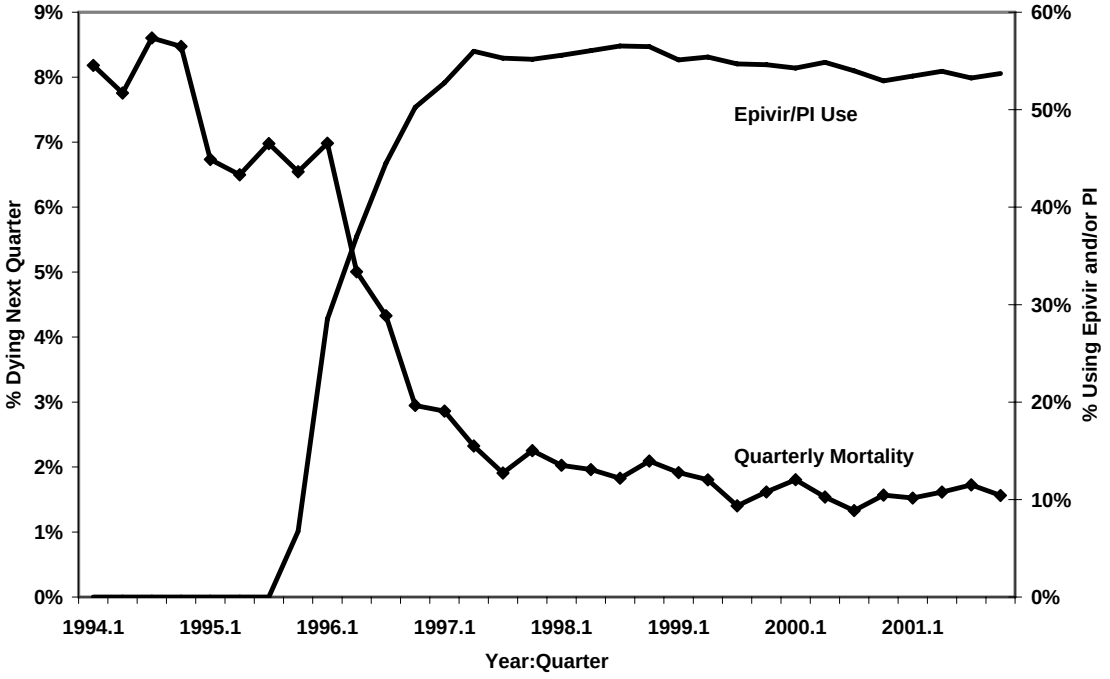

Figure 6: Average Quarterly Spending in the Medicaid HIV/AIDS Sample

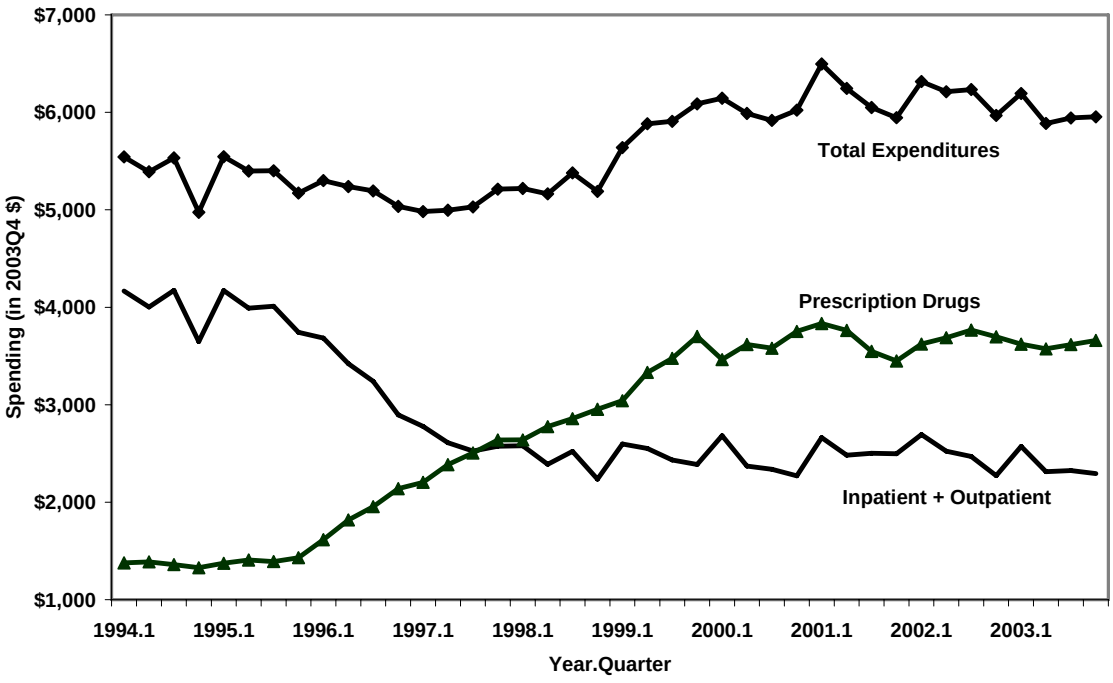

Figure 7: Use of PI and/or Epivir by Gender in the Medicaid HIV/AIDS Sample

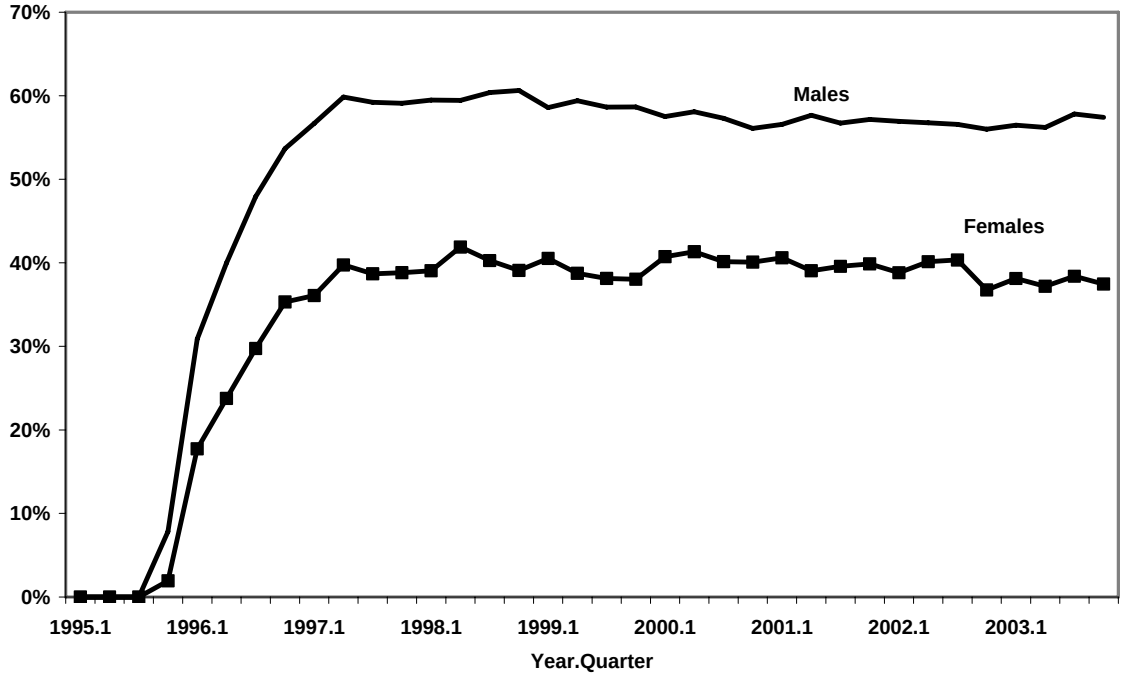

Figure 8: Half-Year Mortality Rates in the Medicaid HIV/AIDS Sample

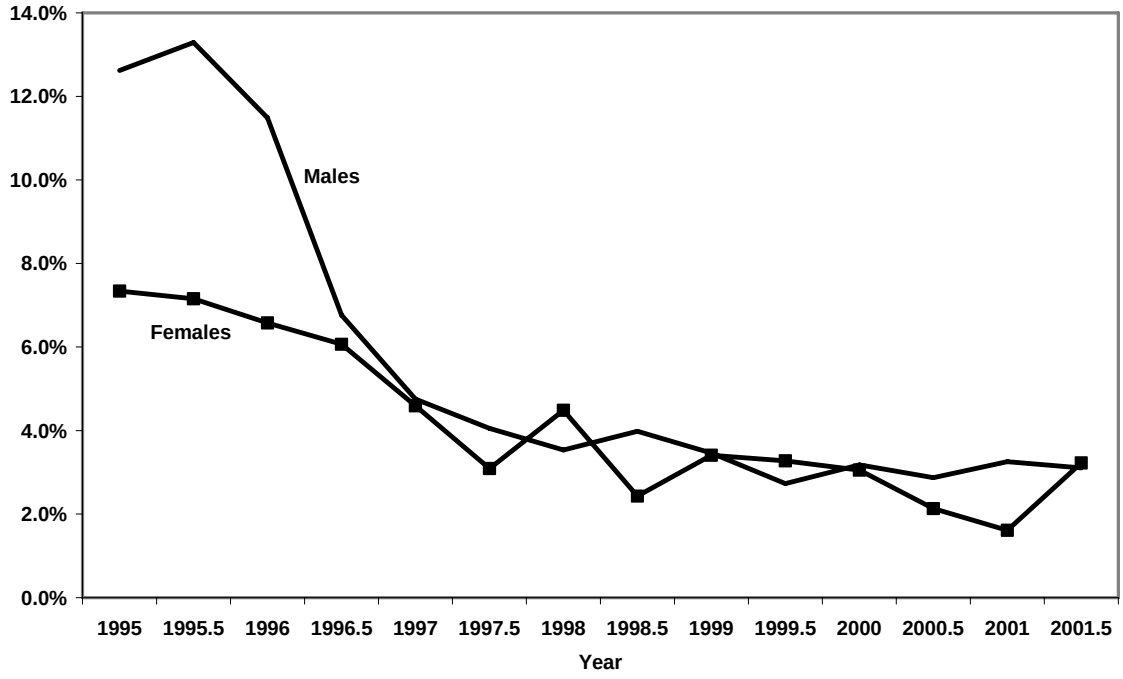

Table 1: Prescription Drugs Approved for Treatment of HIV Infection by 12/31/03

Class	Brand Name	FDA Appr. Date	First script in claims data	Ingredients
NRTI	Retrovir	3/19/1987	1/2/1993	zidovudine
