Three Essays on Health Economics

by

Feng Pan

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Doctoral Committee:

Professor Dean G. Smith, Co-Chair
Assistant Professor Daniel S. Silverman, Co-Chair
Professor Charles C. Brown
Professor A. Mark Fendrick

To my family, for their inspiration, love and support

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CHAPTER I
INTRODUCTION

U.S. health's share of GDP is expected to rise from 16 percent in 2004 to 20 percent in 2015 (Borger et al 2006). Long-term care and prescription drug expenditures are forecast to be two of the fastest growing components of health care spending (Borger et al 2006). Changing demographics pose a great challenge on long-term care spending. Current estimates suggest that the demand for long-term care among the elderly will more than double in the next thirty years (Feder et al 2000). On the prescription drug side, employers and health plans have been increasing cost sharing significantly in an attempt to control rising drug expenditures (Dietz 2004; Robinson 2004). This dissertation consists of three essays on health economics, with the first essay exploring long-term care insurance market, and the other twos examining prescription drug utilizations.

Long-term care has become an important area of health economics and health care policy, as the baby-boomers age and medical costs continue to rise. Its importance lies not only in its share of GDP, but in how long-term care affects economic decisions for individuals over a lifetime and across generations. Despite the high need and high cost of long-term care, few people have purchased private long-term care insurance. In 2004, national aggregate long-term care expenditure exceeds $130 billion, of which one third

was paid for out of pocket by individuals and their families, more than 60% by Medicaid and Medicare, while only 4% was covered by private long-term care policy (Congressional Budget Office 2004).

Extensive theoretical literature has proposed several potential reasons for the lack of demand for private long-term care insurance. One of the most famous papers by Pauly (1990) provided two explanations. First, insurance serves primarily to protect assets. Because long-term care usually happens at the end of life, the value of protecting assets at that time may not worth the trade-off from current consumption. Given the presence of Medicaid, which may serve as a substitute for private financing when elderly exhaust their savings, it is rational for individuals to forgo long-term care insurance coverage even if the insurance is offered at fair premium. Second, individuals with child might not desire insurance because its existence could decrease the amount of informal care their children would otherwise provide. Empirically, however, we have little evidence to support these hypotheses. Mellor (2001) found no evidence that the availability of children or other informal caregivers were substitutes for insurance policy. Sloan and Norton (1997) found that adverse selections and Medicaid program affected private demand for long-term care insurance policy, but they did not find that demand is motivated by either bequest or exchange motives.

The goal of chapter II is to use empirical evidence to explore why so few people purchased long-term care insurance. Specifically, the effects of state long-term care partnership programs on long-term care insurance purchase are evaluated to test the "asset protection" hypothesis. The partnership programs are a hybrid of the public/private approach to finance long-term care services. Currently operating in four states, the

programs allow individuals who buy long-term care insurance policies under the program to protect a certain amount of their assets and become eligible for Medicaid after they exhaust their policy benefits. Traditionally, Medicaid applicants cannot have assets that exceed certain thresholds and must "spend down" or deplete as much of their assets as is required to meet financial eligibility thresholds. To encourage the purchase of private insurance, especially among moderate-income people, the partnership programs allow long-term care insurance policyholders to protect some or all of their assets from Medicaid spend-down requirements during the eligibility determination process, though the four states vary in how they protect their policyholders' assets.

Patient adherence to prescription medications has always been a problem in the management of their illnesses, especially for those with a chronic condition. Poor medical adherence is often associated with undesired health outcome and higher medical costs (McCombs et al 1994). It is estimated that 10% of hospital admissions and 23% of admissions to nursing homes in the United States are due to the complications from medical non-adherence, costing the health care system $100 billion each year (Vermeire, et al 2001). The goal of chapter III is to evaluate whether reducing number of drugs improved patient adherence to medication.

The complexity of the drug regimens is often considered as an important determinant of non-adherence (Vermeire et. al, 2001), especially in people with long period of treatment. The complexity of drug regimen involves both the frequency of expected intake and the number of pills needed to take. Studies have shown that compliance rate is negatively associated with the frequency of daily drug intake (Cramer, et. al., 1989; Detry, et al 1994; Dezii, et al 2002). There is, as yet, relatively little

adherence information about patients who must take more than one medication, relative to those who are on monotherapy, for a specific illness. However, it seems intuitive that with every additional medication a patient must take —each with its own dosing instructions — the potential for error becomes greater.

Fixed dose combination (FDC) drugs are combinations of two or more existing drugs produced in a single tablet to either treat one disease with complimentary actions or treat multiple conditions. Development and marketing of FDCs are becoming increasingly popular, partly due to the fact that for many chronic clinical conditions, evidence-based recommendations require multiple agents to be used simultaneously in complex regimens. FDC drugs have been approved in many therapeutic areas, especially chronic disease treatments like diabetes, lipidemia and hypertension etc. The advocates of FDC drugs expect that patients taking these pills could have better compliance than those with multi-pill therapies, as the reduced number of pills diminishes the complexity of the regiment (Wertheimer et al, 2002; Leichter, et al, 2003). Chapter III uses both fixed effect model and propensity score method to explore the effect of Glucovance®, a FDC of metformin and glyburide used to treat hyperglycemia in diabetes mellitus, on patient adherence, compared to a multi-pill regimen.

In response to increasing prescription drug costs, many employers and health plans have raised drug co-payments. Unfortunately, the evidence suggests that medication cost-sharing indiscriminately reduces the use of both excess and essential medications alike (Ellis et al 2004). In turn, growing evidence suggests that individuals who decrease medication utilization due to out of pocket (OOP) costs have poorer health outcomes

(Piette et al 2004; Heisler et al 2004) and may even incur increases in overall health care costs (Soumerai, et al 1991).

In response to the growing evidence that 'one-size fits all' co-payment harm patients and may even increase costs, a more nuanced approach to health insurance benefits design, in which patients' co-payments are based on the expected clinical benefit of the prescribed drug(s) rather than their acquisition cost, was proposed (Chernew et al 2000; Fendrick et al 2001). Under this Value Based Insurance Design (VBID) theory, the more beneficial the medication, the lower the co-payment, thereby effectively realigning the incentives faced by patients to increase utilization of and adherence to the most beneficial and valuable prescription medications.

Focus On Diabetes (FOD) intervention implemented at the University of Michigan (UM) is the first of its kind designed both to improve the quality of care for UM employees, and to allow for a rigorous evaluation of such a program's effectiveness. The intervention started from July 1, 2006 and provided all UM employees and dependents identified as having diabetes with co-payment reductions for all glycemic agents, anti-hypertensives, lipid lowering agents, and anti-depressants.

One of the important impacts of FOD intervention is patients' drug utilization pattern change. A three-tier formulary is provided to UM employees and their dependents, requiring the lowest co-payments for generic drugs (tier 1), a higher co-payment for the brand-name drugs that are preferred by the health plan (tier 2), and the highest co-payments for brand-name drugs that are not preferred by the health plan (tier 3). The co-payment reductions in FOD intervention were designed to maintain the underlying incentive structure of the formulary such that generic medications (tier 1) had larger co-

payment reductions than branded medications, and preferred brands (tier 2) had larger co-payment reductions than tier 3.

How the graded co-payment changes within tiered formulary affect patient tier utilization pattern has important implication to health plan, as the possible more utilization on non-preferred mediations could impose unnecessary higher costs to health plan. Previous studies have found that the adaptation of an incentive-based formulary and/or increase co-payments resulted in switching to lower tier medications. However it is not clear whether FOD intervention will result in more non-preferred drug utilization or not.

The goal of chapter IV is to evaluate the effects of the FOD intervention on drug utilizations. Specifically, how changes in co-payment reductions affected patient tier switching within drug class is examined in chapter IV. And non-UM enrollees from the same health plan provider (M-CARE) serve as control group in the study, as their employers did not provide such co-payment reductions on these drugs.

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CHAPTER II
DOES "ASSET PROTECTION" ATTRACT PEOPLE TO BUY LONG-TERM CARE INSURANCE?-THE EVIDENCE FROM STATE LONG-TERM CARE INSURANCE PARTNERSHIP PROGRAM

As Americans are enjoying longer life than ever, the need for appropriate long-term care is also growing. It is estimated that people aged 80 years old and above –those most likely to need long-term care – will be increased by about 60% between 2002 and 2020 (Lakdawalla and Philipson, 2001). And today's 65 year old faces a 24% chance of having a year or longer nursing home stay sometime during his or her remaining life (Spillman and Becker, 2005a). Long-term care is very expensive. Nursing home costs in 2004 range from $30,000 to $65,000 per year, and care provided at home can cost up to $19 per hour (Metlife Mature Market Institute, 2006).

However, despite the high need and high cost of long-term care, few people have purchased private long-term care insurance. In 2004, national aggregate long-term care expenditure exceeds $130 billion, of which one third was paid for out of pocket by individuals and their families, more than 60% by Medicaid and Medicare, while only 4% was covered by private long-term care policy (Congressional Budget Office 2004). By contrast, in the health sector as a whole, private insurance pays for 35% of expenditure

and only 17% are paid for out of pocket (National Center for Health Statistics, 2002). The limited insurance coverage for long-term care has important impact for the welfare of the elderly and potentially for their adult children too, as children may have to provide informal care to substitute the formal care. The importance will become more pronounced when the baby-boomers age and medical costs continue to rise.

Extensive theoretical literature has proposed several potential reasons for the lack of demand for private long-term care insurance. On the supply side, market function may be impaired by adverse selection, moral hazard, high transaction costs, imperfect competition or dynamic problems with long-term contracting (Norton, 2000). On the demand side, difficulty understanding low-probability high loss events or misconceptions about the extent of public health insurance coverage for long-term care (Kunreuther 1978) may play a role. One of the most famous papers by Pauly (1990) provided two additional explanations. First, insurance serves primarily to protect assets. Because long-term care usually happens at the end of life, the value of protecting assets at that time may not worth the trade-off from current consumption. Given the presence of Medicaid, which may serve as a substitute for private financing when elderly exhaust their savings, it is rational for individuals to forgo long-term care insurance coverage even if the insurance is offered at fair premium. Second, individuals with children might not desire insurance because its existence could decrease the amount of informal care their children would otherwise provide.

Yet despite these extensive theoretical literatures, we have little empirical evidence to support these hypotheses or provide additional explanations. Brown and Finkelstein (2007) have found that higher premium mark up did limit the purchase of long-term care

insurance. However, they also suggest that supply-side market failure is not sufficient to explain the very small size of long-term care insurance market. Mellor (2001) found no evidence that the availability of children or other informal caregivers were substitutes for insurance policy. Sloan and Morton (1997) found that adverse selections and Medicaid program affected private demand for long-term care insurance policy, but they did not find that demand is motivated by either bequest or exchange motives.

In this chapter, I used additional evidence to test the "asset protection" hypothesis. Medicaid, the joint federal-state health financing program for low-income individuals, pays for long-term care, but only for those who have exhausted nearly all of their own resources first. To receive coverage, individuals must "spend down" their assets and demonstrate that virtually all of their income is being used to pay for their care. Given the fact that Medicaid is not a perfect substitution for private insurance, crowd-out effect from Medicaid may be due to the fact that people has little incentive to protect their asset at the end of life when long term care usually happen (Pauly, 1990). Empirically, however, purchasing a long-term care policy, for most seniors or near seniors, does not guarantee a certain level of asset protection because there remains the risk that they will need long-term care beyond the terms of the private insurance, although they could get better care under private insurance. That is even people purchase LTC insurance, they may exhaust their coverage under the policies and have to deplete their savings to seek Medicaid coverage eventually.

The state long-term care partnership programs offer a natural experiment to test the "asset protection" hypothesis. The partnership programs are a hybrid of the public/private approach to finance long-term care services. Currently operating in four states —

California, Connecticut, Indiana, and New York, implemented since 1994, 1992, 1993 and 1993 respectively — the programs allow individuals who buy long-term care insurance policies under the program to protect a certain amount of their assets and become eligible for Medicaid after they exhaust their policy benefits. Traditionally, Medicaid applicants cannot have assets that exceed certain thresholds and must "spend down" or deplete as much of their assets as is required to meet financial eligibility thresholds. To encourage the purchase of private insurance, especially among moderate-income people, the partnership programs allow long-term care insurance policyholders to protect some or all of their assets from Medicaid spend-down requirements during the eligibility determination process, though the four states vary in how they protect their policyholders' assets.

Using data from Health Retirement Study (1992-2004) and difference-in-difference method, I did a longitudinal analysis of the private long-term care insurance purchasing. I did not find that implementation of long-term care partnership program significantly increase the LTC insurance coverage among the general population and among some subgroups as well. The results, to some extent, support existing theories that protecting asset and leaving bequests to children and spouse are not attracting people to purchase private long-term care insurance coverage.

The chapter proceeds as follows: In section 1, I show the background information on long-term care market, state long-term care insurance partnership programs, and existing theories and empirical evidences on limited private insurance market. In section 2, I describe the empirical methods used, including econometric models, data source and

covariates. In section 3, I present the empirical estimates, followed with discussion of implications and limitation in section 4.

1. BACKGROUND

1.1 Public and Private Coverage for Long Term Care

Long-term care has become an important area of health economics and health care policy, as the baby-boomers age and medical costs continue to rise. Its importance lies not only in its share of GDP but in how long-term care affects economic decisions for individuals over a lifetime and across generations. Long-term care is used by people who need assistance to function in their daily lives. Caring for a chronic illness lasts as long as a person is alive so that medical expenses accumulate unrelentingly. Long-term care is often provided by unpaid caregivers. Many elderly people receive informal care from friends or family, often a spouse or child, in the home. In 1999, two-thirds of older people with disabilities residing in the community relied exclusively on informal, or unpaid, help. Of those who used any formal or paid help, about three-fourths also received unpaid care from friends and family (Spillman and Black, 2005b).

The formal care can be very costly. In 2006, the average cost of care in a nursing home was about $75,000 for a private room and $67,000 for a shared room. In the same year, the average private payment for a home health aide to provide care at home was $19 per hour (Metlife Mature Market Institute, 2006). Assisted living rates averaged $35,600 per year in 2006. Rates vary, depending on region, size of the accommodations, services available, quality of care, and amenities (Metlife Mature Market Institute, 2006).

The Medicaid program is the nation's major source of public financing for long-term care. The Medicaid program accounts for 44 percent of the $173 billion spent in 2001 for

long-term care. Another public health insurance program-Medicare, pays about 17% of the total long-term care expenditure.

Neither Medicaid nor Medicare is an adequate solution for long term care coverage. Medicaid is a means-tested program whereby individuals are covered only if they do not have enough income, assets and insurance to pay for the care. To receive coverage, individuals must "spend down" their countable assets (exempt assets include a home, a car, and funds designated for burial expenses) and demonstrate that virtually all of their income is being used to pay for their care (eligibility rules varies across states). Although special rules allow married couples to set aside income and assets for a community spouse, many states allow community spouses to keep only the federal minimum levels of income and assets. Critics on the "spend down" rules suggest that higher-income elderly may transfer their assets to their children to preserve their bequests and have Medicaid pay for their long-term care services. However, empirical researches demonstrate that very few people transferred their asset to be eligible for Medicaid (O'Brien E, 2005).

Medicare is a federal program that is available to most people at age 65. But it only has the potential to pay for up to a maximum of 100 days in a skilled nursing facility and requires that beneficiary has a 72 hour hospital stay prior to entering the nursing home. In general, Medicare does not adequately cover long-term care expenses. It requires that patients are getting better or showing improvement.

Private coverage of long-term care is very limited. Relatively few older persons have private insurance that covers the cost of long-term care. By 2005, roughly 7 million LTC policies were in force in the United States, and about 10% of Americans over the age of

55 have private insurance protection (America's Health Insurance Plan 2007). Although the private coverage has increased significantly since 1990, only 4% of long-term care expenditure was covered by private insurance (Congressional Budget Office 2004). People without public and private coverage of long-term care have to pay for the care out of pocket, which accounts for almost one third of the long-term care expenditure (Congressional Budget Office 2004).

1.2 Theories and Empirical Evidences

Given the high cost and high probability of long-term care, private insurance should have been attractive to a risk-averse person if there is no supply side market failure. First Purchase of LTC insurance would provide people with coverage when they need LTC services. Without private coverage, they have to pay the services out-of-pocket until they exhaust their savings and be eligible for Medicaid. Under such circumstance they don't have money left for their own and a surviving spouse' comforts or to leave a bequest for children. Second, LTC insurance provides flexibility in choosing care options in the event LTC becomes necessary.

The fact that only a few percent of elderly have purchased private long-term care insurance has been the subject of much theoretical research. The tendency to ignore low-probability, high-loss events that have not occurred recently has been proposed in earlier work (Kunreuther, 1978) as one possible explanation for the limited private long-term care. However this sort of behavior has not been so common in health insurance. Another most common explanation is that the elderly are misinformed. A majority of the elderly, according to survey, is under the mistaken impression that Medicare already provides long-term care coverage (American Association of Retired Persons, 1985). On the supply

side, pricing problems, moral hazard and adverse selection were proposed to explain the limited market (Davis and Rowland 1986).

