

EFFECTS OF MEDICARE PART D ON MEDICAID-MEDICARE DUAL ELIGIBLES WITH HIV

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ABSTRACT

Nadya Maria Belenky: Effects of Medicare Part D on Medicaid-Medicare Dual Eligibles with HIV
(Under the direction of Brian Pence)

The goal of this dissertation was to estimate the effects of Medicare Part D implementation on a range of outcomes in Medicaid-Medicare dual eligibles with HIV. Dual eligibles receive primary coverage from Medicare, while Medicaid provides wrap-around support, both financially and by covering services not included in Medicare coverage. When Medicare Part D was implemented in 2006, Medicaid-Medicare dual eligibles with HIV lost their prescription drug coverage through Medicaid and were auto-enrolled into a Medicare Part D prescription drug plan. Despite benefits to most Medicare enrollees, there were indications that, for dual eligibles, Medicare Part D was associated with mandated cost-sharing and other barriers to medication access. Using 2003-2008 data from the Women's Interagency HIV Study, we created a propensity score matched cohort and used a difference-in-differences approach to compare dual eligibles' outcomes pre- and post-Medicare Part D to those enrolled in Medicaid alone.

The transition to Medicare Part D was associated with a sharp increase in the proportion of dual eligibles with self-reported out-of-pocket prescription drug costs, followed by a more gradual increase in the proportion of dual eligibles using AIDS Drug Assistance Programs (ADAP). Even though Medicare Part D was associated with increased out-of-pocket spending, that increase did not appear to compromise antiretroviral therapy (ART) adherence or antidepressant use. Further, HIV viral load suppression, depressive symptoms, and hospitalization remained stable after Medicare Part D implementation. It is possible that co-occurring increased ADAP use mitigated the increase in out-of-pocket spending, pointing to successful coordination between Medicare Part D and ADAP as well as the vital role of ADAP during insurance transitions for this vulnerable population. These results may also signal that Medicare Part D's designation of ART and antidepressants as protected drug classes had its intended effect.

To Chipmunk and Gazelle, because who else?

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LIST OF ABBREVIATIONS

ACA	Affordable Care Act
ADAP	AIDS Drug Assistance Programs
ART	Antiretroviral Therapy
CMS	Centers for Medicare and Medicaid Services
DiD	Difference-in-Differences
HIV	Human Immunodeficiency Virus
LIS	Low-income Subsidy
MMA	Medicare Modernization Act
OOP	Out-of-Pocket
PDP	Prescription Drug Plan
RNA	Ribonucleic Acid
VL	Viral Load
WIHS	Women's Interagency HIV Study

CHAPTER 1. INTRODUCTION

Overview and Specific Aims

Medicare Part D was designed to improve medication access by reducing financial barriers for Medicare enrollees, many of whom did not have prescription drug coverage. A subset of Medicare enrollees receive a combination of Medicare and Medicaid benefits, and are referred to as “dual eligible.” The goal of this dissertation is to estimate the effects of Medicare Part D implementation on various outcomes in dual eligibles infected with the human immunodeficiency virus (HIV). The implementation of Medicare Part D, Medicare’s prescription drug benefit, may have affected how dual eligibles with HIV access antiretroviral therapy (ART) and other prescription drugs and, consequently, their medication use and health outcomes. Little is known about the effects of Medicare Part D on people with HIV, where the existing studies indicated disruptive effects of Medicare Part D in people with HIV. The rationale for the particularly disruptive effect in this population is based on the demographic and clinical characteristics of dual eligibles with HIV, their prior coverage through Medicaid, and unique rules for how Medicare Part D was applied to dual eligibles.

Medicare and Medicaid are crucial to accessing HIV care and treatment because these programs provide insurance coverage to 56% of adults with HIV in the United States.¹ Although the two programs have different eligibility criteria and distinct application processes, 10% of people with HIV simultaneously meet the eligibility requirements for both Medicaid and Medicare and are enrolled in both programs.² These individuals receive a combination of Medicaid and Medicare benefits and are referred to as “dual eligible.” For dual eligibles, Medicare provides primary coverage, with secondary coverage through Medicaid when Medicare benefits are exhausted.³ Crucially, Medicaid can also serve as the primary coverage source for services not covered by Medicare.^{4,5}

Before 2006, Medicare did not include a prescription drug benefit and dual eligibles received prescription drug coverage through Medicaid. On January 1, 2006, Medicare implemented Medicare Part D, its first prescription drug benefit. In an attempt to safeguard against coverage interruptions in

its most vulnerable population, the Centers for Medicare and Medicaid Services (CMS) auto-enrolled dual eligibles into Medicare Part D prescription drug plans, replacing their drug coverage through Medicaid.⁶ Despite special protections for the medically and financially disadvantaged, the transition to Medicare Part D exposed dual eligibles to changes in payment systems, plan instability, and variation in drug plan formularies and was associated with coverage gaps and treatment interruption in vulnerable populations.⁷ One early survey reported that 20% of dual eligibles had difficulties filling prescriptions after the transition.⁸ Cross-sectional research on a small number of people living with HIV who were covered by Medicare Part D showed an association between the transition and ART interruption.⁹ These initial findings are supported by reports from HIV providers that the majority of their patients had difficulties accessing their prescriptions drugs under Medicare Part D.¹⁰

Treatment interruption may be particularly problematic for dual eligibles with HIV because of complex medication regimens needed to manage both HIV and common co-morbidities such as depressive symptoms. Dual eligibles with HIV depend on consistent ART access to maintain viral load (VL) suppression and protect against HIV-related morbidity and mortality.¹¹ Depression, a common psychiatric comorbidity, has been associated with shortened survival time in individuals with HIV,¹² and untreated depression has been associated with decreased ART adherence and unsuppressed VL.¹³ Despite Medicare Part D's direct and ongoing impact on medication access,¹⁴ the effects of Medicare Part D implementation are not well understood in dual eligibles with HIV.

This study estimated the effects of the transition to Medicare Part D in dual eligible women with HIV. Data from the Women's Interagency HIV Study (WIHS) were used to estimate changes in out-of-pocket costs, medication access, ART and antidepressant medication use as well as related health outcomes and hospitalization associated with the transition to Medicare Part D.

Aim 1: Estimate the effect of the Medicare Part D transition on out-of-pocket prescription drug spending, AIDS Drug Assistance Programs (ADAP) use, ART adherence, and HIV VL suppression in dual eligibles with HIV.

Hypothesis: The transition to Medicare Part D would be associated with increased out-of-pocket (OOP) prescription drug spending, increased ADAP use, reduced ART adherence, and less HIV VL suppression among dual eligibles, after adjusting for temporal trends.

Rationale: The implementation of Medicare Part D in 2006 exposed dual eligibles to changing plan requirements, formulary variation, and loss of Medicaid prescription drug benefit protections. If coverage changes result in increased OOP costs and present barriers to optimal medication use, OOP spending for prescription drugs and ART nonadherence are expected to be greater after Medicare Part D implementation. Following changes in OOP spending, ADAP use is expected to increase to relieve the increased financial burden, and HIV VL suppression is expected to decrease, due to greater ART nonadherence.

Aim 2: Estimate the effect of Medicare Part D on antidepressant use, depressive symptoms, and hospitalization.

Hypothesis: Medicare Part D implementation would be associated with decreased antidepressant use, higher depressive symptom scores, and increased hospitalization.

Rationale: Medicare Part D implementation is expected to result in decreased antidepressant use after 2006. That shift is expected to lead to increased depressive symptoms and hospitalization, mediated through reduced antidepressant medication use.

Structure of Dissertation

This dissertation consists of two discrete papers, corresponding to the two specific aims. Chapter 2 presents the background, rationale, and policy implications of this study. Chapter 3 outlines the analytic methods common to both aims. Chapters 4 and 5 summarize Aims 1 and 2, respectively. Chapter 4 (Aim 1) presents results of Medicare Part D's effect on OOP prescription drug spending, ADAP use, ART adherence, and HIV VL suppression. Chapter 5 (Aim 2) examines Medicare Part D's effect on depression-related outcomes, including hospitalization. Chapter 6 discusses and interprets those results, concluding with policy implications and future research directions.

CHAPTER 2: BACKGROUND

This chapter begins with a review of HIV and HIV treatment and outlines common pathways through which people with HIV access prescription drugs as well as how prescription drug coverage affects people with HIV. It includes a section on the provisions and application of Medicare Part D and a literature review of relevant Medicare Part D studies. The chapter also reviews the characteristics of Medicaid prescription drug benefits prior to Medicare Part D implementation and the federal safety-net programs for prescription drug provision, the AIDS Drug Assistance Programs (ADAP). Finally, this chapter discusses this study's contribution to the literature and policy implications and ends with an overview of the following dissertation chapters.

HIV/AIDS

HIV damages the body's immune system, impeding an individual's ability to ward off infection. When the immune system is weakened, individuals become vulnerable to opportunistic infections, which cause HIV-related morbidity and mortality. Although HIV is incurable, treatment advances in ART have led to significant reductions in HIV-related illness and mortality.¹⁵ In addition to clinical benefits, consistent ART use has led to significant reductions in HIV transmission.¹⁵ Advances in the effectiveness of ART have resulted in a shift toward treating HIV as a chronic condition that can be managed with consistent and adequate access to treatment. These findings highlight the importance of consistent ART use (and access) for individuals living with HIV as well as for the HIV-uninfected population. These findings are also the foundation for the test-and-treat model, which posits that early identification of HIV infection followed by immediate initiation and consistent use of ART could lead to dramatic reductions in the incidence of HIV.¹⁶ Despite effective treatment, access remains a significant barrier for people living with HIV, and within the United States it is estimated that >80% of people with HIV have detectable VLs.^{17,18}

In addition to HIV treatment, people with HIV have a high prevalence of co-morbidities that can affect quality of life and HIV-related health outcomes. Depression is the most common psychiatric

comorbidity in people with HIV.¹⁹ Untreated depressive symptoms have been associated with reduced ART adherence,^{12,13,20} unsuppressed HIV VL,^{21,22} and shortened survival time.²³ By contrast, people with HIV who are treated for depression showed similar ART adherence and viral control as people with HIV who did not have depression,²⁴ underscoring the importance of consistent access to antidepressants in this population.

Pathways to Prescription Drug Access for People with HIV

For many people with HIV, health insurance provides coverage for prescription drugs that would be prohibitively expensive otherwise.²⁵ The majority of people with HIV in the United States rely on public insurance programs for medication access, with 56% receiving coverage through Medicaid or Medicare.¹ Medicaid is a state-administered program designed for certain categorically eligible low-income U.S. citizens. To qualify, individuals must meet financial eligibility criteria and be “categorically eligible” (e.g., have a documented disability).⁵ Separately, individuals become eligible for Medicare, a federally-administered program once they reach age 65 or, if under age 65, by having a permanent disability that qualifies them for Social Security Disability Insurance.³ People with HIV can be categorically eligible for Medicaid by having dependent children or receiving Supplemental Security Income because of documented disability. Among people with HIV who are enrolled in Medicaid or Medicare, 10% meet the eligibility requirements for both Medicaid and Medicare and receive joint coverage (these individuals are referred to as “dual eligibles”).²

AIDS Drug Assistance Programs

AIDS Drug Assistance Programs (ADAPs) function as a safety net for prescription drugs and are intended to improve medication access for low-income, uninsured, and underinsured people with HIV.²⁶ ADAPs are federally funded but administered at the state level, and ADAPs vary state-by-state in available ADAP funding and program scope. Although all ADAPs are federally funded through the Ryan White HIV/AIDS Program, some ADAPs receive additional state funds, further adding to state-by-state variation. Within states, ADAPs are able to determine the scope of the services provided, and states determine their own ADAP drug formularies and financial eligibility criteria. All ADAP formularies include ART but may also include medications to treat other co-morbidities, such as

cardiovascular disease, opportunistic infections, or psychiatric conditions. ADAP enrollment has been shown to affect ART use as well as the use of medications to treat common co-morbidities.²⁷

Effects of insurance and coverage characteristics

Even though health insurance facilitates access to health services by reducing financial barriers, leading to better health outcomes compared to those without coverage,^{28,29} it does not guarantee access. Coverage may be attached to prohibitive cost-sharing requirements, utilization management tools, or other characteristics that create barriers to health services.

Cost-sharing is the amount individuals pay for items or services covered by their health insurance (e.g., hospital stay, physician visit, or prescription drugs). A systematic review of cost-sharing literature indicated that for every 10% increase in cost-sharing there was a 2–6% decrease in prescription drug use.³⁰ In another systematic review on the relationship between other formulary restrictions and medication adherence, 68% of studies found that formulary restrictions were negatively associated with adherence.³¹ The majority of reviewed studies (60%) focused on cost-sharing compared to a small number of studies that focused on clinical outcomes (4%), highlighting the lack of research on the effects of formulary restrictions on health outcomes.^{32,33}

Medicaid-Medicare Dual Eligibility

Dual eligibles are unique among the publicly insured because they receive patchwork coverage through Medicaid and Medicare. Medicare provides primary coverage for dual eligibles, followed by secondary, wrap-around Medicaid coverage when Medicare benefits are exhausted.⁴ In practice, Medicare covers the majority of services for dual eligibles and Medicaid absorbs residual Medicare costs (e.g., insurance premiums). Crucially, Medicaid can also provide coverage for services that are not available through Medicare but still vital to people with HIV, such as long-term care and, before 2006, prescription drug coverage.⁵

Dual eligibles' prescription drug coverage has been a historical exception to Medicare's role as a primary coverage source. Before 2006, Medicare coverage did not include a prescription drug benefit and, consequently, dual eligibles received prescription drugs through their Medicaid benefits. On January 1, 2006, the Medicare Modernization Act introduced Medicare Part D, Medicare's first prescription drug benefit. In an attempt to safeguard against coverage interruptions in its most

vulnerable population, the CMS auto-enrolled dual eligibles into Medicare Part D prescription drug plans, replacing their drug coverage through Medicaid with randomly selected Part D drug plans known as “benchmark plans.”⁶ Even though Medicare Part D premiums were fully subsidized and cost-sharing was minimal for dual eligibles, the transition exposed them to changes in payment systems, formulary variation, and plan instability.³⁴ After initial random assignment to new prescription drug plans at Medicare Part D implementation, dual eligibles continue to be exposed to automatic, random re-assignment if their previous prescription drug plan does not continue to meet benchmark plan requirements.³⁵ Re-assignment can result in coverage disruption if the new prescription drug plan has substantially different coverage or requirements.

Dual eligibles are uniquely vulnerable to coverage disruptions because of their low income and are particularly susceptible to negative consequences of those disruptions because of their high prevalence of co-morbidities³⁶ and fragmented care.³⁷ As a combined consequence of their health and financial needs, dual eligibles make up a disproportionate share of both Medicaid and Medicare spending, and expenditures on dual eligibles are increasing. In 2003, there were four times more Medicare-only enrollees than dual eligible enrollees (30 million vs. 7 million), yet both groups had similar spending levels; \$148 billion for Medicare-only enrollees and \$138 for dual eligible enrollees.³⁸ In 2005, before Medicare Part D implementation, when Medicaid provided prescription drug coverage for dual eligibles, dual eligibles accounted for 46% of Medicaid spending (\$132 billion), even though they represent only 18% of Medicaid enrollees.