NRTI	Videx	10/9/1991	1/4/1993	didanosine
NRTI	Hivid	6/19/1992	1/4/1993	zalcitabine
NRTI	Zerit	6/24/1994	8/6/1994	stavudine
NRTI	Epivir	11/17/1995	11/27/1995	lamivudine
NRTI	Combivir*	9/27/1997	10/17/1997	lamivudine, zidovudine
NRTI	Ziagen	12/17/1998	12/18/1998	abacavir
NRTI	Trizivir**	11/14/2000	12/1/2000	abacavir, zidovudine, lamivudine
NRTI	Viread	10/26/2001	11/1/2001	tenofovir disoproxil fumarate
NRTI	Emtriva	7/2/2003	7/16/2003	emtricitabine
PI	Invirase	12/6/1995	12/11/1995	saquinavir mesylate
PI	Norvir	3/1/1996	3/7/1996	ritonavir
PI	Crixivan	3/13/1996	3/26/1996	indinavir
PI	Viracept	3/14/1997	3/19/1997	nelfinavir mesylate
PI	Fortovase	11/7/1997	11/18/1997	saquinavir
PI	Agenerase	4/15/1999	4/26/1999	amprenavir
PI	Kaletra	9/15/2000	9/20/2000	lopinavir and ritonavir
PI	Lexiva	10/20/2003	11/11/2003	fosamprenavir calcium
NNRTI	Viramune	6/21/1996	8/10/1996	nevirapine
NNRTI	Rescriptor	4/4/1997	4/25/1997	delavirdine
NNRTI	Sustiva	9/17/1998	9/23/1998	efavirenz
FI	Fuzeon	3/13/2003	4/8/2003	enfuvirtide

Source for drug list and approval dates: US FDA at http://www.fda.gov/oashi/aids/virals.html
* Combivir is a combination of Epivir and Retrovir
** Trizivir is a combination of Epivir, Retrovir, and Ziagen