Based on utility maximization models, Pauly (1990) proposed alternative reasons to explain the low coverage of long-term care. He argued that given these reasons, risk-averse, rational and appropriately informed individuals would not buy LTC insurance even if the insurance were offered at fair premiums and there is no loading and adverse selection.

Pauly argued that insurance serves primarily to protect assets. In the case of long-term care, because chronic illness is not curable, utility in the "sick state" is far less than that in the "healthy state". The marginal utility from the consumptions at the sick state in the future may not worth the trade-off from current consumption at healthy state. That is the gain to a risk-averse person from buying coverage against LTC costs is less than the gain from insuring an acute care expense of equal amount. Given the presence of Medicaid, which may serve as a substitute for private financing when elderly exhaust their savings, it is rational for individuals to forgo long-term care insurance coverage even if the insurance is offered at fair premium with modest load.

On the other hand, if long-term care insurance is serve to protect bequest, the greater the utility from bequests and the less sharply marginal utility from bequest declines with age, the greater the demand for LTC insurance. However, Pauly also proposed an intrafamily bargaining hypothesis that individuals with children might not desire insurance because its existence could decrease the amount of informal care their children would otherwise provide. That is the elderly may fear that if they purchase insurance children may institutionalize them when they will be unable to act on their own.

However, despite these extensive theoretical literatures, we have little empirical evidence to support these hypotheses or provide additional explanations. Brown and Finkelstein (2007) have found that higher premium mark up did limit the purchase of long-term care insurance. However, they also suggest that supply-side market failure is not sufficient to explain the very small size of long-term care insurance market, as they found enormous gender differences in pricing that do not translate to differences in coverage. Using different data and analysis method, Cramer et al (2006) also suggests that demand for LTC insurance is very price inelastic, although price was a significant determinant in decisions to purchase LTC coverage[1].

A couple of empirical papers have tested Pauly's child substitution hypothesis. Mellor (2001) found no evidence that the availability of children or other informal caregivers were substitutes for insurance policy. Sloan and Morton (1997) did not find that demand for long-term care insurance is motivated by either bequest or child substitution.

The Medicaid crowd-out hypothesis has been supported by several studies. Sloan and Morton (1997) found evidence that Medicaid crowds out demand for private LTC insurance for persons over age 70 but not for persons in the 51-64 cohort. Brown and Finkelstein (2004) quantified the impact of Medicaid, i.e. the amount by which private LTC coverage would duplicate coverage that would be provided by Medicaid, once the person's assets were depleted. The duplication increased as the wealth decreased. Medicaid would be duplicative of more than half the private LTC coverage in the lower half of the wealth distribution.

[1] The authors used a logit model to predict the purchase of new LTC policy and found that price was a statistically significant predictor. However, when they calculated the marginal effect on probability of buying long-term care insurance, they found that the price elasticity was very small

Sparse empirical evidence to explain small private LTC insurance market has limited implication on public policy. Inelastic demand and Medicaid crowd out evidence suggested that government initiations focusing on LTC insurance price reduction would meet with little success. If Pauly's hypothesis (1990) that lack of incentive to protect assets and bequests is the reason of non-purchase of LTC insurance holds true, any incentives created by policies would be counteracted

In this chapter, I used empirical evidence to test the "asset/bequest protection" hypothesis. State long-term care partnership programs provided a natural experiment for such analysis.

1.3 State Long-Term Care Partnership Program

Over the years, several initiatives aimed at increasing LTC insurance sales have focused on ways to make private LTC insurance policies more attractive. The partnership for long-term care is one of the major interventions (General Accounting Office, 2005).

The long-term care partnership program began in 1987 as a demonstration project funded through the Robert Wood Johnson Foundation. The program is a public-private partnership designed to encourage persons with moderate income to purchase private long-term care insurance to fund their long-term care needs rather than relying on Medicaid. Individuals who buy a partnership policy and eventually need long-term care services first rely on benefits from their private long-term care insurance policy to cover long-term care costs. If the policyholders exhaust private long-term care insurance benefits and need assistance from Medicaid to fund LTC, they may protect some or all of their assets from Medicaid spend-down requirements during the eligibility determination process, though they are still subject to Medicaid income requirement. One goal of the

program is to save money for Medicaid by delaying or eliminating the need for participants to access Medicaid for long-term care services.

As part of the demonstration project, four states—California, Connecticut, Indiana, and New York—developed partnership programs since 1994, 1992, 1993 and 1993 respectively. No more states implemented the program until 2006 after congress approved legislation clearing the way for expanded nationwide LTC partnerships. The four states with partnership programs offer one of three program models to protect buyers' assets: dollar-for-dollar, total asset protection and hybrid. Under dollar-for-dollar model, assets are protected up to the amount of the private insurance benefit paid, while total asset protection model protects all assets when a state-defined minimum benefit package is paid. The hybrid model offers both dollar-for-dollar and total asset protection. The type of asset protection depends on the initial amount of coverage purchased. Total asset protection is available for policies with initial coverage amounts greater than or equal to a coverage level defined by the state.

2. EMPIRICAL METHODS

2.1 Hypotheses

The initial purpose of the state LTC insurance partnership program is to reduce Medicaid spending by encouraging people to purchase private insurance. No expectation on the uptake of LTC insurance policies under the program is found in the literature. As the available information was insufficient in terms of selecting a null hypothesis on the effect of the program, my hypotheses are that the uptake of LTC insurance policies in the experimental states is not different from zero, when compared to non-partnership states, among both general population and subgroups including higher income population, those

with children and married couples.. Also, based on Pauly's theories, "asset protection" from LTC partnership program may not attract people to buy private coverage. People who buy policies under the partnership program would have bought private coverage if there were not partnership programs. That is the partnership program would just have a crowd-out effect: it would crowd out the purchase of regular LTC insurance policies.

2.2 Data

Health and Retirement Study (HRS) data is used for this study. HRS is an on-going, nationally representative survey of older adults in the United States. HRS survey started from 1992. More than 10,000 Americans between the age of 50s and 60s (in 1992) were interviewed every two years. HRS survey contains a wide variety of information on health conditions, insurance coverage, family composition and financial resources. The survey specially asked the respondents about their private long-term care insurance coverage, which states, "Do you have any type of supplementary health insurance coverage, such as Medigap or long-term care insurance that is purchased directly from an insurance company or through a membership organization such as AARP. If yes, what coverage do you have? "(1992 and 1994 questionnaire, although people were asked for general supplementary coverage first, long-term care insurance is listed separately for interviewees to check); "Not including government programs, do you have any insurance which specifically pays any part of long-term care, such as personal or medical care in your home or in a nursing home?" (post-1996 questionnaire).

HRS data has been used by several empirical studies for the purpose of LTC insurance analysis (Mellor 2001, Cramer and Jensen 2006, Sloan and Norton 1997), some of which are widely cited (Mellor 2001, Sloan and Norton 1997).

For the purpose of this study, pooled HRS data from 1992 to 2004 (7 waves) is used to evaluate the effect of the programs on long-term care insurance purchasing. Since Connecticut started the partnership program in 1992 and I use difference-in-difference method to evaluate the program impact, residents from Connecticut are excluded from the study sample. In addition, only respondents are included in the analysis. Responders' spouses who are not respondents are excluded.

Although the rest three partnership program states (California, New York and Indiana) initiated the programs in 1994, 1993 and 1993 respectively, the true implementation year could be considered as the next year following initiation. Because HRS survey asked about events that most likely happened in the previous year, the pre-intervention HRS waves are actually 1992 and 1994, and 1996-2004 (the rest 5 waves) are post-intervention period.

One limitation of the HRS data is that it is restricted to a fixed cohort-those who were 50-60 year old in 1992.

2.3 Econometric Models

Difference-in-difference (DD) estimation has been a commonly used method to estimate causal relationships. The great appeal of DD estimation comes from its simplicity as well as its potential to circumvent many of the endogeneity problems that typically arise when making comparisons between heterogeneous individuals (Bertrand, et al 2004).

Following previous studies such as Gruber and Poterba (1994), I assume that an individual's underlying demand for long-term care insurance, I_i^*, can be described as a

vector of socio-demographic characteristics X_i, income and assets Y_i, and state-partnership program policy P_j:

$$I^*_{itj} = X_{it}\beta + Y_{it}\alpha + P_j\delta_1 + Post * \delta_2 + P_j * Post * \delta_3 + \varepsilon_{itj} \quad (1)$$

Where *i* indexes individuals, *j* states, and *t* years. P is set equal to 1 if the individual is a residence of one of the partnership states an zero otherwise. Post is set to one for years after partnership is implemented in the data (years after 1994), and is zero previously. P*Post thus captures the change in demand for long-term care insurance for residences of partnership states, relative to the residences of non-partnership states, after the implementation of the program.

In practice, I_i^* is unobservable. We observe instead a dummy variable, defined by I_i=1 if I_i^*>0, and I_i =0 otherwise. The error term in the demand equation is assumed to follow a normal distribution. And the parameters are estimated by fitting the pooled HRS data to a probit model.

In additional to the above base model, four more models were estimated to evaluate the effects of asset protection on different populations. The first model has exactly the same specification as the base model, except that it is restricted to individuals with relatively higher income. The rationale for the test is that the partnership is targeted at middle or higher income group, who face the risk of depleting their life-time savings to be eligible for Medicaid if long-term care needed. The higher income group is defined as those whose income per person was greater than $25,000 per year at 1992 dollars. The second model explored if the partnership states have different LTC insurance demand trend than the non-partnership states during the post intervention period. The third and fourth models tested whether individuals with child or spouse are more likely to be

attracted by “asset protection”, given the assumption that the protected asset is most likely to be bequest.

The subgroup analyses are done in two ways. A separate equation is run for higher income group while interaction terms are used for those with children or spouse. There are two reasons. First, as the parameters for interaction terms are measuring relative effect instead of absolute effect, the separate equation is run for high income group to directly get the absolute effect of partnership program on this sub group. Second, population characteristics may differ by income (e.g. race, education, health status etc), but not significantly by marital status and whether having children. Therefore we may expect that some of the parameters of the higher income group are different from those of the general population.

2.4 Covariates

The selection of model covariates is based on previous empirical evidence and theoretical hypothesis. Besides the key independent variables like partnership state and post intervention indicator, the factors that might affect the demand for LTC insurance include demographics, wealth, health status, health services utilizations during the year and state dummies.

The demographic variables include age, gender, education marital status, whether having child, and race and ethnicity. Women are expected to be more likely to purchase LTC insurance because they have a longer life expectancy, implying a higher probability of needing care and of needing it for a longer period of time. Married persons would purchase LTC insurance, because ‘impoverishing one’s spouse… seems to be the major fear of many married elderly” (Pauly, 1990). More educated people are expected to be

less ‘myopic” and more informed, and thus might have higher chance of buying LTC insurance. Because informal child-provided care is a possible substitute for formal LTC, those with children would have lower probability of buying LTC insurance. Race and ethnicity variables are intended to capture cultural differences that might affect the decision to purchase LTC insurance. White is expected to have higher probability to purchase LTC insurance than the minority groups as minority groups tend to use more informal care.

Wealth variables include personal annual income and non-house asset, which are adjusted to 1992 dollars (the base year). The wealthier individuals are expected to be more likely to purchase LTC insurance, since they have lower probability to get Medicaid coverage.

Health status includes self-reported health status, number of ADLs (disability measurement), and number of comorbidities. Health services utilization includes whether hospitalized during the year and whether having nursing home stay during the year. The hypothesis is that people who are “sicker” might expect they may use LTC in the future and are more likely to buy LTC insurance. But on the other hand, the price of LTC insurance for healthier individuals is cheaper than “sicker” ones, which may affect the direction of these variables oppositely.

In addition, the demand for long-term care insurance may be affected by state Medicaid policy. For example, higher eligibility requirements could increase people’s demand for private insurance since it’s hard for them to get public coverage. Thus a set of state dummy variables are included to control for policy variations across states. After adding the state dummy variables, the coefficient of Pj in equation (1) would not be

identified. However, it does not affect the coefficient of the key independent variable P*Post, which measures the effect of LTC partnership program. Also, although some of the state Medicaid policies changed during the study period, none of the partnership states implemented Medicaid policy changes during the same year they started the partnership program. For non-partnership states, some minor Medicaid policy changes were implemented around the intervention years, including changing Medicaid reimbursement rates, minor changes on eligibility rules etc. However, these Medicaid policy changes are expected to have little effect on private LTC demand, as evidences show that they did not affect nursing home utilization (Grabowski and Gruber, 2005). Therefore, only state fixed effect is included in the model.

Finally, since the models include 7 waves of HRS data (1992-2004), time trend (year) is also included as a covariate.

3. RESULTS

3.1 Descriptive Results

Figure 1 compares long-term care insurance coverage rates of states with partnership program and those without over the study period (1992-2004). The rates are adjusted using the HRS weights. During the pre-intervention period (1992-1994), mean coverage rates for the partnership states are 0.72% (1992) and 0.6% (1994), and the rates for non-partnership states are a little higher (1.25% for 1992, and 1.1% for 1994). During the post period (1996-2004), however, the LTC coverage rates of the intervention states became higher except 2004. It is noteworthy that the coverage rates for both groups jumped significantly between 1994 and 1996. Two potential reasons might explain this. First, according to the estimations from Health Insurance Association of America (Cohen,

2003), the annual sales of new LTC policies grew dramatically between 1994 and 1996, with 420,000 in 1994, 514,000 in 1995 and 609,000 in 1996 (see figure 3). The time trend of LTC coverage in figure 1 roughly matches the annual sales of new policies trend from Cohen (2003). These dramatic changes are mainly contributed to the efforts to reduce supply side barriers from long-term care insurance companies. Second, HRS changed the questionnaire on long-term care insurance coverage between 1994 and 1996, which may cause a different interpretation from interviewees and resulted in different answers to the question. However, this change affects control group just as if affects treatment group. Third, the age range of 1992 HRS data is 50-60 years old (although the spouses may fall outside this range, majority respondents from the 1992 cohort are in that range), while the mean age of LTC insurance buyers in the individual market is 67. As the 1992 cohort ages, their probability of buying LTC insurance also increased.

Figure 2 presents the same comparison as figure 1 but for a different group – individuals with income higher than $25,000 in 1992 dollars. This group of people showed similar LTC coverage trends as the overall population, but higher rates. In 1992 and 1994, the LTC coverage rates for higher income individuals were only slightly higher than the rates of general population. However, in 1996, the coverage rates for higher income jumped to 14%-16%, and continue to grow during the rest of years, compared to 9.5%-10.5% for overall population.

The summary statistics of the model covariates are presented in table 1. A total of 53,715 person-years (16,048 for higher income subgroup) are included in the final analysis. 19.6% (21.4% for higher income subgroup) were living in the partnership states. Only 23.5% (28.2% for higher income) of the sample were male. The mean income per

person was $26,670 ($55,690 for higher income) and the mean non-house asset per household was $111,670 ($234,070 for higher income).

3.2 Estimation Results

Table 2 reports results from the probit estimation of the basic specifications for both overall population and higher income subgroup. Marginal effects are reported; the standard errors used to calculate z-statistics are based on robust variance estimates, which account for the fact that observations are not independent within households and over the years. Observations are clustered around state level.

The key explanatory variable is partnership*post. In the model frame work, the partnership state and post intervention variables control for the difference in LTC coverage rates between partnership states and non-partnership states during the pre-intervention period and the general time series trend in insurance coverage. Parternship*post captures the change in LTC insurance demand for partnership states, relative to the control states after intervention. The estimate of its coefficient indicates whether the insurance coverage rate for partnership states changed more after intervention than did the coverage rate for non-partnership states. In table 2, the marginal effect of partnership*post is 0.029 for overall population and 0.047 for higher income subgroup, which suggests that the partnership program increased the probability of buying LTC insurance by 2.9% overall and 4.7% among higher income individuals. However, the estimated effect is not statistically significant for both overall population and higher income subgroup, suggesting that there is no evidence to show that the partnership program increased LTC insurance purchasing.

The marginal effects of other explanatory variables are also presented in table 2. Among the general population, age, gender, marital status, education and race are all significant predictors of LTC insurance purchase in the overall population, and are in line with the hypotheses that I described in the empirical model section. It is noteworthy that having child did not affect LTC insurance purchase, which is consistent with Mellor (2001). Health status and disability are also significantly associated with the insurance demand: people who rated their health as excellent or good and have less ADLs (less disabled) are more likely to purchase LTC insurance, which to some extend contradicts the adverse selection hypothesis, but is consistent with advantageous selection hypothesis (Fang, Keane and Silverman 2008). Another possible explanation is that healthier people could get LTC insurance at lower price. Personal wealth plays a significant role in LTC insurance demand: wealthier individuals are more likely to buy the insurance. However this association diminished as I focused on the higher income individual only, which suggests that the chances of being eligible for Medicaid are almost the same among people whose wealth is above certain level and thus the Medicaid crowed out effect diminished either.