Dual eligibility and prior coverage

By definition, dual eligibles experienced a different transition to Medicare Part D compared to enrollees covered only by Medicare. Before Medicare Part D, 20–30% of Medicare enrollees did not have prescription drug coverage.^{39–41} Dual eligibles receive coverage from Medicaid and Medicare, and, as a consequence, had prior coverage through Medicaid before Medicare Part D implementation. Prior coverage through Medicaid is significant because:

- Even though Medicaid requires co-payments which can vary by state, all levels of Medicaid co-payments are lower than the minimum co-pay for Medicare Part D.

- Medicaid includes special protections that allow enrollees to obtain prescription drugs without co-pay if they are unable to afford the co-payment.
- The majority of studies on Medicare Part D focus on populations without prior coverage, the sub-population that stood to benefit most from improved medication access.

Medicare Part D

Medicare Part D was designed to increase medication use and decrease out-of-pocket costs for prescription drugs. These benefits were largely realized, and Part D was associated with improved access to medication, demonstrated by increased medication use and lower cost for Medicare enrollees over the age of 65.^{42–44} Before Medicare Part D, Medicare did not include a pharmacy benefit. While many Medicare enrollees obtained supplemental coverage, 20–30% of Medicare enrollees did not have any prescription drug coverage before Medicare Part D was implemented.^{39–41} Among the elderly (aged >65 years) without coverage, 50% spent \$1,200 or more on prescription drugs in 2003.⁴⁵ As the median income of individuals over the age of 65 was \$16,000 and prescription drug spending presented a substantial cost burden (~8% of annual income).⁴⁶ Of those who did not have prior coverage, 60–70% enrolled in a Medicare Part D plan⁴⁷ and, consequently, those without prior prescription drug coverage—i.e., those with the most unmet prescription needs—made up the majority of Medicare Part D enrollees. As a result, voluntary enrollment by Medicare enrollees without prior coverage may be a source of selection bias for studies of Medicare Part D implementation, where those that needed prescription drug coverage were more likely to enroll.

Medicare Modernization Act

The Medicare Modernization Act (MMA), the law that implemented Medicare Part D, was built on the assumption that competition among private plans would lower costs for enrollees and increase efficiency.⁴⁸ Part D is available to beneficiaries only through private, stand-alone prescription drug plans. Unlike traditional Medicare, these prescription drug plans follow general CMS guidelines for Part D plans but have the flexibility to determine the details of the plan's benefit (e.g., cost-sharing, utilization management).⁴⁹ As part of its “non-interference” provision, the MMA also prohibits the federal government from negotiating with pharmaceutical companies for lower prices using the purchasing power of Medicare enrollees.⁵⁰

Part D Prescription Drug Plans

Medicare Part D drug plans vary widely in how they structure their benefits, even within low-income subsidy plans. There are several dimensions on which a benefit can vary, including deductibles, premiums, co-pays, and utilization management tools. The most common utilization management tools include prior authorization, step therapy, and quantity limits, all of which are used to control drug use and costs. Since implementation, Part D plans have been shown to vary significantly in the types of utilization management tools and the frequency with which they are applied.⁴⁹ For a consumer to choose between prescription drug plans, they are required to weigh cost and benefit structures of prescription drug plans in combination with their anticipated health needs.

Formulary Guidelines

CMS designated six protected drug classes and required Part D formularies to cover “all or substantially all medications” within those drug classes. Drug classes were antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and ART. However, despite the mandated inclusion of protected drug classes in all formularies, Part D plans were not required to cover all formulations of medications and were allowed to make use of utilization management within the six protected drug classes.⁵¹

Low-Income Subsidy (LIS) Program

OOP costs often present a barrier to medication access, so the MMA created the Low-Income Subsidy (LIS) program to mitigate the effects of Medicare Part D’s mandated cost-sharing. The LIS, which is intended for low-income enrollees, reduces OOP costs associated with Part D by lowering or eliminating premiums, deductibles, copayments, coinsurance, and costs incurred during the coverage gap.⁵² All LIS plans that meet criteria set by Medicare and are referred to as “benchmark plans.”

Dual eligibles receive the LIS automatically, because their enrollment in Medicaid is taken as qualification for LIS need.⁵² As such, their OOP costs are lower than the average Medicare Part D enrollee. Enrollment in LIS means that dual eligibles do not pay a monthly premium, have a \$0 annual deductible, and are not subject to the Medicare Part D coverage gap (“donut hole”). Dual eligibles’

cost-sharing through Medicare Part D is restricted to co-payments for prescription drugs because of their LIS auto-enrollment.

Voluntary Enrollment for Non–Dual Eligibles

Enrollment in Medicare Part D is voluntary for Medicare-only beneficiaries. For Medicare-only beneficiaries, the initial Medicare Part D enrollment period, which took place between November 15, 2005, and May 15, 2006, was an opportunity to enroll in Part D plans where coverage would begin on January 1, 2006.⁵³ Even though each subsequent annual open enrollment period provided Medicare-only enrollees the opportunity to switch plans, only 13% elected to switch plans voluntarily between 2006 and 2010, despite potential cost savings.⁵⁴

Auto-Assignment for Dual Eligibles

There were several key differences between Medicare Part D enrollment for dual eligibles and Medicare-only enrollees. First, dual eligibles were auto-enrolled in Medicare Part D plans to minimize any disruptive effects of the transition. In other words, enrollment was involuntary. Dual eligibles were given a chance to select a prescription drug plan, much like Medicare-only enrollees, and if they did not select a plan, they were enrolled into a randomly selected benchmark plan. Second, all dual eligibles are enrolled in LIS prescription drug plans automatically, because they are already considered means-tested by Medicaid enrollment. Third, dual eligibles are able to switch plans at any point during the calendar year (i.e., there is no open enrollment period for this group).

Random Reassignment for Dual Eligibles

When Part D plans lose benchmark status, CMS reassigns dual eligibles enrolled in the former benchmark plan to a new plan at the beginning of the calendar year. Dual eligibles who are reassigned receive a letter in October containing the name and contact information for their new plan. Since implementation, reassignment rates have been rising, because the number of available prescription drug plans has been shrinking. Between 2007 and 2010, the number of benchmark prescription drug plans dropped from 640 to 307. In 2010, approximately 15% of dual eligibles were reassigned because their 2009 plan lost its benchmark status in 2010.³⁵ Although all plans must meet the same standards to be considered benchmark plans, there is formulary variation between plans. In 2007, the gap in average formulary size (the number of prescription drugs available through

formularies) between the benchmark and non-benchmark formularies was 4%. By 2010, the gap in average formulary size had increased to 7% between plans, which differentially affect dual eligibles.

Plan Selection

Medicare Part D drug plan selection is based on the idea that individuals pick prescription drug plan with characteristics that will maximize their benefits while minimizing OOP costs. In theory, a larger number of Part D plans should allow individuals to tailor their plan selection more closely to their health needs, thereby maximizing benefits while minimizing OOP costs. However, Part D enrollees have indicated difficulties choosing plans that minimize their OOP costs. In 2006, only 12% of Part D beneficiaries chose the least expensive plan. Further, the same study went on to show that Part D beneficiaries could have reduced their prescription drug spending by 31% if they had selected a plan that was more closely aligned with their medication use.⁵⁵ In addition to difficulties selecting plans at implementation, enrollees' ability to select optimal plans given their health needs has not improved since implementation. In 2009, only 5% of beneficiaries chose the least expensive plan and overspent a median \$331 on prescription drugs.⁵⁶

Despite sub-optimal plan selection over several years following Medicare Part D implementation, few enrollees switch plans. Among LIS beneficiaries, which all dual eligibles are, only 11% switch in a given year, even though this population is not restricted to the annual enrollment window that voluntary Medicare enrollees adhere to and may switch plans every month.⁴⁰ It is likely that few switch because of the complex plan characteristics and difficulties understanding the enrollment process.⁵⁷

Co-Functioning with ADAP

In addition to providing prescription drugs, ADAP can also be used to pay for premiums, co-payments, and deductibles for individuals participating in ADAP. In recent years, ADAP has also been used to purchase health insurance and the proportion of ADAP enrollees served through insurance coordination is increasing, growing 14% from 2011 to 2012.⁵⁸ Following Medicare Part D implementation, ADAP began picking up Medicare Part D cost-sharing expenses accrued by ADAP clients who were also Medicare enrollees. By May 15, 2006, ADAP was required to transition from paying for medication to paying for cost-sharing if the ADAP client was enrolled in Medicare Part D.⁵⁹

In the specific case of dual eligibles with HIV, ADAP's role is restricted to Part D copays because, by virtue of receiving LIS, dual eligibles do not pay Medicare Part D premiums and are not subject to the coverage gap.

Medication Part D and OOP Costs

The primary goal of Medicare Part D was to improve access to medication by lowering OOP costs. Previous research has shown a range of effect of Part D on OOP costs, where decreases in OOP costs range from 13% to 18%, or a reduction of \$143 to \$148 annually.^{42,44,60–62} These studies, however, do not take prior coverage into account. A 2010 study estimated the effects of OOP spending stratified by prior drug coverage (no coverage, Medicare HMO, Medigap, or employer-sponsored coverage) and found lower odds of OOP spending in all groups except for the employer-sponsored coverage.⁶³ Dual eligibles transition from robust prior coverage through Medicaid to Medicare Part D, making them more analogous to having employer-sponsored coverage. In the single study in people with HIV on OOP spending following Medicare Part D implementation, 50% of Medicare Part D enrollees reported greater expenditures for prescription drugs under Medicare Part D.⁶⁴

Medicare Part D and Medication Use

Cost-related nonadherence decreased from 14% to 12% between 2005 and 2006 in a representative sample of Medicare beneficiaries.⁶⁵ However, analyses of vulnerable sub-groups, including the non-elderly (disabled and/or <65 years of age) Medicare enrollees, showed no significant changes in cost-related nonadherence after Part D.⁶⁶ There was little change in a 2007 follow-up study of disabled Medicare enrollees with 0–2 morbidities, and the unadjusted prevalence of cost-related non-adherence remained high in 2006, at 19% compared to the 12% in the elderly population of the same morbidity level. Similarly, the proportion of disabled Medicare enrollees foregoing basic needs to pay for medications ranged from 14% to 23% in 2006, compared to the elderly population, which ranged from 4% to 7%.⁶⁶ Disabled Medicare enrollees who represent the majority of HIV-infected Medicare recipients, had high cost-related non-adherence and a substantial proportion were foregoing basic needs to pay for prescription drugs, even after Medicare Part D implementation.⁶⁶

Medicare Part D and Dual Eligibles

A systematic review of Medicare Part D implementation and its effects on medication use indicated that Medicare Part D was associated with increased medication use and decreased OOP costs in the general Medicare population, however its effects on dual eligibles and other vulnerable populations were mixed.⁶¹ This effect is underscored by survey findings from shortly after Medicare Part D implementation reporting that 20% of dual eligibles had experienced difficulties filing prescriptions after the transition to the new insurance program.⁸

Medicare Part D and HIV

Prior to Medicare Part D implementation, policy analysts predicted that the transition would lead to ART interruptions both in the short-term due to the disruptive effect of the initial transition and in the long-term due to increased consumer cost-sharing.³⁴ However, only two studies have examined the effects of Medicare Part D in people with HIV, and none examined clinical outcomes. A cross-sectional study on people with HIV who received coverage through Medicare Part D showed an association between Medicare Part D implementation and self-reported ART interruption, where the odds of ART interruption were six times higher among those covered by Medicare Part D. This study also reported that increased cost was the primary barrier associated with ART interruption.⁹ However, the sample size in this study was small; out of 125 homeless and marginally housed individuals, results are based on 10 patients who reported Medicare Part D coverage. Self-reported difficulties accessing medication in people with HIV were echoed in a second study, where reports by HIV providers indicated that the majority of their patients experienced difficulties accessing their prescription drugs under Medicare Part D.¹⁰

Medicare Part D and Psychotropic Medication Use

Psychotropic drugs may be particularly affected by Medicare Part D for several reasons. First, although CMS protections apply to psychotropic drugs, requiring all plans to cover “most or all” drugs within that drug class, a study by Huskamp et al. indicated that even though prescription drugs within protected drug classes are generally covered, many product formulations of those prescription drugs are often not covered by the low-income plans that dual eligibles are enrolled into.⁵¹ Second, utilization management requirements for psychotropic drugs have increased since 2006, posing

potential access barriers specific to psychotropic drugs.⁶⁷ In addition to studies documenting formulary restrictions for psychotropic medication, a study of dual eligible psychiatric patients revealed that 27.6% had to switch medications due to formulary restrictions in the first year following the transition from Medicaid to Medicare Part D.⁶⁸ In a study restricted to dual eligible beneficiaries with mental illness, 44% of patients experienced problems accessing medication. As a result of drugs not being covered or approved, 19% switched to different medications and 22% indicated that they had difficulty accessing medication because of copayments.⁶⁹

Literature Gap

Despite research suggesting that Medicare Part D affects dual eligibles differently than Medicare-only enrollees, there is limited evidence on the effects of Medicare Part D on dual eligibles with HIV. In the two studies on Medicare Part D and people with HIV, even though the majority of individuals studied were likely to have been dual eligible, the studies focused on people with HIV who are enrolled in Medicare, which included both dual eligibles and Medicare-only enrollees. Further, there are no studies that examine the effect of Medicare Part D on clinical outcomes in either Medicare-only enrollees with HIV or in dual eligibles with HIV.

This study is the first to estimate the effects of Medicare Part D on OOP costs, use of ADAP, and depression- and HIV-related outcomes in dual eligibles with HIV. We used six years of data from a long-term prospective cohort study—the Women’s Interagency HIV Study (WIHS), which is designed to study the natural and treated course of HIV infection in women. Advantages of these data include a dual eligible population observed at interval-based study visits, data that are independent of pharmacy use or care engagement, a control group for temporal trends, and availability laboratory measures of HIV VL.

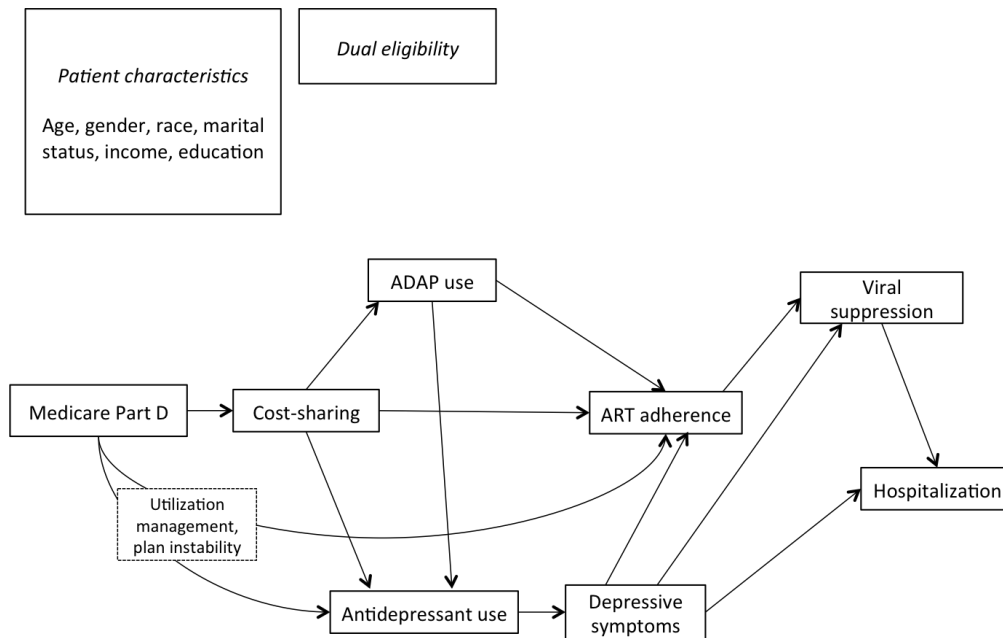


Figure 1. Conceptual model.

