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Impact of the Medicare Part D coverage gap on prescription drug utilization and medication adherence

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by

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DISSERTATION

Submitted in Partial Fulfillment of the Requirements for the Degree of

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DEDICATION

To Anoop, for all his love and support.

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ABSTRACT

The standard Medicare prescription drug benefit includes a coverage gap ($3,850 in true out-of-pocket expenses in 2007) during which beneficiaries pay 100% of their drug costs. The objective of this study was to assess the impact of the Medicare Part D coverage gap on prescription drug utilization and medication adherence by using data from Medicare beneficiaries enrolled in a large health plan in New Mexico.

A quasi-experimental, cross-sectional, retrospective, pre-post with control group study design was used to assess the study objectives. Pre- and post-coverage gap prescription drug utilization and medication adherence, of beneficiaries enrolled in a health plan with no prescription drug coverage during the coverage gap (no coverage plan) was compared with that of beneficiaries enrolled in a plan with generic drug coverage (generic coverage plan) and beneficiaries enrolled in a plan with full prescription drug coverage during the coverage gap (full coverage plan). Pre- and post-

coverage gap prescription drug utilization was assessed using per member total number of prescriptions. Medication Possession Ratio (MPRm) and the Proportion of Days Covered (PDC) were used as measures of medication adherence. Difference-in difference analysis was used to compare pre- and post-coverage gap prescription drug utilization and medication adherence between the three plans.

Of the 14,846 beneficiaries who met the study inclusion and exclusion criteria, 2,661 beneficiaries (17.92%) hit the prescription coverage gap in the year 2007. Difference-in-difference analyses indicated that post-coverage gap, beneficiaries enrolled in the no coverage gap plan, filled significantly less number of prescriptions (14.67 prescriptions less; p=0.001) than beneficiaries in the full coverage plan, and generic coverage plan (12.52 prescriptions less; p=0.001). A significant decrease in post-coverage gap medication adherence was observed between beneficiaries in the no coverage versus full coverage plans for beneficiaries on statins (5.8%), ARB's (16%) and PPI's (18.1%) when measured using the PDC as a measure of adherence. Similarly, a decrease in post-coverage gap medication adherence was observed between beneficiaries in the no coverage versus generic coverage plans for beneficiaries on statins (1.1%) and ARB's (12%) when measured using the PDC as a measure of adherence. No significant post-coverage gap differences were observed between beneficiaries enrolled in the full coverage plan and generic coverage plan for any of the drug classes.

In conclusion, the results of this study indicate that lack of prescription drug coverage during the Medicare Part D coverage gap leads to decreased utilization and adherence to certain essential prescription drugs.

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CHAPTER 1

INTRODUCTION

Medicare

Medicare, a federal insurance program established in 1965, provides health insurance to Americans aged 65 and older and to individuals under age 65 with certain disabilities or end-stage renal disease. (Centers for Medicare and Medicaid Services, 2008a) In 2008, 44 million elderly and disabled Americans, accounting for 15% of the total US population, were eligible for Medicare benefits. (Kaiser Family Foundation, 2008) Prior to 2006, Medicare included three parts - Part A, B and C. In 2006, a prescription drug benefit, referred to as 'Medicare Part D', was introduced.

Medicare Part A, also referred to as hospital insurance, covers inpatient care in hospitals, skilled nursing facilities, hospice care services and home health care services. (Centers for Medicare and Medicaid Services, 2008a) Medicare Part B, also referred to as medical insurance, includes coverage for medically necessary services (such as outpatient care, emergency room services) and some preventive services not covered under Part A. Medicare Part C, also referred to as Medicare Advantage, includes coverage provided by private health insurance companies which contract with the federal government to provide Medicare Part A and B services and typically cover additional benefits such as prescription drug coverage, vision, dental, extra days in hospitals, etc. (Centers for Medicare and Medicaid Services, 2008a) Medicare Part D, also referred to as Medicare prescription drug coverage, includes prescription drug coverage for all Medicare

beneficiaries.

Medicare Part D: The need for prescription drug coverage

In 2002, about 90% of Medicare beneficiaries' were prescribed at least one prescription drug and 30% had three or more chronic conditions requiring prescription drugs. (J Cubanski, Voris, Kitchman, Neuman, & Potetz, 2005) Nearly 45% of Medicare beneficiaries lacked a full year of prescription drug coverage in 2002 and reported about $1,000/year in average out-of-pocket (OOP) expenses on prescription drugs. Further, nearly half of all Medicare beneficiaries had incomes below 200 percent of the federal poverty level (FPL). (J Cubanski, et al., 2005) The statistics presented above define four principal characteristics of Medicare beneficiaries in 2002: 1) they had a disproportionate need for prescription drugs 2) the majority lacked a full year of prescription drug coverage 3) incurred high OOP expenses (relative to their income) and 4) had limited financial resources.

To increase Medicare beneficiaries' access to medications and help lower their prescription drug costs, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 introduced a prescription drug benefit for all Medicare beneficiaries. (Centers for Medicare and Medicaid Services, 2004) Beginning January 1, 2006, this voluntary outpatient prescription drug benefit, commonly referred to as 'Medicare Part D', was made available to all individuals entitled to Medicare Part A or enrolled in Medicare Part B. (Centers for Medicare and Medicaid Services, 2004)

Medicare prescription drug plans

Medicare beneficiaries can obtain Part D benefits either by enrolling in a prescription drug plan or a Medicare Advantage prescription drug plan. Beneficiaries enrolled in the traditional fee-for-service Medicare (Part A and B enrollees) can receive Medicare Part D benefits from prescription drug plans (PDP).(Centers for Medicare and Medicaid Services, 2004; Department of Health and Human Services, 2008) Prescription drug plans are stand-alone plans, that is, these plans only provide prescription drug coverage. Medicare Advantage prescription drug (MA-PD) plans are prescription drug plans offered for beneficiaries enrolled in Medicare Advantage (Medicare Part C) plans. All PDP and MA-PD plans are required to offer a prescription drug benefit that is either based on a standard benefit structure established by the MMA or is actuarially equivalent to the standard benefit structure. Details about PDP and MA-PD plans will be discussed in the next chapter.

Standard Medicare Part D benefit structure

In 2007, the standard Medicare prescription drug benefit included a $265 deductible and 25% coinsurance up to an initial coverage limit of $2,400 in total drug costs. (Kaiser Family Foundation, 2007c) After the initial coverage limit of $2,400 in total drug costs, Medicare offers no coverage until beneficiaries reach $5,451 in total drug costs ($3,850 in true out-of-pocket expenses). During this gap referred to as the 'coverage gap' or the 'doughnut hole', beneficiaries pay 100% of their drug costs. For drug spending above $5,451, referred to as the catastrophic coverage limit, beneficiaries are responsible for a greater of $2/$5 (for generics/brand) co-payments or 5% coinsurance on the amount they spend on prescription drugs.

Medicare Part D Coverage Gap

Initiation of Medicare Part D increased prescription drug coverage and provided financial assistance for a large number of Medicare beneficiaries. One study indicated that Medicare Part D decreased out-of-pocket prescription drug expenditures by 13% and increased prescription utilization by about 6%. (Yin et al., 2008) However, certain aspects of the Part D benefit structure such as cost-sharing requirements and the coverage gap have been controversial issues. Medicare Part D has been structured to include substantial cost-sharing from beneficiaries in the form of deductibles, co-payments and tiered payments. A literature review indicates that elderly patients are price responsive to cost-sharing for prescription drugs, with an estimated price elasticity of -0.2 to -0.6, indicating that a 10% increase in cost-sharing would lead to a 2-6% reduction in utilization of prescription drugs. (Chandra, Gruber, & McKnight, 2007; Gilman & Kautter, 2008; Johnson, Goodman, Hornbrook, & Eldredge, 1997; Pauly, 2004; Tamblyn et al., 2001a) In addition to deductibles and co-insurance, the Medicare Part D coverage gap, during which beneficiaries are required to pay 100% of drug costs, constitutes the highest cost-sharing component.

The coverage gap creates a situation where a beneficiary has no prescription drug coverage. Lack of prescription drug coverage has been associated with decreased medication adherence and higher out-of-pocket expenses, with more pronounced effects for low income and ethnic minorities. (Safran et al., 2005; S. Soumerai et al., 2006; Steinman, Sands, & Covinsky, 2001; Stuart & Grana, 1998) High costs of medications have also been reported to be predictors of poor medication adherence. (National Council on Patient Information and Education, 2007; Osterberg & Blaschke, 2005; P. Rogers &

Bullman, 1995) Poor medication adherence due to the high costs of prescription drugs has been associated with adverse health outcomes, increased hospitalizations and patients perceiving their health as poor. (Cramer JA et al., 2008; DiMatteo MR, Giordani PJ, Lepper HS, & Croghan TW, 2002; Osterberg & Blaschke, 2005; Rector & Venus, 2004)

The Medicare Part D coverage gap also mirrors the prescription drug benefit caps commonly instituted in supplementary Medicare prescription drug plans. Prescription benefit caps have been reported to decrease Medicare beneficiaries' prescription utilization by about 8-30%, decrease medication adherence and increase hospitalizations and emergency room visits. (R Balkrishnan, Byerly, Camacho, Shrestha, & Anderson, 2001; Cox & Henderson, 2002; Hsu et al., 2006; Joyce, Goldman, Karaca-Mandic, & Zheng, 2007; Tseng, Brook, Keeler, Steers, & Mangione, 2004)

In summary, cost-sharing associated with prescription drugs has been associated with decreased prescription drug utilization and adverse clinical and economic outcomes. Based on pharmacy claims data from 1.9 million Medicare beneficiaries, a Kaiser Family Foundation study reported that 14% of Part D enrollees (3.4 million Medicare beneficiaries) reached the coverage gap in 2007. (Hoadley J et al., 2007) Further, the study also reported that 72% PDP and 68% MA-PD plans did not offer any gap coverage in 2007.

The need for this study

Given the large number of Medicare Part D beneficiaries who hit the coverage gap, do not have any prescription drug coverage during the coverage gap and the potentially adverse clinical and economic outcomes associated with decreased prescription utilization and medication adherence, it is important to empirically analyze

the impact of the Medicare Part D coverage gap on prescription utilization and medication adherence. It is important to assess if Medicare beneficiaries exhibit different prescription drug utilization and medication adherence prior to the Medicare Part D coverage gap and during the coverage gap.

The current literature provides limited evidence on the impact of the coverage gap on prescription drug utilization and medication adherence. Using pharmacy claims data, Sun and Lee reported that after reaching the coverage gap, prescription drug utilization decreased by 15.85% and out-of-pocket expenses increased by 88.94%. (F. R. Lichtenberg & Sun, 2007) However, caution should be exercised when interpreting these results as the authors assumed a fixed month, June, as the month beneficiaries hit the coverage gap versus using actual coverage gap dates and referred to the period January-June as the pre-coverage period and the period July to December as the post-coverage gap period. One study based on 2006 data from a large health plan in Pennsylvania reported that prescription drug utilization of beneficiaries with no coverage during the coverage gap was 14% lower compared to beneficiaries with full coverage during the gap. (Zhang, Donohue, Newhouse, & Lave, 2009)

A 2007 Kaiser Family Foundation study, based on pharmacy claims data for 1.9 million Medicare beneficiaries, reported that 20% of the beneficiaries who reached the coverage gap either stopped taking their medications, switched to another medication in the same class, or reduced the number of medications they were taking within the same therapeutic class. (Hoadley J, et al., 2007) Similar results of decreased medication adherence were reported in a survey of Medicare beneficiaries enrolled in a Kaiser Permanente Colorado Medicare Advantage plan. (Cronk, Humphries, Delate, Clark, &

Morris, 2008) Beneficiaries with no gap coverage were nearly five times more likely than beneficiaries with gap coverage to report using a medication cost-lowering strategy such as using less medication than was prescribed or stop taking medication during the coverage gap.

Raebel et al., (2008) used data from two Kaiser Permanente Colorado health plans and reported that beneficiaries who reached the coverage gap had an 85% greater likelihood of inpatient hospitalizations; 60% greater likelihood of ED visit and 12% greater likelihood of office visits compared to beneficiaries who did not reach the coverage gap. (Raebel, Delate, Ellis, & Bayliss, 2008) Further, during the coverage gap, significant reduction in adherence to anti-hyperlipidemics, anti-hypertensives, and anti-depressants was reported.

In summary, a number of studies assessing the impact of Medicare Part D coverage gap on prescription drug utilization and medication adherence are descriptive in nature (Cronk, et al., 2008; Hoadley, Hargrave, Cubanski, & Neuman, 2008). Studies which are based on retrospective claims data either include health plan data and lack direct comparison with a control group (Raebel, et al., 2008); or include a control group and lack health plan data or do not control for selection bias. (Zhang, et al., 2009) Studies are also limited by assumptions of a pseudo coverage gap month. (F. R. Lichtenberg & Sun, 2007)

Therefore, despite evidence of potentially adverse clinical and economic outcomes associated with the lack of prescription drug coverage; an elderly population with disproportionately high need of prescription drugs, high OOP expenses (relative to their income) and limited financial resources, the current literature does not include

methodologically robust studies assessing the impact of the coverage gap on Medicare beneficiaries' utilization of prescription drugs and medication adherence. This study uses a methodologically robust research design which enables control of not only demographic and health plan characteristics but more importantly controls for the effect of time and within person variations while comparing with a control group by using robust econometric analyses. In using a methodologically robust study design with appropriate control of confounding factors, this study will bring forth, the much needed assessment of the impact of lack of prescription drug coverage during the Medicare Part D coverage gap on Medicare beneficiaries' prescription drug utilization and medication adherence.

Medicare in New Mexico

With Medicare part D data not released by CMS, impact of the Medicare Part D coverage gap cannot be assessed in a national sample of Medicare beneficiaries. In the absence of availability of Medicare data at a national level, use of Medicare data from local health plans might provide a reasonable estimate of the impact of Medicare Part D coverage gap on prescription drug utilization and medication adherence. For the purposes of this study, data from Medicare beneficiaries enrolled in a large health plan in New Mexico was used. To ensure that data from New Mexico Medicare beneficiaries would provide a reasonable estimate of the impact of Part D coverage gap on all Medicare beneficiaries', demographics and eligibility statistics of New Mexico Medicare beneficiaries were compared with that of Medicare beneficiaries in the Unites States.

As of February, 2009, 15% (292,603) of the total population in the state of New Mexico received Medicare benefits. Similarly, 15% of total US population received Medicare benefits in 2009. In 2007, three-quarters of New Mexico Medicare beneficiaries were 65 years or older (compared to 83% in US); 55% were female (compared to 57% in US); 39% were Hispanic (compared to 7% in US); and nearly half (48%) were living below 200% of the Federal Poverty Level (compared to 47% in US). (Kaiser Family Foundation, 2007e, 2007f, 2007g, 2007h) In 2008, of the 292,636 New Mexico Medicare beneficiaries eligible to receive Part D benefits, nearly 40% were enrolled in stand alone PDP plans (compare to 39% in US); 22% were enrolled in MA-PD plans (compared to 20% in US); 6% were enrolled in employee plans taking retiree drug subsidies (compared to 13% in US); and nearly 16% received some other form of prescription drug coverage (compared to 13% in US).(Kaiser Family Foundation, 2009) About 85% (251,768) of the Medicare beneficiaries eligible to receive Part D benefits had known creditable drug coverage, that is, had coverage that meets or exceeds the actuarial value of standard Part D coverage in 2009 (compare to 86% in US). (Kaiser Family Foundation, 2009)

Given that Medicare Part D data has not been released by CMS and demographics and eligibility statistics of New Mexico Medicare beneficiaries are very similar to Medicare beneficiaries in the Unites States except for the distribution based on ethnicity, the results from this study will provide a reasonable estimate of the impact of Medicare Part D coverage gap on Medicare beneficiaries' prescription drug utilization and medication adherence.

The purpose of this study is thus to assess the impact of the Medicare Part D coverage gap on prescription drug utilization and medication adherence by using data from beneficiaries enrolled in a large health plan in New Mexico. The specific objectives of this study are as follows.

Study Objectives and Hypotheses

Prescription Drug Utilization

1. To compare prescription drug utilization of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap with prescription drug utilization of Medicare beneficiaries enrolled in a plan providing no prescription drug coverage during the coverage gap.
   Ho: There is no difference in prescription drug utilization of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap and prescription drug utilization of Medicare beneficiaries enrolled in a plan providing no prescription drug coverage during the coverage gap.

2. To compare prescription drug utilization of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan covering generic drugs during the coverage gap with prescription drug utilization of Medicare beneficiaries enrolled in a plan providing no prescription drug coverage during the coverage gap.
   Ho: There is no difference in prescription drug utilization of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan covering generic drugs during the coverage gap and prescription drug utilization of Medicare beneficiaries

enrolled in a plan providing no prescription drug coverage during the coverage gap.

3. To compare prescription drug utilization of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap with prescription drug utilization of Medicare beneficiaries enrolled in a plan covering generic drugs during the coverage gap.

   Ho: There is no difference in prescription drug utilization of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap and prescription drug utilization of Medicare beneficiaries enrolled in a plan covering generic drugs during the coverage gap.

4. To compare medication adherence (to select drug classes) of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap with medication adherence of Medicare beneficiaries enrolled in a plan providing no prescription drug coverage during the coverage gap.

   Ho: There is no difference in medication adherence (to select drug classes) of a sample of New Mexico Medicare beneficiaries enrolled in a plan with full prescription drug coverage during the coverage gap and medication adherence of Medicare beneficiaries enrolled in a plan providing no prescription drug coverage during the coverage gap.

5. To compare medication adherence (to select drug classes) of a sample of New

Mexico Medicare beneficiaries enrolled in a Medicare Part D plan covering generic drugs during the coverage gap with medication adherence of Medicare beneficiaries enrolled in a plan providing no prescription drug coverage during the coverage gap.

Ho: There is no difference in medication adherence (to select drug classes) of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan covering generic drugs during the coverage gap and medication adherence of Medicare beneficiaries enrolled in a plan providing no prescription drug coverage during the coverage gap.

6. To compare medication adherence (to select drug classes) of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap with medication adherence of Medicare beneficiaries enrolled in a plan covering generic drugs during the coverage gap.

   Ho: There is no difference in medication adherence (to select drug classes) of a sample of New Mexico Medicare beneficiaries, enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap and medication adherence of Medicare beneficiaries enrolled in a plan covering generic drugs during the coverage gap.

CHAPTER 2

LITERATURE REVIEW

This chapter provides a review of the literature as related to topics of significant importance to this study. The literature review is divided into four major sections: 1) an overview of Medicare, 2) Medicare and cost-sharing, 3) medication adherence and 4) theoretical framework used to conduct the study.

Section I begins with an overview of Medicare Parts A, B, and C with description of eligibility requirements, enrollment rates, cost and financing of each of the three Medicare parts. Next, the need to introduce Medicare Part D is described, followed by a description of Medicare Part D eligibility requirements, enrollment rates, types of Medicare Part D plans and the standard Medicare prescription drug benefit structure.

Section II of this chapter includes an overview of the literature surrounding Medicare and cost-sharing, beginning with a description of the concept of cost-sharing. Next, the impact of cost-sharing in Medicare on health care utilization is described with reference to six key topics: i) impact of Medicare eligibility on utilization of health care services ii) impact of prescription drug coverage on Medicare beneficiaries' prescription drug utilization, medication adherence and health care utilization iii) impact of changes in co-payments on Medicare beneficiaries' prescription drug utilization, medication adherence and health care utilization iv) impact of prescription benefit caps on Medicare beneficiaries' prescription drug utilization, medication adherence and health care utilization v) impact of Medicare Part D on Medicare beneficiaries' prescription drug utilization, medication adherence and health care utilization and vi) impact of Medicare

Part D coverage gap on Medicare beneficiaries' prescription drug utilization, medication adherence and health care utilization.

Section III is dedicated to medication adherence and includes descriptions related to definition of adherence, factors affecting medication adherence, measurement of medication adherence and adherence measures used in this study. Section IV describes the theoretical framework used in this study. Finally, a summary of literature review is provided.

PART I: AN OVERVIEW OF MEDICARE

Medicare, a federal insurance program, established in 1965 under Title XVIII of the Social Security Act, provides health insurance to Americans aged 65 and older and to individuals under age 65 with certain disabilities or end-stage renal disease. (Centers for Medicare and Medicaid Services, 2008a) In 2008, about 44.2 million elderly and disabled Americans, accounting for 15% of the total US population, were eligible for Medicare benefits. (Kaiser Family Foundation, 2008)

Medicare was initially established (in 1965) to only include individuals aged 65 or older. (Kaiser Family Foundation, 2007d) In 1972, Medicare eligibility was expanded to include individuals under age 65 with permanent disabilities and End-Stage Renal Disease (ESRD). In 2001, the program was expanded to cover individuals with Lou Gehrig's disease.(Kaiser Family Foundation, 2007d) In 2007, Medicare eligibility required an individual to be a citizen or permanent resident of the United States; over age 65; or under age 65 and a Social Security Disability Insurance beneficiary (individuals with a medical determination of disability by Social Security); or under age 65, with

ESRD or Lou Gehrig's disease. (Centers for Medicare and Medicaid Services, 2008b; Social Security Administration, 2008) In 2007, of the nearly 44 million Medicare beneficiaries, 37 million qualified to receive Medicare benefits based on their age (65 and older) and 7 million qualified to receive Medicare benefits due to disabilities or covered disease states (under 65). (Kaiser Family Foundation, 2007d)

Medicare consists of four parts: Part A, B, C and D. Medicare Part A covers inpatient care in hospitals, skilled nursing facilities, hospice care services and home health care services. (Centers for Medicare and Medicaid Services, 2007) Medicare Part B covers physicians' services and outpatient care. Medicare Part C includes coverage for all Medicare Part A and B services and typically includes additional benefits such as vision, hearing, dental, prescription drug coverage, extra days in hospitals, etc. Medicare Part D is an outpatient prescription drug benefit made available to all individuals entitled to Medicare Part A or enrolled in Medicare Part B. Detailed coverage, eligibility requirements and costs associated with Medicare Part A, B, C and D are provided below.

Medicare Part A

Medicare Part A also referred to as hospital insurance, covers inpatient care in hospitals, including care in critical access hospitals (small facilities that give limited outpatient and inpatient services to people in rural areas), and skilled nursing facilities (not custodial or long-term care). Medicare Part A also covers hospice care and some home health care. In 2007, about 43.7 million individuals were entitled to receive Medicare Part A benefits. (Kaiser Family Foundation, 2007d)

Eligibility: Individuals 65 years of age or older are entitled to receive premium free Part A if they are a citizen or permanent resident of the United States and they are either receiving or are eligible to receive benefits from either Social Security or the Railroad Retirement Board or had Medicare-covered government employment; or they (or their spouse) worked for at least 10 years in Medicare-covered employment. Individuals under the age of 65 who have received disability benefits from Social Security or Rail Road Retirement Board for 24 months; or under age 65 with ESRD or Lou Gehrig's disease are eligible to receive premium free Medicare Part D benefits. Individuals not eligible to receive premium free Medicare Part A can purchase it.

Enrollment: Individuals with Social Security or Rail Road retirement benefits or disabled individuals are auto enrolled in Medicare Part A. Individuals with Social Security or Rail Road retirement benefits receive their Medicare card about 3 months before their 65th birthday, disabled individuals receive Medicare benefits on the 25th month of disability; and individuals with ESRD or Lou Gehrig's disease receive Part A the month their disability benefits begin. (Centers for Medicare and Medicaid Services, 2008a)

Individuals not eligible for premium-free Part A, can purchase Medicare Part A either during a 7-month initial enrollment period (which begins 3 months before the individuals 65th birthday and ends 3 months after the individuals 65th birthday); or during the general enrollment period from January 1st–March 31st each year. Individuals receiving health coverage through their (or their spouse's) employer or union can purchase Part A anytime while they are covered under the employer's health plan or during a special enrollment period. The special enrollment period lasts for a 8-month

period that begins the month the employment ends, or the health plan coverage ends, whichever happens first. (Centers for Medicare and Medicaid Services, 2008a)

Cost: In 2007, individuals who were not eligible to receive premium free Part A could purchase it by paying a monthly premium of $410.

Financing: Part A is funded by Medicare taxes with employers and employees each contributing 1.45% of earnings. (Kaiser Family Foundation, 2007b) In 2006, Medicare Part A contributed to about 40% of the total Medicare spending. (Kaiser Family Foundation, 2007d)

Medicare Part B

Medicare Part B, also referred to as medical insurance, includes coverage for medically necessary and some preventive services not covered under Part A. These include physicians' services, outpatient care (including outpatient mental health care), emergency room services, urgently needed services (ambulance services, blood, etc) kidney dialysis and services, some preventive services (bone mass measurement, cardiovascular screening, colorectal cancer screening, diabetes screening, mammograms, pap test, prostate cancer screenings, smoking cessation services, vaccinations, etc) and other medically necessary services (laboratory and diagnostic tests, diabetes supplies, durable medical equipment, occupational therapy, physical therapy, etc). (Centers for Medicare and Medicaid Services, 2008a) In 2007, approximately 40.6 million beneficiaries enrolled in Medicare Part B. (Kaiser Family Foundation, 2007d)

Eligibility: Beneficiaries enrolled in Medicare Part A are automatically enrolled in Medicare Part B unless they specifically decline enrollment in Part B. (Kaiser Family

Foundation, 2007d) About 95% of beneficiaries who enroll in Medicare Part A also enroll in Medicare Part B. Individuals over the age of 65, not enrolled in Medicare Part A, can enroll in Medicare Part B if they are a US citizen or have lived lawfully in the US for at least 5 years. (Social Security Administration, 2008)

Enrollment: Beneficiaries can enroll in Medicare Part B during three periods: initial enrollment period, special enrollment period and general enrollment period. Initial enrollment period includes a 7-month period which begins 3 months before the beneficiary's 65th birthday and ends 3 months after the beneficiary's 65th birthday. (Centers for Medicare and Medicaid Services, 2007; Social Security Administration, 2008) Beneficiaries, who choose not to enroll in Medicare Part B during the initial enrollment period, may be subject to a late enrollment penalty unless they are eligible to enroll during the special enrollment period. The special enrollment period refers to a period of eight months following the end of qualified employer coverage. Beneficiaries who do not enroll in the initial or special enrollment can still enroll during the general enrollment period, which includes the first three months of each year (January 1st to March 31st). However, they are subject to a late enrollment penalty. The penalty is a 10% premium increase for each 12-month period that a beneficiary did not have Medicare Part B. Beneficiaries are required to pay this penalty as long as they have Part B.

Cost: To receive Part B services, beneficiaries are required to pay a deductible and a monthly premium. Medicare Part B premium amounts differ based on a beneficiary's income. A standard Part B premium is applicable to beneficiaries with annual income less than $80,000 filing an individual tax return (or income less than $160,000 for beneficiaries filing joint tax returns). In 2007, the deductible was set at $131

and the standard Part B premium was set at $93.50 per month. After the deductible, Medicare pays 80% of the costs and beneficiaries are responsible for 20% of the costs incurred. Beneficiaries with higher annual incomes are required to pay a higher monthly premium. For example, in 2007, beneficiaries with income between $80,001-100,000 filing individual tax returns (or income between $160,001-$200,000 for beneficiaries filing joint tax returns) paid a monthly Part B premium of $105.80.

Funding: General revenues of the federal government and beneficiary premiums fund Part B. (Kaiser Family Foundation, 2007b) In 2006, Part B accounted for 35% of Medicare spending. (Kaiser Family Foundation, 2007d)

Medicare Part C

Medicare Part C, also referred to as Medicare Advantage (and previously as Medicare +Choice), includes coverage provided by private health insurance companies which contract with the federal government to provide all Medicare Part A and B services and typically cover additional benefits such as vision, hearing, dental, prescription drug coverage, extra days in hospitals, health and wellness programs, etc. Medicare beneficiaries enrolled in a Medicare Advantage plan pay an additional health plan premium (in addition to their Part B premium) depending on the services covered by their plan. (Centers for Medicare and Medicaid Services, 2008a) In 2007, about 20% (8.7 million) of the Medicare beneficiaries nationwide and 59,177 Medicare beneficiaries in New Mexico were enrolled in Medicare Advantage plans. (Kaiser Family Foundation, 2007d)

There are five different types of Medicare Advantage (MA) plans from which

beneficiaries can choose from to receive Medicare Part C benefits. These include Health Maintenance Organizations (HMO), Preferred Provider Organizations (PPO), Private Fee-for-Service Plans (PFFS), Special Needs Plans (SNP), and Medical Savings Account Plans (MSA). These plans differ based on their coverage for services obtained from providers associated within the plans network (in-network) or from providers' outside of the plans network (out-of-network).

MA-HMO plans only cover services obtained from in-network providers. Beneficiaries enrolled with MA-PPO plans are covered for services from out-of-network providers, but receive a financial incentive for obtaining services from in-network providers. Beneficiaries enrolled with MA-PFFS plans may receive services from any Medicare-approved provider or hospital that accepts the plan's payment. MA-SNP plans provide coverage for beneficiaries who require more focused and specialized health care such as those who have both Medicare and Medicaid, who reside in a nursing home, or have certain chronic medical conditions. MA-MSA plan combines a high deductible health plan with a medical savings account. Beneficiaries enrolled in an MSA plan receive an annual deposit into an interest-bearing account, from the Center for Medicare and Medicaid Services (CMS), which they can use to pay for their health care costs. Beneficiaries must meet a high deductible (maximum of $9,500 in 2007), before the plan covers Medicare services. After a beneficiary reaches his/her deductible, the plan is responsible for all Medicare-covered costs. In 2007, MSA plans only covered Part A and B and did not offer any supplemental benefits. However, beneficiaries pay the same cost for receiving care from in-network or out-of-network providers. (Centers for Medicare and Medicaid Services, 2008a)

In 2007, about 71 % MA beneficiaries enrolled in local HMO and PPO plans. Of these, a majority (92%) of the beneficiaries opted to enroll in HMO plans. In order to provide beneficiaries in rural areas greater access to MA plans, the Medicare Modernization Act of 2003 established regional PPO plans in addition to local PPO plans. PFFS plans accounted for 18% of total MA enrollment in 2007. In 2007, over 930,000 beneficiaries (majority of who were dual eligible's) enrolled in SNP plans and about 2,249 beneficiaries enrolled in MSA plans.

Eligibility: Individuals entitled to Medicare Part A and enrolled in Medicare Part B are eligible to enroll in MA plan. (Centers for Medicare and Medicaid Services, 2007) However, individuals with ESRD are not eligible to enroll in MA HMO, PPO, PFFS or MSA plans. Beneficiaries with ESRD could join a MA-SNP plan if one is available in their area of service. If an individual develops ESRD while enrolled in a Medicare Advantage plan, then they can continue to be enrolled in that plan. Further, beneficiaries with successful kidney transplants are eligible to join a MA plan.

Enrollment: Beneficiaries can enroll in MA plans during the initial enrollment period which includes a 7-month period that begins 3 months before the beneficiary's 65th birthday and ends 3 months after the beneficiary's 65th birthday. Beneficiaries, who do not join during the initial enrollment period, can join a MA plan between November 15th and December 31st of each year. Beneficiaries can also join or switch MA plans during the general enrollment period, which includes the first three months of each year. (Centers for Medicare and Medicaid Services, 2007)

Managed care versus traditional Medicare

Proponents of managed care indicate that HMO plans provide greater benefits to individuals through the use of services such as preventive care and provision of additional benefits such as reduced deductibles, etc. Opponents of managed care however, contend that managed care creates barriers to access, for example through use of referrals, etc. Based on an analysis of responses to a CMS survey of approximately 500,000 Medicare beneficiaries, Landon et al (2004) reported that Medicare HMO's are better at providing preventive services while traditional Medicare provides better access to care and more patient satisfaction. (Landon, Zaslavsky, Bernard, Cioffi, & Cleary, 2004)

Characteristics of MA enrollees

The Kaiser Family Foundation released a report comparing MA plan beneficiaries with original Medicare fee for service plan beneficiaries, based on their income, ethnicity, rural versus urban enrollment and health status. (Kaiser Family Foundation, 2007a) This report was based on an analysis of the Medicare Current Beneficiary Survey (MCBS) data for the year 2005.

Income: The Kaiser Family Foundation report indicates that income levels of MA plan beneficiaries are similar to income levels of the original Medicare plan beneficiaries. The report indicates that nearly half (48%) of original Medicare and an equal number of MA plan beneficiaries (50%) live on annual incomes less than $20,000; 19% of original Medicare plan and 22% MA plan beneficiaries have income between $20,000-30,000;

and 34% of original Medicare and 28% of MA plan beneficiaries have income above $30,000.

Ethnicity: Based on the Kaiser Family Foundation report, in 2005, more White (87%) and African American (85%) beneficiaries enrolled in original Medicare plans. While only 13% White and 15% African American beneficiaries enrolled in MA plans, nearly 25% of Hispanic beneficiaries enrolled in MA plans.

Rural versus Urban enrollment: The Kaiser Family Foundation report indicated that MA plan enrollment was higher in urban metro areas compared to rural areas. In 2005, only 2 % of rural Medicare beneficiaries enrolled in MA plans while 18% of beneficiaries in urban metro areas enrolled in MA plans. However, in 2007, the number of rural Medicare beneficiaries enrolling in MA plans increased to about 7%.

Health status measures: The Kaiser Family Foundation report indicates that MA plan beneficiaries are healthier than original Medicare plan beneficiaries when compared on a number of health measures. About 29% original Medicare plan beneficiaries report that they are in fair or poor health status compared to 24% MA plan beneficiaries; 17% original Medicare plan enrollees are under age 65 and have permanent disabilities compared to 7% MA plan enrollees; and 5% of original Medicare plan beneficiaries live in nursing homes and other institutions compared to 3% MA plan beneficiaries.

Medicare Part D

Need for Medicare Part D

Based on data from the Congressional Budget Office, it has been reported that in 2000, approximately 28% of Medicare beneficiaries did not have prescription drug

coverage**.** (Pauly, 2004) Prior to 2003, despite Medicare coverage, seniors (age 65 or older) who did not qualify for federal assistance programs, may have spent up to 50% of their income on medical expenses. (Dalen & Hartz, 2005) In 2003, Medicare beneficiaries spent, on average, $2,322/year for prescription drugs and about 16% of Medicare beneficiaries incurred drug costs greater than $4,000. (Dalen & Hartz, 2005)

To increase Medicare beneficiaries' access to medications and help lower their prescription drug costs, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 introduced a prescription drug benefit for all Medicare beneficiaries. (Centers for Medicare and Medicaid Services, 2004) Beginning January 1, 2006, this voluntary outpatient prescription drug benefit, referred to as 'Medicare Part D', was made available to all eligible Medicare beneficiaries. According to the U.S. Department of Health & Human Services, in 2007, 23.9 million beneficiaries were enrolled in Medicare Part D plans, 15.2 million had creditable drug coverage (from retiree plans, TRICARE, FEHB, Veterans Administration, etc). (Kaiser Family Foundation, 2007c) However, about 4 million beneficiaries, representing about 10% of the Medicare population, despite meeting eligibility requirements, did not enroll in a plan with creditable drug coverage in 2007. (Kaiser Family Foundation, 2007c)

Eligibility: All individuals entitled to Medicare Part A or enrolled in Medicare Part B are eligible to receive Medicare Part D benefits.

Enrollment: Beneficiaries can enroll in Medicare Part D during an initial enrollment period, the special enrollment period or the annual enrollment period. (Centers for Medicare and Medicaid Services, 2007) It is important to note that, although enrollment in Medicare Part D program is voluntary, beneficiaries are subject to a penalty

for late enrollment. Beneficiaries can join the Medicare Part D program, without paying a penalty, if they enroll during the initial enrollment period (which includes a 7-month period that begins 3 months before the beneficiary's 65th birthday and ends 3 months after the beneficiary's 65th birthday). Beneficiaries are eligible to enroll in Medicare Part D, without paying a penalty, during special enrollment periods, if they move out of the service area of the plan they are in; if they have both Medicare and Medicaid; if they live in, or move into or out of an institution (like a nursing home); or if they have creditable prescription drug coverage and that coverage ends. The CMS defines creditable coverage as coverage provided through a group health plan and other specified coverage that meets or exceeds the actuarial value of standard Part D coverage. Unless covered by the initial or special enrollment periods, beneficiaries can pay the late enrollment penalty and enroll in Medicare Part D during an annual six week enrollment period, from November 15th through December 31st. The penalty for late enrollment is calculated by multiplying 1% of the national base beneficiary premium for the year ($27.35 x 1% = $.27 in 2007) by the number of full months that a beneficiary was eligible to join a Medicare drug plan but did not enroll in one. This penalty amount is added each month to the beneficiary's Medicare drug plan premium for as long as they are enrolled in Medicare Part D.

Medicare Part D plan types

Medicare beneficiaries can obtain the prescription drug benefit either by enrolling in a prescription drug plan (PDP) or from a Medicare Advantage prescription drug plan (MA-PD). Prescription drug plans (PDP) are stand-alone plans, that is, these plans only provide prescription drug coverage. Beneficiaries enrolled in the traditional fee-for-

service Medicare (Part A and B enrollees) can receive Medicare Part D benefits from a PDP. (Centers for Medicare and Medicaid Services, 2004; Department of Health and Human Services, 2008) Medicare Advantage prescription drug (MA-PD) plans are prescription drug plans offered for Medicare beneficiaries enrolled in Medicare Advantage (Medicare Part C). Beneficiaries enrolled in Medicare Advantage HMO, PPO and SNP plans can receive Part D benefits only from a MA-PD plan. However, beneficiaries enrolled in a MA-MSA or MA-PFFS plans, which do not offer qualified Part D drug coverage, can receive Part D benefits from a stand-alone PDP.

Enrollment in PDP and MA-PD plans

In 2006, PDP plans had higher enrollment rates compared to MA-PD plans (72 % PDP versus 28 % MA-PD). (Juliette Cubanski & Neuman, 2007) High enrollment in PDP plans may be explained in part by the large number of beneficiaries enrolled in the traditional FFS Medicare. Prior to 2006, 90% of Medicare beneficiaries were enrolled in the traditional FFS program. Beneficiaries in traditional FFS Medicare receive their prescription drug benefit by enrolling in a PDP plan. Further, in 2006, about 7 million low-income beneficiaries were auto-enrolled into PDP plans. Low income beneficiaries accounted for more than 40 percent of all PDP enrollees in 2006. (Juliette Cubanski & Neuman, 2007) The trend of higher enrollment in PDP plans continued through 2007. According to the U.S. Department of Health & Human Services, in 2007, of the 23.9 million Medicare Part D enrollees, 17.3 million were enrolled in stand-alone PDP plans and about 6.6 million were enrolled in MA-PD plans. (Kaiser Family Foundation, 2007c)

Cost of Medicare Part D plans

The cost of Part D plans varies from one region to another, depending on the benefit design, covered drugs, utilization management tools, etc. The monthly national base beneficiary premium for Medicare prescription drug plan, set by CMS, in 2007 was $27.35.(Centers for Medicare and Medicaid Services, 2007) The cost of PDP plans in 2007 ranged from $9.50 for a basic benefit PDP to $135.70 for a PDP with enhanced benefits. (Kaiser Family Foundation, 2007c) In 2006, nearly half of MA-PD HMO plans had no monthly premium and the average premium for MA-PD HMO plans was nearly half that of PDP plans ($16 for MA-PD versus $37 for PDP plans). (Juliette Cubanski & Neuman, 2007)

Standard Medicare prescription drug benefit

The CMS requires that all Medicare Part D plans offer beneficiaries a prescription drug benefit that is either based on a standard benefit structure or is actuarially equivalent to the standard benefit structure. In 2007, the standard Medicare prescription drug benefit included a $265 deductible and 25% coinsurance up to an initial coverage limit of $2,400 in total drug costs. (Kaiser Family Foundation, 2007c) After the initial coverage limit of $2,400, Medicare offers no coverage until beneficiaries reach $5,451 in drug costs ($3,850 in true out-of-pocket expenses). During this gap commonly referred to as the 'coverage gap' or the 'doughnut hole', beneficiaries pay 100% of their drug costs. For drug spending above $5,451, also referred to as the catastrophic coverage limit, beneficiaries are responsible for a greater of $2/$5 (generics/brand name) co-payment or 5% coinsurance on the amount they spend on prescription drugs.

In 2006, however, only seventeen percent of Part D beneficiaries were enrolled in plans offering the standard benefit structure. (Juliette Cubanski & Neuman, 2007) About half (52%) of Medicare beneficiaries were enrolled in plans which were actuarially equivalent to the standard benefit. The actuarially equivalent plans, typically, have no deductible and offer tiered co-payments for covered drugs in lieu of the 25% coinsurance in the standard Part D benefit structure. About 30% of beneficiaries were enrolled in plans which provided enhanced drug benefits, such as prescription drug coverage during the coverage gap, etc. It has also been reported that, compared to PDP plans, a higher number of MA-PD plan enrollees had enhanced coverage in 2006 (17% PDP versus 73% MA-PD).