In table 3, three more specifications were tested by adding additional interaction terms to the basic model for overall population. The first two columns presents the marginal effects and robust standard errors for the model that adds time*post and t*partnership*post to the basic model. The third level interaction (t*partnership*post) captures whether the LTC coverage rates in partnership and non-partnership states had different time trends after intervention. Its marginal effect is -0.003 and insignificant, indicating that the two groups had the same purchasing trend post intervention.

The next two hypotheses tested in table 2 is whether people with child or spouse were more likely to be attractive to the partnership program, as the protected assets from the LTC insurance are more likely to become "bequests". For this purpose, post*kid, partnership*kid and partnership*kid*post, or post*married, partnership*married and partnership*married*post were added to the basic model. Take child as example. The second level interactions were used to control for changes in the demand for insurance among those with child versus no child (post*kid), changes in demand for the partnership states versus non-partnership states (partnership*post), and differences in demand among those who had child and lived in partnership states relative to their counterparts in non-partnership states (partnership*kid). All that remains is to identify the effect of the partnership program on individuals with child and living in partnership states after the intervention. This is the term partnership*kid*post.

The marginal effects of both partnership*kid*post and partnership*married*post are not statistical significant at all, which means that people with child or married are not more attracted to the partnership program, compared to those without child or spouse.

4. DISCUSSION

The state partnership programs allow individuals who buy long-term care insurance policies under the program to protect a certain amount of their assets and become eligible for Medicaid after they exhaust their policy benefits. Using difference in difference method, I compare the change in LTC insurance coverage for the partnership states with that of non-partnership states and have three findings.

First, the results from the basic model indicate that the partnership program increased the probability of buying LTC insurance by 2.9% among the general population and 4.7%

among higher income individuals. However, these effects are not statistically significant, which cannot reject my null hypothesis that the effect of LTC partnership program is zero. From a policy perspective, 2.9% (4.7% in higher income) increase in LTC insurance purchase may be worthy of attention as the relative change is around 30%. A literature search was conducted on the expectations of the partnership program impact. Some program evaluators think the number of policies sold is low (Colby DC, 2006) while some others believe the effect is significant (GAO, 2005). However, none of the program evaluations compared the private LTC insurance purchase between partnership states and non partnership states. That is what they evaluated is the absolute effects not the net effects. This study found that the effect of LTC partnership program is offset by large variance, which to some extent, suggests that LTC partnership program did not significantly increase the private LTC insurance purchase and supports Pauly's hypothesis that in the case of LTC insurance, the fundamental purpose of insurance-"asset protect"-may not attract people. That is people do not have incentive to protect their assets through LTC insurance. In addition, studies on LTC partnership program (General Accounting Office 2005) have shown that 20% of partnership buyers dropped their policies 2 years after their initial purchase, which might explain why the effects of the program diminished over time in figure 1 and 2.

Second, I did not find that individuals with children were significantly more likely to purchase LTC insurance given the partnership program than those without children. That is when people can secure certain amount of asset through partnership program, people with children are not more likely to purchase it. This finding implies that bequest

incentive is not a motivation for people to buy LTC insurance, which is consistent with the findings from Sloan and Morton (1997).

Finally, I found that compared to those without a spouse, married individuals did not show any difference in demand change when they can protect certain amount of their assets through partnership program, although marriage did increase the probability of buying LTC insurance in general. A possible explanation of this lack of response to "asset protection" among married individual is the community spousal asset protection rules. The spouse asset protection rules allow married individuals to keep a range of asset exempted from Medicaid asset test if their spouses enter nursing homes and apply for Medicaid. Because the rule helps people to protect certain amount of assets if their spouses exhausted their asset in long-term care, it functions in a similar way as the partnership program does. Therefore it is reasonable that married couples are no more attracted to the partnership program than those without spouses.

One potential limitation of the study is that the analysis is restricted to a fixed cohort-those who were 50-60 year old in 1992, as this is the only cohort that HRS had followed up during the pre and post intervention periods. It has been estimated that the mean age of LTC policy holders is 67 (Cohen 2003). This study is not able to estimate responses of those who may be more affected by the partnership program. Also, standard life-cycle model may imply that at their age, HRS cohort might not have enough time to make sizable adjustment to their consumption behavior in response to the partnership program. It would be worthy to examine the program effect on younger cohort in the future.

A second limitation of the analysis is the lack of control variables on supply-side factors and other LTC policy changes. A fundamental assumption of difference-in-

difference model is that during the intervention, changes except the partnership programs that might affect the insurance demand should be same across partnership states and non-partnership states. If some states implement other policies that affected insurance demand concurrently, for example, the results could be changed. I have not find any evidence, however, to suggest that other private LTC insurance initiations have coincident shocks.

Third, although the LTC partnership program did not attract more people to buy LTC insurance coverage, it is not clear whether it changed the amount of coverage the buyers purchased. Future work may use detailed insurance data to evaluate the impact of partnership program on the amount of coverage purchased.

Besides Connecticut, New York, Indiana and California, twenty-one other states initiated legislative activity to establish a partnership after congress approved legislation clearing the way for expanded nationwide public-private LTC insurance partnerships in 2006. Future work may extend the difference in difference approach with recent HRS data to evaluate the impact of the partnership program, which could provide longer pre-intervention comparison among older population.

The cost of long-term care is a concern not only for individuals, but for the public. Policymakers are pursuing a number of initiatives to promote private LTC insurance. However, some existing theories have provided less support for the efficacy of public policies by suggesting that the lack of rationale to protect asset may counteract any incentives created by policies (Pauly, 1990; Zweifel and Struwe 1998). Although the results of this chapter are not able to fully explain why so few elderly purchase long-term care insurance, the results suggest that protecting asset and leaving bequests to their children or spouse seem not to attract people to buy long-term care insurance.

Figure 2.1 Long-Term Care Insurance Coverage

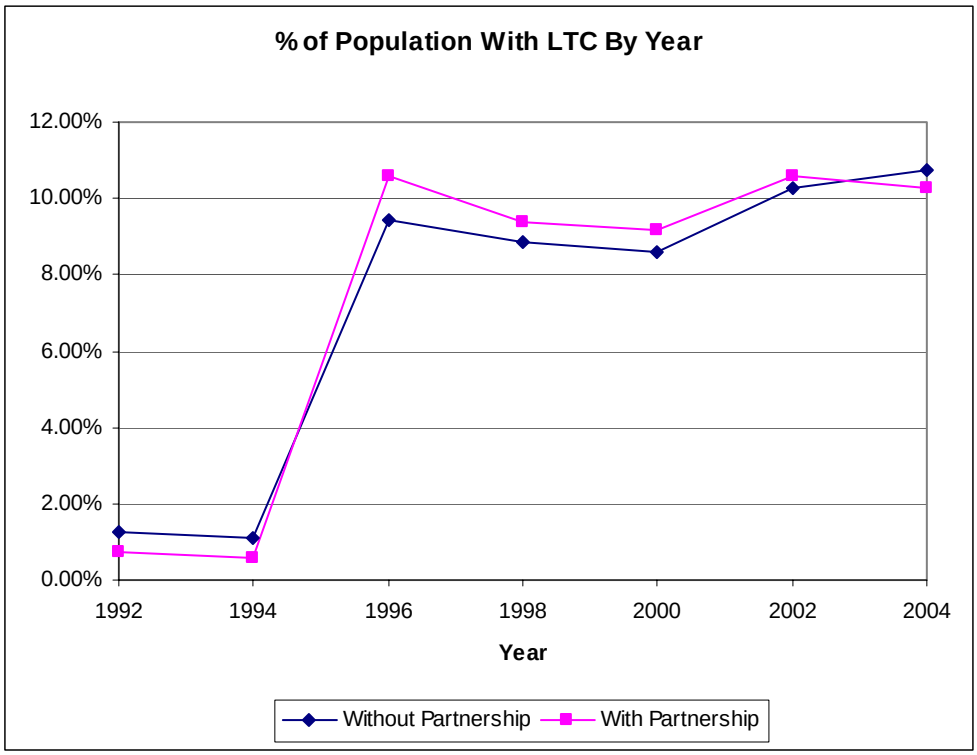


Figure 2.2 Long-Term Care Insurance Coverage-Middle Income

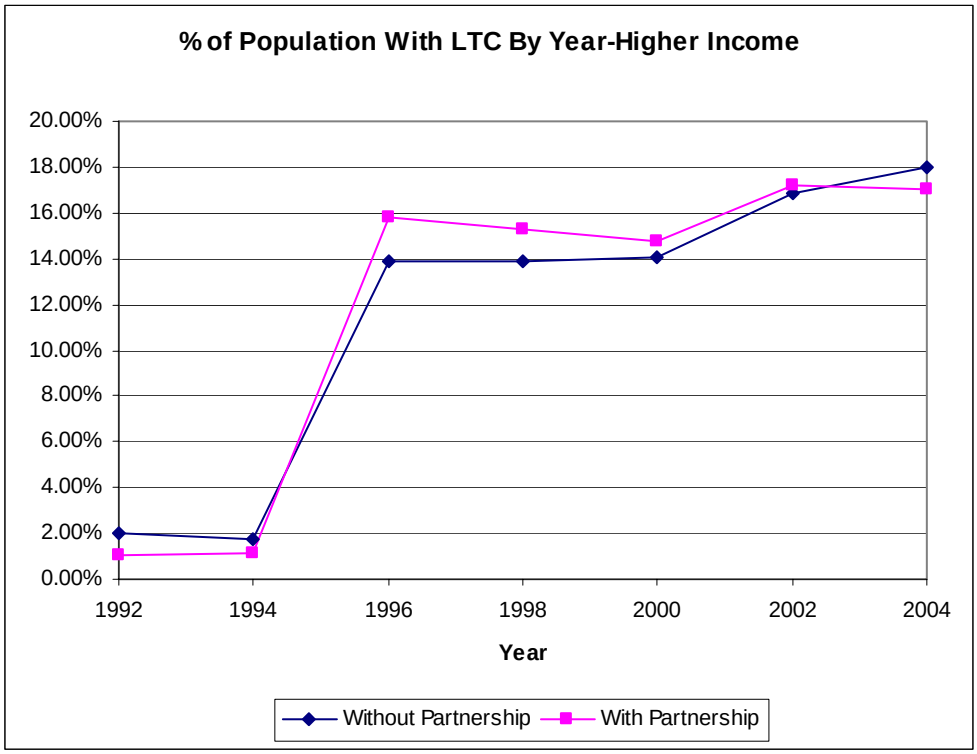
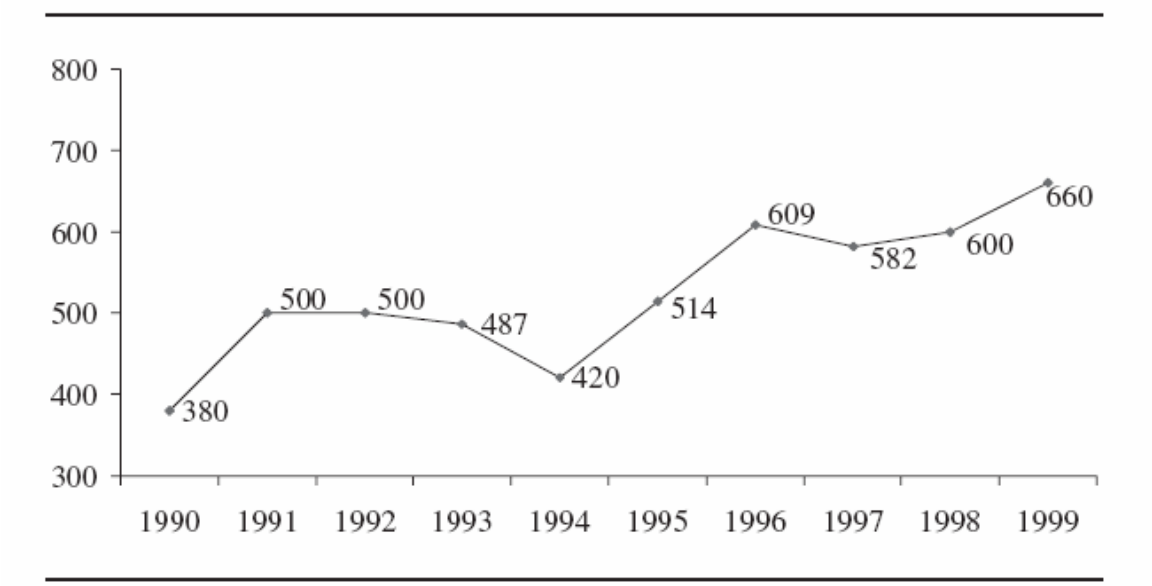


Figure 2.3 Annual Sales of Private Long-Term Care Insurance (in thousands)



Source: Cohen 2003

Table 2.1 Descriptive Statistics

Variables	All		Higher Income	
	Mean	Std. Err	Mean	Std. Err
Partnership State	0.196	0.002	0.214	0.004
Whether having kid	0.298	0.002	0.339	0.004
Married	0.502	0.003	0.596	0.005
Yeas of education	12.249	0.015	13.956	0.022
Male	0.235	0.002	0.282	0.004
Age (years)	64.277	0.052	60.553	0.076
Black	0.111	0.001	0.069	0.002
Hispanic	0.067	0.001	0.030	0.002
Other non-White	0.841	0.002	0.817	0.003
Health status*	2.776	0.006	2.307	0.010
# of ADL	0.293	0.004	0.104	0.004
# of comborbidity	1.712	0.007	1.259	0.011
Hospitalized during the year	0.226	0.002	0.159	0.003
Nursing home stay during the year	0.014	0.001	0.006	0.001
Income/person ($10,000)	2.667	0.026	5.569	0.071
Non-house Asset ($10,000)	11.167	0.212	23.407	0.595
Number of Observations	53,715		16,048	

Note: *Health status rated from 1-5, with 1 as excellent and 5 as poor

Table 2.2 Effects of Partnership Program: Basic Specification

Variable	All			Higher Income		
	ME	Std. Err	P-Value	ME	Std. Err	P-Value
Partnership State	0.024	0.026	0.317	-0.031	0.034	0.396
Post Intervention	0.058*	0.014	0.005	0.069	0.035	0.116
Partnership*post	0.029	0.025	0.192	0.047	0.043	0.233
Time	0.001	0.002	0.656	0.003	0.003	0.190
Whether having kid	-0.002	0.004	0.666	-0.003	0.008	0.670
Married	0.016*	0.003	0.000	0.002	0.007	0.814
Yeas of education	0.008*	0.000	0.000	0.005*	0.002	0.002
Male	-0.012*	0.004	0.001	-0.030*	0.006	0.000
Age (years)	0.001*	0.000	0.000	0.003*	0.000	0.000
Black	-0.018*	0.003	0.000	-0.014	0.008	0.110
Hispanic	-0.032*	0.003	0.000	-0.046*	0.017	0.034
Other non-White	0.021	0.025	0.455	0.046	0.043	0.345
Health status	-0.008*	0.001	0.000	-0.007**	0.003	0.025
# of ADL	-0.004**	0.002	0.041	-0.013	0.008	0.110
# of comborbidity	0.001	0.001	0.431	0.006	0.004	0.119
Hospitalized during the year	0.001	0.003	0.831	0.009	0.007	0.179
Nursing home stay during the year	0.003	0.011	0.797	-0.004	0.024	0.881
Income/person ($10,000)	0.001***	0.0003	0.057	0.0002	0.000	0.562
Non-house Asset ($10,000)	0.0001***	0.0000	0.084	0.000	0.0000	0.280

Note: *significant at 0.01, **significant at 0.05, ***significant at 0.1

Table 2.3 Other specification test

Variable	Trend		Child		Married	
	ME	**Std. Err**	**ME**	**Std. Err**	**ME**	**Std. Err**
Partnership State	0.024	0.026	0.054***	0.053	0.024	0.022
Post Intervention	0.057***	0.019	0.055*	0.013	0.051**	0.015
Partnership*post	0.051*	0.017	0.002	0.038	0.026	0.021
Time	0.001	0.007	0.001	0.002	0.001	0.002
*T*Post*	0.013	0.008	-	-	-	-
*T*Partnership*post*	-0.003	0.003	-	-	-	-
Whether having kid	-0.002	0.004	-0.016	0.008	-0.002	0.004
*Post*kid*	-	-	0.016	0.011	-	-
*Partnership*kid*	-	-	-0.032	0.025	-	-
*Partnership*kid*post*	-	-	0.068	0.074	-	-
Married	0.016*	0.003	0.016*	0.003	-0.004	0.011
*Post*married*	-	-	-	-	0.021***	0.012
*Partnership*married*	-	-	-	-	-0.003	0.018
*Partnership*married*post*	-	-	-	-	0.007	0.015
Yeas of education	0.008*	0.000	0.008*	0.000	0.008*	0.000
Male	-0.012*	0.004	-0.013*	0.004	-0.012*	0.004
Age (years)	0.001*	0.000	0.001*	0.000	0.001*	0.000
Black	-0.019*	0.003	-0.018*	0.003	-0.019*	0.003
Hispanic	-0.032*	0.003	-0.032*	0.003	-0.032*	0.003
Other non-White	0.021	0.026	0.017	0.024	0.021	0.025
Health status	-0.008*	0.001	-0.008*	0.001	-0.008*	0.001
# of ADL	-0.004**	0.002	-0.004**	0.002	-0.004**	0.002
# of comborbidity	0.001	0.001	0.001	0.001	0.001	0.001
Hospitalized during the year	0.001	0.003	0.001	0.003	0.001	0.003
Nursing home stay during the year	0.003	0.011	0.003	0.011	0.003	0.011
Income/person ($10,000)	0.001***	0.0003	0.001***	0.0003	0.001***	0.0003
Non-house Asset ($10,000)	0.0001**	0.0000	0.0001**	0.0000	0.0001**	0.0000

Note: *significant at 0.01; **significant at 0.5; ***significant at 0.1

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CHAPTER III
IMPACT OF FIXED-DOSE COMBINATION DRUGS ON ADHERENCE TO PRESCRIPTION MEDICATIONS

Patient adherence to treatment plays a key role in the management of their illnesses, especially for those with a chronic condition. Poor medical adherence could result in negative health outcomes and increased hospitalizations, which lead to a rise in the overall cost of medical care (McCombs et al 1994). It is estimated that 10% of hospital admissions and 23% of admissions to nursing homes in the United States are due to the complications from medical non-adherence, costing the health care system $100 billion each year (Vermeire, et al 2001).