Conceptual Model

The conceptual model (Figure 1) of this study hinges on two components: 1) the direct, immediate, and continuous effect of Medicare Part D on medication use and 2) dual eligibles' vulnerability to medication disruptions or changes (Figure 2). Dual eligibles lost their Medicaid prescription drug coverage benefits as a result of Medicare Part D implementation and were enrolled, often at random, into Medicare Part D prescription drug plans. The transition from Medicaid's prescription drug benefit to Medicare Part D exposed dual eligibles to variability in formularies, cost-sharing, and utilization management tools.

Once dual eligibles transitioned to Medicare Part D, annual benchmark plan requirements exposed them to plan instability because many prescription drug plans did not meet the benchmark requirements from year to year. Dual eligibles enrolled in benchmark plans that do not meet the Medicare Part D requirements the following year are then randomly re-assigned to new plans that do meet benchmark standards. As a consequence, dual eligibles can be auto-enrolled into plans with different formularies and restrictions each year. In addition to the potential effects of formulary variation and plan instability, characteristics of dual eligibles with HIV, such as having multiple co-

morbid conditions and reduced ability to pay for prescription drugs, have the potential to exacerbate the effects of Medicare Part D.

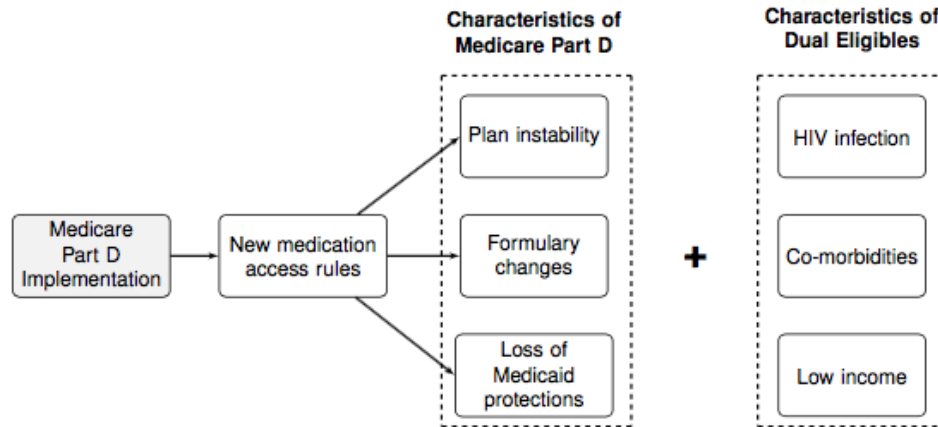


Figure 2. Characteristics of Medicare Part D and dual eligibility.

The goal of Medicare Part D was to improve access to medication for Medicare enrollees by reducing costs. Medicare Part D had beneficial effects for Medicare enrollees, improving medication use and reducing OOP costs. However, prior research indicates that vulnerable subgroups of Medicare enrollees, including dual eligibles, experienced fewer of Medicare Part D's benefits and, in some studies, dual eligibles reported difficulties accessing medications due to increased costs and restrictive formularies or access rules. Although cost-sharing is low under Medicare Part D, even small increases in cost-sharing have been shown to shift medication use, and the extremely low income of the WIHS population of HIV-infected dual eligibles may make them more vulnerable to even small increases in OOP costs.

In addition to its potential effects on medication use, increased cost-sharing may result in a greater proportion of dual eligibles using ADAP to reduce OOP costs. People with HIV use ADAP to access ART but can also use the program to access medication for common comorbidities. Even though all ADAP cover ART, ADAPs are not required to cover psychiatric medication such as antidepressants. However, states with WIHS sites of this study (CA, DC, IL, NY) all included antidepressants in their ADAP formularies during the years in this study (2003–2008). Consequently,

ADAP use may have mitigated effects of Medicare Part D on both ART adherence and antidepressant use in this population. The relationship between ART and viral suppression is well-established, as is the relationship between antidepressant use and depressive symptoms. And finally, both depressive symptoms and unsuppressed HIV VLs have been associated with hospitalization.

Contribution of this Study

This study is the first to quantify the effects of Medicare Part D implementation on dual eligibles with HIV, an understudied and costly population whose medical and financial vulnerabilities and potential for shifting HIV transmission have made them a national priority through the Affordable Care Act (ACA). Examining dual eligibles with HIV has significance because their low income, co-morbidities,³⁶ and fragmented care³⁷ make this population uniquely vulnerable to medication disruptions. Consequently, even though dual eligibles with HIV represent a small proportion of total enrollment in Medicare Part D, they remain a subgroup with strong policy implications.⁷⁰

Prescription drug plan instability and variation are potentially significant drivers of Medicare Part D's effects. Dual eligibles face Medicare Part D plan instability because available plans change annually³⁵ and can result in random re-assignment if the originally assigned plan is no longer available. The interest in strategies to mitigate coverage volatility is driven by CMS and underscored by the ACA.⁷¹ Research on the effects of Medicare Part D implementation over time can provide evidence that shapes those strategies.

Possible ART disruption associated with Medicare Part D has the potential to affect the HIV-negative population, in addition to its direct effects on medication access for dual eligibles with HIV. Estimating the effects of Medicare Part D implementation on outcomes in people with HIV has significance for reducing HIV transmission on a population level. Consistent treatment for both HIV and depressive symptoms have strong implications for reducing HIV transmission at the population level and are the cornerstone of the test-and-treat model.¹⁸

Policy Implications

For the majority of people with HIV, Medicaid and Medicare coverage are essential for consistent medication access. Changes in benefits, such as the transition from Medicaid's prescription drug coverage to Medicare Part D, have the potential to affect medication access and

out-of-pocket costs, and, consequently, medication adherence, health outcomes, and service use. Optimal ART use has been associated with less virologic failure, fewer hospitalizations, and life expectancies that are comparable to those of HIV-negative individuals. In addition to individual-level impact, early and consistent ART reduces HIV transmission to uninfected partners through sexual behavior or drug use, resulting in lower HIV incidence.

In addition to medication use and health outcomes, this study also examines the effect of Medicare Part D on OOP prescription drug spending and ADAP use. In 2012, the national ADAP budget grew to \$2.03 billion annually,⁵⁸ up 8% from the previous year. Because Medicare Part D and ADAP are both designed to improve access to prescription drugs, understanding whether and how Medicare Part D affects ADAP use can contribute to strategies for maximizing the cost-effectiveness of both programs.

Finally, consistent medication access for dual eligibles requires the successful coordination of both coverage sources, Medicare and Medicaid. The ACA prioritizes improved care coordination for dual eligibles in general⁷⁴ and for dual eligibles with HIV in particular. The ACA emphasizes care coordination for dual eligibles through ACA provisions and has created the Federal Coordinated Health Care Office, which is dedicated to translating research on dual eligibles into evidence-based policy.⁷⁵ This study provides estimates of how dual eligibles responded to the initial transition to Medicare Part D in 2006, which represents a similar transition to the one that people with HIV undergo when they enroll in Medicare Part D currently. This study also provides estimates of medication use, health outcomes, and service use for this vulnerable and costly population in the time period after Medicare Part D implementation in 2006 leading up to ACA implementation in 2014.

CHAPTER 3: METHODS

This study examined the effects of Medicare Part D implementation on OOP prescription drug spending, health outcomes, medication use, and hospitalization among dual eligibles with HIV. The proposed study used data from semiannual WIHS visits between 2003 and 2008. All outcomes of interest were examined by comparing the time periods before and after the transition to Medicare Part D. Dual eligibles' automatic and immediate exposure to Medicare Part D after auto-enrollment on January 1, 2006, was a natural experiment and made this a quasi-experimental study. A difference-in-differences approach (DiD) was used to estimate the average effect of Medicare Part D in dual eligibles with HIV while accounting for temporal trends using a matched control group of Medicaid-only enrollees.

To estimate a valid average effect, the DiD approach must satisfy the common trend assumption, meaning that the comparison group must follow a parallel pre-treatment trend as dual eligibles, the analytic group of interest. Our analyses expanded on conventional DiD analysis by matching dual eligibles with a Medicaid-only comparison group using a propensity score matching approach. Under the assumption that the matching captures all relevant differences between the two groups, this matched control group represented the counterfactual outcomes of dual eligibles, i.e., dual eligibles had they not transitioned to Medicare Part D.

Quasi-Experimental Study Design

A quasi-experimental study is defined as a study where treatment randomization is impossible or unfeasible, yet retains similarities with a randomized experiment.⁷⁶ This study mimics a randomized experiment in that temporal order is clearly established and, within dual eligibles, individual characteristics are unlikely to affect the exposure to Medicare Part D. Within quasi-experimental studies, causality is strengthened when alternative causal explanations for the estimated association are implausible. In randomized experiments, alternative causal explanations are made implausible by treatment randomization and the consequent balanced distribution of

covariates. In quasi-experimental studies, alternative causal explanations must be ruled out by minimizing 1) confounding and 2) threats to validity.

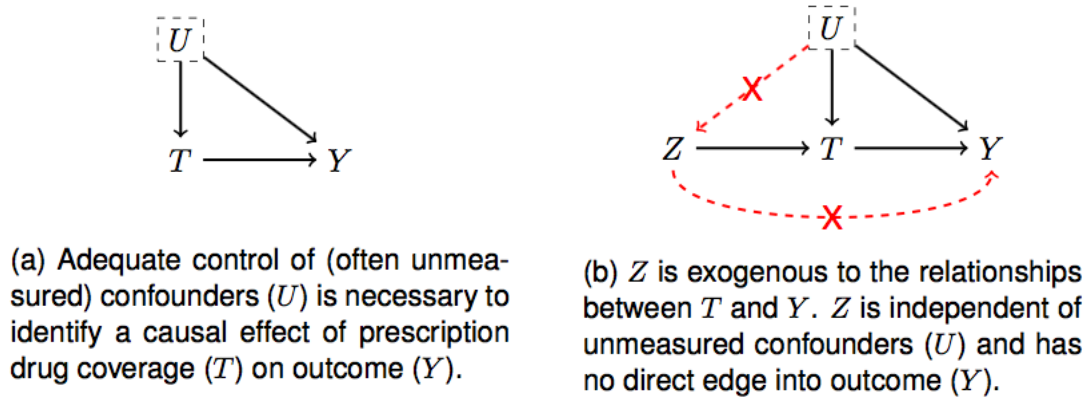


Figure 3. Directed acyclic graph of exogeneity of Medicare Part D implementation (Z) and the effect on medication use (T) and outcome (Y).

Figure 3 illustrates a common limitation of studies on insurance coverage. The estimation of the causal effect of prescription drug coverage (T) on an outcome (Y) requires adequate measurement and control of confounding by individual characteristics (U). Because those confounding factors are often unobserved, adequate statistical control can be difficult and analyses can result in biased estimates (Figure 3a). By contrast, the use of an exogenous policy implementation (Z), such as Medicare Part D implementation, that determines prescription drug coverage (T) but is unaffected by individual characteristics (U) and has no direct effect on the outcomes of interest (Y) limits alternative causal explanations for an observed effect (Figure 3b).⁷⁶

Individual characteristics of dual eligibles are unlikely to influence prescription drug coverage because dual eligibles are auto-enrolled in Medicare Part D. Auto-enrollment strengthens the assumption that the exposure to Medicare Part D is exogenous (Figure 3) and limits the potential for common-cause confounding of Medicare Part D implementation and the outcomes of interest. The primary threat to validity is the possibility of an event unrelated to Medicare Part D temporally coinciding with Medicare Part D implementation and affecting outcomes of dual eligibles. If that were the case, any effect detected within dual eligibles could be misattributed to Medicare Part D despite

being caused by an unrelated event. The DiD approach attempts to adjust for temporal trends by inclusion of a control group, detailed in the section on propensity score matching.

Data Source and Study Population

The primary goal of the proposed study is to estimate the effects of Medicare Part D implementation on Medicaid-Medicare dual eligibles in the WIHS. The WIHS is an ongoing observational study that recruited HIV-positive and HIV-negative women from six original sites in the United States: Washington, DC; the Bronx, NY; Chicago, IL; Los Angeles, CA; and San Francisco, CA. Since enrollment began in 1994, WIHS data have been used to study HIV disease progression. Study visits are conducted every six months and collect data from scripted interviews (self-reported) as well as clinical examination, laboratory measurements, and surveillance (e.g., cancer registries, National Death Registry). At each WIHS visit, the WIHS collects information on medical history, ART and other prescription medications, drug use, sexual behavior, health care use, and depressive symptoms.

The WIHS has enrolled participants in four waves: 1994-1995, 2001-2002, 2011-2012, and 2013-2014. A comparison of the first two enrollment waves showed that participants did not differ by ethnicity, income, or education. Changes in recruitment strategy resulted in differences by age and HIV disease stage between participants enrolled in the 1994-1995 and the 2001-2002 enrollment waves, where participants recruited in 2001-2002 had less advanced HIV disease and were younger than the women recruited in 1994-1995. Only participants enrolled in the first two waves (1994-1995, 2001-2002) were used in the proposed study because only those participants could have been transitioned to Medicare Part D in 2006. This study included available measures from all semi-annual WIHS visits between 2003 and 2008.

Inclusion and Exclusion Criteria

Of the 3,398 HIV-infected women who were enrolled in the WIHS by fall 2014, we restricted the time frame of our analysis to 2003–2008 and excluded women who had missed three consecutive visits between 2003 and 2008. Of the 1,807 women remaining, we further restricted the study to participants who were dual eligible or Medicaid-only in 2005 (n=801), before Medicare Part D implementation.

Measures

Data Collection

All WIHS participants complete a structured, in-person interview every six months, either in English or in Spanish. At each study visit, interview data collected include sociodemographic characteristics, medical and health history, obstetric and gynecologic history, sexual and drug use behaviors, use of healthcare services, and psychological factors. All study visits also include a physical and gynecologic examination, medical record abstraction, and collection of laboratory specimens. For HIV-infected women, laboratory specimen collection includes quantification of HIV VL levels and CD4 cell count.

Exposure Definition and Assessment

This study's exposure of interest was the transition from Medicaid's prescription drug coverage to Medicare Part D. Time period was used to assign dual eligibles' exposure to the Medicare Part D transition. A binary variable was created to indicate the pre- and post-Medicare Part D time periods (2003–2005 and 2006–2008, respectively). For dual eligibles, 2003–2005 represents prescription drug coverage under Medicaid and 2006–2008 represents prescription drug coverage under Medicare Part D. Dual eligibles are considered unexposed in the pre-Medicare Part D time period and exposed during the post-Medicare Part D time period. The Medicaid-only comparison group was considered unexposed for both time periods because these women only received prescription drug coverage through Medicaid during both time periods (**Error! Reference source not found.**).