PART II: MEDICARE AND COST-SHARING

The Medicare program (including Parts A, B and D) has been structured to include substantial cost-sharing from beneficiaries in the form of deductibles, co-payments, and tiered payments. It has been estimated that Medicare pays for less than half (45%) of the costs that beneficiaries incur annually. (Kaiser Family Foundation, 2007b)

Standard and enhanced Medicare Part D benefit structures typically incorporate some level of cost-sharing. While some plans may include a deductible ($250), most include a coinsurance (25% co-insurance in the initial coverage limit), or a co-payment ($5 for generics, $15 for brand name, etc). A majority of Part D plans include an annual prescription drug coverage cap where beneficiaries pay 100 % of drug costs.

With Medicare Part D data not released by CMS, very few studies assessing the impact of Medicare Part D cost-sharing requirements have been conducted. However, a significant body of literature has been dedicated to understanding the impact of cost-sharing on Medicare beneficiaries' prescription drug utilization, medication adherence and health outcomes before Medicare Part D was initiated. Findings from these studies may provide reasonable estimates of the impact of the cost-sharing in Medicare Part D. The following section describes the impact of cost-sharing in Medicare on health care utilization. However, in order to better understand the impact of cost-sharing on Medicare beneficiaries' health care utilization, it is important to first review the theoretical concepts underlying cost-sharing.

Concept of cost-sharing

Economic theory suggests that, in the absence of insurance, an individual's willingness to pay for goods and services is based upon their weighing the costs and benefits of the goods and the services. (Cutler, Zeckhauser, & Anthony, 2000; Remler & Greene, 2009) However, in the presence of insurance, an individual's contribution to the cost of the product might be very little to none, resulting in decreased cost-consciousness on the consumer's part and encouraging higher expenditure. This introduces the moral hazard associated with insurance. As defined by Cuter et al, "moral hazard refers to the likely malfeasance of an individual making purchases that are partly or fully paid for by others". (Cutler, et al., 2000) The concept of moral hazard suggests that individuals will use more services in the presence of insurance, than they would if they had to pay for it themselves. With respect to health insurance, moral hazard is described as individuals

using greater medical care when they have insurance compared to when they do not have health insurance.

Over-utilization of medical care, attributed to moral-hazard, has been contained by employing restrictions on both the demand and the supply side of the provision of medical care. The demand-side control includes consumers sharing in the cost of medical care. Cost-sharing reflects out-of-pocket expenses borne by individuals while seeking medical care. The most commonly used cost-sharing techniques include instituting deductibles, co-insurances, co-payments and prescription drug benefit limits. (Rasell, 1995; Remler & Greene, 2009) Co-insurance refers to a predetermined fixed percentage of total medical costs that an enrollee is responsible to pay (for example, 20% of hospital costs). Co-payment refers to a flat dollar amount, paid by an enrollee each time a medical service is accessed (for example, $10 for each physician visit). Deductibles refer to the amount an enrollee is required to pay each year before the insurance provider starts paying (for example, $250 deductible before prescription drug coverage begins). Prescription drug benefit limits, commonly referred to as 'benefit caps' or 'caps', refer to coverage provided by the insurer up to a certain fixed amount, beyond which the enrollee pays all the costs (for example, a $750 cap on prescription drug coverage). The supply-side control includes monitoring health care providers to ensure that they only provide essential medical care. This dissertation will focus on demand-side control, that is, cost-sharing techniques used to contain medical care costs.

Cost-sharing techniques have been implemented for decades to prevent over-utilization of health care services. However, one of the biggest concerns associated with cost-sharing is that while utilization of non-essential health care services might be

reduced, it might also lead to decreased utilization of essential health care services. (Fairman, 2008; Gianfrancesco, Baines, & Richards, 1994; Goldman, Joyce, & Zheng, 2007; Remler & Greene, 2009) These concerns are based on the complexities involved with making health care decisions. Health care decisions involve considerable uncertainty and trade-offs over time, and consumers might not always make the most rational decisions. To offset short-term cost of medical care, individuals might forgo essential health care, which in the long run might eventually lead to increased health care spending. For example, cost-sharing requirements might prompt individuals to forgo utilization of prescription drugs or preventive care, which might result in long term adverse health outcomes and increased hospitalizations. The literature provides ample evidence of cost-sharing resulting in individuals using fewer health care services compared to when they receive free care or are not subject to any cost-sharing. (Goldman, et al., 2007; Johnson, et al., 1997; Rice & Matsuoka, 2004) Studies conducted with different populations, in different countries, and with different levels of cost-sharing, indicate that cost-sharing reduces health care utilization and thus aids cost-containment. (Goldman, et al., 2007; S. Soumerai, Avorn, Ross-Degnan, & Gortmaker, 1987; Tamblyn et al., 2001b)

A number of studies conducted in the 1970's indicated that medical care demand was responsive to cost-sharing. However, elasticities ranging from -0.14 to -1.5 were reported, indicating that a 10 percent increase in cost-sharing would be associated with a 1.4 to 15 percent decrease in utilization of medical services. (Cutler, et al., 2000) Methodological challenges (lack of control of health insurance generosity and use of average price instead of marginal price) and the high range of elasticities prompted the

United States government to fund a social insurance experiment commonly referred to as the RAND Health Insurance Experiment (HIE).

One of the most important and the largest health insurance study ever conducted, the RAND Health Insurance Experiment (HIE), assessed the impact of cost sharing on utilization of health care services, quality of care, and health status. This landmark, multi-million dollar, randomized field trial, conducted from November 1974-January 1982 addressed two key questions in health care financing: how much more medical care will people use if it is provided free of charge and what are its consequences for their health. The HIE enrolled 3,958 individuals (belonging to 2005 families), between the ages of 14 and 61, from six sites across the United States to provide a regional and urban/rural balance.(Newhouse, 1996) The study excluded any individual who qualified or would qualify during the study period to receive Medicare benefits.

Participating families were randomized to one of fifteen types of health insurance plans: fourteen fee-for-service plans and one HMO-style group plan. Of the fourteen fee-for-service plans, one type offered free care (zero coinsurance) and the other thirteen types involved varying levels of patient cost sharing -25%, 50% or 95% cost-sharing. Three fee-for-service plans offered 25% coinsurance; three offered 50% coinsurance; three offered 95% coinsurance and three offered 25% coinsurance for all services except outpatient dental and mental health which were subject to 50% coinsurance. Out-of-pocket spending for these twelve fee-for-service plans was capped at 5, 10, or 15 % of family income or at $1,000 annually, whichever was lower. One fee-for-service plan referred to as the individual deductible plan included a 95% co-insurance for outpatient services and 0% coinsurance for inpatient services. Out-of-pocket spending for the plan

was capped at $150 per person, with a maximum of spending of $450 per family. Families assigned to the only HMO plan in the study received their care free of charge, similar to the zero percent coinsurance fee-for-service plans. Families participated in the experiment for 3–5 years. (Newhouse, 1996)

Overall, the results of the study indicated that cost sharing resulted in decreased utilization of all types of services – physician services, hospital admissions, prescriptions, dental visits, and mental health treatment. However, the reduced use of health care services were found to have little or no net adverse effect on the health of an average person. However, adverse effects of cost-sharing were reported for the economically disadvantaged (6% of the population). Economically disadvantaged poor, enrolled in free care plans, had lower blood pressure measurements, better vision, better dental health and less prevalence of serious symptoms compared to beneficiaries in co-insurance plans. (Newhouse, 1996) Specific results of the effects of cost-sharing in the RAND study are described below.

Impact of co-insurance rate on medical service utilization: As the co-insurance rates increased, the likelihood of use of any medical service decreased. It was reported that 86.8% of individuals enrolled in a free care plan used medical services compared to an utilization of 78.8% amongst those with 25 percent co-insurance plan and 67.7% amongst those with a 95 percent co-insurance plan. It was reported that cost-sharing led to an equal decrease in utilization of services deemed by experts as medically effective and medically ineffective.

Impact of co-insurance rate on spending indicated that per-person expenditure decreased with increasing co-insurance. The reduced spending with higher cost-sharing

plans was attributed to individuals using fewer services by deciding not to initiate care and not to participants finding lower prices. Beneficiaries enrolled in the 25 percent coinsurance plans spent 20% less than participants with free care, and those with 95 percent coinsurance spent about 30% less than participants with free care. However, it was observed that once a patient entered the health care system, cost sharing only modestly affected the intensity or cost of an episode of care. No differential response to health care expenditure was found across different cost sharing plans based on family income, health status, number of years of enrollment and site of the study.

Impact of co-insurance rate on prescription drug utilization indicated that like other health care services, utilization of prescription drugs decreased with increasing cost-sharing. However, significant differences in utilization between free care and co-insurance plans were reported only for anti-infectives and analgesics.

Impact of co-insurance rate on use of preventive services indicated that cost-sharing resulted in a decrease in the number of preventive services used. For example, among women 45 to 65 years of age, cost sharing reduced the use of pap smears from 65 percent to 52 percent over a three-year period. However, although a significant difference in utilization of preventive services was reported between the free care and co-insurance plans, the percentage of people using any preventive service in the free care plan was only marginally higher than the co-insurance plan.

Participants assigned to the HMO-style group plan were reported to have 39% fewer hospital admissions compared to participants with free care in the fee-for-service system, but they had similar use of outpatient services. Reduced hospitalization rates in the HMO group were attributed to possibly a more intensive out-patient treatment by

HMO's compared to fee-for-service plans. However, no significant differences in health outcomes were found between the HMO and the fee-for-service groups. (Newhouse, 1996)

Given the scope, methodological robustness and length of time over which the RAND HIE was carried out, it has often been referred to as a 'gold standard' for studies assessing the impact of insurance. Results of the RAND study indicated that while cost-sharing reduced utilization of all medical services and decreased spending it did not have adverse effects on the health of an average individual. While the HIE had immense health policy implications, the study did not focus on elderly (over age 65). The following sections describe the impact of cost-sharing as related to the Medicare population with reference to six key topics: a) impact of Medicare eligibility on utilization of health care services b) impact of prescription drug coverage on Medicare beneficiaries' prescription drug utilization, medication adherence and health care utilization c) impact of changes in co-payments on Medicare beneficiaries' prescription drug utilization, medication adherence and health care utilization d) impact of prescription benefit caps on Medicare beneficiaries' prescription drug utilization, medication adherence and health care utilization e) impact of Medicare Part D on prescription drug utilization, medication adherence and health care utilization and f) impact of Medicare Part D coverage gap on prescription drug utilization, medication adherence and health care utilization.

Impact of cost-sharing in Medicare on health care utilization

a) **Impact of Medicare eligibility on utilization of health care services**

Medicare provides a valuable source of health insurance to retirees, previously uninsured individuals and individuals with less comprehensive insurance coverage before Medicare eligibility. Studies have been conducted to assess the impact of Medicare eligibility on utilization of health care services. (Card, Dobkin, & Maestas, 2004; Lichtenberg 2002; McWilliams, Meara, Zaslavsky, & Ayanian, 2007)

Using data from the Health and Retirement Study, Baker et al., assessed the impact of gaining Medicare coverage on overall health and physical functioning for previously uninsured (no insurance before age 65) and previously insured (had private insurance before age 65) individuals. (Baker et al., 2006) Data was collected for previously uninsured and previously insured individuals at three time points: two years before age 65 (t_{-2}), at age 65 (t_0) and 2 years after age 65 (t_2). Changes in overall health were reported for 2 periods: t_{-2} to t_0 and t_0 to t_2. In the time between t_{-2} to t_0, previously uninsured adults reported poor overall health (adjusted relative risk 1.46; 95% CI: 1.03 to 2.04), developing physical difficulty affecting mobility (ARR 1.24; 95% CI: 0.96 to 1.56) and poor agility (ARR 1.33; 95% CI: 1.12 to 1.54), when compared to previously insured individuals. However, after 2 years of receiving Medicare benefits (t_0 to t_2), no difference in overall health and physical functioning was observed between previously uninsured and previously insured individuals.

McWilliams et al (2007), also used data from the Health and Retirement Study and reported that previously uninsured individuals with cardiovascular disease or diabetes reported significant improvements in self-reported health status measures upon receiving Medicare eligibility. (McWilliams, et al., 2007) Compared to individuals with insurance (n=3103), previously uninsured individuals with cardiovascular disease or diabetes (n=

1340), reported significantly improved trends in general health status (differential change in annual trend, +0.26; p = .006), change in general health (+0.02; p= .03), mobility (+0.04; p= .05), agility (+0.08; p = .003); and adverse cardiovascular outcomes such as MI, CHF, etc (–0.015; p = .02) upon Medicare eligibility.(McWilliams, et al., 2007) However, no significant differences were found between the two groups in depressive symptoms (+0.04; p = 0.32). (McWilliams, et al., 2007)

Litchenberg (2002) compared Medicare beneficiaries' hospital discharges, physician visits, and days spent in bed before and after the onset of Medicare benefits. (F. Lichtenberg, 2002) Using data from the National Hospital Discharge Survey for the period 1979-92, Litchenberg (2002) reported trends in hospital discharges as individual's progressed from age 62 to 74. Frequency of hospital discharges were reported to have remained constant over the age 62-64, increased by 9.5% between the ages 64 and 65 and increased by about 0.5% per year between ages 65-74. Using data from the National Ambulatory Medical Care Surveys for the period 1973-1998, Litchenberg reported that the number of physician visits increased by about 2.7% per year from age 65 to 75 and the number of physician visits where at least one drug was prescribed increased by 11.3% from age 64 to age 65. Analysis of data from the National Health Interview Survey for the period 1987-91, indicated that the mean number of days spent in bed (a morbidity measure) over a 12 month period were lower for ages 65-69 compared to ages 60-64 (9.21 versus 9.29 respectively). While the study conducted by Litchenberg provides useful descriptive data, it is important to note that the analysis does not control for any confounding factors such as health status and type of health insurance coverage prior to age 65.

Using data from multiple sources to control for demographic and health status factors, Card et al (2004) reported similar increases in health care utilization with the onset of Medicare benefits.(Card, et al., 2004) Using data from the National Health Interview Surveys (NHIS) for the years 1992-2001 and the Behavioral Risk Factor Surveillance System (BRFSS) for the years 1998-2002, the authors report that hospital admissions increased by 5 to 10 percent at the onset of Medicare benefits. It is interesting to note that higher numbers of hospital admissions were observed for elective procedures (e.g. joint replacement surgeries) compared to emergency admissions. While significant increases in the number of physician visits were reported at age 65 for less educated minorities (blacks and Hispanics), no significant differences were observed for the educated whites. Less educated minorities also reported an improvement in their health status at age 65.

In summary, eligibility to receive Medicare services has been related to an increase in the utilization of health care services. The studies described above indicate that gaining Medicare eligibility leads to about a 5-10% increase in hospital admissions, increase in the number of physician visits for less educated minorities and improvements in general health status for the previously uninsured elderly.

B) Impact of prescription drug coverage on Medicare beneficiaries' prescription drug utilization, medication adherence and health care utilization

Medicare Part D coverage gap presents a situation where beneficiaries are required to pay 100% of the costs for prescription drugs. The coverage gap thus simulates a situation where Medicare beneficiaries do not have any form of prescription drug

coverage. This section describes studies that have assessed the impact of prescription drug coverage on Medicare beneficiaries' prescription drug utilization, medication adherence, health care utilization and spending.

A number of studies have used the Medicare Current Beneficiary Survey (MCBS) to assess the impact of prescription drug coverage on medical services utilization and spending. MCBS is a continuous, panel survey of nearly 12,000 nationally representative aged, disabled, and institutionalized Medicare beneficiaries and since 1991 it has been conducted annually by the CMS.

Using MCBS data for 1995, Davis et al., (1999) indicated that prescription drug utilization for Medicare beneficiaries with no drug coverage was 31% lower than Medicare beneficiaries who had some form of drug coverage. (Davis, Poisal, Chulis, Zarabozo, & Cooper, 1999) In 1995, beneficiaries with no drug coverage, paid an average of $432 in out-of-pocket (OOP) payments for drug expenses compared to $232 in OOP expenses paid by beneficiaries who had some form of drug coverage.

Blustein (2000) used a sample of 4,334 Medicare beneficiaries from the 1995 MCBS to assess the association between prescription drug coverage and likelihood of purchasing anti-hypertensive medications.(Blustein, 2000) The results of the study indicated that, after controlling for demographics, beneficiaries who did not have any drug coverage were 40% more likely to fail to purchase anti-hypertensive drugs compared to beneficiaries with some form of drug insurance (OR=1.42, p=0.002). One of the limitations of this study was that the generosity of different types of drug coverage was not accounted for. Beneficiaries were divided into two broad groups of either having drug coverage or having no drug coverage.

Using data from the MCBS for the year 1997, Federman et al (2001) assessed the impact of prescription drug coverage on utilization of cardiovascular drugs among Medicare beneficiaries with coronary heart disease. (Federman, Adams, Ross-Degnan, Soumerai, & Ayanian, 2001) The study results indicated that Medicare beneficiaries with a history of coronary heart disease and without any form of supplemental prescription drug coverage (i.e., traditional Medicare or self purchased supplemental insurance without prescription drug coverage) were significantly less likely to use statins (OR= 0.16, 95% CI 0.05-0.49;) and nitrates (0.63; 95% CI= 0.40-0.99;) compared to beneficiaries with some form of supplemental insurance (Medicaid, other public program, Medigap, HMO or employer sponsored coverage). However, no significant differences were found in the utilization of β-blockers between Medicare beneficiaries without any drug coverage and beneficiaries with drug coverage. Medicare beneficiaries with no supplemental insurance were also reported to have disproportionately high out-of-pocket expenses compared to beneficiaries with supplemental insurance.

Stuart et al., (2004) assessed the impact of prescription drug coverage on prescription drug utilization and expenditure on hospitalization and physician services, for Medicare beneficiaries diagnosed with COPD. (Stuart, Doshi, Briesacher, Wrobel, & Baysac, 2004) Using the 2000 MCBS data and controlling for patient characteristics, co-morbidities and selection bias (by using propensity score matching), the authors report that prescription drug coverage results in a large, statistically significant 61% difference in prescription drug utilization in beneficiaries with drug coverage compared to those without drug coverage. While the study reported no significant difference in spending on

hospitalizations between the two groups, a statistically significant difference of 29% was observed in spending on physician services between the two groups.

A survey of 4,066 Pennsylvania Medicare beneficiaries indicated that beneficiaries with prescription drug coverage were on average 1.6 times more likely to take prescription medications compared to beneficiaries who did not have any prescription drug coverage.(Stuart & Grana, 1998) Further, beneficiaries with annual income levels greater than $18,000 were 18% more likely to take prescription drugs to treat their medical problems compared to low income beneficiaries (income less $6,000).

Using data from a sample of elderly patients who completed the Survey of Asset and Health Dynamics Among the Oldest Old (1995-96), Steinman et al., (2001) reported that for 4,896 elderly American's age 70 years and older, medication restriction (taking less medication than prescribed) owing to the high cost of prescription medications, was higher amongst beneficiaries with no prescription drug coverage compared to beneficiaries with partial prescription drug coverage, and with full prescription drug coverage.(Steinman, et al., 2001) Amongst beneficiaries with no prescription drug coverage, medication restriction was higher among ethnic minorities compared to whites (OR=2.9, 95% CI: 2-4.2), individuals with income levels less than $10,000 compared to individuals with income levels greater than $20,000 (OR=3.8, 95% CI = 2.4-6.1), and individuals with monthly OOP costs greater than $100 compared to individuals with monthly OOP costs less than $20 (OR=3.3, 95% CI:1.5-7.2). Low income, ethnic minority and beneficiaries with high out-of-pocket expenses who did not have any prescription drug coverage were 3 to15 times more likely to report medication restriction than beneficiaries with partial or full prescription drug coverage.

Results of a study of 3,751 Medicare beneficiaries covered by Medicare and private supplemental insurance, indicated that beneficiaries with least generous prescription drug coverage had a significantly increased risk for mortality compared to beneficiaries with the most generous supplemental insurance drug coverage (adjusted HR = 1.4; 95% CI: 1.0-1.9).(Doescher, Franks, Banthin, & Clancy, 2000)

Soumerai et al., (2006) estimated cost-related medication nonadherence (CRN) among Medicare beneficiaries, by using self-reports of CRN from the 2004 MCBS data. Results of the study indicated that 13% of the elderly beneficiaries reported CRN in 2004. (S. Soumerai, et al., 2006) Medicare beneficiaries, who were younger, female, African-American, had lower income, reported poor health, greater morbidities, and had less generous drug coverage had a significantly greater likelihood of reporting CRN. Beneficiaries with no drug coverage were nearly three times (OR = 2.8; 95% CI: 2.0-3.8) more likely to report CRN; beneficiaries with partial drug coverage were two times (OR = 2.0; 95% CI: 1.5-2.7) more likely and beneficiaries with employer coverage were nearly one and half times more likely (OR = 1.6 ; 95% CI: 1.2-2.2) to report CRN compared to beneficiaries with Medicaid drug coverage. ((S. Soumerai, et al., 2006)

Safran et al., (2002) assessed the impact of prescription drug coverage on out-of-pocket (OOP) costs and medication adherence, using responses from a mail survey of Medicare beneficiaries (n=10,416) residing in eight geographically diverse states, with different types of prescription drug coverage (no coverage, Medicaid, Medigap, employer-sponsored, HMO, state-drug assistance and VA) and in different income groups (low income - up to 200% FPL and non-poor - income greater than 200% FPL). (Safran et al., 2002)

About 18-31 % of seniors did not have prescription drug coverage in the 8 states assessed in this study. Aggregate analyses, including beneficiaries from all 8 states, indicated that 43% of the beneficiaries without any drug coverage spent greater than $100 in monthly OOP costs. For both low-income and non-poor beneficiaries, compared across beneficiaries taking similar number of medications, Medigap was reported to have the least protective drug coverage (35% had ≥$100 monthly OOP costs). Beneficiaries in employer-sponsored, VA, HMO and state drug programs reported much lower monthly OOP costs (12% employer and VA, 19% HMO, and 25% in state drug programs had ≥$100 monthly OOP costs). Seniors with Medicaid had the lowest OOP costs (8% had ≥$100 monthly OOP costs). With respect to medication adherence, about a quarter of beneficiaries without drug coverage reported not filling their prescriptions or skipping doses due to the cost of prescription medications. Further, both low income and non-poor beneficiaries with no drug coverage were nearly three times more likely to forgo taking their medications and not fill their medications compared to beneficiaries with drug coverage (OR = 2.5, $p< 0.001$).

The studies described above indicate that absence of prescription drug coverage decreases utilization of prescription drugs, reduces medication adherence and increases monthly OOP costs. However, these studies provide a very wide estimate – an 18-31% increase in utilization of prescription drugs with provision of prescription drug coverage. Still higher percentages are reported for specific drug classes (40% increase in anti-hypertensives utilization, 63% for COPD drugs, etc). It is important to note that although the results of the studies described above are based on a relatively large sample size, they are cross-sectional in nature, thus precluding causal inferences. Further, none of the

studies except for the one conducted by Stuart et al (1998), account for self-selection bias associated with health insurance.

Self-Selection bias: Self-selection bias stems from the possibility that sicker individuals are more likely to seek health insurance than the healthy.(Cutler, et al., 2000) Individuals who expect to use more services are also more likely to choose more generous insurance plans compared to individuals who expect to use fewer services. Thus, individuals who purchase health insurance or self-select into a more generous health plan may be different from individuals who do not have insurance coverage. It is thus important to control for this bias, commonly referred to as the selection bias, when assessing the effect of prescription drug coverage on utilization. Over the last few years, methodologically robust studies using quasi-experimental study designs that control for selection bias (Khan, Kaestner, & Lin, 2007; Lillard, Rogowski, & Kington, 1999; Shea, Terza, Stuart, & Briesacher, 2007) have been conducted to assess the impact of prescription drug coverage on prescription drug utilization.

Using data from the RAND Elderly Health Supplement to the 1990 Panel Study of Income Dynamics, and after controlling for demographics, health status, and selection bias associated with sicker enrollees choosing prescription drug coverage, Lillard, et al (1999), indicated that prescription drug coverage significantly increased the probability of use of any drug. They predicted that addition of prescription drug coverage in the Medicare program would increase utilization of prescription drugs by about 12% in beneficiaries who have Medicare only (no supplemental prescription drug insurance). (Lillard, et al., 1999)

Shea et al., (2007) assessed the effect of insurance coverage on prescription utilization on Medicare beneficiaries by using 1999 MCBS data. After adjusting for selection bias, the authors report a price elasticity of demand of -0.54, indicating that with a 10% reduction in the price of medications (by purchasing prescription drug coverage), utilization of prescription drugs increases by 5.4%. (Shea, et al., 2007)

Using the MCBS data for the period 1992-2000, Khan et al., (2007) assessed the causal effect of prescription drug coverage on Medicare beneficiaries' prescription drug utilization and health, by using a fixed effects analysis, after conforming sufficient within-person variation in prescription drug coverage and random movement of an individual moving into or out of prescription drug coverage over time. (Khan, et al., 2007) After controlling for demographics and health status, the authors report that prescription drug utilization increased by 14% with public insurance coverage, utilization increased by 6% with employer-sponsored and Medicare HMO coverage; while there was no significant increase in prescription drug utilization with Medigap coverage. The results of the study indicate no effect of prescription drug coverage on hospitalization rates or improvements in health or functional ability; with an exception of improvement in functional ability with Medicare HMO coverage. (Khan, Kaestner, & Lin, 2008; Khan, et al., 2007) The authors do report that prescription drug coverage was associated with a 4% improvement in functional disability for older elderly (age >70 years) and beneficiaries with more than 3 conditions.(Khan, et al., 2008)

Yang et al., (2004) estimated the impact of prescription drug coverage on prescription drug utilization and future health care utilization and spending, using the MCBS data over the period 1992-98. (Yang, Gilleskie, & Norton, 2004) In addition to

controlling for health status, patient characteristics and adverse selection, Yang et al accounted for the dynamics of insurance choice. The authors postulated that i) a patient's health status influences their preference for health insurance, ii) current consumption of different type of medical care (hospitalizations, physician visits, etc) is correlated, iii) past medical care consumption influences current medical care consumption, and iv) current medical consumption influences future medical consumption. Using computer simulations, the authors report that prescription drug coverage increases the demand for prescription drugs by 12-17% over a period of 5 years. However, prescription drug coverage was reported to only slightly increase Medicare Part A and B expenditures over a period of 5 years (average per person expenditure on Part A would increase by 0.9% and Part B by 2.5%). Further the authors report that while prescription drug would decrease mortality rate (5 year survival rate increases by 1.57 percentage points), it would increase disability rate, as the sicker population would live longer. The estimates provided by Yang et al are lower than those predicted by other studies. However, it is important to note that Yang et al present a methodologically robust estimation that accounts for the dynamic nature of insurance choice.

Gowrisankaran and Town (2004) estimate the impact of prescription drug coverage on mortality of Medicare beneficiaries. (Gowrisankaran & Town, 2004) Using county level data for 420 counties, for the period 1993-2000 and controlling for self-selection bias, the authors report that compared to a Medicare FFS plan, enrollment in Medicare + Choice plans without prescription drug coverage significantly increases mortality while enrollment in Medicare + Choice plans providing prescription drug coverage has no effect on mortality rates. The study results indicate that providing prescription drug

coverage to 10% beneficiaries enrolled in Medicare + Choice plans without drug coverage would decrease elderly mortality rate by 2.8 percentage points. In absolute numbers, a 10% increase in enrollment in Medicare + Choice plans which provide drug coverage is expected to save about 49,000 lives.

In summary, the studies described above indicate that prescription drug coverage increases utilization of prescription drugs by 12-17%, with higher values for specific drug classes. Further, lack of prescription drug coverage results in decreased medication adherence and higher out-of-pocket expenses, with more pronounced effects for low income and ethnic minorities. Beneficiaries with high OOP expenses reported 3-15 times higher medication restriction. However, while no associations between prescription drug coverage and use of health care services was reported in studies where methodologically robust research designs were used; a study with a strong design reported decreased mortality with increased prescription drug coverage.

C) Impact of changes in co-payments on Medicare beneficiaries' prescription drug utilization, medication adherence and health care utilization

As indicated earlier, Medicare Part D benefit structure institutes considerable amount of beneficiary cost-sharing. The following section reviews the literature examining the impact of co-payments on prescription drug utilization, medication adherence and health care utilization.

A landmark study assessing the impact of cost-sharing on utilization of health care services was conducted by Soumerai et al., (1997) who reported that restrictive drug policies in the New Jersey Medicaid program resulted in decreased utilization of

prescription drugs. (S. Soumerai, et al., 1987) Soumerai et al compared the state of New Hampshire's Medicaid policy limit of three paid prescriptions per month, replaced nearly a year later by a policy of $1 copayment with the Medicaid policy of the state of New Jersey, which imposed no co-payment requirements. Using 48 months of claims data among 10,734 continuously enrolled Medicaid recipients, the authors indicated that three paid prescriptions per month limit resulted in a 30 percent decrease in the number of prescriptions filled per patient per month with no change observed in the state of New Jersey which implemented no cost-sharing. For patients, on multiple drugs, the three drug limit had the largest impact – with a 46 percent decrease in the number of prescriptions obtained. Decrease in prescription medications was observed for both nonessential (58 percent), and essential medications, such as insulin (28 percent), thiazides (28 percent), and furosemide (30 percent). Reductions in Medicaid prescriptions were minimally offset by increases in the size of the prescription or in out-of-pocket payments.(S. Soumerai, et al., 1987) Instituting a $1 co-pay resulted in near pre-cap level fills and had less effect on patients on multiple drugs. It is also important to note that drug cost savings with the $1 co-payment policy ($0.8 million annually) were comparable to drug cost savings with the three prescription capping policy ($0.4 million annually).

Soumerai et al., (1994) also assessed the impact of the cap on use of psychotropic drugs and acute mental health care by non-institutionalized patients with schizophrenia. (S. Soumerai, McLaughlin, Ross-Degnan, Casteris, & Bollini, 1994) The authors report that the cap resulted in decreased utilization of antipsychotic drugs, antidepressants and lithium, and anxiolytic and hypnotic drugs (range:15 to 49 %, $P<0.01$); increased visits to community mental health centers (range:43 to 57%; $P<0.001$) and increased utilization of

emergency mental health services and partial hospitalization (1.2 to 1.4 episodes per patient per month). Discontinuation of the caps resulted in prescription drug utilization and mental health services utilization return to base line levels (14 months before cap).

In yet another study, Soumerai et al., (1991) reported that for Medicaid beneficiaries aged 60 years or older taking more than 3 prescriptions per month, the 3 drug limit was associated with an increase in the rates of admission to nursing homes (RR = 2.2, 95% CI: 1.2-4.1) and risk of hospitalization (RR = 1.2, 95% CI: 0.8-1.6) when compared to the state of New Jersey which instituted no limits. (S. Soumerai, Ross-Degnan, Avorn, McLaughlin, & Choodnovskiy, 1991) Discontinuation of the caps resulted in return to base line levels of nursing home admissions.

Stuart et al predicted a 15.5% reduction in annual drug use in states with co-payment policies for dual eligible's, by analyzing a sample of 1,302 dual eligibles from the 1992 Medicare Current Beneficiary Survey. (Stuart & Zacker, 1999)

The studies conducted by Soumerai et al while being landmark studies, are based on the Medicaid population. Numerous studies have assessed the impact of changes in co-payments on Medicare beneficiaries' health care utilization. Johnson et al., (1997) compared changes in prescription drug utilization corresponding to changes in co-payments, over four time periods (each lasting two years 1987-88, 88-89, 89-90 and 90-91), for Medicare beneficiaries enrolled in two plans (Social HMO and Medicare Plus) offered by Northwest division of Kaiser Permanente.(Johnson, et al., 1997) Beneficiaries enrolled in the Social HMO plan had a more generous prescription drug benefit design and their co-payment per prescription rose from $1 to $3 to $5 per dispensing from 1987-88-89 and no change thereafter till 1991. Medicare Plus enrollees' had a more restrictive

benefit design and their co-payments increased from 50% with $25 maximum payment per dispensing from 1987-89 to 70% with $30 maximum payment per dispensing in 1989-90, and no change thereafter till 1991.

The results of the study indicated that overall, utilization of prescription drugs decreased with an increase in co-payments over time for both the groups. However, changes in prescription drug utilization were significantly lower in the generous prescription drug benefit design (Social HMO) compared to the restrictive benefit plan (Medicare Plus). After using ANCOVA and controlling for health status, age and baseline costs., the study results indicated that, over the period from 1987 to 1988 (base year), change in annual number of prescription per capita in the HMO group was 1.25 compared to a change of 1.77 in the Medicare Plus group; over the period 1988-89, a change of -1.80 in the HMO group versus a change of -0.10 in Medicare Plus was observed; over the period 1989-90, a change of 1.96 in HMO versus -0.36 in Medicare Plus and over the period 1990-91, a change of 1.73 for HMO versus 1.01 for Medicare Plus group was observed. However, no consistent annual changes in office visits, emergency room visits, home health care visits, hospitalizations or total medical care expenses over the four year period, with changes in the prescription drug benefit structure were reported. The results of this study should be interpreted with caution as the analysis did not control for demographic factors other than age, which might affect utilization, and more importantly did not control for selection bias.

Using data from the California Public Employees Retirement System (CalPERS) Board, Chandra et al., (2007) assessed the impact of changes in co-payment policies on prescription drug utilization for Medicare supplemental plan members, continuously

enrolled in four health plans over the period of January 2000-2003. (Chandra, et al., 2007) In 2001, co-payments for prescription drugs for all PPO plans were increased from $5/$10/$30 to $5/ $15/$30 for generics/formulary brand names/non-formulary brand names respectively, with a $1000 stop-loss per year. In 2002, co-payments for HMO's were increased from $1/$1/$30 to $5/ $15/$30 for generics/formulary brand names/non-formulary brand name respectively. The authors indicate that elderly patients are price responsive to cost-sharing for prescription drugs and reported a price elasticity ranging from -0.46 for PPO's to -1.4 for HMO's, indicating that a 10 percent increase in cost-sharing would lead to a 4.6 percent reduction in drug spending for PPO's and 14% reduction for HMO's.(Chandra, et al., 2007) Additionally, the study results also indicated that higher cost-sharing for HMO's was associated with increased hospitalizations, especially for those with chronic illness or those with high previous medical costs.

Using Marketscan's 2002 Medicare Supplemental and Coordination of Benefits database, Gilman and colleagues (2008) reported a much lower price elasticity of demand for prescription drug expenditure of -0.23, indicating that a 10 percent increase in the out-of-pocket costs would lead to a 2.3 percent reduction in consumer drug spending.(Gilman & Kautter, 2008) It should however, be noted that Gilman et al used data for one year period as against a three year period used by Chandra et al.

Decreased utilization associated with increases in co-payment has also been reported in Canada. Tamblyn et al., (2001) used data from the Régie de l'assurance maladie du Québec (RAMQ), the government health insurance system in Quebec, to assess the impact of a change in prescription drug cost-sharing policy on the utilization of essential and less-essential medications by elderly (age $\geq$ 65) patients. (Tamblyn, et al.,

2001b) Prior to the cost-sharing policy reform, low income elderly had no cost-sharing requirements and all other elderly paid Canadian (CDN) $2 per prescription. In 1996, a new policy was initiated requiring all elderly patients, including low income elderly, to pay 25% coinsurance on all their prescription drugs, with a maximum income based annual ceiling of CDN$200, $500 or $750. In January, 1997, a CDN$100 annual deductible was introduced and the deductible and the coinsurance were prorated quarterly. In July 1997, the policy was changed again and the quarterly prorated deductible and coinsurance, were now prorated monthly to reduce per month payments; with a per month maximum payment ranging from CDN$16.67- $62.50 (based on income).

To assess the impact of the change in the cost-sharing policy on utilization of essential and less-essential medications by elderly (n= 149,283), the researchers analyzed the RAMQ data for 32 months before the August 1996 policy change and 17 months after the August 1996 policy change. The researchers also assessed the adverse events (acute care hospitalization, long term care admission, or death) and ED visits associated with reduction in prescription drug utilization, by analyzing data for a period of 10 months before the August 1996 policy change (pre-policy period) and for 10 months after the August 1996 policy change (post-policy period). Using random-effects, pooled-time series regression with an individual as a unit of analysis, an autoregressive first-order correlation structure (to represent the dependence among subsequent observations) and after adjusting for linear trend across time, seasonal variations, demographics and health status, the authors reported that cost-sharing resulted in a 9.12% decrease in use of essential drugs (95% CI: 8.7%-9.6%) and 15.14% (95% CI, 14.4%-15.9%) decrease in

use of less essential drugs in elderly persons. The rate (per 10,000 person-months) of adverse events associated with reductions in use of essential drugs increased from 5.8 in the pre-policy period to 12.6 in the post-policy period (a net increase of 6.8, 95% CI, 5.6-8.0) and ED visit rates increased by 14.2 (95% CI, 8.5-19.9) per 10,000 person-months. (Tamblyn, et al., 2001b)

However, using the same RAMQ data base for the period 1992-97, Blais et al., (2001) reported no significant reductions in prescription drug utilization. Blais et al assessed the impact of the change in the Quebec prescription drug cost-sharing policy on the utilization of anti-hypertensives (n= 133,146), anticoagulants (n= 45,534), nitrates (n=54,771), and benzodiazepines (n= 26,165). (Blais, Boucher, Couture, Rahme, & LeLorier, 2001) Monthly consumptions of the study medications for the period between August 1992 and June 1996 were compared with monthly consumptions for 13 months (August 1996 to August 1997) following the policy change. Using time series analysis, with the number of prescriptions dispensed per month as the unit of analysis and controlling for data fluctuations from one month to another and seasonal variations, the authors reported no significant changes in utilization for any of the four drug classes during the 13 months following the implementation of cost-sharing. A statistically non-significant decrease (in the number of prescriptions) of 5.1% for nitrates, 1.1% for antihypertensives, 0.8% for benzodiazepines, and a statistically non-significant increase of 1.6% for anticoagulants was observed. However, it is important to note that compared to the study conducted by Blais and colleagues, the study conducted by Tamblyn was methodologically robust in controlling for potential confounders. Further, the unit of analysis (total number of prescriptions dispensed per month) used by Blais et al may have

been too short a period to detect an effect.

Pilote et al., (2002) also used the RAMQ database for the periods 1994-98 and reported that for patients discharged with a diagnosis of acute Myocardial infarction, the proportion of patients who received prescriptions for essential cardiac medications did not decline after the policy change and increased over time. (Pilote, Beck, Richard, & Eisenberg, 2002) Compared to patients admitted in pre-policy periods, patients admitted after the policy reform were more likely to receive prescriptions for β-blockers (OR=1.23, 95% CI 1.16–1.30), ACE inhibitors (OR=1.26, 95% CI 1.19–1.33) and lipid-lowering agents (OR=2.57, 95% CI 2.38–2.78). However, patients admitted in the post-reform period were less likely to receive a prescription for Acetyl Salicylic Acid (OR 0.82, 95% CI 0.78–0.87). The analyses also indicated no change in within-class shift from more to less expensive drugs, after the policy change. No change was reported in rates of readmission for complications, visits to individual physicians, to emergency departments, and mortality rates. The findings did not vary with sex or socioeconomic status. (Pilote, et al., 2002) It is important to note that this study was restricted to individuals with a diagnosis of acute Myocardial infarction while the Tamblyn study assesses the impact of the policy change across a number of other conditions. It is also possible that the diagnosis of a disease state like MI might make individuals less price sensitive, encouraging them to fill prescriptions despite a co-pay increase.

In addition to decreased prescription drug utilization, studies have also reported decreased adherence and poor health outcomes with increases in co-payments. Poor medication adherence associated with increase in drug co-payments was reported by Cole et al. (Cole, Norman, Weatherby, & Walker, 2006) Using a two-stage regression model,

the authors reported that a $10 increase in co-payment of angiotensin-converting enzyme inhibitors was associated with a 2.6% decrease (95% CI: 2.0 to 3.1) in adherence; 0.8% decrease in medical costs (95% CI: -4.2 to 2.5) and 6.1% increase in the risk of hospitalization for CHF (95% CI: 0.5 to12.0). Among patients taking β-blockers, a $10 increase in co-payment was associated with a 1.8% (95% CI: 1.4 to 2.2) decrease in adherence; 2.8% decrease in medical costs (95% CI: -5.9 to 0.1) and 8.7% increase in the risk of hospitalization for CHF (95% CI: 3.8–13.8).(Cole, et al., 2006)

Chernew et al., (2008) assessed the impact of decreasing co-payments on medication adherence of angiotensin-converting enzyme inhibitors (ACEI)/angiotensin-receptor blockers (ARB), beta-blockers, statins, diabetes medications and inhaled corticosteroids. (Chernew et al., 2008) The researchers compared two large employers utilizing the same disease management program but with differing co-payment options. In 2005, the intervention employer reduced its co-payments (generic drugs reduced from $5 to 0 and brand name co-payments reduced by 50%) while the control group employer had no reductions in co-payments. Using difference-in-difference analysis for data spanning a year before and a year after the intervention employer reduced co-payments, the results indicated a statistically significant increase in medication adherence in the intervention group, with an increase of 2.59 percentage points for ACEI/ARB's; 3.02 percentage points for beta-blockers; 4.02 percentage points for diabetes medications; and 3.39 percentage points for statins. However, no significant increase in adherence was observed for inhaled corticosteroids. The elasticity of demand values ranged from -0.11 to -0.2 (ACEI/ARB = -0.118, beta-blockers = -0.112, statins = -0.182, diabetes medications = -0.136 and inhaled corticosteroids = -0.202).