Factors that beget patients' failure to adhere to medication regimens are complex and interwoven. Patients' ability to understand their treatment routines or the reasons for them, side effects, financial barriers, simple forgetfulness, or any combination of these and other determinants, can influence adherence to therapy and ultimately the potential for positive health outcomes. One such factor is the complexity of a patient's treatment regimen.

The complexity of the drug regimens is often considered as an important determinant of non-adherence (Vermeire et. al, 2001), especially in people with long period of treatment. The complexity of drug regimen involves both the frequency of expected intake and the number of pills needed to take. Studies have shown that compliance rate is negatively associated with the frequency of daily drug intake (Cramer, et. al., 1989; Detry, et al 1994; Dezii, et al 2002). There is, as yet, relatively little adherence information about patients who must take more than one medication, relative to those who are on monotherapy, for a specific illness. However, it seems intuitive that with every additional medication a patient must take —each with its own dosing instructions — the potential for error becomes greater.

Fixed dose combination (FDC) drugs are combinations of two or more existing drugs produced in a single tablet to either treat one disease with complimentary actions or treat multiple conditions. Development and marketing of FDCs are becoming increasingly popular, partly due to the fact that for many chronic clinical conditions, evidence-based recommendations require multiple agents to be used simultaneously in complex regimens. FDC drugs have been approved in many therapeutic areas, especially chronic disease treatments like diabetes, lipidemia, hypertension etc.

FDC drugs are usually more expensive than the free dose combinations, and usually restrict physicians to decide both the components and the ratios in which they are used. The advocates of FDC drugs, however, expect that patients taking these pills could have better compliance than those with multi-pill therapies, as the reduced number of pills diminishes the complexity of the regiment (Wertheimer et al, 2002; Leichter, et al, 2003). FDC also offers some financial benefits to its consumers, who only need to pay one co-

payment for multiple drugs. In other words, FDC potentially decreases the cost sharing for those who are under flat co-payment. Studies have shown that higher drug cost sharing caused patients to reduce prescription drugs utilization (Ellis, et al, 2004; Christian-Herman, et al, 2004; Dor and Encinosa, 2004) , while lower co-payment is associated with improved adherence (Chernew et al 2008).

However, published studies evaluating the adherence effects of combination agents report mixed results (Dezii, 2000; Melikian et al 2002), as one study (Dezii, 2000) found that FDC of ACE inhibitor and hydrochlorothiazide raised adherence rates in hypertensive patients by about 20%, while the other (Melikian et al 2002) did not find any effects of FDC of metformin and glyberide among diabetic patients. The implications of the studies are limited in that the findings were based on cross sectional analysis (Melikian et al did multivariate regression to control for some factors, while the others just simply compared the means). Because drug assignment in these observational studies was not randomized, the treated and non-treated groups may differ, and these differences can lead to biased estimates of treatment effect. For example, if doctors are more likely to prescribe the combination drug to patients with low compliance, the cross-sectional studies will underestimate the true effects of these pills on adherence improvement. On the contrary, if the patients with high adherence rate are seeking to switch to the combination pill, their effects will be exaggerated.

In this study, we use both a fixed effect model and propensity score method to explore the effect of Glucovance®, a FDC of metformin and glyburide used to treat hyperglycemia in diabetes mellitus, compared to a multi-pill regimen. We estimated a substantial impact of Glucovance on adherence after controlling for background

characteristics and patients disease history using both propensity score and fixed effect methods. Because propensity score methods cannot control for unobserved factors, we adopted fix-effects models to control for the non-random selection into the therapies and unobserved individual effects. Both approaches yield similar results. That is the use of FDC glucovance is significantly associated with better patient adherence, compared to the use of concurrent two-pill therapy. Glucovance raised adherence rates in diabetic patient by 6.5~11.3%.

The chapter proceeds as follows: In section 1, I show the background information on medication adherence, fixed dose combination drugs, and diabetes. In section 2, I describe the empirical methods used, including econometric models, data source and covariates. In section 3, I present the empirical estimates, followed with discussion of implications and limitation in section 4.

1. BACKGROUND

1.1 Patient Adherence to Medication

Patient adherence to prescribed drugs determines the success of medical interventions, especially for chronic diseases. In the literature, a broad range of factors that may influence patient adherence has been examined. In general, these factors can be classified into three groups: patient characteristics, financial incentives and drug regimen.

To date, the findings from studies that evaluate the influence of patient characteristics on adherence suggest that age, gender, race and socio-economic status are not good indicators of compliance (Vermeire et. al, 2001). Although some associations between patient characteristics and compliance have been found in some studies, the direction of

these associations was not consistent. For example, Sclar and his colleagues (1999) found that in a Medicaid population, younger age is associated with better anti-diabetic medication adherence, while the study on heart failure drugs by Monane and his colleagues (1994) suggests that older people are more likely to have better refill compliance. Also, some studies found that females and Black had better adherence, but others did not observe such association between gender, race and compliance (Steiner and Prochazka, 1997)

A rich amount of studies have shown that higher drug cost sharing caused patients to reduce the expenditure on prescription drugs, either by substituting less expensive alternatives or by reducing the use of medications, especially nonessential medications (Gibson, et al 2005). Four recent studies have explored the effects of cost sharing on patient medication adherence (Pilote, et al, 2002; Ellis, et al, 2004; Christian-Herman, et al, 2004; Dor and Encinosa, 2004), and found a significant relationship between cost sharing and adherence: as cost sharing increases, the adherence rate drops. Dor and Encinosa (2004) also explored the effects of different cost sharing methods on adherence. They show that due to uncertainty in cost sharing, patient compliance is lower under coinsurance than the compliance under flat co-payment among patients with type 2 diabetes.

The complexity of the drug regimens, both the frequency of expected intake and the number of pills needed to take, is an important determinant of non-adherence (Vermeire et. al, 2001). Studies have shown that compliance rate is negatively associated with the frequency of daily drug intake (Cramer, et. al., 1989; Detry, et al 1994; Dezii, et al 2002). In a study of patients who had type 2 diabetes, those who were required to take one-daily

dosing showed 60.5% adherence rates over a 12-month period, while the adherence rate for those who were taking twice-daily dosing was only 44.4% (Dezii, et al 2002).

However, as to the effects of the total number of drugs in the treatment regimen on the adherence rates, no consistent relationship has been found. Three recent papers suggest that reducing the number of pills improves patient adherence (Dailey, et al 2001; Dezii, CM 2000; Melikian, et al 2002). Dailey and his colleagues (2001) analyzed adherence among Medicaid patients with type 2 diabetes. In the one-year follow-up, patients with simple 1-drug anti-hyperglycemic regimens (metformin or sulfonylurea) have better adherence than those with more complex multiple-drug regimens (metformin and sulfonylurea). In another study (Dezii, CM 2000) of adults taking anti-hypertensive medications, the adherence rates of patients taking single-pill combination therapy was higher than those of patients taking the component two-pill medications concurrently. However the study by Melikian and his colleagues did not find differences in adherence rates among newly treated patients who are using either single drug therapy or two-drug therapy. The study by Grant and his colleagues (2003) did not find any association between adherence and the number of medicines prescribed neither.

The most important limitation of these adherence studies on drug regimen is that their comparisons of the adherence rates between therapies are at risk of substantial susceptibility bias, because drug assignment in these studies was not randomized, and little or no attempt was made to adjust for patient characteristics, drug cost and other factors that might have determined drug choice or drug adherence.

1.2 Measuring Adherence

The methods used to measure adherence vary across existing literature. There is no gold-standard method. Traditionally, patient adherence has been based on pill counts, pharmacologic tracers, electronic measurement devices, or patient self-report (Steiner and Prochazka, 1997). But these methods have limited roles in studies of large populations, such as health services research. More recently, pharmacy claims data have become a common tool in the assessment of patient adherence.

Three methods to measure adherence with claims data have been widely used in the literature. The first and most commonly used method is called Medication Possession Ration (MPR), which was first introduced by Sclar and his colleagues (1991). The MPR is often defined as the sum of the days' supply of medication divided by the number of days between the first fill and the date when the last refill runs out. Usually, the MPR is less than 1. But early refilling may lead to an MPR greater than 1. In such a case, the MPR is often truncated at 1, suggesting perfect patient adherence. The MPR is a continuous variable. Some studies used the continuous MPR to measure adherence (Crystal, et al, 1995; Avorn, et al 1998; Pilote et al, 2002). Others often selected a cut-off threshold, such as 80%, to define compliance and noncompliance (Benner, et al, 2002; Degli, et al 2002; Perwien, et al 2004). The selection of appropriate cut-off directly affects the accuracy of measure. In the literature, 80% is one of the most often used thresholds for compliance. The MPR has two major limitations in measuring adherence. First, it requires a uniform follow-up period for all individual, because people with shorter follow-up period may have fewer days of observation and fewer opportunities for non-compliance than individuals with a longer follow-up period. Second, the MPR does

not provide information on the timeliness and consistency of refilling, especially for patients with long follow-up period.

The second method for adherence measure is to evaluate the gaps between prescription refills. Patients are allowed to have a certain grace period between two refills. The grace period begins at the end of the supply of the previous prescription, and is often proportional to the days' supply of the previous prescription. A range from one-half to 3 times the days' supply of the previous prescription has been used as the length of grace period in the literature (Dezii, CM 2000; Sikka, et al 2005). If the patient refills his prescription within the grace period, he is considered as compliant. But if his refill gap exceeds the grace period, the patient is regarded as noncompliant at that point in time. Some studies (Dor and Encinosa, 2004) added partial compliance as a third category by changing the grace period. The advantage of evaluating refill gaps as a measure of adherence is that it provides information on the timeliness and consistency of refilling. But compared to MPR, this method may not consider all the refilling behavior across the observation period. Once an individual is considered as noncompliant, the following refilling is no longer analyzed. Another limitation of the gap method is that the literature lacks a uniform definition for the appropriate length of grace period. The determination of permissible gap is rather arbitrary.

Although there is no gold-standard on adherence measure, MPR is most commonly used. In this study, we use both continuous MPR and adherence gap as our adherence measure.

1.3 Diabetes and Fixed Dose Combination Drug

Diabetes is one of the most common chronic conditions, with 16 million Americans estimated to have this diagnosis (Lewis, 2002). It is the leading cause of adult blindness, kidney failure and amputations, and a leading cause of heart disease. 180,000 people die each year from diabetes in the U.S. The prevalence of diabetes in the U.S. increased by more than 30% over the last ten years. Moreover, the annual costs of diabetes in medical expenditures and lost productivity climbed from $98 billion in 1997 to $132 billion in 2002. As the incidence of diabetes reaches epidemic proportion, leading to spiraling costs, the need to undertake prevention measures is becoming even more pronounced.

There are two types of diabetes: type 1 and type 2. The basic problem in type I diabetes is that the pancreas quits making insulin. Someone with type 1 diabetes must inject replacement insulin to stay alive, and few oral medications are available. In type 2 diabetes, which occurs in about 90% of cases, persons either don't make enough insulin or something interferes with the action of the insulin that is made. For this variant of the disease, six types of oral prescription medications are available during the study period (2000~2001): Sulfonylurea, Meglitinides, Nateglinide, Biguanide (also know as Metformin), Thiazolidinedione, and Alpha-Glucose Inhibitor. Each type of these drugs works differently to control blood sugar levels in the body. For instance, Metformin improves insulin sensitivity, while Sulfonylurea stimulates beta cell to release more insulin.

Standard treatment using oral drugs for type 2 diabetes often meant taking one drug, increasing its dose until patients maxed out, then starting another drug, either alone or in combination with the first drug. It makes sense, then, to combine diabetes drugs in one pill to try to address multiple metabolic defects at once. That was the theory behind the

development of Glucovance—a fixed dose combination of metformin and glyberide, two drugs from Metformin and Sulfonylurea categories respectively. Glucovance was approved by FDA in August, 2000, and marketed right after.

In this chapter, the effect of Glucovance on patient adherence is examined. The hypothesis that FDC drug (Glucovance) improves patient adherence is based on 1) FDC simplify drug regimens and reduced the number of medications may be associated with better adherence; 2) FDC drug decreases the cost sharing for those who are under flat co-payment, as patients pay only one co-payment for two drugs.

2. METHODS

2.1 Empirical Analysis Approaches

To compare the adherence rates between patients taking single-pill combination and those with two-pill therapy, the key empirical problem is that the patients were not randomly selected into anti-diabetic therapies. The use of combination pill is voluntary and is the choice of patients and their physicians. Therefore, differences in observed and unobserved characteristics and factors in the FDC users and non-users may exist, and these differences could lead to biased estimates of treatment effects.

The instrumental variable approach is a common tool to eliminate such selection bias in econometric analysis. An instrumental variable must be correlated with the choice of treatment but otherwise uncorrelated with the error terms of the adherence equation that includes the treatment variable. When such an instrument is used in the regression, the effect of unobserved factors on the choice of treatment will be removed, and the estimates of treatment effect will be unbiased (Wooldridge 2002). However, as the administrative claims data provides little information that would predict patients' choice

of treatment independent of adherence, it is difficult to find a valid instrumental variable. In order to control for the selection bias, we used both propensity score method and fixed effect method to evaluate the effect of FDC on adherence.

2.1.1 Propensity Score Method

The propensity score method has been commonly used to reduce selection biases in observational studies (Pekins et al 2000). A propensity score is the probability of being assigned to the treatment, given a set of observed covariates. Individuals are matched or grouped into strata based on their score. Rosenbaum and Rubin (1983) show that if the exposure to treatment is random within strata defined by the covariates, it is also random within strata defined by the propensity score. In other words, once the propensity scores and covariates within each stratum are balanced between treatment groups, the treatment assignment within each stratum can be functionally regarded as random. As a result, the average effect of treatment on the treated (ATT) can be estimated as follows:

$$ATT = \sum_{q}^{Q} ATT_q \frac{\sum_{i \in I(q)} D_i}{\sum_{\forall_i} D_i}$$

Where q indexes the strata defined over intervals of the propensity score. I(q) is the set of units in strata q. Q is the total number of strata and D is the average treatment effect within each stratum. In this formula, the ATT is a weighted average treatment effect across all strata, and the weight for each stratum is given by the corresponding fraction of treated units. The standard errors of the ATT are usually obtained by bootstrapping.

In empirical analysis, the propensity score method is a two-stage approach. In the first step, the probability of using FDC is estimated by logistic regression model, adjusting the covariates and their interaction terms to balance the propensity score and

covariates distributions within each stratum. In the second stage, stratification matching is used to estimate the average treatment effect based on the above formula. That is the average treatment effect is the weighted average of the adherence differences between FDC users and non-user across the strata.

A limitation of the propensity score method is that it only controls for observed characteristics and unobserved factors to the extent that they are correlated with the observed covariates. It cannot fundamentally remove the selection bias. However, compared to single-stage multivariate models, it is more robust with respect to model specification errors, since there is no functional form assumed for the relationship between adherence and use of FDC in the propensity score approach.

2.1.2 Fixed Effect Model

Given the limitations of propensity score method, we also adopt fixed effect method to evaluate the effect of FDC on adherence. A general specification of the adherence function for 2 time periods is given by

$$y_{it} = \beta_i x_{it} + \gamma_i s_{it} + c_i + u_{it} \qquad t=0, 1$$

where y_{it} measures individual adherence at period t; x_{it} are observed characteristics affecting adherence; s_{it} is a dummy variable indicating the use of combination drug; and c_i is the unobserved person effect that is assumed constant over time. Because we cannot assume that c_i is uncorrelated with x_{it} and s_{it}, the inability to control for c_i in a cross section will lead to an omitted variable bias in the cross-section estimate of β_i and γ_i.