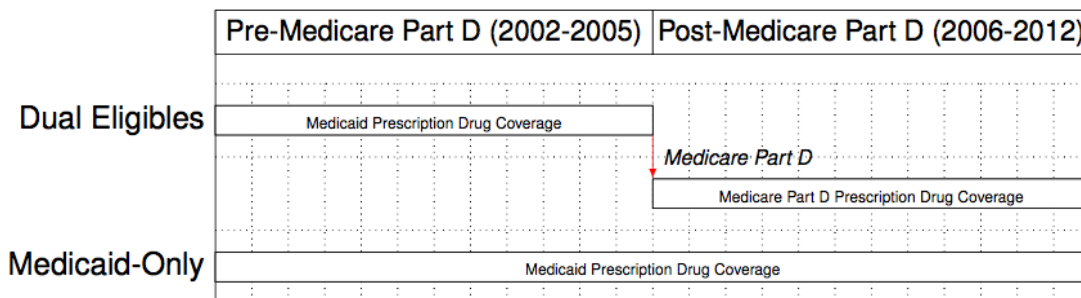


Figure 4. Dual eligibles and comparison group insurance coverage over time.

Outcome Overview

For these analyses, we estimated the effects of Medicare Part D implementation on two broad outcome categories: 1) HIV-related and 2) depression-related (Table 1). Within HIV-related outcomes (Aim 1), we estimated changes in OOP prescription drug spending, ADAP use, ART adherence, and viral suppression. In Aim 2, we estimated depression-related outcomes, including antidepressant use, depressive symptoms, and hospitalization. Details on outcome coding and effects estimated are included in Table 1.

Table 1. Outcome Definitions and Effect Estimates, by Aim

Aim	Outcome	Type	Estimated Treatment Effect	Coding
Aim 1: Cost and HIV-Related Outcomes	OOP prescription drug spending	Binary	Difference in proportion with any OOP spending on prescription drugs	Since last visit: 1: Any OOP spending 0: No OOP spending
	ART adherence*	Binary	Difference in proportion w/ 100% ART adherence	Since last visit: 1: <100% adherent 0: 100% adherent
	ADAP use	Binary	Difference in proportion using ADAP	Since last visit: 1: ADAP use 0: No ADAP use
	Viral suppression	Binary	Difference in proportion who were virally suppressed	At current visit: 1: VL \geq 200 copies/mL 0: VL <200 copies/mL
Aim 2: Depression-Related Outcomes	Antidepressant use	Binary	Difference in proportion using antidepressants	At current visit: 1: any antidepressant use 0: no antidepressant use
	Depressive symptoms	Binary	Difference in proportion with severe depressive symptoms	At current visit: 1: CES-D score \geq 16 0: CES-D score <16
	Hospitalization	Binary	Difference in proportion hospitalized	Since last visit: 1: any hospitalization 0: no hospitalization

* restricted to the subset of participants who were on ART

Statistical Power

Power analyses were conducted to determine the minimum detectable difference in proportion for the primary outcomes of both aims, given the available sample size of dual eligibles in the WIHS and an 80% power threshold. To demonstrate adequate power for the pre-post comparison of the primary outcome for Aim 1, ART adherence, the calculation assume a pooled standard deviation of 25–29%.⁷⁷ For a pre-post comparison of mean adherence in dual eligibles, our power analyses indicated that a simpler, pre-post comparison showed 80% power to detect a 5% change in

mean adherence. Similarly, we estimated that Aim 2 was powered at 80% to detect a 10% change in the proportion of dual eligibles who had an undetectable VL. For both aims, power was calculated specifying a two-sided Type I error probability (α) of 0.05 and included a design effect to the reweighted number of dual eligibles to account for clustering. The design effect was calculated using the number of dual eligibles in the analytic sample.

Statistical Analyses

Visualizing non-parametric trends (Lowess plots)

Before propensity score matching, we plotted outcome variables for visits from 2003 to 2008 using a segmented locally weighted smoothed spline (Lowess)⁷⁸ to visualize trends for dual eligibles and Medicaid-only participants. The plots were segmented at Medicare Part D implementation on January 1, 2006, to visualize any discontinuities associated with the transition. Non-parametric methods have the advantage that they do not require assumptions about the relationship between variables.

Propensity score matching

Observational studies often examine relationships between exposure and outcome that are both associated with or confounded by participant characteristics. Propensity scores are a tool to balance groups on measured covariates and improve the validity of the control group as a counterfactual for the analytic group of interest. In this study, we estimated the effect of Medicare Part D in the dual eligibles rather than the average effect in the full study sample. Consequently, we matched the two groups to set the distribution of covariates in the Medicaid-only participants equal to the distribution in the dual eligibles. This matching approach sets the Medicaid-only enrollees to represent the dual eligibles by aligning the pre-Medicare Part D characteristics of the Medicaid-only group with those of the dual eligibles.

In creating the propensity score, we evaluated covariates by considering the effect that their inclusion had on standardized differences between the two groups following the match. To exclude covariates that could have been affected by Medicare Part D implementation, we restricted our set of covariates to pre-Medicare Part D values. A second consideration was the number of covariates that could be included in a propensity score model. Because the number of dual eligibles in our sample

was small, we were unable to include all possible covariates and were limited to a set of 10 to 15. We created separate sets of propensity scores for the two aims because we were trying to balance the two groups on slightly different characteristics.

After calculating a propensity score for each observation, we conducted balance diagnostics to evaluate whether the propensity score model had been adequately specified. We confirmed that the range of propensity scores between dual eligibles and Medicaid-only enrollees had sufficient overlap (“common support”). Propensity scores must overlap sufficiently between groups because no causal contrast can be made for individuals who do not have a counterfactual within the other group. Common support was assessed by examining the distribution of propensity scores by group for both aims.

We also examined the standardized differences in covariates before and after matching. Standardized differences represent a comparison of the covariate means in units of the pooled standard deviation. Standardized differences provide a way to compare the matched and unmatched means of baseline covariates between dual eligibles and Medicaid-only participants. In addition to standardized differences, we also compared the distributions of baseline covariates within strata of propensity scores. If propensity score models are specified correctly, baseline covariates should be evenly distributed within strata of propensity scores.

After confirming adequate balance, we used the propensity scores to match dual eligibles to Medicaid-only participants, using a 1:1 matching without replacement. In matching without replacement, after a Medicaid-only participant was matched to a dual eligible, that Medicaid-only participant was no longer available to be matched to another dual eligible. Each dual eligible whose propensity score was within the range of common support was matched with a Medicaid-only participant, such that the matched pair had similar propensity score values. Pairs were matched to minimize the within-pair difference in propensity scores. After creating the matched sample, the effects of Medicare Part D on outcomes could be estimated by comparing the two groups.

Difference-in-Differences

The principle behind DiD can be represented in a 2x2 table (Table 2, adapted from Stuart et al.⁷⁹), where the DiD estimate is the change in average outcome \bar{y} over time and between groups (Δ).

Intuitively, the change over time in the dual eligibles ($\bar{y}_{1,post} - \bar{y}_{1,pre}$) can be thought of as a combination of the change in \bar{y} due to Medicare Part D implementation, the exposure of interest, and also any secular time trends, which we would like to remove. The change over time in the Medicaid-only comparison group represents those secular trends and by removing that group's change over time, we are able to isolate the effects of Medicare Part D on outcomes in dual eligibles.

Table 2 Difference-in-Differences Design

	Dual eligibles	Medicaid-only (comparison group)	Difference (between groups)
Pre-Part D	$\bar{y}_{1,pre}$	$\bar{y}_{0,pre}$	$\bar{y}_{1,pre} - \bar{y}_{0,pre}$
Post-Part D	$\bar{y}_{1,post}$	$\bar{y}_{0,post}$	$\bar{y}_{1,post} - \bar{y}_{0,post}$
Change (over time)	$\bar{y}_{1,post} - \bar{y}_{1,pre}$	$\bar{y}_{0,post} - \bar{y}_{0,pre}$	$\Delta = (\bar{y}_{1,post} - \bar{y}_{1,pre}) - (\bar{y}_{0,post} - \bar{y}_{0,pre})$ $= (\bar{y}_{1,pre} - \bar{y}_{0,pre}) - (\bar{y}_{1,post} - \bar{y}_{0,post})$

A key assumption of the DiD approach is that the Medicaid-only group is a valid counterfactual representation of the trends over time that the dual eligible group would have experienced had they not been exposed to Medicare Part D. This assumption is made more reasonable through two study design choices in this study: selection of the comparison group and propensity score matching. Selection of the comparison group can be advantageous to the study's validity if the comparison group captures unobserved trends that cannot be adjusted for using a propensity score based on measured covariates. We selected the Medicaid-only participants as the comparison group, as opposed to the privately insured or the uninsured, because dual eligibles and Medicaid-only participants have the same prescription drug coverage through Medicaid in the pre-Medicare Part D time period. By holding baseline prescription drug coverage constant, this comparison group is likely to reflect a range of unobserved trends in medication access, cost-sharing, enrollment criteria, and utilization management tools associated with Medicaid's prescription drug coverage. Our intentional choice of comparison group strengthens the assumption that the two groups have similar access to prescription drugs before Medicare Part D implementation and that their trends in medication use were similar. Second, we estimated propensity scores to match the two groups on measured covariates, and were able to ensure that we only included participants who were

within the common range of propensity scores between the two groups (common support). By restricting the DiD analysis to individuals who were within the overlapping range of propensity scores, we strengthen the exchangeability assumption. Finally, it is worth noting that the characteristics of the DiD design mean that the outcome levels may differ between groups in the pre–Medicare Part D time period but that the validity of the approach depends on outcome trends in the pre–Medicare Part D time period being similar.⁷⁹ In our study, we conducted a propensity score matched DiD model using the matched cohort of a 1:1 nearest neighbor matched cohort of dual eligibles and Medicaid-only participants (matched DiD model). The results for the propensity score matched DiD model are presented in Chapters 4 and 5, by aim.

In this study, the effect of Medicare Part D was estimated on a range of outcomes using a DiD approach in a matched sample. For binary outcomes, the effect we estimated was the difference between proportion of participants experiencing the outcome in the dual eligible group and proportion of participants experiencing the outcome in the Medicaid-only group. For continuous outcomes, the effect we estimated was the difference in mean outcome of dual eligibles and the mean outcome of Medicaid-only participants. We fit a linear regression model to our longitudinal data, where each observation represented a person-visit. Linear regressions were used to model each outcome as a function of group, time period, and an interaction term for time period (pre- vs. post-Medicare Part D) and insurance group (dual eligible vs. Medicaid-only).

Sensitivity Analyses

Insurance coverage switching ("churning")

Insurance coverage can change over time due to temporary changes in eligibility. We explored the effects of transitioning on and off of insurance coverage ("churning") in both dual eligibles and Medicaid-only participants and its effects on study results in these sensitivity analyses. Despite an annual reapplication process, previous studies have shown that dual eligibles rarely transition in and out of Medicaid.⁸⁰ In a study of non-elderly dual eligibles, it was estimated that 85% of participants received continuous coverage through Medicaid in 2004 and 2005.⁸¹ It is similarly unlikely that Medicare coverage would be lost once disability has been established; the majority of people with HIV become eligible for Medicare by meeting disability criteria and dual eligibles can

therefore be expected to retain their Medicare coverage throughout the study period. Churning is a more common problem for Medicaid enrollees. A study on the loss of Medicaid coverage indicated that within adults, 20%, 43%, and 55% disenrolled from Medicaid within 6, 12, and 23 months after initial Medicaid enrollment, respectively. Six months following disenrollment, 17% of adults had re-enrolled in Medicaid. However, Medicaid eligibility depends on both financial criteria and categorical eligibility (i.e., disability, welfare, pregnancy) and individuals who are eligible for Medicaid based on disability criteria are more stable in their Medicaid coverage, where 30% of Medicaid enrollees lost coverage within 12 months.⁸² Based on previous studies, we estimated that approximately 85% of dual eligibles maintained continuous Medicaid coverage over the course of a year of Medicaid enrollment, and approximately 70% of Medicaid-only enrollees maintained their Medicaid coverage. To assess the sensitivity our analyses to insurance coverage loss, we explore the proportion of time that the dual eligible group and the Medicaid-only group spent as their reported insurance type in 2005 to demonstrate their having spent the majority of their time-on-study as either dual eligible or Medicaid-only in both pre- and post-Medicare Part D time periods.

ART adherence threshold

Initially, we examined adherence using a threshold of 100% ART vs. <100% ART adherence. Alternate categorization of ART adherence were based on previous research, which indicated that $\geq 95\%$ adherence was necessary to achieve viral loads at <400 copies/mL 80% of the time.⁸³ By definition, analyses of ART adherence were also restricted to the subset of the analytic sample that was on ART.

Comparison group validity

For the Medicaid-only beneficiaries to be a valid comparison group for dual eligibles, the two groups must have sufficiently overlapping outcome distributions prior to Medicare Part D implementation. The balance diagnostics for the propensity score strengthen the validity assumption. Based on a priori knowledge about differing health and demographic profiles, we assumed—correctly—that the unmatched sample would differ on mean, pre-Medicare Part D outcome values between the groups. However, DiD still represents a valid analysis in the case where outcome levels differ at baseline, as long as the observed trends between the groups are parallel, which they were

for all outcomes. However, in the case of ADAP use, there was mixed evidence that people with HIV who were enrolled in Medicaid-only were able to access ADAP—its intended purpose is to provide medications to those with inadequate coverage. To test the sensitivity of our ADAP result to the comparison group, we ran additional DiD analyses using other insurance types as comparison groups (privately-insured, uninsured).

Long-term vs. short-term effects

We calculated changes in outcomes for the primary time frame of interest (2003-2008), averaging outcomes over three years pre- and post-Medicare Part D implementation. In addition, we calculated changes in outcomes using two abbreviated time frames: 2004-2007 and 2005-2006.

CHAPTER 4: EFFECTS OF MEDICARE PART D ON MEDICATION ACCESS, ADHERENCE, AND VIRAL SUPPRESSION (AIM 1)

The objective of Aim 1 was to estimate the effect of Medicare Part D on self-reported OOP prescription drug spending, ADAP use, ART adherence, and HIV VL suppression among dual eligibles with HIV. We hypothesized that we would observe an increase in OOP prescription drug spending and in ADAP use. We further hypothesized that the increase in OOP prescription drug spending would lead to increased ART nonadherence and that this treatment disruption would reduce viral suppression.