Magid et al., (1997) reported that co-payment requirements did not have an impact on seeking emergency care (assessed by calculating time needed to arrive at a hospital to seek care) after onset of symptoms of Myocardial Infarction for 830 Medicare HMO beneficiaries, after adjusting for confounding factors. (Magid et al., 1997)

In summary, based on the results of methodologically robust studies described above, it is evident that cost-sharing associated with increased co-insurance rates decreases prescription drug utilization by 2-6%, with larger decreases for specific drug classes. Based on published literature reviews, Pauly estimated a price elasticity of demand for the prescription drug coverage to be in the range of -0.3 to -0.4, indicating that with a 10% increase in the price of medications, utilization of prescription drugs increases by 3-4%. (Pauly, 2004) Cost-sharing has also been associated with decreased adherence, increased costs, and increased out-of-pocket expenses.

D) Impact of prescription benefit caps on Medicare beneficiaries' prescription drug utilization, medication adherence and health care utilization

Prior to Medicare Part D, a majority of Medicare+Choice plans were structured to include an annual dollar cap in their prescription drug benefit. Ninety-four percent of Medicare+Choice plans had an annual cap in the range of $750-$2,000 in 2002. (Tseng, Brook, Keeler, & Mangione, 2003) Beneficiaries were responsible for 100% of the prescription drug costs once they reached their annual caps. Given that very few studies have been conducted using the Medicare Part D data, studies assessing the impact of prescription drug caps might provide a good estimate of the potential impact of the coverage gap in Medicare Part D benefit structure.

Cox et al., (2001) analyzed the impact of capped prescription benefits on medication taking behavior of 378 elderly patients enrolled in a Medicare HMO plan in Arizona. Beneficiaries who reached their prescription cap were more likely to obtain samples from their physicians (OR=2.02, 95% CI: 1.22-3.34), take less than prescribed medications (OR=2.83, 95% CI: 1.55-5.20), and discontinue taking their medications (OR=3.36, 95% CI: 1.63-6.94) compared with beneficiaries who did not reach their prescription cap limit. (Cox, Jernigan, Coons, & Draugalis, 2001)

Tseng et al., (2004) surveyed 1,308 Medicare+Choice beneficiaries with annual prescription drug benefits capped at $750, $1,200 or $2,000. Beneficiaries' exceeding their annual cap of $750 or $ 1,200 were compared with a control group of beneficiaries matched on age and monthly drug spending, who did not exceed their annual cap of $2,000. After controlling for demographic and health characteristics, the results of the study indicated that beneficiaries who exceeded their annual caps reported using less prescribed medication than controls (18% vs. 10%, respectively; P<.001). (Tseng, et al., 2004) Beneficiaries who exceeded their caps indicated that they decreased utilization of statins, proton pump inhibitors, cyclooxygenase 2 inhibitors, diuretics, nonsedating antihistamines, bronchodilators, narcotics, selective serotonin reuptake inhibitors, hormones (conjugated estrogens, thyroid), angiotensin-converting enzyme inhibitors, calcium channel blockers, beta-blockers, antiplatelet blood thinners, benzodiazepines, nonsteroidal anti-inflammatory drugs, H2 blockers, and steroid inhalers.

Hsu et al., (2006) assessed the impact of prescription drug benefit caps on clinical and economic outcomes by comparing 157,275 Medicare+Choice beneficiaries with an annual $1,000 cap and 41,904 beneficiaries with no annual cap. (Hsu, et al., 2006)

Beneficiaries' with annual caps had a 15 percent lower (95 % CI, 11.4 to 18.1) prescription drug utilization of anti-hypertensives; 27 percent lower (95 % CI, 23.1 to 30.4) utilization of lipid-lowering agents and 21 percent lower (95 % CI, 14.3 to 26.6 percent) utilization of anti-diabetic drugs compared to beneficiaries with no annual cap. Adherence to long therapy was lower for beneficiaries' with annual caps compared to beneficiaries with no annual caps as indicated by odds ratios of 1.30 (95 % CI:1.23 to 1.38) for beneficiaries using anti-hypertensives; 1.27 (95 % CI:1.19 to 1.34) for beneficiaries using lipid-lowering agents, and 1.33 (95 % CI:1.18 to 1.48) for beneficiaries using anti-diabetic drugs.(Hsu, et al., 2006) Beneficiaries' with annual caps were also reported to have higher relative rates of visits to the emergency department (relative rate: 1.09, 95 % CI: 1.04 to 1.14), nonelective hospitalizations (relative rate: 1.13, 95 % CI: 1.05 to 1.21), and death (relative rate: 1.22, 95 % CI: 1.07 to 1.38). It is interesting to note that beneficiaries with caps had 28 percent lower pharmacy costs (95 % CI, 25.6 to 30.4) and 4 percent lower office-visit costs (95 % CI, 0.6 to 7.0) than for beneficiaries with no caps.(Hsu, et al., 2006) However, hospital costs for beneficiaries with caps were 13 percent higher (95 % CI, 1.3 to 26.5) and emergency department costs were 9 percent higher (95 % CI, 1.0 to 17.7) compared to beneficiaries with no caps. Further, no significant difference in annual total medical costs were reported between beneficiaries with annual caps and beneficiaries with no annual caps on their prescription drug benefits.

Joyce et al., (2007) compared the impact of prescription drug benefit caps on retirees (age > 65) enrolled in employer sponsored health plans with annual caps of either $1,000 or $2,500 with retirees enrolled in non-capped plans over the period of 2003-

2005. (Joyce, et al., 2007) Using generalized estimating equations to control for demographics, health status, differential monthly trends and enrollment in a capped plan, the authors report that difference in utilization of six classes (anti-hypertensives, anti-diabetics, lipid-lowering, anti-depressant, anti-ulcerants and NSAIDS) of medications was the largest in the last quarter of each year. December of each year of the study marked 15-28% decreased utilization of anti-hypertensives, anti-diabetics, and lipid-lowering agents ; 5-10% decreased utilization of anti-depressants and 20-30% decreased utilization of anti-ulcerants and NSAIDS for beneficiaries enrolled in the $2,500 capped plans compared to those in non-capped plans. However, beneficiaries in capped plans reported higher rates of resumption of drug therapy (after renewed coverage in the following year) for all six drug classes, compared to beneficiaries in non-capped plans. Utilization of generic drugs for beneficiaries in capped and non-capped plans was similar in the first quarter, with the difference increasing towards the end of the year.

Balkrishnan et al., (2001) conducted a study to assess changes in healthcare service utilization after a large HMO changed its prescription drug coverage twice over a period of two years. (R Balkrishnan, et al., 2001) The benefit cap was increased from $500 per year to $200 quarterly, co-payments changed from $6 /$12 in 1997 to $7 /$15 in 1998 for generic/brand names respectively. In 1999, the prescription drug benefit was changed to include unlimited coverage of generic drugs, with a $5 co-payment, and a restriction of brand name drugs to $25-per-month coverage, with a $15 co-payment. The 1998 policy change resulted in 29% increase in prescription costs, 25% increase in annual inpatient admissions, 38% increase in total costs for the HMO while the 1999 policy change resulted in 27% decrease in prescription costs, a 4% decrease in physician visits,

and a 6% decrease in total costs for the HMO. Thus, the results of the study indicate that a prescription drug benefit with no caps on utilization of generic drugs was associated with a reduction in prescription costs and no increases in nonprescription-related healthcare service utilization.

A survey of 221 Medicare+Choice beneficiaries with annual prescription drug caps of either $500 or $1,000 indicated that nearly a quarter of the beneficiaries (24%) took less than the prescribed amount, about 45% obtained samples from physicians, 37% reduced spending on food and/or clothing and about 29% shopped around at other pharmacies to obtain medications at
a lower cost and about 17% received financial assistance from family or friends. (Cox & Henderson, 2002)

In summary, similar to cost-sharing associated with increased co-insurance rates, prescription benefit caps are reported to decrease prescription utilization by about 8-30%. Prescription benefit caps are also reported to increase hospitalizations and emergency room visits, thereby increasing total costs by 13-30%, on average.

The review thus far summarizes studies assessing the impact of prescription drug coverage and cost-sharing on utilization of health care services, using data from prescription drug plans offering coverage before the initiation of Medicare Part D. As indicated earlier these studies provide a good estimate of the impact of Medicare Part D. The following sections of the review relate to studies directly assessing the impact of Medicare Part D by using data from Medicare beneficiaries enrolled in health plans offering Medicare Part D.

E) Impact of Medicare Part D on Medicare beneficiaries' prescription drug utilization, medication adherence and health care utilization

Given that Medicare Part D is a relatively new program and that CMS has not released Medicare Part D data, very few studies directly related to Medicare Part D have been conducted.

Using data from 1998-2000 MCBS and controlling for selection bias, Stuart et al.,(2005) assessed the impact of prescription gaps (months with no prescription drug coverage) on spending for all Medicare beneficiaries and for beneficiaries suffering from diabetes, chronic lung disease and mental illness. (Stuart, Simoni-Wastila, & Chauncey, 2005) More than half (51.3%) of the study population had gaps in their prescription drug coverage, with about a quarter of them with no prescription drug coverage and a quarter with one or more gaps in coverage during the study period. The results of the study indicated that each month with no prescription drug coverage increased spending on average by \$25.13 ($p<0.001$); by \$74.81 ($p<0.001$) for those with chronic lung disease, \$86.91 ($p<0.001$) for mental illness and by \$48.55 ($p<0.06$) for diabetics.

The authors then simulated the impact of Medicare Part D prescription drug coverage on total and out-of-pocket spending. The authors report that Medicare beneficiaries with previous prescription drug coverage would on average spend \$2,683 on prescription drugs in 2006, those suffering from diabetes would spend \$4,005; with chronic lung disease would spend \$4,000 and with mental disease would spend \$4,729 in total drug costs in 2006.(Stuart, et al., 2005) If beneficiaries with no prescription drug coverage enrolled in Medicare Part D spending would increase by 56% for all Medicare beneficiaries (from \$1,584 to \$2,472); by 43% (from \$2,320 to \$3,331) for diabetics, by

79% (from $1,779 to $3,185) for beneficiaries with chronic lung disease and by 61% (from $2,207 to $3,594) for those with mental disease.(Stuart, et al., 2005)

On average, Medicare beneficiaries were projected to be in the coverage gap for 2.3 months, those with diabetes for 4.8 months, those with chronic lung disease for 4.4 months and those with mental illness for 5.3 months.(Stuart, et al., 2005) Based on projected total out-of-pocket (OOP) expenses during the coverage gap, the impact of Medicare Part D coverage gap while not considerable for an average beneficiary (OOP during gap $722); beneficiaries with diabetes (OOP during gap $1,581), chronic lung disease (OOP during gap 1,435) and mental illness (OOP during gap $1,844) would still have considerable out-of-pocket costs during the coverage gap.(Stuart, et al., 2005) However, it is important to note that the results of this study are projected values and the study does not control for drug benefits that might be provided by health plans during the coverage gap, low income and employer sponsored subsidies.

Lichtenberg and Sun, (2007) analyzed a 50% sample of Walgreen's pharmacy claims data for the period September 2004 through December 2006 to assess the impact of Medicare Part D by evaluating changes in the ratio of elderly to nonelderly costs and prescription drug utilization before and after January 1st, 2006. (F. R. Lichtenberg & Sun, 2007) Using difference-in-difference analysis, the authors report that over the period 2005-2006, the nonelderly patient's average costs per day of therapy decreased by 0.4 percent compared to 18.8 percent decrease in elderly patients average costs per day of therapy. With respect to prescription drug utilization, a nonelderly patient's number of days of therapy increased by 6.8 percent compared to a 19.5 percent increase in the number of days of therapy for elderly patients. These results indicate that Medicare Part

D reduced elderly patients out-of-pocket expenses by 18.4 % and increased prescription drug utilization by about 12.8 %.

However, Yin et al., (2008) reported lower values of utilization and out-of-pocket expenses after using the same Walgreens database.(Yin, et al., 2008) After selecting a 5% random sample of beneficiaries from Walgreens database for the period (September 2004-April 2007), Yin et al, indicate that during the ramp-up post-Part D period (January to May 2006 - penalty free enrollment in Part D) average monthly prescription drug utilization increased by 1.1% (95% CI: 0.5-1.7; $P < 0.001$) and out-of-pocket expenditures decreased by 8.8% (95% CI: 6.6-11.0; $P < 0.001$). During the stable post-Part D period (June 2006 to April 2007 - after the deadline for penalty-free enrollment) the effect of Part D coverage translates into 5.9% (CI: 5.1-6.7; $P < 0.001$) increase in prescription utilization and a 13.1% (CI, 9.6-16.6%; $P = 0.003$) decrease in out-of-pocket expenditures.

The study also estimated the effect of Part D, by comparing out-of-pocket costs and utilization among seniors eligible for the benefit (Part D eligible group - age 66 to 79 years) to a control group of seniors not eligible to receive Medicare benefits (Part D ineligible group - age 60 to 63 years). The results of the study indicate that during the pre-Part D period (September 2004-December 2006), no significant differences in trends in out-of-pocket expenditures and prescription drug utilization were observed between the Part D eligible group and Part D ineligible group. During the ramp up and the stable post-Part D period, the eligible group had a comparatively greater decrease in out-of-pocket expenditures and slightly greater increase in prescription drug utilization, than the ineligible group in each period.

Yin et al., list lack of methodological controls in the Lichtenberg study as potential reasons for differences in utilization and costs between their study and the study conducted by Lichtenberg and Sun, although both studies employ the same database.(Yin, et al., 2008) Yin et al., suggest the following drawbacks associated with the Lichtenberg and Sun study: i) analysis was based on a random sample of pharmacy claims, rather than selecting every claim for a random sample of beneficiaries ii) used all nonelderly persons as a control group without matching and controlling for trends in utilization and expenditures among the control participants and iii) used log-transformed ordinary least-squares regressions compared to a GEE log-link model used by Yin et al. (Yin, et al., 2008) Despite methodological differences, both studies indicate a considerable impact of Medicare Part D on prescription drug utilization. However, both these studies did not assess the impact of the Part D coverage gap on medication adherence and more importantly the resulting impact on health outcomes.

Using prescription claims data from Wolters Kluwer Health's database, for the period December, 2004-December, 2007, Ketchman and Simon (2008) compare the impact of Medicare Part D on prescription drug utilization and out-of-pocket for the elderly (age over 66 years as of 2007) compared to the near elderly (age 58-64 as of 2007). (Ketcham & Simon, 2008) After using difference-in-difference analysis and controlling for pure cash transactions, the results of the study indicate that compared to the non-elderly, elderly beneficiaries had 4.7% increase in prescription drug utilization and 21.7% reduction in OOP costs per day's supply of medication for the study period.

Schneeweiss et al., (2009) assessed the impact of Medicare prescription drug coverage and Medicare Part D coverage gap on prescription drug utilization and out-of-

pocket spending for statins, warfarin, clopidogrel and PPIs for seniors who previously lacked drug coverage. (Schneeweiss et al., 2009) It is important to note that in the absence of health plan data, the authors assigned an individual's insurance status as uninsured, based on their costs. Individuals were considered uninsured if they paid 60% or more of the drug price for 80% or more of prescription fills. Using pharmacy claims data from three pharmacy chains for the period January 2005 to December 2006, the authors report that about 12% of the study population hit the coverage gap. Using time-trend analyses, and controlling for demographics and health status measures, the results of the study indicate that compared to baseline period (January 1st to December 31st, 2005), the introduction of Medicare Part D significantly increased utilization of statins by 22 %, of clopidogrel by 11% and PPIs by 37 % for previously uninsured individuals. No significant changes in warfarin use were observed. A decrease in utilization of 5.0 percentage points per month (95% CI: 3.2–6.8) for clopidogrel; decrease in 4.8 (95% CI: 3.8–5.7) for warfarin and decrease of 6.3 (95%CI: 4.8–7.8) for statin use was observed for individuals who hit the coverage gap in 2006. Hitting the coverage gap resulted in out-of-pocket expenses increase of $12 per thirty days supply for warfarin (95% CI: $11–$14) to $65 for clopidogrel (95% CI: $59– $70). Due to the lack of conformation of insurance status, lack of information on health plan data such as the generosity of prescription drug coverage and lack of a control group to account for temporal changes, the results of this study should be interpreted with caution. (Schneeweiss, et al., 2009)

Chen et al., (2008) assessed the effect of Medicare Part D on prescription drug utilization and out-of-pocket spending of psychotropic medications (antidepressants, antipsychotics, and benzodiazepines) using pharmacy claims from a retail pharmacy

chain for the period September 2005 to August 2006.(Chen et al., 2008) Using interrupted time series, the study investigators report that introduction of Medicare Part D resulted in 18% decrease in out-of-pocket payment for antidepressants and 21% decrease in out-of-pocket payment for antipsychotics.(Chen, et al., 2008) However, out-of-pocket expenditure for benzodiazepines increased by 19% after the implementation of Medicare Part D. Following the implementation of Medicare Part D, utilization of antidepressant increased by 7% (from 273,166 to 293,590 prescriptions per month, $p<.001$) and antipsychotic prescriptions increased by 18% (from 41,079 to 48,276 prescriptions per month, $p<.001$). However, utilization of benzodiazepine decreased by 5% (from 238,961 to 226,622 prescriptions per month, $p<.001$) after the introduction of Medicare Part D.(Chen, et al., 2008)

Madden and colleagues (2008) assessed the impact of Medicare prescription drug coverage on cost related medication non-adherence (CRN) by using data from the Medicare Current Beneficiary Survey for the period 2004-2006. (Madden et al., 2008) Self-reports of CRN were used as a measure of adherence and adherence was compared for the period before Medicare Part D implementation (2005) and after Medicare Part D implementation (2006). In addition to controlling for demographics and health status measures, the investigators controlled for historical year-to-year changes in cost-related medication adherence in the absence of Part D. This was accomplished by first calculating odds ratio (OR) of CRN in 2005 compared to CRN in 2004. Next, an OR of CRN in 2006 compared to CRN in 2005 was calculated. Finally, a ratio of these 2 ORs (2006 vs. 2005 relative to 2005 vs. 2004) was calculated to reflect CRN before and after Medicare Part D implementation. Overall, results of the study indicate significant

decreases in the odds of CRN after Medicare Part D implementation (Ratio of OR's = 0.85; 95% CI = 0.74-0.98). Specifically, for beneficiaries in excellent to good health, significant differences in CRN were observed after Medicare Part D implementation (Ratio of OR's = 0.77; 95% CI = 0.63-0.95). However, no significant differences in CRN were reported for beneficiaries with fair to poor health.(Madden, et al., 2008) The study results also indicate that CRN was strongly associated with poorer self-reported health, lower income and higher number of co-morbidities. When interpreting results, it is important to note that this study uses self-reported medication adherence as its outcome measure. Further, while this study assesses the impact of Medicare Part D on medication adherence, it does not assess the impact of the Medicare Part D coverage gap on medication adherence.

Using a Medicare Part D satisfaction survey and retrospective chart reviews, Kim et al., (2008) assessed diabetic Medicare beneficiaries' (n=81) satisfaction with their decision to enroll or not enroll in the Medicare Part D program, and levels of glycosylated hemoglobin (HbA1c), low-density lipoprotein (LDL) and blood pressure before (July 1- December 31, 2005) and after (May 1- October 31, 2006) their decision to enroll in Medicare Part D. (Kim, Touchette, Stubbings, Schullo-Feulner, & Pater, 2008) The study results indicated that, of the 60 patients enrolled in Part D, 80.0% were satisfied with their decision to enroll. Using paired t-test, the authors report no significant differences in mean HbA1c, LDL or blood pressure before and after enrollment in Medicare Part D.(Kim, et al., 2008) However, the results of this might not be reliable due to the use of cross-sectional data, very small sample and no controls for confounding demographic or health status variables.

Hsu et al., (2008) used data collected from telephone interviews of 1040 beneficiaries' enrolled in Kaiser Permanente-Northern California's MA-PD plan for the full year in 2006 to assess their knowledge about the Part D benefit structures and techniques used to cope with medication costs incurred by them.(Hsu et al., 2008) About 8% of all beneficiaries in Kaiser Permanente-Northern California's MA-PD plan hit the coverage gap in 2006. The study results indicate that about 40% (95% CI, 35%-45%) of the interviewed beneficiaries were aware of the coverage gap in their drug plan. Further, as the costs incurred by beneficiaries increased, so did there awareness of the existence of the coverage gap. Results of multivariate logistic regression analyses, controlling for demographic and health status measures, indicate that compared to those who did not hit the coverage gap, beneficiaries who hit the coverage gap had a greater awareness about the coverage gap (difference of 40.3 percentage points, 95% CI: 33.4-47.1). More than a third (36%) beneficiaries reported using at least one form or other of a cost-coping mechanism, 26% reported decreased adherence to prescribed drug use and 9 % reported experiencing financial burden due to their out-of-pocket costs. Of the cost-coping behavior's reported, about 15% (95% CI: 12-18%) indicated switching to a cheaper drug; about 7% (95% CI: 5-10%) split pills under physician's advice; 6% (95% CI:3-9%) went to a non-Kaiser pharmacy; 4% (95% CI: 5-10%) used OTC drugs; 2% (95% CI: 0.4-4%) received samples; 2% borrowed drugs (95% CI:0.3-1.1%); and 0.3 % (95% CI: 0-0.6%) received help from pharmaceutical assistance programs.

Of the decreased adherence reported behaviors, 8% (95% CI: 6-11) reported not refilling a prescription; about 7% (95% CI: 5-9%) reported taking less than prescribed; and 5% (95% CI: 3-7%) reported not filling a new prescription. Among those reporting

financial burden due to high OOP costs, 5% reported going without a necessity (95% CI: 3-7%) and about 4% (95% CI: 3-6%) reported borrowing money to pay for drugs. As expected, the frequency of cost-coping behaviors increased with increased OOP costs. Further, beneficiaries with incomes below $40,000 were significantly more likely to report using a cost-coping technique, reduced adherence and increased financial burden compared to beneficiaries with incomes greater than or equal to $40, 000. While this study provides good descriptive estimates of cost-coping behaviors, the study is limited by its cross-sectional design, potential recall bias, and exclusion of beneficiaries who could not speak English. (Hsu, et al., 2008)

In summary, Medicare Part D coverage is associated with an approximately 6% increase in prescription drug utilization and a 13% decrease in out-of-pocket expenses, with higher amounts reported for specific drug classes.

Medicare Part D coverage gap

Based on an IMS report, it is estimated that, in 2006, about 6 percent (1.5 million) of Medicare Part D enrollees reached the coverage gap. (Hoadley J, et al., 2007) However, due to the fact that a considerable number of beneficiaries were enrolled in Part D for less than the full year in 2006, it is important to note that more than twice the number of beneficiaries hit the coverage gap in subsequent years.

Using nation wide pharmacy claims data for 1.9 million Medicare beneficiaries, from IMS Health, a Kaiser Family Foundation study reported that among Part D enrollees who used at least one prescription drug and did not qualify to receive low income subsidiaries (LIS), more than a quarter (26%) reached the coverage gap in 2007.

(Hoadley, et al., 2008) Only 4% of the beneficiaries reached the catastrophic coverage. However, it is important to note that Medicare beneficiaries who did not take any prescription drug were excluded from this study, thus potentially overestimating the numbers. To estimate the number of beneficiaries who hit the coverage gap, in the total Medicare Part D population, it is important to account for 9% of Medicare beneficiaries who do not take any prescriptions. Including beneficiaries who do not take any prescription drugs, the authors estimate that about 14% of the total population of Part D enrollees, that is, about 3.4 million Medicare beneficiaries reached the coverage gap in 2007.

Thus, despite the prescription drug benefit, about 14-15% of Medicare beneficiaries who have a disproportionate need for prescription drugs, are faced with increased cost-sharing and few plans offer comprehensive coverage during the coverage gap.(Dalen & Hartz, 2005; Hoadley, et al., 2008; S. B. Soumerai & Ross-Degnan, 1999) The findings of this literature review have implications for this study, as the objective of this study is to assess the impact of the coverage gap on Medicare beneficiaries' prescription drug utilization and medication adherence.

F) Impact of Medicare Part D coverage gap on Medicare beneficiaries' prescription drug utilization, medication adherence and health care utilization

The studies conducted with Medicare prescription drug coverage caps conducted before the initiation of Medicare Part D provide a good estimate of the impact of capped benefits. However, most plans had prescription drug coverage caps in the range of $1,000. Standard Medicare Part D plans have a prescription drug cap of $3,000. Only a

few studies have thus far directly assessed the impact of Medicare Part D coverage gap.

The Kaiser Family Study (2008) based on the IMS Health data assessed the impact of Medicare Part D coverage gap on medication use and out-of-pocket costs for enrollees taking one of following eight classes of medications: (1) ACE Inhibitors, (2) drugs used in the treatment of Alzheimer's disease; (3) anti-depressants; (4) ARBs; (5) oral anti-diabetics; (6) drugs used in the treatment of osteoporosis; (7) Proton Pump Inhibitors (PPIs); and (8) statins.(Hoadley, et al., 2008)

Coverage gap: In this study, more than a quarter (26%) of the study population reached the coverage gap in 2007. On average, based on an analysis of the above mentioned 8 drug classes, about 20 percent of beneficiaries who reached the coverage gap made some change in their prescription drug utilization - about 15% stopped taking their medications; about 5% switched to another medication (most often a generic drug) in the same class; and about 1% reduced the number of medications they were taking within the same therapeutic class. (Hoadley, et al., 2008)

Stopped Medications: Specifically, for each class, the percent of beneficiaries who stopped taking medications after hitting the coverage gap include: 20% on PPIs, 15% on anti-depressants, 18% on osteoporosis medications, 16% on ACEI, 14% on ARB's, 13% on statins, 10% on oral anti-diabetics, and 8% on Alzheimer's medications.

Reduced Medications: About 5% of beneficiaries on oral anti-diabetics, 1% on osteoporosis medications and anti-depressants, and 2% on Alzheimer's medications reduced their medication use by stopping at least one of the multiple drugs (within the same class) that they were taking before hitting the coverage gap.

Switched Medications: Specifically, for each class, the percent of beneficiaries

who switched medications after hitting the coverage gap include 8% on oral anti-diabetics, 6% on PPIs and anti-depressants, 5% on statins, 4% on ACEI and Alzheimer's medications, and 3% on ARB's and osteoporosis medications.

Catastrophic coverage: Of the 26% in the study who reached the coverage gap in 2007, only 4% had expenses high enough to receive catastrophic coverage. Among the beneficiaries who stopped taking their medications in the coverage gap and then reached catastrophic coverage, on average, across all 8 classes, about 57% remained off the medications, 37% resumed the medications and 7% started taking new medications after receiving catastrophic coverage. (Hoadley, et al., 2008) Specifically, for each class, the percent of beneficiaries who did not resume taking their stopped medications even after reaching catastrophic coverage include: 66% on ACEI, 60% on osteoporosis and Alzheimer's medications, 58% on PPIs and ARB's, 57% on anti-depressants and oral anti-diabetics, and 47% on statins.(Hoadley, et al., 2008)

Total and out-of-pocket spending: On average, Medicare beneficiaries who did not hit the coverage gap spent about $745, beneficiaries who hit the coverage gap but not the catastrophic coverage spent $3,364 and beneficiaries who hit the catastrophic coverage spent $8,635 in total spending in 2007. Out-of-pocket expenses, on average, for Medicare beneficiaries who did not hit the coverage gap were about $312, for beneficiaries who hit the coverage gap but not the catastrophic coverage were about $1,572 and for beneficiaries who hit the catastrophic coverage were $3,732 in 2007. (Hoadley, et al., 2008)

The results of this study raise considerable concerns for Medicare beneficiaries who hit the coverage gap and stop taking their medications. Of particular concern are

beneficiaries stopping drugs like oral anti-diabetics which could cause serious adverse health consequences. When interpreting the results from this study, it is important to note that this study does not include prescriptions filled by mail-order pharmacies and does not account for free samples received from physicians. This study only provides a descriptive analysis of the impact of Medicare Part D data.

Raebel et al., (2008) assessed the impact of the coverage gap on medication adherence, hospitalizations, emergency department (ED) visits, and outpatient medical office visits for Medicare beneficiaries in two Kaiser Permanente Colorado health plans. One health plan offered the standard Medicare Part D benefit structure with the coverage gap and the other (for retiree beneficiaries) health plan included a benefit structure with no coverage gap. (Raebel, et al., 2008) Health care utilization of beneficiaries who hit the coverage gap was compared with utilization of those who did not hit the coverage gap, for beneficiaries in the standard Medicare Part D benefit structure. To account for seasonal variations, the authors assessed health care utilization for the period after beneficiaries hit the coverage gap in 2006 and compared it with their health care utilization for the same period in the previous year (in 2005). For example if a beneficiary hit the coverage gap in September 2006, then utilization during September to December 2006 would be compared with utilization during September-December 2005. To account for confounding due to age, similar calculations comparing 2005 and 2006 utilizations were conducted for a matched control group which included retiree Medicare beneficiaries who hit the coverage gap in 2006 but were enrolled in a plan with full coverage during the gap.

The results of the study indicated that about 6% of the beneficiaries reached the

coverage gap in 2006. Compared to beneficiaries who did not reach coverage gap, beneficiaries who reached the coverage gap were older, had greater morbidity, received more medications, and had more medical office visits ($P < 0.001$). After controlling for demographics and health status, using Poisson regression, those who reached the coverage gap were reported to have 85% greater likelihood of inpatient hospitalizations (Incidence Rate Ratio (IRR) = 1.85; 95% CI: 1.64–2.09); 60% greater likelihood of ED visit (IRR = 1.60; 95% CI: 1.40-1.83); and 12% greater likelihood of office visit (IRR = 1.12; 95% CI: 1.07-1.16). Comparing 2006 and 2005 utilizations, for both beneficiaries in the standard Medicare plan and those in plan with no coverage gap, the authors report that after reaching the coverage gap, there was no change in hospitalizations and ED visits, while total office visits in 2006 decreased compared to the same time in 2005 (Standard plan IRR = 0.90; 95% CI: 0.86-0.95; Retiree plan IRR =.90; 95% CI: 0.87-0.92). (Raebel, et al., 2008)

Medication adherence in this study was calculated using the medication refill adherence (total days supply/number of days in the study period*100) method. Using Wilcoxon Signed Rank test to compare difference in medication adherence between pre-period (1 year before coverage gap) and post-period (1 year after coverage gap), for beneficiaries enrolled in the standard plan, significant reduction in adherence was observed for anti-hyperlipidemics (3.6 ± 22.4; $p=0.038$); anti-hypertensives (5.3 ± 24.7; $p=0.003$); anti-depressants (6.8 ± 26.3; $p<0.001$); and diuretics (8.3 ± 29.2; $p<0.001$). No significant changes were observed for beneficiaries taking anti-diabetics. For retiree beneficiaries with no coverage gap (matched group), significant differences were found only in adherence to anti-hyperlipidemics ($p=0.031$) and anti-hypertensives ($p = 0.006$).

(Raebel, et al., 2008)

It is important to note that the authors do not report any measures to accommodate oversupply of medications due to early refills, change in drugs within same class or to generics. Further, the authors only report health care utilization in a control group; they do not compare the results of the study group to a control group. Also of significance is the authors note that absence of differences in ED visits and hospitalizations after reaching the coverage gap may be due to lack of power in detecting this difference. (Raebel, et al., 2008)

Impact of the coverage gap on prescription drug utilization has been assessed by Sun and Lee (2007) using prescription claims data collected from a pharmacy benefit management database for 90,615 patients. The study assessed the impact of the coverage gap on prescription drug utilization and costs during two periods- pre period (January 1 to June 30, 2006) and post-period (July 1 to December 31, 2006).(F. R. Lichtenberg & Sun, 2007) The study group, which included beneficiaries in standard PDP plans who reached the coverage gap in June 30, 2006, but not catastrophic coverage in 2006, was compared with a control group which included beneficiaries in non-Part D commercial plans.

Similar to reports from earlier studies, the authors report that individuals who reach the coverage gap (study group) were significantly older (76.34 vs. 73.04 years), sicker (5.39 vs. 3.66 disease conditions), and had high out-of-pocket (OOP) expenses ($2,354 vs. $598) compared to beneficiaries who did not reach the coverage gap (control group). After reaching the coverage gap, average prescription days of therapy decreased in the study group by 15.85% from (1,104 to 929, $p<0.0001$) but increased by 1.77%

(from 680 to 692, p<0.0001) in the control group. It is interesting to note that for beneficiaries who hit the coverage gap, while the average total costs decreased by about 28% (from $2,441 to $929, p<0.0001), out-of-pocket expenses increased by 88.94% ($8777 to $1,657, p<0.0001). However, completely opposite results were reported for the control group: a 2.19 % increase (from $1,322 to $1,351, p<0.0001) in total costs and 5.54% decrease (from $307 to $290, p<0.0001) in OOP costs. Rate of utilization of generic drugs was reported to increase by 25.32% (from 39.77% to 49.84%, p<0.0001) in the study group and only 5.32% (from 51.55% to 54.29%, p<0.0001) in the control group.

Results of a difference in difference analysis indicated that, Medicare Part D coverage gap decreased prescription drug utilization by 187.49 days of therapy (p<0.0001); increased OOP expenses by $796.49 (p<0.0001), and increased rate of generic drug utilization by 7.33% (p<0.0001). While this study provides some evidence of the impact of coverage gap on medication utilization, it only includes patients enrolled in PDP plans, uses non-part D beneficiaries as a control group, only includes beneficiaries who hit the coverage gap in June and does not assess impact of the coverage gap on medication adherence.

Zhang et al., (2009) compared prescription drug utilization for beneficiaries with coverage during the coverage gap (employer-sponsored plan) with prescription drug utilization for beneficiaries with no coverage or some with generic coverage (MA-PD plan) during the coverage gap by using data from a large health plan in Pennsylvania, for the year 2006. (Zhang, et al., 2009) About 25% of beneficiaries in the MA-PD plan and 40% of the beneficiaries in the employer-sponsored plan reached the coverage gap in

2006. After controlling for demographics and health status, the study results indicate that prescription drug utilization of beneficiaries with no coverage in the coverage gap was 14 % lesser (decrease of 0.3 brand names and 0.4 generic prescriptions/month) compared to beneficiaries with full coverage during the gap. Beneficiaries with generic drug coverage, decreased use of their brand-name drugs (decrease of 0.5 brand name prescriptions/month) but increased use of generic medications (increase of 0.36 generic prescriptions/month) compared to beneficiaries with full coverage during the gap. However, caution should be exercised when interpreting these results since the study is based on cross-sectional data with no control for selection bias.

A survey of 915 Medicare beneficiaries enrolled in a Kaiser Permanente Colorado Medicare Advantage plan indicated that beneficiaries with no gap coverage were nearly three times more likely (42% vs. 14%, $p<0.001$) than beneficiaries with gap coverage to report using a medication cost-lowering strategy such as using less medication than was prescribed, stop taking a medication, not fill a prescription, etc during the coverage gap.(Cronk, et al., 2008) Further, beneficiaries with no gap coverage, younger beneficiaries, those in poor health, more than high school education, annual income < 30,000 (excluding LIS), and those who had previously purchased a second-generation anti-psychotic were more likelyto use a cost-lowering strategy. However, the study did not report the impact of the coverage gap on medication adherence.

In summary, as reported in detail above, few studies published in the literature indicate that the Medicare Part D coverage gap decreases prescription drug utilization by about 15%, decreases medication adherence and increases OOP expenses of Medicare beneficiaries. However, it is important to note that these studies are limited by

methodological flaws. Two studies assessing the impact of coverage gap are descriptive in nature. (Cronk, et al., 2008; Hoadley, et al., 2008) Studies which are based on retrospective claims data either include health plan data and lack direct comparison with a control group (Raebel, et al., 2008); or include a control group and lack plan related data and are limited to beneficiaries hitting coverage gap in a particular month as against comparing utilization during different months of the year; (F. R. Lichtenberg & Sun, 2007) or do not control for selection bias. (Zhang, et al., 2009)

Thus, although few studies have been conducted to assess the impact of prescription drug coverage gap on utilization and medication adherence, their results need to be interpreted with caution. The objective of this study is to present results describing the impact of the coverage gap on prescription drug utilization and medication adherence by using a methodologically sound research design. Details of the methods used to accomplish this will be presented in Chapter 3.

PART III: MEDICATION ADHERENCE

Definition of adherence

The National Council on Patient Information and Education (NCPIE) defines compliance as "following a medicine treatment plan developed and agreed on by the patient and his/her health professional". (P. G. Rogers & Bullman, 1996) The NCPIE includes within this definition the term adherence, including two-way communication, patient-centered treatment planning, constant monitoring and agreed-upon dosage or medication adjustments, and cooperative specification of what compliance means for each medication. A more commonly used definition of medication adherence developed by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)

Medication Compliance and Persistence Work Group, refers to the extent to which a patient acts in accordance with the prescribed interval and dose of a medication regimen. (Cramer JA, et al., 2008)

The NCIPE refers to non-compliance as the acts of omission and commission caused due to inadvertent error or intentional decisions. (P. G. Rogers & Bullman, 1996) Included in the acts of omission are behaviors associated with under use of medications such as taking less medicine than prescribed; taking it less frequently than prescribed; taking medicine ‘‘holiday’’; or not taking the prescribed medications at all. Acts of omission also include behaviors such as not obtaining initial or refill prescriptions; and stopping a medicine earlier than prescribed. The NCPIE refers to acts of commission as behaviors related to the dosing of medications. This includes behaviors such as overuse of medications by taking a higher than prescribed dose or taking doses too frequently; mistiming of doses; taking lower than prescribed doses or skipping doses; sharing medicines with family members and knowingly consuming a food, beverage, or drug that can interact with prescribed medications.

Factors affecting Medication Adherence

The literature cites numerous studies assessing the underlying factors associated with the medication adherence. A review of the literature by Balkrishnan succinctly lists the factors affecting elderly patients' medication adherence.(Rajesh Balkrishnan, 1998) These include: race, drug and dosage form, number of medications, cost of medications, insurance coverage, and physician-patient communication. The review reports an inconsistent association between medication adherence and an elderly patients’ age, sex,

socioeconomic status, living arrangement, co-morbidities, number of physician visits, and knowledge, attitudes, and beliefs about health. In another review of determinants of medication adherence in the elderly, Vik et al report that while number of medications and poor patient-healthcare provider relationships (including the use of multiple providers) have been consistently shown to affect non-adherence, most socio-demographic factors may have a limited effect. (Vik, Maxwell, & Hogan, 2004) The authors attribute inconsistent findings in the factors affecting adherence to the numerous methods of used in measuring adherence.

Based on the results of these literature reviews assessing the factors affecting medication adherence in the elderly, a theoretical framework and available data, the factors affecting medication adherence will be controlled for in this study statistically by using these variables as covariates.

Measurement of adherence

Measurement of medication adherence can be best described by classifying them as direct or indirect methods of adherence measurement. Direct methods of adherence measurement include methods such as directly observed therapy, assessment of serum concentrations of the drug or its metabolite in blood or urine, and detection or measurement of pharmacologic tracers added to drug formulations.(Osterberg & Blaschke, 2005) Direct methods while providing an accurate measure of adherence can be inconvenient and time consuming for the patient and very expensive for the investigator.

Indirect methods of adherence measurement include using patient self-reports (questionnaires, medication diaries), assessing clinical response, pill counts, electronic

medication monitors and prescription refill rates.(Osterberg & Blaschke, 2005)

Patient self-reports, aided by the use of questionnaires and asking patients to maintain diaries, have been widely used as a measure medication adherence. While patient self-reports are convenient and easy to use, they might not be accurate due to poor patient recall or incorrect representations by patients. Patient self-reports have been reported to overestimate adherence by as much as 200% compared to adherence measured using biochemical measures and over estimate by 1.3 to 2.0 times when compared to adherence measured using pill counts. (Krueger, Berger, & Felkey, 2005)

Assessment of clinical response, while easy to perform, might not be truly reflective of adherence as clinical response to medications might be affected by factors not related to medication taking behavior.

A commonly used measure of medication adherence is pill counts (counting the number of pills that remain in the patient's medication bottles or vials). Although relatively inexpensive, objective and quantifiable, this method of adherence measurement may not be valid as patients can easily manipulate it (by discarding pills before visits) and this method does not provide information on dose or the time that the medication was ingested.

Electronic medication monitoring overcomes the problems of pill counts with the use of digital monitors installed in the caps of bottles, eye drop dispensers, canisters, etc, to record the time and amount of drug dispensed from the bottle. This method is very accurate, provides information about time and dosing and prevents the problem of patient’s discarding drugs before a visit. However, these monitors are expensive and the act of taking a pill out of the bottle does not confirm consumption. (Osterberg &

Blaschke, 2005)

Pharmacologic tracers, pill counts and electronic compliance monitors are commonly used in randomized clinical trials. Patient self-reports, clinician assessments, and serum drug levels have been used in clinical settings. However, for studies involving large populations or for health services research, where direct adherence measurement is not feasible, pharmacy refill records have been used extensively. With the availability of electronic records, refill records provide a quick and inexpensive method of adherence assessment. However, refill records might provide an inaccurate adherence estimate given that medication acquisition does not necessarily imply medication consumption. But medication acquisition is an important step for medication consumption. Further, the validity of refill records as a measure of adherence has been assessed in a number of studies. Significant correlations between adherence measured using refill records and other measures of adherence like appointment keeping, medication taking, provide some evidence of convergent validity. (Steiner & Prochazka, 1997)

Moderate correlations have been reported when refill adherence measures are compared with serum drug levels or drug effects such as blood pressure control. Association between partial adherence and adverse health outcomes provides some evidence of discriminant validity. Since one of the objectives of this study is to assess Medicare beneficiaries adherence to medications, pharmacy refill records would be the most appropriate and valid method to measure medication adherence in this study.