Panel data may allow us to control for unobserved person effect. With two periods of data (from the pre- to post-combination-drug period), differencing the data could result

in consistent estimation of β_i and γ_i if the personal effect is consistent over time (Wooldridge, 2002). The model becomes

$$y_{i1} - y_{i0} = \beta_i (x_{i1} - x_{i0}) + \gamma_i s_i + (u_{i1} - u_{i0})$$

Where we assume 1) (u_{i1}-u_{i0}) is 0 or unrelated to s_i; 2) strict exogeneity (i.e. $E(u_{it} \mid x_i, s_i) = 0$, t=1,2,…, T)

2.2 Data Source

Insurance claims data from the MarketScan databases maintained by the Medstat group is used for this study. MarketScan database, which include about 11 million individuals who are covered by employer-sponsored health insurance offered by about 45 large employers, is one of the largest databases of privately insured individuals in the US. The complete database contains various files with detailed information on medical conditions, insurance coverage, and payments for persons with any insurance claims for inpatient, outpatient and prescription drug services.

For the purpose of this study only part of the MarketScan databases is analyzed. Two different files from MarketScan 2000-2001 are linked to create a single analysis file. The two files are the Outpatient Prescription Drugs File and Enrollment File from the Commercial Claims and Encounter Database. Outpatient Prescription Drugs File contains the insurance pharmacy claims for all individuals who purchased prescription drugs. The drug claims included information on the type of drug, national drug code, dosage, purchase date, days supplied, co-payment and some patient information like age, gender, employment status etc. We matched National Drug Code Dictionary from US Food and Drug Administration (FDA) to the drug claim file to obtain the complete drug names and

manufactures. The enrollment File linked individuals to their health plan enrollment history.

2.3 Inclusion and Exclusion criteria

We observe a 24-month period from January 1, 2000, to December 31, 2001, and consider individuals who were continuous enrolled with drug coverage during the period. We focus on adult over the age of 18 who were taking oral anti-diabetic medications during the study period.

2.3.1 Propensity Score Sample

Since FDC evaluated in this study became commercially available in August 2000, the study sample for propensity score approach was determined using a two-step process. First, individuals prescribed metformin or sulfonylurea (the anti-diabetic drug category that includes glyburide) or both before July 2000, were identified. Then, those prescribed both metformin and sulfonylurea concurrently (either separately or the FDC) after August 2000 were included in the final sample.

2.3.2 Fixed Effect Model Samples

For the fixed effect method, we constructed two panel datasets. As glucovance, the fixed combination of metformin and glyberide, was available since August 2000, we define the period from January to July 2000 as pre-glucovance period, and January ~December 2001 as post-glucovance period. The first panel data include those who were using either metformin or sulfonylurea (the anti-diabetic drug category that glyberide belongs to) during the pre-period, and either switched to glucovance or took both metformin and sulfonylurea concurrently at some point during the post-period. The samples in the second panel are diabetic patients who had the two-pill therapy

(metformin and sulfonylurea) during the pre-period, and either stayed with the two-pill therapy or switched to the combination pill. The patient adherence and observable personal information were measured for both pre- and post-period.

2.4 Measuring Adherence

Drug adherence was measured by Medication Possession Ratio (MPR). As we described in background section, MPR is defined by the proportion of days on which a patient had medication available. To calculate the MPR, each day in the follow-up period was evaluated as 'covered' or 'not covered' by a prescription fill or refill. If all days were 'covered' by a prescription then adherence was 100%. This MPR algorithm is similar to the adherence measure described by Bryson and colleagues (2007). The days on which a patient prescribed two drugs had only one available was included in the analysis; the MPR was reduced by 50% for these partial adherence days. The continuous MPR is used in this study.

In propensity score approach, the date of the first claim for metformin and sulfonylurea (either separately or in the FDC) between September 1, 2000 and December 31, 2001 was defined as that subject's index date. Each patient was then followed for 180 days after the index claim.

We measure patient adherence for pre and post-FDC periods separately for fixed effect approach, and follow each patient for 90 days since his/her first metformin or sulfonylurea or combination of metfomin and sulfonylurea prescription fill during each period. In addition to MPR measurement, we also measure adherence persistence by evaluating the gaps between prescription refills in the panel data, as the MPR does not provide information on the timeliness and consistency of refilling. If the individual did

not buy another same-class anti-diabetic prescription within 0.5 times the number of days supplied by the current prescription after this prescription ran out, he/she would be considered non-persistence. For example, if a patient filled a 30-day prescription, he would be allowed 45 days (30+0.5*30) to refill the prescription before being classified as not persistent. Herein, each patient is also followed for 90 days after his/her first prescription claim.

2.5 Covariates

To evaluate the likelihood of switching to FDC in propensity score approach, predictors for the switch to FDC were chosen based on adherence literature: demographics (age, gender), geographic region (east, north central, west and south), employment status (hourly worker, union worker, retiree, and dependent), health insurance characteristics (average drug co-payment, type of plan including fee-for service, HMO, PPO and POS), health services utilization during the study period, and co-morbidities. The utilization covariate includes inpatient and outpatient use, number of medications, the percentage of brand name medications, the days supplied per medication refill, and the number of refills during the follow-up period. A binary variable was included to distinguish whether the patient took one or both of the medications (metformin and/or sulfonylurea) at baseline. Adherence rates in the baseline period prior to FDC was calculated and included as a predictor of treatment assignment.

For the fixed effect model, the main independent variable is whether the individual ever used the combination pill glucovance during the post-period. The covariates that changed during the pre- and post-period are the co-payment by patients, the average days supply and the number of other anti-diabetic medications except metformin and

sulfonylurea used by the patient during the 90-day follow-up. Co-payment is averaged for each patient over the follow-up period.

3. RESULTS

3.1 Propensity Score Approach Results

3.1.1 Patient Characteristics

A total of 9,170 diabetic patients were prescribed either the FDC or two-pill regimen in the 180 days follow-up period after glucovance was available. 25% were prescribed the FDC; the remaining 75% were prescribed concurrent two pill therapy.

Table 1 demonstrates the descriptive patient characteristics for FDC users and two pill users. Compared to two pill users, FDC users tended to be younger, mainly lived in the south, and were less likely to be hourly workers or retirees. FDC users, on average, had higher out of pocket costs for their prescriptions and tended to have a less restricted heath plan.

FDC users and two pill users did not differ significantly in terms of co-morbidities and had similar inpatient and outpatient utilization. FDC users were prescribed fewer medications, tended to use more brand-name drugs, and had shorter days supplied per prescription, but more refills. Compared to two pill users, FDC users were less likely to have been prescribed the two component medications before the FDC was available. Importantly, patients eventually prescribed the FDC had lower adherence rates (measured as 90-day MPR) during the baseline period. The propensity score approach or fixed effect would adjust such selection bias and estimate a higher treatment effects.

Propensity score adjustment reduced the magnitude of the covariate imbalance between the groups. Table 2 presents the logit estimates for the propensity of using FDC. When subjects were stratified into 11 strata based on their propensity scores, no statistically significant differences existed between groups within each stratum.

3.1.2 Estimated Treatment Effect

Figure 1 demonstrates the MPR by stratum during the baseline period (Figure 1A) and after the FDC was available (Figure 1B). At baseline, the adherence rates in the two groups were nearly identical within each stratum. During the follow-up period, FDC users had a significantly higher MPR than two pill users, except for stratum 1. The estimated average treatment effect by stratification matching was 0.128, (standard error 0.006). In other words, the MPR of FDC users was approximately 13% higher than that of individuals prescribed two pills.

In sensitivity analysis, we changed the follow up period to 120 days and 90 days. Changing the follow-up period does not affect the treatment effect significantly. The FDC improved the 120-day MPR by 0.124 (standard error 0.007), and 90-day MPR by 0.122 (standard error 0.007), similar to the 180-day result.

3.2 Fixed Effect Approach Results

We constructed two panels for the fixed effect estimation. "Met/Sulf panel" refers to the panel data that includes those who had single drug therapies (either metformin or sulfonylurea) before glucovance was available, and either switched to glucovance or took two-pill therapy (metformin and sulfonylurea) during the post-period. "Met & Sulf panel" is the panel that includes those who took two-pill therapy before the single-pill combination was available. Table 3 gives the mean values of the adherence rates and

some patient characteristics for both glucovance users and non-users during the pre-glucovance period. The panel data show similar patient characteristics as the propensity score approach. Patients with lower adherence rates and higher co-payment were more likely to use the combination drug.

Figure 2 shows the comparisons of adherence rates measured by MPR for both pre- and post-glucovance periods. Again, M/S refers to the data set that includes people who used either metformin or sulfonylurea during the pre-period. 40.9% of the patients in this panel set switched to gluvocance and 59.2% chose the concurrent two-pill therapy after FDC is available. The adherence rates of both users and non-users dropped after they switched to combination pill or two-pill therapy. However, the adherence rate of the non-users decreased about 14.64%, while that of the users only dropped 3.68%. In the M & S panel, whose samples are those taking two-pill therapy during the pre-period, 15.9% switched to glucovance and the other 84.1% stayed with the two-pill therapy during post-period. The adherence rate of the patients who were always taking two-pill therapy declined a little bit during the post-period. But the MPR of the glucovance users increased 4.89% after they switched to the combination pill.

The persistence measure gives similar results. Although the persistent rates declined over time for both glucovance users and non-users, the percentage of persistent non-users was always higher than that of persistent user during the 90-day follow-up period before glucovance was available, as it is shown in figure 3 and figure 4. In the post-glucovance period, the glucovance users had consistently better persistent rates than the non-users, suggesting the combination pill, compared to two-pill therapy, did improve patient adherence.

The OLS regressions with fixed effects adjust observed and unobserved patient characteristic that may affect medication adherence, and find the same conclusion (table 4). Compared with the two-pill therapy, glucovance improved patient adherence measured by MPR by 11.3% for those who used single drug therapy (metformin or sulfonylurea) during the pre-period, and by 6.5% for two-pill therapy patients. The combination pill also increased the percentage of persistent patients at the end of 90-day follow-up by 17.6% in the Met/Sulf panel, and by 14.6% in the Met & Sulf panel.

4. DISCUSSION

Combination drug is not a new concept. But as more and more combination drugs come to the market as an effort by the drug companies to extend the patent life and profitability of the key agent in the combination, it is valuable to assess how these drugs affect patient's adherence to medication. We used both propensity score and fixed effect approaches to control for selection bias. Our estimates for both approaches show similar results: the anti-diabetic FDC drug, glucovance, significantly increased patient adherence to combination therapy when compared to patients prescribed a two-pill regimen. The estimated improvement ranges from 6.5-14.6%, depending on the adherence measure and analytic approach.

The study has some important limitations. First, both propensity score and fixed effect methods cannot fundamentally solve the non-random assignment bias. If the switch to the FDC is correlated with unobserved factors whose effects on adherence change over time, the results might be biased. However, the analysis on FDC users and non users reveals that FDC users tend to be non-compliant compared to the non users. The

traditional OLS analysis might underestimate the FDC effect. Propensity score and fixed effect approaches both corrected for such selection bias problem. Second, due to data availability, only short-term effects were measured. Because switching to the FDC likely involves clinician visit, the importance of good adherence may have been emphasized to the patient in connection with the switch, which could result in improved adherence. Therefore, for this and other reasons, the long term durability of the adherence advantages of FDC drugs is uncertain. Future work could analyze the long-term adherence trend among FDC users versus non-users when data is available, as long-term adherence is more important for patients with chromic illness. Third, the generalizability of these results is limited. The study population included well-insured employees of large companies. Future studies may need to focus on individuals with less generous prescription drug coverage. Also, no information was available on length or severity of disease.

As more than one medication becomes the norm to achieve recommended clinical endpoints for many chronic diseases, the effect of multiple medications on patient adherence becomes especially important. Our findings suggest that compared to two pill therapy, a fixed dose combination can yield important improvements in patient adherence. In the case where the acquisition costs of a FDC product exceeds the cost of the individual agents, cost-effectiveness analyses are warranted to determine whether the clinical advantages attributable to the enhanced adherence are worth the incremental expenditures. In addition, future work should evaluate the effects of FDC on different subgroups to identify the groups that would benefit from FDC most. As FDC is usually

more expensive than the free dose combinations, it would be valuable to identify the groups who have, at least, enough adherence gains to offset the extra costs.

Table 3.1 Comparison of Covariates for FDC Users and Non-FDC Users

Variables	FDC Users	Non-FDC Users	Unadjusted P Value
Demographics			
Age, year Mean (SD)	52.4 (0.13)	54.4 (0.07)	<0.001
18-44 (% of patients)	12.5%	8.5%	<0.001
45-54 (% of patients)	38.6%	36.6%	0.115
55-64 (% of patients)	48.6%	52.5%	<0.001
65+ (% of patients)	0.3%	1.4%	<0.001
Gender(% of male)	55.5%	56.1%	0.345
Region (% of patients)	0.0%	0.0%	
East	12.8%	23.3%	<0.001
North Central	26.1%	26.0%	0.918
South	59.0%	45.7%	<0.001
West	2.0%	5.1%	<0.001
Employment (% of patients)	0.0%	0.0%	
Hourly	24.7%	26.9%	0.048
Union	20.0%	19.0%	0.289
Retiree	28.0%	32.1%	<0.001
Dependent	0.2%	0.3%	0.279
Health Insurance			
Drug Co-payment $ Mean (SD)	13.11 (0.18)	9.60 (0.07)	<0.001
FFS (% of patients)*	25.7%	21.2%	<0.001
HMO(% of patients)*	2.7%	6.9%	<0.001
PPO(% of patients)*	27.8%	29.5%	0.134
POS(% of patients)*	43.8%	42.4%	0.737
Health Services Utilization			
Two-drug users prior to FDC (% of patients)**	32.8%	68.6%	<0.001
Adherence rate prior to FDC Mean (SD)	0.833 (0.004)	0.853 (0.002)	<0.001
No. of Medications Mean (SD)	6.2 (0.10)	7.1 (0.06)	<0.001
% brand-name Medications	94.8%	80.1%	<0.001
Average days supply per fill Mean (SD)	41.8 (0.50)	50.4 (0.32)	<0.001
# of Refills Mean (SD)	3.4 (0.04)	2.6 (0.02)	<0.001
Outpatient encounters Mean (SD)***	19.6 (0.32)	19.6 (0.21)	0.926
Hospitalized at least once***	6.2%	6.0%	0.698
Comorbidities			
Hypertension (% of patients)	53.2%	51.7%	0.233
Heart Failure (% of patients)	5.4%	5.4%	0.980
Depression (% of patients)	18.4%	19.6%	0.249
Propensity Score Mean (SD)	0.505 (0.006)	0.157 (0.002)	<0.001
No. of Observations	2275		

Note: *FFS is Fee-For-Service, HMO is Health Management Organization, PPO is Preferred Provider Organization, POS is Point Of Service
**Two-drug users refers to those who used both metformin and sulfonylurea prior to FDC
***The time frame for inpatient and outpatient encounter is 09/2000~12/2001

Table 3.2 Logit Estimates For Propensity of Using FDC

	Coef.	Std. Err.	P-value	95% C.I.	
Age 45-54	0.111	0.107	0.299	-0.099	0.321
Age 55-64	0.195	0.111	0.078	-0.022	0.412
Age 65+	-0.663	0.515	0.198	-1.672	0.346
Male	-0.136	0.062	0.028	-0.257	-0.015
North Central	0.281	0.102	0.006	0.081	0.480
South	0.150	0.093	0.104	-0.031	0.332
West	-0.552	0.202	0.006	-0.949	-0.156
Hourly	0.085	0.074	0.247	-0.059	0.230
Union	0.404	0.088	0.000	0.231	0.576
Retiree	-0.047	0.074	0.526	-0.191	0.098
Dependent	0.439	0.651	0.500	-0.837	1.714
Drug Co-payment	0.072	0.007	0.000	0.059	0.085
HMO	-1.070	0.186	0.000	-1.434	-0.706
PPO	-0.279	0.088	0.001	-0.450	-0.107
POS	-0.078	0.087	0.372	-0.249	0.093
Two-drug users prior to FDC	-1.678	0.064	0.000	-1.803	-1.553
Adherence rate prior to FDC	0.757	0.182	0.000	0.401	1.112
No. of Medications	0.014	0.029	0.628	-0.043	0.071
% brand-name Medications	4.443	0.190	0.000	4.071	4.814
Average days supply per fill	-0.031	0.002	0.000	-0.035	-0.027
# of Refills	-0.480	0.025	0.000	-0.528	-0.432
Outpatient encounters	0.005	0.002	0.006	0.001	0.008
Hospitalized at least once	-0.007	0.129	0.957	-0.261	0.247
Hypertension	-0.001	0.060	0.984	-0.120	0.117
Heart Failure	-0.010	0.130	0.942	-0.264	0.245
Depression	-0.184	0.079	0.019	-0.338	-0.030
Constant	-2.267	0.309	0.000	-2.872	-1.662