Introduction

More than half of U.S. adults with HIV (56%) receive health insurance coverage through Medicare or Medicaid.⁸⁴ Medicare is a federally administered program that provides health insurance to Americans age 65 and over as well as persons with permanent disabilities under age 65 who receive Social Security Disability Insurance.⁴ Medicaid programs are state-run and have traditionally provided health insurance to certain categories of low-income persons.⁸⁵ Ten percent of adults with HIV meet eligibility criteria for both Medicare, primarily through disability criteria rather than age, and Medicaid, through a combination of income and disability criteria, and are enrolled in both programs (“dual eligibles”).⁸⁶ For dual eligibles, Medicare provides primary coverage while Medicaid absorbs remaining costs and covers services not available through Medicare.⁸⁵ In addition to Medicaid and Medicare, AIDS Drug Assistance Programs (ADAP) serve as a safety-net program, providing HIV-related prescription drugs to low-income individuals who have limited prescription drug coverage.⁵⁹ Dual eligibles with HIV rely on these programs for consistent access to ART, which is crucial to maintaining HIV viral load (VL) suppression.⁸⁷

For adults enrolled in Medicaid, most states offer a prescription drug benefit with a broad formulary with little to no cost-sharing, including protections that allow enrollees to receive their prescriptions without a co-payment, based on ability to pay.³⁴ Prior to the implementation of Medicare Part D in January 2006, Medicare coverage did not include an outpatient prescription drug benefit

and dual eligibles received prescription drug coverage through Medicaid. Since then, coverage for prescription drugs has shifted from Medicaid to Medicare and dual eligibles were required to enroll (or be auto-enrolled) in Medicare Part D for prescription drug coverage at implementation.⁸⁸

Medicare Part D is administered by private prescription drug plans that mandate cost-sharing and vary in the lists of covered drugs (formularies) and rules for accessing those drugs (utilization management).^{34,89} Prior to implementation, policy analysts anticipated that the initial transition would disrupt ART use for people with HIV in the short-term due to changes in which drugs are covered and in the long-term due to increased consumer cost-sharing as their prior coverage through Medicaid was replaced by Medicare Part D.³⁴ Among people with HIV, disruptions in ART can lead to decreased ART adherence and VL suppression, which promote HIV-related morbidity and mortality.¹¹

For example, a survey conducted shortly after Medicare Part D implementation reported that 20% of dual eligibles experienced difficulties filling prescriptions after the transition to Medicare Part D.⁸ Difficulties filling prescriptions included paying more out-of-pocket for prescription drugs than under Medicaid, needing drugs not covered on their plan's formulary, and delayed auto-enrollment into Medicare Part D drug plans.⁸

Only two cross-sectional studies have examined the effects of Medicare Part D on people with HIV, shortly after implementation. One study found that the odds of ART interruption were six times higher among those covered by Medicare Part D compared to those with other or no insurance.⁹ Increased cost was the primary barrier associated with ART interruption. These findings - are supported by reports from HIV providers that the majority of patients had difficulties accessing their prescription drugs under Medicare Part D.¹⁰ Despite reported ART interruption, no studies have examined the effects of Medicare Part D on HIV clinical outcomes, such as HIV VL suppression. Self-reported out-of-pocket spending on prescription drugs was of interest because reports of dual eligibles with HIV linked increases in out-of-pocket cost to ART interruption after Medicare Part D,⁹ even though research on the elderly Medicare population indicated improved medication access after Medicare Part D.⁹⁰ Further, no studies have examined effects of Medicare Part D implementation on ADAP use, despite reported coordination between Medicare Part D and ADAP.⁹¹ The effects on ADAP are of interest because, in addition to providing prescription drugs, ADAP can also provide

wrap-around coverage for people who have certain types of prescription drug coverage but who still face financial barriers to accessing their medications, such as individuals under Medicare Part D.²⁷

This study is the first to estimate the effects of Medicare Part D on out-of-pocket prescription drug spending, ADAP use, ART adherence, and viral suppression in dual eligibles with HIV. We used six years of data from the Women's Interagency HIV Study (WIHS), designed to comprehensively investigate the effects of HIV infection and treatment in women. The WIHS data include laboratory measures of HIV VL and are independent of insurance or pharmacy use, a distinct advantage over clinic or pharmacy claims data.

Methods

Data Source

The WIHS is the largest multisite prospective cohort study of HIV-infected and uninfected women in the United States.^{92,93} During the time frame for this analysis (2003–2008), the six original WIHS study sites were located in the Bronx, NY; Brooklyn, NY; Washington, DC; San Francisco, CA; Los Angeles, CA; and Chicago, IL. Since enrollment began in 1994, the WIHS has collected data on 3,679 HIV-infected participants. Biannual study visits include a physical examination, clinical laboratory measurements, and behavioral questionnaires.

Design and Study Sample

We estimated changes in out-of-pocket prescription drug spending, ADAP use, ART adherence, and viral suppression of dual eligibles after Medicare Part D implementation compared to a matched sample of Medicaid-only enrollees. We excluded women who missed three consecutive visits between 2003 and 2008. We restricted the analysis to participants who 1) were HIV-infected by January 1, 2003, 2) had at least one study visit in both 2005 and 2006, and 3) reported Medicaid-Medicare dual eligibility or Medicaid-only enrollment at Medicare Part D implementation on January 1, 2006. Among 1,634 HIV-infected participants, 1,449 (87%) women had least one visit in 2005 and one visit in 2006. Of those, 801 women met the insurance coverage inclusion criteria for this study, of whom 125 were dual eligibles and 676 had Medicaid only. This study did not include HIV-uninfected WIHS participants or participants who received primary coverage through sources other than Medicaid and Medicare. All participants were under the age of 65 at Medicare Part D implementation

and were assumed to have gained Medicare coverage through disability criteria, rather than age.

Measures

Health Insurance Status

The exposure of interest was the transition to Medicare Part D. Participants reporting dual eligibility in 2005 were considered dual eligible at Medicare Part D implementation on January 1, 2006. The control group included participants reporting Medicaid coverage and no other private or public insurance in 2005 who were considered Medicaid-only at Medicare Part D implementation. We selected Medicaid-only participants because the two groups had identical prescription drug coverage through Medicaid in the pre-Medicare Part D time period.

Outcomes of Interest

Several outcomes were considered: 1) self-reported out-of-pocket spending on prescription drugs, 2) self-reported ADAP use, 3) self-reported ART adherence, and 4) HIV viral suppression.

Out-of-pocket spending on prescription drugs was categorized as “none”, “<\$25”, “\$25–\$200”, “\$201–\$500”, and “>\$500.” Participants reported out-of-pocket prescription drug spending since the last study visit (the past six months). Spending was collapsed to create a binary indicator for any out-of-pocket prescription drug spending versus none because only 23% of dual eligibles indicated any out-of-pocket spending in 2005. In addition, the distribution was skewed and over half of participants indicated out-of-pocket costs in the <\$25 range in 2005. We also examined ADAP use, motivated by reported coordination between Medicare Part D and ADAP.⁹¹ Participants reported whether they used ADAP at each study visit. In these analyses, ADAP use was coded as a binary indicator for any use vs. none since the last study visit.

ART adherence was coded as a binary variable, indicating either <100% or 100% adherence since last visit. In a sensitivity analysis, we also examined an alternative definition of adherence, 95% or greater vs. <95%. VL measurements were taken every six months using the NucliSens assay (Organon Teknika Corp.), which had a lower limit of detection of 80 copies/mL during the time period of this analysis. We defined viral suppression as HIV VL \leq 200 copies/mL.⁹⁴ Missing values for all outcome measures and covariates were carried forward from last available visit.

Statistical Analysis

We explored the relationship between Medicare Part D and outcome variables using a segmented locally weighted smoothed spline (Lowess)⁷⁸ to visualize trends for dual eligibles and Medicaid-only participants non-parametrically. We allowed for inflection points at Medicare Part D implementation on January 1, 2006, to visualize discontinuities associated with the transition. A Lowess plot fits a polynomial at each time point using weighted least squares, thus “smoothing” the outcome levels between data points.

Propensity Score Matching

We created a propensity score–matched cohort in which we matched dual eligibles with Medicaid-only participants. Under the assumption that the propensity score model was specified correctly, propensity scores should balance covariates between the two groups in the pre–Medicare Part D period, strengthening the assumption that the matched Medicaid-only group represents an appropriate counterfactual for dual eligibles had that group not transitioned to Medicare Part D.

We used logistic regression to create propensity scores, with dual eligibility as the dependent variable and potential confounders as independent variables. We used a 1:1 nearest neighbor matching approach, without replacement, and dual eligibles were matched with the Medicaid-only participants with the propensity score that was nearest to their own. The covariate balance between dual eligibles and the matched control group was evaluated by comparing standard differences of means and t-test statistics between the two groups. We included baseline (pre–Medicare Part D) values for the following variables in the logistic regression models to create propensity scores: age at visit, race/ethnicity, education, employment, ADAP use, out-of-pocket prescription drug spending, and HIV VL. Continuous variables (age, VL) were included in the logistic regression as splines and categorical variables were dichotomized. We used the psmatch2 program in Stata (StataCorp, College Station, TX) to perform the 1:1 match.⁹⁵

We estimated the effects of Medicare Part D implementation on dual eligibles with HIV using a difference-in-difference (DiD) approach in a propensity score matched cohort. The DiD approach compares the average changes from pre– to post–Medicare Part D in dual eligibles, the group that was affected by the transition, to the average changes during the same time period in participants

with Medicaid only, a group unaffected by Medicare Part D. The resulting “difference-in-differences” can be attributed to the policy change if the assumption of parallel trends is met—the two groups can be balanced on baseline covariates—and there is sufficient overlap in the propensity scores between the matched groups. Linear regression was used to estimate the change in the proportion of participants experiencing outcomes of interest. Our Medicaid-only control group allowed us to estimate changes in the outcomes of dual eligibles while controlling for temporal trends (e.g., advances in ART).

Finally, we performed several sensitivity analyses to test the assumptions inherent in propensity score matching and DiD analyses. We explored the parallel trends assumption using the Lowess plots, tested the balance of baseline covariates, and quantified propensity score overlap of the two matched groups. Sensitivity analyses included abbreviating pre- and post-Medicare Part D time periods (i.e., restricting to the 2004–2007 and 2005–2006 time periods) and specifying different sets of covariates in the propensity score model. All statistical analyses were performed using Stata 13 (StataCorp, College Station, TX).

Results

A total of 801 women were included in this analysis, of which 125 (16%) were dual eligible and 676 (84%) had Medicaid only (Table 1). Median age of dual eligibles was higher than participants on Medicaid only (47; interquartile range [IQR]: 41, 52 vs. 43; IQR: 38, 49, respectively). Among dual eligible participants, 57% were African American compared to 68% of Medicaid-only participants. In 2005, 10% of dual eligibles participated in ADAP compared to the 5% of Medicaid-only participants who participated in ADAP. A greater proportion of dual eligibles had completed high school or higher compared to Medicaid-only participants (76% vs. 48%); and a lower proportion of dual eligibles reported an annual household income of <\$12,000 compared to those with Medicaid only (62% vs. 67%). Finally, a greater proportion of dual eligibles were virally suppressed compared to Medicaid-only participants (59% vs. 48%) despite similar reported ART use and ART adherence levels.

Following Medicare Part D implementation, Lowess plots showed a sharp increase in out-of-pocket prescription drug spending in 2006 (Figure 5a). Although reports of any out-of-pocket spending attenuated over the following two years, dual eligibles’ out-of-pocket spending did not return

to pre–Medicare Part D levels. Lowess plots showed a more gradual increase in ADAP use, compared to the sharp rise in out-of-pocket spending, among dual eligibles (Figure 5b).

Lowess plots of ART adherence showed no inflection points for either group. Viral suppression appeared to be increasing over time in both groups, possibly corresponding to advances in ART, with no discontinuity following Medicare Part D implementation (Figure 5c-d). Lowess plots also indicated that the parallel trend assumption held for all outcomes of interest during the pre–Medicare Part D time period, strengthening the validity of the DiD analyses.

The set of variables used in the propensity score matching resulted in a covariate balance between the two groups on sociodemographics, medication use and related spending, and health status (Table 3). Propensity score overlap was judged to be sufficient between the two groups. In the propensity-score matched DiD analyses, dual eligibles showed increases in out-of-pocket spending on prescription drugs, with 23% reporting any out-of-pocket spending for prescription drugs in the pre–Medicare Part D time period in contrast to 41% in the post–Medicare Part D time period (Table 4). Adjusting for any temporal trends by subtracting the change in the matched control group, the DiD estimate attributed to the transition to Medicare Part D was an average 20% change (95% CI: 12%–27%) in proportion of dual eligibles reporting out-of-pocket spending. ADAP use increased by 10% among dual eligibles following Medicare Part D implementation (95% CI: 3%–18%).

Levels of self-reported ART adherence were comparable in dual eligibles and Medicaid-only enrollees in the pre–Medicare Part D time period (47% vs. 39%) and in the post–Medicare Part D time period (48% vs. 44%), and DiD estimation did not attribute a significant change to the transition. Similarly, DiD estimation did not attribute a significant change in the proportion of dual eligibles who were virally suppressed, after adjusting for temporal trends.

Discussion

This is first study to examine the effects of Medicare Part D implementation on out-of-pocket prescription medication costs, ART adherence, viral suppression, and ADAP use among HIV-infected women enrolled in Medicaid and Medicare (dual eligibles). As anticipated, the proportion of dual eligibles reporting out-of-pocket spending for prescription drugs increased following Medicare Part D implementation. Despite this increase, ART adherence and viral suppression remained stable after

the transition to Medicare Part D. The proportion of dual eligibles using ADAP also increased in the Medicare Part D time period, though the increase was more gradual following the rise in out-of-pocket prescription drug spending. Taken together, these results suggest that although the transition to Medicare Part D was associated with increased self-reported out-of-pocket costs and ADAP use, ART adherence and viral suppression remained stable.

Cost-Sharing and Out-of-Pocket Prescription Drug Spending

Our findings differed from previous research that reported no change in dual eligibles' out-of-pocket prescription drug costs in either the transition or the stable period following Medicare Part D implementation.⁹⁶ However, those study results were based on a sample of elderly dual eligibles, whose health needs differ from non-elderly HIV-infected populations. Our findings are supported by the one previous study of HIV-infected individuals, in which 60% of those enrolled in a Medicare Part D prescription drug plans reported increased out-of-pocket prescription drug expenditures shortly after implementation.⁹

ADAP Use and Medicare Part D

Lowess plots indicate an increase in ADAP use following the increase in out-of-pocket prescription drug spending. These findings are supported by reports of coordinated coverage of dual eligibles through Medicare Part D and ADAP.⁹¹ It warrants noting that despite the rise in ADAP use and the financial advantages of using ADAP in combination with Medicare Part D, only 22% of dual eligibles in this study reported ADAP use and 41% still reported out-of-pocket prescription drug spending in 2008.

ART Adherence and Viral Suppression

Given reports of ART interruption and increased out-of-pocket prescription drug costs shortly after Medicare Part D implementation,^{9,10} we hypothesized that an increase in out-of-pocket prescription drug spending would lead to decreased ART adherence and, consequently, decreased VL suppression. However, we found that dual eligibles' ART adherence remained stable over time. There are several explanations for consistent ART adherence. First, it is possible that increased enrollment in ADAP mitigated any effects of increased spending, resulting in stable ART adherence. Second, despite large increases in the proportion of dual eligibles with any out-of-pocket prescription

drug spending, the bulk of participants reported low out-of-pocket spending. For persons with out-of-pocket costs, 54% of participants reported out-of-pocket costs ranging from \$1-\$25, and 42% of participants had out-of-pocket costs ranging from \$26-\$200 in the prior six months. Even though two-thirds (66%) of the study population reported a household income <\$12,000 per year, it is possible that the costs were not high enough to lead to cost-related nonadherence to ART. Finally, we also considered the possibility that the burden of out-of-pocket spending may have translated to also a reduction in spending on other essential needs (e.g., food, child care, housing, etc.) or that WIHS participants may have been more conscientious about their adherence due to their long-term involvement with the WIHS.