Adherence from refill records can be assessed either as a continuous or a dichotomous measure. A continuous measure of adherence may be defined as "one which offers three or more ordered response categories, or is based on multiple adherence

criteria, or uses a reliable, validated continuous measure to assess adherence." (DiMatteo MR, et al., 2002) A dichotomous measure, as the name suggests, involves two categories (eg. adherent versus non-adherent, etc) based on cut-off values decided by researchers to define the extent of adherence or non-adherence. The results of a meta-analysis of 63 studies analyzing patient adherence to medications, indicated that compared to dichotomous measures, continuous measures should be used to measure adherence. (DiMatteo MR, et al., 2002)

After an extensive review of the literature, Hess et al., (2006), compiled a list of eleven most commonly used adherence measures, described in Table 1. (Hess, Raebel, Conner, & Malone, 2006) These include Continuous, Single-Interval Measure of Medication Availability (CSA);Continuous Measure of Medication Acquisition (CMA); Compliance rate (CR); Days Between Fills Adherence Rate (DBR); Continuous Measure of Medication Gaps (CMG); Continuous Multiple Interval Measure of Oversupply (CMOS); Medication Possession Ratio (MPR); Refill Compliance Rate (RCR); Medication Possession Ratio, modified (MPRm); Medication Refill Adherence (MRA); and Proportion of Days Covered (PDC). Hess et al., calculated and compared medication adherence values derived by using each of these methods on data from the LOSE Weight (Long-term Outcomes of Sibutramine Effectiveness on Weight) study.

Medication adherence calculations using all eleven measures indicated that, of the eleven, CMA, MPR and MRA provided the same adherence value of 63.5%. Calculations based on PDC resulted in a slightly lower adherence value of 63.0%. CMG and CMOS, the gap measures resulted in adherence of 0.365 and 0.370 respectively. Higher adherence values were reported with the use of CR (84.4%), MPRm (86.6%),

RCR (104.8%), and CSA (109.7%), as methods to measure adherence. (Hess, et al., 2006)

The authors note several important points about each method of calculation. They indicate that when medication adherence calculations include more than one refill per day and if refills occur close to the study completion date, CSA can be biased. CMG and CMOS are essentially treatment gap measures and maybe difficult to interpret. The biggest limitation of using the MPR is the inconsistency in the terminology used in the literature to describe it. Numerous published measures of adherence with different formulae used for calculations have been termed "MPR". The biggest limitation of using CR, RCR, DBR and MRA as measures of adherence is that the period from last dispensation until study completion is disregarded. The MPRm method overcomes this limitation by adding a number of days to the evaluation period which is equal to the days' supply obtained at the last fill. However, due to the assumption that each individual will be 100% adherent during the last dispensation period, use of MPRm results in higher values of adherence. (Hess, et al., 2006)

Using North Carolina Medicaid claims of 7069 patients (aggregated for each person as person-quarters) suffering from Schizophrenia, Martin et al compared medication adherence when measured using the PDC and two variants of MPR (MPR and truncated MPR- MPR capped at 1.0). (Martin et al., 2009) The proportion of days covered (PDC) measures the proportion of days a patient has a drug available, in the study interval, by assigning a simple binary measure indicating the presence or absence of the study drug for each day in the study period. Drug oversupplies from early refills are thus not included in PDC calculations. MPR is calculated by adding the total days' supply

Table 1: Measures of Medication Adherence

Measure	Formula
Continuous Measure of Medication Acquisition (CMA)	cumulative days' supply of medication obtained / total days to next fill or to end of observation period
Continuous Measure of Medication Gaps (CMG)	total days of treatment gaps / total days to next fill or end of observation period
Continuous Multiple Interval Measure of Oversupply (CMOS)	total days of treatment gaps (+) or surplus (–) / total days in observation period
Compliance rate (CR)	(total days supplied – last days' supply) / (last claim date – first claim date) × 100
Continuous, Single-Interval Measure of Medication Availability (CSA)	days' supply obtained at beginning of interval/days in interval
Days Between Fills Adherence Rate (DBR)	1 – [(last claim date – first claim date) – total days' supply] / (last claim date – first claim date) × 100
Medication Possession Ratio (MPR)	days' supply: days in period
Medication Possession Ratio, modified (MPRm)	[total days supply / (last claim date – first claim date + last days' supply)] × 100
Medication Refill Adherence (MRA)	(total days' supply / total number of days evaluated) × 100
Proportion of Days Covered (PDC)	total days supply (medication availability) / total number of days evaluated × 100%, capped at 1.0
Refill Compliance Rate (RCR)	[(sum of quantity dispensed over interval / quantity to be taken per day) × 100] / number of days in interval between first and last refill

for all medications and dividing by the number of days in the study period. Therefore, in this study, the numerator for PDC included the number of days one or more antipsychotics was available and the MPR numerator included the total days' supply of antipsychotics. The denominator for both MPR and PDC were total days in each person quarter. The results of the study indicated that PDC provides a more conservative estimate of medication adherence compared to medication adherence when calculated by using the MPR (mean PDC= 0.607, mean truncated MPR= 0.640, and mean MPR =0.695; $p < 0.001$) The differences between medication adherence measured using the PDC and MPR were more pronounced when calculated for patients who switched therapy (mean PDC=0.562, mean MPR =0.690, and mean truncated MPR=0.624; $p < 0.001$) and for patients with prescribed therapeutic duplication (mean PDC=0.669, mean truncated MPR=0.774, and mean MPR=1.238; $p < 0.001$). In these cases, compared to the PDC, medication adherence was overestimated by nearly 11% when measured using the MPR and overestimated by nearly 60% when measured using the truncated MPR. The authors reported that in certain cases with therapeutic duplication, use of MPR as a measure of adherence resulted in adherence values nearly 85% higher than values obtained when measured using the PDC.

Adherence measures used in this study

Based on the review of studies described above, established validity and recommendations from the ISPOR task force on compliance, the two most commonly used and validated measures of adherence in studies involving pharmacy refill records – the Medication Possession Ratio (MPRm) and the Proportion of Days covered (PDC) will be used in this study. (Hess, et al., 2006; Martin, et al., 2009; Peterson AM et al., 2007)

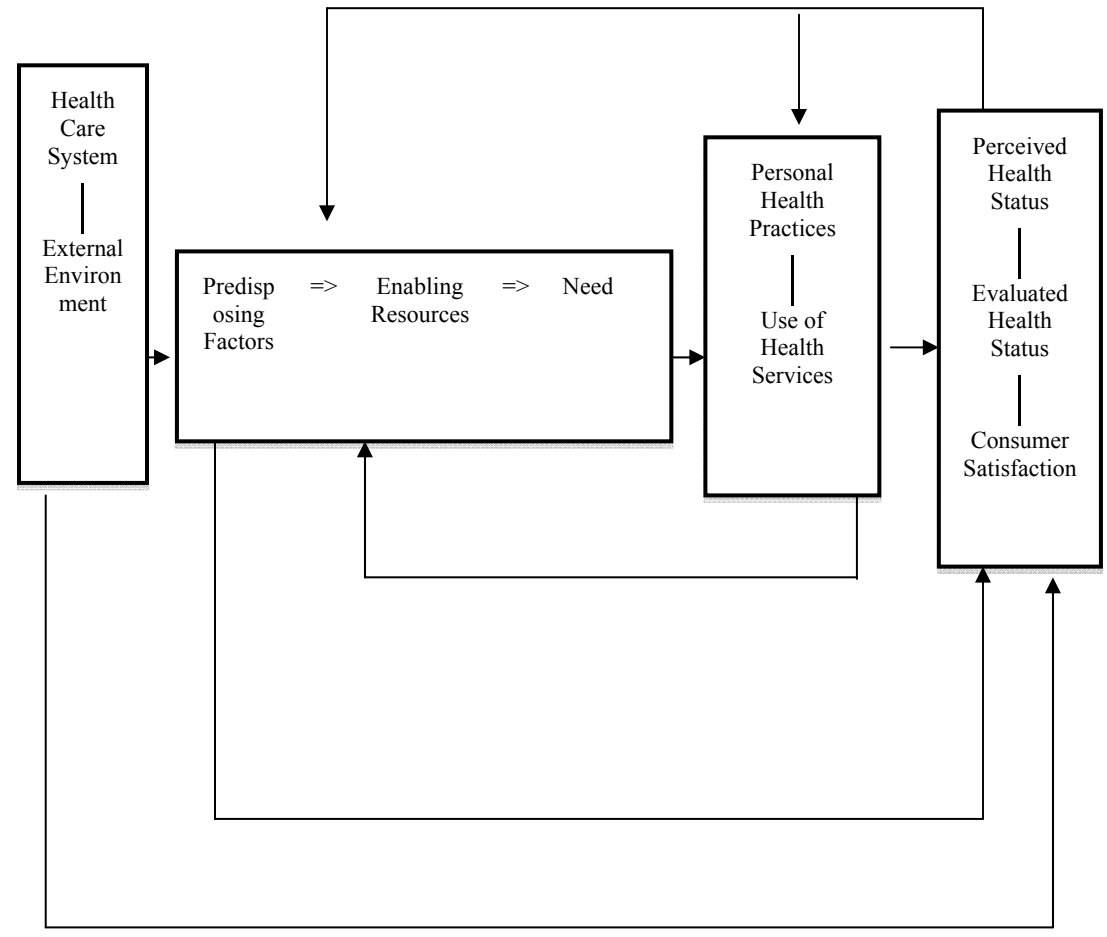
The MPRm is calculated by summing the number of days supplied for all but the last refill, divided by the number of days between the first and the last refill. The PDC is calculated by dividing the total days a medication is available by total number of days evaluated in the study period. The MPR and PDC have a range of 0-1, with a higher number indicating higher adherence. A ratio of greater than 1.0 is possible when adherence is measured using the MPR, with values greater than 1 indicating an oversupply, switching, etc. The PDC on the other hand is capped at 1.0 and is not affected by oversupply of medications. Adherence calculation related details associated with over supplies, switching, etc will be described at length in Chapter 3.

SECTION IV: THEORETICAL FRAMEWORK

The objectives of this study will be analyzed using the framework provided by one of the most widely used model to study health service's use - the Andersen's Behavioral Model of Health Services Use as a guide. The model originally developed in 1968, has been modified multiple times. (Andersen, 1995) The 1995 modification model, which is most frequently used in studies assessing health service use, will be used in this study.(Andersen, 1995) The model as depicted in figure 1 is based on the premise that outcomes (health status and satisfaction) are dependent on environment factors, population characteristics and health behavior factors.

Environment factors refer to a composite measure of health care system factors and external environment factors. Health care system factors include factors related to national health policy, health care resources available and their organization in the health care system that impact health services use. External environment factors refer to

Figure 1 The Andersen's Behavioral Model of Health Services Use*



*Source: Andersen, 1995

physical, political and economic components in a health care system that impact use of health care services. (Andersen, 1995)

Population characteristics include predisposing factors, enabling resources and need. Predisposing factors include demographic variables such as age, gender, marital status, education, race/ethnicity, and occupation, as well as an individual's health beliefs and attitudes. Enabling resources refer to availability and accessibility of family and community resources such as income, insurance status, etc. Need factors refer to an individual's perceptions of their health status and their need for medical care. (Andersen, 1995)

Health behavior factors are a composite measure of personal health practices such as diet, exercise, etc and measures of health services use including type, site, purpose and coordinated services in an episode of illness.(Andersen, 1995)

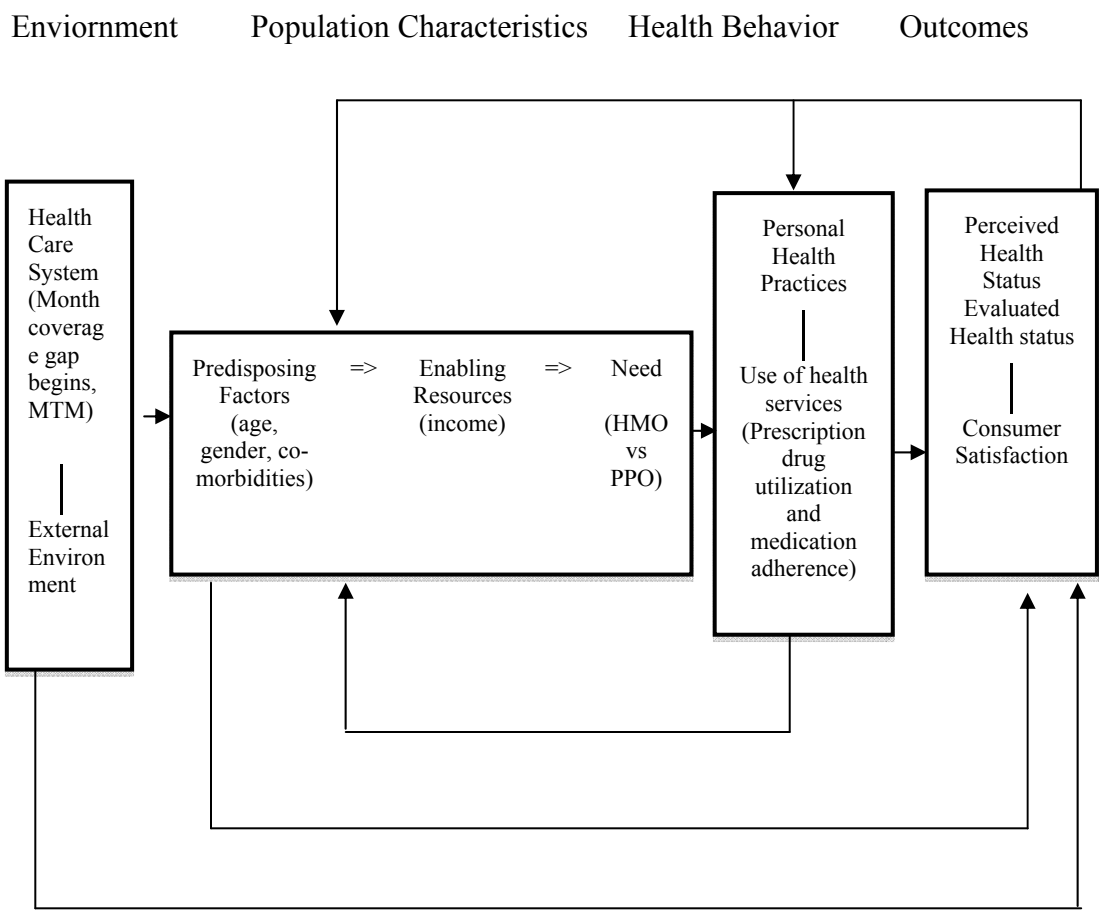
Outcomes include perceived and evaluated health status and consumer satisfaction. Perceived health status as the name suggests reflects the health status, as a population perceives it while evaluated health status refers to the health status as evaluated by professionals. (Andersen, 1995) Consumer satisfaction, an explicit outcome of health services includes convenience, availability, financing, provider characteristics and quality of care. The feedback loops in the model reflect the dynamic and recursive nature of a health services model. (Andersen, 1995)

Andersen's model is a comprehensive model which presents a complete framework of various factors influencing health services utilization. While it is desirable that all variables described in the model be measured to adequately assess health care utilization, this study uses data from a pre-existing database and data required to assess

each variable might not be available. For the purposes of this study, the Andersen's model framework is used as a theoretical guide to assess the impact of the Medicare Part D coverage gap on Medicare beneficiaries' prescription drug utilization and medication adherence, based upon the data available. Figure 2 represents the variables assessed in this study based on the availability of data. Environment factors which refer to a composite measure of health care system factors and external environment factors, assessed in this study, include the month in which the coverage gap starts and an individual's receipt of MTM services. The month in which an individual's coverage gap starts is dependent on the coverage gap limit set by CMS and thus represents a healthcare system factor. Acceptance to receive MTM services are an individual's choice. However, eligibility requirements determining receipt of MTM services are preset by the CMS. Thus, receipt of MTM services is also considered as a healthcare system factor.

Predisposing factors, which refer to the demographic variables assessed in this study, include age, gender and co-morbidities. Data representing other predisposing factors such as marital status, education, race/ethnicity, occupation, and an individual's health beliefs and attitudes was not available. Enabling resources refer to availability and accessibility of family and community resources. Income will be considered as an enabling resource in this study, as an individual's income might influence their decision on the type of the prescription drug coverage plan that they choose to enroll (generic/full/no coverage during the gap). Need factors refer to an individual's perceptions of their health status and their need for medical care. While the data does not provide a direct measurement of need factors, an individual's choice to enroll in a HMO or PPO plan might be reflective of their perception of their health status and their need for medical care. Therefore, HMO

Figure 2: The Andersen's Behavioral Model of Health Services Use (with variables used in the study) *



*Source: Andersen, 1995

vs. PPO enrollment will be included as a need factor in this study.

Health behavior factors are a composite measure of personal health practices such as diet, exercise, etc and measures of health services use. Data related to individual's personal health practices was not available. The health behavior assessed in this study refers to an individual's prescription drug utilization and medication adherence before and after hitting the coverage gap. Health behavior assessment thus reflects the desired outcome to be measured in this study. The outcomes represented in Andersen's model include health status and satisfaction. The data available for this study did not lend support to measure the outcomes listed in the Andersen's health behavior model and were truncated at measurement of health services use.

SUMMARY OF LITERATURE REVIEW

Medicare, a federal insurance program established in 1965, provides health insurance to Americans aged 65 and older and to individuals under age 65 with certain disabilities or end-stage renal disease. Medicare consists of four parts: Part A, B, C and D. Medicare Part A covers inpatient care in hospitals; Medicare Part B covers physicians' services and outpatient care; and Medicare Part C, in addition to covering Part A and B services, typically includes additional benefits such as vision, dental, prescription drug coverage, etc.

To increase Medicare beneficiaries' access to medications and help lower their prescription drug costs, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 introduced a prescription drug benefit, for all Medicare beneficiaries, referred to as 'Medicare Part D'. A review of the literature

indicates that Medicare Part D coverage is associated with an approximately 6% increase in prescription drug utilization and a 13% decrease in out-of-pocket expenses, with higher amounts reported for specific drug classes. However, it is also important to note that Medicare Part D has been structured to include substantial cost-sharing from beneficiaries in the form of deductibles, co-payments, and tiered payments.

A significant body of literature has been dedicated to understanding the impact of cost-sharing on Medicare beneficiaries' prescription drug utilization, medication adherence and health outcomes before Medicare Part D was initiated. With Medicare Part D data not released by CMS, findings from these studies may provide reasonable estimates of the impact of cost-sharing in Medicare Part D on health care utilization. A review of the literature indicates that cost-sharing in the form of increased co-insurance rates decreases prescription drug utilization in the elderly by 2-6%, with larger decreases for specific drug classes. Cost-sharing has also been associated with decreased adherence, increased costs, and increased out-of-pocket expenses. Further, cost-sharing in the form of prescription benefit caps have been reported to decrease Medicare beneficiaries' prescription utilization by about 8-30%, increase hospitalizations and emergency room visits, and increase total costs by 13-30%, on average.

While the studies assessing the impact of cost-sharing on Medicare beneficiaries, conducted before the initiation of Medicare Part D, provide a reasonable estimate of the impact of cost-sharing in Medicare Part D, most studies are based on plans with prescription drug coverage caps in the range of $1,000. Standard Medicare Part D plans in 2007 had cost sharing in the amount of approximately up to $4,000. Medicare Part D coverage gap, the largest cost-sharing component of the Part D structure, has been

estimated to affect approximately 14-15% of Medicare beneficiaries in 2007. Only a few studies have thus far directly assessed the impact of Medicare Part D coverage gap. Results of these studies indicate that the Medicare Part D coverage gap decreases prescription drug utilization by about 15%, decreases medication adherence and increases OOP expenses of Medicare beneficiaries. However, it is important to note that these results are based on studies which are either descriptive in nature or are limited by methodological flaws (lack of control groups, lack of health plan data, inaccurate estimation of coverage gap status, etc). Thus, although few studies have been conducted to assess the impact of prescription drug coverage gap on utilization and medication adherence, their results need to be interpreted with caution.

The objective of this study is to assess the impact of the Medicare Part D coverage gap on prescription drug utilization and medication adherence by using a methodologically sound research design which is theoretically guided by the Andersen's Behavioral Model of Health Services Use, accurately assesses the coverage gap status, incorporates health plan data, includes a control group, accounts for confounding variables, uses two validated measures of adherence and uses robust econometric techniques for data analyses. Details of the methods to assess the study objectives are provided in chapter 3.

CHAPTER 3

METHODS

This chapter presents a detailed description of the methods used to conduct the study. The chapter begins with a description of the Human Research Review Committee approval to conduct this study, followed by an overview of the study research design, and a description of the study participants. Next, the study inclusion and exclusion criteria are discussed followed by a description of sample size calculations. Cost calculations used to determine if a beneficiary remains in the initial coverage limit, hits the coverage gap or is covered under catastrophic coverage followed by validity checks of the cost calculations are presented.

The steps involved in data cleaning are described, followed by a description of the independent variables used in this study. Definitions and steps involved in measuring prescription drug utilization and medication adherence are described next, followed by examples of medication adherence calculations for three hypothetical cases and a description of the ten drug classes selected for medication adherence calculations. A description of the covariates used in the study is provided including a description of the measure and validation of the co-morbidity score, income assessment for beneficiaries in the study and MTM services provided by XYZ health care services. Following this is a description of the description of sample clinics and the data available on utilization of Medicare Part A and B services by beneficiaries who hit the coverage gap and total medical costs incurred pre- and post-coverage gap. The last section of the chapter describes the statistical data analyses planned for this study.

Human research review committee approval

The University of New Mexico Health Sciences Center Human Research Review Committee (HRRC) reviewed and granted approval for the study after an expedited review. A copy of the HRRC approval letter is included in Appendix A. A waiver of HIPPA authorization and a waiver for informed consent were obtained.

Data required for this study was abstracted from the electronic data repository from a large managed care organization in New Mexico, henceforth referred to as XYZ health care services. Information from electronic medical and pharmacy records was used for this study. These data include detailed information on pharmacy claims (prescription fills, costs of prescription drugs, etc), demographic data (e.g., age, gender, ZIP codes etc), medical claims (e.g. diagnostic codes, etc), and data from XYZ health care services' sample clinics (information about prescriptions obtained by beneficiaries from sample clinics). Full compliance with the Health Insurance Portability and Accountability Act (HIPPA) regulations as required by UNM HRRC was maintained when conducting this research.

Research design

A quasi-experimental, cross-sectional, retrospective, pre-post with control group study design was used to assess the study objectives. The study objectives examined prescription drug utilization and medication adherence, before and after hitting the coverage gap, of beneficiaries enrolled in a health plan with no prescription drug coverage during the coverage gap (study group) was compared with that of beneficiaries

enrolled in a plan with generic drug coverage and full prescription drug coverage during the coverage gap (control group). Pharmacy and medical claims data from a large managed care organization in New Mexico were used to answer the study objectives. Data was abstracted for the period January 1 to December 31, 2007.

Study participants

Study participants included Medicare beneficiaries enrolled in Medicare Advantage prescription drug (MA-PD) plans offered by XYZ health care services. MA-PD plan beneficiaries can choose between two plans offered by the XYZ health care services - the Senior Care plan (HMO) and the Medicare Preferred Provider Organization (PPO) plan to receive Medicare Part D benefits. The Senior Care HMO plan only covers services obtained from providers associated within the plans network while the Medicare PPO plan covers services obtained from both in-network and out-of-network providers. However, with respect to Part D benefits, both the HMO and the PPO plans provide the same prescription drug benefits. Beneficiaries enrolled in the Senior Care (HMO) plan and the Medicare PPO plans further have an option to choose between two plans referred to as plan 2 and plan 3. The primary difference between plan 2 and plan 3 (for both Senior Care and PPO plan) is coverage of prescription drugs during the coverage gap. Plan 2, hence forth referred to as the 'no coverage' plan, does not offer any coverage of prescription drugs during the coverage gap. Medicare beneficiaries enrolled in plan 2, represent the study group. Plan 3 hence forth referred to as the 'generic coverage' plan is a plan which covers all preferred generics during the coverage gap. Medicare beneficiaries enrolled in the generic coverage plan represent one control group. Medicare

beneficiaries enrolled in an employer-sponsored plan, which covers both brand name and generics in the coverage gap, hence forth referred to as the 'full coverage' plan, will be used as a second control group. Details about premiums, deductibles, and coverage for no coverage, generic coverage and full coverage plans are listed in Table 2.

In 2007, XYZ healthcare services' Medicare Senior Care Plan had 18,731 enrollees and Medicare PPO plan had 4,608 enrollees and the employer-sponsored plan had 2,232 enrollees. Medicare beneficiaries who met the study eligibility criteria were thus selected from a pool of 25,571 beneficiaries in Medicare Senior care, PPO and employer sponsored plans.

Inclusion criteria

Medicare beneficiaries who were at least 65 years of age, non-institutionalized, continuously enrolled in a XYZ health care services MA-PD plan from January 1, 2007 to December 31, 2007 were included in the study.

Exclusion criteria

Medicare beneficiaries who received any form of financial assistance from external sources were excluded from the study. Medicare beneficiaries who were dual eligible (i.e. eligible for both Medicare and Medicaid), beneficiaries with low income subsidies, beneficiaries eligible for military retirement benefits (TRICARE), beneficiaries eligible for Veteran benefits (VA), beneficiaries eligible for federal retiree benefits, and beneficiaries in long term care facilities were excluded from the study.

Table 2: Coverage details for no coverage, generic coverage and full coverage plans

Benefits	No Coverage Plan	Generic Coverage Plan	Full Coverage Plan
Premium	No additional premium beyond the Medicare Part B premium of $93.50 each month	A $57.00 monthly premium in addition to Medicare Part B premium of $93.50 each month	Variable
Deductible	No deductible		
Initial Coverage	*Generic/Preferred Brand /Non-Pref. Brand* **Retail Pharmacy** $4/33/55 for 30 days supply (DS) *Specialty:* $100 **Mail Order** $8/83/165 for 90 DS		*Generic/Preferred Brand /Non-Preferred Brand* **Retail Pharmacy** $5/20/45 for 30 DS *Specialty:* $100 **Mail Order** $10/50/145 for 90 DS
Coverage Gap	**No gap coverage** Beneficiaries pay 100% of prescription drug costs	**All generics covered** **Retail Pharmacy** *Generic* $4 for 30 DS $12 for 90 DS **Mail Order** $8 for 90 DS Beneficiaries pay 100% for all other prescription drug costs.	**All drugs covered** **Retail Pharmacy** *Gen/Pref Brand /Non-Pref Brand* $5/20/45 for 30 DS $15/105/165 for 90 DS *Specialty:* $100 **Mail Order** $10/50/145 for 90 DS
Catastrophic Coverage	Beneficiaries pay the greater of: $2.25 for Generic/$5.60 for all other drugs or 5% co-insurance		

Sample size calculations

Sample size calculations are based on the primary objective of the study, which is to assess the impact of the Medicare Part D coverage gap on prescription drug utilization and medication adherence. Due to lack of available information required to calculate the sample size based on multivariate tests, univariate paired t-tests were used to conduct the sample size calculations. Additionally, since multivariate tests have higher power compared to univariate tests, sample size estimates based on univariate tests provide more conservative estimates compared to sample size estimates based on multivariate tests. (Stevens, 2002) The NCSS/PASS software was used for sample size calculations. (NCSS/PASS, 2008)

a) Impact of the coverage gap on prescription drug utilization

In order to estimate the sample size required to compare Medicare beneficiaries' prescription drug utilization before and after hitting the coverage gap, results from the study conducted by Sun and Lee (2007) were used. The authors report that after reaching the coverage gap, Medicare beneficiaries' average prescription days of therapy decreased by 15.85% (from 1,104 to 929 days of therapy, $p<0.0001$). Standard deviation (SD) values are not reported as a part of the Sun and Lee study results. For the purposes of this study, sample size was estimated for a range of possible standard deviation (100, 500, and 1000) values. By using a standard deviation of 1000, which is nearly as large as the reported mean, a very conservative estimate of sample size is provided. Using a paired t-test, at a level of significance=0.05, power=80%, effect size=0.18 (calculated based on pre-period mean prescription drug utilization=1104 and post-period mean prescription

drug utilization =929, SD = 1000), the most conservative estimate of sample size was 259 beneficiaries. Sample size estimates based on a range of SD values are presented in Table 3.

Table 3: Sample Size Estimation for Prescription Drug Utilization

N	Prescription days therapy		SD	Effect Size	Power
	Pre-coverage gap mean*	Post-coverage gap mean*			
5	1104	929	100	1.75	0.83
67	1104	929	500	0.35	0.80
259	1104	929	1000	0.18	0.80

*Estimates reported in the study conducted by Sun and Lee (2007)

b) Impact of the coverage gap on medication adherence

In order to estimate the sample size required for comparing Medicare beneficiaries' medication adherence before and after the coverage gap, results from the study conducted by Raebel et al., (2008) were used. (Raebel, et al., 2008) Raebel et al., calculated medication adherence using the medication refill adherence (total days supply/number of days in the study period*100) method. Medication Possession Ratio (MPRm) and the Proportion of Days covered (PDC) are used as measures of medication adherence for the purposes of our study. As reported in detail in the literature review, medication adherence calculated using MPR is equivalent to medication adherence calculated using MRA. Thus, although Raebel et al., used a different measure of medication adherence, adherence values reported in their study provide reasonable

estimates for sample size calculations.

Based on the results of the Raebel et al study, the pre-period (before the coverage gap) and post-period (after the coverage gap) medication adherence means and SD values for drug classes relevant to our study (statins, anti-hypertensive and oral anti-diabetic medications) are reported in table 4. Using a paired t-test, at a level of significance=0.05, power=80%, effect size=0.17 (calculated based on pre-period mean adherence=91 and post-period mean adherence=87.3, SD=22.4), the most conservative estimate of the sample size was 290 beneficiaries.

Table 4 : Sample Size Estimation for Medication Adherence

Drug class	N	Medication Refill Adherence		SD	Effect Size
		Pre-coverage gap mean adherence*	Post-coverage gap mean adherence*		
Statins	290	91	87.3	22.4	0.17
Anti-hypertensives	173	89.8	84.5	24.7	0.22
Oral anti-diabetics	245	95.1	91.7	18.9	0.18

*Estimates reported in the study conducted by Raebel et al (2007)

Determination of initial coverage limit, coverage gap and catastrophic coverage

Total costs and true out-of-pocket (TrOOP) costs are used to assess if a Medicare beneficiary remains in the initial coverage limit, hits the coverage gap or is covered under catastrophic coverage. Total costs represent the costs associated with filling a prescription drug and include the amount XYZ health care services pays and the amount a beneficiary

pays (co-pay) after filling a prescription drug.

True out-of-pocket costs, on the other hand, only include costs incurred by the beneficiary. TrOOP costs are the prescription drug costs that count toward the annual out-of-pocket threshold that beneficiaries must reach before catastrophic drug coverage begins. (Centers for Medicare and Medicaid Services, 2006) Deductibles, co-payments, and co-insurance amounts that a beneficiary pays contribute towards TrOOP. More specifically, the payments that count toward TrOOP costs include the beneficiary's own out-of-pocket spending; payments made by a family member or official charity on behalf of the beneficiary; payments by a qualified charity; and payments made by a State Pharmaceutical Assistance Program.(Centers for Medicare and Medicaid Services, 2006) Payments that do not count toward TrOOP costs include premiums paid by the beneficiary; payments made by a group health plan (e.g., employer or retiree plan); payments made by government programs (e.g., Veterans Affairs or TRICARE); payments covered by an automobile insurer; and payments made by Part D plans as part of an enhanced plan benefit package. (Department of Health and Human Services, 2007) For beneficiaries enrolled in standard Part D plans, TrOOP costs in 2007 included $265 deductible, $535 coinsurance during initial coverage and $3050 during the coverage gap, which add up to $3,850.

Medicare beneficiaries enrolled in XYZ health care services MA-PD plans are not required to pay any deductible. Details about co-payment amounts that beneficiaries are required to pay during the initial coverage limit, coverage gap and catastrophic coverage are listed in table 2. The following steps were taken to assess if a beneficiary remains in the initial coverage limit, hits the coverage gap or is covered under catastrophic coverage:

1) Total drug costs (ingredient cost + dispensing fee) were calculated for each beneficiary. The next step involved determining beneficiaries who had total costs less than $2,400 and beneficiaries who had total costs greater than $2,400. Beneficiaries who had total costs less than $2,400 represented beneficiaries who remained in the initial coverage limit. Beneficiaries who had total costs greater than $2,400 were beneficiaries who hit the coverage gap.
2) For beneficiaries with total drug costs greater than $2,400, their true out-of -pocket costs were calculated. Beneficiaries who incurred TrOOP costs less than or equal to $3,850 and beneficiaries who incurred TrOOP costs greater than $3,850 were identified. Beneficiaries with TrOOP costs less than or equal to $3,850 represented beneficiaries who remained in the coverage gap through the entire year. Beneficiaries with TrOOP costs greater than $3,850 represented beneficiaries who were covered under the catastrophic coverage limit.

Validity of Cost Calculations

XYZ health care services use a pharmacy benefit management (PBM) company that follows each MA-PD plan enrollee's costs to determine if they are in the initial coverage limit, have hit the coverage gap or are covered under the catastrophic coverage limit. However, a comprehensive listing of beneficiaries who hit the coverage gap and their respective total and TrOOP costs for 2007was not available from the PBM. Only by accessing each patient's record through the PBM system, available only on the health plan computer systems, would it be possible to identify these patients. Further these costs from individual records could not be transferred into a database for additional analyses.

Thus, for the purposes of this study, total and TrOOP costs were calculated for each beneficiary by tracking costs associated with all their claims for the year 2007 from XYZ healthcare services pharmacy claims database. To ensure that the cost calculations performed for the purposes of this study were accurate, costs listed in the PBM records for 250 patients were cross checked with costs calculated for the purposes of this study.

Data Cleaning

The following steps were taken to clean the data before analyzing it:

1. Medicare beneficiaries who were at least 65 years of age, non-institutionalized, enrolled in a Medicare Advantage prescription drug plan, enrolled in an employer sponsored benefit plan and received no additional financial assistance from external sources (eg LIS, TRICARE, etc) were identified.
2. Only members who had a full year of coverage (January 1–December 31, 2007) were included. Members who died before the end of the year were also excluded.
3. All claims for drugs covered under Medicare Part B were deleted based on GPI numbers. A list of all Part B drugs deleted and their GPI numbers is included in Appendix B.
4. XYZ health care services covers Prilosec® for all Medicare beneficiaries. Since Prilosec® is an OTC medication and does not contribute towards TrOOP costs, all Prilosec claims® were deleted for the purposes of cost calculations.
5. Reversed claims: A large number of duplicate claims existed in the data base due to multiple processes and reversals for one claim. The following steps were taken to ensure that only one valid claim existed for each fill.

a) Each claim has a distinct claim number. All claims for each member were ordered by claim number.

b) Each claim had a claim status associated with it. A claim status of 'P' indicates that the claim was processed and a claim status of 'R' indicates that the claim was reversed. If the same claim appeared more than once during the entire year, then three possible scenarios can occur:

i) The number of times a claim is processed (P) is greater than the number of times a claim is reversed (R), i.e. P>R. This implies that the claim was eventually processed. Therefore, the claim was included.

ii) The number of times a claim is processed (P) is less than the number of times a claim is reversed (R), i.e., P<R. This implies that the claim was eventually reversed. Therefore, the claim was deleted.

iii) The number of times a claim is processed (P) is equal to the number of times a claim is reversed (R), i.e., P = R. In this case, there can be two scenarios – 1) claims are resolved on a date, which occurs after the date that the claim was originally submitted and 2) claims are resolved on the same date that the claim was originally submitted.

Different date: If a claim was processed on one date and reversed on another date, then the claim status listed for the latter date was accepted. For example, let us consider a claim which was processed on 1/10/07 and then the claim was reversed on 1/15/07. This claim was considered as reversed.

Same date: The data does not include a time stamp that reflects the time a claim was processed or reversed. For scenarios where a claim was processed and then reversed on the same day, it was difficult to judge whether the claim was eventually processed

or reversed. These claims were deleted from the analyses.

Description of study variables

a) Independent Variable

The independent variable in this study was the coverage gap status, measured at two levels: pre-coverage gap and post-coverage gap. Pre-coverage gap refers to the period before an individual hits the coverage gap and post-coverage gap refers to the period during the coverage gap.

b) Dependent Variables or Outcome Measures

Prescription drug utilization

Prescription drug utilization refers to a measure of how many and how often, plan members use prescription medications in a given year. The standard and most widely used measure of prescription drug utilization, included in the Health Plan Employer Data and Information Set (HEDIS®) is the outpatient drug utilization measured as the total number of prescriptions per member per year. (Chawla AJ, Hatzmann MR, & Long SR, 2001) For the purposes of this study, prescription drug utilization was assessed using per member total number of prescriptions. (Khan, et al., 2008; Klepser, Huether, Handke, & Williams, 2007; F. R. Lichtenberg & Sun, 2007) Prescription drug utilization was calculated before a beneficiary hits the coverage gap (pre-coverage utilization) and during the coverage gap (post-coverage utilization). Prescription drug utilization included claims filled in mail order and retail pharmacies. Claims that had a 90 days' supply were adjusted to reflect a 30 days supply. For example, a claim with a 90 days' supply was

adjusted to reflect 3 claims. This approach has been used in the literature. (Klepser, et al., 2007)

Medication Adherence

Based on established validity and recommendations from the ISPOR task force on compliance, the two most commonly used and validated measures of adherence in studies involving pharmacy refill records – the Medication Possession Ratio (MPRm) and the Proportion of Days Covered (PDC) were used in this study. (Hess, et al., 2006; Peterson AM, et al., 2007) The MPRm is calculated by summing the number of days supplied for all but the last refill, divided by the number of days between the first and the last refill. The PDC is calculated by dividing the total days a medication is available by total number of days evaluated in the study period.

Steps and Assumptions considered for medication adherence calculation

The following steps and assumptions were considered to calculate medication adherence:

1) Two adherence values, the pre-MPR/PDC and the post-MPR/PDC, were calculated for each Medicare beneficiary. The pre-MPR/PDC reflects adherence before a beneficiary hits the coverage gap and the post-MPR/PDC reflects adherence during the coverage gap.
2) The day a beneficiary's total costs are equal to $2400, was considered as the day a beneficiary hits the coverage gap. Since the data does not include time stamps, all prescriptions filled on the day a beneficiary hits the coverage gap were considered as prescriptions filled before hitting the coverage gap.

3) Medication adherence was calculated by using December 31st as the end date. To understand the importance of using December 31st as the end date and not the last claim filled by the beneficiary, let us consider the following example. Suppose a beneficiary John hits the coverage gap on 8/15/07. John fills his prescription for simvastatin on the first of every month from 1/1/07 through 8/1/07. However, John fills no prescriptions for simvastatin from 9/1/07 through 12/31/07. If we use 8/1/07 as the end date, John's adherence would be 100% although John does not fill any prescriptions for 4 months after hitting the coverage gap. This is the time period we are most interested in analyzing and hence 12/31/07 was used as the end date.
4) If a beneficiary's days supply for their last fill was greater than the number of days in the calendar year, then the days supply was updated to reflect the number of days left in the calendar year. For example, if a beneficiary filled a 30 days' supply on 12/18/07, then the days' supply for the claim was updated to 14 days (12/31/07-12/18/07 = 14).
5) The variable days supply associated with dosage forms such as injectables, inhalers, etc might result in incorrect estimates. Thus, as is frequently done in studies assessing medication adherence, only oral dosage forms were considered for the purposes of medication adherence calculations.
6) Medication adherence was calculated per drug class and not for specific drugs. As long as a beneficiary filled a medication in a drug class, the beneficiary was considered adherent. For example, a beneficiary's adherence to statins is reported, not his adherence to simvastatin or pravastatin in particular.

7) It is assumed that a beneficiary is prescribed only one medication per drug class. For example, it is assumed that a beneficiary on statin will be prescribed either simvastatin or pravastatin but not both.