Table 3.3 The means during the pre-glucovance period

Variables	Met/Sulf Panel Users	Met/Sulf Panel Non-Users	Met & Sulf Panel Users	Met & Sulf Panel Non-Users
MPR	0.854*	0.878	0.808*	0.846
Persistent	0.620*	0.683	0.549*	0.621
Ave. Days Supply	43.606**	45.530	45.703*	51.108
Co-payment	9.569**	9.038	9.068*	8.236
Num of Other Drugs	0.249*	0.205	0.264	0.248
Hourly	0.241	0.249	0.262	0.280
Union	0.195	0.180	0.195	0.195
Retiree	0.270	0.270	0.287**	0.323
Age 55+	0.447	0.470	0.495**	0.536
Female	0.456	0.435	0.457	0.443
Dependent	0.003	0.002	0.001	0.004
North Central	0.262	0.246	0.246	0.267
South	0.598*	0.450	0.574*	0.457
West	0.020*	0.053	0.037**	0.053
N.of Observations	1854	2674	923	5790

* The mean of glucovance users is significantly different from the mean of non-users at 0.01
** The mean of glucovance users is significantly different from the mean of non-users at 0.05

Table 3.4 Fixed Effect Estimates

Variables	OLS estimates with MPR as outcome			
	Sulf/Met Users		Sulf & Met Users	
	Coef.	Std. Err.	Coef.	Std. Err.
Glucovance users	0.113*	0.0083	0.065*	0.0087
Ave. Days Supply	0.003*	0.0003	0.003*	0.0002
Co-payment	-0.001**	0.0006	-0.001***	0.0004
Num of Other Drugs	-0.007	0.0085	-0.007	0.0063
Constant	-0.110*	0.0102	-0.008	0.0082
	OLS Estimates with persistence as outcome			
	Sulf/Met Users		Sulf & Met Users	
	Coef.	Std. Err.	Coef.	Std. Err.
Glucovance users	0.176*	0.0186	0.146*	0.0017
Ave. Days Supply	0.006*	0.0005	0.005*	0.0005
Co-payment	-0.002***	0.0010	-0.003*	0.0012
Num of Other Drugs	-0.049*	0.0181	-0.044*	0.0152
Constant	-0.160*	0.0232	-0.069*	0.0209

Note: 1.*Significant at 0.01, **Significant at 0.05, ***Significant at 0.1
2. All standard errors are robust standard errors

Figure 3.1 Medication Possession Ratio by Propensity Score Stratum, Before and After the Availability of the Fixed Dose Combination Product

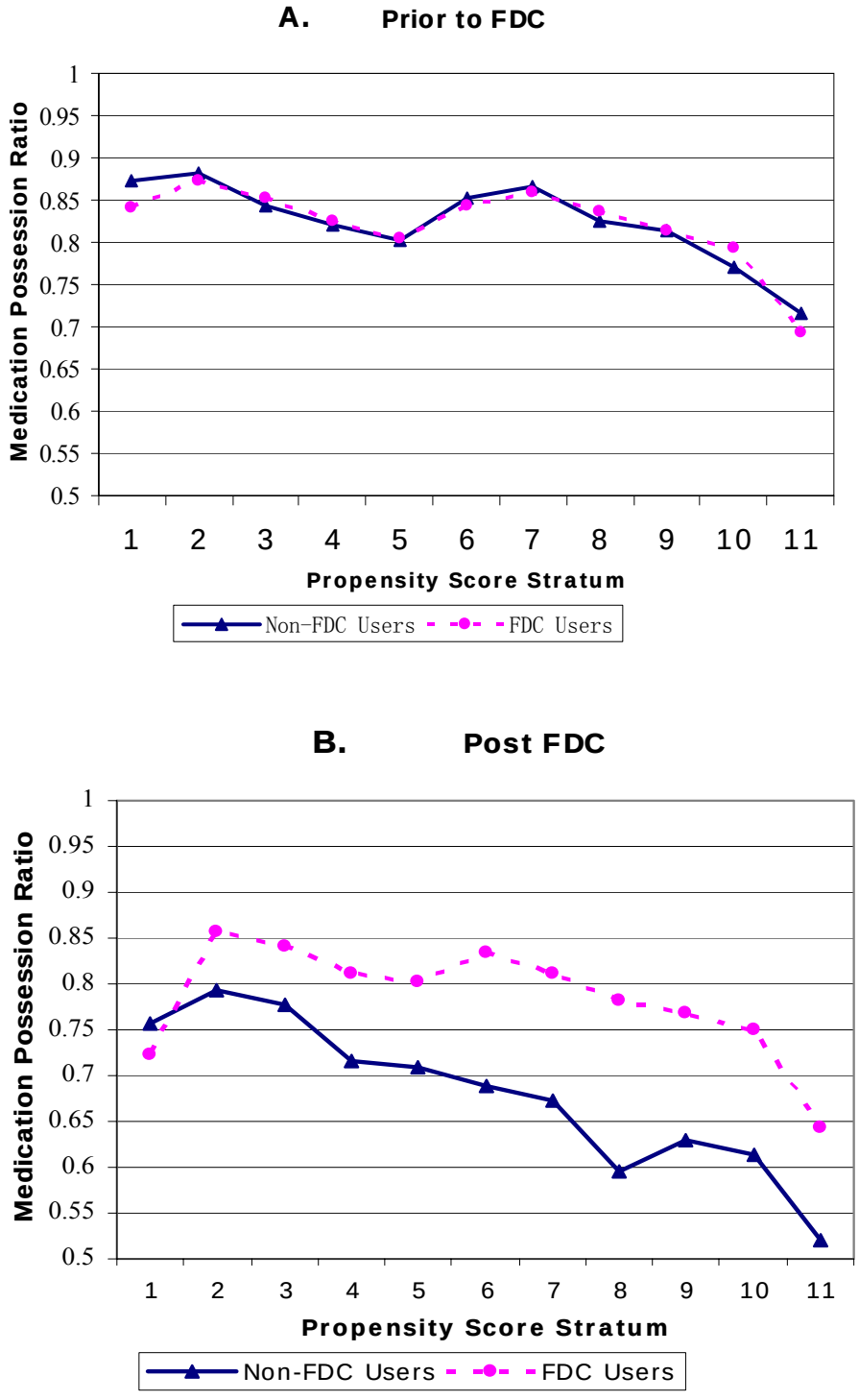


Figure 3.2 Panel data Comparison on MPRs

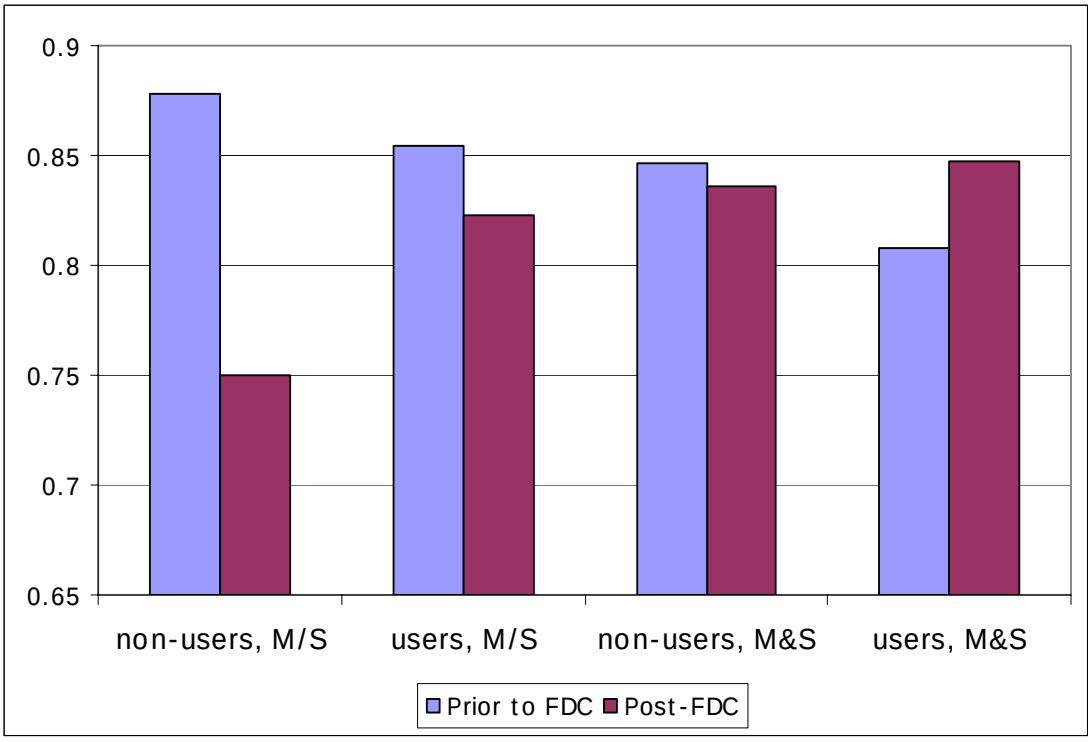


Figure 3.3 Persistence Curves for Met/Sulf Panel

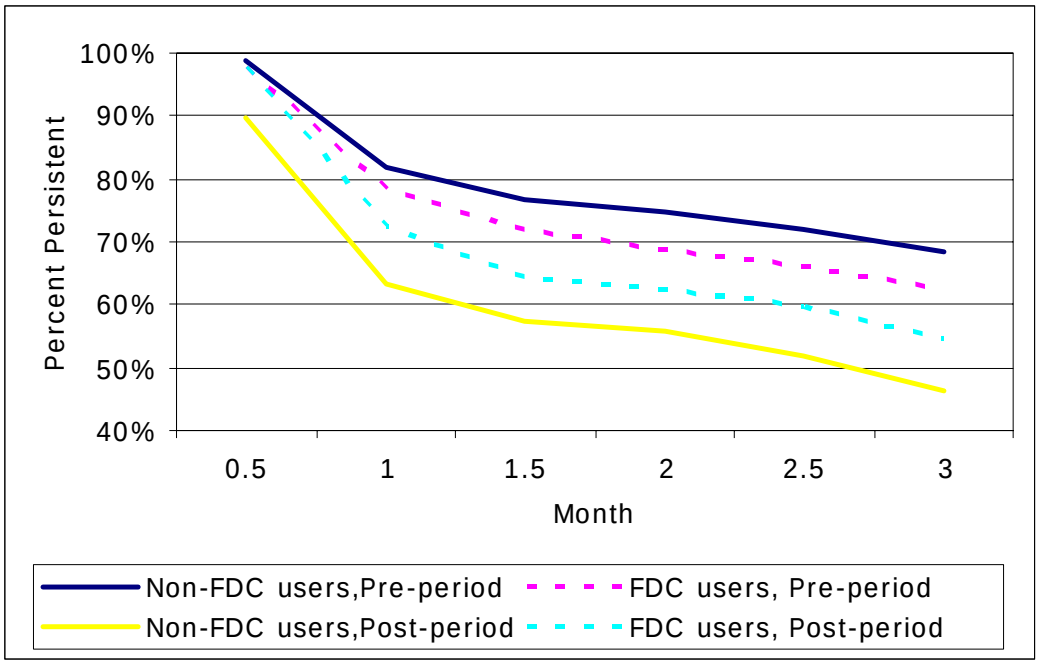
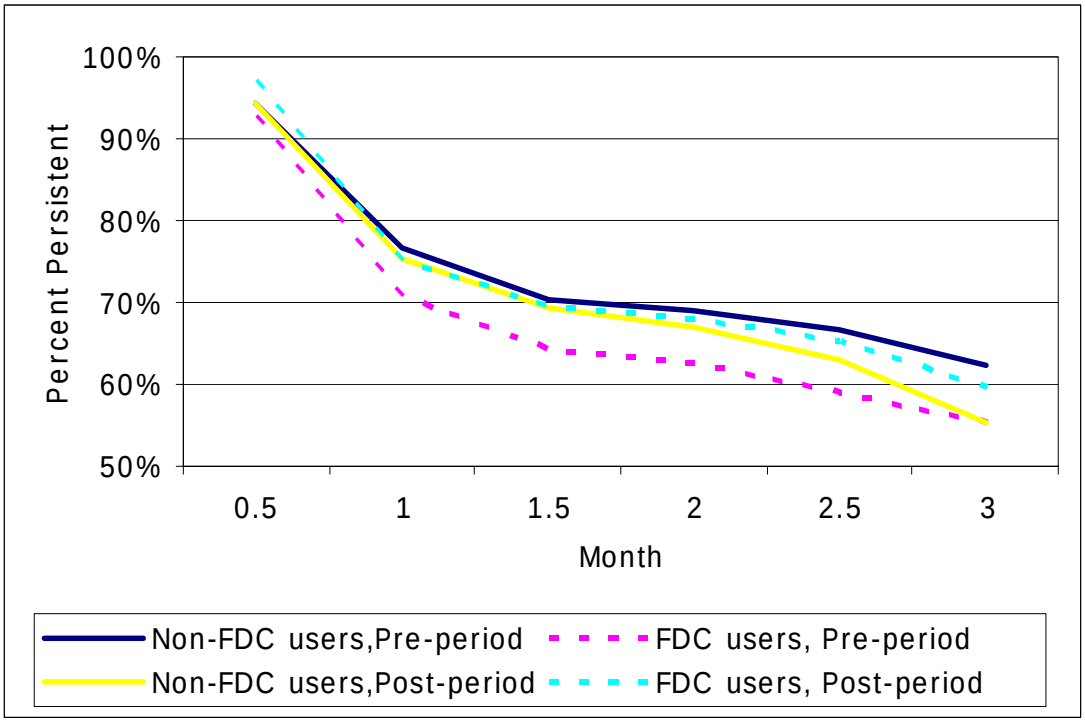


Figure 3.4 Persistence Curves for Met & Sulf Panel



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CHAPTER IV
THE EFFECT OF CO-PAYMENT CHANGE ON PRESCRIPTION DRUG UTILIZATION-TIER SHIFTING

1. BACKGROUND

Prescription drug costs have been the fastest growing component of health care spending in the United States during the early 21st century. In 2002, $162 billion was spent on prescription drugs (a 15% increase from the prior year) and the costs of prescription drugs are expected to continue rising sharply (Kaiser Family Foundation, 2004). In response, employers and health benefit managers have been increasingly shifting costs to employees in an attempt to control rising drug expenditures (Dietz 2004; Robinson 2004). Patient cost-sharing is designed to reduce health care use (Zweifel 2000; Newhouse 1993) and, empirically, the literature is quite clear that increased medication co-payments work as desired, leading to a reduction in medication utilization (Ellis et al 2004; Federman et al 2001, Goldman et al 2004; Johnson et al 1997; Piette et al 2004). The critical issue surrounding medication cost-sharing, though, is whether patients can determine which drugs are most valuable to their health and then, in turn, whether they will choose to prioritize their medications accordingly to maximize health outcomes.

Unfortunately, the evidence suggests that medication cost-sharing indiscriminately reduces the use of both excess and essential medications alike (Ellis et al 2004; Federman et al 2001, Goldman et al 2004; Johnson et al 1997; Piette et al 2004). In turn, growing evidence suggests that individuals who decrease medication utilization due to out of pocket (OOP) costs have poorer health outcomes (Johnson et al 1997; Piette et al 2004; Heisler et al 2004; Schoen et al 2001) and may even incur increases in overall health care costs (Soumerai, et al 1991).

In response to the growing evidence that 'one-size fits all' co-payment harm patients and may even increase costs, a more nuanced approach to health insurance benefits design, in which patients' co-payments are based on the expected clinical benefit of the prescribed drug(s) rather than their acquisition cost, was proposed (Chernew et al 2000; Fendrick et al 2001). Under this Value Based Insurance Design (VBID) theory, the more beneficial the medication, the lower the co-payment, thereby effectively realigning the incentives faced by patients to increase utilization of and adherence to the most beneficial and valuable prescription medications.

Empirically, it appears that the appeal of such clinically-based benefits has taken root primarily outside of medicine – in the business world. In an effort to reduce high cost claims, FORTUNE 500 employer (and self-insurer) Pitney Bowes lowered medication co-payments for asthma and diabetes medications in 2001 and reported a one year one million dollar savings in the Wall Street Journal (Hensley 2004). A few other health plans are experimenting with similar strategies. CIGNA HealthCare offers a four-tier formulary option it terms the "tiered clinical utility" approach, with "life-saving" drugs in the lowest co-payment tier and "lifestyle" drugs in the highest co-payment tier

(Fendrick 2005). While these clinically sensitive benefit designs hold promise for improving the quality and value of care, there have been no well designed evaluations, and certainly no prospective, controlled evaluations, of these more nuanced benefit designs.

The Focus On Diabetes (FOD) intervention implemented at the University of Michigan (UM) is the first of its kind designed both to improve the quality of care for UM employees, and to allow for a rigorous evaluation of such a program's effectiveness. Diabetes was chosen as the initial condition because of the improved ability to identify diabetes through pharmacy claims, and because a detailed assessment in the UM population identified clear underutilization of evidence-based therapies in employees and dependents with diabetes. The intervention started from July 1, 2006 and provided all UM employees and dependents identified as having diabetes with co-payment reductions for all glycemic agents, anti-hypertensives, lipid lowering agents, and anti-depressants.