Similarly, we also found no evidence of changes in VL suppression in dual eligibles associated with Medicare Part D. Though the proportion of dual eligibles who were virally suppressed increased between the pre- and post-Medicare Part D time periods, the increase was similar to the trend observed in the Medicaid-only comparison group, indicating that both groups benefit from improvements in ART. In the context of this study, those results suggest that the stability of viral suppression may be the result of increased use of ADAP rather than the result of improved medication access through Medicare Part D. This interpretation is supported by other studies, in which ADAP use was associated with an increased use of ART⁹⁷ and increased likelihood of viral suppression.⁹⁸

Limitations

Out-of-pocket costs, ART adherence, and ADAP use are self-reported in the WIHS over a period of six months, which may have led to misclassification or recall bias. Our study was also limited to dual-eligible women with HIV who participate in a longitudinal cohort study, and results may not be generalizable to all dual eligibles with HIV. Finally, propensity scores can only balance groups on measured covariates and, as in all observational studies, unmeasured covariates may confound our results.

Despite these limitations, the outcomes have a unique advantage over claims and clinic data in that study visits occur at six-month intervals and are independent of insurance status or prescription fill behavior. This study has an additional advantage that it allowed us to study the effects

of Medicare Part D on a laboratory measure of viral load suppression, a key indicator of effective ART use.

Conclusions

Prior studies showed improved medication access following Medicare Part D implementation in many Medicare enrollees. However, dual eligible women with HIV, an understudied and medically vulnerable group, did not reflect those improvements in medication access or reduced out-of-pocket prescription drug costs seen in other Medicare enrollees. Our results underscore the importance of ADAP's role in maintaining medication access and viral suppression during federally mandated insurance coverage transitions. Although ADAP is essential in providing HIV medications to those who have no insurance, the program also appears to benefit dual eligibles with HIV by reducing out-of-pocket spending on prescription drugs.

This study has implications beyond Medicare Part D and dual eligibles with HIV. Medicare Part D's market-based, consumer-driven prescription drug plans are analogous to the privatized, market-based coverage that many people with HIV encounter through health insurance exchanges following the implementation of the Affordable Care Act (ACA). An additional similarity is that the ACA allows ADAP to provide similar wrap-around benefits for people with HIV as ADAP provided for dual eligibles under Medicare Part D, covering premiums and co-payments for prescription drugs. This study underscores that medication safety-net programs such as ADAP may be vital in ensuring smooth insurance coverage transitions, an important lesson as people with HIV transition to private prescription drug coverage under the ACA.

Table 3. Baseline Characteristics of Medicaid-Medicare Dual Eligibles and Medicaid-Only Participants, Aim 1, Women's Interagency HIV Study (2005)

	Unmatched sample (n=801)			Propensity score-matched sample (n=236)		
	Dual Eligibles (n=125)	Medicaid-only (n=676)	p-value ^a	Dual Eligibles (n=118)	Medicaid-only (n=118)	p-value ^a
Age in years, median (IQR)	47 (41, 52)	43 (38, 49)	0.005	46 (41, 52)	46 (41, 52)	0.603
African American, %	56.5	67.9	0.014	59.0	64.4	0.394
Hispanic Ethnicity, %	24.2	26.6	0.575	23.9	23.7	0.971
WIHS Site, %						
Bronx	15.2	28.7	0.002	16.1	23.7	0.144
Brooklyn	20.0	23.5	0.391	20.3	16.9	0.506
Washington, DC	8.0	8.6	0.831	8.5	11.9	0.391
Los Angeles	20.0	11.0	0.005	19.5	15.3	0.393
San Francisco	24.0	15.1	0.014	22.0	17.8	0.417
Chicago	12.8	13.2	0.912	13.6	14.4	0.852
ADAP	10.4	5.1	0.019	7.7	7.6	0.985
Any out-of-pocket prescription spending, %	22.8	12.9	0.004	21.6	14.5	0.165
100% ART adherent ^b	51.2	43.2	0.127	51.2	48.4	0.719
CES-D, median (IQR)	14 (3.5, 28.5)	15 (6, 25)	0.844	14 (3, 27)	15 (4, 27)	0.698
Household income <\$12,000/year, %	62.1	67.1	0.278	62.2	60.9	0.849
Graduated high school, %	76.4	48.1	<0.0001	25.5	27.0	0.792
Employed, %	12.9	18.6	0.129	12.1	10.0	0.558
CD4 cell count, median (IQR)	466 (312, 643)	416 (249, 622)	0.265	484 (324, 658)	476 (316, 728)	0.396
Virally Suppressed ^c , %	59.3	48.0	0.021	59.6	64.7	0.447

Abbreviations: ADAP, AIDS Drug Assistance Programs; ART, antiretroviral therapy; CES-D, Center for Epidemiologic Studies Depression Scale; IQR, interquartile range; HIV, Human Immunodeficiency Virus; WIHS, Women's Interagency HIV Study

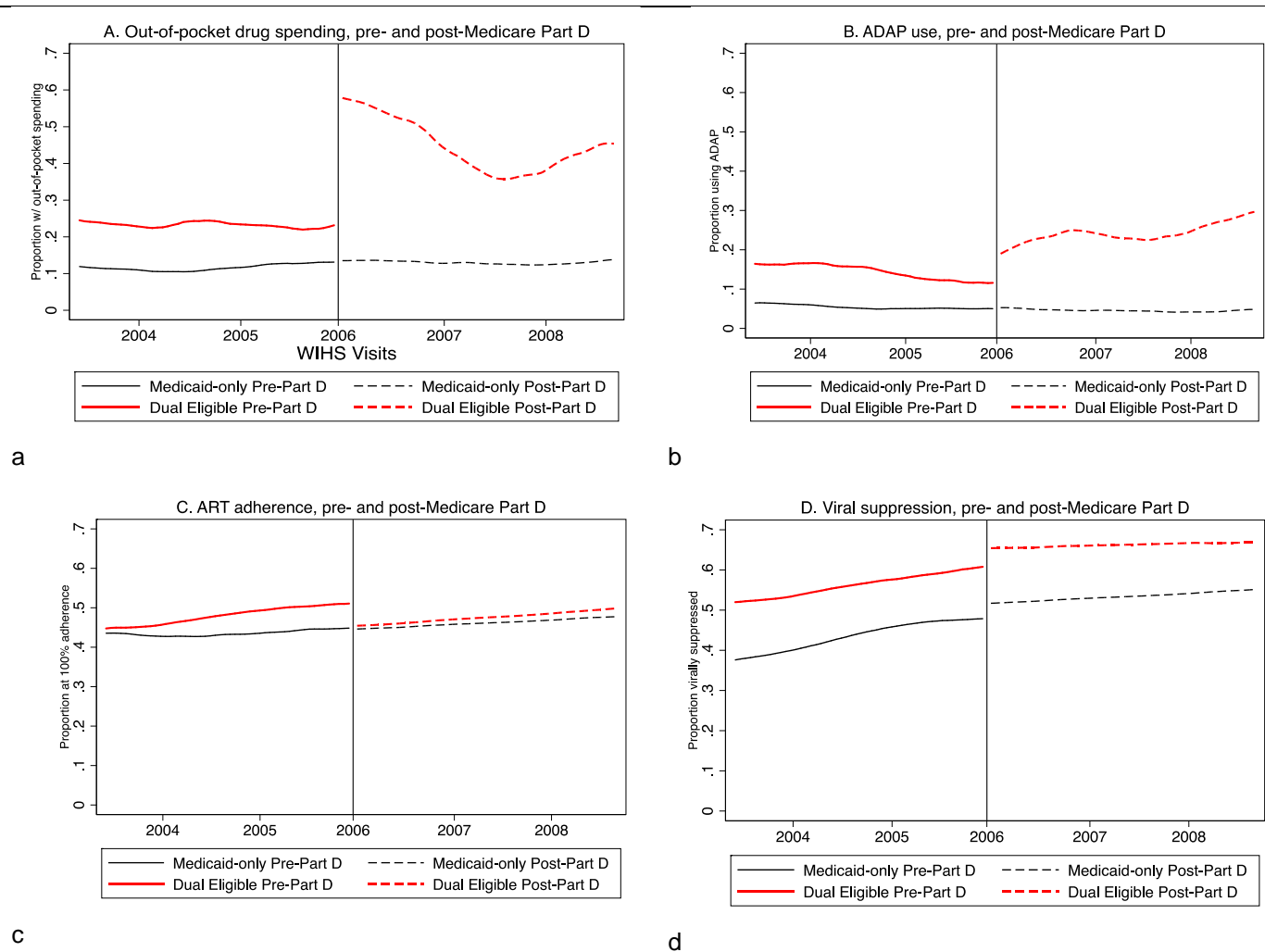
^a Statistical significance tested using *t* tests

^b Proportions calculated within subset of dual eligibles (n=103) and Medicaid-only participants (n=461) on ART

^c Viral suppression corresponds to a VL measurement of <200 copies/mL

Table 4. Difference-in-Differences Estimates—Average Proportion Change in Pre- and Post-Medicare Part D Time Period, by Insurance Type, Women's Interagency HIV Study 2003–2008, Aim 1

	% with OOP spending			% Using ADAP			% ART adherent			% Virally suppressed		
	%	SE	p-value	%	SE	p-value	%	SE	p-value	%	SE	p-value
Pre-Medicare Part D (2003-2005)												
Medicaid-only	0.23			0.13			0.39			0.50		
Dual eligible	0.24			0.14			0.47			0.55		
Difference	0.01	0.04	0.859	0.01	0.04	0.716	0.08	0.05	0.155	0.05	0.05	0.361
Post-Medicare Part D (2006-2008)												
Medicaid-only	0.21			0.10			0.44			0.62		
Dual eligible	0.41			0.22			0.48			0.66		
Difference	0.20	0.04	<0.001	0.12	0.04	0.004	0.04	0.05	0.440	0.05	0.05	0.337
Difference-in-Differences	0.20	0.04	<0.001	0.10	0.04	0.007	-0.04	0.05	0.440	-0.001	0.05	0.987
Abbreviations: ADAP, AIDS Drug Assistance Program; ART, Antiretroviral Therapy; OOP, out-of-pocket; VL, viral load; SE, standard error												



Abbreviations: ADAP, AIDS Drug Assistance Program; ART, Antiretroviral Therapy

Figure 5. Change in proportion of outcome of interest, by insurance type and time period in the Women's Interagency HIV Study (WIHS), 2002–2008, Aim 1.

CHAPTER 5: EFFECTS OF MEDICARE PART D ON MENTAL HEALTH TREATMENT AND OUTCOMES (AIM 2)

The objective of Aim 2 was to estimate the effect of Medicare Part D on self-reported antidepressant use, depressive symptoms, and hospitalization among dual eligibles with HIV. We hypothesized that we would observe a decrease in antidepressant use among dual eligibles after Medicare Part D implementation and that this decrease would remain after adjusting for temporal trends using a matched control group of Medicaid-only participants. We further hypothesized that this disruption in antidepressant treatment would lead to an increase in depressive symptoms and hospitalization.

Introduction

Depression is the most common psychiatric comorbidity in people with HIV.¹ Untreated depressive symptoms have been associated with reduced antiretroviral therapy (ART) adherence,²⁻⁴ unsuppressed HIV viral load,^{5,6} and shortened survival time.⁷ In turn, sub-optimal antiretroviral therapy (ART) adherence has been shown to increase the risk of hospitalization in women with HIV.⁸ By contrast, people with HIV who are treated for depression showed similar ART adherence and viral control to people with HIV who did not have depression,⁹ highlighting antidepressant use as a point of intervention with the potential to improve depression, hospitalization, and HIV outcomes.

For many people with HIV, health insurance facilitates access to prescription drugs, such as antidepressants, that would be prohibitively expensive otherwise.¹⁰ Further, the majority of people with HIV rely on public insurance programs for medication access, with 56% receiving coverage through Medicaid or Medicare. Medicare provides health insurance to Americans age 65 and over as well as to persons under the age of 65 with permanent disabilities.¹¹ Medicaid programs have traditionally provided health insurance to certain categories of low-income persons. Of adults with HIV, 10% meet eligibility criteria for Medicare and Medicaid and are enrolled in both programs (referred to as “dual eligibles”).¹² For dual eligibles, Medicare provides

primary coverage while Medicaid absorbs the remaining costs and can also provide primary coverage for services not available through Medicare.¹³

Before 2006, Medicare did not include a prescription drug benefit and dual eligibles were covered under Medicaid's prescription drug benefit. On January 1, 2006, Medicare implemented its own prescription drug benefit, Medicare Part D, and required dual eligibles to transition their prescription drug coverage from Medicaid to Medicare Part D.¹⁴ The goal of Medicare Part D was to improve medication access by reducing financial barriers for Medicare enrollees. Although a systematic review of Medicare Part D implementation and its effects on medication use indicated that Medicare Part D was associated with increased medication use and decreased out-of-pocket costs in the general Medicare population, the effects on dual eligibles and other vulnerable populations was mixed.¹⁵ In the transition to Medicare Part D, dual eligibles were enrolled in prescription drug plans that, within general guidelines, determined their own formularies and medication access rules, which often varied widely by plan. Further, cost-sharing for prescription drugs was mandated under Medicare Part D.¹⁶ By contrast, Medicaid's prescription drug benefit had a broader benefits package, only allowed nominal cost-sharing,¹⁷ and included additional protections that allowed enrollees to receive their prescriptions without co-payment if they are unable to pay.¹⁶

Cost-sharing and medication disruptions are a special concern for dual eligibles with mental health conditions because this population has a limited ability to pay for medications and disruptions can have rapid consequences for symptoms and health service use.¹⁸ Two studies examined the effects of Medicare Part D on dual eligibles with mental illness shortly after implementation.^{19,20} In the first study, psychiatrists indicated that 44% of their dually eligible patients had difficulties accessing a psychiatric medication shortly after Medicare Part D implementation. Of dual eligibles who had difficulty accessing medication, 22% had difficulty paying for their medications.¹⁹ The second study demonstrated that access problems for dual eligibles with psychiatric conditions did not decrease during the first year after Medicare Part D implementation but increased slightly instead.²⁰ These studies indicate that Medicare Part D was associated with financial and administrative barriers to medication access for dual eligibles with

mental health conditions and that those barriers were sustained over at least the first year after implementation.

Medicare Part D implementation has also been associated with psychiatric medication switching or discontinuation.^{20,21} Of dual eligibles with psychiatric conditions who reported difficulties accessing medication, 19% had to switch to a different drug¹⁹ and 29% discontinued or temporarily stopped their medication because of coverage limitations.²⁰ Increased switching following Medicare Part D may adversely affect mental health outcomes because psychotropic drug classes are less therapeutically interchangeable than medications for other chronic conditions (e.g., nonsteroidal anti-inflammatory drugs).²² Prescription drug plans within Medicare have shown variable medication switching rates, indicating some plans may be more appropriate for dual eligibles with psychiatric conditions.²³

Given indications of increased cost-sharing, variation in prescription drug plan formularies, and reports of dual eligibles' psychiatric medication disruption and discontinuation associated with Medicare Part D, the goal of this study was to estimate the effects of Medicare Part D on antidepressant use, changes in depressive symptoms, and subsequent risks for hospitalization among women with HIV. We used six years of data from a longitudinal cohort study—the Women's Interagency HIV Study (WIHS), which investigates the long-term effects of HIV-infection and treatment in women.