Medication Possession Ratio (MPRm) Calculation

The MPRm is calculated by summing the number of days supplied for all but the last refill, divided by the number of days between the first and the last refill.(Hess, et al., 2006) Days supply is an estimate of how many days a prescription is intended to last and is calculated by dividing the number of doses in the prescription by the number of doses per day. For example, a prescription of 30 tablets twice a day equals to 15 days' supply. The MPR is a ratio with a range of 0-1, with a higher number indicating higher adherence. A ratio of greater than 1.0 is also possible, indicating an oversupply.

$$\text{MPRm} = \frac{\text{total days supply}}{(\text{last claim date} - \text{first claim date}) + \text{last days' supply}} \times 100$$

This formula is traditionally used to calculate the MPRm. However, this formula does not account for medication oversupply - an important aspect to be considered while calculating medication adherence. (Peterson AM, et al., 2007) Beneficiaries' might have an oversupply of medication due to early refills, switching to different medications or switching to a different dose. Therefore, for the purposes of this study, two values of MPRm will be reported. One MPRm, henceforth referred to as "Traditional MPR", was calculated without accounting for medication oversupply. Another value referred to as updated MPRm, henceforth referred to as "Updated MPR" was calculated by accounting for medication oversupply. The following steps were taken to account for oversupply required for the updated MPR calculations.

1. **Oversupply due to early refills:** XYZ health care services allow patients to refill prescriptions once they have exhausted 75% of their medications. Thus, for prescriptions with 30 days' supply, a beneficiary can fill a prescription with 8 days supply left. To understand the importance of adjusting for this oversupply due to early refills, let us consider the following example. Let us consider a beneficiary John who refills his prescription for Simvastatin each month when he is left with 8 day's supply. Suppose John continues his pattern of refilling 8 days before his supply is exhausted for 10 months. Over a period of 10 months, John would have 80 extra days' supply. Now suppose John hits the coverage gap on October 30th. With 80 extra days supply accrued over time, John has enough medication to cover the remaining 2 months. Thus, in John's case, absence of a refill after hitting the coverage gap, does not necessarily imply that he is non-adherent.

   Further, oversupply of medications accrued in the pre-coverage gap period was carried forward to the post-coverage gap period. Medication oversupply was assessed by comparing a beneficiary's total days supply for the entire pre-coverage gap period with the days between first and last fill in the pre-coverage gap period. To understand this better, let us consider claims for a beneficiary listed in table 5.

   Total days supply for the period from 03/27/07 to 5/22/07 = 60.

   Days between 03/27/07to 5/22/07 = 56.

   Oversupply = Days supply-days between 03/27/07to 5/22/07

   = 60-56 = 4

Therefore, 4 days will be subtracted from the numerator in the pre-coverage gap period and added to the numerator of the post-coverage gap period.

Table 5: Example of claims to assess oversupply due to early refills for MPR calculation

Statin	Date Filled	Days Supply
simvastatin	03/27/07	30
simvastatin	05/22/07	30

2. **Oversupply due to switching within the same class:** A beneficiary might be switched to a different medication in the same drug class for reasons such as side-effects or costs (availability of a cheaper alternative). For example, let us consider all claims for statins for a beneficiary John, listed in table 6.

Table 6: Example of claims to assess oversupply due to switching within the same class for MPR calculation

Statin	Date Filled	Days supply
simvastatin	02/16/07	30
simvastatin	03/10/07	30
pravastatin	03/27/07	30
pravastatin	04/18/07	30
pravastatin	5/22/07	30

John is prescribed a 30 days' supply of Simvastatin on 02/16/07. John then refills a 30 days' supply for simvastatin on 3/10/07. Thus, John has simvastain which would last him until 4/8/2007. However, John is switched to pravastatin on 3/27/2007. Thus, for the period between 3/27/07 and 4/10/2007 John has both simvastatin and pravastatin in his possession. As a result of the switch, has 13 days of oversupply (30 days' supply available - 17 days' supply used). There are two options to deal with this oversupply of 13 days due to switching. Either we assume that John might use the

excess medication at some later point in time or assume that John will discard the 13 days oversupply of simvastatin. The more conservative estimate, that John will use the oversupply at a later time will be used for this study. Therefore, as described in 'a' above, 13 days will be subtracted from the numerator in the pre-coverage gap period and added to the numerator of the post-coverage gap period. However, alternative calculations based on the assumption that John will discard the oversupply will also be conducted and results compared.

Therefore, to accurately calculate medication adherence, the PDC and two MPR values will be calculated. The traditional MPR will be calculated without accounting for medication oversupply and the updated MPR will be calculated by accounting for the oversupply.

$$\text{Traditional Pre-MPR} = \frac{\text{TDS}}{(\text{last claim date} - \text{first claim date}) + \text{last days' supply}}$$

$$\text{Traditional Post-MPR} = \frac{\text{TDS}}{(\text{last claim date} - \text{first claim date}) + \text{last days' supply}}$$

$$\text{Updated Pre- MPR} = \frac{\text{TDS-OS}}{(\text{last claim date} - \text{first claim date}) + \text{last days' supply}}$$

$$\text{Updated Post-MPR} = \frac{\text{TDS+ OS}}{(\text{last claim date} - \text{first claim date}) + \text{last days' supply}}$$

Proportion of Days Covered Calculation

The proportion of days covered (PDC) measures the proportion of days a patient has a drug available, in the study interval, by assigning a simple binary measure indicating

the presence or absence of the study drug for each day in the study period. Drug oversupplies from early refills are thus not included in PDC calculations. The PDC is a ratio with a range of 0-1, with a higher number indicating higher adherence. A ratio of greater than 1.0 is not possible, as the PDC is capped at 1.0. (Martin, et al., 2009)

$$\text{PDC} = \frac{\text{total days medication is available}}{\text{total number of days evaluated}} \times 100$$

The following steps were used to calculate PDC:

1. The numerator in the PDC is calculated by checking if a beneficiary has medication coverage for each day in the study period. Dummy variables with values of 0 or 1 are created for each day in the period. If a beneficiary has prescription drug coverage for a particular day he is given a value of 1. If he does not have prescription drug coverage for a particular day he is given a value of 0. The sum of all days that a beneficiary has medication coverage will provide the numerator for the PDC calculation. This approach is very useful when measuring PDC for a therapeutic class, where beneficiaries are concurrently prescribed more than one medication from the same therapeutic class. It is also useful to account for drug switches, addition of drugs within a class, etc. Counting medications per day prevents over-estimation of adherence values.
2. **Oversupply due to switching:** Oversupply due to switching to a different drug is automatically accounted for in the PDC calculations. To understand how oversupply is accounted for in the PDC calculations, let us consider, all claims for statins for a beneficiary John, listed in table 7.

Table 7: Example of claims to assess oversupply due to switching for PDC calculation

Drug	Date Filled	DS
simvastatin	02/16/07	30
simvastatin	03/10/07	30
pravastatin	03/27/07	30
pravastatin	04/18/07	30
pravastatin	05/22/07	30
pravastatin	06/21/07	30
pravastatin	07/21/07	30
pravastatin	08/23/07	30
pravastatin	09/20/07	30

John is prescribed a 30 days' supply of Simvastatin on 02/16/07. John refills a 30 days' supply for his Simvastatin on 3/10/07. Thus, John has simvastain which would last him until 4/8/2007. However, John is switched to pravastatin on 3/27/2007. Thus, for the period between 3/27/07 and 4/10/2007 John has both Simvastatin and Pravastatin in his possession. As described in step 1, when calculating PDC, dummy variables indicating a presence or absence of a drug are assigned for each day. As is depicted in table 8, one dummy variable assessing days supply for simvastatin and one dummy variable assessing days supply for pravastatin are created. John has values of 1 for both simvastatin and pravastatin for the period from 3/27/07 to 4/8/07. As depicted in table 8, the dummy variable for total medications available will reflect a value of 1 on days that a beneficiary has both simvastatin and pravastatin, thus automatically accounting for the oversupply. The numerator for the PDC reflects the total days medications are available, irrespective of whether it was a simvastatin or a pravastatin.

Table 8: Example for claims to assess oversupply due to early refills for PDC calculation

	2/16	**2/17 - 3/09**	**3/10 - 3/26**	**3/27**	**3/28 - 4/08**	**4/09 - 9/20**	**Total**
simvastatin	1	1	1	1	1	0	60
pravastatin	0	0	0	1	1	1	177
Total days supply							**237**
Total days statin avail	1	1	1	1	1	1	**221**

3. **Oversupply due to early refills:** As described in the MPR calculations, when a beneficiary has an oversupply due to early refills, it is important to carry forward the oversupply from the pre-PDC period to the post-PDC period. At the end of each claim, an assessment is made to check if the days supply is greater than the days between that claim and the next claim. For example, let us consider two consecutive claims on 2/16/07 on 3/10/07 (table 7). The days supply for the period between 3/10/07 to 2/16/07 is 30 days while there are only 22 days between 3/10/07 to 2/16/07. Thus the beneficiary has 8 days oversupply. This oversupply of 8 days will be carried forward to the next fill period on 3/10/07. Similarly any oversupply from the fill on 3/10/2007 will be added to the 8 days oversupply from the fill on 2/16/07 and this process is continued for each fill in the study period. If a beneficiary continues filling his prescriptions in a timely manner then all oversupply accumulated at the end of the study period is discarded and PDC is capped at 1. If a beneficiary has gaps between fills, then days supply from the oversupply, sufficient to cover the gap period will be added and the remainder carried forward.

4. Denominator in the PDC calculation is the number of days in the study period.

Examples of Traditional MPR, Updated MPR and PDC calculations
In order to better understand steps involved in MPR and PDC calculations three cases where beneficiaries either have oversupply or undersupply of medications or are switched to medications in the same class are depicted below.

CASE 1: BENEFICIARY WITH NO SWITCHING

Medication Possession Ratio (MPR)

i) Pre-MPR

Step1: Let us consider a beneficiary who is prescribed simvastatin. Table 9 below lists all claims filled by the beneficiary from January1 –December 31, 2007.

Table 9: Example of all claims considered for MPR calculation

Drug	Date filled	Days' Supply (DS)
simvastatin	01/23/07	30
simvastatin	02/21/07	90
simvastatin	05/22/07	90
simvastatin	08/28/07	30
simvastatin	12/18/07	30

Step 2: The beneficiary hits the coverage gap on 7/11/07. Thus, the pre-period includes all claims filled before 7/11/07 (as depicted in table 10). The Pre-period MPR is calculated as follows:

Table 10: Example of pre-period claims considered for MPR calculation

Date filled	DS
01/23/07	30
02/21/07	90
05/22/07	90

Traditional Pre-MPR = TDS

Days between 05/22/07 to 01/23/07 + Days' supply of 5/22/07

Total Days Supply = 30+90+90 = 210

Days between 05/22/07- 01/23/07 = 120

Days' supply of 5/22/07=90

Pre-MPR = 210

119+90

= 210

209

Traditional Pre-MPR = 1.004

Step 3: Oversupply (OS) for the period 05/22/07-01/23/07 is assessed by calculating the difference between the total DS till 5/22/07 and the days between 05/22/07-01/23/07.

OS = total DS till 5/22/07–Days between 05/22/07-01/23/07

OS= 120-119 =1

Updated Pre- MPR= TDS- OS

Days between 05/22/07 to 01/23/07 + Days' supply of 5/22/07

= 210-1

209

= 209 = 1

209

Updated Pre- MPR = 1

ii) Post- MPR

Step 1: The post-period includes all claims filled after 7/11/07.

*Step 2:*The beneficiary's last claim is updated to reflect the number of days from the date filled to 12/31/07. (Updated days supply is bold faced)

Table 11: Example of post-period claims considered for MPR calculation

Date filled	DS	Updated DS
08/28/07	30	30
12/18/07	30	**13**

Step 3: The oversupply from the pre-period is added to the numerator of the post-period MPR calculation. Therefore,

Traditional Post- MPR = $\frac{\text{TDS}}{\text{Days between 12/31/07 to 08/28/07+ Days supply of 12/18/07}}$

Updated Post-MPR = $\frac{\text{TDS +OS}}{\text{Days between 12/31/07 to 08/28/07+ Days supply of 12/18/07}}$

Total Days Supply = 30+13 = 43

Days between 12/31/07 to 08/28/07= 125

Oversupply (OS) from the Pre-period =1

Last days supply = Days supply of 12/18/07 = 13

Therefore,

Traditional Post- MPR = $\frac{43}{}$

125+13

Traditional Post-MPR = 0.312

Updated Post-MPR = 43+1
125+13

Updated Post-MPR = 0.319

Proportion of Days Covered (PDC)

i) **Pre- PDC**

Step 1: The beneficiary hits the coverage gap on 7/11/07. Thus, the pre-period includes all claims till 7/11/07. (as shown in table 10)

Table 12: Example of all claims considered for PDC calculation

	1/23	1/24-2/20	2/20	2/21-5/21	5/22	5/23-7/10	7/11	Total
simvastatin	1	1	1	1	1	1	1	169
Total days supply								170
Total days meds. available	1	1	1	1	1	1	1	169

Step2:

Total Days Medication Available from 1/23/07 to 7/11/07 = 169 (as shown in table 12)

Days between 1/23/07 to 7/11/07 =169

PDC = total days medication is available
total number of days evaluated, capped at 1.0

= 169
169

Pre-PDC = 1.00

Oversupply (OS) for the pre-period (07/11/07-01/23/07) is difference between the total days medications available and days supply.

OS = 170-169 =1

ii) Post- PDC

Step 1: The beneficiary hits the coverage gap on 7/11/07. The post-period includes all claims from 7/12/07 to 12/31/07 as shown in the table 13.

Table 13: Example of pre-period claims considered for PDC calculation

	7/12	**7/13 - 8/19**	**8/20**	**8/21**	**8/21-8/27**	**8/28-9/26**	**9/27-12/17**	**12/18-12/31**	**Total**
simvastatin	1	1	1	0	0	1	0	1	84
Total days supply									84
Total days meds. available	1	1	1	1	0	1	0	1	**84**

Step 2:

Total days medication is available from 7/12/07 to 12/31/07= 84

Days between 12/31/07 to 7/12/07 =172

Post-PDC = total days medication is available
total number of days evaluated, capped at 1.0

= 84
172

Post-PDC = 0.488

In summary, table 14 lists the adherence values when calculated using different measures of adherence.

Table 14: Summary of pre- and post coverage gap medication adherence for a beneficiary with no switching

	Pre-Coverage gap	Post-Coverage Gap
Traditional MPR	**1.004**	**0.312**
Updated MPR	**1.000**	**0.319**
PDC	**1.000**	**0.488**

CASE II: MPR and PDC for beneficiary with switching

Step 1: Let us consider a beneficiary who is switched from simvastatin to pravastatin on 3/27/07, as depicted in table 15. The beneficiary utilizes only 17 days supply of simvastatin (3/10/07 -3/27/07) and therefore has 13 days oversupply which will be carried forward.

i) Pre- MPR

Step 2:

The beneficiary hits the coverage gap on 9/25/07. Thus, the pre-period includes all claims filled before 9/25/07 (as depicted in table 16) and post-period includes all claims filled after 9/25/07.

Table 15: Example of all claims considered for MPR calculation

Drug	Date Filled	DS
simvastatin	02/16/07	30
simvastatin	03/10/07	30
pravastatin	03/27/07	30
pravastatin	04/18/07	30
pravastatin	05/22/07	30
pravastatin	06/21/07	30
pravastatin	07/21/07	30
pravastatin	08/23/07	30
pravastatin	09/20/07	30
pravastatin	10/18/07	30
pravastatin	11/23/07	30
pravastatin	12/22/07	30
pravastatin	12/31/07	0

Table 16: Example of pre-period claims considered for MPR calculation

Drug	Date Filled	DS
simvastatin	02/16/07	30
simvastatin	03/10/07	30
pravastatin	03/27/07	30
pravastatin	04/18/07	30
pravastatin	05/22/07	30
pravastatin	06/21/07	30
pravastatin	07/21/07	30
pravastatin	08/23/07	30
pravastatin	09/20/07	30

Traditional MPR = $\frac{\text{TDS}}{\text{Days between 09/20/07 to 02/16/07 + Days' supply of 09/20/07}}$

Days between 09/20/07 to 02/16/07 = 216

Total Days Supply = 270

Last days supply = Days supply of 09/20/07 = 30

Traditional Pre-MPR = $\frac{270}{216+30}$

$= \frac{270}{246}$

Traditional Pre-MPR = 1.098

Step 3:

OS = DS from 2/16/07 till 9/20/07–Days between 9/20/07-2/16/07

OS= 240-216=24

Updated Pre-MPR = $\frac{\text{TDS -OS}}{\text{Days between 09/20/07 to 02/16/07 + Days' supply of 09/20/07}}$

$= \frac{270-24}{246}$

Updated Pre-MPR = 1

ii) Post- MPR

Step 1: The post-period includes all claims filled after 9/20/07 (table 17).

*Step 2:*The beneficiary's last claim is updated to reflect the number of days from the date filled to 12/31/07. (Updated days supply is bold faced)

Table 17: Example of post-period claims considered for MPR calculation

Drug	Date Filled	DS	Updated DS
pravastatin	10/18/07	30	30
pravastatin	11/23/07	30	30
pravastatin	12/22/07	30	**9**

Total Days Supply = 30+30+9=69

Days between 12/31/07 to 10/18/07= 74

Last days supply = Days supply of 12/22/07 = 9

Traditional Post- MPR = TDS

Days between 12/31/07 to 10/18/07+ Days supply of 12/22/07

Traditional MPR = 69

74+9

Traditional post-MPR = 0.831

Step 3: The oversupply from the pre-period is added to the numerator of the post-period MPR calculation. Therefore,

Post- MPR = TDS +OS

Days between 12/31/07 to 10/18/07+ Days supply of 12/22/07

Oversupply (OS) from the Pre-period =24

Post-MPR = 69+24

74+9

Updated Post-MPR = 1.120

Proportion of Days Covered (PDC)

i) Pre-PDC

Step 1: The beneficiary hits the coverage gap on 9/25/07. Table 18 reflects all claims filled by the beneficiary for the pre-period.

Table 18: Example of pre-period claims considered for PDC calculation

	2/16	2/17-3/09	3/10-3/26	3/27	3/28-4/08	4/09-9/25	Total
simvastatin	1	1	1	1	1	0	60
pravastatin	0	0	0	1	1	1	182
Total days supply							**242**
Total days medication (statin) is available	1	1	1	1	1	1	**221**

Step 2:

Total Days Medication Available from 2/16/07 to 9/25/07 = 221

Days between 2/16/07 to 9/25/07 =221

PDC = total days medications available
total number of days evaluated, capped at 1.0

PDC = 221
221

Pre-PDC = 1.00

Step 3: OS = DS from 2/16/07 till 9/25/07–Days between 9/25/07-2/16/07

OS= 242-221=21

ii) Post-Period PDC

Step 1: The beneficiary hits the coverage gap on 9/25/07. The post-period includes all claims from 9/26/07 to 12/31/07 shown in the table 19 below.

Table 19: Example of post-period claims considered for PDC calculation

	9/26	10/18-11/16	11/17-11/23	11/24-12/21	12/22-12/31	Total
pravastatin	1	1	0	1	1	94
Total days supply						**94**
Total days medication is available	1	1	1	1	1	**96**

Step2:

Total Days Medication Available from 9/26/07 to 12/31/07 = 94

Days between 12/31/07 to 9/26/07 =96

Post-PDC = total days medications available
total number of days evaluated, capped at 1.0

Post-PDC = 96
96

Post-PDC = 1

In summary, table 20 lists the adherence values when calculated using different measures of adherence.

Table 20: Summary of pre- and post coverage gap medication adherence measures for a beneficiary with switching

	Pre-Coverage gap	Post-Coverage Gap
Traditional MPR	**1.098**	**0.831**
Updated MPR	**1.000**	**1.120**
PDC	**1.000**	**1.000**

CASE III: Beneficiary with under supply

i) Pre-MPR

Step1: Let us consider a beneficiary who is prescribed Simvastatin. Table 21 below lists all claims filled by the beneficiary from January1 –December 31, 2007.

Table 21: Example of all claims considered for MPR calculation

Drug	Date Filled	DS
simvastatin	01/09/07	30
simvastatin	02/03/07	30
simvastatin	03/06/07	30
simvastatin	04/10/07	30
simvastatin	05/11/07	30
simvastatin	06/08/07	30
simvastatin	07/10/07	30
simvastatin	08/28/07	30

Step 2: The beneficiary hits the coverage gap on 11/29/07. Thus, the pre-period includes all claims filled before 11/29/07 (table 22).

Table 22: Example of pre-period claims considered for MPR calculation

Drug	Date Filled	DS
simvastatin	01/09/07	30
simvastatin	02/03/07	30
simvastatin	03/06/07	30
simvastatin	04/10/07	30
simvastatin	05/11/07	30
simvastatin	06/08/07	30
simvastatin	07/10/07	30
simvastatin	08/28/07	30

Traditional Pre-MPR = TDS

Days between 08/28/07 to 01/09/07 + Days' supply of 08/28/07

Total Days Supply = 240

Days between 08/28/07 to 01/09/07 = 231

Last days supply = Days supply of 08/28/07 = 30

Pre-MPR = $\frac{240}{231+30}$

$= \frac{240}{261}$

Traditional Pre-MPR = 0.919

Step 3: Oversupply (OS) for the period 08/28/07 to 01/09/07 is assessed by calculating the difference between the total DS till 08/28/07 and the days between 08/28/07 to 01/09/07.

OS =210-231= -21

Since the days supply is less than the days between, there is no oversupply for this period. Further, since there is no oversupply, for this case,

Traditional Pre-MPR = Updated Pre-MPR = 0.919

ii) Post- MPR

The post-period includes all claims filled after the day the beneficiary hits the coverage gap, that is after 11/29/07. Since the beneficiary has no claims after 8/28/07 and no oversupply, the post-period MPR for the beneficiary is 0.

Traditional Post-MPR = Updated Post-MPR = 0

Proportion of Days Covered

i) Pre- PDC

Step 1: The beneficiary hits the coverage gap on 11/29/07. Table 23 reflects all claims filled by the beneficiary for the pre-period.

Table 23: Example of pre-period claims considered for MPR calculation

	1/9 - 2/2	**2/3 - 3/4**	**3 / 5**	**3/6 - 4/4**	**4/5 - 4/8**	**4 / 9**	**4/10- 5/9**	**5/10**	**5/11 - 6/7**	**6/8 - 7/7**	**7/8 - 7/9**	**7/10 - 8/8**	**8/9 - 8/28**	**8/28- 9/26**	**9/27 - 11/29**	**Total**
Sim.	1	1	0	1	0	0	1	0	1	1	0	1	0	1	0	240
DS																240
Med ava.	1	1	1	1	1	0	1	0	1	1	1	1	0	1	0	240

Step2:

Total Days Medication Available from 1/9/07 to 11/29/07 = 240

Days between 1/9/07 to 11/29/07 =324

PDC = total days medications available
total number of days evaluated, capped at 1.0

Pre-PDC = 240 = 0.741
324

Pre-PDC = 0.741

ii) Post- PDC

The post-period includes all claims filled after the day the beneficiary hits the coverage gap, that is, after 11/29/07. Since the beneficiary has no claims after 8/28/07 and no

oversupply,the post-period PDC for the beneficiary is 0.

Post-PDC = 0

In summary, table 24 lists the adherence values when calculated using different measures of adherence

Table 24: Summary of pre- and post coverage gap medication adherence measures for a beneficiary with under supply

	Pre-Coverage Gap	Post-Coverage Gap
Traditional MPR	**0.919**	**0**
Updated MPR	**0.919**	**0**
PDC	**0.741**	**0**

Drug classes selected for medication adherence calculations

Prescription drug utilization was calculated for all medications that a beneficiary was prescribed. However, adherence calculations were limited to ten classes of medications identified as drugs used to treat commonly occurring chronic conditions in the Medicare population. (Brenson & Horvath, 2002; Hoadley, et al., 2008; Moxey ED, O'Connor JP, Novielli KD, Teutsch S, & Nash DB, 2003) Except for PPI's, these drug classes have also been previously classified as "essential" and not typically dispensed "as needed". (Tamblyn, et al., 2001a) Further, a geriatric clinical pharmacist identified these drugs as drugs most commonly used in the Medicare population and indicated that an analysis of their utilization and adherence would have clinical significance. The ten drug classes include- statins, ACEI, beta-blockers, ARB's, CCB, thiazide diuretics, SSRI's, PPIs, thyroid hormones, and biguanides.

Co-variates

Based on the Andersen's Behavioral Model of Health Services Use as described in depth in chapter 2 and a review of the literature citing factors affecting medication adherence, the following variables were used as covariates: age, gender, income, month in which the coverage gap starts, plan (HMO vs. PPO), MTM and co-morbidity score.(Andersen, 1995; Rajesh Balkrishnan, 1998; Vik, et al., 2004) Data on age, gender, month in which the coverage gap starts and HMO versus PPO plan enrollment were readily available from the data set. The data did not provide for a direct calculation of the co-morbidity score. Therefore, an individual's risk score reported by the health plan for each enrolled beneficiary was used as a proxy for the co-morbidity score. Detailed description of the risk score and validity of using the risk score as a measure of co-morbidity are provided below. The data also did not provide an assessment of an individual's income but was derived based on zip-codes. Detailed description of income estimation based on zip-code date is provided below. While the CMS mandates provision of MTM services for eligible Medicare beneficiaries, the type and extent of MTM services offered by health plans is not established by the CMS. Details of MTM services provided by XYZ healthcare services are listed below.

a) Co-morbidity score assessment

With administrative databases, Charlson's co-morbidity index or Diagnostics Cost Group are commonly used for assessing co-morbidities. (de Groot, Beckerman, Lankhorst, & Bouter, 2003; Pope et al., 2000) However, due to mis-communications to the health plan computing personnel, ICD9-CM codes required to calculate Charlson's co-morbidity

index or Diagnostic Cost Groups were available only for a sample of the study population (633 beneficiaries). For the purposes of this study, clinical episodes based risk scores assigned to each member by XYZ health services, to identify high risk patients and to measure health risk for a member, were used as a measure of co-morbidity. A member's risk score is a measure of the relative resources expected to be required for their medical care.(Ingenix, 2009)A member's risk score is calculated based on their clinical episodes of care, utilization of prescription drugs and medical services over the previous year. A member's risk scores for 2008 reflects his/her 2007 utilization. XYZ healthcare services uses a product developed by a large professional organization which specializes in this field of work, to generate this score for its beneficiaries. The following steps are used to calculate a beneficiary's risk score:

1. Episodes of care: All medical and pharmacy claims for a member are classified into mutually exclusive categories referred to as "episodes of care". These episodes of care describe a member's observed mix of conditions and underlying co-morbid conditions and/or complications. A member's episodes of care and the services provided within those episodes describe a member's mix of clinical conditions, the severity of those conditions, and the member's overall level of risk. The episodes of care are then classified into one of 22 categories (Infectious Diseases, Endocrinology, Hematology, Psychiatry, Chemical Dependency, Neurology, Ophthalmology, Cardiology, Otolaryngology, Pulmonology, Gastroenterology, Hepatology, Nephrology, Urology, Obstetrics, Gynecology, Dermatology, Orthopedics & Rheumatology, Neonatology, Preventative & Administrative, Late Effects, Environmental Trauma & Poisoning, Isolated Signs & Symptoms). (Ingenix, 2009)

2. Base Markers: The episodes of care for each member are further grouped into homogeneous risk categories (episodes with similar clinical and risk characteristics are combined into the same group) called base markers. Two types of base markers are used. The first type of base marker derives directly from a member's episodes of care. Episodes with similar clinical and risk characteristics are combined into the same group. A total of more than 120 episode-related base markers are identified. Examples of this type of base-markers include AIDS/HIV; CHF, with co-morbidity; benign hypertension; and other endocrinology. The second type of base marker focuses on a small number of higher risk, chronic conditions. Patients with these conditions are identified separately from other patients with the same mix of episodes, providing a more accurate measurement of future risk. Examples of these higher risk conditions include ALS, cystic fibrosis, and multiple sclerosis. Finally, for some clinically-related base markers hierarchies are applied, which allow focus on a single clinical condition most responsible for future risk. As a result of this, episodes best describing a patient's underlying medical condition within a general disease category are identified. For example, a patient with both coronary artery disease (CAD) and congestive heart failure (CHF) episode activity would only receive a base marker for CHF. Demographic markers of risk, describing a member's age and gender are also created in this step.
3. Service-Based Risk Markers: Each member's medical services utilization, observed within an episode of care, are used to generate service-based risk markers. These markers are generated based on a beneficiaries utilization of services such as inpatient stay, ER, significant contacts with a physician, and use of pharmacy services. Service

based markers capture relevant utilization related to a disease or condition by describing the prior use of medical services for a member related to those episodes of care included in a base marker. While base markers identify a patient with a given condition, the service-based markers supplement base markers by providing an indicator of differences in patient severity within that condition.

In addition to base and service based markers, pharmacy based markers are also created as a means to both identify patients with diseases or conditions or provide an indicator of severity for patients with the same base marker. Pharmacy markers are assigned using the presence of a therapeutic agent within specific episodes of care. For example, patients identified with an episode for major depression who also receive anti-depressant/anti-anxiety medications are identified. (Ingenix, 2009)

4. Member Clinical Profiles: An episode-based, clinical profile is created for each member after collecting all markers for a member. This profile describes whether each member had (or did not have) each of the more than 450 markers of risk. All members are also assigned an age-sex marker.
5. Weighting of the clinical Profile: Weights describing the contribution of each marker to overall patient risk are applied to each member. These weights were estimated using enrollment and medical and pharmacy claims data for a large managed care population (including more than twenty health plans enrolling more than 17 million lives).
6. Risk Computation: The clinical profile and weights are combined to compute a member's risk score. A person's risk score is based on the sum of risk weights for each marker observed. The formula used to compute risk can be described as: Risk $o,i = \Sigma br,o^*$ Marker i,r ; where Risk o,i is the risk score for outcome o for individual i;

Marker i,r indicates the individual's risk marker (r) assignments, and the b's are the risk weights – one for each marker. The markers are a series of 0,1 variables (1 =marker is observed, 0= marker is not observed). The risk score is a measure of the member's future relative risk for an inpatient stay and a predictor of their future health care costs. (Ingenix, 2009)

7. Interpretation of risk score: Risk is generally measured in reference to a "standard population" that is assigned a risk score of 1.00. An individual or group with a risk score of 1.15 would be expected to require 15% more healthcare resources than the standard population. A member with a risk score of 0.85 would be expected to consume 15% fewer resources.

Validation of risk score: To ensure that the risk score is a valid measure of co-morbidity, Charlson's co-morbidity score was calculated for members for whom ICD-9 codes were available and was co-related to the risk score assigned to the beneficiary. A significant, positive co-relation between the Charlson's co-morbidity score and the member's risk score will provide some evidence of construct validity. Charlson's co-morbidity index is calculated by assigning a weight of 1, 2, 3, or 6 to nineteen disease conditions. A sum of all the weights provides the Charlson's co-morbidity index.(Charlson, Pompei, Ales, & MacKenzie, 1987) For the purposes of this study, Charlson's co-morbidity score was calculated using the algorithm developed by Quan et al. (Quan et al., 2005) Further, the risk score is based on a predictive modeling technique similar to the technique used to calculate the Diagnostic Cost Groups, a commonly used and validated measure of co-morbidity calculated using administrative databases. (Pope, et al., 2000)

b) Income

Data about median household income levels based on a beneficiary's ZIP code of residence, reported in the 2000 US Census data base, were used as a proxy of the beneficiary's income. This approach of using ZIP codes based socio-economic characteristics as a proxy for an individual's characteristics has been validated and is widely used in utilization studies. (Geronimus, Bound, & Neidert, 1995; Gornick et al., 1996; Krieger, 1992; Smith, Ben-Shlomo, & Hart, 1999)

It is important to note that, for the purposes of this study, 2000 US census data are used. Thus, there is an assumption that there have not been significant changes in the income of the population by ZIP code between 2000 and 2007. The most current Census Bureau data available are 2007 American Community Survey (ACS) data. ACS data are not available at the ZIP Code level. ACS data are available only for Metropolitan Statistical Areas and cities and counties of a certain minimal size.(US Census Bureau, 2009) Since we do not have access to metropolitan area data, 2000 Census data for ZIP Code geography are used for this study. Further, ZIP code data cannot be aggregated to counties or metro areas, as ZIP Codes do not recognize county boundaries and they can even cross state lines.(Compton, 2009)

c) Medication Therapy Management

Medication therapy management (MTM) has been defined as "a distinct service or group of services that optimize therapeutic outcomes for individual patients". Medicare beneficiaries who have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, COPD and congestive heart failure); take multiple covered Part D drugs;

and are likely to incur greater than $4,000 annually in total drug costs are eligible to receive MTM services. MTM encompasses a broad range of professional activities and responsibilities which include but are not limited to formulating a medication treatment plan; performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events; and providing information, support services and resources designed to enhance patient adherence with his/her therapeutic regimens.

XYZ health care services sends MTM eligible members an invitation to schedule an appointment with a clinical pharmacist. The clinical pharmacist evaluates a member's medication record prior to appointment. As a part of MTM services, the clinical pharmacist identifies opportunities for the member to lower average monthly pharmacy costs by suggesting strategies such as switching to generic, tablet splitting, more cost effective formulary alternatives, eliminating duplicate or unnecessary prescriptions, prescription to over-the-counter switches, etc. The clinical pharmacist also identifies medication related problems such as overdosage, underdosage, adverse drug reaction, untreated medical condition, failure to receive medication, drug interaction, drug use without an indication, etc. Finally, the clinical pharmacist documents the number of changes accepted by the beneficiary to the number of recommended changes and documents patient safety related problems identified and the results. With all the MTM services available to beneficiaries, it is possible that, beneficiaries who receive MTM services may have higher adherence rates compared to those do not receive MTM services. Therefore, for the purposes of this study, utilization of MTM services was statistically controlled for by including it as a covariate.

Sample Clinics

XYZ health care services have a sample clinic where beneficiaries, upon referral from their physician, can receive free medication samples. Medications obtained by beneficiaries through the sample clinic are recorded in a database. However, due to manual entry of data in a manner inconsistent with the pharmacy claims, despite best efforts, it was not possible to connect this database to the pharmacy claims database.

Additional Outcomes assessed in the study

a) Utilization of Medicare Part A and B services by beneficiaries who hit the coverage gap

XYZ health care services provided data on emergency room visits, inpatient and outpatient hospitalizations and ICD-9 codes for 633 beneficiaries who hit the coverage gap. However, XYZ healthcare services did not provide the date that these services were provided. Thus, it was not possible to assess if the utilization of these services occurred before a beneficiary hit the coverage gap or after hitting the coverage gap. This data was however used to calculate the Charlson's co-morbidity index for the 633 beneficiaries.

b) Medical Costs incurred by beneficiaries who hit the coverage gap

XYZ health care services provided data on medical costs associated with Medicare Part A and B services for beneficiaries who hit the coverage gap. Medical costs refer to the costs that were associated with medical claims (all claims except for pharmacy claims) and paid by XYZ healthcare services for the beneficiary. It is important to note that these costs were calculated based on the month in which a beneficiary hit the coverage gap and

are not a very accurate representation of pre-coverage gap and post-coverage gap medical costs. For example, a beneficiary who hit the coverage gap on the 25th of June would be classified as hitting the coverage gap in June and all costs incurred by the beneficiary before 25th June were also included as costs incurred after hitting the coverage gap.

XYZ healthcare services provided charts comparing a) differences in medical costs between the entire XYZ Senior Care population enrolled in MA-PD plans with costs of beneficiaries who reached the coverage gap in 2007; b) the difference in medical costs per member per month (PMPM) incurred before the beneficiary reached the coverage gap and after the beneficiary reached the coverage gap; and c) for beneficiaries whose medical costs were higher after reaching the Part D gap, the difference in PMPMs before and after reaching the coverage gap, in specific utilization categories [emergency room visits, inpatient hospitalizations, outpatient hospitalizations, and other (all costs not included in the previous 3 categories)].

Data Analysis

Descriptive statistics (mean, SD, median, minimum, maximum) were analyzed for all study variables. In order to detect any outliers or miscoded data, frequencies were analyzed for each variable. Baseline demographics were assessed by using univariate tests such as independent t-tests, paired t-tests, ANOVA or chi-square where appropriate. All tests were analyzed at a 0.05 level of significance.

Difference-in-Difference Analysis

In order to assess the impact of the Medicare Part D coverage gap on prescription drug

utilization and medication adherence a difference-in-difference analysis was used. Difference-in-difference (DiD) analysis has been widely used to assess the impact of natural experiments, such as health care policy changes, where researchers have no control on the allocation of individuals to a control group (not affected by a change in environment) or a treatment group (affected by a change in environment). DiD analysis estimates the difference between the before and after outcome for the treatment group and the before and after outcome for the control group.

DiD analysis used to assess the impact of a policy change can best be described using the following equation:

DiD = (outcome after policy change in treatment group – outcome before policy change in treatment group) – (outcome after policy change in control group – outcome before policy change in control group)

If we define μ_{it} to be the mean of the outcome in group i at time t. Let i=0 for the control group and i=1 for the treatment group and t=0 to be a pre-treatment period and t=1 to be the post-treatment period. Then,

$$D = \left(\mu_{11} - \mu_{10} \right) - \left(\mu_{01} - \mu_{00} \right)$$

Where,

D = DiD estimator

μ_{11} = is mean of the outcome in treatment group in the post-period

μ_{10} = is mean of the outcome in treatment group in the pre-period

μ_{01} = is mean of the outcome in control group in the post-period

μ_{00} = is mean of the outcome in control group in the pre-period

In order to use the difference-in-difference analysis it is important to ensure that the

underlying trend in the outcome variable is the same for both treatment and control group. This assumption was checked by comparing the outcome variable in the control and treatment group in the pre-treatment period. Using the difference-in-difference approach eliminates biases that result from inherent pre-treatment differences between the control and treatment group, which are constant over time. In addition to elimination of biases due to observed or unobserved pre-treatment differences, biases as a result of time based comparisons are also eliminated. Addition of regressors further helps eliminate effects of confounding factors. For the purposes of this study, the outcome variable y which represents MPR or prescription drug utilization can be defined as

$$Y = \beta_0 + \beta_1 * \text{Time} + \beta_2 * \text{Group} + \beta_3 * (\text{Time} * \text{Group}) + \beta_4 * \text{Age} \ldots\ldots + \beta_n * \text{Covariates} + e$$

Time 0 = Pre – Coverage Gap
1 = Post – Coverage Gap
Group 0 = Employer / Generic Coverage
1 = No Coverage
β_3 DID estimator (Interaction coefficient)

The difference-in-difference analysis was conducted three times to address the study objective. The first analysis included comparing prescription drug utilization and medication adherence between beneficiaries enrolled in a plan providing no gap coverage with beneficiaries enrolled in a plan with full prescription drug coverage. The second analysis included comparing prescription drug utilization and medication adherence between beneficiaries enrolled in a plan providing no gap coverage with beneficiaries enrolled in a plan with generic drug coverage. The third analysis included comparing prescription drug utilization and medication adherence between beneficiaries enrolled in

a plan providing generic drug coverage with beneficiaries enrolled in a plan with full prescription drug coverage. As a result of conducting three different analyses within the same dataset, an alpha-slippage occurs. In order to correct the alpha-slippage, a Bonferroni's correction was applied and all analyses were tested at a level of significance of 0.017 (0.05/3).

Data analyses required to address study objectives:

1. To compare prescription drug utilization of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap with prescription drug utilization of Medicare beneficiaries enrolled in a plan providing no gap coverage.
    - Data: Medicare beneficiaries enrolled in plans with full prescription drug coverage and no prescription drug coverage during the coverage gap.
    - Difference-in difference analysis with prescription drug utilization as the dependant variable was used to compare prescription drug utilization pre- and post- coverage gap between Medicare beneficiaries enrolled in plans with full prescription drug coverage and no prescription drug coverage during the coverage gap. All covariates listed in the covariates section were controlled for.

2. To compare prescription drug utilization of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan covering generic drugs during the coverage gap with prescription drug utilization of Medicare beneficiaries enrolled in a plan providing no gap coverage.

- Data: Medicare beneficiaries enrolled in plans with generic drug coverage and no prescription drug coverage during the coverage gap.
- Difference-in difference analysis with prescription drug utilization as the dependant variable was used to compare prescription drug utilization pre- and post- coverage gap between Medicare beneficiaries enrolled in plans with generic drug coverage and no prescription drug coverage during the coverage gap. All covariates listed in the covariates section were controlled.

3. To compare prescription drug utilization of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap with prescription drug utilization of Medicare beneficiaries enrolled in a plan covering generic drugs during the coverage gap.
   - Data: Medicare beneficiaries enrolled in plans with full prescription drug coverage and generic drug coverage during the coverage gap.
   - Difference-in difference analysis with prescription drug utilization as the dependant variable was used to compare prescription drug utilization pre- and post- coverage gap between Medicare beneficiaries enrolled in plans with full prescription drug coverage and generic drug coverage during the coverage gap. All covariates listed in the covariates section were controlled.

4. To compare medication adherence (to select drug classes) of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap with medication adherence of

Medicare beneficiaries enrolled in a plan providing no prescription drug coverage during the coverage gap.

- Data: Medicare beneficiaries enrolled in plans with full prescription drug coverage and no prescription drug coverage during the coverage gap.
- Difference-in difference analysis with medication adherence as the dependant variable was used to compare medication adherence pre- and post- coverage gap between Medicare beneficiaries enrolled in plans with full prescription drug coverage and no prescription drug coverage during the coverage gap.