Table 2: Summary Statistics for the Medicaid HIV/AIDS Sample

	1994	1997	2000	2003
Average Age	38.4	40.7	43.0	45.1
% Ages 0-17	2.5%	2.6%	2.5%	2.2%
% Ages 18-29	12.0%	8.5%	4.4%	3.8%
% Ages 30-39	44.1%	38.7%	32.0%	21.9%
% Ages 40-49	29.3%	33.1%	37.7%	41.8%
% Ages 50-64	10.0%	13.4%	19.2%	25.3%
% Ages 65+	2.1%	3.8%	4.3%	4.9%
% Black	21.1%	23.4%	24.5%	25.0%
% Female	15.2%	21.3%	21.8%	22.3%
Inpatient Spending	7125	4309	3900	3510
Outpatient Spending	5091	4870	5007	5455
RX Spending	4122	7769	11913	12120
Total Spending	16338	16948	20820	21084
% Die in Year	23.0%	7.5%	5.2%	-
% Any Inpatient	47.8%	39.8%	30.0%	27.9%
Eligible Months	8.9	10.1	10.4	10.8
% Medicare	28.0%	39.2%	43.3%	44.7%
# in Sample	3221	3687	4275	4976

Includes Medicaid-eligible individuals in the 24 percent CA sample with 1 or more HIV/AIDS claims in current or previous year. Excludes those with one or more months in a Medicaid managed care plan or in one of the eight counties with a county-organized health system. Expenditures are inflation-adjusted to December 2001 dollars using the CPI for urban consumers.

Table 3: Determinants of Treatment Utilization Before and After the Entry of PI-Epivir

	Die Next Quarter?		Any HIV Drug?		Any PI or Epivir?		Any HIV Drug?	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
HIV Severity Percentile		.1600***		.2617***		.5704***		.6120***
		(.0108)		(.0243)		(.0206)		(.0215)
Female	-.0305***	-.0152**	-.0797***	-.0549***	-.1276***	-.0793***	-.1277***	-.0759***
	(.0065)	(.0065)	(.0188)	(.0182)	(.0183)	(.0164)	(.0200)	(.0177)
Black	-0.0005	0.0015	-.0283	-0.0249	-.1211***	-.1070***	-.0965***	-.0812***
	(.0069)	(.0067)	(.0176)	(.0172)	(.0168)	(.0153)	(.0183)	(.0166)
Age 15-24	-.0449***	-.0233**	-.0686*	-0.0332	-.2052***	-.1188***	-.2123***	-.1196***
	(.0111)	(.0115)	(.0414)	(.0394)	(.0414)	(.0397)	(.0465)	(.0427)
Age 25-34	-.0170***	-.0133**	-0.0052	0.0007	-.0322*	-0.0246	-.0363**	-.0280*
	(.0066)	(.0064)	(.0180)	(.0177)	(.0176)	(.0161)	(.0184)	(.0168)
Age 45-54	0.0109	0.0131	0.0201	0.0237	-0.0021	0.0027	-.0088	-0.0036
	(.0088)	(.0087)	(.0220)	(.0216)	(.0216)	(.0195)	(.0222)	(.0200)
Age 55-64	0.0125	0.0176	0.0615	.0697*	-.0757**	-.0439	-.0688*	-0.0346
	(.0151)	(.0145)	(.0399)	(.0382)	(.0340)	(.0292)	(.0368)	(.0306)
Age 65+	-.0196	0.0101	-.2456***	-.1969***	-.3071***	-.1876***	-.3618***	-.2336***
	(.0135)	(.0136)	(.0324)	(.0304)	(.0412)	(.0351)	(.0416)	(.0348)
Medicare	-.0151**	0.0010	.0698***	.0961***	.1140***	.1499***	.1055***	.1440***
	(.0064)	(.0063)	(.0177)	(.0174)	(.0163)	(.0147)	(.0168)	(.0151)
Quarters Included	95Q1-95Q3	95Q1-95Q3	95Q1-95Q3	95Q1-95Q3	96Q1-96Q4	96Q1-96Q4	96Q1-96Q4	96Q1-96Q4
# Observations	7259	7259	7259	7259	10523	10523	10523	10523
Quarter Effects?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
R-squared	0.0061	0.0398	0.0213	0.0471	0.0810	0.1865	0.0641	0.1823
Mean of Dep Var	0.064	0.064	0.293	0.293	0.414	0.414	0.476	0.476
# of Individuals	2951	2951	2951	2951	3280	3280	3280	3280

Sample includes all individuals with one or more HIV/AIDS claims in the quarter or in a previous quarter and who are eligible for Medicaid and still alive at the end of the quarter. Unit of observation is the person-quarter. All specifications are estimated as linear probability models and include quarter fixed effects. Standard errors are clustered by individual.