Methods

Data Source

The WIHS prospectively studies women who are HIV-infected and women at high risk for HIV infection enrolled at multiple U.S. study sites.^{24,25} Since its initiation in 1994, the WIHS has collected data on 3,398 HIV-infected women. We restricted our analyses to biannual WIHS visits between 2003 and 2008. During the timeframe of this study, the WIHS consisted of six study sites located in the Bronx, NY; Brooklyn, NY; Washington, DC; San Francisco, CA; Los Angeles, CA; and Chicago, IL. Study visits include a physical examination, survey questions, and laboratory measurements.

Design and Study Sample

We estimated the effects of Medicare Part D implementation on changes in outcomes of dual eligible participants while controlling for temporal trends using data from participants who received coverage through Medicaid only. Participants who missed three consecutive visits between 2003 and 2008 were administratively censored. We further restricted our study to participants who 1) were HIV-infected in 2003 and 2) reported Medicaid-Medicare dual eligibility or Medicaid-only enrollment in 2005 as indicators of their transition to Medicare Part D on January 1, 2006. There were 1,807 HIV-infected participants who attended study visits between 2003 and 2008 and had not missed more than three consecutive visits in that timeframe. Of those, 125 dual eligibles and 676 Medicaid-only participants met the inclusion criteria for this study.

Measures

Health Insurance Status

Although dual eligibles were the focus of this study, we categorized participants into two mutually exclusive groups by insurance status. Participants who were dual eligibles at any point in 2005 were considered dual eligible at the transition to Medicare Part D and made up our analytic group of interest. Participants who reported Medicaid coverage and no other private or public insurance in 2005 were considered Medicaid-only at the transition to Medicare Part D and made up our matched control group.

Outcomes of Interest

We considered the following outcomes: 1) antidepressant use, 2) depressive symptoms, and 3) hospitalization.

We examined pharmacologic treatment of depression by assessing the proportion of participants who self-reported antidepressant use since their last study visit, i.e., antidepressant use in the last six months. The binary indicator of any antidepressant use corresponded to a measure of use or nonuse of a prescribed medication with a primary indication for treating depression.

Depressive symptoms were assessed at each WIHS visit using the Center for Epidemiologic Studies Depression Scale (CES-D).²⁶ The instrument uses a 20-item scale in

which each item is rated on frequency of occurrence in the past seven days. Scores range from 0 to 60. We also examined a binary indicator of “probable depression” where participants were classified as having probable depression if their CES-D score was 16 or more.²⁶ We considered a third specification, a binary indicator of self-reported depression for which participants were asked assess whether they had several medical conditions, including depression, since the last study visit.

Finally, we assessed inpatient hospitalization. Emergency room usage that did not result in hospital admission was not considered. In addition to the binary indicator of any hospitalization in the six-month interval since the previous study visit, we also assessed the number of hospitalizations.

Statistical Analysis

Before creating the propensity score matched cohort, we plotted outcome variables for visits from 2003 to 2008 using a segmented locally weighted smoothed spline (Lowess).²⁷ Lowess plots were created for each outcome to non-parametrically visualize pre- and post-Medicare Part D trends for dual eligibles and Medicaid-only participants. The plots were segmented at Medicare Part D implementation on January 1, 2006, for both groups to visualize any discontinuities associated with the transition.

Propensity score matching

We used propensity scores to match dual eligibles with study participants who were enrolled in Medicaid only. The two groups were matched on propensity scores because it is possible that an unadjusted comparison between dual eligibles and the Medicaid-only could be confounded by differences inherent in the two groups. The goal of propensity score matching is to balance covariates between the two groups in the pre-Medicare Part D time period. Covariate balance strengthens the assumption that the matched control group represents the dual eligibles' counterfactual outcomes.

Propensity scores were created using logistic regression, where dual eligibility was a function of the pre-treatment covariates. After estimating the propensity scores, dual eligibles were matched 1:1 with Medicaid-only participants using a nearest-neighbor matching approach,

without replacement. Of the baseline (pre–Medicare Part D) variables considered for the propensity score model, our final set included: African American ethnicity, viral load, age, hospitalization, any psychotropic medication use, and total number of medications (ART and other). As continuous variables, age and viral load were included as splines, and categorical variables were dichotomized. Baseline values for time-varying variable were restricted to values from study visits in 2005. We used Stata’s psmatch2 program (StataCorp, College Station, TX) to match the groups by propensity score.²⁸

Finally, we used a difference-in-differences (DiD) approach on the propensity score matched cohort to estimate the effects of Medicare Part D implementation on dual eligibles with HIV. The Medicaid-only comparison group allowed us to control for temporal trends (e.g., advances in ART or antidepressants) that are common to both groups. The DiD approach consists of a linear model with an interaction term for insurance group (dual eligible or Medicaid-only) and time period (pre– or post–Medicare Part D). The approach allowed us to compare the average changes in proportions between pre– and post–Medicare Part D in dual eligibles, the group that was affected by the implementation, to the average changes in proportions between pre– to post–Medicare Part D in participants with Medicaid only, the group that was unaffected by Medicare Part D. The resulting difference-in-differences can be attributed to the policy change if both groups have parallel trends in the pre–Medicare Part D time period, known as the parallel trends assumption.²⁹

Sensitivity analyses included examination of short-term and long-term effects of Medicare Part D by abbreviating pre– and post–Medicare Part D time periods (2004–2007, 2005–2006) as well as comparing propensity score model specifications and outcome variable definitions. All statistical analyses were performed using Stata 13 (StataCorp, College Station, TX).

Results

Eight hundred and one women met the inclusion criteria, of which 125 (16%) were dual eligibles and 676 (84%) were Medicaid-only (Table 5). Before propensity score matching, dual eligibles differed from Medicaid-only participants in age, ethnicity, education, WIHS site, out-of-pocket prescription drug spending, antidepressant use, hospitalization, and viral suppression. The

median age of dual eligibles was higher (47; IQR: 41-52) compared to Medicaid-only participants (43; IQR: 38-49). Fewer dual eligibles were African American compared to participants who were Medicaid-only (57% vs. 68%). A greater proportion of dual eligibles completed high school or higher levels of education compared to Medicaid-only participants (74% vs. 48%). Annual household income was low overall and two-thirds of participants (66%) earned less than \$12,000 annually, where 21% earned less than \$6,000 (result not shown). Despite their higher household income, education levels, and better viral suppression, a greater proportion of dual eligibles reported being hospitalized in the six months since their last visit (24%) compared to Medicaid-only participants (17%).

There was a striking difference in the levels of antidepressant use between dual eligibles and Medicaid-only participants in 2005. Over 38% of dual eligibles reported antidepressant use compared to 18% of Medicaid-only participants. This finding was more pronounced in dual eligibles with severe depressive symptoms (CESD ≥ 16), of whom 49% were on antidepressants compared to 25% of Medicaid-only participants with severe depressive symptoms (result not shown). Despite different levels of antidepressant use, dual eligibles and Medicaid-only participants had similar levels of depressive symptoms, and both groups had median CES-D scores of 14.

Before matching on the propensity score, we created Lowess plots for all outcomes to visualize trend breaks associated with Medicare Part D and to provide graphical support for the parallel trend assumption (Figure 6a–c). None of the outcomes of interest showed obvious trend breaks at Medicare Part D implementation in 2006. Lowess plots indicated that the parallel trend assumption held for all outcomes of interest and supported the validity of the DiD analyses. After matching on the propensity score, our sample was limited to 117 dual eligibles (94% of the 125 participants who were dual eligible in 2005) whose propensity scores were within the range of the propensity scores of the control group and a matched group of 117 Medicaid-only participants.

Within the matched cohort, we estimated the DiD for all outcomes of interest and obtained the average change in proportion in dual eligibles between the two time periods, adjusted for temporal trends (Table 6). After accounting for temporal trends by subtracting the

effect in the matched control group, the implementation of Medicare Part D did not seem to have an impact on dual eligibles' antidepressant use, depressive symptoms, or hospitalization.

Discussion

This study yielded several key findings. First, the unmatched, unadjusted comparison between dual eligibles and Medicaid-only participants showed that, in 2005, antidepressant use was significantly higher among dual eligibles than among participants with Medicaid only (38% vs. 18%), despite similar levels of depressive symptoms. Further, a greater proportion of dual eligibles with severe depressive symptoms reported antidepressant use in 2005 compared to Medicaid-only participants with severe depressive symptoms (49% vs. 25%). However, both groups received prescription drug coverage through Medicaid in 2005, making it unlikely that prescription drug coverage characteristics (formularies, utilization management tools, etc.) are responsible for this difference in antidepressant use.

Under conditions that effectively hold prescription drug coverage constant between the two groups, there are several possible explanations for these findings. First, there are several other differences between dual eligibles and Medicaid-only enrollees in 2005 (age, ethnicity, education, hospitalization, viral suppression, and WIHS site). However, the association between insurance type and antidepressant use remained after adjustment for the variables mentioned. Second, people with psychotropic medication needs may be more likely to become Medicare enrollees through mental health–related disability. Third, although dual eligibles received prescription drug coverage through Medicaid before 2006, they were still receiving medical coverage through Medicare. Dual eligibles may have been able to access medical care more easily than Medicaid enrollees, and access to care, rather than prescription drug coverage, may determine antidepressant use. This interpretation is supported by studies showing that Medicare's provider reimbursements were 39% higher than Medicaid's provider reimbursements and that providers were more likely to accept new patients who were Medicare enrollees compared to Medicaid enrollees.^{30,31}

The DiD analyses indicated that Medicare Part D implementation did not affect antidepressant use in dual eligibles despite the program's mandatory cost-sharing. Although

antidepressant use did not appear to be disrupted by Medicare Part D implementation, it is possible that Medicare Part D drug plans led to enrollees to switch to less effective antidepressants. Prior Medicare Part D research indicated that of dual eligibles had difficulty accessing a psychiatric medication following Medicare Part D, 19% were switched to a different drug because their prescribed medication was either not covered or not approved.³²

Despite prior evidence of potentially sub-optimal medication switching, our analyses also did not detect a change in depressive symptoms. Depressive symptoms remained stable in both groups throughout the study period. Finally, dual eligibles showed no change in hospitalization following Medicare Part D—the proportion of dual eligibles being admitted to the hospital over a six-month time period remained approximately 20% both before and after Medicare Part D implementation.

Limitations

WIHS does not collect data on insurance characteristics and we were unable to examine specific characteristics of Medicare Part D prescription drug plans, such as use of utilization management tools for antidepressants.³⁴ It is possible that study visits occurring at six-month intervals are too far apart to detect acute disruptive effects, as identified in prior studies on medication access. However, given the periodic timing of the WIHS data collection, these findings indicate that Medicare Part D did not have a sustained, long-term effect on antidepressant use, depressive symptoms, or hospitalization. Finally, all WIHS participants are women and dual eligible women may have distinct patterns of antidepressant use, depression, and health service use that limit generalizability. Despite these limitations, this study has the advantage that data are collected independently of insurance status, medical care engagement, or prescription fill behavior. These data are a valuable resource for studying medication access problems because claims data may selectively represent people who successfully fill medications.

Conclusions

Coordinating care and managing costs for dual eligible eligibles is a vital health policy issue. This study highlights key differences between dual eligibles and Medicaid enrollees and adds to the limited body of knowledge on how transitioning prescription drug coverage from

Medicaid to Medicare Part D affects mental health and related service use. We found that while receiving the same prescription drug coverage through Medicaid in 2005, a greater proportion of dual eligibles used antidepressants compared to Medicaid-only participants, despite similar levels of depressive symptoms. Although prior research of Medicare Part D and dual eligibles with HIV indicated difficulty accessing medications after the transition³³ we identified no such effect on antidepressant use. This analysis also identified no changes in depressive symptoms or hospitalization following Medicare Part D implementation. These findings may indicate that protections for psychotropic drug classes under Medicare Part D were meeting their intended function in this vulnerable population several years after implementation. Stable medication use may also be due to better access to medical care for dual eligibles through Medicare both before and after Medicare Part D implementation, which may eclipse any effects of the transition in prescription drug coverage.

Table 5. Baseline Characteristics of Medicaid-Medicare Dual Eligibles and Medicaid-Only Participants, Women's Interagency HIV Study (2005), Aim 2

	Unmatched sample (n = 801)			Propensity score matched sample (n = 234)		
	Dual Eligibles (n = 125)	Medicaid-only (n = 676)	P value ^a	Dual Eligibles (n = 117)	Medicaid-only (n = 117)	P value ^a
Age, median (IQR)	47 (41, 52)	43 (38, 49)	<0.000	46 (41, 52)	46 (41, 51)	0.794
African American, %	56.5	67.9	0.014	59.4	59.4	1.000
Hispanic	24.2	26.6	0.575	23.2	31.0	0.146
Ethnicity, %						
WIHS Site, %						
Bronx	15.2	28.7	0.002	15.3	40.2	0.000
Brooklyn	20.0	23.5	0.391	22.4	19.7	0.747
Washington, DC	8.0	8.6	0.831	7.7	5.1	0.426
Los Angeles	20.0	11.0	0.005	18.8	7.7	0.012
San Francisco	24.0	15.1	0.014	23.1	15.4	0.137
Chicago	12.8	13.2	0.912	13.7	12.0	0.672
Out-of-pocket Rx spending	22.8	12.9	0.004	22.6	14.8	0.129
100% ART adherent ^b	51.2	43.2	0.127	52.6	48.4	0.563
Antidepressant use, %	38.2	18.4	0.000	37.6	35.9	0.787
CES-D score, median (IQR)	14 (3.5, 28.5)	15 (6, 25)	0.844	14 (6, 24)	14 (4, 29)	0.845
Hospitalized, %	23.5	17.2	0.020	19.7	17.9	0.739
Income <\$12,000/year, %	62.4	67.1	0.324	62.9	70.0	0.286
Education, %						
Less than high school	25.6	51.9	<0.000	25.0	23.3	0.760
Employed, %	12.9	18.6	0.129	11.2	12.9	0.687
Lowest observed CD4, median (IQR)	466 (312, 643)	416 (249, 622)	0.265	422 (291, 643)	452 (279, 644)	0.894
Suppressed HIV VL ^c	59.3	48.0	0.021	56.5	60.9	0.505

Abbreviations: CES-D, Center for Epidemiologic Studies Depression Scale; IQR, inter-quartile range; HIV, Human Immunodeficiency Virus

^a Statistical significance tested using *t* tests

^b Proportions calculated within subset on ART

^c Suppressed HIV VL corresponds to a viral load measurement of <200 copies/mL

Table 6. Difference-in-Differences Estimates – Average Proportion Change in Pre- and Post-Medicare Part D Time Period, by Insurance Type, Women's Interagency HIV Study 2003-2008, Aim 2

	Antidepressant Use			Severe Depressive Symptoms (CESD \geq 16)			Hospitalization		
	%	SE	p-value	%	SE	p-value	%	SE	p-value
Pre-Part Medicare Part D									
Medicaid-only	26.3			44.2			19.4		
Dual eligible	33.2			48.0			19.4		
Difference	+7.0	0.05	0.133	+3.8	0.05	0.456	+0.0	0.03	0.992
Post-Part Medicare Part D									
Medicaid-only	32.8			43.4			19.9		
Dual eligible	36.1			46.2			20.6		
Difference	+3.4	0.05	0.505	+2.8	0.05	0.579	+0.8	0.03	0.811
Difference-in-Differences	-3.6	0.04	0.367	-1.0	0.04	0.786	+0.8	0.03	0.805
Abbreviations: CESD, Center for Epidemiologic Studies Depression Scale; SE, Standard Error									