5. To compare medication adherence (to select drug classes) of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan covering generic drugs during the coverage gap with medication adherence of Medicare beneficiaries enrolled in a plan providing no prescription drug coverage during the coverage gap.
   - Data: Medicare beneficiaries enrolled in plans with generic drug coverage and no prescription drug coverage during the coverage gap.
   - Difference-in difference analysis with medication adherence as the dependant variable was used to compare medication adherence pre- and post- coverage gap between Medicare beneficiaries enrolled in plans with generic drug coverage and no prescription drug coverage during the coverage gap.

6. To compare medication adherence (to select drug classes) of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap with medication adherence of

Medicare beneficiaries enrolled in a plan covering generic drugs during the coverage gap.

- Data: Medicare beneficiaries enrolled in plans with full prescription drug coverage and generic drug coverage during the coverage gap.
- Difference-in difference analysis with medication adherence as the dependant variable was used to compare medication adherence pre- and post- coverage gap between Medicare beneficiaries enrolled in plans with full prescription drug coverage and generic drug coverage during the coverage gap.

SUMMARY

This study focuses on Medicare beneficiaries enrolled in Medicare Advantage prescription drug (MA-PD) plans offered by XYZ health care services. A quasi-experimental, cross-sectional, retrospective, pre-post with control group study design was used to assess the impact of Medicare Part D coverage gap on prescription drug utilization and medication adherence. Medicare beneficiaries who met the study eligibility criteria and were enrolled in a plan with full prescription drug coverage, a plan with generic drug coverage or a plan with no prescription coverage during the coverage gap were selected from a pool of 25,571 beneficiaries. Total costs and true out-of-pocket (TrOOP) costs were used to assess if a Medicare beneficiary remained in the initial coverage limit, hit the coverage gap or was covered under catastrophic coverage. Beneficiaries with total drug costs greater than $2,400 and true out-of -pocket (TrOOP) costs less than or equal to $3,850 represented beneficiaries who remained in the coverage gap through the entire year. Beneficiaries with total drug costs greater than $2,400 and

TrOOP costs greater than $3,850 represented beneficiaries who were covered under the catastrophic coverage limit.

Pre- and post-coverage gap prescription drug utilization was assessed using per member total number of prescriptions. Medication Possession Ratio (MPRm) and the Proportion of Days Covered (PDC) were used as measures of medication adherence in this study. Descriptive statistics were analyzed for all study variables. Difference-in difference analysis, with prescription drug utilization and medication adherence as the dependant variables, was used to compare prescription drug utilization pre- and post-coverage gap between: a) Medicare beneficiaries enrolled in plans with full prescription drug coverage and no prescription drug coverage during the coverage gap; b) Medicare beneficiaries enrolled in plans c) Medicare beneficiaries enrolled in plans with generic prescription drug coverage and no prescription drug coverage during the coverage gap and with full prescription drug coverage and generic prescription drug coverage during the coverage gap. The DiD analysis controlled for age, gender, income, month in which the coverage gap starts, plan (HMO vs. PPO), MTM and co-morbidity score as covariates. The next chapter presents the results obtained after conducting the data analyses.

CHAPTER 4

RESULTS

The study results are described in chapter 4. The chapter begins with a description of the study population and study sample, followed by results of the number of beneficiaries who hit the coverage gap in 2007 and results of the data validity check as related to accuracy of the cost calculations and validity of using the risk score as a measure of co-morbidity. Next, demographics of the study sample are presented, followed by a description of the number of beneficiaries who hit the coverage gap in each month (January-December) of 2007. In the next section, results of univariate analysis comparing overall prescription drug utilization among beneficiaries enrolled in the three Medicare Advantage plans and a descriptive analysis of pre-and post-coverage gap prescription drug utilization and medication adherence for ten select drug classes is provided. Following the descriptive analyses, are results of the difference-in-difference analysis assessing the impact of the coverage gap on prescription drug utilization and medication adherence for the ten selected drug classes. Finally, per member per month total medical costs incurred before and after beneficiaries hit the coverage gap are provided.

Study population and sample selection

The study sample was selected from 23,339 Medicare beneficiaries enrolled in XYZ health services' senior care HMO and PPO plans and 2,232 beneficiaries enrolled in employer-sponsored health plans. A total of 14,846 beneficiaries, accounting for 436,087 claims, met the study inclusion and exclusion criteria. Of these, 7,684 members were enrolled in a plan which provided no prescription drug coverage during the coverage gap,

henceforth referred to as 'no coverage' plan; 5,777 were enrolled in a plan which covered generic drugs during the coverage gap, henceforth referred to as the 'generic coverage' plan and 1,385 were enrolled in an employer sponsored plan which provided full prescription drug coverage during the coverage gap, henceforth referred to as the 'full coverage' plan. The 14,846 beneficiaries who met the study inclusion and exclusion criteria were analyzed further to identify beneficiaries who hit the coverage gap in 2007.

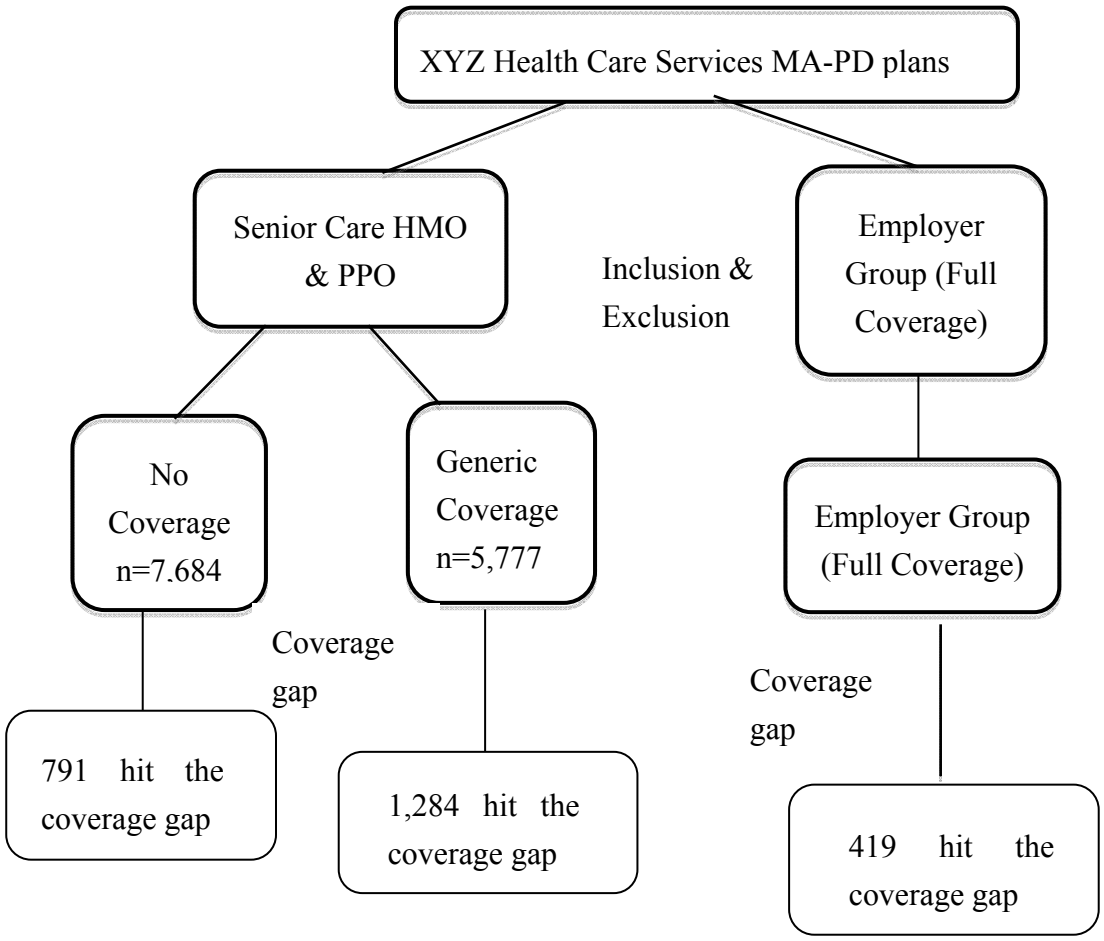
Coverage Gap

Of the 14,846 beneficiaries who met the study inclusion and exclusion criteria, 2,661 beneficiaries (17.92%) hit the coverage gap in the year 2007. Nearly seventeen percent or 2,494 beneficiaries remained in the coverage gap and less than 1% or 117 beneficiaries reached the catastrophic coverage limit in the year 2007. This study will focus on the 2,494 beneficiaries who hit the coverage gap and remained in the coverage gap in 2007. Of these 2,494 beneficiaries, 791 (31.72%) were enrolled in the plan with no coverage, 1284 (51.48%) were enrolled in the plan with generic coverage and 419 (16.80%) were enrolled in the plan with full coverage. Figure 4 presents the study sample and number of beneficiaries who reached the coverage gap in 2007.

Data validity: Accuracy of cost calculations

The most critical aspect of this study was the identification of beneficiaries who hit the coverage gap. Total costs and true out-of-pocket (TrOOP) costs are used to assess if a Medicare beneficiary remains in the initial coverage limit, hits the coverage gap or is

Figure 3: Study sample and number of beneficiaries who reached the coverage gap in 2007



covered under catastrophic coverage. As described in chapter 3, to ensure that cost calculations were accurate, total costs calculated for the purposes of this study were compared with total costs reported by the health plan for 250 (~10%) beneficiaries.

The comparison indicated discrepancy in costs for 11 out of the 250 beneficiaries. Further examination indicated that the cost discrepancy stemmed from truncating the number of digits in the GPI numbers used to identify drugs covered under Medicare Part B. For example, 10 digits of a GPI number "9940407000****" were used instead of 12 digits "994040700001**". To ensure that this discrepancy did not result in inaccurate identifications, each GPI number used to identify drugs covered under Medicare Part B was then reviewed by a clinical pharmacist employed at XYZ healthcare services. Following all corrections, costs were recalculated and the costs for the 11 beneficiaries were rechecked to confirm that accurate costs calculations were conducted for this study. No further discrepancy provided an assurance that all costs calculated for the purposes of this study were accurate.

Validity of using risk score as a measure of co-morbidity

Medical claims with ICD-9 codes required for the assessment of the Charlson's co-morbidity score were available only for 633 beneficiaries. Therefore, Charlson's co-morbidity score was calculated only for these 633 beneficiaries. As described in chapter 3, the risk score was used as a measure of co-morbidity. To ensure that the risk score is a valid measure of co-morbidity, risk scores for 633 members were correlated with Charlson's co-morbidity score calculated for these beneficiaries. Significant positive correlations ($r = 0.614$, $p = 0.01$) between the risk scores and Charlson's co-morbidity

scores calculated for 633 members provides some evidence of construct validity.

Demographics of beneficiaries who hit the coverage gap

Table 24 and table 25 present the demographic characteristics of members who hit the coverage gap in 2007. The mean age of beneficiaries who hit the coverage gap was 72.59 ±9.20 and nearly 60% of the beneficiaries were females. Their mean co-morbidity score was 6.55±6.27 and less than 10% of the beneficiaries received MTM services. The average income of beneficiaries who hit the coverage gap was $39,602.00 ± 11,465.12 and three-quarters of the beneficiaries were enrolled in HMO plans. Average total cost incurred by beneficiaries who hit the coverage gap in the year 2007 was $3,002.38 ±2,222.39 with average TrOOP expenses amounting to $1,075.06 ±709.74.

Demographics of beneficiaries enrolled in no coverage, generic coverage and full coverage plans

Table 25 and table 26 present a comparison of demographic characteristics of beneficiaries enrolled in no coverage, generic coverage and full coverage plans. An analysis of variance indicated that significant difference in age existed between beneficiaries in no coverage and full coverage plans ($F(2, 2491) = 10.98$, $p < 0.05$, mean difference = 2.49; and between generic and full coverage plan (mean difference = 2.12) beneficiaries. Similarly, significant difference in total costs existed between beneficiaries in no coverage and full coverage plans ($F(2, 2491) = 80.56$, $p < 0.05$; mean difference =1,581.51) and generic and no coverage plan beneficiaries (mean difference = 1,351.87). Total costs were highest for beneficiaries in the full coverage plan but very similar for beneficiaries in the no coverage and generic coverage plans. Significant differences in co-

Table 25: Demographics (continuous variables)

	All Mean (S.D.)	No Coverage Plan	Generic Coverage Plan	Full Coverage Plan
N	2494	791	1284	419
Age*	72.59 (9.20)	73.20 (9.83)	72.83 (9.18)	70.71 (7.73)
Income (median)	39,602.00	38,370.00	39,670.00	39,375.69
Co-morbidity* risk score	6.55 (6.27)	6.25 (5.74)	7.00 (4.90)	5.72 (4.12)
Total cost* (median)	3,002.38	2,857.94	2,949.11	3,775.00
Total OOP (median)	1,075.06	1,194.11	1,107.65	768.85

* Significant differences between three groups at $p \leq 0.05$

Table 26: Demographic Information (categorical variables)

	All n (%)	No Coverage Plan n (%)	Generic Coverage Plan n (%)	Full Coverage Plan n (%)
Male*	1004 (40.32)	320 (40.46)	483 (37.62)	201 (47.97)
Female*	1490 (59.84)	471 (59.54)	801 (62.38)	218 (52.03)
Received MTM*	234 (9.40)	57 (7.21)	165 (12.85)	12 (2.86)
PPO*	640 (25.70)	197 (24.91)	218 (16.98)	225 (53.70)
HMO*	1,854 (74.46)	594 (75.09)	1066 (83.02)	194 (46.30)

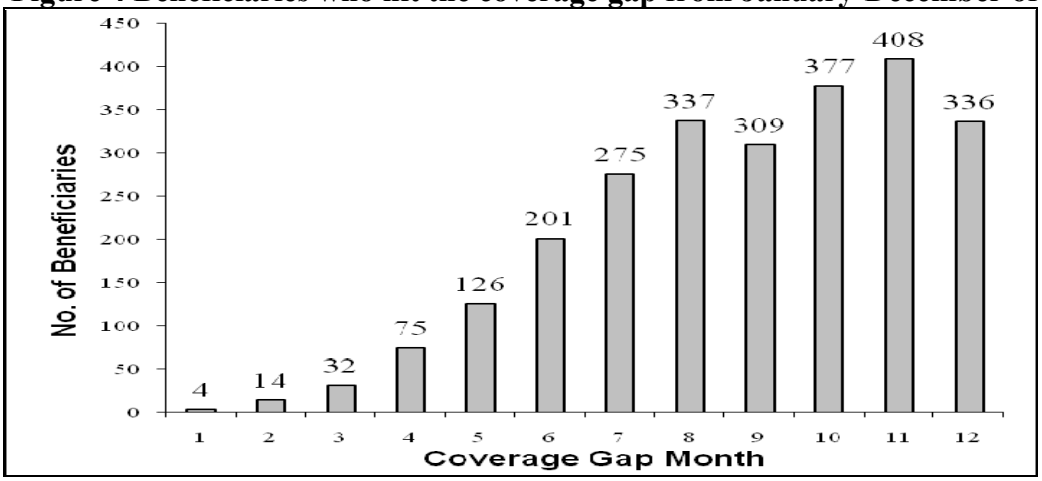
*Significant differences across three groups at $p \leq 0.05$

morbidity risk scores were found between beneficiaries in no coverage and generic coverage plans (F (2, 2491) =7.95, p <0.05; mean difference = 0.75) and beneficiaries in generic and full coverage (mean difference=1.28). Co-morbidity scores were highest for beneficiaries enrolled in generic coverage plans followed by beneficiaries enrolled in no coverage plans and lowest for beneficiaries in full coverage plans. A comparison of categorical demographic variables conducted by using a chi-square analysis (Table 26) indicates that the number of male and female Medicare beneficiaries' differed significantly across the three plans ($\chi^2(2, N = 2494) = 14.10, p<0.05$). Similarly the number of beneficiaries receiving MTM services ($\chi^2(2, N = 2494) = 43.50, p<0.05$) and the number of beneficiaries enrolled in HMO and PPO plans ($\chi^2(2, N = 2494) = 147.32, p<0.05$) varied significantly across the three plans.

Coverage gap month

Figure 5 represents the number of beneficiaries who hit the coverage gap from January-December of 2007. Nearly 90% (2243) of the beneficiaries hit the coverage gap during the period June–December 2007.

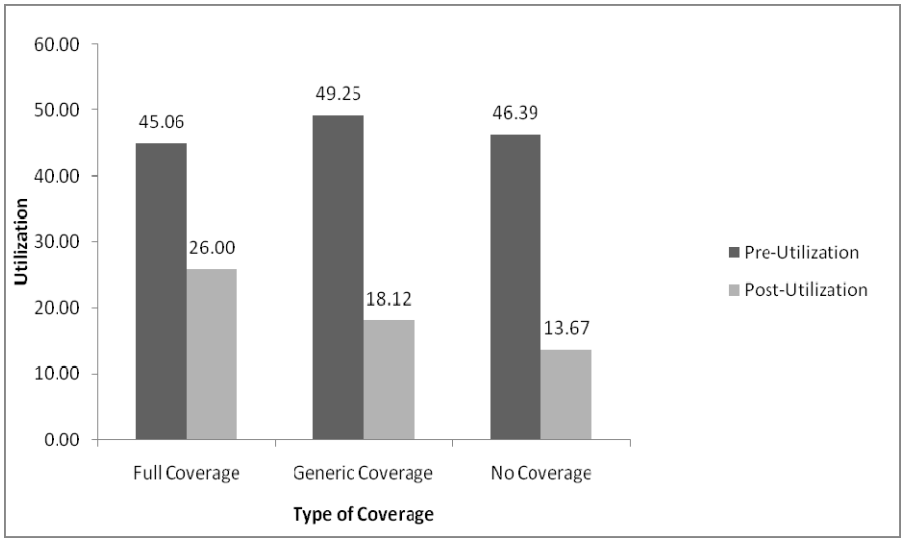
Figure 4 Beneficiaries who hit the coverage gap from January-December of 2007



Univariate analysis comparing prescription drug utilization among three plans

Figure 6 presents mean pre-utilization (utilization before a beneficiary hits the coverage gap) and post-utilization (utilization after a beneficiary hits the coverage gap) rates for beneficiaries enrolled in each of the three plans. As is evident from the figure, overall pre-utilization is higher in all three groups compared to the post-utilization. Post-utilization is lowest for beneficiaries enrolled in the no coverage followed by beneficiaries enrolled in the generic coverage plan and with post-utilization being highest for beneficiaries enrolled in the plan with full coverage. Paired t-tests indicate significant differences in pre- and post-prescription drug utilization (mean difference = 32.74 ± 23.32) for beneficiaries enrolled in the no coverage plan (t (790) =39.48, p = 0.05); generic coverage plan (mean difference = 31.30 ± 27.95, t (1283) =39.91, p = 0.05); and the full coverage plan (mean difference = 19.05 ±34.43, t (418) =11.32, p = 0.05).

Figure 5 Mean pre-and post-utilization rates for beneficiaries enrolled in the three plans



Descriptive analyses of pre- and post- utilzation and medication adherence for select drug classes

Tables 27-36 represent mean (S.D.) pre- and post-utilization and pre- and post-medication adherence of beneficiaries in all groups (overall), beneficiaries enroled in no coverage, generic coverage and full coverage plans for select ten classes of prescription drugs. These ten drug classes include: statins, ACEI, beta-blockers, ARB's, CCB, thiazide diuretics, SSRI's, PPIs, thyroid hormones, and biguanides.

Pre- and post-utilization: As is evident in tables 27-36, descriptive analyses of pre- and post-utilization of statins, ACEI, beta-blockers, ARB's, CCB, thiazide diuretics, SSRI's, PPIs, thyroid hormones, and biguanides indicates that utilization decreased overall and for beneficiaries in all three plans (full coverage, generic coverage and no coverage) after they hit the coverage gap.

Medication adherence: With respect to medication adherence, descriptive anlayses indicated that pre-post medication adherence differred based on the measure of medication adherence (tables 27-36). Medication adherence when measured using the PDC decreased overall and for beneficiaries in all three groups after beneficiaries hit the coverage gap. However, when measured using the MPR (Updated MPR and traditional MPR), descriptive analyses indicate that medication adherence increased overall and for beneficiaries in all three groups after beneficiaries hit the coverage gap. This trend was observed for all ten drug classes of statins, ACEI, beta-blockers, ARB's, CCB, thiazide diuretics, SSRI's, PPIs, thyroid hormones, and biguanides.

Table 27: Pre- and post- utilzation and medication adherence of beneficiaries on statins

Statins	Overall		Full Coverage		Generic Coverage		No Coverage	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Pre-Utilization	1291	51.403 (18.294)	221	48.760 (18.103)	684	52.838 (18.976)	386	50.376 (16.926)
Post-utilization	1291	19.520 (21.009)	221	27.970 (28.087)	684	19.168 (20.135)	386	15.303 (15.807)
Pre-PDC	1256	0.864 (0.195)	213	0.884 (0.179)	666	0.861 (0.192)	377	0.859 (0.207)
Post-PDC	1256	0.748 (0.337)	213	0.805 (0.316)	666	0.747 (0.333)	377	0.717 (0.350)
Updated Pre-MPR	856	0.938 (0.104)	160	0.952 (0.080)	451	0.937 (0.101)	245	0.930 (0.121)
Updated Post-MPR	856	1.157 (1.870)	160	1.159 (0.778)	451	1.055 (0.403)	245	1.345 (3.392)
Traditional Pre-MPR	856	0.964 (0.143)	160	0.992 (0.148)	451	0.960 (0.138)	245	0.952 (0.147)
Traditional Post-MPR	856	0.974 (0.178)	160	0.977 (0.120)	451	0.980 (0.206)	245	0.960 (0.151)

Table 28: Pre- and post- utilzation and medication adherence of beneficiaries on ACEI

ACEI	Overall		Full Coverage		Generic Coverage		No Coverage	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Pre-Utilization	886	54.595 (18.172)	297	52.90 (18.537)	464	55.87 (18.692)	125	53.32 (17.074)
Post-utilization	886	20.113 (20.867)	297	27.08 (28.935)	464	21.09 (20.476)	125	15.66 (15.918)
Pre-PDC	845	0.855 (0.210)	117	0.855 (0.233)	446	0.845 (0.215)	282	0.872 (0.191)
Post-PDC	845	0.753 (0.351)	117	0.809 (0.308)	446	0.737 (0.369)	282	0.756 (0.338)
Updated Pre-MPR	592	0.937 (0.113)	87	0.933 (0.134)	314	0.934 (0.115)	191	0.944 (0.099)
Updated Post-MPR	592	1.149 (1.144)	87	1.197 (0.592)	314	1.068 (0.310)	191	1.259 (1.932)
Traditional Pre-MPR	592	0.969 (0.164)	87	0.966 (0.170)	314	0.960 (0.149)	191	0.984 (0.182)
Traditional Post-MPR	592	0.984 (0.150)	87	0.986 (0.142)	314	0.984 (0.154)	191	0.981 (0.147)

Table 29: Pre- and post- utilzation and medication adherence of beneficiaries on CCI

CCI	Overall		Full Coverage		Generic Coverage		No Coverage	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Pre-Utilization	832	55.905 (18.888)	132	54.917 (19.638)	436	56.817 (19.116)	264	54.894 (18.106)
Post-utilization	832	20.772 (21.335)	132	29.129 (27.356)	436	21.248 (20.812)	264	15.807 (16.99)
Pre-PDC	802	0.852 (0.211)	126	0.909 (0.178)	420	0.843 (0.213)	256	0.839 (0.219)
Post-PDC	802	0.757 (0.341)	126	0.848 (0.292)	420	0.734 (0.348)	256	0.751 (0.345)
Updated Pre-MPR	562	0.926 (0.130)	95	0.957 (0.108)	292	0.915 (0.141)	175	0.929 (0.117)
Updated Post-MPR	562	1.244 (1.718)	95	1.530 (2.231)	292	1.085 (0.510)	175	1.353 (2.509)
Traditional Pre-MPR	562	0.958 (0.171)	95	0.999 (0.158)	292	0.950 (0.191)	175	0.949 (0.137)
Traditional Post-MPR	562	0.981 (0.200)	95	1.019 (0.316)	292	0.971 (0.176)	175	0.977 (0.149)

Table 30: Pre- and post- utilzation and medication adherence of beneficiaries on beta-blockers

Beta-blockers	Overall		Full Coverage		Generic Coverage		No Coverage	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Pre-Utilization	884	55.825 (18.886)	135	54.689 (19.502)	464	56.597 (19.210)	285	55.105 (18.049)
Post-utilization	884	20.433 (21.091)	135	28.956 (27.268)	464	21.056 (20.615)	285	15.382 (16.693)
Pre-PDC	852	0.849 (0.216)	129	0.911 (0.177)	447	0.841 (0.216)	276	0.832 (0.226)
Post-PDC	852	0.752 (0.346)	129	0.852 (0.289)	447	0.732 (0.349)	276	0.736 (0.357)
Updated Pre-MPR	593	0.927 (0.128)	97	0.958 (0.107)	310	0.917 (0.140)	186	0.928 (0.115)
Updated Post-MPR	593	1.244 (1.685)	97	1.556 (2.228)	310	1.081 (0.497)	186	1.354 (2.446)
Traditional Pre-MPR	593	0.960 (0.172)	97	1.005 (0.166)	310	0.952 (0.190)	186	0.950 (0.139)
Traditional Post-MPR	593	0.981 (0.197)	97	1.023 (0.314)	310	0.971 (0.174)	186	0.977 (0.145)

Table 31: Pre- and post- utilzation and medication adherence of beneficiaries on ARB's

ARB's	Overall		Full Coverage		Generic Coverage		No Coverage	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Pre-Utilization	356	52.919 (18.141)	75	49.347 (17.554)	191	55.764 (18.456)	90	49.856 (17.079)
Post-utilization	356	20.472 (19.520)	75	29.720 (24.857)	191	19.079 (17.635)	90	15.722 (15.592)
Pre-PDC	340	0.863 (0.188)	71	0.896 (0.164)	185	0.855 (0.192)	84	0.853 (0.195)
Post-PDC	340	0.703 (0.359)	71	0.836 (0.288)	185	0.682 (0.357)	84	0.636 (0.389)
Updated Pre-MPR	216	0.943 (0.090)	57	0.950 (0.091)	114	0.941 (0.088)	45	0.938 (0.096)
Updated Post-MPR	216	1.066 (0.361)	57	1.031 (0.179)	114	1.086 (0.450)	45	1.059 (0.266)
Traditional Pre-MPR	216	0.974 (0.138)	57	0.974 (0.119)	114	0.976 (0.149)	45	0.970 (0.134)
Traditional Post-MPR	216	0.967 (0.157)	57	0.990 (0.135)	114	0.955 (0.185)	45	0.969 (0.096)

Table 32: Pre- and post- utilzation and medication adherence of beneficiaries on thiazide diuretics

Thiazide Diuretics	Overall		Full Coverage		Generic Coverage		No Coverage	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Pre-Utilization	421	56.240 (18.751)	78	53.910 (17.193)	217	58.364 (19.013)	126	54.024 (18.932)
Post-utilization	421	20.862 (19.510)	78	28.167 (24.055)	217	21.106 (18.911)	126	15.921 (15.702)
Pre-PDC	380	0.781 (0.277)	69	0.790 (0.286)	200	0.778 (0.270)	111	0.782 (0.285)
Post-PDC	380	0.623 (0.406)	69	0.642 (0.400)	200	0.605 (0.409)	111	0.643 (0.408)
Updated Pre-MPR	225	0.934 (0.124)	41	0.957 (0.086)	119	0.925 (0.136)	65	0.935 (0.120)
Updated Post-MPR	225	1.130 (0.717)	41	1.218 (0.784)	119	1.084 (0.479)	65	1.159 (0.990)
Traditional Pre-MPR	225	0.967 (0.178)	41	0.984 (0.122)	119	0.963 (0.204)	65	0.965 (0.155)
Traditional Post-MPR	225	0.976 (0.172)	41	1.006 (0.146)	119	0.971 (0.210)	65	0.966 (0.086)

Table 33:Pre- and post- utilzation and medication adherence of beneficiaries on SSRI

SSRI	Overall		Full Coverage		Generic Coverage		No Coverage	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Pre-Utilization	668	50.295 (19.383)	101	46.950 (18.432)	359	51.763 (20.289)	208	49.385 (18.012)
Post-utilization	668	22.204 (22.234)	101	34.436 (31.280)	359	21.816 (20.891)	208	16.933 (16.254)
Pre-PDC	623	0.810 (0.247)	93	0.865 (0.184)	334	0.800 (0.255)	196	0.801 (0.256)
Post-PDC	623	0.659 (0.385)	93	0.767 (0.332)	334	0.649 (0.389)	196	0.623 (0.394)
Updated Pre-MPR	414	0.924 (0.121)	72	0.942 (0.095)	217	0.921 (0.127)	125	0.918 (0.126)
Updated Post-MPR	414	1.102 (0.728)	72	1.192 (1.345)	217	1.086 (0.574)	125	1.079 (0.389)
Traditional Pre-MPR	414	0.954 (0.161)	72	0.970 (0.125)	217	0.948 (0.164)	125	0.954 (0.174)
Traditional Post-MPR	414	(0.975) (0.169)	72	(0.999) (0.152)	217	(0.975) (0.163)	125	(0.961) (0.186)

Table 34: Pre- and post- utilzation and medication adherence of beneficiaries on PPI

PPI	Overall		Full Coverage		Generic Coverage		No Coverage	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Pre-Utilization	628	48.632 (18.671)	150	45.167 (18.472)	310	50.058 (19.282)	168	49.095 (17.371)
Post-utilization	628	22.490 (23.754)	150	32.200 (29.985)	310	21.716 (22.048)	168	15.250 (16.682)
Pre-PDC	559	0.754 (0.280)	133	0.853 (0.223)	277	0.730 (0.280)	149	0.712 (0.306)
Post-PDC	559	0.555 (0.416)	133	0.784 (0.321)	277	0.495 (0.419)	149	0.461 (0.411)
Updated Pre-MPR	301	0.919 (0.139)	104	0.940 (0.113)	134	0.906 (0.145)	63	0.913 (0.164)
Updated Post-MPR	301	1.161 (1.558)	104	1.121 (0.415)	134	1.073 (0.799)	63	1.412 (3.162)
Traditional Pre-MPR	301	0.954 (0.195)	104	0.987 (0.196)	134	0.941 (0.201)	63	0.927 (0.175)
Traditional Post-MPR	301	0.969 (0.196)	104	0.999 (0.181)	134	0.949 (0.199)	63	0.963 (0.208)

Table 35: Pre- and post- utilzation and medication adherence of beneficiaries on thyroid hormones

Thyroid	Overall		Full Coverage		Generic Coverage		No Coverage	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Pre-Utilization	720	53.410 (19.103)	122	50.934 (18.477)	398	54.889 (19.408)	200	51.975 (18.689)
Post-utilization	720	21.275 (22.016)	122	31.959 (29.357)	398	19.977 (20.436)	200	17.340 (17.470)
Updated Pre-PDC	693	0.899 (0.158)	117	0.927 (0.129)	382	0.885 (0.170)	194	0.908 (0.145)
Updated Post-PDC	693	0.828 (0.280)	117	0.888 (0.250)	382	0.800 (0.302)	194	0.848 (0.245)
Pre-MPR	521	0.940 (0.104)	102	0.966 (0.070)	274	0.930 (0.114)	145	0.940 (0.100)
Post-MPR	521	1.287 (1.369)	102	1.251 (1.110)	274	1.321 (1.488)	145	1.246 (1.303)
Traditional Pre-MPR	521	0.989 (0.199)	102	1.021 (0.167)	274	0.980 (0.216)	145	0.983 (0.185)
Traditional Post-MPR	521	1.005 (0.193)	102	1.036 (0.171)	274	1.010 (0.210)	145	0.974 (0.167)

Table 36: Pre- and post- utilzation and medication adherence of beneficiaries on biguanides

Biguanides	Overall		Full Coverage		Generic Coverage		No Coverage	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Pre-Utilization	413	54.884 (19.550)	75	48.933 (18.386)	238	56.475 (19.900)	100	55.560 (18.880)
Post-utilization	413	22.988 (22.470)	75	34.040 (26.971)	238	22.391 (22.148)	100	16.120 (15.560)
Pre-PDC	392	0.841 (0.212)	71	0.926 (0.102)	227	0.830 (0.220)	94	0.803 (0.236)
Post-PDC	392	0.732 (0.333)	71	0.840 (0.233)	227	0.718 (0.341)	94	0.682 (0.363)
Updated Pre-MPR	281	0.917 (0.135)	60	0.956 (0.066)	165	0.901 (0.156)	56	0.922 (0.114)
Updated Post-MPR	281	1.044 (0.379)	60	1.069 (0.436)	165	1.058 (0.401)	56	0.977 (0.208)
Traditional Pre-MPR	281	0.944 (0.179)	60	0.987 (0.113)	165	0.928 (0.201)	56	0.945 (0.162)
Traditional Post-MPR	281	0.967 (0.156)	60	0.974 (0.119)	165	0.975 (0.174)	56	0.934 (0.130)

Difference-in-Difference analysis: Prescription drug utilization

Tables 37-39 reflect results of the difference-in-difference analysis comparing prescription drug utilization before and after the coverage gap for beneficiaries enrolled in the no coverage plan, generic coverage plan and the full coverage plan. Beneficiaries enrolled in the no coverage gap plan filled 14.67 prescriptions less than beneficiaries in the full coverage plan, after hitting the coverage gap ($p=0.001$). Similar differences were noted between beneficiaries enrolled in the generic coverage plan and the no coverage plan. Beneficiaries enrolled in the no coverage plan filled 12.52 prescriptions less than beneficiaries in the generic coverage plan, after hitting the coverage gap ($p=0.001$). However, no significant differences in prescription drug utilization, after hitting the coverage gap, were noted upon comparison of beneficiaries enrolled in the full coverage plan with beneficiaries enrolled in the generic coverage plan.

Table 37: Prescription drug utilization: Difference-in-difference analysis: Full versus No Coverage Plan

Parameter	Estimate	SE	P-value
N	1210		
Gender	-1.38	0.67	0.04
MTM	-1.26	1.42	0.37
HMO	-0.33	0.72	0.64
Plan type	8.61	0.88	0.001*
Time	34.14	1.05	0.001*
Age	0.13	0.04	0.001*
Income	0.001	0.001	0.02
Risk	0.36	0.06	0.001*
Coverage gap month	-3.91	0.14	0.001*
DiD (Plan type* time interaction)	**-14.67**	**1.77**	**0.001***

Table 38: Prescription drug utilization: Difference-in-difference analysis: Generic versus no coverage plan

Parameter	Estimate	SE	P-value
N	2075		
Gender	-1.24	0.58	0.03
MTM	-2.99	0.97	0.001*
HMO	1.00	0.70	0.15
Plan type	5.87	0.88	0.001*
Time	31.79	0.89	0.001*
Age	0.07	0.03	0.02
Income	0.001	0.001	0.29
Risk	0.44	0.04	0.001*
Coverage gap month	-3.86	0.13	0.001*
DiD (Plan type* time interaction)	**-12.52**	**1.78**	**0.001***

Table 39: Prescription drug utilization: Difference-in-difference analysis: Generic versus full coverage plan

Parameter	Estimate	SE	P-value
N	1703		
Gender	-0.675	0.492	0.170
MTM	-3.839	0.811	0.001*
HMO	0.576	0.628	0.359
Plan type	-2.390	0.565	0.001*
Time	31.793	0.787	0.001*
Age	0.065	0.027	0.014*
Income	0.000	0.000	0.004*
Risk	0.324	0.036	0.001*
Coverage gap month	-3.961	0.114	0.001*
DiD (Plan type* time interaction)	**2.088**	**1.293**	**0.107**

Difference-in-Difference Analysis: Medication adherence

Tables 40-69 reflect results of the difference-in-difference (DiD) analysis for the ten drug classes. For each drug class, three tables are presented. The first table for each drug class compares pre- and post- medication adherence for beneficiaries enrolled in the full coverage plan versus beneficiaries enrolled in the no coverage plan. The second table for each drug class compares pre- and post- medication adherence for beneficiaries enrolled in the generic coverage versus those enrolled in the no coverage plan. The third table for each drug class compares pre- and post- medication adherence for beneficiaries enrolled in the full coverage versus those enrolled in the generic coverage plan. The DiD analyses controls for the following covariates : age, gender, beneficiaries receiving MTM services, beneficiaries enrolled in HMO plans, plan type (full versus no coverage plan), time (pre-coverage gap versus post-coverage gap), risk score (which reflects a beneficiaries co-morbidities), income and the month in which a beneficiary hit the coverage gap.

DiD analyses without discarding oversupply due to drug switches within the same medication class were also conducted. However, no differences in results were observed when compared to results obtained by discarding the oversupply due to drug switches within the same medication class. Therefore, only the results obtained by discarding the oversupply due to drug switches within the same medication class are reported.

Statins: Difference-in-Difference analysis - Full versus no coverage plans

Table 40 compares pre- and post-medication adherence to statins for beneficiaries enrolled in full coverage versus no coverage plans. As was noted in the descriptive analyses, the impact of the coverage gap on medication adherence varied depending on

the method used to measure medication adherence. When medication adherence was measured using the PDC method, medication adherence of beneficiaries in the no coverage gap compared to beneficiaries in the full coverage plan decreased significantly by 0.058 (5.8%, $p \leq 0.017$) after hitting the coverage gap. However, when measured using the updated MPR and MPR traditional methods, there was no significant difference in pre- and post medication adherence for beneficiaries in the no coverage plan compared to beneficiaries in the full coverage plan.

Statins: Difference-in-Difference analysis - Generic versus no coverage plans

Table 41 compares pre- and post-medication adherence to statins for beneficiaries enrolled in generic coverage versus no coverage plans. As was observed for the generic versus no coverage plans, when medication adherence was measured using the PDC method, medication adherence of beneficiaries in the no coverage plan compared to beneficiaries in the generic coverage plan decreased significantly by 0.011 (1.1%, $p \leq 0.017$) after beneficiaries hit the coverage gap. However, when measured using the MPR and MPR traditional methods, there was no significant difference in pre- and post medication adherence for beneficiaries in the no coverage plan compared to beneficiaries in the generic coverage plan.