Table 4: The Heterogeneous Impact of PI-Epivir on Mortality

	(1)	(2)	(3)	(4)	(5)	(6)
Any PI or Epivir	-.0101***	-.0126***	-.0394***	-.0461***	.0102*	
	(.0035)	(.0036)	(.0039)	(.0039)	(.0061)	
HIV Severity Percentile			.1370***	.1026***	.1203***	.1185***
			(.0062)	(.0063)	(.0073)	(.0070)
Any PI or Ep * HIV Severity					-.0959***	-.0825***
					(.0120)	(.0068)
Female		-.0218***	-.0112***	-.0156***	-.0141***	-.0144***
		(.0035)	(.0034)	(.0034)	(.0034)	(.0034)
Black		0.0015	0.0024	0.0028	0.0029	0.0028
		(.0038)	(.0036)	(.0036)	(.0036)	(.0036)
Age 15-24		-.0453***	-.0299***	-.0274***	-.0267***	-.0269***
		(.0066)	(.0068)	(.0078)	(.0079)	(.0079)
Age 25-34		-.0189***	-.0186***	-.0165***	-.0169***	-.0168***
		(.0048)	(.0047)	(.0046)	(.0046)	(.0046)
Age 35-44		-.0075	-.0091**	-.0067	-.0070	-0.0070
		(.0047)	(.0046)	(.0045)	(.0045)	(.0045)
Age 55-64		-.0080	-0.0038	-0.0061	-0.0055	-0.0057
		(.0080)	(.0078)	(.0077)	(.0077)	(.0077)
Age 65+		-.0092	0.0120	0.0104	0.0140	0.0132
		(.0090)	(.0090)	(.0088)	(.0088)	(.0088)
Medicare		-.0095***	0.0028	-0.0035	-0.0043	-0.0040
		(.0034)	(.0033)	(.0033)	(.0033)	(.0033)
# Other RX Claims				.0020***	0.0020***	.0020***
				(.0002)	(.0002)	(.0002)
# Other Outpatient Claims				.0004***	.0004***	.0004***
				(.0001)	(.0001)	(.0001)
# Other Inpatient Claims				0.0008	0.0008	0.0008
				(.0008)	(.0008)	(.0008)
Quarters Included	95Q1-96Q4	95Q1-96Q4	95Q1-96Q4	95Q1-96Q4	95Q1-96Q4	95Q1-96Q4
# Observations	20235	20235	20235	20235	20235	20235
Quarter Effects?	Yes	Yes	Yes	Yes	Yes	Yes
R-squared	0.0060	0.0095	0.0393	0.0607	0.0630	0.0629
# Individuals	4152	4152	4152	4152	4152	4152

Sample includes all individuals with one or more HIV/AIDS claims in the quarter or in a previous quarter and who are eligible for Medicaid and still alive at the end of the quarter. Unit of observation is the person-quarter. All specifications are estimated as linear probability models and include quarter fixed effects. Standard errors are clustered by individual.