One of the important impacts of FOD intervention is patients' drug utilization pattern change. Incentive-based or tiered formularies, which provide financial incentives (i.e. lower co-payments) for enrollees to choose drugs that are preferred by the payer, has been a popular drug benefit design to curb the increasing costs of prescription drug (Gabel et al, 2002). Incentive-based formularies are intended to preserve choice for patients and physicians by providing some level of coverage for most drugs while encouraging patients and their physicians to select the drugs that are more cost effective for the plan. The use of incentive-based formularies could also result in increased bargaining power for plans to negotiate rebates with drug manufactures by promising an increased volume of prescriptions for the preferred drugs (Frank, 2001)

A three-tier formulary, now the most common type and provided to UM employees and their dependents, requires the lowest co-payments for generic drugs (tier 1), a higher co-payment for the brand-name drugs that are preferred by the health plan (tier 2), and the highest co-payments for brand-name drugs that are not preferred by the health plan (tier 3). The co-payment reductions in FOD intervention were designed to maintain the underlying incentive structure of the formulary such that generic medications (tier 1) had larger co-payment reductions than branded medications, and preferred brands (tier 2) had larger co-payment reductions than tier 3. Specifically, the generic drug co-payment reduced from $7 to $0 (100%), preferred brand-name drugs from $14 to $7 (50%), and non-preferred brand-name drugs from $24 to $18 (25%).

How the graded co-payment changes within tiered formulary affect patient tier utilization pattern has important implication to health plan, as the possible more utilization on non-preferred mediations could impose unnecessary higher costs to health plan. Previous studies have found that the adaptation of an incentive-based formulary and/or increase co-payments resulted in switching to lower tier medications. However it is not clear whether FOD intervention will result in more non-preferred drug utilization or not.

Standard economic theory predicts that changes in prices directly affect the relative quantities of products purchased. Every price change can be decomposed into an income effect and a substitution effect. The income effect from co-payment reduction may lead to more consumption of costly drugs as the patients' budget constraint is relaxed. This hypothesis will hold if patients believe that the higher tier medications (especially brand name versus generic drugs) have better quality, and thus prefer them. The substitution

effect, on the other hand, may shift the utilization toward lower tiered drugs, since graded co-payment reductions changed the relative price among drugs in different tiers, and generic drugs became relatively cheaper than brand-name ones, and non-preferred drugs are relatively more costly than preferred ones to patients.

Extensive literature has studied relative price change on product selection and some (Smith DG and Rose LC) found that the use of uniform dollar change induced increased consumption of the lower priced alternatives given limits of insurance coverage. In addition, price reduction could increase the amount of utilization among all tiers. That is patients may start to take more drugs and be more adherent to the treatment regimens. Although the quantity effect of the co-payment reduction is not evaluated in this study, it may reduce the income effect from the price reduction. Given the economic theories and empirical evidence, we would hypothesize that the graded co-payment reduction may switch patients from higher tier to lower tier.

In this chapter, the effects of the FOD intervention on drug utilizations are evaluated. Specifically, we examined how changes in co-payment reductions on the targeted drugs affected patient tier switching within drug class. Non-UM enrollees from the same health plan provider (M-CARE) serve as control group in the study, as their employers did not provide such co-payment reductions on these drugs.

The analyses show that the graded co-payment reductions did not change the tier use on diabetic and anti-hypertensive medications, as most UM patients remained on their original tier after intervention. However, for the lipid lowering medications and anti-depressants, the effect of co-payment reduction is not clear, because patent expiration and

formulary changes on both UM and control groups accompanied co-payment reductions during the study period.

The chapter proceeds as follows: In section 2, I describe the empirical methods used, including FOD intervention details, data source, concurrent drug benefit changes and statistical analyses. In section 3, I present the empirical results, followed with discussion of implications, limitation and future work in section 4.

2. EMPIRICAL ANALYSIS

2.1 Focus On Diabetes Intervention

On July 2006, the University of Michigan implemented the Focus On Diabetes (FOD) intervention, which was designed as a prospective, controlled intervention of targeted co-payment reductions for high value pharmacotherapies in diabetes. The intervention population consists of UM active employees and their dependents continuously enrolled in SXC Health Solutions (the sole pharmacy benefit provider for UM) and M-CARE (the medical health plan), and identified as diabetic based on at least one pharmacy claim for diabetic hypoglycemic medications (oral or injectable) or supplies within the 12 months prior to study initiation.

An educational letter was sent to the entire UM community one month prior to initiation of the co-payment reductions, which provided information on the general health benefits of medication adherence, the specific benefits of the drugs selected for intervention, and a brief description of the impending co-payment reductions. A parallel letter was sent to the control group (described below) which differed from the UM letter in that it excluded information about the co-payment reductions (but included all of the

same educational content). The two letters also differed in that, while both provided a phone number for questions (phone staffed by a registered nurse), the letter to UM employees and dependents also contained a statement allowing individuals to opt out of or opt into the study.

While the FOD intervention is designed to reduce financial barriers to effective therapies, it does not preclude the concomitant use of other incentive structures already in place. Prior to the intervention, UM employed a 3-tiered formulary with co-payments of $7, $14, and $24 for generic, preferred brand, and non-preferred brand medications, respectively. This underlying benefit structure remains intact with the value based benefit overlaid. Further, to maintain incentives to minimize cost (when health remains unaffected), the intervention lowers co-payments in a graded fashion (tier 1's co-payment decreases by 100%, tier 2's by 50% and tier 3's by 25%) to a new 3-tiered benefit structure of $0, $7, and $18 for the medications of interest.

2.2 Control Group

Non-UM enrollees from the same health plan provider M-CARE were identified as the control population. M-CARE is a large managed care organization in south east Michigan, and was owned by the University at the time FOD was initiated. The same pharmacy claims criteria used to identify the UM employees with diabetes (the intervention group) were used to identify the non-UM managed care enrollees with diabetes (the control group).

The control group is employees and their dependents from about 170 employers in south east Michigan. Many of them are relatively small employers, with more than 50% of them having less than 250 M-CARE enrollees. Although these employers have

different prescription drug benefit, they all employed 3-tier formulary with varying co-payment requirements, and no co-payment change happened among these employers at the same time as the FOD intervention period. The characteristics of the control group are presented in the results section.

2.3 Inclusion Criteria

Enrollment files, pharmacy claim data and medical utilization claim data were obtained from M-CARE. For the purpose of this study, an 18 month period from January 01, 2006 to June 30, 2007 is analyzed (6 months prior to and 1 year after FOD intervention). Individuals who were continuously enrolled with drug coverage over this entire period and have at least one diabetic medication claim during the year prior to intervention are considered. In addition, this study considers tier switching only. Discontinuation from treatment or uptake is not analyzed here. Therefore only those with at least one fill of the study drug class prior to the intervention and at least another fill of the same drug class during the post period are included.

2.4 Drug Class

Focus On Diabetes intervention involved four groups of drug classes: glycemic (diabetic) agents, anti-hypertensives, lipid lowering agents and anti-depressants. Table 1 presents the four drug class groups, the drug classes within each group and their corresponding shares in each group. Most of the drug consumptions concentrated in a few major drug classes. Statins, for example, accounted for 82% of utilization of lipid lowering agents.

In this study, tier switching is analyzed within drug classes listed in the table 1. That is if a patient was taking two drugs from the same medication group, she/he is counted

twice in the analyses for that drug group. The reason is that although patients may switch among the drug classes within the same medication group, it is very common that patients take multiple drugs from different drug classes within the same group, as each of these drugs works differently to treat conditions and sometimes they are complimentary to each other. For the treatment of diabetes, for example, patients usually start with one drug, increase its dose until maximum dosing, and then start another class of drug, either alone or in combination with the first drug.

2.5 Concurrent Changes to Drug Benefit

Other than FOD intervention, the University of Michigan made some drug formulary changes during the study period, by moving some brand name drugs from tier 2 to tier 3. At the same time, formulary changes happened among the employers in the control group too. Because the control group consists of 170 employers (many of them are small business), these formulary changes vary across control group patients. All of these might complicate the tier switching analysis. Table 2 lists all the formulary changes during the study period among both intervention and control groups. The corresponding market shares of these drugs are presented in table 1.

In addition, the patents of two major brand-name drugs from Statin and SSRIs/SNRI drug classes expired around the same time FOD intervention began. Zocor, a Statin agent produced by Merck, and Zoloft, a SSRI drug produced by Pfizer, lost their patents on July 23, 2006 and June 30, 2006 respectively. Because generic drugs were available right after the patent expirations, we may expect a shift from brand name to generic tier among these two drug classes.

2.6 Analysis

In the primary analysis, individuals in the data were sorted into three groups:

(0) Down shifting – individuals who switched to lower formulary tier but using the same drug class during the post intervention period.

(1) No change – those who remained on their original formulary tier during the study period

(2) Up shifting – individuals who switched to higher formulary tier but using the same drug class during post intervention period

Additionally, a secondary outcome was analyzed, which measures the switch to and from generic tier within each drug class. That is the variable will be 0 if the patient switched from brand name to generic drug, 1 if the patient remained on brand name or generic drugs, and 2 if the patient switched from generic to brand name drug. In addition, if a patient had multiple claims for the same drug class, the latest claims during each period (pre and post intervention periods) are included in the study.

3. RESULTS

3.1 Population Characteristics

Table 3 presents the study population characteristics and overall tier utilization before and after FOD intervention for both the intervention group – the University of Michigan employees and their dependents, and the control group – the non-U of M enrollees in M-CARE health plan. A total number of 759 UM enrollees and 1491 non-UM enrollees meet the inclusion criteria. The two groups have similar mean age (50 years old) and gender distribution (50% female). UM enrollees had a little bit higher number of

concurrent medications (5.55 vs 4.96), longer average drug days supply (64 days vs 59 days), and lower average co-payment ($12.68 vs $14.65) before the FOD intervention.

The average co-payment UM enrollees paid after the intervention decreased more than 50% (from $12.68 to $4.97), while the co-payment for the control group remains almost unchanged.

The total medication consumption on each tier for both pre and post intervention periods are also presented in table 3. Before intervention, UM enrollees have higher consumption of generic and preferred brand name drugs, while non-UM enrollees have higher percentage on non-preferred brand name drugs. During the post intervention period, however, both groups have a significant shift to generic drugs (UM group increased by 10%, and control group increased by 6%). This can be explained by the fact that two major drugs, Zocor (Statins) and Zoloft (SSRIs), lost their patent almost at the same time the intervention began. Besides switching to first tier, about 4% of UM drug utilizations shifted to the highest tier, resulting in relative less consumption of preferred brand name drugs. The control group, on the other hand, moved in an opposite direction, with more preferred brand name drug utilization and less tier 3 use.

The preliminary summary of drug tier utilization pattern change reveals that the effect of FOD intervention is mixed with those of patent expirations and concurrent drug benefit changes. A detailed drug utilization analysis by medication groups and drug classes is described in the next section.

3.2 Tier Utilization Patterns By Medication Groups

Figure 1-4 show the tier utilization distributions by medication groups during both pre and post intervention periods. In diabetic medication group, UM enrollees were almost

unaffected by the intervention in terms of tier utilization. Non-UM enrollees had more preferred brand name diabetic drug utilization during the post period, while their generic drug use did not change. The formulary change table (table 2) shows that one of metformin drugs was moved from tier 3 to tier 2, and metformin has about 54% share of the total diabetic drug consumption (table 1), which explained why the control group increased their use on preferred diabetic medications. For anti-hypertensives (figure 2), the tier utilization nearly remained the same after intervention for both treatment and control group. Although the control group had some formulary change on anti-hypertensives during the study period (table 2), the number of drugs moving from tier 2 to tier 3 equals the number of drugs from tier 3 to tier 2.

For lipid lowering agents and anti-depressants, however, tier utilization changed significantly during post-intervention period (figure 3 and 4). These changes are mainly due to the patent expiration of Zocor (Statins) and Zoloft (SSRIs). UM enrollees had relatively higher increase in generic lipid lowering agents utilization, while the control group had higher increase in generic anti-depressants use. For UM enrollees, 4 Statin drugs moved from tier 2 to tier 3 during the post intervention period, but there is no change in formulary tier of anti-depressants. As a result, UM enrollees increased both tier 1 and tier 3 consumptions of lipid lowering drugs and decreased preferred brand name use, while just replaced some of the tier 2 use with generic drugs in anti-depressants group. Among the non-UM group, patent expirations were mixed with more complex formulary change on lipid lowering agents (table 2). Consequently, the non-UM group increased both tier 1 and tier 2 utilization of lipid lowering drugs and reduced non-preferred brand name consumption.

The analyses on individual tier shifting by medication groups show similar results as the figures (table 4 and 5). Utilizations by formulary tiers on diabetic drugs and anti-hypertensives did not change among UM enrollees after the FOD intervention, as majority of the patients remained no change (diabetic drugs 99.17%, anti-hypertensives 96%). Among non-UM enrollees, drug formulary changes led to slightly higher tier shifting rates on these two medication groups.

Among lipid lowering agents and anti-depressants, fewer patients remained on the same drug tiers during post intervention period. 30% UM enrollees shifted to lower tier of lipid lower agents and 23.3% moved to higher tier. The combination of Zocor patent expiration and formulary changes toward moving more tier 3 drugs to tier 2 resulted in 47% of non-UM enrollees shifting to lower tiers in this drug group. For anti-depressants, about 25% UM enrollees and 20% non-UM enrollees changed their tiers. And more patients in UM group (7.4%) moved to higher formulary tier than the non-UM group (2.25%).

Separate analyses on Statin and SSRIs/SNRIs are presented in table 6, as these two drug classes had patent expiration during the study period. 38.9% of UM patients moved to generic Statin, compared to 23.7% of non-UM patients. However, non-UM enrollees had higher rates (22.65%) of shifting to generic SSRIs than the UM treatment group (18%). The co-payment reductions on UM side cannot explain the different relative shifting rates in these two drug classes. Rather, the formulary changes provide some explanations. UM moved more brand-name Statin drugs from tier 2 to tier 3 to encourage the use of generic drugs after Zocor lost its patent, while non-UM employers moved Zoloft to tier 3 after its patent expired to encourage the use of generic version.

4. DISCUSSION

Focus On Diabetes is a drug benefit experiment conducted on the University of Michigan employees and their dependents. The FOD experiment reduced drug co-payments of four types of prescription medications for diabetic patients. This study evaluates how the co-payment reduction affected patient formulary tier utilization patterns. The analyses show that the graded co-payment reductions did not change the tier use on diabetic and anti-hypertensive medications, as most people remained on their original tier after intervention. However, for the lipid lowering medications and anti-depressants, the effect of co-payment reduction is not clear, due to the fact that patent expiration and formulary changes on both UM and control groups accompanied co-payment reductions during the study period. Patent expirations of Zocor (Simvastatin) and Zoloft (Sertraline HCL) resulted in significant shifting from brand-name to generic drugs. Moving brand-name drugs from tier 2 to tier 3 encouraged the use of generic drugs.

This study has several important limitations. First, the effects of concurrent formulary changes are mixed with that of co-payment reductions. It is hard to evaluate the pure graded co-payment reductions on tier shifting behavior, especially for the use of lipid lowering agents and anti-depressants. Second, the control group consists of 170 employers. The ongoing changes to their drug benefits are not unanimous and the heterogeneity may make the control group less comparable to the intervention group. Future work may use UM patients themselves as control, by comparing their tier utilization on non-FOD intervention drugs to the FOD intervention drugs. In addition, the University of Michigan enrollees are well insured population. The average co-payment

UM patients paid before FOD intervention was less than $13. The generalizability of these results is limited. Future studies may need to focus on individuals with less generous drug benefit, as patients with high co-payments are more sensitive to the benefit change.

In conclusion, this study found that graded co-payment reductions had little effect on patient tier switching. Neither income effect nor price effect dominated in the drug price reduction. Instead, the availability of new generic drugs after the patents of brand-name drugs expired and drug formulary changes had significant impact on tier shifting.