Statins: Difference-in-Difference analysis - Full versus generic coverage

Table 42 compares pre- and post-medication adherence to statins for beneficiaries enrolled in full coverage versus generic coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to

beneficiaries in the full coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Table 40: Statins Difference-in-difference analysis: Full versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
N	568			390			390		
Gender	0.016	0.017	0.333	0.023	0.013	0.034*	0.011	0.011	0.356
MTM	-0.020	0.033	0.551	-0.011	0.020	0.561	0.008	0.021	0.688
HMO	-0.003	0.018	0.883	-0.002	0.012	0.858	0.004	0.012	0.756
Plan type	-0.070	0.031	0.023*	-0.203	0.283	0.474	0.013	0.015	0.401
Time	0.138	0.014	0.001*	-0.434	0.178	0.015*	-0.011	0.012	0.355
Age	-0.020	0.033	0.551	0.001	0.001	0.939	0.000	0.001	0.978
Risk	-0.003	0.018	0.883	-0.002	0.001	0.077*	-0.001	0.001	0.586
Income	0.001	0.001	0.001*	0.001	0.001	0.001*	0.001	0.000	.001*
Coverage gap month	-0.013	0.004	0.001*	-0.003	0.003	0.150	0.003	0.003	0.226
DiD (Plan type* time interaction)	**-0.058**	**0.024**	**0.014***	**0.223**	**0.282**	**0.430**	**0.029**	**0.019**	**0.122**

Table 41: Statins Difference-in-difference analysis: Generic versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
N	998			668			668		
Gender	0.024	0.013	0.057	0.023	0.009	0.009	0.017	0.010	0.084
MTM	0.003	0.021	0.876	-0.011	0.013*	0.385	-0.016	0.015	0.277
HMO	-0.010	0.016	0.547	0.009	0.011*	0.428	0.011	0.012	0.362
Plan Type	-0.028	0.022	0.206	0.302	0.169	0.073	-0.020	0.016	0.192
Time	0.116	0.011	0.001*	-0.120	0.100	0.228	-0.020	0.010	0.056*
Age	0.000	0.001	0.001*	0.001*	0.001*	0.510	0.001	0.001	0.733
Risk	0.001	0.001	0.066	-0.003	0.001*	0.001*	-0.002	0.001	0.018*
Income	-0.003	0.001	0.001*	0.001	0.001*	0.001*	0.001	0.001	0.001*
Coverage gap month	0.001	0.001	0.001*	-0.003	0.002	0.219	0.003	0.003	0.281
DiD (Plan type* time interaction)	**-0.011**	**0.003**	**0.001***	**0.313**	**0.168**	**0.063**	**-0.009**	**0.018**	**0.604**

Table 42: Statins Difference-in-difference analysis: Full versus generic coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
N	846			663			663		
Gender	0.041	0.020	0.06	0.019	0.004	0.016*	0.023	0.050	0.068
MTM	0.001	0.021	0.887	-0.010	0.018	0.584	-0.014	0.015	0.452
HMO	-0.020	0.014	0.609	0.004	0.011	0.411	0.032	0.022	0.556
Plan type	0.047	0.027	0.081	-0.001	0.142	0.579	-0.009	0.018	0.574
Time	0.116	0.011	0.001*	0.167	0.014	0.064	-0.020	0.011	0.058*
Age	0.001	0.001	0.066	0.001	0.001	0.310	0.000	0.001	0.733
Risk	-0.001	0.001	0.001*	-0.001	0.001	0.001*	-0.002	0.001	0.018*
Income	0.001	0.001	0.001*	0.001	0.001	0.001*	0.001	0.001	0.001*
Coverage gap month	-0.011	0.003	0.001*	-0.013	0.004	0.142	0.016	0.001	0.308
DiD (Plan type* time interaction)	**-0.022**	**0.018**	**0.241**	**0.418**	**0.114**	**0.074**	**0.135**	**0.048**	**0.736**

ACEI

ACEI: Difference-in-Difference analysis - Full versus no coverage plans

Table 43 compares pre- and post-medication adherence to ACEI for beneficiaries enrolled in full coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the no coverage plan compared to beneficiaries in the full coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

ACEI: Difference-in-Difference analysis - Generic versus no coverage plans

Table 44 compares pre- and post-medication adherence to ACEI for beneficiaries enrolled in generic coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plan compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

ACEI: Difference-in-Difference analysis - Full versus generic coverage

Table 45 compares pre- and post-medication adherence to ACEI for beneficiaries enrolled in full coverage versus generic coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the full coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Table 43: ACEI: Difference-in-difference analysis: Full versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
N	381			262			262		
Gender	0.906	0.117	0.001*	-0.010	0.014	0.488	0.003	0.017	0.857
MTM	0.036	0.021	0.092	0.038	0.032	0.233	-0.061	0.037	0.104
HMO	-0.004	0.048	0.926	-0.002	0.016	0.914	0.006	0.018	0.741
Plan type	-0.018	0.026	0.483	0.033	0.062	0.592	0.001	0.021	0.945
Time	-0.168	0.038	0.479	-0.168	0.034	0.001*	0.002	0.014	0.889
Age	0.113	0.016	0.001*	0.000	0.001	0.599	-0.001	0.001	0.380
Risk	-0.001	0.001	0.362	-0.002	0.001	0.155	-0.001	0.002	0.660
Income	-0.003	0.002	0.136	0.000	0.000	0.001*	0.001	0.000	.001*
Coverage gap month	0.000	0.000	0.001*	-0.010	0.003	0.005*	0.001	0.004	0.953
DiD (Plan type* time interaction)	**-0.052**	**0.026**	**0.042**	**0.056**	**0.060**	**0.351**	**-0.027**	**0.025**	**0.293**

Table 44: ACEI: Difference-in-difference analysis: Generic versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
N	542			387			387		
Gender	0.005	0.019	0.802	-0.017	0.013	0.164	-0.009	0.013	0.454
MTM	0.037	0.032	0.246	0.017	0.019	0.386	0.025	0.019	0.187
HMO	-0.018	0.024	0.450	0.009	0.015	0.566	0.008	0.015	0.598
Plan type	0.049	0.038	0.197	0.081	0.046	0.075	-0.006	0.020	0.751
Time	0.107	0.013	0.001*	-0.134	0.020	0.001*	-0.022	0.011	0.044
Age	-0.001	0.001	0.279	0.000	0.001	0.917	0.000	0.001	0.626
Risk	-0.003	0.002	0.050*	-0.001	0.001	0.224	-0.001	0.001	0.500
Income	0.000	0.000	0.001*	0.000	0.000	0.001*	0.000	0.000	.001*
Coverage gap month	-0.016	0.005	0.001*	-0.009	0.003	0.006*	-0.002	0.003	0.531
DiD (Plan type* time interaction)	**-0.058**	**0.029**	**0.046**	**-0.090**	**0.043**	**0.040**	**-0.001**	**0.024**	**0.969**

Table 45:ACEI: Difference-in-difference analysis: Full versus generic coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
N	695			483			483		
Gender	0.022	0.016	0.173	0.004	0.010	0.668	0.005	0.012	0.654
MTM	0.014	0.027	0.598	0.026	0.016	0.109	0.016	0.019	0.384
HMO	-0.017	0.020	0.393	-0.024	0.013	0.052	-0.025	0.015	0.097
Plan type	-0.024	0.028	0.389	-0.046	0.035	0.185	0.000	0.015	0.993
Time	0.114	0.017	0.001*	-0.168	0.026	0.001*	0.002	0.014	0.865
Age	-0.001	0.001	0.125	0.000	0.001	0.690	-0.001	0.001	0.146
Risk	-0.003	0.001	0.045	-0.002	0.001	0.019*	-0.001	0.001	0.195
Income	0.000	0.000	0.001*	0.000	0.000	0.001*	0.001	0.000	0.001*
Coverage gap month	-0.010	0.004	0.010*	-0.008	0.003	0.002*	-.003	0.003	0.334
DiD (Plan type* time interaction)	-0.007	0.021	0.743	0.034	0.033	0.313	-0.025	0.018	0.165

ARB

ARB: Difference-in-Difference analysis - Full versus no coverage plans

Table 46 compares pre- and post-medication adherence to ARB for beneficiaries enrolled in full coverage versus no coverage plans. When medication adherence was measured using the PDC method, medication adherence of beneficiaries in the no coverage plan compared to beneficiaries in the full coverage plan decreased significantly by 0.160 (16.0%, $p \leq 0.017$) after hitting the coverage gap. However, when measured using the updated MPR and MPR traditional methods, there was no significant difference in pre- and post medication adherence for beneficiaries in the no coverage plan compared to beneficiaries in the full coverage plan.

ARB: Difference-in-Difference analysis - Generic versus no coverage plans

Table 47 compares pre- and post-medication adherence to ARB for beneficiaries enrolled in generic coverage versus no coverage plans. Medication adherence of beneficiaries in the no coverage plan compared to beneficiaries in the generic coverage plan decreased significantly by 0.121 (12.1%, $p \leq 0.017$) when measured using the PDC. However, when measured using the updated MPR or the MPR traditional method, there was no significant difference in pre- and post medication adherence for beneficiaries in the no coverage plan compared to beneficiaries in the generic coverage plan.

ARB: Difference-in-Difference analysis - Full versus generic coverage plans

Table 48 compares pre- and post-medication adherence to ARB for beneficiaries enrolled in generic coverage versus full coverage plans. No significant differences were found in

medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the full coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Table 46:ARB: Difference-in-difference analysis: Full versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
N	147			97			97		
Gender	0.022	0.031	0.488	0.043	0.020	0.037	0.045	0.021	0.031
MTM	-0.036	0.055	0.507	-0.045	0.040	0.264	-0.018	0.040	0.665
HMO	0.027	0.036	0.448	0.018	0.022	0.411	0.009	0.022	0.692
Plan type	0.202	0.060	0.001*	-0.021	0.046	0.648	0.019	0.029	0.507
Time	0.208	0.032	0.001*	-0.117	0.033	0.001*	-0.004	0.025	0.869
Age	0.004	0.002	0.106	0.001	0.001	0.585	0.002	0.002	0.157
Risk	-0.006	0.004	0.200	-0.001	0.003	0.643	-0.001	0.003	0.665
Income	0.000	0.000	0.268	0.000	0.000	0.001*	0.000	0.000	0.001*
Coverage gap month	-0.007	0.007	0.347	-0.002	0.005	0.680	-0.003	0.005	0.548
DiD (Plan type* time interaction)	**-0.160**	**0.046**	**0.001***	**0.033**	**0.043**	**0.449**	**-0.013**	**0.033**	**0.700**

Table 47:ARB: Difference-in-difference analysis: Generic versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	250			167			167		
Gender	0.003	0.024	0.900	0.017	0.015	0.234	0.017	0.019	0.354
MTM	0.106	0.034	0.002	-0.007	0.022	0.740	0.022	0.028	0.448
HMO	0.027	0.031	0.387	0.018	0.019	0.347	0.012	0.025	0.614
Plan type	0.114	0.049	0.019	-0.077	0.064	0.232	0.017	0.031	0.574
Time	0.169	0.022	.001	-0.149	0.035	0.001	0.016	0.020	0.414
Age	0.007	0.001	.001	0.001	0.001	0.375	0.002	0.001	0.050
Risk	-0.008	0.002	0.001	-0.002	0.001	0.123	-0.002	0.002	0.288
Income	0.000	0.000	0.001	0.000	0.000	0.001	0.000	0.000	0.001
Coverage gap month	-0.012	0.005	0.029	-0.008	0.004	0.025	-0.005	0.005	0.285
DiD (Plan type* time interaction)	**-0.121**	**0.042**	**0.004***	**0.065**	**0.061**	**0.287**	**-0.033**	**0.034**	**0.335**

Table 48: ARB: Difference-in-difference analysis: Full versus generic coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	259			152			152		
Gender	0.015	0.025	0.558	0.024	0.016	0.132	0.012	0.020	0.557
MTM	0.052	0.033	0.116	-0.023	0.022	0.285	-0.003	0.027	0.920
HMO	0.027	0.037	0.457	0.010	0.023	0.666	0.021	0.029	0.477
Plan type	0.070	0.050	0.160	0.049	0.075	0.520	-0.005	0.031	0.860
Time	0.208	0.036	0.001 *	-0.117	0.062	0.064	-0.004	0.034	0.904
Age	0.006	0.002	0.000 *	0.001	0.001	0.745	0.002	0.001	0.156
Risk	-0.008	0.002	0.001 *	-0.003	0.002	0.028 *	-0.002	0.002	0.211
Income	0.001	0.001	0.001 *	0.001	0.001	0.001 *	0.001	0.001	0.001*
Coverage gap month	-0.014	0.006	0.023 *	-0.006	0.004	0.172	0.001	0.005	0.833
DiD (Plan type* time interaction)	**-0.039**	**0.043**	**0.368**	**-0.033**	**0.073**	**0.656**	**0.020**	**0.040**	**0.612**

Beta-blockers: Difference-in-Difference analysis - Full versus no coverage plans

Table 49 compares pre- and post-medication adherence to beta-blockers for beneficiaries enrolled in full coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the full coverage plans compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Beta-blockers: Difference-in-Difference analysis - Generic versus no coverage plans

Table 50 compares pre- and post-medication adherence to beta-blockers for beneficiaries enrolled in generic coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Beta-blockers: Difference-in-Difference analysis - Full versus generic coverage

Table 51 compares pre- and post-medication adherence to beta-blockers for beneficiaries enrolled in full coverage versus generic coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the full coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Table 49: Beta-blockers: Difference-in-difference analysis: Full versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
N	378			254			254		
Gender	-0.006	0.022	0.789	0.004	0.014	0.790	-0.005	0.015	0.740
MTM	0.004	0.047	0.926	-0.036	0.030	0.230	-0.010	0.032	0.751
HMO	-0.025	0.024	0.302	0.009	0.016	0.564	0.003	0.017	0.867
Plan type	0.096	0.039	0.014	0.076	0.053	0.158	0.036	0.030	0.238
Time	0.094	0.016	0.001*	-0.136	0.031	0.001*	-0.021	0.021	0.322
Age	-0.001	0.001	0.583	-0.001	0.001	0.335	-0.001	0.001	0.576
Risk	-0.003	0.002	0.149	-0.002	0.001	0.088	-0.003	0.002	0.053
Income	0.000	0.000	0.001*	0.000	0.000	.001*	0.000	0.000	.001*
Coverage gap month	-0.009	0.005	0.072	-0.003	0.003	0.406	-0.001	0.004	0.693
DiD (Plan type* time interaction)	**-0.030**	**0.029**	**0.310**	**-0.059**	**0.054**	**0.271**	**0.003**	**0.036**	**0.939**

Table 50: Beta blockers: Difference-in-difference analysis: Generic versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	679			467			467		
Gender	0.048	0.042	0.252	-0.013	0.040	0.742	-0.018	0.035	0.610
MTM	-0.135	0.067	0.043	0.055	0.059	0.358	0.038	0.051	0.458
HMO	0.061	0.053	0.248	0.040	0.050	0.428	0.029	0.043	0.507
Plan type	-0.053	0.052	0.310	-0.031	0.054	0.562	-0.057	0.047	0.224
Time	-0.179	0.072	0.014	-0.321	0.050	0.001	-0.247	0.052	.001
Age	-0.002	0.002	0.478	0.000	0.002	0.902	0.000	0.002	0.999
Risk	-0.005	0.003	0.043	-0.007	0.003	0.006	-0.007	0.002	0.002
Income	0.014	0.020	0.474	0.037	0.019	0.051	0.049	0.016	0.003
Coverage gap month	0.039	0.010	0.000	0.005	0.011	0.661	0.016	0.009	0.097
DiD (Plan type* time interaction)	**0.094**	**0.092**	**0.308**	**0.077**	**0.062**	**0.218**	**0.105**	**0.065**	**0.105**

Table 51:Beta blockers: Difference-in-difference analysis: Full versus generic coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
N	526			275			275		
Gender	-0.024	0.019	0.198	-0.019	0.014	0.177	-0.037	-2.230	0.027
MTM	0.003	0.029	0.931	0.016	0.020	0.418	-0.001	-0.030	0.973
HMO	0.024	0.022	0.278	0.008	0.016	0.612	-0.002	-0.110	0.916
Plan type	0.087	0.035	0.015	0.096	0.048	0.045	0.047	1.650	0.099
Time	0.103	0.013	0.001	-0.128	0.023	0.001	-0.018	-1.160	0.247
Age	-0.001	0.001	0.306	0.000	0.001	0.697	-0.001	-1.250	0.213
Risk	-0.002	0.001	0.097	0.000	0.001	0.846	0.000	0.040	0.968
Income	0.000	0.000	0.001	0.000	0.000	0.001	0.000	0.000	0.001
Coverage gap month	-0.008	0.004	0.051	0.000	0.003	0.978	0.000	-0.100	0.918
DiD (Plan type* time interaction)	**-0.038**	**0.027**	**0.157**	**-0.067**	**0.047**	**0.154**	**-0.004**	**-0.140**	**0.889**

Biguanides

Biguanides: Difference-in-Difference analysis - Full versus no coverage plans

Table 52 compares pre- and post-medication adherence to biguanides for beneficiaries enrolled in full coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the full coverage plans compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Biguanides: Difference-in-Difference analysis - Generic versus no coverage plans

Table 53 compares pre- and post-medication adherence to biguanides for beneficiaries enrolled in generic coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Biguanides: Difference-in-Difference analysis - Full versus generic coverage

Table 54 compares pre- and post-medication adherence to biguanides for beneficiaries enrolled in full coverage versus generic coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the full coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Table 52: Biguanides: Difference-in-difference analysis: Full versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	155			110			110		
Gender	0.062	0.032	0.054	0.003	0.180	0.855	0.016	0.019	0.406
MTM	0.053	0.066	0.423	0.046	1.220	0.224	0.041	0.040	0.312
HMO	0.032	0.036	0.380	0.022	1.040	0.299	0.025	0.022	0.269
Plan type	0.142	0.055	0.011*	0.063	0.940	0.351	0.033	0.026	0.208
Time	0.122	0.028	0.001*	-0.056	-1.160	0.249	0.015	0.024	0.546
Age	0.000	0.002	0.966	-0.001	-0.400	0.689	0.000	0.001	0.855
Risk	-0.004	0.003	0.171	-0.002	-1.060	0.293	-0.004	0.002	0.049
Income	0.000	0.000	0.986	0.000	0.000	.001*	0.000	0.000	.001*
Coverage gap month	-0.009	0.007	0.206	-0.010	-2.230	0.028	-0.003	0.005	0.570
DiD (Plan type* time interaction)	**-0.041**	**0.044**	**0.346**	**-0.053**	**-0.800**	**0.424**	**-0.005**	**0.034**	**0.872**

Table 53: Biguanides: Difference-in-difference analysis: Generic versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	306			218			218		
Gender	0.048	0.026	0.071	0.002	0.020	0.938	0.007	0.018	0.685
MTM	0.033	0.039	0.409	0.064	0.028	0.024	0.013	0.025	0.598
HMO	-0.001	0.035	0.974	-0.005	0.027	0.861	0.034	0.024	0.152
Plan type	0.053	0.044	0.224	0.082	0.058	0.161	0.048	0.024	0.050 *
Time	0.122	0.030	0.001*	-0.056	0.051	0.276	0.015	0.032	0.649
Age	0.000	0.002	0.984	0.000	0.001	0.988	0.000	0.001	0.772
Risk	-0.006	0.002	0.004*	-0.002	0.002	0.360	-0.003	0.002	.039*
Income	0.000	0.000	0.340	0.000	0.000	0.001*	0.000	0.000	.001*
Coverage gap month	-0.011	0.007	0.107	-0.014	0.006	0.020*	0.003	0.005	0.538
DiD (Plan type* time interaction)	**-0.013**	**0.035**	**0.717**	**-0.100**	**0.059**	**0.089**	**-0.057**	**0.037**	**0.123**

Table 54: Biguanides: Difference-in-difference analysis: Full versus generic coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	283			217			217		
Gender	0.013	0.024	0.605	-0.011	0.019	0.578	0.010	0.017	0.554
MTM	0.028	0.037	0.451	0.066	0.027	0.016	0.025	0.024	0.310
HMO	-0.027	0.032	0.397	-0.011	0.025	0.658	0.026	0.022	0.238
Plan type	0.093	0.045	0.042	-0.020	0.064	0.750	-0.009	0.024	0.716
Time	0.109	0.017	0.001*	-0.156	0.033	0.001*	-0.043	0.018	.017*
Age	0.000	0.002	0.835	0.000	0.001	0.854	-0.001	0.001	0.564
Risk	-0.006	0.002	0.006	-0.002	0.002	0.373	-0.003	0.002	0.124
Income	0.000	0.000	0.443	0.000	0.000	0.001*	0.000	0.000	.001*
Coverage gap month	-0.010	0.006	0.098	-0.012	0.005	0.021*	0.001	0.005	0.795
DiD (Plan type* time interaction)	**-0.028**	**0.036**	**0.425**	**0.047**	**0.064**	**0.463**	**0.052**	**0.035**	**0.136**

Diuretics

Diuretics: Difference-in-Difference analysis - Full versus no coverage plans

Table 55 compares pre- and post-medication adherence to diuretics for beneficiaries enrolled in full coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the full coverage plans compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Diuretics: Difference-in-Difference analysis - Generic versus no coverage plans

Table 56 compares pre- and post-medication adherence to diuretics for beneficiaries enrolled in generic coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Diuretics: Difference-in-Difference analysis - Full versus generic coverage plans

Table 57 compares pre- and post-medication adherence to diuretics for beneficiaries enrolled in full coverage versus generic coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the full coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Table 55: Diuretics: Difference-in-difference analysis: Full versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	170			97			97		
Gender	0.104	0.044	0.019	0.016	0.024	0.505	0.023	0.018	0.201
MTM	-0.043	0.087	0.622	0.037	0.042	0.371	0.056	0.032	0.083
HMO	0.039	0.048	0.413	-0.018	0.026	0.506	0.004	0.020	0.834
Plan type	-0.025	0.067	0.711	0.054	0.195	0.782	0.030	0.026	0.257
Time	0.144	0.030	.001*	-0.238	0.122	0.055	-0.006	0.023	0.801
Age	0.003	0.003	0.246	0.001	0.002	0.590	0.002	0.001	0.275
Risk	-0.004	0.004	0.307	-0.005	0.003	0.150	-0.004	0.003	0.128
Income	0.000	0.000	0.806	0.000	0.000	0.609	0.000	0.000	.001*
Coverage gap month	0.004	0.011	0.694	0.003	0.006	0.646	0.010	0.005	0.039
DiD (Plan type* time interaction)	**0.008**	**0.048**	**0.870**	**-0.023**	**0.193**	**0.905**	**-0.009**	**0.036**	**0.799**

Table 56: Diuretics: Difference-in-difference analysis: Generic versus No Coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	329			167			167		
Gender	0.002	0.033	0.536	-0.005	0.020	0.806	0.017	0.002	0.450
MTM	0.012	0.053	0.817	-0.015	0.030	0.613	0.012	0.033	0.708
HMO	0.051	0.042	0.231	0.008	0.026	0.761	0.039	0.029	0.190
Plan type	-0.015	0.049	0.754	-0.070	0.114	0.538	0.021	0.028	0.434
Time	0.143	0.032	0.001	-0.238	0.091	0.011	-0.005	0.027	0.832
Age	0.002	0.002	0.211	0.001	0.001	0.627	0.002	0.001	0.061
Risk	-0.005	0.002	0.062	-0.005	0.002	0.785	0.001	0.002	0.611
Income	-0.001	0.001	0.837	-0.001	0.001	0.600	-0.001	0.001	0.115
Coverage gap month	0.003	0.008	0.709	0.003	0.005	0.498	0.004	0.006	0.453
DiD (Plan type* time interaction)	**0.024**	**0.039**	**0.548**	**0.071**	**0.113**	**0.525**	**-0.007**	**0.033**	**0.820**

Table 57: Diuretics: Difference-in-difference analysis: Full versus Generic Coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	263			157			157		
Gender	0.039	0.035	0.265	-0.010	0.021	0.641	-0.006	0.025	0.811
MTM	0.040	0.062	0.521	-0.039	0.033	0.237	-0.015	0.039	0.713
HMO	0.072	0.042	0.089	0.023	0.025	0.346	0.060	0.030	0.045
Plan type	-0.026	0.060	0.666	0.128	0.106	0.228	0.018	0.038	0.633
Time	0.167	0.023	0.001 *	-0.166	0.052	0.002 *	-0.014	0.021	0.519
Age	0.005	0.002	0.024	0.002	0.001	0.221	0.003	0.002	.033*
Risk	-0.004	0.003	0.183	0.001	0.002	0.892	0.001	0.003	0.664
Income	0.001	0.001	0.618	0.001	0.001	0.698	0.001	0.001	0.254
Coverage gap month	-0.006	0.009	0.452	0.001	0.005	0.966	0.003	0.006	0.597
DiD (Plan type* time interaction)	**-0.016**	**0.045**	**0.727**	**-0.095**	**0.103**	**0.360**	**-0.002**	**0.041**	**0.969**

SSRI: Difference-in-Difference analysis - Full versus no coverage plans

Table 58 compares pre- and post-medication adherence to SSRI for beneficiaries enrolled in full coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the no coverage plan compared to beneficiaries in the full prescription drug coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

SSRI: Difference-in-Difference analysis - Generic versus no coverage plans

Table 59 compares pre- and post-medication adherence to SSRI for beneficiaries enrolled in generic coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

SSRI: Difference-in-Difference analysis - Full versus generic coverage plans

Table 60 compares pre- and post-medication adherence to SSRI for beneficiaries enrolled in full coverage versus generic coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the full coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Table 58: SSRI: Difference-in-difference analysis: Full versus No Coverage Plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	267			181			181		
Gender	0.041	0.031	0.179	-0.014	0.018	0.441	-0.005	0.020	0.803
MTM	0.065	0.048	0.172	0.035	0.027	0.210	0.061	0.031	0.047
HMO	0.038	0.031	0.227	0.019	0.018	0.301	0.025	0.020	0.229
Plan type	0.105	0.049	0.003	0.162	0.133	0.506	0.017	0.028	0.548
Time	0.174	0.021	0.001	0.001	0.079	0.044	-0.009	0.019	0.615
Age	0.002	0.001	0.095	-0.001	0.001	0.241	0.001	0.001	0.679
Risk	-0.008	0.002	0.002	-0.001	0.001	0.398	-0.005	0.001	0.791
Income	0.001	0.001	0.607	-0.001	0.001	0.001	0.001	0.001	0.001
Coverage gap month	-0.023	0.005	0.001	-0.013	0.003	0.001	-0.009	0.004	0.024
DiD (Plan type* time interaction)	**-0.076 -0.078**	**0.036 0.036**	**0.033 0.032**	**-0.084 -0.104**	**0.131 0.130**	**0.523 0.423**	**-0.024 -0.018**	**0.033 0.031**	**0.479 0.563**

Table 59: SSRI: Difference-in-difference analysis: Generic versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	502			328			328		
Gender	0.025	0.025	0.317	0.003	0.016	0.873	0.006	0.019	0.628
MTM	0.052	0.035	0.139	0.021	0.020	0.309	0.014	0.160	0.419
HMO	0.006	0.031	0.835	-0.008	0.018	0.663	0.019	0.014	0.549
Plan type	0.033	0.037	0.370	-0.016	0.046	0.724	-0.024	0.038	0.614
Time	0.175	0.021	0.001	-0.162	0.036	0.001	-0.118	0.012	0.008
Age	0.001	0.001	0.332	0.001	0.001	0.553	0.001	0.001	0.236
Risk	-0.002	0.002	0.200	-0.001	0.001	0.536	-0.001	0.001	0.185
Income	0.001	0.001	.001	0.001	0.001	0.001	0.001	0.001	0.001
Coverage gap month	-0.027	0.005	0.001	-0.010	0.003	0.004	-0.009	0.004	0.017
DiD (Plan type* time interaction)	**-0.030**	**0.027**	**0.256**	**0.024**	**0.045**	**0.584**	**0.014**	**0.061**	**0.716**

Table 60: SSRI: Difference-in-difference analysis: Full versus generic coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	408			219			219		
Gender	0.019	0.026	0.453	-0.009	0.015	0.565	-0.011	0.016	0.495
MTM	0.063	0.037	0.089	0.015	0.022	0.494	-0.011	0.022	0.615
HMO	0.011	0.030	0.707	-0.008	0.017	0.653	0.008	0.018	0.639
Plan type	0.074	0.046	0.110	0.116	0.106	0.275	0.022	0.023	0.341
Time	0.144	0.016	0.001	-0.138	0.053	0.009	-0.025	0.014	0.064
Age	0.001	0.001	0.742	-0.001	0.001	0.289	0.001	0.001	0.606
Risk	-0.001	0.002	0.528	0.001	0.001	0.984	0.001	0.001	0.803
Income	0.000	0.000	0.001	0.000	0.000	0.001	0.001	0.000	0.001
Coverage gap month	-0.024	0.005	0.001	-0.009	0.003	0.005	-0.001	0.003	0.717
DiD (Plan type* time interaction)	**-0.046**	**0.034**	**0.170**	**-0.109**	**0.105**	**0.301**	**-0.008**	**0.027**	**0.771**

Thyroid Hormones

Thyroid Hormones: Difference-in-Difference analysis - Full versus no coverage plans

Table 61 compares pre- and post-medication adherence to thyroid hormones for beneficiaries enrolled in full coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the full coverage plans compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Thyroid Hormones: Difference-in-Difference analysis - Generic versus no coverage plans

Table 62 compares pre- and post-medication adherence to thyroid hormone for beneficiaries enrolled in generic coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Thyroid Hormones: Difference-in-Difference analysis - Full versus generic coverage

Table 63 compares pre- and post-medication adherence to thyroid hormones for beneficiaries enrolled in full coverage versus generic coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the full coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Table 61: Thyroid Hormones: Difference-in-difference analysis: Full versus No Coverage

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
N	299			237			237		
Gender	-0.044	0.018	0.019	-0.013	0.014	0.325	0.008	0.021	0.710
MTM	0.001	0.032	0.973	-0.009	0.022	0.696	0.043	0.034	0.216
HMO	0.012	0.018	0.501	0.001	0.013	0.953	0.053	0.021	0.011
Plan type	0.040	0.031	0.194	0.010	0.165	0.954	0.046	0.024	0.055
Time	0.061	0.016	0.001	-0.312	0.105	0.003	0.011	0.018	0.526
Age	0.003	0.001	0.004	0.002	0.001	0.017	0.002	0.001	0.078
Risk	-0.002	0.002	0.241	-0.002	0.001	0.097	-0.002	0.002	0.326
Income	0.001	0.001	.001	0.001	0.001	.001	0.001	0.001	.001
Coverage gap month	-0.004	0.003	0.235	-0.003	0.003	0.234	-0.008	0.004	0.055
DiD (Plan type* time interaction)	**-0.014**	**0.026**	**0.580**	**0.018**	**0.164**	**0.912**	**-0.025**	**0.028**	**0.377**

Table 62: Thyroid: Difference-in-difference analysis: Generic versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
N	550			397			397		
Gender	0.003	0.017	0.839	-0.003	0.014	0.812	0.015	0.021	0.479
MTM	-0.012	0.023	0.595	-0.012	0.016	0.475	0.010	0.025	0.671
HMO	0.010	0.020	0.621	0.001	0.016	0.929	0.041	0.023	0.083
Plan type	-0.040	0.026	0.120	0.071	0.153	0.642	0.044	0.021	0.032
Time	0.061	0.018	0.001	-0.312	0.122	0.011	0.011	0.018	0.529
Age	0.001	0.001	0.200	0.001	0.001	0.247	-0.001	0.001	0.455
Risk	0.001	0.001	0.814	0.001	0.001	0.675	0.001	0.001	0.730
Income	0.001	0.001	0.001	0.000	0.001	.001	0.001	0.001	.001
Coverage gap month	-0.003	0.003	0.317	-0.003	0.003	0.339	0.005	0.004	0.207
DiD (Plan type* time interaction)	**0.019**	**0.022**	**0.388**	**-0.082**	**0.151**	**0.586**	**-0.043**	**0.022**	**0.058**

Table 63: Thyroid: Difference-in-difference analysis: Full versus generic coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
N	477			356			356		
Gender	-0.003	0.018	0.849	0.001	0.013	0.997	-0.005	0.021	0.815
MTM	0.001	0.024	0.979	0.008	0.016	0.630	0.044	0.025	0.076
HMO	0.008	0.020	0.693	-0.003	0.014	0.827	0.013	0.022	0.569
Plan type	0.072	0.032	0.027	-0.068	0.168	0.686	0.008	0.025	0.743
Time	0.080	0.013	0.001	-0.394	0.087	0.001	-0.031	0.014	0.024
Age	0.001	0.001	0.660	0.001	0.001	0.918	-0.002	0.001	0.050
Risk	0.001	0.001	0.946	0.001	0.001	0.612	0.001	0.001	0.992
Income	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	.001
Coverage gap month	-0.006	0.003	0.060	-0.004	0.003	0.110	-0.005	0.004	0.185
DiD (Plan type* time interaction)	**-0.033**	**0.026**	**0.197**	**0.100**	**0.167**	**0.547**	**0.891**	**0.034**	**0.364**

PPI

PPI: Difference-in-Difference analysis - Full versus no coverage plans

Table 64 compares pre- and post-medication adherence to PPI for beneficiaries enrolled in full coverage versus no coverage plans. The impact of the coverage gap on medication adherence varied depending on the method used to measure medication adherence. When medication adherence was measured using the PDC method, medication adherence of beneficiaries in the no coverage gap compared to beneficiaries in the full coverage plan decreased significantly by 0.181 (18.1%, $p \leq 0.017$) after hitting the coverage gap. However, when measured using the updated MPR and MPR traditional methods, there was no significant difference in pre- and post medication adherence for beneficiaries in the no coverage plan compared to beneficiaries in the full coverage plan.

PPI: Difference-in-Difference analysis - Generic versus no coverage plans

Table 65 compares pre- and post-medication adherence to PPI for beneficiaries enrolled in generic coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

PPI: Difference-in-Difference analysis - Full versus generic coverage plans

Table 66 compares pre- and post-medication adherence to PPI for beneficiaries enrolled in full coverage versus generic coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to

beneficiaries in the full coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Table 64: PPI: Difference-in-difference analysis: Full versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
N	273			161			161		
Gender	0.001	0.032	0.998	-0.006	0.022	0.796	-0.013	0.023	0.582
MTM	0.072	0.067	0.282	0.072	0.038	0.059	0.035	0.041	0.384
HMO	0.003	0.034	0.926	0.015	0.023	0.525	0.040	0.025	0.101
Plan type	0.267	0.047	0.001	0.108	0.062	0.083	0.044	0.032	0.164
Time	0.251	0.026	0.001	-0.089	0.049	0.073	-0.019	0.031	0.544
Age	0.001	0.002	0.710	-0.002	0.001	0.224	-0.002	0.001	0.272
Risk	-0.008	0.003	0.006	-0.006	0.002	0.008	-0.005	0.002	0.051
Income	0.000	0.000	0.177	0.000	0.000	0.001	0.000	0.000	0.258
Coverage gap month	-0.026	0.007	0.000	-0.007	0.005	0.141	-0.005	0.005	0.307
DiD (Plan type* time interaction)	**-0.181**	**0.037**	**0.001***	**-0.094**	**0.062**	**0.131**	**0.008**	**0.039**	**0.831**

Table 65: PPI: Difference-in-difference analysis: Generic versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	403			185			185		
Gender	0.008	0.030	0.786	0.001	0.023	0.949	0.010	0.022	0.645
MTM	-0.046	0.048	0.335	-0.033	0.031	0.281	-0.040	0.030	0.177
HMO	-0.029	0.037	0.443	0.040	0.029	0.174	0.031	0.028	0.274
Plan type	0.011	0.045	0.798	0.015	0.050	0.757	0.011	0.029	0.711
Time	0.251	0.030	0.001*	-0.089	0.042	0.036	-0.019	0.034	0.578
Age	0.001	0.001	0.844	0.000	0.001	0.937	0.001	0.001	0.256
Risk	-0.004	0.002	0.103	-0.004	0.002	0.056	-0.002	0.002	0.366
Income	0.001	0.001	0.192	0.001	0.001	0.001	0.001	0.001	.001*
Coverage gap month	-0.022	0.007	0.001*	-0.005	0.006	0.412	0.010	0.005	0.072
DiD (Plan type* time interaction)	**-0.017**	**0.038**	**0.642**	**-0.019**	**0.051**	**0.705**	**0.009**	**0.042**	**0.826**

Table 66: PPI: Difference-in-difference analysis: Full versus generic coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	392			228			228		
Gender	0.027	0.028	0.333	0.032	0.018	0.075	0.034	0.021	0.097
MTM	-0.019	0.045	0.673	-0.010	0.026	0.695	-0.029	0.031	0.345
HMO	-0.003	0.032	0.936	0.011	0.019	0.567	0.025	0.023	0.278
Plan type	0.263	0.044	0.001	0.095	0.050	0.058	0.042	0.027	0.122
Time	0.233	0.020	0.001	-0.109	0.033	0.001	-0.010	0.023	0.661
Age	0.001	0.001	0.898	0.000	0.001	0.797	0.001	0.001	0.303
Risk	-0.004	0.002	0.121	-0.006	0.002	0.001	-0.004	0.002	0.045
Income	0.000	0.000	0.497	0.000	0.000	0.001	0.000	0.000	0.001
Coverage gap month	-0.018	0.006	0.001	-0.010	0.004	0.010	-0.002	0.004	0.599
DiD (Plan type* time interaction)	**-0.074**	**0.035**	**0.189**	**-0.075**	**0.049**	**0.126**	**0.000**	**0.034**	**0.990**

CCI

CCI: Difference-in-Difference analysis - Full versus no coverage plans

Table 67 compares pre- and post-medication adherence to CCI for beneficiaries enrolled in full coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

CCI: Difference-in-Difference analysis - Generic versus no coverage plans

Table 687 compares pre- and post-medication adherence to CCI for beneficiaries enrolled in generic coverage versus no coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

CCI: Difference-in-Difference analysis - Full versus generic coverage

Table 69 compares pre- and post-medication adherence to CCI for beneficiaries enrolled in full coverage versus generic coverage plans. No significant differences were found in medication adherence of beneficiaries in the generic coverage plans compared to beneficiaries in the no coverage plan irrespective of whether adherence was measured using the PDC, updated MPR or MPR traditional methods.

Table 67: CCI: Difference-in-difference analysis: Full versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	295			211			211		
Gender	0.011	0.022	0.612	-0.004	0.013	0.785	0.013	0.017	0.449
MTM	-0.063	0.043	0.149	-0.022	0.022	0.320	0.026	0.029	0.366
HMO	0.009	0.024	0.722	0.006	0.014	0.670	0.009	0.018	0.629
Plan type	0.082	0.041	0.044*	-0.017	0.051	0.742	-0.016	0.020	0.433
Time	0.106	0.018	0.001*	-0.153	0.030	0.001*	-0.027	0.014	0.064
Age	0.001	0.001	0.641	0.000	0.001	0.644	0.000	0.001	0.971
Risk	0.001	0.002	0.489	-0.001	0.001	0.333	0.000	0.002	0.885
Income	0.000	0.000	.001*	0.001	0.001	0.001*	0.000	0.000	.001*
Coverage gap month	-0.009	0.005	0.057	-0.002	0.003	0.578	-0.002	0.004	0.688
DiD (Plan type* time interaction)	**-0.048**	**0.030**	**0.108**	**0.031**	**0.049**	**0.536**	**0.001**	**0.024**	**0.988**

Table 68: CCI: Difference-in-difference analysis: Generic versus no coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	553			406			406		
Gender	0.027	0.020	0.177	-0.004	0.011	0.684	-0.004	0.013	0.785
MTM	-0.001	0.028	0.973	0.006	0.014	0.680	-0.022	0.022	0.320
HMO	-0.012	0.025	0.628	-0.006	0.013	0.665	0.006	0.014	0.670
Plan type	0.000	0.031	0.997	-0.012	0.039	0.757	-0.017	0.051	0.742
Time	0.106	0.018	0.001	-0.153	0.031	0.001	-0.153	0.030	0.001*
Age	0.000	0.001	0.775	0.001	0.001	0.984	0.000	0.001	0.644
Risk	-0.005	0.001	0.000	-0.003	0.001	0.001	-0.001	0.001	0.333
Income	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001*
Coverage gap month	-0.021	0.004	0.001	-0.006	0.002	0.020	-0.002	0.003	0.578
DiD (Plan type* time interaction)	**-0.023**	**0.023**	**0.308**	**0.016**	**0.038**	**0.676**	**0.010**	**0.001**	**0.894**

Table 69: CCI: Difference-in-difference analysis: Full versus generic coverage plan

Parameter	PDC			MPR Updated			MPR Traditional		
	Estimate	SE	P-value	Estimate	SE	P-value	Estimate	SE	P-value
n	474			346			346		
Gender	0.012	0.021	0.582	-0.015	0.011	0.190	-0.006	0.015	0.681
MTM	0.002	0.032	0.943	0.009	0.016	0.580	0.023	0.022	0.286
HMO	-0.008	0.025	0.764	0.006	0.014	0.668	-0.004	0.018	0.819
Plan type	0.060	0.038	0.109	-0.009	0.047	0.850	-0.001	0.022	0.973
Time	0.083	0.013	0.001	-0.137	0.021	0.001	-0.014	0.012	0.256
Age	0.000	0.001	0.921	0.000	0.001	0.874	-0.001	0.001	0.484
Risk	-0.006	0.001	0.001	-0.002	0.001	0.019	0.001	0.001	0.903
Income	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	.001
Coverage gap month	-0.017	0.004	0.001	-0.005	0.003	0.045	-0.001	0.003	0.828
DiD (Plan type* time interaction)	**-0.025**	**0.027**	**0.360**	**0.015**	**0.046**	**0.743**	**-0.013**	**0.026**	**0.612**

Medical Costs incurred by beneficiaries who hit the coverage gap

XYZ health care services provided data on medical costs associated with Medicare Part A and B services for beneficiaries who hit the coverage gap. Medical costs refer to the costs that were associated with medical claims (all claims except for pharmacy claims) and paid by XYZ healthcare services for the beneficiary.

Figure 7 compares differences in medical costs between beneficiaries enrolled in a Medicare Part D plan but did not reach the coverage gap with beneficiaries who reached the coverage gap. As is evident in the graph, medical costs incurred by beneficiaries who hit the coverage gap were nearly double the costs incurred by beneficiaries who did not hit the coverage gap. This trend was observed across all 12 months.