Table 5: The Heterogeneous Impact of PI-Epivir on Medicaid Expenditures

	All Patients			Dual Eligibles Excluded		
	All	RX Only	IP-OP Only	All	RX Only	IP-OP Only
	(1)	(2)	(3)	(4)	(5)	(6)
Any PI or Epivir	967***	1473***	-505*	381	1039***	-658
	(377)	(225)	(306)	(705)	(365)	(608)
HIV Severity Percentile	5224***	289*	4935***	5332***	451***	4881***
	(596)	(150)	(564)	(675)	(157)	(635)
Any PI or Ep * HIV Severity	-1287**	428	-1715***	-1770*	698	-2468***
	(635)	(350)	(525)	(1074)	(541)	(917)
Female	-676***	-432***	-244	-944***	-449	-495
	(234)	(74)	(222)	(289)	(65)	(281)
Black	124	-358***	483***	332	-398	730***
	(200)	(74)	(186)	(258)	(61)	(252)
Age 15-24	3205*	58	3147*	3718*	167	3551*
	(1899)	(148)	(1840)	(2041)	(175)	(1969)
Age 25-34	293	56	238	545*	133	412
	(230)	(109)	(206)	(309)	(116)	(289)
Age 35-44	242	26	216	484*	75	408
	(207)	(101)	(183)	(284)	(104)	(265)
Age 55-64	394	-325***	720	472	-218*	689
	(515)	(111)	(520)	(554)	(124)	(555)
Age 65+	234	-644***	410	2270	-300**	2569
	(345)	(116)	(325)	(2988)	(134)	(2991)
Medicare	-458	168	-626**			
	(324)	(119)	(302)			
Medicare * Percentile	-2544***	317	-2862***			
	(595)	(268)	(520)			
# Other RX Claims	148***	117***	31***	158***	110***	48***
	(11)	(7)	(9)	(18)	(9)	(15)
# Other Outpatient Claims	63***	2	61***	69***	2	67***
	(9)	(2)	(8)	(10)	(2)	(10)
# Other Inpatient Claims	315***	-24***	339***	279***	-20***	300***
	(75)	(8)	(80)	(71)	(7)	(76)
Quarters Included	95Q1-96Q4	95Q1-96Q4	95Q1-96Q4	95Q1-96Q4	95Q1-96Q4	95Q1-96Q4
# Observations	19448	19448	19448	12626	12626	12626
Quarter Effects?	Yes	Yes	Yes	Yes	Yes	Yes
R-squared	0.2157	0.3680	0.1480	0.1935	0.3587	0.1299
# Individuals	4048	4048	4048	3014	3014	3014

The dependent variable in columns 1 and 4 is equal to Medicaid spending in the next quarter. The other columns differentiate between spending on prescription drugs and all other services. Sample in specifications 1, 2, and 3 includes all individuals with one or more HIV/AIDS claims in the quarter or in a previous quarter and who are eligible for Medicaid and still alive at the end of the quarter. The last three specifications exclude individuals with one or more months of Medicare enrollment. Unit of observation is the person-quarter. All specifications include quarter fixed effects. Standard errors are clustered by individual. Expenditures are adjusted to December 2001 dollars using the CPI-U.

Table 6: Pre-Post Differences by Gender and Race in Utilization, Spending, and Mortality

	(1)	(2)	(3)	(4)	(5)	(6)
	Any HIV RX	Any PI-Epivir	Total Spending	RX Spending	IP+OP Spending	Die Next Qtr?
Female	-.099***	-.012***	-775**	-523***	-253	-.034***
	(.017)	(.004)	(359)	(117)	(299)	(.005)
Black	-.036**	-.010**	80	-422***	502*	0.004
	(.017)	(.004)	(320)	(102)	(286)	(.006)
Post	.302***	.624***	-78	938***	-1015***	-.049***
	(.013)	(.012)	(222)	(102)	(182)	(.005)
Female * Post	-.107***	-.213***	62	-498***	559	.032***
	(.024)	(.023)	(450)	(156)	(408)	(.008)
Black * Post	-.088***	-.150***	189	-353**	542	0.003
	(.025)	(.023)	(491)	(138)	(459)	(.009)
Constant	.317***	0.014***	4792	1473	3320	.071***
	(.009)	(.002)	(170)	(64)	(148)	(.003)
# Observations	20235	20235	20235	20235	20235	20235
# Individuals	4152	4152	4152	4152	4152	4152
R-squared	0.059	0.261	0.001	0.023	0.003	0.007
Quarters Included	95Q1-96Q4	95Q1-96Q4	95Q1-96Q4	95Q1-96Q4	95Q1-96Q4	95Q1-96Q4

Sample includes all individuals with one or more HIV/AIDS claims in the quarter or in a previous quarter and who are eligible for Medicaid and still alive at the end of the quarter. Unit of observation is the person-quarter. Specifications 1, 2, and 5 are estimated as linear probability models. All specifications include quarter fixed effects. Standard errors are clustered by individual. Expenditures are adjusted to December 2001 dollars using the CPI-U.