Table 4.1 Drug Classes for Analyses

Medication Group	Drug Class Name	% Share of the Medication Group
GLYCEMIC AGENTS	Metformin	53.93%
	Sulfonylureas	22.61%
	TZDs (glitazones)	19.01%
	Others	4.45%
ANTIHYPERTENSIVES	ACE/ARBs	50.09%
	Beta Blockers	20.71%
	CCBs	9.16%
	Diuretics	17.23%
	Other antihypertensives	2.80%
LIPID LOWERING AGENTS	Statins	81.68%
	Zetia	5.45%
	Other lipid lowering agents	12.86%
ANTIDEPRESSANTS	SSRIs/SNRIs	62.75%
	Tricyclics	9.97%
	Other antidepressants	27.29%

Table 4.2 Formulary Changes During Study Period

Drug Class	Employer	Change	# of drugs
all other glycemic agent	Non-UM	From tier 3 to tier 2	3
all other glycemic agent	Non-UM	From tier 2 to tier 3	2
metformine	Non-UM	From tier 3 to tier 2	1
ACE/ARBs	Non-UM	From tier 2 to tier 3	4
ACE/ARBs	Non-UM	From tier 3 to tier 2	2
Beta Blockers	Non-UM	From tier 3 to tier 2	1
CCB	Non-UM	From tier 3 to tier 2	1
Statin	UM	From Tier 2 to tier 3	4
Statin	Non-UM	From Tier 2 to tier 3	2
Statin	Non-UM	From tier 3 to tier 2	2
Zetia	Non-UM	From tier 3 to tier 2	1
other lipid lowering agnet	Non-UM	From tier 3 to tier 2	2
SSRIs/SNRI	Non-UM	From Tier 2 to tier 3	1

Table 4.3 Study Population Treatment Use and Characteristics

	UM Enrollees		Non-UM Enrollees	
	Mean	S.E.	Mean	S.E.
% on generic drugs-pre period	61.5%	-	58.0%	-
% on preferred brand-name drugs-pre period	35.1%	-	29.1%	-
% on non-preferred brand-name drugs-pre period	3.4%	-	12.9%	-
% on generic drugs-post period	70.3%	-	64.2%	-
% on preferred brand-name drugs-post period	22.1%	-	31.4%	-
% on non-preferred brand-name drugs-post period	7.6%	-	4.4%	-
Age (Years)	49.69	0.38	50.73	0.26
Female	50.1%	-	49.4%	0.01
Dependent	36.8%	-	30.7%	0.01
Number of Concurrent Medications	5.55	0.10	4.96	0.06
Average drug days supply	64.63	0.92	59.03	0.71
Average Co-payment - pre period	$ 12.68	0.07	$ 14.65	$ 0.06
Average Co-payment - post period	$ 4.97	0.05	$ 15.26	0.05
Number of Eligible Patients	759		1491	

Table 4.4 Tier Shifting Patterns

Medication Gorup		UM Employee		Non-UM Employee		Difference (UM - Non-UM)
		Freq.	Percent	Freq.	Percent	
Diabetic Drugs	Down shift	4	0.42%	60	3.41%	-2.99%
	No Change	953	99.17%	1,668	94.83%	4.34%
	Up shift	4	0.42%	31	1.76%	-1.34%
Anti-Hypertensives	Down shift	18	2.05%	94	5.33%	-3.28%
	No Change	841	96.00%	1,589	90.03%	5.97%
	Up shift	17	1.94%	82	4.65%	-2.71%
Lipid Lowering Drugs	Down shift	177	29.90%	539	46.83%	-16.93%
	No Change	277	46.79%	558	48.48%	-1.69%
	Up shift	138	23.31%	54	4.69%	18.62%
Anti-Depressants	Down shift	43	16.80%	65	18.26%	-1.46%
	No Change	194	75.78%	283	79.49%	-3.71%
	Up shift	19	7.42%	8	2.25%	5.17%

Table 4.5 Generic Drug Utilization Patterns – All Drug Groups

Medication Gorup		UM Employee		Non-UM Employee		Difference (UM - Non-UM)
		Freq.	Percent	Freq.	Percent	
Diabetic Drugs	Shift to Generic	4	0.42%	3	0.17%	0.25%
	No Change	953	99.17%	1,732	98.47%	0.70%
	Shift from Generic to Brand name	4	0.42%	24	1.36%	-0.94%
Anti-Hypertensives	Shift to Generic	18	2.05%	52	2.95%	-0.90%
	No Change	842	96.12%	1,677	95.01%	1.11%
	Shift from Generic to Brand name	16	1.83%	36	2.04%	-0.21%
Lipid Lowering Drugs	Shift to Generic	172	33.40%	186	19.18%	14.22%
	No Change	337	65.44%	773	79.69%	-14.25%
	Shift from Generic to Brand name	6	11.70%	11	11.30%	0.40%
Anti-Depressants	Shift to Generic	43	16.80%	65	18.26%	-1.46%
	No Change	199	77.73%	285	80.06%	-2.33%
	Shift from Generic to Brand name	14	5.47%	6	1.69%	3.78%

Table 4.6 Generic Drug Utilization Patterns – Statins and SSRIs/SNRIs

Drug Class		UM Employee		Non-UM Employee		Difference (UM - Non-UM)
		Freq.	Percent	Freq.	Percent	
Statin	Shift to Generic	170	38.90%	184	23.71%	15.19%
	No Change	262	59.95%	584	75.26%	-15.30%
	Shift from Generic to Brand name	5	1.14%	8	1.03%	0.11%
SSRIs/ SNRIs	Shift to Generic	27	18.00%	53	22.65%	-4.65%
	No Change	112	74.67%	176	75.21%	-0.55%
	Shift from Generic to Brand name	11	7.33%	5	2.14%	5.20%

Figure 4.1 Tier Distribution: Diabetic Drugs

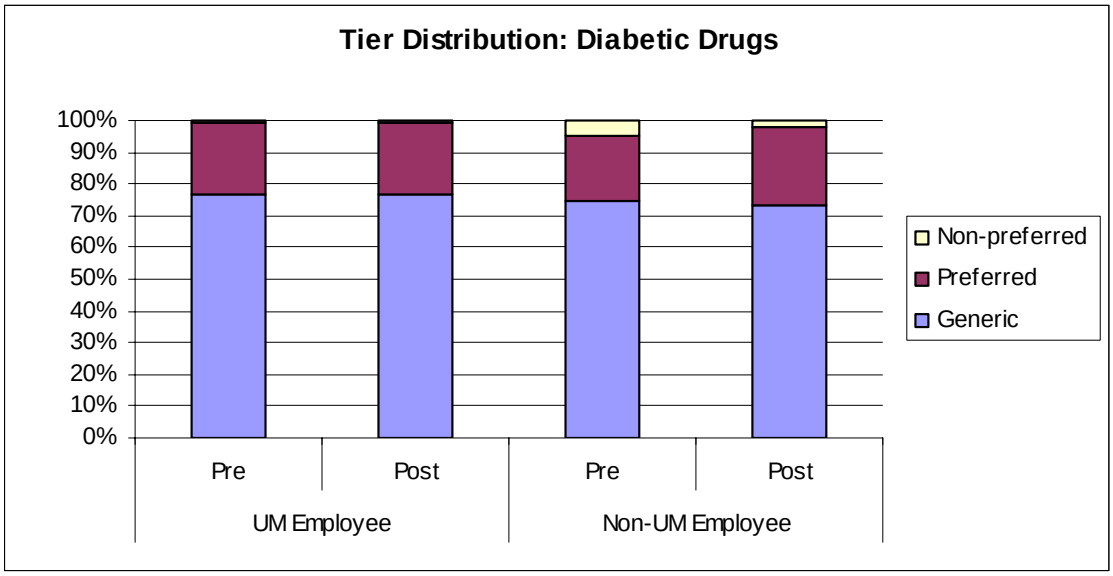


Figure 4.2 Tier Distribution: Anti-Hypertensives

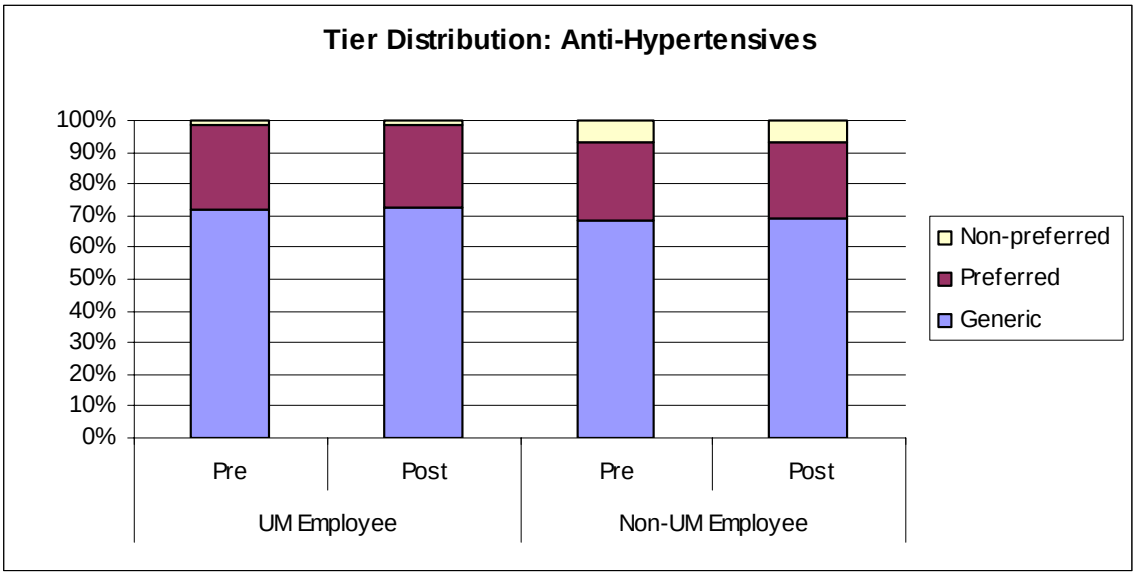


Figure 4.3 Tier Distribution: Lipid Lowering Drugs

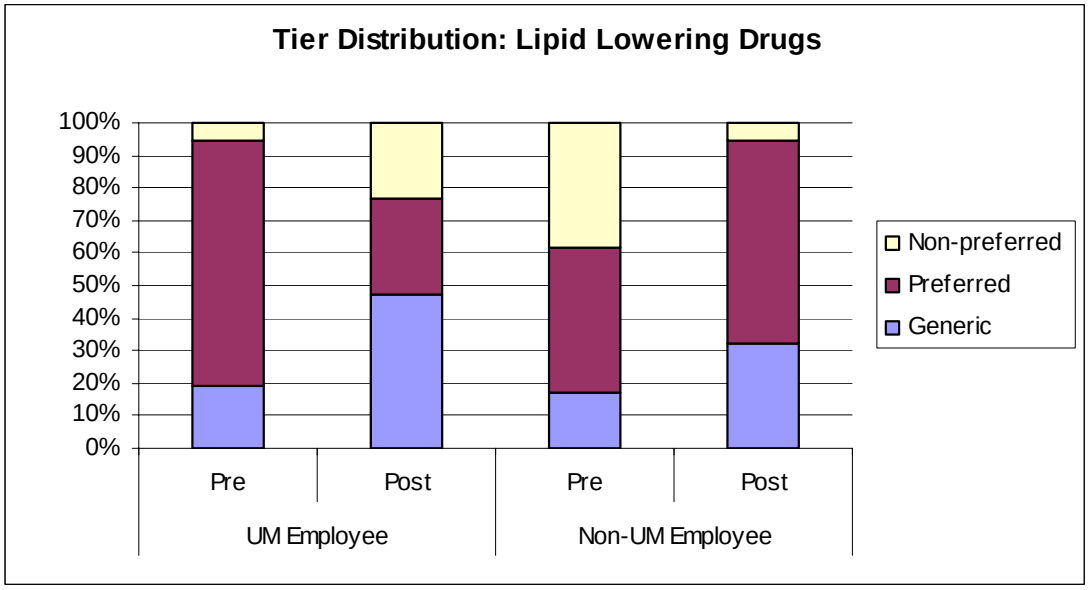
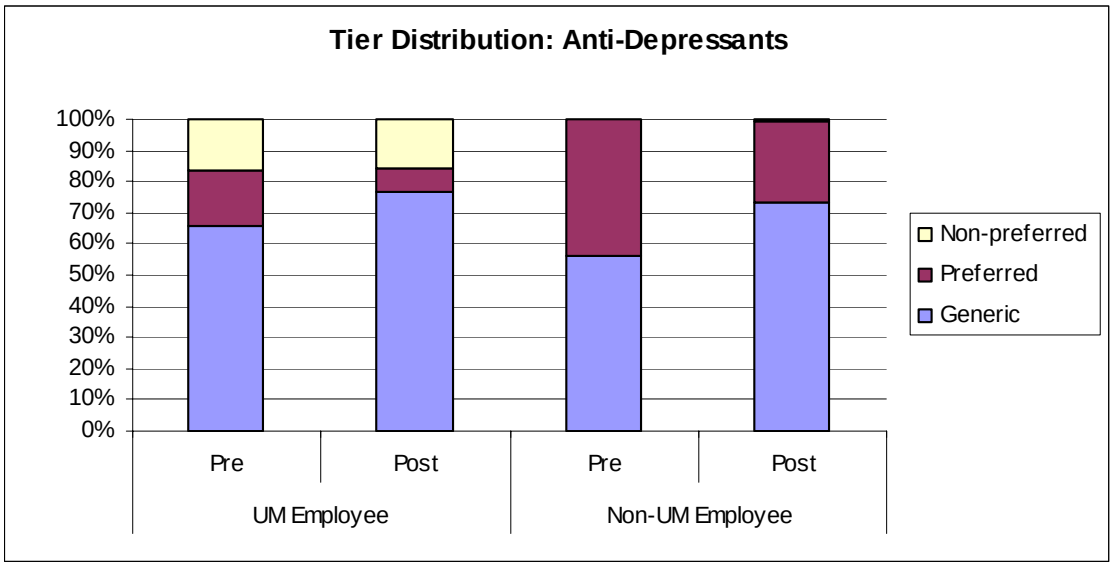


Figure 4.4 Tier Distribution: Anti-Depressants



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CHAPTER V
CONCLUSIONS

Increased demand for long-term care services and rising prescription drug costs has attracted growing concerns from health care researchers and policy makers. The goals of this dissertation are to improve our understandings on long-term care insurance market and on patient prescription drug utilization.

The cost of long-term care is a concern not only for individuals, but for the public, as Medicaid and Medicare pay for the majority of the long-term care services. Policymakers are pursuing a number of initiatives to promote private LTC insurance coverage. However, some existing theories have provided less support for the efficacy of public policies by suggesting that the lack of rationale to protect asset may counteract any incentives created by policies (Pauly, 1990; Zweifel and Struwe 1998). Chapter II of this dissertation explores whether lack of incentive to protect asset can explain the limited private long-term care insurance market.

The state partnership programs allow individuals who buy long-term care insurance policies under the program to protect a certain amount of their assets and become eligible for Medicaid after they exhaust their policy benefits. Using difference in difference method, I compare the change in LTC insurance coverage for the partnership states with

that of non-partnership states. Chapter II finds that implementation of long-term care partnership program did not increases long-term care insurance coverage among both general population and those who are more likely to be attracted to the asset protection feature, including higher income people, those with children and married individuals. The results, to some extent, support existing theories that protecting asset and leaving bequests to children and spouse are not attracting people to purchase private long-term care insurance coverage.

Fourteen years after the first partnership program implemented, twenty-one other states initiated legislative activity to establish a partnership after congress approved legislation clearing the way for expanded nationwide public-private LTC insurance partnerships in 2006. Future work may extend the difference in difference approach with recent HRS data to evaluate the impact of the partnership program, which could not only provide longer pre-intervention comparison but also test the asset protection hypothesis among older cohort who has higher demand for long-term care services. In addition, although the study in chapter II did not find that partnership program attracted more people to buy LTC insurance coverage, it is not clear whether it changed the amount of coverage the buyers purchased. Future work may use detailed insurance data to evaluate the impact of partnership program on the amount of coverage purchased.

Chapter III studied the effect of fixed dose combination (FDC) drugs on patient adherence to medication, compared to multi-pill therapy. As more and more combination drugs come to the market as an effort by the drug companies to extend the patent life and profitability of the key agent in the combination, it is valuable to assess how these drugs affect patient's adherence to medication. We used both propensity score and fixed effect

approaches to control for selection bias. Our estimates for both approaches show similar results: the anti-diabetic FDC drug, glucovance, significantly increased patient adherence to combination therapy when compared to patients prescribed a two-pill regimen.

As combination therapies become more and more popular for the treatment of many chronic diseases, the effect of multiple medications on patient adherence becomes especially important. Findings from chapter III suggest that compared to two pill therapy, a fixed dose combination can yield important improvements in patient adherence. In the case where the costs of a FDC product exceeds the cost of the individual agents, cost-effectiveness analyses are desired to determine whether the clinical advantages attributable to the enhanced adherence are worth the incremental expenditures. Besides, it will be interesting to see future researches evaluating the effects of FDC on different subgroups to identify the groups that would benefit from FDC most. Since FDC is usually more expensive than the free dose combinations, it would be valuable to identify the groups who have, at least, enough adherence gains to offset the extra costs. Additionally, due to data availability, only short-term adherence effects were measured. In the management of chronic disease, however, long-term adherence would be more important for maintaining desired health status. Future research calls for analysis on the long-term adherence trend among FDC users versus non-users when data is available.

Chapter IV of this dissertation evaluated how drug co-payment reduction affected patient formulary tier utilization patterns. Focus On Diabetes is a drug benefit experiment conducted on the University of Michigan employees and their dependents. The FOD experiment reduced drug co-payments of four types of prescription medications for diabetic patients. The analyses in chapter IV found that graded co-payment reductions

had little effect on patient tier switching. Neither income effect nor price effect dominated in the drug price reduction. Instead, the availability of new generic drugs after the patents of brand-name drugs expired and drug formulary changes had significant impact on tier shifting. The study is limited by its selection of control group, which consists of more than 100 employers. The ongoing changes to their drug benefits are not unanimous and the heterogeneity may make the control group less comparable to the intervention group. Future work could use UM patients themselves as control, by comparing their tier utilization on non-FOD intervention drugs to the FOD intervention drugs.