Figure 6 Comparison of per member per month medical costs for beneficiaries who did not hit the coverage gap with beneficiaries who hit the coverage gap by month

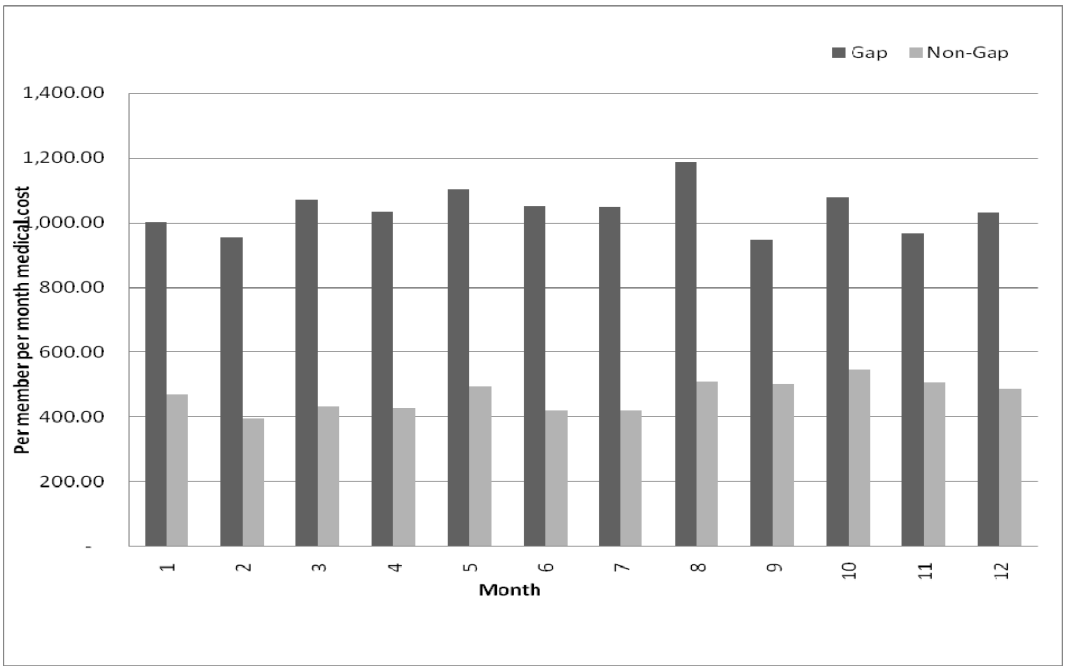
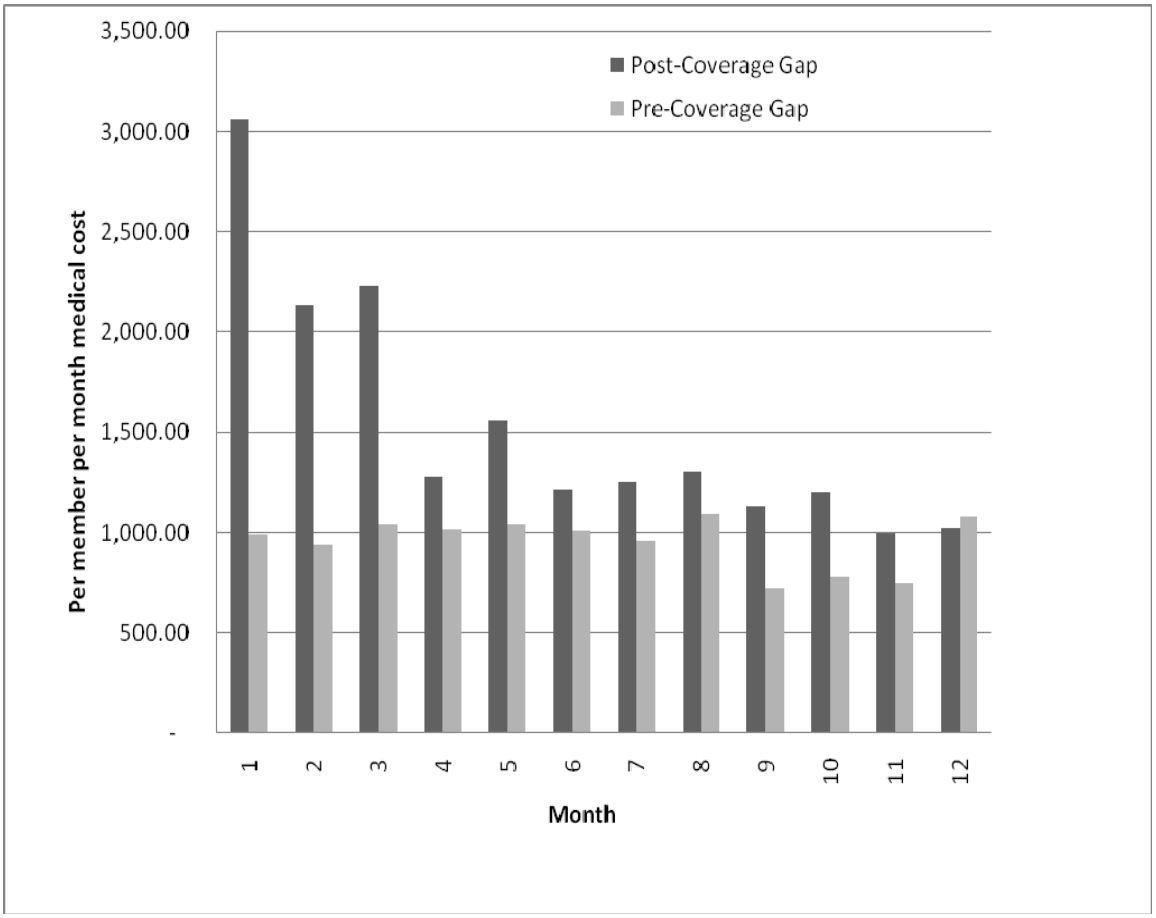


Figure 8 compares the difference in per member per month (PMPM) medical costs incurred pre- and post-coverage gap for beneficiaries who hit the coverage gap in 2007. The graph indicates that the after hitting the coverage gap there was considerable increase in the per member per month total medical costs compared to their costs before hitting the coverage gap. The costs difference pre- and post-coverage gap was observed to be higher during the first 6 months of the year relative to the last 6 months of the year.

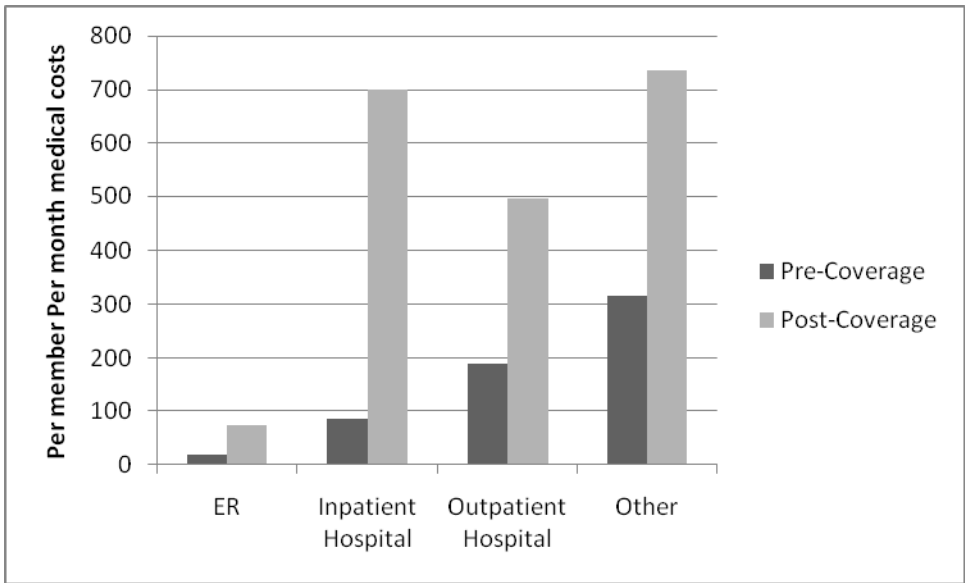
Figure 7 Comparison of per member per month medical costs Pre- and Post-Coverage gap for each month



XYZ healthcare services reported that of all the beneficiaries who hit the coverage gap, for nearly quarter of beneficiaries (633 beneficiaries), higher costs were incurred

during the post- coverage gap compared to costs spent on these beneficiaries before they hit the coverage gap. The PMPMs for 633 beneficiaries in specific utilization categories (emergency room visits, inpatient hospitalizations, outpatient hospitalizations, and other (all costs not included in the previous 3 categories) is reported in figure 9. The largest difference in costs pre- and post- coverage gap was observed for inpatient costs and the least difference was observed for emergency room visits.

Figure 8 Comparison of per member per month medical costs Pre- and Post-Coverage gap by specific categories



SUMMARY

Nearly seventeen percent or 2,494 beneficiaries remained in the coverage gap and less than 1% or 117 beneficiaries reached the catastrophic coverage limit in the year 2007. Beneficiaries in the no coverage gap plan filled significantly less number of prescriptions than beneficiaries in the full or generic coverage plans after hitting the coverage gap. A

comparison of medication adherence of beneficiaries in the full coverage versus no coverage plans, indicated a decrease in post-coverage gap medication adherence for beneficiaries taking statins, ARB's and PPI's when measured using the PDC as a measure of adherence. A comparison of medication adherence of beneficiaries in the generic coverage versus no coverage plans indicated a decrease in post-coverage gap medication adherence for beneficiaries taking statins and ARB's, when measured using the PDC as a measure of adherence. No significant post-coverage gap differences were observed between beneficiaries enrolled in the full coverage plan and generic coverage plan for any of the drug classes.

CHAPTER 5

DISCUSSION

This chapter presents a discussion of the study results and recommendations for future research. The chapter begins with a discussion of results with respect to each of the research objectives and other important findings in the study. Following the discussion of the results, the limitations of the research design and recommendations for future research are presented. Finally, strengths of this study, significant findings and implications from this study are presented.

Discussion of study results

Medicare Part D coverage gap

Nearly eighteen percent of beneficiaries, enrolled in an MA-PD plan offered by XYZ services who met the study inclusion and exclusion criteria, hit the coverage gap in the year 2007. Nearly seventeen percent or 2,494 beneficiaries remained in the coverage gap and less than 1% or 117 beneficiaries reached the catastrophic coverage limit in the year 2007. A study conducted by the Kaiser Family Foundation reported similar results. The study estimates indicated that 14% of Part D enrollees (3.4 million Medicare beneficiaries) reached the coverage gap in 2007. (Hoadley J, et al., 2007). Results from a study conducted by Zhang and colleagues (2009) indicated that 5 percent of Medicare beneficiaries in the study reached the catastrophic coverage level.(Zhang, et al., 2009)

Nearly 90% of beneficiaries hit the coverage gap in the last 6 months of the year with about one fifth (21.22%) of the beneficiaries hitting the coverage gap in the months

of June and July, 2007. With less than one percent of all beneficiaries who hit the coverage gap being covered under catastrophic coverage limit, this translates to nearly ninety percent of Medicare beneficiaries who hit the coverage gap, having no prescription drug coverage for about 5 or 6 months. The 2010 health care reform legislation, includes a clause on reduction of the out-of-pocket amount that qualifies for Part D catastrophic coverage beginning 2014 through 2019.(Kaiser Family Foundation, 2010b) With only 1% beneficiaries in this study and 5% from the study conducted by Zang and colleagues (2009) hitting the catastrophic coverage results, these results bring to light the significance of reduction in catastrophic coverage limits.(Zhang, et al., 2009) However, in lieu of a phased reduction in the catastrophic coverage limits beginning only in 2014 and spread out over a period of 5 years proposed under the current health care reform legislation, a more immediate reduction in the catastrophic coverage limit may be more advantageous to Medicare beneficiaries.

Of the beneficiaries who hit the coverage gap, nearly one third (31.72%) were enrolled in a plan which offered no prescription drug coverage during the coverage gap, nearly half were enrolled in a plan which covered generic drugs during the coverage gap and the remaining 17% were enrolled in a plan which covered both brand name and generic drugs during the coverage gap. Similar results were reported by Zhang et al (2009), with about 25 percent of beneficiaries enrolled in a plan without prescription drug coverage during the coverage gap hit the coverage gap.(Zhang, et al., 2009) The results from this study indicate that nearly a third of Medicare beneficiaries who hit the coverage gap did not have any prescription drug coverage during 2007.

The 2010 health care reform does address increased coverage during the Medicare Part D coverage gap. Under the proposed Medicare reform legislation, the coverage gap will be phased from 100% coverage gap in 2010 to 25% coverage gap by 2020. Specifically, the legislation indicates that in 2010, Part D enrollees with any spending in the coverage gap will receive a $250 rebate. (Kaiser Family Foundation, 2010b) Medicare coverage discount programs will be initiated in 2011, with pharmaceutical manufacturers providing a 50 percent discount on brand-name drugs to Part D enrollees with spending in the coverage gap. A reduction in coinsurance for generic drugs in the coverage gap is slated beginning in 2011, and a reduction in coinsurance for brand-name drugs in the gap is slated beginning in 2013. The beneficiary coinsurance rate for both brands and generics are slated to reduce from 100 percent in 2010 to 25 percent in 2020, until enrollees qualify for catastrophic coverage.(Kaiser Family Foundation, 2010b) This translates into Medicare beneficiaries being responsible for 25% of their prescription drug costs in 2020 with higher percentages in the preceding decade. Therefore, even with the health care reform, Medicare beneficiaries are exposed to considerable amounts of cost-sharing over the next decade and beyond.

As has been described at length in chapter 2, cost-sharing and lack of prescription drug coverage are associated with decreased prescription drug utilization. Decreased prescription drug utilization in Medicare beneficiaries has been associated with decreased adherence, increased hospitalizations, increased emergency department visits and higher out-of-pocket costs.(Chandra, et al., 2007; Chernew, et al., 2008; Hsu, et al., 2006; Joyce, et al., 2007; S. Soumerai, et al., 2006; Steinman, et al., 2001; Stuart & Grana, 1998; Tamblyn, et al., 2001a; Tseng, et al., 2004)

Demographics of beneficiaries who hit the coverage gap

Medicare beneficiaries who hit the coverage gap were on average 73 years old, female, had high number of co-morbid conditions, and an annual income of approximately $40,000. It is important to note that for a group of individuals with about $40,000 in annual income, average true out-of-pocket (OOP) expenses of $1,075 for prescription drugs alone might place considerable financial burden and may potentially lead to decreased utilization of prescription drugs. In essence, beneficiaries who hit the coverage gap in this study had poorer health, low income, and high out-of-pocket costs. In addition to OOP expenses associated with prescription drugs, Medicare beneficiaries may also bear expenses for other health care needs such as hospitalizations, Medicare Part A and B premiums, etc. Medicare beneficiaries with high out-of-pocket expenses are less likely to fill prescription drugs.(S. Soumerai, et al., 2006; Steinman, et al., 2001) As indicated above, decreased prescription drug utilization is associated with adverse clinical and economic outcomes and as health care reform is underway in the United States, it is important to consider these characteristics. (Chandra, et al., 2007; Chernew, et al., 2008; Hsu, et al., 2006; Joyce, et al., 2007; S. Soumerai, et al., 2006; Steinman, et al., 2001; Stuart & Grana, 1998; Tamblyn, et al., 2001a; Tseng, et al., 2004)

Pre- and Post-coverage gap prescription drug utilization in a sample of New Mexico Medicare beneficiaries

The first objective of the study was to compare prescription drug utilization of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap with prescription drug utilization

of Medicare beneficiaries enrolled in a plan providing no gap coverage. The results of this study indicate that beneficiaries enrolled in a health plan which does not cover prescription drugs during the coverage gap, fill significantly fewer prescriptions (15 prescriptions) than beneficiaries who have prescription drug coverage during the coverage gap. A decrease in prescription drug utilization, (15.85% decrease in average days of therapy) after beneficiaries hit the coverage gap, was reported by Sun and Lee.(Sun & Lee, 2007) Zhang, et al, also reported that prescription drug utilization of beneficiaries with no prescription drug coverage during the coverage gap was 14% lower compared to utilization of beneficiaries with full prescription drug coverage during the gap. (Zhang, et al., 2009)

Decreased prescription drug utilization has been associated with adverse clinical and economic events. With the limitation that only one year of data was available and data on the exact date a beneficiary hit the coverage gap was not available, the results from this study describe a very clear trend of increased medical costs borne by XYZ health care services for beneficiaries who hit the coverage gap. The results of this study found that medical costs incurred by beneficiaries who hit the coverage gap were nearly double the costs incurred by beneficiaries who did not hit the coverage gap. This trend was observed across all 12 months. Further, higher costs were incurred in the post-coverage gap period compared to costs spent on these beneficiaries before they hit the coverage gap. Additionally, the largest difference in costs pre- and post- coverage gap was observed for inpatient costs and the smallest difference was observed for emergency room visits. From an economic stand point, the costs associated with increased hospitalizations and emergency room visits, as a result of lower utilization of prescription

drugs are also paid by Medicare and at higher amount than it would typically cost to include coverage of prescription drugs. This basic principle is important to highlight when arguments against provision of prescription drugs during the coverage gap are made.

The second objective of the study was to compare prescription drug utilization of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan covering generic drugs during the coverage gap with prescription drug utilization of Medicare beneficiaries enrolled in a plan providing no gap coverage. The results of this study indicate that beneficiaries enrolled in a health plan which does not cover prescription drugs during the coverage gap, fill significantly fewer prescriptions (13 prescriptions) than beneficiaries who have generic drug coverage during the coverage gap. A review of the literature indicated that studies comparing prescription drug utilization between plans covering generic drugs during the coverage gap and plans providing no prescription drug coverage during the coverage gap have not been reported. However, one study reported that a prescription drug benefit with no caps on utilization of generic drugs was associated with a reduction in prescription costs and no increases in nonprescription-related healthcare service utilization. (R Balkrishnan, et al., 2001)

The third objective of the study was to compare prescription drug utilization of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap with prescription drug utilization of Medicare beneficiaries enrolled in a plan covering generic drugs during the coverage gap. No difference in prescription drug utilization, after hitting the coverage gap, was found when beneficiaries in the full coverage plan were compared with beneficiaries in

the generic coverage plan. These results bring forth a very important consideration from a health policy perspective. The results of this study indicate that prescription drug utilization of beneficiaries enrolled in a plan covering generic prescription drugs during the coverage gap are comparable to the prescription drug utilization of beneficiaries enrolled in a plan covering all prescription drugs. Given that generic drugs are considerably cheaper compared to brand name prescription drugs, inclusion of generic drugs in the coverage gap may prevent the adverse clinical and economic outcomes due to lack of prescription drug coverage without placing considerable economic burden on Medicare.

The 2010 health care reform legislation includes a reduction in coinsurance for generic drugs in the coverage gap beginning in 2011and a reduction in coinsurance for brand-name drugs in the gap is slated beginning in 2013. The beneficiary coinsurance rate for both brands and generics are slated to reduce from 100 percent in 2010 to 25 percent in 2020. The results of this study indicate that prescription drug utilization of beneficiaries enrolled in a plan covering generic prescription drugs during the coverage gap are comparable to that of beneficiaries enrolled in a plan covering all prescription drugs. Therefore, in lieu of brand name coverage during the coverage gap, a more pragmatic option from an economic standpoint might be 100% inclusion of generic drugs during the coverage gap beginning immediately instead of a phased decrease in co-insurance of brand name prescription drugs. Research could be conducted to compare cost-savings introduced by providing no coverage of brand name prescription drugs and the cost borne by the provision of 100% generic drug coverage during the coverage gap.

Pre- and Post-coverage gap medication adherence in a sample of New Mexico Medicare beneficiaries

The fourth objective of the study was to compare medication adherence to ten select drug classes, of a sample of New Mexico Medicare beneficiaries, enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap with medication adherence of Medicare beneficiaries enrolled in a plan providing no gap coverage. A comparison of medication adherence of beneficiaries in the full coverage versus no coverage plans, indicated a decrease in post-coverage gap medication adherence for beneficiaries on statins, ARB's and PPI's when measured using the PDC as a measure of adherence. Post-coverage gap, for beneficiaries in the no coverage plan, adherence to statins decreased significantly by 5.8%, adherence to ARB's decreased significantly by 16%, and adherence to PPI's decreased significantly by 18.1%. Although not significant, decreased medication adherence was observed for ACEI, SSRI's, beta-blockers, biguanides, diuretics, thyroid hormones and CCI.

A study conducted by Raebel, et. al (2008) also reported significant reduction in adherence to anti-hyperlipidemics, anti-hypertensives, anti-depressants and diuretics. (Raebel, et al., 2008) Another study conducted by the Kaiser Family Foundation (2008) reported that 20% beneficiaries on PPIs, 15% on anti-depressants, 18% on osteoporosis medications, 16% on ACEI, 14% on ARB's, 13% on statins, 8% on Alzheimer's medications and 10% on oral anti-diabetics stopped taking medications after hitting the coverage gap. (Hoadley J, et al., 2007) However, it is important to note that both these studies are descriptive in nature and methodologically limited due to lack of control of confounding factors. The results reported based on this study, however, are based on a

quasi-experimental, cross-sectional, retrospective, pre-post with control group study design.

Improvements in clinical outcomes have been reported for various disease states with improved medication adherence. Reports indicate a significant decrease in depression severity (for patients with major depression) with a 20-25% improvement in adherence to antidepressants (W. Katon et al., 1996; Wayne Katon et al., 2001; W. Katon et al., 1995; Peveler, George, Kinmonth, Campbell, & Thompson, 1999); significant improvements in HbA1c levels have been observed with a 10% increase in adherence to anti-diabetic medications (Pladevall et al., 2004); significant improvements in LDL cholesterol levels have been observed with a 10-30% increase in adherence to cholesterol lowering medications (Lee, Grace, & Taylor, 2006; Pladevall, et al., 2004); and significant improvements in blood pressure control have been observed with a 8-30% increase in adherence to antihypertensives. (Lee, et al., 2006; Schroeder, Fahey, & Ebrahim, 2004) Based on this literature review, the decreased adherence even at the low values observed in this study, may result in adverse clinical outcomes such as increased hospitalizations, emergency visits and increased costs. (Chandra, et al., 2007; Chernew, et al., 2008; Hsu, et al., 2006; Joyce, et al., 2007; S. Soumerai, et al., 2006; Steinman, et al., 2001; Stuart & Grana, 1998; Tamblyn, et al., 2001a; Tseng, et al., 2004)

In 2007, a study conducted by Dana Goldman and colleagues examined the relationship between copayments for cholesterol-lowering drugs and compliance in the year after initiation of therapy and the association between compliance and subsequent hospital and emergency department (ED) use for up to four years after initiation, using claims data from eighty-eight health plans during 1997-2001.(Goldman, et al., 2007)

Results of the study indicated significant adverse impact of copayments on compliance in all risk groups with each $10 rise in copayments associated with a decrease of five percentage points in average compliance in a plan-year. The authors estimated that for high- and medium-risk patients', reducing copayments on cholesterol-lowering medications from $10 to $0, pharmacy payments would have increased by $486 million, but inpatient hospital spending would have declined by $839 million. Further, spending on ED visits would also have declined.

The results of this study indicated significant decrease in adherence for statins, ARB's and PPI's for beneficiaries enrolled in the no coverage plans. It is important to consider the potential clinical and economic adverse impacts with decreased adherence, particularly of essential medications such as statins, ARB's, and PPI's. Further, decreased medication adherence to essential medications is of considerable concern in the Medicare population as the Medicare population typically includes older patients with high number of co-morbid conditions, low income and high OOP expenses. It is thus important to weigh the cost of inclusion of prescription drugs during the coverage gap with the potential costs and impacts on health due to clinical adverse events associated with reduced medication adherence of essential medications.

The fifth objective of the study was to compare medication adherence to select drug classes, of a sample of New Mexico Medicare beneficiaries, enrolled in a Medicare Part D plan covering generic drugs during the coverage gap with medication adherence of Medicare beneficiaries enrolled in a plan providing no gap coverage. A comparison of medication adherence of beneficiaries in the generic coverage versus no coverage plans indicated a decrease in post-coverage gap medication adherence for beneficiaries taking

statins and ARB's, when measured using the PDC as a measure of adherence. Post-coverage gap, for beneficiaries in the no coverage plan, adherence to statins decreased significantly by 1.1% and adherence to ARB's decreased by 12.1%. A review of the literature indicated that studies comparing adherence to medications between plans covering generic drugs during the coverage gap and plans providing no prescription drug during the coverage gap have not been reported. Given that inclusion of generic drugs during the coverage gap results in greater medication adherence compared to no prescription drug coverage during the coverage gap, and generic drugs are cheaper than brand name drugs, as stated earlier, it is important to consider provision of generic drugs during the coverage gap.

The sixth objective of the study was to compare medication adherence to ten select drug classes, of a sample of New Mexico Medicare beneficiaries enrolled in a Medicare Part D plan with full prescription drug coverage during the coverage gap with medication adherence of Medicare beneficiaries enrolled in a plan covering generic drugs during the coverage gap. No significant post-coverage gap differences were observed between beneficiaries enrolled in the full coverage plan and generic coverage plan for any of the drug classes. A review of the literature indicated that studies comparing adherence to medications between plans covering generic drugs during the coverage gap and plans providing full prescription drug coverage during the coverage gap have not been reported, thus precluding comparisons to other studies. Based on these results, with no differences between adherence with generic or full prescription drug coverage during the coverage gap, as was described earlier, inclusion of generic drugs during the coverage gap may alleviate not only the clinical adverse outcomes but also the economic adverse

outcomes.

In addition to assessing the impact of the Medicare Part D coverage gap on prescription drug utilization and medication adherence, this research brought forth important findings. Based on the difference-in-difference analyses, it was observed that when comparing beneficiaries enrolled in the generic coverage plan with beneficiaries enrolled in the no coverage plan and full coverage plans, beneficiaries who did not receive MTM services had lower prescription drug utilization than beneficiaries who received MTM services. XYZ health care services provides MTM eligible members an invitation to schedule an appointment with a clinical pharmacist. The clinical pharmacist identifies opportunities for the member to lower average monthly pharmacy costs by suggesting strategies such as switching to generic, tablet splitting, more cost effective formulary alternatives, eliminating duplicate or unnecessary prescriptions, prescription to over-the-counter switches, etc. The clinical pharmacist also identifies medication related problems such as overdosage, underdosage, adverse drug reaction, untreated medical condition, failure to receive medication, drug interaction, drug use without an indication, etc. Based on the results of this study, the MTM services provided by a clinical pharmacist translate into improved prescription drug utilization. This represents an important finding and highlights the importance of MTM services provided by clinical pharmacists improving prescription drug utilization and thus clinical outcomes.

Further, the results of the study also indicated that, irrespective of the health plan that beneficiaries were enrolled in, a beneficiary's income and risk score were significant predictors of prescription drug utilization and medication adherence for a majority of the drug classes. The exclusion criteria of this study were set such that beneficiaries who

received low income subsidies were excluded from the analyses. Therefore, this study represents beneficiaries who did not qualify for any financial help and their low income resulted in decreased prescription drug utilization and medication adherence. Similarly, beneficiaries with high risk scores, that is, beneficiaries with high co-morbidities had reduced prescription drug utilization and medication adherence for a majority of the drug classes irrespective of the health plan they were enrolled in. As health care reform is underway, it is important to provide additional financial support and added prescription drug coverage to low income beneficiaries and beneficiaries with a higher number of co-morbidities.

Measures of medication adherence

The results of this study bring forth an important methodological consideration. Significant differences in medication adherence were observed only when adherence was measured using the PDC and not when measured using the updated MPR and MPR traditional methods. The updated MPR and MPR traditional methods resulted in an over-inflated adherence value. The algorithms used in this study were checked multiple times for accuracy. Further, as a validity check of the algorithms, the results on medication adherence calculations obtained by using the algorithms were cross checked with manual calculations for a few beneficiaries and consistent results provided evidence that calculation errors were unlikely. One explanation for inflated adherence value when measured using the MPR might be due to the fact that the MPR does not accurately account for oversupply of medications which result in higher values. Even when oversupply from one period is accounted for by transferring it to the next period, the results are inflated depending on the amount of oversupply that is carried forward from

one period to another. For the purposes of difference-in-difference analyses, outlying MPR values (>1.2, a cut-off commonly employed in the literature) were deleted from analyses. Despite this, the 20% excess MPR, potentially impacted the results. One consideration, if an MPR is to be used for analyses, depending on the objective of the study, more accurate results might be obtained with truncating the MPR to value of 1. The PDC, on the other hand, does not need any adjustments as it measures adherence based on availability of medications on a per day basis and is a more robust measure of adherence. Similar concerns of over-inflated projection of adherence values when using MPR instead of the PDC as a measure of adherence have been reported in the literature. (Martin, et al., 2009)

The results of this study bring to light the criticality and the importance of choosing an appropriate measure of adherence. An MPR has its advantage in its simplicity of calculation and widespread use. It is an appropriate measure of adherence when the objective of determining adherence is a very quick measure of a patient's medication consumption behavior in clinical settings or for the purposes of patient counseling, etc. It is important to note however, that the traditional MPR formula does not allow for accounting of drug switches and over-supplies without modifications to the formula reported in the literature. As the formula used for traditional MPR calculations does not permit for carrying over medication from one period to another, it is not a suitable measure of adherence when comparing adherence in two periods of time. Drug switches, over-supply and carryover of medications from one time period to another can be accomplished by adjusting the formula as was done in this study. Adjustment of the formula does involve a fair amount of complexity to ensure accurate calculations,

especially when using large databases. Further, this adjustment brings forth the issue of very high MPR values at the end of the period which leads to statistical issues when using the MPR as a unit of analyses. It is important that researchers appropriately truncate the MPR when using it in additional analyses.

Although significant complexity is associated with calculating the PDC, it provides an accurate measure of adherence as it assesses if a patient has medication for each day in the period being assessed and also carries forward excess medications from one period to another. Based on the results of this study, it is recommended that when the objective of measurement of adherence is assessing a policy impact as was done in this study it is important to use the more robust measure of adherence- the PDC. Similar recommendations and concerns of over-inflated projection of adherence values when using MPR instead of the PDC as a measure of adherence have been reported in the literature. (Martin, et al., 2009)

Limitations

The results of this study should be interpreted in the light of some limitations. This study uses a retrospective database, which limits inference of a cause-effect relationship. However, the use of a quasi-experimental research design comparing the study group with a control group and use of robust analytical techniques such as the difference-in-difference analysis which aid in assessing the impact of the effects of time and within subject variations while controlling for confounding factors provide confidence in interpretation of results.

Medication adherence in this study is calculated from a pharmacy claims database. Data from pharmacy claims only implies that prescriptions were filled but does

not confirm that medications were ingested by the patient. However, medication possession is the first and necessary step for consumption of medication and MPR has been widely used and validated as a measure of adherence.

Medication adherence is impacted by a number of factors such as patient characteristics, health care provider related characteristics, environmental barriers, education, socio-economic status, etc. The data available for this study did not provide for some of these variables which might impact adherence calculations and the results of the study should be interpreted in the light of this limitation. However, where possible, proxy measures have been used. For example, although information about health status was not available, co-morbidity scores were assessed and used as an indicator of a beneficiary's health status. While income at an individual level was not available, zip code based income was used as an indicator of socio-economic status. Further demographic and health plan related factors were controlled for in this study.

There is a potential for selection bias in this study. It is possible that beneficiaries choose one health plan over another based on their anticipation of health care needs. For example, a sicker beneficiary might choose a plan which offers gap coverage compared to a healthier beneficiary. Every effort was made to control for selection bias in this study by using statistical controls for confounding factors such as control for health plan type and co-morbidities.

As per the MMA, pharmacies are required to submit all claims for prescription drugs purchased by Medicare beneficiaries, as they contribute toward TrOOP costs, which determines their eligibility for catastrophic coverage. However, it is possible that some pharmacies may not submit claims for cash payments. It is also possible that some

beneficiaries may receive free samples from their physicians, receive financial assistance from pharmaceutical manufacturers or purchase prescription drugs on the Internet. It was not possible to account for medications which Medicare beneficiaries receive from these sources and should be considered when interpreting results of this study.

The results of this study are based on enrollees from one health plan in New Mexico. This limits the generalizability of the findings to other populations. However, the health plan data used for this study is one of the largest health plans in New Mexico and has broad coverage which might provide a representative sample for Medicare beneficiaries in New Mexico. Further, the population characteristics of Medicare beneficiaries in New Mexico are very similar to the characteristics of US Medicare beneficiaries. The results of this study may thus be generalizable to Medicare beneficiaries in other health plans in New Mexico and other parts of the country.

Future research

Upon data availability from the CMS, it is important to assess the impact of the coverage gap on prescription drug utilization and medication adherence on a national sample of Medicare beneficiaries. Also upon data availability from the CMS, it would be interesting to compare the impact of the Part D coverage gap on beneficiaries enrolled in PDP plans with beneficiaries enrolled in MA-PD plans. Another important area of research is the assessment of the impact of the coverage gap on different ethnic groups. With three years of Medicare Part D data available, it would be interesting to observe the patterns of utilization and medication adherence of beneficiaries who hit the coverage gap from one calendar year to another.

Strengths of this study

Few studies have assessed the impact of the Medicare Part D coverage gap. Further, the studies conducted to date lack adequate methodological robustness. The results of this study however, are based on a quasi-experimental, cross-sectional, retrospective, pre-post with control group study design. This study design controls for demographic and health plan characteristics, and more importantly controls for the effect of time and within person variations while comparing with a control group by using robust statistical methods. To the best of our knowledge this study is the first methodologically robust study to assess the impact of the coverage gap on prescription drug utilization and medication adherence.

This study, upon publication in scientific journals, may also add to the literature on the importance of choosing the right method of measurement of medication adherence. Based on a review of the literature conducted for this study, it was observed that the literature around measures of medication adherence is very inconsistent and no clear guidelines are available even from task forces. Different studies have used different measures of adherence. The terminology and the definitions used to describe a measure of adherence are also highly inconsistent. Even measures of adherence have been described very inconsistently in the literature. For example, one study describes the PDC as equivalent to the MPR when it is truncated to 1. (Hess, et al., 2006) These inconsistencies resulted in the use of three different methods of medication adherence measurement for the purposes of this study. This study highlights the robustness and importance of using the PDC as a measure of medication adherence, particularly for health policy research issues. Based on the results of this study it is our recommendation

that the PDC which calculates availability of medication per day be used as a measure of adherence as against using measures such as the MPR which might result in over inflated adherence values.

Significance and Implications from this study

Despite introduction of Medicare Part D, nearly 17% of Medicare beneficiaries in this study did not have any prescription drug coverage for a period of time during the year. The results of this study further confirm reports in the literature that lack of prescription drug coverage, as is experienced by beneficiaries who hit the coverage gap, leads to decreased prescription drug utilization and decreased medication adherence of essential medications such as anti-hypertensives, anti-hyperlipidemics, and proton pump inhibitors. With the caveat of limitations of the data used, this study provides some evidence on the adverse clinical and economic impacts of decreased utilization and medication adherence of essential prescription drugs. From a purely economic perspective, it is important to note that short-term savings from decreased prescription drug coverage of essential drugs might be offset by increased costs due to increased hospitalizations and emergency department visits over a long term. Thus based on the results of this study it is our recommendation that the coverage gap be eliminated from the Medicare Part D benefit structure.

The coverage gap amount has increased every year since the inception of Medicare Part D. In 2009, for plans offering the standard Medicare Part D benefit, the coverage gap amounted to $3,454 and it has been projected that the coverage gap will exceed $6,000 by 2016. (Hoadley J, Thompsoni J, Hargrave E, Cubanski J, & Neuman T, 2008) This is concerning as the literature provides ample evidence that Medicare

beneficiaries have a disproportionate need of prescription drugs, incur high OOP expenses (relative to their income) and have limited financial resources. (J Cubanski, et al., 2005) The House and Senate healthcare reform bills have proposed phasing out the coinsurance rate in the coverage gap from 100% to the standard 25% amount by 2020. (Kaiser Family Foundation, 2010a) While this is a step in the right direction, it is critical to understand the adverse clinical and economic outcomes associated with the lack of adequate prescription drug coverage for another decade.

In conclusion, the results from this study, in addition to providing further evidence that lack of prescription drug coverage leads to decreased utilization of essential prescription drugs, also highlight that no significant post-coverage gap differences were observed between beneficiaries enrolled in the full coverage plan and generic coverage plan for any of the drug classes. Based on these results, in the interim, as the coverage gap is being proposed to be phased out, provision of generic drugs during the coverage gap would be beneficial to Medicare beneficiaries.

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APPENDICES

Appendix A: UNM HRRC Approval

THE UNIVERSITY OF NEW MEXICO
HEALTH SCIENCES CENTER

Human Research Review Committee
MSC 08 4560 BMSB Room B71
1 University of New Mexico~Albuquerque, NM 87131-0001
(505) 272-1129 Facsimile (505) 272-0803
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01-Oct-2008

Borrego, Matthew Elvi, Ph.D., R.Ph.
College of Pharmacy

SUBJECT: HRRC Approval of New Research Protocol
HRRC#: 08-458
Study Title: Impact of the Medicare part D coverage gap on prescription drug utilization and medication adherence
Type of Review: Expedited Review
Approval Date: 01-Oct-2008
Expiration Date: 30-Sep-2009

Dear Dr. Borrego:

The Human Research Review Committee (HRRC) has reviewed and approved* the above-mentioned research protocol including the following:

1. HRRC Expedited Review Application submitted 09/29/08
2. Protocol submitted 09/29/08

Consent decision:
Waived the requirement for informed consent
HIPAA Authorization Addendum waived

This study is approved to enroll only the number of subjects listed in the application, protocol and consentform(s). If the PI wants to enroll additional subjects, it is the responsibility of the PI to submit an Amendment/Change to the HRRC before the approved number of enrolled subjects is exceeded. If increased enrollment is requested, the application, protocol and/or consent form(s) must also be amended to include the new target.

Sincerely,

Mark Holdsworth, Pharm.D., BCOP
Executive Chair
Human Research Review Committee

* Under the provisions of this institution's Federal Wide Assurance (FWA00003255), the HRRC has determined that this proposal provides adequate safeguards for protecting the rights and welfare of the subjects involved in the study and is in compliance with HHS Regulations (45 CFR 46), FDA Regulations (21 CFR 50, 56).

Appendix B: List of Medicare Part B Drugs Excluded with their GPI numbers

GPI	PRODUCT
3090361010****	AGALSIDASE BETA
8540001000****	ALBUMIN, HUMAN
75100010002020	BACLOFEN INTRATHECAL INJ 0.05 MG/ML (50 MCG/M)
75100010006440	BACLOFEN INTRATHECAL KIT 2000 MCG/ML
75100010006420	BACLOFEN INTRATHECAL KIT 500 MCG/ML
8680701200****	BOTULINUM TOXIN TYPE A
444000150018**	BUDESONIDE (INHALATION) SUSP
213000050003**	CAPECITABINE TABS
994020200020**	CYCLOSPORINE SOLN
453040200020**	DORNASE ALFA SOLN
4017004010****	EPOPROSTENOL SODIUM
215000100001**	ETOPOSIDE CAPS
1910001000****	HEPATITIS B IMMUNE GLOBULIN (HUMAN)
221000254021**	HYDROCORTISONE SOD SUCCINATE SOLR
758000400022**	HYLAN INJ
8270005000****	IMIGLUCERASE
1910002010****	IMMUNE GLOBULIN (HUMAN) IV
5250504000****	INFLIXIMAB
21405010156420	LEUPROLIDE ACETATE (3 MONTH) FOR INJ KIT 11.2
21405010106405	LEUPROLIDE ACETATE FOR INJ KIT 3.75 MG
21405010156430	LEUPROLIDE ACETATE (3 MONTH) FOR INJ KIT 22.5
21405010206430	LEUPROLIDE ACETATE (4 MONTH) FOR INJ KIT 30 M
21405010106410	LEUPROLIDE ACETATE FOR INJ KIT 7.5 MG
442010451025**	LEVALBUTEROL HCL NEBU
140401010****	MEDROXYPROGESTERONE ACETATE (ANTINEOPLASTIC)
221000301018**	METHYLPREDNISOLONE ACETATE SUSP
3017007010****	OCTREOTIDE ACETATE
8665505030****	PEGAPTANIB SODIUM
160000450025**	PENTAMIDINE ISETHIONATE NEBU
4510001010****	PROTEINASE INHIBITOR (HUMAN)
1910004500****	RABIES IMMUNE GLOBULIN (HUMAN)
5907007010****	RISPERIDONE MICROSPHERES
75800070102020	SODIUM HYALURONATE INTRA-ARTICULAR INJ 10 MG
994040800020**	TACROLIMUS SOLN
70000700025**	TOBRAMYCIN NEBU
3004209000****	ZOLEDRONIC ACID
3090361010****	AGALSIDASE BETA

540001000****	ALBUMIN, HUMAN
110000500****	ALTRETAMINE
4530402000****	DORNASE ALFA
4017004010****	EPOPROSTENOL SODIUM
1910001000****	HEPATITIS B IMMUNE GLOBULIN (HUMAN)
270005000****	IMIGLUCERASE
1910002010****	IMMUNE GLOBULIN (HUMAN) IV
5250504000****	INFLIXIMAB
2140501010****	LEUPROLIDE ACETATE
3017007010****	OCTREOTIDE ACETATE
4510001010****	PROTEINASE INHIBITOR (HUMAN)
1910004500****	RABIES IMMUNE GLOBULIN (HUMAN)
5907007010****	RISPERIDONE MICROSPHERES
44201010102100	ALBUTEROL SULFATE FOR NEBU SOLN
44201010102515	ALBUTEROL SULFATE SOLN NEBU 0.083%
44209902012015	ALBUTEROL-IPRATROPIUM NEBU SOLN 2.5(3)-0.5 MG
994060100003**	AZATHIOPRINE TABS
211000100003**	BUSULFAN TABS
213000050003**	CAPECITABINE TABS
211010200003**	CYCLOPHOSPHAMIDE TABS
994020200001**	CYCLOSPORINE CAPS
9940202030****	CYCLOSPORINE MODIFIED (FOR MICROEMULSION)
21500010000120	ETOPOSIDE CAP 50 MG
15000100001**	ETOPOSIDE CAPS
44100030102020	IPRATROPIUM BROMIDE INHAL SOLN 0.02%
11010400003**	MELPHALAN TABS
213000400003**	MERCAPTOPURINE TABS
214022500003**	MITOTANE TABS
94030301001**	MYCOPHENOLATE MOFETIL CAPS
994030301003**	MYCOPHENOLATE MOFETIL TABS
9940407000****	SIROLIMUS
994040800001**	TACROLIMUS CAPS
3004209000****	ZOLEDRONIC ACID
94100030006100	DIABETIC SUPPLIES
97202025006300	DIABETIC SUPPLIES