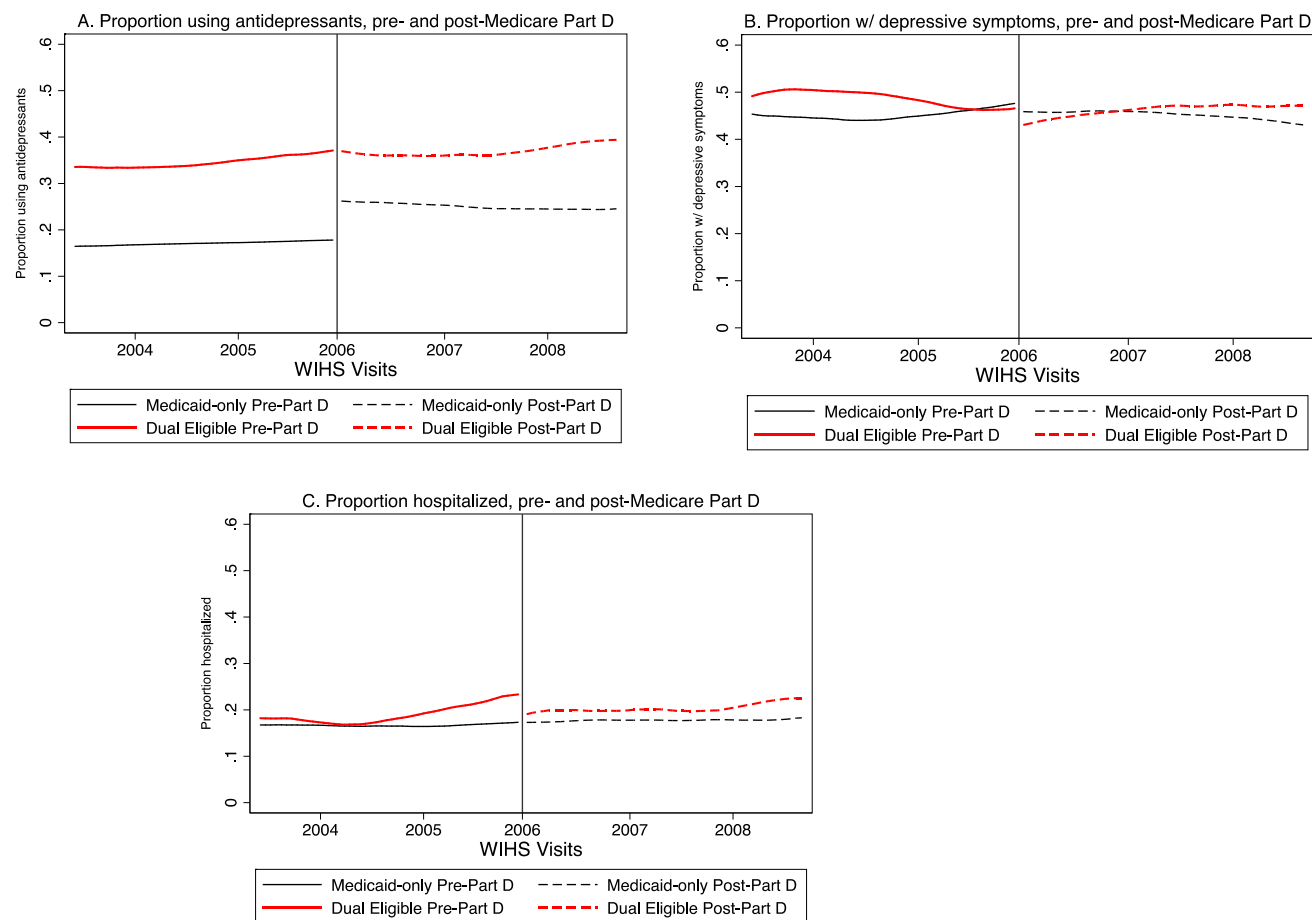


Figure 6. Change in proportion of outcome of interest, by insurance type, time period in the Women's Interagency HIV Study (WIHS), 2002–2008, Aim 2

CHAPTER 6: DISCUSSION

Medicare Part D is a federally funded, privately administered prescription drug benefit implemented on January 1, 2006. The goal of Medicare Part D was to improve medication access by reducing financial barriers for Medicare enrollees, many of whom did not have prescription drug coverage before 2006. For many enrollees over the age of 65, Medicare Part D implementation was associated with improved access to medication and lower OOP costs;^{42–44} however, its effects on dual eligibles and other vulnerable populations was mixed.⁶¹ Few studies have examined the effects of Medicare Part D on dual eligibles with HIV.^{9,10} This was the first study to examine the effects of Medicare Part D implementation on OOP prescription medication costs, ADAP use, ART adherence, and viral suppression among dual eligibles with HIV.

This dissertation produced several key findings. First, our results indicate that the proportion of dual eligibles with OOP prescription drug spending increased dramatically following Medicare Part D and that the increase was sustained in the years following Medicare Part D implementation. However, although the proportion of dual eligibles with OOP prescription drug spending appeared to increase, levels of medication use (ART adherence and proportion using antidepressants) remained stable. These findings are consistent with previous work showing no improvement in medication access in nonelderly disabled and depressed Medicare beneficiaries after Medicare Part D^{60,111,65} which contrasted with gains in medication use and reductions in OOP costs seen in elderly Medicare-only enrollees.^{42–44} In addition, our findings lend support to the previous study that indicated cost-related access problems for people with HIV following Medicare Part D implementation.⁹

Second, the combination of stable medication use (both ART adherence and antidepressant use) and the increased proportion of dual eligibles using ADAP use may indicate that the potential impact of increased OOP costs on medication use were mitigated by ADAP use. This interpretation is supported by the temporal order of the changes in spending and ADAP: The immediate increase in the proportion of dual eligibles reporting OOP prescription drug spending

was followed by a more gradual increase in the proportion of dual eligibles reporting ADAP use. In addition to providing people with HIV with access to ART, many ADAP formularies, which vary by state, also provide people with HIV with medications such as antidepressants, to treat common comorbidities.²⁷ As such, the increase in ADAP use stood to stabilize both ART adherence and antidepressant use.

Further, despite the rise in ADAP use and the financial advantages of using ADAP in combination with Medicare Part D, only 22% of dual eligibles in this study reported ADAP use in the post-Medicare Part D time period while 41% still reported OOP prescription drug spending. This discrepancy, combined with the very low income of this study population, is indicative that many dual eligibles with HIV are not making full use of ADAP benefits available to them despite coordination and co-financing between ADAP and Medicare Part D.

One of the most notable advantages of the data source used in this dissertation, compared to data used for prior Medicare Part D research is the inclusion of regularly collected laboratory measurements of HIV VL. Most Medicare Part D studies are limited to claims data or cross-sectional survey data and do not include laboratory measures. Though viral suppression increased in both groups over time, there was no difference in the proportions of dual eligibles who were virally suppressed associated with Medicare Part D. Given the stable medication use observed in both Aims 1 and 2, stable depressive symptoms and hospitalization levels over both time periods were in line with our other findings.

Differences Between Dual Eligibles and Medicaid-Only Participants

Our descriptive analyses in Aim 2 showed several differences between the two groups in the pre-Medicare Part D time period. First, the unmatched, unadjusted comparison between dual eligibles and Medicaid-only participants showed that, in 2005, antidepressant use was significantly higher among dual eligibles than among participants with Medicaid only (38% vs. 18%) despite similar levels of depressive symptoms. This result is striking because the two groups both received prescription drug coverage through Medicaid in the pre-Medicare Part D time period and had similar levels of depressive symptoms. The discrepancy was similar but more exaggerated in dual eligibles with severe depressive symptoms (CESD \geq 16) who reported antidepressant use in 2005, compared to Medicaid-only participants with severe depressive

symptoms (49% vs. 25%). In exploratory analyses, antidepressant use remained significantly different between the two groups even after adjustment for other baseline differences. It is possible that people with HIV and mental health conditions may be more likely to become dual eligible through disability. It is also possible that medical care, rather than prescription drug coverage, is a stronger determinant of access to antidepressants, would explain our finding, given higher provider reimbursements from Medicare compared to Medicaid.^{107,108}

Limitations

There are several limitations of these data and this study. First, most outcomes were self-reported in the WIHS over approximately six months, which may have led to misclassification or recall bias. Second, because the WIHS is a study of HIV-infected and -uninfected women, these results are limited to dual eligible women with HIV. Further, the dual eligible women in the WIHS are participants in a long-running HIV cohort study that may be associated with better care engagement and medication adherence compared to dual eligible women who are not participants in longitudinal cohort studies.

Though our use of propensity score allowed us to achieve covariate balance between the two groups, and we were able to quantify the degree of common support between the two groups, we were only able to match the two groups on measured covariates. As in all observational studies, unmeasured covariates may still confound our study results. We were also limited in the number of covariates that we could use to estimate the propensity scores due to the small sample size of dual eligibles.

Implications for Policy and Research

Implications for ADAP

This study has several implications for ADAP policy and research. First, findings from this study provide evidence for coordination between Medicare Part D and ADAP, previously indicated in reports on people with HIV and ADAP use around the time of Medicare Part D implementation.²⁷ In the context of other study results, the combination of increased out-of-pocket costs and stable medication may be due to the stabilizing effects of ADAP on dual eligibles with HIV who are transitioning to Medicare Part D. If ADAP does mitigate Medicare Part D cost-sharing, the coordination between Medicare Part D and ADAP may contribute to stable health

outcomes for people with HIV who transition to Medicare Part D and underscores the benefits of coordinated functioning between Medicare Part D and ADAP for people with HIV.

Second, the ADAP budget has historically been used to purchase and provide prescription drugs directly to people with HIV, however ADAP's role has been shifting to co-financing insurance coverage in recent years. In 2011, \$1.5 billion of the ADAP budget was dedicated to direct provision of prescription drugs and providing medications to ADAP clients made up 79% of ADAP expenditures.⁵⁸ By contrast, only 16% of ADAP expenditures went towards insurance premiums, deductibles, and co-payments in that year. The coordination between ADAP and Medicare Part D at implementation was a demonstration of ADAP's shifting role from direct provision of prescription drugs to ADAP covering Medicare Part D prescription drug co-payments. Our findings indicate that Medicare Part D did result in an increased use of ADAP and support the need for future studies on whether that increase stabilizes medication use by mitigating OOP spending for dual eligibles with HIV. As the role of ADAP continues to develop, this study provides evidence of increased ADAP use after Medicare Part D implementation when ADAP shifted from direct provision of medication to co-financing dual eligibles' medication access in combination with a primary payer such as Medicare Part D. These coordinated efforts may have safeguarded this vulnerable population from medication disruption in the initial transition to Medicare Part D and may continue to mitigate the effects of cost-sharing for the people with HIV who have enrolled in Medicare Part D since 2006.

Implications for Medicare Part D

Although our findings are restricted to Medicare Part D implementation in 2006, these results may generalize to people with HIV who are transitioning from being Medicaid-only to being dual eligible at any point after 2006. Since implementation of Medicare Part D, when people with HIV covered by Medicaid only eventually meet the eligibility criteria for Medicare, they become dual eligible, lose their prescription drug coverage through Medicaid, and are enrolled in Medicare Part D. In other words, this study examined a transition that happened to all dual eligibles with HIV in 2006, but individuals with HIV continue to experience that same transition as they become eligible for Medicare on top of their Medicaid enrollment in the years following Medicare Part D implementation. If these findings extend beyond the initial implementation in 2006 and generalize

to all transitioning dual eligibles, they indicate that dual eligibles may be relying on programs outside of Medicare Part D to maintain stable medication access and reduce the sudden increase in OOP costs that they experience.

Implications for the ACA

Following the implementation of the ACA in 2014, many people with HIV are using health insurance exchanges to gain insurance coverage. Health insurance exchanges share several key similarities with Medicare Part D. Both are instances in which the federal government contracts with private insurance plans, where the federal government sets general standards that plans must adhere to but within those guidelines can vary widely on cost-sharing and utilization management strategies. Both health insurance exchanges and Medicare Part D provide a range of plans under the assumption that consumers select prescription drug plans that maximize access to needed services and minimize costs. An additional, crucial similarity is that the ACA allows ADAP to provide similar wraparound benefits for people with HIV as ADAP provided for dual eligibles under Medicare Part D, covering premiums and co-payments for prescription drugs. Given the similarities between the two avenues to accessing insurance coverage, our findings highlight the importance of ADAP during coverage transitions and indicate an advantage to coordination and co-financing with ADAP.

Research Implications

In addition to implications for policy, this study has implications for future research on dual eligibles. First, this study was limited to the 2006 transition of dual eligibles, and future studies should move beyond studying Medicare Part D implementation by examining the effects of the transition from Medicaid to Medicare Part D when Medicaid-only participants become dual eligible at any point in time after 2006. In other words, instead of examining the transition of all dual eligibles from Medicaid to Medicare Part D, future studies would examine that same transition in individuals as they move from being enrolled in Medicaid-only to being dual eligible after 2006 and, consequently, move from prescription drug coverage through Medicaid to prescription drug coverage through Medicare Part D. By examining transitioning individuals after Medicare Part D implementation, these studies will be able to triangulate the effects of prescription drug coverage versus medical and prescription drug coverage because the transitioning population will receive

both prescription drug coverage and medical coverage through Medicaid pre-transition, unlike the dual eligibles in this study, who received prescription drug coverage through Medicaid and medical coverage through Medicare in the pre-Medicare Part D time period. Longitudinal WIHS data collection in the WIHS lends itself well to the study of individual transitions from one insurance type to another because study visits occur at six-month intervals and the same individuals are followed over time.

Second, descriptive findings in this study revealed interesting discrepancies between the prevalence of antidepressant use among dual eligibles compared to Medicaid-only enrollees, despite similar levels of depressive symptoms. Further research examining the relationship between dual eligibility and Medicaid-only coverage over time may shed light on the associations between coverage type and access to psychotropic medications. The WIHS' longitudinal data also allows for a more nuanced exploration of the differences in antidepressant use between HIV-infected dual eligibles and Medicaid-only enrollees, which we observed in the pre-Medicare Part D time period in Aim 2. Building off of this study, we plan to examine differential antidepressant use in the pre-Medicare Part D time period, when both Medicaid-only and dual eligibles received prescription drug coverage through Medicare. We will explore the temporal relationships between insurance coverage, antidepressant use, and depressive symptoms, restricting to WIHS visits before 2006 and focusing on dual eligibles and Medicaid-only participants.

Conclusion

Our findings show an increase in the proportion of dual eligibles with HIV reporting out-of-pocket costs following the implementation of Medicare Part D. The increase in costs was sustained over several years following implementation. In addition to an increased proportion of dual eligibles reporting out-of-pocket costs, dual eligibles also reported increase ADAP use, pointing toward coordination between Medicare Part D and ADAP. However, medication use, health outcomes, and health service use were stable following Medicare Part D implantation. Although there are several possible interpretations for increased costs and stable medication use and health outcomes, the increase in ADAP use underscores that safety-net programs such as ADAP may be vital in ensuring continuous coverage of both ART and antidepressants following insurance transitions, as OOP costs can be affected by policy changes. The protective feature of

ADAP covering medication copayments, and its apparent coordination with Medicare Part D may be applicable to people with HIV as they transition from Medicaid to private prescription drug coverage using health insurance exchanges.

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